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Pallone Statement at Hearing on H.R. 3299, the "Strengthening Public Health Emergency Response Act"

Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) delivered the following statement today at a Health Subcommittee Hearing on "Examining H.R. 3299, the Strengthening Public Health Emergency Response Act."

Thank you, Mr. Chairman. Since the attacks of September 11th, Congress has worked in a bipartisan manner to increase our efforts to combat and respond to biological threats. However, experts have repeatedly warned that our ability to respond to biological threats must be improved.

Earlier this year the Subcommittee on Oversight and Investigations heard from members of the Blue Ribbon Panel on Biodefense and other experts about the U.S.'s biodefense preparedness. According to this report, the United States "does not afford the biological threat the same level of attention as it does other threats." The report notes that we lack a centralized leader for biodefense, a comprehensive national strategic plan, and a dedicated budget for biodefense. This comprehensive review also offered 33 recommendations about how Congress and the Administration can improve our preparedness.

H.R. 3299, the Strengthening Public Health Emergency Response Act, includes a number of provisions that would make progress in improving our readiness.

While I support the intent of this legislation, I do have some concerns that I am interested in discussing with our panel of witnesses today. One such area is related to the Hospital Preparedness Program. This legislation would limit the amount of funding that the Assistant Secretary for Preparedness and Response can use to operate this program to three percent of the program's total funding. I am concerned that this limitation, while well-intended, would limit the ability of ASPR to effectively oversee and evaluate the Hospital Preparedness Program. This limitation also would eliminate funding for other efforts that support our health care preparedness, response, and recovery ecosystem. This change may harm rather than strengthen our health system preparedness.

I am also concerned about the delegation of contract authority to the Biomedical Advanced Research and Development Authority or BARDA. Like other HHS divisions, ASPR operates the contracting office for all divisions and programs under its authority. This structure ensures that federal investments are made through a fair and open process that is free of any conflicts. Removing ASPR oversight could lead to undue influence on the contracting process by the BARDA Director, another program officer, or an outside source.

Finally, I want to express serious concerns about further expanding the tropical disease priority review voucher program. This program, created in 2007, was intended to incentivize research and development of drugs to treat tropical diseases that disproportionately affect poor and marginalized populations. Once a qualifying drug is approved, the sponsor receives a priority review voucher that entitles the sponsor to a second six-month review of any other human drug application. The sponsor is also able to sell this voucher. Recently, a priority review voucher sold for $350 million. Since creation of the tropical disease PRV program, three PRVs have been awarded.

There has been significant interest from industry and others in expanding this program as a way to encourage development of medical countermeasures. While I believe we should explore additional ways to incentivize medical countermeasure development, I do not believe expanding the tropical disease PRV program is the answer. Not only could expansion decrease the value of a PRV and the incentive to develop drugs under such programs, but it also increases the burden on FDA to expedite review of additional applications that may not otherwise qualify for expedited review. This undermines the agency's public health mission.

I'm concerned that expansion would only exacerbate known flaws in the current program. For example, current law requires FDA to award vouchers to sponsors even if a drug was previously approved in other countries. Additionally, there is no requirement that a sponsor market a product approved under the program. Therefore, there is no guarantee that these drugs are actually helping the people Congress intended to help.

I look forward to hearing from our government witnesses on these issues. And, as the Committee moves forward with this legislation, I hope there will be an opportunity for Members to hear from additional stakeholders about these concerns and how they can best be addressed.

Thank you.

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