Congress of the United States
U.S. House of Representatives
Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515–6315

# MEMORANDUM

**TO**: Members of the Committee on Small Business

**FROM**: Committee Majority Staff

**DATE:** May 3, 2024

**RE**: Full Committee Hearing Titled: "Stifling Innovation: Examining the Impacts of Regulatory Burdens on Small Businesses in Healthcare"

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On **Wednesday**, **May 8, 2024 at 10:00 AM ET**, the Committee on Small Business will hold a hearing titled "**Stifling Innovation: Examining the Impacts of Regulatory Burdens on Small Businesses in Healthcare**." The meeting will convene in room 2360 of the Rayburn House Office Building. The purpose of this hearing is to examine the challenges small businesses face in the healthcare industry.

## I. Witnesses

- **Dr. Brian J. Miller, M.D., M.B.A., M.P.H.,** Assistant Professor of Medicine, Johns Hopkins University School of Medicine
- **Dr. David Anthony Eagle, M.D.,** Medical Oncologist & Chair of Legislative Affairs and Patient Advocacy, Community Oncology Alliance
- **Mr. William J. Newell, J.D.,** Chief Executive Officer, Sutro Biopharma, Inc.
- **Dr. Diana Zuckerman,** President, National Center for Health Research

## II. Background

Whether it's high tech, manufacturing, or energy development, small businesses are at the vanguard of innovation across industries. Today's small businesses in health care face unique, and sometimes insurmountable, challenges. Increasing regulations, burdensome reporting requirements, rising costs, and red tape across federal agencies make business success in the health care industry particularly challenging. These challenges stifle innovation, putting Americans' health at risk.

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and ensuring the safety of our nation's food supply, cosmetics, and

products that emit radiation.[1] However, the FDA must balance safety with innovation so that the United States can continue to be one of the greatest engines of medical innovation. Today's FDA tends to search for absolute certainty and safety rather than allowing innovation to flourish. The quest for absolute certainty makes introducing new drugs, treatments, and therapies into the market incredibly risky and often unattainable. Further, the capital and resources required to navigate the FDA's complex approval process often keeps small entities out of the marketplace completely.

While the FDA must prioritize the safety and efficacy of drugs, the merely 10 percent odds that a drug will become approved deters investment and keeps innovators out of the marketplace. Larger pharmaceutical companies often have the resources to shoulder that risk in hopes of profiting once the drug becomes available. Small entities do not have that luxury and are thus kept out of the market unless they can find outside assistance.

Small providers are not exempt from the heavy hand of the FDA and are, like their larger counterparts, often unable to offer treatments stuck in the regulatory pipeline that they believe could help their patients. Beyond just the development of treatments and drugs, providers are riddled with heavy compliance burdens across government entities.

Like all other small businesses, small medical providers are forced to navigate a flurry of regulations coming out of federal agencies as well as those from private insurance companies. And unlike their larger counterparts, small providers often do not have the resources to hire compliance officers to ensure that they are complying with every small requirement that may be imposed on them.

As a result, mergers and acquisitions in the health care sector have increased in recent years. The reality is, however, that too often consolidation decreases the quality of care, eliminates competition, limits physician-patient connections, and eliminates the opportunity for physicians to own their own businesses in pursuit of the American dream.[2]

## III. Conclusion

It is the FDA's premiere responsibility to balance human health and safety with innovation and advancement. The reality is, however, that absolute certainty is typically not an option and if regulators set out in pursuit of that rather than balancing it with the need to innovate, patients will also suffer. Small businesses are the engine of ingenuity across the U.S. economy and are especially critical in the health care industry. Regulations and arduous approval processes, compounded with requirements from private insurance companies make the risk for small entities incredibly high and survival difficult.

[1] *What We Do*, U.S. FOOD & DRUG ADMIN. (Nov. 21, 2023).
[2] *How Hospital Consolidation Hurts Americans*, AHIP (Aug. 26, 2021).