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Leighton Ku, PhD, MPH, Florence Tyler and Marsha Simon, SM, PhD

October 2022

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

MJS &Co.

Acknowledgements

The authors gratefully thank Mary Anne Chafee, Debbie Change, Ruth Katz, Jerry Klepner, Karen Pollittz, Tim Westmoreland and Deborah von Zingkelnagel, for their willingness to be interviewed for this project, as well as for their work on the Vaccines for Children Program legislation in 1993. We thank Naomi Seiler of George Washington University for her thoughtful review and comments. We also thank Simon & Co. team members Karen Late, Juliana Cameron and Tierney Collins.

The primary funder for this project was Sanofi which supported Simon & Co. George Washington University was a subawardee of Simon & Co.

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Executive Summary

Congress passed the Vaccines for Children (VFC) program as part of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) after a call to action by President Bill Clinton. VFC is a federal entitlement program that has successfully provided vaccines at no cost to millions of Medicaid-eligible, uninsured, partially insured, and other needy children. This report focuses on the legislative intent of Congress in creating VFC. The legislation does not specifically define what vaccines are covered and instead places the authority to determine the list of recommended pediatric vaccines with the Advisory Committee on Immunization Practices (ACIP), a federal advisory committee of the Centers for Disease Control and Prevention (CDC).

Our assessment, based on a review of legislative and historical documents as well as interviews with experts who were key congressional or administration staff when the legislation was being developed, is that the responsibility for determining the list of covered vaccines was entrusted to ACIP, acting under the authority of the Secretary of Health and Human Services (HHS) and Director of CDC, because of the committee's scientific and technical expertise and because ACIP was insulated from politics. The original charge to ACIP – which was created by the Surgeon General in 1964 – authorized it to consider a wide range of preventive agents that could help control communicable diseases, including some that were not considered traditional vaccines. Our assessment is that Congress affirmatively chose to have experts in ACIP determine the list of vaccines under VFC, which includes the authority to consider innovative preventive agents that provide immunity against communicable diseases. Our assessment does not include a recommendation of whether VFC should or should not approve the use of any particular preventive agent, only that the legislative history indicates that consideration of a broad range of preventive agents falls within the scope of ACIP's authority, and that ACIP has authority to subject any such preventive agents to its scientific review and recommendation process.

Introduction

The Vaccines for Children (VFC) program has been a critical component of U.S. child health policy since its enactment in the Omnibus Budget Reconciliation Act of 1993 (OBRA 93 and implementation beginning in 1994. VFC provides access to authorized vaccines at no cost to Medicaid-eligible children, uninsured children, children whose insurance coverage excludes vaccines and Indian children, which amounts to roughly half of all American children.[1] Spurred by a measles epidemic in 1989-91, which might have been prevented by higher vaccination rates of preschool children, the program entitles children who might otherwise lack financial access to developmentally appropriate vaccines that have been approved by the Food and Drug Administration (FDA) and recommended by ACIP.[2]

VFC is credited with substantially increasing vaccination rates among U.S. children, thereby preventing harm from infectious diseases, as well as narrowing racial/ethnic disparities in those rates.[3] A 2014 assessment by the CDC estimated that higher vaccination rates prevented 322 million infections and 21 million hospitalizations among children, saving $295 billion in medical costs and nearly $1.4 trillion in overall societal costs.[4]

The specific question addressed in this paper – raised in part by Sanofi, a pharmaceutical manufacturer and funder of this project – is whether the legislative intent of VFC is consistent with coverage of innovative, disease-preventing agents. Such agents include monoclonal antibodies (mAbs). For example, a mAb is under development that aims to prevent Respiratory Syncytial Virus (RSV), a common and serious communicable disease that affects children, especially infants.[5] [6] [7] MAbs are not traditional vaccines in terms of their mechanisms of action but, may also be used to prevent infections. Traditional vaccines, like attenuated viruses, provide active immunization – stimulating the patient's immune response to produce antibodies often over a period of time, while some mAbs may provide passive immunization. They are long-acting laboratory-designed antibodies that are directly given to the patient to directly confer immunity and prevent infection. Such mAbs could play an important role in the immunization landscape for certain illnesses such as RSV, where infants may benefit from immediate, directly conferred (rather than induced) immunity. (Note: Some mAbs are also used as antiviral medications for treatment of certain diseases, as compared to prevention, including COVID-19. This paper focuses on innovative agents, like preventive mAbs, and their role in the immunization landscape. The policy question is whether VFC could support the purchase and distribution of such innovative preventive agents.

Study Objective and Methodology

The objective of this study is to examine the legislative history of the VFC program to assess the legislative intent of Congress and the Clinton administration (which originated the proposal) in the program, specifically to understand whether innovative agents like preventive mAbs or immunoglobulins could be considered for coverage in VFC. We do not make any recommendation about whether such agents or whether specific products *should* be approved for use in VFC; we lack the scientific expertise to make such a recommendation. Rather, the specific issue is whether the creators of the legislation intended to allow the program to cover other agents, beyond traditional vaccines, that can prevent communicable diseases.

To do so, we reviewed the legislative history of the program, as revealed in a literature and document review, and interviewed key individuals in July, August and September 2022 who were involved in the development and ultimate enactment of the VFC legislation as Sec. 13631 of OBRA 93, P.L. 103-66.[1] We note that by 2022, almost 30 years after enactment and creation of the program, all the staff contacted had long since left their positions. The staff contacted were developed based on a list of Congressional staff initially prepared by Marsha Simon, who had been a senior Senate health staffer on one of the two committees of jurisdiction, the Labor and Human Resources Committee. Although she was not involved in drafting the VFC legislation, she worked on VFC in other ways, both advising Sen. Ted Kennedy, chair of the committee, on the program's design and managing the committee's OBRA 93 provisions including VFC.

Using an informed consent process, we contacted the former staff and asked them if they were involved in the legislation. If they asked for backup information, we shared a number of legislative documents (e.g., bills, hearings, and final legislative language). If they consented, we interviewed them and asked if they had other suggestions for persons to interview. Through that process, we also contacted two former HHS staff who were actively involved, as our interviewees were clear that VFC was an administration, more than congressional, initiative. Between July and September 2022, we interviewed seven experts involved in the legislation. We heard consistent information in these interviews, reaching what qualitative researchers call "saturation," so that it was not necessary to conduct further interviews.[8] All interviewees worked for the Democratic side, which was in the majority of both chambers at the time of the bill's passage. We invited minority (i.e., Republican) staff who were involved, but none accepted our interview invitation.

Pediatric Vaccine Initiatives Prior to VFC

Even before VFC, the federal government had an interest in supporting childhood immunizations. In 1962, President John F. Kennedy signed the Vaccination Assistance Act of 1962, which developed a program also known as the Section 317 Immunization Grant Program that provided grants to states and cities to help them purchase vaccines for mass immunization programs, using federal annual appropriations funding.[9]

In 1964, the Surgeon General created the Advisory Committee on Immunization Practices (ACIP), under CDC's jurisdiction, in order to have a single body with scientific and technical expertise that could consider evidence and offer advice about vaccine policy and administration. ACIP's original charge was specifically not limited to any technical definition of vaccines but encompassed "preventive agents" generally as part of broader immunization efforts, efforts that provide protection from infectious disease through stimulating the body's immune response. Minutes of its first meeting noted that:

> The Committee is charged with the responsibility of advising the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control. Included among the agents to be considered by the Committee are inactivated and live-attenuated bacterial, rickettsial and viral agents; toxoids; anti-toxins; chemoprophylactic agents; and immune globulins. The Committee shall concern itself with immunization schedules, dosages and routes of administration and indications and contraindications for the use of these agents.[10]

From 1989 to 1991, a measles epidemic (with over 55,000 cases) increased public concern about the need to increase vaccinations among children to prevent communicable diseases. In late 1991, Sen. Don Riegle, Chair of the Subcommittee on Health for Families and the Uninsured in the Senate Finance Committee, proposed a Comprehensive Child Health Immunization Act (S. 2116) to expand and organize a child immunization effort, including an authorization for annual appropriations, and held a hearing on the topic,[11] although the legislation did not advance.

The Legislative History of VFC

In early 1993, newly-elected President Bill Clinton proposed a broad initiative "to ensure that all of America's children are immunized on schedule against vaccine-preventable diseases such as polio, mumps, measles, whooping cough, and diphtheria."[12] Spurred by the recent measles epidemic and findings that vaccination rates were considered inadequate and that rates were even further depressed among low-income and minority children, the proposed initiative would have established a universal entitlement for children. It was noted that many children lacked financial access to vaccines, both because some children were uninsured and because private insurance at that time often did not include coverage for vaccines. (Note: It was not until the 2010 Affordable Care Act (ACA) that federal law required most private insurance policies to cover key preventive services including vaccinations.)

The White House and the Department of Health and Human Services (HHS) and worked with Congress to develop legislation for a major childhood immunization program that could serve all children. In April 1993, the chairs of the committees of jurisdiction proposed three key bills in response to the President Clinton's call to action:

- H.R. 1640, Comprehensive Child Immunization Act of 1993, proposed by Rep. Henry Waxman, Chair of the Health and Environment Subcommittee of the House Energy and Commerce Committee.

- S. 732, also called Comprehensive Child Immunization Act of 1993, proposed by Sen. Ted Kennedy, Chair of the Senate Labor and Human Resources Committee.
- S.733, the Comprehensive Child Health Immunization Act of 1993, proposed by Sen. Don Riegle, Chair of the Subcommittee on Health for Families and the Uninsured of the Senate Finance Committee.

While the bills differed, there was a strong common interest. In fact, the Senate Labor and Human Resources Committee and the House Energy and Commerce Committee held an unusual joint committee hearing on their bills on April 21, 1993, featuring testimony by Donna Shalala, the Secretary of HHS.[13]

Neither these nor subsequent bills specifically named the vaccines that should be covered under VFC but instead described an approach to revising the list of covered vaccines. All three of these early bills proposed relying on panels convened by HHS to determine the vaccines covered under the new programs. Both S. 732 and H.R. 1640 required vaccines to be selected by ACIP, which as of 1993 was recommending six vaccines.[14] S. 733 called upon HHS to develop and revise lists on an annual basis without specifying how.

The immunization initiative became a component of a broader budget reconciliation strategy, which eventually coalesced under OBRA 93. Budget reconciliation is a special legislative approach to fast-track high priority fiscal legislation.[15] Under the Congressional Budget Act of 1974, reconciliation bills allow expedited consideration of legislation that "reconciles" budgetary targets in the annual Congressional budget resolution with relevant authorizing legislation, which often involves combining multiple bills from separate Senate and House committees. Budget reconciliation votes on motions to proceed and final passage cannot be filibustered on the floor of the Senate, which permits them to be debated and passed with a simple majority of the Senate, rather than the 60 votes needed to stop a filibuster. Reconciliation bills primarily relate to authorizing legislation that affects entitlement, taxation or debt reduction, not provisions to authorize programs funded through the separate annual appropriations process.

Including the initiative in the budget reconciliation process ultimately had three important consequences. First, it meant VFC would be an entitlement program, not subject to annual appropriations. Second, it made the total cost of the program more important because the legislation was subject to overall budget limits specified in the budget resolution. And, third, despite the cost, the initiative was otherwise easier to pass because it would be bundled with other high priority proposals in an omnibus bill that could be passed by a simple majority in the Senate.

As with much legislation, there were disagreements and negotiations about the shape of the initiative. Our review of legislative documents and interviews with key staff revealed that major areas of contention were:

- The scope of eligibility: whether it would be universal for all children, only for children on Medicaid or for a subset of children (children covered by Medicaid, uninsured children, children whose insurance did not cover vaccines and Indian children, as established in the final legislation). Some of the objection to a universal program concerned the notion that it might cover children of millionaires (an early 1993 staff memo illustrated this concern mentioning "Donald Trump's kids" as examples of rich children), as well as the cost of a universal initiative.[16]
- Whether the underlying causes of low vaccination rates were related to financial barriers, as compared to other factors such as poor parental awareness or the limited number of providers who could or would provide free or low-cost vaccines to children in low-income families. Another

disputed problem was the seriousness of supply shortages because manufacturers had limited incentives to produce adequate supplies of the vaccines when there was low uptake.

- Methods of purchasing, storage and distribution of the vaccines, including how the vaccines would be purchased, how prices would be established, how they would be stored and distributed, and who would be able to provide the vaccines (e.g., only community health centers and public clinics or also private physicians).[8]
- Whether universal federal purchases, price-setting or negotiations would reduce revenue for pharmaceutical companies and thereby stymie innovation in the development of new vaccines or other pharmaceutical products. An alternative view was that vaccine support programs could stimulate the demand and supply a steady market for pediatric vaccines, thereby fostering innovation and competition.
- Whether the program would be structured as an entitlement versus a grant program funded through annual appropriations. We were informed that Sen. Dale Bumpers, long known as a champion of vaccines and a member of the Senate Appropriations Committee, favored a grant approach initially, although he subsequently sponsored an amendment to OBRA in the Senate under which it was an entitlement limited to Medicaid children.

Our review indicated that a consensus existed about the need for efforts to bolster vaccination rates in order to reduce the spread of communicable diseases to children, but the mention of specific diseases and vaccines was largely limited to vaccines and vaccine-preventable communicable diseases known at the time. At that time, there was almost no awareness about the potential for novel disease preventing products such as mAbs or immunoglobulins for prevention of communicable diseases.

There was consensus that decisions about these vaccines as preventive agents should be made by a technically knowledgeable, science-based entity that was insulated from the political process, such as ACIP. Both historical documents and our expert interviews revealed there was also a consensus about the need to periodically update the list of covered vaccines as scientific knowledge and availability of vaccines advanced.

After the initial proposed bills, other relevant bills were proposed:

- H.R. 2138, the Medicare and Medicaid Budget Reconciliation Act of 1993, was filed on May 17, 1933 by Rep. Waxman. This bill included a number of Medicare and Medicaid policies that could be included as part of a reconciliation package. Sec. 5181 of this version modified eligibility for vaccines to children on Medicaid, uninsured children, children whose insurance coverage did not include vaccines and Indian children, as did the final legislation. It specified that ACIP was to determine the list of vaccines. The program was designed as an entitlement to states to receive federally-purchased vaccines for distribution to eligible children.
- H.R. 2264, the final version of OBRA 93 introduced in the House by Rep. Martin Sabo, Chair of the House Budget Committee, to the Committee of the Whole, prior to House passage on May 25, 1993 and passed on May 27. This was an omnibus bill developed with input from multiple authorizing committees, in compliance with the Congressional budget resolution. The immunization provisions were based on H.R. 2138, described above.
- H.R. 2432, the Responsible Parent Immunization Plan Act of 1993, was introduced by Rep. David Camp on June 16, 1993. It was a Republican counterpart to Democratic bills. It focused on efforts to increase responsible parent behavior, such as by requiring immunizations for families receiving benefits under AFDC or the Food Stamp Program, as well as by establishing an authorization of an appropriation to buy vaccines for uninsured children. It authorized HHS to

determine and revise the list of vaccines covered. The bill did not advance in the Democratic-controlled House.

- S. 1134, the Omnibus Budget Reconciliation Act of 1993, was filed by Sen. Jim Sasser, Chair of the Senate Budget Committee, on June 22, 1993. Like H.R. 2264, it was assembled with input from the various authorizing committees required to meet their spending and revenue "reconciliation instructions" from the Budget Committee. The version of the immunization legislation contained in this bill largely resembled S. 733 from the Senate Finance Committee, which closely followed the House reconciliation bill.

A significant event in the Senate debate came from a floor amendment to OBRA by Sen. Dale Bumpers, submitted during the "Vote-a-rama" phase of potential amendments prior to initial Senate passage on June 24, 1993. As noted earlier, Sen. Bumpers was viewed as a champion for and expert on childhood immunizations. His amendment would have granted eligibility for the free vaccines only to children on Medicaid but allowed states to purchase additional vaccines for distribution based on the federal price, with funding supported by the appropriations process.[17] [18] It would have substantially reduced the scope and cost of the program. The amendment passed by voice vote after a bipartisan vote of 69 to 39, with support from 39 Republican and 30 Democratic Senators to waive a Sen. Riegle budget point of order against the amendment, despite the opposition from Democratic leadership.

The Final Version of OBRA 93

The House and Senate assigned conferees to reconcile the House and Senate versions of the OBRA legislation. The final version of the child immunization section approved by the conference committee was much closer to the House version (H.R. 2264/2138) proposed by Rep. Waxman than the Bumpers amendment version, although it was more limited than Waxman's initial proposal. The conference version of OBRA 93 was approved in the House on August 5, 1993. In final consideration of the bill in the Senate on August 6, Sen. Danforth (R-M) raised a point of order to overturn a decision by the Parliamentarian (which found that the bill did not violate the "Byrd rule" and was therefore germane to budget issues and majority vote privileges of a reconciliation bill), but lost the vote 43-57, clearing the way for final Senate passage later that day. President Clinton signed OBRA 93 on August 10, 1993, becoming Public Law 103-66.

In the final bill the program was named the "Vaccines for Children program" and established an entitlement to the free vaccines for children on Medicaid, uninsured children, children who receive vaccines from federally qualified health centers or rural health clinics who are not otherwise insured for vaccines, and Indian children.[1] It established a system to purchase and distribute the vaccines at no cost through registered providers, including private pediatricians or other physicians, and reimbursed them for administration of the vaccine.

The final legislation (Sec. 13631) defines vaccines by referencing subsection (e): "*The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee of Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).*"

Subsequent public health assessments of VFC have attributed much of its success in the years since enactment to two elements of the legislation.[2] [9] The first element is VFC's open-ended entitlement status, which ensures that there is adequate funding and a stable program structure to provide vaccines for eligible children, independent of the uncertainties of the federal appropriations process. Second is the role of ACIP as a technically knowledgeable and credible body that reviews and determines the list of covered vaccines based on scientific evidence, insulated from other political or

governmental considerations. Over the years, ACIP has expanded the list of covered vaccines from six to sixteen, increasing the range of preventive agents, as well as the diseases that can be prevented through safe and effective vaccinations.

Highlights of Key Interviews

In addition to our review of the legislative history of VFC and ACIP, we spoke to seven experts who worked on the legislation while it was being developed, considered and enacted in the early 1990s; some had worked on this issue even before the 1993 legislative session. They include: **Tim Westmoreland**, **Ruth Katz, Mary Ann Chafee, Debbie Chang,** and **Deborah von Zinkelnagel,** who were key Congressional staff, as well as **Jerry Klepner** and **Karen Pollitz**, who were key staff at HHS. In the three decades since that time, all have left those positions, but kindly consented to speak with us.

Collectively, they described the origins of the legislation, the perspectives of their respective bosses who chaired key committees or worked on legislation for the administration, and disagreements and compromises made as the legislation evolved. We specifically asked all of them about the intent of Congress in giving ACIP the central role in determining what would be on the "pediatric vaccine" list and the need to ensure that new scientific developments could be considered. While they mentioned policy disagreements in many areas during the development of the legislation, there were no significant differences in their recollection of key facts, although in some cases it was difficult to remember some details decades later.

Tim Westmoreland was a counsel for the majority staff on the House Energy and Commerce, Subcommittee on Health and the Environment, under Congressman Henry Waxman. With Ruth Katz (chief public health counsel on the subcommittee), he worked closely with members of the Clinton administration and other Congressional offices to originate and guide the legislation. He recalled the initiative as originating from the Clinton White House: President Clinton had even begun to discuss the idea during his presidential campaign in 1992 and, after winning, hoped it could be an initial achievement in his Administration and perhaps a "warm up" to a later national health reform effort. Secretary of HHS Donna Shalala called Rep. Waxman to ask him to introduce the legislation as chair of the Health and the Environment Subcommittee of Energy and Commerce Committee with both public health and Medicaid jurisdiction. Westmoreland recalled that Rep. Waxman hoped that the legislation would remove all barriers to vaccines and relative preventive care for children. There were some disagreements over the original proposal, including the issue of universal eligibility and whether the program should be structured as an entitlement or a grant program.

The initial bill (H.R. 1640) proposed by Rep. Waxman, developed in consultation with HHS and the White House policy staff, proposed giving the authority to establish the list of vaccines to ACIP, because it was a well-respected body with scientific expertise and credibility in the area of vaccines and prevention of communicable diseases. This had not been an element of the original Clinton proposal.

Ruth Katz (see above) worked closely with Tim Westmoreland on this legislation on behalf of Rep. Waxman and the House Subcommittee on Health and the Environment. Since we interviewed Westmoreland first, our interview of Katz was more focused. She recalled that their office had a more expansive vision of the program, a universal program akin to that proposed by the Clinton Administration, although they had to modify the draft bill as it evolved, ultimately leading to the version that was accepted in the House-Senate conference committee and the final OBRA 93 legislation. She concurred that there was a universal consensus about the salience of having ACIP

determine the list of vaccines available under VFC because of the committees' recognized technical expertise in assessing future innovations and public health needs. She noted also that an alternative, such as specifying the vaccines in the legislation, was unacceptable because it would require constantly amending the legislation as new scientific information became available, which would be politically difficult and was outside the expertise of Congress anyway.

Debbie Chang was the staff policy director for Sen. Don Riegle, who chaired the Senate Finance Subcommittee on Families and the Uninsured. Because of Riegle's role on the powerful Senate Finance Committee, Chang was the lead staff person in the Senate, working closely with Sen. Kennedy's and Rep. Waxman's staff as well as with HHS and the White House. She remembered a White House meeting in February 1993, where the newly elected President discussed his interest in the initiative and sought support from Congress. As noted above, their office had already supported broader childhood immunization efforts even before Clinton was elected and agreed to shepherd the new initiative. While there were some disagreements about some details of the nascent legislation as the bill evolved within the Senate, there was a broad agreement about the importance of the issue and the use of an expert panel to determine the list of pediatric vaccines. Since ACIP was already formed, had the right technical expertise and was considered credible, it was an appropriate body for that purpose. While she did not recall specific discussion about preventive agents that were not approved by FDA as traditional vaccines, she recalled interest in ongoing innovation in vaccine development and concern about the relative shortage of vaccine manufacturers.

Ms. Chang had an important role in crafting language for the bill that met specifications for budget reconciliation and potential points of order. A particular concern was the threat of a violation of the "Byrd rule," a Senate procedural rule concerning whether elements of budget reconciliation legislation are germane to budget issues.[15] Violations of the Byrd rule can lead to provisions being struck from the bill, unless there is a vote of 60 votes or more. When this became an issue, the Parliamentarian ruled that there was not a Byrd rule violation, clearing the way for retention in the budget reconciliation, although there was a floor vote proposed by Sen. Danforth to deny reconciliation under the Byrd rule, but that vote failed, clearing the way for Senate passage. As noted above, the reconciliation provisions that came from Sen. Riegle's bill were modified by the floor amendment submitted by Sen. Bumpers. But after the Senate-House conference committee, the final OBRA resembled the version from the House Energy and Commerce Committee and was closer to Riegle's bill.

Jerry Klepner served as the Assistant Secretary for Legislation in HHS, the office that handles Congressional relations, reporting to Secretary Shalala. He recalled that President Clinton (and First Lady Hillary Clinton) had promoted the child health initiative during the 1992 presidential campaign. Once President Clinton was in office, Klepner's office was tasked with working with Congress, the White House and CDC to achieve that goal. The initial idea from the Clinton Administration was for a universal purchase of vaccines through the federal government for all children, with supplementary warehousing and distribution of those vaccine products throughout the country. They had a strong preference to establish the new program as an entitlement that would have permanent budget authority and funding, rather than be subject to the political ups and downs and delays of the appropriations process. Although the Administration did not originally propose using ACIP, it supported designating ACIP as the body to determine which vaccines would be eligible, to ensure that there was a *science-based* body deciding which vaccines should be covered. Klepner reiterated the importance of being science-based several times. An additional factor was to keep the selection process insulated from politics, which could be the driving factor if Congress had to select the

vaccines. HHS was supportive of ensuring that the process permitted multiple manufacturers of vaccine products to be eligible, believing that competition could help keep prices down.

Karen Pollitz worked closely with Jerry Klepner; she was the Deputy Assistant Secretary for Health Legislation at HHS. She was appointed after Klepner and was less involved at the very beginning but played more of a role later. She recalled that CDC expressed a strong preference for a broad entitlement program, as opposed to one requiring annual appropriations. There was substantial discussion and debate about eligibility, purchasing, storage and distribution of the vaccines, but there was consensus on the need to keep the list of vaccines up to date and everyone involved in discussions supported the role of ACIP in making determinations. She noted that ACIP was considered better insulated from politics, as compared to letting an executive branch political appointee develop the list.

Mary Ann Chaffee was a health legislative assistant to Sen. Dale Bumpers (D-Ark). Sen. Bumpers had longstanding interest in childhood vaccination and was an advocate for immunizations. Even earlier in his career as a governor of Arkansas, he and his wife, Betty Bumpers, had championed vaccination initiatives. As a member of the Senate Appropriations Committee, he had worked with the Carter and subsequent administrations to support funding for the Section 317 immunization grant program. Their office was concerned about the scope and structure of the program, preferring a more limited program with a stronger role for states in the distribution of vaccines, using the existing commercial channels of trade, as opposed to a more federalized approach. She described the Senator's belief that the program should be well thought out and done by experts on the subject. She mentioned that the Senator illustrated the point on the Senate floor about careful design, using a specially designed insulated box that held vaccines to show how a carefully thought out, recognizing current reality, was essential.

Despite Sen. Bumpers' interest and expertise, he was not a member of relevant authorizing committees, such as Senate Finance or Labor and Human Resources Committees, which limited his ability to influence and shape the legislation through the normal committee process. He proposed an amendment that was approved on the floor of the Senate in debate on the OBRA legislation, described above, that reshaped and limited the program. However, the language was modified in the House-Senate conference committee, but Sen. Bumpers was not a member of the conference committee. With support from both Senate and House Democratic leaders, the version that ultimately emerged from the conference committee was primarily based on Rep. Waxman's language. Sen. Bumpers was influential in championing increased efforts for child immunizations but had less of a role in its final specifications.

Deborah von Zinkelnagel served as a health policy advisor to Sen. Ted Kennedy on the Senate Labor and Human Resources Committee (later renamed the Health, Education, Labor and Pensions Committee), which had jurisdiction over certain public health functions, such as the CDC. She focused on communicable diseases and maternal and child health issues and helped staff the joint Senate-House committee hearing on child immunization in April 1993. As the bill evolved and became part of the budget reconciliation process, she acknowledged that the role of the Senate Finance Committee (and Debbie Chang) became increasingly important, although the committees worked closely together in development and final passage of the legislation. Her role focused on ensuring that the bill retained strong public health elements that were appropriate for the control of communicable diseases. While the general vision and importance of bolstering pediatric vaccinations to protect vulnerable children was widely shared, they had some reservations that the President's original vision may have been overly broad, a view shared by some in the CDC. The Congressional legislation secured important progress but was more restrained.

She agreed that there was a consensus of support for the role of ACIP in determining and revising the vaccines to be covered under the legislation because of the committee's technical expertise in this area. They recognized that further technological innovations would occur and that under the Secretary's authority ACIP could assess the new information and vaccine products. In retrospect today, she noted that certain provisions of the legislation, such as authorizing HHS to conduct price negotiations with vaccine manufacturers, were foresighted in nature and continue to be important issues in drug and vaccine policy.

Assessment of Legislative Intent Regarding Innovative Agents

In establishing VFC, Congress did not specifically define what a "pediatric vaccine" was, but referred to a list developed by ACIP. As we have described, there was a clear and consistent desire of Congress to place that responsibility in the hands of a scientific body with technical expertise in this area that was insulated from politics, as compared to decisions that might be made by Congress or political appointees at HHS. Nonetheless, ACIP operates under the authority of the Secretary of HHS and Director of CDC.

ACIP met those criteria. Its members are selected by HHS based on applications and nominations for voting members who have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine, plus one member who is a consumer representative to offer perspectives on the social and community aspects of vaccination.[19] There are non-voting *ex officio* members who are government officials as well as liaisons from relevant scientific and professional associations. Since 1972, when ACIP was designated as a federal advisory committee, it has operated under principles of transparency, such as requiring open meetings and reporting.[20]

As noted earlier, ACIP has always been authorized to consider a broad array of preventive agents for communicable disease control, not just traditional vaccines that have a particular mechanism of action. The original charge for ACIP in 1964 was to give advice about "*the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control. Included among the agents to be considered by the Committee are inactivated and live-attenuated bacterial, rickettsial and viral agents; toxoids; anti-toxins; chemoprophylactic agents; and immune globulins*."[10] ACIP has defined immunization broadly: "Immunization can be active or passive. Active immunization is the production of antibody or other immune responses through administration of a vaccine or toxoid. Passive immunization means the provision of temporary immunity by the administration of preformed antibodies." [21] ACIP's current charter, updated in March 2022, states that ACIP may recommend "the general use of vaccines and immune globulin preparations as a class of biologic agents" and the "use of specific antibody products for prevention of infectious diseases," indicating the committee's continuing recognition of the potential role of novel immunizing preventive agents like mAbs or immune globulins.[22]

Much of ACIPs technical review of preventive agents is conducted by working groups of selected experts, who then prepare recommendations for the overall ACIP voting membership. Since 2010, ACIP has used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess evidence about vaccines in a consistent and transparent fashion.[23] Since 2019, ACIP has also used health economics information to be considered in its assessments.[24]

In 2019, ACIP recommended some use of novel immunizing preventive agents in recommending the role of immunoglobulins as adjuncts to vaccinations for Hepatitis A.[25] ACIP has already convened both adult and pediatric working groups that have met to examine monoclonal antibodies for RSV, although the recommendations are still pending.[26] In discussion of RSV, the CDC

working group has described a number of potential preventive agents for RSV, including mAbs, as "vaccines."[24]

Our assessment, based on the legislative intent of Congress in creating the Vaccines for Children program and in designating the Advisory Committee on Immunization Practices to determine the list of pediatric vaccines covered by VFC, is *that ACIP has the authority to examine a broad array of preventive agents for communicable disease control, including innovative agents that immunize against communicable childhood diseases, and to include them in the list of vaccines that would be covered by VFC.* This view has also been supported by Prof. Sara Rosenbaum, a legal expert who was a White House staff person during the development of the VFC provision of OBRA 93 and who was a voting member of ACIP from 2009 to 2013.[27]

This interpretation does not mean that ACIP *ought to* include any particular mAb that prevents communicable diseases on the VFC list, or that ACIP *ought to* include any particular *other product* on the VFC list. It simply means the evidence indicates that Congress affirmatively delegated the authority to make such determinations to ACIP on the basis of its technical expertise, and that the history of ACIP indicates that it has a broad authority to assess all preventive agents for potential inclusion in the VFC. Any such product-specific decisions should be made after a sound scientific review of the evidence by ACIP, as well as meeting other relevant federal requirements, such as FDA approval.

Potential Future Innovations

The recent worldwide emergence of the COVID-19 pandemic and the even more recent concern about a monkeypox epidemic has heightened public health concern about the risks of communicable diseases, including newly emergent ones, and the importance of agents that may help prevent transmission. At the same time, technological innovation is expanding the potential range of preventive immunizing agents that can prevent and help control communicable diseases. Vaccine support programs like VFC can help expand access to vaccines to those who might otherwise have problems getting access, reducing the number who become infected. At the same time, to the extent that these programs increase utilization of vaccines, they may help sustain markets for vaccines to provide incentives for production and further technical innovations.

VFC has successfully increased vaccination rates, lowered racial disparities, reduced infections and prevented premature deaths among children.[3] [4] It built upon an earlier (and still extant) federal program, the Section 317 Immunization Grant Program, which supports local, state and federal immunization programs. Since 1993, VFC has been a critical part of protecting the health of children by expanding access to vaccines to prevent the spread of communicable diseases. As new communicable disease threats confront the nation and the world, it will be important to assure that VFC has the flexibility and authority to update the list of covered vaccines.

Additional Federal Policies to Expand Access to Vaccines.

Sec. 2713 of the ACA marked the next major step in expanding access to vaccinations and preventive services. It requires that most private insurance and Medicare beneficiaries and Medicaid adults covered under ACA expansions be offered evidence-based preventive services without cost-sharing, including vaccinations recommended by ACIP, as well as preventive services recommended by the U.S. Preventive Health Services Task Force (USPSTF) or child or women's health services recommended by the Health Resources and Services Administration (HRSA). This guarantees access to free vaccinations (and other preventive services) to a broad group of Americans, particularly adults with private insurance, or Medicaid beneficiaries newly eligible under the ACA (nondisabled, childless poor adults). The recently enacted Inflation Reduction Act eliminates cost sharing for Part D covered

vaccines for Medicare beneficiaries in January 2023. In addition, traditional Medicaid adult beneficiaries, as of October 2023, will for the first time have coverage on all ACA recommended vaccines without nominal cost-sharing.

A legal challenge to these policies is possible. A recent case in a U.S. federal district court in Texas – *Braidwood Management v Becerra* (previously called *Kelley v Becerra*) – raised the issue of the constitutionality of delegating certain decisions to entities like ACIP.[28] [29] The issue in that case dealt with the ACA's delegation of decisions about required preventive services and vaccines to ACIP, USPSTF and HRSA. The plaintiffs argued that this violated the so-called 'nondelegation doctrine' by granting executive authority to bodies not appointed by the President without providing an 'intelligible principle' to guide the agencies' discretion. In *Braidwood,* the court found that the use of ACIP and HRSA did not violate the nondelegation doctrine because both are ultimately subject to the authority of the Secretary of HHS (and in ACIP's case the CDC director) who is a Presidential appointee, but the court did not agree about the authority of the USPSTF to require coverage of Pre-Exposure Prophylaxis (PrEP) for prevention of HIV transmission. The court still has not specified its final recommendations in this case, as of mid-September 2022. Nonetheless, the case is controversial and is likely to be appealed, perhaps ultimately reaching the Supreme Court, so the issues remain unresolved for now.[30]

In its fiscal year 2023 budget proposal, the Biden Administration proposed creating a mandatory Vaccines for Adults program as a counterpart to VFC, as well as expanding VFC to children eligible for the Children's Health Insurance Program (CHIP).[31] A public health law expert has also further articulated the potential importance of a VFC-like program for adults, to provide an ongoing sustainable safety net program for vaccine access for adults, in light of the problems of the COVID-19 pandemic and the need for a broader vaccine support system.[32] These proposals have not advanced further, but reflect a perception that the VFC has been a model program and could form a basis for future efforts to support the availability of immunizing preventive agents to address communicable disease outbreaks and preserve public health.

References

[1] Centers for Disease Control and Prevention. VFC Program Distribution of Pediatric Vaccines. No date. This includes the text of Sec. 13631 of OBRA 93 and conference report language. https://www.cdc.gov/vaccines/programs/vfc/about/distribution.html

[2] Schwartz J, Colgrove J. The Vaccines for Children Program at 25 — Access, Affordability, and Sustainability. *New Eng J Med.* 2020 June; 382(24): 2277-79.

[3] Walsh B, Doherty E, O'Neill C. Since the Start of the Vaccines for Children Program, Uptake Has Increased, and Most Disparities Have Decreased. *Health Affairs.* 2016 Feb; 35(2): 356–364:

[4] Whitney C, et al. Benefits from Immunization During the Vaccines for Children Program Era, United States, 1994–2013. *MWMR.* 2014 April; 63(16): 352-55.

[5] Avalere Health. Innovations in Prevention: Implications for Pediatric Patient Access and Public Health. Nov. 2020. https://avalere.com/wp-content/uploads/2020/12/20201116_Sanofi-RSV-mAb-White-Paper_v5.0.pdf

[6] Workgroup Presentations for CDC's Advisory Committee on Immunization Practices about Respiratory Syncytial Virus. June 23, 2022. https://www.youtube.com/watch?v=BBrCiGMys5Y

[7] Hammitt L, Dagan R, Yuan Y, et al. Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants. *New Eng J Med.* 2022 Mar 3;386(9):837-846.

[8] Saunders B. et al. Saturation in qualitative research: exploring its conceptualization and operationalization. *Quality and Quantity.* 2018; 52(4): 1893–1907.

[9] Roper L, Hall MA, Cohn A. Overview of the United States' Immunization Program. J. *Infectious Diseases.* 2021; 224(S4): S443–51

[10] Minutes, Meeting No. 1, Advisory Committee on Immunization Practices, May 25-26, 1964. Dated July 6, 1964. https://stacks.cdc.gov/view/cdc/77545

[11] Impact of Medicaid on Child Immunization. Hearing Before the Senate Subcommittee on Health for Families and the Uninsured, Senate Finance Committee, June 1, 2022. S. Hrg. 102-885. US Govt Printing Office.

[12] Robinson C, Sepe S, Lin K. The President's Child Immunization Initiative- A Summary of the Problem and the Response. *Pub Health Rep.* 1993 Jul; 108(4): 419-26.

[13] Comprehensive Child Immunization Act of 1993. Joint Hearing of the Senate Labor and Human Resources Committee and House Energy and Commerce Committee, April 21, 1993. Serial Number 103-23, House Energy and Commerce Committee. US Govt Printing Office.

[14] The specific vaccines were referenced in the testimony of HHS Secretary Shalala in the Joint Congressional hearing, cited above.

[15] Kogan R, Reich D. Introduction to Budget "Reconciliation". Center on Budget and Policy Priorities. Updated May 6, 2022. https://www.cbpp.org/research/federal-budget/introduction-to-budget-reconciliation

[16] Memo from Marsha Simon and Deborah von Zinkelnagel, legislative staff to Sen. Ted Kennedy, Feb. 4, 1993. Shared by Marsha Simon.

[17] Congressional Record. June 24, 1993, pg. 14115-6. Text of Bumpers amendment and floor discussion.

[18] Childhood Immunization Program Expanded. *1993 CQ Almanac*. Pg. 368.

[19] Centers for Disease Control and Prevention. ACIP Committee Members. https://www.cdc.gov/vaccines/acip/members/index.html

[20] Smith J, Hinman A, Pickering L. History and Evolution of the Advisory Committee on Immunization Practices — United States, 1964–2014. *MMWR*. 2014 Oct; 63(42): 955-958.

[21] Centers for Disease Control and Prevention. Vaccine Recommendations and Guidelines of the ACIP – Appendix 1: Glossary, Centers. for Disease Control & Prevention. Mar. 15, 2022, https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/glossary.html.

[22] Centers for Disease Control and Prevention. ACIP Charter. Updated March 2022. https://www.cdc.gov/vaccines/acip/committee/charter.html

[23] Centers for Disease Control and Prevention. GRADE Evidence Tables – Recommendations in MMWR. No date. https://www.cdc.gov/vaccines/acip/recs/grade/table-refs.html

[24] Centers for Disease Control and Prevention. CIP: Guidance for Health Economics Studies, effective as of the ACIP meeting of October 23-24, 2019. https://www.cdc.gov/vaccines/acip/committee/economic-studies.html

[25] Advisory Committee on Immunization Practices. Vaccines for Children Program: Vaccines to Prevent Hepatitis A. Resolution No. 6/19-6. https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html

[26] Centers for Disease Control and Prevention. ACIP Work Groups. No date. https://www.cdc.gov/vaccines/acip/workgroups.html#rsv-pediatric

[27] Rosenbaum S. A Twenty-First Century Vaccines for Children Program. *Health Affairs Forefront*. Jul. 12, 2022. https://www.healthaffairs.org/content/forefront/twenty-first-century-vaccines-children-program

[28] Memorandum and Order from Judge Reed O'Connor, US District Court, Northern District of Texas, Fort Worth Division re: *Braidwood Management, Inc. v. Xavier Becerra*, Sept. 7, 2022.

[29] Keith K. Court Holds That Key ACA Preventive Services Requirements Are Unconstitutional. *Health Affairs Forefront*. Sept. 8, 2022. https://www.healthaffairs.org/content/forefront/court-holds-key-aca-preventive-services-requirements-unconstitutional?utm_medium=email&utm_source=hat&utm_campaign=narrative&utm_content=9+9+2022&vgo_ee=o3eP1FgyD9RQHmjzxmpLgA%3D%3D

[30] Jost T. Texas Judge Finds ACA Requirement for Preventive Services Without Cost Sharing Invalid. Sept. 14, 2022. https://www.commonwealthfund.org/blog/2022/texas-judge-finds-aca-requirement-preventive-services-without-cost-sharing-invalid

[31] Dept. of Health and Human Services. *FY 2023 Budget in Brief*. https://www.hhs.gov/sites/default/files/fy-2023-budget-in-brief.pdf

[32] Hughes R. Rethinking Access to Immunizations After COVID-19: Assuring A Vaccine Safety Net for All American. *Health Affairs Forefront*. April 7, 2022. https://www.healthaffairs.org/do/10.1377/forefront.20220406.527026/

[30] Advisory Committee on Immunization Practices (ACIP): ACIP Charter, Centers for Disease Control & Prevention (Mar. 31, 2022), https://www.cdc.gov/vaccines/acip/committee/charter.html.