University of Minnesota PI Submits EUA Application to FDA for Fluvoxamine

TrialSite Staff
December 27, 2021

7 Comments

The University of Minnesota's David Boulware went on the record that he went through the process of submitting an Emergency Use Authorization (EUA) application for fluvoxamine to the U.S. Food and Drug Administration (FDA).

While the Professor of Medicine, Division of Infectious Diseases and International Medicine at the University of Minnesota recently discussed the promise of the Pfizer antiviral called PAXLOVID, he notes that the medicine isn't available today and that the FDA has only authorized it for use by those classified as high-risk unvaccinated people or persons with weak immune systems. But there are so many other needs during this pandemic.

He notes the third option in a University of Minnesota press release—fluvoxamine declaring that the SSRI "based on two randomized trials" offers a 30% reduction in hospitalization or lengthy emergency department visits. The academic medical center principal investigator declared, "On December 21, I submitted an application to the FDA requesting Emergency Use Authorization (EUA) to recognize its clinical benefit." Boulware declared he hopes that his action will lead to a response by the regulatory body in the form of guidance, which could spur physicians to embrace the low-cost, available repurposed drug.

Hi-tech entrepreneur Steve Kirsch founded the COVID-19 Early Treatment Fund (CETF) during the early part of the pandemic to fund early treatment studies. Thanks to Kirsch's early funding, studies at Washington University School of Medicine in St. Louis, and then the TOGETHER trial led by Edward Mills, this repurposed drug now should be authorized for use against COVID-19. Dr. Michael Goodkin, a member of the *TrialSite* advisory committee has issued a statement to the Infectious Disease Society of America (IDSA): why haven't they accepted fluvoxamine?

Some front-line physicians and medical specialists believe that up to 85% of the lives lost during the pandemic in America alone could have been saved with early treatment options.

The University of Minnesota continues a nationwide early at-home treatment trial testing fluvoxamine and other existing medicines. More information is available at covidout.com.

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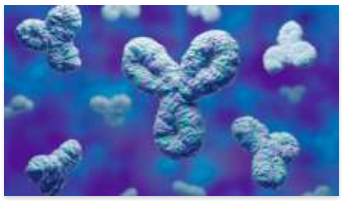

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Source: University of Minnesota

Categories: News

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TrialSite Staff

Responses

HenryLahore

Write a response...

Publish

Ken.Kaplan_Esq
December 28, 2021

Report Comment

FYI: Here's a link to the current NIH info re fluvoxamine: https://www.covid19treatmentguidelines.nih.gov/therapies/immunomodulators/fluvoxamine/

And here's a link to an objective discussion of the research findings from a respected emergency department physician: https://rebelem.com/the-together-trial-covid-19-and-fluvoxamine-take-two/

Comment: I think there's a benefit to knowing both sides of every story. That's why I read @trialsitenews.com. But, there are other good sources of medical research and I see no reason to ignore those sources.

Reply

PeterYim
December 28, 2021

Report Comment

My only point is that if this researcher believes the drug works, he should not be withholding it from his patients – assigning them to placebo.

Reply

Ken.Kaplan_Esq

December 28, 2021 Report Comment

I agree with your premise, but I must also consider the possibility that the researcher may not yet be entirely “sold” on his research.

That’s why a contrary view may be useful, as it suggests (right or wrong) that the case for fluvoxamine isn’t yet made.

OTOH, the case for molnupiravir, remdesivir, et al., is also not entirely made – but that’s not stopped the FDA from approving/authorizing said drugs.

This leads to the political controversy – which I shall leave to others.

Reply

Ken.Kaplan_Esq Report Comment
December 28, 2021

P.S. My post immediately above was intended for @PeterYim

Reply

PeterYim Report Comment
December 28, 2021

I don’t know this researcher’s motives, character, circumstances etc but I will generalize. I believe the greatest failure of the pandemic has been the failure of the medical profession to understand that they are not merely technicians/care givers but also moral actors. These professionals appreciate civil protest in the abstract but view their role in society as exempt from that sort of personal/professional risk and sacrifice.

Reply

GoodComrade Report Comment
December 28, 2021

I am not sure why fluvoxamine needs any EUA–it's already an FDA-approved drug, so physicians are free to use off-label; only a new drug, not previously approved by FDA, will need an EUA before a physician can prescribe.

Reply

PeterYim
December 27, 2021

Report Comment

This researcher is bizarre. He is currently an investigator in a trial (https://clinicaltrials.gov/ct2/show/NCT04510194) randomizing patients to this drug and placebo.

Reply

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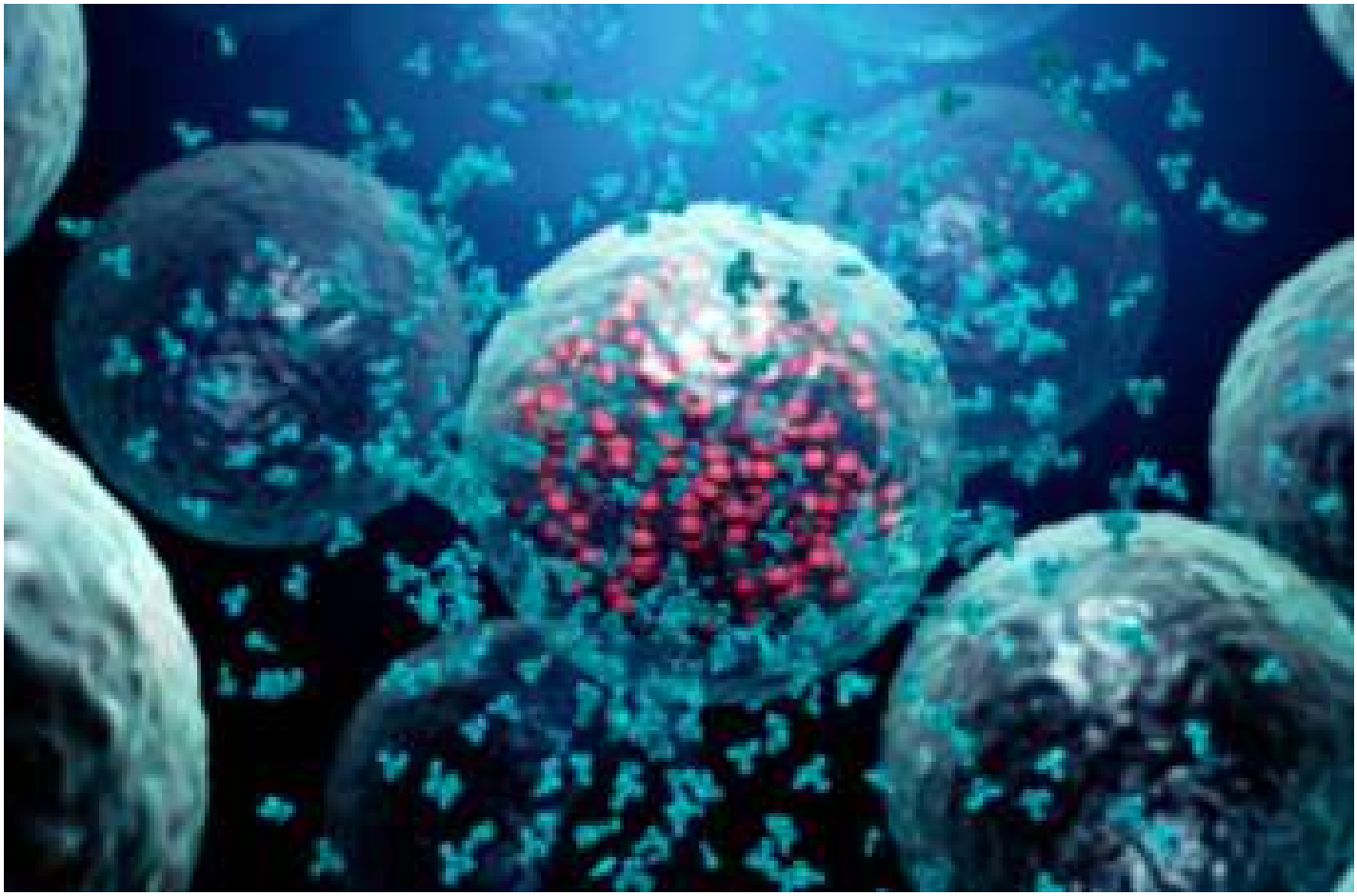

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