



EUROPEAN
BLOOD
ALLIANCE

The supply of plasma-derived medicinal products in the future of Europe

28/29
April 2022
Rome, Italy

ARE THERE ANY PERSPECTIVES AND STRATEGIES FOR A
COMMON POLICY FOR A EUROPEAN SELF-SUFFICIENCY
ON PLASMA-DERIVED MEDICINAL PRODUCTS?

Pierre Tiberghien
European Blood Alliance



EUROPEAN BLOOD ALLIANCE

Membership organisation

Representing Non-Profit Blood Services across Europe

25 members, 3 observers

President: Pierre Tiberghien (EFS)

Vice President: Daphne Thijssen (Sanquin)

Executive Director: Peter O'Leary

Medical Director: Dragoslav Domanovic

Members:



Observers:



17 million donations
Serving 470 million citizens





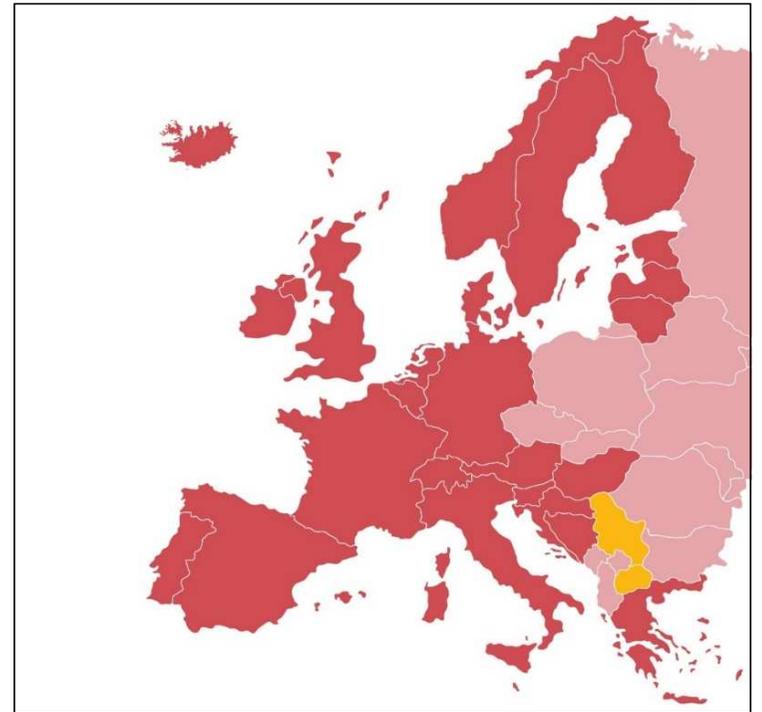
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Mission:

“To contribute to the **availability, quality, safety and cost-effectiveness** of the blood and tissue and cell supply for the citizens of Europe by developing and maintaining an efficient and strong collaboration amongst European blood and tissue and cell services”.

Core values:

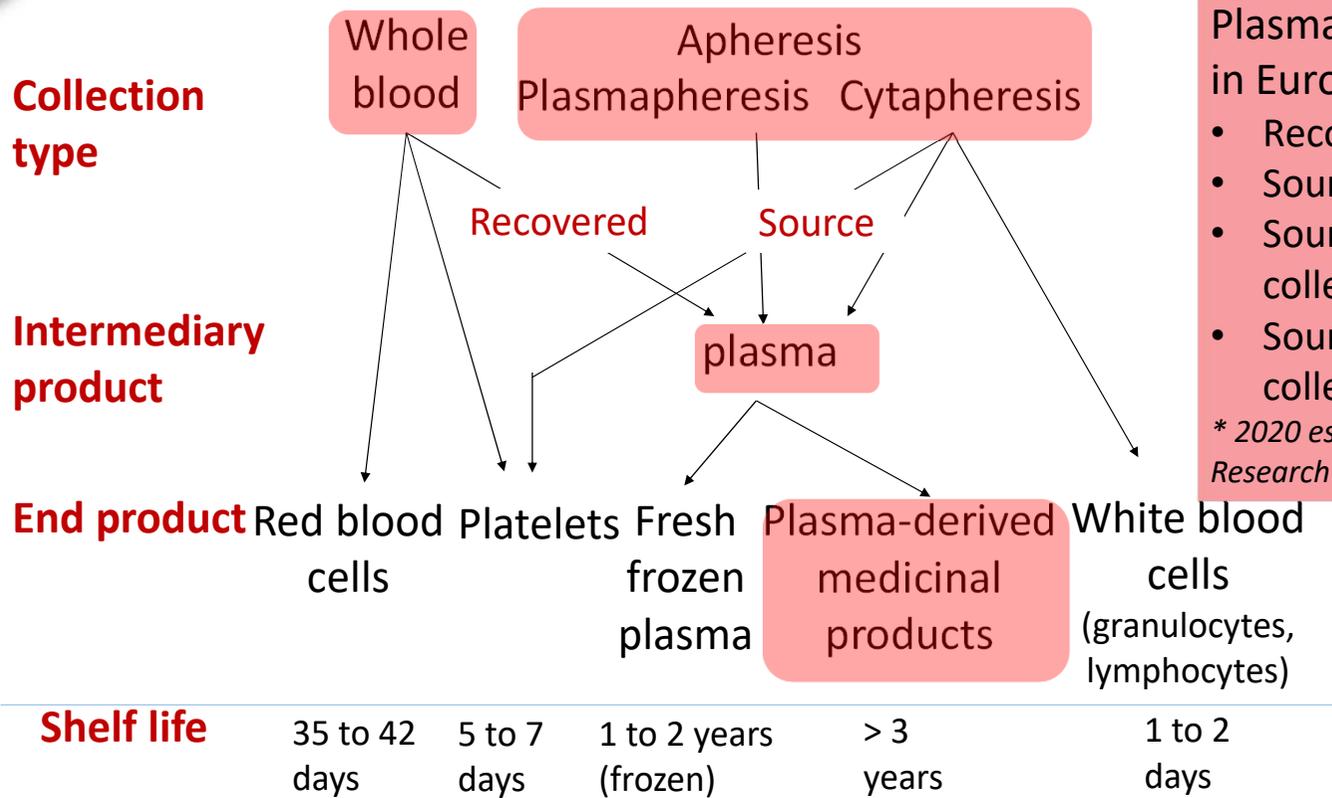
- Patient Care
- Donor Safety
- Voluntary Non-Remunerated Donation
- Openness through Information
- Sharing and Excellence through Evidence



Safe blood for Europe



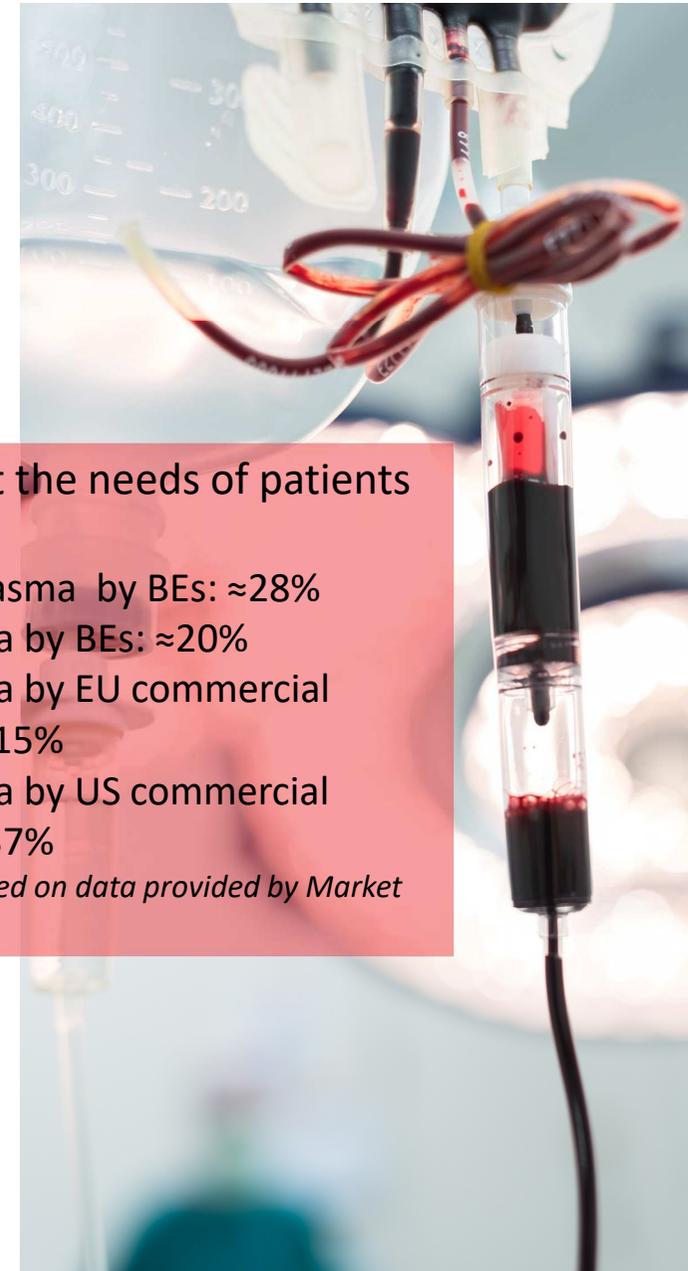
17 million blood donations, serving 470 million people



Plasma to meet the needs of patients in Europe*

- Recovered plasma by BEs: ≈28%
- Source plasma by BEs: ≈20%
- Source plasma by EU commercial collectors : ≈ 15%
- Source plasma by US commercial collectors: ≈ 37%

* 2020 estimates based on data provided by Market Research Bureau, Inc.





Collecting the plasma needed to meet the patients needs in Europe

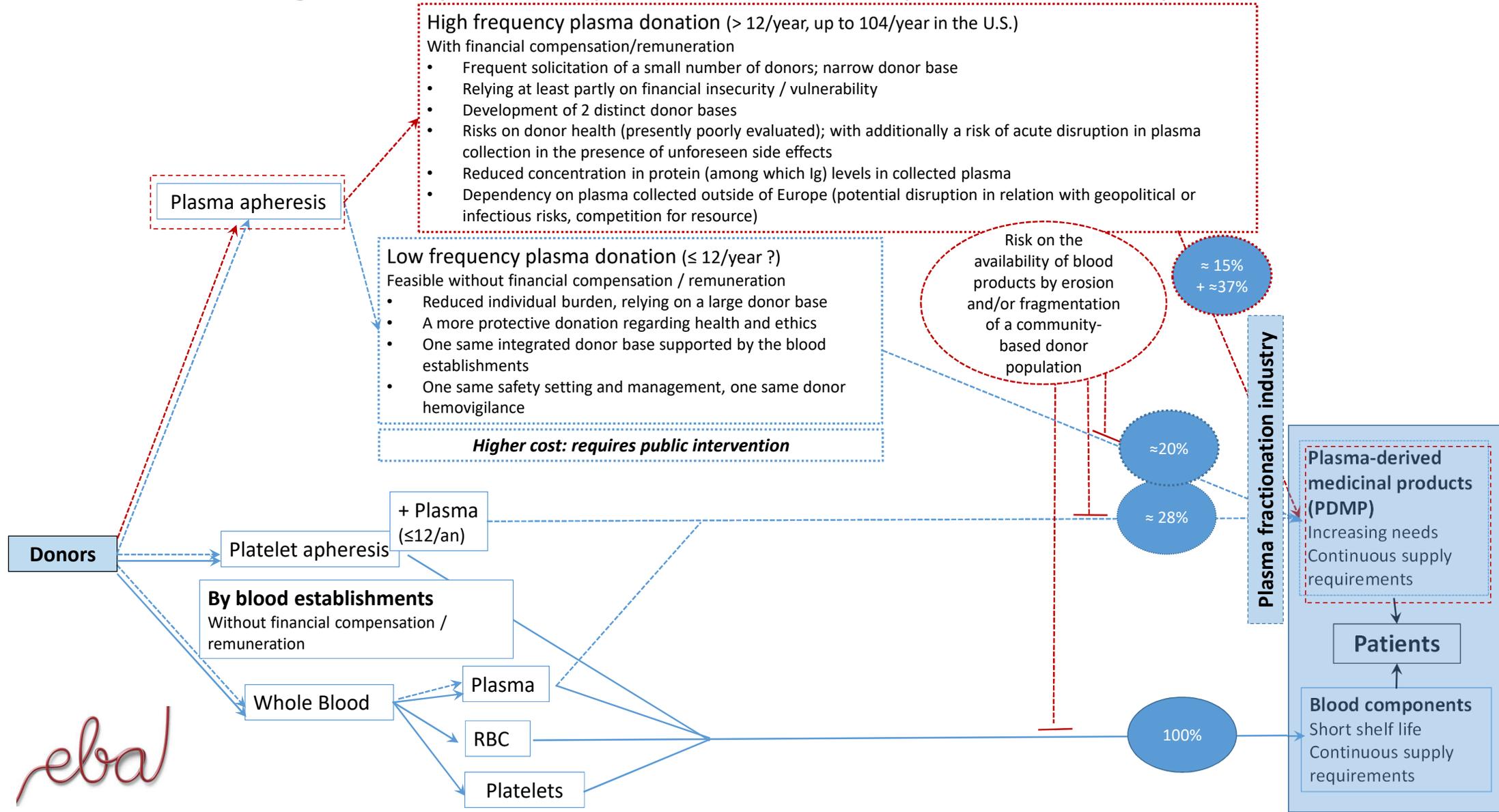
- Plasma is a **critical substance of human origin** that allows for the production of plasma-derived medicinal products (PDMPs), notably polyvalent immunoglobulins. Plasma therefore fits the definition of **a strategic resource**.
- By and large, **35 to 40% of current needs for PDMPs in Europe** depend on plasma collected outside of Europe, mostly in the United-States.
- Achieving the **highest level of human health protection today and tomorrow** is a public health objective enshrined in the law of the European Union (EU).
- **Reshoring the health manufacturing sites for health products** with the creation of a European ecosystem for health has become priority for the EU.



Collecting the plasma needed to meet the patients needs in Europe

- The **Covid-19 health crisis** has further underscored the need for greater European independence regarding supplies of medicines such as PDMPs
- Reaching a **sufficient level of self-sufficiency** in plasma for fractionation to ensure **European strategic independence** is a key factor in sustaining the long-term supply of PDMPs needed by patients in the Europe.
- Based on current immunoglobulin use in Europe, the need for apheresis (source) plasma may be estimated to be **≈ 20 litres (i.e. ≈ 28 apheresis)/1000 habitants/year**.
- **European not for profit blood establishments are fully committed to maintaining a supply of blood and plasma** to best meet the needs of European patients while enforcing safety and quality measures to protect both the patients and the donors.

Providing blood components and plasma-derived medicinal products to meet the patients needs



Increasing non-remunerated plasma collection by European blood establishments

- To ensure European strategic independence regarding PDMPs
- To reduce plasma donor burden
- To safeguard plasma donor safety
- To prevent a “competition for donor”- related risk on the supply of labile blood products in Europe

- Collection of plasma, a substance of human origin:
 - a public service responsibility
 - a service of general interest

Strengthening unpaid plasma collection capacity in Europe will improve overall sustainability and resilience regarding PDMPs availability and meeting patients’ needs.

The European Blood Alliance is committed to achieving this important public health objective.

Increase



Services of General Interest (SGI) as a tool for public support to plasma collection programs

- To ensure Eur
- To reduce pla
- To safeguard
- To prevent a

- Collection of
 - a public
 - a service

Strengthening

- **Economic activities** that public authorities identify as being of **particular importance to citizens**
- Would not be supplied (or would be supplied under different conditions) if there were no public intervention
- EU member countries classify as being of general interest and, therefore, subject to **specific public service obligations** and **eligible to Member state aid** in the form of **public service compensation**
- Provided either by the state or by the private sector.

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Services of General Interest (SGI) as a tool for public support to plasma collection programs

European Commission - Press release



COVID-19: Commission supports blood services to increase COVID-19 convalescent plasma collection

Brussels, 11 January 2021

- Action financed through the **Emergency Support Instrument**, for a total of **€36 million**
- In 14 Member States and the UK (over 150 blood establishments in total).
- Purchase of plasmapheresis machines and associated equipment, including collection kits, storage equipment, laboratory testing and characterization of plasma and organizational changes within blood centers.

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Tiberghien P. Increasing unpaid plasma collection by blood establishments to ensure availability of plasma-derived medicinal products and blood components in Europe. Transf Clin Biol, 2021
Tiberghien P, Frostin M, Thibaut JB, Meyer W, Rodriguez. Protecting blood donor health to meet the patient’s needs. Blood Transf, 2022

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Tiberghien P. Increasing unpaid plasma collection
Tiberghien P, Frostin M, Thibaut



EBA's commitment to increased plasma collection in Europe

- Benchmarking / promoting best practices
- Encouraging innovation (donor recruitment, collection technology, plasma center management)
- Communicating : social media, publications
- Interacting with DG Santé (EC), EDQM, Health authorities of Member States

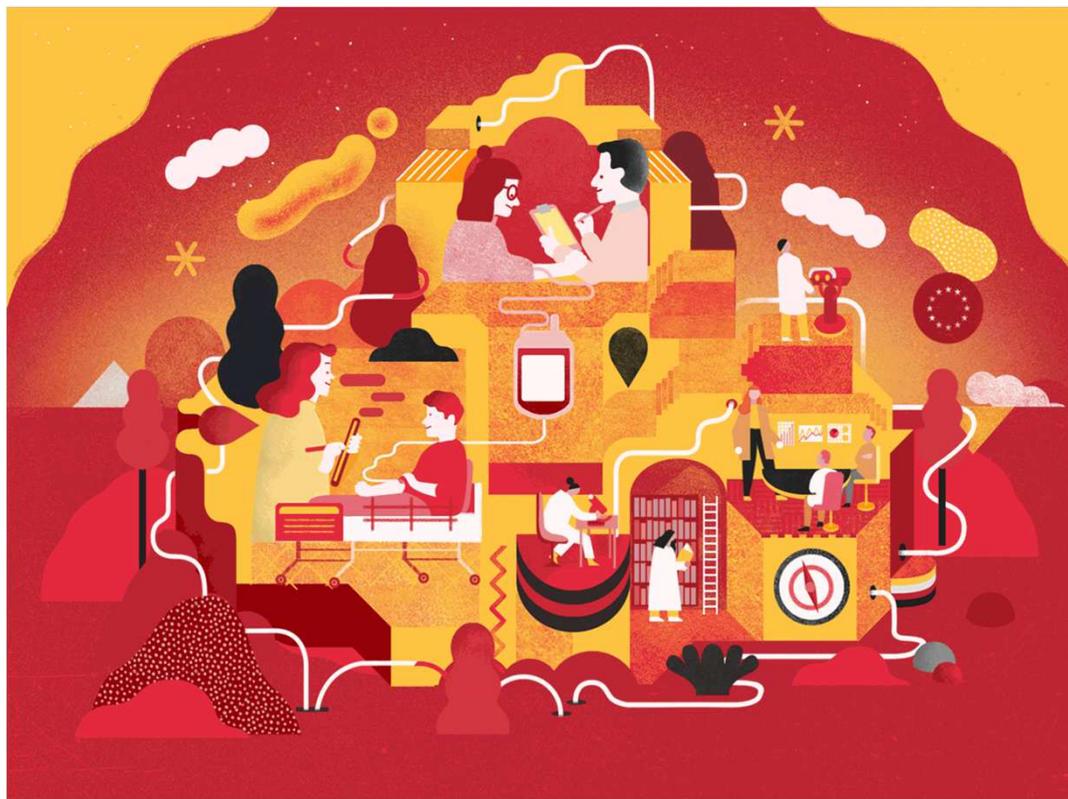
- EBA position papers and publications
- EBA internal webinars on all aspects of plasma collection
- IFPA / EBA conferences on plasma collection and supply (1/2020 and 4/2022, Amsterdam)
- SUPPLY project, a collaborative approach with IPFA, EHA, FIODS, Universities

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Thank you

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