RESOLUTION CONCERNING the passage of a fifth reauthorization of the Prescription Drug User Fee Act (PDUFA)

WHEREAS, since its inception in 1992 and through four subsequent reauthorizations, the Prescription Drug User Fee Act (PDUFA) has facilitated a faster, safer process of approving the development of new medicines, which in turn has led to the employment of countless union workers tasked with building the facilities necessary to manufacture these drugs; and

WHEREAS, in the years before the implementation of PDUFA, 70 percent of new medicines were first marketed overseas and 60 percent of new medicines were on the market overseas for one or more years before they were approved in the United States; and

WHEREAS, as a direct result of provisions in PDUFA the turnaround for review and approval of new drugs by the Federal Drug Administration (FDA) has been cut by over half from over 2 years to less than 1 year, and in recent years the United States has launched around 50 percent of all new active substances entering the world market; and

WHEREAS, this faster approval process has led to innovation within the biopharmaceutical sector that has resulted in over 1,500 new medicines designed to fight cancer, diabetes, HIV/AIDS, cardiovascular disease, neurological disorders, and more to be manufactured in America, reach the market quicker, and save lives; and

WHEREAS, the competitive edge created by PDUFA has allowed the U.S. biopharmaceutical sector to compete globally while maintaining a significant employment footprint domestically, supporting more than 4.4 million American jobs; and

WHEREAS, each year America's building trades unions spend $1 billion – none of it taxpayer money – on training and certification programs that ensure their workforce remains the best in the world and able to meet the exacting standards required to build facilities to manufacture newly approved medicines; and

WHEREAS, the continued success of the partnership between labor and management in the biopharmaceutical industry is reliant on PDUFA legislation providing a focused mandate that empowers the FDA to approve new medicines efficiently and safely; and

WHEREAS, the current PDUFA reauthorization is set to expire in September, 2017; therefore be it,

RESOLVED that the union and industry Trustees of the Pharmaceutical Industry Labor-Management Association call on the United States Congress to pass a timely PDUFA reauthorization that ensures continued predictability, consistency, and transparency in the human drug review program; and

BE IT FURTHER RESOLVED that PILMA supports a PDUFA reauthorization that will help create domestic jobs, foster a pro-innovation environment, sustain investment in regulatory science, and streamline initiatives to help ensure efficiency and safety in the FDA's human drug review process; and

BE IT FURTHER RESOLVED that PILMA urges Members of Congress to refrain from adding amendments, riders, or any subsequent provisions to the PDUFA reauthorization that will hamper the legislation's ability to effectively regulate the development and approval of new medicines; and

BE IT FURTHER RESOLVED that PILMA will communicate to Members of Congress, along with other key allies and stakeholders, its support for a strong PDUFA reauthorization that ensures Americans will continue to have first access to life-saving biopharmaceutical medicines throughout the length of the reauthorization, and urge them to join PILMA in advocating for this position.