A call for immediate, coordinated and comprehensive federal action to end the epidemic of opioid addiction and overdose deaths

June 30, 2017

The Honorable Chris Christie
Governor of New Jersey
Chair, President's Commission on Combating Drug Addiction and the Opioid Crisis

Dear Governor Christie:

On behalf of the FED UP Coalition, a national organization representing dozens of organizations across the country dedicated to ending the opioid addiction crisis, we are submitting public comments related to the first meeting of the President's Commission on June 16, 2017.

FED UP! Coalition members, largely families impacted by the addiction crisis exploding in our country, share a common concern our federal government is failing to stem the rising tide of opioid addiction and overdose deaths. Soon to be released CDC 2016 overdose statistics will serve as a gruesome reminder of that fact.

Our Coalition listened to the proceedings on June 16 and have the following comments and suggestions for the Commission moving forward. Disappointingly, a significant and seemingly obvious area of discussion which was not addressed is the role the Food and Drug Administration (FDA) plays in the labeling and approval of new opioid analgesics.

The FDA, in its review of new opioid drug applications, uses a flawed presumption that these medicines are "safe if used as prescribed". That presumption has led to over 30 opioid products on the U.S. market. Today, we have clear evidence from more than 300,000 opioid-related overdose deaths since 1999 that aggressive opioid prescribing is fueling a public health crisis. Medically prescribed pathways to opioid addiction are common and widely accepted in the health and medical communities as a significant part of the problem. It is time for FDA to change its outdated opioid policies that govern labeling and new approvals.

The FDA seemingly is focused on supporting the use of Abuse Deterrent Formulations (ADF's) as their priority contribution to addressing the crisis. However, ADF's are equally as addictive as other formulations, cause overdose deaths in the same manner and are clearly not without their own risks. Preventing injection and intranasal use of prescription opioids does not require fancy new technology that can be patented. Simply keeping a low opioid to filler ratio in a pill will produce a formulation that is unattractive for misuse by snorting or injecting. In the future, *the FDA should be focused on limiting the total morphine equivalent dosage and limiting promotion of aggressive use by opioid manufacturers.*

The FDA continues to require from opioid manufacturers a Risk Evaluation and Mitigation

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Strategy (REMS) guidance document to ensure that the benefits of their drug outweigh its risks. However, the REMS document in use today, developed by and with the pharmaceutical industry itself, has become a "how to prescribe" guide rather than a fair evaluation of benefits and risk. *The FDA must commit to creating a new REMS which is completely free from industry influence and one which explicitly corrects past misinformation about opioids that can lead to overprescribing.*

The FDA has avoided the use of advisory committees after facing a backlash for approving Zohydro over the objection of an advisory committee. Since the controversy, FDA has avoided consulting advisory committees for approval of new opioids altogether. (Now only committing to do so for limited issues such as pediatric uses.) *The FDA should be required to create an advisory committee for every new opioid drug and/or every new use of opioid drugs and to justify to Congress when and if the Commissioner overrules the judgment of an advisory committee.*

FDA should improve the labeling of opioid drugs by adding limits on dosage and duration. CDC's voluntary prescribing guidelines for use of opioid drugs for chronic pain are predicated on: avoiding use of opioids for long-term chronic pain if possible, starting patients on the lowest dosage as a start point, and prescribing for the shortest possible duration. FDA should develop labeling requirements consistent with the core principles embedded in the CDC guidelines. *New labels should include dose and duration limits.*

Finally, the first commission meeting included advocates from three organizations with financial ties to the pharmaceutical industry. Such groups often limit their focus and advocacy to abuse instead of focusing on the root of the problem, an epidemic of addiction caused by overprescribing. *To ensure discussion of a wider range of needed solutions, the Commission should invite advocacy organizations that do not accept funding from opioid manufacturers.*

The Commission's charter specifically calls for the identification and evaluation of all programs and activities to improve the Federal response to drug addiction and the opioid crisis. We believe our recommendations for future commission deliberations will help meet that charter requirement and ensure the full breadth of potential solutions is embedded in the group's findings for the President.

Sincerely,

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