

Allan Coukell, Senior Director, Drugs, Medical Devices, and Food Safety, Pew Charitable Trusts

Questions for the record for September 19 hearing “Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development”

The Honorable Joseph R. Pitts

- 1. What are other countries or the European Union doing to help spur research and development for anti-infectives? Which initiatives are working well and which will likely have the most significant impact to draw more companies to anti-infective product development moving forward?**

To support antibiotic development, the European Union established the Innovative Medicines Initiative (IMI), a partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations trade group. IMI includes a program called New Drugs for Bad Bugs (ND4BB), which is funding projects to develop guidelines for designing and developing new drugs to target resistant pathogens, establish a pan-European network of clinical trials sites, facilitate information sharing, and provide concrete recommendations for new commercial models that provide industry with investment incentives while ensuring that new antibiotics are used wisely. Four of these projects are ongoing while another three projects are still in development. While it is too soon to assess the impact of the ND4BB program, companies have welcomed the EU’s public-private partnership approach to tackle antibiotic resistance and address some of the key barriers to the development of effective antibiotics.

The Honorable Marsha Blackburn

- 1. Our committee has enacted important reforms like the GAIN Act to stimulate development of new antibiotics, but realize more work needs to be done. It is my hope that as part of the 21st Century Cures effort we’ll put additional incentives in place for antibiotics that are designed as Qualified Infectious Disease Products (or QIDPs). What other specific incentives do you recommend Congress consider for FDA designated QIDPs?**

Pew supported the GAIN Act as an important first step to addressing some of the economic challenges to antibiotic development and we appreciate the Committee’s leadership on this issue. To date, 39 antibiotics in development have received qualified infectious disease product (QIDP) status under GAIN. Of these, three have recently received FDA approval, with a fourth decision expected by the end of this year. But more needs to be done to encourage drug companies to enter and stay in antibiotic development, particularly for drugs to treat multidrug resistant infections. For this reason, Pew supports the creation of a new regulatory pathway for antibiotics that meet an unmet medical need and are intended to treat serious and life-threatening

infections in a limited population of patients. Any drug approved under this pathway would also qualify as a QIDP and therefore be eligible for additional exclusivity, as well as fast track and priority review, as authorized under GAIN.

Representatives Gingrey and Green and their bipartisan colleagues have introduced the Antibiotic Development to Advance Patient Treatment (ADAPT) Act to create a limited population antibacterial drug (or LPAD) pathway. ADAPT would allow drug developers to bring drugs through the approval process for narrow indications, which would make these clinical trials more feasible than the larger clinical trials that companies now have to conduct in order to get a broader indication.

- 2. Congress via GAIN gave FDA a very important tool, to designate certain anti-infectives as Qualified Infectious Disease Products (QIDP); and the agency has made good progress on QIDP guidance, as well as designating over 30 developmental antibiotics as QIDPs. If we create other incentives as we should – real incentives are needed – we must avoid a situation where there’s confusion and differences over what qualifies for which type of incentives across different agencies of HHS. Will you respond to this statement?**

The National Institutes of Health, the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services, as well as agencies outside of HHS and academic and industry partners, can all play roles in addressing the economic, regulatory, and scientific challenges that stymie antibiotic drug development

It is certainly important that leaders in Congress and the Administration ensure that federally funded research and incentives are transparent and coordinated, but differences in incentive programs are not inherently problematic. Different agencies at HHS can influence drug development at different stages in the process, and the barriers at each of those stages are different, and thus we would expect responsive policy solutions to also be different. For example, if NIH were to only fund research anticipated to lead to the development of QIDPs, or, more narrowly, drugs that would qualify for an LPAD pathway, significant advancements in basic science that could lead to new classes of broad-spectrum antibiotics could be missed. But later in the development process – e.g. as product sponsors are seeking FDA approval -- barriers may be more significant for drugs targeting narrow populations where clinical trials are more difficult and thus policy solutions targeting that smaller subset of drugs, such as the ADAPT Act, are more appropriate.

Given the urgent need for new antibiotics, it is important that everyone involved in the drug discovery process understand what programs exist within the federal government to facilitate antibiotic development. We believe that effective outreach to the research community, including

academic and industry researchers, is an essential component of any meaningful national strategy to address antibiotic resistance.