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BULLETIN:

WHITE HOUSE, FDA, AND OPIOIDS

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by Lynne Peterson

In conjunction with Prescription Opioid and Heroin Epidemic Awareness Week (September 18-24), the White House announced several steps to combat opioid misuse and abuse, including:

- Expanding substance use disorder treatment for veterans and their families under TRICARE to include coverage of intensive outpatient programs and treatment of opioid use disorders with medication-assisted treatment.
- Working with the Chinese government to combat the supply of fentanyl and its analogues coming into the U.S.
- Increasing the patient limit from 100 to 275 for practitioners prescribing buprenorphine to treat opioid use disorders.

For its part, the FDA announced a competition with a $40,000 prize to the person/company that develops the best mobile phone app for connecting opioid users experiencing an overdose with whoever is nearby and has naloxone (an opioid antidote) with them. The 2016 Naloxone App Competition is a public contest, and the FDA – with support from the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) – is inviting computer programmers, public health advocates, clinical researchers, entrepreneurs, and innovators from all disciplines to enter the contest.

So, much like you call an Uber, you would call a naloxone carrier. The FDA said the app is intended to be used by opioid users themselves, family members, or even strangers who encounter someone having an opioid overdose episode.

There will be a 2-day code-a-thon at the FDA campus on October 19-20, 2016, with final submissions due by November 7, 2016.

Asked if a naloxone app would be subject to regulation by the FDA as a medical device, Peter Lurie, MD, MPH, the FDA's associate commissioner for public health strategy and analysis, said, "It depends on the particular nature of the product being submitted…or whether the FDA chooses to exercise that jurisdiction. There are some app functionalities, like finding a user's location that are not considered to be devices and would not need premarket review. Other functions…may require FDA review."

Asked if the app is intended to have any education aspect since many users may not know what an opioid overdose looks like, Dr. Lurie said, "Ultimately the design of the app is in the hands of the developer, but it is at least possible that the programmer would want to put that kind of information into the app…[Users] might benefit from understanding what an opioid overdose looks like because one ideally would like the product to get to the person who needs it the most."

Asked if Good Samaritan laws would protect someone who provides naloxone, or if there would be liability issues, Dr. Lurie said, "That is a complex matter. There are Good Samaritan laws that vary from state to state…but I presume that the app developers will do the homework and take those kinds of considerations into account."

Asked if the FDA has conducted other app challenges, an FDA medical officer said, "The FDA ran one other prize competition, a 2014 food safety competition, and the winner of that competition developed a technology to more rapidly identify salmonella in fresh produce, and they are working with the FDA on rolling that out."

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