



THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

April 4, 2014

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing on “Improving Predictability and Transparency in DEA and FDA Processes”

On Monday, April 7, 2014, the Subcommittee on Health will hold a hearing entitled “Improving Predictability and Transparency in DEA and FDA Processes.” The Subcommittee will convene at 3:00 p.m. in 2123 Rayburn House Office Building. At the hearing, the Subcommittee will review H.R. 4299, the “Improving Regulatory Transparency for New Medical Therapies Act,” H.R. 4069, the “Ensuring Patient Access and Effective Drug Enforcement Act,” and H.R. 4250, the “Sunscreen Innovation Act.”

I. WITNESSES¹

Panel One

- Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; and
- Mr. Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

Panel Two

- Dr. Nathan B. Fountain, Chair, Medical Advisory Board, Epilepsy Foundation;
- Mr. John M. Gray, President and CEO, Healthcare Distribution Management Association;
- Mr. D. Linden Barber, Partner and Director, DEA Compliance Operations, Quarles & Brady; and,
- Ms. Wendy K.D. Selig, President and CEO, Melanoma Research Alliance.

II. LEGISLATION

H.R. 4299, the “Improving Regulatory Transparency for New Medical Therapies Act”

¹ Additional witnesses may be added.

Chairman Pitts and Ranking Member Pallone introduced H.R. 4299 on March 26, 2014. Currently, new drug products containing substances that previously have not been marketed in the United States and that have abuse potential must be scheduled under the Controlled Substances Act (CSA) by the Drug Enforcement Agency (DEA) prior to being marketed. Under the CSA, there is no deadline for the DEA to make a scheduling decision after receiving a recommendation from the Food and Drug Administration (FDA), and the delays in DEA's decisions have increased significantly. H.R. 4299 would rectify that problem by ensuring DEA acts in a timely manner.

H.R. 4069, the "Ensuring Patient Access and Effective Drug Enforcement Act"

H.R. 4069 was introduced by Representative Marino and Representative Blackburn on March 20, 2014. The bill would help prevent prescription drug abuse while ensuring that patients have access to needed medications by fostering better collaboration between drug manufacturers, wholesalers, pharmacies, DEA, and FDA.

H.R. 4250, the "Sunscreen Innovation Act"

Representative Whitfield and Representative Dingell introduced H.R. 4250 on March 13, 2014, as a solution to the current backlog of sunscreen ingredients currently pending at FDA. FDA has not approved a new sunscreen ingredient since the late 1990's, and this bill would reform the process to ensure that new sunscreen ingredients are reviewed in a timely manner.

III. STAFF CONTACT

If you have any questions regarding the hearing, please contact Carly McWilliams or John Stone at (202) 225-2927.