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Barbara Arango, MBA Schaumburg, IL August 7, 2020

The Honorable Alex Azar Secretary U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, D.C. 20201

Via Electronic Mail

Dear Secretary Azar:

As health professionals working in clinical research, members of the Academy of Physicians in Clinical Research (APCR) are deeply concerned about threats to the discovery and development of new drugs. Today, the United States is the leader in developing biopharmaceuticals and in making them available to patients. According to a Galen Institute study, 96% of new cancer therapies are available in the U.S. compared to 73% in Germany, 66% in France and 54% in Japan. The recently announced Executive Orders on international reference pricing or "Most Favored Nation" could seriously damage America's health care system and leadership in medical innovation.

Price controls imported from countries where governments set prices substantially lower than those in the US is a policy that lawmakers have debated for years, but never passed—and for good reason. The reference prices in this model come from socialized health care systems in countries where patients currently experience long wait times for treatment, fewer treatment and therapy options, and poor provider-patient relationships. Bringing this model to the U.S. will compromise the ability of U.S. physicians to provide the best possible treatment option for each case.

In the midst of a global pandemic, price controls represent a short-sighted policy that will increase the risk for millions of our sickest and most vulnerable patients. What Americans want now is easy access to medical care and existing therapies and assurance that everything possible is being done to develop vaccines and treatments to combat the current pandemic.

APCR notes that patients who can afford to do so come to the U.S. for lifesaving medical care not available in their own countries. Many of these patients come from the countries from which international reference prices will be imported.

International reference pricing will undoubtedly compromise our lead in innovation, forcing the U.S. to rely on other countries for treatment, therapies, and maybe even a coronavirus vaccine. Now is not the time to limit drug and biotech companies in their ability to research and develop treatments that could save countless lives.

APCR commends the intent of the Executive Orders to address the current system of rebates which adds significantly to the price of prescription drugs,

but provides little or no support to help develop new therapies or even to help patients afford existing therapies. We are concerned however that the EO stipulates that this policy change can only be implemented if it doesn't increase premiums.

While we truly appreciate the Administration's commitment to finding solutions that will make prescription drugs affordable for Americans, reference pricing alone cannot guarantee our research enterprise will remain competitive in drug innovation. We need policies that will ensure America's long-term leadership both in developing new drugs and in making them affordable for patients. We hope to work together with policymakers and health care stakeholders to find a better solution for all.

Sincerely,

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Lyndon Mansfield, MD, FAPCR, CPI

President

Academy of Physicians in Clinical Research