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

December 18, 2017

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Docket No. FDA-2017-N-5608 for "Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments."

Submitted Electronically

Dear Commissioner Gottlieb:

On behalf of FED UP!, a national coalition representing dozens of organizations across the country dedicated to ending the opioid addiction epidemic, we are submitting public comments related to how Food and Drug Administration (FDA) authorities can or should be used to address this opioid addiction crisis through the newly established Opioid Policy Steering Committee (OPSC).

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. Coalition members believe the FDA in particular should do more. It is past time for FDA to change its outdated opioid policies that govern labeling, new opioid analgesic approvals, and required education and training.

Thank you for seeking public comments on actions FDA should take to bring the opioid crisis under control. We are grateful for this opportunity.

Our comments respond to three specific interest areas.

What more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions?

We strongly recommend the FDA implement the recommendations of the National Academy of Sciences (NAS) report on "*Balancing Societal and Individual Benefits and Risks of Opioid Use*" completed in July of this year. The NAS report recommends that FDA overhaul its policies on opioid analgesics.

Several lessons can be taken from the NAS review.

- A paradigm change will be required from FDA to challenge a past flawed review presumption that opioid medications are "safe if used as prescribed". Ample empirical proof from the over 350,000 opioid-implicated overdose deaths since 1999, strongly demonstrate vast opioid overprescribing is contributing to addiction and mortality even from those taking such medications as directed.
- Opioid drugs create a dependence/tolerance/addiction result not present in other analgesics which must require a broader assessment of safety and efficacy in FDA reviews.
- FDA should recognize the risks associated with abuse-deterrent formulations. These variants are equally as addictive as non abuse-deterrent opioid products and those risks should be a consideration in such product approvals.
- The NAS recommendations also have direct implications for how FDA designs clinical trials for new opioid drug applications. With a clear recognition that long-term use of opioid drugs is producing demonstrable increases in addicted patients, 60 or 90 day clinical trials are completely inadequate to assess long-term use risks.

What steps can FDA take with respect to dispensing and packaging (*e.g.*, unit of use) to facilitate consistency of and promote appropriate prescribing practice?

The NAS report recommends FDA utilize a new risk-benefit framework for full consideration of health effects of opioid misuse for product removal decisions. We believe that framework should apply to Ultra High Dose Unit (UHDU) opioids.

The Coalition strongly recommends FDA take steps to remove or limit the use of UHDU opioids. Such products, formulations when taken as directed exceed 90 morphine milligram equivalents (MME) per day in a daily dose are deemed by CDC to be dangerously high. A person who inappropriately takes even a single extra dose of an UHDU opioid or a person with no opioid tolerance who ingests a single dose could experience a fatal overdose from a single pill. Even when taken as directed for chronic pain UHDU opioids are associated with increased risk for addiction, overdose, vehicular accidents, neuroendocrine dysfunction, and hyperalgesia. Ample treatment alternatives exist and such high dose formulations should not be dispensed.

FDA should also 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 as well as 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.

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Should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?

FED UP! strongly believes a mandatory education program should be implemented for all DEA registrants who intend to prescribe opioid drugs for more than 3 days. Deficiencies in education related to pain management and addiction are well-documented issues confronting medical practitioners and educators. Until recently, this knowledge gap has been partially filled by pharmaceutical representatives.

The newly developed education curriculum should reflect the following:

- The training program should be developed completely free from pharmaceutical company influence nor involve entities or individuals with direct financial ties to the industry.
- Coverage of prescribing practices must be consistent with CDC's opioid prescribing guidelines.
- The program's curriculum must address use of non opioid analgesics as well as non pharmacological alternatives.
- Required training should adequately address signs of opioid dependency, appropriate treatment of opioid addiction and emphasize the addiction potential of opioid drugs and in particular addiction risks associated with long-term use.
- The mandatory education should be limited to prescribers who provide patients with more than a three-day supply – no mandatory education will be required for those prescribers recommending a course of treatment involving fewer days of use.
- An opt-out provision will allow those prescribers who agree to prescribe fewer than three days to be free from the mandatory education requirement.
- The training curriculum design should be on a "par" with training required for the use of buprenorphine (no less than 8 hours of training).

The FDA must do more to protect the public through careful and considered re-assessment of the risks and benefits of highly addictive opioid drugs in all their regulatory and decision making processes. We believe our recommendations respond directly to this imperative.

Sincerely,

The Advocacy Committee of the FED UP! Coalition to End the Opioid Epidemic

Daniel Busch, MD, StopDrugDeath.com (IL); Karen Carlini, Dynamite Youth Center Foundation (NY); Trudy Duffy (FL); Don Flattery, VA Governor's Task Force on Prescription Drug and Heroin Abuse (NC); Don Holman (VA); Andrew Kolodny, MD, Physicians for Responsible Opioid Prescribing (NY); Anthony LaGreca (MA); April Rovero, National Coalition Against Prescription Drug Abuse (CA); Judy Rummler, Steve Rummler Hope Network (MN); Emily Walden, STOPPNOW (KY).