extensions received by FDA after the foregoing time limit need not be considered. FDA may grant the request in full, provide for a shorter extension than requested, or deny the request. In the event FDA denies the request in whole or in part, it shall explain its reasons in writing; in the event FDA denies any extension (except ones that have not been timely filed by *ARC*), *ARC* shall have 3 *days* following receipt of FDA's decision to either comply with the determination in the manner described in paragraph IX.A. or appeal the adverse determination to the Court.

F. With respect to all penalties assessed under this Order, the following limitations and principles shall apply:

1. **Annual Penalty Caps**. The total penalties that *ARC* may incur under this Order are capped as follows:

a. For conduct that occurs within the first year following the entry of this Order, *ARC* penalties shall not exceed 1 per cent of the gross annual revenues generated by *ARC's* Biomedical Services, which amount is currently reflected in *ARC*'s 2002 Annual Report in the Consolidated Statement of Activities as "Operating revenues and gains – Products and services: Biomedical."($1.924 billion))

b. For conduct that occurs within the second year following the entry of this Order, *ARC* penalties shall not exceed 2 per cent of the gross annual revenues generated by *ARC's* Biomedical Services;

c. For conduct that occurs within the third year following the entry of this Order, *ARC* penalties shall not exceed 3 per cent of the gross annual revenues generated by *ARC's* Biomedical Services; and

d. For conduct that occurs within the fourth year following the entry of this Order and for the duration of the Order, *ARC* penalties shall not exceed 4 per cent of the gross annual revenues generated by *ARC's* Biomedical Services.

e. The only funding source for financial penalties that FDA may seek under this Order shall be the gross annual operating revenues and gains generated by *ARC* Biomedical Products and Services, as defined in subparagraph (a).

2. **Statute of Limitations**. Except as provided in paragraph IX.F.5, FDA shall not assess any penalty under this paragraph (IX) for any violation(s) that occurred more than 270 days prior to the issuance by FDA investigators of a Form FDA-482 (Notice of Inspection) or more than 270 days prior to FDA's discovery of and written notification to *ARC* of such violation(s).

3. **Self-identification, Correction, and Documentation**. If *ARC* identifies a violation(s), corrects the violation(s) to FDA's satisfaction, and has contemporaneously documented that fact in writing with a document signed by an *ARC* employee with knowledge of the facts before FDA has issued an FDA-482 (Notice of Inspection) for the facility in which the violation has occurred, or has independently become aware of the violation(s), no penalty for such violation(s) shall be assessed by FDA. The documentation described in this subparagraph shall be retained by *ARC* at the relevant facility and available to *ARC Biomedical Headquarters* and shall be provided by *ARC* to FDA investigators upon their request. FDA shall consider this documentation when deciding whether to issue a notice of adverse determination or to assess a penalty under this Order. FDA shall not assess a penalty for any violation that has been properly identified, documented, and brought to FDA's attention in compliance with this subparagraph.

4. **One Event, One Penalty**. When the same factual "event" may be categorized as a violation of more than one regulation, FDA may not penalize *ARC* for violations of multiple regulations. When an event may be penalized under more than one provision of this Order (e.g., when the release of an unsuitable product was caused by *ARC's* violation of *CGMP*, *ARC* understands and agrees that it has waived the right to appeal, and will not seek judicial review of, the decision as to which provision (e.g., paragraph IV.B.17 or IX of this Order) FDA may use to calculate a penalty. Although the parties acknowledge that what constitutes an "event" for penalty purposes is not readily definable, the following principles apply: If a line employee commits a violation and an *ARC* supervisor fails to detect that violation, there are two events. Subsequent failures by *ARC* relating to the same initial violation(s) (e.g., failure to correct the violation after it had been detected by the line employee's supervisor) constitute additional events. If the same "events" occur at more than one facility, such occurrences are additional events.

5. All penalties assessed under this Order shall be based on the year in which the violative conduct occurred. The annual cap amounts described in paragraph IX.F.1 of this Order shall also be attributed solely to the year in which the violative conduct occurred. Accordingly, it is possible that *ARC* might be required to pay penalties in any particular year in an amount that appears to exceed the annual penalty cap for that year; however, as provided in the preceding sentences of this paragraph, such apparently excessive penalty assessments will in fact reflect violative conduct that has occurred during more than one year. The parties understand that the purpose of this subparagraph is to ensure that penalty assessments are based on *ARC* conduct rather than when FDA inspections were conducted or evaluated in relation to the end of an accounting year.

6. The parties agree that the *ARC* annual report for the immediately preceding year shall be the only source used to determine the amount of gross annual revenues generated by *ARC* Biomedical Services when calculating the annual cap amount described in paragraph IX.F.1 above. All payments assessed under this Order shall be paid by *ARC* no later than 30 days after *ARC* notifies FDA pursuant to subparagraph IX.A that it will not dispute the penalties assessed in FDA's adverse determination or, when applicable, no later than 30 days after a final Order by the district court.

7. All payments made pursuant to this Order shall be payable to the United States Treasury and shall be made by electronic transfer to the Treasury of the United States in accordance with instructions that will be provided by the Office of Consumer Litigation, Civil Division, United States Department of Justice, Suite 950 North, 1331 Pennsylvania Avenue, Washington, D.C. 20004. In addition, *ARC* shall, contemporaneous with the electronic transfer, provide written notification to the Director, Baltimore District, and the Office of the Associate Commissioner of Regulatory Affairs that such payment has been made.

X. DISTRIBUTION OF *UNSUITABLE BLOOD OR BLOOD COMPONENTS* BY *ARC*:

A. **Penalty Provision.** Except as provided in paragraph X.B of this Order, for each unit of *unsuitable blood or blood component* that *ARC* distributes after entry of this Order for which FDA determines that the release was preventable by *ARC*, FDA may assess a penalty, in the amounts set forth in subparagraphs 1 and 2 of this paragraph (X.A).

1. If FDA determines that there is a reasonable probability that the use of, or exposure to, the product may cause serious adverse health consequences or death, FDA may assess a penalty of up to $50,000 for each such unit of *blood* or *blood component*.

2. If FDA determines that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, FDA may assess a penalty of up to $5,000 for each such unit of *blood* or each such *blood component*. Notwithstanding the foregoing, FDA shall not assess ARC under this subparagraph (X.A.2) for the improper release of more than 100 units in any one event.

In addition, when considering whether to assess a penalty and the amount of penalty under this paragraph (X.A.2), FDA shall consider, among others, the following factors: (1) the potential effect of the event on the public health, e.g., the number and seriousness of exposures; (2) *ARC*'s trends with respect to the same or similar events involving the release of unsuitable products; and (3) the degree to which *ARC* contributed to the improper release of the *blood* or *blood components*. The parties understand and agree that because of the subjective and fact-dependent nature of these judgments, assessments for apparently similar situations may not appear comparable.

B. **Penalty Exceptions.** Notwithstanding paragraph X.A, *ARC* shall not be assessed any penalty if *ARC* demonstrates to FDA's satisfaction that neither the *unsuitability* of the *blood or blood component* nor the distribution of such *blood* or *blood component* was ARC's fault. These instances include the following:

1. The donor's *blood* or *blood component* was contaminated with bacteria and documentation exists establishing that *ARC* complied with *the law*, *ARC SOPs*, and this Order, and there is no evidence that the bacterial contamination was caused during collection, manufacture, processing, packing, storage, or distribution of the *blood* or *blood components*;

2. The manufacturer of *equipment* or supplies used to manufacture or test *blood* or a *blood component* has notified *ARC* of a defect in its *equipment* or supplies, thereby necessitating a *retrieval* of *blood* or *blood components* made or tested with the *equipment* or supplies, and *ARC* had no prior notice of the defective *equipment* or supplies and could not reasonably have been expected to detect the defect on its own through use or examination of the *equipment* or supplies prior to use;

3. Following a donation, *ARC* receives *post donation information* and *ARC* follows its *SOPs* and *CGMP* for handling *blood* and *blood components* associated with p*ost donation information*; and

4. *Blood* or *blood components* that were processed according to *CGMP* and *SOPs* must be retrieved because they are found to have been collected from a donor who subsequently tests positive for an infectious disease.

5. In addition, FDA recognizes that there may be some instances, not specified above, in which the release of unsuitable products will occur without any fault by *ARC*. If *ARC* demonstrates to FDA's satisfaction that the release of unsuitable products was not in any way attributable to *ARC's* failure to comply with *CGMP*, this Order, or *the law*, then *ARC* shall pay no penalty for products released under such circumstances.

C. **Additional Penalty for Re-Release of *Unsuitable* Returned *Blood Components.*** FDA may assess an additional penalty of up to $50,000 for each unit of *unsuitable blood or blood component* that was returned by a consignee and re-released for distribution by *ARC*, if *ARC* had the ability to determine that the *blood* or *blood component* was *unsuitable*, and failed to do so. *ARC* shall not be assessed the foregoing penalty if *ARC* demonstrates to FDA's satisfaction that

ARC took appropriate steps to bring *blood* and *blood components* into compliance with *the law, ARC SOPs*, and this Order.

D. **45 *Day* Notification to FDA.** For each day or fraction thereof, following the 45 *days* after *ARC* initially learns that a unit of *unsuitable blood or blood component* was distributed (or re-distributed), that *ARC* or one of its *regions* fails to notify FDA's Baltimore District Office in writing of such distribution, and to report the information described in subparagraphs 1 - 5 of this paragraph (X.D), FDA may, in addition to any other penalties assessed pursuant to this Order, assess a penalty of up to $10,000 for each such unit of *unsuitable blood or blood component*. This reporting requirement is in addition to the reporting requirement under 21 C.F.R. § 600.14. *ARC*'s 45 *day* written notification to FDA's Baltimore District Office shall, at a minimum, contain the following information:

1. Identification of all known units of *blood, blood components,* and *blood component* types involved in the distribution.

2. Identification of all known lot numbers, serial numbers, unit numbers, Whole Blood Numbers, and expiration dates for *blood* or *blood components* involved in the distribution.

3. The name and address of all facilities known to be involved in the manufacture and distribution of the *unsuitable blood or blood components*.

4. A complete and accurate description of the event causing the *unsuitable blood or blood component*, based on all information available at the time of notification.

5. The total volume of *unsuitable blood* and of each type of *unsuitable blood component* distributed, and the estimated amount of *unsuitable blood* and of each type of *unsuitable blood component* available and on the market at all levels, with *blood* and *blood component* expiration dates.

E. **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.

F. **Required Record Review.** If *ARC* fails, within 10 *days* of initially discovering a *problem* that may result or may have resulted in the release for distribution of units of *unsuitable blood or blood components*, to review and document the review of all records necessary to determine whether distribution of units of *unsuitable blood or blood components* in fact occurred and to identify all related units of *unsuitable blood or blood components* that were, may have been, or may be distributed, then FDA may assess per diem penalties of up to $10,000 until all such records have been reviewed, and such review has been fully documented, signed, and dated by persons who completed the review.

G. **FDA Retrieval Notification.** In the event FDA notifies *ARC* in writing to notify consignees and retrieve *blood* or *blood components* from the market, and *ARC* agrees with FDA's notification, *ARC* shall take steps to notify consignees and retrieve the *blood* or *blood components* within 24 hours of receiving FDA's notification. *ARC* shall complete all *retrievals* within 60 *days* after initiating such action. If *ARC* believes additional time is necessary, it shall within 40 *days* of initiating the *retrieval,* submit a written request to FDA for an extension of time and shall provide facts supporting the need for and length of the requested extension. FDA

may assess a penalty of up to $10,000 for each *day* beyond the 60th *day*, or for each day after the expiration of any such extension, that *ARC* has failed to complete all steps to notify consignees and retrieve *blood* and *blood components* from the market. The *retrieval* notification authority in this paragraph is apart from, and in addition to, the recall provisions under 21 C.F.R. § 7.45, and nothing in this Order shall be construed to limit the recall provisions under 21 C.F.R. § 7.45.

H. If *ARC* disagrees with FDA's *retrieval* notification, the *penalty, review, and appeal procedures* set forth in paragraph IX of this Order shall apply, except that the 10 *day* time frames set forth in that paragraph shall be shortened to 5 *days*.

XI. REQUIREMENTS FOR SUBMISSIONS TO *ARC SENIOR MANAGEMENT* AND/OR *ARC BIOMEDICAL SERVICES SENIOR MANAGEMENT*: For each report or plan that this Order requires *ARC* personnel to submit to *ARC senior management* and/or *ARC Biomedical Services senior management* the following requirements apply:

A. Each report or plan to be submitted to *ARC senior management* shall be submitted to each of the individuals identified in the definition of *ARC senior management*. Any summary reports sent to *ARC senior management* as part of the Quarterly Quality Assurance Report or otherwise shall contain information that is sufficient to enable *ARC senior management* to take all actions necessary to accomplish the objectives of this Order as set forth in paragraph XIX. All such ARC senior managers shall, within 10 *days* of receipt, sign and date each report or plan to acknowledge that they have received and read the report or plan.

B. Each report or plan to be submitted to *ARC Biomedical Services senior management* shall be submitted to each of the individuals identified in the definition of *ARC Biomedical Services senior management*. All such *ARC* Biomedical Services senior managers shall review, sign, and date each report within 10 days of receipt. In addition, each *ARC* Biomedical Services

senior manager shall either state in writing that, consistent with his or her responsibilities, he or she agrees with the conclusions in the report or plan (except *FDA-483s*), or shall state in writing his or her objections or disagreements with the report or plan (except *FDA-483s*), including the basis for the objections or disagreements.

XII. QUALIFICATIONS OF CONSULTANTS: All consultants retained by *ARC* to comply with this Order shall be, by education, training, and experience, qualified to conduct inspections of *ARC*'s blood services operations to determine whether the methods, facilities, and controls are operated and administered in conformity with *the law*, *ARC SOPs*, and this Order.

XIII. REIMBURSEMENT OF INSPECTION COSTS: *ARC* shall reimburse FDA for the costs of all FDA inspections and examinations that FDA deems necessary to evaluate *ARC*'s compliance with this Order, at the rate of $67.17 per hour and fraction thereof per representative for inspection work, $80.49 per hour or fraction thereof per representative for analytical and review work, 36 cents per mile for travel expenses and the full cost of airfare, if necessary, and up to $253.00 per day per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court. Furthermore, if *ARC* violates any provision of this Order and is found in civil or criminal contempt thereof, it shall, in addition to other remedies, reimburse the plaintiff for its attorney fees, investigational expenses, and court costs relating to such contempt proceedings.

XIV. AVAILABILITY OF INFORMATION: All data, reports, plans, summaries, and certifications required by this Order shall be made available to FDA upon request as soon as practicable, and shall be subject to verification by FDA during inspections of *ARC* facilities.

XV. INSPECTION AUTHORITY; RECORDS INTEGRITY.

A. *ARC* shall permit duly authorized FDA representatives, as FDA deems necessary and without notice, to make such inspections and to take any other measures necessary to monitor compliance with this Order, including, but not limited to, conducting inspections of *ARC Biomedical Headquarters* and each *region* and *laboratory*; of all articles of drug therein, including any unit of *blood, blood component,* or other biological product; of all *equipment*, finished and unfinished materials, *blood* containers, labeling, records (including, but not limited to, all *computer software*, *computer software* printouts and *utility program* printouts referencing all identifiers of unsuitable donors and reports required to be made by this Order), files, papers, processes, and controls therein; taking photographs; collecting samples of any articles; and copying any of the foregoing records. The costs of all such inspections, sample analyses, and review work shall be borne by *ARC* at the rates specified above. The inspections described in this Order shall be permitted upon presentation of a copy of this Order and appropriate credentials. Such inspection authority shall be apart from, and in addition to, the authority to make inspections under *the law*.

B. Whenever during an inspection FDA requests *ARC* documents relating to *CGMP* or *ARC's* compliance with this Order, ARC shall provide the documents as soon as practicable (i.e., for purposes of this subparagraph and absent extraordinary circumstances, within 24 hours of FDA's request when the documents are at the facility being inspected, and within 48 hours of FDA's request when the documents are not at the facility being inspected). In no event may *ARC* in any way create any attachment or add information to a document after it has been requested by FDA and before it has been provided to FDA.

XVI. ACTS ENJOINED: After entry of this Order, *ARC*; its President and Chief Executive Officer; the Executive Vice President and Chief Executive Officer, Biomedical Services; the

Senior Vice President and Chief Operating Officer, Biomedical Services; the Senior Vice President, Quality and Regulatory Affairs, Biomedical Services; the Vice President and Chief Operating Officer, Plasma Services, Biomedical Services; the Vice President, Chief Scientific Officer, Biomedical Services; the Chief Information Officer; Director of Training, Biomedical Services; Customer Business Unit Vice Presidents, Biomedical Services; Regional and Laboratory Chief Executive Officers, Biomedical Services; and all of *ARC*'s other officers, agents, employees, attorneys, and those persons who have received actual notice of this Order and who are in active concert or participation with any of the foregoing persons, are permanently enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce any *blood, blood component,* or other biological product that is misbranded within the meaning of 21 U.S.C. § 352(a) or 42 U.S.C. § 262(b), or adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210-211, or 21 C.F.R. Parts 600-680, in that methods used in, or facilities or controls used for its collection, manufacture, processing, packing, holding, or distribution do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that the article meets the requirements of *the law* as to safety, and has the identity and strength, and meets the quality and *purity* characteristics, which it purports or is represented to possess;

B. violating 21 U.S.C. § 331(k), by causing any drug, including any *blood, blood component*, or other biological product that is being held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(a) or 42 U.S.C. § 262(b), or adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210-211, or 21 C.F.R. Parts 600-680;

C. violating regulations promulgated pursuant to the *PHS Act*, 42 U.S.C. § 262, at 21 C.F.R. Parts 600-680, establishing standards designed to assure the continued *purity* of *blood* and *blood components*; and

D. violating regulations promulgated pursuant to the *PHS Act*, 42 U.S.C. § 264, at 21 C.F.R. Parts 600-680, designed to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and from one state to another state.

XVII. SERVICE OF ORDER ON ALL ENJOINED: Within 10 *days* after the date of entry of this Order, *ARC* shall provide a copy of this Order to each person specified in paragraph IV above. Within 30 *days* after entry of this Order, *ARC* shall ensure that all other *ARC* personnel are aware of the terms of this Order, either by providing them with copies or by posting copies in conspicuous places frequented by and readily available to blood services personnel. *ARC* also shall, within 40 *days* after entry of this Order, provide FDA with an affidavit based on personal knowledge of the affiant stating the fact and manner of compliance with this paragraph and identify the names and positions of all persons provided with a copy of the Order pursuant to this paragraph.

XVIII. CHANGES TO *ARC*:

A. <u>Structural Changes.</u> *ARC* shall notify FDA in writing at least 30 *days* before any reorganization, dissolution, or assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, the merger, elimination, or creation of any *region* or *laboratory*, or any other change of the corporate structure or function of *ARC* that may affect compliance obligations arising out of this Order. *ARC* shall serve a copy of this Order on any prospective purchaser or assign at least 15 *days* prior to the change in ownership

and shall obtain a signed statement from the prospective purchaser or assign that it has read and understands the terms of this Order. *ARC* shall furnish plaintiff an affidavit of compliance with this paragraph no later than 5 *days* prior to such change in ownership. Nothing in this Order shall be construed to prevent *ARC* from undertaking an orderly transfer of assets, an orderly withdrawal of service from any *region*, or from applying for revocation of FDA License 190, pursuant to 21 C.F.R. § 601.5(a). However, in the event *ARC* decides to apply for revocation of FDA License 190, it shall notify FDA in writing at least 120 *days* before making such request.

B. **Personnel Changes.** Commencing with the date of entry of this Order, *ARC* shall report in writing to FDA all *ARC senior management* and *ARC Biomedical Services senior management* changes within 10 *days* of occurrence and shall identify all acting or interim *ARC senior management* and *ARC Biomedical Services senior management* personnel within 10 *days* of selection.

XIX. ACCOMPLISHING ORDER OBJECTIVES: *ARC* shall take all actions necessary to accomplish the objectives of this Order, including personnel actions, ensuring the availability of and expenditure of monies, *retrieval* of *blood* or *blood components*, and partial or complete suspension of operations of one or more *regions* and/or *laboratories*. *ARC* shall notify FDA within 24 hours of any such suspensions of operations and shall notify FDA within 10 *days* of taking any other significant corrective action; both types of notification shall be in writing.

XX. STANDARD OF REVIEW: All decisions conferred upon FDA in this Order shall be vested in the discretion of FDA. FDA's decisions under this Order shall be reviewed, if necessary, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). In the event *ARC* challenges any FDA decision under this Order, FDA's decision shall be reviewed on

the basis of written information that was before FDA when the decision was made. No discovery may be had by either party.

Notwithstanding the foregoing, ARC understands and agrees that in those circumstances in which FDA is authorized to impose a penalty "up to" a certain amount, ARC has waived the right to appeal and will not seek judicial review of the amount of any penalty imposed under this Order and that it may only seek administrative review of the amounts of penalties imposed by FDA. The parties understand and agree that because determining the penalty amounts under this Order is highly fact-dependant and subjective, penalty assessments for apparently similar situations may not appear comparable. The parties further agree that *ARC* may only ask the Court to review, under the standard described in this paragraph, whether FDA has properly decided *whether* to assess a penalty under this Order.

XXI. OTHER LEGAL OBLIGATIONS UNAFFECTED BY ORDER: *ARC*'s obligations under this Order do not modify or absolve *ARC* from any obligation to comply with *the law*, or any other federal statute or regulation.

XXII. RELIEF FROM ORDER: If there have been no significant failures to comply with *the law*, *ARC SOPs*, or this Order during the 60 month period after entry of this Order, *ARC* may petition the Court for relief from this Order, and FDA will not object.

XXIII. RETENTION OF JURISDICTION: This Court shall retain jurisdiction over this action and the parties hereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

XXIV. PAYMENT OF COSTS: Except as provided above in paragraphs XIII and XV, each party shall bear its own costs and attorneys fees.

SO ORDERED:

Dated this 15-16 day of April 2003.

JOHN GARRETT PENN
United States District Judge

We hereby consent to the entry of the foregoing Order:

FOR AMERICAN RED CROSS:

MARSHA J. EVANS
President and Chief Executive Officer
American National Red Cross

RAMESH THADANI
Executive Vice President and
Chief Executive Officer
Biomedical Services
American National Red Cross

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