DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION

REPORT TO CONGRESS ON Section 317
IMMUNIZATION PROGRAM

Senate Appropriations Committee

[Signature]
Julie Louise Gerberding, M.D., M.P.H.
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Executive Summary
In its report on the Fiscal Year (FY) 2008 budget for the Department of Health and Human Services, the Senate Appropriations Committee stated the following:

The Committee is pleased with the report on the 317 program that CDC provided, and expects the report to be updated and promptly submitted next year by February 1, 2008, to reflect fiscal year 2009 cost estimates. The updated report should also include an estimate of optimum State and local operations funding as well as CDC operations funding needed relative to current levels to conduct and support childhood, adolescent and adult programs. This estimate should include the cost of vaccine administration; surveillance and assessment of changes in immunization rates; vaccine storage, handling and quality assurance; implementation of centralized vaccine distribution practices; needs to support provider and public outreach and education on new vaccines; identification of barriers to immunization and strategies to address such barriers; maintenance, utilization, and enhancement of Immunization Information Systems (IIS) including integration with public health preparedness and other public health information technology systems; innovative strategies to increase coverage rates in hard-to-reach populations and geographic pockets of need; and other nonvaccine resource needs of a comprehensive immunization program. Each of these activities is critical to ensuring the delivery of lifesaving vaccines to our nation. The Committee urges CDC to consider integrating the data from this report into its budget justification on an annual basis. (Page 80-81, Senate Report 110-107)

Approach
The Centers for Disease Control and Prevention (CDC) calculated estimates of need in four separate amounts: 1) Vaccine purchase; 2) Operations; 3) Vaccine Administration; and 4) Vaccine Safety.

The vaccine purchase estimate was calculated by restricting the Section 317 program to include only two categories of individuals: (a) underinsured children and adolescents who are not eligible for Vaccines for Children (VFC) vaccine and who are not fully insured for vaccines, and (b) uninsured adults. National Immunization Survey (NIS) Insurance Module results from 2006 were used to estimate the size of the populations of underinsured children and adolescents. Data from the 2005 National Health Interview Survey (NHIS) were used to determine adult population by age and insurance status, as well as estimates of people considered high-risk for influenza and pneumococcal disease. The vaccine purchase budget represents the minimum federal contract cost to purchase the recommended vaccines for children, adolescents, and adults, and assumes that no new vaccines will be recommended prior to 2009.

The operations estimate for FY 2009 was benchmarked against FY 2000, which was prior to the introduction of the many new pediatric, adolescent, and adult vaccines, reflecting a time when operations funding was sufficient to accommodate all vaccine recommendations. The operations funding per dose of federal contract vaccine in 2000 was extrapolated to the number of new doses recommended for children and adolescents since 2000, as well as to the number of doses of adult vaccines to be purchased through the Section 317 program in steady-state funding. Thus, this operations estimate accounts for the eight new vaccine recommendations made since 2000.
We did not include an estimate for the vaccine administration fee because the Section 317 does not pay for clinical administration of vaccines. The approximate Medicare payment rate for vaccine administration fee for adults is $18.00 per dose.

An estimate for vaccine safety costs in FY 2009 were developed based on increasing the functionality of the primary four main activities of the program and what could actually be accomplished in FY 2009: 1) Identifying and Analyzing Safety Concerns; 2) Testing Potential Vaccine Safety Hypotheses; 3) Collaborating with Partners to Develop the Nation’s Vaccine Safety Research Priorities; and 4) Fortifying the Nation’s Vaccine Safety Infrastructure to Prepare for and Respond to Public Health Emergencies.

Although it would not be feasible for the immunization program to absorb this funding amount in one FY, the following estimates reflect a fully implemented program.

This report represents the professional judgment estimates of CDC Staff on the size and scope of the Section 317 Immunization Program, and is provided without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to the Congress are developed.

1. Vaccine Purchase

*The Committee is pleased with the report on the 317 program that CDC provided, and expects the report to be updated and promptly submitted next year by February 1, 2008, to reflect fiscal year 2009 cost estimates. (Page 80, Senate Report 110-107)*

**Total Vaccine Purchase: $571.3 million (Table 1)**

This section includes CDC’s updated funding estimate for Section 317 pediatric, adolescent and adult vaccine purchase for FY 2009. The Section 317 program is a discretionary federal grant program that allows for states to have flexibility based on state needs for the use of recommended vaccines. Historically, the majority of Section 317 vaccine has been used to vaccinate underinsured children who are not eligible for VFC vaccine, and at times for underinsured and uninsured adults. For the purposes of this funding estimate, we have limited the vaccine purchase estimates for the Section 317 program to serve two specific groups:

a) Underinsured children and adolescents (from 0 through 18 years of age) who are not eligible for vaccine provided by the VFC program, regardless of where they seek vaccination. Underinsured children and adolescents include those whose health insurance coverage does not include the cost of all vaccines.

b) Uninsured adults (from 19 through 64 years of age), who live below 200 percent of the federal poverty level. Adults >64 years of age are eligible for Medicare, and are excluded from the adult vaccine purchase estimate.

a) **Underinsured children and adolescents**

The underinsured children and adolescents identified in this report include those whose health insurance coverage does not include the cost of all vaccines, but who are not eligible to receive VFC vaccine. By statute, the VFC program covers underinsured children who receive vaccinations through Federally Qualified Health Centers (FQHC) or
Rural Health Clinics (RHC). The Section 317 program and state discretionary funds provide a safety net for these children. The vaccine purchase estimates for children and adolescents were calculated separately because the proportion of uninsured adolescents is substantially different than the proportion of uninsured young children; however the approach used for each population was identical.

- The vaccine purchase estimate for each population was based on the Advisory Committee on Immunization Practices (ACIP) vaccine recommendations, and includes the amount of money needed to purchase routine vaccinations (no catch-up campaigns are included in these estimates).
- Data were used from the insurance module included in the 2006 NIS to define the uninsured pediatric and adolescent populations eligible to receive Section 317 vaccine.
- The NIS provides data on the percentage of children born in the United States in one year (referred to as a birth cohort) who are uninsured (11.6 percent). The same information is provided for adolescents (20.8 percent). Underinsured children and adolescents are those whose health insurance coverage (public or private) does not include the cost of all vaccines.
- The respective pediatric and adolescent populations eligible for Section 317 vaccine were calculated by multiplying the uninsured percentages by one annual birth cohort (4,000,000 persons).
- Underinsured children and adolescents who are eligible to receive VFC vaccine were excluded from the Section 317 vaccine-eligible groups. This subtraction avoids having the Section 317 program supplant or duplicate VFC funding. The number of children/adolescents who receive vaccine doses at FQHC/RHC networks was also measured in the 2006 NIS.
- The vaccine purchase estimate subtotal was calculated by multiplying the final, eligible pediatric and adolescent populations by the amount required to vaccinate with all age-appropriate vaccinations. The amount required to vaccinate children and adolescents assumes 100 percent vaccination coverage for the eligible population for all ACIP recommended vaccines except influenza, which is estimated at a 60 percent vaccination level.
- To determine the final vaccine purchase estimate, the amount of funding contributed by state contracts was removed from the vaccine purchase estimates so that the Section 317 vaccine purchase budget does not supplant state funding. The amount of money provided through state funding varies from year to year, and it is not guaranteed that the amount of state contributions in FY 2009 will meet or exceed the amount included in the vaccine purchase estimates. However, this report reflects no supplanting of current (as of FY 2006) state effort.

**Underinsured children: $250.8 million**

- Data from the NIS report 11.6 percent of children from one annual birth cohort (4,000,000 persons) are underinsured for vaccines. 0.116 X 4,000,000= 464,000 underinsured children are eligible for Section 317 vaccine.
- 33,015 underinsured children were removed from the population eligible for Section 317 vaccine because they fit the eligibility criteria for VFC vaccine. They include children
who are served through the VFC safety-net and are receiving vaccine in FQHC/RHC networks.

- 464,000 – 33,015 = 430,985 underinsured children eligible for Section 317 vaccine.
- In FY 2009, it is estimated that it will cost $797.17 to fully vaccinate one child with all recommended routine vaccinations to age 11 (excluding influenza), using the least expensive projected prices for FY 2009 (e.g., no combination vaccines). Costs to vaccinate include 100 percent coverage with the following vaccinations: Diphtheria, Tetanus toxoid, and acellular Pertussis; Haemophilus Influenzae Type b; Measles, Mumps, and Rubella; Inactivated Poliovirus Hepatitis B; Varicella, Pneumococcal Conjugate Vaccine, Rotavirus, and Hepatitis A.
- In FY 2009, it is estimated that it will cost $63.84 to vaccinate one child with Influenza vaccine. The vaccine purchase cost estimate includes 60 percent coverage with the Influenza vaccine. The number of underinsured children eligible for 317 Influenza vaccines is 258,591.
- \((430,985 \times 797.17) + (258,591 \times 63.84) = 360,076,761\)
- $109,253,302 was subtracted for vaccines purchased through state contracts.
- **Total amount: $250,823,459.**

**Underinsured adolescents: $180.7 million**

- Data from the NIS report that 20.8 percent of adolescents from one annual birth cohort (4,000,000 persons) are underinsured for vaccines. \(0.208 \times 4,000,000 = 832,000\) underinsured adolescents eligible for Section 317 vaccine.
- 832,000 – 84,842 = 747,158 underinsured adolescents eligible for Section 317 vaccine.
- In FY 2009, it is estimated that it will cost $109.05 to fully vaccinate an adolescent male aged 11 to 19 with Meningococcal Conjugate Vaccine and Tetanus toxoid, reduced Diphtheria, and acellular Pertussis (Tdap) vaccines.
- Vaccinating adolescent females also includes a three-dose series of the Human Papillomavirus (HPV) vaccine, bringing the cost to fully vaccinate a female up to $414.18.
- Assuming a 50:50 ratio of males to females, this is equal to an average cost of $261.62 to fully vaccinate one adolescent.
- \(747,158 \times 261.62 = 195,471,476.\)
- $14,771,549 was subtracted for vaccines purchased through state contracts.
- **Total amount: $180,699,927.**

**b) Uninsured adults: $139.8 million**

- While the majority of Section 317 funds are dedicated to the vaccination of children, programs also use Section 317 funds to vaccinate adults. Adult vaccine coverage has not experienced the same successes as vaccine coverage among children. CDC’s funding estimate for vaccine purchase for adults was calculated using the following approach:
• The vaccine purchase estimates for the uninsured adult population are based on the ACIP recommended vaccines and include the costs to administer routine vaccinations.

• In order to determine the number of adults eligible to receive Section 317 vaccine, data were used from the 2005 NHIS to provide information about population by age and insurance status, as well as estimates of people considered high-risk for influenza and pneumococcal disease.

• The eligible uninsured adult population was calculated separately for each of the six vaccines as noted below, based on the age recommendations and high-risk specifications particular for that vaccine.

• Population estimates were then adjusted for poverty level and 2008 population projections, based on U.S. Census Bureau data. Only those adults living within 200 percent of the federal poverty level were included in the final purchase estimates (an annual income of $20,320 for one unrelated individual under the age of 65). Adults >64 years of age are eligible for Medicare, and are excluded from the vaccine purchase estimates.

• Estimates were made to predict the percent of eligible adults who would get vaccinated (referred to as vaccine uptake) in FY 2009. The percentage of vaccine uptake included in the calculation varies by vaccine and is informed by evidence-based data available for each of the vaccines.

• The vaccine purchase estimate subtotal for each vaccine was calculated by multiplying the final population projected in the vaccine uptake by the cost of the vaccine.

• Vaccine purchase estimates are provided in an overall adult vaccine purchase estimate of $156,479,912.

• $16,664,474 in state contracts was removed from the overall adult vaccine purchase estimate to ensure the Section 317 budget does not supplant state contributions. State contract contributions are not removed from the individual vaccine purchase estimates; only from the overall adult vaccine purchase estimate.

• Total amount: $139,815,438.

Influenza Total: $22.6 million

• 2,447,395 individuals 19 to 64 years of age, uninsured, living at or under 200 percent of the poverty line, and recommended for influenza vaccine (this includes adults 19–49 who are considered high-risk for influenza, and all adults aged 50–64).

• 578,568 individuals at or under 200 percent of the poverty line, uninsured, and 19 to 49 years of age are household contacts of high-risk individuals for whom influenza vaccine is annually recommended.

• 2,447,395 + 578,568 =3,025,963 total eligible population of high-risk adults and their household contacts.

• Projected uptake for flu vaccine in FY 2009 is 60 percent, consistent with Healthy People 2010 goals of annual influenza vaccination for this targeted high-risk group of adults.

• 3,025,963 X 0.6 = 1,815,577 adults.

• Estimated federal contract price for one dose of adult influenza vaccine in FY 2009 = $12.44. Since there are multiple influenza vaccines available for adults, the cost per dose reflects a weighted average of the influenza vaccines used for calendar year 2006. The average price was then inflated to reflect the projected cost for FY 2009.
1,815,577 X $12.44 = $22,585,778.

Total amount: $22,585,778
**Tdap Total: $30.8 million**
- 9,391,677 individuals 19 to 64 years of age, uninsured, and living at or under 200 percent of the poverty line.
- Projected uptake for Tdap vaccine in FY 2009 is 10 percent; 939,167 adults.
- Estimated federal contract price for 1 dose of Tdap vaccine in FY 2009 = $32.75.
- 939,167 X $32.75 = $30,757,719.
- **Total amount: $30,757,719.**

**HPV Total: $47.8 million**
- 1,567,877 women in the U.S. are 19 to 26 years of age, uninsured, and living at or under 200 percent of the poverty line. Women >26 years are not recommended for HPV vaccine.
- Projected uptake for HPV vaccine in FY 2009 is 10 percent; 156,787 adults. Estimated federal contract price for one dose of HPV vaccine in FY 2009 is $101.71 and $305.13 for the three dose series of this vaccine in 2009.
- 156,787 X $305.13 = $47,840,417.
- **Total amount: $47,840,417.**

**Hepatitis B Total: $51.6 million**
- The population estimate for Hepatitis B was determined based on the recommendation that Hepatitis B should be universally administered in health care settings and settings where healthcare is provided (e.g., STD/HIV prevention and treatment clinics, drug treatment centers, and correctional facilities) where a high proportion of those being served are at risk for Hepatitis B infection.
- This high-risk venue based population estimate includes all individuals presenting at high-risk sites, and does not attempt to determine insurance or poverty level status.
- 2,763,965 individuals are seen annually in STD clinics, or HIV/AIDS counseling and testing facilities.
- The population estimate for this vaccine was reduced from 2,763,965 to 2,487,569 because some individuals may be seen in more than one type of clinic (that is, the population estimate removed potential duplication).
- An additional 2,016,000 individuals are seen in Methadone or other drug treatment facilities, and are otherwise considered to be among high-risk populations.
- $2,487,569 + 2,016,000 = 4,503,569 adults are eligible for Hepatitis B vaccination.
- Projected uptake for Hepatitis B vaccine in FY 2009 is 15 percent; 675,535 adults.
- Estimated federal contract price for one dose of HepB vaccine in FY 2009 = $25.47, and $76.41 for the full three-dose series.
- 675,535 X $76.41 = $51,617,629.
- **Total amount: $51,617,629.**

**Pneumococcal Polysaccharide Vaccine (PPV) Total: $1.5 million**
- 916,365 individuals 19 to 64 years of age are considered high-risk for pneumococcal vaccination, are uninsured, and are living at 200 percent of the poverty level or below.
- Projected uptake for PPV vaccine in FY 2009 is 10 percent; 91,636 adults.
- Estimated federal contract price for one dose of PPV vaccine in FY 2009 = $16.71.
- 91,636 X $16.71 = $1,531,237.
- **Total amount: $1,531,237.**

**Herpes Zoster Total: $2.2 million**

- 615,416 adults age 60–64 are uninsured and living under 200 percent of the federal poverty level (65+ are eligible for Medicare).
- Projected uptake for Herpes Zoster vaccine in FY 2009 is 3 percent; 18,462 adults.
- 18,462 X $116.30 = $2,147,131.
- **Total amount: $2,147,131.**
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<thead>
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<tr>
<td>Pediatric</td>
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<tr>
<td>Influenza</td>
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<td>Other vaccines</td>
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<td>Adult</td>
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<tr>
<td>Tdap:</td>
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<tr>
<td>HPV:$^6$</td>
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<tr>
<td>HepB:$^6$</td>
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<td>PPV:</td>
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<tr>
<td>Zoster:</td>
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<tr>
<td>Total:</td>
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$^1$ Individuals included in FQHC column represent VFC-eligible individuals and are removed from the population eligible for Section 317 vaccine

$^2$ Proportion of 317 eligible population included in the vaccine purchase estimate

$^3$ State contract amounts (based on CY2006 actuals), are removed from vaccine cost estimates

$^4$ Pediatric vaccine cost ($861.01) includes the following vaccines: Diphtheria, Tetanus toxoid, and acellular Pertussis; Haemophilus Influenzae Type b (Hib); Measles, Mumps, and Rubella (MMR); Inactivated Poliovirus (IPV); Hepatitis B; Varicella, Pneumococcal Conjugate Vaccine (PCV7). Rotavirus, Hepatitis A

$^5$ Adolescent vaccine cost for females ($414.18) includes the following vaccines: Meningococcal Conjugate Vaccine (MCV4); Tetanus, Diphtheria, acellular Pertussis (Tdap); Human Papillomavirus (HPV)

$^6$ Adolescent vaccine cost for males ($109.05) includes the following vaccines: MCV4; Tdap

$^7$ Human Papillomavirus and Hepatitis B are three-dose series vaccines. Therefore, a total of 5,814,966 doses of vaccine are factored into the adult vaccination cost

$^8$ Total cost is calculated as: (Final Population X Vaccine Cost)- State Contract
2. Operations Funding

This estimate should include the cost of vaccine administration; surveillance and assessment of changes in immunization rates; vaccine storage, handling, and quality assurance; implementation of centralized vaccine distribution practices; needs to support provider and public outreach and education on new vaccines; identification of barriers to immunization and strategies to address such barriers; maintenance, utilization, and enhancement of Immunization Information Systems [IIS] including integration with public health preparedness and other public health information technology systems; innovative strategies to increase coverage rates in hard-to-reach populations and geographic pockets of need; and other nonvaccine resource needs of a comprehensive immunization program. Each of these activities is critical to ensuring the delivery of lifesaving vaccines to our nation. The Committee urges CDC to consider integrating the data from this report into its budget justification on an annual basis. (Page 80-81, Senate Report 110-107)

Operations: $530.6 million (Table 2)

It takes more than vaccine to fully vaccinate a population. Overall, according to the 2000 Institute of Medicine report, "Calling the Shots," operations funding is vital to the integration of new vaccines into routine medical care for everyone, increasing vaccination coverage rates and decreasing racial and ethnic disparities. Operations funds support front line public health professionals, including nurses who administer vaccines; professionals who work with immunization providers to enroll them in federal or state programs and to improve their immunization practices and handling of vaccines; and managers who coordinate the direct and complex activities necessary to assure the vaccination of a population. Operations funds also pay for the delivery of vaccines, syringes, and other equipment needed to vaccinate as well as immunization information systems to track the vaccination status of individuals.

Section 317 Operations funding supports vaccination infrastructure and direct service delivery, and encompasses the direct labor, administration, supplies, facilities and equipment, training and overhead costs related to each state’s immunization program. Although the VFC program has become the primary source of federal vaccine purchase funding, the vast majority of infrastructure support for immunization programs within states comes from the Section 317 immunization operations program (IOM 2000, p.157). In whole or part, Section 317 operations funding supports activities that (1) direct public vaccine provision; (2) oversee provider quality by conducting assessments, training programs, and compliance monitoring; (3) develop immunization registries; (4) support school-based and community-based vaccine service delivery programs; (5) create and deliver consumer information; (6) conduct vaccine-preventable disease surveillance; and (7) conduct population needs assessments.

Additionally, funds received by CDC for program management and surveillance in the prevention budget line are used to assist states in the operation of their vaccination programs. Activities supported by these funds include: program operations management, vaccine supply contracting and assurance, health services research, public and provider education, information and partnerships, vaccine coverage assessment and surveillance, and technical assistance for immunization information systems. Prevention funding also supports vital research and surveillance on vaccine-preventable diseases. The newer vaccines are targeted at complex infectious diseases where surveillance needs are increasingly intricate and difficult (e.g., HPV).
Additionally, CDC’s prevention dollars assist the grantees with disease surveillance costs that go beyond the state immunization programs in terms of laboratory infrastructure, research, and technical assistance.

Of particular importance is an adolescent operations platform to keep pace with this new population that is the leading edge of immunizations in the United States. Prior to 2005, the only routine vaccination for adolescents was a tetanus booster. Now three vaccines are recommended, Tdap: MCV, and HPV. CDC and the federal government are making a large investment in the purchase of these adolescent vaccines, yet the infrastructure does not exist to deliver vaccines effectively, and measure vaccine uptake and impact. Once fully developed, it is estimated that the national immunization program will deliver annually nearly 2.6 million doses of adolescent vaccines purchased through Section 317. Administration of vaccines in adolescence requires innovative new approaches to the delivery of preventive services in healthcare systems that are capable of improving levels of adolescent health.

It is necessary to educate providers, parents, and adolescents about these recommendations. Many adolescents no longer seek care from their pediatricians who are familiar with immunization. Adolescents may see gynecologists, adolescent specialty doctors, orthopedists, or only seek medical care in an emergency room setting. Additionally, adolescents may seek medical care in non-traditional medical settings such as school and university health centers as well as family planning or sexually transmitted disease clinics. These nontraditional settings must also be incorporated as immunization providers.

A comprehensive and coordinated adult immunization program should be considered within each state, with leadership at the national, state, and local levels, to encourage participation of private and public health care providers in offering immunizations to adults under the guidelines established in the ACIP schedule. Specific activities that are essential to improving the adult vaccination program include: working with partners to support state health departments in developing comprehensive plans for vaccination of adults; addressing and eliminating persistent racial and ethnic disparities in adult immunization coverage levels; promoting standing orders and patient/provider reminder systems; and improving physician and institutional practices that lead to increased vaccination coverage among adults. These efforts include providing guidelines and training for health care providers, tracking disease and vaccination coverage levels, negotiating federal vaccine purchase contracts, and collaborating with other agencies and partners to improve adult vaccination coverage levels. CDC will also continue working with federal, public, and private sector partners as well as vaccine manufacturers to improve annual influenza vaccine uptake, and identify strategies to improve coverage.

**Methods**

In order to determine the operations cost associated with these activities, we have developed a methodology that is based on determining the operations funding required to direct one dose of vaccine. The cost per dose includes infrastructure costs related to surveillance and assessment of changes in immunization rates; vaccine storage, handling, and quality assurance; implementation of the centralized vaccine distribution system; support of provider and public outreach and education on new vaccines; identification of barriers to immunizations and strategies to address such barriers; maintenance, utilization, and enhancement of Immunization Information Systems
(IIS) including integration with public health preparedness; and strategies to increase coverage in hard-to-reach populations and geographic pockets of need.

The operations funding estimate was calculated using the following approach:

- The cost per dose calculation was benchmarked against FY 2000, prior to the licensure of many new pediatric, adolescent, and adult vaccines. The methodology uses the operations funding available in FY 2000 as a baseline budget for distributing the doses needed to fulfill the vaccine recommendations in place in 2000.

- The actual budget appropriated to Section 317 state infrastructure/operations in FY 2000 was $138.3 million. In addition, CDC Section 317 Immunization Program Operations funding totaled $61.2 million. We have subtracted $5.7 million from the CDC Program Operations amount, to account for the money that was apportioned to the Vaccine Safety Datalink, resulting in a total Section 317 Program Operations/Infrastructure budget of $193.8 million. The cost estimate for vaccine safety is not included in this operations estimate calculation; instead it is a stand-alone estimate in the fourth section of this report.

- Because the VFC program was implemented in context of the Section 317 program, we see this as an integrated public program. We have therefore included VFC doses with Section 317 doses in the operations estimates.

- When combined with VFC operations ($50 million) funding, the total operations budget available in FY 2000 was $238.1 million.

- The cost per dose ratio was calculated by dividing the number of publicly purchased vaccine doses distributed in 2000 (50.6 million) into the total amount of operations funding available for the year (238.1 million). \( \frac{238,132,873}{50,650,229} = 4.70 \) in operations costs per dose of vaccine distributed.


- The $5.69 rate was then applied to the total amount of doses projected for public purchase in FY 2009. The determination of doses needed for FY 2009 was calculated by adding the baseline number of doses delivered in 2000 with the number of doses of newly recommended vaccines since 2000.

- Between 2000 and 2006, eight new vaccine recommendations were made for pediatric, adolescent, and adult populations. As a result of these new vaccine recommendations, an additional 42.6 million doses of vaccine will need to be distributed along with the 50.6 million baseline doses that were distributed in 2000.

- This adjusted cost per dose rate of $5.69 was applied to the projected number of doses needed for FY 2009 (93.2 million doses), for a total operations budget of $530.6 million.
Table 2: Operations

<table>
<thead>
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<th>Year</th>
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<th>Operations Cost per dose</th>
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<td></td>
<td>317 operations:</td>
<td>$132,596,873</td>
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<tr>
<td></td>
<td>VFC operations:</td>
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<tr>
<td>2000</td>
<td>Total baseline doses:</td>
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<td>Operations/ dose</td>
<td>$238,132,873</td>
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<td>= 50,650,229</td>
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<tr>
<td>2009</td>
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<tr>
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<td>Pediatric/adolescent:</td>
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<td>($4.70 adjusted for 2007 dollars):</td>
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<td>Total operations:</td>
<td>93,253,321</td>
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<td>X $5.69</td>
<td>$530,611,396</td>
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Table 3: New ACIP vaccine recommendations since 2000

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Year of Introduction</th>
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<tbody>
<tr>
<td>Pneumococcal Conjugate Vaccine (4 Doses)</td>
<td>2000</td>
</tr>
<tr>
<td>Influenza (6 Doses)</td>
<td>2004 (6 to 23 months – 3 Doses) 2006 (24 to 59 months – 6 Doses)</td>
</tr>
<tr>
<td>Hepatitis A (2 Doses)</td>
<td>2005</td>
</tr>
<tr>
<td>Tdap (Tetanus Toxoid, reduced diphtheria toxoid and acellular pertussis (1 Dose)*</td>
<td>2005</td>
</tr>
<tr>
<td>Meningococcal Conjugate Vaccine (MCV) (1 Dose)</td>
<td>2005</td>
</tr>
<tr>
<td>Rotavirus (3 doses)</td>
<td>2006</td>
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<tr>
<td>Second Dose Varicella</td>
<td>2006</td>
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<tr>
<td>Human Papillomavirus Vaccine (HPV) (3 doses) {Females Only}</td>
<td>2006</td>
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<tr>
<td>Herpes Zoster Vaccine*</td>
<td>2006</td>
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* Tdap vaccine replaced the Td vaccine and is therefore not included in the count of new vaccine doses
* Herpes Zoster vaccine is an ACIP provisional recommendation

3. Vaccine Administration

This estimate should include the cost of vaccine administration. (Page 81, Senate Report 110-107)

Vaccine administration

The Section 317 program has never included vaccine administration fees, and it would require the development of a new mechanism to pay a clinical administration fee. This report does not estimate the cost of such a new mechanism. The approximate Medicare payment rate for vaccine administration fee for adults is $18.00 per dose.
4. Vaccine Safety
Vaccine Safety: $43.6 million
CDC plays a major role in the federal post-licensure vaccine safety monitoring system and collaborates with other federal agencies to assess immunization safety activities and develop a vaccine safety research agenda. Post-licensure vaccine safety studies are better able to detect rare, unusual, or delayed adverse events because they assess safety under actual conditions of vaccine use when they are administered to large, diverse populations over a longer time period. CDC’s primary goals for its post-licensure vaccine safety surveillance system are to protect the health of the public and maintain public confidence in immunization programs.

Vaccine safety funding supports and enhances immunization safety activities required to operate a comprehensive immunization program. In Fiscal Year 2007, CDC received base funding of $21.6 million for vaccine safety activities to support the following activities:

- Identifying and analyzing safety concerns through the Vaccine Adverse Event Reporting System (VAERS): $2.7 million
- Testing potential vaccine safety hypotheses through the Vaccine Safety Datalink (VSD) and the Clinical Immunization Safety Assessment (CISA) Network: $16.1 million
- Program operations that includes the Brighton Collaboration, general and business operations and health marketing: $2.8 million

1. Identifying and Analyzing Safety Concerns-VAERS: With current staff and resources, VAERS cannot keep pace with the increasing number of vaccines that are licensed for use. From 2001 to 2006 there has been a 9.4 percent increase in the number of vaccines distributed and this has led to a 30.5 percent rise in the number of vaccine adverse events reported to VAERS. CDC requests an additional $5 million in FY 2009 for VAERS that will be used to:
   - Increase the number of specialized staff who can analyze VAERS reports;
   - Integrate new electronic technologies that make VAERS reports easier to access and submit; and,
   - Develop and implement new education, outreach, and training to increase the use of case definitions by scientists, health care providers and the public.

2. Testing Potential Vaccine Safety Hypotheses – VSD and CISA: VSD provides comprehensive medical and immunization histories for more than 5.5 million people annually, which are used to answer vaccine safety questions. The eight VSD sites include: Group Health Cooperative Center (Seattle, Washington), Harvard Pilgrim Health Care (Boston, Massachusetts), Healthpartners Research Foundation (Minneapolis, Minnesota), Kaiser Permanente Colorado (Denver, Colorado), Kaiser Permanente Northwest (Portland, Oregon), Marshfield Clinic Research Foundation (Marshfield, Wisconsin), Northern California Kaiser Permanente (Oakland, California), and Southern California Kaiser Permanente Health Care Plan (Los Angeles, California).

VSD has demonstrated associations between intussusception following Rotashield vaccination and the risk of seizures following Measles, Mumps, Rubella (MMR) or whole-cell pertussis vaccine. Multiple VSD studies have also provided reassuring evidence of safety for expanded pediatric influenza vaccine recommendations. VSD developed a rapid sequential monitoring
system that is being used to study vaccine safety concerns about RotaTeq vaccine and intussusception, Menactra (meningococcal conjugate vaccine) and Guillain-Barre syndrome, and the safety of Gardasil (HPV). CDC requests an additional $13 million in FY 2009 for VSD that will be used to:

- Expand the VSD population to collect adult data at all participating sites
- Expand the number of participating managed care organizations to 15

CISA is a network of six academic sites that conducts clinical research and collects biological samples to identify and study the pathophysiology of vaccine-associated adverse events. The CISA centers include Johns Hopkins University, Northern California Kaiser, Stanford University Medical Center, Vanderbilt University Medical Center, Boston University Medical Center, and Columbia University Medical Center.

CISA has identified the study of human genomics and how it affects risk for developing vaccine adverse events as a new and high priority. CISA is currently engaged in two such studies: one study is looking at immune response candidate genes and whole genome associations for the risk of myopericarditis following smallpox vaccination; the other study is looking at genetic risk factors for developing rheumatoid arthritis following vaccination. In January 2008, CISA will host a National Vaccine Program Office-sponsored conference, “Understanding the Genetic Basis of Vaccine Safety,” to identify short- and long-term strategies for integrating genomics into vaccine safety. CDC requests an additional $30 million in FY 2009 for CISA that will be used to:

- Expand the number of participating sites to eight
- Develop a genomics initiative that supports new genomics studies in CISA sites

3. Program Operations and Brighton Collaboration: Brighton Collaboration is an international collaboration of professionals that has developed, evaluated and disseminated 21 globally accepted standardized case definitions and guidelines for use in vaccine safety surveillance and research. CDC requests an additional $10 million in FY 2009 for program operations and Brighton Collaboration that will be used to evaluate the applicability, sensitivity and specificity of case definitions in clinical pre- and post-licensure vaccine safety trials and post-marketing surveillance systems.

Discussion on Vaccine Purchase, Operations, Administration Fee and Vaccine Safety

This report represents the professional judgment estimate of the Centers for Disease Control and Prevention Staff on the size and scope of the Section 317 Immunization Program, and is provided without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to the Congress are developed. CDC’s estimate for a fully implemented Section 317 program is $1145.6 million. Although it would not be feasible for the immunization program to absorb this funding amount in one fiscal year, this estimate reflects a fully implemented program.

Vaccine purchase

$571.3 million is the CDC's funding estimate of the Section 317 funding needed to implement ACIP’s recommended vaccine schedule for children, adolescents, and adults. The methods used in this funding estimate calculation were conservative, and limited the scope of the Section 317 program to only serving as a safety net for financially vulnerable individuals.
Although the number of underinsured children is not increasing substantially, the cost to vaccinate children up to 18 years of age has increased markedly; $186.29 in 1999, and $970.06 (male), and $1275.19 (female) projected for 2009. This translates into increasing vaccine purchase estimates for children and adolescents.

The approach to determining the eligible population for Section 317 vaccine did not consider where a child or adolescent receives the vaccine. This allows for parents to access care through their provider of choice. Enabling access to vaccines in the medical home for primary care promotes continuity of care and allows other clinical preventive services to be provided simultaneously; thus increasing efficiency of primary care.

Adult vaccination has not achieved the successes of the childhood immunization, in spite of the great benefits to adult vaccination.

**Operations**
Due to advances in biotechnology in new vaccines, children, adolescents, and adults can be protected from more infectious diseases. New vaccines and newly vaccine preventable diseases require important infrastructure components that in many cases have not been established. CDC’s funding estimate is $530,611,396 to support operations.

**Vaccine Administration fee**
In contrast to Medicare and Medicaid, which pay an administration fee and have mechanisms for payment to providers, the Section 317 program has never paid for clinical administration of vaccine and has no current mechanism to do so.

**Vaccine Safety**
Vaccine safety is required to operate a comprehensive immunization program capable of attaining and maintaining high coverage levels required to protect the community from vaccine preventable diseases, and assuring that vaccine is available. CDC’s funding estimate is $43,600,000 to support the vaccine safety component of a comprehensive immunization program.

**Conclusion**
The Section 317 program plays a critical role in the nation’s immunization system. It saves lives as well as dollars, and allows the federal government to provide the public with a strong level of protection from vaccine preventable diseases. Targeting vaccines appropriately, assuring that vaccines are as safe as possible, and assessing the impact of expanded immunization programs for children, adolescents, and adults through disease and coverage surveillance are important public health activities necessary to protect people from vaccine preventable diseases. These public health activities are not conducted by other sectors or agencies and are necessary to support the implementation of effective immunization programs.