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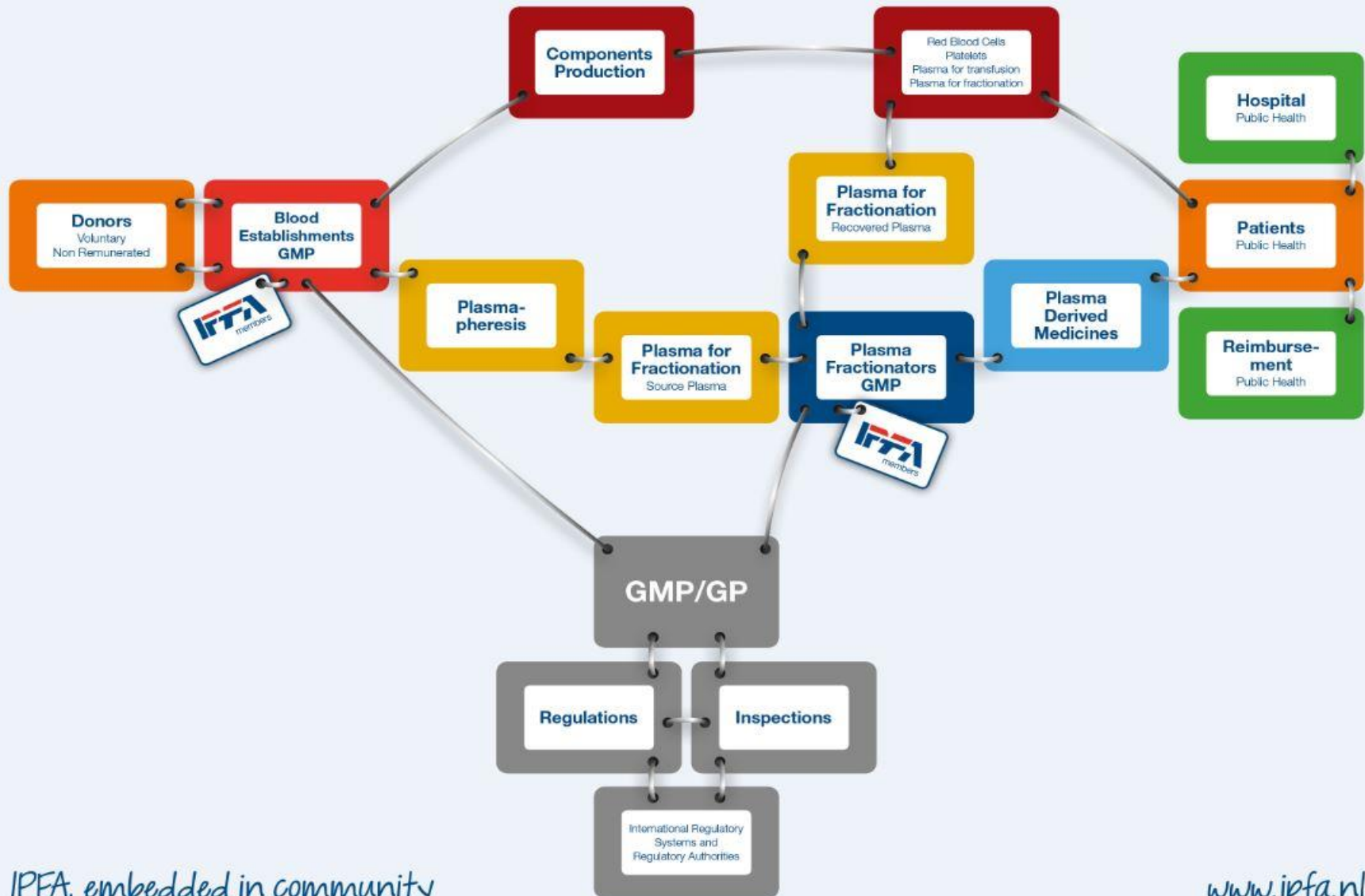
Plasma, a Strategic Resource:

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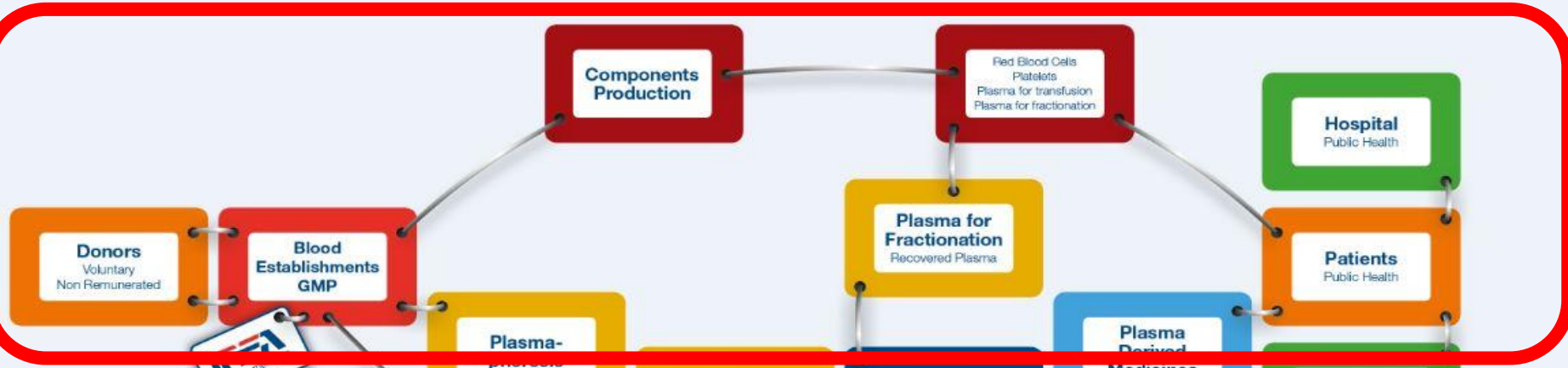
January 14, 2020

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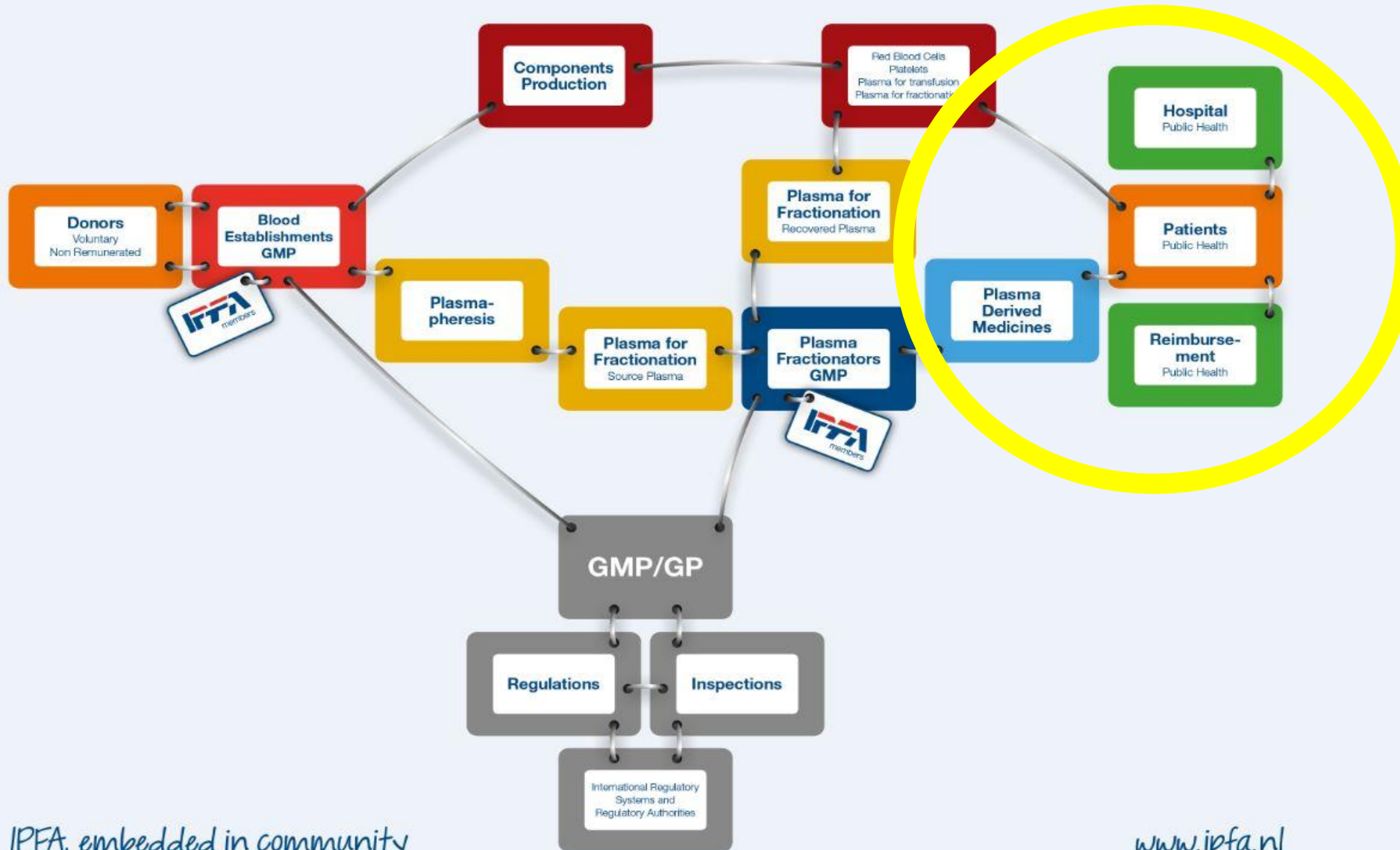
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Focus on:

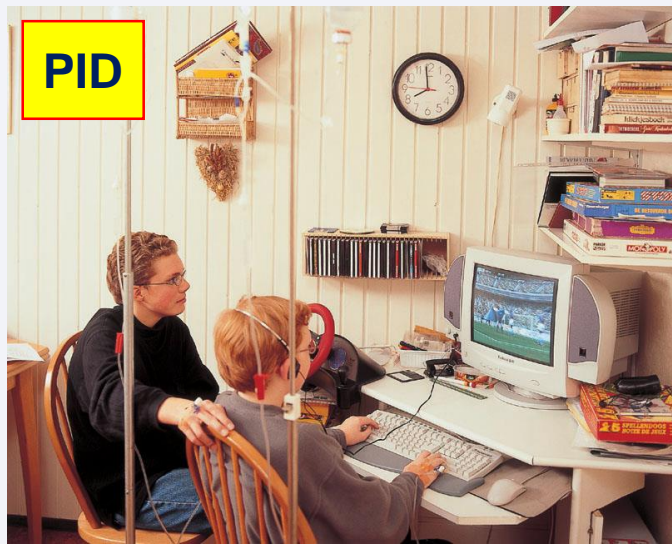
Whole Blood, Red Cells, Platelets, Plasma for Transfusion

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PID



- Abortus (spontaneous)
- Asthma
- Autism
- Critical Illness polyneuropathy (CIP)
- M. Crohn
- Dermatomyositis/polymyositis
- Diabetes mellitus
- Hematological coagulation disorders
- Hematological, immunological, cellular disorders
- Infections in neonates

ITP



- Chron. Inflamm. Demyelinating Polyneuropathy (CIDP)
- Guillan-Barré syndrome
- Multifocal Motor Neuropathy(MMN)

- Multiple Sclerosis (MS)
- Myasthenia Gravis
- Parvo-B19 associated anemia
- Post-transfusion Purpura
- Rheumatoid arthritis
- Sepsis
- Stiff Person Syndrome
- SLE
- Therapy resist. epilepsy children
- M. Alzheimer
- Etc. Etc.



Kawasaki Disease

PDMPs have many functions in clinical therapy

Replacement therapy:

pro- and anti coagulant factor concentrates,
polyvalent immunoglobulins,
specific or hyper-immune immunoglobulins,
albumin,
alpha 1-antitrysin,
C1-esterase inhibitor concentrate.

% diagnosed and treated patients worldwide

- Haemophilia A/B:	30 %	and	25%
- PID:	< 10 %	and	6 %
- AAT deficiency:	10 %	and	3 %

Immune modulating therapy:

intravenous immunoglobulin,
alpha 1 antitrypsin.

Anti-inflammation therapy:

intravenous immunoglobulin,
anti-thrombin,
activated protein C.

Antagonist function:

prothrombin complex concentrate,
activated prothrombin complex concentrate

Drug delivery:

fibrin glue / tissue sealant,
transferrin

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www.ipfa.nl

60 % of the world' plasma supply comes from
only one (1) country.

Plasma should be considered as a

Strategic Resource

COMMENTARY

Plasma is a strategic resource

Paul F.W. Strengers^{1,2} and Harvey G. Klein³

Prospects and Risks

- No supply guarantee
- Emergence of new TTI, that interrupts the current plasma collections in the US
- New clinical indications – resulting in use of IgG for common conditions
(*eg. neuroimaging shows AMBAR plasmapheresis/albumin/IVIg clinical trial's positive effects in patients with mild-to-moderate Alzheimer's disease. Grifols. December 6, 2019*)
- Trade agreements, market forces, price, currency fluctuations, etc.
-

COMMENTARY

Plasma is a strategic resource

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No supply guarantee. Shortages of IgG products in Europe (2018)

2017-2018 United Kingdom:

IVIG. Insufficient supply, supply instability, reduction of products commissioned, cost containment, cheapest products only, company withdrawal from market.

2018 France:

IVIG. Supply tensions.

2018 Netherlands:

Hyper immune IgG. Supply tensions.

2018 Romania:

IVIG. Supply withdrawal from market due to clawback tax set by government

Other countries with supply tensions:

Cyprus, Germany, Greece, Hungary, Latvia, Lithuania, Portugal.

No supply guarantee: Shortages of IVIG/SCIG in USA (2019)

Drug shortage leaves patients without
immune-disorder treatment,

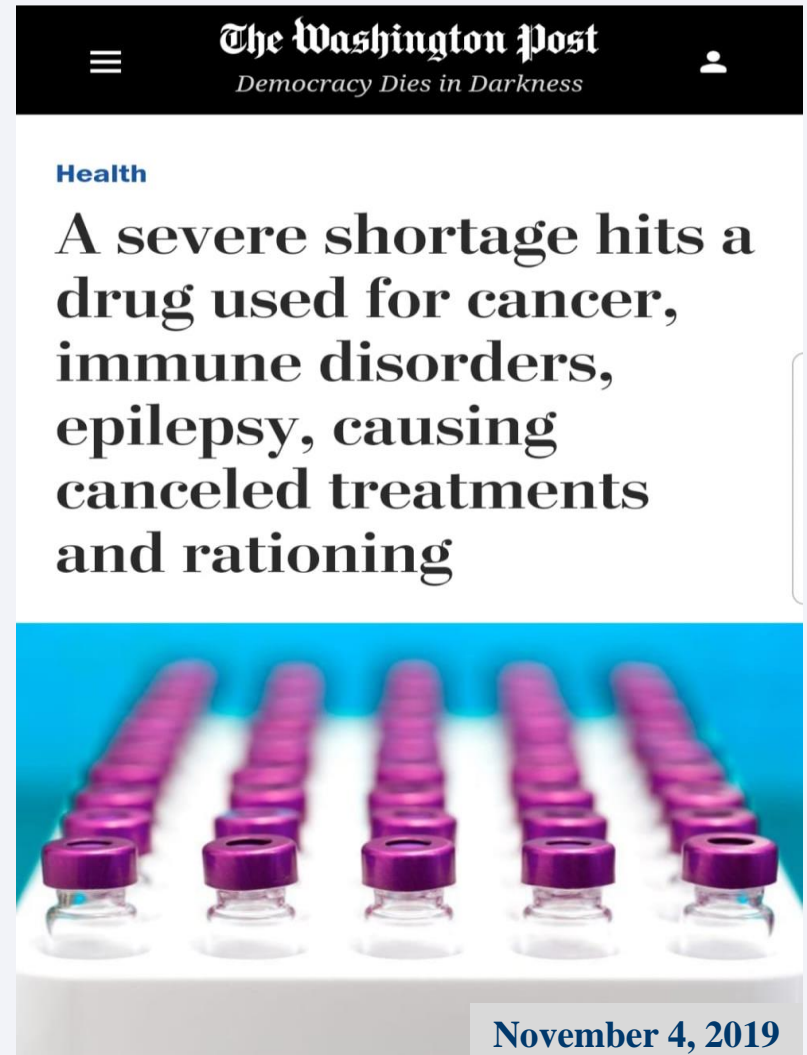
Peter Loftus, Wall Street Journal, 2019-08-09.

Information about Immune Globulin
(Human) Product Shortage

U.S. FDA, 2019-08-09

Letter to FDA regarding drug shortages
as a public health concern

Hon. Gary Peters. US Senator., 2019-08-21



Emergence of new TTI

2005 WHO List of evidence of TTI Page 13

Table 3: EVIDENCE OF TRANSMISSION OF INFECTIOUS AGENTS BY HUMAN BLOOD ⁹

INFECTIOUS AGENTS	CELLULAR BLOOD COMPONENTS	PLASMA	PLASMA PRODUCTS
VIRUSES			
HIV I & II	+	+	+
HBV	+	+	+
HCV	+	+	+
Hepatitis Delta virus	+	+	+
HAV	+	+	+
HEV	+	+	+
HGV	+	+	+
TT virus	+	+	+
Parvovirus B19	+	+	+
Human T-cell leukemia virus I & II	+	-	-
Cytomegalovirus	+	-	-
Epstein Barr virus	+	-	-
West Nile virus	+	?	-
Dengue virus	+	?	-
Human Herpes virus-8	?	-	-
Simian foamy virus	? ¹⁰	?	-
Severe Acute Respiratory Syndrome virus	? ¹¹	?	-
BACTERIA			
Spirochete (syphilis)	+	-	-
Parasites			
Babesia microti	+	-	-
Plasmodium (Malaria)	+	-	-
Leishmania (Leishmaniosis)	+	-	-
Trypanosoma cruzi (Chagas Disease)	+	-	-
UNCONVENTIONAL AGENTS/TSE			
Creutzfeldt Jakob Disease agent	-	-	-
Variant Creutzfeldt Jakob Disease agent	+	?	- ¹²

+ : evidence of transmission; - : no evidence of transmission; ? : questionable or unknown

⁹ Most viral transmissions associated to plasma products took place prior to the introduction of efficient viral inactivation or removal procedures

¹⁰ Transmitted by contact with animal blood but not reported by transfusion

¹¹ Limited epidemiological surveys have not revealed transmission of SARS coronavirus by transfusion but further confirmation may be needed

¹² Investigational studies performed by plasma fractionators using spiked TSE agents indicate that several purification steps used in the manufacture of some plasma products are likely to remove prion agents. These data may not necessarily be extrapolated to clearance of the endogenous form of the TSE agent in human blood.

In 2005:

**No Chikungunya
No ZIKA
No Mers-Corona**

**No MSM donor
deferral policies
relaxation**

**No HIV pre-exposure
prophylaxis**

Interruptions of supply of blood and plasma

Examples:

1980's : HIV (worldwide)

1996 : variant Creutzfeldt Jakob Disease (UK, Ireland)

2002 : West Nile Virus (La Réunion)

2003 : Dengue virus (Puerto Rico)

2016 : Zika Virus (Puerto Rico)

Risks for US supply of plasma ?

- For prion diseases (Chronic Wastage Disease?)
- For non-envelop viruses < 15 nM, no effective pathogen inactivating treatments available
- Epidemics of infections that may affect donor recruitment (swine flu, SARS, MERS-CV)

Risk for global supply of PDMPs following interruptions of US plasma supply ?

- Disasterous consequences for global supplies of PDMPs

Strategic Resource and Strategic Independence What to do ?

- Reduce supply dependency on one region/country
- Establish appropriate balance between domestic supply and importation
- Develop strategies which mitigate the risks of supply disruption (TTIs, shortages, markets, conflicts etc)
- Promote and support diverse plasma supply and product manufacture
- Establish 'demand management' plans
- Keep donor health and safety of equal importance as patient health and safety

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patients need your plasma

www.ipfa.nl



AMSTERDAM

14-15 JANUARY 2020
IPFA/EBA Workshop on
Plasma Collection

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Thank you for your attention