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FDA Modernization Act Clears Important Subcommittee Changing One Word Could Help Revolutionize Modern Medical Research

May 16, 2022 (Albuquerque, NM) -- Phoenix Zones Initiative (PZI) applauds the US House Subcommittee on Health for unanimously passing the FDA Modernization Act, which would eliminate the Food and Drug Administration's Depression-era requirement for animal testing in the preclinical phase of drug development.

When passed, this act will significantly move the needle to modernize medical research.

On May 11, 2022, the subcommittee voted 30-0 to move this bill forward as a rider in a broader legislative package, HR 7667, to reauthorize FDA user fee agreements. The bill now moves to the full House Committee on Energy and Commerce, for an anticipated markup session on May 18.

This bill opens the door to ethical advancements in drug trials by deleting one word from Section 505 of the Food, Drug, and Cosmetic Act of 1938.

Striking the word "animal" and inserting the words "nonclinical tests," the bill language goes on to define nonclinical tests as including cell-based assays, organ chips and microphysiological systems, sophisticated computer modeling, and other human or nonhuman biology-based test methods.

The bill does not eliminate animal testing among the allowed nonclinical testing methods, pointing to the tremendous work still to be done in creating an ethical, modern medical research system—including PZI's efforts to extend human research protections to animals.

Passage of this bill would end eight decades of the FDA's animal testing requirement, allowing drug developers to employ more reliable and human-relevant technologies to replace unethical and outdated animal tests.

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"Scientific and ethical innovators should not be held back by an eighty-year-old misleading mandate that requires animal testing and slows progress," said PZI CEO Dr. Hope Ferdowsian.

The <u>language in Section 701</u> (page 97) of the bill package points to the profound impact of striking just one word.

PZI has worked independently and in coalition with other advocacy organizations and experts in medicine and bioethics to advance this bill, and PZI CEO Dr. Hope Ferdowsian <u>submitted testimony</u> to the Subcommittee on Health in support of the FDA Modernization Act.

The bipartisan bill was introduced as companion bills in both the House and Senate. It was originally cosponsored by Senators Cory Booker, D-NJ; Rand Paul, R-KY; Ben Ray Luján, D-NM; John Kennedy, R-LA; and Mike Braun, R-IN; and introduced in the House by Representatives Vern Buchanan, R-FL; Elaine Luria, D-VA; Nancy Mace, R-SC; Mikie Sherrill, D-NJ; and Brendan Boyle, D-PA.

About Dr. Hope Ferdowsian

Dr. Ferdowsian is president and CEO of Phoenix Zones Initiative and author of *Phoenix Zones: Where Strength Is Born and Resilience Lives*. For more than two decades, as a double board-certified internal medicine and preventive medicine physician, she has worked to address the interconnected rights, health, and wellbeing of human and nonhuman beings.

Dr. Ferdowsian's work across six continents has included collaboration with the Office of the Surgeon General of the United States and the development of medical, public health, and educational resources for nongovernmental organizations, national governments, and intergovernmental organizations such as the World Health Organization. She has also served as an invited expert for the United Nations High-Level Political Forum on Sustainable Development. Her work has been featured by *Scientific American*, the Huffington Post, the BBC, Voice of America, and other international media outlets. In 2017, she was named a Humanitarian of the Year in the American College of Physicians. She is also an associate professor at the University of New Mexico School of Medicine, a co-director of the Society for Asylum Medicine, and a medical expert for Physicians for Human Rights.

About Phoenix Zones Initiative

Phoenix Zones Initiative is a global nonprofit organization that advances the interconnected rights, health, and wellbeing of people, animals, and the planet through education, research, and advocacy. Led by physicians and a diverse team, Phoenix Zones Initiative focuses on widespread ethical and structural change. Phoenix Zones Initiative advances social, economic, and environmental policy to uplift the most vulnerable and marginalized, including children and animals, and the organization also provides resources so that others can do the same. Follow Phoenix Zones Initiative on Facebook, Instagram, Twitter, LinkedIn, YouTube, and the Phoenix Zones Initiative website.