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RE: NVAC – February 7-8, 2007 meeting

Dear Dr. Agwunobi:

I am sorry you were unable to join us at our last meeting, but would like to express to you our pleasure in having RADM Art Lawrence address the Committee on behalf of the Department. Dr. Lawrence expressed his pressing concerns including reconsideration of the National Vaccine Plan, prioritization and directing of resources, and clear communication of the developed plans to Congress. He also emphasized the high return on investment of vaccines to underline their economic importance.

Following Dr. Lawrence, Dr. Gellin introduced a discussion of the National Vaccine Plan, noting that much has changed since the previous plan in 1994. As we are both aware, vaccines have new prominence, and there exists potential for making advancements in several areas. Dr. Ray Strikas took a moment to familiarize the audience with the background for the National Vaccine Plan, beginning with a review of the legal basis for the 1994 National Vaccine Plan and its goals and priorities. He presented the immunization schedule for 2007 for both children and adults and noted that there have been striking improvements in childhood vaccination coverage for both older and newer vaccines. The adult population has not demonstrated the same improvements, and racial and ethnic disparities remain. He concluded with a presentation of the priorities and top concerns for consideration in revision of the National Vaccine Plan.

Following the presentation by Dr. Strikas, I presented a progress report of the NVAC Adolescent Working Group, which I chair. As you had requested, we have been hard at work developing a white paper. I am pleased to report that we have developed a "final draft" (enclosed), which the Committee has been given an opportunity to review in preparation for a special meeting of the NVAC, which will be held by conference call on April 20th, during which the Committee anticipates that, following discussion and public comment periods, will vote to endorse. The paper evaluates issues such as adolescent patterns of care utilization, consent issues, financing, school mandates, and communication specific to adolescents. Future work will focus on developing specific recommendations addressing each of the issues.

Dr. Neal A. Halsey of the Institute for Vaccine Safety at Johns Hopkins Bloomberg School of Public Health then presented information regarding the Infectious Diseases Society of America's (IDSA) working principles and the activities of the Immunization Working Group. IDSA issued principles, in part, to apply lessons learned from successes in the pediatric immunization program to the adult and adolescent population, to guide IDSA staff in supporting legislation, and to help focus the activities of the Immunization Working Group. Examples of current challenges are declining tetanus toxoid coverage with age and lower coverage in minority populations.

Dr. Alan R. Hinman then reviewed the progress of immunization information systems. NVAC initiated a registry initiative in 1997, given the demands of assessing coverage in an ever-changing and growing population. The system can assist in retrieving immunization histories to avoid the costs of unnecessary vaccinations, and the system assisted in this regard following the displacement of families affected by Hurricane Katrina. After discussion concerning several areas of concern, the NVAC gave pending approval to the report.

After addressing these administrative issues, the Committee heard reports from the following agencies, departments, advisory committees, and liaisons: National Vaccine Program Office—Dr. Gellin, Advisory Committee on Immunization Practices/National Center for Immunization and Respiratory Diseases (NCIRD) —Dr. Anne Schuchat, Advisory Committee on Childhood Vaccines/Vaccine Injury Compensation Program—Dr. Geoffrey Evans, Vaccines and Related Biological Products Advisory Committee/FDA—Dr. Norman W. Baylor, National Institutes of Health—Dr. George Curlin, Department of Defense—Dr. Renata J.M. Engler, Veterans Affairs—Dr. Valdiserri, United States Agency for International Development—Mr. Neal Brandes, America's Health Insurance Plans—Dr. Wayne Rawlins.

Dr. Kristine Sheedy of the Office of Health Communication of NCIRD then presented information to NVAC concerning National Influenza Vaccination Week. She noted that many partners were involved in the effort, and plans are already underway for this year. She indicated that it would likely take many years to change behavior and increase vaccine demand.

Following Dr. Sheedy's presentation, Dr. Gregory S. Wallace of the NCIRD Immunization Services Division reviewed the data about influenza distribution for 2006–2007. He compared the results observed this year in terms of timing and doses distributed with results from previous years. The highest percentage of distribution observed was from private providers, and most other providers, including State and local health departments, accounted for less than 10 percent of distribution.

Dr. Benjamin Schwartz of the HHS NVPO presented issues surrounding the prioritization of vaccinations for pandemic influenza. The guidance has changed from initial recommendations following input from public engagement sessions, evolving planning assumptions, and evolving pandemic response strategies. An Interagency Pandemic Vaccine Prioritization Working Group has met weekly and is working on developing a strategy using multiple sources of information.

Following Dr. Schwartz's presentation, Mr. Brian Kamoie of the Office of Policy and Strategic Planning of the Office of the Assistant Secretary for Preparedness and Response discussed the implementation of the Pandemic and All-Hazards Preparedness Act. The act created a new Assistant Secretary for Preparedness and Response, who has authority over the National Disaster Medical Service and the Hospital Preparedness Cooperative Agreement Program. He indicated the importance of the statute and the impact that it will have upon future activities.

In the final proposed action of the day, Dr. Sharon G. Humiston of the University of Rochester Medical Center requested changing the name of the Subcommittee on Communication and Public Engagement to the Subcommittee on Public Communication, Consultation, and Participation. NVAC voted to support this requested name change.

After a final request for discussion and public comment, the meeting was adjourned. Because of the need to abbreviate our schedule, the Subcommittees met on the morning of the second day and will report back to the full committee and the public at our next meeting.

Please feel free to contact me with any questions or concerns you may have in regard to any of the Committee's activities. The next NVAC meeting is scheduled for June 7-8, 2007. I hope you will be able to join us.

Sincerely yours,

Gary Freed

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The Promise and Challenge of Adolescent Immunization

Adolescent Working Group of the
National Vaccine Advisory Committee

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The National Vaccine Advisory Committee (NVAC) created a working group to address issues related to adolescent immunization. In response to a request from the Assistant Secretary for Health, this Working Group conducted an assessment of the current landscape of adolescent immunization and identified issues that will require national attention in the coming months and years if current and future recommended adolescent immunizations will be used to their potential. Following identification and the achievement of a national consensus on the issues to be addressed, the NVAC, through its Adolescent Working Group, will receive input from a variety of stakeholders to develop policy recommendations to address these issues.

There is now a unique and important opportunity through immunization to reduce morbidity and save lives of adolescents in the United States. Adolescents hold the promise of a productive and satisfying adulthood, but this promise may be threatened by a variety of preventable health conditions. Several health issues are of national concern for the adolescent population, including obesity and substance abuse. However, many of these problems are frustrating because there are no clear and effective actions which, if implemented, can impact virtually the entire age group. Conversely, vaccine preventable diseases are unique in that they are both serious *and* readily preventable.

Our country has a long history of using immunizations to protect individuals and populations at both ends of the age spectrum, but little experience between those ranges. Now, several new vaccines have created an imperative to reach the adolescent population and to protect them against a group of significant – but imminently preventable – diseases, thereby increasing the chance of our youth to enjoy long and productive lives. However, to achieve the promise of these new preventive health interventions our nation must focus on effective vaccine delivery to this population.

Specifically, three new vaccines are now available and recommended for adolescents that prevent a total of 5 diseases that can have a range of devastating health consequences.[1] Individual vaccines protect against meningococcal meningitis and human papilloma virus and a combined vaccine protects against tetanus, diphtheria and pertussis. All three vaccines have been shown to be safe and effective.

THE DISEASES NOW PREVENTABLE THROUGH ADOLESCENT IMMUNIZATION

Meningococcal Vaccine

Meningococcal disease is a bacterial infection that is the leading cause of meningitis among children 2 – 18 years of age in the United States and a cause of severe and devastating sepsis.[2] Of the 2600 individuals in the U.S. who contract meningococcal disease each year, 10-15% will die despite aggressive treatment. Of those who survive, debilitating side effects are common, including loss of limbs, deafness, mental retardation, seizure disorders, and strokes. The meningococcal conjugate vaccine was licensed in 2005 and is recommended for all children at their routine recommended early adolescent visit (11-12 years of age) as well as those entering high school and for college freshmen living in dormitories.[3,4]

Human Papilloma Virus Vaccine

More than 9500 women are diagnosed with, and more than 3500 women die from, cervical cancer in the United States each year. In 2002 the overall incidence of cervical cancer was 8.7 per 100,000 women. The vast majority of cervical cancers are caused by the human papilloma virus.[5] The recently licensed HPV vaccine was shown in clinical trials to provide 100% protection against the two types of human papilloma virus (types 16 and 18) that cause 70% of cervical cancer as well as the two types (6 and 11) that cause 90% of genital warts. The vaccine is recommended to be given to 11-12 year old adolescent girls in a three-dose series over six months. Previously unvaccinated females 13-26 years of age are also recommended to receive this vaccine.[6]

Tdap Vaccine

The combined Tdap vaccine protects against tetanus, diphtheria and pertussis.[7] Despite substantial success in vaccinating infants against these diseases, coverage is not complete, and protection against pertussis appears to wane after 5 – 10 years. Consequently, a large proportion of reported cases of pertussis in the United States are now found in the adolescent age group, and many outbreaks occur in school settings where adolescents congregate. Further, adolescents are now a reservoir of disease which can infect infants. A large proportion (38%) of adolescents with pertussis report prolonged coughing of greater than one month resulting in multiple health care visits as well as school absenteeism.[7] In 2006, the Advisory Committee on Immunization Practices (ACIP) recommended that "adolescents aged 11-18 years should receive a single dose of Tdap instead of tetanus and diphtheria toxoids vaccine (Td) for booster immunization against tetanus, diphtheria, and pertussis."[7] The preferred age for receiving the vaccine is 11-12 years.

A NEW ERA IN ADOLESCENT IMMUNIZATION

Understanding and acting upon the imperative of ensuring that these new vaccines as well as the previously recommended vaccines are administered to the adolescent population requires a paradigm shift on the part of health care providers, policy makers, and parents alike. Historically, vaccination has been framed as an intervention for young children, while behavioral health challenges like nutrition and sexual behavior are illustrative of key issues that compromise adolescent health. Indeed, vaccinations for young children *are* important. And the behavioral health challenges that face adolescents *are* critical. But at the same time, there are now immunizations that can prevent serious and life-threatening diseases among adolescents.

The ability to effectively prevent significant morbidity and potential mortality, especially among a population that constitutes our Nation's future, creates an imperative to make adolescent vaccination a national health priority.

Adolescent Health Care Utilization

Ensuring that there exists an effective means of delivering these vaccines is a necessary precursor for high vaccine coverage rates. Unfortunately, unlike infants, the delivery of preventive care for adolescents is more complex. The imperative to provide and promote adolescent vaccination will require the support of an infrastructure for this to be accomplished effectively and at a reasonable cost.

The unfortunate reality is that fewer adolescents, compared with other pediatric age groups, access the medical system for preventive care, either in public or private delivery venues. When they do access the health care system, it is most often for acute care[6]. If the U.S. is to achieve high rates of vaccine coverage for adolescents, there will need to be a system that meets their needs and fits their patterns of behavior.

Currently, the utilization of the existing private or public health preventive care infrastructure to achieve high vaccination coverage rates for these new vaccines among adolescents is woefully inadequate. Adolescents access a patchwork of sites and services for health information and health care; in fact, research to date is mixed on the extent to which adolescents get health care – particularly preventive care - at all. Recent analyses of national data suggest that over 30% of adolescents receive no health care in a 12 month period.[8] Although more than 50% do have some type of visit to a primary care provider, the probability of having a primary care visit in a given year declines substantially with increasing age.[9] A study of medical records from Harvard Pilgrim Health Care, demonstrated that most visits by adolescents (73%) were for acute, not preventive care. Within this insured population, all with assigned primary care providers, 33% of 11 year olds had no preventive care visits in any given year. This number increased to 44% for those 17 years of age. Even fewer adolescents have the three health visits required to complete the HPV vaccine series.[10] Thus, even in a "best case" scenario of insured children in a well-organized health care delivery system, with assigned primary care providers, preventive care is markedly underutilized and not sufficiently organized to reach desired immunization rates.

Other research has shown that adolescents self-report a much higher rate of preventive visits in a given year.[11] However, this finding is not supported by billing data from the Health Plan Employer Data Information Set (HEDIS), in which a study demonstrated that only 34% of adolescents had a preventive visit over a 12-month period.[12] This apparent contradiction may be the result of adolescents erroneously perceiving health care visits in general to be preventive when many of them are, in fact addressing specific health concerns. Another possibility is that physicians may be providing preventive services but coding the visit for something other than well care when preventive care is not covered by insurance. Regardless, it appears likely that adolescents overestimate their own use of preventive care.

Adolescents do, however, identify unmet needs in their own health care use; in the National Longitudinal Study of Adolescent Health, almost 20% reported that there was a time in the past year when they thought they should obtain medical care, but did not.[13] Bringing adolescents into the health care system by promoting vaccinations could be thought of as a "hook" that brings them into the system for other important health and health care messages and activities, including important advice and screening as they transition into adulthood.

New Ideas for Old Problems

The issues surrounding adolescent immunization compel our nation to consider new ways of looking at old problems. Although adolescents have long not utilized preventive health care, it is now even more important they do so. This results in the need to raise new issues that warrant public debate including the identification of where fiscal and programmatic responsibility lies within the government (e.g., local, state, federal) and the private sector to achieve preventive health goals for this age group. Further, levels of responsibility for adolescent immunization across and among diverse entities (i.e., public health and educational systems) must be considered.

In order to create a system for adolescent immunization, we have to assess the motivation and obstacles for participation across potential settings, identify real and

potential logistical issues, and assess funding constraints and solutions. It is likely that unprecedented collaborative efforts and creative approaches may be necessary to achieve recommended vaccination rates among the adolescent population.

ISSUES TO ADDRESS

There are several unique issues that challenge the U.S. health care system to fully vaccinate the adolescent population. These challenges must be acknowledged, evaluated and discussed openly if our nation is to create an accessible and effective network for adolescent vaccination. Among those topics with unique applications to adolescent immunization are venues for vaccine administration, consent for immunizations, communication, financing, surveillance, and the potential for school mandates.

Venue

There exist limited entry points used regularly by adolescents to enter the health care system. Helping adolescents move into a system of care would require both increasing utilization at the entry points that do exist and also creating new, and more easily accessible entry points – some of which will necessarily fall outside of what we typically consider the traditional health care system.

Although physician offices can provide vaccines to a significant portion of adolescents, without a significant change in health care seeking behavior patterns and greater attention being paid to missed opportunities for immunization in this age group, other venues must be considered to reach national immunization goals and assure maximum protection.

The question therefore arises as to what aspect of the health care community best serves to identify, capture and provide service to adolescents. Certainly, vaccinations have long been the purview of the primary care physician. However, in the case of

adolescents' health care utilization patterns, this venue may actually not be the ideal location for all adolescents. Additional health care settings likely to provide additional access include pharmacies, family planning and sexually transmitted infection clinics, obstetrician-gynecologists, emergency departments, teen clinics and health departments. Each venue must be evaluated to assess its potential in both attracting critical numbers of adolescents as well as supporting the necessary infrastructure for their immunization with all recommended vaccines for this age group. However, these sites will not replace the role of the primary care physician in the delivery of comprehensive preventive care.

When considering locations where adolescents congregate and may be available to receive health care, schools are frequently cited as an obvious locale. Vaccinating adolescents in schools has a number of obvious challenges (e.g., organization, financing) that warrant substantial study and consideration over whether this is a potential "best" venue. Therefore, the advantages and disadvantages of school-based vaccinations for adolescents have to be assessed empirically and fully.

Likely none of these potential venues, by itself, attracts a significant enough proportion of adolescents on which to base a population-wide strategy. Public discourse is also needed to consider the public and private investment required to explore approaches to improving access/availability and perhaps most importantly, to create the productive collaborations without which a move toward achieving full adolescent vaccine coverage cannot succeed.

Consent

The ability of adolescents to consent for health care – including vaccinations – differs substantially by state and by health condition.[14] This variability could have a significant impact on our nation's ability to achieve immunization coverage in this age group. Therefore significant and potentially controversial issues arise upon making a vaccination available to adolescents – especially in nontraditional settings. For example, some states may allow adolescents to consent to receive their own vaccinations, but

others may not. Although consent requirements are the purview of states, there may be utility in the provision of a federal template for recommendations on the issue. It is also possible that in some states new vaccines which protect against sexually transmitted diseases may have different consent status than other vaccines, as does treatment for sexually transmitted infections. A review and examination of consent laws as they exist and pertain to adolescent vaccines in the context of creating the infrastructure necessary to achieve high levels of adolescent vaccination must be conducted.

Communication Specific to Adolescents

A new approach to communication and new communications materials is necessary to ensure that the public, providers, parents and the adolescents themselves understand the need and the appropriate timing of these vaccinations. In the infant and childhood vaccine setting, education and information are geared toward parents. However, if adolescents are receiving care with or without parental involvement, information must be focused on the adolescents themselves in addition to parents and providers. Knowledge about reaching adolescents should be garnered from other health and health care areas and brought to bear on vaccine issues. Convincing adolescents and young adults to engage in preventive behaviors is difficult. It is unknown whether the need for an injection will be even more challenging to disseminate than other messages. Current policies and programs have not been successful in immunizing a significant portion of adolescents with the previously recommended tetanus booster. Especially in the case of those vaccines against STIs, it will be critical to ensure that adolescents understand the limitations of the vaccines and continue to protect themselves in other ways.

Financing

Financing issues regarding adolescent immunization are unique in two specific areas, the cost of adolescent vaccines, and the rate of insurance coverage for adolescents.

These new vaccines for adolescents are among the most expensive vaccines recommended today for any age group. Their aggregate estimated price in the private

sector is approximately $500. As such, their inclusion in the recommended immunization series has the potential to put a significant strain on both the public and private financing sectors. These costs, when combined with the fact that fewer adolescents have insurance coverage (public or private) for preventive services than other children must be addressed if we as a nation hope to realize the promise of these vaccines. [15,16] Otherwise, the financial barriers for adolescents themselves, as well as the providers who may also incur significant financial burden associated with these vaccines, may impede implementation of these recommendations.

In the public sector, a smaller proportion of adolescents, compared with infants, are eligible for the federal Vaccines For Children program. [17] Thus, greater strain on state budgets will likely result if these recommendations are to be fully implemented.

Surveillance

Experts worldwide recognize surveillance as important to effective implementation and evaluation of public health programs.[18-21] U.S. surveillance systems have constrained capacity to yield data related to disease burden, vaccination coverage, and vaccination impact among adolescents. For example, while data pertaining to adolescents will be collected through the National Immunization Survey for the 4th quarters of 2006 and 2007, these data will not be state-specific. Furthermore, there is no funding source for future, more comprehensive surveillance critical to guiding program planning and policy.

Well-defined national vaccination coverage targets are needed for adolescents. A limited number of goals for coverage among adolescents aged 13-15 years were included in the *Healthy People 2010.*[22] However, future goals should be defined clearly.

For surveillance systems to work, many healthcare providers delivering immunizations to adolescents in communities and other settings (e.g., military, corrections facilities, colleges) will require education regarding the importance of disease reporting, adverse

event reporting, and participating in immunization information systems (IIS). In turn, most states need to strengthen these systems and healthcare quality measures linked to IIS warrant consideration.

School Mandates

School entry requirements, or mandates, have proven to be an effective mechanism to raise immunization rates among children in the U.S.[23-25] These new adolescent vaccines raise the issue as to whether such laws should be considered as part of a strategy for achieving high immunization rates. As school entry requirements are under the purview of individual states, there is no federal legislative role in this process. However, states have relied on guidance from specific federal agencies regarding such requirements in the past. Because some of these new vaccines differ from older vaccines with regard to the nature of transmission of the disease they prevent, they raise novel legal and policy issues that must be addressed to determine if a school mandate strategy should be implemented.

MOVING FORWARD

The National Vaccine Advisory Committee will move forward expeditiously to develop recommendations for the nation to address the most acute issues regarding adolescent immunization as outlined in this problem statement (Table 1).

Our nation is in a new position regarding the health care of adolescents. With increasing challenges to their health, including obesity, diabetes, sexually transmitted diseases and poor mental health, adolescents are vulnerable as they grow into adults. With three new vaccines available to combat five serious diseases there is an opportunity to prevent these specific illnesses, help adolescents increase their health care access and to support their growth and development to productive adults. There is also unique opportunity to establish a culture of immunization among adolescents that may lead them to pursue immunization as adults as well as eventually for their own children in greater numbers. Now, our nation must find the ways to ensure the promise of these new preventive measures are fulfilled. Some of these issues raised will require

additional information to determine the best course of action. For the future of our nation, the time to begin this process is now.

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Table 1.

The Most Acute Issues Facing Successful Adolescent Immunization

1. Modifications in the adolescent health care infrastructure to support the additional needs generated by new vaccines.

2. Development of additional venues to supplement the current adolescent healthcare infrastructure for immunization.

3. Standardization and clarification of consent laws for the administration of vaccinations to minors.

4. Creation of novel communication strategies to facilitate information dissemination to the parents, guardians and the adolescents themselves on the importance of immunization.

5. Generation of financial strategies for the public and private sector to make administration of immunizations to adolescents financially viable to patients and providers.

6. Development of long-term surveillance strategies to assess disease burden, vaccination average, and vaccine impact among adolescents.