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ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

November 17, 2015

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Full Committee markup of H.R. 1321, H.R. 2017, H.R. 3014, H.R. 3537, H.R. 3716, H.R. 3821, H. J. Res. 71, H.J. Res. 72, and S. 611.

On Tuesday, November 17, 2015, at 4:00 p.m. in room 2123 Rayburn House Office Building, the full Committee on Energy and Commerce will conduct opening statements for the markup of H.R. 1321, Microbead-Free Waters Act of 2015; H.R. 2017, Common Sense Nutrition Disclosure Act of 2015, as amended by the Subcommittee on Health; H.R. 3014, Medical Controlled Substances Transportation Act; H.R. 3537, Synthetic Drug Control Act of 2015; H.R. 3716, Ensuring Terminated Providers Are Removed from Medicaid and CHIP Act, as amended by the Subcommittee on Health; H.R. 3821, Medicaid Directory of Caregivers Act, as amended by the Subcommittee on Health; H.J. Res. 71, Providing for congressional disapproval under chapter 8 of title 5, United States Code, of a rule submitted by the Environmental Protection Agency relating to "Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units"; H.J. Res. 72, Providing for congressional disapproval under chapter 8 of title 5, United States Code, of a rule submitted by the Environmental Protection Agency relating to "Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units"; and S. 611, Grassroots Rural and Small Community Water Systems Assistance Act. The Committee will reconvene on Wednesday, November 18, at 10:00 a.m. in 2123 Rayburn House Office Building.

I. H.R. 1321, THE MICROBEAD-FREE WATERS ACT OF 2015

A. Background

On March 6, 2015, Ranking Member Frank Pallone, Jr. and Chairman Fred Upton introduced H.R. 1321, the Microbead-Free Waters Act of 2015. In recent years, a number of

personal care products, most notably face washes and scrubs, have utilized microplastic particles, or microbeads, as exfoliants.

While there is no evidence of negative health effects on users of these products, research has shown environmental impacts on water bodies from their increased use. When microbeads are added to these products, they travel through wastewater systems. Due to their small size they are more likely to escape capture by preliminary treatment screens at wastewater plants and home water treatment than larger particles.[1]

Numerous natural, biodegradable alternatives to synthetic plastic microbeads already exist in commerce and product supply chains, including apricot seeds, walnut shells, and pecan shell powder. Several personal care product companies have already announced plans to phase out the use of synthetic plastic microbeads in their products in favor of natural exfoliants, including Proctor & Gamble and Johnson & Johnson.[2]

B. Changes to the Bill Reported Out of Subcommittee

On May 14, 2015, the Subcommittee on Health favorably forwarded H.R. 1321 to the full Committee, as introduced, by a voice vote, with the understanding that certain changes were going to be made prior to markup in the full Committee. Following are changes to the bill that will be incorporated in an Amendment in the Nature of a Substitute (AINS).

1. Definition of Plastic Microbead

The AINS defines "plastic microbead" as any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof. The amendment also does not define "biodegradable plastic," and thus prohibits the use of biodegradable plastic alternatives. Many of the state-passed microbeads laws have allowed for biodegradable plastic alternatives and numerous stakeholders have raised concerns with the use of biodegradable plastic.

2. Timeline of Phase Out and Inclusion of Over-the-Counter Drug Products

The amendment accelerates the timeline for phase out of plastic microbeads in cosmetics and over-the-counter drug products (OTCs). Manufacturing of cosmetics containing plastic microbeads will be prohibited on July 1, 2017, and for sale on July 1, 2018. Manufacturing of OTCs containing plastic microbeads will be prohibited on July 1, 2018, and for sale on July 1, 2019.

3. Preemption

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[1] Lisa S. Fendall and Mary A. Sewell, *Contributing to Marine Pollution by Washing your Face: Microplastics in Facial Cleansers*, Marine Pollution Bulletin 58, no. 8, 1225-1228 (2009).

[2] Johnson & Johnson, *P&G to Phase Out Microbeads*, Environmental Leader (August 1, 2013) (www.environmentalleader.com/2013/08/01/johnson-johnson-pg-to-phase-out-microbeads/).

The amendment includes language that no state or political subdivision of a state may directly or indirectly establish restrictions with respect to the manufacture or sale of cosmetics containing plastic microbeads. Several states, beginning with Illinois in 2014, have passed laws banning plastic microbeads in cosmetics. Most state laws share the same text that begins the phase out in 2018 and allows for biodegradable plastic microbeads to be used as an alternative. In October 2015, California passed a law that bans biodegradable plastic and goes into effect January 1, 2020. The definition of "plastic microbead" in the AINS is similar to the definition in many of the state-passed bills, and the timeline of the phase out is earlier than any state-passed law.

II. H.R. 2017, THE COMMON SENSE NUTRITION DISCLOSURE ACT OF 2015 AND AN AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2017

The markup will consider an amended version of H.R. 2017, the Common Sense Nutrition Disclosure Act of 2015, introduced by Representative McMorris Rodgers (R-WA). On November 4, 2015, the Subcommittee on Health adopted an amendment in the nature of a substitute by voice vote during consideration of H.R. 2017, and favorably forwarded the bill as amended to the full Committee by a voice vote.

A. Changes Made by the AINS to H.R. 2017 and Their Effects on Covered Entities, Covered Menu Items, Nutritional Labeling Compliance Dates, and Pre-emption of Civil Lawsuits and State Implementation of Labeling Requirements

The revised definition of 'restaurant or similar retail food establishment' has been removed. As originally drafted, H.R. 2017 proposed narrowing the definition of the term 'restaurant or similar retail food establishment' to a retail food establishment that derives 50 percent or more of their total revenue from the sale of food for immediate consumption or prepared and processed on site. This new definition would have the practical effect of exempting some retail food establishments, including some grocery stores and convenience stores. By removing this definition, the AINS eliminates this carve-out.

The scope of menu items subject to calorie labeling (defined as "standard menu items") would be narrowed to menu items "with the same recipe prepared in substantially the same way with substantially the same food components that … is routinely included on a menu or menu board or routinely offered as a self-service food or food on display at 20 or more locations doing business under the same name." Thus, rather than all items routinely on the menu being subject to the menu labeling requirement (as under the FDA final rule), only those menu items routinely offered in at least 20 locations with the same recipe are subject to the menu labeling requirements. Under this change, covered establishments can make minor alterations to their standardized recipes and avoid menu labeling requirements. Items that appear fewer than 60 days per calendar year on a menu are already excluded from the menu labeling requirement under the FDA final rule.

Calorie information would only have to be provided on one menu or menu board in a covered restaurant or retail food establishment, rather than, as FDA's final rule requires, on all menus and menu boards from which a customer could order food. This information would also not have to be provided on any off-site menus, such as menu flyers offering home delivery.

Additionally, if a majority of the restaurant/establishment's orders are placed remotely (e.g., by phone or internet), it can provide the information exclusively on a remote-access menu such as through a website. Thus, even if 49 percent of an establishment's revenue came from customers ordering from menu boards inside the establishment, those boards would not have to provide any calorie information.

Covered establishments would also be allowed to provide calorie information per serving size determined by the establishment, so long as they included the number of servings in the menu item. This option would be in addition to the two options already allowed in the FDA final rule: calories per whole menu item (e.g., pizza pie), or calories per discrete serving unit (e.g., pizza slice) so long as the total number of serving units in the standard menu item is also listed. Serving sizes are difficult to compare between foods, and often do not reflect what a person actually eats as a serving. In fact, serving sizes are often set at sizes much smaller than what a person typically consumes, which wrongly suggests that people will consume fewer calories than is usual.

Restaurants and retail food establishments would also be allowed to provide calorie information for variable menu items – those that come in different flavors, varieties, or combinations, but are listed as a single menu item (such as ice cream, pizza, or doughnuts) – in ranges, averages, individual labeling of flavors or components, or labeling of a present standard build (the version of a menu item most commonly ordered by consumers).

Covered restaurants and retail food establishments would no longer have to provide FDA, upon request, with certifications or signed statements by responsible individuals certifying that they are in compliance with the menu labeling requirements, removing a mechanism by which FDA could help ensure that someone at each establishment is taking responsibility for complying with the menu labeling requirements.

As amended, H.R. 2017 also shields covered establishments from any civil lawsuits (except those brought by federal or state governments) for not complying with federal menu labeling requirements. It also shields establishments not subject to the menu labeling requirements (e.g., because they are not part of a chain with 20 or more locations) from civil lawsuits for not complying with state menu labeling requirements to which they are subject. Further, H.R. 2017 would preempt the ability of States and localities to implement nutrition labeling requirements.

Finally, the compliance date for the menu labeling requirements would be further extended until two years after the promulgation of final regulations pursuant to the Common Sense Nutrition Disclosure Act of 2015. Meaning, the requirements would not be able to go into effect until after this legislation was enacted, regulations promulgated and finalized, and a two year compliance period. The menu labeling requirements were enacted as a part of the

Affordable Care Act, passed in March 2010, giving covered establishments more than six years to prepare for the requirement to provide calorie information.

III. H.R. 3014, THE MEDICAL CONTROLLED SUBSTANCES TRANSPORTATION ACT

H.R. 3014, introduced by Representative Sessions (R-TX), would allow a physician to transport controlled substances to another practice setting or to a Presidentially-declared disaster area, if the physician is registered to dispense controlled substances listed on schedules II, III, IV, or V, and the physicians enters into a specific agreement with the DEA. The agreement would require a physician to provide advance notification to the DEA of any such transport, identify the controlled substances to be transported and the locations to and from which the controlled substances will be transported, the intended dates of transport, anticipated travel time and more. The physician is also required under the agreement to maintain records in the physician's primary practice setting on the dispensing of any controlled substance transported, including the location and quantity. Further, the duration of such transport is limited to no more than 72 consecutive hours.

Currently, physicians are prohibited from transporting controlled substances away from their registered practice locations to other locations. This legislation would allow, for example, athletic team physicians to transport a supply of controlled substances to athletic games in other states, or physicians to bring controlled substances to respond to a disaster.

At its November 4, 2015 markup, the Subcommittee on Health favorably forwarded H.R. 3014 to the full Committee by a voice vote.

IV. H.R. 3537, THE SYNTHETIC DRUG CONTROL ACT OF 2015

H.R. 3537 was introduced by Representatives Dent (R-PA), Himes (D-CT), Holmes Norton (D-DC), and Jolly (R-FL). At its November 4, 2015 markup, the Subcommittee on Health favorably forwarded H.R. 3537 to the full Committee by a voice vote.

This legislation would add a list of 316 synthetic drugs identified by DEA to Schedule I of the Controlled Substances Act (CSA), broken out into nine different classes including cannabinoids and opioids. The legislation would also make any compound that is chemically or pharmacologically similar to a controlled substance in Schedule I or II of the CSA to be legally treated as though it was listed in that same schedule. Currently, under the Controlled Substances Analogue Enforcement Act (the Analogue Act), substances must be substantially similar in chemical structure and pharmacologically similar to be considered as listed in Schedule I or II. The legislation would also narrow the Analogue Act so that it would only apply to the manufacture, importation, distribution, and sale of drugs, not possession. These changes are intended to assist with the prosecution of synthetic drug manufacturers and distributors and inhibit its use in the prosecution of people who are simply users of the drugs.

The synthetic drugs that are the target of the legislation are chemically modified versions of existing Schedule I drugs, modified to escape control by DEA while still retaining or

enhancing their potential for abuse. For example, some are designed to mimic or enhance the effects of drugs such as marijuana, cocaine, or methamphetamine. The effects and potential dangers of these substances are not well known. Use of synthetic drugs is reportedly on the rise, leading some to call on Congress to legislatively schedule specific substances. In June 2012, Congress passed the Synthetic Drug Control Act of 2011, to among other things, schedule selected synthetic stimulants and other synthetic substances. Criticisms have been raised about scheduling substances legislatively, with some arguing that the current formal scheduling process is too laborious to schedule synthetic drugs, which chemists can manipulate and modify relatively quickly. Concerns have also been raised by stakeholders, including pharmaceutical companies and the research community, about the difficulty of conducting research on substances that are listed on Schedule I and including the list of substances outlined in the legislation on Schedule I could preclude scientific or medical research into these substances.

V. H.R. 3716, THE ENSURING TERMINATED PROVIDERS ARE REMOVED FROM MEDICAID AND CHIP ACT

H.R. 3716, introduced by Representatives Bucshon (R-IN), Butterfield (D-NC) and Welch (D-VT) implements OIG recommendations from two reports to strengthen authorities originally authorized under the ACA to ensure that providers terminated in one state Medicaid program cannot simply enroll in different state's Medicaid program.[3] It would require states to report the termination of any individual or entity from the state's Medicaid/CHIP program to the Secretary for inclusion in the termination database that is accessible to states. The legislation would also require the Secretary to develop uniform criteria for states to use when submitting information on terminated providers. The legislation would additionally require providers offering care through managed care plans to enroll as a Medicaid provider with states.

At its November 4, 2015 Subcommittee on Health markup, an AINS making additional technical changes to the underlying legislation, extending certain implementation dates and ensuring statutory alignment with existing law, was adopted by a voice vote. The Subcommittee favorably forwarded the H.R. 3716, as amended, to the full Committee by a voice vote. An additional amendment in the nature of a substitute to be considered at the full Committee markup makes additional technical changes recommended by the Administration to ensure full existing provider appeals processes are preserved.

VI. H.R. 3821, THE MEDICAID DIRECTORY OF CAREGIVERS ACT

H.R. 3821, introduced by Representatives Collins (R-NY) and Tonko (D-NY), requires states that participate in fee-for-service Medicaid to publish a provider directory. Managed care

[3] The Department of Health and Human Services' Office of the Inspector General published two reports that provide the basis for the provider terminations legislation under consideration for the hearing: *CMS System for Sharing Information About Terminated Providers Needs Improvement* (March 2014) (OEI-06-12-00031), and *Providers Terminated from One State Medicaid Program Continued Participating in Other States* (August 2015) (OEI-06-12-00030).

plans in Medicaid are required to maintain such directories, and while many states already maintain provider directories in their fee-for-service programs, it is not a requirement. The proposed legislation stipulates minimum items to be included in the directory, but does not limit states to such items. It is important to note that many states make use of both fee-for-service and managed care in different components of their Medicaid programs. While the requirements in this legislation are not as comprehensive as the provisions related to this issue in CMS's recently proposed rule for managed care, additional technical assistance was incorporated in the bill through an AINS which was adopted by a voice vote at the November 4, 2015 Subcommittee on Health markup, further aligning this legislation with managed care requirements. The Subcommittee favorably forwarded H.R. 3821 to the full Committee, as amended, by a voice vote. Another amendment in the nature of a substitute to be considered at the full Committee markup makes additional technical changes recommended by the Administration.

VII. H.J. RES. 71 AND H.J. RES. 72

H.J. Res. 71 provides for congressional disapproval of the Environmental Protection Agency's (EPA) recent final carbon pollution rule for new power plants. H.J. Res. 72 provides for congressional disapproval of EPA's recent final carbon pollution rule for existing power plants, commonly known as the Clean Power Plan.

A. Background

On August 3, 2015, EPA Administrator Gina McCarthy signed two final rules to regulate carbon pollution from power plants: the Clean Power Plan for existing sources and standards for new, modified and reconstructed sources.[4] The two rules were published in the Federal Register on October 23, 2015. The same day, 26 states filed legal challenges in the U.S. Court of Appeals for the District of Columbia Circuit challenging the final rule for existing power plants.[5]

On October 26, 2015, Energy and Power Subcommittee Chairman Ed Whitfield (R-KY) introduced resolutions of disapproval for both rules in the House.[6] Companion resolutions have been introduced in the Senate by Senator Mitch McConnell (R-KY).

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[4] For further background information on the two rules, please see the Democratic memo from the October 7, 2015, hearing on "EPA's CO_2 Regulations for New and Existing Power Plants" (democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/ Dem-Memo-EP-CO2-Regulations-2015-10-7.pdf).

[5] Mississippi filed a legal challenge to the rule on November 4, 2015, bringing the total number of States challenging the Clean Power Plan up to 27. For further background information on the legal challenges to the Clean Power Plan, please see the Democratic memo from the October 22, 2015, hearing on "EPA's CO_2 Regulations for New and Existing Power Plants: Legal Perspectives" (democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/Dem-Memo-EP-CO2-Regs-Day2-2015-10-22.pdf).

[6] *See,* Majority Staff, House Committee on Energy and Commerce, *Congressional Review Act Resolutions to Fight Administration's Cap and Trade Assault* (Oct. 26, 2015) (energycommerce.house.gov/fact-sheet/111bd-congressional-review-act-resolutions#sthash.

On November 2, 2015, the Subcommittee on Energy and Power marked up H.J. Res. 71 and H.J. Res. 72. No amendments were offered during the markup, and ultimately both resolutions were favorably forwarded to the full Committee by a vote of 15 to 12, with no Democratic members supporting final passage.

B. Congressional Review Act

The Congressional Review Act (CRA) is an oversight tool that Congress may use to overturn a major rule issued by a federal agency. The CRA requires agencies to report on their rulemaking activities to Congress and provides Congress with a special set of procedures under which to consider legislation to overturn those rules. Upon receipt of the report in Congress, Members then can introduce and take action on a joint resolution of disapproval.[7]

As a practical matter, for purposes of the legislative process in the House, bills and joint resolutions are generally interchangeable. It is anticipated that H.J. Res. 71 and H.J. Res. 72 will follow regular order in the Committee. To avoid the need for a conference on a disapproval resolution, "[o]nce one house of Congress has adopted a joint resolution of disapproval, it is then sent over to the receiving house for consideration," and "any vote in the receiving house will be on the joint resolution that was sent over."[8] Most of the expedited consideration provisions of the CRA apply only to the Senate.

If the President vetoes the joint disapproval resolutions, then the final rules cannot take effect for 30 session days, unless the House or Senate votes to sustain the vetoes. If the joint disapproval resolutions are enacted, then EPA would not be able to reissue these rules or rules that are substantially similar.[9] This is particularly important for H.J. Res. 71 and H.J. Res. 72, since it would preclude this administration, or any other, from taking meaningful action to curb carbon emissions from power plants.

VIII. S. 611, GRASSROOTS RURAL AND SMALL COMMUNITY WATER SYSTEMS ASSISTANCE ACT

S. 611 would reauthorize technical assistance to small public water systems under the Safe Drinking Water Act (SDWA) through 2020 at current funding levels. It would also clarify that nonprofit organizations are eligible for funding under the program, and establishes criteria for selecting among eligible nonprofit entities.

Ats71m2C.dpuf).

[7] For more background information on the CRA please see; Congressional Research Service, *The Congressional Review Act: Frequently Asked Questions* (Apr. 17, 2015) (R43992); and Congressional Research Service, *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act* (Oct. 10, 2001) (RL31160).

[8] Center for Progressive Reform, *The Congressional Review Act: A Primer* (Jan. 10, 2009) (www.progressivereform.org/articles/congressional_review_act_primer.pdf).

[9] 5 U.S.C. § 801(b).

In addition, the bill directs the EPA Administrator to give preference to nonprofit organizations that, in the Administrator's discretion, "are the most qualified and experienced in providing training and technical assistance to small public water systems and that the small community water systems in that State find to be the most beneficial and effective." The bill does not define the terms "most qualified" or "experienced" or provide direction to EPA on how to ascertain what groups small systems find beneficial.

S. 611 was introduced in the Senate on February 27, 2015, by Senator Roger Wicker (R-MS).[10] It is a companion to H.R. 2853, introduced by Representatives Gregg Harper (R-MS) and Paul Tonko (D-NY) on June 23, 2015. The bill was reported by the Senate Committee on Environment and Public Works on April 29, 2015, and passed the Senate by unanimous consent on June 9, 2015.

The Subcommittee on Environment and the Economy held a hearing on October 22, 2015 on S. 611 to hear testimony regarding technical assistance and the impacts of current funding levels from two non-profit organizations, the Mississippi Rural Water Association and the Rural Community Assistance Partnership. EPA submitted additional testimony for the record.[11]

The Subcommittee marked up S. 611 on October 28, 2015.[12] Democratic members offered a series of amendments highlighting water-related issues that Democratic members would like to consider at future hearings.[13] Rep. Tonko offered amendments en bloc that would have made clarifying changes to the legislative text, including the specific programs that could be funded under technical assistance as defined in S. 611. Rep. Shimkus resolved that

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[10] S. 611, the Grassroots Rural and Small Community Water Systems Assistance Act, introduced February 27, 2015 (www.govtrack.us/congress/bills/114/s611).

[11] For more background information and witness testimony, please see the Democratic memo and documents from October 22, 2015, *hearing on Technical Assistance for Rural Water Systems: S. 611, the "Grassroots Rural and Small Community Water Systems Assistance Act*" (democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-technical-assistance-for-rural-water-systems-s-611-the).

[12] For more background information about S. 611, please see the Democratic memos from October 28, 2015, markup of S. 611, the "Grassroots Rural and Small Community Water Systems Assistance Act" (democrats-energycommerce.house.gov/committee-activity/markups/markup-of-s-611-grassroots-rural-and-small-community-water-systems).

[13] For reference, amendments offered were: 1) Tonko amendments en bloc clarifying the meaning behind language used in S. 611 and an amendment to reauthorize the SRF from 2015 to 2020, adjusting existing authorization for inflation; 2) Pallone amendment to reauthorize the brownfields program and raises the authorization level from 2015 to 2021 to address backlog of eligible contaminated sites; 3) Green amendment to restrict electronic waste (e-waste) exports; 4) Capps amendment to create a grant program to help water systems increase resiliency to climate change and adapt to its effects; and 5) McNerney amendment requiring EPA to prepare a strategic plan to address and mitigate the effects of drought on water systems.

Republicans would work with Democrats on report language. All amendments were withdrawn and S. 611 was favorably forwarded to the full committee by a voice vote.