Description of document:	Final reporting documents for fifteen (15) investigations conducted by the Office of Personnel Management (OPM) Office of the Inspector General (OIG), 2006-2013
Request date:	06-April-2015
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UNITED STATES OFFICE OF PERSONNEL MANAGEMENT
Washington, DC 20415

Office of the
Inspector General

June 15, 2015

Via e-mail

This is in response to your Freedom of Information Act (FOIA) request of April 6, 2015, in which you asked for the final reporting documents for fifteen investigations conducted by the Office of Personnel Management (OPM) Office of the Inspector General (OIG).

The attached documents are responsive to your request. They include reports of investigations and closing memoranda for fourteen of the investigations listed in your request. With respect to investigation IA 2011-00011, the final investigative report may be found online at http://www.opm.gov/our-inspector-general/special-reports-and-reviews/final-investigative-report-%E2%80%93-improper-contracting-and-procurement-practices-utilized-to-circumvent-the-competitive-bid-process.pdf. The remaining 14 files have been compiled into a single PDF and are presented in the following order:

Please note that some information contained in the responsive documents has been redacted pursuant to 5 U.S.C. § 552(b)(5), to protect against disclosure of the deliberative processes of OPM OIG; 5 U.S.C. § 552(b)(7)(C), to prevent the unwarranted invasion of individuals' personal privacy; 5 U.S.C. § 552(b)(7)(D), to prevent the disclosure of confidential sources; 5 U.S.C. § 552(b)(7)(E), to prevent publication of information that would risk circumvention of the law; and 5 U.S.C. § 552(b)(7)(F), to avoid endangering individuals' life or physical safety.

If you wish to appeal this response, you should contact, in writing, J. David Cope, FOIA Appeals Officer, Room 6400, 1900 E Street, NW, Washington, DC 20415. Please include a copy of your initial request, a copy of this letter, and a statement explaining why you disagree with our decision. You should write "Freedom of Information Act Appeal" on the front of the envelope and on the first page of the appeal letter.

Sincerely,

Tanner Horton-Jones
Attorney-Advisor

Enclosures

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT

Washington, DC 20415

Office of the
Inspector General

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The responsibility of the U.S. Office of Personnel Management (OPM), Office of the Inspector General (OIG) is to prevent, detect and investigate fraud concerning programs operated and administered by OPM, including the Federal Employees Health Benefits Program (FEHBP). FEHBP benefits are afforded to all federal employed upon employment to the civil service. The Federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet their needs, and also has the choice of adding family members, such as spouse and children. On average, each Federal agency contributes 73% of the employee's health premium to pay for the health benefits afforded to each Federal employee and their dependents.

BASIS OF INVESTIGATION

The following report relates to the investigation of Scios, Inc and their pharmaceutical medication Natrecor. In summary, from August 2001 through April 2003 Scios was involved in illegal scheme that promoted the off label promotion of their congestive heart failure medication, Natrecor.

The case was referred to OPM/OIG by the Department of Justice and OPM/OIG case number I2006-0103 was opened.

STATUTES VIOLATED

21 U.S.C. § 331, 21 U.S.C. § 333- Introducing a misbranded drug into interstate commerce

CASE SUMMARY

In August 2005, an complaint was filed in the Northern District of California and the Office of Personnel Management Office of Inspector General received the aforementioned civil complaint regarding Strom v Scios and subsequently opened a case. The complaint focused on Scios' off-label promotion of Natrecor.

In August 2001, the United States Food and Drug Administration ("FDA") approved Natrecor solely for the treatment of patients experiencing acutely decompensated congestive heart failure with dyspnea (shortness of breath) at rest or with minimal activity.

Between August 2001 and April 2003 the company began to engage in the off-label promotion of Natrecor to increase the patient population and their usage thereby increasing sales and profits. Scios marketed to physicians that since Natrecor worked for acute heart failure patients, it should work for any and all heart failure patients. Specifically they engaged in promotion of Natrecor to serve as a "tune-up" drug for more functional heart failure patients to keep them from needing emergency room visits.

During this timeframe, Scios launched an aggressive campaign to market the drug for scheduled outpatient infusions for patients with less severe heart failure. These infusions generally involved visits to an outpatient clinic or doctor's office for four to six hour infusions one or two times per week for several weeks or months. Using or promoting Natrecor in this manner was not included in the FDA approved label for this drug.

Scios did not promote the expanded use of Natrecor on scientific evidence, instead they used the results of a small and misleading pilot study to encourage the outpatient use of Natrecor. Scios sponsored an extensive speaker program through which doctors were paid to tout the purported benefits of serial outpatient use of Natrecor. Scios also urged doctors and hospitals to set up outpatient clinics specifically to administer the serial outpatient infusions, in some cases providing funds to defray the costs of setting up clinics, and supplied providers with extensive resources and support for billing for the outpatient infusions.

During late 2005, it was learned that Natrecor was mostly administered in an inpatient setting, and therefore include the cost of pharmacy and in and out patient claims for various health insurance programs.

In September 2007, after receiving the exposure drug data from the queried contracted FEHBP Plans, OPM/OIG Forensic Auditor (FA) (b) (7)(C), (b) (7)(F) reviewed and summarized the claims information. FA (b) (7)(C), (b) (7)(F) identified FEHBP exposure are reviewing claims from Blue Cross Blue Shield (BCBSA), Government Employees Hospital Association (GEHA) and Coventry (CVTY), which totaled $1,965,456.16 related to the allegations.

On July 7, 2011, the United States filed a one-count Criminal Information charging Scios with a misdemeanor violation of 21 U.S.C. §§ 331(a) and 333(a)(1) by having caused the introduction and delivery for introduction into interstate commerce of the drug Natrecor that was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling lacked adequate directions for its use.

On October 5, 2011, Scios was convicted on 21 U.S.C. § 331 (a) and 333 (a)(1) Causing the Introduction of a Misbranded Drug into Interstate Commerce. On the same day, Scios was sentenced to three years' probation, a one hundred twenty five dollar assessment fee and a eighty five million dollar fine.

CONCLUSION/DISPOSITION

On November 4, 2013, as part of a global resolution with the federal government (totaling $2.2 billion), Johnson and Johnson and Scios have agreed to pay $184 million to the federal government to resolve their civil liability for the alleged false claims to federal health care programs resulting from their off-label marketing of Natrecor. As part of the civil settlement, the FEHBP will receive $474,743.00 plus $172,031.80 (Lost Investment Income), less the 3% allocation to the Department of Justice totaling $19,403.24, resulting in $627,371.56 returned to the FEHBP.

Signed: _____

Special Agent (b) (7)(C), (b) (7)(F)

Signed: _____

(b) (7)(C), (b) (7)(F)

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT

Washington, DC 20415

Office of the
Inspector General

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The responsibility of the U.S. Office of Personnel Management (OPM), Office of the Inspector General (OIG) is to prevent, detect and investigate fraud concerning programs operated and administered by OPM, including the Federal Employees Health Benefits Program (FEHBP). FEHBP benefits are afforded to all federal employed upon employment to the civil service. The Federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet their needs, and also has the choice of adding family members, such as spouse and children. On average, each Federal agency contributes 73% of the employee's health premium to pay for the health benefits afforded to each Federal employee and their dependents.

BASIS OF INVESTIGATION

The following report relates to the investigation of Amgen, Inc., regarding the drugs Aranesp, Epogen, Neulasta and Enbrel. On or about December 2006 several qui tam complaints were filed in the Eastern District of New York alleging that Amgen has marketed the drug "Aranesp" and the others in a way that has compromised Doctor's independent medical judgment and threatened patient safety through the use of kickbacks and off-label promotion. Office of Personnel Management Office of Inspector General received the referral and subsequently opened a complaint

Investigation into the case revealed that Amgen promoted the use of Aranesp for certain off-label indications including for Anemia of Cancer, Anemia of Chronic Disease, and Myelodysplastic Syndrome, including through the use of articles in which Amgen's authorship role was not fully disclosed. Amgen also promoted the use of Aranesp for certain off-label dosing regimens, including bi-weekly and front loading of dosing in oncology as well as every 3 week and monthly dosing in nephrology. Amgen promoted the use of the drug Enbrel for off-label indication mild psoriasis and an off-label dosing regimen for psoriasis patients and made unsupported or insufficiently supported claims regarding Enbrel's safety. Amgen promoted Enbrel at twice its approved dose. Enbrel is a medication used in the treatment of moderate to severe plaque psoriasis, psoriatic arthritis, and moderate to severe rheumatoid arthritis.
Amgen also promoted the sale and use of Aranesp for indications which were not approved by the Food and Drug Administration (FDA)
Amgen promoted also the sale and use of Aranesp for dosing intervals, amounts or regimens that were not approved by the FDA.

Amgen reported inaccurate Average Sales Prices (ASA), Best Prices and Average Manufacturer Prices (AMP) for Aranesp, Epogen, Neulasta and Enbrel.

STATUTES VIOLATED

21 USC 331 Introducing a Misbranded Drug into Interstate Commerce

CASE SUMMARY

Between May 2004 through November 2010 several qui tam complaints were files in the Eastern District of New York alleging that Amgen has marketed the drug "Aranesp" and other drugs in a way that has compromised Doctor's independent medical judgment and threatened patient safety through the use of kickbacks and off-label promotion. It was alleged that Amgen was secretly using the International Nephrology Network (INN) to leverage with doctors. It was also alleged that they were engaged in a calculated fraudulent marketing scheme in which the company manipulated "flimsy" clinical science to advance its profits.

In 2006 OPM-OIG received a referral and subsequently opened a complaint.

On or about November 2008, several relators were interviewed and provided documents to collaborate their allegation. The USAO subpoenaed the company for documents related to different studies and the marketing of the drugs.

On or about December 2008, the International Nephology Network met with the government to explain their relationship with Amgen and to answer questions regarding the allegation.

On or about April 2009, several witnesses including former and current employees were interviewed.

On May 17, 2011, reporting agent submitted all claims data to USAO.

On June 18, 2011, the government presented their case to the company

On July 13, 2011, Amgen responded to the government.

On July 29, 2011, Amgen started to negotiate a settlement agreement with the government.

On or about December 19, 2012, a Global Settlement Agreement between Amgen, Inc. and the United States was finalized. The settlement was filed in the Eastern District of New York and combined several Amgen cases, including: seven of these cases currently are pending in the Eastern District of New York; two are pending in the District of Massachusetts and one in the Western District of Washington. The ten cases are: United States ex rel. Cantor v. Amgen, Inc., Civil Action No. CV-04 -2511 (E.D.N. Y), United States ex rel Osiecki v. Amgen, Inc., Civil Action No. CV-05-5025 (E.D.N.Y.), United States ex rel. Westmoreland v. Amgen, Inc., Civil Action No. 06-CV-10972 (D. Mass.), United States ex rel. Arriazola v. Amgen, Inc., Civil Action No. CV 06-3232 (E.D.N.Y.) United States ex rel. Horwitz v. Amgen Inc., Civil Action No. C07-0248 (W.D. Wash.) United States ex rel. Kelly v. Amgen Corporation, Civil Action No. CV-08-4157 (E.D.N.Y.) United States ex rel. Hanks v. Amgen, Inc., Civil Action No. CV 08-3096 (E.D.N.Y.) United States ex rel. Ferrante v. Amgen, Inc., Civil Action No. CV-08-3931 (E.D.N.Y.) United States ex rel. Tucker v. Amgen, Inc., Civil Action No. CV-09-0887 (E.D.N.Y.), and United States ex rel. DJAF Partnership v. Amgen, Inc., Civil Action No. 11-CV-11242 (D. Mass.).
As part of the plea agreement and criminal settlement, Amgen entered a guilty plea before U.S. District Judge Sterling Johnson of the Eastern District of New York to criminal information Charging the company with illegally introducing a misbranded drug, Aranesp, into interstate commerce. Under the Food, Drug and Cosmetic Act, it is illegal for drug companies to introduce into the marketplace drugs that the company intends will be used "off-label," i.e., for uses or at doses not approved by the FDA. Aranesp is an erythropoiesis-stimulating agent (ESA) that was approved by the FDA at calibrated doses for particular patient populations suffering from anemia. In order to increase sales of Aranesp and reap the resulting profits, Amgen illegally sold the drug with the intention that it be used at off-label doses that the FDA had specifically considered and rejected, and for an off-label treatment that the FDA had never approved.

Under the terms of the criminal plea agreement, Amgen will pay a criminal fine of $136 million and criminal forfeiture in the amount of $14 million. As part of the civil settlement, Amgen has agreed to pay $612 million ($587.2 million to the United States and $24.8 million to the states) to resolve claims that it caused false claims to be submitted to Medicare, Medicaid and other government insurance programs.

The federal civil settlement agreement encompasses allegations that Amgen: (1) promoted Aranesp and two other drugs that it manufactured, Enbrel and Neulasta, for off-label uses and doses that were, not approved by the FDA and not properly reimbursable by federal insurance programs; (2) offered illegal kickbacks to a wide range of entities in an effort to influence health care providers to select its products for use, regardless of whether they were reimbursable by federal health care programs or were medically necessary; and (3) engaged in false price reporting practices involving several of its drugs. As part of the global settlement, Amgen has also agreed to enter into a Corporate Integrity Agreement (CIA) with

HHS-OIG that will govern its conduct, and ensure careful oversight of its branding and marketing practices.

CONCLUSION/DISPOSITION

Signed: _____

Special Agent (b) (7)(C), (b) (7)(F)

Signed: _____

(b) (7)(C), (b) (7)(F)

OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

DATE: December 20, 2013

CASE NO: I 2009 00091 (previously C 2008 00199)

STAFF ASSIGNED: (b) (7)(C), (b) (7)(F)

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The United States Office of Personnel Management (OPM) Office of the Inspector General (OIG) is responsible for preventing, detecting, and investigating fraud concerning programs operated and administered by OPM, including the Federal Employees Health Benefits Program (FEHBP). FEHBP benefits are afforded to all federal employees upon employment to civil service. The federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet his or her needs. The federal employee also has the choice of adding family members, such as a spouse and children, to receive FEHBP benefits. On average, each federal agency contributes 73% of the employee's health premium to pay for the health benefits for each federal employee and his/her dependents.

BASIS OF INVESTIGATION

The following report relates to the investigation of Janssen Pharmaceuticals Inc. (Janssen), a subsidiary of Johnson & Johnson, regarding the drugs Risperdal and Invega. Between April 2004 and December 2004 and in January 2010, four Qui Tam Complaints were filed in the Eastern District of Pennsylvania (EDPA), alleging violations of the False Claims Act, in that Janssen promoted the use of Risperdal and Invega for medically unnecessary and unsafe usage for persons for whom either initial or sustained use of the drug was inappropriate or unsafe. In addition, Janssen conspired with doctors to cause to be presented false or fraudulent claims for payment in violation of 31 U.S.C. 3729(a)(3). Janssen was aggressively marketing Risperdal as a cure-all remedy for a broad spectrum of psychiatric maladies including but not limited to, anger management, dementia, post-traumatic stress, mood disorders, and refractory depression. OPM-OIG received the referrals and subsequently opened four complaints, later closing three and combining them into one. US ex rel C.M. & J.D. v Janssen Pharmaceutical (C 2005 00251), US ex rel L.P. v Janssen Pharmaceutical (C 2005 00228) and US ex rel K.B. v Ortho McNeil

Janssen Pharmaceutical (C 2010 00595).

CASE SUMMARY

In December 1993, the United States Food and Drug Administration (FDA) approved Risperdal for the "management of the manifestations of psychotic disorders". Janssen promoted Risperdal to health care providers for the treatment of psychotic symptoms and associated behaviors exhibited by elderly, non-schizophrenic patients who suffered from dementia and who exhibited behavioral symptoms associated with Alzheimer's disease – even though the drug was approved only to treat schizophrenia.

In April 2004, the first of four Qui Tam Complaints was filed by Relator, V.S. in EDPA.

In February 2005, the investigation was assigned to Special Agent (b) (7)(C), (b) (7)(F).

Negotiations/settlements talks started around 2009.

In November 2010, OPM-OIG closed the investigation based on Judge Frederica Massiah-Jackson's, of the Philadelphia Court of Common Pleas, decision to grant Janssen's motion of a non-suit. Judge Frederica Massiah-Jackson ruled that Pennsylvania officials failed to convince her that Janssen had hid the side effects and/or risks of Risperdal from the public and consequently fooled the State into paying millions more than they should have paid for the drug.

The United States Attorney's Office decided to intervene and the investigation was re-opened at OPM-OIG in November 2011.

In February 2012, the fourth Qui Tam, US ex rel K.B. v Ortho McNeil Janssen (C 2010 00595), which was assigned to reporting Special Agent was closed in OPM-OIG's case tracking and combined with this investigation. This investigation was then reassigned to reporting Special Agent.

The Relators alleged Janssen was aggressively marketing Risperdal as a cure-all remedy for a number of psychiatric diseases including but not limited to, anger management, dementia, post-traumatic stress, mood disorders, and depression. Relators also alleged that Janssen knowingly caused medical personnel and pharmacists to submit claims to the United States for payment and/or reimbursement to cover the use of Risperdal for the treatment of dementia. This was done through off-label marketing and promotion. Additionally, it was alleged that Janssen engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label use of Risperdal and other drugs, such as Invega, which was marketed to replace Risperdal and was also promoted for off-label uses for other than schizophrenic disorder.

From 1999 to 2005 Janssen Pharmaceuticals Inc., marketed Risperdal to control behavioral

disturbances in dementia patients. For most of this time period, Risperdal was approved only to treat schizophrenia. During this time sales representatives promoted Risperdal to physicians and other prescribers who treated elderly dementia patients by urging the prescribers to use Risperdal to treat symptoms such as anxiety, agitation, depression, hostility and confusion.

They created written sales aids, which were used by Janssen's ElderCare sales force that emphasized symptoms and minimized any mention of the FDA-approved use, treatment of schizophrenia. The company also provided incentives for off-label promotion and intended use by basing sales representatives' bonuses on total sales of Risperdal in their sales areas, not just sales for FDA-approved uses.

They also promoted the antipsychotic drug for use in children and individuals with mental disabilities, knowing that Risperal posed certain health risks to children. Nonetheless, one of Janssen's Key Base Business Goals was to grow and protect the drug's market share with child/adolescent patients. Janssen instructed its sales representatives to call on child psychiatrists, as well as mental health facilities that primarily treated children, and to market Risperdal as safe and effective for symptoms of various childhood disorders, such as attention deficit hyperactivity disorder, oppositional defiant disorder, obsessive-compulsive disorder and autism. Until late 2006, Risperdal was not approved for use in children for any purpose, and the FDA repeatedly warned the company against promoting it for use in children.

Invega was approved only for the treatment of schizophrenia and schizoaffective disorder, the government alleges that, from 2006 through 2009, J&J and Janssen marketed the drug for off-label indications and made false and misleading statements about its safety and efficacy.

SUBJECTS

JANSSEN PHARMACEUTICALS INC. (A SUBSIDIARY OF JOHNSON & JOHNSON)
Previous Name ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS INC.
1125 Trenton Harbourton Road
Titusville, New Jersey 08560

STATUTES VIOLATED

21 U.S.C. 331 (a) and 333 (a)(1) Causing the Introduction of a Misbranded Drug into Interstate Commerce in violation of the federal Food Drug and Cosmetic Act (FDCA).

CONCLUSION

In November 2013, the United States filed an Information charging Janssen with one count of introducing the drug Risperdal into interstate commerce without adequate directions for an intended use, in part evidenced by its promotion of Risperdal for uses not approved by the FDA

(off-label promotion), between March 2002 and December 2003 and thereby introducing a misbranded drug into interstate commerce, in violation of Title 21, United States Code, Section § 331(a) and 333(a)(1), a misdemeanor.

DISPOSITION

Janssen was convicted on 21 U.S.C. § 331 (a) and 333 (a)(1) Causing the Introduction of a Misbranded Drug into Interstate Commerce in violation of the federal Food Drug and Cosmetic Act (FDCA). Janssen agreed to pay a $125 special assessment fee, $334,000,000 criminal fine, and criminal forfeiture of $66,000,000 in substitute assets. Janssen agreed to pay $1,273,024,000.00 to the United States and the Medicaid Participating States collectively, as part of a global resolution. The United States will receive $749,240,137 plus accrued interest. The Federal Employees Health Benefits Program (FEHBP) was awarded $38,157,474.20.

SIGNED BY: _____ Date:

(b) (7)(C), (b) (7)(F)
New Jersey Resident Agency

APPROVED BY: Date:

(b) (7)(C), (b) (7)(F)
Eastern Operations

OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

DATE: April 5, 2013

CASE NO: I 2009 00916

STAFF ASSIGNED: (b) (7)(C), (b) (7)(F)

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The responsibility of the U.S. Office of Personnel Management (OPM), Office of the Inspector General (OIG) is to prevent, detect and investigate fraud concerning programs operated and administered by OPM, including the Federal Employees Health Benefits Program (FEHBP). FEHBP benefits are afforded to all federal employed upon employment to the civil service. The Federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet their needs, and also has the choice of adding family members, such as spouse and children. On average, each Federal agency contributes 73% of the employee's health premium to pay for the health benefits afforded to each Federal employee and their dependents.

BASIS OF INVESTIGATION

The following report relates to the investigation of Par Pharmaceutical Companies which was referred to OPM/OIG by the Department of Justice.

STATUTES VIOLATED

Food, Drug, and Cosmetic Act, misbranded drug introduced to interstate commerce, Title 21, United States Code Sections 331(a), 333 (a)(1), 352(f)(1), and

False Claims Act, Title 31 U.S.C Sections 3729-3733.

CASE SUMMARY

This case was referred to OPM/OIG by the Department of Justice in September of 2009. This was the third of three complaints filed in the District of New Jersey regarding Par

Pharmaceutical Companies. All three complaints asserted that Par Pharmaceutical Companies engaged in the Misbranding and Off Label Promotion of the pharmaceutical Megace and Megace ES. In 1993, the FDA approved Megace and Megace ES to treat patients diagnosed with AIDS and suffered from significant weight loss. In 2002, Par approached, however they never pursued the approval process nor did they conduct clinical trials to support the use Megace and Megace ES to treat geriatric wasting. Between 2002 and 2005, Par's market research showed the overwhelming majority of Megace and Megace ES prescriptions were written for the treatment of non AIDS related geriatric wasting.

On March 5, 2013, Par Pharmaceutical Companies pleaded guilty to a one count criminal Information charging Par with Misbranding Megace and Megace ES in violation of the Federal Food, Drug, and Cosmetic Act and agreed to pay $45 million to resolve both the criminal and civil cases in Par's non FDA approved promotion of Megace and Megace ES.

As part of the criminal plea regarding the violation of the Food Drug and Cosmetic Act for introducing the misbranded drug into interstate commerce, Par was sentenced to pay an $18 million fine and was ordered to pay $4.5 million in criminal forfeiture.

The civil settlement resolves the False Claims Act violation related to Par representatives made inaccurate, unsupported and misleading statements about the use of Megace and Megace ES in geriatric patients. Par agreed to pay $22.5 million to resolve their civil liability.

As part of the civil settlement OPM received $423,977, less the 3% DOJ off set totaling $12,719.69, resulting in $411,257.69 being returned to the FEHBP.

The case was investigated by HHS-OIG, FBI, FDA, VA-OIG and OPM-OIG.

CONCLUSION/DISPOSITION

As part of the civil settlement OPM received $423,977, less the 3% DOJ off set totaling $12,719.69, resulting in $411,257.69 being returned to the FEHBP.

Signed: _____

Signed: _____

DATE: May 7, 2014

CASE NO: I 2010 00607

STAFF ASSIGNED: (b) (7)(C), (b) (7)(F)

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

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BASIS OF INVESTIGATION

The following report relates to the investigation of Astellas Pharma US Inc. (Astellas) regarding the drug Mycamine. In April 2010, the Office of Personnel Management-Office of Inspector General received a Complaint from the Eastern District of Pennsylvania, United States Attorney's Office regarding Astellas. The Relators alleged that Astellas submitted or caused to be submitted fraudulent claims by promoting the off-label use of the drug Mycamine (an antifungal drug) to children's hospitals and other pediatric prescribers, despite the fact that Mycamine had only been approved by the Food and Drug Administration (FDA) to treat adult patients; and providing kickbacks to physicians for appearances promoting Mycamine.

CASE SUMMARY

Between 2005 and 2010, Astellas knowingly marketed and promoted the sale of Mycamine for pediatric use, which was not a medically accepted indication and, therefore, not covered by

federal health care programs. During this time period, the FDA approved Mycamine to treat adult patients suffering from serious and invasive infections caused by the fungus Candida, including infections in the esophagus, the blood and the abdomen, and to prevent Candida infections in adults undergoing stem cell transplants. From 2005 through June 2013, however, Mycamine was not approved to treat pediatric patients for any use.

SUBJECTS
ASTELLAS PHARMA US INC.
Three Parkway North
Deerfield, IL 60015

STATUTES VIOLATED
31 U.S.C. 3730 Violation of the False Claims Act

CONCLUSION
In April 2014, Astellas signed a settlement agreement to pay $7.3 million. The federal government will receive $4.2 million and state Medicaid programs will receive $3.1 million.

DISPOSITION
The Federal Employees Health Benefits Program (FEHBP) was awarded $209,253.83, minus the 3% DOJ allocation of $6277.61, leaving a net recovery to the FEHBP of $202,976.22.

SIGNED BY: _____ Date:
(b) (7)(C), (b) (7)(F), Special Agent
New Jersey Resident Agency

APPROVED BY: Date:
(b) (7)(C), (b) (7)(F)
Eastern Operations

OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

DATE: March 31, 2014

CASE NO: I 2010 00808

STAFF ASSIGNED: (b) (7)(C), (b) (7)(F)

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The United States Office of Personnel Management (OPM) Office of the Inspector General (OIG) is responsible for preventing, detecting, and investigating fraud concerning programs operated and administered by OPM, including the Federal Employees Health Benefits Program (FEHBP). FEHBP benefits are afforded to all federal employees upon employment to civil service. The federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet his or her needs. The federal employee also has the choice of adding family members, such as a spouse and children, to receive FEHBP benefits. On average, each federal agency contributes 73% of the employee's health premium to pay for the health benefits for each federal employee and his/her dependents.

BASIS OF INVESTIGATION

The following report relates to the investigation of Endo Pharmaceuticals Inc. (Endo), a subsidiary of Endo Health Solutions Inc. regarding the drug Liododerm. In July 2005 and June 2010, two Qui Tam Complaints were filed in the Eastern District of Pennsylvania (EDPA), respectively. The Relators alleged that Endo distributed, marketed, and sold pharmaceutical products in the United States, including a drug approved for the treatment of the pain associated with post-herpetic neuralgia (PHN) sold under the trade name of Lidoderm. From September 1999 through the present, Endo manufactured, marketed, and sold Lidoderm for pain other than that associated with PHN.

CASE SUMMARY

Between 2002 and 2006, Endo introduced into interstate commerce Lidoderm that was misbranded under the Federal Food, Drug and Cosmetic Act (FDCA). Lidoderm was approved

by the United States Food and Drug Administration (FDA), only for the relief of pain associated with PHN, a complication of shingles. During the relevant time period, the Lidoderm distributed nationwide by Endo was misbranded. Endo knowingly promoted the sale and use of Lidoderm for conditions for which it had not been approved by the FDA, including for the use in treatment of non-PHN related pain, such as lower back pain, diabetic neuropathy, carpal tunnel syndrome and chronic pain, which were not medically-accepted indications and were not covered by Medicare, Medicaid, and other Federal Health Care Programs; and these prescriptions were paid for or reimbursed by Medicaid, Medicare, or other Federal Health Care Programs.

SUBJECTS

ENDO PHARMACEUTICAL INC.
(A SUBSIDIARY OF ENDO HEALTH SOLUTIONS, INC.)
1400 Atwater Drive
Malvern, PA 19355

STATUTES VIOLATED

21 U.S.C. 331 (a) and 333 (a)(1) Causing the Introduction of a Misbranded Drug into Interstate Commerce in violation of the federal Food Drug and Cosmetic Act (FDCA).

CONCLUSION

In Februray 2014, a Criminal Information was filed in the Northern District of New York, the government charged that, between 2002 and 2006, Endo Pharmaceuticals Inc. introduced into interstate commerce Lidoderm that was misbranded under the Federal Food, Drug and Cosmetic Act (FDCA). In addition, Endo agreed to settle its potential civil liability in connection with its marketing of Lidoderm.

DISPOSITION

In February 2014, Endo Pharmaceuticals Inc. agreed to pay $192.7 million to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm for uses not approved as safe and effective by the FDA. The resolution includes a deferred prosecution agreement and forfeiture totaling $20.8 million and civil false claims settlements with the federal government and the states and the District of Columbia totaling $171.9 million.

The Federal Employees Health Benefits Program (FEHBP) was awarded $6,629,886.05, minus the 3% DOJ allocation of $198,896.58, leaving a net recovery to the FHEBP of $6,430,989.47.

SIGNED BY: _____ Date:

(b) (7)(C), (b) (7)(F), Special Agent
New Jersey Resident Agency

APPROVED BY: Date:

(b) (7)(C), (b) (7)(F)
Eastern Operations

OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

DATE: 09/12/2013

CASE NO: I 2011 00001

STAFF ASSIGNED: S/A (b) (7)(C), (b) (7)(F)

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The responsibility of OPM's Office of Inspector General (OIG) is to prevent, detect, and investigate fraud concerning programs operated and administered by OPM, including CSRS and Federal Employee Retirement System (FERS). CSRS benefits are afforded to federal employees, known as "annuitants", upon retirement from civil service. The annuitant receives CSRS benefits throughout his/her lifetime based on his/her age, average salary and length of federal service computation as provided under Title 5, Chapter 89, Code of Federal Regulations (CFR).

Prior to retirement, the annuitant has the option to choose a spousal benefit, where upon the annuitants' death, CSRS benefits would be transferred to the surviving spouse. The maximum spousal survivor benefit can only be 55% percent of retirement benefit paid to the retired federal employee. There is no benefit for the surviving children, except for children under 18 years of age or 22 years of age if a full time student. A survivor annuity is payable only upon OPM's approval of an application from the eligible family member. OPM randomly sends letters to annuitants for the purpose of updating addresses and to request death information, if the annuitant is deceased.

BASIS OF INVESTIGATION

This case was referred to the OPM/OIG/Office of Investigations by the OPM Retirement Inspections Branch (RIB), Retirement Service (RS), regarding potential fraud, relating to CSRS annuitant/survivor annuitant (b) (7)(C) . (b) (7)(C) died on (b) (7)(C) , yet retirement payments continued to be deposited into her Bank of America account through September 1, 2010. The Office of Investigations initiated an investigation to determine whether the CSRS benefits were fraudulently obtained.

STATUTES VIOLATED

Title 18 U.S.C. § 641 – Theft of Government Funds/Property.

CASE SUMMARY

In September 2010, OPM-Retirement Service stopped the annuity/survivor annuity payments based on the confirmation of (b) (7)(C) 's death. At the time the payments were stopped, (b) (7)(C) was receiving net annuity payments in the amount of $1,605.00 per month. (b) (7)(C) was also receiving survivor annuity payments in the amount of $1,351.92 per month, on behalf of her deceased husband (b) (7)(C) . The total overpayment between the time of (b) (7)(C) 's death in (b) (7)(C) and the cessation of the payments in September 2010 totaled $398,773.96.

A review of the relevant retirement files revealed that (b) (7)(C), (b) (7)(F) was listed as the informant on (b) (7)(C) 's death certificate. In addition, (b) (7)(C) 's Designation of Beneficiary form listed (b) (7)(C), (b) (7)(F) and (b) (7)(C) as her children. A law enforcement check revealed that (b) (7)(C) died in 1989. The investigation also disclosed that (b) (7)(C), (b) (7)(F) resided at (b) (7)(C), (b) (7)(F) , and was employed by (b) (7)(C), (b) (7)(F) .

Based on OPM's internal retirement records, after (b) (7)(C) passed away, her annuity and survivor benefits continued to be routinely electronically deposited into Bank of America account number (b) (7)(C) .

In October 2010, this case was presented and accepted for prosecution by the U.S. Attorney's Office (USAO) for the District of Maryland (MD). The USAO-MD authorized the issuance of subpoenas relating to financial accounts in the name of (b) (7)(C) and (b) (7)(C), (b) (7)(F) . A review of the financial records confirmed that the annuity/survivor annuity payments were being deposited into (b) (7)(C) 's bank account. The investigation further disclosed that after (b) (7)(C) passed away, (b) (7)(C), (b) (7)(F) wrote checks to herself from her mother's bank account, forged her mother's signature, and endorsed the checks by signing her name, and using the money for personal use.

On May 2, 2011, Office of Investigations (OI) Special Agents attempted to interview (b) (7)(C), (b) (7)(F) . (b) (7)(C), (b) (7)(F) refused to identify herself and speak to the agents. Agents identified her based on OI's investigation, including photograph and other information. When agents displayed their credentials and asked if she was (b) (7)(C), (b) (7)(F) or (b) (7)(C), (b) (7)(F) she said no. When agents asked to see her identification, she refused.

On July 26, 2011, OI Special Agents learned through (b) (7)(C), (b) (7)(F) 's employer, (b) (7)(C), (b) (7)(F) , that (b) (7)(C), (b) (7)(F) 's last physical day (b) (7)(C), (b) (7)(F) also asked her

employer not to forward her last pay check to the address on file. [redacted] did not provide a forwarding address. The Office of Investigations (OI) subsequently learned that [redacted] moved to the [redacted], Georgia area.

On December 5, 2012, [redacted] was indicted by a Federal Grand Jury seated in the U.S. District Court for the District of Maryland, on six counts of violating 18 U.S.C. § 641 (Theft of Government Funds/Property) . The U.S. District Court issued an arrest warrant for [redacted]

On December 12, 2012, OI Special Agents, with the assistance of the Georgia Bureau of Investigation (GBI), located and arrested [redacted] in [redacted], Georgia. During the custodial interview, [redacted] admitted to the fraud. [redacted] was transported to the U.S. Marshals Service in [redacted], Georgia for processing. Following, [redacted] appeared before the Honorable Magistrate Judge [redacted], in the U.S. District Court, Northern District of Georgia, for her initial appearance and was released on bond.

On June 10, 2013, [redacted] entered a guilty plea to one (1) count of 18 U.S.C. § 641 (Theft of Government Funds/Property). Sentencing was scheduled for [redacted] in the U.S. District Court, Northern District of Georgia before the Honorable Judge [redacted].

CONCLUSION/DISPOSITION

On August 27, 2013, [redacted] appeared before the Honorable Judge [redacted] in the U.S. District Court, Northern District of Georgia, for sentencing. Judge [redacted] sentenced [redacted] to the following:

- Incarceration - 18 months
- Supervised release - 3 years
- Restitution - $398,773.96
- Special Assessment fine: $100.00

APPROVALS

[redacted] _____ Date: _____
Special Agent

[redacted] _____ Date: _____
[redacted]

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT
Washington, DC 20415

Office of the
Inspector General

February 6, 2012

MEMORANDUM FOR ELAINE KAPLAN
General Counsel

FROM: MICHAEL R. ESSER
Assistant Inspector General for Audits

SUBJECT: Review of OPM's Transit Benefits Program (limited scope)
(Report Number 1K-RS-00-12-027)

The purpose of this memorandum is to communicate the results of our review of OPM's Transit Benefits Program (limited scope).

Executive Summary

The U.S. Office of Personnel Management (OPM), Office of the Inspector General (OIG) has completed a review of transit benefits received by a sample of 74 OPM employees. Currently, OPM has about 1,408 employees participating in its Transit Benefits Program.

The OIG performed this review due to potential violations of the Transit Benefit Program by OPM employees identified by your office. We analyzed the sampled employees' Telework agreements, OPM building access data and other relevant information and compared actual commuting costs to transit benefits received for 67 of the sampled employees. For the remaining seven employees sampled, we were unable to perform an analysis due to the lack of documentation. Our analysis determined that 56 of the 67 employees in our review received excess transit benefits totaling $58,785 between December 2008 and June 2011.

Background

As part of a national effort to improve air quality and reduce traffic congestion through the increase of commuting by means other than single-occupancy motor vehicles, the Federal Employees Clean Air Incentive Act (FECAIA Pub.L.103-172) was enacted in December 1993 and permanently authorized Federal participation in the Transit Benefit Program.

Executive Order 13150 (Order), signed April 21, 2000, ordered the reduction of Federal employees' contribution to traffic congestion and air pollution, and an expansion of their commuting alternatives, through a mass transportation and vanpool transportation fringe benefit program. The Order provided that by no later than October 1, 2000, Federal agencies were to implement a transportation fringe benefit program to qualified Federal employees giving them the option to exclude, from taxable wages and compensation, employee commuting costs incurred through the use of mass transportation and vanpools, not to exceed the maximum level

allowed by law (26 U.S.C. 132 (f)(2)). To implement the Order, Federal agencies were required to develop plans in consultation with the Department of the Treasury, the Department of Transportation, the Environmental Protection Agency, the Office of Personnel Management, the General Services Administration, and the Office of Management and Budget.

In May 2007, OMB issued a memorandum to the Heads of Departments and Agencies requiring agencies to implement a minimum number of internal controls for the administration of the Federal Transit Benefit Program. The internal controls included:

- Application requirements for each employee requesting benefits such as home and work addresses; commuting cost breakdown; certification of eligibility; and a signature that no false statements were made on the application.
- Independent verification of eligibility information such as commuting costs, by approving officials.
- Implementation of procedures by the agencies including checking transit benefit applicants against parking records; adjusting benefits due to travel, leave or address changes; and removal from the program when an employee leaves the agencies.

The Department of Transportation's Transit Benefit Program was established in 1991 when the Federal Transit Administration (FTA) began pilot testing a program. The Department of Transportation is responsible for administering the transit benefit program for OPM.

OPM is responsible for managing its employees transit benefit program, including ensuring that employees complete the transit benefit application, including the Fare Benefits Application (OPM form 1710), Public Transportation Benefit Expense Worksheet, Public Transportation Benefit Program Application (OPM form 1648), and that they submit SmarTrip information (card numbers, amount requested, etc.).

Objective

The objective of our review was to determine whether the 74 OPM employees sampled received transit benefits in excess of their actual commuting costs.

Scope and Methodology

In February 2011, your office issued an internal memorandum stating that some employees appeared to have received transit benefits in excess of their actual commuting costs. In addition, it appeared that one employee received transit benefits and was a prime holder of a car pool parking pass, which was stated as a violation of both the car pool and transit benefits rules.

In March 2011, your office sent a memorandum to OPM's Facilities, Security, and Contracting office requesting that they ensure that the amount of transit benefits paid to the employees in question was correct given the number of days the employees commuted to the office, and to deal with any past overpayments that may have been made to the employees. Your office also suggested that the matter be referred to the Inspector General if initial conclusions were confirmed.

OPM's Deputy Chief Financial Officer requested that OPM's Policy and Internal Control (PIC) office evaluate the information provided by your office. PIC performed a review of the initial list of names provided by OGC and determined that 136 employees received questionable benefits and that 50 of the employees may have received overpayments after June 2008.

At your office's request and based on the PIC results, the OIG's management made the decision to perform a review of transit benefits for the 50 employees identified by PIC.

An initial sample of 50 employees was selected based on PIC's results. Another 24 employees were added during our analysis.

The scope of the review consisted of transit benefits received by the 74 employees sampled from December 2008 through June 2011.

No data was provided for seven of the employees sampled, and for the remaining 67 employees, we obtained all or portions the following data:

- Daily OPM Theodore Roosevelt Building (TRB) access data for the period December 2008 through June 2011.
- Employees transit benefit amounts received from December 2008 through June 2011.
- Telework agreements, including completed Fare Benefits Applications, Public Transportation Benefit Program Applications[1], and Public Transportation Benefit Expense Worksheets[2].

OPM's Facilities, Security, and Contracting office provided the daily TRB access data. The Chief Financial Officer provided the employees transit benefit reimbursements, as received from the Department of Transportation. OPM's transit benefit coordinator provided the Telework agreements[3].

We reviewed the data and prepared analyses to ensure that the 67 employees' actual commuting costs were not less than the amount of transit benefits received from December 2008 through June 2011.

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1 Fare Benefits Applications and Public Transportation Benefit Program Applications are agreements between OPM and the employee that state the amount of fare subsidy the employee will receive. Employees also certify that they are eligible for benefits; the amount of monthly and/or quarterly transit costs they incur, excluding parking; are not requesting more benefits than necessary; and do not have a federally subsidized parking permit. In addition, the applications contain a false statement warning informing employees that any false, fictitious, or fraudulent statements on their signed applications may subject them to criminal prosecution.

2 Public Transportation Benefit Expense Worksheets detail the employees' mode of transportation (metro, vanpool, commuter rail/bus); departure location; daily, weekly and/or monthly travel expenses; whether the employees work a compressed work schedule (9 or 10 hour workdays) or a regular 8-hour workday; and how many days per month the employee is scheduled to work.

3 Telework agreements are voluntary contracts between OPM and the employee to participate in an alternative worksite (telecommuting) program. The agreement includes the alternative worksite location; phone numbers; guidelines on protecting personally identifiable information and equipment; and other work related guidelines.

Due to the sensitivity of this review, we did not perform employee and supervisor interviews. The OIG recommends that employee and supervisor interviews be performed before any actions are considered against the employees in question to document any special circumstances or other relevant information.

Results

Our analysis determined that 56 of 67 employees in our review received excess transit benefits in the amount of $58,785. Of the total, 10 employees were vanpool riders that received excess transit benefits of $13,208 over their certified commuting costs. In addition, 10 of the 56 employees in question, including vanpool and non-vanpool riders, were also carpool members.

For the remaining seven employees sampled, we were unable to perform an analysis due to the lack of documentation.

Details of our results will be made available to you upon request.

If you have any additional analysis for us to perform or questions related to our review, please contact me on [redacted]

Attachment

Cc: [redacted], Deputy Assistant General Counsel,
Office of the General Counsel

[redacted], Counsel,
Office of the General Counsel

Attachment

Transit Benefit Review (December 2008 through June 2011)
Audit Report Number: 1K-RS-00-12-027

SCHEDULE OF RESULTS

TOTAL EXCESS FARE SUBSIDY RECEIVED BY OPM EMPLOYEES		
Excess transit benefits received by non-vanpool riders (Reviewed Samples)	$ (45,577)	
Number of employees that received excess transit benefits (less vanpool riders)		46
Total excess transit benefits received by vanpool riders (Reviewed Samples)	(13,208)	
Number of employees reviewed (from original Chief Financial Officer/Policy and Internal Control sample) that received excess transit benefits (vanpool riders only)		10
Total number of employees that received excess transit benefits (including vanpool riders)		56
Total excess transit benefits received (including vanpool riders)	$ (58,785)	
TOTAL SELECTED SAMPLES		
Total number of samples selected		74
Total number of samples selected and not reviewed		(7)
Total number of samples reviewed		67
OCFO/PIC SELECTED SAMPLES		
Number of OCFO/PIC samples		50
Number of OCFO/PIC samples selected and not reviewed		(5)
Number of samples reviewed from original OCFO/PIC selection		45
OIG SELECTED SAMPLES		
Number of additional samples selected by the OIG		24
Number of additional samples selected by the OIG that were not reviewed		(2)
Number of additional samples selected by the OIG that were reviewed		22
NUMBER OF SAMPLES IN CARPOOLS		
Number of samples in carpools		10

OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

DATE: July 9, 2014

CASE NO: I-2011-00201

STAFF ASSIGNED: SA (b) (7)(C), (b) (7)(F)

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The responsibility of the Office of Personnel Management's (OPM) Office of Inspector General (OIG) is to prevent, detect, and investigate fraud concerning programs operated and administered by OPM, such as the Federal Employees Health Benefits Program (FEHBP).

FEHBP benefits are afforded to all federal employees upon employment to civil service. The federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet his or her needs. The federal employee also has the choice of adding family members, such as a spouse and children, to receive FEHBP benefits. On average, each federal agency contributes 73% of the employee's health premium to pay for the health benefits for each federal employee and his/her dependents.

BASIS OF INVESTIGATION

On January 6, 2011, the Office of Personnel Management, Office of Inspector General (OPM/OIG) received a qui tam complaint from the Commercial Litigation Branch, Civil Division, of the U.S. Department of Justice. The complaint alleged that AstraZeneca, LP (AstraZeneca) a pharmaceutical manufacturer that distributes, markets, and sells pharmaceutical products in the United States, made payments of illegal financial inducements in the hundreds of millions of dollars to Medco Health Solutions, Inc (Medco) in order to obtain a favorable position of AstraZeneca's drug Nexium on Medco's formulary, in an effort to increase the promotion and purchasing of Nexium. It is further alleged that AstraZeneca's conduct was in knowing violation of the terms of its Corporate Integrity Agreement with the U.S. Department of Health and Human Services-Office of Counsel to the Inspector General, dated from June 4, 2003 through its expiration date of June 4, 2008.

STATUTES VIOLATED

As to: N/A

CASE SUMMARY

This investigation was the result of a qui tam complaint filed in the State of Delaware. In addition to the allegations of illegal financial inducements to Medco, the complainant alleged that AstraZeneca evaded its obligations under the Best Price Statute in presenting, or causing to be presented, false claims to government health care programs by fraudulently disguising rebates and discounts on the drug Nexium as value-added, in-kind discounts on other AstraZeneca drugs such as Prilosec, Toprol XL, and Plendil.

The U.S. Attorney's Office (USAO) for the District of Delaware requested claims data from Medicare, Medicaid, and the FEHBP, relative to the aforementioned drugs. The OIG's Major Frauds Unit provided the requested claims data. An analysis of those claims, as well as interviews of several former employees, prompted the USAO to issue subpoenas to AstraZeneca for sales and marketing data.

On July 7, 2014, the USAO for the District of Delaware notified the OPM/OIG that the Department of Justice has decided not to include FEHBP claims in the investigation because the focus of the investigation is now centered around AstraZeneca's involvement in the Retiree Drug Subsidy Program, which is covered by the Medicare program.

CONCLUSION/DISPOSITION

The USAO is not including FEHBP claims in their investigation. Therefore, it is recommended that this investigation be closed.

Signed: _____
(b) (7)(C), (b) (7)(F), Special Agent
Baltimore Resident Agency

Signed: _____
(b) (7)(C), (b) (7)(F)
Eastern Field Operations

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT

Washington, DC 20415

Office of the
Inspector General

REPORT OF INVESTIGATION

PROGRAM OVERVIEW

The responsibility of the U.S. Office of Personnel Management (OPM), Office of the Inspector General (OIG) is to prevent, detect and investigate fraud concerning programs operated and administered by OPM, including the Federal Employees Health Benefits Program (FEHBP). FEHBP benefits are afforded to all federal employed upon employment to the civil service. The Federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet their needs, and also has the choice of adding family members, such as spouse and children. On average, each Federal agency contributes 73% of the employee's health premium to pay for the health benefits afforded to each Federal employee and their dependents.

BASIS OF INVESTIGATION

The following report relates to the investigation of Amgen, Inc. regarding the medication Aranesp. In summary, it was alleged that during the period from September 1, 2003 through December 31, 2011 Amgen was involved in illegal conduct with regards to its anemia medication Aranesp.

The case was referred to OPM/OIG by the Department of Justice and OPM/OIG case number I2011-0814 was opened.

STATUTES VIOLATED

31 U.S.C. § 3730(b) False Claims Act

CASE SUMMARY

On or about September 7, 2011, the Office of Personnel Management- Office of Inspector General received a copy of an open complaint against Amgen, Inc. In summary, it was alleged that Amgen was involved in illegal conduct with regards to its anemia medication Aranesp. Specifically, it was alleged that Amgen:

- Acted alone and/or in combination with Omnicare, PharMerica and Kindred Healthcare to switch a competitor medication to Aranesp for nursing home patients.

- Paid physicians, nurses and other health care providers to promote Aranesp on-label and off-label.
- Engaged in off-label promotion of Aranesp through Continuing Medical Education programs .

Aranesp is a medication approved to treat lower than normal red blood cells (anemia) caused by chronic kidney disease or chemotherapy.

On or about October 4, 2011, Forensic Auditor (FA) (b) (7)(C), (b) (7)(F) requested pharmaceutical and medical data exposure from all FEHBP carriers.

On or about September 27, 2012, Special Agent (SA) (b) (7)(C), (b) (7)(F) spoke with DOJ attorney (b) (7)(C), (b) (7)(F). (b) (7)(C), (b) (7)(F) explained that the specific data set needed from FEHBP was only Aranesp prescriptions dispensed at Long Term Care (LTC) facilities, summarize the data by year, and summarize three LTC facilities (Pharmerica, Omnicare and Kindred).

On October 2, 2012, SA (b) (7)(C), (b) (7)(F) and FA (b) (7)(C), (b) (7)(F), finalized the analysis according to (b) (7)(C), (b) (7)(F)'s specifications.

In December 2012, after receiving the exposure drug data from the queried contracted FEHBP Plans, FA (b) (7)(C), (b) (7)(F) reviewed and summarized the data. The FEHBP data received from the American Postal Workers Union (APWU), Government Employees Hospital Administration (GEHA), Coventry (CVTY), Blue Cross Blue Shield Administration (BCBSA) and Kaiser Permanente totaled $993,599 (billed) and $802,712 (paid) related to the allegations.

On or about April 2, 2013, the United States Attorney's Office in the District of South Carolina contended, according to the settlement agreement, Amgen offered and paid illegal remuneration to long-term care pharmacy providers Omnicare Inc. (Omnicare), PharMerica Corporation (PharMerica), and Kindred Healthcare Inc. (Kindred) in the form of purported market-share rebates, purported volume-based rebates, grants, honoraria, speaker fees, consulting services, dinners, travel, or the purchase of unnecessary data, and that this illegal remuneration was offered and paid for the purpose of inducing Omnicare, PharMerica, and Kindred to recommend Aranesp and to influence health care providers' selection and utilization of Aranesp within nursing homes, skilled nursing facilities, and long-term care settings.

The complaint also stated that Amgen encouraged the implementation of "Therapeutic Interchange" programs (also known as "switching" programs) intended to identify patients who were taking a competitor drug and switch those patients to Aranesp. The complaint further alleged that Amgen urged Omnicare, PharMerica, and Kindred to expand the market for Aranesp by: (a) pressuring consultant pharmacists employed by Omnicare, PharMerica, and Kindred to recommend Aranesp for patients for

whom no physician had diagnosed anemia associated with chronic renal failure, the patient had no prior history of anemia associated with chronic renal failure, and the patient had no outward symptoms of anemia associated with chronic renal failure; and (b) promoting the use of protocols, distributing materials, and sponsoring programs designed to recommend Aranesp's use in patients who did not have "anemia associated with chronic renal failure," as specified in the approved labeling for Aranesp.

CONCLUSION/DISPOSITION

On or about April 2, 2013, as part of the civil settlement filed in the District of South Carolina, Amgen agreed to pay various government programs $24,900,000. The FEHBP will receive $88,232.00 plus $25,441.31 (Lost Investment Income) equaling $113,673.31, less the three percent allocation to the Department of Justice totaling $3,410.20, resulting in a recovery of $110,263.11

CASE UPDATE: The original allegation included both a Federal False Claims violation along with a Civil Kickback Violation. Initially, the FEHBP was included in the off label promotion False Claims violated which resulted in a civil settlement in April 2013 and excluded from the Omnicare Civil Kickback Violation. On March 25, 2014, OPM was notified that Omnicare settled to a Federal False Claims violation that resolved any liability related to claims submitted for reimbursement. Omnicare agreed to pay $4.19 million in restitution to various government health insurance programs of which the FEHBP received $33,444.77. (b) (5)

Signed: _____

Special Agent (b) (7)(C), (b) (7)(F)

Signed: _____

(b) (7)(C), (b) (7)(F)

United States
Office of
Personnel
Management

OFFICE OF THE INSPECTOR GENERAL

July 30, 2014

Case Agent: (b) (7)(C), (b) (7)(F)
Special Agent – Atlanta GA Resident Agency

Case No: I 2012 00084

FINAL REPORT OF INVESTIGATION

The following report of investigation relates to Carondelet Health Network, Carondelet St. Mary's Hospital, and Carondelet St. Joseph's Hospital (collectively "Carondelet") located in Tucson Arizona, which has agreed to pay $35 million to resolve its civil liability arising from the company's charging Medicare, Arizona Medicaid, and the FEHBP from improper billing for inpatient rehabilitation facility services by failing to meet rehabilitation therapy time requirements and failing to perform other required services (e.g., pre-admission screening, plan of care documentation, team conference meeting documentation).

PROGRAM OVERVIEW

The responsibility of the Office of Personnel Management's (OPM) Office of Inspector General (OIG) is to prevent, detect, and investigate fraud concerning programs operated and administered by OPM. Federal Employees Health Benefits Program (FEHBP) benefits are afforded to all federal employees upon employment to civil service. The federal employee has the opportunity to select from over 300 FEHBP contracted health insurance carriers that meet his or her needs. The federal employee also has the choice of adding family members, such as a spouse and children, to receive FEHBP benefits. On average, each federal agency contributes

73% of the employee's health premium to pay for the health benefits for each federal employee and his/her dependents.

BASIS OF INVESTIGATION

The case originated by a qui tam filed on or about November 15, 2011, in the United States District Court for the District of Arizona captioned United States ex rel. Bloink v. Carondelet Health Network, et al., bearing case number CV-11-721-TUC-FRZ, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b). The allegation stated that Carondelet falsely billed Government Health Programs for inpatient rehabilitation facility services by failing to meet rehabilitation therapy time requirements and failing to perform other required services.

STATUTES VIOLATED

Violations:
31 U.S.C. § 3729 – 3733 - False Claims Act
42 U.S.C. § 1320a-7a – Civil Monetary Penalties Law
31 U.S.C. § 3802-3812 – Program Fraud Civil Remedies Act

CASE SUMMARY

The case originated by a qui tam filed on or about November 15, 2011, in the United States District Court for the District of Arizona captioned United States ex rel. Bloink v. Carondelet Health Network, et al., bearing case number CV-11-721-TUC-FRZ, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b).

Carondelet Health Network is an Arizona non-profit corporation incorporated on or about November 26, 1956, with its principal place of business located at 2202 North Forbes Road,

Tucson, Arizona 85745. At all relevant times, Carondelet was trading as and/or was doing business as both Carondelet St. Mary's Hospital, which is located at 1601 West St. Mary's Road, Tucson, Arizona 85745, and Carondelet St. Joseph's Hospital, which is located at 350 North Wilmot Road, Tucson, Arizona 85711. The allegation stated that Carondelet falsely billed Government Health Programs for inpatient rehabilitation facility services by failing to meet rehabilitation therapy time requirements and failing to perform other required services. (e.g., pre-admission screening, plan of care documentation, team conference meeting documentation). More specifically, the United States contends that from April 7, 2004, through December 31, 2011, Carondelet knowingly and falsely billed, or caused to be billed, Medicare, FEHBP, and Medicaid for inpatient rehabilitation facility services that were not properly reimbursable under applicable coverage criteria because the patients were not appropriate for inpatient rehabilitation facility services.

CONCLUSION

On July 29, 2014, Carondelet entered into a Final Settlement Agreement with the United States to resolve the issues identified. The total settlement amount is $35,000,000.00 (Settlement Amount) of which $394,889.00 will be paid to OPM for losses incurred by the FEHB Program. The settlement figure represents a 1.75 x multiplier on single damages and represents a 30% error rate established by a compromise to the Defense Team expert's error rate of 13% and the Governments expert's error rate of 48%. The FEHBP loss time frame is from April 2007 – December 2011. HHS-OIG has entered into a Corporate Integrity Agreement with Carondelet and has given them a release from liability and from exclusion for which OPM concurred.

The total settlement is for $35,000,000. The FEHBP was awarded $394,889.00 minus the 3% Department of Justice fee 3% ($11,846.67) for a total recovery of $383,042.33. An additional $58,102.42 was calculated in lost investment income (LII) to the US Treasury but was not included by the USAO. DOJ in its approval chose not to apply a multiplier to the FEHB single damages. The funds will come to OPM as an IPAC distribution and should be distributed as follows:

Insurance Carrier	Percentage	Dollars
AETNA	42.36	$ 162,256.73
American Postal Workers Union (APWU)	2.57	$ 9,844.19
BCBS/Federal Employee Program (FEP) Director's Office	35.55	$ 136,171.55
Coventry (Mail Handlers)	16.44	$ 62,972.16
National Association of Letter Carriers (NALC)	3.08	$ 11,797.70
Total	**100%**	**$ 383,042.33**

Signature: _____ Date: 07/30/2014
(b) (7)(C), (b) (7)(F), Special Agent / Atlanta RA

Signature: _____ Date: 07/30/2014
(b) (7)(C), (b) (7)(F) / Eastern Region Operations

REPORT OF INVESTIGATION

October 17, 2013

CASE NAME: (b) (7)(C), (b) (7)(F)

CASE NUMBER: I 2012 00356

CASE AGENT: (b) (7)(C), (b) (7)(F)

INTRODUCTION

The following information relates to (b) (7)(C), (b) (7)(F), a former Investigations Case Analyst, GS-1801-12, step 4, with the Federal Investigative Services (FIS), U.S. Office of Personnel Management (OPM), who failed to work reported hours and falsified the number of reviewed investigative cases, on numerous time and attendance reports and weekly production sheets, from on or about April 2010 through March 2012.

As a journeyman-level case analyst, (b) (7)(C), (b) (7)(F) was responsible for reviewing investigative material on completed background investigations to identify any reporting deficiencies and ensure that all national and OPM guidelines were met prior to submitting to the adjudicating agency. The investigative reviews of Reports of Investigation (ROI) and other investigative material on completed background investigations by (b) (7)(C), (b) (7)(F) were utilized and relied upon by the agencies requesting the background investigations to determine whether the subjects were suitable for positions having access to classified information, for positions impacting national security, or for receiving or retaining security clearances.

PROGRAM OVERVIEW

The responsibility of the OPM, Office of the Inspector General (OIG) is to prevent, detect, and investigate fraud, waste and abuse within programs operated and administered by OPM, including FIS background investigations.

FIS, formerly known as the Center for Federal Investigative Services or the Federal Investigative Services Division, through its workforce of approximately 7,300 investigators, is responsible for conducting background investigations for numerous federal agencies and their contractors, on

individuals either employed by or seeking employment with those agencies or contractors. In the 2010 fiscal year, FIS processed approximately 2 million investigations.

In conducting background investigations, the investigators conduct interviews of individuals who have information about the person who is the subject of the review. In addition, the investigators seek out, obtain, and review documentary evidence, such as employment records, to verify and corroborate information provided by either the subject of the background investigation or by persons interviewed during the investigation. After conducting interviews and obtaining documentary evidence, the investigators prepare a ROI containing the results of the interviews and document reviews, and electronically submit the material to OPM in Washington, D.C. Case analysts are responsible for reviewing the investigators' completed background investigations to identify any reporting deficiencies and ensure compliance with all national and OPM guidelines. OPM then provides a copy of the investigative file to the requesting agency, which uses the information to determine an individual's eligibility/suitability for employment or a security clearance.

BASIS OF INVESTIGATION

In or about April 2012, the OPM/OIG received a referral from the FIS, Integrity Assurance Group (IA), relating to allegations that [redacted], assigned to the FIS field office location in Boyers, Pennsylvania (Butler County), regularly submitted fraudulent time and attendance (T&A) biweekly reports during a two year period, which resulted in receiving financial compensation for *"overtime"* and *"compensatory"* hours not actually worked. Subsequent to receipt of this information, a complaint was initiated and the investigation was assigned to Special Agent [redacted].

STATUTES VIOLATED

Title 18 U.S.C. §1001	Making a False Statement
Title 18 U.S.C. §641	Theft of Public Money, Property or Records

CASE SUMMARY

In February, 2012, OPM/FIS Integrity Assurance (IA) Investigators interviewed [redacted]'s supervisor [redacted], OPM/FIS, Boyers, PA, in response to notification from [redacted] regarding [redacted]'s production statistics and T&A discrepancies. According to [redacted], he noticed discrepancies with the number of closed cases [redacted] claimed to have closed on her weekly *"production sheets"* when compared to the number of closed cases within OPM's Personnel Investigations Processing System (PIPS), from the start of fiscal year October 2011 to February 2012. [redacted]'s review confirmed [redacted]'s

production sheets claimed an excess of 200 more ROI case closings than what was actually recorded in PIPS. PIPS is the official database and tracking system used by OPM/FIS to record and monitor an individual employee's work product, statistics, productivity, and other activities associated with their daily work assignments. These initial findings prompted [redacted] to notify the FIS/IA group and initiate an inquiry.

On March 9, 2012, FIS/IA investigators interviewed [redacted] to question her regarding discrepancies between her PIPS Activity Reports and the corresponding T&A reports and production sheets submitted by [redacted] since January 2012. [redacted] denied falsifying employee production sheets and T&A reports and attributed any discrepancies to unintentional errors when inputting the corresponding records into the PIPS system. [redacted] signed a sworn affidavit at the conclusion of the interview.

On March 29, 2012, FIS/IA investigators conducted a follow-up interview with [redacted] admitted to providing a false statement to the FIS/IA investigators during the March 9, 2012 interview and admitted she regularly overstated hours worked on her T&A reports since March 2010 and has only worked on average 30 hours per week. [redacted] also admitted that all overtime hours worked since March 2010 to the present were fraudulently reported and as a result she received financial compensation for hours not actually worked.

[redacted] admitted falsifying her T&A due to financial restrictions and her needing to buy food items for her family. [redacted] stated she never worked a complete 8 hour workday during the 2 year period and she regularly worked 6 hour workdays. [redacted] further admitted she used the additional time to run family errands and pick up her child from the local aftercare facility. [redacted]'s detailed admission is recorded in a signed sworn Affidavit.

According to [redacted]'s admission, she admitted she was falsely compensated for overtime hours worked in excess of 700 hours of overtime and that she received overtime pay and compensatory time earned in excess of $39,000.

On or about April 20, 2012, FIS IA notified the OPM/OIG of the allegations concerning [redacted], specifically that she received monetary compensation for overtime hours not actually worked and falsified the number of ROIs she reviewed on a weekly basis. (b) (7)(C), (b) (7)(F) [redacted]. Quality & Integrity Assurance, FIS (Q&IA) advised that substantial information existed to corroborate and confirm the allegations against [redacted] and that their review of evidentiary documents was ongoing.

On May 1, 2012, at a Security Clearance Revocation Hearing, [redacted] recanted the admissions concerning T&A fraud that she had previously made to FIS/IA investigators.

On July 19, 2012, Special Agent (b) (7)(C), (b) (7)(F), accompanied by (b) (7)(C), (b) (7)(F) [redacted], Q&IA, met with Assistant U.S. Attorney (AUSA) (b) (7)(C), (b) (7)(F) of the Fraud

Division, U.S. Attorney's Office -Western District of Pennsylvania (Pittsburg). AUSA [redacted] agreed to review all evidentiary documents associated with the allegations and further consider the case for criminal prosecution.

On February 28, 2013, AUSA [redacted] explained that although [redacted] previously admitted to FIS/IA investigators that, from spring 2010 to February 2012, she did not work stated overtime and normally worked less than an 8 hour workday which allowed her to earn fraudulent income in excess of $39,000; his office was only able to confirm through the documentary evidence a potential loss to the Government in the range of approximately $3,000, over a 3 to 4 month period, from late November 2011 – March 2012.

AUSA [redacted] further explained their assessment was based on identifying supporting evidence that was able to stand alone and prove [redacted]'s T&A fabrication without the written statement of admission she provided to FIS/IA investigators on March 29, 2012. Therefore, as a result of conducting a thorough review of the investigation and supporting evidence, AUSA [redacted] declined to further consider the matter for criminal prosecution.

As a result of obtaining a criminal declination from the Department of Justice, (b) (7)(C), (b) (7)(F) [redacted], Q&IA, agreed to continue with pursuing administrative disciplinary actions against [redacted].

CONCLUSION/DISPOSITION

On December 17, 2012, the recommending official, (b) (7)(C), (b) (7)(F) [redacted], Supervisory Investigations Case Analyst, FIS, submitted a "*Proposed Removal*" memorandum for the removal of [redacted] from her position as an Investigations Case Analyst. This action was proposed under the procedures in 5 U.S.C. Section 7513 and 5 C.F.R. Part 752, in order to promote the efficiency of the service. The *Proposed Removal* was based on [redacted]'s ***"Failure to Work Reported Hours and Lack of Candor."***

On March 30, 2013, [redacted] submitted a written complaint via email to OPM Director John Berry alleging that the FIS-IA investigators who interviewed her on March 29, 2012 coerced and intimidated her into signing the Affidavit in which she admitted to T&A fraud. That allegation was investigated separately by the OIG, reference case number C-13-00524.

On August 1, 2013, the deciding official, (b) (7)(C), (b) (7)(F) [redacted], Investigations Quality Review, FIS, submitted the final *Removal Decision* memorandum to [redacted] and her attorney. (b) (7)(C), (b) (7)(F) decided to remove [redacted] primarily due to her Failure to Work Reported Hours and Lack of Candor. (b) (7)(C), (b) (7)(F)'s penalty determination took into consideration the relevant factors set forth in *Douglas v. Veterans Administration*, 5 M.S.P.R. 280 (1981) (the *Douglas* factors) and determined that removal was the appropriate penalty.

SUBJECT OF INVESTIGATION

Name: (b) (7)(C), (b) (7)(F)
DOB:
SSN:
FBI:

(b) (7)(C)

Signed: _____
Special Agent (b) (7)(C), (b) (7)(F)
Special Investigations

Signed: _____
Michelle B. Schmitz, AIGI

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT
Washington, DC 20415

Office of the
Inspector General

May 30, 2013

MEMORANDUM FOR ELAINE KAPLAN
Acting Director

FROM: PATRICK E. McFARLAND
Inspector General

SUBJECT: Management Advisory, Anonymous Complaint Regarding Interference with the Qualitifications Review Board Process

On or about October 17, 2012, the U.S. Office of Personnel Management (OPM), Office of the Inspector General's (OIG) Fraud Hotline received an anonymous complaint alleging that Daniel Ashe, Director, U.S. Fish and Wildlife Service (FWS), Department of the Interior (DOI) contacted former OPM Director John Berry regarding a Senior Executive Service (SES) Qualifications Review Board (QRB) panel. Reference OIG case number I-13-00079. The anonymous complainant further alleged that SES candidate (b) (7)(C), (b) (7)(F) was not certified by the QRB, and Mr. Ashe attempted to ensure through former Director Berry that (b) (7)(C), (b) (7)(F) be certified on a subsequent QRB panel review. According to the anonymous complainant, former Director Berry intervened by asking his staff to ensure the candidate was certified on the second review.

If true, the alleged actions would have been a violation of *Merit System Principles, Title 5 USC §2301(a)(1)(b)(1) and (2)* which requires that recruitment "should be determined solely on the basis of relative ability, knowledge and skills, after fair and open competition which assures that all receive equal opportunity." A violation of the Merit System Principles by the former Director Berry or any member of his staff would further constitute a violation of the *Standards of Ethical Conduct, Title 5, Code of Federal Regulations, Part 2635, Subpart I.*

These anonymous allegations were not substantiated. Our investigation confirmed that Mr. Ashe contacted former Director Berry regarding (b) (7)(C), (b) (7)(F) However, this contact did not influence or undermine the QRB process. Former Director Berry did not ask OPM staff to ensure that (b) (7)(C), (b) (7)(F) was certified by the QRB panel.

CASE SUMMARY:

On November 2, 2012, we interviewed Stephen T. Shih, Esquire, Deputy Associate Director, Executive Resources & Employee Development office, OPM. According to Mr. Shih, Angela Bailey, Deputy Associate Director, Recruitment & Hiring office, OPM, informed him that Mr. Ashe contacted former Director Berry regarding the QRB panel's non-certification of

(b) (7)(C), (b) (7)(F). However, Mr. Shih advised his office was never instructed by former Director Berry, any member of his staff, or Ms. Bailey, to ensure the QRB panel certify (b) (7)(C), (b) (7)(F)'s SES application if/when it was resubmitted by DOI.

Mr. Shih stated his office is guided under the authority of the *Merit System Principles* and their process is completely independent of influence from the Director of OPM or any other entities in the Federal Government. Mr. Shih explained that a QRB panel consists of three SES members assigned to review SES candidate packages. If an individual candidate's package is not certified during the initial review, it is a requirement that the same panel review the candidate's package upon resubmission. (b) (7)(C), (b) (7)(F), the Lead Human Resources Specialist for OPM's Senior Executive Resource Services office, is responsible for selecting and scheduling the QRB panel. Mr. Shih further stated the members of QRB panels remain anonymous to outside entities, to include the OPM Office of the Director, and the only individuals with knowledge of the QRB panel members' identities are he and his immediate staff.

Mr. Shih advised that throughout the QRB panel review process, his office only communicates with the designated department's headquarters element (Human Capital Office), and not the agency heads within the respective departments. Mr. Shih explained that Mr. Ashe is required to communicate all matters concerning an SES applicant's QRB process through the designated headquarters authority at DOI, who in this case is Pamela Malam, the Deputy Assistant Secretary for Human Capital and Diversity. Ms. Malam's office is responsible for coordinating with OPM on all QRB submissions, and receives feedback and communication on rejected candidates' deficiencies from Mr. Shih's office.

Mr. Shih explained that it is apparent Mr. Ashe did not follow procedure when he contacted former Director Berry directly. Through hearsay, Mr. Shih understands that Mr. Ashe did not have a good working relationship with his agency's Chief Human Capital Office and failed to effectively communicate his concerns with them. Mr. Shih admitted it is not uncommon for an agency head to contact him directly or the OPM Office of the Director to inquire or complain about the QRB panel's disapproval of an individual candidate. In these instances, it is the responsibility of OPM officials to educate and thoroughly explain the QRB process, then promptly direct the respective agency heads to contact their individual agency's Chief Human Capital Office for further technical support and/or guidance.

On November 5, 2012, we interviewed (b) (7)(C), (b) (7)(F), Lead Human Resources Specialist for Senior Executive Resource Services office, OPM. (b) (7)(C), (b) (7)(F) stated around October 2012, she was made aware that Mr. Ashe sent an email to former Director Berry about his concerns that (b) (7)(C), (b) (7)(F)'s initial submission was not certified by the QRB panel in late July 2012. (b) (7)(C), (b) (7)(F) stated she is almost certain that former Director Berry did not in any way communicate promises or assure Mr. Ashe that (b) (7)(C), (b) (7)(F) would be certified on her second attempt. (b) (7)(C), (b) (7)(F) is also of the opinion that former Director Berry would have either personally communicated or advised someone on his staff to inform Mr. Ashe to contact his agency's Chief Human Capital Office for further guidance and technical support.

(b) (7)(C), (b) (7)(F) explained that she works for Mr. Shih and is responsible for selecting the three member QRB panels who review SES candidate application packages. The identities of SES members selected to the panel are not disclosed per the Code of Federal Regulations. (b) (7)(C), (b) (7)(F)'s office is responsible for reporting the QRB panel's decisions back to the applicant's agency Chief Human Capital Office. (b) (7)(C), (b) (7)(F)'s primary points of contact at DOI are (b) (7)(C), (b) (7)(F) and (b) (7)(C), (b) (7)(F), both Human Resource Specialists in the Executive Resources Division of the DOI Office of Human Capital.

While explaining the QRB process, (b) (7)(C), (b) (7)(F) stated that, to ensure there is no appearance of undue influence or conflicts of interest, active senior executives employed with OPM are not required to volunteer and participate on QRB panels.

(b) (7)(C), (b) (7)(F) stated the QRB panel reviewed and decided not to certify (b) (7)(C), (b) (7)(F)'s application package on or about July 24, 2012. Once the non-certification decision was made by the panel, a response report was forwarded to (b) (7)(C), (b) (7)(F) at DOI. DOI was solely responsible for reporting the findings back to the candidate ((b) (7)(C), (b) (7)(F)) and the hiring agency official (Mr. Ashe). According to (b) (7)(C), (b) (7)(F), (b) (7)(C), (b) (7)(F) and DOI were required to respond to the deficiencies outlined in the report's findings within two months and resubmit an application package with the recommended corrections.

As of November 5, 2012 (b) (7)(C), (b) (7)(F) has not received the second submission from DOI for (b) (7)(C), (b) (7)(F). According to (b) (7)(C), (b) (7)(F), (b) (7)(C), (b) (7)(F) was applying for the SES position of Assistant Director for Science Application, job announcement (b) (7)(C), (b) (7)(F). The announcement was originally posted on USAJobs from (b) (7)(C), (b) (7)(F)

On November 19, 2012, we interviewed Pamela R. Malam, Deputy Assistant Secretary – Human Capital & Diversity, DOI. According to Ms. Malam, (b) (7)(C), (b) (7)(F)'s SES application package was initially submitted directly to OPM through Mr. Ashe's office, without receiving the appropriate level of feedback and guidance from her office. Ms. Malam suggested that the lack of guidance, oversight, and support more than likely led to the initial non-certification by the QRB panel. Ms. Malam further advised the actions of the FWS were out of the ordinary. Normally the various agencies within DOI comply with the SES adjudicative process by submitting the applicant packages to her office to receive policy guidance and assistance prior to their submission to the QRB.

Ms. Malam said she was stunned when she learned that Mr. Ashe contacted former Director Berry directly in October 2012, to voice his concern that (b) (7)(C), (b) (7)(F) was not certified by the QRB panel, and to express his views of why he believed (b) (7)(C), (b) (7)(F) should receive a favorable adjudication. Ms. Malam advised that although she is not certain what intentions Mr. Ashe had when contacting former Director Berry, she is of the opinion that Mr. Ashe's communication with former Director Berry was highly inappropriate.

Ms. Malam advised she informed her manager, Rhea Suh, DOI's Chief Financial Officer and the Assistant Secretary for Policy, Management & Budget, of Mr. Ashe's contact with former Director Berry regarding (b) (7)(C), (b) (7)(F). Subsequently, Ms. Suh met with Mr. Ashe, at which time he said he did not intend to influence the adjudicative process when he contacted former Director Berry.

Ms. Malam stated former Director Berry previously worked at DOI and she has known him for a number of years. Ms. Malam acknowledged that Mr. Ashe is also a former colleague of former Director Berry, and worked with him when he was at DOI. Ms. Malam opined that it is more than likely that Director Berry was helpful when speaking to Mr. Ashe and only provided him with policy and regulatory guidance.

Ms. Malam explained her office has been in close communication with Mr. Shih, and FWS is in the process of resubmitting (b) (7)(C), (b) (7)(F)'s packet to OPM. Ms. Malam advised that (b) (7)(C), (b) (7)(F)'s business acumen competencies, one of the Executive Core Qualifications for Executive Performance, were weak and needed further development. Therefore, under guidance from Ms. Malam, Mr. Ashe agreed to resubmit (b) (7)(C), (b) (7)(F)'s application package with additional recommendations, to include a sponsor letter from Mr. Ashe to Mr. Shih, an Executive/Individual Development Plan, and a recommendation for a "Criterion C" approval.

Ms. Malam voluntarily provided email correspondence forwarded to her from Mr. Shih on October 25, 2012. The emails confirm that Mr. Ashe communicated with former Director Berry regarding (b) (7)(C), (b) (7)(F) and sought his assistance.

Mr. Ashe's email to former Director Berry; sent on Thursday, October 25, 2012 @ 10:41 am
Subject: (b) (7)(C), (b) (7)(F)

> *"John, just spoke to [redacted] I underestimated quite a bit. She has 14 employees: 5 are GS-15's Nearly $40m annual science budget and our plan is to grow that at least two-fold over the next 3 years. She manages several national-level leadership teams, including a FWS Science Council that has over 15 members.*
>
> *It's much more than a Senior Leader position. As I mentioned, it was SES when I held the position. When we went to advertise after I left it, the Dept. said they didn't have the SES ceiling, so we agreed to make it an SL, with the caveat that we would convert it back to SES when a slot was available.*
>
> [redacted] *actually doesn't care, but she is part of an overall leadership team made up of SESers and she should be their equal. It seems fundamentally unfair to me that when white-guy Dan Ashe was in the job, it merited SES status, but now it doesn't, even though her responsibilities are much more significant. She is bringing so much to this organization, and to our effort to recruit a workforce for the future. I need to keep her, and need help in doing that.*
>
> *Thanks for all your doing to help*
>
> *Dan."*

Former Director Berry's response to Mr. Ashe, October 25, 2012, 10:49:03 AM EDT:

> *"I will do everything that I can to help within the obvious bounds of regulation and law Angie and Michael, please note the new information."*
>
> *[Angie is Angela Bailey, Associate Director for Employee Services & Chief Human Capital Officer; and Michael is Michael Grant, Senior Advisor to the Director]*

In the course of our investigation we interviewed Angela Bailey on November 26, 2012. Ms. Bailey stated sometime in October 2012, former Director Berry informed her that Mr. Ashe had contacted him, via electronic mail and/or phone, to inquire about (b) (7)(C), (b) (7)(F)'s application status after she was not certified by the QRB panel. According to Ms. Bailey, former Director Berry asked Ms. Bailey and Michael Grant, Senior Advisor to the OPM Director, to follow-up with Mr. Shih and ensure the overall QRB process was administered correctly, objectively, and above-board. Subsequently, Ms. Bailey contacted Mr. Shih and discussed the matter with him.

According to Ms. Bailey, Mr. Shih then contacted Ms. Malam at DOI to inquire why Mr. Ashe contacted former Director Berry directly, instead of vetting his concerns and inquiries through Ms. Malam's office. Ms. Bailey later learned from Mr. Shih that Mr. Ashe initially skipped the DOI process and did not vet (b) (7)(C), (b) (7)(F)'s SES applicant package through DOI's Chief Human Capital Office prior to submitting it to the QRB panel. Ms. Bailey further explained that the normal course of action is for the submitting agency to work closely with the agency's Chief Human Capital Office and receive guidance prior to submitting the SES applicant package to OPM.

Ms. Bailey explained that it is not uncommon to periodically receive inquiries from an agency head if one of their SES applicants does not successfully pass the QRB on their first attempt. Ms. Bailey opined that Mr. Ashe's actions were not nefarious in any way and he did not intend to pressure or influence former Director Berry.

On December 17, 2012, we interviewed former Director Berry. He stated he initially spoke to Mr. Ashe on October 16, 2012, after receiving an email from him regarding (b) (7)(C), (b) (7)(F). The same evening, former Director Berry had another phone conversation with Mr. Ashe to further discuss the matter. Former Director Berry recalled that Mr. Ashe explained (b) (7)(C), (b) (7)(F) was well qualified for an SES position. According to former Director Berry, he responded to Mr. Ashe's inquiry and comments by thoroughly explaining the QRB process. In addition, former Director Berry informed Mr. Ashe there was a two-strike rule with the QRB process, and if (b) (7)(C), (b) (7)(F) did not qualify on her second attempt she would be not be eligible to reapply for one year.

Former Director Berry also explained to Mr. Ashe how OPM professionals are able to assist and provide further guidance and advice when the respective Human Resource teams effectively communicate with each other.

Former Director Berry voluntarily provided the copies of the emails he exchanged with Mr. Ashe and with OPM executive staff from October 16 – 25, 2012, regarding Mr. Ashe's inquiry.

Former Director Berry's email communication with Mr. Ashe on October 25, 2012:

> *"I will do everything that I can to help within the obvious bounds of regulation and law. Angie and Michael, please note the new information."*

Mr. Ashe's email response to former Director Berry on October 25, 2012:

> *"I know you way too well to think you would even get close to stepping out-of-the-bounds of law or regulations. Do what is possible. If that's not enough, then we'll move on."*

Former Director Berry stated he referred Mr. Ashe's inquiry to Angela Bailey, Michael Grant, and Stephen Shih to handle appropriately. Former Director Berry further stated he never intervened with the QRB process and he does not communicate with the QRB panelists or ever know who they are.

Former Director Berry stated that after responding to an email sent by Mr. Ashe on October 25, 2012, he has not heard anything further about the status of (b) (7)(C), (b) (7)(F).

On January 24, 2013, we interviewed Daniel Ashe with the assistance of Special Agent (b) (7)(C), (b) (7)(F) of the DOI OIG. Mr. Ashe signed a DOI OIG Garrity Warning form, *"Warnings and Assurances for Voluntary Interview"* and agreed to provide a statement and answer questions related to the investigation.

Mr. Ashe stated he selected (b) (7)(C), (b) (7)(F) for the SES position in the spring of 2012 and her SES application package was submitted to the QRB in the summer of 2012. According to Mr. Ashe, he soon learned (b) (7)(C), (b) (7)(F)'s application package was not certified. In response to the notification, Mr. Ashe contacted former Director Berry in October 2012, with concerns and questions about the QRB disapproval. Mr. Ashe said he requested advice on how to proceed and what to do to work with the QRB in preparing for the resubmission of (b) (7)(C), (b) (7)(F)'s application package.

According to Mr. Ashe, former Director Berry made it very clear that the QRB process was independent and he had no influence over the process. Mr. Ashe stated former Director Berry agreed to assist Mr. Ashe by sending him through the appropriate channels and referring him to the experts at OPM, who were able to assist and advise him on how to prepare the application and address his concerns prior to resubmission to the QRB.

Mr. Ashe advised that after his discussion with former Director Berry he and his staff communicated and worked closely with senior DOI Human Resources officials to prepare (b) (7)(C), (b) (7)(F)'s application package. Mr. Ashe advised he primarily communicated with DOI's Rhea Suh; Pamela Malam.; and Denise Sheehan, Assistant Director for Budget, Planning and Human Capital and the Chief Human Capital Officer for the FWS. In addition, Mr. Ashe stated his agency also hired an independent contractor to assist them with (b) (7)(C), (b) (7)(F)'s application package.

Mr. Ashe adamantly denied he ever attempted to use his 20-year professional relationship with former Director Berry to improperly influence the SES process on behalf of (b) (7)(C), (b) (7)(F). Mr. Ashe advised he first met and worked with former Director Berry when they worked on Capitol Hill and former Director Berry worked for Steny Hoyer, the U.S. Representative for

Maryland's 5th Congressional district. According to Mr. Ashe, they were later colleagues at DOI when Mr. Ashe was the Chief of the National Wildlife Refuge and former Director Berry was the Assistant Secretary for Policy, Management, and Budget.

Mr. Ashe advised his relationship with former Director Berry is primarily professional and they never socialized outside work, but, he considered former Director Berry a friend.

Mr. Ashe stated he was contacted by Ms. Suh in January 2013, and she informed him that (b) (7)(C), (b) (7)(F) s revised SES application package was again not certified by the QRB.

If you have any questions please do not hesitate to contact me, at 606-1200, or someone from your staff may contact Deputy Assistant Inspector General for Investigations Kimberly A. Howell, at (b) (7)(C), (b) (7)(F), or Special Agent (b) (7)(C), (b) (7)(F), at (b) (7)(C), (b) (7)(F)

OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

REPORT OF INVESTIGATION

September 30, 2014

CASE NUMBER: I-13-00757

CASE NAME: (b) (7)(D) [redacted]

CASE AGENT: Special Agent (b) (7)(C), (b) (7)(F) [redacted]

INTRODUCTION

The following information relates to allegations of contract fraud involving both current and noncurrent contracts, between (b) (7)(D) [redacted], and the U.S. Office of Personnel Management (OPM). In (b) (7)(D) [redacted], Confidential Source (b) (7)(D) [redacted] filed a formal complaint with the OPM Office of the Inspector General (OIG) (b) (7)(D) [redacted]. Also, the complainant alleged that (b) (7)(D) [redacted]

(b) (7)(D) [redacted]

PROGRAM OVERVIEW

The responsibility of the OPM-OIG is to prevent, detect, and investigate fraud, waste and abuse within programs operated and administered by OPM, including Facilities, Security, and Contracting (FSC).

The OPM's core mission is to recruit, retain, and honor a world-class workforce and FSC manages a broad array of OPM's key day-to-day operational programs in support of its core

mission, to include Contracting Management. Contracting Management provides centralized contract management to support OPM's operations and government-wide mission. Contracting Management is subject to abide by OPM Contracting Policy, and the Federal Acquisition Regulations (FAR) like all other executive agencies.

(b) (7)(D) [redacted]

BASIS OF INVESTIGATION

(b) (7)(D) [redacted]. As a result of (b) (7)(D) complaints made to the Hotline the allegations were consolidated and the investigation was assigned to Special Investigations.

STATUTES VIOLATED

(b) (7)(D) [redacted]

[redacted]

[redacted]

CASE SUMMARY

(b) (7)(D) [redacted]

(b) (7)(D)

[redacted]

(b) (7)(D)

[redacted]

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(b) (7)(D) [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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(b) (7)(D) [redacted]

(b) (7)(D) [redacted]

(b) (7)(D) [redacted]

The below referenced is a summarized chronology of the contract information provided by (b) (7)(C) (b) (7)(F) [redacted] on (b) (7)(D) [redacted]

CHRONOLOGY OF COMMITMENTS

(b) (7)(D) [redacted]

CONCLUSION/DISPOSITION

Allegation #1 – (b) (7)(D) [redacted]

(b) (7)(D) [redacted]

As a result of the thorough investigative inquiry and review of (b) (7)(D) [redacted], no information was uncovered during the course of the investigation to corroborate the allegations of False Claims and/or the Ratification of Unauthorized Commitments violation(s), therefore the allegations were found to be unsubstantiated.

Allegation #2 – (b) (7)(D) [redacted]

In the course of conducting our investigation, we confirmed that post-issuance of the Management Advisory Report in (b) (7)(D) [redacted] at the (b) (7)(D) [redacted]

As background, prior to the implementation of SUNFLOWER operating as OPM's asset management tool, OPM utilized a paper-based system to maintain its property logs, and over the past few years, several items, to include (b) (7)(D) [redacted] were deemed unaccounted for as a result of an antiquated inventory management process. In addition, items issued, returned, or exchanged were not dynamically updated, most significantly when items were passed between TRB and FIS.

(b) (7)(E) [redacted]

(b) (7)(E)

Allegation #3 - (b) (7)(D):

(b) (7)(D)

Signed: (b) (7)(C), (b) (7)(F)

Special Agent (b) (7)(C), (b) (7)(F)
Special Investigations

Signed: (b) (7)(C), (b) (7)(F)

(b) (7)(C), (b) (7)(F)