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January 6, 2012

Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Secretary Sebelius,

I have just received a 15-page Food and Drug Administration (FDA) document summarizing its September through October 2010 inspection of the national American Red Cross (ARC) Donor Client Support Center (DCSC) in Philadelphia, Pa., one of two such national centers at which blood donor management activities, previously done in ARC regional offices, have recently been centralized.

This in-depth, two-month inspection found hundreds of violations of the 2003 Consent Decree the ARC and the FDA had previously agreed upon, which outlines requirements for the ARC to ensure safety of the nation's blood supply and details specified penalties for each of a number of different violations. After evaluating the results of this inspection, the FDA, in conjunction with other officials in the Department of Health and Human Services (HHS), decided to impose financial penalties of almost $10 million on the ARC for violating the terms of the Consent Decree. Although the internal decision to impose this large monetary penalty was made almost three months ago, the penalty has never been assessed or publicly announced. I strongly urge you to take final action and impose this financial penalty.

The health impact of these findings is well summarized on the first page of the FDA 483 Inspection Report stating that:

> "ARC has failed to comply with Paragraph IV of the Amended Consent Decree of Permanent Injunction entered on April 15, 2003 (hereafter, referred to as the Decree), in that **ARC has failed to '… establish, implement and continuously maintain adequate methods, facilities, systems, and controls to ensure that ARC does not collect, manufacture, process, pack, hold, or distribute any article of drug … [including any article of blood, blood component, or other biological product] that is adulterated …; misbranded …; or otherwise in violation of the *FD&C Act*, the *PHS Act*, and regulations promulgated thereunder**, including but not limited to, 21 C.F.R. Parts 210-211 and Parts 600-680."[1] [emphasis added]

[1] Form 483 from FDA Inspection (9/2/10 - 10/29/10) of the American Red Cross Donor and Client Support Center, Philadelphia, PA. page 1, last paragraph.

Examples of some of the findings from this inspection (cited from the Form 483 Inspection Report) are listed below:

- "ARC management had concerns about the DCSC performance and that it continued to be understaffed and had a backlog of approximately 18,000 donor management cases that had not been process verified." (Form 483, page 2)

- The backlog in the Philadelphia office included "3,552 open cases (and 306 DRIRs [donor reactions/injury reports])," dating as far back as August 2009 for the open cases and as far back as July 2009 for the open DRIRs. (Form 483, page 3)

- "On 9/29/10, a review of 13 randomly selected DRIR case files opened in the DCSC in 1/10, 2/10, and 3/10, but not yet process verified, found six with no final quality review and six with no Medical Director review, as required." (Form 483, page 7)

- A section of the 483 inspection report, entitled *Significant Corrective Action Report (SCA) — **Health Department Notifications of Confirmed Positive Infectious Disease Markers***, includes the following*:*

  "This SCA [submitted to the FDA 7/22/10] **pertains to the notification to health departments when a donor has been determined to be confirmed positive for infectious disease markers, such as HIV, Hepatitis B, Hepatitis C, West Nile Virus and syphilis, as required in ARC's Directive [redacted]. ARC's failure to notify health departments was initially identified during an FDA inspection from 5/24/10 to 6/4/10."** [emphasis added]

  "… Because there was no formal corrective action plan developed for this SCA and there was no follow up or monitoring of this review performed at the DCSC, it was not until the status of the retrospective review was requested on 9/22/10 by the FDA [during its inspection] that it was discovered all health department notifications had not been made and **some health departments were not notified for months after confirmed positive disease markers [in donor blood] were received.**" (Form 483, pages 10 and 11) [emphasis added]

- Another section of this inspection report, entitled ***Management of the National Donor Deferral Registry (NDDR) and Problem Management Associated With the NDDR*** (a national list of all unsuitable blood donors), includes the following:

  "The Philadelphia DCSC has failed to follow ARC's Problem Management SOP's in that the **problems associated [with] the proper deferral of donors in the NDDR are not thoroughly investigated. For example … Problem Report [A] …: The problem description indicates that HIV confirmatory test results were received at the DCSC on 4/25/10 but a [redacted] assertion was not added to the donor record that place the donor in the NDDR when the next monthly [redacted] was going to be performed by the Philadelphia DCSC on 5/7/10 … A Level 3 investigation was performed but did not include a reason why it took 22 days from the date the DCSC received the test results on 4/25/10 to discover that the donor was not placed in the NDDR. … This problem has yet to be closed."** (Form 483, page 11) [emphasis added]

- Another section of this inspection report, entitled ***Health History Deferrals and Associated Problem Management Issues***, includes the following:

"[T]he DCSC informed FDA that it discovered that the DCSC failed … to conduct a review of each listed donor with prior donations for potentially unsuitable blood components requiring quarantine, retrieval and consignee's notification in accordance with [redacted] procedures. (Form 483, page 13)

- The last section in the inspection report is entitled ***Problem Management — Missed Timeframes*** and includes the following:

Query Activity	Number of Problems Found
"48-hour notification to consignee not performed, not complete and/or not timely for the distribution of unsuitable blood or blood products"	90

(Form 483, pages 14 and 15)

The authority to require this timely notification under the Consent Decree is found in Paragraph X.E (page 65 of the Consent Decree):

> **"48 Hour Consignee Notification and *Blood* and *Blood Component Retrieval*.** Within 48 hours after initially learning that an unit of *unsuitable blood or blood component* has been distributed, *ARC* shall, without waiting for FDA to request *retrieval*, notify consignees and FDA's Baltimore District Office and, when the *blood* or *blood components* have not been used, initiate retrieval of the *unsuitable blood* or *blood components* from the marketplace. For each *day* that *ARC* fails, within 48 hours of initially learning that an *unsuitable blood component* was distributed, to notify FDA's Baltimore District Office and consignees, FDA may, in addition to other penalties assessed under this Order, assess per diem penalties of up to $10,000."

In addition to this Missed Timeframe violation, there were also 193 violations listed as "Problem logged into [redacted] greater than five days after discovery."

In summary, among the serious findings during the FDA inspection was the overall failure to "ensure that ARC does not collect, manufacture, process, pack, hold, or distribute any article of drug … [including any article of blood, blood component, or other biological product] that is adulterated …; misbranded …; or otherwise in violation …"

Specific examples of this failure included:

- **18,000 backlogged donor management cases, including 3,552 open cases (and 306 DRIRs (donor reactions/injury reports)) in the Philadelphia office alone, dating as far back as August 2009 for the open cases and as far back as July 2009 for the open DRIRs.**

- **The ARC's failure to notify health departments when a donor has been determined to be confirmed positive for infectious disease markers, such as HIV, Hepatitis B, Hepatitis C, West Nile Virus, and syphilis, as required in ARC's Directive.**

- **Failure to promptly add to the NDDR (a list of all unsuitable blood donors) or thoroughly investigate problems associated with the deferral of donors. For example, HIV confirmatory test results on a donor were received at the DCSC on April 25, 2010, but a [redacted] assertion was**

not added to the donor record. It took 22 days from the date the DCSC received the test results on April 25, 2010, to discover that the donor was not placed in the NDDR.

- **The DCSC failed to conduct a review of each listed donor with prior donations for potentially unsuitable blood components requiring quarantine, retrieval, and consignee's notification, in accordance with [redacted] procedures.**

- **In 90 cases, the DCSC failed to notify those to whom blood had been consigned, promptly or completely or at all — within the required 48-hour time interval — concerning the distribution of unsuitable blood or blood products.**

- **In 193 instances, problems were logged into [redacted] greater than five days after discovery.**

In announcing the most recent previous FDA fine against the ARC ($16 million in June 2010), the FDA stated that it "is encouraged by recent efforts made by the Red Cross leadership and will work closely with them to achieve full compliance. The FDA is hopeful these fines will encourage the Red Cross to act more quickly to take the actions necessary to address and correct the issues that have contributed to these violations." The ARC response to this fine was to say that it was based on conditions that had already been corrected since the FDA inspections that caused the agency to impose the penalties.

As of last year, the total amount of fines against the ARC by the FDA since the 2003 Consent Decree was $37 million, but the substandard performance of critical ARC blood handling functions continues, as documented in the recent FDA inspection report.

The longer HHS delays in imposing the financial penalties mandated under the 2003 Consent Decree, the more opportunity it will afford the ARC to again claim, correctly or not, that things are much better now.

Sincerely,

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group