



COMMITTEE ON
ENERGY & COMMERCE
DEMOCRATS
RANKING MEMBER FRANK PALLONE, JR.

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Pallone Statement at Health Subcommittee Markup

Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) today delivered the following remarks at a Health Subcommittee markup on H.R. 3299, the “Strengthening Public Health Emergency Response Act of 2015,” and H.R. 291, the “Sports Medicine Licensure Clarity Act of 2015.”

Thank you, Mr. Chairman. Today the Committee is considering two bipartisan bills. The first H.R. 3299, the Strengthening Public Health Emergency Response Act, strives to help increase our emergency preparedness in two key ways. First, it would improve our medical countermeasure capabilities within the Biomedical Advanced Research and Development Authority or BARDA at HHS. And, second it would provide additional incentives to companies that choose to manufacture medical countermeasures.

The second bill H.R. 921, the Sports Medicine Licensure Clarity Act of 2016, would ensure that sports medicine professionals who travel with sports teams have access to their liability insurance. I want to thank the Chairman and his staff for their willingness to work with us to address some of the concerns that have been raised regarding both of these bills.

I also want to thank my colleagues and sponsors of H.R. 3299, Ms. Brooks and Ms. Eshoo, for their commitment to improving our ability to respond to biological threats. This bill includes a lot of important provisions that will make a real difference, but I want to highlight two remaining concerns I have with it.

While I support making improvements to BARDA’s contracting process, I worry about the consequences of injecting undue influence into the contracting process if the contracting office is moved to report directly to the BARDA Director. I understand this provision is intended to speed up the contracting process. But as we heard at our hearing, BARDA’s Acting Director opposes this change because it attempts to fix a problem that doesn’t exist and could have the reverse effect of actually slowing down the process. In fact, he explained that BARDA’s average contracting timelines already take less time to complete than allowed by HHS guidelines and that the current process has a track record of success in meeting emergencies. For example, the completion of a recent contract to supply blood to Puerto Rico in response to the Zika epidemic was completed in six business days.

I am also worried about the consequences of further expanding the tropical disease priority review voucher (PRV) program under this bill. The PRV program was intended to incentivize research and development of drugs to prevent and treat tropical diseases that disproportionately affect poor and marginalized people. To date, the program has

not worked as intended, and there are serious, unresolved issues that must be addressed before the program is expanded.

For example, under the current program, sponsors were rewarded even though they did not invest in new drug research and development, or did not facilitate drug access to those suffering in poor and underdeveloped countries. This conflicts with the goals Congress had when it created the program in 2007.

I still believe we should explore other ways to incentivize medical countermeasure development, but expanding the tropical disease PRV program is not the answer. I remain concerned about the impact the program expansion will have – both on the value of a PRV as an incentive for drug development and on FDA resources. An influx of PRVs will reduce market value and therefore reduce incentives to invest in research and development of drugs to prevent or treat rare pediatric diseases, tropical diseases, and medical countermeasures. Additionally, an influx of PRVs will undermine FDA's core public health mission. Every time a PRV is redeemed, the agency must divert resources away from other critical work which could delay approval of important human drugs.

Despite my concerns, I look forward to working with the Chairman and the rest of the subcommittee to further discuss how to resolve existing issues so that we can end up with a bill that will appropriately incentivize development of medical countermeasures and best serve the American people.

H.R. 921, the Sports Medicine Licensure Clarity Act of 2015 will ensure that sports medicine professionals are covered by their liability insurance while they are traveling with their teams. Medical licensure is state-specific, so when a provider travels with a team, they are often practicing without a license and without their medical liability insurance. This is a commonsense bill that solves a problem unique to sports medicine professionals since they travel around the country with their teams. What's important is that it does not allow these providers to practice beyond the scope of their license or to treat athletes off the field.

I'm pleased that the sponsors were able to work with the Committee and stakeholders to ensure that the bill achieves the right balance. I want to thank Mr. Guthrie and Representative Cedric Richmond from Louisiana for being open to these changes and I urge members to support its passage.

Thank you and I yield back.

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