



Statement Opposing S.B. 2276

The Biotechnology Industry Organization (BIO) respectfully submits the following statement in opposition to the universal vaccine purchase program set forth in Senate Bill 2276. While we recognize that the state is seeking options to increase the administrative ease of vaccine administration, we believe that the proposed program would have exactly the opposite effect: creating a large state-run bureaucracy established for the sole purpose of purchasing and distributing vaccines. Further, the program stands to jeopardize the nation-leading vaccination rates North Dakota already enjoys, decrease the State's attractiveness for biotechnology investment, and potentially places the State's existing contract for vaccines with the U.S. Centers for Disease Control (CDC) in jeopardy. It is for all these reasons that we believe the Committee should reject S.B. 2276.

BIO is a national trade organization, based in Washington, D.C., representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in research and development of healthcare, agricultural, industrial and environmental biotechnology products.

Initially, we want to point out that while we recognize that administrative process issues exist with local public health administration and follow-up under the current vaccine program in North Dakota, it is also true that these local public health units account for only about 10% of immunizations given in North Dakota. This bill places in jeopardy a currently-existing immunization program with the third highest immunization rate in the United States in order to deal with billing and administration issues for a very small proportion of the vaccine landscape in the State. Surely there are more narrowly tailored options the state can explore short of a wholesale reorganization of an already very successful program. BIO would be happy to participate in a discussion of these alternative options.

What is more is that a universal purchase program, as envisioned in S.B. 2276, is legally suspect. More specifically, because the Vaccines for Children (VFC) contract that the State has with the CDC to purchase vaccines for certain underinsured individuals has strict prohibitions on the resale of vaccines purchased through the program, the proposed universal purchase option in this bill, with the corresponding insurance company assessment, risks running afoul of North

Dakota's entire VFC contract. More specific detail on this issue is provided in the attached analysis done by BIO's outside legal counsel.

Finally, universal purchase programs like the one envisioned in S.B. 2276 send a message to start-up and established biotechnology companies and investors that a state is hostile to a private market for new and innovative therapies. This is exactly the wrong message any state wants to send during this time of economic recovery and job re-creation. Certainly North Dakota, a state that has invested so much in growing a competitive biotechnology industry, does not want to begin sending mixed messages to new investors.

It is for all these reasons that **BIO opposes Senate Bill 2276**. Surely there are less draconian measures the State can take to address minor administrative issues in certain vaccine administration sectors. And we at BIO stand ready to help in any discussion of alternatives.

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Legal and Public Health Policy Concerns Regarding
State Use of Private Funds to Buy through the VFC Program

OVERVIEW

Under the Vaccines for Children (VFC) program, created by Section 13631 of Omnibus Budget Reconciliation Act of 1993 (OBRA 93),¹ the Centers for Disease Control and Prevention (CDC) is authorized to contract with vaccine manufacturers to ensure that every state has a sufficient quantity of vaccines to vaccinate specified classes of disadvantaged children—namely: uninsured, Medicaid-eligible or underinsured children,² and children of Indian tribes.³ This program sets forth a laudable goal that the Biotechnology Industry Organization (BIO) fully supports.

Recently, however, several states have attempted to fund the purchase of additional vaccines for already insured children through the federal VFC contract by using funds provided by insurance companies or other private entities. While this may initially seem to be attractive to states for various reasons, these programs violate the stated purpose and intent of the VFC program; ultimately are likely to cost the programs and the states more money; and may also constitute a violation of federal contracting law. More specifically, using private funds in this manner could:

- Lead to an increase in a state’s administrative costs for its immunization programs;
- Serve as a de-facto subsidy to private insurers and health plans;
- Represent a misinterpretation of the standard VFC contract by inappropriately using the optional purchase contract clause;
- Distort both the state and national vaccine marketplace significantly enough over the long-term to cause an adverse economic impact on the states’ ability to effectively maximize their immunization funds; and
- Would be unnecessary as these programs will become obsolete in light of the health insurance expansion and vaccine coverage provisions included as part of the Affordable Care Act of 2010 (ACA).

Initially, one of the more relevant upcoming health system changes under the ACA will render these programs unnecessary. Specifically, pursuant to the terms of the ACA, by 2014 most, if not all, private insurers will be required to cover all vaccines recommended by the CDC’s Advisory Committee on Immunization Practices (ACIP) at first-dollar for individuals of all ages. Given that immunizations will be available free of charge to nearly every citizen, there is no reason to believe that a state setting up a program to buy vaccines from the federal contract will make any difference whatsoever in state immunization rates.

Over the next few years children and adolescents who are uninsured or *underinsured* are expected to shift into health plans providing first-dollar coverage for vaccines or into new state exchanges when they become available. In the interim, programs buying off of the VFC contract by using insurance pools should be discontinued, or at least strongly discouraged, as they represent an unnecessary subsidy to private insurers and a shift in the national vaccine marketplace that may negatively impact future vaccine supply and private investment. Additionally, and as importantly, these programs may conflict with several federal contracting standards.

¹ Pub. L. No. 103-66, § 13631, 107 Stat. 312, 636-45 (codified at 42 U.S.C. § 1396s).

² This category includes children immunized with qualified vaccine in Federally-qualified health centers or rural health centers who are not insured with respect to the vaccine. 42 U.S.C. § 1396s(b)(2)(A)(iii).

³ 42 U.S.C. § 1396s(b)(2) (collectively “VFC-eligible children”).

1) The VFC Program Permits Purchases With State Appropriated Funds – Not Private Insurance Funds

In addition to the core purpose of providing vaccine for VFC-eligible classes of children, each state may use its own funds to purchase additional vaccine from VFC contracts for additional non-VFC-eligible children⁴ in connection with the state’s administration of its pediatric immunization program.⁵ *OBRA 93 intended such “optional” purchasing for state vaccine programs to be funded by state appropriated funds. It was not intended to permit others (such as private insurers) to gain access to a public benefit.*

Consistent with this limitation, CDC’s VFC contracts state that “[i]n addition [to purchases for VFC-eligible children], States may opt to purchase vaccine under any resulting contract not included in [the] above categories by using their own funding mechanism.”⁶ A state “funding mechanism” must be understood in the context of its legislative history—which contemplated public, not private funds—and the CDC’s administration of the VFC program.⁷ State funds by definition must be limited to the money appropriated by state legislatures. Indeed, just as state funds are “revenue or money of a [state] body”⁸ “established for a specific [state] purpose,”⁹ so too are appropriations, which result from “[a] legislative body’s act of setting aside a sum of money for a public purpose.”¹⁰ *Our interpretation of this language is that only these state funds can be used to purchase vaccines under the VFC Program.*

2) Private Funding of State Vaccine Purchases May Violate VFC Contracts

By using money from private insurance companies to fund optional vaccine purchases, states are, in some sense, selling the vaccine to those companies at discounted prices in violation of the VFC contract. In its contracts with manufacturers, CDC prohibits such sales by strictly limiting the distribution of vaccines purchased through the VFC contracts to those specifically permitted by the VFC statute. Specifically:

- Vaccines obtained under this contract shall be used only as authorized under section 1928 of the Social Security Act. *Sale of such vaccine to any person or entity is strictly prohibited;*¹¹ and
- Vaccines obtained under this contract shall be used only in children 18 years of age and younger as authorized under Section 1928 of the Social Security Act. *Sale of such vaccine to any person or entity is strictly prohibited. Free*

⁴ 42 U.S.C. § 1396s(d)(4)(B).

⁵ OBRA 93 requires each state to provide for a program for the distribution of pediatric vaccine for the immunization of “vaccine-eligible children,” which include VFC-eligible children and state vaccine-eligible children. 42 U.S.C. § 1396a(a)(62). State vaccine-eligible children, are those children “within a class of children for which the State is purchasing the vaccine pursuant” to the optional funding provisions of § 1396(d)(4)(B).

⁶ CDC VFC Solicitation No. 2010-N-11860, § B; CDC VFC Solicitation No. 2010-N-11873, § B.1.

⁷ See 139 Cong. Rec. 19,824 (1993).

⁸ See Black’s Law Dictionary (9th ed. 2009) (defining “public fund”).

⁹ See *id.* (defining “fund”).

¹⁰ *Id.* (defining “appropriation”).

¹¹ See, e.g., CDC VFC Solicitation No. 2010-N-11860 (Flu), § C.1.18, Restrictions on Use of Vaccines (emphasis added).

*distribution of such vaccine is also prohibited, except where such vaccine is administered in the context of Grantee immunization program activities.*¹²

The term “sale” has been defined in a simple sense as “[t]he transfer of property or title for a price.”¹³ This term includes situations where product is paid for or “covered” by a third party such as the private vaccine pooling arrangements contemplated by some of the states.¹⁴ It is the essence of these state insurance funding proposals: an insurance company pays the state to purchase vaccine at a discounted price for the beneficiaries of the state or insurance company immunization program that the company (or the state) otherwise would have had to negotiate directly with the manufacturer.¹⁵

3) Private Funding Subsidizes Health Plans and May Impact Future Vaccine Supply

Over the years, Federal agencies that procure these products have witnessed many—often creative— attempts by third parties to improperly access Federal contracts for drugs and biologics. Responses to these attempts have been swift and severe¹⁶ because such attempts undermine the government’s basic goals when contracting for supplies.

First, these attempts have been viewed in the past by the government and policymakers as potentially undermining the government’s ability to obtain favorable terms and conditions for its procurements. Second, these attempts to improperly access a Federal contract have been viewed as eroding the government’s ability to maintain sources of supply that are willing to contract with the government. As a result, they ultimately threaten the availability of necessary products for the government’s beneficiaries and programs.

As such, contract language prohibiting resale is a standard term in the government’s multiple award contracts such as the CDC’s VFC contracts. One stark example of this type of language can be found in Federal Supply Schedule (FSS) contracts administered by the General Services Administration and the Department of Veterans Affairs, which place a clear resale limitation on FSS contract users.¹⁷ Just as clearly, CDC states that products obtained from VFC contracts cannot be sold or given away. Simply put, we believe the sale of vaccine bought under the VFC contract is unauthorized and undermines the CDC’s ability to administer the VFC program, which inhibits its goal to provide necessary vaccine to VFC-eligible children.

These strict limits also are of critical importance in terms of maintaining adequate supply of vaccine for children in the specified classes set forth in the VFC statute. By the terms of the VFC contract, vaccine manufacturers must honor orders from state purchasers: “[State optional] orders shall not be subject to refusal by the manufacturers.”¹⁸ To permit a dramatic increase in inappropriate or unauthorized

¹² CDC VFC Solicitation No. 2010-N-11873 (Non-Flu), § C.17, Restrictions on Use of Vaccines (emphasis added).

¹³ Black’s Law Dictionary (9th ed. 2009).

¹⁴ See, e.g., Dep’t of Veterans Affairs, Office of Gen. Counsel, “Dear Manufacturer of Covered Drugs Letter” (Oct. 14, 2004) (TRICARE Retail Pharmacy rebates); 10 U.S.C. § 1074g(f) (same); 32 C.F.R. § 199.21(q) (same).

¹⁵ The VFC statute was never intended to replace the existing ability of states to negotiate contracts directly with manufacturers to obtain vaccine for non-VFC children: OBRA 93 was “not intend[ed] to limit [a] State’s current ability to negotiate independently for vaccine purchasers, if they do not elect this option.”). H.R. Rep. No. 103-111, at 230 (1993), *reprinted in* 1993 U.S.C.C.A.N. 378, 557.

¹⁶ See, e.g., Dep’t of Veterans Affairs, Nat’l Acquisition Ctr., “Dear Contractor Letter” (Oct. 1, 1999) (discussing improper access of Federal Supply Schedule prices by certain Indian tribes).

¹⁷ See, e.g., GSA Order 4800.2F ¶ 7(d)(5) (2009) (“Authorization to use GSA sources of supply under the authority cited in this paragraph does not include purchases for resale unless the contract, grant, cooperative agreement, or funding agreement authorizes such activity.”).

¹⁸ CDC VFC Solicitation No. 2010-N-11860, § B; CDC VFC Solicitation No. 2010-N-11873, § B.1.

state optional orders, based on privately-funded initiatives to gain access to the VFC contracts, would decrease the total vaccine available under each contract's maximum order quantity threshold. Put another way, the state pooling arrangements would redirect a large portion of a potentially limited quantity of vaccine from the specified classes of children who are meant to benefit from the VFC program, to the general population. This could prove untenable in the long-run.

And, taken to their logical end, state insurance-funded arrangements could result in providing manufacturer-subsidized vaccine to every child in the state—insured or otherwise. This would create a subsidy for the insurance companies, as the costs of immunizing their beneficiaries would be reduced.

The implications of this subsidy are the distortion of the current economic dynamic associated with either the VFC Program, the rest of the vaccine marketplace, or both. Assuming the normal economic trade-offs between the VFC Program and the rest of the marketplace occur, a distortion in the volume of vaccines under the VFC Program would adversely impact the weight and composition of the rest of the vaccine market. Ultimately, over some period of time, and based on the normal economic dynamics of a free market, a state's purchasing power would be diminished.

The small group of vaccine manufacturers welcomes ACA's focus on prevention and immunization. We are hopeful that ACA will strengthen markets and create incentives for new investments around vaccines. We would also suggest that state and federal governments have a strong interest in a robust vaccine marketplace: ACA's focus on prevention could lead to new vaccine market entrants. But, this will only occur if the marketplace is robust and competitive. If governments signal now that they are willing to replace the private vaccine market (which might blossom under ACA provisions) with government purchase programs --that potentially subsidize private payers at the expense of manufacturers -- it is reasonable to assume then that a more robust and competitive vaccine industry and market will not materialize.

4) Provisions in the Affordable Care Act Reduce the Need for State Purchases

Title I of the ACA included key provisions that are expected to have a positive impact on coverage of preventive services, and especially immunizations, over the next several years. New health plans are now required to offer first-dollar coverage of all ACIP-recommended vaccines for all individuals¹⁹. This provision, coupled with the creation of the Essential Benefits Package and the State Exchanges²⁰, is anticipated to significantly reduce the number of underinsured and uninsured children in the nation, thereby helping to reduce any existing burden on state budgets.

Given this significant change in the private insurance markets, there is no longer the need for states to expend additional resources to use their funds to buy vaccines off of the VFC contract, and there certainly is no need for the inappropriate use of funds from private insurers in possible violation of VFC contracts. Over the next few years, children and adolescents who are currently uninsured or underinsured are expected to shift into new state exchanges or health plans. In the interim, programs such as insurance pools should be discontinued, or at least strongly discouraged, as they represent an unnecessary subsidy to health plans and a shift in the national vaccine marketplace that could negatively impact future vaccine supply.

In sum, with the understanding that laws and legislative intent are subject to interpretation, we firmly believe that these programs that purchase VFC vaccines using private funds may violate legal standards and could lead to unintentional negative consequences in the vaccine marketplace. At a minimum these

¹⁹ Pub. L. 111-148 & 111-152, § 1001, page 14.

²⁰ Pub. L. 111-148 & 111-152, § 1311, page 66.

“assessment” programs violate the intent and spirit of the law and represent flawed public health policy. Taking into account the planned changes to the health system over the next few years, these programs are unnecessary and will serve principally to create another state-run bureaucracy while adding significantly to a state’s administrative cost burden without immunizing more children.

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