

Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Markup on H.R. 4299, H.R. 4709, and H.R. 4631
Subcommittee on Health
May 28, 2014

Thank you, Chairman Pitts, for convening today's markup on the three public health bills, H.R. 4299, H.R. 4709, and H.R. 4631.

H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, would require the Drug Enforcement Administration to schedule a new FDA-approved drug containing controlled substances within 45 days. It also would require the Drug Enforcement Administration to make a decision within 180 days on a registration application to manufacture or distribute controlled substances for use in clinical trials. The bill is aimed at minimizing delays in getting new FDA-approved controlled substance prescription drugs to patients in need. I think the bill would make a significant contribution to solving this problem.

H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014, would add definitions to two phrases in the Controlled Substances Act, "consistent with the public health and safety" and "imminent danger" to better focus DEA's enforcement activities. It also would require the Drug Enforcement Administration 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 registration. And it would require the Secretary of Health and Human Services, in consultation with the Administrator of the Drug Enforcement Administration, to submit a report to Congress on patient access to prescription drugs that are controlled substances and how to prevent diversion and abuse of such drugs. The goal of the bill is to help drug distributors, pharmacies, and others work with the Drug Enforcement Administration to achieve the difficult balance between keeping controlled substance prescription drugs away from drug abusers but not from patients who need them.

H.R. 4631, the Combating Autism Reauthorization Act of 2014, would extend autism spectrum disorder activities at the Department of Health and Human Services and ensure these efforts are better coordinated with activities across the federal government. Recent data from the Centers for Disease Control and Prevention show more children are receiving an autism diagnosis. Continued federal support for autism activities at HHS will help us learn more about risk factors and causes of autism. And it will help ensure that more of our kids can benefit from early diagnosis and intervention. There are a few outstanding issues members and staff are working to resolve. But I am pleased with the progress that has been made so far and confident we can achieve our shared goal of bipartisan, bicameral consensus legislation as the bill advances through Committee.

I thank the bills' sponsors – Chairman Pitts, Ranking Member Pallone, Congressman Marino, Congressman Smith, and Congressman Doyle. I would also like to commend the bill sponsors' staff, and the Committee staff on both sides of the aisle, for their work on these bills. I support the three measures and urge my colleagues to do the same.