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The Honorable Frank Pallone, Jr.
House Committee on Energy & Commerce
United States House of Representatives
Washington, D.C. 20515

The Honorable Gene Green
House Committee on Energy & Commerce
United States House of Representatives
Washington, D.C. 201515

Dear Mr. Pallone and Mr. Green,

I am writing regarding the Strengthening Public Health Emergency Response Act of 2015 (H.R. 3299) which would extend the priority review voucher program to medical countermeasures.

I was one of the authors of the 2006 *Health Affairs* paper that proposed the priority review voucher program (Ridley, Grabowski, and Moe 2006). Our aim was to encourage development of new drugs for neglected diseases. In 2012, Congress extended the voucher program to rare pediatric diseases. I am writing to highlight the trade-offs associated with extending the voucher program to more diseases.

Like neglected diseases, there is little private financial incentive to develop medical countermeasures. Furthermore, there is potentially enormous need. Hence, it is important to create incentives to develop new treatments as medical countermeasures.

Viewed in isolation, it makes perfect sense to add medical countermeasures to the diseases eligible for priority review vouchers. However, members of Congress should be aware that adding voucher-eligible diseases will drive down the price of vouchers and thus drive down the incentive to develop treatments for diseases already on the list. In the current issue of *Health Affairs*, my coauthor and I estimated that if one voucher is available in a year, it will be worth more than $200 million, but if four vouchers are available, then the price could fall below $100 million (Ridley and Régnier 2006). If voucher prices fall below $100 million, then the expected net present value of the voucher would fall below the typical cost of a Phase III clinical trial and FDA submission. Hence, the voucher would not provide sufficient incentive for drug development and additional incentives would be needed, such as a profitable commercial market or the promise of government purchase.

To limit the supply of vouchers and thus maintain high voucher prices, members of Congress have two levers: limiting the eligible diseases and limiting the characteristics of the drugs. For example, Congress could restrict voucher eligibility to only truly novel drugs or only drugs for which the drug developer conducted new trials. Furthermore, Congress could require the voucher recipients have filed a report describing their access plan prior to drug submission. In the case of medical countermeasures, the access plan would be providing the drug to the government.

If Congress does not make medical countermeasures eligible for vouchers, then a prize should be considered. The US government could create a prize of $350 million per approved new drug for medical countermeasures. A prize of this size would replicate the highest sales price of a

voucher. Perhaps the funds could be found in the existing budgets of the Department of Defense or Health and Human Services. A $350 million prize will likely be too small to excite large pharmaceutical manufacturers, because of their high cost structure (unless they choose to participate as a source of pride for their employees). However, even if large manufacturers are not interested, many small drug developers would likely be interested. There are many small developers, and surely some developers have drugs for infectious diseases that would be easy to test at relatively cost. An advantage of a prize (pull) mechanism is that government officials need not know about these small companies in advance, they need only know about the companies if they succeed. My experience with the priority review voucher has been that there are many small companies that few have heard of, but are willing and able to develop drugs for infectious diseases at relatively low cost.

One way in which Congress could strengthen the voucher program and drug review more broadly would be to loosen the limits on pay for scientific reviewers at the Food and Drug Administration. The priority review voucher puts an extra strain on the FDA because it requires faster review. However, every priority review voucher redeemed comes with $5 million in user fees ($2.4 million for the standard fee and $2.7 million for the voucher) from the developer. So FDA has extra money to hire staff, but if FDA cannot attract new staff given pay restrictions, then the extra fees are not particularly helpful, and the voucher program creates a heavy burden for the FDA.

I am grateful to the members of Congress for their enthusiasm for the voucher program and for looking for ways to strengthen it. As I've worked with Congressional staff on the voucher program, I have been thoroughly impressed with those I have met on both sides of the aisle. They seem genuinely interested in getting things right.

Sincerely,

David Ridley, PhD
Duke University

C: Chairman Fred Upton