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PRIVATIZATION OF THE BIOLOGIC PRODUCTS PROGRAM

By Pam Graham, Fiscal Analyst

The late-night sessions that marked the end of the 88th Legislature also signaled the end of the State's 60-plus years of involvement in the development and production of vaccines and other biologic products. In the last weeks of the legislative session, the Legislature passed House Bills 6191 and 6192, which create a process for the conveyance or transfer of the Michigan Biologic Products Institute to a non-State entity. The Institute, formerly known as the Michigan Biologic Products Division, has had a long and laudatory history. Beginning in 1986, however, questions began to arise concerning the propriety of the State's involvement in what some considered a private sector enterprise. Strong legislative support, partially spurred by a national vaccine shortage that year, kept the Program in operation. Various changes in both Federal policy and the vaccine industry since the mid-1980s have led to another reconsideration of the State's role in the production of pharmaceutical products. The end result is House Bills 6191 and 6192, the blueprint for conveying the operation to a private entity.

In 1921, in response to a continuing diphtheria epidemic that saw Michigan with the highest diphtheria rates in the world, then-Governor Groesbeck asked the Legislature to enact legislation that would allow the State to produce, purchase, and distribute products to treat or prevent diphtheria, and to manufacture the products if and when the purchase price exceeded the cost of production. It wasn't until 1925 that the price of diphtheria antitoxins rose to such a level that the State began to produce its own products. By 1926, the Department of Public Health had already begun to branch out and produce products other than just those for the control of diphtheria, including a typhoid vaccine, silver nitrate, and various other reagents. In 1927, the Legislature repealed the 1921 law that allowed the manufacture of products related to the control of diphtheria only, and replaced it with a law that gave the Department the authority to produce or purchase any biologic product necessary to control the spread of communicable disease and to distribute such products free of charge.

Over the next several decades, the Program continued to produce and develop vaccines and other biologic products important in the control of the spread of disease in both humans and animals. Currently the products manufactured through the Program include all of the following: Diphtheria, Tetanus, and Pertussis (DTP) vaccine, Tetanus Toxoid, Diphtheria-Tetanus Toxoids, Rabies vaccine, Anthrax vaccine, Botulinum Toxoid, Pertussis vaccine, human albumin, immune serum globulin, and anti-hemophilic factor.

The intent to privatize the biologic products function first arose in the mid-1980s. Historically, the products manufactured by the Program had been made available free of charge to the residents of the State primarily through the local public health network. Some of the products had been sold at cost to other states, while others were distributed to nonstate entities through contracts. In Governor Blanchard's budget recommendation for fiscal year (FY) 1986-87, a proposal was put forward to eliminate all State General Fund/General Purpose support for the Program. The proposal assumed that the Department would begin to assess a charge for the products it distributed, possibly including those distributed in the State to meet a public health need. Many viewed this proposal as the first step in the elimination of the Biologic Products Program. During the course of deliberations over this proposal, questions arose over the appropriateness of the State's involvement in the manufacture of products that, with a few exceptions, were also manufactured in the private sector.

Just prior to the Governor's proposal and the questions it spurred, there was a national DTP

vaccine shortage. Michigan and Massachusetts, the only states that manufactured their own DTP vaccine, were the only states not faced with this shortage. (Massachusetts is scheduled to transfer its Biologics Program to the University of Massachusetts in January 1997.) The primary reason for the shortage was that two of the three private manufacturers of that vaccine at that time, citing product liability concerns, ceased production of the DTP vaccine in 1984. Largely due to concerns over continued availability of key vaccines, the Legislature rejected the Governor's proposal and restored State General Fund support and the Program continued.

In the early 1990s, plans to privatize the Biologic Products Program were discussed again. In the earlier discussions, vaccine shortages and the apparent mass exodus of the private sector from the vaccine production business, provided little option for the State but to continue its own Program. Changes in Federal vaccine policy and in the vaccine industry itself, however, had changed the context of the privatization discussion.

The Federal Childhood Vaccine Injury Act of 1986 had a significant impact on the revival of the vaccine industry. Under the Federal Act, an excise tax was assessed on each dose of vaccine produced. The tax was then used to fund a national vaccine injury compensation pool. The tax was also assessed on vaccines produced by the Biologic Products Program, even though the Program is immune from liability. The effect of the Federal Act was twofold. First, private manufacturers' exposure to liability was significantly reduced, thus leading to a return of the private sector to vaccine production. Second, the cost to the State of manufacturing its own vaccines was increased substantially with the imposition of the excise tax, thus reducing the cost savings that had been associated historically with the State's production of its own vaccines.

The provisions of the Federal Omnibus Budget Reconciliation Act of 1993 (OBRA 93) also had an impact on the level of cost savings that could be achieved by the State through the manufacture of its own vaccines. This Act expanded the scope of the Federal government's provision of childhood vaccines. According to Department of Public Health figures at the time that OBRA 93 was enacted, prior to OBRA 93, the Federal government provided the State with approximately 50% of the childhood vaccines administered through Department programs. Following OBRA 93, the Department estimated that the Federal government would provide between 75% and 90% of the needed childhood vaccines. The annual savings realized by the State through its production of the DTP vaccine were reduced significantly as a result of OBRA 93.

Certain changes in the vaccine industry that began to occur in the early '90s provided further impetus for the privatization of the State's Biologic Products Program. One of the changes was the development of a new version of the Pertussis component of the DTP vaccine, the mainstay of the State's Program. The version used historically, and the version used in the State's DTP vaccine, was whole cell Pertussis vaccine. This component has been perceived to be associated with most of the adverse reactions to the DTP vaccine. A new acellular Pertussis vaccine has been developed and appears to be similar to the whole cell vaccine in terms of effectiveness, but somewhat lower in risk. It is generally believed that this new acellular vaccine will make the State's whole cell vaccine obsolete in very short order.

The other change occurring in the vaccine industry is the combining of various vaccines into a single vaccine. For example, a combined DTP- *Haemophilus influenzae* type-b vaccine is already licensed and distributed. This and other combined vaccines will rapidly replace the demand for the State's DTP vaccine.

With the above described changes in the vaccine production environment, the deteriorating physical plant that houses the Biologic Products Program, and no foreseeable growth in State funding for the Program, privatization efforts began in earnest in 1992. The State entered into an agreement with the private pharmaceutical firm SmithKline Beechum (SKB), under which SKB would distribute State-produced DTP and rabies vaccines out of State, and SKB and the State would work together to develop a combination vaccine using components provided by both the State and SKB. It was generally believed that SKB would eventually buy the State's Program, and, in fact, the State's contract gives

SKB the right of first refusal in the event the Program is put up for sale. SmithKline Beechum, however, has not made an offer to purchase the program to date.

In December 1995, Governor Engler issued Executive Order (E.O.) 1995-25, which established the Michigan Biologic Products Institute as an autonomous State agency with a two-year life span. The Biologic Products Program was transferred to the Institute. The E.O. also established the Biologic Products Commission as a temporary entity with a life span of no more than two years. The Commission was charged with overseeing the operation of the Biologic Products Institute, and preparing a plan for the transfer of the Institute to a private entity within the two-year term of the Institute. The Legislature did not reject Executive Order 1995-25. The plan to privatize the Biologic Products program was now official.

Through the passage of House Bills 6191 and 6192 at the end of the 88th legislative session, the Legislature provided the mechanism for finalizing the privatization process. House Bill 6192 creates the Michigan Biologic Products Institute Transfer Act. The Act authorizes the Michigan Biologic Products Commission, subject to the approval of the State Administrative Board, to negotiate the conveyance, or transfer, of all or part of the assets and liabilities of the Michigan Biologic Products Institute to one or more entities. Any money received from the sale of the Institute will be deposited in the Pharmaceutical Products Fund to be used first to meet FY 1996-97 appropriation obligations associated with the Institute, then to support the costs associated with the conveyance of the Institute, and finally to purchase vaccines and other biologic products necessary for the protection of the public's health.

One way or another, by February 1998, in all likelihood, the Michigan Biologic Products Institute will no longer be a State-operated entity. Either the Institute will have been transferred to a private entity pursuant to the provisions of House Bill 6192, or the two-year life span of the Institute conferred under E.O. 1995-25 will have expired. In many respects, given the changes in Federal vaccine policy, the changes in the vaccine industry, and the changes in the availability and allocation of State resources, the privatization of, or the possible termination of the State's Biologic Products Institute is probably inevitable. Whether the vaccine shortages experienced by the nation in the mid-1980s will recur, or whether the private sector can be depended upon to provide a steady supply of necessary products in the future, remains to be seen. Whatever occurs, Michigan will now be in the same position as the other 49 states when it comes to addressing vaccine supply issues.