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H.R. 2672

“PRESERVING ACCESS TO ORPHAN DRUGS ACT OF 2011”

Why did you introduce H.R. 2672, the "Preserving Access to Orphan Drugs Act of 2011?"

Patients coping each day with rare and often life-threatening diseases depend on having continued access to the latest, most-innovative treatments. It is critical to ensure that the enactment of the Affordable Care Act does not put these treatments out of reach for patients or discourage investment and research essential to developing new drugs and improving the effectiveness of others used to treat rare diseases.

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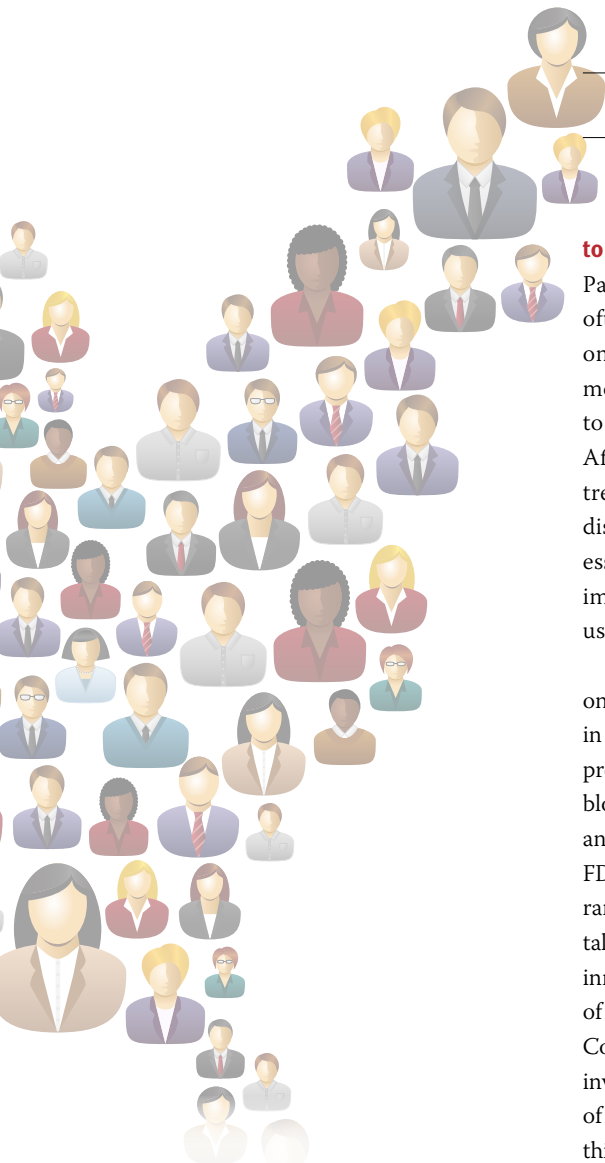
Since its enactment, the ODA has successfully supported bringing more than 350 drugs and biological therapies to market. By comparison, fewer than 10 products to treat rare diseases came to the market in the 10 years prior to the ODA enactment. Congress should not turn back the clock to an era when it was much more difficult to get these medicines to the patients whose lives depend on them.

However, there are serious concerns that the Affordable Care Act (ACA) enacted in March of 2010 could jeopardize the progress made since enactment of ODA. The health-care law placed a new annual pharmaceutical fee on the sale of branded drugs. That law exempts orphan drugs from paying the fee, but the exemption

is narrowly defined. H.R. 2672 would clarify or modify that exclusion to apply to all drugs solely indicated to treat one or more rare diseases. This legislation would preserve and build upon the incentives for orphan drug development that Congress has supported for more than two decades.

The common sense legislation I've introduced has the support of fellow Pennsylvania Congressman Jason Altmire of the 4th District, who is an original co-sponsor of the bill. Both Congressman Altmire's district in Southwestern Pennsylvania and my district in Southeastern Pennsylvania are home to a number of innovative biotechnology and biopharmaceutical manufacturers. Every day, the talented researchers and workers at these companies produce therapies for rare diseases. The annual fee in the health care law enacted in 2010 would hamper these efforts and could stifle innovation into orphan therapy development. A number of manufacturers, including CSL Behring, the members of PPTA, and several other biotechnology companies in Pennsylvania have been instrumental in raising awareness about the need for H.R. 2672 and how this proposal would spur innovation.

I'm also pleased that Pennsylvania's two U.S. Senators, Pat Toomey and Robert Casey Jr. along with Senator Wyden from Oregon have introduced an identical, bipartisan bill in the Senate. Further, patient groups support this legislation, including the National Organization for Rare Disorders, the Immune Deficiency Foundation and the Alpha 1 Foundation. All of these groups understand the need to preserve future development of rare disease therapies. I am hopeful that all of these efforts will result in enactment of our legislation, but more importantly continued access to treatment for patients and continued investment in the companies that create jobs and contribute to the vitality of our communities. ☺



H.R. 2672, the "Preserving Access to Orphan Drugs Act of 2011" introduced by Rep. Gerlach in the summer would modify the orphan drug exclusion of a new tax on branded drugs enacted as part of the Affordable Care Act (ACA).

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