Blood Banks and Plasma Centers:
Converging Strategies for Meeting Patient Needs

Chris Healey, Vice President Public Affairs, Grifols

GRIFOLS | 75 ANNIVERSARY

Innovators in addressing patient needs on a global scale.



SHAPING
AN INDUSTRY

José Antonio Grifols Lucas (right) and Dr. Edwin J. Cohn (left) attending the International Blood Transfusion Congress, 1951

The pioneers of bedside apheresis (José Antonio Grifols Lucas) and plasma fractionation (Dr. Edwin J. Cohn).

Consolidated and Vertically Integrated Industry

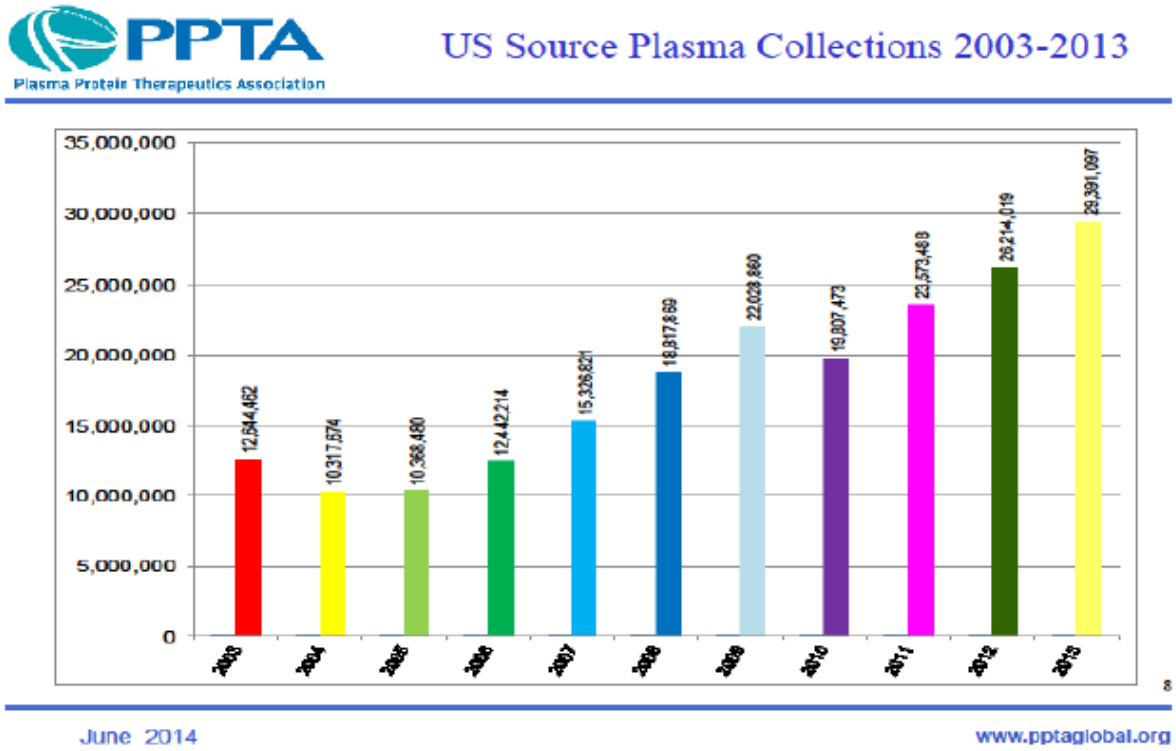
1985 - Principal Producers of Human Plasma Derivatives for the US Market		
Company	Location	Ownership
Alpha Therapuetics	California	Green Cross (Japan)
Armour	Illinois	Cannaught (Canada)
Connaught	Canada	Revlon (USA)
Cutter	North Carolina	Bayer (Germany)
Hyland	California	Baxter Travenol (USA)
Immuno	Michigan/Austria	Immuno (Austria)
Massachusetts State Lab	Massachusetts	State of Massachusetts
Michigan State Lab	Michigan	State of Michigan
New York Blood Center	New York	New York Blood Center
Swiss Red Cross	Switzerland	Swiss Red Cross
Netherlands Red Cross	Netherlands	Netherlands Red Cross
Source: Blood Policy and Technology, US Congress, Office of Technology Assessment (1985), Table 21.		

Sources of Plasma Worldwide

In 2014, 36.9 MM liters of plasma were fractionated worldwide

75% from plasmapheresis (85% from the US)

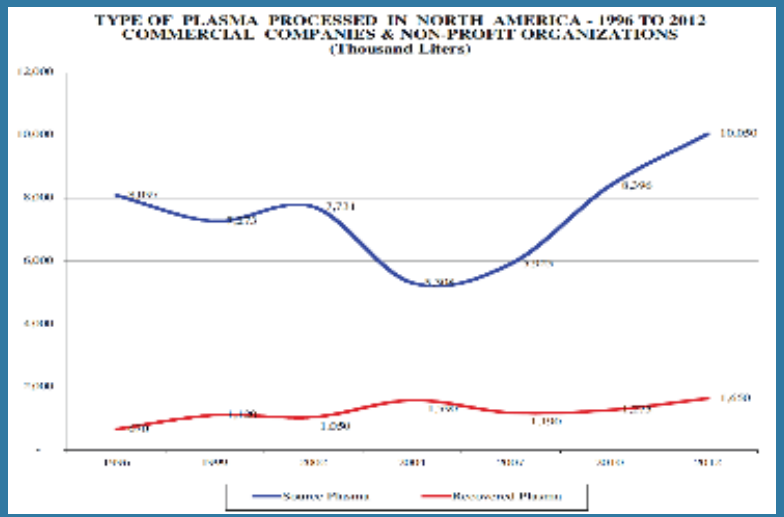
- 27.9 MM obtained by plasmapheresis
- 8.9 MM obtained by whole blood donations

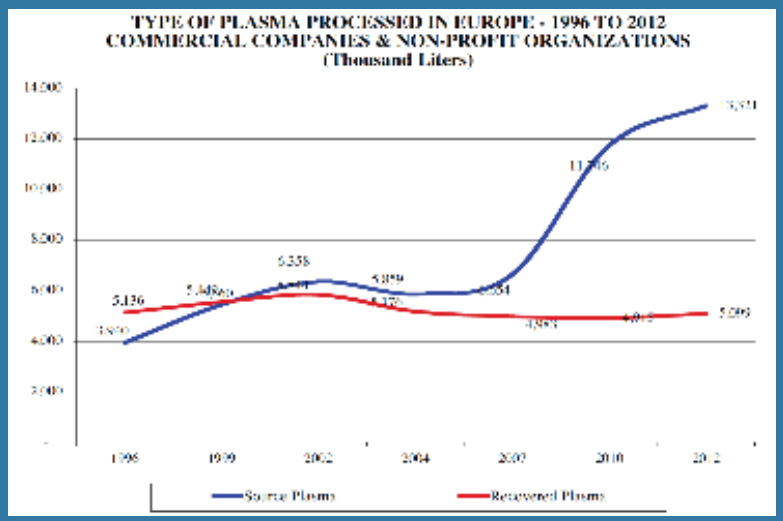


Changing dynamics in the sources of plasma for PDMP

- Dramatic increases in Source Plasma since the early 2000's
- Flat and recently declining availability of recovered plasma.

Do the labels we use benefit or harm patient access to PDMP?

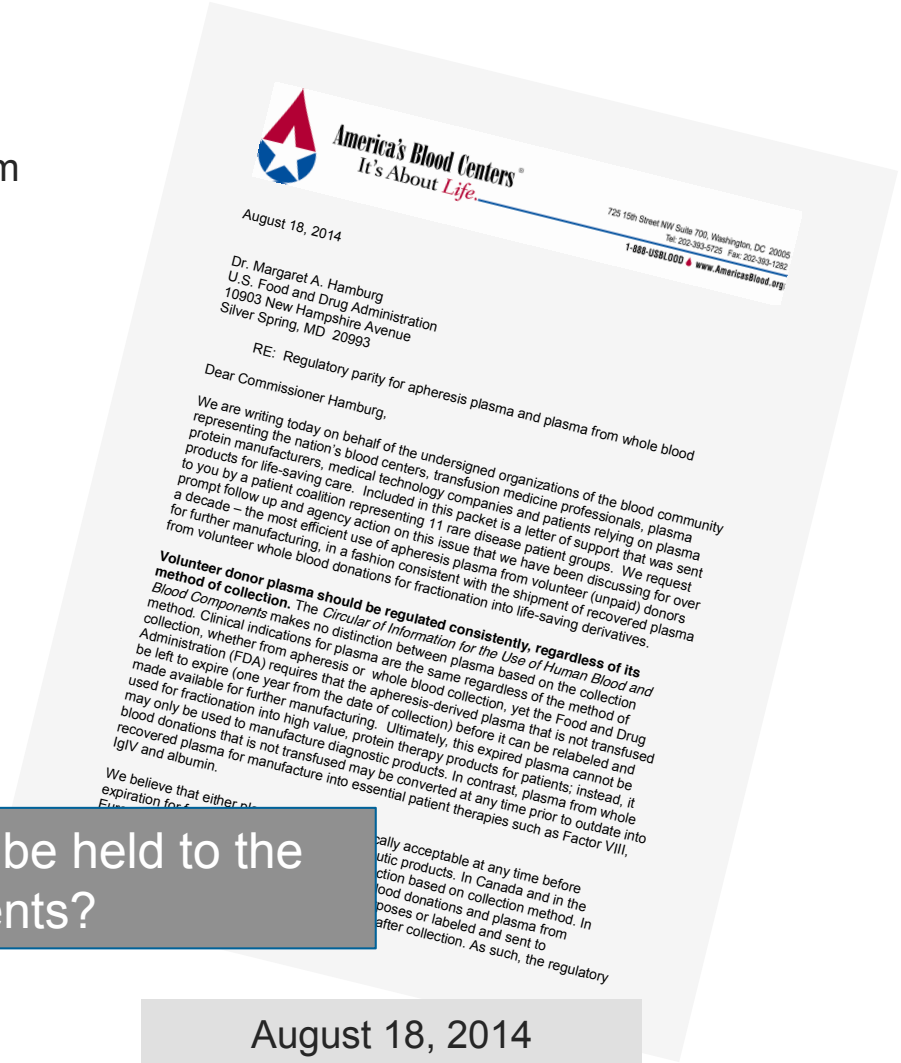




When is Source Plasma not Source Plasma? When it is *apheresis plasma*.

We request prompt follow up and agency action on this issue . . . the most efficient use of apheresis plasma from volunteer (unpaid) donors for further manufacturing . . . for fractionation into life-saving derivatives.

Volunteer donor plasma should be regulated consistently, regardless of its method of collection. The *Circular of Information for the Use of Human Blood and Blood Components* makes no distinction between plasma based on the collection method. Clinical indications for plasma are the same regardless of the method of collection, whether from apheresis or whole blood collection. . . .


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August 18, 2014

Dr. Margaret A. Hamburg
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Regulatory parity for apheresis plasma and plasma from whole blood

Dear Commissioner Hamburg,

We are writing today on behalf of the undersigned organizations of the blood community representing the nation's blood centers, transfusion medicine professionals, plasma protein manufacturers, medical technology companies and patients relying on plasma products for life-saving care. Included in this packet is a letter of support that was sent to you by a patient coalition representing 11 rare disease patient groups. We request prompt follow up and agency action on this issue that we have been discussing for over a decade – the most efficient use of apheresis plasma from volunteer (unpaid) donors for further manufacturing, in a fashion consistent with the shipment of recovered plasma from volunteer whole blood donations for fractionation into life-saving derivatives.

Volunteer donor plasma should be regulated consistently, regardless of its method of collection. The *Circular of Information for the Use of Human Blood and Blood Components* makes no distinction between plasma based on the collection method. Clinical indications for plasma are the same regardless of the collection, whether from apheresis or whole blood collection, yet the Food and Drug Administration (FDA) requires that the apheresis-derived plasma that is not transfused be left to expire (one year from the date of collection) before it can be relabeled and made available for further manufacturing. Ultimately, this expired plasma cannot be used for fractionation into high value, protein therapy products for patients; instead, it may only be used to manufacture diagnostic products. In contrast, plasma from whole blood donations that is not transfused may be converted at any time prior to outdate into recovered plasma for manufacture into essential patient therapies such as Factor VIII, IgIV and albumin.

We believe that either pl
expiration for f
cally acceptable at any time before
utic products. In Canada and in the
ction based on collection method. In
lood donations and plasma from
poses or labeled and sent to
after collection. As such, the regulatory

August 18, 2014

Shouldn't all plasma for PDMP be held to the same standards and requirements?

Threats to Patient Access and Treatment



World Health Organization

The Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation

This declaration on 'Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation (VNRD)'[1] is founded on the policies articulated in numerous global and regional resolutions of the World Health Organization (WHO) (1–7), and other international organizations (8–13) which recommend voluntary non-remunerated donations as the foundation of a safe and adequate supply of blood and blood products and affirm the achievement of self-sufficiency in safe blood and blood products[2] based on VNRD as an important national policy direction for ensuring a safe, secure and sufficient supply of blood and blood products (blood components for transfusion and plasma-derived medicinal products) for patient care.

World Health Assembly resolution WHA63.12: *Availability, Safety and Quality of Blood Products* (2010) urges WHO Member States 'to take all the necessary steps to establish, implement and support nationally coordinated, efficiently managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency. Self-sufficiency in safe blood and blood products based on VNRD means that the national needs of patients for these products, as assessed within the framework of the national health system, are met in a timely manner, that patients have equitable access to transfusion services and blood products and that these products are obtained from voluntary non-remunerated donations of national, and where needed, of regional origin, such as from neighbouring countries (7).

We, being 153 representatives of ministries of health, national blood programmes, national blood transfusion services, national public health agencies, national regulatory bodies, national plasma fractionation institutes; representatives of international, intergovernmental and nongovernmental organizations, and experts in transfusion medicine from 51 countries from all WHO regions participated in the WHO High-level Policy Makers Forum on Achieving Self-sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation, held on 8–9 October 2013 in Rome, Italy[3]. This Forum was organized jointly by the World Health Organization, the Ministry of Health, Italy, and the Ministry of Health, Labour and Welfare, Japan, in collaboration with the Council of Europe, European Commission, International Federation of Red Cross and Red Crescent Societies, International Society of Blood Transfusion, International Federation of Blood Donor Organizations and European Blood Alliance. At the Forum, we endorse the following:

Recognizing that meeting the clinical needs of patients for safe blood and blood products is of paramount importance, and that it is the responsibility of national health authorities to meet these needs through moving towards self-sufficiency, based on VNRD;

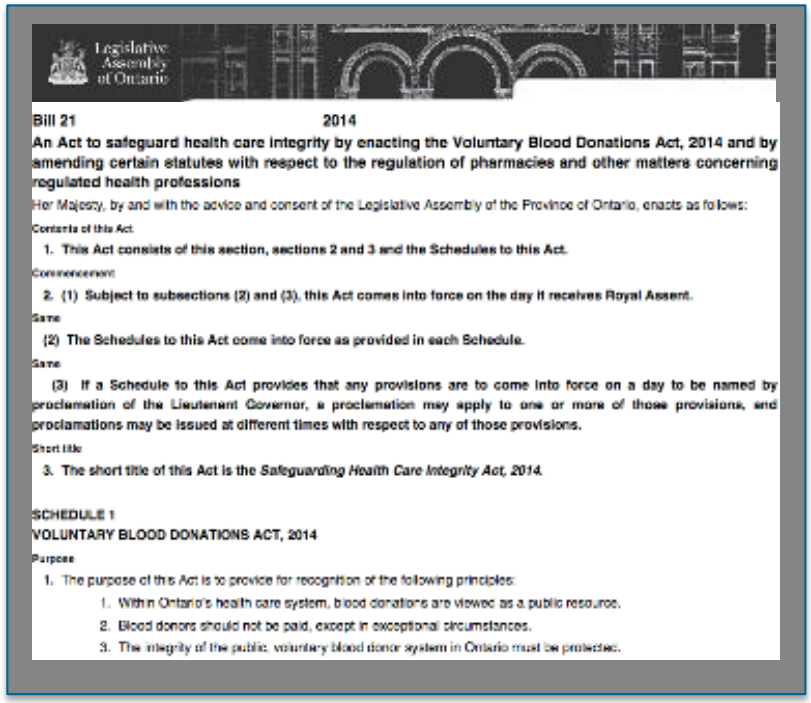
Affirming that measures to promote donor health and safety, equitable and timely access to safe blood and blood products of assured quality and efficacy from VNRD and the appropriate use of such products are essential for quality and safe health service provision and to meet the clinical needs of patients as part of universal health coverage;

1

[1] Voluntary non-remunerated donation in this context includes the donation of blood, plasma and other blood components.
[2] Blood products are defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products.
[3] http://www.who.int/bloodsafety

ROME DECLARATION ON SELF SUFFICIENCY

Ontario Prohibits Paid Donation



Legislative Assembly of Ontario

Bill 21 **2014**

An Act to safeguard health care integrity by enacting the Voluntary Blood Donations Act, 2014 and by amending certain statutes with respect to the regulation of pharmacies and other matters concerning regulated health professions

Her Majesty, by and with the advice and consent of the Legislative Assembly of the Province of Ontario, enacts as follows:

Contents of this Act

1. This Act consists of this section, sections 2 and 3 and the Schedules to this Act.

Commencement

2. (1) Subject to subsections (2) and (3), this Act comes into force on the day it receives Royal Assent.

Same

(2) The Schedules to this Act come into force as provided in each Schedule.

Same

(3) If a Schedule to this Act provides that any provisions are to come into force on a day to be named by proclamation of the Lieutenant Governor, a proclamation may apply to one or more of those provisions, and proclamations may be issued at different times with respect to any of those provisions.

Short title

3. The short title of this Act is the *Safeguarding Health Care Integrity Act, 2014*.

SCHEDULE 1
VOLUNTARY BLOOD DONATIONS ACT, 2014

Purpose

1. The purpose of this Act is to provide for recognition of the following principles:
   1. Within Ontario's health care system, blood donations are viewed as a public resource.
   2. Blood donors should not be paid, except in exceptional circumstances.
   3. The integrity of the public, voluntary blood donor system in Ontario must be protected.

Whose interests are at work here?

GRIFOLS 75 ANNIVERSARY

The Voice of the Patient Community is Clear



Compensation for Plasma Donation in Ontario: A CAUTIONARY TALE



PLUS
AMERICAN PLASMA USERS COALITION

June 2, 2014

Dr. Margaret Chan
Director General
World Health Organization
Geneva, Switzerland
chanm@who.int

Subject: Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation

Dear Dr. Chan,

The American Plasma Users Coalition (APLUS) is a coalition of national patient organizations created to address the unique needs of patients with rare diseases that use life-saving plasma protein therapies. Together our coalition represents more than 125,000 Americans living with chronic disorders who depend upon plasma protein therapies to lead healthy, productive lives.

We are writing to express concerns regarding the Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation. We also stand in support of statements by our counterpart, the Platform of Plasma Protein Users (PLUS), in PLUS's letter dated May 21, 2014.

We agree with PLUS that the Rome Declaration recommendations may seriously and adversely impact access to treatments for patients relying on life-saving and life-enhancing plasma derived medicinal products, several of which are classified by WHO as essential medicines both for adults and children.

In the United States there is no policy restricting remunerated voluntary donations of plasma. The majority of safe and effective plasma derived medicinal products are produced from plasma obtained through apheresis of remunerated plasma donors. There is no evidence that remunerated plasma donations have increased safety risks for patients in the United States. Rather, there is a robust and safe supply of plasma products for the ever-increasing demand for such products to treat various rare and chronic disorders.

While we support the importance of voluntary blood and plasma donation for labile products, we believe that if recommendations in the Rome Declaration are implemented, there will be a serious decline in the supply of plasma-derived medicinal products, which will leave patients who need life-saving plasma treatments at severe risk of not having access to their treatments. On several occasions we have indicated our support for the importance of and necessary coexistence of both voluntary and remunerated systems as essential.[abc]

According to estimates of the Market Research Bureau, in 2010, 32.8 million liters of plasma (recovered and apheresis) will be collected worldwide. Of this amount, 20.4 million liters (62%) will be collected in North America;[d] the vast majority of this amount is collected in the United States. Plasma derivatives made from United States source and recovered plasma are essential if we are to meet patient needs globally. Without these products, there will be a global shortage

1 | Page

The HIV crisis of the 1980's has taught us all that the patient voice is essential in policy-making.

Treatment Gap for Patients in Need

75% of people with bleeding disorders still receive very inadequate treatment or no treatment at all. The percentage is even higher for those with von Willebrand disease and rare factor deficiencies.

Of the estimated 100,000 people with Alpha-1 in the U.S., 90% don't know they have it.

IDF conducted a national internet survey in 2010, which showed that less than half (46%) of patients with PIDD who have a diagnosis which IG is the recommended therapy are being treated with any form of IG.

PDMP Growth Drivers – Unmet Patient Need

We have only scratched the surface of potential therapeutic uses from proteins found in human plasma.

- More than 1,000 proteins have been identified in human plasma
- Only 20 of those identified currently have therapeutic application
- From that, only 4 proteins account for more than 70% of patient use
- 200 therapeutic uses have been identified for PDMP

An inadequate supply of plasma that meets internationally recognized standards for fractionation is considered to be one of the major factors limiting the global availability of plasma-derived medicinal products. *" - WHO, Towards Self-Sufficiency in Safe Blood Products based on Voluntary Non-Renumerated Donation, Global Status 2013*

An Evolution in the Relationship Between the Blood and Plasma Sectors

A relatively peaceful co-existence for more than 40 years.

Numbers of plasma centers and blood centers in select US cities.

Location (City, State)	Number of Plasma Donation Centers	Number of Blood Donation Centers
Phoenix, AZ	3	2
Dallas, TX	5	4
El Paso, TX	6	5
Milwaukee, WI	3	3
Indianapolis, IN	5	3
San Diego, CA	2	3
Salt Lake City, UT	4	3
Fayetteville, NC	3	2
Moorhead, MN, and Fargo, ND	3	4
Orlando, FL	3	7
Colorado Springs, CO	2	4
Cleveland, OH	3	1

Given the changing supply dynamics for blood and recovered plasma – how will the relationship between blood banks and plasma centers change?

Shared approaches on ensuring blood and plasma supply









Addressing Challenges Going Forward

Shedding old stereotypes and biases



Blood Plasma, Sweat, and Tears

When cobbling together a livable income, many of America's poorest people rely on the stipends they receive for donating plasma.

Accommodating changing market dynamics

CALVARY
NOW PLAYING
GET TICKETS

The New York Times | http://nyti.ms/1mx3JhG

BUSINESS DAY | NYT NOW

Blood Industry Shrinks as Transfusions Decline

By MATTHEW L. WALD AUG. 22, 2014

Changes in medicine have eliminated the need for millions of blood transfusions, which is good news for patients getting procedures like coronary bypasses and other procedures that once required a lot of blood.

But the trend is wreaking havoc in the blood bank business, forcing a wave of mergers and job cutbacks unlike anything the industry, which became large scale after World War II, has ever seen.

Transfusions are down almost one-third over the last five years, to about 11 million units last year from about 15 million units, according to the American Red Cross, which has about 40 percent of the market. With "minimally invasive" techniques like laparoscopic surgery and other shifts in medicine, demand for blood continues to drop despite population growth and a soaring number of people over 65, who have the most surgeries requiring blood.

Blood bank revenue is falling, and the decline may reach $1.5 billion a year this year from a high of $5 billion in 2008.

As fewer units of blood are used, hospitals, seeing strong supply and weak demand, are asking for a lower price per unit.

As a result, the blood bank business has already lost some jobs, and the losses will reach as high as 12,000 within the next three to five years, roughly a quarter of the total in the industry, according to the Red Cross. Officials there expressed some concern that the decline could reduce the system's ability to respond to crises or to invest in new products or research.

From time to time since 2008, the Red Cross operated at a deficit. But it balanced its budget partly by cutting 1,500 jobs. Shaun Gilmore, president of Biomedical Services at the American Red Cross, said the organization was also looking to give up some real estate as it shrinks its operations to an appropriate size.

End

Converging Strategies for Meeting Patient Needs

Mark W. Skinner JD
IPFA / BCA Symposium – Future for Blood and Plasma Donation
28 September 2015
Dallas, Texas

Skinner IPA Ltd. 2015

APLUS, PLUS – Globally Connected

- **The American Plasma Users Coalition** (APLUS) is a coalition of national patient organizations created to address the unique needs of patients with rare diseases that use life-saving plasma protein therapies. Together our coalition represents more than 125,000 Americans living with chronic disorders who depend upon plasma protein therapies to lead healthy, productive lives.
- **The Platform of Plasma Protein Users** (PLUS) is a consortium of 7 patient organizations representing people living with treatable rare plasma related disorders such as haemophilia, primary immunodeficiencies and alpha1 anti-trypsin deficiency among others. Together these organizations they represent the views of more than 110,000 people living with treatable rare plasma related disorders in Europe.

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PLUS Consensus Statements



The International Journal of Transfusion Medicine
Vox Sanguinis

REPORT

The Dublin Consensus Statement on vital issues relating to the collection of blood and plasma and the manufacture of plasma products

B. O. Mahony[1] & A. Turner[2]

[1]Irish Haemophilia Society, Steering Group PL
[2]National Blood Authority, Canberra, Australi

Vox Sanguinis

Received: 14 January 2010,
accepted 14 January 2010

The requirement for plasma produc
both source and recovered plasma
many medical conditions is projecte
tially in the course of the next 5 year
tions representing many thousands
disorders who are dependant on p
from plasma formed a coalition of p
2009. PLUS represents the concerted
sations, the International Patients Or
Immunodeficiency (IPOPI), the Worl
philia (WFH), the European Haemoph
Alfa Europe, Idiopathic Thrombocy
port Organisation (ITP), Hereditary
tional (HAE) and Guillain Barre
International (GBS/CIDP).

Over the last thirty years, the ma
of an increasing range of stable cli
availability of plasmapheresis collect
to the development of a commerc
plasma-only donations from remune
tries that do not permit a remun
plasma collections are limited to th
establishments operating with non-
The growing global requirement
plasma products [1] to meet the he
mean that plasma from both the c
the blood sectors are essential to

Correspondence: Brian O. Mahony Chief Exec
Society Steering Group PLUS, Cathedral Cour
8, Ireland
E-mail: brian@haemophilia.ie

VoxSanguinis

The International Journal of Transfusion Medicine

ISBT International Society of Blood Transfusion

REPORT

The Dublin Consensus St
relating to the collectio
and plasma-derived mec

B. O'Mahony[1] & A. Turner[2]

[1]Chief Executive, Irish Haemophilia Society, Steering Group
[2]Chief Executive, National Blood Authority, Canberra, Austr

Vox Sanguinis

Received: 7 June 2011,
accepted 10 June 2011

Following a conference in Dublin in 2010, a
statement was published in this journal (1).
2011, a follow-up conference was convened
under the auspices of the plasma users coalitio
further consider the statement produced in Dubl
The goal was to negotiate a revised set of princi
could be potentially accepted by most stakehold
ing global patient, donors, manufacturing and p
ganisations. PLUS was eager to continue the c
dialogue that commenced between key stake
2010.

PLUS represents the concerted views of ser
organisations, whose members are dependent o
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is to help encourage the production of a sufficier
safe and effective plasma-derived medicina
(PDMPs) to meet the global needs of patients. B
ing that the collection systems for blood comp
PDMPs are interrelated in a number of cou
meeting considered the collection of both blood
and the manufacture of PDMPs from both the in
not for profit sectors, and the views of nati
authorities, patient and donor organisations.

The meeting was attended by the followi
representing organisations as follows:
PLUS members: Brian O'Mahony (Convenor)
Haemophilia Consortium (EHC) and Irish H
Society, David Watters-IPOPI, Larry Warn
Prevot-IPOPI, Uwe Schlenkrich-EHC, David P.

Correspondence: Brian O'Mahony, Irish Haemophilia Society
Group PLUS, Cathedral Court, New Street South, Dublin 8, Ir
E-mail: brian@haemophilia.ie

INTERNATIONAL FORUM

The Dublin Consensus Statement 2012 on optimised supply of plasma-derived medicinal products

Brian O'Mahony

Irish Haemophilia Society, Steering Group PLUS, Dublin, Ireland

Following previous consensus conferences in Dublin in 2010 and 2011, consensus statements were published[1,2] on vital issues relating to the collection and provision of blood components and plasma-derived medicinal products. Following the publication of the statement from the 2011 conference, it was agreed by participants that the focus of the next consensus conference should be on optimisation of the supply of plasma-derived medicinal products. In January 2012 a further conference was convened in Dublin under the auspices of the plasma users coalition (PLUS) to discuss the relevant issues relating to optimising the supply of plasma-derived medicinal products and to see whether a consensus could be achieved with regard to recommendations to be made to assist in achieving this objective which could be potentially accepted by most stakeholders including global patients, donors, manufacturing and provider organisations. PLUS was eager to continue the constructive dialogue that had taken place between key stakeholders in 2010 and 2011.

PLUS represents the concerted views of seven patients' organisations, whose members are dependent on products manufactured from plasma. The goal of PLUS in this work is to help encourage the production of a sufficient supply of safe and effective plasma-derived medicinal products to meet the global needs of patients. Recognising that the collection systems for blood components and plasma-derived medicinal products are interrelated in a number of countries, this meeting considered the strategic considerations relating to the supply of plasma-derived medicinal products globally, the manufacture of plasma-derived medicinal products by both industry and the not-for-profit sectors, and the views of national blood authorities and patient and donor organisations.

The meeting was attended by the following persons representing organisations as follows:

- PLUS members: Brian O'Mahony (Convenor), European Haemophilia Consortium (EHC) and Irish Haemophilia Society; Larry Warren and Johan Prevot, International Patients Organisation for Primary Immunodeficiency (IPOPI); David Page, World Federation of Hemophilia (WFH);
- *Other participants*: Mark Skinner, A-PLUS and WFH; Charles Waller and Albert Farrugia, Plasma Proteins Therapeutics Association (PPTA); Robert Perry and Theo Evers, International Plasma Fractionation Association (IPFA); Roger Dodd, International Society of Blood Transfusion (ISBT); Karin Magnussen, International Federation of Blood Donor Organizations (IFBDO); Jim MacPherson, America's Blood Centers (ABC); Gilles Folléa, European Blood Alliance (EBA); Mark Weinstein, Food and Drug Administration (FDA); Ian Mumford, Canadian Blood Services (CBS); Paul Strengers, Sanquin; Cees van der Poel and Joan O Riordan, European Directorate for the Quality of Medicines and Healthcare (EDQM); Patrick Robert, Market Research Bureau and William Murphy, Health Service Executive, Ireland who chaired the discussion. The representatives from EDQM and FDA attended as observers and were not requested to consider endorsing the resulting statement.

A number of other organisations were invited to send representatives, including the World Health Organization, Thalassemia International Federation and the International Federation of Red Cross and Red Crescent Societies but were unable to attend due to other commitments.

The Dublin Consensus 2012 statement was agreed by all the participants present as being suitable for submission to their organisations for consideration and possible endorsement.

As of September 1st, 2012, the Dublin Consensus Statement 2012 had been fully endorsed by the following organisations: PLUS member organisations*, the A-PLUS (American Plasma Users coalition)†, the Network of Rare Blood Disorder Organisations (Canada)‡, the International

*PLUS members comprise the International Patients Organisation for Primary Immunodeficiency (IPOPI), the World Federation of Hemophilia (WFH), the European Haemophilia Consortium (EHC), Alfa Europe, Idiopathic Thrombocytopenic Purpura Support Organisation (ITP), Hereditary Angiodema International (HAEI), and Guillain–Barre Syndrome Foundation International (GBS/CIDP).
†The American Plasma Users coalition comprises the following organisations: the Alpha 1 Association, Alpha 1 Foundation GBS/CIDP Foundation International, Committee of Ten Thousand, Hemophilia Federation of America, Immune Deficiency Foundation, Jeffrey Modell Foundation, National Hemophilia Foundation, Platelet Disorder Support Association, and Patient Services Incorporated.
‡Network of Rare Blood Disorder Organisations, Canada - Answering TTP (Thrombotic Thrombocytopenic Purpura), Aplastic Anemia and Myelodysplasia Association of Canada (AAMAC), Canadian Association of Paroxysmal Nocturnal Hemoglobinuria (PNH), Canadian Hemophilia Society (CHS), Canadian Hereditary Angioedema Network (CHAEN), Canadian Immunodeficiencies Patient Organization (CIPO), Canadian Organization for Rare Disorders (CORD), Canadian Association for Porphyria (CAP), Quebec Sickle Cell Anemia Association (QSA), Sickle Cell Association of Ontario (SCAO), Sickle Cell Disease Parents' Support Group of Ottawa (SCDPSC), and the Thalassemia Foundation of Canada (TCF).

Blood Transfus 2013; 11: 623-6 DOI 10.2450/2013.0044-13
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- Endorsed by 29 Patient Organizations whose members rely upon plasma derived medicinal prodcuts
- Endorsed or supported in principle by:
  - IPFA (2010,2011,2012)
  - EBA (2010,2011,2012
  - ISBT (2010,2011,2012)
  - PPTA (2010,2011,2012)
  - FIODS (2011,2012)
  - Attended by FDA, EMA, WHO

PLUS Consensus Statements

Consensus 2010

- "Plasma products made from both non – remunerated and remunerated donations are currently essential to meet global health needs."
- "Activities undertaken to collect or promote adequate supplies of blood products should take into account the ability of those who collect plasma for fractionation to meet the requirements of patients who rely on these therapies."
- "The needs of patients should determine the optimal collection of blood and plasma."

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PLUS Consensus Statements

Consensus 2011

- "Provide an adequate supply of PDMPs from recovered and source plasma to meet patient needs on a global level"
  - do not seek to ban or stigmatise 1 supply
- "An insufficient supply is a major risk to patients"
- "All donations should be voluntary"
  - replacement donors
  - payment or time off work – both voluntary
- "Organisations involved in blood and plasma collection should co-operate with the goal of ensuring the health of the donor and potential blood component and PDMP recipients."

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Component Plasma



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1-888-USBLOOD www.AmericasBlood.org

August 18, 2014

Dr. Margaret A. Hamburg
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Regulatory parity for apheresis plasma and plasma from whole blood

Dear Commissioner Ham

We are writing today on b
representing the nation's
protein manufacturers, m
products for life-saving ca
to you by a patient coalitio
prompt follow up and age
a decade – the most effic
for further manufacturing,
from volunteer whole bloo

**Volunteer donor plasma
method of collection.** Th
Blood Components make
method. Clinical indicatio
collection, whether from a
Administration (FDA) requ
be left to expire (one year
made available for further
used for fractionation into
may only be used to man
blood donations that is no
recovered plasma for ma
IgIV and albumin.

We believe that either pla
expiration for further man
European Union, the regu
these countries, plasma c
apheresis can be used ei
fractionators for further m

Sincerely,

Christine A. Gundlach
Chief Executive Officer

Miriam A. Markowitz
Chief Executive Officer

J. Chris Hrouda
Executive Vice President

Jan M. Bull
President and CEO

Robert Perry

Stephen J. Ubl
President and CEO

America's Blood Centers
It's About Life.

AABB

American Red Cross

PPTA

IPFA

AdvaMed

cc: Jay Epstein, MD
Director, Office of Blood Research & Review

Karen Midthun, M.D.
Director, Center for Biologics Evaluation and Research

Richard Denny, MD
Director, Division of Blood Components and Devices

PLUS

August 18, 2014

Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Regulatory parity for apheresis plasma and plasma from whole blood

Dear Commissioner Hamburg,

The American Plasma Users Coalition

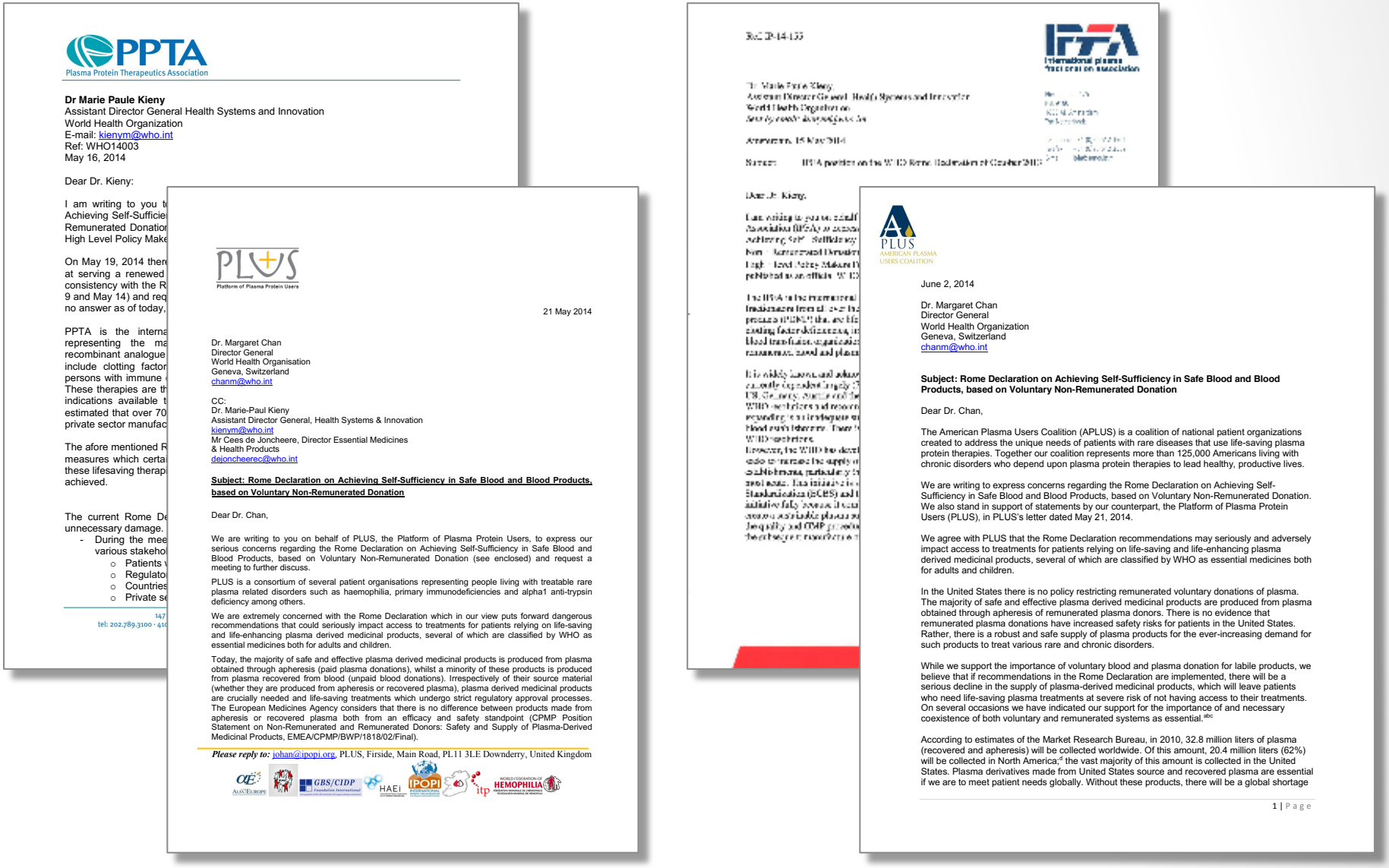
For these reasons, APLUS supports the blood community's collective appeal to the FDA and the issuance of a regulatory pathway or guidance document that allows flexibility for blood centers in labeling apheresis plasma similar to recovered plasma for further manufacture into plasma protein therapies. Please contact Larry LaVoie larry.lavoie@aplus.org if you have any questions.

Sincerely,

Alpha-1 Foundation
Coalition for Transparent
GRIFOLS Foundation (International)
Hemophilia Federation of America
Immune Deficiency Foundation
Jeffrey Modell Foundation
National Hemophilia Foundation
Patient Services Incorporated
Plasma Protein Therapeutics Association
US Hereditary Angioedema Association

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Rome Declaration



PPTA
Plasma Protein Therapeutics Association

Dr Marie Paule Kieny
Assistant Director General Health Systems and Innovation
World Health Organization
E-mail: kienym@who.int
Ref: WHO14003
May 16, 2014

Dear Dr. Kieny:

I am writing to you t
Achieving Self-Sufficie
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tel: 202.789.3100 · 41

PLUS
Platform of Plasma Protein Users

21 May 2014

Dr. Margaret Chan
Director General
World Health Organisation
Geneva, Switzerland
chanm@who.int

CC:
Dr. Marie-Paul Kieny
Assistant Director General, Health Systems & Innovation
kienym@who.int
Mr Cees de Joncheere, Director Essential Medicines
& Health Products
dejoncheerec@who.int

Subject: Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation

Dear Dr. Chan,

We are writing to you on behalf of PLUS, the Platform of Plasma Protein Users, to express our serious concerns regarding the Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation (see enclosed) and request a meeting to further discuss.

PLUS is a consortium of several patient organisations representing people living with treatable rare plasma related disorders such as haemophilia, primary immunodeficiencies and alpha1 anti-trypsin deficiency among others.

We are extremely concerned with the Rome Declaration which in our view puts forward dangerous recommendations that could seriously impact access to treatments for patients relying on life-saving and life-enhancing plasma derived medicinal products, several of which are classified by WHO as essential medicines both for adults and children.

Today, the majority of safe and effective plasma derived medicinal products is produced from plasma obtained through apheresis (paid plasma donations), whilst a minority of these products is produced from plasma recovered from blood (unpaid blood donations). Irrespectively of their source material (whether they are produced from apheresis or recovered plasma), plasma derived medicinal products are crucially needed and life-saving treatments which undergo strict regulatory approval processes. The European Medicines Agency considers that there is no difference between products made from apheresis or recovered plasma both from an efficacy and safety standpoint (CPMP Position Statement on Non-Remunerated and Remunerated Donors: Safety and Supply of Plasma-Derived Medicinal Products, EMEA/CPMP/BWP/1818/02/Final).

Please reply to: johan@ipopi.org, PLUS, Firside, Main Road, PL11 3LE Downderry, United Kingdom

IPFA
International plasma fractionation association

Ref: 14-133

Dear Dr. Kieny,

PLUS
AMERICAN PLASMA USERS COALITION

June 2, 2014

Dr. Margaret Chan
Director General
World Health Organization
Geneva, Switzerland
chanm@who.int

Subject: Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation

Dear Dr. Chan,

The American Plasma Users Coalition (APLUS) is a coalition of national patient organizations created to address the unique needs of patients with rare diseases that use life-saving plasma protein therapies. Together our coalition represents more than 125,000 Americans living with chronic disorders who depend upon plasma protein therapies to lead healthy, productive lives.

We are writing to express concerns regarding the Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation. We also stand in support of statements by our counterpart, the Platform of Plasma Protein Users (PLUS), in PLUS's letter dated May 21, 2014.

We agree with PLUS that the Rome Declaration recommendations may seriously and adversely impact access to treatments for patients relying on life-saving and life-enhancing plasma derived medicinal products, several of which are classified by WHO as essential medicines both for adults and children.

In the United States there is no policy restricting remunerated voluntary donations of plasma. The majority of safe and effective plasma derived medicinal products are produced from plasma obtained through apheresis of remunerated plasma donors. There is no evidence that remunerated plasma donations have increased safety risks for patients in the United States. Rather, there is a robust and safe supply of plasma products for the ever-increasing demand for such products to treat various rare and chronic disorders.

While we support the importance of voluntary blood and plasma donation for labile products, we believe that if recommendations in the Rome Declaration are implemented, there will be a serious decline in the supply of plasma-derived medicinal products, which will leave patients who need life-saving plasma treatments at severe risk of not having access to their treatments. On several occasions we have indicated our support for the importance of and necessary coexistence of both voluntary and remunerated systems as essential.[abc]

According to estimates of the Market Research Bureau, in 2010, 32.8 million liters of plasma (recovered and apheresis) will be collected worldwide. Of this amount, 20.4 million liters (62%) will be collected in North America;[d] the vast majority of this amount is collected in the United States. Plasma derivatives made from United States source and recovered plasma are essential if we are to meet patient needs globally. Without these products, there will be a global shortage

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Building together upon shared goals

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Working toward a common future

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