

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 stakeholder 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 your 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
<b>Ways and Means</b>				
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
<b>Energy &amp; Commerce</b>				
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 Depart-

ment'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.

1853. A letter from the Associate Administrator, Agricultural Marketing Service, Fruit and Vegetable Programs, Department of Agriculture, transmitting the Department's final rule — Tart Cherries Grown in the States of Michigan, et al.; Free and Restricted Percentages for the 2014-15 Crop Year for Tart Cherries [Doc. No.: AMS-FV-14-0077; FV14-930-2 FR] received June 15, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.

1854. A letter from the Finance and Loan Analyst, Rural Development, Department of Agriculture, transmitting the Department's final rule — Reserve Account (RIN: 0575-AC99) received June 15, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.

1855. 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 — Irish Potatoes Grown in Colorado; Relaxation of the Handling Regulation for Area No. 3 [Doc. No.: AMS-FV-14-0092; FV15-948-1 FIR] received June 15, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.

1856. A letter from the Assistant Secretary for Legislation, Department of Health and Human Services, transmitting the Fiscal Year 2013 Annual Progress Report to Congress on the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program, pursuant to the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109-129), as amended; to the Committee on Energy and Commerce.

1857. A letter from the Assistant Secretary for Legislation, Department of Health and Human Services, transmitting the Fiscal Year 2012 Annual Progress Report on the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory Program, pursuant to the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109-129), as amended; to the Committee on Energy and Commerce.

1858. A letter from the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, transmitting the Department's final rule — Addition of Certain Person to the Entity List [Docket No.: 150304211-5211-01] (RIN: 0694-AG55) received June 15, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Foreign Affairs.

1859. A letter from the Assistant Secretary, Legislative Affairs, Department of State, transmitting a certification of proposed issuance of an export license, pursuant to Secs. 36(c) and 36(d) of the Arms Export Control Act, Transmittal No.: DDTT 15-047; to the Committee on Foreign Affairs.

1860. A letter from the Secretary, Department of Education, transmitting the Department's FY 2014 annual report, pursuant to Sec. 203 of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 (No FEAR Act), Pub. L. 107-174; to the Committee on Oversight and Government Reform.

1861. A letter from the Director, Office of Personnel Management, transmitting the Office's final rule — Federal Employees Health Benefits Program; Rate Setting for Community-Rated Plans (RIN: 3206-AN00) received June 15, 2015, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Oversight and Government Reform.

1862. A letter from the Deputy Secretary, Department of Veterans Affairs, and Principal Deputy Under Secretary of Defense for Personnel and Readiness, Department of Defense, transmitting the Department of Veterans Affairs and Department of Defense Joint Executive Committee FY 2014 Annual

Report, pursuant to 38 U.S.C. 8111; jointly to the Committees on Armed Services and Veterans' Affairs.

#### REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. McCAUL: Committee on Homeland Security. H.R. 1626. A bill to reduce duplication of information technology at the Department of Homeland Security, and for other purposes; with an amendment (Rept. 114-162). Referred to the Committee of the Whole House on the state of the Union.

Mr. McCAUL: Committee on Homeland Security. H.R. 1633. A bill to provide for certain improvements relating to the tracking and reporting of employees of the Department of Homeland Security placed on administrative leave, or any other type of paid non-duty status without charge to leave, for personnel matters, and for other purposes; with an amendment (Rept. 114-163). Referred to the Committee of the Whole House on the state of the Union.

Mr. McCAUL: Committee on Homeland Security. H.R. 2200. A bill to amend the Homeland Security Act of 2002 to establish chemical, biological, radiological, and nuclear intelligence and information sharing functions of the Office of Intelligence and Analysis of the Department of Homeland Security and to require dissemination of information analyzed by the Department to entities with responsibilities relating to homeland security, and for other purposes; with an amendment (Rept. 114-164). Referred to the Committee of the Whole House on the state of the Union.

Mr. McCAUL: Committee on Homeland Security. H.R. 2206. A bill to amend the Homeland Security Act of 2002 to require recipients of State Homeland Security Grant Program funding to preserve and strengthen interoperable emergency communications capabilities, and for other purposes; with an amendment (Rept. 114-165). Referred to the Committee of the Whole House on the state of the Union.

Mr. McCAUL: Committee on Homeland Security. H.R. 1640. A bill to direct the Secretary of Homeland Security to submit to Congress a report on the Department of Homeland Security headquarters consolidation project in the National Capital Region, and for other purposes; with an amendment (Rept. 114-166). Referred to the Committee of the Whole House on the state of the Union.

Mr. SESSIONS: Committee on Rules. House Resolution 321. Resolution providing for consideration of the Senate amendment to the bill (H.R. 2146) to amend the Internal Revenue Code of 1986 to allow Federal law enforcement officers, firefighters, and air traffic controllers to make penalty-free withdrawals from governmental plans after age 50, and for other purposes (Rept. 114-167). Referred to the House Calendar.

#### PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XII, public bills and resolutions of the following titles were introduced and severally referred, as follows:

By Mr. ELLISON (for himself, Ms. MOORE, Mr. McGOVERN, Mr. JOHNSON of Georgia, Mr. McDERMOTT, Mr. TAKANO, Mr. GUTIERREZ, Ms. JACKSON LEE, Mr. HONDA, Mr. WELCH, Ms. LEE, Mr. GRIJALVA, Mr. HASTINGS, Ms. NORTON, Mr. CICILLINE, Mr. AL GREEN

of Texas, Mr. CONYERS, Mrs. DAVIS of California, and Ms. JUDY CHU of California):

H.R. 2798. A bill to modify provisions of law relating to refugee resettlement, and for other purposes; to the Committee on the Judiciary, and in addition to the Committees on Foreign Affairs, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. GRIFFITH (for himself, Mrs. BEATTY, Mr. SENSENBRENNER, Mr. HARPER, Mr. THOMPSON of California, and Mr. DAVID SCOTT of Georgia):

H.R. 2799. A bill to amend title XVIII of the Social Security Act to expand access to stroke telehealth services under the Medicare program; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. WALBERG (for himself, Mrs. NOEM, Mr. SMITH of New Jersey, and Ms. JENKINS of Kansas):

H.R. 2800. A bill to amend the Civil Rights Act of 1964 to provide protections against pregnancy discrimination in the workplace, and for other purposes; to the Committee on Education and the Workforce.

By Mr. BABIN (for himself, Mr. BARLETTA, and Mr. RATCLIFFE):

H.R. 2801. A bill to prohibit the Administrator of General Services from leasing space for certain purposes; to the Committee on Transportation and Infrastructure.

By Mr. LABRADOR (for himself, Mr. COLLINS of Georgia, Mr. JONES, Mr. SESSIONS, Mr. DUNCAN of South Carolina, Mrs. HARTZLER, Mr. CRAMER, Mr. NEUGEBAUER, Mr. PEARCE, Mr. LAMBORN, Mr. SAM JOHNSON of Texas, Mr. SANFORD, Mrs. BLACKBURN, Mr. ROTHFUS, Mr. FRANKS of Arizona, Mr. MULLIN, Mr. POMPEO, Mr. SMITH of Texas, Mr. PITTENGER, Mr. WALBERG, Mr. JODY B. HICE of Georgia, Mr. MARCHANT, Mr. LIPINSKI, Mr. JORDAN, Mr. PALMER, Mr. MEADOWS, Mr. ALLEN, Mr. HUELSKAMP, Mr. PITTS, Mr. GRAVES of Georgia, Mr. MILLER of Florida, Mr. GARRETT, Mr. FINCHER, Mr. SALMON, Mr. WEST-MORELAND, Mr. SMITH of New Jersey, Mr. GROTHMAN, Mr. HARRIS, Mrs. WAGNER, Mr. WEBER of Texas, Mr. FLEMING, Mr. KELLY of Pennsylvania, Mr. BABIN, Mr. YOHO, Mr. CHAFFETZ, Mr. FORTENBERRY, Mr. PALAZZO, Mr. CARTER of Texas, Mr. ROUZER, Mrs. BLACK, Mr. BRAT, Mr. MOONEY of West Virginia, Mr. GOSAR, Mr. BISHOP of Utah, Mrs. LOVE, Mr. GOWDY, Mr. ADERHOLT, and Mr. STEWART):

H.R. 2802. A bill to prevent discriminatory treatment of any person on the basis of views held with respect to marriage; to the Committee on Oversight and Government Reform, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. ZELDIN:

H.R. 2803. A bill to amend the Elementary and Secondary Education Act of 1965 to ensure State control over academic standards, and for other purposes; to the Committee on Education and the Workforce.

By Mr. CARTWRIGHT (for himself, Ms. TSONGAS, Mr. CONNOLLY, Mr. ELLISON, Mr. LANGEVIN, Mr. LOWENTHAL, Ms. NORTON, Mr. POCAN, Mr. POLIS,