

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

May 27, 2014

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee on Health Markup on H.R. 4299, Improving Regulatory Transparency for New Medical Therapies Act; H.R. 4709, Ensuring Patient Access and Effective Drug Enforcement Act of 2014; and H.R. 4631, Combating Autism Reauthorization Act of 2014.

On Wednesday, May 28, 2014, at 2:00 p.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Health will meet in open markup session on three bills: (1) H.R. 4299, *Improving Regulatory Transparency for New Medical Therapies Act*; (2) H.R. 4709, *Ensuring Patient Access and Effective Drug Enforcement Act of 2014*; and (3) H.R. 4631, *Combating Autism Reauthorization Act of 2014*.

All of the bills are bipartisan measures that have our support. The following memo supplements information provided in the Republican memo circulated on May 23, 2014.

I. H.R. 4299, Improving Regulatory Transparency for New Medical Therapies Act

H.R. 4299 would require the Drug Enforcement Administration (DEA) to place a drug or substance into the schedule recommended by the Food and Drug Administration (FDA) within 45 days of receiving the FDA recommendation. It also would require the DEA to make a final decision within 180 days on a registration application to manufacture or distribute a controlled substance to be used only in connection with a clinical trial.

II. H.R. 4709, Ensuring Patient Access and Effective Drug Enforcement Act of 2014

H.R. 4709 would provide definitions in the Controlled Substances Act for the phrases “consistent with the public health and safety” and “imminent danger.” It also would require the DEA to provide registrants an opportunity to submit an action plan to correct any violations of

law or regulation for which DEA is considering revoking or suspending their controlled substance. And it would require FDA, in consultation with DEA, to submit a report one year after enactment to Congress on patient access to controlled substances medicines, and on collaborative efforts to benefit patients and prevent diversion and abuse of controlled substances.

III. H.R. 4631, Combatting Autism Reauthorization Act of 2014

H.R. 4631 would reauthorize the Combating Autism Act (CAA), which was first authorized in 2006 and subsequently reauthorized in 2011.¹ CAA expanded upon autism provisions included in the Children's Health Act of 2000.² As noted in the Republican memo, the bill extends research and surveillance activities; education, early detection, and intervention efforts; and the work of the Interagency Autism Coordinating Committee. A manager's amendment is anticipated, reflecting ongoing bipartisan and bicameral efforts to achieve consensus legislation.

¹ Pub. L. No. 109-416; Pub. L. No. 112-32.

² Pub. L. No. 106-310.