March 14, 2021

Mr. Dan Barry
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: RIN 0991-ZA52: Making Permanent Regulatory Flexibilities During COVID-19.

Dear Mr. Barry:

Americans for Prosperity is pleased to submit this response to the Department's request for information. We strongly support the Food and Drug Administration's proposal to make permanent its temporary policy of waiving certain unnecessary bureaucratic requirements for 84 kinds of medical devices in order to save lives during the ongoing Covid-19 pandemic. Based on the well-documented safety of these devices, we agree with the FDA that their temporary exemption from 510(k) pre-market notification should be made permanent.

The Covid-19 crisis has exposed a tragic reality. America's health care system actually stands in the way of doctors, nurses, and medical researchers helping people. It's why the vast majority of Americans share Americans for Prosperity's conviction that it is critical to empower medical professionals and innovators with the flexibility to get people the care they need. At the beginning of the pandemic, the Department of Health and Human Services took early and decisive action to temporarily remove barriers between medical professionals and patients, in order to save lives. If those barriers weren't needed then, why would they be needed now?

AFP also strongly supports efforts to streamline and improve medical device approval and clearance procedures generally. If a medical device, drug, or therapy has been shown to be safe, patients and doctors should be allowed to try it. As a general rule, bureaucratic rules unrelated to safety should never be allowed to come between patients and their doctors.

About the Department's Proposal

Generally, under the 510(k) process, a device that is "substantially equivalent" to another legally marketed device is "cleared," as opposed to "approved," by FDA for legal marketing in the United States. But despite being relatively straightforward, the clearance process can impose on medical innovators unjustifiable costs and unconscionable delays. Even for simple devices like gloves and thermometers, which pose no serious threat of patient harm, the process can cost

hundreds of thousands, or even millions, of dollars and delay a product's availability for months or years. And contrary to congressional intent, the burdens imposed by the existing clearance process often act as an economic trade barrier, favoring large established device manufacturing companies over new entrants in vital health care markets.

The Department issued guidance documents providing numerous regulatory flexibilities, including a temporary waiver of Food and Drug Administration (FDA) premarket notification requirements under section 510(k) of the Food, Drug, and Cosmetic Act. Building on those flexibilities, the Department permanently exempted seven class I devices from the 510(k) pre-market notification requirement.

The Department now proposes to permanently exempt an additional 84 device types (83 class II devices and one unclassified device type) from the 510(k) pre-market notification requirement, for which premarket review was temporarily waived during the public health emergency. These 84 categories of devices include certain kinds of needles, ventilators, cannulas, catheters, electronic stethoscopes, air purifiers, oximeters, pressure gauges, heat sterilizers, sleep apnea devices, and surgical masks and hoods, as well as software for monitoring medical devices that, for example, help manage the safety of drug infusions, monitor fetal heart rates, and deliver behavioral therapy to patients with psychiatric disorders. FDA has used its robust post-approval adverse-event monitoring systems to ensure that these kinds of devices are in fact safe. To subject these devices to continued costly and time-consuming bureaucratic pre-approval procedures defies common sense.

Beyond this particular proposal, AFP urges FDA to work with the Department to institutionalize all of the many valuable lessons learned during the pandemic, and in particular to streamline and improve federal medical device approval and clearance procedures generally, in order to expedite the availability of safe medical devices for the American people. In improving its procedures, the Department must of course take care to put patients first. FDA exists to ensure patient safety, and should put the interests of consumers ahead of corporations. Happily, the 84 listed types of devices have had essentially zero post-clearance adverse events. When adverse events have occurred, they have been minor, such as a latex glove causing a skin rash. The sensible policy with respect to such devices is to ensure appropriate labeling and warnings so that patients and doctors can make informed choices.

About Americans for Prosperity

Americans for Prosperity is a national grassroots organization whose more than 2.2 million activists are dedicated to the belief that every person has a unique set of gifts and the ability to contribute to society in their own way – an idea that has inspired progress since our country's founding. Driven by this belief, we engage in broad-based grassroots outreach to advocate for long-term solutions to the country's biggest problems that prevent people from realizing their incredible potential — unsustainable government spending and debt, a broken immigration system, a rigged economy, and a host of other important issues. AFP activists engage friends and neighbors on key issues and encourage them to take an active role in advancing a free and open society, where every person can realize their American dream. We recruit and unite concerned individuals in all 50 states to advance policies that will help people improve their lives.

About AFP's National "Health Care Reimagined" Campaign

In recent years, AFP activists have successfully advocated for health care reforms to improve patient access in states across the country.[1] Since April 20, 2020, AFP has led a nationwide campaign focused on making crucial reforms to ensure people have access to the care they need.[2] We seek reforms to help those harmed by Covid-19 and to ensure the country is better prepared for a future outbreak. Our multi-million dollar campaign includes advertising, digital outreach, lobbying, and grassroots engagement from AFP's 2.2 million activists. We promote a positive vision for health care that focuses on facilitating immediate, meaningful improvements to America's health care system. To promote public education, we have established a campaign website and a video series built around the theme, "Reimagine Health Care," to improve health care for every American.[3] [4] On May 12, 2020, AFP led 35 national organizations in urging Congress to lock in commonsense waivers issued by the Department in response to the Covid-19 outbreak.[5] On June 10, 2020, AFP increased its commitment to this cause by launching a multimillion-dollar digital video ad campaign urging Congress to make permanent several of the lifesaving regulatory waivers issued by the Department and other federal agencies in response to the Covid-19 outbreak.[6] A 2020 poll conducted by AFP and YouGov found that after respondents were presented with information about emergency measures, Americans support changes to our health care system that grant medical professionals greater flexibility in providing care and responding to Covid-19.[7] Among our findings:

- 58 percent of Americans agree that, prior to the emergency, health care rules and regulations prevented doctors, nurses, and medical professionals from helping people.
- 83 percent of Americans agree America's health care professionals should have more flexibility to provide health care as they and their patients see fit.
- 78 percent of Americans support relaxing health care restrictions to give more flexibility to doctors, nurses, and researchers who are fighting coronavirus.

In view of these facts, Americans for Prosperity is pleased to support the Department's proposal.

Sincerely,

Dean Clancy
Senior Health Policy Fellow

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[1] https://americansforprosperity.org/florida-becomes-first-southern-state-to-repeal-health-care-barrier/.
[2] https://americansforprosperity.org/americans-for-prosperity-launches-health-care-reimagined-campaign/.
[3] https://americansforprosperity.org/health-care-reimagined/.
[4] Americans for Prosperity, Health Care Reimagined, https://www.youtube.com/watch?v=mjQU_3dO2xA.
[5] https://mk0xituxemauaaa56cm7.kinstacdn.com/wp-content/uploads/2020/05/AFP-healthcare-coalition-letter.pdf.
[6] https://thehill.com/homenews/campaign/493592-koch-backed-group-to-spend-millions-promoting-changes-to-health-system.
[7] https://mk0xituxemauaaa56cm7.kinstacdn.com/wp-content/uploads/2020/04/YouGov-AFP-Poll.pdf.