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**June 25, 2018, Meeting Minutes (Webinar)**

**Committee Members in Attendance**

Kimberly M. Thompson, Sc.D., Chair  
Steve Black, M.D.  
Jay C. Butler, M.D., CPE, FAAP, FACP,  
FIDSA  
Melody Anne Butler, B.Sc.N., RN  
Timothy Cooke, Ph.D.  
Leonard Friedland, M.D.  
Ann Ginsberg, M.D., Ph.D.  
Robert H. Hopkins Jr., M.D., MACP, FAAP  
Mary Anne Jackson, M.D., FAAP, FPIDS,  
FIDSA  
Melissa Martinez, M.D., FAAFP  
Cody Meissner, M.D., FAAP  
Nathaniel Smith, M.D., M.P.H.  
Geeta Swamy, M.D., FACOG

**NVAC Ex Officio Members**

Armen Donabedian, Ph.D. (for Rick Bright,  
Ph.D.), Biomedical Advanced Research  
and Development Authority (BARDA)  
Marion Gruber, Ph.D., Food and Drug  
Administration (FDA)  
Mary Beth Hance (for Jeffrey Kelman,  
M.D., M.M.Sc.), Centers for Medicare  
and Medicaid Services  
Jane Kim, M.D., M.P.H. (for Troy  
Knighton, M.Ed., Ed.S., LPC),  
Department of Veterans Affairs  
Jeffrey McCollum, D.V.M., M.P.H., Indian  
Health Service  
Justin A. Mills, M.D., M.P.H., Agency for  
Healthcare Research and Quality  
Barbara Mulach, Ph.D., National Institutes  
of Health (NIH)  
Narayan Nair, M.D., CAPT, Division of  
Injury Compensation Programs, Health  
Resources and Services Administration

Kristin Pope, M.Ed., Centers for Disease  
Control and Prevention (CDC)  
Judith Steinberg, M.D., M.P.H., Bureau of  
Primary Health Care, Health Resources  
and Services Administration

**NVAC Liaison Representatives**

Nancy M. Bennett, M.D., M.S., Advisory  
Committee on Immunization Practices  
(ACIP)  
James S. Blumenstock, Association of State  
and Territorial Health Officials  
Gina Charos, Public Health Agency of  
Canada  
Rebecca Coyle, M.S.Ed., American  
Immunization Registry Association  
Kathryn Edwards, M.D., Vaccines and  
Related Biological Products Advisory  
Committee  
Kristen R. Ehresmann, RN, M.P.H.,  
Association of Immunization Managers  
Jean-Venable "Kelly" Goode, Pharm.D.,  
BCPS, FAPhA, FCCP, American  
Pharmacists Association  
James David Nordin, M.D., M.P.H.,  
America's Health Insurance Plans  
Alexandra Stewart, J.D., Advisory  
Commission on Childhood Vaccines

**Acting Designated Federal Officer**

Angela Shen, Sc.D., M.P.H., CAPT, Senior  
Advisor, National Vaccine Program  
Office (NVPO), Department of Health  
and Human Services (HHS)

## **Proceedings**

### **Welcome and Call to Order—Angela Shen, Sc.D., M.P.H., CAPT, Senior Advisor, NVPO, HHS**

As the Designated Federal Official for the NVAC, Dr. Shen called the meeting to order at 2 p.m. She outlined key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for NVAC members. Dr. Shen thanked the NVPO staff for their support in organizing the meeting and called the roll.

### **Opening Remarks and Outgoing Member Recognition—ADM Brett P. Giroir, M.D., Assistant Secretary for Health (ASH), HHS**

Dr. Giroir said he has looked forward to attending an NVAC meeting since starting his tenure as ASH. He believes vaccines are among the most important public health invention in modern times, and improving the vaccine enterprise is vital. He described his vision of transforming the country's sick-care system into a health-promoting system and lifting up those who are suffering disproportionately, especially due to preventable diseases. In this regard, nothing is more important than making sure that children and adults benefit from available vaccines and that a framework exists for future vaccine innovation and development. To achieve these goals requires collaboration inside and outside of government and throughout many sectors, as exemplified by the NVAC.

Dr. Giroir thanked all the NVAC members and the stakeholders who gave their input on the HPV Vaccine Implementation Report. Improving HPV vaccination rates is a priority for the ASH, because it is a cancer-preventing and life-saving vaccine. Dr. Giroir commended NVAC for its strong deliberation process, which provides HHS with valuable advice. He looked forward to the final report and to developing an implementation plan informed by it.

Dr. Giroir recognized two NVAC members—Saad Omer, M.B.B.S., M.P.H., Ph.D. and Nathaniel Smith, M.D., M.P.H.— who will be transitioning off the Committee following this meeting. Dr. Giroir thanked them for their commitment and service, and acknowledged their significant and substantial contributions to the NVAC and to HHS.

In addition, Dr. Giroir thanked Dr. Shen, who is retiring from the U.S. Public Health Service Commissioned Corps after 22 years of service and will no longer be the Designated Federal Official for NVAC. Dr. Shen has incredible knowledge of and deep passion for improving protection against vaccine-preventable diseases across the life span. She has led many important activities, often focusing on improving adult immunization rates, which could potentially save thousands and perhaps millions from future suffering and death. Dr. Shen also led the NVPO effort to prepare the report to Congress on vaccine innovation required by the 21st Century Cures Act, which involved extensive collaboration with a vast array of partners.

Finally, Dr. Giroir thanked Lauren Chambers, the NVPO professional staff member who managed NVAC until last week. Ms. Chambers has taken a new Federal government position, and Dr. Giroir was confident that she would be highly productive there, as she has been with NVPO.

In closing, Dr. Giroir said that before he completes his tenure as ASH, he wants to see positive upticks in the vaccine enterprise that can be counted so that the impact on future generations is clear.

**NVPO Update—Melinda Wharton, M.D., M.P.H., Acting Director, NVPO**

Dr. Wharton thanked the NVAC for providing HHS with important scientific information and expert insight from within and outside of government. She described the charge by the former ASH to the NVAC to provide brief recommendations on improving HPV vaccine coverage rates. Dr. Wharton thanked the HPV Vaccine Implementation Working Group (WG) for developing the report to be presented at this meeting.

**Chair’s Report—Kimberly M. Thompson, Sc.D., NVAC Chair**

Dr. Thompson welcomed the meeting participants and thanked the NVPO staff, especially Ms. Chambers and Dr. Shen for their efforts. On behalf of the NVAC, she thanked Dr. Saad Omer for his contributions as an NVAC member, noting in particular his efforts related to discussions of vaccine confidence and his service as the co-chair of a recent Maternal Immunization Working Group. Dr. Thompson also thanked Dr. Nate Smith for his contributions to the NVAC, noting in particular his service as co-chair of the Mid-Course Review of the 2010 National Vaccine Action Plan and the HPV Vaccine Implementation Working Groups.

Dr. Thompson gave an overview of the agenda and meeting proceedings. She noted two public planned comment periods: one for comments about the HPV Vaccine Implementation WG report after the Working Group discussions and another at the end of the meeting for general input. All public comments will appear in the public record. Written comments can be sent to the NVAC for consideration by e-mail ([nvac@hhs.gov](mailto:nvac@hhs.gov)). The minutes and presentations of past meetings are available online at <http://www.hhs.gov/nvpo/nvac/index.html>. NVAC is scheduled to meet next in person on September 12–13, 2018. Dr. Thompson thanked Dr. Smith and Dr. Geeta Swamy for co-chairing the HPV Implementation WG and turned to discussion of the final draft of the report.

**Implementation of HPV Vaccine Recommendations: WG Report, Recommendations, and Vote**

**Overview—Nathaniel Smith, M.D., M.P.H., NVAC Voting Member**

Dr. Smith reviewed the charge to NVAC by the ASH to produce a brief report by June 2018 on recommendations to strengthen the effectiveness of national, State, and local efforts to improve HPV vaccination coverage rates. The ASH specifically requested input on four questions/topics, and the draft recommendations are organized around them.

Dr. Smith said all the public comments received so far were reviewed and adjudicated by the WG as indicated in the comment grid. He added the receipt of editorial comments, which the WG also considered. The charge questions/topics and the WG recommendations follow:

*Focus Area 1: Many national organizations are currently supporting HPV vaccination efforts. Are there additional, national organizations that might contribute to increasing HPV vaccination coverage?*

**Recommendations for Focus Area 1**

- 1.1 To promote inclusion of new health care partners, the ASH should encourage further development, dissemination, and implementation of evidence-based practitioner resources and support collaborative relationships.
- 1.2 The ASH should encourage enhanced engagement with payers, employers, and quality improvement organizations to increase communication to beneficiaries about HPV vaccine coverage and the importance of receiving the full HPV vaccination series.
- 1.3 The ASH should encourage employers and payers to link value-based payment to provider benchmarks for HPV vaccination.

1.4 The ASH should encourage the Health Resources and Services Administration (HRSA) to include an HPV vaccination adolescent measure in the Uniform Data System, which serves as a reporting requirement for HRSA grantees in community health centers, migrant health centers, health centers for homeless grantees, and public housing primary care organizations. The data should be used to improve health center performance and operation and to identify trends over time.

*Focus Area 2: At the State level, many States have formed coalitions to support HPV vaccination efforts. Is there general guidance for States that do not yet have coalitions?*

**Recommendations for Focus Area 2**

- 2.1 The ASH should engage with and encourage State health officials to use existing, publicly available resources for coalition building and partner coordination, including the National HPV Vaccination Roundtable’s “State Coalitions and Roundtable Guide.”
- 2.2 The ASH should encourage continued collaboration and active engagement between immunization and cancer advocacy groups to increase the availability of resources for HPV immunization.

*Focus Area 3: Integrated health care delivery networks can successfully integrate comprehensive quality improvement approaches to increase vaccination coverage rates. How can State immunization programs and coalitions engage with health systems to work together on improving HPV vaccination coverage?*

**Recommendations for Focus Area 3**

- 3.1 The ASH should work with State health officials and local health departments as key immunization leaders to engage with regional and local health systems and integrated delivery network (IDN) executives to prioritize HPV vaccination as an effective means for cancer prevention and to develop accountability mechanisms to track and incentivize performance.
- 3.2 The ASH should engage the Office of the National Coordinator for Health Information Technology (ONC), State Health Officials, and partners to support interoperability by encouraging bi-directional electronic data exchange and broad use of immunization data across electronic health records (EHRs), immunization information systems (IISs), and with all Federal partners, particularly as it relates to HPV immunization. Activities may include:
  - 3.2.1 Supporting the onboarding process of new users (i.e. getting a provider organization ready to send, submit, and query patient data from an EHR to the IIS), including adult providers.
  - 3.2.2 Developing a memorandum of understanding or data use agreement between the Department of Defense (DoD), Department of Veteran Affairs (VA), and immunization information systems (IISs) to support immunization data exchange.
  - 3.2.3 Supporting the acceleration of current EHR, pharmacy information systems, and IIS standardization efforts, including promoting functionality that supports query and response for clinical decision support.
- 3.3 The ASH should work with State health officials, local health departments, and their partners to encourage the use of IISs and EHRs to:

3.3.1 Generate coverage assessments for a provider's population for use in targeting reminder efforts for adolescents that are due and past due for HPV vaccination.

3.3.2 Assess opportunities to vaccinate individuals within a provider's practice to reduce missed opportunities to vaccinate and increase protection for populations (e.g., through the use of clinical decision support and quality improvement processes such as Assessment, Feedback, Incentives, and eXchange [AFIX]).

*Focus Area 4: Please specify recommendations on how to meet the needs of providers in rural areas.*

#### **Recommendations for Focus Area 4**

4.1 The ASH should request further research be conducted to better understand the needs of rural providers in supporting the administration of or referral to vaccination services in rural environments and to identify and determine barriers to accessing vaccination services for patients in rural settings.

4.2 The ASH should encourage the increased use of technology-based, telemedicine systems such as tele-consulting and tele-mentoring partnerships to reach rural and underserved communities to strengthen provider education on HPV vaccination and cancer prevention.

4.3 The ASH should support a stronger HHS-wide social media presence to improve the reach of communication strategies and engage parents and adolescents to build trust and recognition directly about the importance of HPV vaccination and how to best engage patients in rural communities.

#### ***Committee Discussion***

James David Nordin, M.D., M.P.H., applauded the WG for highlighting the role of HPV vaccine for cancer prevention rather than to prevent sexually transmitted disease, which often complicates the discussion in pediatric care settings. Dr. Smith provided a brief summary of the organizations that submitted public comments. He also noted comments from two individuals, including on comment that included data from a number of projects collected within a local high school and college community related to HPV education and vaccine promotion. Dr. Swamy added that the public comments were helpful, and some were particularly on point, such as comments about the inclusion of local partners and coalitions. Dr. Thompson said she was pleased with the WG's thoroughness in responding to comments on the report and asked for a motion to approve the draft report, which was offered and seconded.

Several members expressed appreciation and praise for the report. Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA, also noted that the American Academy of Nursing just released a policy brief on the need to accelerate uptake of HPV vaccine across the country, which she said that she would share with the committee. The recognition of NVPO staff transitions occurring with respect to supporting the NVAC led to recognition of an action item for the NVPO to let NVAC members know whom to contact with information or questions in light of the departure of Dr. Shen and Ms. Chambers.

#### ***Public Comment***

**Theresa Wrangham of the National Vaccine Information Center (NVIC)** noted that the NVAC appeared to be in a rush to vote on the draft report document and to obtain comments through the *Federal Register*. She was disappointed that the public could not see the edits made

to the report, as have been shown with these sorts of documents at previous NVAC meetings. Ms. Wrangham noted that informed consent is not outside the charge to NVAC. Rather, it should be intrinsic to every consideration of this Committee as part of its charge is to put forth vaccines that prevent injuries and deaths.

Ms. Wrangham said the HPV vaccine involves a lot of expense. Recent data submitted by her organization as part of the public comments noted that the impact of this vaccine will be unknown for decades. She noted that the same information was also presented at the February ACIP meeting. She questioned as to whether these comments had been considered and whether the WG addressed the issue of privacy concerns also raised in the public comments. She emphasized that cervical cancer is highly treatable, and the ACIP has recognized the success of Pap smears [in identifying cervical cancer], as has the CDC report to Congress in 2006. ACIP data show that the HPV vaccine is probably not responsible for any of the declines being seen in cervical cancer. Ms. Wrangham encouraged the NVAC to take a deeper look at the issues. She called for more attention to consumer protections and transparency of information and a commitment to ensure that public comments are revealed to the public as well as the edits to the document made following public comments, in keeping with the Federal Advisory Committee Act.

No other comments were offered on the draft report. Dr. Thompson noted that the virtual meeting format had led to limitations with respect to sharing documents that would have been available in printed form to all in person attendees, and asked the NVPO staff to ensure the availability of documents to all attendees to NVAC meetings, whether the meeting is in-person or virtual. She then called for the vote, and the NVAC members unanimously approved the report and recommendations of the HPV Vaccine Implementation WG as written.

### **Overview of the 21<sup>st</sup> Century Cures Report on Vaccine Innovation—Angela Shen, Sc.D., M.P.H., CAPT, Senior Advisor, NVPO, HHS**

Dr. Shen summarized the report submitted to Congress on [Encouraging Vaccine Innovation: Promoting the Development of Vaccines that Minimize the Burden of Infectious Diseases in the 21st Century](#). The report draws from the National Vaccine Plan and the mid-course review of that document, as well as expertise from within and outside of HHS. The report determined that the vaccine enterprise is well established and has benefited from innovation and domestic and global partnerships. However, the enterprise is very complex, and vaccine development is at a turning point several reasons:

- The business model prioritizes candidate vaccines for which there is likely to be a large market.
- Substantial investment is needed to address the scientific challenges.
- Uncertainty about public health priorities and vaccine demand cloud the potential return on investment (ROI) and risks.

Successful innovation requires small companies taking novel approaches to developing candidates, large companies with the resources to manufacture and market vaccines, and Federal agencies to assist at every step, from basic science through regulatory approval. Dr. Shen outlined four specific challenges to innovation and opportunities to address them, summarized in the table:

Challenge	Opportunity	Examples
Limited understanding of the science to develop optimal vaccines	Enhance scientific understanding of immune response mechanisms	<ul style="list-style-type: none"> <li>• NIH and CDC support for population research</li> <li>• Federal investments in promising adjuvants</li> <li>• Ongoing support for clinical development and translation</li> </ul>
Challenging clinical trial design for specific populations	Regulatory flexibility and novel scientific tool development	<ul style="list-style-type: none"> <li>• Innovative and flexible FDA approaches to regulatory approval</li> <li>• FDA support for novel data sources to support regulatory approval, such as biomarkers and real-world evidence</li> </ul>
Need for convergence of regulatory requirements across countries	Enhance global activities	<ul style="list-style-type: none"> <li>• Uptake of FDA best practices</li> <li>• Adoption of internationally recognized technical guidance documents or standards and scientific principles</li> <li>• Improved international coordination through agreements on specific issues, such as clinical endpoints</li> </ul>
Uncertain ROI for new and improved vaccines	Increase surveillance and epidemiologic studies	<ul style="list-style-type: none"> <li>• CDC's reliable epidemiological data</li> <li>• CDC and NIH support for global surveillance and global clinical trial sites</li> </ul>
	Enhance frequency and transparency of communication with U.S. Government, industry, and international stakeholders	<ul style="list-style-type: none"> <li>• FDA communication with industry</li> <li>• Improved communication between CDC and industry on potential recommendations for product use</li> <li>• Standardized ACIP guidelines and timelines for recommending vaccines</li> </ul>
	Improve vaccine uptake	<ul style="list-style-type: none"> <li>• Sustained, ongoing efforts to improve uptake of effective vaccines among those at risk for vaccine-preventable diseases</li> <li>• The currently rising uptake suggests a potential future market</li> </ul>
	Forge public-private partnerships	<ul style="list-style-type: none"> <li>• BARDA partnerships with industry around vaccine development and procurement</li> <li>• Federal support for development of vaccines with small markets or low estimated ROI</li> <li>• Leveraging of Federal investments to act as incentives for development</li> </ul>

**Discussion**

Steve Black, M.D., said organizations like the Coalition for Epidemic Preparedness Innovations are helping to identify more candidates, but only a few manufacturers can invest the billion dollars required for Phase III studies. Without action, the problem of getting promising vaccines through the research stage and into manufacturing will persist.

Dr. Black also proposed that the NVAC look more closely at the potential role for vaccines in combating antibiotic-resistant bacteria, which may require new trial designs and new ways of thinking about the regulatory process. Dr. Thompson reminded the members that the NVAC published a [paper](#) on this topic in 2016, and that several NVAC members participated in subgroups of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria,

which culminated in the publication of a 2017 [report](#) on economic incentives for development, including vaccines.

Melissa Martinez, M.D., FAAFP, suggested that some innovations in the research and development process could have a positive impact on the cost of vaccines and, thus, access to them. Leonard Friedland, M.D., said that new technologies can lead to lower product costs in the long term, but new technology requires major investment.

Timothy Cooke, Ph.D., pointed out that companies take economic risks in product development that affect the costs of the product. He also noted the lack of a business model to support development of preventive vaccines for infectious diseases, as investors increasingly focus on immunotherapy and orphan diseases, for which product prices can be very high. Public-private partnerships are the only mechanism supporting infectious disease vaccine development, and many of them are only effective in moving products through Phase II studies. A robust, attractive commercial market is crucial to getting big pharmaceutical companies engaged in bringing products forward, and that may conflict with concerns about cost and access. Moreover, much more spending goes to treating disease than to prevention. Dr. Cooke concluded that more attention is needed to the value of vaccines.

Ann Ginsberg, M.D., Ph.D., called for more discussion of sustainable funding mechanisms. Developers should not rely on commercial markets alone; the government plays an important role by providing incentives or conducting some of the research needed. Dr. Ginsberg raised concerns that the Gates Foundation and others are funding more of their own, internal research, which could have the effect of decreasing innovation and diversity of thought in the field. She concluded that increasing the amount of money spent on prevention, rather than cutting costs, should be taken seriously.

Cody Meissner, M.D., FAAP, observed that dialogue between developers and CDC around ACIP evaluations and recommendation is important to ensure that developers can anticipate some of the concerns that may arise. He also noted that there is little transparency around how vaccine prices are set. New methods are needed to measure the value of vaccines, going beyond dollars to prevention of pain and suffering. Dr. Thompson agreed on the need for continued discussion of vaccine innovation and incentives; she said methods exist for economic analysis to support recognition of the value of vaccines, but there has been little investment in making the case for vaccines overall.

Nancy M. Bennett, M.D., M.S., said ACIP reviews a lot of economic data on the impact of vaccines in the context of making its recommendations. She noted the belief that preventive care should be not just cost-effective but cost-saving as a “ridiculous” threshold for any medical intervention. Rather than look at how much vaccines cost, there should be more assessment of the disease burden, said Dr. Bennett. More consideration also should be given to the use of vaccines in certain subpopulations or specific situations, which influences cost-effectiveness data.

Dr. Shen said the discussion underscored some of the key issues raised during development of the report, such as the importance of catalytic investments and communication about public health priorities.

#### **Topics for Future NVAC Discussion**

- The handoff from small firms developing vaccines to large ones that can push them through the trial and regulatory processes
- The potential role for vaccines in combating antibiotic-resistant bacteria



- Development of sustainable funding mechanisms to support vaccine innovation
- Increasing transparency of Federal investments in vaccine innovation, as discussed in the NVAC's Mid-Course Review of the 2010 National Vaccine Action Plan
- Successes and failures of public-private partnerships in vaccine development

**Update from the 2017–2018 Influenza Season and Next Steps—Erin Connelly, M.P.Aff., National Center for Immunization and Respiratory Diseases, CDC**

Despite a bad influenza season and some negative media coverage, Ms. Connelly stressed that influenza vaccine remains the best defense against this serious health threat. It can save children's lives. It reduces hospitalization for some and helps reduce illness among those with chronic health conditions. The vaccine also may result in a milder disease for those who do get sick.

CDC takes a comprehensive approach to communication about flu vaccine and the risks of influenza and invests in a broad range of activities to help its partners spread the message. All of its messaging efforts begin with qualitative and quantitative research about strategies, outcomes, and goals. Messages are refined based on data and lessons learned from previous seasons. CDC holds planning calls to share messages with partners.

As an example of translating research into practice, Ms. Connelly pointed to data indicating that parents are motivated by their roles as their child's protector, which CDC incorporated into its messaging around vaccination. To test, refine, and disseminate its messages, the agency relies heavily on partners on the ground.

In light of the growing use of digital media, CDC increasingly designs materials with mobile devices in mind. Because providers continue to be the most trusted source of recommendations, CDC focuses on reaching providers, while still making materials available for everyone. Ms. Connelly noted that CDC borrows from other successful campaigns. For example, it plans to adapt the "How I Recommend" video series from the HPV vaccination campaign to its influenza vaccine campaign. Ms. Connelly concluded that CDC feels well prepared for the upcoming campaign, thanks to a slew of motivated partners and stakeholders.

**Public Comment**

**Ms. Wrangham of the NVIC** said her organization's mission is to prevent vaccine injuries and deaths through public education and voluntary, educated decision-making. She reminded the Committee that its charge is not just optimal disease prevention but also optimal prevention of vaccine injury and death. When discussing vaccine innovation and how to bring more vaccines to market, it is important to keep in mind the gaps identified by the Institute of Medicine around mechanisms of injury for current vaccines. It appears that efforts are moving forward without a clear understanding of vaccines' mechanisms for injury. Influenza vaccine, for example, is one of the most compensated injuries for adults under the Vaccine Injury Compensation Program. Ms. Wrangham encouraged the Committee to discuss how to close the existing gaps that appear to be broadening and how flexible regulatory standards at the FDA also contribute to those gaps in understanding. She called for a bigger effort to acknowledge the other side of the coin around vaccines, which can cause injury and death. NVAC bears the burden of both making sure that there are adequate vaccines available to the public for the prevention of disease and that people get good information and are able to make voluntary choices about products that can cause life-changing injury or death.

**Wrap Up and Adjournment—Kimberly M. Thompson, Sc.D., NVAC Chair**

Dr. Thompson thanked the NVPO staff and all those who contribute to NVAC and the vaccine enterprise. Dr. Thompson noted that she missed having the opportunity to hear brief reports from the NVAC Ex Officio and Liaison members, but noted that the written reports received were sent to NVAC members prior to the call. She asked the NVPO to consider how to post reports from Ex officios and Liaisons when NVAC meets virtually such that they are available to all (they are attached in the appendices of these minutes). Dr. Thompson adjourned the meeting at 4:20 p.m.