

**SALE OF STATE VACCINE LAB:
DELAY FOR 2 YEARS**

**House Bill 5300 (Substitute H-1)
First Analysis (11-13-97)**

**Sponsor: Rep. Lingg Brewer
Committee: House Oversight and Ethics**

THE APPARENT PROBLEM:

In a move to privatize the state vaccine laboratory, Governor Engler issued Executive Reorganization Order (ERO) 1995-25 which, 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 session, 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 have been raised about the process of privatizing the institute's assets, including the possible impact on the sale of these assets given that the institute's director and deputy director have formed a

corporation to bid on the institute's assets. Legislation has been

introduced to slow the process of divesting the state of the Michigan Biologic Products Institute.

THE CONTENT OF THE BILL:

The bill would amend the Michigan Biologic Products Institute Act to statutorily establish both the Michigan Biologic Products Institute and the Michigan Biologic Products Commission under provisions similar to those in the 1995 executive reorganization order (ERO 1995-25), and to extend the lives of both agencies for two years past their current expiration date. Thus, the bill would specify that, effective February 5, 1998, the Michigan Biologic Products Institute and the Michigan Biologic Products Commission would be established as temporary agencies with lives of not more than two years.

The Michigan Biologic Products Institute. Paralleling language in the 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 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 assume "all functions, duties, contractual obligations, responsibilities, inventory, tangible and intangible property, and employees of the Biologic Products Division of the Department of Community Health, including, but not limited to, administration of the Pharmaceutical Products Fund, pursuant to 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."*

The bill also would extend until February 5, 2000, the current deadline (the expiration of the life of the commission, currently set for February 4, 1998) by which time any assets not sold would be transferred to the Department of Management and Budget or another state executive department, as directed by the State Administrative Board.

Application of the Freedom of Information Act to commission documents. The bill would require that writings prepared, owned, used, in the possession of, or kept by the commission in the performance of an official function -- including, but not limited to, documents related to the conveyance of the institute's assets -- would have to be made available to the public in compliance with the Freedom of Information Act.

Terms of 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 bill would require that the terms of the conveyance require that the "transferee":

(1) sell pediatric vaccines to the state at a fixed price, adjusted annually according to the Detroit consumer price index (defined in the bill as "the most comprehensive index of consumer prices available for the Detroit area from the Bureau of Labor Statistics of the United States Department of Labor); and

(2) annually pay the state a royalty of 30 percent of the gross annual sales of federally licensed products (and product components) it made and sold.

Institute employees. 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."

The bill would require that before the effective date of the conveyance of the institute's assets the state administrative board also obtain appropriate employment, from one or more state agencies or departments, both (a) for institute employees who elected not to continue to work for the "transferee," but who wanted to continue to work for the state, and (b) for employees who wanted to work for the "transferee" but who also wanted to return to state employment within 12 months after the effective date of the conveyance.

MCL 333.26333 et al.

BACKGROUND INFORMATION:

The Michigan Biologic Products Institute. The Michigan Biologic Products Institute Transfer Act defines "assets" of the institute to include not only real and personal property and product inventory, but also 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 real property associated with the institute (including mineral rights), and, more particularly, two parcels of land, one in Ingham County of 12.56 acres ("more or less") and one in Clinton County of 46.94 acres ("more or less"); (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, both manufactured products that have -- and have not -- been released by the federal Food and Drug Administration for public sale and use and products -- and their components -- that are in the process of being manufactured. Reportedly, 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.

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."

Commission to negotiate and approve agreements on behalf of the state for conveying all or some of the

The order, which took effect on February 4, 1996, transferred both the Michigan Biologic Products Division (which, among other things, made vaccines both for state public health childhood immunization programs and, under contract, for the military) of the Department of Public Health and 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), which was to be sold to private bidders no later than February 4, 1998. The ERO also created a temporary, three-member 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, as well as making necessary administrative internal organizational changes to complete the "realignment of responsibilities" prescribed by the order and ("immediately") entering 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, created a Michigan Biologic Products

institute's assets, authorized the State Administrative Board to convey the assets and liabilities (not defined in the act) of the state related to the operation of the Michigan Biologic Products Institute, as well as including a statement of legislative intent [Section 2], an explicit authorization for institute employees to bid on the institute's assets and/or 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.

Legislative intent. 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.

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 from the Department of Management and Budget.

The commission is authorized by the act to do all of the following relative to conveying assets under the act:

** Determine the assets that are subject to the proposed conveyance, as well as the liabilities (a term not defined in the act) of the institute ("if any") that a proposed "transferee" 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.

Employee acquisition of institute assets and/or employment by private buyers. 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." [Section 7]

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]

FISCAL IMPLICATIONS:

Fiscal information is not available.

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 will 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 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.

The bill would address some of these issues by slowing down the privatization process, giving the state up to two more years to obtain information on the value of these state assets that is above question and clearly not dependant on information from public employees who also are potential purchasers of these assets. The bill also would require that the Michigan Biologic Products Commission documents be available under the Freedom of Information Act, and that more adequate safeguards for current public employees of the institute be added to the law authorizing and requiring privatization of the institute. Given the number of questions that have been raised -- both in the legislature and in the public media about the appraisal and sales process -- the bill definitely is needed.

Against:

Opponents of the bill argue that further investigation of the sale of the Michigan Biologic Products Institute not only is unnecessary, but may actually be detrimental to the sale process by driving off legitimate bidders and by irritating valued customers. They argue that all parties to

the sales transaction are behaving in compliance with applicable laws, and that ample oversight has been built into the sales process itself to ensure that the state receives "fair consideration" for the assets and liabilities of the institute. They point out that the legislature decided, on a bipartisan vote, late last session to sell the institute's assets, and 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). They also 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. Opponents also point out that no appropriation exists for the institute or commission beyond February 1998 (the deadline for the sale of the institute's assets and the dissolution of the commission), and that the bill cannot achieve its purported aim without additional appropriations. Finally, reportedly on the morning of the day on which the House Committee on Oversight and Ethics reported the bill out of committee, the Michigan Biologic Products Commission met and disqualified the bid involving the director and deputy director of the institute, so the issue of "insider trading" no longer is an issue.

Response:

First, there appears to be general, bipartisan agreement that the state should, indeed, get out of the business of developing and manufacturing vaccines, so the disagreement addressed by the bill is over the process, not over the eventual goal. However, the fact that a previous legislature (and one in which both houses were held by a majority of one political party, which no longer is the case) made a decision to sell the state's biologic products production assets under a very short deadline and with minimal or no legislative oversight (and which some legislators vigorously contested at the time) has no bearing on what the current legislature may decide to do about this issue. It is a well established fact 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 depends on the fact that the state lab was prohibited from developing a newer product, at least in the case of the acellular pertussis vaccine, and some people have suggested that this is part of a pattern of deliberate devaluation of a valuable state resource for the sake of

privatization. Finally, the fact that all parties are behaving in compliance 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. The fact that appropriations for the institute and commission will expire in February 1998 -- and that the bill would extend their existence past this date -- could be easily rectified by legislative appropriations. Reportedly, the state has been subsidizing the state vaccine lab since at least 1993. Wouldn't it make sense to extend this subsidy, if it meant that the taxpayers would realize a return on their investment of possibly millions of dollars more than if privatization is pushed through under current deadlines? Finally, the fact that the commission reportedly has very recently decided to disqualify the bid by the director and deputy director of the institute, while apparently removing at least the likelihood that state employees will benefit unduly from their "insider" status, does not remove their influence on the initial appraisal of the value of the institute's assets upon which the commission, presumably, will in part base its decision on selling these assets.

POSITIONS:

The Department of Community Health opposes the bill.
(11-23-97)

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.