

November 5, 2020

ADM Brett P. Giroir
Assistant Secretary for Health

The Honorable Alex Azar
Secretary U.S. Department of Health and Human Services

Honorable James Carroll
Director, Office of National Drug Control Policy

Dr. Stephen M. Hahn
Commissioner Federal Drug Administration

Dr. Redford R. Redfield
Director, Center of Disease Control and Prevention

Dr. Nora D. Volkow
Director, National Institute on Drug Abuse

Dear ADM Giroir, Secretary Azar, Director Carroll, Commissioner Hahn, Director Redfield, and Director Volkow:

The San Diego public health, medical, law enforcement, and legal community have united in the fight against the fentanyl epidemic. We represent one of many communities across America who is struggling not just with COVID-19, but also with the unprecedented rise in fentanyl deaths. Our county death toll for fentanyl in 2020 will more than double from 2019. We have activated a multi-agency and cross discipline effort to change that trajectory, but we need your help. We are writing to request federal assistance by cutting red tape and allowing for Emergency Use Authorization that would allow adding Fentanyl to Instant Drugs of Abuse Testing.

The United States currently has NO fentanyl instant drug tests that are part of a panel of drug tests. A clinician who orders a random urine drug test at a hospital or clinic will receive the tradition drugs of abuse panel such as THC, Methamphetamine, Cocaine, PCP, and Opioids. If a clinician orders a urine drug test they should be concerned just as much with fentanyl as they are with other drugs of abuse. Most clinicians do not have access to rapid fentanyl drug testing, and the few that do have access must order it as a separate test using a fentanyl reagent to be used with an approved chemistry analyzer.

The medical community needs the appropriate tools and data to fight the fentanyl crisis. Fentanyl mortality data is an important public health measure, but it does not make a direct clinical impact. A real time positive fentanyl drug test in the hands of a clinician can lead awareness to an unsuspecting patient, warning by the patient to friends who may be using, a prescription for naloxone, and referral to treatment for opioid use disorder. Further, the medical

examiner and prosecutors may rely on hospital drug tests in answering family questions about a person who died or give direction in a possible murder investigation. The fentanyl crisis and the testing gap leads to this urgent request to allow for emergency use authorization for including fentanyl in drugs of abuse drug panel.

We were informed that instant fentanyl drug testing as part of a panel was submitted to the FDA, but rejected due to not meeting a predicate standard. We appreciate the FDA wanting a more sensitive test for fentanyl, however the clinical community now has NO panel test that includes fentanyl. During this crisis period, it would be essential to have a test with 90% sensitivity rather than no test at all.

COVID tests have been given emergency use without extra high sensitivity standards due to the benefit/risk calculation of the pandemic. We argue that emergency use for fentanyl testing have a similar benefit/risk calculation for the fentanyl epidemic.

Thank you all for your dedication, sacrifice and work on behalf of the American people. We know that you are expert in moving an agenda towards saving lives.

Very Respectfully,

Dave King
San Diego and Imperial County HIDTA Director

Roneet Lev, MD
Emergency and Addiction Physician, Former CMO ONDCP

William D. Gore
Sheriff, San Diego County Sheriff's Department

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