

H. CARL McCALL  
STATE COMPTROLLER



A.E. SMITH STATE OFFICE BUILDING  
ALBANY, NEW YORK 12236

STATE OF NEW YORK  
OFFICE OF THE STATE COMPTROLLER

May 22, 1997

Barbara Ann DeBuono, M.D.  
Commissioner, Department of Health  
President, Health Research, Inc.  
Corning Tower Building  
Empire State Plaza  
Albany, New York 12237

Re: Department of Health  
Health Research, Inc.  
Report 97-S-11

Dear Dr. DeBuono:

Pursuant to the State Comptroller's authority as set forth in Section 1, Article V of the State Constitution and Section 8, Article 2 of the State Finance Law, we have audited certain aspects of Health Research, Incorporated's joint venture agreement with Institut Merieux concerning its technology transfer program. The audit covered the period April 1, 1993 through June 30, 1996.

**A. Background**

Health Research, Incorporated (HRI) was established in 1953 as a not-for-profit corporation, by administrative action of the Commissioner of the Department of Health (Department) who is also President of HRI. HRI's primary purpose is to administer Federal, State and private funding to support, supplement and extend the research functions and programs of the Department. Gifts and donations made to HRI are tax-exempt. During the 1995-96 State fiscal year HRI received about \$164.5 million from grants, contracts and donations, and earned \$4.6 million from technology transfer revenues, investment interest and contract fees. HRI employs over 1,400 administrative and technical support staff.

Most of HRI's major research projects are carried out in State facilities, using State scientists and available administrative and laboratory resources. HRI employees often work side-by-side with Department employees and generally share similar job responsibilities. HRI maintains its executive office in Rensselaer, New York, and operates divisions in Albany and Buffalo. The Albany Division works in cooperation with the Wadsworth Center for Laboratories and Research, which is the Department's research arm. The Buffalo Division works in cooperation with Roswell Park Memorial Institute, primarily a cancer research hospital operated by the Department.

The Department contracts with HRI. The major provisions of the contract are:

- the Department is responsible for the overall supervision and direction of HRI activities;
- HRI pays the State monthly for a portion of the State's indirect costs (personal service, facilities and support services provided by the Department); and
- the State authorizes HRI to serve as the technology transfer and copyright administrator for the Department.

This contract is generally renewed every two years and is submitted for the Attorney General and State Comptroller's approval.

In 1986, HRI entered into a joint venture agreement (agreement) with the Institut Merieux (Merieux), a private corporation, based in France, creating the Virogenetics Corporation (Virogenetics), which is located in Rensselaer, New York. The purpose of Virogenetics is to develop the pox-virus vaccinia technology which was invented by a Department employee.

Under the terms of the agreement, HRI provided Virogenetics with exclusive, royalty-free rights to the technology in return for 49 percent of Virogenetics stock. The agreement provided Merieux an option to increase its 51 percent share in Virogenetics to 80 percent by purchasing shares from HRI, which Merieux exercised in December 1990.

The agreement further provided Merieux with the option of purchasing the remaining 20 percent share of Virogenetics held by HRI, at a fair market value negotiated between HRI and Merieux during the period March 31, 1995 through March 30, 1996. The agreement also provided HRI the option of requiring Merieux to purchase the remaining shares.

## **B. Audit Scope, Objective and Methodology**

We audited HRI's administration of the agreement with Merieux and Virogenetics for the period April 1, 1993 through June 30, 1996. The primary objective of our audit was to determine whether HRI has taken appropriate steps to protect the State's interest in the transfer of the pox-virus vaccinia technology. To accomplish our objective we: surveyed HRI operations; reviewed State laws, rules and regulations; examined HRI policies and procedures; and reviewed contracts between the Department and HRI, between HRI and the Merieux, and between HRI and Virogenetics. In addition, we reviewed Department, HRI and Virogenetics financial and management related records, and interviewed

Department and HRI officials.

We conducted our audit in accordance with generally accepted government auditing standards. Such standards require that we plan and perform our audit to adequately assess those operations of HRI that are included within the audit scope. Further, these standards require that we understand HRI's internal control structure and compliance with those laws, rules and regulations that are relevant to the operations included in our audit scope. An audit includes examining, on a test basis, evidence supporting transactions recorded in the accounting and operating records and applying such other auditing procedures as we consider necessary in the circumstances. An audit also includes assessing the estimates, judgments, and decisions made by management. We believe that our audit provides a reasonable basis for our findings, conclusions and recommendations.

We use a risk-based approach to select activities for audit. We focus our audit efforts on those activities we have identified through a preliminary survey as having the greatest probability for needing improvement. Consequently, by design, we use finite audit resources to identify where and how improvements can be made. We devote little audit effort reviewing operations that may be relatively efficient or effective. As a result, we prepare our audit reports on an "exception basis." This report, therefore, highlights those areas needing improvement and does not address activities that may be functioning properly.

### **C. Results of Audit**

We found HRI was not adequately monitoring the terms of its agreement with Merieux regarding Virogenetics nor fully monitoring Virogenetics' progress in developing and marketing the pox-virus vaccinia, which was licensed to them. As a result, neither the Department nor HRI could be adequately assured that the State's interest would be protected during the fair market valuation period and subsequent buy-out option period that began on September 30, 1995.

During the audit, we brought our concerns to the attention of Department and HRI officials, and recommended postponement of these contract terms as allowed by the agreement. In response, Department and HRI officials took steps to postpone the buy-out option period. In May 1996, the Office of the State Comptroller approved a proposed extension of these contract terms, which begin August 31, 1997 and September 30, 1998, respectively.

### **Technology Transfer**

We reviewed HRI's efforts to ensure that the State's interests had been protected and that the terms of the agreement with Merieux and Virogenetics were carried out. According to the agreement:

- HRI should receive annual, reasonably detailed progress reports from Merieux and Virogenetics;
- HRI should receive annual certified financial statements from Virogenetics;
- Merieux and Virogenetics must make their financial and research records available to

HRI or its representatives; and

- Merieux and Virogenetics must do their best to sell developed products.

From 1986 to 1995, HRI did not request any progress reports or review Merieux's or Virogenetics' research or marketing efforts. Between 1993 and 1995, HRI received unaudited financial statements from Virogenetics. These statements did not contain any of the Notes to the Financial Statements and had only basic information without descriptions of the accounts. In addition, because HRI had not reviewed such records or reports, it was not possible for HRI to determine whether Merieux and Virogenetics did their best to sell developed products. Department officials disagree with our assertion that HRI did not adequately monitor the terms of the agreement, indicating that HRI attended at least 20 quarterly status meetings where reports were presented and extensively discussed. HRI's Executive Director told us that he is invited to, and attends, Board and quarterly management meetings, and that he also receives verbal progress reports. Department officials also informed us that HRI accepts non-certified financial statements from Virogenetics in a cooperative effort to reduce costs, so that more funding can be made available for research and because the finances of Virogenetics are straight forward. While these activities may have been of some value, in our judgment they are not sufficient to meet the oversight responsibilities specified in the agreement.

The agreement provided that, beginning March 31, 1995, HRI and Merieux were to initiate efforts to determine the fair and reasonable value of Virogenetics. Merieux had the option of purchasing HRI's shares at a fair and reasonable value beginning March 31, 1996. Department officials told us that they had begun discussions with Merieux in April 1995 regarding the buy-out option period and had retained legal counsel, with expertise in this field, in early June 1995. However, at the time our audit fieldwork commenced in July 1995, we determined that HRI was not adequately prepared to make a fair market valuation of Virogenetics or proceed with a buy-out because it had not been adequately monitoring the agreement.

We brought our concerns to the attention of Department and HRI officials, and immediately recommended postponement of these contract terms, as allowed by the agreement. Department and HRI officials agreed with our recommendations. In May 1996, the Office of the State Comptroller approved a proposed extension of these contract terms, which was formally executed in June 1996. The new fair market valuation period begins August 31, 1997 and extends through September 30, 1998 and the buy-out option period begins September 30, 1998 and extends until March 31, 1999.

Department officials assured us that in no event would they have proceeded with a buy-out without a thoroughly researched valuation. They indicated that legal counsel was in the process of gathering the information to perform a valuation when the individual they were dealing with at Merieux left the company. Subsequent discussions with Merieux officials determined that both parties did not want to proceed with the buyout at that time.

Had Merieux exercised its buy-out option during the original period, there was a risk that Virogenetics could have been undervalued and there was a potential for significant investment and future revenue losses to the State. Since the time required for development and marketing of new products can be considerable, revenues from such products may not be realized for many years. For

example, one HRI licensed product, unrelated to Virogenetics, called the Prostate Antigen Test, has produced \$7.5 million in royalties to HRI since 1992. This invention was first disclosed in 1979. Revenues were delayed because of factors such as development time and regulatory reviews, delays that are common in biomedical technology research. In our prior audit of HRI (Report 89-S-34, issued November 15, 1989), the Executive Director of HRI indicated that future Virogenetics' sales may exceed \$100 million annually. The Executive Director told us this figure was a guess, but also conceded that one new product could produce such revenues.

In addition, the agreement provides for determining the valuation of Virogenetics by an independent investment banker if HRI and the Institut cannot agree on the fair market value of Virogenetics. To protect the State's interest, the Department should review any proposed agreement with an independent investment banker.

### **Recommendations**

1. *During the period leading up to August 31, 1997 and to protect the State's interest, HRI and the Department should ensure that all terms of the agreement are complied with and that all appropriate steps to establish Virogenetics' fair market value are taken.*
2. *To protect the State's interest, the Department should review any proposed agreement with an independent investment banker.*

A draft copy of this report was provided to Department officials for their review and comment. Their comments have been considered in preparing this report and are included as Appendix A. Department officials generally agree with our recommendations.

Within 90 days after the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Health shall report to the Governor, the State Comptroller and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons therefor.

Major contributors to this report were William Nealon, Thomas Nowinski, William Hughes, William O'Reilly, Robert Russell, Michael Sawicz, and Paul Bachman.

We wish to thank the management and staff at the Department and HRI for the courtesies and cooperation extended to our auditors during this audit.

Very truly yours,

Kevin M. McClune

Audit Director

cc: Patricia Woodworth