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SALE OF STATE VACCINE LABORATORY

House Bill 5300 as enrolled

Public Act 8 of 1998

Sponsor: Rep. Lingg Brewer

House Committee: House Oversight

and Ethics

Senate Committee: Appropriations

Senate Bill 846 as enrolled Public Act 9 of 1998

Sponsor: Sen. Robert Geake

Senate Committee: Appropriations House Committee: Appropriations

Second Analysis (2-10-99)

THE APPARENT PROBLEM:

In a move to privatize the state vaccine laboratory, Governor Engler issued Executive Reorganization Order (ERO) 1995-25. The order, among other things, transferred the Michigan Biologic Products Division of the then-Department of Public Health to a two-year, temporary state agency, the Michigan Biologic Products Institute, which was to be sold to a private business no later than two years after the executive order took effect.

Legislation implementing privatization of the state vaccine laboratory was quickly enacted at the end of the 1995-96 legislative section, in the form of the Michigan Biologic Products Institute Transfer Act (Public Act 522 of 1996). Among other things, the act specifically allows institute employees (or a group composed in whole or in part of institute employees) to "bid on or make a proposal to acquire the assets and enter into [one] or more agreements related to the conveyance of all or a portion of the assets to the employee or group." (Otherwise, Article 4, Section 10 of the state constitution prohibits members of the legislature and state officers from "be[ing] interested directly or indirectly in any contract with the state or any political subdivision thereof which shall cause a substantial conflict of interest" and requires the legislature to implement this provision by appropriate legislation, which has taken the form of Public Act 318 of 1968.) The MBPI transfer act also exempts

employees of the institute who accept employment with a potential "acquirer" of the institute's assets from violating the state ethics act (Public Act 196 of 1973) so long as the employee provides written notice to the commission of the proposed employment and terms before the agreement is executed.

Though the executive order specified that its provisions were to become effective December 15, 1995, it actually became effective on February 4, 1996. Thus, the deadline for privatization of the laboratory became February 4, 1998. Questions were raised about the process of privatizing the institute's assets, and legislation was introduced in both houses of the legislature-- in the House in October 1997 and in January 1998 in the Senate -- to extend the deadline for selling the Michigan Biologic Products Institute to the private sector and to appropriate additional funds for the operation of the institute until it is sold.

THE CONTENT OF THE BILLS:

House Bill 5300 would amend the Michigan Biologic Products Institute Act to statutorily establish the Michigan Biologic Products Institute as an independent, autonomous state agency in the Department of Community Health and to statutorily establish the Michigan Biologic Products Commission as a temporary state commission. Senate Bill 846

would amend the same act, adding three new sections (MCL 333.26336a, 333.26336b, and 333.2633c) to make an \$18 million supplemental appropriation to the Department of Community Health for fiscal year 1997-98 to be used for operating the Michigan Biologic Products Institute and to repeal the \$9 million appropriation in the 1997-98 General Government Appropriation Act. Of the \$18 million appropriation, \$15 million would come from biologic products sales and other revenues and \$3 million from federal revenues. The bill also would allow the institute to receive the following "contingency" funds, should they become available: up to \$5 million in federal contingency funds, up to \$5 million in state restricted contingency funds, up to \$100,000 in local contingency funds, and up to \$500,000 in private contingency funds.

The Michigan Biologic Products Institute. Effective February 17, 1998, House Bill 5300 would transfer the Michigan Biologic Products Institute, which was established by Executive Order 1995-25 (see BACKGROUND INFORMATION), to the Department of Community Health as a "Type I" transfer.

Paralleling language in the 1995 executive order, the bill would specify that the institute would be "an independent and autonomous entity." The institute and its director, who still would be appointed by the governor, would exercise the powers and perform the duties prescribed by the act "independently of the principal executive departments of this state, including but not limited to, personnel, budgeting, procurement, and management-related functions." (In comparison, the executive order says that the institute "shall be an independent and autonomous entity with the intent that its authority, powers, duties and responsibilities and the authority, powers, duties and responsibilities of the Director, including personnel, budgeting, procurement and management-related functions, be exercised free from the direction and supervision of the principal departments of the Executive Branch.")

The bill would specify that the director of the institute would be the head of the institute, within the meaning of the Executive Reorganization Act of 1965, and would be the "appointing authority" for purposes of Section 5 of Article XI of the state constitution of 1963 (which provides for the classified state civil service). The executive order, in comparison, says that the director "shall be the head of the Institute within the meaning of the Constitution of the State of Michigan of 1963, and of the Executive Organization

Act of 1965, and shall be the Appointing Authority as the term is used in the Constitution of the State of Michigan of 1963, and in the rules and procedures of the Civil Service Commission."

Finally, under the bill, the institute would have the powers, duties, and responsibilities prescribed in -- and would operate under and in accordance with -- Executive Order 1995-25.

The Michigan Biologic Products Commission. As in the executive order, under the bill, the commission would consist of three voting members appointed by the governor who weren't employees of the institute and who would serve at the pleasure of the governor. The governor would designate one of the appointed members to serve as commission chair, also at the pleasure of the governor. Commission members would continue to serve without compensation, but be reimbursed for necessary travel and other expenses under the standard travel regulations of the Department of Management and Budget. (The executive order refers to "reimbursement for necessary travel and expenses according to relevant procedures of the Civil Service Commission and the Department of Management and Budget.")

The commission would have the powers, duties, and responsibilities prescribed in the executive order, which requires the commission to "provide supervision, policy control and direction to the Institute, and the Director," and which allows it ("consistent with the provisions of the executive order") to "establish general goals and objectives relating to the operation and development of the [institute] for the guidance of the Director."

The executive order further requires the commission to do the following:

- 1. Within eight (8) months of their initial organization meeting, prepare, or cause to be prepared under contract, a detailed business plan with supporting documentation, including, but not limited to, any necessary legislation, describing the means by which the Michigan Biologic Products Institute will be transferred out of state government and into the private sector within the two year term of this temporary agency status under this Executive Order.
- 2. As part of the business plan, cause the fair market value of all state property, inventory, equipment and other assets associated with the manufacture of biologic products to be determined.

- 3. Contract with the initial Director; designate and contract with any future Directors.
- 4. Perform such other duties and responsibilities as may be assigned or transferred to the Commission by statute or executive order."

Senate Bill 846 also would amend the Michigan Biologic Products Institute Transfer Act to appropriate \$18 million for the fiscal year ending September 30, 1998, to the Department of Community Health for the operation of the Michigan Biologic Products Institute, and to repeal an earlier \$9 million appropriation for the same fiscal year. Senate Bill 846 as enrolled became Public Act 9 of 1998.

<u>Tie-bar</u>. Neither bill would take effect unless the other bill were enacted. (House Bill 5300 was enacted as Public Act 8 of 1998; Senate Bill 846 was enacted as Public Act 9 of 1998.)

MCL 333.26333 et al.

BACKGROUND INFORMATION:

State production of vaccines and biologic products. As an article in the November/December 1997 Senate Fiscal Agency "Notes on the Budget and Economy" ("Privatization of the Biologic Products Program," by fiscal analyst Pam Graham) notes, the history of state involvement in producing vaccines and other "biologic products" was a result of the diphtheria epidemic of 1921, during which Michigan is said to have had the highest diphtheria rates in the world. Though the state started out producing only a diphtheria vaccine, over time it expanded its production to include other products, including a typhoid vaccine, silver nitrate (once used to prevent gonorrheal infection in the eyes of newborn infants), DPT (diphtheria-pertussis-tetanus) vaccine, tetanus toxoid, diphtheria-tetanus toxoids, rabies vaccine, anthrax vaccine (Michigan is the only American producer of this vaccine), botulinum toxiod, pertussis vaccine, human albumin (a blood product). immune serum globulin, and anti-hemophilic factor. As the SFA article notes, historically, the products manufactured by the Department of Public Health's Biologic Products Division were made available free of charge to state residents, primarily through the local public health network. In addition, some of the products were sold at cost to other states, and some to nongovernmental entities through contracts.

The original 1921 legislation allowed the state to make products related to the control of diphtheria, but this law was repealed and replaced in 1927 with a law that allowed the Department of Public Health "to produce or purchase any biologic product necessary to control the spread of communicable disease and to distribute such products free of charge." (SFA "Note") Over the years, the Department of Public Health continued to produce and develop vaccines and other biologic products important in controlling the spread of disease in both humans and in non-human animals. State production of vaccines was important not only with regard to the 1920s diphtheria epidemic, however. In the mid-1980s, when there was a national shortage of the DPT vaccine (due, reportedly, primarily to the fact that two of the only three private manufacturers of the DPT vaccine at that time stopped making it, citing product liability concerns), Michigan was one of only two states (the other being Massachusetts) not affected by the shortage because it produced its own vaccine (as did Massachusetts).

However, as the SFA article notes, beginning in the mid-1980s questions began to be raised about the propriety of the state being involved in what by that time had become a major private sector enterprise (namely, the production of vaccines and other biologic products). In fact, the governor's 1986-87 budget recommendation apparently included a proposal to eliminate all state general fund/general purpose appropriations for the Department of Public Health's biologic products program, under the assumption that the department would begin to charge for the products it distributed, possibly including those it had historically distributed free of charge in the state to meet public health needs. Despite the temporary resurgence of support in the mid-1980s for the state to remain involved in the production of vaccines in light of the exodus of private manufacturers from the DPT vaccine market, subsequent changes both in federal policy, in the vaccine industry, and in the general political climate changed the context of the privatization discussion.

The 1986 Federal Childhood Vaccine Injury Act significantly reduced private manufacturers' exposure to liability -- thereby leading to a return of private sector industry to vaccine production -- even as it increased the cost of production to the two states still manufacturing their own vaccines. The 1986 federal law, among other things, assessed an excise tax on each dose of vaccine produced, and used the tax to

fund a national vaccine injury compensation pool. While this reduced private vaccine manufacturers' costs by significantly reducing their liability, it increased the costs to the states producing their own vaccines without any corresponding benefit (since the state programs already were protected by governmental immunity). The 1993 Federal Omnibus Budget Reconciliation Act (OBRA 93) also reduced the cost savings to the two states still producing their own vaccines by expanding the scope of the federal government's provision of childhood vaccines. According to the SFA article, before the 1993 federal OBRA, the federal government provided the state with approximately 50 percent of the vaccines administered through the state Department of Public Health; after enactment of OBRA 93, the department estimated that the federal government would provide between 75 and 90 percent of the state's needed vaccines. Thus, OBRA 93 significantly reduced the annual savings realized by the state through its production of the DPT vaccine, while the 1986 federal vaccination indemnification law added to the state's costs in producing such vaccines.

Finally, as the SFA article notes, changes in the vaccine industry since the early 1990s also have provided further impetus for the privatization of the state's biologic products program. One involves the development of an "acellular" pertussis vaccine (which European countries had been using for years because it has fewer adverse side effects than the older, wholecell pertussis vaccine, which is what the United States had been using and which the state had produced in its combined diphtheria-pertussis-tetnaus vaccine) and the industry trend toward combining ever greater numbers of vaccines into single "combination" doses (for example, a combined DPT-Haemophilus influenzae type-b vaccine already is licensed and distributed). Thus, one of the state program's "mainstay" vaccines, the DPT vaccine, is virtually outmoded and not in great demand.

Executive Reorganization Order (ERO) 1995-25. Executive Reorganization Order 1995-25, which sought to privatize the state vaccine laboratory, found that:

(a) "[T]he functions, duties and responsibilities assigned to the Biologic Products Division [of the Department of Public Health] c[ould] be more effectively administered and executed outside the Michigan Department of Public Health, due in part to the need of the Biologic Products Division to meet Federal regulatory and commercial requirements";

- (b) "[T]he long-term capability of the Biologic Products Division to meet Federal regulatory and other commercial requirements c[ould] best be achieved by removing the Division from state government as soon as is practicable"; and
- (c) "[T]he manufacture of products by the Biologic Products Division [was] not critical to the mission of the Michigan Department of Public Health."

The order, which took effect on February 4, 1996, transferred (a) the Michigan Biologic Products Division of the Department of Public Health and (b) the Pharmaceutical Product Fund (which was housed in the Department of Treasury but administered by the Department of Public Health) to a newly-created temporary state agency, the Michigan Biologic Products Institute (MBPI). The MBPI was to be sold to private bidders no later than February 4, 1998.

The executive order also created a temporary, threemember Michigan Biologic Products Commission, appointed by the governor and charged with determining the fair market value of the institute and developing a plan (including any necessary legislation) for selling the institute to a private sector business within this two-year time period.

Finally, the order required the director of the institute:

- ** to provide executive direction and supervision for implementing the "transfers" of the institute's assets,
- ** to make necessary administrative internal organizational changes to complete the "realignment of responsibilities" prescribed by the order and
- ** to ("immediately") enter into negotiations with other state departments or individuals or groups outside of state government to obtain services such as personnel, budgeting, procurement, security, maintenance, and janitorial services.

The Michigan Biologic Products Institute Transfer Act. Legislation to implement the governor's order to sell the Biologic Products Division of the Department of Public Health (now the newly-created Michigan Biologic Products Institute) was introduced in November 1996, signed by the governor in December 1996, and given immediate effect. The Michigan Biologic Products Institute Transfer Act (Public Act 522 of 1996), among other things, (a) creates a Michigan Biologic Products Commission to negotiate

and approve agreements on behalf of the state for conveying all or some of the institute's assets, and (b) authorizes the State Administrative Board to convey the assets (defined in the act -- see below) and liabilities (not defined in the act) of the state related to the operation of the Michigan Biologic Products Institute.

The act also includes a statement of legislative intent [Section 2], an explicit authorization for institute employees to bid on the institute's assets and to work for the private business that buys the institute's assets [Section 7], and provisions for disposing of the money received from the sale of the institute's assets.

<u>Legislative intent.</u> The act says that the legislature found and declared all of the following:

- (a) That increasing regulatory costs, the need to replace manufacturing facilities, the need to develop and the cost of developing new biologic products, the changing pediatric vaccine market, and the need to serve other markets outside the borders of this state have adversely affected the ability of the state to sustain a viable, self-supporting operation for the manufacture and distribution of vaccines and blood derivative products.
- (b) That allowing the Michigan biologic products institute to be conveyed to a private enterprise would assist the institute to become self-sustaining, avoid the need for future state general fund subsidies, retain the employment of many employees of the institute, and assure the state's access to biologic products to protect Michigan's citizens from infectious disease.
- (c) That the conveyance of the assets associated with the institute will not impair the public health mission of the department of community health and, if the institute is not conveyed to a private enterprise, the operations of the institute will be discontinued. If the operations of the institute are discontinued, the legislature recognizes the need for the disposal of the institute and of costs related to disposal of the assets associated with the institute, both of which the legislature desires to offset by authorizing the conveyance of the assets associated with the institute to a private enterprise.

<u>Institute assets.</u> The Michigan Biologic Products Institute Transfer Act defines institute assets as including real and personal property, product inventory, and intangible property. More specifically, the act defines "assets" to mean "all or part of the

following that are associated with the institute and are subject to conveyance [itself defined in the act to mean 'sale, transfer, assignment, or other disposition'] under" the act:

- (1) Real property, which is defined to mean all or a portion of the almost 60 acres of real property (including mineral rights) in northwest Lansing associated with the institute. More specifically, the institute's "real property" consists of 59.5 acres of land, some of which (12.56 acres) is in Ingham County and the majority of which (46.94 acres) is in Clinton County;
- (2) Personal property (not defined in the act);
- (3) Intangible property (not defined in the act); and
- (4) "Product inventory," which the act says includes, but is not limited to, (a) manufactured products that have and have not been released by the federal Food and Drug Administration for public sale and use and (b) products and their components that are in the process of being manufactured.

Reportedly, 47 of the institute's nearly 60 acres consist of vacant land next to the Lansing Capitol City airport, and the institute also has some 30 or more buildings, some of which reportedly are being renovated with money from the federal government and from a private pharmaceutical manufacturer.

The Michigan Biologic Products Commission. The three-member commission consists of a representative from the governor's office, the director of the Department of Community Health, and a representative (the state budget director) from the Department of Management and Budget.

The act authorizes the commission to do all of the following in conveying the institute's assets:

- ** Determine the assets and liabilities of the institute that are subject to the proposed conveyance that a proposed "transferee" (that is, buyer) would be required to assume;
- ** Negotiate and approve agreements on behalf of the state for the conveyance (i.e. sale, transfer, assignment, or other disposition) of all or part of the institute's assets (and for the assumption of the liabilities all, some, or none of its liabilities) to one or more "transferees," and to authorize an agreement negotiated and approved by the commission to include

"any term determined by the commission to be necessary or convenient for the conveyance of the assets" (including, but not limited to, the retention or rights, interests, and easements in or in the favor of the state to certain assets; an agreement on behalf of the state to grant rights for the future purchase of assets kept by the state; agreements on behalf of the state to buy or sell -- or joint production agreements related to -- steam and other utility services from assets kept or conveyed by the state; agreements on behalf of the state for providing service or products by one or more state agencies to a "transferee" and vice versa; "option" or similar agreements on behalf of and in favor of the state related to the buy back of all or part of "conveyed" assets "upon the occurrence of events specified in the option or similar agreement"; and deeds and other instruments of conveyance associated with real property);

- ** Retain a selling agent to help the commission market the institute's assets and liabilities;
- ** Solicit prospective buyers or other "transferees" for the institute's assets "using the method or methods considered most appropriate by the commission";
- ** Recommend to the state administrative board the terms of one or more proposed agreements with one or more proposed "transferees" for conveying all or some of the institute's assets and for the assumption of all, some, or none of its liabilities:
- ** Upon approval of the state administrative board, authorize the commission chair (or his or her designee) to execute agreements, deeds and other instruments of conveyance, bills of sale, and closing documents necessary to complete the conveyance of all or some of the institute's assets; and
- ** Exercise any other power necessary or convenient to effect or complete the transactions permitted under the act, including, but not limited to, all actions necessary to transfer permits and licenses related to the institute's operation.

Statutory requirements for conveyance. Under the MBPI transfer act, the state administrative board, upon recommendation of the Michigan Biologic Products Commission, may approve and authorize the conveyance of the institute's assets and the assumption of its liabilities subject to certain specified conditions. Thus, before the effective date of the conveyance, the board must determine that the "consideration" to be received is "fair and adequate so that the credit of the

state does not need to be granted to a public or private person, association, or corporation." The terms of the conveyance also must require the "transferee" to provide the state with preferential access to biologic products (including, but not limited to, the first option to access vaccines and biologic products) made by the institute on the effective date of the agreement and licensed by the federal Food and Drug Administration or subsequently made by the "transferee," with this preferential access to be "as determined by the state, and for the period and subject to conditions and prices contained in the agreement").

The MBPI transfer act also requires that the conveyance include a commitment by the proposed "transferee" to continue to employ, for at least a year after the agreement took effect, institute employees who wanted to continue working for the "transferee."

Employee acquisition of institute assets and employment by private buyers. Section 7 of the act explicitly authorizes institute employees ("an institute employee or a group composed in whole or in part of employees of the institute") to bid on or make proposals to acquire the institute's assets and to enter into an agreement or agreements related to the conveyance of all or some of the assets to the employee or group. The act also explicitly exempts institute employees -- "[w]hen acting with the knowledge or upon the direction of the commission or in entering into an agreement to accept employment with a potential acquirer of the assets" -- from state law (Public Act 196 of 1973) otherwise prohibiting state employees from, among other things, profiting from their official position or authority or benefiting financially from confidential information obtained by reason of their state employment, so long as the employee(s) act "with the knowledge or upon the direction of the commission or in entering into an agreement to accept employment with a potential acquirer [i.e. private buyer] of the [institute's] assets . . . if the employee provided written notice to the commission of the proposed employment and the terms of that agreement before its execution."

Disposal of money from the sale of the institute. Up to \$2.5 million from the sale of the institute can be spent on selling the institute, with up to another \$2.5 million authorized for costs related to "employee separation" from the institute. Except for state or local taxes, the act specifies that the sale of the institute's assets is "free and clear of any liens, claims or interests of the state or of a person claiming through or under the state" (thus, for example, products developed by

individual -- or teams of -- state employees working for the institute or its predecessor, the division of the Department of Public Health, would be sold along with the institute and could not be claimed by the employee-developer unless he or she was a private buyer under the act's provisions).

Thus, up to \$2.5 million from the sale can be spent on seller's fees, separation costs (including expenses incurred in moving non-institute employee work stations and other equipment to other state offices and converting institute facilities to private operations), and to pay "other costs related to the negotiation and closing of the agreement for the conveyance of the assets, including title insurance and any opinions or reports required by the State Administrative Board, and the fees of attorneys and consultants used to develop and complete the conveyance." Up to another \$2.5 million from the sale of the institute can be used (a) "[f]or payment of accrued sick and annual leave time to employees of the institute upon separation of employment from the state if current fiscal year appropriations available for that purpose are insufficient;" (b) "[f]or reimbursement of the state for payouts for accrued sick and annual leave time from current fiscal year appropriations available for that purpose to employees of the institute upon separation of employment from the state;" and (c) "[t]o reimburse the state employees' retirement system for the actuarial cost of providing an optional early-out program for employees of the institute whose combined age and service credit equal 70 or greater, regardless of age, on the date of separation of employment." (The act also provided for \$2 million to be appropriated for the fiscal year ending September 30, 1997 and used to renovate ["phase 1-B"] "building 16 for regulatory compliance purposes.")

The rest of the money from the sale (i.e. apart from the \$5 million above) is to go to the Pharmaceutical Products Fund, which is to be administered by the Department of Community Health (the successor state agency to, among other agencies, the Department of Public Health, which had formerly administered the fund) and used only for buying "vaccines and other biologic products necessary to promote and protect the public health." Any institute assets not sold by February 4, 1998 [when the commission is set to expire] are to go to the Department of Management and Budget ["or any other state executive department"], depending on where the state administrative board decided they should go. (Sections 6, 8, and 9)

Chronology.

- ** 1992: The state enters into an agreement with the private pharmaceutical firm SmithKline Beecham (SKB), under which SKB distributes state-produced DPT and rabies vaccines out of state, and SKB and the state are to work together to develop a combination vaccine using both SKB and state-provided components. The contract includes a provision that gives SKB right of first refusal if the state biologic products program is put up for sale.
- ** December 5, 1995: The governor issues Executive Order 1995-25, which removes the Biologic Products Division from the Department of Public Health and establishes it as a temporary, two-year autonomous agency called the Michigan Biologic Products Institute (MBPI) with a temporary governing agency, the Michigan Biologic Products Institute Commission.
- ** November 12, 1996: KPMG Peat Marwick, the valuation and appraisal group retained by the state to make a preliminary determination of the fair market valued of the equity of the institute (as of October 18, 1996), submits a letter to the Department of Management and Budget concluding that it is their "preliminary opinion that the fair market value of the equity of the Michigan Biologic Products Institute on a going-concern basis at the valuation date ranged from nominal, assuming projected anthrax vaccine sales of 1.5 million to 2.5 million doses annually, to \$10.5 million, assuming anthrax vaccine sales of 3.0 million to 5.0 million doses annually at a price of \$3.25 per dose." The letter notes that the valuation approach taken to determine the preliminary value of the institute was the "income approach," under which "value is based upon the estimated future income streams associated with a specific asset, considering the remaining life of the asset, the average annual rate of return anticipated, and market rates of return." The letter also sets out limiting conditions and assumptions, and notes that "For various reasons, the price at which the equity of MBPI might be sold in a specific transaction between specific parties on a specific date might be significantly different from its fair market value as expressed in [the] letter."
- ** November 14, 1996: House Bill 6192, which would convey the assets and liabilities of the institute to the private sector, is introduced and referred to the House Appropriations Committee.

- ** November 20, 1996: House Bill 6192 is reported from committee in version H-1* and referred to second reading.
- ** December 3, 1996: House Bill 6192 (H-1*) is amended, adopted, placed on third reading and passes the House.
- ** December 4, 1996: House Bill 6192 is referred to the Senate Appropriations Committee.
- ** December 5, 1996: House Bill 6192 is reported without amendments from the Senate Committee.
- ** December 11, 1996: House Bill 6192 is reported by the Committee of the Whole, placed on third reading, passes the Senate, and is ordered enrolled.
- ** December 31, 1996: House Bill 6192 is presented to the governor, signed, filed with the secretary of state, and assigned Public Act 522 of 1996, with immediate effect.
- ** January 7, 1997: The director and deputy director of the institute form Michigan Biologic Products, Inc. for the purpose of buying the institute.
- ** January 13, 1997: Public Act 522 of 1996, the Michigan Biologic Products Institute Transfer Act, takes effect.
- ** April 1997: The Michigan Biologic Products Commission engages a selling agent, W.Y. Campbell of Detroit in April 1997, which prepares a marketing strategy, an "offering memorandum" and a "bidders' library," which contains proprietary and other information available for review by potential buyers who sign a confidentiality agreement. At the same time, the state administrative board engages the services of First of Michigan Corporation of Detroit to render the independent "fairness opinion" (of the terms of any conveyance agreement that the commission might make) as required by Public Act 522 of 1996.
- ** May 1997: House Resolution 57 is introduced into the House and referred to the Committee on House Oversight and Ethics. The resolution requests the commission and the state building authority to refrain from selling the institute until an independent appraisal of its value is presented to the legislature.
- ** July 1, 1997: The commission officially put the assets and liabilities of the institute up for sale.

- ** July 9, 1997: The selling agent advertises the sale of the institute in the *Wall Street Journal* in addition to directly soliciting potential buyers.
- ** July 17, 1997: The House Subcommittee on the Sale of the Michigan Biologic Products Institute (a subcommittee of the Standing Committee on House Oversight and Ethics) holds the first of three hearings on the sale of the institute.
- ** August 5, 1997: The commission votes to close the official offering period by August 15.
- ** August 15, 1997: Sixteen (according to the Senate Fiscal Agency) or 22 (according to the Office of Auditor General) firms sign confidentiality agreements by this date, and are given an additional week to revise their agreements and to review the bidders' library. The firms are then asked to sign letters of intent that provide non-binding ranges of value and to prepare to conduct initial "due diligence." Seven (according to the Senate Fiscal Agency) or 5 (according to the Office of Auditor General) firms sign letters of intent. (The auditor general notes that in addition to the 5 potential buvers who signed letters of intent, SmithKline Beecham -- a pharmaceutical firm and an institute customer -- also was allowed to continue in the bidding process because it had a contractual right of first refusal in the event that the institute was put up for
- ** August 21, 1997: The House Subcommittee on the Sale of the Michigan Biologic Products Institute holds its second hearing with the Michigan Biologic Products Commission chair on the agenda for "directed testimony."
- ** August 22, 1997: The commission sets this date as the deadline by which potential buyers must sign a confidentiality agreement allowing them to obtain an offering memorandum.
- ** August 25 through September 26, 1997: The commission arranges 2-day site visits for the firms that signed letters of intent. The site visit gives the potential bidders access to the bidders library, a tour of the institute buildings and grounds, and interviews with institute management. One potential buyer drops out at this point.
- ** September 5, 1997: The commission sets this date as the deadline by which potential buyers who were sent an offering memorandum must submit a

nonbinding letter of intent. The potential buyers who meet this deadline -- one of which is Michigan Biologic Products, Inc. -- are allowed to continue on in the sale process. In addition, SmithKline Beecham, under its contractual agreement, also is allowed to continue in the process under its contractual right of first refusal in the event that the institute was put up for sale.

- ** September 19, 1997: The House Subcommittee on the Sale of the Michigan Biologic Products Institute holds its third and final meeting.
- ** September 26, 1997: The draft majority report of the House Subcommittee on the Sale of the Michigan Biologic Products Institute is released.
- ** October 7, 1997: The draft minority report of the House Subcommittee on the Sale of the Michigan Biologic Products Institute is released.
- ** October 10, 1997: The commission provides the potential buyers copies of its preferred asset purchase agreement, which outlines the conditions of the transfer.
- ** October 10, 1997: House Bill 5300, which would extend the life of the institute for two years, is introduced into the House and referred to the Committee on House Oversight and Ethics.
- ** October 29, 1997: The commission gives the potential buyers this date by which to submit a proposed acquisition price, terms of a preferential access agreement for biologic products, and comments on the proposed asset purchase agreement.
- ** November 3, 1997: By this date, all but three potential bidders drop out of the bidding process.
- ** November 5, 1997: The commission gives one of the potential buyers, Michigan Biologic Products, Inc. (the firm formed by the institute's director and deputy director and other institute managers) five days to demonstrate its financial viability.
- ** November 10, 1997: The commission disqualifies Michigan Biologic Products, Inc. from the bidding process because it was unable to provide proof of sufficient working capital. At the same time, one of the other two potential buyers withdraws from the bidding process, leaving one remaining potential buyer.

- ** November 12, 1997: House Bill 5300, in substitute version H-1, is reported from the Committee on House Oversight and Ethics and referred to second reading.
- ** December 16, 1997: The U.S. Department of Defense announces that it will vaccinate every member of the armed services against anthrax (the only American manufacturer of this vaccine is the Michigan Biologic Products Institute).
- ** January 2, 1998: The commission reopens the bidding process for the sale of the institute.
- ** January 14, 1998: Senate Bill 846, which would transfer the Michigan Biologic Products Institute to the Department of Community Health and extend funding for the institute for the full 1997-98 fiscal year, is introduced and referred to the Senate Appropriations Committee
- ** January 22, 1998: House Bill 5300 (H-1) is adopted by the House; an H-7 substitute, which closely resembles Senate Bill 846 as introduced, is adopted, amended, and passed.
- ** January 27, 1998: House Bill 5300 (H-7) is referred to the Senate Appropriations Committee.
- ** January 28, 1998: Senate Bill 846, in substitute version S-1, is reported from the Senate Appropriations Committee, referred to general orders, reported by the Senate committee of the whole, and placed on third reading.
- ** January 29, 1998: Senate Bill 846 (S-1) passes the Senate and is referred to the House Appropriations Committee.
- ** February 4, 1998: House Bill 5300 (H-7) is discharged from the Senate Appropriations committee and referred to general orders.
- ** February 5, 1998: House Bill 5300 in version S-1 is tie-barred to Senate Bill 846, reported by the Senate committee of the whole, and placed on third reading.
- ** February 10, 1998: House Bill 5300 (S-1) passes the Senate.
- ** February 12, 1998: Senate Bill 846 is reported from House Appropriations in substitute version H-1, now only an appropriations bill. The Senate concurs in

the House substitute, and the bill is ordered enrolled. The House also concurs in the Senate substitute for House Bill 5300, and the bill is ordered enrolled.

- ** February 18, 1998: On the date originally set by the Michigan Biologics Product Commission for completion of the sale of the institute, the governor signs House Bill 5300 (Public Act 8 of 1998) and Senate Bill 846 (Public Act 9 of 1998). Both are given immediate effect.
- ** June 2, 1998: The commission recommends to the state administrative board that the institute be sold to BioPort, Inc. for approximately \$25 million in cash, secured notes, donated products, and royalties. BioPort, Inc., is a Michigan corporation owned by three investors: Intervac L.L.C., a Maryland-based pharmaceutical investment firm with a 58 percent ownership; Michigan Biologic Products, headed by the current institute director, with a 32 percent ownership; and Neogen Corporation, a Lansing-based developer and manufacturer of food safety test kits and veterinary products, with a 10 percent ownership.
- ** June 30, 1998: First of Michigan Corporation of Detroit, hired by the state to render the statutorily required "fairness opinion," issues its letter to the state administrative board, concluding that, based on its review, the transaction whereby the state may sell the assets of the Michigan Biologic Products Institute to Bioport Corporation, "from a financial point of view, is fair to the State of Michigan."
- ** July 6, 1998: The Office of the Auditor General issues its review of the process used by the Michigan Biologic Products Commission to convey the assets and liabilities of the Michigan Biologic Products Institute. The review concludes that the commission complied with the provisions of Public Act 522 of 1996 and that the commission's process was reasonable.
- ** July 7, 1998: The state administrative board votes to sell the institute to BioPort, Inc.
- ** July 9, 1998: The House Fiscal Agency issues its review of the Michigan One Corporation's "fairness opinion" on the proposed sale of the institute as required by Public Act 8 of 1998 (enrolled House Bill 5300).
- ** September 2, 1998: After the state completes its environmental study of the 60-acre property on

Lansing's northwest side, the sale of the institute to BioPort is finalized.

Terms of the sale to BioPort. According to the July 9, 1998, "Independent Fairness Opinion" memorandum presented by the director of the House Fiscal Agency to the House leadership as required by Public Act 8 of 1998 (enrolled House Bill 5300), the basic elements of the sale of the Michigan Biologic Products Institute to BioPort Corporation would be as follows:

- ** At closing, BioPort would pay \$2.25 million by wire transfer and deposit \$1 million cash in an escrow fund that would exist for two years from the closing date and would be used to defray any damages BioPort suffered from "material misrepresentation or nonfulfillment of any provision, agreement or covenant on the part of the [state]".
- ** One year from the closing date of the purchase, BioPort would pay (in full) \$3.15 million in non-negotiable notes at 8 percent interest and \$4.5 million in non-negotiable notes with no interest.
- ** Certain state contracts with the federal Department of Defense, valued at \$4.5 million, would be transferred to BioPort to be used as working capital during its first year of operation, but the loss to the state of these funds would be offset by BioPort paying, over a five-year amortization schedule, \$4.5 million at 8 percent interest on each of the one-year anniversary dates from the closing date. The first \$1 million installment payment would be deposited in the escrow fund established on the date of the sale.
- ** BioPort would pay "base royalty payments" of up to \$5 million, with a maximum of \$1 million a year, over the five-year term of the agreement as follows: annual royalties amounting to 5 percent on all net domestic sales (except for domestic civil anthrax vaccine sales) and 3 percent on "pre-commission" international sales. Subject to the \$5 million cap, these "base royalty payments" also would include a payment for the sixth year following the closing date of the sale of the institute from sales of the anthrax vaccine (again, excluding domestic civil anthrax vaccine sales). In addition to these "base royalty payments," if there were any domestic civil anthrax vaccine sales in each of the six years following the sale of the institute, BioPort would pay 5 percent of such sales.
- ** BioPort would donate three products, with a total current estimated value of \$3.7 million, for each of the five years following sale of the institute, as

follows: 4,000 doses of "rabies vaccine absorbed," with a total estimated value of \$3,027,600; 17,500 vials containing 2 milliliters each of human immune globulin, with a total estimated value of \$315,000; and 13,000 doses of pediatric diphtheria-tetanus toxiods, with a total estimated value of \$347,750.

** For five years, and at an annual rate of \$120,773 (plus \$24,000 for utilities), BioPort would lease to the state Building 29, which would continue to house the neonatal testing unit of the Department of Community Health. According to the House Fiscal Agency memorandum, this five-year rate would be equivalent to a 50 percent discount to the state for leased space, though there also would be a provision for a not-yet-determined "escalation" formula and pro rata pass-through of maintenance and property tax costs.

In addition, the state would remain liable for any contamination that had occurred during its 70 years of owning the state vaccine laboratory, though the cost of any required environmental remediation would reduce the consideration paid to the state by no more than \$1 million.

The Michigan Biologic Products Transfer Act specifies certain conditions under which the Michigan Biologic Products Commission may convey the institute, including giving the state preferential access to biologic products, requiring the purchaser to continue employing institute employees for at least one year, and allowing institute employees to bid or acquire institute assets. Accordingly, the purchase agreement would also include the following provisions:

- ** For a five-year period, manufactured biologic products would be available to the state on a preferential basis at applicable market prices. BioPort also would agree to supply all of the state's needs for biologic products, subject to the limits of its manufacturing capacity and other binding contractual obligations.
- ** BioPort would offer all institute employees of record employment for at least one year from the closing date of the sale of the Institute.
- ** Institute employees would have an opportunity to participate in an employee stock ownership program based on company profitability and employee productivity, with 20 percent of BioPort's stock being reserved for employee participation.

** The House Fiscal Agency memorandum also notes that "It is intended that the level of compensation will be comparable to that presently paid by the state for salaries, wages, and benefits paid to existing employees."

FISCAL IMPLICATIONS:

According to the Senate Fiscal Agency, <u>Senate Bill 846</u> would appropriate \$18 million for the continued operation of the Michigan Biologic Products Institute for the rest of fiscal year 1997-98 or until it was sold. Of that amount, \$3 million would be from federal revenue and \$15 million would come from state restricted revenue. The bill also would authorize 200 full-time equated positions for the operation of the Michigan Biologic Products Institute in fiscal year 1997-89. (1-28-98)

According to the House Fiscal Agency's July 9, 1998, memorandum reviewing the results of the independent fairness opinion on the proposed sale of the Michigan Biologic Products Institute, the state will receive \$2.25 million in cash from the sale of the institute. In addition, the buyer would deposit \$1 million cash in a two-year escrow fund to defray any damages the buyer suffered resulting from material misrepresentation or non-fulfillment of any provision, agreement or covenant on the part of the state, to which would be added another \$1 million one year later from installment payments due under interest-free nonnegotiable notes. Thus, the \$1 million cash on sale and the \$1 million payment due under the interest-free nonnegotiable notes one year later might not ultimately be available to the state as proceeds from the sale.

In addition, the buyer would pay up to \$5 million, over a period of five years, in royalties on sales, plus a royalty on certain potential sales for each of the six years covering the sale closing date. (This amount obviously would be determined by the actual sales figures.) The buyer also would donate an estimated \$3.7 million worth of vaccines over a five-year period, and would lease a building back to the state at a reported 50 percent discount for five years following the sale.

Thus, depending on how much of the escrow account was used by the buyer and on the volume of sales over the five years following the sale of the institute (which would determine the amount of money the state received in royalties), the state would get \$2.25 million in cash, a possible maximum of \$2 million

from the escrow account after two years, and, over the next five years, up to \$5 million in royalties plus an estimated \$3.7 million worth of donated vaccines and savings of potentially 50 percent on the leasing of a building that would continue to house the Department of Community Health's neonatal testing unit.

ARGUMENTS:

For:

While there is general bipartisan agreement that the state vaccine lab should indeed be sold to private sector business(es), serious ethical and financial concerns about the proposed privatization of the state facility have been raised. In particular, significant disagreement exists over whether or not the assets of the institute have been adequately appraised, over the largely nonpublic process for privatizing these assets and the commission's apparent reluctance to divulge relevant information regarding conditions and terms of the proposed sale, over the haste with which the privatization is being pursued, and over the role that possible "insider trading" by potential public employee purchasers has played in the privatization process.

Concerns about the possibility that the assets of the state lab were grossly undervalued were raised when the legislation (Public Acts 521 and 522 of 1996) implementing the governor's 1995 executive order to sell the institute's assets (see the HLAS analyses of House Bills 6191 and 6192 of 1996) was proceeding through the legislature in the 1995-96 legislative session. Significant concerns also were raised about whether the sale of the state facility would have a detrimental effect on the ability of Michigan citizens to obtain access to vitally-needed vaccines in times of vaccine shortages (as occurred in the 1980s), and it was suggested that the process used to further the goal of privatizing the state's vaccine lab was skewed toward achieving privatization at any cost -- including selling state assets for far below their actual value and putting the privatization process on a "fast track" that also greatly impeded responsible legislative oversight. The commission's refusal to provide the legislature with requested information also has troubled some, as has the reported refusal of members of the commission and of the institute director to appear before and respond to questions from the legislative committee investigating these issues.

Although the Michigan Biologic Products Institute Transfer Act exempted institute employees from the state ethics act with regard to bidding or proposing to acquire institute assets, proponents of the bill have

raised serious questions about the role of "insider" public employees who provided information for the preliminary appraisal of the value of the institute's assets that apparently has been used for all subsequent estimates of the value of the institute's assets for the purpose of selling to the private sector. Proponents argue that the 1996 preliminary determination of the "fair market value" of the institute -- which concluded that the value of the equity of the institute as of October 8, 1996, ranged from "nominal" to \$10.5 million -- may not be adequate or accurate because it was based in part on information provided by public employees who also intended to bid on these assets and partly because questions have been raised over whether all of the assets were considered (or were adequately considered) in the appraisal. Proponents of the bill argue that these state assets should be sold for the highest possible price, and that the process -- and its relative secrecy -- so far raises serious questions as to whether or not this will occur under present law.

House Bill 5300 would address some of these issues by extending the deadline for the sale of the institute and by requiring the governing boards of the House and Senate Fiscal Agencies to appoint someone to monitor the progress and review the results of the independent opinion of the fairness and adequacy of "the consideration for the assets or liabilities" of the institute that currently is required under the act. Senate Bill 846 would appropriate funds for the continued operation of the institute and commission for the rest of fiscal year 1997-98, allowing the commission to reopen the bidding process and for the eventual conveyance of the institute to be done in a timely manner.

In addditon, the sale of the state vaccine lab needs to be delayed due to a number of unforseen circumstances, including the fact that all but one of the potential buyers had either dropped out of the bidding process or had been (in the case of Michigan Biologic Products, Inc.) disqualifed by the commission. In addition, SmithKline Beecham's contract with the state, which gave it right of first refusal should the lab be put up for sale, reportedly has been terminated, which potentially increases the likelihood that more private companies might be interested in buying the lab since they won't have to contend with a possible rival deciding the issue for them. Finally, the federal government's announcement in January 1998 that it plans to vaccinate every member of the armed forces against anthrax means that the state vaccine lab's value may well be considerably more than before the announcement. (For, since the state lab is the only

domestic manufacturer of an anthrax vaccine, it most likely will be the federal government's preferred vendor.) Thus, the bidding for the lab should be reopened and the sale date of February 18, 1998, be extended for this new bidding round.

Against:

Opponents of the bill have argued that adequate oversight already has been built into the sales process itself in order to ensure that the state receives "fair consideration" for the assets and liabilities of the institute. They point out that the legislature decided last session, on a solid bipartisan vote, to sell the institute's assets, and that the entire issue of continued state involvement in vaccine and biologic products production was thoroughly debated during passage of this legislation. They argue that retreating from the impending sale and reestablishing the agency is simply not justified.

Opponents of the bill also argue that there is no state purpose being met by the vaccine and blood products laboratories, and that some of the assets (such as the whole-cell pertussis vaccine) have been superseded by newer products developed in the private sector (in this case, an acellular pertussis vaccine). Opponents further argue that the state, which reportedly is the last in the nation to own its own vaccine laboratory, does not have the resources to engage in the kind of costly and time-consuming research and development that is required for vaccines, and that continued state support for the manufacture and distribution of vaccines and blood derivative products has been a drain on the state budget in the past and will continue to be so in the future.

Response:

First, there appears to be general, bipartisan agreement that at this point the state should, indeed, get out of the business of developing and manufacturing vaccines. So the disagreement addressed by the bill no longer is over the eventual sale of the state vaccine lab but rather over the process under which the sale appears to be proceeding.

Secondly, while it is true that bipartisan legislation was enacted in the 1995-96 to implement the governor's executive order privatizing the state vaccine lab, this process was carried out by a legislature in which both the House and Senate were controlled by the same political party to which the governor belongs. Moreover, the legislation was

introduced and enacted so quickly -- it was introduced in November 1996 and signed into law by the governor one month later -- that even though some legislators vigorously objected at the time there never was time to "thoroughly debate" the issue. Extending the deadline for selling the lab in order to ensure that the state receives fair value for the lab's assets is not an unreasonable move. In any case, a previous legislature's decisions clearly are not legally binding on what the current legislature decides to do. It is well established legally that past legislatures cannot bind future legislatures, so to argue that the issue already has been settled is beside the point.

The fact that some of the current vaccine products have been superseded by newer products also apparently is due to the fact that the state lab was prohibited from developing a newer product, at least in the case of the acellular pertussis vaccine. Some people have suggested that this prohibition was part of a pattern of deliberate devaluation of a valuable state resource for the sake of privatization.

Finally, the fact that all parties have been complying with applicable law, if this is indeed the case, does not address the adequacy of that law, which many question and which the bill would begin to rectify.

Against:

While the purchase agreement between the state and the buyer of the state vaccine lab reportedly fulfills the minimum conveyance requirements set forth in the original legislation implementing the executive order to privatize the lab, some people believe that these provisions do not provide adequate legislative oversight nor do they adequately protect current lab employees. Thus, for example, the version of House Bill 5300 reported by the House Oversight and Ethics Committee would have required the records of the Michigan Biologic Products Institute Commission to be available under the Freedom of Information Act and would have required the commission to obtain appropriate state employment for institute employees who chose not to remain with the institute once it had been privatized. At one point, the bill also would have required the directors of the House and Senate Fiscal Agencies to jointly arrange for retaining the services of an independent appraiser to develop an independent appraisal of the institute's fair market value and to make that appraisal available to the legislature before the commission recommended approving sale of the

lab. But in the Senate substitute for the bill, the FOIA provisions were stricken, along with the employee protection provisions and the fiscal agencies' independent appraisals. The process still does not permit adequate public and legislative oversight nor does it protect soon-to-be "privatized" state employees beyond the minimum guarantee of one year's employment after the lab is sold.

Analyst: S. Ekstrom

[■]This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.