



A REPORT  
TO THE  
ARIZONA LEGISLATURE

Performance Audit Division

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Performance Audit and Sunset Review

# Arizona Biomedical Research Commission

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September • 2008  
REPORT NO. 08-05



**Debra K. Davenport**  
Auditor General

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**STATE OF ARIZONA**  
**OFFICE OF THE**  
**AUDITOR GENERAL**

**DEBRA K. DAVENPORT, CPA**  
AUDITOR GENERAL

**WILLIAM THOMSON**  
DEPUTY AUDITOR GENERAL

September 15, 2008

Members of the Arizona Legislature

The Honorable Janet Napolitano, Governor

Dr. Dawn Schroeder, Executive Director  
Arizona Biomedical Research Commission

Transmitted herewith is a report of the Auditor General, A Performance Audit and Sunset Review of the Arizona Biomedical Research Commission (Commission). This report is in response to an October 5, 2006, resolution of the Joint Legislative Audit Committee. The performance audit was conducted as part of the sunset review process prescribed in Arizona Revised Statutes §41-2951 et seq. I am also transmitting with this report a copy of the Report Highlights for this audit to provide a quick summary for your convenience.

As outlined in its response, the Commission agrees with all of the findings and plans to implement all of the recommendations.

My staff and I will be pleased to discuss or clarify items in the report.

This report will be released to the public on September 16, 2008.

Sincerely,

Debbie Davenport  
Auditor General

Attachment

# SUMMARY

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The Office of the Auditor General has conducted a performance audit and sunset review of the Arizona Biomedical Research Commission (Commission) pursuant to an October 5, 2006, resolution of the Joint Legislative Audit Committee. This audit was conducted as part of the sunset review process prescribed in Arizona Revised Statutes (A.R.S.) §41-2951 et seq.

The Commission was created in 1984 to provide monies to individuals, organizations, corporations, and institutions, public or private, in this state that conduct research on the causes and cures, medically accepted treatments, or prevention of diseases, including new drug discovery and development. It does this in two primary ways:

- The Commission provides about \$6.6 million annually through a competitive contract process to various Arizona medical research institutions employing biomedical researchers. The Commission's contracts vary in size, with smaller projects receiving up to \$50,000 per year and larger projects receiving between \$150,000 and \$250,000 per year. The Commission's contracts generally last up to 3 years, and its larger projects are designated for collaborative projects involving multiple researchers and institutions. Awarded contracts have included projects related to Alzheimer's Disease, cancer, cerebral palsy, Parkinson's Disease, and the West Nile Virus.
- The Commission provides \$5.5 million annually to a nonprofit biomedical research organization known as the Translational Genomics Research Institute (TGen) headquartered in Phoenix. TGen is a private nonprofit research institute performing research on a variety of diseases such as prostate cancer, renal (kidney) disease, and Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease).

The Commission does not receive General Fund monies. Rather, it receives funding primarily from two non-General Fund sources, tobacco tax revenues and lottery fund monies, which are used to cover its personal services and related benefits and operating expenses, the research project contracts, and the TGen contract.

## Commission-funded projects appear to have positive impacts, but impacts could be better documented and reported (see pages 11 through 20)

Biomedical research funded by the Commission appears to benefit the State in several ways. However, the Commission can take steps to better demonstrate and report those impacts. Auditors found that the Commission could collect more complete information about what these projects accomplish and make more information available to the public.

- **Impact of projects can be better documented and reported**—To help identify impacts, auditors compiled and reviewed information about 27 competitive contract projects that received funding between fiscal years 2001 and 2007. Impacts included more than 100 published articles about the research conducted, numerous collaborations among researchers and institutions, and direct application to needs that are relevant to Arizona, such as research about Valley Fever. The Commission is collecting and reporting information about some of these impacts, such as number of publications. However, other impact information, such as the number of patents or number and amount of additional research grants resulting from commission-funded projects, is only partially collected and is not included in the Commission's annual report. Collecting and reporting more complete impact information in the Commission's annual report, as well as making the annual report available on its Web site, would further help show how the Commission's funding of biomedical research projects has positive impacts.
- **Commission should require and report impact information on TGen**—The Commission annually provides \$5.5 million to TGen for operating expenses such as personnel, professional and outside services, equipment, supplies, travel, and other administrative costs. According to TGen, national entities do not offer grants that provide funding solely for these operating costs. The Commission's contract requires TGen to provide to the Commission an annual report that contains a summary of TGen's activities and includes such impacts as grants obtained and patents applied for and granted. According to commission and TGen officials, the Commission receives information on TGen's activities through the contractually required annual report as well as through one commission member's participation on TGen's Board, and periodic meetings and tours. However, auditors' review of TGen's annual reports found that although TGen is providing a summary of its activities, these reports did not always contain all of the contractually required information, and that the Commission does not include TGen's impact information in its annual report. For example, auditors found that the TGen reports submitted for fiscal years 2003 through 2007 did not contain information on patents. A commission official

indicated that it is satisfied with the information it is receiving about TGen and according to TGen, all required information is requested and reported to the Commission through a variety of means. However, the Commission should ensure that TGen includes all contractually required information in its annual report. In addition, the Commission should require TGen to include other measures, such as the number and types of jobs created and the relevance of TGen's activities to Arizona-specific populations or needs. Finally, the Commission should include in its annual report some of the impacts reported in TGen's annual reports.



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# INTRODUCTION & BACKGROUND

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The Office of the Auditor General has conducted a performance audit and sunset review of the Arizona Biomedical Research Commission (Commission) pursuant to an October 5, 2006, resolution of the Joint Legislative Audit Committee. This audit was conducted as part of the sunset review process prescribed in Arizona Revised Statutes (A.R.S.) §41-2951 et seq.

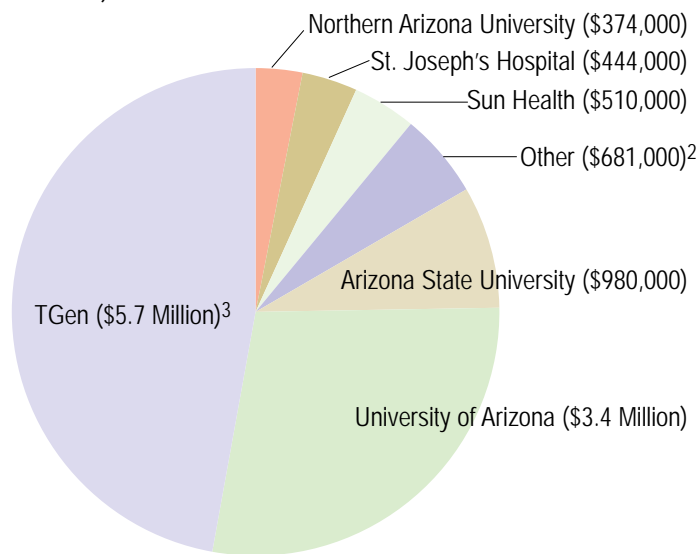
## History and purpose

The Commission was created in 1984 to provide monies to individuals, organizations, corporations, and institutions, public or private, in this state that conduct research on the causes and cures, medically accepted treatments, or prevention of diseases, including new drug discovery and development. It does this primarily by annually providing: (1) approximately \$6.6 million through a competitive contract process to various Arizona medical research institutions employing biomedical researchers and (2) \$5.5 million to a nonprofit biomedical research organization known as the Translational Genomics Research Institute (TGen) headquartered in Phoenix (see Figure 1, page 2). The Commission receives Arizona tobacco tax revenues and Arizona Lottery fund monies to pay for its contracts with the various research institutions and TGen.

## Commission provides monies for competitive contract projects

Individuals, organizations, and institutions in the State conducting biomedical research have an opportunity to annually request commission funding to support their projects. The Commission uses a competitive process to decide which projects should be awarded funding, and also requires that the researchers receiving commission monies submit progress reports that commission staff review prior to authorizing payments.

Figure 1: Distribution of Commission's Awarded Research Monies<sup>1</sup>  
Fiscal Year 2008  
(Unaudited)



<sup>1</sup> Amounts are rounded to the nearest thousand.

<sup>2</sup> The Other category consists of awards to four institutions: Mayo Clinic Scottsdale, \$250,000; Inter Tribal Council, \$150,000; Molecular Profiling Institute, \$145,000; and Mayo Clinic Arizona, \$136,000.

<sup>3</sup> In addition to the \$5.5 million TGen received from the Commission's Health Research Fund, TGen also received over \$200,000 through the Commission's competitive contract process.

Source: Auditor General staff analysis of the Commission's fiscal year 2008 competitive projects database and its February 23, 2007, Amendment to Funding Agreement with TGen.

Commission uses competitive process to award project funding—Annually, the Commission issues a Request for Proposal (RFP) for biomedical research contracts to Arizona medical research entities and individuals. The RFP requests proposals from individuals, organizations, corporations, and institutions in the State for projects or services that advance research into the diagnosis, causes, and prevention of diseases as well as for the treatment and formulation of cures. For example, commission-funded projects have included those related to Alzheimer's Disease, cancer, cerebral palsy, Parkinson's Disease, and the West Nile Virus (see textbox, page 3, for example projects). Project proposals are reviewed and scored based on several criteria (see textbox), by both commission members and commission-contracted, out-of-state peer reviewers who are considered to be scientific, health, and medical experts. The Commission's criteria are similar to criteria used by the National Institutes of Health, which funds medical research projects nationally.

### Key Proposal Evaluation Criteria

- Scientific merit and uniqueness
- Adequacy of researcher's facility and staff
- Project's relevance to Arizonans
- Training and competence of principal investigator and staff

Source: Auditor General staff review of the Commission's RFP for fiscal year 2009 awards and Peer Review Questionnaire criteria.

## Examples of Commission Contract Projects

- **New Drug for Rheumatoid Arthritis** (Fiscal years 2005 through 2007; contract total \$150,000)

This project by Sun Health Research Institute in Sun City involved working with the drug sodium narcistatin and two other anti-cancer drugs to discover which was the most effective to treat the inflammation and bone loss that characterize rheumatoid arthritis. The project results support sodium narcistatin as a safe, effective, and, according to the main project researcher, possibly less expensive candidate for use in treating rheumatoid arthritis. Further, this project provided necessary data to present the drug to a pharmaceutical company, after which it may become available for public use. The researcher reported that without the Commission's funding the project would not have been able to continue.
- **Comparing Smoking Cessation Treatments for Persons with Serious Mental Illness** (Fiscal years 2003 through 2005; contract total \$329,000)

This project, which was awarded to La Frontera Center (a comprehensive behavioral health services provider) in Tucson, included 121 participants and focused on smoking cessation treatments for people with serious mental illness. According to information for this randomized, controlled project, this population's smoking rate is 2–3 times higher than the general population and cessation interventions for this population are understudied. This project found that overall, participants were able to reduce the amount they were smoking by about 66 percent but, by the most conservative tests, nicotine replacement patches did not improve smoking cessation rates over just monetary incentives alone.

Source: Auditor General staff review of self-reported annual progress report information and interviews with project researchers.

The Commission's RFP allows projects to request different funding amounts and the funding is typically provided for 3 years. For example, the Commission awards small contracts for up to \$50,000 per year that are generally for new researchers, pilot programs, and projects with limited scope. The Commission also awards contracts of up to \$150,000 per year for collaborative projects involving multiple researchers and institutions. The Commission's largest contracts of up to \$250,000 per year require both collaboration and matching monies from the contractors. According to a commission official, once the project proposals are scored, contract awards are made based on ranking and the monies available for that year. Since the Commission generally funds a project for up to 3 years, the amount of money that is available for new projects is determined based on projected revenues and an analysis of ongoing projects' expenditures. In fiscal year 2008, the Commission awarded new contracts to 13 small projects and 7 large projects (see Table 1, page 4).

Some research institutions submit more proposals than others, and therefore may receive more contracts. For example, according to the Commission's fiscal year 2007 annual report, the University of Arizona submitted 76 project proposals, and 14 were accepted for fiscal year 2008. By contrast, Arizona State University submitted 24 project proposals, and 3 received contracts.

**Table 1:** Competitive Contracts  
Fiscal Years 2006 through 2008  
(Unaudited)

	Fiscal Year 2006		Fiscal Year 2007		Fiscal Year 2008	
	Number of Contracts	Contract Award Amount <sup>1</sup>	Number of Contracts	Contract Award Amount <sup>1</sup>	Number of Contracts	Contract Award Amount <sup>1</sup>
New contracts						
Small	17	\$ 846,939	20	\$ 985,749	13	\$ 589,436
Large	<u>13</u>	<u>2,203,963</u>	<u>8</u>	<u>1,259,436</u>	<u>7</u>	<u>958,111</u>
	<u>30</u>	<u>3,050,902</u>	<u>28</u>	<u>2,245,185</u>	<u>20</u>	<u>1,547,547</u>
Continuing contracts						
Small	19	925,065	24	1,185,627	36	1,785,161
Large	<u>17</u>	<u>2,461,768</u>	<u>21</u>	<u>3,496,752</u>	<u>19</u>	<u>3,264,322</u>
	<u>36</u>	<u>3,386,833</u>	<u>45</u>	<u>4,682,379</u>	<u>55</u>	<u>5,049,483</u>
<b>Total</b>	<u>66</u>	<u>\$6,437,735</u>	<u>73</u>	<u>\$6,927,564</u>	<u>75</u>	<u>\$6,597,030</u>

<sup>1</sup> Commission contracts usually last up to 3 years. However, this column represents the monies awarded on contracts for the applicable fiscal year only.

Source: Auditor General staff analysis of the Commission's competitive contract project data for fiscal years 2006 through 2008.

**Commission monitors project contracts**—According to commission staff, at the beginning of each contract year, the Commission requires project award recipients to submit an annual budget summary that shows the amounts the researcher expects to spend in different categories such as personnel, equipment, supplies, and travel. The Commission also requires that quarterly and annual expenditure reports be submitted for review and comparison with the annual budget summary prior to payment issuance. A researcher can reassign approved amounts from one category to another, but when reassigning amounts to or from the personnel or equipment categories, the research institution must request a budget transfer in writing. After commission staff review the expenditures, the researcher's institution is reimbursed for the authorized expenditures. In addition, the Commission requires that an annual progress report be submitted before each year's final payment is made. The researcher is required to include in the annual progress report information such as the status of the research, whether he/she has published any information about the research, and whether he/she has received additional monies from other sources for the project.

## Commission provides monies to TGen

From fiscal years 2003 through 2007, the Legislature appropriated a total of \$5.5 million of the Commission's Health Research Fund monies annually to TGen. The Legislature appropriated \$500,000 of this amount through fiscal year 2012. Further, in 2007, the Commission voted to continue providing the other \$5 million in funding from its Health Research monies annually to TGen through fiscal year 2012.

TGen is a private nonprofit research institute performing advanced translational genomics research on neurologic and metabolic diseases. For example, auditors learned from a presentation given by TGen officials that it has performed research on a variety of diseases such as prostate cancer, renal (kidney) disease, and Amyotrophic Lateral Sclerosis, or ALS (Lou Gehrig's Disease). Further, TGen reported being involved in collaborative biomedical research projects with the Scottsdale Mayo Clinic, and it has collaborated with the State's three universities to apply for grants. Additionally, TGen reported that it is collaborating with institutions internationally in countries such as Switzerland, Mexico, and Singapore.

Based on a review of legislative hearing minutes, it appears that the Legislature appropriated these monies to TGen because biotechnology is a fast-growing segment of the United States economy, and establishing a world-class genomics institute in Arizona would advance economic development by increasing employment levels and improve Arizona citizens' health prospects. Once the \$5 million legislative appropriation ended, according to the Commission, its review of TGen determined that TGen was serving as a central hub of activities encouraging and promoting collaborative research among Arizona biomedical research institutions. Further, it indicated that an independent economic impact analysis of TGen showed that TGen was making progress toward building its economic base and that additional state funding was needed to ensure TGen could meet its goal of becoming self-sufficient. In addition, the Governor requested the Commission to continue the funding. Based on these factors, the Commission decided to continue to provide funding to TGen for an additional 5 years.

TGen's gross revenue was over \$25 million in fiscal year 2003 and nearly \$45 million in fiscal year 2007.<sup>1</sup> The State's contract with TGen indicates that the state monies provided to TGen are to be used to pay for such costs as personnel, professional and outside services, equipment, supplies, travel, and other administrative expenses. According to TGen, national entities do not offer grants that provide funding solely for operating costs.

<sup>1</sup> These amounts are based on information TGen provided to the Internal Revenue Service.

## Staffing and organization

The Commission is composed of nine commissioners appointed by the Governor for 3-year terms, with three commissioners each from the general public, the medical community, and the scientific research community. As of June 2008, according to a commission official and the Commission's fiscal year 2007 annual report, the general public commissioners include an attorney, an accountant/director of an Alzheimer's Disease institute, and a policy and political affairs vice president for the Arizona Medical Association. Commissioners representing the medical and scientific research community include, among others, a vascular surgeon, a director of clinical education, a professor of physiology and medical anatomy, and a human geneticist.

The Commission has six staff. The Executive Director and Deputy Director oversee the Commission's administrative responsibilities, including developing the annual competitive contract Request for Proposal, planning the competitive contract project budget, and overseeing the other four employees. These staff do such things as receive and record the peer review scores and process the peer reviewers' payments, facilitate commissioner and staff payroll, receive Request for Proposal responses and check them for completeness, process payments to research institutions, and monitor the commission-funded contracts by ensuring that researchers submit quarterly and annual reports.

## Budget

As shown in Table 2 (see page 7), the Commission does not receive any General Fund monies. Rather, its revenue comes primarily from two non-General Fund sources. The Commission receives money from Arizona tobacco tax revenues and Arizona Lottery proceeds. According to statutes, the Commission receives 5 cents of each dollar deposited into the Tobacco Products Tax Fund and the Tobacco Tax and Health Care Fund, which totaled \$10.3 million in fiscal year 2008. Between fiscal years 1995 and 2001, the Commission was restricted to spending tobacco tax monies on tobacco-related medical research, but then A.R.S. §36-275 was amended to allow the Commission to spend these monies on nontobacco-related medical research. Additionally, the Commission receives 11.8 percent of Arizona Lottery monies deposited into the Healthy Arizona Fund. In fiscal year 2008, it received \$2.5 million from this source. The Commission's Arizona Lottery monies are unrestricted and can be spent on any type of medical research.

As shown in Table 2, the Commission's tobacco tax revenues can fluctuate each year because the amount the Commission receives depends upon how much is generated by tobacco taxes. According to a commission official, because

Table 2: Schedule of Revenues, Expenditures, and Changes in Fund Balance<sup>1</sup>  
 Fiscal Years 2006 through 2008  
 (Unaudited)

	<b>2006</b> (Actual)	<b>2007</b> (Actual)	<b>2008</b> (Actual)
<b>Revenues:</b>			
Tobacco sales taxes <sup>2</sup>	\$16,034,127	\$12,335,473	\$10,334,953
Lottery proceeds <sup>3</sup>	2,309,716	2,439,296	2,515,843
Interest income	<u>285,728</u>	<u>475,155</u>	<u>511,131</u>
Total revenues	<u>18,629,571</u>	<u>15,249,924</u>	<u>13,361,927</u>
<b>Expenditures and operating transfers:</b>			
Personal services and related benefits	436,133	477,409	494,132
Professional and outside services <sup>4</sup>	15,131,178	11,858,102	10,636,810
Travel, in-state	11,258	3,464	1,014
Aid to individuals <sup>5</sup>	9,017	10,901	8,047
Other operating	64,401	62,072	66,588
Equipment	<u>15,304</u>	<u>12,618</u>	<u>22,118</u>
Total expenditures	15,667,291	12,424,566	11,228,709
Net operating transfers out <sup>6</sup>	<u>999,997</u>	<u>1,000,747</u>	<u>1,006,830</u>
Total expenditures and operating transfers out	<u>16,667,288</u>	<u>13,425,313</u>	<u>12,235,539</u>
Net change in fund balance	1,962,283	1,824,611	1,126,388
Fund balance, beginning of year	<u>8,850,204</u>	<u>10,812,487</u>	<u>12,637,098</u>
Fund balance, end of year <sup>7</sup>	<u>\$10,812,487</u>	<u>\$12,637,098</u>	<u>\$13,763,486</u>

<sup>1</sup> This schedule includes financial activity for both of the Commission's funds. The Commission maintains the Disease Control Research Fund and the Health Research Fund as authorized by A.R.S. §§36-274 and 36-275, respectively.

<sup>2</sup> Amount consists of 5 cents of every dollar deposited into the Tobacco Products Tax Fund and the Tobacco Tax and Health Care Fund that the Commission receives under A.R.S. §§36-770 and 36-773, respectively. In addition, the fiscal year 2006 amount includes \$3 million of tobacco sales taxes appropriated to the Department of Health Services but allocated to the Commission to pay for Alzheimer's research projects conducted by TGen in accordance with Laws 2005, Chapter 286, §44.

<sup>3</sup> Amount consists of monies appropriated to the Commission from the lottery revenues pursuant to Proposition 203, a 1996 voter-approved initiative. The Commission receives 11.8 percent of the amount distributed to the Healthy Arizona funds.

<sup>4</sup> Amount primarily consists of monies paid to the Arizona universities and research institutions for competitive contracts, and to TGen.

<sup>5</sup> According to the Commission, the amount consists of payments for the Commission's employee tuition assistance program.

<sup>6</sup> Amount primarily consists of a \$1 million transfer to the Department of Health Services for Alzheimer's disease research as required by each year's General Appropriations Act.

<sup>7</sup> According to the Commission, ending fund balances are primarily designated for contracts the Commission has entered into that extend up to 3 years. In addition, lottery proceeds are primarily received at the end of the year and, therefore, are not available until the next fiscal year to pay contract expenditures. This also contributes to a larger fund balance at year-end.

Source: Auditor General staff analysis of the Arizona Financial Information System (AFIS) Accounting Event Transaction File for fiscal years 2006 through 2008, and the AFIS Trial Balance by Fund report for fiscal year 2006.



commission-funded projects generally last up to 3 years and its tobacco tax revenues fluctuate, it must carefully manage its budget and maintain a fund balance sufficient to ensure that it can pay for all contracts each year. For example, because the tobacco tax revenues have been decreasing and the Commission must fund TGen \$5.5 million per year, the Commission decided to fund only smaller \$50,000 contracts in fiscal year 2009.

Statute requires that a portion of lottery monies generated be given to other agencies before the Commission receives its amount. The Commission became eligible to receive a share of lottery proceeds in 1996. However, based on the amount of lottery proceeds generated and the use of those proceeds for other statutory obligations, the Commission did not receive a share of lottery monies until fiscal year 2004. As shown in Table 2, since fiscal year 2006, the Commission has received more than \$2 million annually from the Arizona Lottery.

The Commission's largest expenditure is for professional and outside services. This category primarily includes monies paid for its research contracts and TGen contract, but it also includes monies paid to patent attorneys and the peer reviewers who have a part in reviewing and scoring contract proposals.<sup>1</sup> Additionally, a portion of the tobacco tax revenues and lottery monies is used by the Commission for its personal services and related benefits and operating expenses.

## Scope and methodology

This performance audit and sunset review focused on illustrating the impact of projects receiving commission monies between fiscal years 2001 and 2007, and determining whether the Commission gathers appropriate impact information. This report contains one finding and associated recommendations:

- Commission-funded research projects appear to result in benefits for the State, but the Commission should enhance its efforts to gather and report the impacts of the projects it funds. Based on information reported by project researchers, commission-funded research results in a number of positive impacts for the State, such as bringing in millions of dollars in additional research monies from other granting organizations, and addressing Arizona-specific concerns, such as conducting research on Valley Fever and sun-induced skin cancer. Although the Commission gathers and reports some important impact information, obtaining or reporting additional information, such as the number of patents and jobs resulting from commission-funded research contracts and its TGen contract, will improve its ability to demonstrate the impact of the monies provided for these contracts.

<sup>1</sup> Peer reviewers are paid \$75 to \$100 for each peer review. According to commission staff, an average of 300 peer reviews are conducted each fiscal year.

The Commission's performance was also analyzed in accordance with the 12 statutory sunset factors (see pages 21 through 25).

Auditors used a number of methods to obtain information about the issues addressed in this report. Auditors' general methods included reviewing Arizona statutes and the Commission's annual reports for fiscal years 2003 through 2007; attending three commission meetings; and interviewing commissioners, commission management, and staff to obtain general information about the Commission and determine its statutory responsibilities and requirements. In addition, to obtain a general understanding of its internal controls, auditors reviewed commission policies, procedures, and request for proposal requirements, and observed commission staff performing their work.

In addition, the following specific methods were used:

- To illustrate the impact of the Commission's projects and determine whether the projects the Commission funds appear to have a positive benefit for the State, auditors reviewed a random sample of hard-copy files for 27 commission projects.<sup>1</sup> Auditors conducted follow-up interviews with ten researchers from the 27 projects to obtain the most updated information about project accomplishments and to obtain information not contained in the file. Additionally, auditors interviewed or corresponded with four individuals familiar with medical research in specific medical disciplines such as cerebral palsy treatments and Parkinson's Disease to gain their assessment of the relative impact of commission-funded projects. In addition, to determine if the Commission was gathering appropriate impact information, auditors analyzed various articles and documents about the impacts of biomedical research, and obtained information on impact-reporting practices in four other states and for the Science Foundation Arizona.<sup>2</sup> Auditors also attended a meeting for the Commission's Parkinson's Disease project and interviewed representatives from the Michael J. Fox Foundation who are also providing monies for part of this project. Finally, auditors reviewed TGen contract information and annual reports, attended a TGen presentation, and toured a TGen facility in Phoenix.
- To determine if the Commission is functioning in accordance with the 12 statutory sunset factors, auditors reviewed applicable statutes, interviewed and corresponded with commission management, reviewed the State's open meeting laws and the Commission's compliance with them, and reviewed various commission contracts.

<sup>1</sup> The 27 projects reviewed consisted of projects receiving commission funding in fiscal years 2001 through 2007. The selected projects represent a variety of research institutions, including 15 projects from the University of Arizona, 7 projects from Arizona State University, and 5 projects from other institutions.

<sup>2</sup> These four entities include the Roman Reed Spinal Cord Injury Research Fund in California, the James and Esther King Biomedical Research Program in Florida, the Indiana 21st Century Research and Technology Fund, and the New Jersey Commission on Spinal Cord Research.

- To develop information for the Introduction and Background section, auditors compiled unaudited information from the Arizona Financial Information System (AFIS), state laws, a Commission RFP and Peer Review Questionnaire, the Commission's database containing competitive contract project information, and other agency-provided documents.

This audit was conducted in accordance with government auditing standards.

The Auditor General and staff express appreciation to the members of the Arizona Biomedical Research Commission and the Executive Director and staff for their cooperation and assistance throughout the audit.

# FINDING 1

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## Commission-funded projects appear to have positive impacts, but impacts could be better documented and reported

Biomedical research projects that the Arizona Biomedical Research Commission (Commission) funds appear to benefit the State, but the Commission can take steps to better demonstrate and report the impacts. The Commission annually collects information on some important impacts of the projects it funds, such as articles published or projects researching medical issues relevant to Arizona. Other impact information, such as the number of patents or number and amount of additional research grants resulting from commission-funded projects, is only partially collected and is not reported. Collecting and reporting more complete impact information in the Commission's annual report, as well as making the annual report available on its Web site, would further help show how the Commission is operating in the public interest. In addition, although the Translational Genomics Research Institute (TGen) annually reports some impact information to the Commission, it does not include all impacts in its annual report as required by the contract, and the Commission does not report TGen impacts in the Commission's annual report. Since the Commission's funding for TGen represents nearly half of all the funding the Commission provides for research projects and services each year, better reporting of TGen's impacts would help show what is being accomplished through the State's support.

## Some impact measures collected partially or not at all; most not included in annual report

According to information reported by researchers, commission-funded projects appear to have resulted in positive outcomes. As indicated in the Introduction and Background (see pages 1 through 10), the Commission annually provides approximately \$6.6 million to Arizona institutions for biomedical research projects.

The Commission does not report much of the impact information it collects.

Many of the positive outcomes of these projects, however, are not made visible because the Commission gathers only partial or no information about them and does not include them in its annual report.

To help identify the impacts of these projects, auditors evaluated self-reported information submitted to the Commission from 27 randomly selected commission-funded competitive contract projects that received funding between fiscal years 2001 and 2007. Auditors conducted follow-up interviews with ten researchers from the 27 projects to obtain the most updated information about project accomplishments and to obtain information not contained in the file.<sup>1</sup> In addition, auditors reviewed various articles and documents about the impacts of biomedical research and obtained information on impact-reporting practices in four other states and for the Science Foundation Arizona to identify some additional measures that the Commission could collect information about to help further demonstrate project impacts.

As illustrated in Table 3, this work demonstrated that a wider range of measures is available than the Commission is currently reporting. It also demonstrated that measures currently being collected are not necessarily complete.

**Table 3:** Types of Information Collected and Reported For Commission-Funded Projects Fiscal Years 2001 through 2007

Type of Information	Was Information Collected?	Was Information Reported?
Number of patents	Partial	No
Additional research monies received from other sources	Partial	No
Number of publications	Yes	Yes
Number of presentations	Partial	Partial
Project relevance to Arizona	Yes	No
Number of collaborative projects	Yes	No
Number and types of jobs funded	Yes	No
Number of projects involving translational research <sup>1</sup>	Yes	Yes

<sup>1</sup> Translational research is medical research that attempts to more directly connect basic research to patient care.

Source: Auditor General staff analysis of the Commission's Annual Report for fiscal year 2007, budget summaries and file review of the 27 commission-funded projects between fiscal years 2001 and 2007, and the Commission's fiscal year 2007 annual progress report form.

<sup>1</sup> To identify the potential impacts of commission-funded projects, auditors reviewed commission files for 27 projects, including 15 projects the Commission funded at the University of Arizona, 7 projects at Arizona State University, and 5 projects at other institutions. See Introduction and Background, pages 1 through 10, for more information.

First, the Commission is only partially collecting information on three important impacts and should include all three in its annual report. Specifically:

- **Patents**—Patents represent accomplishments, and the Commission collects information on patents where it is the controlling party (see textbox), but it should also collect information on other patents from projects it funds, and it should include patent information in its annual report. A patent is considered beneficial because it provides protection for project discoveries that have potential for commercialization, and patents may also generate revenue for the Commission. According to the Commission, it is the controlling party for eight patents, including one for a compound that inhibits cancer tumor growth and one for a compound that inhibits cancer cells from expelling anticancer drugs. If the Commission provides the largest direct payment of monies on a project that obtains a patent, then according to the Commission's contracts, it may be considered the controlling party and has a right to a percentage of the revenues generated from the patent.<sup>1</sup>

Even if the Commission is not a controlling party of a patent, the Commission should require researchers whose projects have received commission funding to report all patents the project received. Even though the Commission may not be the controlling party, if it contributed funding to a research project that received a patent, that patent demonstrates a positive impact of the Commission's funding. The Commission requires researchers who receive commission funding to provide an annual progress report on their projects. The Commission should require researchers to include information on all patents received in the annual progress report. Finally, once this information is collected, to help better demonstrate the positive impacts of the projects it funds, the Commission should include patent information in its annual report.

- **Additional research monies received**—One impact of the commission-funded research projects is that some may apply for and receive additional research monies from private or national organizations. Based on information reported by researchers in the sample of 27 projects reviewed, auditors found that 16 projects received at least 27 additional grants totaling over \$19 million. These additional monies can supplement the state monies the Commission awarded.

According to experts, researchers, and granting organizations, large research grants from federal government and private organizations are often needed to conduct significant research, but are more likely to be awarded to projects that already have preliminary data showing positive outcomes. According to the Commission, one purpose of its small contract awards (i.e., those up to \$50,000

### Patent Definitions

**Patent:** The grant of a property right issued by the government that confers upon the creator of an invention the sole right to make, use, and sell that invention for a set period of time.

**Controlling Party:** The party to the contract that makes the largest verifiable payment to the research being performed.

Source: The United States Patent and Trademark Office Web site as of June 4, 2008, and commission contract.

<sup>1</sup> According to the Commission, as of May 2008, it had received \$30,000 in fees as a result of licensing one of these patents, and this money was used to offset commission expenditures related to seeking a patent.

## Parkinson's Disease Project

Fiscal years 2006 through 2008; contract total \$750,000

This project seeks to understand and better define the causes, identify biomarkers, and find new treatments for Parkinson's Disease by working with subjects enrolled in a brain and body donation program. Subjects, normal controls and those with Parkinson's disease, are studied from the time of enrollment through autopsy examination after death. This project involves a consortium of Arizona institutions collaborating on multiple projects at ASU, Banner Health, Barrow Neurological Institute, Mayo Clinic Arizona, Sun Health Research Institute, and TGen. As of June 2008, the project had conducted more than 5,000 clinical evaluations on over 1,000 living patients and over 1,000 autopsy examinations.

According to representatives from the Michael J. Fox Foundation, which also provided funding for this project, this project is unique because no other project in their portfolio, and possibly in the country, has access to a post-mortem brain and body bank for Parkinson's Disease, Alzheimer's Disease, and control group patients. This project is important because it may discover identifying markers leading to early diagnosis and intervention, identification of different types of the disease and how drugs affect these types at various stages, and improvements in quality of life for patients who currently have the disease until a cure is found.

- 14 publications
- 22 presentations
- \$2.8 million award from the Michael J. Fox Foundation

Source: Auditor General staff review of commission database and annual report information, self-reported annual progress report information, information from the project researcher, interview with Michael J. Fox Foundation representatives, and information from the Foundation's Web site.

per year) is to provide support in the early stages of research when preliminary data needs to be gathered, and which then allows the researcher to apply for larger grants.

Although the Commission collects information about additional research monies received by commission-funded projects, this information is sometimes incomplete. The Commission's annual progress report form requests researchers of commission-funded projects to provide a description of direct and indirect funding received and a list of sources of support. However, auditors found that researchers sometimes did not provide complete information regarding other awards such as the source, the number of other awards, or the amount of funding. The Commission should revise its annual progress report form to require that researchers report both the source and the amount of each additional grant received. In addition, the Commission should include this information in its annual report.

- **Publications and presentations**—Two related project outcome measures are the number of publications issued and the number of presentations given; the Commission collects information on the first, but not the second. In the sample of 27 projects auditors reviewed, researchers for 18 of the projects reported a total of 107 publications resulting from the projects the Commission funded.

## Alzheimer's Disease Project

Fiscal years 2001 through 2003; contract total \$378,000

This project from Sun Health Research Institute in Sun City, Arizona, branched into several additional projects that the Commission funded, totaling an estimated \$2 million since 2001. A primary discovery of these projects is that copper found in tap water, coupled with high cholesterol, could be a link to the progression and possibly the onset of Alzheimer's. Further, drinking purified or distilled water could substantially reduce the rate of progressively severe cognitive deterioration in the disease. Additionally, the researcher directed a clinical study showing that Lipitor™, a cholesterol-lowering medication, slows the progression of and reduces the deterioration caused by Alzheimer's Disease.

- 43 publications
- More than \$2 million in additional grants

Source: Auditor General staff review of commission database and annual report, self-reported annual progress report information, interview with project researcher, and review of Sun Health Research Institute Web site.

Publications are a common measure used to determine the success of a research project and a way for sharing research discoveries.<sup>1</sup> Presentations, like publications, are a way for sharing research discoveries, and Arizona researchers may be invited to orally present research discoveries or progress at conferences or other speaking events, including those held in Arizona. According to one researcher, presentations are important because they provide a convenient forum in which to disseminate important and timely information to the public and to other health professionals throughout the State.

Although the Commission does not ask researchers to report on the presentations they make regarding commission-funded projects, some researchers have reported the information to the Commission. For the 27 projects auditors reviewed, researchers for 10 of the projects reported conducting a total of 25 presentations. For example, one researcher reported giving an oral presentation and a poster session in 2007 about acupuncture for children with cerebral palsy at the Society for Acupuncture Research Conference in Baltimore, Maryland. The Commission should continue requesting information about publications. Further, to ensure the Commission has complete information on presentations, it should also require researchers to provide information about presentations in their annual progress reports. The Commission can also more clearly illustrate information about presentations given by separating this information from publications and consistently labeling it as presentation information in its annual report.

Second, the Commission is collecting information on three important impact measures, and it should include information on them in its annual report. Specifically:

- **Special Arizona populations or needs**—A project's relevance to specific Arizona populations and needs is one factor that the Commission collects information

<sup>1</sup> According to the Commission, publications include abstracts or articles presented in peer-reviewed journals.



on and considers in deciding which projects to fund. Four of the 27 projects auditors reviewed addressed a special Arizona population or need, including research about Valley Fever and cures using desert plants. In addition, narrative project information in the Commission's fiscal years 2006 and 2007 annual reports identified that the Commission has funded other projects that address concerns specifically relevant to Arizona, such as a scorpion antivenom project (see textbox below), a sun-induced skin cancer project, a project studying increased heart attack mortality related to air pollution in metropolitan areas such as Phoenix, and a project related to researching the high incidents of rheumatoid arthritis in the Tucson area. Although this impact may be discerned by reading narrative project information in the annual report, the Commission could better highlight this impact by including in its annual report a summary of the number of projects that focus on Arizona-specific populations or needs.

### Scorpion Antivenom Project

Fiscal years 2006 through 2008; contract total \$540,553

This project initially began in 2000 when the Arizona producer of scorpion antivenom retired and experts reported that the State would run out of the antivenom in the next 5 years. Beginning in fiscal year 2005, the Legislature appropriated \$150,000 annually through the Department of Health Services to distribute antivenom that was donated by a pharmaceutical company in Mexico. This project first received funding in 2006 to conduct clinical tests to obtain the federal Food and Drug Administration's (FDA) approval, and to create a video protocol to train physicians to diagnose and treat patients with scorpion stings. The University of Arizona provided matching monies for this project, and the Commission granted this project a 1-year extension for 2009 to complete testing for FDA approval.

According to the researcher, every year over 8,000 Arizonans are stung by scorpions, and stings from certain scorpions found primarily in Arizona can be potentially life-threatening for children and extremely painful for adults. Since its inception, the project has made antivenom available to 250 patients in Arizona through their participation in the study. The program has trained over 150 doctors, and 21 hospitals throughout Arizona are participating in the study. The researcher hopes that the FDA will make its final decision to approve or disapprove the antivenom sometime in 2009.

Source: Auditor General staff review of commission database and annual report information, self-reported annual progress report information, and interview with the project researcher.

- **Project collaboration**—The Commission considers collaborations a positive impact and believes collaborations increase the efficiency of biomedical research by reducing repetition and addressing interrelated components of the same problem. Similar to the National Institutes of Health, which encourages collaborations as a way for multiple disciplines to share knowledge and provides specific funds for such research, the Commission encourages collaboration between researchers by offering larger awards (e.g., \$150,000 and \$250,000

## BioTechnology Collaboration Project

Fiscal years 2005 through 2007; contract total \$300,000

This project created a Web-based data management system to help Arizona researchers to collaborate with others around the world on large-scale clinical studies. According to the project's researcher, most institutions use different computer systems, which makes sharing information difficult, time-consuming, and costly. The Web-based system will give researchers a central place to enter their data, control its visibility, and easily view data other researchers have contributed. Study results will be more timely as they are available immediately when data is entered. All Arizona researchers and institutions have free access to the results of the system. A similar system created by this researcher is now used by the National Institutes of Health.

The Web-based system has been used for projects including:

- A Lou Gehrig's Disease study sponsored by the Muscular Dystrophy Association and run by TGen with 10 national institutions, including the Mayo Clinic in Scottsdale.
- A brain cancer study that is a collaboration between TGen and 15 global institutions across 10 countries.

Source: Auditor General staff review of commission database, self-reported annual progress report information, and an interview and e-mail correspondence with the project researcher.

per year) for collaborative projects. Of the 27 projects auditors reviewed, 18 were large collaborative projects, and 4 additional small projects involved collaboration, even though this was not required. According to the Commission, in the past it was common practice for researchers to work individually, but increasingly, multiple-investigator, multiple-institution, and/or interdisciplinary collaborative projects have become more prevalent. Because the Commission supports collaboration, it should include the number of collaborative projects funded each year in its annual report.

- **Information on jobs funded**—The creation of jobs is an important impact of the Commission's providing funding to biomedical research projects. Each commission-funded project is required to annually submit a budget summary, which includes information such as employees' names and position titles, and the amount of commission money used to fully or partially fund the position. Based on a review of the final year budget summaries for the 27 projects in the auditor's sample, commission money was used to fully fund 23 positions at a cost of about \$800,000 and to partially fund 80 positions at a cost of about \$1.4 million. Positions funded included principal investigators, research technicians and assistants, and program coordinators. Since the number of jobs fully or partially funded is an important economic benefit for the State, the Commission should include this information in its annual report.

## Research Categories

**Basic Research:** Scientific studies that increase knowledge of basic life processes.

**Translational research:** Medical research that attempts to more directly connect basic research to patient care.

**Clinical research:** The study of drugs, biologics, or devices in human subjects with the intent to discover potential effects and/or determine safety or usefulness.

Source: Auditor General staff analysis of the Commission's 2007 Annual Report information.

Third, the Commission should continue to collect information on one important impact measure and should continue to include it in its annual report. Specifically:

- **Translational Research**—According to a report prepared for the Commission, translational research (see textbox) is research that converts basic research knowledge into such real world technologies as drugs, vaccines, and diagnostic devices. The production, distribution, and marketing of these technologies drive the creation of new jobs, attract related industry to the area, and bring cutting-edge technologies to the state's patient population.<sup>1</sup> In its fiscal year 2007 annual report, the Commission categorized the projects receiving commission funding into three categories: basic, translational, and clinical. According to the Commission, translational research is often underfunded even though this step in the research process is needed to move basic research beyond the lab on toward the clinic and to commercialization. As noted in the Commission's 2007 report, 15 of the Commission's 72 projects were translational research projects.

Finally, although individual project information is available on the Commission's Web site, the annual report is available only by mail. Therefore, to improve accessibility, the Commission should include its annual report on its Web site.

## Commission should require and report impact information on TGen

The Commission annually provides \$5.5 million to TGen for operating expenses such as personnel, professional and outside services, equipment, supplies, travel, and other administrative expenses. According to TGen, national entities do not offer grants that provide funding solely for operating costs. Without the Commission's funding, TGen believes it would not have the monies necessary to compete and continue seeking National Institutes of Health and other research grants. Although the Commission's funding for operating costs does not directly support specific research projects, based on legislative hearing minutes, it appears that the Legislature appropriated these monies to TGen because establishing a world-class genomics institute would advance economic development and improve Arizona citizens' health prospects.

The Commission's contract with TGen requires TGen to provide to the Commission an annual report that contains a summary of TGen's activities, which includes impacts such as grants obtained, patents applied for and granted,

<sup>1</sup> Battelle Memorial Institute. *Seizing the Translational Research Opportunity in Arizona*. A report to the Arizona Biomedical Commission and the Flinn Foundation. Columbus, OH: Battelle Memorial Institute, June 2006.

commercialization of intellectual property, articles and abstracts published, and spin-offs.<sup>1</sup> Auditors found that TGen is reporting some information on grants and published articles and abstracts, and also includes some additional information such as the number and type of new positions created and information on its collaborations with other bioscience entities. However, auditors' review of TGen's annual reports found that these reports did not always contain all of the contractually required information, and that the Commission does not include TGen's impact information in its annual report. For example, auditors found that the TGen reports submitted for fiscal years 2003 through 2007 did not contain information on patents, and only two reports contained information on the commercialization of intellectual property and spin-offs. A commission official indicated that it is satisfied with the information it is receiving from TGen. According to commission and TGen officials, the Commission receives information on TGen's activities through the contractually required annual report as well as through one commission member's participation on TGen's Board, and periodic meetings and tours. In addition, according to TGen, all required information is requested and reported to the Commission through a variety of means; however, TGen is willing to include all of the information in its future annual reports to the Commission.

Although the Commission is receiving TGen impact information through several means, to better ensure that the public is aware of TGen's impacts, the Commission should ensure that TGen reports all contractually required information, and that this impact information is included in the Commission's annual report. Further, to bring the TGen reporting in line with the other key impact items identified for non-TGen, commission-funded projects, the Commission should also require that TGen annually report information on the numbers and types of jobs created, numbers of presentations given, projects that are specific to Arizona populations or needs, and collaborations.

Impact information annually provided by TGen should also be included in the Commission's annual report.

## Recommendations:

1. The Commission should take steps to collect more complete impact information on commission-funded projects by revising its annual progress report request form to require researchers to report information on:
  - a. Patents received, whether or not the Commission is the controlling party.
  - b. Both the source and amount of additional funding received.
  - c. Presentations given related to commission-funded projects.

<sup>1</sup> A spin-off is a new company that is created based on the discovery or findings of a research project.

2. The Commission should report more complete impact information in its annual report by including information on the number of patents, additional funding received, presentations given, projects relevant to Arizona-specific populations or needs, collaborations, and the number and types of jobs receiving full or partial commission funding.
3. The Commission should improve accessibility to its annual report by posting the annual report on its Web site.
4. The Commission should ensure that TGen's annual report effectively presents impact information by:
  - a. Ensuring that TGen reports all contractually required impacts.
  - b. Requiring that TGen also report on the number and types of jobs created as well as the other key impact items identified for commission-funded projects, including presentations, projects relevant to Arizona-specific populations or needs, and collaborations.
5. The Commission should include in its annual report some of the impacts reported in TGen's annual report.

# SUNSET FACTORS

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In accordance with Arizona Revised Statutes (A.R.S). §41-2954, the Legislature should consider the following 12 factors in determining whether the Arizona Biomedical Research Commission (Commission) should be continued or terminated.

**1. The objective and purpose in establishing the Commission.**

The Legislature established the Disease Control Research Commission (Commission) in 1984 to improve the health of Arizonans by providing funding for research into the causes, treatments, and cures for diseases. In 2005, the Commission's name was changed by statute to the Arizona Biomedical Research Commission. To carry out its responsibility, a nine-member Commission is empowered by A.R.S. §36-273(A)(1) to:

*"...Contract with individuals, organizations, corporations and institutions, public or private, in this state for any projects or services that, in the commission's determination, may advance research into the causes, the epidemiology and diagnosis, the formulation of cures, the medically accepted treatment or the prevention of diseases including new drug discovery and development."*

**2. The effectiveness with which the Commission has met its objective and purpose and the efficiency with which it has operated.**

As indicated above, the Commission is empowered to contract with individuals, organizations, corporations, and institutions, public or private, in this state to conduct biomedical research. In fiscal year 2008, the Commission provided approximately \$6.6 million to 75 research contracts that were awarded on a competitive basis. The Commission also provided \$5.5 million to the Translational Genomics Research Institute (TGen), a nonprofit Arizona biomedical research institute. As discussed in Finding 1 of this report, the projects that the Commission has provided funding to appear to benefit Arizona. For example, based on information reported by researchers, 16 of the 27 projects auditors reviewed obtained additional funding from other sources totaling over \$19 million (see Finding 1, pages 11 through 20). In addition, according to narrative project information in the Commission's fiscal years 2006

and 2007 annual reports, the Commission has provided monies to research projects that focus on Arizona-specific needs, such as a project related to researching the high incidence of rheumatoid arthritis in the Tucson area and a scorpion antivenom project.

Auditors did not identify any efficiency concerns, but did identify the need for the Commission to enhance its efforts to gather and report project impacts. For example, the Commission should require researchers to report additional information to the Commission, such as the number of patents resulting from commission-funded projects and the number of presentations given on commission-funded projects. In addition, the Commission should include this information in its annual report and make this report available on its Web site (see Finding 1, pages 11 through 20).

**3. The extent to which the Commission has operated within the public interest.**

The Commission has operated within the public interest by contracting with entities that conduct research related to the causes, treatments, and prevention of diseases, including issues that especially impact Arizonans' health. For example, one of the Commission's contract projects is conducting the clinical testing necessary to obtain federal Food and Drug Administration approval for scorpion antivenom. In addition, the Commission provides monies for research associated with specific diseases, such as Parkinson's Disease, Rheumatoid Arthritis, and Alzheimer's Disease, which affect members of the public (see Introduction and Background, pages 1 through 10, and Finding 1, pages 11 through 20).

**4. The extent to which rules adopted by the Commission are consistent with the legislative mandate.**

This factor is not applicable because the Commission does not have statutory authority to promulgate rules.

**5. The extent to which the Commission has encouraged input from the public before adopting its rules and the extent to which it has informed the public as to its actions and their expected impact on the public.**

Although the Commission does not have statutory authority to promulgate rules, it takes steps to inform the public of its actions. For example, the Commission's meetings are open to the public, and it makes information available on its Web site, including its active Requests for Proposals (RFPs) for research projects and a listing of projects that have been awarded. In addition, the Commission produces an annual report, which, according to the Commission, was distributed in 2008 to about 125 state government, university, nonprofit organization officials, and others. Further, according to the Commission, it

distributes close to 1,000 copies of its annual RFPs to Arizona biomedical researchers and briefs Arizona legislators on its activities and progress in the biomedical sciences. However, as mentioned above, auditors found that the Commission should request additional information regarding projects it has funded and include this information in its annual report to further help illustrate the impact of commission-funded projects. Further, the Commission should include its annual report on its Web site (see Finding 1, pages 11 through 20).

In addition, auditors found that the Commission was not fully complying with Arizona's open-meeting laws. The Commission did not ensure that its meeting dates, times, and agendas were posted for public viewing, and the Secretary of State's Office did not have the required notice on where the Commission would post its meeting information for public viewing. However, during the audit, the Commission made changes to correct these issues.

**6. The extent to which the Commission has been able to investigate and resolve complaints that are within its jurisdiction.**

This factor is not applicable because the Commission is not a regulatory agency and, therefore, has no need to investigate and resolve complaints regarding regulated persons or entities.

**7. The extent to which the Attorney General or any other applicable agency of state government has the authority to prosecute actions under the enabling legislation.**

This factor is not applicable because the Commission is not a regulatory agency with enforcement or oversight responsibilities. However, the Commission has signed an agreement with the Attorney General's Office for legal services support.

**8. The extent to which the Commission has addressed deficiencies in its enabling statutes, which prevent it from fulfilling its statutory mandate.**

The Commission has successfully sought changes to its statutes since 1998. For example:

- Laws 1998, Chapter 12—This change modified A.R.S. §36-273 to provide the Commission the authority to enter into technology transfer agreements. According to a commission official, technology transfer is the process of converting scientific findings from research laboratories into useful products by the commercial sector. Further, while the Commission owned some technology, it did not have the authority to license it to another entity for commercialization purposes. Therefore, the Commission sought this statutory change to generate a return on its investment in the technology, which could then be used to fund additional research contracts.



- Laws 1998, Chapter 99—This amendment modified A.R.S. §36-272 to change the Department of Health Services Director from the Commission's chairperson to a non-voting member and allow the DHS Director to send a designee.
- Laws 2001, Chapter 387—This change amended A.R.S. §36-275 to allow the Commission to spend tobacco tax monies on nontobacco-related research.
- Laws 2005, Chapter 170—These changes amended A.R.S. §36-271 to revise the Commission's name from the Disease Control Research Commission to the Biomedical Research Commission, and A.R.S. §36-272 provided for additional compensation of commission members. According to a commission official, the Commission's name was changed to better reflect the work the Commission does. Commission compensation changed so that members now receive \$200 per day for every day of active service and are eligible for additional compensation for expenditures incurred in attending meetings.

According to a commission official, as of May 2008 the Commission did not have any plans to seek legislative changes in 2009.

**9. The extent to which changes are necessary in the laws of the Commission to adequately comply with the factors listed in the sunset law.**

This audit did not identify a need for any legislative changes.

**10. The extent to which the termination of the Commission would significantly harm the public health, safety, or welfare.**

Although terminating the Commission would not necessarily harm the public's safety or welfare, the Commission funds projects that focus on research that can help improve individuals' health. For example, commission-funded projects have focused on specific diseases that can affect all people, including Arizonans, such as cancer, Parkinson's Disease, and Alzheimer's Disease. In addition, auditors determined after reviewing a sample of 27 projects that 4 of the projects addressed a special Arizona population or need, including research about Valley Fever and cures using desert plants. Additionally, the commission-funded projects can also result in some economic benefits to Arizona if commission-sponsored researchers receive additional monies from other sources to continue their work.

11. **The extent to which the level of regulation exercised by the Commission is appropriate and whether less or more stringent levels of regulation would be appropriate.**

This factor is not applicable because the Commission does not have regulatory authority.

12. **The extent to which the Commission has used private contractors in the performance of its duties and how effective use of private contractors could be accomplished.**

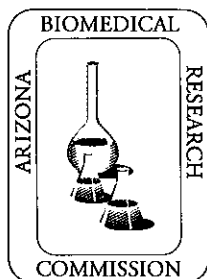
The Commission uses several private contractors. In December 2006, the Commission extended its 2-year cost reimbursement contract with the Battelle Memorial Institute through September 2008. In 2002, prior to the initial 2004 contract with the Commission, Battelle worked with business, economic development, governmental, and university leaders to assess Arizona's competitive position in the biosciences and develop an Arizona biosciences economic roadmap with recommended strategies for Arizona to pursue in the next 10 years. According to an Arizona Bioscience Roadmap document, Battelle is considered a world-wide leader in the development, commercialization, and transfer of technology. An aspect of the Roadmap's overall goal is to make Arizona a leading Southwestern state in selective biosciences. According to a commission official, Battelle's work with the Commission is instrumental in helping it participate with other bioscience stakeholders in Arizona to meet the roadmap goals. For example, one of the strategies outlined in the plan is to build up the State's bioscience research infrastructure, and one of the ways to do this is to secure federal investments to build Arizona's bioscience capacity. According to the Commission, it has worked with Battelle, university leaders, and bioscience researchers to apply for the Clinical and Translational Science award from the National Institutes of Health. According to a commission official, this award will bring federal monies to the State to be used to build a collaborative bioscience consortium and will further Arizona's progress toward the roadmap goals. In addition to this work, Battelle is involved in developing and maintaining the Commission's Web site.

The Commission also contracts with a lobbyist that keeps the Commission informed about legislation that could impact it. According to the Commission, it also depends on the specialized scientific expertise of over 200 peer reviewers whose evaluations of project proposals enable the Commission to make careful contract award decisions. Finally, although the Commission has an Attorney General's Office representative who, according to the Commission, helps with issues including contracting and state procurement law, it also contracts with outside legal counsel as needed for assistance with special areas such as intellectual property issues related to patents.

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# AGENCY RESPONSE





September 5, 2008

Ms. Debbie Davenport  
Auditor General  
2910 North 44<sup>th</sup> Street, Suite 410  
Phoenix, Arizona 85018

Janet Napolitano  
GOVERNOR

Dear Ms. Davenport:

I have reviewed the Performance Audit and Sunset Review Report of the Arizona Biomedical Research Commission. I have discussed the draft report with members of the Commission.

COMMISSIONERS:

David Landrith, MPA  
David Jerman, MBA  
Gregorio Garcia, JD

In accordance with Joint Legislative Audit Committee procedures, the Commission response to the performance audit and sunset review recommendations are as follows:

Manuel Modiano, MD  
T. Lon Owen, PhD  
Joan Rankin Shapiro, MD, PhD

1. The Commission should take steps to collect more complete impact information on commission funded projects by requiring researchers to report information on:
  - a. Patents received, whether or not the Commission is the controlling party.
  - b. Both the source and amount of additional funding received.
  - c. Presentations given related to commission funded projects.

Colleen Brophy, MD  
Barbara Wuebbels, RN, MS  
Eve Shapiro, MD

The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Dawn C. Schroeder,  
DDS, MA  
EXECUTIVE DIRECTOR

2. The Commission should report more complete impact information in its annual report by including information on the number of patents, additional funding received, presentations given, projects relevant to Arizona specific populations or needs, collaborations, and the number and types of jobs receiving full or partial commission funding.

James Matthews,  
MPA, HR-CP  
DEPUTY DIRECTOR

The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

3. The Commission should improve accessibility to its annual report by posting the annual report on its website.

15 SOUTH 15TH AVENUE  
SUITE 103-A  
PHOENIX, AZ 85007  
PHONE: 602.542.1028  
FAX: 602.542.6380

The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

4. The Commission should ensure that TGen's annual report effectively presents impact information by:
  - a. Ensuring that TGen reports all contractually required impacts.

The finding of Auditor General is agreed to the audit recommendation will be implemented.

- b. Requiring that TGen also report on the number and types of jobs created as well as the other key impact items identified for commission-funded projects, including presentations, projects relevant to Arizona-specific populations or needs, and collaborations

The finding of Auditor General is agreed to the audit recommendation will be implemented.

5. The Commission should include in its annual report some of the impacts reported in TGen's annual report.

The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

The work of the Arizona Biomedical Research Commission is intricate and complex. The Auditor General staff and especially the on-site auditors and their supervisor were willing listeners and learners. Their attendance at Commission meetings and interactions with Commission members was both professional and welcomed. The Commission thanks them for their hard work, suggestions, and cooperation.

Submitted on Behalf of the Commission,

Dawn C. Schroeder, D.D.S., M.A.  
Executive Director

## Performance Audit Division reports issued within the last 24 months

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<b>06-09</b>	Department of Health Services—Behavioral Health Services for Adults with Serious Mental Illness in Maricopa County	<b>07-10</b>	Department of Economic Security—Division of Child Support Enforcement
<b>07-01</b>	Arizona Board of Fingerprinting	<b>07-11</b>	Arizona Supreme Court, Administrative Office of the Courts—Juvenile Detention Centers
<b>07-02</b>	Arizona Department of Racing and Arizona Racing Commission	<b>07-12</b>	Department of Environmental Quality—Vehicle Emissions Inspection Programs
<b>07-03</b>	Arizona Department of Transportation—Highway Maintenance	<b>07-13</b>	Arizona Supreme Court, Administrative Office of the Courts—Juvenile Treatment Programs
<b>07-04</b>	Arizona Department of Transportation—Sunset Factors	<b>08-01</b>	Electric Competition
<b>07-05</b>	Arizona Structural Pest Control Commission	<b>08-02</b>	Arizona’s Universities—Technology Transfer Programs
<b>07-06</b>	Arizona School Facilities Board	<b>08-03</b>	Arizona’s Universities—Capital Project Financing
<b>07-07</b>	Board of Homeopathic Medical Examiners	<b>08-04</b>	Arizona’s Universities—Information Technology Security
<b>07-08</b>	Arizona State Land Department		
<b>07-09</b>	Commission for Postsecondary Education		

## Future Performance Audit Division reports

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Board of Podiatry Examiners