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BIO Comments – Adult Immunization: Complex challenges and recommendations for improvement – A report of the Adult Immunization Working Group of the National Vaccine Advisory Committee

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the report of the National Vaccine Advisory Committee (NVAC) Adult Immunization Working Group entitled "*Adult Immunization: Complex challenges and recommendations for improvement.*" BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO membership includes both current and future vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to innovative and life-saving vaccines for all individuals. BIO and its member companies are greatly encouraged by the report generated by the National Vaccine Advisory Committee's (NVAC) Adult Immunization Working Group (AIWG). Childhood immunization programs in the United States have been very successful, achieving high vaccination rates for children and teens. Vaccination programs for adults have been less successful for many reasons including the broad population affected, access and financial barriers and lack of physician and consumer knowledge. Although many organizations have developed reports related to adult

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immunization barriers and plans for increasing immunization, the report of the NVAC AIWG is one of the most comprehensive on the subject.

The report tackles the complex issues of adult immunization in a positive, collaborative and forward-thinking manner. We believe that there are numerous positive aspects discussed in the report, such as:

- The strong message about the need for leadership within the federal government in order for the country to increase adult immunizations;
- The Assistant Secretary for Health is a reasonable choice to coordinate an adult immunization program as long as there is close coordination with the CDC.
- The importance of the multi-factorial nature of this endeavor and thus the need to assign responsibilities to a broad group of stakeholders in both the public and private sectors;
- Ways to involve and reinforce the broad array of community immunizers, such as pharmacists and alternate care sites;
- A very important list of research areas that BIO has also stated are necessary to better inform policy makers and relay the value of adult immunization, such as a CDC-developed cost-effectiveness model.

BIO would like to offer the following comments as well as a set of recommendations.

Overall Comments:

BIO feels that there are several areas where the report could place more emphasis. These are areas where the AIWG may want to reinforce the potential impact of new initiatives or include a broader discussion of the role of other initiatives.

First, the report does not completely factor in the potential opportunities and challenges of some key provisions of the Affordable Care Act (ACA). While an exhaustive review of each provision is not necessary for the report itself, a more significant discussion of the potential impact could help in the development of the strategic plan and its subsequent initiatives.

- Health plan provisions:
    - The report discusses the opportunity presented by the new provisions requiring all private health plans to cover all ACIP-recommended vaccines at no cost-sharing. As health plans lose their grandfathered status over the next 2-4 years more adults should have increased access to vaccines. In addition, health plans that participate in the State exchanges will be required to cover an essential set of benefits. The stakeholders involved in adult immunizations should ensure that the essential benefits include coverage for immunizations for all ages at first-dollar coverage.
- Medicaid Provisions:
    - New provisions in ACA that may lead to a marked expansion of Medicaid to childless adults. Experts estimate that an additional 18 million adults

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between the ages of 19 and 64 may be added to State programs, thus offering increased access to providers, immunizations and other preventive services.
    - The ACA also included a 1% increase in the federal match (FMAP) for those states that offer preventive services to their adult Medicaid beneficiaries at no cost-sharing.
    - While the inclusion of the 1% FMAP offers an incentive to states for the newly eligible Medicaid recipients, the ACA created a potential inequity for existing Medicaid beneficiaries, many of whom are from the most vulnerable populations. While states may offer first-dollar coverage for adult vaccines to new Medicaid eligibles, other adult Medicaid recipients may still be required to pay a share of their vaccine costs. In comparison, as mentioned above, private health plan beneficiaries will receive their preventive services without cost-sharing.
    - To help increase the number of primary care providers for Medicaid recipients the ACA increased provider reimbursement for Medicaid providers for 2 years (2013-2014) to Medicare levels.
    - Lastly, ACA required that the Centers for Medicaid and Medicare Services (CMS) develop the Medicaid Quality Measurement Program for adults. Measures that include adult immunizations could encourage States to cover these and other preventive measures without cost-sharing to help increase immunization rates. At present, however, there is only one immunization measure included in the initial core set of quality measures proposed on January 1, 2011.
- Medicare provisions:
    - Medicare providers are now required to offer a Personalized Prevention Plan to their Medicare beneficiaries. This individualized plan must include a review of preventive services, including immunizations that should be discussed with the beneficiary specific to their needs. This plan, coupled with the CDC's Health Risk Assessment (HRA) could serve as a model for other provider-based tools.

Secondly, the report does not completely address the potential positive impact of two specific initiatives designed to build better infrastructure across many different provider types.

- Health information technology (HIT) systems:
    - The report does not completely factor in the investments being made in health IT systems such as the electronic health and medical records (EHR and EMR) and "meaningful use." These systems can serve as a mechanism to help facilitate provision of adult vaccines by health care providers over the next 3-5 years as hospitals and physician offices invest in new technologies. Part of the requirements of these investments is that they link to established state immunization information systems (IIS) (i.e. registries). These immunization systems may prove very helpful in

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facilitating adult immunization as they could drive provider behavior, track uptake and help establish and measure performance and quality.

- Quality Measures:
  - As mentioned, the ACA includes the development of a set of quality measures for the adult Medicaid population. The report does not completely address the role and potential positive impact of varying types of existing quality measures, especially the impact that HEDIS requirements and private sector or employer-based measurement programs can have on immunization rates.

Lastly, several other topics could be discussed more broadly or could be approached in a different manner:

- Use of 317 funds for adult immunizations is stressed, which is a very positive point. However, in most instances the report suggests using these additional funds to *purchase* adult vaccines and not to *build* adult immunization infrastructure, such as to improve ISSs.
- Many of the strategic recommendations have only government participants in the beginning and only add other stakeholders, such as provider organizations and industry, after key strategic decisions have been made. Organizations such as the National Quality Forum (NQF) and the National Committee for Quality Assurance (NCQA), for example, are added as stakeholders later in the process.
- The research questions proposed on page 47 may be better addressed as part of NVPO's National Vaccine Plan. The interaction of the National Vaccine Plan and the AIWG report could be addressed as part of the research section.

Recommendations:

1. In general BIO found the report to be thorough and thoughtful. Because most of the recommendations in the report will take years to achieve, we strongly encourage the rapid development of a comprehensive strategic plan. This strategic plan should present a "road map" for accomplishing a set of specific goals and should also outline the resources required.

2. We suggest that the recommendations within that plan be prioritized to facilitate implementation. The Working Group should identify some "low-hanging fruit" (like promoting alternative vaccinators) and methods proven to drive up rates (like performance measures) and advance those earlier.

3. Given the limited available federal funds due to the current budget environment, perhaps prioritization could be given to recommendations that do not require federal funds. For example, some activities in the private sector could be implemented earlier and should therefore be prioritized over others that may require federal or state appropriations.

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4. We suggest the addition of a table at the end of the report that captures the stakeholders who may have a role in the implementation of each specific recommendation. This appendix was used in the National Vaccine Plan and is helpful in capturing the broad array of organizations that may be needed to adequately address a specific issue or initiative.

5. The report stresses that the infrastructure needed for adult immunization differs from existing childhood programs. It is unclear what parts of existing VFC and CDC infrastructure could or should be leveraged for adult immunization programs. However, relying too heavily on the current ordering and distribution systems used under VFC may not resolve issues for a broad and varied adult immunization provider network. Emphasis should be placed on the specific tenants of VFC infrastructure that will aid in building adult immunization programs.

6. Although ACA is mentioned, the opportunities and challenges it presents should be more rigorously analyzed and examined. Some possible recommendations include:

   - The potential impact of additional vaccine quality measures for Medicaid, Medicare, and the private sector should be fully evaluated.

   - Medicaid: equality in coverage for newly eligible and previously eligible recipients has not been clearly secured. The Working Group should recommend that CMS issue guidance to support equal access without cost sharing for all ACIP recommended vaccines for all Medicaid patients.

   - Medicare Part D: challenges related to access to vaccines could be addressed without moving all vaccines into Medicare Part B. The Working Group should recommend additional ways to address the access barrier to allow physician offices to administer and be reimbursed for a vaccine covered under Part D. Co-pay's in Part D should be evaluated to determine if they are a barrier to immunization uptake.

   - Medicare Part B: the Centers for Medicare and Medicaid Services (CMS) has communicated through its Medicare Learning Network[1] that the Annual Wellness Visit (AWV) can include a Personalized Prevention Plan. In its February communication CMS stated that all ACIP-recommended vaccines should be included in the individual screening checklist for its beneficiaries. However, many providers and patients may not be aware of all of the vaccines covered under Medicare Part D *and* Part B that should be discussed. The AIWG should encourage CMS to promote all appropriate

[1] Centers for Medicare and Medicaid Services (CMS), Medicare Learning Network, MLN Matters® Number MM7079 Revised, Release Date February 15,2011, pages 1-6.

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vaccines for this population and also encourage them to address reimbursement issues that affect both providers and patients.

- Support for alternative channel vaccination means those locations must be included as "in network" providers for private health plans. The Working Group should address barriers faced by pharmacies and other alternate care sites being treated as "out of network" providers for private plans. This is also a significant issue for public health departments, which are often also considered "out of network" for private and public plans.

- Adequate reimbursement for federally qualified health centers (FQHCs): Immunization services are currently included in the FQHC encounter fee reimbursement and the total amount of reimbursement for one encounter is often less than the cost of vaccines recommended for the individual. As the Medicaid population is expanded, this could be an important barrier to access and therefore it should be examined.

7. America's Health Insurance Plans (AHIP) estimates of coverage on page 20 refer to the number of products that are offered, rather than the number of people covered. However, this data may become less relevant as plans lose their "grandfathered" status. Estimates of "grandfathered" plans and actual covered lives would be more helpful.

8. When discussing expanding the provider network to include pharmacists, special attention should be paid to the barriers to patients and reimbursement in this area. We suggest that the following could be added to line 21 on page 41: "with the existing barriers to patients and the reimbursement of vaccinations identified and removed."

9. The following issues could be added to the *Research Needs* section (pages 43-47):
   - The addition of an explicit research agenda on a set of composite quality measures for adult immunization;

   - Evaluation of the impact of increased Medicaid reimbursement for vaccines under the ACA. This research should be conducted as soon as possible after the new rates are implemented to permit legislators to continue this provision if it is successful.

10. As mentioned above, the discussion of the potential value of current investments in health IT infrastructure could be greatly expanded. The lack of integrated vaccine registries and reminder or assessment systems should be evaluated. The Working Group should reinforce the need for interoperability between electronic medical record systems and immunization systems. In addition the AIWG should consider making recommendations that encourage providers to

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populate adult immunizations registries, where applicable. An analysis of the "meaningful use" provisions should help generate a set of more specific and comprehensive recommendations that leverage this new infrastructure.

11. The language relating to the standardized Medicaid administration rate should be clarified. It is important that any analysis undertaken thoroughly evaluate the potential impact of both creating a "floor" and raising the "ceiling" for vaccine administration rates. These analyses should examine what changes would actually influence provider behaviors. .

12. BIO and its members understand the concerns related to maintaining adequate supply of adult vaccines. We recommend that the Working Group stress the need for a robust and vibrant private sector marketplace for all vaccines. A strong market will encourage both existing and new companies to invest in the development of new vaccines to meet a growing medical need.

Conclusion

BIO appreciates the opportunity to comment on the very important report on adult immunizations. We look forward to continuing to work with the National Vaccine Program Office, NVAC and the Adult Immunization Working Group to address these critical issues in the future. Please feel free to contact me at 202-962-6664 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

With Sincerest Regards,

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