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22 Oct 2020 | **Analysis**

Patient Warehousing Emerges As Another COVID-19 Vaccine Confidence Problem

by Derrick Gingery

CDC officials designing distribution plans worry some eligible for vaccination may wait for a better product to emerge.

Federal officials are now confronting another challenge for the uptake of a potential coronavirus vaccine – patient warehousing – along with waning public confidence in product safety and efficacy.

Hesitancy to take the first coronavirus vaccines because of unclear safety or efficacy and political influence is already pervasive in the US. Now, another group is emerging that may be reluctant to receive the first vaccines because a better product may be on the way.

During the 22 October Vaccines and Related Biological Products Advisory Committee meeting on coronavirus vaccine development and approval issues, committee member Michael Kurilla, director of the National Institutes of Health's National Center for Advancing Translational Sciences Division of Clinical Innovation, suggested sponsors' willingness to trumpet positive clinical data may drive people in prioritized groups to refuse the first products on the market.

See box for more stories on the FDA's advisory committee meeting on COVID vaccines.

"Given that companies tend to try to take advantage of every promotable advantage, the potential is set up that there will be vaccines available, either licensed or under [emergency use authorization], but something better may be coming along in another two or three months and people want to wait," Kurilla said. "Have you thought about how that

More Coverage Of The COVID Vaccines Advisory Committee

- *COVID-19 Vaccines: Advisory Committee Picks Apart US FDA Guidance On Efficacy*

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messaging is going to go? So that everyone is just not waiting for the perfect vaccine?"

One example may be the possibility of needing only one injection rather than two several weeks apart. Vaccine leaders *Pfizer Inc.* and partner *BioNTech SE*, as well as *Moderna, Inc.*, are developing mRNA candidates that will require two injections.

Threshold, Endpoints

- *Advisors Agree with US FDA On Placebo Control Post- COVID-19 Vaccine EUA... But Offer No Help In Getting There*

Johnson & Johnson launched a Phase III trial for a single-shot coronavirus vaccine on 23 September. (Also see "*Coronavirus Update: J&J's Single Shot Could Catch Up With Frontrunners*" - Scrip, 24 Sep, 2020.) That product's easier administration could push patients and providers to consider refusing the Pfizer and Moderna vaccines, which are much closer to an EUA, to wait for the J&J product.

Assuming positive safety and efficacy data, the Pfizer and Moderna candidates could receive an emergency use authorization before the end of 2020, while J&J is not expected to receive an EUA until the first quarter of 2021. Dosing in the Janssen study is currently paused due to an unexplained illness. (Also see "*Where The COVID Vaccine Trials Stand: A Snapshot Of The Leaders And Rest Of The Field*" - Pink Sheet, 21 Oct, 2020.)

Capt. Janell Routh, medical officer in the Centers for Disease Control and Prevention's National Center for Influenza and National Respiratory Diseases Division of Viral Diseases, said during the FDA meeting the warehousing issue may be a real concern, but is "not the message we want to convey."

"I do think we are going to really lean forward into the promotion of the vaccines that are available, and make sure again, that we have a wide footprint to get them out and available to people as quickly as possible," she said.

Warehousing is more common with chronic disease patients. Often, physicians understand that early drug approvals are stepping-stones to better products and advise patients against taking them. The race for a Hepatitis C treatment included some treatments that were thought to be short-term solutions and patients refused to take them because better treatments were on the horizon. (Also see "*Payers Should Brace For Next Hepatitis C Drug "Onslaught" – Express Scripts*" - Pink Sheet, 5 Mar, 2013.)

[*Editor's note: Please join us for a deeper, virtual dive into issues related the COVID as part of the*

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FDA-CMS Summit on Dec. 7-9. Registration is now open for the event, which will include a special panel of FDA and industry leaders discussing what the post-pandemic landscape will look like.]

Confidence Problems Stem In Part From Term 'EUA,' Offit Says

During the advisory committee meeting, Reagan Udall Foundation CEO Susan Winckler and researcher Chris Wilks gave examples of the ongoing vaccine confidence problems, such as increasing distrust of government and the medical establishment, and perceptions that politics and economics are being prioritized over science.

VRBPAC committee member Paul Offit, a pediatrics professor in the Children's Hospital of Philadelphia Division of Infectious Diseases, said part of the problem is a misunderstanding of the definition of EUA.

Offit said an EUA suggested a product is permitted, which is a very low bar compared to full licensure. But after hearing FDA officials describe the requirements to receive an EUA, he said the requirements for both pathways are very similar.

Because of the similar standards for approval and emergency authorization, "I wish we could get rid of the word EUA," he said.

Sheldon Toubman, a staff attorney at the New Haven (CT) Legal Assistance Association and the committee consumer representative, said the FDA should avoid using an EUA for a vaccine because the public perceives the product is being rushed.

While the FDA seems committed to using the EUA pathway, Center for Biologics Evaluation and Research Director Peter Marks has emphasized that to receive an EUA, a vaccine will have to meet safety efficacy requirements that are similar to those of a BLA. (Also see "*US FDA Expects COVID-19 Vaccines To Meet 'EUA Plus' Standards, Marks Says*" - Pink Sheet, 10 Sep, 2020.)

Mandated Vaccination Under An EUA Not Allowed

One way to avoid vaccine confidence questions could be requiring some groups to receive it, although that is not allowed under the EUA mechanism.

When asked whether a vaccine mandate had been considered, committee member Capt. Amanda Cohn, chief medical officer of the CDC National Center for Immunizations and Respiratory Diseases, said the federal government cannot require people to take a vaccine. She said private employers could mandate employees receive a fully licensed vaccine, but employees have the right to refuse a vaccine made available under an EUA.

Routh also said mandating vaccine receipt is difficult, even in hospitals.

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“I think what we need to do, rather than mandating vaccine is really to build trust and confidence in these vaccine candidates,” she said. “I'd much prefer rather than mandating vaccine to build that confidence in our healthcare provider infrastructure.”

Polling has consistently showed a significant portion of the public may not take a coronavirus vaccine when it is available for a variety of reasons. (Also see "*Speed Of Coronavirus Vaccine Development May Hurt Public Confidence*" - Pink Sheet, 14 Jun, 2020.)

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