



Health Policy Briefing

March 11, 2019

FDA Administrator Gottlieb Announces Resignation

Administrator of Food and Drugs Scott Gottlieb announced his decision to resign effective next month. According to his formal statement, Gottlieb is leaving the agency to spend more time with his family. His replacement has not yet been announced. During his two years at the Food and Drug Administration (FDA) he led the agency’s response to the opioid epidemic, prioritized the approval of generic drugs, and spearheaded a plan to curb youth vaping. His contributions were praised by lawmakers on both sides of the aisle and by U.S. Department of Health and Human Services (HHS) Secretary Alex Azar following the announcement of his resignation.

Lawmakers Consider Measles Outbreaks and Rise of Under-Vaccination

Lawmakers have turned their focus to recent measles outbreaks across the country resulting from a small but growing portion of the population questioning the safety of vaccines and the rise of under-vaccination. The measles outbreaks have been the subject of two congressional hearings in recent weeks. Reps. Adam Schiff (D-Calif.) and Michael Burgess (R-Texas) introduced a bipartisan resolution ([H.Res. 179](#)) last week recognizing the importance of vaccines and urging parents to immunize their children. In response to a request for information from Rep. Schiff, Chairman of the House Intelligence Committee, [Facebook](#) and [Google](#) released details of their plans to address misinformation about vaccines. Schiff had expressed concerns about the platforms promoting information that discouraged parents from vaccinating their children. The Annals of Internal Medicine also published new research last week reaffirming the medical consensus denying any connection between the measles, mumps, rubella (MMR) vaccine and autism. Researchers also concluded that vaccination is not likely to trigger any developmental disorders.

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Toomey, Klobuchar Introduce Medical Device Tax Repeal

Sens. Pat Toomey (R-Pa.) and Amy Klobuchar (D-Minn.) have introduced legislation ([S. 692](#)) to permanently repeal the Affordable Care Act's (ACA) medical device tax. The 2.3 percent federal excise tax on medical devices has been suspended and delayed since it became law. Most recently, the tax was retroactively delayed and will now go into effect on January 1, 2020. The Senate bill currently has 25 bipartisan cosponsors.

Dems to Include Money for Gun Violence Research in CDC Funding

Democratic appropriators plan to request funding for the Centers for Disease Control and Prevention (CDC) to conduct research on gun violence, according to Labor-HHS-Education Appropriations Subcommittee Chair Rosa DeLauro (D-Conn.). The subcommittee's ranking member Tom Cole (R-Okla.) has opposed such provisions in the past but has more recently appeared open to a compromise, suggesting that gun violence research be funded while preserving the Dickey-Amendment, which prohibits federal researchers from advocating for gun control. It is unclear how gun violence research funding would fare in the GOP-controlled Senate.

Hoyer Previews House Appropriations Plans

House Majority Leader Steny Hoyer (D-Md.) hopes to spend the month of June passing the 12 annual appropriations bills, he told the House Budget Committee last week. Lawmakers will first have to reach an agreement to raise spending caps under the Budget Control Act (BCA) so that appropriators have top-line spending limits to work with. Without a new agreement, discretionary spending caps will be cut to the levels outlined in the BCA for fiscal year (FY) 2020 – approximately \$126 billion less than FY 2019. The White House plans to request deep cuts to nondefense discretionary spending, while tapping into Overseas Contingency Operations (OCO) funds to remain within the cap for defense spending, a plan which Democrats say they will oppose. The first part of the President's budget is expected to be released today.

Eli Lilly to Release Authorized Insulin Generic

Drug company Eli Lilly announced last week that it will introduce a less expensive, authorized generic version of its insulin that will cost half the price of the brand-name drug. The pricing process surrounding insulin, which has seen significant increases in cost in recent years, is the subject of several congressional investigations. While Eli Lilly's decision was praised by lawmakers on both sides of the aisle, policymakers also cautioned that more needs to be done to ensure access to life-saving medications like insulin. Following the announcement, Senate Finance Committee Chairman Chuck Grassley (R-Iowa) reminded Eli Lilly, Novo Nordisk, and Sanofi to respond to his previous request for information regarding insulin pricing practices.

Upcoming Congressional Hearings and Meetings

House Oversight and Reform Subcommittee on Economic and Consumer Policy hearing “Examining the Public Health Risks of Carcinogens in Consumer Products;” 10:00 a.m., 2154 Rayburn Bldg.; March 12

House Energy and Commerce Health Subcommittee hearing “The Fiscal Year 2020 HHS Budget;” 12:00 p.m., 2123 Rayburn Bldg.; March 12

House Energy and Commerce Health Subcommittee hearing “Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition;” 10:00 a.m., 2123 Rayburn Bldg.; March 13

House Appropriations Labor, Health and Human Service, Education, and Related Agencies Subcommittee hearing “Department of Health and Human Services Budget Request for FY 2020;” 2:00 p.m., 2358-C Rayburn Bldg.; March 13

Senate Appropriations Subcommittee on Departments of Labor, Health and Human Services, and Education, and Related Agencies hearing to examine the Ebola outbreak in the Democratic Republic of the Congo and other emerging health threats; 10:00 a.m., 124 Dirksen Bldg.; March 14

Senate Finance Committee hearing “The President’s Fiscal Year 2020 Budget;” 10:15 a.m., 215 Dirksen Bldg.; March 14

Recently Introduced Health Legislation

S.640 — A bill to amend title XVIII of the Social Security Act to require pharmacy-negotiated price concessions to be included in negotiated prices at the point-of-sale under part D of the Medicare program, and for other purposes; Sponsor: Sen. Kennedy, John [R-LA]; Committees: Senate - Finance

H.Res.179 — Recognizing the importance of vaccinations and immunizations in the United States; Sponsor: Rep. Schiff, Adam B. [D-CA-28]; Committees: House - Energy and Commerce

H.R.1499 — To prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes; Sponsor: Rep. Rush, Bobby L. [D-IL-1]; Committees: House - Energy and Commerce, Judiciary

H.R.1503 — To amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes; Sponsor: Rep. Kelly, Robin L. [D-IL-2]; Committees: House - Energy and Commerce

H.R.1506 — To amend the Federal Food, Drug, and Cosmetic Act to ensure that valid generic drugs may enter the market; Sponsor: Rep. Barragan, Nanette Diaz [D-CA-44]; Committees: House - Energy and Commerce, Judiciary

H.R.1510 — To amend the Public Health Service Act to provide for a Patient and State Stability Fund; Sponsor: Rep. Burgess, Michael C. [R-TX-26]; Committees: House - Energy and Commerce, Ways and Means

H.R.1518 — To amend title XVIII of the Social Security Act to remove the exclusion of Medicare coverage for hearing aids and examinations therefor, and for other purposes; Sponsor: Rep. Dingell, Debbie [D-MI-12]; Committees: House - Energy and Commerce, Ways and Means

H.R.1520 — To amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes; Sponsor: Rep. Eshoo, Anna G. [D-CA-18]; Committees: House - Energy and Commerce

H.R.1527 — To amend title 38, United States Code, to authorize the Secretary of Veterans Affairs to enter into contracts and agreements for the placement of veterans in non-Department medical foster homes for certain veterans who are unable to live independently; Sponsor: Rep. Higgins, Clay [R-LA-3]; Committees: House - Veterans' Affairs

H.R.1528 — To amend the Omnibus Crime Control and Safe Streets Act of 1968 to reauthorize the comprehensive opioid abuse grant program, and for other purposes; Sponsor: Rep. Joyce, David P. [R-OH-14]; Committees: House - Judiciary

H.R.1530 — To amend title XVIII of the Social Security Act to provide for the coordination of programs to prevent and treat obesity, and for other purposes; Sponsor: Rep. Kind, Ron [D-WI-3]; Committees: House - Energy and Commerce, Ways and Means

H.R.1533 — To amend title XVIII of the Social Security Act to improve access to mental health services under the Medicare program; Sponsor: Rep. Lee, Barbara [D-CA-13]; Committees: House - Energy and Commerce, Ways and Means

S.Res.94 — A resolution expressing the sense of the Senate that the Department of Justice should protect individuals with pre-existing medical conditions by defending the Patient Protection and Affordable Care Act (Public Law 111-148; 124 Stat. 119) in Texas v. United States, No. 4:18-cv-00167-O (N.D. Tex.), in which the plaintiffs seek to invalidate protections for individuals with pre-existing medical conditions; Sponsor: Sen. Hirono, Mazie K. [D-HI]; Committees: Senate - Judiciary

S.657 — A bill to amend title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.658 — A bill to provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.659 — A bill to provide for certain additional requirements with respect to patent disclosures; Sponsor: Sen. Collins, Susan M. [R-ME]; Committees: Senate - Health, Education, Labor, and Pensions

S.660 — A bill to address abuse of the Food and Drug Administration's citizen petition process by brand drug manufacturers; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.180 — Supporting the designation of March 2019 as National Colorectal Cancer Awareness Month; Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Oversight and Reform

H.Res.181 — Expressing support for designation of May 30 as "National Bartter Syndrome Day"; Sponsor: Rep. Ryan, Tim [D-OH-13]; Committees: House - Oversight and Reform

H.R.1551 — To amend title XI of the Social Security Act to improve the quality, health outcomes, and value of maternity care under the Medicaid and CHIP programs by developing maternity care quality measures and supporting maternity care quality collaboratives; Sponsor: Rep. Engel, Eliot L. [D-NY-16]; Committees: House - Energy and Commerce, Ways and Means

H.R.1554 — To amend the Higher Education Act of 1965 to provide for interest-free deferment on student loans for borrowers serving in a medical or dental internship or residency program; Sponsor: Rep. Babin, Brian [R-TX-36]; Committees: House - Education and Labor

H.R.1559 — To amend the Public Health Service Act to strengthen program integrity and enhance low-income patient benefits for safety net providers; Sponsor: Rep. Collins, Chris [R-NY-27]; Committees: House - Energy and Commerce

H.R.1564 — To amend title XVIII of the Social Security Act to stabilize and modernize the provision of partial hospitalization services under the Medicare Program, and for other purposes; Sponsor: Rep. Hastings, Alcee L. [D-FL-20]; Committees: House - Ways and Means, Energy and Commerce

H.R.1570 — To amend title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening; Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Energy and Commerce, Ways and Means

S.668 — A bill to amend title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Finance

S.680 — A bill to amend the Internal Revenue Code of 1986 to treat certain amounts paid for physical activity, fitness, and exercise as amounts paid for medical care; Sponsor: Sen. Thune, John [R-SD]; Committees: Senate - Finance

S.684 — A bill to amend the Internal Revenue Code of 1986 to repeal the excise tax on high cost employer-sponsored health coverage; Sponsor: Sen. Heinrich, Martin [D-NM]; Committees: Senate - Finance

H.Res.188 — Expressing support for designation of July as National Sarcoma Awareness Month. Sponsor: Rep. Duffy, Sean P. [R-WI-7]; Committees: House - Oversight and Reform

H.R.1587 — To direct the Secretary of Health and Human Services to enter into a 10-year arrangement with the National Academy of Sciences to conduct and update biennially a study on the effects of State legalized marijuana programs, and for other purposes; Sponsor: Rep. Gabbard, Tulsi [D-HI-2]; Committees: House - Energy and Commerce, Judiciary, Education and Labor

H.R.1597 — To designate the same individual serving as the Chief Nurse Officer of the Public Health Service as the National Nurse for Public Health; Sponsor: Rep. Johnson, Eddie Bernice [D-TX-30]; Committees: House - Energy and Commerce

H.R.1603 — To amend the Toxic Substances Control Act to prohibit the manufacture, processing, and distribution in commerce of asbestos and asbestos-containing mixtures and articles, and for other purposes; Sponsor: Rep. Bonamici, Suzanne [D-OR-1]; Committees: House - Energy and Commerce, Education and Labor

H.R.1614 — To amend the Controlled Substances Act to establish additional registration requirements for prescribers of opioids, and for other purposes; Sponsor: Rep. Katko, John [R-NY-24]; Committees: House - Energy and Commerce, Judiciary

S.691 — A bill to amend title XVIII of the Social Security Act to enhance prescription drug affordability by expanding access to assistance with out-of-pocket costs under Medicare part D for low-income seniors and individuals with disabilities; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Finance

S.692 — A bill to amend the Internal Revenue Code of 1986 to repeal the excise tax on medical devices; Sponsor: Sen. Toomey, Pat [R-PA]; Committees: Senate - Finance

S.696 — A bill to designate the same individual serving as the Chief Nurse Officer of the Public Health Service as the National Nurse for Public Health; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate - Health, Education, Labor, and Pensions

S.709 — A bill to establish an interactive dashboard to allow the public to review information on the price and utilization of prescription drugs purchased by Federal programs; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions

S.717 — A bill to amend the Toxic Substances Control Act to prohibit the manufacture, processing, and distribution in commerce of asbestos and asbestos-containing mixtures and articles, and for other purposes; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate - Environment and Public Works

S.724 — A bill to amend the Controlled Substances Act to establish additional registration requirements for prescribers of opioids, and for other purposes; Sponsor: Sen. Gillibrand, Kirsten E. [D-NY]; Committees: Senate - Judiciary

S.726 — A bill to amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of cosmetics; Sponsor: Sen. Feinstein, Dianne [D-CA]; Committees: Senate - Health, Education, Labor, and Pensions