



**House
Legislative
Analysis
Section**

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SALE OF STATE VACCINE LAB

**House Bill 6191 as introduced
House Bill 6192 (Substitute H-1*)
First Analysis (11-21-96)**

**Sponsor: Rep. Donald H. Gilmer
Committee: Appropriations**

THE APPARENT PROBLEM:

Since 1926, the Biologic Products Division of the Department of Public Health (now the Department of Community Health) has been manufacturing vaccines and blood derivatives with the aim of protecting Michigan citizens from infectious diseases. The state currently manufactures vaccines for tetanus, rabies, pertussis, DTP (diphtheria-tetanus-typhoid), DT (pediatric), and anthrax, as well as the blood derivatives albumin, immune serum globulin, and anti-hemophilic factor, at its facilities located in north Lansing.

Governor Engler seeks to privatize the state vaccine laboratory, reasoning that the manufacture of these products is not critical to the public health mission of the state and citing rapid changes in the biotechnology industry, an increasingly complex federal regulatory climate for the pharmaceutical industry, and state government constraints (such as civil service regulations, the annual legislative appropriations process, and extensive controls over public procurement) that are not conducive to operating the facility in a financially viable and competitive manner.

In Executive Order 1995-25, issued December 5, 1995, the governor removed the Biologic Products Division from the Department of Public Health and established it as an autonomous, temporary agency known as the Michigan Biologic Products Institute (MBPI) governed by a three-member commission, the Michigan Biologic Products Commission. The commission was charged with determining the fair market value of the assets of the institute, and developing a plan, including any necessary legislation, for privatizing the institute within two years.

Legislation has been introduced to implement the privatization of the Michigan Biologic Products Institute, formerly the Biologic Products Division of the (former) Department of Public Health.

THE CONTENT OF THE BILLS:

House Bill 6192 would provide for the sale and conveyance of the assets and liabilities of the state-owned and operated Michigan Biological Products Institute.

Legislative findings. The bill specifies that the legislature finds and declares the following to be true:

* 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 state borders all have adversely affected the state's ability to sustain a viable, self-supporting operation for the manufacture and distribution of vaccines and blood derivative products.

* 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, enable many employees to retain their jobs with the institute, and assure the state's access to biologic products to protect the state's citizens from infectious disease.

* The conveyance of the institute's assets would not impair the public health mission of the Department of Community Health and, if the institute was not conveyed to a private enterprise, its operations could be discontinued. If operations were discontinued, the legislature recognizes the need to dispose of its facilities and the state's expense for costs related to employee separation from the institute and of costs related to disposal of its assets, both of which the legislature desires to offset by authorizing the conveyance of the institute's assets to a private enterprise.

Assets. Under the bill, "assets" would mean all or part of the following that were associated with the institute and would be subject to conveyance under the bill:

House Bills 6191 and 6192 (11-21-96)

* Real property, including all mineral rights, except that if minerals were developed on the real estate, the agreement entered into under the bill would have to provide for the state to receive at least one-half of all profits generated from such development. The bill also includes a definition of "real property," which basically would include the legal description of parcels of land associated with the institute and currently owned by the state;

* Personal property;

* Intangible property; and

* Product inventory, including, but not limited to, manufactured products that had been released by the federal Food and Drug Administration for public sale and use, manufactured products that had not been released by the FDA for public sale and use, and products that were in the process of being manufactured and components of those products.

Commission powers, duties. Subject to the bill's requirements, including approval by the state administrative board, the Michigan Biologic Products Commission (which was established by executive order 1995-25) could perform one or more of the following acts relative to conveying the institute's assets:

* Determine which assets would be subject to the proposed conveyance;

* Determine which liabilities of the institute, if any, that a proposed transferee would have to assume;

* Negotiate and approve agreements on the state's behalf for the conveyance of all or a portion of the assets to one or more transferees and for the assumption of all, a portion of, or none of the liabilities of the institute by one or more transferees. Any such agreement could include any term determined by the commission to be necessary or convenient for conveying various specified assets;

* Retain a selling agent to assist the commission in marketing the institute's assets and liabilities;

* Solicit prospective purchasers or other transferees for the assets using the method(s) 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 a portion of the institute's assets to one or more transferees and for the assuming all, a portion of, or none of its liabilities;

* Upon approval of the state administrative board, authorize the 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 part of its assets.

* Exercise any other power necessary or convenient to effect or complete the sale of the institute, including, but not limited to, all actions necessary to transfer permits and licenses related to the operation of the institute.

The commission could--for and on the state's behalf, without explaining why or being liable for, and at any time and in any respect--do all of the following: amend or terminate any activities with respect to the conveying of assets; commence and terminate discussion with any or all persons seeking to acquire assets; reject any or all proposals to acquire the assets; and negotiate and consummate the conveyance of assets with any person. These provisions would not restrict the commission's right to enter into a binding purchase agreement upon approval of the state administrative board.

The commission would have to identify in an agreement for the conveyance of the assets the consideration to be received in exchange for the conveyance, and, in addition to consideration recognized in the legislative findings, the commission could accept as part of the conveyance any other valuable consideration.

Board approval of conveyance agreement. Upon the commission's recommendation, the state administrative board could approve and authorize the chair or his or her designee to execute one or more agreements, instruments of conveyance, and bills of sale in the state's name for the conveyance of all or part of the assets to one or more transferees, and for assuming all, part or none of the institute's liabilities by one or more transferees, subject to all of the following:

* Before the agreement's effective date, the board would have to determine that the proposed consideration was fair and adequate so that the state's credit would not need to be granted to a public or private person, association or corporation.

* The agreement's terms would have to require the transferee to give the state preferential access to biologic products (for use in the state) from among those products and product components made by the institute on the agreement's effective date and licensed by the FDA or subsequently made by the transferee, as determined by the state, and for a period and subject to conditions and prices set forth in the agreement.

* Before the agreement's effective date, the board would have to determine that the agreement would include a commitment by the proposed transferee to continue employing institute employees who elected to remain employed with the transferee, for at least one year after the agreement's effective date. This provision would not affect the transferee's ability to terminate an employee's employment for cause.

If more than one transferee was recommended by the commission to the board, the requirements for giving the state preferential access to biologic products and the requirement to retain employees for at least one year would apply to the appropriate transferee. The board, in its sole discretion, could evaluate the terms of any commission recommendation and approve or reject any commission recommendations made under the bill without assigning reasons for the evaluation, approval or rejection. In addition, the board would have to receive, before the agreement's effective date, an independent opinion that the consideration for the institute's assets or liabilities, or both, was fair and adequate. The board could rely on the opinions or reports of legal counsel, independent appraisers, accountants, financial advisors, and other experts when performing its duties and exercising its powers.

Auditor general review. The auditor general would have to review the entire process used by the commission to convey the institute's assets and liabilities and report the results of the review to the legislature before the board approved the proposed agreement.

Pharmaceutical products fund. Monetary consideration received under the bill in conveying the institute's assets would have to be deposited in this fund and, except as otherwise provided in the bill, would have to be used solely for the purchase of vaccines and other biologic products needed to protect the public health.

Money in the fund that was not needed to fund appropriations for the 1996-97 state fiscal year general government budget (Public Act 364 of 1996) would be appropriated for the following purposes and in the following order of priority:

* Payment of fees associated with the services provided by a selling agent in marketing the assets, if such services were retained and used by the commission;

* For payment of accrued sick and annual leave time to institute employees upon being separated from employment with the state if current fiscal year appropriations available for the purpose were insufficient, and for reimbursing the state for payouts for accrued sick and annual leave time from current fiscal year

appropriations available for that purpose to these employees;

* To reimburse the State Employees' Retirement System for the actuarial cost of providing an optional early retirement plan for institute employees whose combined age and service credit equaled 70 or greater, regardless of age, on the date of their separation from state employment;

* Separation costs including, but not limited to, expenses incurred in moving non-institute employee work stations and other equipment in to other state office locations and converting the institute's facilities to private operations;

* To pay other costs related to the negotiation and closing of the agreement for the conveyance of assets, including title insurance and any opinions or reports required by the board, and the fees of attorneys and consultants used to develop and complete the conveyance.

The bill would cap the amounts that could be expended on fees for an agent to market the institute's assets, for separation costs, and for negotiation and closing costs at \$2.5 million; and amounts for employees' sick and annual leave time, to reimburse the state for these costs, and to reimburse SERS for the actuarial cost of providing employees early retirement under the bill would also be capped at \$2.5 million. The bill also would provide for an appropriation of \$2 million to the institute for the 1996-97 fiscal year for certain renovations to an institute building; of this, \$630,000 would be appropriated from other federal revenues and \$1.37 million would be appropriated from biologic product sales and other revenue.

All unexpended money in the fund would have to be retained in the fund at the end of the fiscal year in which the conveyance of institute assets was completed. After the conveyance was completed, the community public health agency within the Department of Community Health would have to administer the fund.

Employee provisions. An institute employee or a group composed in whole or in part of institute employees could bid on or make a proposal to acquire the assets and enter into one or more agreements related to the conveyance of all or some of the assets to the employee or group. When acting with the knowledge or upon the commission's direction or in entering into an agreement to accept employment with a potential acquirer of institute assets, an institute employee would not be considered to have violated Public Act 196 of 1973, the act providing for standards of ethical conduct by public officers and employees, if he or she provided written notice to the commission of the proposed employment agreement and its terms before it was executed.

Claims. The court of claims would have exclusive jurisdiction over a claim asserted against the state and arising out of or related to the bill's provisions. The validity of the proceedings of, or the determinations made by, the board or the commission under the bill would be conclusive if not challenged by filing suit with the court of claims within 60 days after the action that was the subject of the suit was taken. The bill would prohibit someone from bringing or maintaining an action related to a product manufactured by the institute or to recover damages for injuries to persons unless the action was commenced within six months after the claim first accrued to the plaintiff or to someone through whom the plaintiff claimed. A claim subject to this provision would accrue at the time the plaintiff or someone through whom the plaintiff claimed discovered or should have discovered through reasonable diligence the claim's existence or the injury that was the basis for the claim.

Other provisions. Except for taxes otherwise imposed by the state or one of its political subdivisions, the conveyance of assets permitted by the bill would be free and clear of any liens, claims or interests of the state or of a person claiming through or under the state.

In addition, except for the fund, any assets that had not been conveyed on or before the expiration of the commission's life would have to be transferred to the Department of Management and Budget or any other state department, as the board could direct. Not less than 90 days after the conveyance of assets and liabilities was completed, the board would have to make a report in writing to the legislature of the terms of the conveyance.

House Bill 6191 would amend the State Employees Retirement Act (MCL 38.171 et al.) to provide an early retirement option and a special buy-in option for certain employees of the Michigan Biological Products Institute, in the event that the institute was sold. In addition, the bill specifies that employees of the MBPI who were vested in the retirement system on or before the sale of the institute would be entitled to all of the rights, privileges, and benefits provided by the act that were accrued as of the date of the sale.

Purchase of service credit. Under the bill, an employee of MBPI who had at least five years of service but less than 10 years on the date of the sale of the institute would be allowed to purchase additional service credit in order to obtain 10 years of service credit, the amount needed to become "vested" in the system. A person who purchased service credit under the bill would be eligible for health care benefits upon retiring to the same extent as a person with 10 years of service credit who vested on the same date. (Note: This provision contains a section reference that appears to be incorrect.) The employee would have

to make the choice to purchase the service credit within one year after the date of the sale, and would have 11 years after that date to pay, at actuarial cost, for the service credit. To be eligible to purchase service credit under the bill, a person would have to be an employee of MBPI on the effective date of the sale of the institute, and would have to maintain employment with the new owner for at least one year, unless the employee was laid off by the new employer for reasons other than good cause.

If a person purchased service credit under the bill and then returned to state employment before reaching retirement age, he or she would have to accumulate at least 10 years of service (not counting the years of purchased service credit) before becoming vested in the system.

Early retirement option. The bill would provide an early retirement option for employees of the MBPI whose age and length of service equaled 70 or more on the date of the sale of the institute. A person retiring under this provision would receive a full retirement allowance, and there would be no minimum age requirement for those eligible.

FISCAL IMPLICATIONS:

According to the House Fiscal Agency, the fiscal impact of **House Bill 6192**, which would provide for the sale of the institute, is indeterminate. The HFA analysis cites the preliminary determination of the fair market value of the institute by KPMG Peat Marwick LLP, which places the value of the institute as a going-concern as of October 18, 1996 ranging from "nominal" to \$10.5 million. In addition, according to HFA, the bill would cause the state to incur certain transaction costs (selling agent fees, legal fees, employee sick and annual leave payouts, employee retirement costs, title insurance costs) which cannot be determined at this time. Further, the bill contains an additional appropriation for \$2 million for the institute for fiscal year 1996-97 for the construction/renovation purposes related to regulatory compliance. Of this \$2 million, \$630,000 would be appropriated from federal funds and \$1,370,000 would be appropriated from biologic product sales and other revenue. (11-19-96)

The House Fiscal Agency reports that **House Bill 6191** would result in increased costs for the State Employees Retirement System. If all eligible employees chose to participate, the bill would result in a cost of \$1,088,500 for the early retirement provisions, and over \$300,000 for the buy-in provisions of the bill. It should be noted that House Bill 6192 provides for reimbursement of this cost to the retirement system from the proceeds of the sale of the institute. Not included in the cost estimates above are any costs for state-paid health care benefits to retirees that

would be incurred due to the bill's provisions. Retiree health care costs are paid on a cash basis in the year the costs actually are incurred (rather than paid on an actuarial basis for future retirees). (11-20-96)

ARGUMENTS:

For:

The bills would facilitate the administration's goal of selling the assets of the Michigan Biologic Products Institute. They would provide for an orderly, open process for transferring the state assets to a private sector entity for a fair price. In addition, they would provide for fair treatment of the institute's employees, requiring the new employer to retain current employees for at least one year, and providing an early retirement option for long-time state employees, as well as enhanced future retirement options for those who may be displaced by the transition.

According to the commission's report to the governor, operating a vaccine research and manufacturing facility within the constraints of a state agency is no longer a viable or efficient means to meet the state's public health goals. The institute's primary pediatric vaccine is obsolete, its manufacturing facilities are in need of replacement, and the institute needs a new product pipeline that can only be supplied by a private business concern. The state's own public health facilities now use many more vaccines made by private firms than made by the institute; usage has dropped from over 700,000 doses in 1993 to 447,200 doses in 1995, and the annual total for 1996 is projected to be below 200,000 doses. Distribution in 1997 is expected to fall as low as 20,000 doses. A newer, state-of-the-art pediatric pertussis vaccine (Pa) and more comprehensive combination vaccines (e.g., DTPa Hib) are rapidly displacing the institute's DTPw vaccine, long its major reason for existence.

Michigan is the last state in the nation to still own and operate its own vaccine lab. While making its own DTPw vaccine helped Michigan through the vaccine shortage of the 1980s, the advent of new federal programs has resulted in a resurgence of private manufacturers that make pediatric vaccines. Shortages like the ones seen in the 1980s are not expected to recur. Further, the state's mission to protect the public health through immunization of children will not be compromised by sale of the institute. The federal government's Vaccines for Children program fills the vaccine needs of all the other states; there is no need for Michigan to continue an obsolete tradition.

Perhaps most importantly, it is inappropriate for state government to own the means of production of a product

in a capitalistic democracy. State government has no business taking risks with public funds in pursuit of future profits, and it should not be in competition with the private sector using the advantage of taxpayer capital. Competing with today's biotechnology industry is not essential to fulfilling the state's public health mission.

Against:

Several concerns have been raised about these bills, both about their substance and about the process that has been followed since the governor's executive order was issued.

** It has been suggested that the Peat Marwick study has grossly undervalued the assets of the vaccine production facilities, including its products and licenses. Some say that the license on the anthrax vaccine alone is worth significantly more than the highest estimate placed on the total assets of the facilities. It is suggested that the consultant's access to pertinent information may have been restricted.

** A significant concern is whether sale of the state facility will have a detrimental effect on the ability of Michigan citizens to obtain access to vitally-needed vaccines. During the 1980s, a worldwide shortage of the DTP vaccine caused most other states to scramble to fill their public health needs. Because Michigan manufactured its own DTP vaccine, it did not have to endure this shortage. Other states that get their supplies of vaccines through the federal program must take their chances when shortages occur; for all practical purposes, it is a "first come, first served" system. Does Michigan want to join into this chancy proposition?

** It has been suggested that the process used to further the goal of privatizing the state's vaccine lab has been skewed toward achieving privatization, perhaps at any cost. Legislators who would have liked to have been involved in the commission's deliberations report that they were not notified of proceedings. Likewise, the bills appear to be on an extremely fast track, not allowing for sufficient time for all parties to examine their language and possible implications.

POSITIONS:

The chair of the Michigan Biologic Products Commission testified in support of the bills before the House Appropriations Committee. (11-20-96)

Analysts: D. Martens/T. Iversen

■ 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.