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June 26, 2017

The Honorable Michael Burgess
Chairman, Health Subcommittee
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member, Health Subcommittee
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green:

Public Citizen is a national consumer advocacy organization with more than 400,000 members and supporters. We advocate on an array of issue areas to advance the public interest, including ensuring prescription drugs meet high safety and efficacy standards and are made more affordable both in the U.S. and abroad.

While we are encouraged by the attention given to antimicrobial resistance by members of the Energy and Commerce Health Subcommittee in its June 6 hearing, "Examining Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA)", we are concerned that incentive mechanisms under consideration are more focused on delivering profits to pharmaceutical manufacturers than ensuring research and development meets public health needs.

Specifically, we oppose the use of market entry rewards (MER) and transferable intellectual property (IP) as incentive mechanisms for antimicrobial drug development for the reasons enumerated below, and urge you to reject their inclusion in PAHPA or any other legislation.

1) Investments in R&D and innovation must not focus exclusively on bringing new antimicrobial drugs to market, but also on other areas of innovation that are needed to most effectively combat antimicrobial resistance, including repurposing of older antibiotics, adapting existing drugs to specific local needs, exploring the role of combination products, researching and developing new diagnostic and vaccine technologies, sustainable implementation of new technologies within health programs and piloting and scaling of improved antimicrobial use practices. MER and transferable IP approaches fail to recognize the importance of innovation beyond bringing new antimicrobial drugs to market.

2) R&D incentives must not sacrifice the needs of other patient groups. If awarded, transferable IP vouchers would extend the monopoly of other, essentially unrelated prescription drug products through lengthening patent, data or market exclusivity. Manufacturers would have the incentive to apply transferable IP to the most expensive, blockbuster treatments. For example,

prescription drug manufacturers regularly price cancer treatments at more than $10,000 per month.[1] As a result, cancer patients are more than 2.5 times more likely to declare bankruptcy than people without cancer.[2] Beyond the financial hardship, cancer patients that file for bankruptcy are at nearly two-times higher risk for mortality than those who do not file bankruptcy.[3] Delaying generic and biosimilar competition on these and other exorbitantly priced therapies would diminish access to medicines, cause financial hardship, strain health program resources and lead to preventable suffering and death.

3) R&D incentives must be coherent with the principles that all countries, including the United States, agreed to in the 2016 UN High Level Declaration on AMR. The 2016 UN High Level Declaration on AMR states "we acknowledge the importance of delinking the cost of investment in research and development on antimicrobial resistance from the price and volume of sales so as to facilitate equitable and affordable access…" High prices prevent equitable access by making medicines unaffordable for some, while profits driven by high sales volume would provide incentive for maximizing sales, which would be contrary to good stewardship. MER and transferable IP vouchers would fail to delink R&D from high prices and volume-based sales, perpetuating a profit focus with expensive drugs and limited patient access; they would not facilitate equitable and affordable access. Existing vouchers, namely Priority Review Vouchers (PRVs) rewarded to developers of medicines for rare and neglected diseases, do not include any conditions on affordability or availability of those medicines. Vouchers do not encourage stewardship of newly developed antibiotics.

4) R&D incentives for new antibiotics must not inappropriately reward manufacturers for bringing new drugs to market that do not have high clinical utility. Academic researchers have pointed out that more than 40% of antibiotics brought to market from 1980 to 2009 have been withdrawn – more than triple the rate of withdrawal of any other therapeutic category – and the majority of those withdrawals were for reasons unrelated to safety.[4] This is likely due to the large number of follow-on product approvals that are not clinically significant. Manufacturers should not be rewarded with a windfall for bringing new drugs to market when those drugs do not provide increased clinical benefit compared to existing, lower-cost treatments. For example, the overly-broad Qualifying Infectious Disease Product designation covers almost any newly marketed antibiotic and has not spurred development of clinically useful antibiotics.

Lowering clinical trial standards for antibiotic drugs through the ADAPT Act and increasing profit incentives for antibiotic manufacturers through the GAIN Act have not provided the innovation that is needed to combat antimicrobial resistance. Further eroding clinical trial standards or augmenting profit motives should not be expected to succeed where these policies have failed.

Instead, policies to support R&D should change the innovation ecosystem by facilitating collaboration through sharing of research results, trial data, and pooling IP rights, where appropriate. R&D should be

[1] https://www.mskcc.org/research-areas/programs-centers/health-policy-outcomes/cost-drugs
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4240626/
[3] http://ascopubs.org/doi/full/10.1200/JCO.2015.64.6620?sid=c2a35840-5f19-4c2f-9153-ed9abf2d7533&
[4] http://journals.sagepub.com/doi/pdf/10.1111/jlme.12079

guided by the principles of delinking the cost of R&D from the price and volume of sale; transparency of R&D costs, clinical trial data and pricing; fair return on public investment; and coupling upstream incentives with access and stewardship downstream.

Again, we urge you to reject the inclusion of market entry rewards or intellectual property vouchers in PAHPA or any other legislation.

Thank you for your time and attention.

Sincerely,

Steven Knievel, Access to Medicines Advocate, Public Citizen
Peter Maybarduk, Director, Public Citizen's Access to Medicines Program

Cc: Members of the House Committee on Energy and Commerce, Health Subcommittee