US donor vCJD risk more accurately by incorporating the information about the magnitude of the BSE epidemic in the UK in a given year.

Variable: $V_{y/1996}$ - The number of visits to the UK by US travelers in year y compared to the number of visits in 1996 (calculated in A-IV. C. 1. a. ii. a.).

Variable: $DR_{S\text{-}FR(age),y}$ - Number of Source Plasma donors with history of travel to France in year y by age groups

The number of Source Plasma donors who have traveled to France was allocated to individual travel year based on the yearly distribution of visits to France.

$$DR_{S-FR(age)y} = DR_{S-FR(age)} \times V_{y/1996} / \sum_{y=1980}^{1996} V_{y/1996} \qquad \text{(IV.C.1.b-7)}$$

for travel during 1980-1996;

$$DR_{S-FR(age)y} = DR_{S-FR(age)1996} \times V_{y/1996} \qquad \text{(IV.C.1.b-8)}$$

for travel after 1996

Assumption used in the model: The yearly frequency and distribution of travel to France by US donors was ascertained from UK travel data and the blood donor survey data (TSEAC 2000). Therefore, in calculating the US donor risk for vCJD, donors the yearly distribution of travel visits by age groups was adjusted to account for the requirement that donors be 18 years of age or older. The model also accounted for the fact that some younger donors born during the period 1980 to 1986 may not have been born and would have essentially a zero chance of being exposed to BSE agent. Therefore, donors 18 years of age in 2002 were assumed to have zero exposure to the BSE agent prior to 1985, those 19 years of age in 2002 were assumed to have zero exposure prior to 1984, those 20 years of age in 2002 were assumed to have zero exposure prior to 1983, those 21 years of age in 2002 were assumed to have zero exposure prior to 1982, those 22 years of age in 2002 were assumed to have zero exposure prior to 1981. The model assumed that there was zero exposure of all donors prior to 1980.

A-IV. C. 1. b. ii. b. Number of US Source Plasma donors and duration of travel to France by age group

There are no data detailing the travel histories of Source Plasma donors available. Travel data for blood donors was used for Source Plasma donors after an adjustment for the frequency of travel based on the age of Source Plasma donors and the age-specific odds ratios for travel, which were obtained from 1980-1996 Blood Donor Travel Survey (TSEAC, 2000).

The model further subdivides the number of Source Plasma donors who traveled to France in a specific year by duration of stay. While there were no specific travel data detailing travel patterns to France since 1980 available for US Source Plasma donors, data on travel patterns for whole blood donors was used as a proxy. Donor travel in the model was subdivided into categories based on the percentage of blood donors

who traveled to France for certain durations (Watanabe, 2000) (>5yrs, ≤5yrs, etc) was used in this risk assessment.

Variable: i - The duration interval used to group blood donors who had traveled to France from 1980-1996 based on the time they spent in France (same variable used above in section A-IV. C. 1. a. i.).

Variable: D_i - The average duration of time for interval i (months) (same variable used above in section A-IV. C. 1. i.).

Variable: $DR_{S\text{-}FR(age),y}$ - the number of Source Plasma donors who traveled to France in year y by age group (calculated in A-IV. C. 1. b. ii.)

Variable: $Perc_{BIDR\text{-}FRi/FR}$- The percentage of blood donors who traveled for a specific duration interval i among all donors who have ever traveled to France (calculated in A-IV. C. 1. b. i.)

Variable: $DR_{S\text{-}FR(age)y,i}$ - Number of Source Plasma donors among an age group who have traveled to France in year y for a duration of i and is represented by the equation:

$$DR_{S-FR(age)y,i} = DR_{S-FR(age)y} \times Perc_{DR-FRi/FR} \qquad \text{(IV.C.1.b-9)}$$

A-IV. C. 1. b. ii. c. Number of US recovered plasma donors with history of travel to France in a specific year between 1980 and 1996 – and by age group

Recovered plasma is plasma that is separated or "recovered" from a unit of whole blood soon after the blood is collected. As expected, recovered plasma donor donation characteristics mirror those of whole blood donors. A recovered plasma donor can donate plasma a maximum of six times per year – and on average a recovered donation is approximately 200 milliliters (versus an average of 700 milliliters for a Source Plasma donation).

Variable: y – **Year of travel** (same variable used above in section A-IV. C. 1. b. ii. a) to France since 1980 by US plasma donors.

Variable: **age** – Age of the population by five-year increments (same variable used above in section A-IV. B. 1.).

Variable: $DR_{R(age)}$ - Number of potential recovered plasma donors per year by age group (described in section A-IV. B. 2).

Variable: $Perc_{BIDR\text{-}FR(age)}$ (calculated in section A-IV.C.1.b.i.)- The percentage blood donors from an age group who have traveled to France between 1980-1996

Variable: $DR_{R\text{-}FR(age)}$ - Number of recovered plasma donors who traveled to France from 1980 through 1996 by age groups and is represented by the equation:

$$DR_{R-FR(age)} = DR_{R(age)} \times Perc_{BIDR-FR(age)} \quad \text{(IV.C.1.b-10)}$$

The risk a traveler was exposed to BSE in France is proportional to the magnitude of the BSE epidemic in the UK in the year of travel. Because the major exposure risk in France is assumed to be from consumption of BSE contaminated beef imported from the UK , the model subdivides recovered plasma donors and groups them by year of travel. This provides a more precise estimate of the risk by incorporating the specific information on donor and donation characteristics and details that better capture the dynamics of the BSE epidemic in the UK on a year by year basis.

Variable: $V_{y/1996}$ - The number of visits to the UK by US travelers in year *y* compared to the number of visits in 1996 (calculated in A-IV.C.1.a)

Variable: $DR_{R-FR(age),y}$ - Number of recovered plasma donors with a history of travel to France in year by age groups

Number of recovered plasma donors who have traveled to France was allocated to individual travel year based on the yearly distribution of visits to the UK by US travelers.

$$DR_{R-FR(age)y} = DR_{R-FR(age)} \times V_{y/1996} / \sum_{y=1980}^{1996} V_{y/1996} \quad \text{(IV.C.1.b-11)}$$

for travel during 1980-1996;

$$DR_{R-FR(age)y} = DR_{R-FR(age)1996} \times V_{y/1996} \quad \text{(IV.C.1.b-12)}$$

for travel after 1996

Assumptions used in the model: The yearly distribution of travel to France by US donors is similar to the yearly distribution of travel to the UK by US donors- this is based on travel data and the blood donor survey (TSEAC 2000). The yearly distribution of travel visits by each age group was adjusted to account for the minimum age of 18 when a donor can donate plasma or blood. Therefore, in calculating the US donor risk for vCJD the yearly distribution of travel visits by each age group was adjusted to account for this requirement. The model adjusted the potential vCJD exposure for younger donors who were born during the period from 1980 to 1986 and would have essentially a zero chance of being exposed to the BSE agent in the years prior to their birth. Therefore, donors 18 years of age in 2002 were assumed to have zero exposure to the BSE agent prior to 1985, those 19 years of age in 2002 were assumed to have zero exposure prior to 1984, those 20 years of age in 2002 were assumed to have zero exposure prior to 1983, those 21 years of age in 2002 were assumed to have zero exposure prior to 1982, those 22 years of age in 2002 were assumed to have zero exposure prior to 1981. The model assumed that there was zero exposure of all donors prior to 1980.

A-IV. C. 1. b. ii. d. US recovered plasma donors with a history of travel to France and specific year of travel and duration of travel by age group

Recovered plasma donors who traveled to France in a specific year ($DR_{R\text{-}FR(age)y}$) since 1980 were further partitioned into the subgroups based on travel duration and by 5-year age groups. Data on the percentage

of blood donors who traveled to France since 1980 for certain duration(s) (TSEAC, 2000) was used in this risk assessment.

Variable: i - The duration interval used to group blood donors who had traveled to France from 1980-1996 based on the time they spent in France (same variable used above in section A-IV. C. 1.)

Variable: D_i - The average duration of time for interval i (months) (same variable used above in section A-IV. C. 1.)

Variable: $DR_{R\text{-}FR(age)y}$ - The number of recovered plasma donors who traveled to France in year y by age group (calculated in A-IV. C. 1. b. iv. c.)

Variable: $Perc_{BIDR\text{-}FR/FR}$ - The percentage of blood donors who traveled for a specific duration interval i among all donors who have ever traveled to France (calculated in A-IV. C. 1. b. ii. a.)

Variable: $DR_{R\text{-}FR(age)y,i}$ - Number of recovered plasma donors among an age group who have traveled to France in year, y ,for duration of i.

$$DR_{R-FR(age)y,i} = DR_{R-FR(age)y} \times Perc_{DR-FRi/FR} \qquad \text{(IV.C.1.b-13)}$$

A-IV.C. 1. b. iii. US plasma donors with history of travel to France: Adjustment of the relative risk for France based on the magnitude of the UK BSE risk and by travel duration in a specific year

As indicated in previous sections the FDA model assumed that the relative vCJD risk for UK residents residing for any five-year period or longer from 1980 through 1996 is assumed to have a value of 1, because exposure to BSE in the UK was greater than any other country. The relative risk value of 1 equates to 100% of the UK asymptomatic and symptomatic vCJD prevalence which is difficult to estimate. The relative risk value for France is 0.05 (or 5% of the UK risk). The relative risk value is assigned based on factors such as domestic UK beef consumption, and the rate and number of vCJD cases, and indigenous BSE cases that may have occurred (TSEAC 2004). France received meat and bone meal from the UK during the BSE epidemic and approximately 5% of its beef was imported from the UK as of August 2006, France reported 20 cases of vCJD in its human population. Additionally, the model included calculations on the estimated duration of travel in France or residence by US plasma donors to generate a more accurate vCJD risk estimate. Current US vCJD geographic deferral policy defers donors with a history of residence in France for a period of 5 years or more since 1980.

A-IV. C. 1. b. iii. a. US plasma donors with a history of travel to France: Average accumulated risk of residence since 1980

Variable: R_{FR} – The cumulative risk of individual residents of France from 1980 till present; assuming that the cumulative risk of a UK individual from 1980 through 1996 is 1.

Assumption used in the model: The average cumulative risk of a resident of France since 1980 is 0.05 relative to 1, the average accumulated risk of UK individual since 1980, based on UK beef imports, vCJD cases and indigenous BSE in France

A-IV. C. 1. b. iii. b. US plasma donors with history of travel to France: Proportional risk of individual resident per year since 1980

Variable: y – **year** (same variable used in A-IV. C. 1. a. iv.)

Variable: BSE_{UKy} (same variable used in A-IV. C. 1. a. iii.)

Variable: BSE_{FRy} - Annual numbers of reported BSE cases in France including indigenous and imported cases

Data used in the model: Data on the annual number of reported BSE cases in France was obtained from the World organization for animal health (OIE) (2005).

Variable: R_{FRy} - Proportional risk in France in a specific year

Assumptions used in the model:

- Variant CJD Risk in France occurred starting in 1980 to the present. Evidence indicates that vCJD and BSE cases are still emerging.
- Risk is additive, and can be pro-rated in a yearly and further monthly basis.
- Yearly rate of the risk in France is proportional to the reported BSE annual cases (including indigenous and imported cases) in France.

A-IV. C. 1. b. iii. c. US plasma donors with a history of travel to France: Potential vCJD risk for donors who traveled in year y for a period of i

Variable: $R_{DR\text{-}FRJ}$ - The risk of an individual US donor who traveled to France in a specific year with a specific duration of travel, assuming a cumulative risk for a UK individual from 1980 through 1996 is 1 (or equivalent to the UK vCJD prevalence for the entire UK population).

The vCJD risk for the US plasma donor subpopulation that traveled to France in a specific year for a specific duration was calculated by applying a prorated monthly rate of risk, which was calculated based on the yearly rate of the risk in France during the year of travel. The blood donor travel survey (TSEAC, 2000) collected information on the accumulated stay of the donors in France from 1980 through 1996, which, for simplicity, was used to calculate the duration of consecutive stay, when calculated the risk.

Assumptions used in the model:

- Risk is proportional to the duration of the stay
- All travelers have consecutive stays
- US plasma donor subpopulation having more than 5 years accumulated stay in France have average risk of 0.05, which is the same as the average risk of individual resident of France (equivalent to 5% of the UK vCJD prevalence).

$$R_{DR-FRy,i} = (R_{FRy} / 12) \times D_i \qquad \text{(IV.C. 1. b-14)}$$

for i< 1 years;

$$R_{DR-FRy,i} = (Average(R_{FRy} : R_{FR(y+i)}) / 12) \times D_i \qquad \text{(IV.C.1.b-15)}$$

for 5 years <i>=1 year;

$$R_{DR-FRy,i} = 0.05 \qquad \text{(IV.C.1.b-16)}$$

for i>= 5 years

A-IV.C. 1. b. iv. US plasma donors with history of travel to France: Probability of vCJD infection for donor of a specific age group, in a specific year, for a specific duration, i

This section describes the portion of the model that estimates the potential probability that a US plasma donor in a specific age group who traveled to France for a specific duration since 1980 was infected with vCJD.

Variable: $Pr_{vCJD-FR(age)}$ Probability of vCJD infection in an individual resident of France in a specific age.

Variable: $Pr_{vCJD-DR-FR(age)y,i}$ - Probability of infection for individual US plasma donor of a specific age group who have traveled to France in a specific year for a specific duration.

Assumption about variable: Probability of vCJD infection being proportional to the risk of exposure to the BSE agent and represented by the equation:

$$\Pr_{vCJD-DR-FR(age)y,i} = \Pr_{vCJD-UK(age)} \times R_{DR-FRy,i} \qquad \text{(IV.C.1.b-17)}$$

A-IV.C. 1. b. v. Total number of all US plasma donors with a history of travel to France: Number potentially infected with vCJD

A-IV.C. 1. b. v. a. Number of US Source Plasma donors with a history of travel to France and potentially infected with vCJD

Plasma is collected from Source Plasma donors in a process called plasmapheresis in which approximately 700 milliliters of plasma are collected. Source Plasma donors donate an average of 14 units per year, but can donate up to 48 times per year.

This component of the model estimates the number of US Source Plasma donors potentially infected with vCJD during travel to the UK from 1980 through 1996.

Variable: $DR_{vCJD\text{-}S\text{-}FR(age)y,l}$ - Number of Source Plasma donors potentially infected with vCJD during travel to France since 1980 by age, year and duration of travel.

$$DR_{vCJD-S-FR(age)y,l} = Bionomial(DR_{S-FR(age)y,l}, \Pr_{vCJD-DR-FR(age)y,l}) \quad \text{(IV.C.1.b-18)}$$

Variable: $DR_{vCJD\text{-}S\text{-}FRy}$ - Number of Source Plasma donors potentially infected with vCJD in year y during travel/residence in France.

$$DR_{vCJD-S-FRy} = \sum_{Age=18-19\,yrs}^{50-54\,yrs} \sum_{l=1\,day-3\,months}^{>=5\,years} DR_{vCJD-S-FR(age)y,l} \quad \text{(IV.C.1.a-19)}$$

Variable: $DR_{vCJD\text{-}S\text{-}FR\text{-}Defy}$ - Number of Source Plasma donors potentially infected with vCJD in year y and meet deferral criteria.

Current deferral policy defers individuals who have a history of travel to France since 1980 for an accumulated time of over 5 years from donating blood and plasma. The number of potentially infected donors who meet deferral criteria was calculated by equation:

$$DR_{vCJD-S-FR-Defy} = \sum_{Age=18-19}^{50-54\,yrs} DR_{vCJD-S-FR(age)y,l>=5\,years} \quad \text{(IV.C.1.a-20)}$$

Variable: $DR_{vCJD\text{-}S\text{-}FR\text{-}Resy}$ - Residual risk due to the number of Source Plasma donors potentially infected with vCJD in year y and not deferred by current policy

$$DR_{vCJD-S-FR-Resy} = \sum_{Age=18-19\,yrs}^{50-54\,yrs} \sum_{l=1-30\,days}^{>3-5\,years} DR_{vCJD-S-FR(age)y,l} \quad \text{(IV.C.1.a-21)}$$

APPENDIX A

A-IV. C. 1. b. v. b. Number of US Source Plasma donors with history of travel to France and potentially infected and vCJD agent is present in the blood

Perhaps the most critical component of the model is the estimation of whether a plasma donation was collected from a vCJD infected donor who had infectious vCJD agent in their blood (i.e., was prionemic at the time of donation). Based on data from animal studies, the model assumes that vCJD infectious individuals have infectious vCJD agent present in the blood during the last half of the incubation period. This portion of the model calculates the number of Source Plasma donors who may potentially contain infectious vCJD agent in their blood at the time of donation.

Variable: *y*-The calendar year in which a plasma donor traveled and infected with vCJD

Assumption used in the model: This risk assessment assesses the risk for pdFVIII product made in 2002 (but risk is assumed to be similar up to the year 2006).

Variable: $T_{Inf\text{-}2002y}$-Time Period between infection/travel and year of 2002 when the plasma was collected

Variable: $Pr\text{-}LH_y$-Probability the individual is in the last half incubation period of the disease, if infected in year y

Variable: $T_{Inf\text{-}2002y}$-Time period between infection and travel and 2002 when the plasma was collected

$$T_{Inf-2002\,y} = 2002 - y \qquad \text{(IV.C.1.b-22)}$$

For an individual to have vCJD agent present in their blood and plasma (prionemic) in 2002, the elapsed period of time since infection up to 2002 ($I_{Inf\text{-}2002y}$) should be equal to or less than the remaining half of incubation period of the disease; in another words, the incubation period of the disease should be equal to or less than twice as much as $I_{Inf\text{-}2002y}$.

Assumption used in the model The variability and uncertainty of the incubation period of vCJD is represented mathematically by a gamma distribution, specifically Gamma (4.7, 3.6). A gamma distribution is usually used to represent processes that occur sequentially, in this case infection, incubation period of the disease, etc. The distribution is defined by two parameters (or arguments) that produce the shape of the curve and generates a mean incubation period of 14 years and a median incubation period of 13 years.

Variable: $Pr_{LH\text{-}y}$ -The probability an individual will be prionemic in the year 2002, was determined using the distribution:

Cumulative frequency of Gamma (4.7, 3.6), at x=2×(1997-y)

Variable: $DR_{vCJD\text{-}S\text{-}FRy}$- Total number of Source Plasma donors potentially infected with vCJD in year y during travel/residency in France (calculated in A-IV. C. 1. b. v. a.)

Variable: $DR_{vCJD\text{-}S\text{-}FR\text{-}LHy}$ - Total number of Source Plasma donors potentially infected with vCJD in year y during travel/residency in France and in the last half incubation period of the disease.

$$DR_{vCJD-S-FR-LHy} = Binomial(DR_{vCJD-S-FRy}, \Pr_{LH-y}) \quad \text{(IV.C.1.b-23)}$$

Variable: $DR_{vCJD\text{-}S\text{-}FR\text{-}defy}$- Total number of Source Plasma donors potentially infected with vCJD in year y during travel/residency in France and met deferral criteria (calculated in A-IV. C. 1. b. v. a)

Variable: $DR_{vCJD\text{-}S\text{-}FR\text{-}def\text{-}LHy}$ - Total number of Source Plasma donors in the last-half of the incubation period of the disease who met deferral criteria.

$$DR_{vCJD-S-FR-Def-LHy} = Binomial(DR_{vCJD-S-FR-Defy}, \Pr_{LH-y}) \quad \text{(IV.C.1.b-24)}$$

Variable: $DR_{vCJD\text{-}S\text{-}FR\text{-}Resy}$- Total number of Source Plasma donors potentially infected with vCJD in year y during travel/residency in France and did not met deferral criteria (calculated in A-IV. C. 1. b. v. a)

Variable: $DR_{vCJD\text{-}S\text{-}FR\text{-}Res\text{-}LHy}$ - Total number of Source Plasma donors in the last half incubation period of the disease who did not met deferral criteria or were not deferred is represented by the equation:

$$DR_{vCJD-S-FR-Res-LHy} = Binomial(DR_{vCJD-S-FR-Resy}, \Pr_{LH-y}) \quad \text{(IV.C.1.b-25)}$$

A-IV.C. 1. b. v. c. Number of US recovered plasma donors with a history of travel to France and potentially infected with vCJD

Variable: $DR_{vCJD\text{-}R\text{-}FR(age)y,i}$ - Number of recovered plasma donors potentially infected with vCJD during travel to France since 1980 by age, year and duration of travel

$$DR_{vCJD-R-FR(age)y,i} = Bionomial(DR_{R-FR(age)y,i}, \Pr_{vCJD-DR-FR(age)y,i}) \quad \text{(IV.C.1.b-26)}$$

Variable: $DR_{vCJD\text{-}R\text{-}FRy}$ - Total number of recovered plasma donors potentially infected with vCJD in year y:

$$DR_{vCJD-R-FRy} = \sum_{Age=18-19}^{50-54} \sum_{1=1day-3months}^{>=5years} DR_{vCJD-R-FR(age)y,i} \quad \text{(IV.C.1.b-27)}$$

Current deferral policy defers individuals who have history of travel to France since 1980 for an accumulated residence of 5 years or more from donating blood and plasma. The number of potentially infected donors who meet the deferral criteria was calculated by equation:

$$DR_{vCJD-R-FR-Defy} = \sum_{Age=18-19}^{50-54\,yrs} DR_{vCJD-R-FR(age)y,i>=5\,years} \quad \text{(IV.C.1.b-28)}$$

Variable: $DR_{vCJD-S-FR-Resy}$- The residual risk due to the number of recovered plasma donors potentially infected with vCJD in year y and not deferred by current policy

$$DR_{vCJD-R-FR-Resy} = \sum_{Age=18-19yrs}^{50-54\,yrs} \sum_{i=1-30days}^{>3-5\,years} DR_{vCJD-R-FR(age)y,i} \quad \text{(IV.C.1.b-29)}$$

A-IV. C. 1. b. v. d. Number of US recovered plasma donors with history of travel to France and potentially infected and vCJD agent is present in the blood

As discussed in the sections on Source Plasma (above) the most critical component of the model is the estimation of whether a plasma donation was collected from a vCJD infected donor who had infectious vCJD agent in their blood (i.e., was prionemic at the time of donation). Based on data from animal studies, the model assumes that vCJD infectious individuals have infectious vCJD agent present in the blood during the last half of the incubation period. This portion of the model calculates the number of recovered plasma donors who may potentially contain infectious vCJD agent in their blood at the time of donation.

Variable: Pr_{LH-y} -The probability an individual will have vCJD agent present in their blood or present (prionemic) at the time of donation in the year 2002 (calculated in A-IV.C.1.a.v. b.)

Variable: $DR_{vCJD-R-FRy}$- Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residence in France (calculated in A-IV. C. 1. b. v. c.)

Variable: $DR_{vCJD-R-FR-LHy}$ - Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residence in France and in the last half incubation period of the disease.

$$DR_{vCJD-R-FR-LHy} = Binomial(DR_{vCJD-R-FRy,}\ \Pr_{LH-y}) \quad \text{(IV.C.1.b-30)}$$

Variable: $DR_{vCJD-R-FR-defy}$- Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residency in France and met deferral criteria (calculated in A-IV. C. 1. b. v. c)

Variable: $DR_{vCJD-R-FR-def-LHy}$ - Total number of recovered plasma donors in the last half incubation period of the disease who met deferral criteria and presumably were deferred from donation.

$$DR_{vCJD-R-FR-Def-LHy} = Binomial(DR_{vCJD-R-FR-Defy,}\ \Pr_{LH-y}) \quad \text{(IV.C.1.b-31)}$$

Variable: $DR_{vCJD\text{-}R\text{-}FR\text{-}Resy}$ - Total number of recovered plasma donors potentially infected with vCJD in year y during travel/residency in France and did not met deferral criteria and were likely not deferred from donation (calculated in A-IV. C. 1. b. v. c.)

Variable: $DR_{vCJD\text{-}R\text{-}FR\text{-}Res\text{-}LHy}$ - Total number of recovered plasma donors in the last half incubation period of the disease who did not meet deferral criteria and were likely not deferred from donation.

$$DR_{vCJD-R-FR-Res-LHy} = Binomial(DR_{vCJD-R-FR-Resy}, \Pr_{LH-y}) \quad \text{(IV.C.1.b-32)}$$

A-IV. C. 1. b. v. e. Number of all US plasma donors with history of travel to France and potentially infected with vCJD

This section sums the number of all US plasma donors, predicted by the model to donate to plasma pools used in manufacturing pdFVIII made from plasma collected in the US. This includes recovered plasma donors and Source Plasma donors, and generates an estimate for the total number of donors potentially infected with vCJD during extended travel to France since 1980.

Variable: $DR_{vCJD\text{-}FR}$ - Total number of plasma donors potentially infected with vCJD during travel/residence in France

$$DR_{vCJD-FR} = \sum_{y=1980}^{1996} DR_{vCJD-S-FRy} + \sum_{y=1980}^{1996} DR_{vCJD-R-FRy} \quad \text{(IV.C.1.b-33)}$$

Variable: $DR_{vCJD\text{-}FR\text{-}Def}$ - Total number of plasma donors potentially infected with vCJD during travel/residence in France and meet deferral criteria

$$DR_{vCJD-FR-Def} = \sum_{y=1980}^{2002} DR_{vCJD-S-FR-Defy} + \sum_{y=1980}^{2002} DR_{vCJD-R-FR-Defy} \quad \text{(IV.C.1.b-34)}$$

Variable: $DR_{vCJD\text{-}FR\text{-}Res}$ - Total number of plasma donors potentially infected with vCJD during travel/residence in the UK and did not meet deferral criteria

$$DR_{vCJD-FR-Res} = \sum_{y=1980}^{2002} DR_{vCJD-S-FR-Resy} + \sum_{y=1980}^{2002} DR_{vCJD-R-FR-Resy} \quad \text{(IV.C.1.b-35)}$$

A-IV. C. 1. b. v. f. Total number of US plasma donors with history of travel to France and are potentially infected and vCJD agent is present in the blood

Again, whether a donor contains vCJD agent in their blood is a pivotal calculation in the model since a donation from such an individual would contain vCJD agent that may find its way into a large plasma pool of thousands of donations that are used to manufacture pdFVIII. This section sums the number of