National Vaccine Advisory Committee
September 2020 Meeting Update

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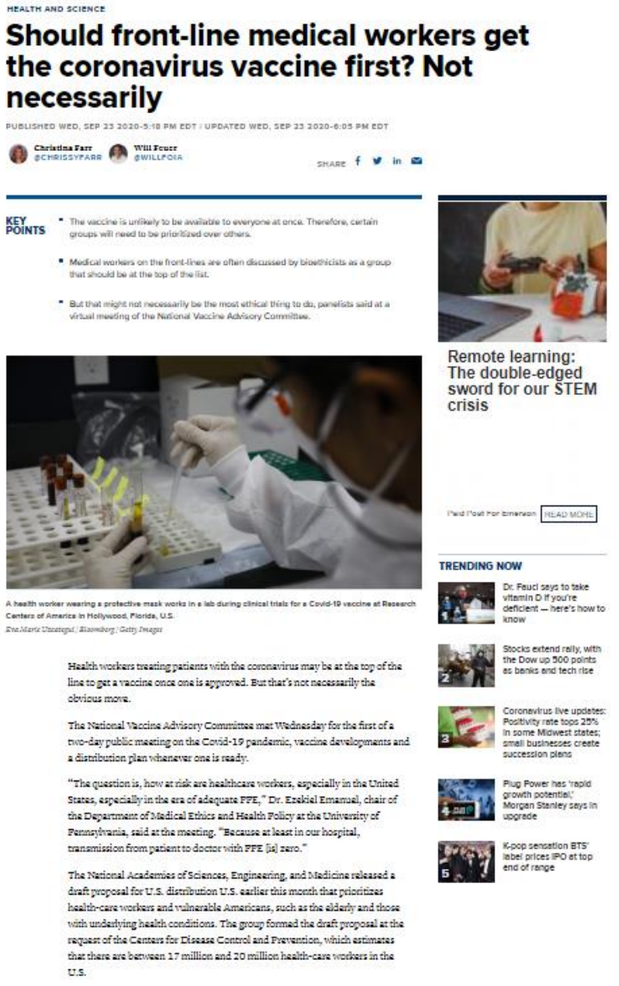
Acting Designated Federal Official

October 1, 2020

NVAC Meeting Highlights

- Charge from Admiral Giroir
- Vote on Letter with Recommendations to Build Confidence in COVID-19 Vaccine Development
- Amazing Sessions with Wonderful Expert Speakers



HEALTH AND SCIENCE

Should front-line medical workers get the coronavirus vaccine first? Not necessarily

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KEY POINTS

- The vaccine is unlikely to be available to everyone at once. Therefore, certain groups will need to be prioritized over others.
- Medical workers on the front-lines are often discussed by bioethicists as a group that should be at the top of the list.
- But that might not necessarily be the most ethical thing to do, panelists said at a virtual meeting of the National Vaccine Advisory Committee.

A health worker wearing a protective mask works in a lab during clinical trials for a Covid-19 vaccine at Research Centers of America in Hollywood, Florida, U.S.

Eva Marie Uzcategui / Bloomberg / Getty Images

Health workers treating patients with the coronavirus may be at the top of the line to get a vaccine once one is approved. But that's not necessarily the obvious move.

The National Vaccine Advisory Committee met Wednesday for the first of a two-day public meeting on the Covid-19 pandemic, vaccine developments and a distribution plan whenever one is ready.

"The question is, how at risk are healthcare workers, especially in the United States, especially in the era of adequate PPE," Dr. Ezekiel Emanuel, chair of the Department of Medical Ethics and Health Policy at the University of Pennsylvania, said at the meeting. "Because at least in our hospital, transmission from patient to doctor with PPE [is] zero."

The National Academies of Sciences, Engineering, and Medicine released a draft proposal for U.S. distribution U.S. earlier this month that prioritizes health-care workers and vulnerable Americans, such as the elderly and those with underlying health conditions. The group formed the draft proposal at the request of the Centers for Disease Control and Prevention, which estimates that there are between 17 million and 20 million health-care workers in the U.S.

Remote learning: The double-edged sword for our STEM crisis

TRENDING NOW

1 Dr. Fauci says to take vitamin D if you're deficient — here's how to know

2 Stocks extend rally, with the Dow up 500 points as banks and tech rise

3 Coronavirus live updates: Positivity rate tops 25% in some Midwest states; small businesses create succession plans

4 Plug Power has 'rapid growth potential,' Morgan Stanley says in upgrade

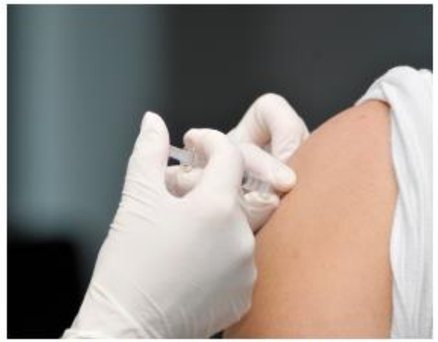
5 K-pop sensation BTS' label prices IPO at top end of range

AAP News

Vaccine advisory group: Don't rush COVID-19 vaccine approval

Melissa Jenco, News Content Editor

September 23, 2020



Editor's note: For the latest news on COVID-19, visit https://www.aappublications.org/news/2020/01/28/coronavirus.

The National Vaccine Advisory Committee (NVAC) is urging federal authorities to use a traditional approval process for a COVID-19 vaccine despite the possibility it could take months.

The Food and Drug Administration's (FDA's) Biologics License Application process "is both time-tested for rigor and is well trusted by the public and to put it in a nutshell we think it should be considered the default for approval of this vaccine as it is for all others," said John B. Dunn, M.D., M.P.H., FAAP, who co-chairs the NVAC Vaccine Confidence Subcommittee with H. Cody Meissner, M.D., FAAP.

NVAC member Leonard Friedland, M.D., vice president and director of scientific affairs and public health at GSK Vaccines, said that process is very formal and detailed. It can take a year, although sometimes it is shorter. By contrast, the FDA's emergency use authorization (EUA) can take a matter of days and isn't as transparent, he said.

Dr. Dunn said NVAC recognizes hundreds of people are dying daily and an EUA may be warranted for some high-risk groups.

"What the recommendation emphasizes is that the use of such an expedited processes should only be done circumspectly and with a real abundance of caution," said Dr. Dunn, medical director of preventive care, clinical lead for immunization population management at Kaiser Permanente Washington.

Agenda Highlights– September 23, 2020

SERVING UP EQUITY: HEALTH-IN-ALL APPROACHES FOR COVID-19 VACCINATION

- **Dr. Kirsten Bibbins-Domingo**, University of California, San Francisco
- **Dr. Rebecca Weintraub**, Harvard Medical School
- **Dr. Dominic Mack**, Morehouse School of Medicine
- **Dr. Oliver Brooks**, National Medical Association

ALLOCATION AND PRIORITIZATION: CONSIDERATIONS AND RECOMMENDATIONS FOR THE DISTRIBUTION OF COVID-19 VACCINES

- **Dr. Ezekiel Emanuel**, University of Pennsylvania
- **Dr. Sara Oliver**, Centers for Disease Control and Prevention

PERSPECTIVES FROM THE FIELD: OPERATION WARP SPEED

Dr. Moncef Slaoui, HHS

VACCINE CONFIDENCE SUBCOMMITTEE UPDATE

Dr. John Dunn, Vaccine Confidence Subcommittee Co-Chair

THE INFODEMIC, COVID-19 IMMUNIZATION, AND THE PUBLIC'S HEALTH

- **Dr. Monica Schoch-Spana,** Johns Hopkins University
- **Dr. Julia Wu**, Harvard University
- **Dr. Claire Wardle,** First Draft

IMMUNIZATON INFORMATION SYSTEMS TO SUPPORT THE COVID-19 RESPONSE

- **Holly Groom**, Kaiser Permanente Northwest
- **Rebecca Coyle**, American Immunization Registry Association
- **Amy Pisani,** Vaccinate Your Family
- **Dr. Sean O'Leary**, University of Colorado

COVID-19 CHARGE DISCUSSION

Dr. Robert Hopkins, NVAC Chair

Agenda Highlights– September 24, 2020

PROGRESS IN USING VACCINES TO PREVENT SUPERBUGS

- **Dr. Amanda Cash,** HHS
- **Dr. Dennis Dixon**, NIH
- **Dr. Greg Frank**, BIO
- **Dr. Tony Fiore**, CDC
- **Dr. Tamara Pilishvili**, CDC
- **Dr. Amber Smith**, University of Tennessee Health Science Center

FLU VACCINATION DURING COVID-19

- **Dr. Ram Koppaka**, CDC
- **Dr. Justin Mills**, AHRQ
- **Dr. L.J. Tan,** Immunization Action Coalition
- **Lawrence Gostin**, Georgetown University
- **Dr. Laura Lee Hall,** Center for Sustainable Health Care Quality and Equity
- **Dr. Jules van Binsbergen**, University of Pennsylvania

OVERDUE IMMUNIZATION: GETTING BACK ON TRACK

- **Dr. Melinda Wharton**, CDC
- **Dr. Mitch Rothholz,** American Pharmacists Association
- **Ann Aikin for Dr. David Kim**, HHS

EVIDENCE AND EQUITY: WHAT WORKS TO DECREASE DISPARITIES IN IMMUNIZATION

- **Dr. Akhenaten Benjamin Siankam Tankwanchi,** University of Washington
- **Dr. Randall Williams,** Missouri Health Department of Health and Senior Services
- **Dr. Melissa Martinez,** University of New Mexico and NVAC Member
- **Sheri Winsper,** National Quality Forum

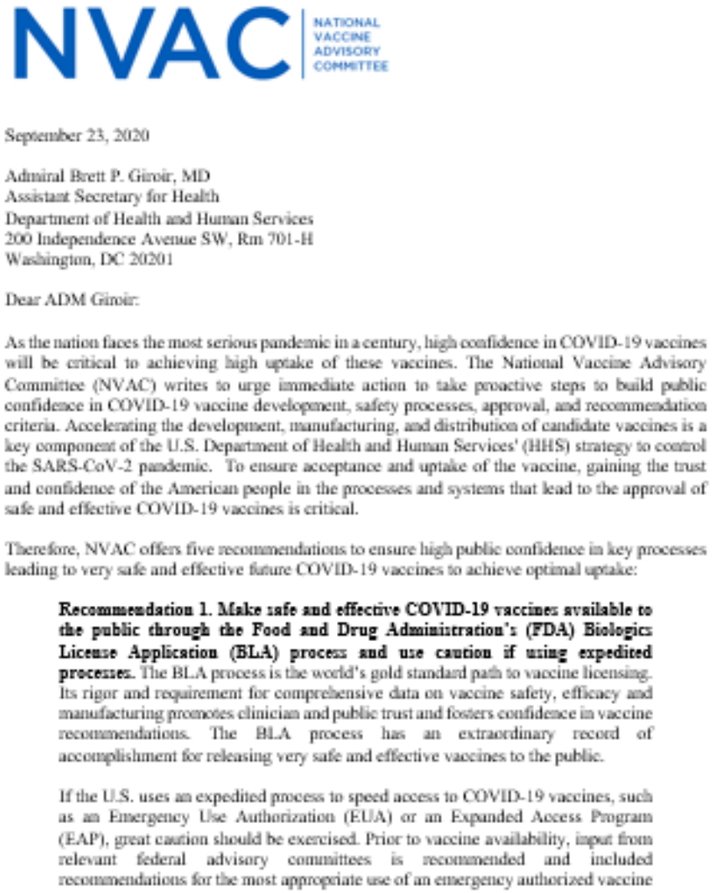
FEDERAL AGENCY AND LIAISION REPRESENTATIVE UPDATES

COVID-19 CHARGE DISCUSSION

Dr. Robert Hopkins, NVAC Chair

NVAC Letter to Build Confidence in COVID-19 Vaccine Development

- Five Recommendations:
  1. Make safe and effective COVID-19 vaccines available to the public through the Food and Drug Administration's (FDA) **Biologics License Application (BLA)** process and **use caution if using expedited processes**.
  2. Rapidly deploy and coordinate assets in vaccine safety monitoring through a **federal immunization safety task force**.
  3. Promptly create a **unified, proactive, highly visible communication structure** to regularly inform the American public about COVID-19 vaccine development, safety processes, approval, and recommendation criteria.
  4. Establish an independent group of vaccine and public health experts (e.g., the National Academies of Science, Engineering, and Medicine) to conduct **ongoing, rapid reviews of available data** from the federal safety monitoring systems.
  5. Conduct **community and stakeholder engagement** to inform COVID-19 vaccine-related policies and to increase the likelihood that these policies will be supported by communities and groups disproportionately affected by COVID-19.
- Overwhelmingly Approved on 9/23/2020



NVAC NATIONAL VACCINE ADVISORY COMMITTEE

September 23, 2020

Admiral Brett P. Giroir, MD
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue SW, Rm 701-H
Washington, DC 20201

Dear ADM Giroir:

As the nation faces the most serious pandemic in a century, high confidence in COVID-19 vaccines will be critical to achieving high uptake of these vaccines. The National Vaccine Advisory Committee (NVAC) writes to urge immediate action to take proactive steps to build public confidence in COVID-19 vaccine development, safety processes, approval, and recommendation criteria. Accelerating the development, manufacturing, and distribution of candidate vaccines is a key component of the U.S. Department of Health and Human Services' (HHS) strategy to control the SARS-CoV-2 pandemic. To ensure acceptance and uptake of the vaccine, gaining the trust and confidence of the American people in the processes and systems that lead to the approval of safe and effective COVID-19 vaccines is critical.

Therefore, NVAC offers five recommendations to ensure high public confidence in key processes leading to very safe and effective future COVID-19 vaccines to achieve optimal uptake:

Recommendation 1. Make safe and effective COVID-19 vaccines available to the public through the Food and Drug Administration's (FDA) Biologics License Application (BLA) process and use caution if using expedited processes. The BLA process is the world's gold standard path to vaccine licensing. Its rigor and requirement for comprehensive data on vaccine safety, efficacy and manufacturing promotes clinician and public trust and fosters confidence in vaccine recommendations. The BLA process has an extraordinary record of accomplishment for releasing very safe and effective vaccines to the public.

If the U.S. uses an expedited process to speed access to COVID-19 vaccines, such as an Emergency Use Authorization (EUA) or an Expanded Access Program (EAP), great caution should be exercised. Prior to vaccine availability, input from relevant federal advisory committees is recommended and included recommendations for the most appropriate use of an emergency authorized vaccine

New Charge—Three Tasks

1. To Support Communications to Enhance Informed Vaccine Decision Making: What should HHS do **before, during, and after the COVID-19 vaccination campaign to improve the confidence in these vaccines and our Nation's immunization system** especially within **underserved communities**, including racial and ethnic minorities?

2. To enhance vaccination of diverse populations: The FDA standards for approval and licensure of vaccines for COVID-19 addresses safety and effectiveness and encourages inclusion of minorities, the elderly, pregnant women, and people with medical comorbidities in clinical trials. In particular, for the COVID 19 vaccine, I am interested in the **approach the nation should take in regard to vaccination of children**, given that there will be relatively little data on children from some of the early clinical trials? As context, the case fatality rate for Children under age 18 is .02%. **What is the appropriate approach, and timing, of generating the needed data and proceeding to potential childhood vaccination as we move forward?**

3. To Develop New and Improved Vaccines: What **lessons can we learn from COVID-19 vaccine development** more broadly to promote **innovation** and **shorten timelines** to increase availability of new vaccines to the American public?

Thank You

Learn more: www.hhs.gov/vaccines/nvac

Background Slides

Recommendation 1

Recommendation 1. Make safe and effective COVID-19 vaccines available to the public through the Food and Drug Administration's (FDA) Biologics License Application (BLA) process and use caution if using expedited processes. The BLA process is the world's gold standard path to vaccine licensing. Its rigor and requirement for comprehensive data on vaccine safety, efficacy and manufacturing promotes clinician and public trust and fosters confidence in vaccine recommendations. The BLA process has an extraordinary record of accomplishment for releasing very safe and effective vaccines to the public.

If the U.S. uses an expedited process to speed access to COVID-19 vaccines, such as an Emergency Use Authorization (EUA) or an Expanded Access Program (EAP), great caution should be exercised. Prior to vaccine availability, input from relevant federal advisory committees is recommended and included recommendations for the most appropriate use of an emergency authorized vaccine for both prioritized, high-risk populations as well as the public. All safety and efficacy decisions, and the processes for making these decisions, should be fully transparent and communicated in a clear manner to the public to strengthen confidence in such expedited approaches. Any expedited mechanisms should also detail their impact on concurrent and future Operation Warp Speed clinical trials so that novel vaccines will continue to be developed.

Recommendation 2

Recommendation 2. Rapidly deploy and coordinate assets in vaccine safety monitoring through a federal immunization safety task force. The 2009-10 H1N1 monovalent influenza vaccine safety efforts provide a model for the expansion of routine safety monitoring for a pandemic vaccine and coordination of federal assets in vaccine safety monitoring (e.g., the Vaccine Adverse Event Reporting System and administrative databases such as the Vaccine Safety Datalink, Sentinel Post-Licensure Rapid Immunization Safety Monitoring Program, Centers for Medicare and Medicaid Services, Department of Defense and Veterans Administration, and individual case review through the Clinical Immunization Safety Assessment network). It will be critical to ensure that post-approval safety surveillance is capable of rapidly and credibly defining the safety profile of COVID-19 vaccines using every system available to the U.S. government and globally, in a coordinated manner.

Recommendation 3

Recommendation 3. Promptly create a unified, proactive, highly visible communication structure to regularly inform the American public about COVID-19 vaccine development, safety processes, approval, and recommendation criteria. To build the public's confidence in COVID-19 vaccine development, licensing and recommendations, it is critical to ensure a broad understanding of these processes through frequent, consistent, and visible communication, including forums where the public can ask questions about the process. Therefore, NVAC recommends charging a group of HHS experts, such as leaders of Operation Warp Speed, the FDA, National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC), to provide weekly updates to the media and the public on the status, timeline, and emerging information related to COVID-19 vaccine development, safety processes, approval, and recommendation criteria. All HHS COVID-19 vaccine communication efforts should adhere to the HHS National Vaccine Plan communication processes and principles.

Recommendation 4

Recommendation 4. Establish an independent group of vaccine and public health experts (e.g., the National Academies of Science, Engineering, and Medicine) to conduct ongoing, rapid reviews of available data from the federal safety monitoring systems. Make the findings and reviews available in real time to HHS leadership, relevant federal advisory committees, and the public. NVAC recommends this independent group of outside experts advise the Assistant Secretary for Health and the Assistant Secretary for Preparedness and Response on the presence, investigation, interpretation, and implications of possible side effects of COVID-19 vaccines. As an advisory group, the committee would assess risks, and could recommend ways to distinguish unrelated occurrences from true vaccine reactions, anticipate and respond to coincident events, evaluate side effects associated with a vaccine, and recommend ways to publicize the Countermeasures Injury Compensation Program.

Recommendation 5

Recommendation 5. Conduct community and stakeholder engagement to inform COVID-19 vaccine-related policies and to increase the likelihood that these policies will be supported by communities and groups disproportionately affected by COVID-19. As the SARS-CoV-2 pandemic has amplified already existing health disparities, COVID-19 vaccine policies must address the needs of populations who are disproportionally affected by the pandemic. NVAC recommends engaging with representatives from communities and populations of interest to leverage the knowledge, skills, trust within the communities, and expertise to listen to their concerns; share resources; and ascertain their values, priorities, and beliefs related to COVID-19 vaccine development, licensing, acceptance and widespread uptake in order to inform policy and practice decisions. Vital information received during community and stakeholder engagement can be used to provide the necessary technical assistance and support to community representatives in their direct service efforts to build public confidence in the COVID-19 vaccines.