The American Red Cross Biomedical Services failed to promptly investigate, correct, and prevent the pervasive failure to control non-conforming and potentially non-conforming blood products. A review of records from twelve-four ARC Blood Service Regions for the period December 2006 through April 2008, revealed that ARC logged into SmartCAPA approximately 116 exception reports involving the distribution of blood products that ARC identified as non-conforming or potentially non-conforming, but had failed to prevent from being distributed. These problems resulted in retrieval of 218 non-conforming blood products. (This is not an all-inclusive number because ARC also logged problems into DTS during this period.)

For example:

- ARC logged into [redacted] approximately 29 exception reports involving donor suitability, such as health history or Blood Donation Record deviations that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately 43 of those blood products. The exception reports are: [redacted]

- ARC logged into [redacted] approximately six exception reports involving ABO/Rh discrepancies and one HLA discrepancy that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately 5 blood products. The exception reports are: [redacted]

- ARC logged into [redacted] approximately two exception reports involving whole blood number discrepancies that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately nine blood products. The exception reports are: [redacted]

- ARC logged into [redacted] approximately three exception reports involving potential air contamination during the blood collection process that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately 12 blood products. The exception reports are: [redacted]

- ARC logged into [redacted] approximately six exception reports involving incomplete or unreviewed Apheresis Procedure Records that were detected by ARC but the associated blood products were not controlled to prevent their distribution pending a determination regarding their suitability for transfusion. These problems resulted in retrieval of approximately nine blood products. The exception reports are: [redacted]
American Red Cross Biomedical Services failed to submit biological product deviations (BPDs) within 45 days as required in Paragraph X.D. of the April 15, 2003 Consent Decree of Permanent Injunction. The decree states in part that ARC must notify the FDA Baltimore District and report the identification of all known distributed units and the lot numbers, unit numbers, whole blood numbers, and expiration dates; the name and address of involved facilities, and a description of the event that caused the unsuitability to occur 45 days after initially learning that an unsuitable unit was distributed.

A review of American Red Cross Biomedical Services region exception reports, logged from December 21, 2005 through April 2008, revealed that ARC did not submit approximately 10 biological product deviation reports (BPDRs) to FDA within 45 days after initially learning that approximately 27 non-conforming blood products, as identified by ARC, were distributed. For example:

- ARC logged into [b] (4) approximately three exception reports involving donor suitability Blood Donation Record deviations that were ultimately detected by ARC after failing to gain control of the product prior to performing the 200% review. The following exception reports are:

  [b] (4) was discovered on 4/19/2007 and reported to FDA on 6/12/2007.
  [b] (4) was discovered on 7/22/2007 and reported to FDA on 11/9/2007.
  [b] (4) was discovered on 5/1/2007 and reported to FDA on 11/19/2007.

  These problems resulted in the retrieval of approximately 5 blood products.

- ARC logged into [b] (4) approximately one exception report involving the distribution of non-conforming blood products with unacceptable temperatures. Exception [b] (4) was discovered 9/19/2007 and was submitted to FDA as a BPDR on 3/11/2008.
The American Red Cross Biomedical Services failed to submit 48 hour consignee notifications as required in Paragraph X.E. of the April 11, 2003 Consent Decree of Permanent Injunction. The decree states in part that "Within 48 hours of initially learning that an unsuitable unit was distributed, ARC must notify consignees and the BLT-DO."

A review of American Red Cross Biomedical Services region exception reports, logged from December 2001 through April 2008, revealed that ARC did not submit approximately 20 consignee notifications to FDA within 48 hours of initially learning that approximately 61 non-conforming blood products, as identified by ARC, were distributed.

For Example:

- ARC logged into approximately five exception reports involving donor suitability Blood Donation Record deviations that were ultimately detected by ARC after failing to gain control of the product prior to performing the 200% review. The following exception reports are:

  - the exception report was discovered on 8/17/2007 and reported to FDA on 8/23/2007.
  - the exception report was discovered on 4/19/2007 and reported to FDA on 5/7/2007.
  - the exception report was discovered on 6/27/2006 and reported to FDA on 7/18/2007.
  - the exception report was discovered on 7/22/2007 and reported to FDA on 9/13/2007.
  - the exception report was discovered on 5/1/2007 and reported to FDA on 9/10/2007.

  These problems resulted in the retrieval of approximately 9 blood products.

- ARC logged into approximately one exception report involving the distribution of non-conforming blood products with unacceptable temperatures. Exception was discovered 9/19/2007 and was reported to FDA in a 48 hour notification on 10/4/2007.

  This problem resulted in the retrieval of approximately 14 blood products.

- ARC logged into approximately two exception reports involving ABO/Rh discrepancies related to blood products and blood product labeling. Exception was discovered on 5/23/2007 and the 48 hour notification was submitted to FDA on 6/22/2007. Exception was discovered on 11/8/2007 and the 48 hour notification was submitted to FDA on 11/12/2007.

  These problems resulted in the retrieval of approximately 3 blood products.