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

WHEREAS, since its inception in 1992 and through five subsequent reauthorizations, the Prescription Drug User Fee Act (PDUFA) has facilitated a more efficient, safer process of Food and Drug Administration (FDA) review and approval 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 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 over 70 percent of all new active substances entering the world market; and,

WHEREAS, the "gold standard" of FDA medicine review that PDUFA supports has led to more timely access to over 1,700 new medicines developed to fight cancer, diabetes, HIV/AIDS, cardiovascular disease, neurological disorders, fostering introduction of new medicines and cures to U.S. patients first; 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 nearly $2 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 and maintain 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, 2022; 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 maintain the integrity of the PDUFA VII Commitment Letter and 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.