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Docket No. FDA-2021-N-0173. for "Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments."

The Vaccine Considerations Project is currently tracking the concerns of individuals and public health officials regarding the Janssen Biotech vaccine.

Public Health Concerns for Disadvantaged Communities

One of the most widely held concerns amongst public health officials is that the reduced efficacy percentages of the Janssen Biotech vaccine (72% in the U.S.; 66% worldwide), relative to the two approved mRNA vaccines (94% and 95%), will make it a second-class vaccine, provided in disproportionate numbers to disadvantaged and marginalized communities.

Certain attributes of the Janssen Biotech vaccine, such as the one-dose regimen, and the lack of cold-storage requirements, could prove advantageous for "hard-to-reach" individuals in marginalized communities.

The concern is that these advantages for a relatively small segment of the population could be used as justifications to distribute the Janssen Biotech vaccine to the broader communities within which these hard-to-reach individuals reside, with the net result being a further exasperation of health inequities for some communities.

Severe Community Impact of Efficacy Disparities

The recent decision by the CDC to allow those that have completed their vaccine regimen to forego quarantine when otherwise called for, indicates confidence that those who have been vaccinated with the approved mRNA vaccines who are not presenting COVID symptoms are not likely to infect others.

There is wide consensus that the trial efficacy numbers of the approved mRNA vaccines cannot be compared side-by-side with the Janssen Biotech vaccine efficacy numbers because of differences in trial conditions, such as the prevalence of new, resistant variants.

The existing efficacy data thus far, though, seems to indicate that there will be a measurable, if not a significant, difference in the incidence of symptomatic sickness amongst the population given the Janssen Biotech vaccine vs. the previously approved mRNA vaccines.

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Recent news stories have featured health experts encouraging the public to focus on the “important numbers” - that the Janssen Biotech vaccine seems to be as effective as the previously approved vaccines in preventing hospitalizations and deaths.

While preventing hospitalizations and deaths is critically important, it is of the utmost importance that the FDA does not overlook the life-changing impacts of higher numbers of less severe, but nonetheless symptomatic sickness spread amongst the community.

Life-Changing Impacts

Some severe consequences for individuals, families, and communities include:

- more missed work
- more risk and spread to non-vaccinated family members
- and more long-term health impacts related to persistent “long-hauler” symptoms.

Compounding the matter is that less affluent communities are less able to weather these challenges than more affluent communities.

FDA Responsibilities

Most experts agree that until vaccine supply meets vaccine demand, adding more vaccine supply through the Emergency Use Authorization of the Janssen Biotech vaccine if it meets the FDA’s requirements to do so, is appropriate.

What must be ensured, from all the governmental agencies, including the FDA, is that the dangers of exasperating health inequities through the approval and distribution of the Janssen Biotech vaccine are acknowledged, and appropriate guidance is provided to avoid creating negative health impacts on marginalized communities based on limited vaccine options.

This is the third paragraph of the FDA’s mission statement: “***FDA is responsible for advancing the public health*** by helping to speed innovations that make medical products more effective, safer, and more affordable and ***by helping the public get the accurate, science-based information they need to use medical products*** **and foods** ***to maintain and improve their health***.” - https://www.fda.gov/about-fda/what-we-do

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Providing guidance to address this situation in strong alignment with the FDA's mission. It can be restated nearly word-for-word within the context of the FDA's mission: ***The FDA has the opportunity to advance the public health by helping the public get the accurate, science-based information they need regarding the potential personal and familial impacts of getting one vaccine vs. another, in order to maintain and improve their health.***

Lasting Impacts on Trust and Hesitancy

The FDA being very up front and transparent around these differences, and associated impacts on the community, are all the more important because of the prevalence of vaccine hesitancy amongst many marginalized communities.

If data, and related media stories, come out showing that marginalized communities are faring worse with COVID, at least in part, due to disparate vaccine options, it will further deepen mistrust and skepticism by many.

Increased mistrust would negatively impact uptake of vaccines now, and likely in the future, possibly to the degree that it prevents the country from reaching the national vaccination percentages necessary to eliminate community spread.

Jared Krupnick
Founder, Vaccine Considerations Project

Postscript on Building Trust and Confidence

There seems to be a stunningly glaring oversight in the vaccine consideration process - that the outside experts that are being asked to provide written comments like these, or to present oral presentations, must submit these comments, and the oral presenters must submit their slides, before the clinical trial data for the vaccine is released a couple of days before the VRBPAC meeting.

If the FDA and the VRBPAC want the best feedback possible from subject matter experts, shouldn't the schedule be structured to allow those experts to review and assess the data before written comments and slides are due?

Just like the FDA has a couple of weeks to process the data before it is presented at the VRBPAC meeting, shouldn't the outside experts, whose input they seek, have a couple of weeks, or at least any time, to review and analyze the data?

Is This All for Show?

The lack of opportunity for experts to see clinical trial data prior to the deadline for them to comment on such data could lead some to conclude that the FDA is not, in fact, interested in the most qualified and rigorous evaluation of the vaccine.

Since the comment and slide submission schedule precludes an analysis from even being possible, it could give the appearance that the outside expert comments are a formality, and more for show, rather than a genuine interest on the FDA's part in receiving thoughtful consideration by respected experts in their fields.

Opportunity for the FDA to Build Trust and Confidence

In a moment of pervasive vaccine hesitancy and mistrust, one would hope the FDA is committed to doing what is within its power to gain and build trust and confidence. It seems that soliciting comments in a way that allows experts to provide their expertise is a rather low-hanging fruit.

If there was a genuine interest in hearing and considering the input, analysis, and recommendations of outside experts, then it seems that the FDA could arrange the submission schedule to accommodate that.