

**UNITED STATES OF AMERICA
MERIT SYSTEMS PROTECTION BOARD**

No.

SPECIAL COUNSEL, Petitioner

v.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. PUBLIC HEALTH
SERVICE, Respondent.**

REQUEST FOR STAY OF PERSONNEL ACTION

I. INTRODUCTION

Pursuant to 5 U.S.C. § 1214(b)(1)(A), the U.S. Office of Special Counsel (OSC) requests that the Merit Systems Protection Board (Board) retroactively stay the 2010 annual performance evaluation given to Lieutenant Junior Grade (LTJG) Paul T. Hardy on December 23, 2010. This annual performance evaluation was given to Mr. Hardy by his Food and Drug Administration (FDA) non-Commissioned Corps supervisors, Donald J. St. Pierre (Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety) and Alberto Gutierrez (Director of this same office). The OSC seeks this stay because this negative and apparently retaliatory performance evaluation will result in his termination from the Public Health Service Commissioned Corps effective October 9, 2011.

Based upon the facts and arguments set forth below, OSC has reasonable grounds to believe that the annual negative performance evaluation given to Mr. Hardy was a prohibited personnel practice, a violation of the Whistleblower Protection Act. A stay of the annual

performance appraisal is appropriate to maintain the *status quo ante* while OSC completes its investigation and determine what further action is warranted.

II. STATEMENT OF FACTS

Paul T. Hardy is a LTJG (0-2) in the U.S. Public Health Service Corps (USPHSC). On or about April 2, 2007, Mr. Hardy was hired to work in the Food and Drug Administration (FDA) as a civilian Regulatory Review Officer. He became a member of the USPHSC on March 16, 2009, appointed under the authority of 42 U.S.C. § 209. Since January 2010 Mr. Hardy has been assigned to the FDA's Center for Devices and Radiological Health, Division of Radiological Devices, Office of In Vitro Diagnostic Device Evaluation and Safety.

Mr. Hardy's scientific expertise is in biomedical engineering. From July 2008 to October 2010, Mr. Hardy had been reporting his concerns about computer topography and other medical imaging devices approved by the FDA. More specifically, Mr. Hardy and other FDA scientists reported to FDA management officials (including Mr. St. Pierre, Mr. Gutierrez and others), members of Congress, and members of the press that the FDA was approving computer-aided diagnostic devices that do not work, that the approved breast and colon cancer screening devices are ineffective, and that they expose patients to high levels of radiation. For example, Mr. Hardy led a team of scientists that refused to recommend approval of the Carestream Health Inc. KODAK DirectView Computed Radiography Mammography ("Carestream DirectView"), a digital mammography device used to diagnose breast cancer.

In April 2010, FDA managers made a referral to the HHS Office of Inspector General alleging possible criminal misconduct by Mr. Hardy and others. The complaint alleged the release of unauthorized information to the press and Congress shortly after an article appeared in

the March 29, 2010, *New York Times* exposing the team's concerns with the FDA approval process for digital imaging equipment.

On August 18, 2010, Mr. St. Pierre informed Mr. Hardy via email that the issues with the approval of the Carestream DirectView had resulted in Mr. Pierre having concerns about Mr. Hardy's performance. Mr. Pierre further ordered Mr. Hardy to submit a completed approval package for the Carestream DirectView and to edit reports to ensure consistency.

In November 2010, HHS IG Special Agent Scott Vantrease wrote a letter to Center for Devices and Radiological Health management officials informing them that he was closing his criminal investigation of allegations that Mr. Hardy and others inappropriately released information by reporting to Congress and the media that they had concerns about the approval process for devices under reviewed by that office. In his letter, Mr. Vantrease indicated that his office would be taking no further action but he noted that Center for Device and Radiological Health officials told him that they had enough evidence to proceed against Mr. Hardy and others through their "administrative processes."

Notwithstanding Mr. Hardy's concerns about the Carestream DirectView, FDA managers approved the device in late December 2010 or early January 2011.

On December 23, 2010, Mr. Hardy was given a negative and allegedly defamatory annual performance evaluation. The overall rating was Marginal. The negative and allegedly false comments included the following: "The Officer has not demonstrated any strong qualities or superior skills;" "Needs most improvement in leadership, communication, professionalism, planning and judgment;" and his leadership was "unsatisfactory." All of Mr. Hardy's three previous performance evaluations (2007-2009) were either Fully Successful or Exceptional, and contained no such negative comments.

On January 5, 2011, Mr. Hardy was given a USOHSC Reviewing Officer Statement (ROS) that was also negative because it was based on the December 23, 2010, negative annual performance evaluation.

On May 5, 2011, Mr. Hardy was placed on "Non-Duty with Pay Status." He was forced to surrender his employee identification badge and was prohibited from entering any FDA/HHS facility.

On September 9, 2011, Mr. Hardy received a letter from Captain Gregory Stevens, USPHS, informing him that because the 2011 Engineer Annual Promotion Board (relying on the negative ROS) recommended against his promotion to 0-3, USPHSC directives require that officers with less than 20 years of service (like Mr. Hardy) be terminated from federal service.

III. LEGAL ANALYSIS

A. Standard For Requesting Stay of a Personnel Action

The Office of Special Counsel (OSC) may request the Board to stay any personnel action if it determines there are reasonable grounds to believe that a personnel action was taken as a result of a prohibited personnel practice. 5 U.S.C. § 1214(b)(1)(A)(i). Any stay granted under Section 1214(b)(1) shall be granted within three calendar days (excluding Saturdays, Sundays, and legal holidays) after the OSC's stay request. 5 U.S.C. § 1214(b)(1)(A)(iii). Unless this stay request is denied within the three-day period, it is considered granted by operation of law. 5 C.F.R. § 1201.136(a).

The Board has interpreted section 1214(b)(1)(A) to require it to grant a stay as long as OSC's claim is not clearly unreasonable based on the attendant facts and circumstances. Special Counsel, ex rel. Perfetto v. Dep't of Navy, 85 M.S.P.R. 454, 457 (2000). The Board shall grant a stay unless it finds that the OSC's determination does not fall within the "range of rationality."

In re Kass, 2 M.S.P.R. 79, 96 (1980). Because an initial stay is designed to provide the OSC with time to complete an investigation, it can be granted on the basis of relatively little information. Special Counsel v. Dep't of Transportation, 70 M.S.P.R. 578, 580 (1996). Moreover, the facts in the record must be viewed in the light that is most favorable to a finding that there are reasonable grounds to believe the personnel action is the result of a prohibited personnel practice. Id. Finally, the Board gives deference to the OSC's determination that it has "reasonable grounds to believe" that a prohibited personnel practice has occurred. In re Kass, at 96.

Based on the evidence gathered to date, a retroactive stay of the performance evaluation given to Mr. Hardy on December 23, 2010, by his FDA non-Commissioned Corps supervisors is appropriate because OSC has reasonable grounds to believe that Mr. Hardy's negative performance appraisal was a violation of 5 U.S.C. § 2302(b)(8) and will result in Mr. Hardy's termination from the Public Health Service Commission Corps effective October 9, 2011. The Board has granted retroactive stays where the facts support a reasonable grounds to believe that a personnel action taken in the past was the result of a prohibited personnel practice. Special Counsel v. Department of Veterans Affairs, 45 M.S.P.R. 403 (1990).

B. OSC Has Reasonable Grounds To Believe That Mr. Hardy Received a Negative Performance Appraisal Which Resulted in his Subsequent Termination Because He Made A Protected Disclosure.

It is a prohibited personnel practice for anyone with personnel action authority to take a personnel action against an employee because the employee made a protected disclosure. 5 U.S.C. § 2302(b)(8). To establish a *prima facie* violation of section 2302(b)(8), OSC must establish that: (1) the employee made a protected disclosure of information; (2) the official(s) who recommended or took the personnel action had actual or constructive knowledge of the

protected disclosures; (3) a personnel action was threatened or taken; and, (4) the protected disclosure was a contributing factor in the personnel action decision. See, e.g., Special Counsel, ex rel. Hopkins v. Department of Transportation, 90 M.S.P.R. 154, 156 (2001).

1. Employee

OSC has a reasonable basis to believe that Mr. Hardy was terminated from the USPHSC because of whistleblowing while performing a non-Commissioned Corps function and working under the supervision of civil service employees as defined in 5 U.S.C. § 2105. As explained below, Mr. Hardy is an employee as defined in 5 U.S.C. § 2105 and is entitled to protection under 5 U.S.C. § 2302 (b)(8). See Fishbein v. Department of Health and Human Services, 102 M.S.P.R. 4 (2006) (a special consultant appointed under 42 U.S.C. § 209(f) can be an “employee” under 5 U.S.C. § 2105); Usharauli v. Dept. of Health and Human Services, 116 M.S.P.R. 383 (2011) (a research fellow appointed to the National Institute of Health under 42 U.S.C. § 209(g) is covered under 5 U.S.C. § 2302(b)(8) as long as he or she meets the definition of an “employee” under 5 U.S.C. § 2105(a)).

In order to be classified as an employee pursuant to 5 U.S.C. § 2105, Mr. Hardy must have been (1) engaged in the performance of a federal function under the authority of law or an executive act; (2) under the supervision of a named federal official while engaged in the performance of the duties of his position; and (3) appointed by a named federal official acting in his official capacity. Ang v. Department of State (and Homeland Security), 103 M.S.P.R. 324 (2006).

Mr. Hardy was working in the FDA’s Center for Devices and Radiological Health, Division of Radiological Devices, Office of In Vitro Diagnostic Device Evaluation and Safety. The Center for Devices and Radiological Health is the organization component within the FDA

responsible for applying federal regulations to firms who manufacture, repack, relabel, and/or import medical devices sold in the United States. Specifically, the Office of In Vitro Diagnostic Device Evaluation and Safety protects public health by overseeing the regulation of in vitro diagnostic services. Accordingly, Mr. Hardy as a Regulatory Review Officer for this organizational unit of the FDA was engaged in the performance of a federal function under the authority of law or an executive act. Mr. Hardy's job responsibilities required that he evaluate and apply all applicable federal laws and executive acts to the products and devices he was tasked to review and ensure that these devices complied with applicable medical safety federal regulations.

Mr. Hardy was supervised by FDA civil service employees Donald J. St. Pierre and Alberto Gutierrez. Both Mr. St. Pierre and Mr. Gutierrez are federal officials and federal employees, and both were responsible for the supervision and oversight of Mr. Hardy's performance of duties of his position as a Regulatory Review Officer at the FDA.

Pursuant to Executive Order, the Secretary of HHS has been delegated the authority to hire USPHSC members. Accordingly, Mr. Hardy was appointed by a named federal official, the HHS Secretary, acting in his or her official capacity. Essentially, Mr. Hardy is being terminated from the USPHSC because of actions taken by FDA officials, and because of job functions he performed for the FDA. As such, Mr. Hardy is an employee as defined in 5 U.S.C. § 2105, and is thus entitled to protection under 5 U.S.C. § 2302 (b)(8).¹

¹ Mr. Hardy's situation is not unlike that of a National Guard Technician who is required to perform both military and civilian functions. In *Kostan v. Arizona National Guard*, 50 M.S.P.R. 182 (1991), the Board determined it had jurisdiction to review a personnel action taken against a national guard technician related to his civilian duties and responsibilities. Using this same analogy here the Board should find that Mr. Hardy is entitled to protection under the Whistleblower Protection Act because even though he is a member of the USPHSC, he was retaliated against by a non-Commissioned Corps supervisor for making disclosures related to his non-Commissioned Corps duties.

Moreover, the Whistleblower Protection Act (WPA) is remedial legislation, and the Board construes its provisions liberally to embrace all cases fairly within its scope, so as to effectuate the WPA. Fishbein v. Department of Health and Human Services, 102 M.S.P.R. 4, 8 (2006), citing Glover v. Department of the Army, 94 M.S.P.R. 534 (2003). By enacting the WPA, Congress intended to send a strong clear message to whistleblowers that Congress desires to protect them from retaliation related to their whistleblowing. Marano v. Department of Justice, 2 F.3d 1137, 1140 (Fed. Cir. 1993). The purpose of the WPA is to create an atmosphere within government agencies favorable to the disclosure and correction of improper or illegal acts especially when the improper acts are acts of management officials. Caddell v. Department of Justice, 96 F.3d 1367 (Fed.Cir. 1996). Accordingly, in this case, it is appropriate to afford Mr. Hardy whistleblower protection so as to favor the disclosure and correction of the improper acts by management officials of HHS/FDA.

2. Protected Disclosure

A protected disclosure is a disclosure that a disinterested observer would have a reasonable basis to believe evidenced, for instance, a substantial and specific danger to public health and safety. Acting Special Counsel ex rel. Finkle v. Department of Labor, 93 M.S.P.R. 409, 413-414 (2003) (Board granted an initial stay of 45 days of a personnel action where it was alleged that employee's geographic reassignment was because the employee made a disclosure that evidenced a substantial and specific danger to public health and safety when he reported that agency officials failed to test agency inspectors for exposure to beryllium which can cause a fatal lung ailment).

In this case, a disinterested observer would have a reasonable basis to believe that Mr. Hardy's disclosures evidenced a danger to public health and safety. For example, from 2008

through 2010, Mr. Hardy voiced concerns to senior FDA managers, members of Congress and media outlets that FDA managers were improperly approving and forcing subordinate FDA scientists and experts to approve dangerous and ineffective medical devices. Specifically, Mr. Hardy reported concerns that CT colonography machines, mammography computer-aided detection machines, spine analysis devices, and ultrasounds were initially designated as not cleared for use, and only received approval after FDA managers had pressured subordinate employees to circumvent standard protocol and change their initial findings.

As a result of these actions by HHS and FDA management officials, Mr. Hardy and others alleged that an inappropriately approved CT colonography machine could expose patients to an unwarranted risk of radiation exposure and lead to instances of solid organ and abdominal cancer. Mr. Hardy also disclosed that FDA managers pushed for approval of the Carestream DirectView, a machine that had substantial radiological imaging deficiencies that would not allow physicians to adequately and sufficiently distinguish malignant breast cancer from benign lesions.

Accordingly, because Mr. Hardy's disclosures concerned devices used to screen the general American population and because his disclosures raised issues related to exposing the general population to unwarranted radiation exposure and ineffective cancer screening devices, Mr. Hardy made a disclosure that a disinterested observer could reasonably believe evidenced a substantial and specific danger to public health and safety.

2. Knowledge

Knowledge may be established by demonstrating that the responsible official possessed actual or constructive knowledge of the disclosure. Actual knowledge may be shown directly or through circumstantial evidence. Bonggat v. Department of the Navy, 56 M.S.P.R. 402, 407

(1993). Constructive knowledge can be established by showing that an official with actual or constructive knowledge influenced the deciding official. McClellan v. Department of Defense, 53 M.S.P.R. 139, 147 (1994); Marchese v. Department of the Navy, 65 M.S.P.R. 104, 109 (1994).

In this case, Mr. Hardy's disclosures were well known as they appeared in reports to FDA management officials (including Mr. St. Pierre and others), members of Congress, and members of the press and media outlets such as the *New York Times*. Moreover, upon learning of Mr. Hardy's public disclosures, it appears that FDA officials initiated an investigation into Mr. Hardy's actions and accused him of releasing sensitive information. Furthermore, in Mr. Hardy's performance appraisal, FDA managers rated Mr. Hardy as "Marginal" and included in the narrative references Mr. Hardy's refusal to timely approve the Carestream DirectView that Mr. Hardy and others believed could not provide sufficient screening for breast cancer.

Finally, it was this 2010 annual performance appraisal that served as the basis for the negative ROS and subsequent September 9, 2011, termination letter signed by Captain Gregory Stevens. As such it also appears that Captain Stevens possessed, at minimum, a constructive knowledge of Mr. Hardy's disclosure. Russell v. Department of Justice, 76 M.S.P.R. 311 (1997) (found actual knowledge on part officials who influenced official making decision concerning a personnel action was sufficient to establish constructive knowledge on part of the deciding official).

3. Covered Personnel Action

A performance appraisal is a "covered" personnel action as defined in 5 U.S.C. § 2302(a)(2)(A)(v).

4. Contributing Factor

As the final element of the *prima facie* case, OSC must establish that Mr. Hardy's disclosures, i.e. whistleblowing, were a contributing factor in the agency's decision to issue Mr. Hardy a negative performance evaluation that resulted in his termination. Contributing factor means "any factor which, alone or in connection with other factors, tends to affect in any way the outcome of the decision." Marano v. Department of Justice, 2 F.3d 1137, 1140 (Fed.Cir. 1993).

In this case, OSC has evidence that FDA officials were angered by Mr. Hardy's disclosures and initiated an investigation into whether, in making his disclosures, Mr. Hardy inappropriately released agency information. When the Office of Investigations closed the matter in November 2010, it advised officials for the Center for Devices and Radiological Health that they could decide to pursue the matter through "administrative processes." Moreover, the negative performance appraisal that Mr. Hardy subsequently received cited lack of leadership in premarket areas and specifically cited the Carestream DirectView case as an example of Mr. Hardy's performance deficiencies. Clearly, and based on the above, OSC has a reasonable basis to believe that Mr. Hardy's protected disclosures were a contributing factor in the negative annual performance appraisal given to him by Mr. St. Pierre and Mr. Gutierrez on December 23, 2010.

IV. CONCLUSION

For the reasons set forth above, OSC has reasonable grounds to believe that FDA officials issued Mr. Hardy a "Marginal" performance appraisal in violation of 5 U.S.C. § 2302(b)(8). Thus, a stay of the negative performance evaluation, which resulted in Mr. Hardy's termination from the USPHSC, would be appropriate while OSC completes its investigation to

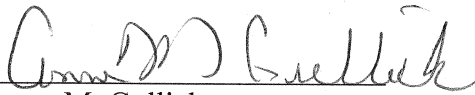
determine whether a prohibited personnel practice has occurred and whether further action is warranted. Because Mr. Hardy's discharge from the uniformed service was a foreseeable and proximate result of his performance evaluation, the Board should also stay that discharge in order to preserve the status quo until an investigation may be completed. Special Counsel v. Department of Transportation, 71 M.S.P. R. 661, 664-665 (1996).

WHEREFORE, for the reasons stated herein, OSC respectfully requests that the Board grant a stay of the performance evaluation given to Paul T. Hardy on December 23, 2010, by his FDA non-Commissioned Corps supervisors.

Respectfully submitted,

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Dallas, Texas
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