

June 10, 2014

The Honorable Fred Upton
2183 Rayburn House Office Building
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The Honorable Diana DeGette
2368 Rayburn House Office Building
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Submitted electronically to cures@mail.house.gov

RE: IDSAs Members' Group Response to 2nd White Paper — 21st Century Cures: An Update on the President's Council of Advisors on Science and Technology (PCAST) 2012 Report on Propelling Innovation

Dear Chairman Upton and Representative DeGette:

As infectious diseases physicians and scientists, we applaud the House Energy & Commerce Committee for launching its 21st Century Cures initiative. Further, we appreciate your review of the recommendations provided in the 2012 President's Council of Advisors on Science and Technology (PCAST) *Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation*. As you know, we are in the midst of the public health crisis of rapidly rising antibiotic resistance. Many of us who work in clinical settings see increasing numbers of patients who have infections that we cannot effectively treat with current antibiotics. Additionally, economic and regulatory disincentives continue to keep pharmaceutical companies on the sidelines of antibiotics research and development (R&D). For these reasons, we ask that you act without delay on the 2012 PCAST recommendation of a limited population drug approval pathway by advancing the widely supported Antibiotic Development to Advance Patient Treatment (ADAPT) Act, H.R. 3742.

The bipartisan ADAPT Act establishes a new limited population approval pathway for antibiotics to treat serious or life-threatening infections where an unmet medical need exists. The legislation would allow the Food and Drug Administration (FDA) to approve ADAPT drugs based upon smaller clinical trials. It is often not feasible for these drugs to be developed using traditional, large clinical trials due to the limited numbers of patients in whom these infections currently occur. ADAPT drugs would need to meet FDA standards of evidence for safety and effectiveness for the limited indicated population. ADAPT would guide proper stewardship of covered drugs with numerous mechanisms, including a statement on the label that the "drug is indicated for use in a limited and specific population." This provision could be strengthened by including a prominent visual element, such as a logo, to make it simple for the health care community to quickly recognize that these drugs are approved for a limited population and must be used prudently.

The 2012 PCAST report is joined by the 2013 Centers for Disease Control and Prevention report on antibiotic resistant threats in the United States, 2014 World Health Organization global report on antibiotic resistance, and the 2014 progress report of the Transatlantic Taskforce on Antimicrobial Resistance in stressing the urgency of the crisis and calling for the development of new drugs. The

threat from antibiotic resistance and the lack of new drugs is well documented. However, we are increasingly concerned that a lack of action is costing lives.

According to CDC, approximately 23,000 Americans will die this year due to antibiotic-resistant infections. This is a very conservative estimate due to limited surveillance and data collection capabilities. The economic costs of antibiotic resistance are high as well. Antibiotic resistant infections cost the U.S. health care system an estimated \$20 billion annually (including 8 million additional hospital days) and \$34 billion in societal costs.

We urge the House Energy & Commerce Committee to move quickly to advance the ADAPT Act. The legislation has bipartisan support and fits well within the scope of the 21st Century Cures initiative. With patients losing their lives to multi-drug resistant infections, we don't have a day to waste.

Sincerely,

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