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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

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MEMORANDUM

July 13, 2014

To: Energy and Commerce Committee Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: H.R. 4771, "Designer Anabolic Steroid Control Act;" H.R. 4250, "Sunscreen Innovation Act," as amended; H.R. 594, "Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments of 2014," as amended; H.R. 669, "Sudden Unexpected Death and Data Enhancement and Awareness Act," as amended; H.R. 4290, "Wakefield Act of 2014," as amended; H.R. 5057, "EPS Service Parts Act of 2014;" and, H.R. 4450, "Travel Promotion, Enhancement, and Modernization Act of 2014," as amended.

On Monday, July 14, 2014, at 4:00 p.m. in room 2123 of the Rayburn House Office Building, the full Committee on Energy and Commerce will conduct opening statements for the markup of H.R. 4771, "Designer Anabolic Steroid Control Act;" H.R. 4250, "Sunscreen Innovation Act," as amended; H.R. 594, "Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments of 2014," as amended; H.R. 669, "Sudden Unexpected Death and Data Enhancement and Awareness Act," as amended; H.R. 4290, "Wakefield Act of 2014," as amended; H.R. 5057, "EPS Service Parts Act of 2014;" and, H.R. 4450, "Travel Promotion, Enhancement, and Modernization Act of 2014," as amended. The Committee will reconvene on Tuesday, July 15, at 10:00 a.m. in 2123 Rayburn House Office Building.

I. H.R. 4771, DESIGNER ANABOLIC STERIOD CONTROL ACT

Anabolic steroids are synthetic variants of the male sex hormone testosterone. They have a number of therapeutic uses, but are also used by muscle builders and athletes to improve performance. Long term or high dosage use can cause adverse health effects, including damage

to the liver and heart; and testicular atrophy.[1] They are listed as Schedule III controlled substances under the Controlled Substances Act (CSA).[2]

The CSA contains a list of chemicals defined as anabolic steroids. However, chemists are able to design around the list, creating new anabolic steroids that are not on the CSA list. The Drug Enforcement Agency (DEA), therefore, has a more difficult time taking enforcement actions against people using them.

H.R. 4771 is sponsored by Rep. Joe Pitts (R-PA) and Rep. Frank Pallone, Jr. (D-NJ). The bill will add 25 new chemicals to the list of substances that meet the CSA definition of anabolic steroid, thereby facilitating their control by the DEA. The bill also will make it easier for DEA to add subsequent designer chemicals to the list of anabolic steroids, and increases civil and criminal penalties for offenses pertaining to anabolic steroids. The Subcommittee on Health held a markup of H.R. 4771 on June 19, 2014, and approved the legislation for full Committee consideration by voice vote. The bill coming before the full Committee contains a number of technical changes from the bill that passed the Subcommittee on Health, reflecting comments from the FDA and the DEA.

II. H.R. 4250, SUNSCREEN INNOVATION ACT

Sunscreens sold in the United States are marketed as over-the-counter (OTC) drugs regulated by the Food and Drug Administration (FDA).[3] The current regulatory process by which FDA evaluates OTC drugs to see if they are generally recognized as safe and effective is cumbersome and has no statutory deadlines. As a result, there are eight sunscreen applications that have languished at FDA, some for up to 11 years. H.R. 4250 is intended to create a process by which both these pending applications and new applications that meet all specified requirements can be reviewed in a timely manner.

H.R. 4250 is sponsored by Rep. Edward Whitfield (R-KY) and Rep. John D. Dingell (D-MI). The Subcommittee on Health held a markup of an Amendment in the Nature of a Substitute to H.R. 4250 on June 19, 2014, and approved the legislation for full Committee consideration by voice vote. The full Committee markup will be on a new Amendment in the Nature of a Substitute to H.R. 4250.

As originally introduced, H.R. 4250 would have amended the Food, Drug, and Cosmetic Act to set up a system under which sunscreens that had been marketed continuously for at least five years in the United States or elsewhere, and that met certain other conditions, would be eligible for review by an FDA advisory committee. After the advisory committee issued its recommendation, FDA would have 45 days to affirm or deny the recommendation. If FDA did not deny an approval recommendation within 45 days, the sunscreen would automatically be

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[1] National Institute of Drug Abuse, *Drug Facts: Anabolic Steroids* (July 2012) (online at www.drugabuse.gov/publications/drugfacts/anabolic-steroids).

[2] 21 USC 802 (41).

[3] 21 CFR 352.

allowed on the market as generally recognized as safe and effective. The bill also would have provided an appeals process for situations in which the company disagreed with the FDA determination.

The Amendment in the Nature of a Substitute to H.R. 4250 that was marked up in Subcommittee on June 19, 2014, would have created a system under which FDA would retain the responsibility for reviewing sunscreen marketing applications. FDA also would have been required to have each pending and new application evaluated by an advisory committee. It indicated that there would be deadlines for each step of the process, but these deadlines would be specified in a later version of the bill. It also specified all data requirements for applications.

The Amendment in the Nature of a Substitute to H.R. 4250 that is to be marked up by the full Committee specifies FDA timelines for each step in the sunscreen evaluation and approval process. It establishes different sets of timelines for applications depending on whether they are pending at FDA at the time of enactment or are submitted after enactment of the bill.

Pending applications must receive a proposed marketing determination, or a determination that more information is required before FDA can make a marketing determination, within 90 days of enactment. That time period is reduced to 45 days if FDA has already issued a letter to the applicant specifying that such additional information is required. Pending applications for which additional information is required must receive a final marketing determination from FDA 210 days from when the information is submitted if no advisory committee meeting is convened, or 270 days for applications for which an advisory committee is convened.

New applications for which no additional information is required must receive a final marketing determination within 555 days of submission of the application. This timeframe includes the eligibility determination, filing determination, application review, and meeting of an advisory committee. It also includes FDA publication of the proposed determination, public comment period, FDA review of the comments, and publication of the final marketing determination. If FDA finds that additional information is required to enable it to make a final determination, it must issue the final marketing determination within 210 days of receiving the requested information.

The bill requires the Commissioner of FDA to take over the determination process from the Director of the FDA Center for Drug Evaluation and Research if it fails to meet the timelines.

The bill no longer specifies data requirements for applications, but instead requires FDA to issue guidance about such required information within one year of enactment. However, all timelines still apply prior to issuance of that guidance, so it will not result in any delays. The subchapter of the Food, Drug, and Cosmetic Act established by the bill would sunset five years from date of enactment.

III. H.R. 594, PAUL. D. WELLSTONE MUSCULAR DYSTROPHY COMMUNITY ASSISTANCE, RESEARCH AND EDUCATION (MD CARE) AMENDMENTS OF 2014

Muscular dystrophy is a group of over 30 genetic diseases that cause progressive weakness and degeneration of certain muscles impacting movement.[4] The MD CARE Act was originally passed in 2001 and reauthorized in 2008.[5] The goals of the legislation were to improve research, surveillance, and educational efforts regarding muscular dystrophy.

H.R. 594 is sponsored by Rep. Michael Burgess (R-TX) and Rep. Eliot Engel (D-NY). The bill reflects new scientific advances, as well as the needs of adults living with muscular dystrophy. The Subcommittee on Health held a markup of H.R. 594 on June 19, 2014, and approved the legislation for full Committee consideration, with an amendment, by voice vote.

IV. H.R. 669, SUDDEN UNEXPECTED DEATH DATA ENHANCEMENT AND AWARENESS ACT

The Centers for Disease Control and Prevention (CDC) oversee a number of programs related to stillbirths and unexpected deaths of infants and young children. CDC tracks the number of stillbirths through the National Vital Statistics System.[6] CDC also supports a registry to monitor sudden, unexpected infant deaths (SUID) in nine states, and the agency recently announced a partnership with the National Institutes of Health (NIH) to launch a registry tracking unexpected deaths in individuals under age 24, in up to 15 states or major metropolitan areas.[7] Finally, CDC has developed guidelines and training materials to assist death scene investigators in SUID cases.[8]

H.R. 669 is sponsored by Rep. Frank Pallone, Jr. (D-NJ) and Rep. Peter King (R-NY). The bill will enhance surveillance on stillbirth, SUID, and Sudden Unexplained Death in Childhood (SUDC); improve the development of standard protocols for use in death scene investigations and autopsies surrounding these deaths; allow the Secretary of Health and Human

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[4] National Institute of Neurological Disorders and Stroke, *NINDS Muscular Dystrophy Information Page* (online at www.ninds.nih.gov/disorders/md/md.htm).

[5] Pub. L. No. 107-84; Pub. L. No. 110-361.

[6] Centers for Disease Control and Prevention, *National Vital Statistics System* (accessed June 14, 2014) (online at www.cdc.gov/nchs/fetal_death.htm).

[7] Department of Health and Human Services, *Fiscal Year 2014 Centers for Disease Control and Prevention Justification of Estimates for Appropriation Committees* (online at www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2014_CJ_CDC_FINAL.pdf); *NIH and CDC launch registry for sudden death in the young,* National Institutes of Health (Oct. 24, 2013) (online at www.nih.gov/news/health/oct2013/nhlbi-24.htm).

[8] Centers for Disease Control and Prevention, *Sudden Unexplained Infant Death Investigation Training Material* (accessed June 14, 2014) (online at www.cdc.gov/sids/trainingmaterial.htm).

Services to conduct training activities regarding these protocols; and require CDC, in consultation with NIH, to submit a report to Congress on current activities related to stillbirth, SUID, and SUDC, and evaluate the possibility of expanding programs related to SUDC specifically. The Subcommittee on Health held a legislative hearing on H.R. 669 on November 20, 2013, and held a markup of this legislation on June 19, 2014, at which the Subcommittee approved the legislation for full Committee consideration, with an amendment, by voice vote.

V. H.R. 4290, WAKEFIELD ACT OF 2014

The Emergency Medical Services for Children (EMSC) Program began in 1984.[9] In, FY 2014, the program funded 78 grants to state governments and institutes of higher learning to improve pediatric emergency care.[10]

H.R. 4290 is sponsored by Rep. Jim Matheson (D-UT) and Rep. Peter King (R-NY). The bill reauthorizes the EMSC Program at the currently-authorized funding level of $30 million for each of FY 2015 through FY 2019. The Subcommittee on Health held a markup of H.R. 4290 on June 19, 2014, and approved sending the legislation for full Committee consideration, with an amendment, by voice vote.

VI. H.R. 5057, EPS SERVICE PARTS ACT OF 2014

On July 9, 2014, Rep. Gardner (R-CO) and Rep. Tonko (D-NY) introduced H.R. 5057, the EPS Service Parts Act of 2014. This bipartisan legislation has broad stakeholder support.

External power supplies (EPS) are the block boxes that convert household electric current into the type of current needed to operate a consumer product, such as a laptop computer or smart phone. The 2007 Energy Independence and Security Act established energy efficiency standards for EPS. The Act also created an exemption for service and spare parts.

The Department of Energy (DOE) issued updated efficiency standards in February 2014. The rulemaking did not include an exemption for service and spare parts.

The bill establishes a four-year exemption from the 2014 efficiency standard for EPS service and spare parts, which will still be required to meet the 2007 standards. Under the bill, DOE may require manufacturers of exempted products to report the number of units shipped as service and spare parts in order to track the use of the exemption. In addition, the bill provides DOE will the authority to limit the exemption through rulemaking if the Secretary determines that the exemption is resulting in a significant reduction in the energy savings that otherwise would have been achieved from the 2014 efficiency standard. The bill provides DOE with the authority to establish similar exemptions for spare parts in future amended EPS efficiency standards and to require reporting on the number of units shipped under such exemptions.

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[9] Pub. L. No. 98-555.

[10] Department of Health and Human Services, *Fiscal Year 2015 Health Research and Services Administration Justification of Estimates for Appropriation Committees* (online at www.hrsa.gov/about/budget/budgetjustification2015.pdf).

VII. H.R. 4450, TRAVEL PROMOTION, ENHANCEMENT, AND MODERNIZATION ACT OF 2014

Brand USA is organized as a public-private partnership. Together with several industry advisory groups, Brand USA plans advertising programs and activities designed to promote travel to the United States and develops industry partnerships to help further that goal.

Brand USA is financed by a combination of public and private funds. Private-sector funding may come from either cash or in-kind contributions, with such contributions able to make up a maximum of 80 percent of the private sector's financial contribution to the organization. Public matching funds are contributed from the Travel Promotion Fund, a U.S. Treasury fund sourced by a portion of the Electronic System for Travel Authorization (ESTA) fee, which is collected from foreign visitors to the United States by the Department of Homeland Security. For fiscal year 2012, Brand USA received $100 million in public funding from ESTA fees, matching the private-sector contribution 2-to-1. For fiscal years 2013 through 2015, TPA authorizes a maximum annual public contribution of $100 million at a private-sector matching ratio of 1-to-1.[11]

Currently, a sunset clause established under the Travel Promotion Act prohibits the Secretary of Commerce from collecting the fee supporting the Travel Promotion Fund after September 30, 2015.[12] H.R. 4450 would reauthorize the Act through September 30, 2020. It directs Brand USA and the Secretary of Commerce to meet biannually to review the procedures to determine the fair market value of goods and service to be received as in-kind private-sector contributions, and lowers the acceptable portion of private-sector contributions that may be in-kind to 75 percent. H.R. 4450 further requires Brand USA to establish performance metrics to measure the impact of its marketing efforts as well as any cost or benefit to the national economy, and to put into place a competitive procurement process for any contracts into which it enters. The bill also directs Brand USA to submit a report to Congress in response to any recommendations it receives from the Government Accountability Office within a 60-day period.

Following the adoption by the Subcommittee on Commerce, Manufacturing, and Trade of an amendment proposed by Rep. Schakowsky , the bill also directs the Department of Commerce to establish formal and publicly available procedures for revising or resolving differences regarding Brand USA's in-kind contributions policy, requires Brand USA to explain any single expenditure over $500,000, and specifies the nature of Brand USA performance metrics to be established for measuring the effectiveness of the program.

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[11] Government Accountability Office, *Brand USA Needs Plans for Measuring Performance and Updated Policy on Private Sector Contributions* (July 25, 2013) (GAO-13-705).

[12] 8 U.S.C. § 1187(h)(3)(B).