# Adult Immunization Priorities in the United States\*

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Immunization has proven to be among the most successful of public immunization has proven to be among the most successful of public health interventions (Freed, Bordley, and Defriese 1993). By the early 1990s, reported cases of six of the country's worst scourges (diphtheria, tetanus, polio, measles, rubella, and mumps) had been reduced from peak levels by over 99 percent (see table 1). In 1991 there were fewer than 500 reported deaths from vaccine-preventable diseases of childhood (U.S. Department of Health and Human Services 1994b).

By comparison, today in the United States at least 100 times as many adults as children die each year from vaccine-preventable diseases. Three infectious diseases—influenza, pneumococcal infections, and hepatitis B—are responsible for 50,000 to 70,000 or more adult deaths per year on average (Fedson 1994b). Pneumococcal infections are the largest killer by far, followed by influenza and, to a much less extent, hepatitis B. (However, because pneumococcal infections frequently follow influenza, it is often difficult to separate these diseases by etiology.) The Centers for Disease Control and Prevention (CDC) estimates that if adult

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Disease	Maximum no. of cases (y)	1993 cases <sup>a</sup>	Percent reduction
Diphtheria	206,939 (1921)	0	100.0
Pertussis	265,269 (1934)	6,132	<b>97</b> .7
Tetanus <sup>b</sup>	1,560 (1923)	9	99.4
Poliomyelitis (paralytic)	21,269 (1952)	0 <sup>c</sup>	100.0
Measles	894,134 (1941)	277	99.9
Rubella	57,686 (1969)	188	99.7
Congenital rubella syndrome	20,000 (1964–65)	7	99.9
Mumps	152,209 (1968)	1,630	98.9

 TABLE 1

 Reported Cases of Vaccine-Preventable Childhood Diseases in the United States.

<sup>a</sup>Provisional data that may change because of late reporting.

<sup>b</sup>Data from the CDC on tetanus refer to 1992 deaths, not cases. The provisional number of tetanus cases for 1993 is 42.

<sup>c</sup>Excludes an estimated four cases of vaccine-associated paralysis.

Source: Fedson 1994b. Data from the National Immunization Program, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia.

immunization recommendations were followed, 31,510 additional deaths could be prevented each year (U.S. Department of Health and Human Services 1994b). Much of this mortality is concentrated among the elderly; however, CDC has estimated that, in 1991, more than 168,000 years of potential life were lost *prior to age 65* owing to pneumonia and influenza (P&I) disease (Centers for Disease Control 1991). Together, P&I disease represents the sixth leading cause of death in the United States (see table 2).

Pneumococcal Disease and Influenza among the Elderly

# Pneumococcal Disease

Among the elderly alone, there are almost 270,000 cases of pneumococcal disease each year. *Streptococcus pneumoniae* (the causative bacteria) is responsible for between 15 and 50 percent of all adult, communityacquired pneumonias and is the leading cause of pneumonia requiring hospitalization (American College of Physicians . . . 1994). And yet, in Adult Immunization Priorities in the United States

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Rank order and cause of death	Number	Percent <sup>a</sup>	Rate <sup>b</sup> 281.4 204.1
1. Heart Disease	717,706	33	
2. Cancer	520,578	24	
3. Stroke	143,769	7	56.4
4. Chronic lung disease	91,938	4	36.0
5. Accidents	86,777	4	34.0
6. Pneumonia and influenza	75,719	3	29.7
7. Diabetes	50,067	2	19.6
8. AIDS	33,566	2	13.2
9. Suicide	30,484	1	12.0
10. Violence	25,488	1	10.0
All other causes	396,832	18	156.6

TABLE 2The Ten Leading Causes of Death in the United States, 1992

<sup>a</sup>Does not add to 100 due to rounding.

<sup>b</sup>Rates per 100,000 population.

Source: U.S. Department of Health and Human Services 1995.

1993 only 27 percent of the noninstitutionalized elderly population had ever been vaccinated against pneumococcal disease. Antibiotic treatment, rather than prevention, continues to be physicians' predominant practice pattern, despite a case fatality rate of more than 40 percent for pneumococcal bacteremia in persons 65 years of age or older (Breiman et al. 1990). Recent studies show that, in the early 1990s, fully 16.4 percent of *S. pneumoniae* strains were resistant to at least one type or class of antimicrobial drug, whereas resistance to penicillin and other such agents were considered a "laboratory curiosity" in the 1980s and before (Breiman et al. 1994). These alarming reports put an even higher premium on preventing rather than treating pneumococcal disease (Simberkoff 1994; *Science* 1994).

#### Influenza

In an average year, about 5 to 10 percent of the elderly population become ill during influenza outbreaks (about 2 to 3.6 million persons in 1995). Approximately 300,000 deaths have been attributed to the A(H3N2) influenza strain since it emerged more than 20 years ago. Flu epidemics occur almost every year, and in an average year influenza is associated with 20,000 deaths (N. Arden, February 7, 1996: personal communication). Yet, the most recent data available from CDC's National Health Interview Survey indicate that in 1993 only about one in two elderly persons had received influenza vaccine during the previous vaccination season. Preliminary findings from the Health Care Financing Administration's (HCFA) Current Beneficiaries Survey suggest that in 1994 as many as 60 percent of beneficiaries may have received flu vaccine (U.S. General Accounting Office 1995).

From a societal perspective, pneumococcal disease and influenza are very costly. Hospitals are reimbursed from \$750 million to \$1 billion by HCFA for the treatment of influenza-associated illness during epidemic periods, and almost a half-billion dollars in nonepidemic years (U.S. General Accounting Office 1995). Yet these sums represent a fraction of the total costs because only 25 percent of all pneumococcal pneumonia cases, and less than 1 percent of influenza cases, in persons 65 and above are hospitalized (U.S. General Accounting Office 1995). CDC reports that the direct medical costs of influenza alone are as much as \$4.6 billion a year, and that total direct and indirect costs of a severe influenza epidemic are at least \$12 billion (U.S. Department of Health and Human Services 1994a,b). A number of studies have demonstrated the cost-effectiveness of pneumococcal and influenza vaccination of persons 65 years old and older (U.S. Office of Technology Assessment 1979, 1981; Riddiough, Sisk, and Bell 1983; Sisk and Riegelman 1986; Nichol et al. 1994). Fedson (1994a) has shown that pneumococcal and influenza immunizations are far more cost-effective than other screening, prevention, and treatment interventions (for cancer, coronary heart disease, and renal disease) for elderly persons.

Federal Immunization Priorities

The Health Care and Financing Administration began Medicare coverage of pneumococcal vaccine for all elderly beneficiaries in 1981, hepatitis B vaccine coverage for high- and intermediary-risk beneficiaries in 1984, and influenza vaccine for all elderly beneficiaries in 1993. Before Medicare began covering immunization services for adults, the federal government conducted three flu immunization programs. In 1976, Con-

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gress passed a joint resolution making \$135 million available for a comprehensive, nationwide influenza immunization program.<sup>1</sup> Between October and December of 1976, nearly 43 million doses of swine flu vaccine were administered to the U.S. population. However, the program was truncated when it was learned that the relative risk of Guillain-Barré syndrome was greater in vaccinated than in unvaccinated persons. Moreover, the anticipated epidemic never materialized (U.S. General Accounting Office 1977; U.S. Department of Health, Education, and Welfare 1979). Two smaller immunization programs, funded with less than \$10 million during each of the 1978–79 and 1979–80 flu seasons, were designed to immunize only those persons at highest risk of complications or death from flu (U.S. General Accounting Office 1980).

In fiscal year 1994 (FY94), HCFA spent \$85.7 million on Part B reimbursement of providers for the cost and administration of pneumococcal and influenza vaccination for elderly and disabled persons. (Fewer than \$100,000 was spent promoting flu and pneumonia shots to beneficiaries.) This expenditure pales in comparison to the remaining federal funds spent on immunization activities that year. In FY94 Congress appropriated \$770.9 million for immunization activities to the three major Public Health Service (PHS) agencies: CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). NIH and FDA generally concentrate on vaccine research and development. CDC received the bulk of these funds (\$528 million), primarily to provide project grants for immunization services to states and local health departments. (In FY93, 20.8 percent of CDC's total budget was spent on immunization activities, an amount second only to HIV/AIDS prevention, which accounted for almost one-third of CDC's funding [Centers for Disease Control and Prevention 1993].)

When some members of Congress became aware of high levels of vaccine-preventable disease and death in the adult population, low rates of vaccine utilization, and the potential for significant cost savings from vaccination, they asked the General Accounting Office (GAO), the investigative arm of Congress, to evaluate the Department of Health and Human Service's (DHHS) efforts to improve levels of adult immuniza-

<sup>&</sup>lt;sup>1</sup>P.L. 94-266; P.L. 94-380.

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tion. In its recently released report, GAO found that CDC spent less than \$1 million of its \$528 million FY94 immunization appropriation on adult immunization activities; and of 289 staff positions in the agency's National Immunization Program (NIP), only five were dedicated to its Adult Immunization Initiative (U.S. General Accounting Office 1995). In short, GAO found that almost all federal immunization funds were spent on programs for children.

In view of the marked disparity between both the high incidence of P&I disease and low adult immunization rates, and the relatively low funding level for activities to promote adult immunization, GAO inquired about CDC's immunization priorities. The director of the agency's NIP was asked, "Has adult immunization been a priority of the NIP? If not, what have been the NIP's priorities?" He replied in a letter: "We receive no specified funding for adult immunization efforts. NIP has no budget line item with which to address adult immunization activities." The NIP director concluded that although "CDC considers adult immunization a top, but unfunded, priority . . . major Executive and Legislative Branch reports indicate that childhood immunization should be CDC's key priority" (W. A. Orenstein, April 22, 1994: personal communication).

In a subsequent conference with CDC officials, GAO requested documentation supporting these statements. CDC agreed to review legislative documents and determine whether the agency is *precluded* from spending resources on adult immunization activities. In response to this request, the director of CDC wrote:

Key Legislative Branch documents providing guidance to immunization programs ... [including] ... the Vaccination Assistance Act of 1962 ... and current authorizing legislation ... clearly document that Congress has directed childhood immunization as the Centers for Disease Control and Prevention's (CDC) key immunization priority. (D. Satcher, August 19, 1994: personal communication)

Thus, in brief, top CDC officials responded to the GAO investigation by maintaining that although the agency considers adult immunization a top priority, CDC allocated almost all of its immunization budget to childhood activities in FY94 *because Congress directed it to do so*. In their written statements, the officials used elements of each of the following arguments to support this position: Adult Immunization Priorities in the United States

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- One argument is that CDC is *legally prohibited* from using federal immunization funds for adult programs. This is implied in the letter from CDC's director, which states that "current authorizing legislation" is a critical document, clearly showing childhood immunization to be the immunization priority for CDC.
- A second argument focuses on the *availability of funding* for adult immunization activities. According to this argument, CDC's appropriations bills preclude the agency from spending federal immunization resources on adult programs by earmarking all, or nearly all, such funds for childhood programs. This is implied in the NIP director's description of adult immunization as a "top, but *unfunded*, priority" (italics added).
- A third, more subtle, argument begins with the acknowledgment that CDC is vested with statutory authority and has funds available to promote adult as well as childhood immunization programs. The law is interpreted as *allowing*, but not *requiring*, CDC to fund adult immunization programs. According to this argument, CDC uses its *discretion* to allocate immunization resources in accordance with the will of the legislative and executive branches of government. The agency considers the wishes of Congress and the President to be clear: each places the highest priority on childhood immunization.

In the following sections, I assess the support for each of these arguments. I do not assert that CDC has unequivocally adopted one or the other argument, but rather that top agency officials utilized elements of all three in their responses to a recent congressional investigation of adult immunization priorities in the United States.

To address the first of the three arguments—namely, that CDC is legally barred from funding adult immunization activities—I present a legislative analysis of the statutory authority for federal immunization programs under CDC from the original legislation, passed in 1962, to the current authorization. I answer the question, Is the organic authority for CDC's immunization activities age limiting?

To address the second argument—namely, that CDC's immunization appropriation precludes the funding of adult programs—I present an overview of the restrictions and allowances in CDC's FY94 appropriation bill. I also review House, Senate, and conference reports associated with the bill. I answer the question, Does the language in these legis-

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lative documents impede or in some way restrict CDC from spending federal immunization resources on adult programs?

The third argument—that CDC's immunization priorities reflect the will of the Congress and the higher levels of the executive branch raises fundamental questions about CDC's role as public health advocate. Is CDC's role restricted to that of responding to political mandates and directives? To what extent, if any, should the agency attempt to influence public health policy? In the context of these questions, I examine the record of the FY94 House appropriation hearings to determine whether CDC attempted to inform Congress about the public health significance of adult immunization problems, or whether childhood programs were the agency's sole immunization concern.

Are There Legal Restrictions to Promoting Adult Programs?

As the major recipient of federal immunization funding, CDC sponsors multiple immunization activities. Some of these include disease surveillance and epidemiological studies undertaken by the agency's National Center for Infectious Diseases, but CDC distributes the majority of its immunization funding as project grants to states and other public entities under the authority of section 317 of the Public Health Service Act<sup>2</sup> (PHSA). Section 317 was added to the PHSA by the Vaccination Assistance Act of 1962,<sup>3</sup> which laid the cornerstone of a national vaccination policy.

### The Vaccination Assistance Act of 1962

On February 27, 1962, President Kennedy delivered a message to Congress on the nation's health programs in which he stated: "The basic resource of a nation is its people. Its strength can be no greater than the health and vitality of its population. Preventable sickness, disability, and physical or mental incapacity are matters of both individual and

<sup>&</sup>lt;sup>2</sup>Classified to 42 U.S.C.A. § 247b.

<sup>&</sup>lt;sup>3</sup>P.L. 87-868.

national concern."<sup>4</sup> In this speech the President recommended that Congress consider a nationwide vaccination program. On the same day, the Department of Health, Education, and Welfare submitted a draft legislative proposal to the Speaker of the House, and a few days later the chairman of the Committee on Interstate and Foreign Commerce introduced the bill, which was then referred to his committee.

Hearings on H.R. 10541 were held by the committee on May 15 and 16, 1962. Following review and revision, the amended bill was reported by the committee on June 18 and was passed by the House on June 26. In the Senate, the bill was referred to the Committee on Labor and Public Welfare. The committee did not hold hearings, reporting the bill without amendment on August 22. The bill was passed by the Senate on October 4 and signed into law on October 23 by President Kennedy.

The Vaccination Assistance Act of 1962 (hereafter VAA), as the new law was designated, was enacted to provide federal support "to assist States and communities to carry out intensive vaccination programs." Such programs were to be

of limited duration [and] so designed and conducted as to achieve . . the immunization against poliomyelitis, diphtheria, whooping cough and tetanus . . . of all, or practically all, susceptible persons in a community, particularly children who are under the age of five years . . . .<sup>5</sup>

Although the VAA emphasized federal assistance for childhood immunization programs, the phrase "all, or practically all, susceptible persons" reflects a more general concern with establishing a public health rationale for designing and conducting vaccination programs. According to the Senate committee report accompanying the bill, "In interpreting the term 'susceptible' the States would be guided by practical epidemiologic considerations relating to the relative probability of persons in certain age groups contracting the disease in question."<sup>6</sup> Although the VAA limited federally sponsored vaccination assistance to the four, primarily childhood, diseases specified in the act, subsequent

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<sup>&</sup>lt;sup>4</sup> H. Rep. No. 1835, 87th Cong., 2d Sess. (1962).

<sup>&</sup>lt;sup>5</sup> U.S. Statutes at Large, 76:1155 (1962).

<sup>&</sup>lt;sup>6</sup>S. Rep. No. 1907, 87th Cong., 2d Sess. (1962).

enactments substantially extended the provision of section 317 funds for other diseases.

#### Subsequent Enactments

The Community Health Services Extension Amendments of 1965<sup>7</sup> extended the expiring provisions of the VAA for three additional years, struck out the "limited duration" characterization of vaccination assistance programs, and replaced the name "intensive vaccination program" with the more general title "immunization program." Significantly, this legislation also provided the authority for federal funds to be used to pay "costs in connection with immunization programs against any other disease of an infectious nature which the Surgeon General finds represents a major public health problem in terms of high mortality, morbidity, disability, or epidemic potential . . . . "<sup>8</sup>

Consistent with the "all, or practically all, susceptible persons" phrase in the VAA, this and subsequent legislation continued to suggest a rationale for targeting vaccination assistance based on public health needs. A 1970 enactment,<sup>9</sup> for instance, directed the secretary to "give consideration to the relative extent of problems relating to one or more" of the diseases specified in the law.<sup>10</sup>

Although the 1965 amendment provided funding authority under section 317 of the PHSA for any infectious disease targeted by the surgeon general, Congress nonetheless enacted categorical grant programs for a number of specific diseases in subsequent legislation. Table 3 traces this expansion in specified authority for particular diseases under section 317. As categorical grant authority broadened, so did the program name for section 317 authority—to its present "preventive health service" programs title.

In 1976, section 317 was revised and amended by a bill that provided *separate* authority for childhood immunization programs and "other disease control programs." This age-based distinction in immunization funding was repeated in the subsequent reauthorization bill.<sup>11</sup> A further

<sup>&</sup>lt;sup>7</sup> P.L. 89-109.

<sup>&</sup>lt;sup>8</sup> U.S. Statutes at Large, 79:436 (1965).

<sup>&</sup>lt;sup>9</sup> P.L. 91-464.

<sup>&</sup>lt;sup>10</sup> U.S. Statutes at Large, 84:988 (1970); 86:748 (1972); 90:701 (1976).

<sup>&</sup>lt;sup>11</sup> P.L. 94-317; P.L. 95-626.

Adult Immunization Priorities in the United States

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TABLE 3
Legislation That Expanded Categorical Program Grant Authority
of Section 317 of the Public Health Service Act

Year	Public law	Diseases specified
1962	P.L. 87-868	Poliomyelitis, diphtheria, whooping cough, tetanus
1965	P.L. 89-109	Measles; any disease of an infectious nature
1970	P.L. 91-464	Tuberculosis, venereal disease, rubella, Rh disease, and other communicable diseases
1974	P.L. 93-354	Diabetes mellitus
1975	P.L. 94-63	Diseases borne by rodents
1976	<b>P.L.</b> 94-317	Arthritis, hypertension, pulmonary, and cardiovascular diseases

division was put into effect when the Omnibus Budget Reconciliation Act of 1981 (OBRA 81)<sup>12</sup> created two distinct prongs of funding for immunization programs. It amended the categorical grant program for preventive health services under section 317 of the PHSA to authorize childhood immunization *without* reauthorizing funding for the residual category of disease control or preventive health service programs, which included adult immunization. But OBRA 81 also created the Preventive Health Services Block Grant, which consolidated eight categorical grant programs and incorporated adult immunization under the provision for "comprehensive public health services, including immunization services."<sup>13</sup> Thus, during the four-year period when OBRA 81 was in effect, section 317 categorical grants were limited to serve children only, but block grants were provided for immunization services without an age limitation.

The age restriction imposed on section 317 categorical grant programs by OBRA 81 was lifted by the Preventive Health Amendments of 1984.<sup>14</sup> According to the accompanying Senate report, the 1984 enactment was intended to amend section 317 authority "so that beneficiaries of the program would no longer be limited to children."<sup>15</sup> The

<sup>&</sup>lt;sup>12</sup> P.L. 97-35.

<sup>&</sup>lt;sup>13</sup> P.L. 97-35, § 901(a)(1)(D).

<sup>&</sup>lt;sup>14</sup> P.L. 98-555.

<sup>&</sup>lt;sup>15</sup> S. Rep. No. 100-108, 100th Cong., 2d Sess. (1984), p. 964.

new bill simply substituted the phrase "immunize individuals against vaccine-preventable diseases" for the previous "immunize children against immunizable diseases." This new language, which clearly identifies individuals in general, rather than children per se, as the beneficiaries of federal immunization programs, was retained in both subsequent reauthorization bills.<sup>16</sup> Thus, current authority for section 317 immunization programs for children only.

# Are There Funding Restrictions to Promoting Adult Programs?

The *authority* for federal-state immunization activities was provided for the five-year period FY91 to FY95 by Public Law 101-502, but *funding* for CDC's year-to-year immunization operations and programs is determined through the annual budget process. For this reason, agency officials appear before their appropriations committees each year, whereas they typically testify before their authorization committees less frequently. Despite the existence of procedural rules in the House and Senate to prohibit unauthorized appropriations,<sup>17</sup> some appropriations bills nevertheless include substantive program guidance that cannot be traced back to current authorizing legislation.

Considering how the federal budget process works, it is understandable that agency officials look to appropriations bills for program directives and glean additional expression of congressional intent from accompanying committee reports. (It should be kept in mind, however, that, in contrast to bills, reports are not legally binding.) This method of priority setting is reflected in the letters to GAO from top CDC officials. As stated earlier, these officials cited recent appropriations bills and accompanying reports to support the position that "childhood immunization should be CDC's key priority" and that adult immunization is "unfunded."

Did CDC's recent appropriation bill—the 1994 Appropriations Act for the Departments of Labor, Health and Human Services, Education,

<sup>&</sup>lt;sup>16</sup> P.L. 100-177; P.L. 101-502.

<sup>&</sup>lt;sup>17</sup> House Doc. 102-192. Our American Government, 1993.

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1(1 01, and related agencies<sup>18</sup>—preclude or severely restrict its use of section 317 funds to support adult immunization programs? Analysis of the bill indicates that it is not age limiting, even in intent. The bill's language is general. It simply directs CDC to carry out the titles of the Public Health Service Act authorizing CDC activity. Since statutory authority for federal immunization expenditures was explicitly broadened in 1984 to include adults as beneficiaries, we can conclude that CDC's FY94 appropriation bill per se did not provide legislative guidance on the relative distribution of immunization funds to children and adults *above and beyond what is already contained in the authorizing legislation*.

This finding, together with those described in the preceding section, lead to the conclusion that there is no basis in the law—in either authorizing or appropriation legislation—to support the argument that there is a legal bar, or a funding restriction, on the promotion of adult immunization programs under section 317 of the PHSA.

CDC's officials do accurately point out, however, that the reports accompanying the agency's FY94 appropriation bills unequivocally express the committees' primary interest in childhood immunization programs. The House report, for example, states that the "bill includes \$449,393,000 for the childhood immunization program."<sup>19</sup> It also states that CDC project grants are intended to "assist State and local agencies in planning, developing, and conducting childhood immunization programs." And although the report accompanying the Senate appropriation bill stated that the "appropriate administration of safe and effective vaccines remains the most cost-effective method of preventing human suffering and reducing economic costs resulting from vaccine-preventable diseases," an enumeration of specific funding areas followed in which children and childhood programs were mentioned no less than 13 times, whereas adult programs went unnoticed.<sup>20</sup>

Nevertheless, these reports should not be interpreted as expressing congressional intent to *rule out* the use of federal immunization funds for adult programs. Indeed, as the following passage from the House report shows, allowance was made for CDC to engage in internal priority setting without the necessity of age-based constraints:

<sup>&</sup>lt;sup>18</sup> P.L. 103-112.

<sup>&</sup>lt;sup>19</sup> H. Rep. No. 103-156, 1st Sess. (1993), p. 42.

<sup>&</sup>lt;sup>20</sup> S. Rep. No. 103-143, 1st Sess. (1993), p. 63.

The recommended level includes funding to be distributed in consultation with the National Vaccine Program and its National Vaccine Advisory Committee to meet the need for funding emerging high priority vaccine projects within the agencies of the Public Health Service.<sup>19</sup>

Moreover, in a section of the report headed "Infectious Diseases," the committee encouraged CDC to develop "new or improved prevention and control methods and techniques" for pneumococcal disease, among others. The committee also observed that the number of CDC staff working on non-HIV infectious diseases during the last decade has declined, and it "encourages CDC to place a higher priority on emerging microbial threats."<sup>21</sup> In the Senate report, the amount of funds specifically targeted for children's programs (\$271.3 million) added up to only about one-half of the total allocation for immunization activities (\$554.3 million).<sup>22</sup> One could argue, therefore, that Congress intended to leave CDC with a large amount of "discretionary" immunization funds, which it could allocate in accordance with its internally determined immunization priorities.

CDC's Public Health Role: Politics and Priorities

Recall that a third rationale suggested by CDC officials for limiting adult immunization funding is that the agency should use its *discretion*, under the authority granted in section 317 of the PHSA and elsewhere, to allocate funds exclusively, or almost exclusively, to childhood programs. According to this argument, CDC officials follow legislative and high-level executive branch directives, either because they concur with them, because they believe that compliance is prudent, or for both reasons.

Of the three arguments or rationales implied in CDC's responses to the GAO investigation of adult immunization, this appears to have the greatest validity for two reasons. First, it acknowledges that neither the organic authority provided by CDC's oversight committees nor the funding set by the agency's appropriations committees prohibits or severely restricts its promotion of adult immunization programs. Second, this

<sup>&</sup>lt;sup>21</sup> H. Rep. No. 103–156, 1st Sess. (1993), p. 43.

<sup>&</sup>lt;sup>22</sup> S. Rep. No. 103-143, 1st Sess. (1993), p. 63ff.

rationale acknowledges the real, often blunt, political pressures that help determine CDC's public health priorities and agenda.

Whereas the two preceding sections show that the authority and funding for federal immunization activities are not age limiting—that CDC is not precluded from promoting adult immunization programs these analyses also demonstrate that Congress has communicated to CDC an almost overriding interest in childhood immunization programs. In addition, over the last few years another important influence on CDC's immunization priorities has been the strong advocacy of the Clinton administration for the President's Childhood Immunization Initiative (CII).

The seminal event launching the CII occurred during a 1993 presidential visit to a Washington, D.C., health clinic. In the spring of the following year the President elaborated his interest in childhood immunization during a special Rose Garden ceremony. CDC was assigned responsibility for the CII, and it formally announced the initiative in the February 4, 1994, issue of Morbidity and Mortality Weekly Report. The CII was designed to develop a comprehensive national response to undervaccination among children. Its goals, which include the elimination of indigenous cases of six vaccine-preventible diseases, are to be achieved through five broad areas of activity: improved vaccination delivery services; reduced vaccine costs for parents (through the Vaccines for Children [VFC] program); increased community participation, education, and partnerships; more efficient monitoring of disease and vaccination coverage; and improved vaccines and vaccine use. Except for the VFC program, which received separate provisions under the Omnibus Budget and Reconciliation Act of 1993 (OBRA 93), funding for the bulk of CII activities was provided through section 317 of the PHSA. Supplemental funds were appropriated in FY92, and section 317 funds were tripled in FY94. Since the CII was launched, section 317 funds have been distributed to state, territorial, and local health agencies on the basis of Immunization Action Plans (IAPs) they submit in response to CDC's CII-based guidelines for improving the nation's childhood vaccine delivery infrastructure.

#### Immunization Leader or Follower?

When CDC officials were asked by GAO whether adult immunization is an agency priority, they focused their responses on the agency's obli-

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gation to *respond* to "major Executive and Legislative branch reports [which] indicate that childhood immunization should be CDC's key priority" (W.A. Orenstein 1994: personal communication). In that same letter to GAO, the director also wrote that "CDC considers adult immunization a top, but unfunded priority." But if CDC has not funded adult programs, it is reasonable to ask what it has done to make adult immunization a priority.

The issue raised here is both more general and more fundamental than the specific concern with adult immunization. By focusing only on CDC's obligation to *respond* to legislative and executive branch directives, top agency officials diminish the agency's role as both an agent of change and as a major actor on the public health policy stage. In light of its response to the GAO investigation, it seems ironic that CDC (with an FY93 staff of almost 6,000 and a budget of \$1.9 billion) has also described itself as the "nation's prevention agency," whose mission is "to improve health and quality of life . . . for all people" by, among other things, working to "advocate sound public health policies" (Centers for Disease Control 1993).

CDC's mission statement acknowledges, even advertises, the fact that the agency does more than merely respond to legislative and executive branch directives. As the guardian of the nation's health, CDC helps set public health priorities and policies in a number of ways. CDC's various centers develop program initiatives, and agency officials seek support for these initiatives both within CDC and in the PHS and DHHS more generally. Moreover, each year CDC officials exercise considerable influence over the scope and direction of the agency's agenda by assisting in the development of the President's DHHS budget requests. And CDC officials also affect the nation's public health agenda by educating members of congressional committees and their staff about the most pressing public health issues and needs in the country.

An important occasion for CDC to influence Congress, and in turn to affect federal immunization policy, is the agency's annual appropriations process, when it is asked to prepare justifications of CDC budget estimates for the upcoming fiscal year. These hearings afford CDC the opportunity to alert members of Congress that, although the agency considers adult immunization a priority, the programs are "unfunded" because there is a lack of awareness or concern in the legislative and (higher-level) executive branches of government.

#### Adult Immunization Priorities in the United States

This opportunity was completely missed in FY94. The record of CDC's testimony shows that agency officials did not inform the committee about low rates of adult immunization and high rates of vaccinepreventable disease and death among elderly and high-risk adults (U.S. House of Representatives 1993). Furthermore, the record shows that CDC officials did not ask for an increased allocation of immunization resources for adult programs in their justification of the agency's budget estimates. Whereas the justification for requests for immunization funds fills eight pages and contains seven direct references to childhood, preschool, or infant immunization programs, and 24 additional references to children, preschoolers, or infants, it does not once refer to adult immunization programs. (The single remark on the susceptibility of adults to vaccine-preventable disease focuses on the fact that hepatitis-B virus infection is concentrated among young adults.)

Will CDC continue to miss important opportunities to inform Congress directly that P&I disease is the sixth leading cause of death in the United States? That safe, reasonably effective, and universally available vaccines to prevent many of these deaths are underutilized? And that, although adult immunization is a top CDC priority, the agency is inhibited from allocating more immunization resources to reduce P&I disease and hepatitis B because it believes Congress and the President are reluctant to use federal immunization funds for any purpose other than childhood programs?

#### Conclusions

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The NIP director told GAO that adult immunization is a "top, but unfunded priority" at CDC, but the evidence considered here casts doubt on this statement. There are at least three reasons to contest the assertion that adult programs are unfunded: First, the legislative analysis of CDC's authority to provide immunization program grants indicates that, over an extended period of time, whatever other changes Congress has made in the federal immunization program, it has never used language that would bar adult immunization, nor does the history of enactments suggest that such a bar was contemplated. Second, because CDC's appropriations bill and the reports accompanying the bill do not preclude or severely restrict the funding of adult programs, the agency has presumptive power to use its discretion to allocate immunization funds to serve the public health. And third, considering that CDC's NIP did spend some money on adult immunization in FY94, it is unlikely that, if pushed, the agency's officials would argue that it acted illegally.

Even the assertion that adult immunization is a priority at CDC is belied by the testimony of officials during the agency's appropriations process. When presented with the opportunity during FY94 hearings, CDC officials did not attempt to influence existing immunization priorities by informing the agency's appropriation committees about adult immunization problems, or by advocating funding for programs to enhance adult immunization.

Is it reasonable to believe that CDC is hamstrung by Congress from spending more federal immunization funds on adult programs? I have raised the possibility that CDC can exert more authority to increase adult immunization rates and to lower morbidity and mortality from pneumococcal pneumonia, influenza, and hepatitis B by educating Congress on the need for increased efforts to promote adult immunization.

## Enhancing Federal Support for Adult Immunization

Assuming that a fixed amount of resources is available to be used for immunization services, the "ideal" mix of childhood and adult programs is, ultimately, a policy issue. Several current imbalances should be considered. It is estimated that more than 500,000 cases of pneumococcal disease occur each year in the United States (U.S. Department of Health and Human Services 1994a). At present levels of immunization program efforts, fewer than 500 persons die from vaccine-preventable diseases of childhood in the United States each year, whereas 50,000 to 70,000 persons die of pneumococcal infections, influenza, and hepatitis B in an average year (Fedson 1994b). At least 98 percent of children are fully immunized by school entry, whereas only slightly over one-quarter of adults 65 years old or older have received Medicare-covered pneumococcal vaccine.

This article has raised questions about CDC's role in setting adult immunization priorities in the United States. It should not be interpreted as an indictment of the agency's Adult Immunization Initiative, which has been in operation since 1985. With the equivalent of only five full-time positions, NIP staff have disseminated information and educational materials to professional and lay groups, supported conferences, published articles in professional journals, and collaborated with other HHS agencies and outside organizations on adult vaccination projects. They have worked with staff from HCFA and various health care organizations on the Hawaii Pneumococcal Disease Initiative (Williams 1992) and the Medicare Influenza Demonstration (Abt Associates 1993). NIP staff also have assisted the National Vaccine Program Office in developing the National Vaccine Plan, and have collaborated with nonprofit organizations in research on immunization practices and priorities in HMOs, nursing homes, hospitals, and medical schools.

With only a fraction of the agency's immunization funds, the NIP adult immunization staff have made substantial accomplishments. However, CDC management has yet to exercise the agency's discretion to mount, or even encourage, a broad-based, nationwide effort to improve adult immunization rates. HHS has received expert advice about how to increase adult immunization rates and lower P&I disease from the subcommittee on adult immunization of the congressionally mandated National Vaccine Advisory Committee (NVAC)<sup>23</sup> (Fedson 1994b; U.S. Department of Health and Human Services 1994b). Yet, the department's FY94–95 National Vaccine Plan failed to specify whether any of the NVAC's 18 recommendations and 72 suggested strategies would become "funded priorities," a category that would lead to their broad-scale adoption.

#### What Should CDC Do?

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First, CDC officials should put teeth in their assertion that adult immunization is a top agency priority. In FY94, CDC distributed almost one-half billion dollars of section 317 funds to states and local entities for immunization program grants (IPGs). Grant applicants developed action plans in accordance with CDC guidelines, and funds were distributed on the basis of the quality of submitted plans. In the past, CDC has not included the promotion of adult immunization among the 26 grant requirements (U.S. General Accounting Office 1995). The agency could begin requiring that state and local health organizations submit

303

<sup>&</sup>lt;sup>23</sup> P.L. 99-660.

plans for adult programs, following guidelines based on the strategies discussed below, if they are to receive section 317 funds.

CDC should continue to enhance its promotion of programs to build upon adult immunization strategies that are known to be the most effective in lowering P&I disease. Findings from the GAO synthesis of research literature indicate that promotional efforts that increase health care providers' compliance with immunization guidelines are likely to be more effective than efforts to influence consumers directly (U.S. General Accounting Office 1995; see also Gyorkos et al. 1994). Physicians' recommendations have a strong, positive influence on patients' vaccination decisions (even among patients with negative attitudes toward vaccination), but physicians often forget to offer vaccination to their eligible patients. Physician reminder systems (such as checklists in medical charts or computer-based reminders) are proven remedies for this tendency to omit preventive health care practices. Another successful provider-based strategy is the use of standing orders to vaccinate eligible patients. The effectiveness of this approach often depends on the transfer of vaccination responsibilities to nonphysician health care providers. In private practice settings, patient population-based tracking systems have been used to increase immunization rates by identifying patients in need of vaccination.

Perhaps the most direct and efficient strategy CDC can pursue to reduce pneumococcal disease is to encourage promotional efforts that target high-risk patients in hospitals. Research conducted in the United States, Canada, and the United Kingdom shows that from one-half to two-thirds of all patients admitted to hospitals with pneumococcal disease had missed at least one opportunity to be vaccinated in the previous five years during a prior hospitalization, at which time their medical records indicated they were at high risk for P&I disease. Yet, according to CDC officials, in 1994 over 60 percent of medical/surgical hospitals in the United States had no policy for vaccinating inpatients or outpatients against pneumococcal disease or influenza (U.S. General Accounting Office 1995). CDC can take a more active role in exploring ways of encouraging hospital-based adult immunization policies, perhaps in conjunction with HCFA's Peer Review Organizations, the Joint Commission on Accreditation of Health Care Organizations, and the National Committee for Quality Assurance.

It is time to reconsider the current ordering of immunization priorities in the United States. According to GAO, DHHS responded to its adult immunization report by stating "that the Congress has previously guided CDC to place priority on childhood immunization." The report continues: "However, GAO concluded that one reason why the Congress has not emphasized a public health role in adult immunization is because HHS has not taken a leadership role in promoting its importance" (U.S. General Accounting Office 1995, 5). Pneumococcal and influenza vaccination are universally available under Medicare and hepatitis B vaccine is covered for many beneficiaries, yet these diseases continue to be major killers of older Americans. The laws of the land neither prohibit nor restrict increased use of immunization funds for adult programs. Effective strategies to enhance adult immunization rates have been identified. Now, the political will is needed to bring adults into a truly nationwide immunization effort.

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