

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PAC CARB) January 30, 2019 – SIDP President Kerry LaPlante’s Public Comments

Thank you, Chairperson Blaser, Vice Chair King, Officer Musmar, and the entire HHS Advisory Council.

My name is Kerry LaPlante, I have been a clinical Infectious Diseases pharmacist, researcher, and antimicrobial stewardship educator for over 15 years. I have stood alongside my physician, nursing, and microbiology colleagues designing antimicrobial therapy for our patients that have no options for treatment as their bacteria is fully resistant to nearly every antibiotic available for human use. Together, we scramble to concoct mixtures of antibiotics, using *in vitro* data, hoping to override resistance and hoping for synergy to save our dying patients. Many of these patients have already endured and overcome months of chemotherapy, only to find themselves kicked down and fighting for their lives – again.

But in addition to my personal experience and request, I am here in my role as President of the Society of Infectious Diseases Pharmacists (SIDP) – a society that has been a dedicated player in antimicrobial stewardship, research, education, and advocacy for nearly 30 years.

Our vision is “**Safe and effective antimicrobial use for now and the future.**”

Our focus is **Advocating for our patients.**

I’d like to put forward two priority requests to PAC CARB framed in both Antimicrobial Use and Innovation.

First, Improving the Antimicrobial Pipeline, Usage, and Access.

SIDP applauds the goals of this task force which include infection prevention and stewardship, surveillance, diagnostics, treatment innovation, research, and international approaches. SIDP submitted formal recommendations for each of these goals in the Request for Information (RFI) process.

While we appreciate these goals – all are important – we urge this HHS Advisory Council to prioritize Goal 4 [*authored by SIDP’s Policy, Government, and Advocacy Team.*]

Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines

Specifically,

- 1) Promote the development of new antibiotics.** As pharmacists, we must ensure access to anti-infective agents through increased regulation, coordination with insurance providers, and public/private/academic manufacturing partnerships. There is

an overall need for additional “push” and “pull” incentives that promote investment for discovery and development of new antibiotics.

- Create innovative new funding mechanisms and partnerships for antibiotic research for CDC, NIH, AHRQ and FDA.
- Advise recommendations that reform CMS policy towards inpatient reimbursement of antibiotics outside of the current DRG payment system.
- Develop a system that incorporates local epidemiology and patient risk that moves away from a “one-size-fits-all” approach. Emphasis should be placed on **reimbursement for appropriateness of use**, rather than amount of use.
- Develop a framework for value-based pricing/reimbursement like those used in hepatitis C therapies and cancer treatments.

2) Protect the supply of existing drugs. Each day – pharmacists juggle national anti-infective drug shortages which are associated with patient harm and can increase risk of *Clostridioides (Clostridium) difficile*, and under-treatment of serious infections due to the lack of appropriate agents.

- We suggest a **new** priority that will further develop strategies to mitigate the impact of anti-infective shortages and decrease the risk of shortages from occurring through enhanced communication and early response from manufacturers and the FDA. Key anti-infective agents that are both generic and essential to public health should be identified and public/private/academic partnerships should be developed to ensure a consistent supply of key agents is available.

Lastly, the PAC CARB serves as the primary external body to inform the federal government efforts in antimicrobial resistance. We applaud the hard work and dedication of the physicians, veterinarians, and researchers on the PAC CARB, but the lack of pharmacy expertise on this committee should be noted.

Antimicrobial resistance is a drug safety issue. Pharmacists are medication safety and efficacy experts. Like our Infectious Diseases physician colleagues, our ID trained pharmacists have over 10 years of formal education, residency, and can include fellowship training in antimicrobial pharmacology, antimicrobial stewardship, safety, and efficacy.

We lead antimicrobial stewardship efforts at our institutions, coordinate medication access, ensure appropriate use, and are critical in safeguarding appropriate antibiotic use. On behalf of our over 1500 national and global ID and antimicrobial stewardship pharmacist members, I ask that Infectious Diseases pharmacist expertise be represented on this Advisory Council to the US Health and Human Services.

Thank you.