COALITION for a PROSPEROUS AMERICA

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June 2, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Flawed generic bioequivalence studies and FDA failure to suspend authorizations

Commissioner Califf:

We write regarding FDA' actions allowing certain generic medicines to be sold to patients despite faulty, and potentially fraudulent, bioequivalence data that should support their safety and efficacy.

Last fall, FDA notified some drugmakers that bioequivalence studies needed to be repeated due to problems with tests run by Synchron (Ahmedabad, India) and Panexcell Clinical Laboratories (Navi Mumbai, India). As you are well aware, bioequivalence studies are conducted to show that a generic medicine releases the same amount of an active ingredient in the body as a brand-name medicine.

At the same time FDA notified Synchron and Panexcell – they also changed the therapeutic rating to "BX" for any approved abbreviated new drugs applications (ANDAs) that relied on data from those companies. The new rating of "BX" means that the generic drug products are insufficient for FDA to determine therapeutic equivalence with brand drug products. These generic drug products are still approved and can be prescribed – but they can no longer be automatically substitutable at the pharmacy.

The European Medicines Agency (EMA), in contrast, is recommending suspending marketing authorization for dozens of generics drugs after finding problems with the bioequivalence tests conducted by a contract research organization.

EMA took issue with quality and reliability of data in bioequivalence studies run by Synchron. Generic manufacturers that relied on Synchron testing must now provide alternative data to demonstrate bioequivalence for most of the 100 medicines examined.

And while EMA has suspended authorizations for all generics tested at Panexcell's Mumbai, India site – FDA has not. We have grave concern that FDA has lost its ability to be the "Gold Standard" of safety and efficacy and is instead jeopardizing patient health and safety to appease foreign generic drug manufacturers.

In lieu of these events and inactions – what is FDA doing to ensure patients are made aware of these faulty generics? Will FDA follow EMA's lead in banning these potentially dangerous medicines? Is FDA regularly testing product to keep patients safe? What are you and the Biden

administration doing to increase domestic approval and production of these medicines in a fully regulated environment? We look forward to receiving answers to these important questions. Thank you.

Sincerely,

Zach Mottl, Chairman

Coalition for a Prosperous America

Michael Stumo, CEO

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