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The Heartland INSTITUTE

A nonprofit organization devoted to discovering, developing, and promoting free-market solutions to social and economic problems.

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The Honorable Donald Trump
President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

The undersigned organizations, which represent millions of Americans, write in support of Free to Choose Medicine (FTCM), a plan to reform the U.S. Food and Drug Administration's (FDA) drug certification process. We advocate for the expansion of FDA's "parallel track"—originally created in 1992 to give AIDS/HIV patients accelerated access to potentially life-saving medications—to include *all* patients with serious ailments. The FTCM plan would also create a database to collect patients' experiences with drugs as an alternative to the protracted FDA clinical trial process.

It takes on average 12 years and $2.9 billion to bring a drug from lab to market. For the millions of Americans with debilitating diseases, 12 years is far too long to wait for a drug that could save or dramatically improve their lives. In a country rooted in a commitment to personal freedom, patients ought to be free to choose the drugs they need to live longer or enjoy pain-free lives.

This view is supported by numerous polls. For example, a recent survey commissioned by The Heartland Institute found that 95 percent of Americans across the political spectrum support allowing patients and their doctors to make health care decisions, rather than government bureaucrats.

For these reasons, we propose a structural reform that would allow drug manufacturers developing treatments for patients with a chronic or terminal illnesses to place potentially life-saving medications on the Free to Choose Medicine track. This is an alternative to the status quo clinical trial process, which is lengthy, costly, and rife with government red tape.

On the FTCM track, treatments that have passed FDA Phase I safety tests and at least one Phase II efficacy trial could be made available to patients. Patient data would be logged in a Tradeoff Evaluation Drug Database, which could supplement clinical trials or be used for a new FDA certification process. The FTCM track would give start-ups and small businesses, which can't afford to spend billions of dollars and endure a decade of delays, an opportunity to offer innovative treatments that could revolutionize modern medicine.

Medical technology is rapidly evolving, and it is transforming how researchers diagnose ailments and develop "miracle" cures. Unfortunately, the antiquated FDA drug approval process stifles the potential marvels modern medicine could offer.

Free to Choose Medicine is not a Band-Aid solution. Rather, it would address the root problems that are suppressing innovation in the drug marketplace. This structural reform would create incentives for drug manufacturers to use the parallel track, giving access to patients sooner.

Our organizations represent Americans from coast to coast, including patients, health care professionals, policy experts, and advocates. We urge the Trump administration to act now. Please transform the antiquated drug approval process by adopting Free to Choose Medicine, a reform that would unleash America's innovation and ingenuity, alleviate unnecessary pain and suffering, and possibly save millions of lives.

Sincerely,

Jim Lakely, President (Interim)
The Heartland Institute

Frank Burroughs, Founder
Abigail Alliance for Better Access to Developmental Drugs

Marilyn Singleton. M.D., J.D., President
Association of American Physicians and Surgeons

Dan Weber, President
Association of Mature American Citizens (AMAC)

Norman Singleton, President
Campaign for Liberty

Iain Murry, Vice President
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Annie Swartz, Founder
Contagious For a Cure

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Robert Fellner, Director of Policy
Nevada Policy Research Institute

Dr. Oran Smith, Senior Fellow
Palmetto Promise Institute

Paul Gessing, President
Rio Grande Foundation

Bette Grande, CEO
Roughrider Policy Center

Dr. Roger Stark, Health Care Analyst
Washington Policy Center