WASHINGTON VACCINE ASSOCIATION

Ensuring Funds for Childhood Vaccines

What:	Special Purpose Board of Directors Meeting
Date & Time:	Thursday, September 28, 2023; 12:00-2:00 p.m. (PT)
Call in Number:	Zoom Invite Below
Location:	Webinar/Teleconference
Zoom Link:	To register for the meeting, please review the Public Comment Protocol then email wvameetings@wavaccine.org at least two business days in advance of the meeting.

Notice: The meeting may be recorded for the benefit of the minute-taker. The WVA intends to delete the recording after the minutes are approved.

Agenda for Board of Directors Meeting

Approx. Time	Page		Topic/Anticipated Action (Votes are in Red)	Presented by:
12:00-12:10 p.m.			1. Welcome & Introductions a. Notification of Recording	J. Dunn/J. Zell
12:10-12:35 p.m.	Pg. 4-9	*	2. Framing of Issues a. DOH Funding Request & Reasoning b. Summary of WVA Actions c. Legislative Change	M. Roberts J. Zell M. Roberts
12:35-12:45 p.m.	Pg. 10-12	*	3. Vaccine Committee Report a. Summary of Testimony/Discussion b. Formal Recommendations	E. Marcuse
12:45-2:00 p.m.			4. Executive Session (public excluded)	

*Indicates agenda item attached
Red text indicates an action item

September 28, 2023
WVA Special Purpose Board Meeting
Proposed Form of Votes

The following are suggested forms of votes only. They are intended to be an aid to facilitate work by individual directors and committee members.

Executive Session:

Relating to Nirsevimab Funding for 2023-24 RSV Season (4.d.):

VOTED: ***Denial Option***: To deny the Washington State Department of Health's request on August 29, 2023, for WVA to fund Nirsevimab during the 2023-24 RSV Season.

Approval (Reserves) Option: To approve the Washington State Department of Health's request on August 29, 2023, to fund Nirsevimab during the 2023-24 RSV Season and to direct the Executive Director to transfer the WVA's assets to the State for vaccine purchases as requested by the DOH as soon as administratively practicable.

Approval (Conditional – Payer commitments) Option: To approve the WVA to provide funding to the State for Nirsevimab during the 2023-24 RSV Season subject to the following conditions:

- The Executive Director ma obtains a substantial bulk of payer commitments to pay their proportionate shares of costs and fees to the WVA for Nirsevimab, with such commitments memorialized in a writing substantially similar to the "Payer Contribution Agreements for Nirsevimab" presented to the Board at the meeting; and the Executive Director shall not transfer funds from WVA's assets to the State without obtaining payer contribution commitments for WVA or securing other appropriate funding sources for WVA to recover such amounts.

Approval (Conditional – Payer commitments + Line of credit): To approve WVA to provide funding to the State for Nirsevimab during the 2023-24 RSV Season subject to the following conditions:

- The Executive Director makes reasonable efforts to obtain commitments from payers to pay their proportionate shares of costs and fees that WVA pays, or that WVA is requested to pay, to the State, with such commitments memorialized in a writing substantially similar to the "Payer Contribution Agreements for Nirsevimab" presented to the Board at the meeting; and
- The Executive Director makes reasonable efforts to obtain other appropriate funding sources and uses such funds, including credit approved separately by this Board, to cover amounts that WVA pays, or is requested to pay, to the State that have not been backed by payer contribution commitments; and
- The Executive Director shall not transfer funds from WVA's assets to the State without obtaining payer contribution commitments or securing other

appropriate funding sources for WVA to recover such amounts.

Relating to Legislative Amendment (4.e.):

VOTED: To ratify actions of the Executive Committee authorizing pursuit of a legislation amendment to revise the definition of "vaccine" in RCW 70.290.010(10) and to direct the Executive Director to continue with such legislative efforts in coordination with the Washington State Department of Health and other stakeholders.

[To ratify actions of the Executive Committee authorizing pursuit of a legislation amendment to revise the definition of "vaccine" in RCW 70.290.010(10) and to direct the Executive Director to continue with such legislative efforts in coordination with the Washington State Department of Health and other stakeholders with edits made at the meeting.]

VOTED: To authorize the engagement of one or more lobbyists to support WVA's legislative efforts and payer contributions for Nirsevimab during the 2023-24 RSV season.

[To authorize the engagement of one or more lobbyists to support WVA's legislative efforts and payer contributions for Nirsevimab during the 2023-24 RSV season with edits made at the meeting.]

Relating to Service Contracts (4.h.):

VOTED: To ratify actions of the Executive Committee in engaging Stoel Rives LLP as special counsel for legal services.

[To ratify actions of the Executive Committee in engaging Stoel Rives LLP as special counsel for legal services with edits made at the meeting.]

VOTED: To authorize the engagement of Helms & Company, Inc., for additional consulting and operational support relating to Nirsevimab with a not to exceed budget.

[To authorize the engagement of Helms & Company, Inc., for additional consulting and operational support relating to Nirsevimab with a not to exceed budget with edits made at the meeting.]

Relating to Line of Credit (4.h.):

VOTED: To authorize WVA to obtain credit from Key Bank in the amount necessary to support the funding of immunizations listed on CDC contract for the Vaccines for Children Program that are administered to commercially insured children.

[To authorize WVA to obtain credit from Key Bank in the amount necessary to support the funding of immunizations listed on CDC contract for the Vaccines for Children Program that are administered to commercially insured children with edits made at the meeting.]

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Prevention and Community Health
Post Office Box 47830
Olympia, Washington 98504-7830
711 Washington Relay Service

August 31, 2023

SUBJECT: Request to Select Nirsevimab for Immediate Funding through the WVA

Chair Dunn, Members of the Board, and the Washington Vaccine Association -

In accordance with chapter RCW 70.290.050, the Department of Health would like to formally request the Washington Vaccine Association (WVA) select Nirsevimab for immediate funding through the WVA.

Nirsevimab is a new immunization that helps protect infants under 8 months and some older babies at increased risk of severe illness caused by respiratory syncytial virus (RSV). RSV is a seasonal, highly contagious virus that affects 97% of children by the age of 2[1]. Low-income children of color are at high risk of severe RSV[2]. Although common, the virus can be dangerous for infants and young children:

- **It is the leading cause of hospitalization for babies less than a year old**[3]. Each year in the United States, an estimated 58,000-80,000 children younger than 5 years are hospitalized due to RSV infection.[4] Infants who are hospitalized with RSV may require oxygen, IV fluids, and mechanical ventilation.
- **RSV can have lasting health impacts**. It is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia in children younger than 1 in the United States[5] and it increases long-term risks of developing asthma.[6]
- **Each year in the United States RSV leads to approximately 100–300 deaths** in children younger than 5 years old.[7]

In August 2023, Nirsevimab was recommended by the CDC Advisory Committee on Immunization Practices (ACIP). It is a long-acting monoclonal antibody product which **has been shown to reduce the risk of both hospitalizations and healthcare visits for RSV in infants by about 80 percent**. It is administered as an injection and provides critical protection during a baby's first RSV season, when they're most at risk for severe illness.

Nirsevimab is expected to be available in the fall of 2023 which coincides with the start of the state's respiratory virus season. Having this new immunization available through the state's Childhood Vaccine Program will help prevent RSV in Washington's babies and infants at a critical time of year.

We appreciate your consideration and continued partnership. If you'd like additional information on Nirsevimab, please contact me at Michele.Roberts@doh.wa.gov.

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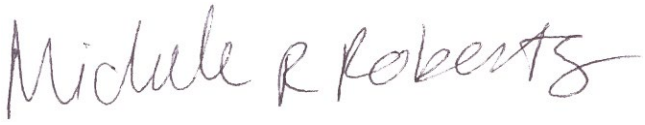
[1] "RSV and Infants: a Respiratory Disease That Can Be Deadly." American Lung Association. October 20, 2021. https://www.lung.org/blog/about-rsv-and-infants
[2] "RSV Health Equity Action Report." National Minority Quality Forum. August 23 2023. https://rsvequityaction.org/wp-content/uploads/2023/07/RSV_Report.pdf
[3] "RSV in Infants and Young Children." Centers for Disease Control and Prevention. August 21 2023. https://www.cdc.gov/rsv/high-risk/infants-young-children.html
[4] "RSV in Infants and Young Children." Centers for Disease Control and Prevention. August 21 2023. https://www.cdc.gov/rsv/high-risk/infants-young-children.html
[5] "RSV (Respiratory Syncytial Virus)." Yale Medicine. August 21 2023. https://www.yalemedicine.org/conditions/rsv-respiratory-syncytial-virus
[6] "Is there a link between RSV and asthma development?" Rachel Zimlich, RN, BSN. Contemporary Pediatrics, September 3, 2019. https://www.contemporarypediatrics.com/view/there-link-between-rsv-and-asthmadevelopment
[7] Hansen CL, Chaves SS, Demont C, Viboud C. Mortality Associated With Influenza and Respiratory Syncytial Virus in the US, 1999-2018. JAMA Network Open. 2022 Feb 1;5(2):e220527.

Sincerely,



Michele Roberts, MPH, MCHES
Assistant Secretary - Division of Prevention and Community Health (PCH)

Cc: Umair A. Shah, MD, MPH - Secretary of Health - Department of Health
Lacy Fehrenbach - Chief of Prevention, Safety and Health - Department of Health
Kristin Peterson - Chief of Policy, Planning and Evaluation - Department of Health
Jamilia Sherls-Jones, DNP, MPH, RN, CPN, CDP - Director, Office of Immunization - Department of Health

BILL REQUEST - CODE REVISER'S OFFICE

BILL REQ. #: Z-0415.2/24 2nd draft

ATTY/TYPIST: MW:akl

AN ACT Relating to updating the Washington vaccine association's definitions; amending RCW 70.290.010; and declaring an emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 70.290.010 and 2010 c 174 s 1 are each amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Association" means the Washington vaccine association.

(2) "Covered lives" means all persons under the age of nineteen in Washington state who are:

(a) Covered under an individual or group health benefit plan issued or delivered in Washington state or an individual or group health benefit plan that otherwise provides benefits to Washington residents; or

(b) Enrolled in a group health benefit plan administered by a third-party administrator. Persons under the age of nineteen for whom federal funding is used to purchase vaccines or who are enrolled in state purchased health care programs covering low-income children including, but not limited to, apple health for kids under RCW 74.09.470 and the basic health plan under chapter 70.47 RCW are not considered "covered lives" under this chapter.

(3) "Estimated vaccine cost" means the estimated cost to the state over the course of a state fiscal year for the purchase and distribution of vaccines purchased at the federal discount rate by the department of health.

(4) "Health benefit plan" has the same meaning as defined in RCW 48.43.005 and also includes health benefit plans administered by a third-party administrator.

(5) "Health carrier" has the same meaning as defined in RCW 48.43.005.

(6) "Secretary" means the secretary of the department of health.

(7) "State supplied vaccine" means vaccine purchased by the state department of health for covered lives for whom the state is purchasing vaccine using state funds raised via assessments on health carriers and third-party administrators as provided in this chapter.

(8) "Third-party administrator" means any person or entity who, on behalf of a health insurer or health care purchaser, receives or collects charges, contributions, or premiums for, or adjusts or settles claims on or for, residents of Washington state or Washington health care providers and facilities.

(9) "Total nonfederal program cost" means the estimated vaccine cost less the amount of federal revenue available to the state for the purchase and distribution of vaccines.

(10) "Vaccine" means ((~~a preparation of killed or attenuated living microorganisms, or fraction thereof, that upon administration stimulates immunity that protects against disease and is~~)) an immunization approved by the federal food and drug administration as safe and effective and recommended by the advisory committee on immunization practices of the centers for disease control and prevention for administration to children under the age of nineteen years.

NEW SECTION. **Sec. 2.** This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately.

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September 7, 2023

OFFICE OF IMMUNIZATION

Washington State Department of Health

Dear Immunization Partners,

This is an update on the Washington State Department of Health's work to plan for nirsevimab release.

Nirsevimab is a new long-acting monoclonal antibody injection that is expected to be available starting in October. It is now recommended for routine use to prevent respiratory syncytial virus (RSV) lower respiratory tract infection (LRTI) in

- All infants younger than age 8 months during their first RSV season.
- Children ages 8-19 months entering their second RSV season who are American Indian, Alaska Native, or at an increased risk for severe disease.

The Washington State Department of Health is taking steps in collaboration with the Washington Vaccine Association to include nirsevimab-alip (trade name Beyfortus) as part of the state's Childhood Vaccine Program so it is available for all eligible babies in Washington. The Childhood Vaccine Program increases vaccine access by providing publicly-purchased vaccines to enrolled providers. This allows providers to offer childhood vaccines at no cost to the patient.

We do have a technical challenge with the state law that is the foundation for the Washington Vaccine Association public/private partnership that supports our state universal purchase system. We are working collaboratively on both short- and long-term solutions and hope to have more specific information to share by late September.

While nirsevimab is not yet available through the Childhood Vaccine Program, we have the following updates to share:

- Nirsevimab is a monoclonal antibody injection and not a vaccine. ACIP voted to include this product on the routine childhood vaccine schedule on August 3.
- We've had discussions with Washington State Association of Local Public Health Officials, the Washington State Hospital Association, Washington Chapter of the American Academy of Pediatrics, and other partners to share updates and identify barriers.
- CDC is still developing its contract with the manufacturer of nirsevimab. We anticipate the availability of product from the contract as early as October.
- We're collaborating with the CDC and our immunization information system vendor to incorporate nirsevimab into the Washington Immunization Information System (WAIIS). As our team gathers more information, we will provide guidance on reporting to the WAIIS.
- We will have more information to share in late September.

Actions providers can take now:

- Prepare to have conversations with parents/guardians about nirsevimab. A direct recommendation from a trusted health care provider remains one of the most effective ways to increase acceptance and immunization rates.
- Ensure your facility is enrolled with the Childhood Vaccine Program now so that you are ready to order nirsevimab for eligible babies and children when it becomes available.
- Hospitals and birthing centers can establish procedures for administering nirsevimab to babies prior to discharge. They should document the dose given and coordinate with the infant's primary care provider for continuity of care.
- Update Electronic Medical or Health Record (EMR/EHR) applications to add NDC, CVX, and CPT codes for nirsevimab. There may be challenges for partners currently exchanging data with the WAIIS based on how their triggers are configured to send data. We recommend starting conversations with your system vendor on nirsevimab.
- Read clinical guidance for nirsevimab: Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

We understand the urgency and importance of having access to nirsevimab this respiratory disease season. We are working diligently through solutions and finalizing details.

We appreciate your patience and partnership. Please reach out to WAChildhoodVaccines@doh.wa.gov if you have questions.

Sincerely,

Jamilia Sherls-Jones, DNP, MPH, RN, CPN, CDP
Director, Office of
Immunization Department of
Health

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Washington State Department of HEALTH

Meeting Notes
Special RSV Vaccine Committee Meeting
September 21, 2023; 7:00-8:00 a.m. PT

I. Attendance. This meeting was conducted solely by webinar. Participating in all or part of the meeting were the following individuals:

Attendees
Ed Marcuse, MD, Emeritus Professor of Pediatrics, University of Washington
Amy Carter, MD, Allegro Pediatrics
Helen Chea, MD, Molina Healthcare
John Dunn, MD, Kaiser Permanente
Beth Harvey, MD, South Sound Pediatrics
Chad Murphy, Premera
Amy Person, MD, Benton-Franklin Health District
Kristi A. Rice, MD, Providence
Janel Jorgenson, Washington Department of Health
Michele Roberts, Washington Department of Health
Hailey Sly, Washington Department of Health
Sherri Zorn, MD, Independent Consultant
Jeff Gombosky, PhD, Pharmaceutical Research and Manufacturers of America
Pam Sheffield, MD, Aetna
Juliet Dang, PhD, Sequirus
Carrie Jenner, MD, Pierce County Immunization Coalition
Rick Hourigan, MHA, MD, Cigna
Breelyn Young, GSK
Frank Bell, MD, Swedish
Nicholas Fisher, Sanofi
Neil Kaneshiro, Premera
Julia G. Zell, MA, Esq., WVA Executive Director
Patrick Miller, MPH, WVA Administrative Director
Cheri Cagle, WVA Stakeholder Liaison
Ashley Ithal, MPH, WVA Project Support Leader
Leslie Walker, CPA, Mason+Rich

II. Summary of Actions Taken and/or Recommended

The Vaccine Committee voted to adopt the following recommendations to be presented to the Board of Directors:

1. WVA to Work with DOH to Make RSV Monoclonal Antibody Part of WA State Universal Vaccine Purchase Program.
2. WVA to Develop a Funding Mechanism to Protect Against Liability Pending Modification of Statute Governing WVA.
3. WVA to Collaborate with DOH, WCAAP, and Others to Modify Statute this Legislative Session to Update Definition of Vaccine.

III. Minutes

Welcome and Introductions
At 7:02 a.m. Dr. Marcuse called the meeting to order. Ms. Zell announced that the meeting would be recorded for the benefit of the minute taker, to be deleted once the minutes are approved.

Dr. Marcuse provided an overview of Nirsevimab, which was recommended by the Advisory Committee on Immunization Practices for inclusion on the CDC's immunization schedule and the Vaccines for Children program. It is a monoclonal antibody providing passive immunization in infants and toddlers against RSV. Dr. Marcuse reviewed the role of the WVA and the Vaccine Committee in making recommendations on which immunizations to purchase for the state universal vaccine program. He noted that virtually all universally available vaccines have been listed on federal contract and are available under the program. He discussed, however, that Nirsevimab presents a unique issue. Nirsevimab is not a vaccine that stimulates active immunity in the vaccinee but an antibody confers passive immunity. Therefore, it does not fit under the statutory definition of vaccine in the WVA's establishing statute. Dr. Marcuse confirmed that the purpose of today's meeting is for the Vaccine Committee to come to consensus on recommendation(s) that will be presented to the Board of Directors at the special board meeting on September 28, 2023.

WCAAP Presentations
Dr. Marcuse discussed the importance to obtain consultation from third-party, non board member experts to inform the Committee's deliberations and recommendations on this matter.

Dr. Marcuse introduced Dr. Frank Bell (Swedish), who is a pediatric infection disease specialist based in the Tacoma, Washington area. Dr. Bell discussed that RSV is the predominant cause of hospitalization of infants globally. He referenced statistics provided in materials that were circulated to Committee members in advance of today's meeting. Dr. Bell described RSV as a ubiquitous virus—one that all infants will have experienced by the end of their second RSV season. Some infants may have mild symptoms, but many have congestion of upper and/or lower airways, leading to respiratory distress and difficulty feeding. Dr. Bell noted that 1 to 3 percent of infants who experience RSV in their first winter season have required hospitalization to receive nutrition, intravenous fluids, respiratory support, and/or supplemental oxygen.

Dr. Bell next provided a clinical overview of immunization development for RSV since the virus was discovered about 30 years ago. He discussed how early attempts to produce an inactivated vaccine seemed to lead to more aggressive disease in infants subsequently infected by the virus, rather than abrogation or prevention. Dr. Bell also touched on the RSV monoclonal antibody currently on the market, Synagis, noting that while we have seen some success, this has proven to be a relatively costly strategy for a product that is and very difficult to deliver (monthly injections throughout the season). Dr. Bell discussed that we have gained a much better understanding of RSV and we have made extraordinary progress on immunization technologies. He views Nirsevimab to be highly effective, safe, without appreciative side effects, and "our best shot" to help infants against RSV.

Dr. Marcuse next introduced Dr. Amy Carter (Allegro Pediatrics), who is a pediatrician and Chief Medical Officer practicing at one of the largest pediatric practices in Washington State, to provide a clinician's perspective about the demand and the feasibility of administering Nirsevimab as part of primary care. Dr. Carter noted that pediatricians and patients are very excited about Nirsevimab; she views this as the beginning of a paradigm shift in RSV prevention.

Dr. Carter provided estimates of the number of infants Allegro expects to see across the two groups for which ACIP recommendations have been issued (infants under 8 months of age entering their first RSV season, and high-risk infants between 8 and 19 months of age entering their second RSV season)—approximately 32,000 patients. She believes it would be feasible for Allegro to administer Nirsevimab to these patients if it is included in the state universal vaccine program. She noted that this is a well-known and trusted system throughout the State, and that providers already have standing working relationships and proven workflows for ordering and distribution.

Dr. Carter next discussed her concerns if WVA does not fund Nirsevimab. Ultimately, she believes that a two-product system would place significant burdens (in terms of ordering costs, storage space, staffing, and workflows); would increase the risk of error and impact patient safety; and would lead to disparities in access and health outcomes. In particular, she discussed that providers would need to adjust a lot of capital on short notice if they were to have to privately purchase Nirsevimab for this upcoming season. For Allegro, she estimates a $1.5 million outlay. She noted that the cost of Nirsevimab is significant enough to cause providers to be conservative in any private purchasing to avoid "over-ordering," and that this could lead to a lack of supply in the middle of the season.

Dr. Carter closed her remarks by noting the public health policy behind the state universal vaccine program. She cautioned against further eroding the public's trust in science and in vaccines by failing to include Nirsevimab in the program. She also noted that equitable access to Nirsevimab will take pressure off our urgent care and emergency room providers to treat infants who can now be protected from severe disease.

Dr. Marcuse called on Janel Jorgenson to discuss the position of the Washington State Department of Health (DOH). Ms. Jorgenson discussed that the state universal vaccine program has been in place for over 30 years. She discussed what this program provides for Washington: equitable access to vaccines regardless of insurance statute; reduction in state expenditures by purchasing via CDC federal contract (on average, 30% savings over all); mitigation of financial, staffing, inventory, and related burdens on providers under a two-product system: i.e, one for VFC eligible patients and one for all others.. Ms. Jorgenson acknowledged the issue unique among ACIP immunization recommendations to Nirsevimab, because it does not fall within WVA's statutory definition of a vaccine. She confirmed that DOH is seeking a statutory change to align the State's definition with ACIP's replacing the term vaccine with immunization which would allow products like Nirsevimab to be added to the state universal vaccine program if recommended by ACIP and covered by VFC. DOH requests WVA to support the DOH's efforts to include Nirsevimab in the state universal vaccine program.

Dr. Marcuse called on Ms. Zell to discuss the challenges with providing Nirsevimab for the upcoming season, as well as the longer-term strategy to include this in the program moving forward. Ms. Zell confirmed that WVA has determined that the statutory definition would not encompass Nirsevimab, and that WVA is working closely with the DOH and the State AG to effectuate the statutory change. She also discussed WVA's efforts to identify funding approaches for the upcoming season that could be presented to the Board of Directors on September 28 for consideration. She discussed in particular the potential for payers to commit to voluntarily fund Nirsevimab for this season, so that assessments do not begin until the legislation passes. She also discussed the potential for WVA to secure other appropriate funding to avoid use of its reserves before the legislation has passed. She noted that all of these options are subject to approval of the Board of Directors, which will meet on September 28. Kiran Griffith provided additional comments on legal risks to WVA with funding Nirsevimab before the legislation passes and what is being considered to mitigate these risks while supporting equitable access to the product.

Dr. Marcuse proposed that the Vaccine Committee consider and vote on the following recommendations to the Board regarding Nirsevimab:

1. WVA to Work with DOH to Make RSV Monoclonal Antibody Part of WA State Universal Vaccine Purchase Program this respiratory season.
2. WVA to Develop a Funding Mechanism to Protect Against Liability Pending Modification of Statute Governing WVA.
3. WVA to Collaborate with DOH, WCAAP, and Others to Modify Statute this Legislative Session to Update Definition of Vaccine.

Dr. Marcuse then opened the meeting up for general discussion. Key questions and comments included the following:

- What are the WVA's reserves and what are these amounts meant to be used for?
- What is the scope of WVA's authority to collect assessments under the statute? What is the legal risk to WVA to use reserves to pre-fund Nirsevimab before the statute is changed? What risk mitigation steps could be taken?
- Recognition that the Vaccine Committee's role is focused on clinical considerations and public health impact relating to a vaccine under proposed recommendations #1 and #3. Proposed recommendation #2 raises other legal and funding considerations beyond the focus of this Committee, but it is important context for the Committee to consider given the legal risks to the organization.

Next Steps

Upon motion duly made and seconded, it was unanimously:

VOTED: 11 in favor of proposed recommendations #1 and #3, no opposition. 10 in favor of proposed recommendation #2, no opposition.

IV. Public Comments

No public comments.

V. Closing

The meeting adjourned at 7:57 a.m. PT.