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April 2018

# VETERANS AFFAIRS RESEARCH

## Actions Needed to Help Better Identify Agency Inventions

# GAO Highlights

Highlights of [GAO-18-325](#), a report to the Committee on Veterans' Affairs, House of Representatives

## Why GAO Did This Study

VA manages a \$1.9 billion research program that has produced numerous healthcare inventions, such as the pacemaker. In 2000, VA created a program to help transfer VA inventions to the private sector so that they can be commercialized and used by veterans and the public, while VA retains ownership and collects royalties. Many of VA's 3,000 researchers also hold positions at universities, which take the lead in commercializing inventions developed by these researchers. Researchers and universities are required to disclose such inventions to VA, and universities are to report on commercialization activities according to their agreements with VA.

GAO was asked to examine VA's ability to ensure its ownership of inventions made with VA resources. This report examines, among other things, the extent to which VA has taken steps to ensure that (1) researchers disclose inventions and (2) universities report on commercialization activities for joint inventions. GAO reviewed laws; policies; a nongeneralizable sample of university agreements based on backlogs of disclosures, among other factors; and interviews with officials and researchers from VA medical centers and their affiliated universities.

## What GAO Recommends

GAO recommends that VA (1) make training about invention disclosure mandatory and (2) provide universities with a standardized method for annual reporting. VA concurred with GAO's recommendations.

View [GAO-18-325](#). For more information, contact John Neumann at (202) 512-3841 or [neumannj@gao.gov](mailto:neumannj@gao.gov)

April 2018

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### Actions Needed to Help Better Identify Agency Inventions

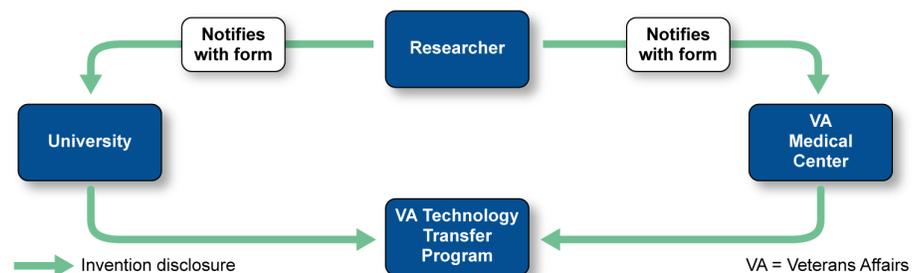
## What GAO Found

The Department of Veterans Affairs (VA) has taken steps to educate agency researchers about its requirements to disclose inventions to VA, but officials reported that researchers have not consistently done so. VA policy requires researchers to disclose inventions to both VA and the university they work for even when they do not use VA resources. GAO found, through discussions with VA officials and researchers, that several factors contribute to researchers not consistently disclosing their inventions, including that VA researchers may have:

- disclosed inventions to their university, assuming the university would then disclose them to VA;
- not been familiar with VA's invention disclosure process, because they may not have frequently developed inventions; or
- thought that invention disclosure was unnecessary when they did not use VA resources to develop their invention.

In 2017, VA staff visited universities and VA medical centers 26 times to meet with researchers about invention disclosure. Also, VA created an online training course to educate researchers on the need to disclose inventions, but the training is not mandatory, and about 4 percent of researchers took it. Without mandatory training to communicate invention disclosure requirements—consistent with federal internal control standards for internally communicating quality information—VA researchers may not be fully informed about those requirements, which can result in lost technology transfer opportunities and royalties for VA.

#### Path of Invention Disclosures at the Department of Veterans Affairs (VA)



Source: GAO analysis of VA data. | GAO-18-325

VA has improved communication with universities but has not ensured that they are consistently reporting information on commercialization activities for joint inventions. VA reported that about three-quarters of VA's 79 university partners did not submit the annual reports required by VA in 2017. GAO reviewed a nongeneralizable sample of agreements VA has with universities and found that reporting requirements about timing and content of reports were unclear. Without providing a standardized method that clearly guides universities in fulfilling VA's reporting requirements, consistent with federal standards for internal control, VA cannot ensure that it has adequate information to account for its licenses and royalties.

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## Abbreviations

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| PDF | portable document format       |
| VA  | Department of Veterans Affairs |

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April 25, 2018

The Honorable David P. Roe, M.D.  
Chairman  
The Honorable Tim Walz  
Ranking Member  
Committee on Veterans' Affairs  
House of Representatives

For more than 90 years, the Department of Veterans Affairs (VA) has managed a research program that has led to healthcare breakthroughs that improve the lives of veterans and the public. According to VA, the department has been instrumental in medical advancements such as therapies for tuberculosis following World War II, the implantable cardiac pacemaker, concepts for computerized axial tomography scans (commonly referred to as CAT scans), the first successful liver transplants, and the first powered ankle-foot prosthesis.

In 2000, VA created a technology transfer program to help transfer the use of inventions to the private sector so that the inventions could be commercialized and used by veterans and the public at large, while VA would retain ownership and collect royalties for its inventions.<sup>1</sup> Today VA oversees a research program that spends \$1.9 billion annually and employs more than 3,000 researchers focused on health issues such as cancer, diabetes, traumatic brain injury, and other conditions affecting veterans. In fiscal year 2016, VA patents from such research resulted in 45 licenses providing the agency about \$316,000 in royalties, according to VA officials.<sup>2</sup>

VA's research program is unique in that the majority of VA's researchers are dually appointed—they work at VA and at another research institution,

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<sup>1</sup>Technology transfer is the process of transferring scientific findings from one organization to another for the purpose of further development and commercialization. Commercialization is the process of developing, producing, and delivering marketable products or services for sale.

<sup>2</sup>In addition to receiving royalties for patents, VA also receives royalties for materials and intellectual property that is protected as proprietary information, or a trade secret. See appendix I for the amount of royalties VA reported receiving from licenses shared with universities and from VA's solely owned licenses in fiscal year 2016, and for the number of patents VA jointly owns with each university from calendar year 2000 through November 2017.

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such as a university or medical college. VA's dually appointed researchers' inventions are subject to agreements between VA and the university and are considered joint inventions.<sup>3</sup> In most cases, the affiliated university is responsible for the bulk of technology transfer activities, including filing patents, finding licensees to further develop the technology, and collecting and distributing royalties. The process, from disclosure of the invention to VA to commercialization of the invention, requires coordination between researchers and administrators at VA medical centers and staff at VA's technology transfer office, as well as between VA's technology transfer office and the affiliated universities.

Congress has raised questions about the extent to which VA is consistently asserting ownership of inventions developed with its resources. You asked us to examine the VA technology transfer program to ensure VA was not missing opportunities to obtain rights to inventions developed using VA resources. This report examines the extent to which VA has taken steps to ensure that (1) researchers and universities disclose inventions and (2) universities have reported information to VA about commercialization activities for joint inventions.

For both objectives, we reviewed documents provided by VA, affiliated universities, and a VA advisory committee. These included documents on the history of VA's technology transfer program; technology transfer policies and procedures; and documents outlining challenges faced in implementing the program and recent efforts to address these challenges. We also examined relevant statutes and regulations. We compared VA's procedures, policies, and internal and external communications to federal internal control standards for control activities and information and communication.<sup>4</sup> We also interviewed officials from the VA technology transfer office and the VA Office of the General Counsel; officials selected through a nonprobability sample of six VA medical centers and their affiliated universities; and two of the three members of a subcommittee of the National Research Advisory Council that submitted a report to VA on the department's technology transfer program in fiscal year 2017.<sup>5</sup> We

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<sup>3</sup>VA refers to the universities, medical colleges, and other schools of medicine with which it has arrangements for dual appointees as academic affiliates, but for the purposes of our report we refer to all of them as affiliated universities.

<sup>4</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

<sup>5</sup>We invited all three members of the subcommittee to meet, and one was not available.

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conducted site visits at five of the six VA medical centers—Atlanta, Georgia; Baltimore, Maryland; Palo Alto and San Francisco, California; and Salt Lake City, Utah—for interviews with researchers who were inventors and with the Associate Chiefs of Staff for Research at each medical center, to whom we refer as the research administrators. We also met with officials of each of the universities affiliated with the respective medical centers—Emory University; the University of Maryland at Baltimore; Stanford University; the University of California, particularly the University of California at San Francisco; and the University of Utah. In addition, we conducted telephone interviews with researchers and the research administrator at the sixth VA medical center in Cleveland, Ohio, and officials of the university affiliated with it, Case Western Reserve University. We selected the medical centers and their respective university affiliates based on high levels of license activity or backlogs of disclosures, among other factors. The results of these interviews are not generalizable to all VA medical centers and their affiliated universities but provide illustrative examples.

The VA technology transfer program is affiliated with 79 universities and has agreements in place with all but three of these. VA began negotiating these, which we refer to as original agreements, soon after the creation of the VA technology transfer program in 2000. Beginning in fiscal year 2015, VA initiated a new type of agreement establishing new provisions for VA, which we will refer to as new agreements. We reviewed original agreements for five of the six universities in our sample. One of the universities in our sample, Emory University, did not have an agreement with VA as of January 2018.<sup>6</sup> We also reviewed a nonprobability sample of an additional three original agreements with other universities based on their licensing and commercialization activities, for a total of eight original agreements. In addition to the original agreements, we also reviewed the first eight new agreements that VA negotiated with universities. In total, we reviewed 16 agreements—the 8 original agreements and 8 new ones to determine whether they contained requirements for disclosure and reporting to VA.

For objective two, we requested and reviewed annual reports from VA for the eight universities whose original technology transfer agreements we reviewed. The annual reports VA provided were those the eight

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<sup>6</sup>Emory University had agreements for individual inventions, but we did not include those agreements in our analysis because they were not comparable to the agreements with the other universities.

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universities submitted to VA in 2016 and 2017, covering technology transfer activities, for a total of 12 reports. Not every university submitted an annual report to VA for each year; instead, at least one university provided an annual report that was late from a prior year, going back as far as 2011. We reviewed at least one annual report from each of the eight universities.

We conducted this performance audit from October 2016 to April 2018, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

Just after World War II, VA developed affiliations with medical schools to improve acute care and physical and mental rehabilitation for veterans. As part of the relationship, VA medical centers have contributed to the education of medical students and residents. Besides medical students and residents, other dual appointees—clinicians and researchers—spend either a full 40-hour week or a fraction of the work week at VA and other time at the affiliated university.

On January 23, 1950, Executive Order 10,096 established that the government shall obtain the entire right, title, and interest in and to all inventions made by government employees during working hours; with a contribution by the government of facilities, equipment, materials, funds, or information, or time and services of other government employees on official duty; or which bear a direct relation to or are made as a consequence of the employee's duties.<sup>7</sup> Since the early 1980s, the federal government has taken several actions related to technology transfer from federal laboratories.

Technology transfer is the process of transferring scientific findings from one organization to another for the purpose of further development and commercialization. In this regard, federal agencies are authorized to issue licenses to outside entities granting rights to make, use, or sell

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<sup>7</sup>Exec. Order No. 10,096, 15 Fed. Reg. 389 (Jan. 25, 1950).

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government owned inventions.<sup>8</sup> One of the first technology transfer laws, the Stevenson-Wydler Technology Innovation Act of 1980, articulated the need for a strong national policy supporting domestic technology transfer. The law requires federal laboratories to establish an office of research and technology applications and devote budget and personnel resources to promoting technology cooperation and the transfer of technologies to private industry and state and local governments. In addition, the act requires federal agencies that operate or direct federal laboratories to report information on technology transfer performance annually to the Office of Management and Budget, as part of their annual budget submission. Copies of those reports should be transmitted to the Secretary of Commerce who must submit a summary report to Congress and the President.

For many years after the Stevenson-Wydler Technology Innovation Act of 1980, VA waived ownership rights to inventions generated by its researchers, leaving the responsibilities for patenting, marketing, and licensing with the inventor and the VA medical center's university partner. As a result of this practice, according to former VA officials, some VA research was not commercialized because VA did not have a technology transfer program or other means to promote commercialization.

In 2000, VA created the VA Technology Transfer Program to facilitate the commercialization of VA inventions to benefit veterans and the American public. VA developed technology transfer agreements with universities to help facilitate technology transfer. Under the terms of the agreements, the universities can take the lead on patenting and commercialization, and VA can retain joint ownership of inventions. Among other things, the original agreements gave the universities the right of first refusal to apply for and manage patents, market the technologies, negotiate licenses, and collect royalties to be shared with VA.

As of November 2017, the VA Technology Transfer Office, located in Washington, D.C., employed five technology transfer specialists responsible for all technology transfer activities for VA's solely owned

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<sup>8</sup>35 U.S.C. § 208; 37 C.F.R. § 404.4. Federal agencies are authorized to issue licenses granting exclusive, partially exclusive, or nonexclusive rights to make, use, or sell government-owned inventions and are required to share royalty and other income with the federal inventor. Under an exclusive license, only one licensee has the right to make, use, or sell an invention during the patent's 20-year life. Under a partially exclusive license, the number of licensees, term of exclusivity, field of use, or territory of use may be restricted.

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inventions. These inventions may come from more than 3,000 VA researchers at over 100 VA medical centers, as well as from VA employees at other VA locations.<sup>9</sup> In addition, the technology transfer specialists are responsible for coordinating with universities on inventions made by dually appointed researchers. According to VA officials, VA relies on affiliated universities for most of the technology transfer efforts connected with such inventions, since the universities have their own offices with expertise in technology transfer and are usually willing to take the lead.

Under a Veterans Health Administration 2002 policy on invention disclosures, which was revised in January 2017, VA employees who invent something are directed to disclose those inventions to VA using a disclosure form and complete a certification form to certify whether VA resources were used.<sup>10</sup> VA employees are to disclose inventions to VA even if they were not created with VA resources.<sup>11</sup> Affiliated universities may also require dually appointed researchers to disclose inventions to the university. Under agreements between the universities and VA, universities are required to disclose a dually appointed researcher's invention to VA, as an additional assurance to aid VA in capturing relevant inventions. Similarly, VA is to notify the university when a dually appointed researcher's invention comes to its attention.

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<sup>9</sup>For example, VA officials said a VA nurse developed a sterile drape for overhead patient lift systems in hospitals; a safety risk manager and a public affairs specialist developed a suicide prevention door; and an employee of VA's National Cemetery Administration developed novel casket handling technology.

<sup>10</sup>The 2002 policy required VA employees with inventions to complete VA certifications providing sufficient information and detail for VA to ascertain ownership rights for submission to the inventor's supervisor before being sent to VA's Technology Transfer Office. The 2017 policy requires researchers to provide both an invention disclosure and a certification form. In addition, the 2017 policy allows researchers to submit their university disclosure form to VA to fulfill the VA disclosure form requirement, if it contains all of the same information that the VA requires.

<sup>11</sup>U.S. Department of Veterans Affairs, Veterans Health Administration, *Intellectual Property*. VHA Handbook 1200.18 (Nov. 1, 2002) and *Determination of Rights for Inventions and Discoveries*, VHA Directive 1200.18 (Jan. 11, 2017). The VA policy and process for invention disclosure apply to all VA employees. The current VHA directive defines an employee as an officer or employee, civilian or military, of VA. Part-time, without compensation employees and part-time consultants are included. Additionally, the term "employee" includes special government employees, individuals working for VA pursuant to the intergovernmental Personnel Act, or a consultant. However, our report focuses on VA researchers since they are predominantly responsible for inventions among VA employees.

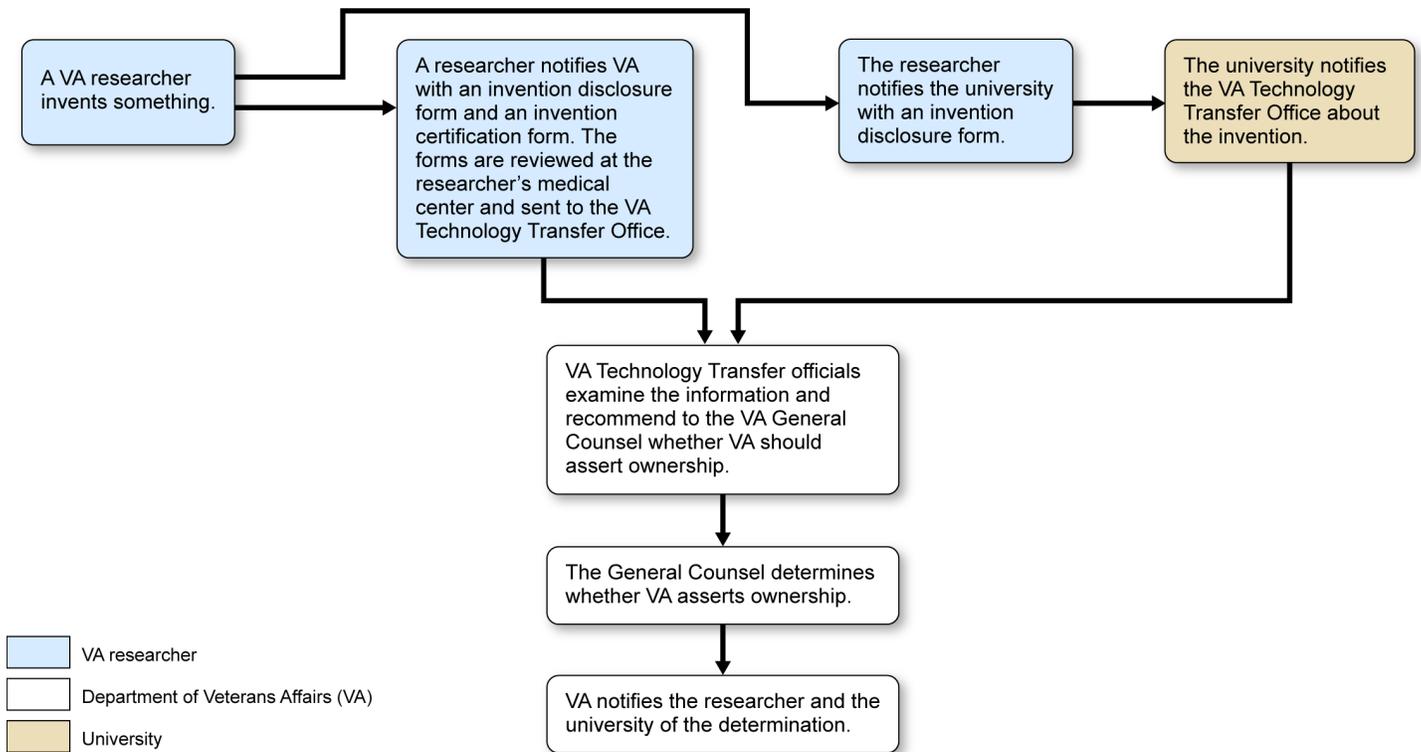
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According to VA policy, researchers' supervisors or research administrators at VA medical centers are to review the disclosure forms and send them to the VA Technology Transfer Office. The office evaluates the information and provides a recommendation to VA's General Counsel on whether VA should assert ownership.<sup>12</sup> If General Counsel's review finds that VA should assert ownership, the General Counsel notifies the VA researcher's and the VA medical center's research and development office of the determination. The Technology Transfer Office then notifies the researcher's university about VA's ownership of the invention. At this point the department expects the university to include VA as an owner during the patenting process, according to VA officials. Figure 1 shows VA's process for determining ownership of inventions created by dually appointed researchers, according to VA policies.

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<sup>12</sup>According to VA officials, researchers can complete the certification form stating that they voluntarily agree to assign ownership rights in cases where VA resources were used. However, if the researcher does not voluntarily assign ownership rights, VA can assert ownership rights if VA resources were used. If a researcher does not agree with VA's assertion of ownership rights, however, he or she can appeal to the National Institute of Standards and Technology, which can make a final determination. VA officials said appeals are rare.

**Figure 1: Department of Veteran Affairs' (VA) Process for Determining Ownership of Inventions of Dually Appointed Researchers**



Source: GAO based on Department of Veterans Affairs data. | GAO-18-325

If the university takes the lead on an invention of a dually appointed researcher, original VA agreements require universities to provide annual reports to update VA on commercialization activities, such as progress in licensing inventions or collecting royalties from licensees. While less commonly used, alternative processes for commercialization are shown in appendix I.

We and others have identified a number of challenges associated with technology transfer from federal research facilities.<sup>13</sup> For example, we found that technology transfer is often not a priority for laboratory managers; researchers may not understand the potential commercial

<sup>13</sup>For more information on challenges faced in technology transfer, see GAO, *Technology Transfer: Federal Laboratory Consortium Should Increase Communication with Potential Customers to Improve Initiatives*, GAO-15-127, (Washington, D.C.; Oct. 3, 2014).

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applicability of their innovations; or the technologies are often not developed enough for use in market-ready products and may require investment of additional time and money to develop. We also have reported that pharmaceutical inventions in particular may take a relatively long time to develop.<sup>14</sup> For example, the entire discovery, development, and review process of a new drug can take up to 15 years.

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## VA Has Taken Steps to Educate Researchers and Universities about Requirements but Could Enhance Researchers' Training

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### VA Has Taken Steps to Educate Researchers but Reported that Researchers Have Not Always Disclosed Their Inventions

Although VA has taken steps to educate researchers about disclosure of inventions, VA officials reported that the researchers have not consistently disclosed inventions to the department because they did not always fully understand VA's disclosure policy. Officials from VA's technology transfer office told us on multiple occasions that they believed researchers did not consistently disclose inventions. For example, in December 2016, VA officials said that once the technology transfer office began sending researchers e-mail notices about the need to disclose inventions, the number of disclosures increased, which they said suggested underreporting had been occurring. In March 2017, the officials told us that many of the inventions from more than 50 researchers during a 5-year period at one university had not been disclosed until VA checked with the university and discovered the error. By November 2017, VA technology transfer officials thought disclosure had improved throughout VA, but they were still not able to describe the extent of the problem.

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<sup>14</sup>For more information on how reported research and development spending and new drug approvals have changed over time see GAO, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, [GAO-18-40](#), (Washington, D.C.; Nov. 17, 2017).

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The researchers we interviewed at the six medical centers in our sample generally believed that they had properly disclosed inventions. However, according to VA officials, a university official, and two VA researchers, there could be several reasons that contributed to researchers not consistently disclosing their inventions to VA, including the following:

- Researchers may have disclosed inventions to their university, assuming the university would disclose them to VA on their behalf.
- Researchers may have disclosed their inventions to the university because it was more convenient than disclosing to VA, as the university's technology transfer officials were more accessible to answer questions.
- Researchers were not familiar with VA's invention disclosure process because the process was not routine to them.
- Researchers may have believed they did not use VA resources and did not realize they were still required to disclose to VA.
- VA research administrators may not always have reminded researchers of the need to disclose inventions, as they did not consider this requirement a priority.

VA made efforts since fiscal year 2016 to inform researchers about its disclosure policy. For example, according to VA officials, the department has increased its in-person communication with VA researchers. In the first 8 months of fiscal year 2017, VA staff made 26 visits to universities and VA medical centers to meet with researchers to encourage the disclosure of inventions.<sup>15</sup> However, VA officials said participation rates among researchers at these voluntary meetings were low in some cases. At one medical center, only the research administrator and one other researcher attended the meeting, according to the administrator.

In addition, VA established an online training program in 2017 covering the invention disclosure process, but the training is not mandatory. VA provided us with a report from October 2017 indicating that out of over 3,000 eligible researchers, 130 had taken the training (about 4 percent). One VA research administrator said that mandatory training would be helpful. Under federal internal control standards, management is to internally communicate the necessary quality information to achieve the entity's objectives, such as by communicating that information down and

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<sup>15</sup> VA technology transfer officials said that they made 10 visits to universities and VA medical centers in fiscal year 2016.

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across reporting lines to enable personnel to perform key roles in achieving those objectives. Given that VA has not made the meetings or online training on disclosure policy mandatory, its importance may not be clear to all researchers. Also, because researchers do not make discoveries every year, and the process is not routine, taking such training once may not be sufficient to educate users. Without requiring researchers to take online training on the invention disclosure process annually, researchers may not be fully informed about the requirement to disclose inventions, which can result in lost technology transfer opportunities and lost royalties for VA if the inventions are not disclosed.<sup>16</sup>

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### VA Has Taken Steps to Make Universities Aware of VA Researchers and Disclosure Requirements

Based on our interviews with VA and university officials in our sample, since fiscal year 2016, the department took steps to make universities aware of VA researchers and their disclosure requirements in an effort to improve university disclosures to VA. We reviewed 16 agreements between VA and affiliated universities, including the five universities with agreements in our sample, and all of the universities agreed to disclose joint inventions to the department. However, VA officials we interviewed said that universities may not always disclose all inventions to VA. Although they said they could not identify the extent of the problem, the officials highlighted one university in our sample that had not disclosed inventions to VA for at least 5 years. This university did not disclose inventions to VA, as agreed, until prompted by VA's technology transfer office late in fiscal year 2016. Responsible university officials said they had assumed the dually appointed researchers were disclosing the inventions to VA. According to VA officials, when the VA technology transfer office received a report from the university in fiscal year 2017 that covered 5 years of disclosures, VA learned it had not received 80 percent of the disclosures from that university for that period.<sup>17</sup> VA officials said

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<sup>16</sup>If a researcher publishes or presents research findings prior to filing a patent application, it can prevent the invention from ever being patented because the invention would no longer be considered novel. Specifically, VA's 2017 policy on determination of rights for inventions and disclosures states that novelty-destroying public disclosure may occur when a description of an invention is published, demonstrated, sold, offered for sale or disclosed orally or in writing to a third party prior to filing a patent application.

<sup>17</sup>The university also failed to submit semi-annual reports to VA, as called for in their agreement. University officials told us they were not certain how many years had passed without providing reports to VA, but VA agreed that they could conduct a review for a 5-year period because older inventions might not be as valuable. To create the report university officials said they compared invention disclosures they received with a recent list of VA employees that VA provided.

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they had not contacted the university sooner because their technology transfer office had been understaffed until early in calendar year 2016. VA officials from the technology transfer office had not identified a similar problem of this magnitude with the other universities, including those in our sample.

According to our interviews with VA and university officials, some of VA's university partners may not have been aware of which researchers were also VA employees because the universities' lists of VA researchers were not current and universities generally relied on the researchers to disclose whether they were VA employees. Furthermore, in some cases, the university disclosure forms did not specifically ask whether the researcher also worked at VA. For example, two of the six forms used by universities in our sample did not specifically ask the researcher to indicate whether they were VA employees. Upon recognizing some shortcomings in universities' disclosures to VA, the department provided current lists of VA researchers at affiliated VA medical centers to their respective universities in fiscal year 2017, and VA technology transfer officials said they intend to provide such updated lists to the universities semi-annually. VA officials said that universities may not be using these lists, but they will not know until time has elapsed. VA technology transfer officials said their site visits to VA medical centers—they conducted 26 visits in fiscal year 2017—along with other communications with their counterparts at the universities should help the disclosure process.

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## VA Increased Communication with Universities about Reporting Commercialization Activities but Has Not Ensured that Such Activities Are Consistently Reported

VA has increased communication with universities since 2016 to help ensure that universities report information about commercialization activities for joint inventions, but universities' reporting remained inconsistent as of January 2018, according to VA. Under the original agreements, such as the ones in our sample of eight agreements, universities have the exclusive right to license and commercialize joint inventions. VA's awareness of the commercialization of such inventions depends on universities providing this information through annual reports, as required by the agreements. However, according to VA officials, prior to 2011, only about 20 percent of the 79 universities with which VA has agreements submitted annual reports. According to VA officials, VA made an effort to increase annual reporting, and by 2013 it was up to 80 percent. The officials said, however, that the percentage of universities submitting annual reports dropped again after losing staff in the technology transfer office—the office retained only three staff in subsequent years until fiscal year 2017 when there were 11 staff, including 5 technology transfer specialists.

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In addition, VA officials we interviewed said that there was some confusion among universities regarding when they needed to submit annual reports. For example, they said that some universities may not have understood whether they needed to provide annual reports during years when there was no new patenting or licensing activity. The officials said that this was at least part of the reason some universities did not submit annual reports. VA officials told us that they expect universities to provide annual reports even when there is no new patenting or licensing activity, and in fiscal year 2016 technology transfer officials e-mailed universities to clarify this expectation. The officials also said that in October 2016 they sent a letter to each of the 79 universities with which the department has agreements to remind universities to submit the required annual reports. Further, as stated earlier, VA staff made 26 visits to VA medical centers and universities in the first 8 months of fiscal year 2017 to discuss reporting and disclosure requirements. However, VA reported that 24 percent of the 79 affiliated universities provided annual reports in fiscal year 2017 even after VA's outreach. Because they did not always receive annual reports, VA officials said they were often not aware of a joint license until the university sent VA the first royalty check for a joint invention.<sup>18</sup> VA officials said they plan to conduct audits to check the accuracy of university information.

Beginning in fiscal year 2015, VA began creating new agreements with universities to give VA enhanced responsibility in licensing and commercialization of joint inventions. By the end of fiscal year 2017, VA had new agreements in place with 11 of the 79 universities. Based on our review of 8 of the new agreements,<sup>19</sup> VA will now, for the first time, have the option to take the lead in licensing joint inventions. For inventions for which VA does not take the lead role, under the new agreements, it will have the right to review and provide input on all joint licenses. This new provision improves VA's awareness of any joint licenses created in the future. However, because original agreements did not include this

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<sup>18</sup>Another reason that VA could not identify all licenses for joint inventions patented from 2012 through 2017—a period for which we sought licenses—was because of problems with the software program it used to track inventions; as a result of these problems, officials said that the department could not provide us with complete information. The VA technology transfer office adopted a new software program to track inventions in 2014, and VA has been taking steps to customize it to be more useful and to better align with data from previous invention management systems, according to VA officials.

<sup>19</sup>As of April 2017, VA had eight agreements in place, which we reviewed. By November 2017, VA had three more agreements in place, according to VA officials, but we did not review those.

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provision, VA will still need to rely on accurate and updated annual reports from universities for information on licenses negotiated under those agreements.

In addition, the new agreements do not improve or clarify language from the original agreements about what details need to be included in the annual reports. According to our analysis, these eight new agreements, similar to the original eight agreements we reviewed, do not contain details on the specific information and format in which to present the annual report. For example, both the original and four of the new agreements we reviewed require universities to provide an annual report,<sup>20</sup> but four other new agreements state that the universities will provide annual reports upon request. The original agreements as well as all eight of the new agreements indicate that reports should include the status of all patent prosecution, commercial development, and licensing activity on joint inventions but do not explain whether an annual report is needed if there has been no commercialization activity. As noted above, VA officials said universities were confused about whether they were required to report to VA if they had no new activity in a given period; however, VA officials told us they still need reports in these situations.

Furthermore, based on our analysis of 12 annual reports from eight universities, the format and content of the reports has been inconsistent. Four universities submitted reports in a spreadsheet format; two universities submitted reports in portable document format (PDF); one university submitted a report in a Word format; and one submitted five different documents, including both PDF and spreadsheet. In addition to differences in format, the annual reports differed considerably in the content they provided—the more detailed annual reports included patent application numbers, patent expenses, the status of patent applications, and information about whether the patent had been licensed. In contrast, the less detailed annual reports did not provide any of this information on patents for the joint inventions. Moreover, one university only included active license agreements in its annual report, while other universities also included license agreements that were terminated. VA officials we interviewed agreed that the reports are not very detailed or standardized

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<sup>20</sup>In the case of the four new agreements with annual reporting requirements, the requirement applies to the university if it is the lead party for commercialization of one or more VA joint inventions. If, however, VA is the lead party, the agency must provide an annual report to the university.

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but said they would like to eventually standardize the annual report format and content so they can use the reports to track and audit joint inventions

The differences in annual reports exist because VA has not provided the universities with a standardized method for reporting, including the format that should be used for the annual reports and the content to include in them. Under federal standards for internal control, management should design control activities to achieve objectives and respond to risks. Such control activities include providing a standardized method that guides universities in fulfilling VA's reporting requirements to ensure the objectives of the program are being achieved. Without providing a standardized method that clearly guides universities in fulfilling VA's reporting requirements for these annual reports, including their format and content, the department will not be able to ensure detailed and standardized annual reports that include details about licenses and royalties. VA officials said that they were working on a template for universities to use in reporting on commercialization activities for joint inventions. However it is not clear whether the template would inform universities of VA's requirements to submit an annual report even if they had no new commercialization activity in a given period.

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## Conclusions

VA manages a research program unique within the federal government in that most of its researchers are dually appointed to universities, and their inventions are jointly owned by VA and the universities, which typically take the lead on commercialization activities. While VA has taken steps to educate researchers about requirements for researchers and universities to disclose inventions to VA, VA officials reported that researchers have not consistently done so, because they did not always fully understand the policy. Given that VA has not made its online training on disclosure policy mandatory, the policy's importance may not be clear to researchers. Also, because researchers do not make discoveries every year, and the process of disclosure is not routine, taking such training once may not be sufficient. Without requiring researchers to take online training on the invention disclosure process annually, researchers may not be fully informed about the requirement to disclose inventions, which can result in lost technology transfer opportunities as well as lost royalties for VA if the inventions are not disclosed.

VA has also taken steps to improve communication with universities to increase reporting of commercialization activities, but said that such reporting by universities is inconsistent, and VA may not have adequate information to account for all of its licenses and royalties. Without

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providing a standardized method that clearly guides universities in fulfilling VA's reporting requirements for these annual reports, including their format and content, the department will not be able to ensure detailed and standardized annual reports.

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## Recommendations for Executive Action

We are making the following two recommendations to VA:

The Under Secretary of Health should make VA's online training on invention disclosure mandatory for researchers and require that it be completed annually. (Recommendation 1)

The Under Secretary of Health should provide a standardized method that guides universities in fulfilling VA's reporting requirements for these annual reports, including their format and content. (Recommendation 2)

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## Agency Comments

We provided a draft of this report to the Department of Veterans Affairs for review and comment. In written comments reproduced in appendix II, VA agreed with our recommendations. Specifically, for our first recommendation, VA said it will develop a plan to ensure its researchers complete online technology transfer training on invention disclosure annually. Furthermore, the plan will contain contingencies for those who do not meet the requirements. The department expects to issue a training requirement, train staff, and also demonstrate training is done by September 2019. In addition, for our second recommendation, VA said it will develop a standardized method that guides universities in fulfilling VA's reporting requirements for the university technology transfer annual reports. VA has a target completion date of December 2018. VA also provided technical comments, which we incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At this time, we will send copies of this report to the appropriate congressional committees, the Secretary of Veterans Affairs, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or [neumannj@gao.gov](mailto:neumannj@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to the report are listed in appendix III.

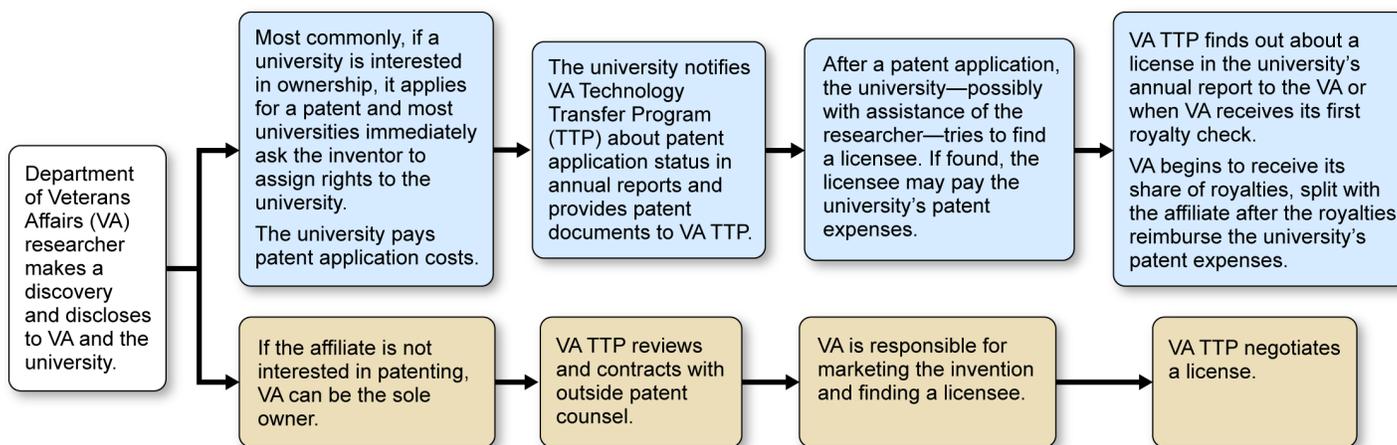
A handwritten signature in black ink, appearing to read "John Neumann", with a long horizontal flourish extending to the right.

John Neumann  
Director  
Natural Resources and Environment

# Appendix I: Department of Veterans Affairs Commercialization Process, Revenue, and Total Joint Patents with Universities

The process for commercializing a Department of Veterans Affairs (VA) invention can take several avenues. Generally a university takes the lead on inventions of dual appointees who work for VA and a university, and VA researchers who are not dually appointed rely on VA to patent and license their inventions. Also, VA can take the lead on joint inventions, for example, if the university is not interested in ownership. (see fig. 2).

**Figure 2: Department of Veterans Affairs' (VA) Process for Commercialization of Joint Inventions by Researchers Working for VA and a University**



Source: GAO based on Veterans Affairs data. | GAO-18-325

Note: VA's research program is unique in that the majority of VA's researchers are dually appointed—they work at VA and at another research institution, such as a university or medical college. In cases where researchers are dually appointed, their inventions are subject to agreements between VA and the university and are considered joint inventions.

VA received about \$316,000 in royalties from 45 licenses for its inventions in fiscal year 2016 (see table 1). VA has U.S. and foreign patents. From calendar years 2000 through November 2017, the U.S. Patent and Trademark Office has granted VA 82 patents for which VA is the sole assignee, according to VA officials. Also, table 2 shows by university the breakdown of the 206 patents for which VA shares ownership with an affiliate.

**Appendix I: Department of Veterans Affairs  
Commercialization Process, Revenue, and  
Total Joint Patents with Universities**

**Table 1: Department of Veterans Affairs' (VA) Royalties from Licenses in Fiscal Year 2016**

| <b>VA affiliated university sharing the license</b> | <b>Number of licenses with royalties</b> | <b>Amount of VA royalties</b> |
|---|--|-------------------------------|
| Baylor College of Medicine                          | 1  | \$1,988                       |
| Boston College                                      | 1  | 2,212                         |
| Cleveland Clinic                                    | 1  | 3,403                         |
| Stanford University                                 | 11                                       | 90,285                        |
| University of California                            | 15                                       | 64,864                        |
| University of Illinois                              | 1  | 2,311                         |
| University of Iowa                                  | 1  | 1,500                         |
| University of Michigan                              | 1  | 773                           |
| University of Minnesota                             | 1  | 2,447                         |
| University of Pittsburgh                            | 2  | 3076                          |
| University of Southern Florida Research Foundation  | 2  | 1,203                         |
| Virginia Commonwealth University                    | 1  | 12,750                        |
| Wayne State University                              | 1  | 252                           |
| Wisconsin Alumni Research Foundation                | 1  | 10,940                        |
| <b>Subtotal</b>                                     | <b>40</b>                                | <b>\$198,006</b>              |
| VA sole licenses                                    |  | \$118,548                     |
| <b>Total royalties to VA</b>                        | <b>45</b>                                | <b>\$316,554</b>              |

Source: GAO based on Veterans Affairs data | GAO-18-325

**Table 2: The Number of Joint Patents Owned by the Department of Veterans Affairs (VA) and Universities**

|    | <b>Affiliated university</b>         | <b>Number of patents shared with VA</b> |
|----|--------------------------------------|---|
| 1  | University of California             | 44                                      |
| 2  | Oregon Health and Science University | 40                                      |
| 3  | Stanford University                  | 17                                      |
| 4  | University of South Florida          | 13                                      |
| 5  | University of Maryland, Baltimore    | 9                                       |
| 6  | University of Miami                  | 9                                       |
| 7  | Emory University                     | 8                                       |
| 8  | University of Arkansas               | 6                                       |
| 9  | University of Illinois               | 5                                       |
| 10 | University of Minnesota              | 5                                       |
| 11 | Case Western Reserve University      | 4                                       |
| 12 | Harvard College                      | 4                                       |

**Appendix I: Department of Veterans Affairs  
Commercialization Process, Revenue, and  
Total Joint Patents with Universities**

|              | <b>Affiliated university</b>         | <b>Number of patents shared with VA</b> |
|--------------|--------------------------------------|---|
| 13           | Tulane University                    | 4                                       |
| 14           | University of Utah                   | 4                                       |
| 15           | Loma Linda University                | 3                                       |
| 16           | University of Iowa                   | 3                                       |
| 17           | University of Pittsburgh             | 3                                       |
| 18           | Medical University of South Carolina | 2                                       |
| 19           | New York University                  | 2                                       |
| 20           | University of Arizona                | 2                                       |
| 21           | University of Florida                | 2                                       |
| 22           | University of Michigan               | 2                                       |
| 23           | University of Notre Dame             | 2                                       |
| 24           | Vanderbilt University                | 2                                       |
| 25           | Washington University in St. Louis   | 2                                       |
| 26           | Wayne State University               | 2                                       |
| 27           | Duke University                      | 1                                       |
| 28           | George Washington University         | 1                                       |
| 29           | Rensselaer Polytechnic Institute     | 1                                       |
| 30           | University of Alabama at Birmingham  | 1                                       |
| 31           | University of Pennsylvania           | 1                                       |
| 32           | University of Texas                  | 1                                       |
| 33           | Virginia Commonwealth University     | 1                                       |
| <b>Total</b> |                                      | <b>206</b>                              |

Source: GAO based on Veterans Affairs data | GAO-18-325

Note: In addition to the patents in this table, which show the number of U.S. patents that VA shared with individual universities, VA shared 78 U.S. patents with 2 or more other entities, at least one of which is a university. VA also has sole ownership of other U.S. patents and patents in other countries.

# Appendix II: Comments from the Department of Veterans Affairs



DEPARTMENT OF VETERANS AFFAIRS  
WASHINGTON DC 20420

March 7, 2018

Mr. John Neumann  
Director  
Natural Resources and Environment  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Dear Mr. Neumann:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "**VETERANS AFFAIRS RESEARCH: Actions Needed to Help Better Identify Agency Inventions**" (GAO-18-325).

The enclosure provides general and technical comments, and sets forth the actions to be taken to address the GAO draft report recommendations.

VA appreciates the opportunity to comment on your draft report.

Sincerely,

A handwritten signature in black ink that reads "Gina S. Farrisee".

Gina S. Farrisee  
Deputy Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Comments to  
Government Accountability Office (GAO) Draft Report  
**VETERANS AFFAIRS RESEARCH: Actions Needed to Help Better  
Identify Agency Inventions**  
(GAO-18-325)

**Recommendation 1: The Under Secretary for Health should require that  
researchers complete VA's online training on invention disclosure annually.**

**VA Comment:** Concur. The Veterans Health Administration (VHA) is committed to ensuring proper education is provided to researchers on how to make appropriate invention disclosures.

VHA's Office of Research and Development (ORD) will develop a plan to ensure Department of Veterans Affairs (VA) researchers complete VA's online technology transfer training on invention disclosure annually. ORD's plan will also contain contingencies for those who do not meet the requirements. ORD's target completion date accounts for time to implement the plan and collect results.

The recommendation will require 1.5 years to complete because VA has to demonstrate that the online training is done annually. This year, ORD will put out the training requirement and train staff for year one and then they will have to demonstrate that the training is also done in year two. The status is in process with a target completion date of September 2019.

**Recommendation 2: The Under Secretary for Health should provide a  
standardized method that guides universities in fulfilling VA's reporting  
requirements for these annual reports, including their format and content.**

**VA Comment:** Concur. VHA agrees that a standardized process for guiding university affiliates on reporting requirements will provide a consistent process across the boundaries. ORD will develop a standardized method that guides universities in fulfilling VA's reporting requirements for the university technology transfer annual reports. ORD will provide guidelines on a standard format and content for the reports. The status is in process with a target completion date of December 2018.

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# Appendix III: GAO Contacts and Staff Acknowledgments

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## GAO Contact

John Neumann, (202) 512-3841 or [neumannj@gao.gov](mailto:neumannj@gao.gov).

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## Staff Acknowledgments

In addition to the contact named above, Rob Marek (Assistant Director), Daniel Semick (Analyst in Charge), Ivelisse Aviles, Navaiyoti Barkakati, Kevin Bray, Ellen Fried, Matthew Hunter, Cynthia Saunders, Dan C. Royer, Ardith Spence, and Kiki Theodoropoulos made key contributions to this report.

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