Report on
RESEARCH COMPLIANCE

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News and Analysis for Colleges, Universities, AMCs and Other Non-Federal Entities

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Farm Bill Adds Fuel to Battle Over USDA Removal of AWA Enforcement Reports

Seven years ago, Cindy Smith, then administrator of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), proclaimed that by offering a trove of new data to the public it would be sending a strong message, literally, to the world about what happens to those who violate the Animal Welfare Act (AWA).

"It is clear that certain repeat offenders are not taking issues of animal welfare and humane treatment seriously enough. In turn, APHIS will not only be moving more swiftly to take enforcement action, but we will be making information about those enforcement actions available to the public on our web site," Smith said in an April 30, 2010, statement *(RRC 5/6/10)*.

Further, Smith announced that, beginning the following month, APHIS would post "monthly press releases that include case summaries where the agency is charging people and businesses with violations of the AWA," resuming a policy that had been discontinued in 2002. "The press releases will also provide summary information about closed enforcement cases and penalties levied," the agency said.

But that was then, and this is now, as they say.

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For Harvard, Affiliated Hospital, Alleged Misconduct Carried $10 Million Price Tag

For perhaps the first time, a research organization has repaid the federal government for research funds that may have been fraudulently obtained—prior to a formal finding or admission that illegal acts were committed.

In this case, Brigham and Women's Hospital (BWH) and its parent corporation agreed to pay $10 million to settle allegations of False Claim Act (FCA) violations associated with NIH-funded cardiac stem cell research. Authorities are still investigating whether there was misconduct by the three investigators named in the settlement, which their attorney said was negotiated without their knowledge or involvement.

Among the many other twists in the case that began five years ago is that BWH itself told the federal government about the suspected irregularities in the work conducted by researchers Piero Anversa, M.D., Annarosa Leri, M.D., and Jan Kajstura. Their lab has since been closed and they no longer work at BWH.

The HHS Office of Research Integrity (ORI), which investigates fabrication, falsification and plagiarism in research funded by the Public Health Service, has made no finding against the three; they could face sanctions ranging from debarment to supervision should misconduct be confirmed. ORI recently announced sanctions in two new cases, including one in which an administrative law judge

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HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

Editor
Theresa Defino
theresa.defino@hcca-info.org

Copy Editor
Nancy L. Gordon
nancy.gordon@hcca-info.org

upheld a 2016 debarment of a University of California researcher (see story, p. 3).

BWH also has not issued any findings and did not admit to any wrong-doing as part of the settlement, which lays the blame on the three investigators.

"The settlement resolves allegations that Dr. Anversa, along with Dr. Annarosa Leri and Dr. Jan Kajstura, knew or should have known that their laboratory promulgated and relied upon manipulated and falsified information, including confocal microscope images and carbon-14 age data for cells, in applications submitted for NIH research grant awards concerning the purported ability of stem cells to repair damage to the heart," announced the U.S. Attorney's Office for the District of Massachusetts, part of the Department of Justice (DOJ).

Multiple Problems Cited

According to DOJ, "problems with the work of the laboratory" were:

- "improper protocols"
- "invalid and inaccurately characterized cardiac stem cells"
- "reckless or deliberately misleading record-keeping"
- "discrepancies and/or fabrication of data and images included in applications and publications."

Further, "at the direction of these BWH scientists, the Anversa laboratory included false scientific information in claims to NIH in order to obtain and use funds from NIH grants," DOJ said.

BWH sent *RRC* a statement in response to the settlement but would not respond to specific questions.

"In accordance with federal regulations and institutional policy, BWH conducted an investigation that identified data integrity concerns in federally funded grant applications submitted by the Anversa lab," the hospital said in a statement sent to *RRC* on July 13. "BWH independently evaluated the issues relative to the federal false claims requirements. Following that evaluation, BWH self-disclosed this matter to appropriate government entities and ceased drawing implicated funds."

In the statement provided to *RRC,* the hospital added that the "lab has been closed, and the labs' leaders are no longer with the institution. BWH is committed to ensuring that research conducted at the institution is done under the most rigorous scientific standards, and has made significant enhancements to research integrity compliance protocols as a result of this event."

The spokeswoman did not respond to *RRC*'s request for details on the "enhancements" cited in the statement.

BWH's research misconduct investigation began in 2013 with the required inquiry phase; it eventually grew to question data that was published in *Circulation* and two papers submitted to other journals.

Misconduct investigations are confidential, but Anversa and Leri revealed details of what BWH was pursuing when they filed suit over the investigation itself, in 2014.

They accused Gretchen Brodnicki, Harvard Medical School's Dean for Faculty and Research Integrity, BWH President Elizabeth Nabel, the school itself and Partners HealthCare System, Inc., of "breach of contract and violation of the covenant of good faith and fair dealing," "tortious interference with advantageous business relations or prospective contractual relations" and violation of state laws against "unfair or deceptive acts or practices" and against "tortious invasion of privacy *(RRC 2/15, p. 1)."*

At the time of the alleged misconduct, Anversa, a cardiovascular scientist, was a professor of anesthesia and medicine at Harvard Medical School (HMS), director of BWH's Center for Regenerative Medicine

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Editor: Theresa Defino

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and head of a lab "focusing on myocardial regeneration and cardiac stem cells," according to court documents.

Leri was a "physician and researcher focusing on the molecular biology of cardiac stem cells" and an associate professor of anesthesia and associate professor of medicine; she also was a principal investigator in the lab.

In July 2015, the case was dismissed on the grounds that BWH's misconduct investigation had not concluded, and that the physicians could pursue administrative remedies later if the outcome was not to their liking.

According to court records, at issue in the misconduct investigation are data supplied by the Lawrence Livermore National Labs' (LLNL) Center for Accelerator Mass Spectrometry. But the researcher who did the calculations said he did not provide all the data that were published.

In her order granting BWH's motion to dismiss the suit about the misconduct investigation, U.S. District Judge Denise Casper recounted the chronology of the case.

Quoting from BWH's investigation, Casper said BWH began looking into three "initial allegations," namely that:

New Misconduct Cases Require Supervision, Debarment

The HHS Office of Research Integrity (ORI) issued two new findings in July, one of which stemmed from of an admission of wrongdoing by an animal lab worker. The other was confirmation of a debarment decision ORI made in 2016 regarding misconduct involving seven grant applications and three publications, one dating back to 2004.

The cases bring ORI's total misconduct findings so far this year to just three. The first of 2017, issued in May, ended a 10-month drought for the agency, which sanctions Public Health Service (PHS)-supported researchers who commit fabrication, falsification or plagiarism *(RRC 6/17, p. 1).*

In other recent research integrity and misconduct news, Brigham and Womens Hospital and its parent organization reached a $10 million settlement with the Department of Justice over allegations that problems with one of its research labs amounted to violations of the False Claims Act (see story, p. 1).

Misconduct Involved Rat Data

The newest case involves Alec Mirchandani, described by ORI as a former post-baccalaureate research volunteer in the Center for Complex Systems and Brain Sciences at Florida Atlantic University.

Mirchandani "engaged in research misconduct by knowingly and intentionally: (1) fabricating the results of the T-maze behavioral experiment for control mice, (2) falsifying the laboratory and vivarium entry logs in an effort to cover up his actions, and (3) reporting the fabricated and falsified data to his laboratory supervisors."

Falsifications and fabrications occurred during a two-week period in June of last year, ORI said.

Mirchandani, ORI said, "incorporated and recorded the fabricated and falsified data with his previous data in his laboratory notebook and reported the results to his laboratory supervisor and principal investigator, such that the experimental control data (five animals) for experiments conducted from January 2016-June 30, 2016, were not accurately represented."

As part of a settlement, Mirchandani agreed that he would be supervised for a year if he "receives or applies for PHS support" for a two-year period from June 29. For one year from that date, he will also "exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of one year."

False Data Needn't Be Published

This case is atypical for ORI in that the misconduct did not occur in a published paper or a grant application, but nonetheless falls within the agency's purview. The PHS 2005 research misconduct statute requires ORI to pursue misconduct defined as "fabrication, falsification, or plagiarism" when it occurs in "proposing, performing, or reviewing research, or in reporting research results."

Further, the statute states that:

"(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

continued

(1) "Anversa and Leri falsified and/or fabricated the C-14 measurements in the 2012 *Circulation* paper by reporting 108 distinct data points when LLNL provided data for only 88 distinct measurements and reporting 8 data points with values inconsistent with the measurements provided by LLNL;"

(2) "Anversa and Leri falsified and/or fabricated data in the 2012 *Circulation* paper by assigning isotope ratios to samples that have not been measured or reported by LLNL;" and (3) "Anversa and Leri 'falsified and/or fabricated data relating to the characterization of stem cells' and notes that '[q]uestions have arisen regarding the reproducibility of the phenotyping of cell populations.'"

However, the inquiry "expanded to include a fourth allegation, relating to Kajstura's apparent manipulation of confocal microscope images in an unpublished manuscript that had been submitted to the journals *The Lancet* and *Science* in 2013."

The FCA settlement seems to have come as a surprise.

Attorney Tracey Miner, who represents the physicians in their suit against BWH, told *RRC* she has "no idea why the hospital decided to report this to the U.S. Attorney's Office or to settle for such a large amount."

Miner, a partner in the Boston firm of Demeo LLP, added that Leri and Anversa were not "involved in the settlement process, nor have they been named

New Misconduct Cases, continued

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion."

In 2011, ORI debarred University of Michigan post-doc student Vipul Bhrigu for three years; his misconduct consisted of intentionally sabotaging another's work *(RRC 6/11, p. 1).*

A year later, Creighton University research assistant Calleen Zach was found to have committed misconduct when she made up research participants in order to collect their cash stipends *(RRC 3/12, p. 3).*

On July 6, ORI published a notice in the *Federal Register* stating it was taking final action to debar Frank Sauer, a former University of California Riverside (UCR) biochemist specializing in epigenetics, for five years. As permitted by law, Sauer, whose work was supported by NIH and the National Science Foundation (NSF), opposed the finding through an appeals process that concludes with a ruling by an HHS administrative law judge (ALJ).

Debarment Ends in 2020

According to the May 22 decision by ALJ Leslie Rogall, Sauer told UCR that some images contained a "visual distortion," and also that there was "honest error" involved in other alleged misconduct. However, in requesting an appeal to ORI, Sauer offered, in Rogall's words, a "dubious allegation that he was the victim of sabotage either due to revenge or the acts of an anti-gene technology crusade." Rogall found this argument immaterial because "he ultimately reported the data…without regard for the truth of the information."

Prior to ORI's investigation, UCR concluded that Sauer had "committed 21 instances of research misconduct." UCR's inquiry was triggered by an anonymous complaint received in 2011. After a separate investigation in 2014 by NSF's Office of Inspector General (OIG) found misconduct, the agency debarred Sauer governmentwide from "participation as a peer reviewer, advisor or consultant for NSF" and required him to "complete a comprehensive training course on the responsible conduct of research."

ORI's sanctions, which prohibit Sauer from serving as an advisor to PHS as well as from accepting PHS funding, will conclude July 20, 2020, the date established by NSF in its debarment action. ORI also "will send a notice" to the *Proceedings of the National Academy of Sciences* requesting retraction of a 2010 article containing falsifications.

Sauer could not be reached for comment. He was not represented by an attorney during the appeal.

The May case also involved an admission. Brandi Baughman, formerly an NIH "research training awardee" agreed to a three-year supervisory plan after admitting to fabricating or falsifying 11 figures in a 2016 article *(RRC 7/17, p. 11).*

Link to settlement announcements: https://ori.hhs.gov/case_summary

Link to ALJ decision regarding Sauer: http://tinyurl.com/y9ubvffg.

defendants in any lawsuit. Both vehemently deny that they did anything wrong. They relied on their longstanding colleague, Jan Kajstura's work, which had shown no signs of misconduct for the years that he worked with him."

In comments to Retraction Watch, Miner said it was "outrageous" that BWH "has sought to unfairly tarnish the reputations of Drs. Anversa and Leri, scientists who have pioneered groundbreaking work in cardiac stem cell reproduction."

Miner also told Retraction Watch that it "has long been known that Drs. Anversa and Leri relied on the work of a senior scientist in the lab in presenting data for grants and in publications. No one has ever shown that either Dr. Anversa or Dr. Leri participated in the fraud or was aware of it at the time."

With the misconduct investigations by BWH and ORI still ongoing, Miner expressed concern that the FCA settlement could taint the outcome.

"Theoretically, the research misconduct proceedings should be based only on the preponderance of the evidence submitted to it and not outside factors such as this one, which my clients had no involvement in or control over," Miner told *RRC.* "Given the adverse publicity caused by the settlement, I am concerned that the panel members will be influenced by it, even if they try to ignore it." Outside of the court case, Miner is not representing the researchers, she said.

Asked where Anversa and Leri are now, Miner said she couldn't say. "I can't comment on where they are now as any publicity as to where they are may hurt them," she said.

Unique Settlement?

BWH's agreement breaks the mold of previous FCA cases involving research funds. In recent years, several universities have made payments to settle FCA allegations but they did not specifically involve misconduct.

For example, last July, Columbia University agreed to pay $9.5 million to settle FCA allegations, admitting that it "acknowledges and accepts responsibility" for charging a higher on-campus indirect cost (also called facilities and administrative, or F&A) rate on more than 400 NIH grants for psychiatry and neuroscience research that was actually performed rent-free in state-owned facilities *(RRC 8/16, p. 1).*

Two years earlier, Columbia and affiliated entities agreed to a $9.02 million settlement for effort reporting issues with grants for an HIV/AIDS program *(RRC 12/14, p. 4)*. Both cases were initiated by whistleblowers.

Other recent FCA settlements involving universities include $3 million paid by Northwestern University and $1.5 million paid by Emory University *(RRC 10/13, p. 1)*.

Institutions also occasionally repay grant funds following an audit finding (see story, p. 7).

In a particularly high-profile case that did involve misconduct, one university made a repayment following a misconduct finding for an investigator. This involved Dong-Pyou Han, formerly a lab manager with Iowa State University (ISU), who agreed to a settlement with ORI after confessing to doctoring HIV rabbit sera tests. He later was sentenced to 57 months in prison following an unusual criminal prosecution *(RRC 8/15, p. 1)*.

ISU paid $2.5 million back to NIH, while Han agreed to make restitution of $7.2 million. *(RRC 8/15, p. 3)*. A FCA case was never brought against him or ISU.

Miner said she does "not expect" BWH to "seek any part of the settlement from Dr. Anversa or Dr. Leri" to cover the $10 million BWH has spent.

Link: http://tinyurl.com/ycljgpbn ✧

With Adequate Preparation, Close-Out Woes Can Be Limited

In recent years, the Government Accountability Office has documented that federal agencies are holding billions in unobligated balances that hadn't been closed out, but, perhaps more significantly, funds that agencies had failed to de-obligate and recapture.

As a result, federal awarding agencies are putting more pressure on funding recipients to complete their closeouts on time.

In a recent webinar, Bob Lloyd, principal with Federal Fund Management Advisor, reviewed some of the closeout requirements that apply to awardees as contained in the Office of Management and Budget Uniform Guidance for Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, known as the OMB UG.

Some agencies follow the UG's closeout deadline of 90 days from the end of the period of performance or project end date, but others, such as NIH and the National Science Foundation, allow 120 days.

Expenditures Must Be Reconciled

Among the tasks in closeout are those that relate to expenditures. Prior to the closeout deadline, awardees must "liquidate" or pay all outstanding obligations, Lloyd said.

An awardee may discover during closeout that it has drawn down "excess cash that it did not need to disperse for obligations incurred," Lloyd said. "If that kind of thing has happened, not only is that to be refunded,

but also [should] any interest that was earned related to those funds because that interest belongs to the federal government."

This situation might be a red flag for a grantee that it has a "cash management problem," which may lead to adverse audit findings, Lloyd added.

Financial reconciliation of "federal and non-federal shares" also needs to occur.

"What a lot of organizations do during the performance period is they simply report their expenditures based on the matching share configuration that exists in the award without regard to whether or not they are actually meeting the cost-share in every quarterly reporting period," Lloyd warned. "The point I am making here is, at the end of the project or program, that is going to have to be reconciled to actual" matching contributions.

If there is a problem of underpayment by the awardee, "closeout could involve an adjustment to the federal share…you could end up having to repay federal funds," he said.

Another issue is program income, which is earned "as a direct result of grant-funded activity." When accrued after the period of performance, such funds "do not become unrestricted" but must be tracked and used according to the original purpose of the grant, he said.

Closeout reporting requirements are found under 2 CFR 200.327-329.

Report Real, Personal Property

Reports are to be filed for both "real" and "personal" property acquired with the award funds. Real property, defined as "land and buildings purchased or constructed with federal funds, is reported on SF 429. With real property there may be a "continuing federal interest," he noted. "In other words, the recipient is going to use the property for its original purpose as long as it's needed." There may be situations where awarding agencies force the sale or recovery of the property.

Personal property refers to equipment and supplies, Lloyd said. This is reported on the SF 428 series.

Also reported are publications, patents and other "intangible property that has been created or bought with federal funds."

Remember to follow retention requirements when it comes to the records that form the basis of the reports.

As Lloyd put it, "records…live on after closeout. OMB has reconstituted the record retention requirements associated with grants in sections 200.333-337."

Noting that prime and subrecipients each keep their own records, Lloyd pointed out that the UG is silent on contractors and records.

"If your organization is purchasing goods or services from another organization, whether it's a commercial entity or a government, or non-profit...and you want that contractor to hold their records, you need to put a provision in the contract that stipulates that," he said.

He recommends grantees "keep everything," because there is often staff and investigator turnover once a project ends. It is important to retain the "institutional memory" connected with the grant.

Records are to be kept for "at least three years" following submission of both the annual and the final financial report. Lloyd also pointed out that it is allowable, if not preferred, to store documents electronically.

If Needed, Seek Extra Time

To ensure timely reporting by subawardees, organizations should create earlier deadlines than the ones the prime is facing, Lloyd said. These need to be incorporated in subaward agreements and contracts. The prime or pass-through organization can also seek more time.

As Lloyd noted, all of these tasks are to be completed within 90 days (or 120), but "extensions are possible." Several types of extensions might be applicable, such as a "no-cost extension," which will move the date that the performance period concludes.

Under Section 200.308(d) an organization may be able to give itself an extra 12 months without seeking agency approval; this is applicable to research organizations, according to Lloyd.

In addition, an agency can obtain extra time through a "prior approval" process. It is also possible for awardees to get additional time to "liquidate obligations" and to complete their reporting obligations, Lloyd said.

As part of closeout, the entity submits its final financial report, called SF 425, as well as its final performance report (both of these are also filed annually). Sending these reports signals to the awarding agency that it must now fulfill its requirements under closeout, Lloyd said.

Like awardees, agencies have their own closeout deadline—"one year from acceptance of final reports," said Lloyd.

The awardee's obligations continue after the closeout, particularly if an audit is done and the organization has a finding that results in a repayment. In this case, the final financial report will need to be revised and resubmitted, Lloyd said. This triggers the start of a "new record retention clock."

All grants administered during a fiscal year "are subject to audit testing," Lloyd said, under the single audit requirements.

"The [organization's] auditor will decide either based on statistical sampling or judgmental sampling which

grants to test and it may very well be that a particular individual grant or subgrant might never be tested," Lloyd said.

But, he stressed, "there's nothing in the rules that says every grant has to be tested or audited or that there has to be a close-out audit. That concept pretty well died in the 1980s and '90s."

However, inspectors general can come in at any time to review a grant, with the "only limitation on their ability to audit [being] the availability of records," Lloyd said.

If an organization "has a standard record retention policy that is consistent with section 333-337 and it disposes of records that are no longer needed after three years, then the federal auditors would not be able to conduct that work," he said. "On the other hand, as long as an organization has got the records, the federal government's audit rights continue."

For more information on the webinar, visit http://tinyurl.com/y995zvxn. ✧

In Audit of Columbia U, NSF Warns Not to Look to the Future

In the first audit resolution report it has issued since October, the National Science Foundation (NSF) requested that Columbia University repay $335,000, a little less than a third of the amount that the agency's Office of Inspector General (OIG) questioned in a 2016 audit.

Columbia joins a growing list of universities and other higher education institutions for whom OIG questioned salary costs that NSF later allowed, including Georgetown University and Florida State University. NSF has stated that OIG misinterpreted NSF's policies *(RRC 11/16, p. 5)*.

In Columbia's case, NSF allowed $774,976 in senior salary costs. NSF also is permitting another $91,830 in various transactions OIG flagged in the audit, which contains redactions.

Timing of Purchases Questioned

The unallowable costs can serve as a warning to other grantees, namely that they must ensure, and document, that expenditures related directly to the award-funded research are spent at the right time: not before an award is made, nor after, nor too close to the end of the funding period.

As part of Columbia's audit, dated July 8, 2016, OIG questioned $1.201 million in costs claimed on 53 grants expended from April 1, 2011, to March 31, 2013 (*RRC 7/28/16*).

NSF is seeking repayment of $258,191 for equipment, materials and supplies; $21,382 in transactions; $22,414 for expenditures occurring "after award expiration;" and $3,198 that was expended before the "award effective date."

Among the largest of the items that OIG questioned are:

◆ $75,788 for equipment purchased two months before the expiration of a nine-year award. In its defense, Columbia contended the equipment "was needed to examine the [redacted] which only became clear in the latter part of the research."

◆ $40,000 for two pieces of equipment. The first, priced at $16,000, was purchased four months and the second, for $24,000, at three months prior to the expiration of a three-year award. The $16,000 was apparently for a compressor, based on inconsistent redactions, but it is not clear what the $24,000 was for. "Due to the nature of the research the equipment could only be utilized once all data related to the entire project (which included several photonic devices) was collected, completed, and verified and (sic) equipment fabricated by the" co-principal (co-PI) investigator, Columbia said in arguing that the costs were allowable.

◆ $12,624 for "rental accommodations for a PI while on a research sabbatical from July to December 2010. The PI gave up his apartment during the sabbatical and charged NSF for an apartment in [redacted]. Payment for travel accommodation is allowable only when traveling away from an employee's official duty station, and therefore, it is not reasonable to charge the award for basic living accommodations in [redacted]," OIG said.

◆ $3,198 purchase of a MacBook Pro that was acquired on March 12, 2011 for "an award that did not begin until July 1, 2011." This may have been permitted with NSF prior approval, but OIG said none was requested.

OIG recommended that Columbia "strengthen the administrative and management controls and processes to ensure that charges occurring more than 90 days prior to the award effective date are not charged to an award without NSF approval."

Audit to Have Training Purpose

In their response to the draft audit, Columbia officials said they were "committed to complying with all applicable NSF policies and guidelines and maintains a strong internal control environment designed to support this commitment."

The audit, they added, will be a learning experience.

As robust training for faculty, including Officers of Instruction and Officers of Research, and staff supporting NSF awards is an integral part of our control environment, Columbia will utilize this audit to further enhance its training programs."

NSF did not require Columbia to make changes. NSF said it "accepts the University's stated corrective actions as responsive to the recommendations and considers the recommendations to be resolved and closed. NSF commends the University on its efforts to proactively enhance its system of internal controls to ensure compliance under federal awards."

RRC contacted Columbia for its reaction to the audit resolution.

"We are pleased that the University's cooperation with NSF led to this resolution of the audit and that the matter can now be closed. The University is not planning to appeal," university officials told *RRC* in a statement.

Link to audit resolution: http://tinyurl.com/yc8k25xg.✧

Bill Fuels Battle Over AWA Reports

continued from p. 1

In February, the press releases, inspection reports, warning letters and other previously public documents were removed from APHIS' website, and news releases about enforcement actions ceased (*RRC 2/23/17*). Some reports have been reposted but are not searchable except by organization type and state; they are downloadable as a single PDF and are not separated by years. This makes it virtually impossible to use them.

When they were available, the documents gave insight into issues such as lack of water for rabbits at California State University, Fresno, and expired pharmaceuticals at Pima Medical Institute in Arizona, both of which led to citations in 2015.

Similarly, the documents revealed that Texas Biomedical Research Institute, home of the Southwest National Primate Research Center, was fined $25,714, according to a Dec. 13, 2011, letter *(RRC 2/23/12).*

USDA's Office of Inspector General released a report in 2014 that found that from 2009-2013, APHIS inspectors had cited approximately half of institutional animal care and use committees at all "registered research facilities" for AWA violations *(RRC 2/15, p. 5).*

The Humane Society of the United States (HSUS) says APHIS' recent decision to delete records—which the agency said it took in the name of privacy—violate a 2009 settlement agreement. In addition, USDA has been sued for removing the documents by the Animal Defense League and others; those suits are pending.

Now Congress has added its voice. On July 12, the House Appropriations Committee passed USDA's funding bill and accompanying report for fiscal year 2018 that asks for the agency to "promptly…restore all legally permissible records," previously removed among related requirements.

Bill Seeks 'Prompt Review'

The following passage appears on page 27 of the report.

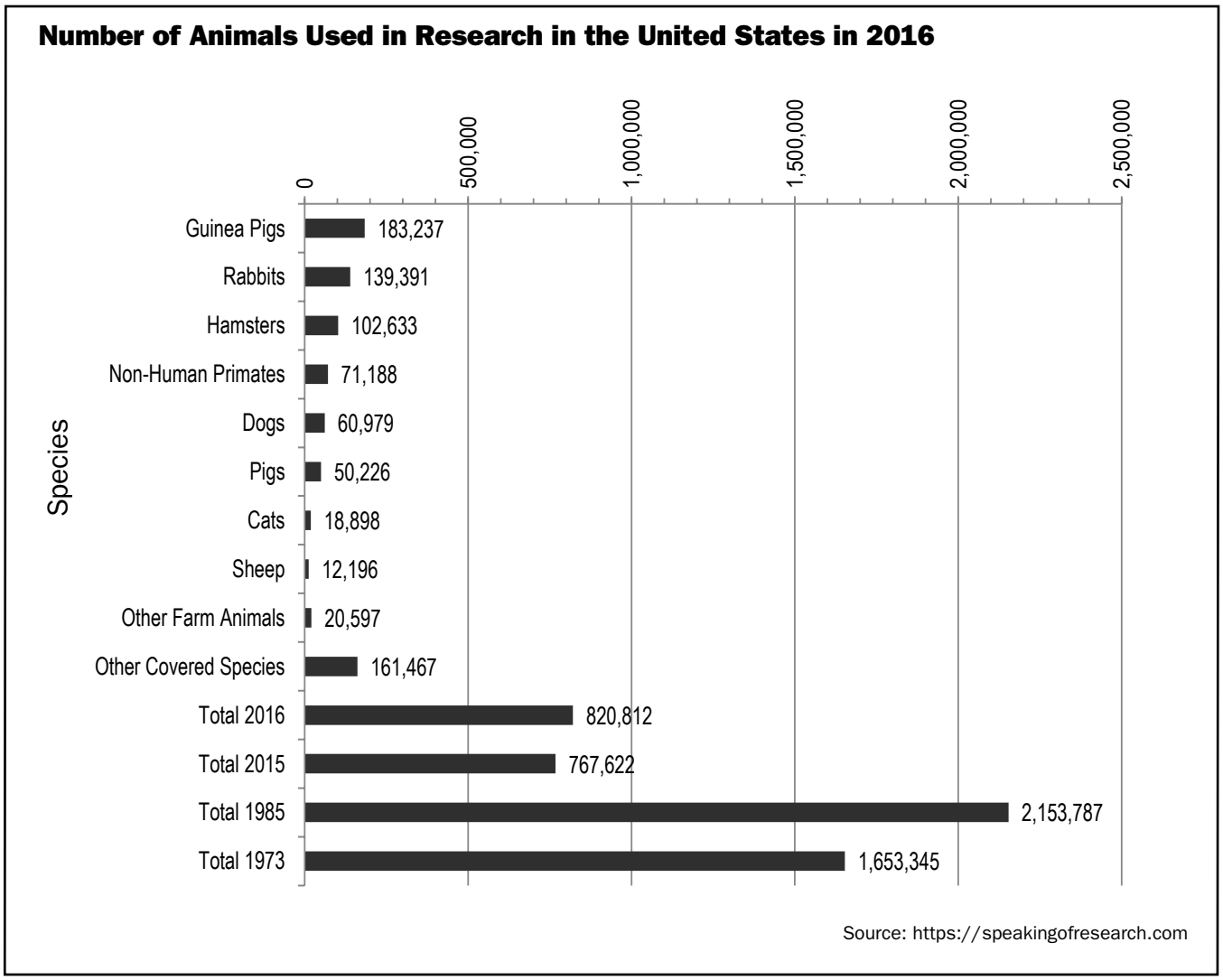
"Animal Welfare Inspection Records.—On February 3, 2017, USDA restricted the public's access to the search tool for the Animal Care Inspection System in order to conduct a comprehensive review of the information on its website. Such an action limited the public's review of inspection reports, research facility annual reports, and lists of persons licensed and registered under the AWA, as well as lists of persons licensed by USDA-certified horse industry organizations and associations to inspect horses for compliance with the Horse Protection Act (HPA). While the Committee recognizes the need to strike a balance between the privacy rights and personal identifiable information of regulated entities and the public's need to know if regulated parties or institutions are complying with federal law, USDA must utilize the resources provided in this bill to promptly finish reviewing the information on its website, restore all legally permissible records previously removed, and resume posting on the USDA website. The online searchable database should allow analysis and comparison of data and include all inspection reports, annual reports, and other documents related to enforcement of the HPA and the AWA."

To have the force of law, the funding bill will need to be passed by the full Congress with the accompanying language approved and be signed by President Trump.

Still, HSUS and others that have argued for the records were heartened by the committee's action.

"Many members of Congress are concerned about the removal of the documents and want to see the information restored immediately, including in a searchable format, such as through reinstatement of the database," Kathleen Conlee, HSUS vice president for animal research issues, told *RRC.* HSUS is "pleased that Congress is taking action to get the results we are seeking."

In 2005, APHIS removed some reports while President Bush was in office, which led to litigation by HSUS. The case was settled when APHIS agreed



to post annual reports and others documents (*RRC 7/9, p. 4*).

The farm bill language comes on the heels of two other bills introduced shortly after the reports disappeared. S. 503 and H.R. 1368 are identical versions of the Animal Welfare Accountability and Transparency Act, introduced on March 3, 2017, by Oregon's Democratic members of Congress, Sen. Ron Wyden and Rep. Earl Blumenauer. To date, the Senate bill has gained five cosponsors while the House has 45.

Within 90 days of enactment, the bills call for the USDA to "maintain and promptly make available to the public in an online searchable database in a machine-readable format on the website" of USDA "the entirety of each report of any inspection conducted, and record of any enforcement action taken" related to the AWA and the HPA.

The bills "would also prevent violators of these animal welfare laws from receiving certain business-related tax breaks for five years," according to a joint statement from the bills' sponsors.

"For the life of me, I can't understand why USDA would hide this vital information. In doing so, it's protecting animal abusers. It's unacceptable," Blumenauer said after the introduction. "The agency must restore transparency, and those who treat animals with cruelty should not receive the same benefits as those who play by the rules."

On June 7, HSUS and other organizations held an event at USDA to deliver 160,000 signatures on a petition to restore the reports.

APHIS: We Are in Compliance

For its part, APHIS contends it isn't in violation of the HSUS settlement. Tanya Espinosa, USDA-APHIS public affairs specialist, pointed *RRC* to

the same webpage that is only searchable by state, saying the annual reports are "currently posted online."

Since the first change in February, APHIS has been adding some reports back on a monthly basis, but, as noted, they are not searchable in a reasonable way. Old news releases are still missing. Furthermore, APHIS announced it was posting newly conducted inspection reports (but again, not in a searchable database). For these, it also removed some information.

"As part of the comprehensive review of information, APHIS is continuing to closely review animal inventories that accompany inspection reports," the agency said in an online note dated June 16. "For this reason, the newly posted inspection reports do not include animal inventories, though APHIS intends to make information regarding animal inventories available again in the future."

Chris Needham, USDA-APHIS congressional relations specialist, told *RRC* on July 13 that the agency "just became aware of the language this week. We're reviewing it now, and considering what steps we might need to take should the language pass."

Researchers Also Seek Restoration

It's not just animal rights groups that are pushing for the reports; Speaking of Research, an international organization that advocates for researchers who use animals in research, has as well.

"We believe the availability of data can foster an environment of openness and transparency about animal research. When information is hidden, particularly where it was once available, the public will naturally wonder why many stakeholders have cause for concern: the public wonders what is being hidden and why, and researchers must devote even more resources to combatting the public perception that they are not transparent," the group said in a February blog post.

RRC shared the new farm bill language with Tom Holder, director of the group. In response, he said the organization would "welcome a return of the searchable…database. Greater transparency is an important step in reassuring the public that animal research is carefully conducted, humane, and important for the medical and veterinary developments that many of us rely on."

February was not the first time APHIS had deleted information that was previously available online.

In April of last year, *RRC* noticed that warning letters no longer detailed objectionable conditions and circumstances that were discovered and only cited a portion of the allegedly violated regulations. This required a new, second step to locate the relevant inspection report.

At the time, APHIS' Espinosa told *RRC* such information was removed to "streamline the process."

Meanwhile, animal research is continuing, of course, and may be growing. In support of transparency, Speaking of Research published 2016 data about the numbers of animals covered by the AWA that were involved in research—data that came unannounced from USDA, itself.

Animal Research Was Up in 2016

The numbers show that, after many years of declines, 2016 saw nearly a 7% gain.

As Speaking of Research noted in a June 1 blog post, the "statistics do not include all animals as most mice, rats, and fish are not covered" under the AWA.

"Comparing the 2015 and 2016 statistics, there has been a small rise in the use of most species, apart from dogs (down 0.2%) and cats (down 5.2%)," the post states. "The largest rises were found in non-human primates (up 15%) and sheep (up 14%). Furthermore, it should be noted that this 6.9% rise comes a year after an 8% fall, putting the total number of animals used in 2016 slightly below the levels in 2014." (For details, see chart, p. 9).

Time will tell if, and when, the inspection and other reports will return in a useable and searchable manner.

But will the news releases announcing sanctions and warnings that former APHIS Director Smith was so proud of be returning? Maybe not.

"There are no plans to resume posting press releases of enforcement actions at this time," Espinosa told *RRC* on July 12.

Link to APHIS enforcement actions webpage: http://tinyurl.com/hw4c8ht

Link to appropriations bill: http://tinyurl.com/ychy4mat

Link to Animal Welfare Accountability Act: http://tinyurl.com/y9jwauj8

Link to HSUS petition: http://tinyurl.com/y9opuykz.✧

In This Month's E-News

The following are summaries of news transmitted to RRC *subscribers this month in email issues, the date of which is indicated in parentheses following each item. Weekly email and monthly print issues of* RRC *are archived on your subscriber-only website. Please call 888-580-8373 or email service@hcca-info.org if you require a password to access* RRC*'s subscriber-only website or are not receiving weekly email issues of the newsletter.*

◆ **By a 28-22 vote, the House Appropriations Committee on July 19 approved a fiscal year (FY) 2018 appropriations bill that gives NIH a $1.1 billion increase and forbids the agency from modifying indirect cost rates, defying the Trump administration, which sought to slash funding by 18% and drop facilities and administrative (F&A) payments by perhaps 50% or more.** If passed unchanged by the full House and Senate, the bill would give NIH $35.2 billion, $8.6 billion more than Trump's proposal; the overall HHS budget would be $77.6 billion, "a decrease of $542 million below last year's enacted level and $14.5 billion above the President's budget request," the committee said. In addition, Sec. 228 of the bill requires NIH to make indirect cost payments as prescribed by law and "to the same extent and in the same manner as the NIH applied such provisions in the third quarter of fiscal year 2017." Further, NIH is forbidden from expending any funds "to develop or implement a modified approach to such provisions," or make related changes. The administration's FY 2018 budget called for an 18% decrease in NIH funding and a cap on F&A rates of 10% *(RRC 5/25/17)*. The Association of American Universities (AAU) and other organizations praised the bill when it was released on July 12, saying the subcommittee that drafted it "demonstrated a keen understanding of the importance of scientific infrastructure and the facilities and administrative costs that support cutting-edge labs across the country." *(7/20/17)*

◆ **Alec Mirchandani, a former post-baccalaureate research volunteer in the Center for Complex Systems and Brain Sciences at Florida Atlantic University, "engaged in research misconduct** by knowingly and intentionally: (1) fabricating the results of the T-maze behavioral experiment for control mice, (2) falsifying the laboratory and vivarium entry logs in an effort to cover up his actions, and (3) reporting the fabricated and falsified data to his laboratory supervisors," the HHS Office of Research Integrity (ORI) said in a July 19 Federal Register notice. Falsifications and fabrications occurred during a two-week period in June of last year, ORI said. As part of a settlement, Mirchandani agreed that he would be supervised for a year if he "receives or applies" for Public Health Service (PHS) support during a two-year period beginning June 29. He also will not advise PHS for one year beginning June 29. The misconduct does not appear to have involved data that were published or used in a grant application. *(7/20/17)*

◆ **The Department of Energy (DoE) could take a number of steps to reduce burdens associated with research funding, including excluding "restrictions and prior approval requirements of publications and foreign students/nationals in solicitations and agreements for basic fundamental research" and using a "template specifically tailored to support basic fundamental research to save time and effort negotiating contracts for such activity,"** according to a July 14 letter submitted by AAU, the Council on Governmental Relations and the Association of Public and Land-Grant Universities. Governmentwide, federal agencies are soliciting feedback from regulated communities in compliance with the president's executive order, "Reducing Regulation and Controlling Regulatory Costs." The organizations also proposed that DoE standardize indemnification language and requirements for human subjects research, and provide better support for solicitations. *(7/20/17)*

◆ **An administrative law judge (ALJ) has upheld a 2016 misconduct finding and debarment by the HHS Office of Research Integrity (ORI) against Frank Sauer, a former University of California (UC), Riverside investigator.** ORI investigates fabrication, falsification and plagiarism in Public Health Service (PHS)-funded research. This marks the second ORI finding to be issued in the past two months, following a drought of 10 months *(RRC 6/17, p. 1)*. Sauer claimed he was not responsible for falsifications that appeared in seven NIH grant applications and three published papers, according to a notice in the July 6, 2017, Federal Register. In confirming the finding, ALJ Leslie Rogall wrote that Sauer's "dubious allegation that he was the victim of sabotage either due

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to revenge or the acts of an anti-gene technology crusade" was immaterial because "he ultimately reported the data…without regard for the truth of the information." Sauer was an associate professor of biochemistry. *(7/13/17)*

◆ **In keeping with previous decisions, the National Science Foundation has pushed aside a recommendation by its Office of Inspector General that it disallow $774,976 in senior salary costs expended by Columbia University that OIG said exceeded NSF's two-month limit.** NSF has previously allowed such costs at several universities, including Georgetown University and Florida State University, stating that OIG had misinterpreted NSF's policies *(RRC 11/16, p. 5)*. NSF also is permitting another $91,830 in various transactions OIG flagged in the 2016 audit. However, NSF disallowed $334,949 out of $1,201,755 in total questioned costs. Specifically, NSF is seeking repayment for $258,191 in equipment, materials and supplies; $21,382 in transactions; $22,414 in expenditures occurring "after award expiration;" and $3,198 that occurred before the "award effective date." NSF said Columbia had already repaid $41,186 and owed $293,763. In reference to OIG's compliance and internal control recommendations, "NSF accepts the University's stated corrective actions as responsive to the recommendations and considers the recommendations to be resolved and closed. NSF commends the University on its efforts to proactively enhance its system of internal controls to ensure compliance under federal awards," the agency said. *(7/13/17)*

◆ **Institutions that use a payroll certification process to track employees' grant-funded research activities could better ensure compliance with the Office of Management and Budget's (OMB) Uniform Guidance if they shared more information with their principal investigators (PIs), according to the National Science Foundation (NSF) Office of Inspector General (OIG).** "[W]e caution that no matter how well the system of controls is designed, Federal award recipients must ensure consistent implementation," OIG added in a memorandum, part of an "informal" response to OMB about a payroll certification pilot program. "Without strong internal controls in place to regularly monitor the costs charged to Federal awards for personnel expenses, the annual certifications may not be reliable and useful to Federal agencies to ensure that personnel expenses are allowable, allocable, and reasonable." Dated June 21, the memorandum is from Mark Bell, assistant inspector general for audit, to Hai "Gil" Tran, an OMB policy analyst. NSF and HHS OIGs each completed audits of two institutions participating in the pilot, which was conducted under the auspices of the Federal Demonstration Partnership; the final audit, of the University of California, Riverside, was issued in February *(RRC 3/17, p. 1)*. *(6/29/17)*

◆ **The Association of American Medical Colleges (AAMC) and three other organizations representing research universities have requested that HHS delay the compliance date of the revised Common Rule by one year, to Jan. 19, 2019, for most provisions and to Jan. 19, 2021, for the mandate to use a single institutional review board (IRB).** The rule is among those being reviewed by the new administration because of its publication date, which was just days before President Trump took office *(RRC 6/17, p. 5)*. A delay is necessary, AAMC, the Association of American Universities, the Council on Governmental Relations and the Association of Public and Land-grant Universities argued, because of the uncertainty created by the review process. An extra year would "allow institutions adequate time to come into compliance with all provisions of the revised rule." In their June 17 letter to Jerry Menikoff, director of the HHS Office for Human Research Protections, the groups also requested that OHRP "allow the regulated community to move forward with those provisions that would reduce administrative burden for investigators, one of the stated goals of this regulatory effort, on or before the effective date. These include certain exclusions and exemptions, elimination of the continuing review requirement for certain types or stages of research and elimination of IRB review of grant applications."

The letter comes on the heels of a request by the HHS Secretary's Advisory Committee on Human Research Protections, which argued for a one-year/three-year implementation schedule tied to whatever date HHS determines is the effective date of the revised rule once the review concludes *(RRC 7/17, p. 6)*. The Association for the Accreditation of Human Research Protections Programs has also sought a delay, but it is advocating for a compliance date for all provisions that is three years from the original effective date. *(6/29/17)*