

June 30, 2010

Reference No.: FASC10025

Gene Dodaro
Acting Comptroller General
Attention: Board of Governors of the Patient-Centered Outcomes Research Institute
441 G Street, NW
Washington, DC 20548

RE: Nominations to the Board of Governors of the Patient-Centered Outcomes Research Institute

Dear Mr. Dodaro:

On behalf of the Plasma Protein Therapeutics Association (“PPTA”), I am submitting the nominations of Mary Gustafson and Albert Farrugia for consideration for a seat reserved for a pharmaceutical manufacturer representative on the Board of Governors for the Patient-Centered Outcomes Research Institute. PPTA is the association that represents human plasma collection centers and the manufacturers of medicinal therapies, including albumin, alpha₁-proteinase inhibitor, blood clotting factors, and immune globulin, from this human plasma. Some of our members also use recombinant DNA technology to produce blood clotting factors. Collectively, these therapies – both plasma-derived and recombinant – are known as “plasma protein therapies.”

The branded pharmaceuticals, the generics, the biologicals, the vaccines, and the plasma protein therapeutics industries each offer their own distinct value to the patients they serve. Because not all “drug manufacturers” are the same, it is imperative that the Institute’s Board has a representative from the plasma protein therapeutics industry.

Plasma protein therapies are used almost exclusively to treat rare diseases and disorders, including hemophilia, dozens of primary immunodeficiency diseases, idiopathic thrombocytopenic purpura, chronic inflammatory demyelinating polyneuropathy, B cell chronic lymphocytic leukemia, and alpha₁-proteinase inhibitor deficiency. Many of these disorders are genetic, chronic, and life threatening conditions that require, as part of the standard of care, patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. Very often, plasma protein therapies are the only viable treatment option for these patients.

We are confident that the expert advisory panel that the new law will require to be assembled in each instance a rare disease is being considered for a comparative

effectiveness research (“CER”) study will serve to preserve unencumbered patient access to the most medically appropriate therapy for the individual needs of the patient who is suffering from the rare disorder. For example, patients with rare conditions may receive a range of treatment interventions in the absence of a consensus “standard of care” or any recent clinical guideline, so it can be difficult to establish a consistent comparator for a CER study. The patients and physicians on this advisory panel will be able to clearly convey such types of treatment regimen nuances to the Institute and use their expertise to not only assist in the design of a CER study for a rare disease or condition, but also determine the relative value and feasibility of conducting such a study. Notwithstanding this safeguard, PPTA believes that it is vital for the rare disease community, including manufacturers, patients, and physicians, to have appropriate representation on the Institute’s Board of Governors. Mary Gustafson and Albert Farrugia would both add tremendous value to the Board because of their many years of professional experiences in both the public and private sector.

Mary Gustafson is currently the Vice President of Global Regulatory Policy at PPTA. With 20 years of experience at the Food and Drug Administration, including her leading roles at the Center for Biologics Evaluation and Research as the Director of the Division of Blood Applications in the Office of Blood Research and Review and as the Chief of the Blood Products and Diagnostics Branch in the Division of Product Certification in the Office of Biological Product Review, Ms. Gustafson has a wealth of experience in the regulation of blood products, and has evolved into a leading expert in the plasma protein therapeutics industry. At FDA, Ms. Gustafson also spent eight years in various roles as a Consumer Safety Officer where she handled regulatory compliance for biologicals and sterile drugs, as well as pre-market approvals for biologicals. Prior to joining PPTA, Ms. Gustafson served as the Senior Director of Regulatory Affairs at Nabi Biopharmaceuticals in Boca Raton, FL. Ms. Gustafson has a MS degree in Pathology from the University of Tennessee Center for the Health Sciences, is certified as a medical technologist and specialist in blood banking by the American Society for Clinical Pathology, and as a quality manager and auditor by the American Society for Quality.

Albert Farrugia is currently the Senior Director of Global Access at PPTA. Dr. Farrugia is the former Head of Blood and Tissue Services of the Therapeutic Goods Administration (“TGA”), the Australian Commonwealth’s regulatory agency for the pharmaceutical sector, where he spent 14 years of his career. Prior to his work at TGA, Dr. Farrugia spent 15 years in blood systems in Malta, the United Kingdom, and Australia. Dr. Farrugia received his BSc from the University of Malta in 1978 and his PhD from the Department of Transfusion Medicine in the University of Edinburgh in 1984. In 1988, he was elected a Fellow of the British Institute of Biomedical Sciences. He has had an active research career and has published more than 120 papers, invited reviews and book chapters, and has edited two books. He has served on the World Health Organization (“WHO”) Global Blood Safety Collaboration, the European Pharmacopeia Commission and the Council of Europe Committee Quality Assurance in Blood Transfusion. As well as being a member of the WHO’s Expert Advisory Panel on

Biological Standardization, he has been a senior adviser on blood and tissues to the governments and non-government agencies, including the Medical Advisory Board of the World Federation of Hemophilia with responsibility for blood safety issues. He is also a Visiting Professor in the University of Western Australia and the University of Canberra.

While we understand that there are a limited number of industry seats, we believe either Mary Gustafson or Albert Farrugia would be a tremendous asset to the Institute's Board of Governors. Their agency experience, combined with their well documented passions for research and patient safety, make them ideal candidates to help shape comparative effectiveness research in the United States. Moreover, their unique understanding of the rare diseases treated with complex plasma protein therapies position both candidates to offer experienced, clinical counsel in carrying out the duties of the Board. Thank you for your consideration.

Sincerely,



Julie A. Birkofer
Senior Vice President, PPTA North America

Attachments

Mary Gustafson

PROFESSIONAL PROFILE

- 7 years in plasma therapeutics trade association
- 2 1/2 years in biopharmaceutical industry regulatory affairs
- 24 years in Commissioned Corps, U.S. Public Health Service, 0-6 (Captain)
- 20 years regulatory experience with Food and Drug Administration in premarket approval for biologics, drugs, and medical devices and regulatory compliance for biologics and sterile drugs
- 20+ years management experience
- 8 years clinical blood bank experience

EMPLOYMENT HISTORY

2003-Present *Vice President, Global Regulatory Policy, Plasma Protein Therapeutics Association (PPTA), Annapolis, MD*

Coordinates global regulatory policy and responsible for regulatory policy in the US. Leads efforts on global harmonization for plasma and plasma therapeutics. Manages North American Regulatory and Compliance Steering Committee and numerous issue specific task forces.

2000-2003 *Senior Director, Regulatory Affairs/Plasma, Nabi Biopharmaceuticals, Boca Raton, FL*

Supervised departmental operations, formulated regulatory strategy, provided advice and direction regarding regulatory requirements, and served as liaison/representative for submissions to regulatory agencies.

1992-2000 *Director, Division of Blood Applications, Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, Rockville, MD*

As a member of CBER's senior management team, directed a division of approximately 50 professional and support personnel (annual budget \$450,000). Provided regulatory leadership for premarket applications (biologics license applications/supplements, 510K's, PMA's, NDA's, ANDA's) processed by OBRR. Responsible for technical review of blood and blood components, blood bank reagents and blood establishment computer software applications.

1988-1992 *Chief, Blood Products and Diagnostics Branch, Division of Product Certification, Office of Biological Product Review, CBER, FDA, Rockville, MD*

Directed a branch of approximately 20 professional and support personnel in premarket application management, review and policy development.

1986-1988 *Consumer Safety Officer, Division of Product Certification, Center for Drugs and Biologics, FDA, Rockville, MD*

Served as staff member in division with regulatory responsibilities for premarket applications for biological products.

1982-1986 *Consumer Safety Officer, Sterile Drugs and Biologics Branch, Division of Biological Product Compliance, National Center for Drugs and Biologics, FDA*

Processed compliance actions, including recalls, biologics license suspensions/revocations, warning letters, injunctions, seizures, and prosecution recommendations, for biologics and sterile drug product areas.

1980-1982 *Consumer Safety Officer, Case Guidance Branch, Division of Compliance, Bureau of Biologics, FDA, Rockville, MD*

Processed compliance actions, including recalls, biologics license suspensions/revocations, warning letters, injunctions, seizures, and prosecution recommendations, for biological product areas.

1977-1980 *Technical Supervisor, Blood Bank Department, Clinical Center, national Institutes of Health (NIH), Bethesda, MD*

Supervise a staff of approximately 12 professionals in blood donor processing, compatibility testing and problem serology.

1972-1977 *Staff Technologist, NIH (1976-77), Methodist Hospital, Memphis, TN (1974-75), Stormont-Vail Hospital, Topeka, KS (1972-1974)*

EDUCATION

- Master of Science in Pathology: 1975
University of Tennessee Center for the Health Sciences, Graduate School
Memphis, Tennessee
- Bachelor of Science in Biology: 1972
Fort Hays State University, Hays, Kansas

PROFESSIONAL CERTIFICATION

- Certified Quality Manager (CQMgr.), American Society for Quality (ASQ): 1999
- Certified Quality Auditor (CQA), American Society for Quality (ASQ): 1999
- Specialist in Blood Banking (SBB), American Society for Clinical Pathology (ASCP): 1976
- Medical Technologist (MT), American Society for Clinical Pathology (ASCP): 1972

AWARDS RECEIVED

- Public Health Service, Commissioned Corps Awards: Outstanding Service medal, 1999, 2000; Commendation Medal, 1990; PHS Citation, 1994, 1989; Outstanding Unit Citation, 1992; Unit Commendation, 2000, 1999(2), 1998(3), 1997(3), 1995, 1993, 1988, 1984
- Center Director's Awards: Group Regulatory Review Award, 1996; Program Operations Award, 1995; Hope Hopps Memorial Award, 1993
- Commissioner's Special Citation, 1988

PROFESSIONAL ASSOCIATIONS

- American Association of Blood Banks (AABB)
- The Retired Officers Association
- Regulatory Affairs Professional Society (RAPS)
- American Society for Quality (ASQ)

Present Liaison Activities

- AABB Standards Committee and Donor History Questionnaire Interorganizational Task Force

Past Liaison Activities

- AABB: Standards Committee; Technical Manual Committee; *ad hoc* Committee for "Circular of Information; Information Systems Committee"
- International Society for Blood Transfusion (ISBT) Working Party on Blood Banking Automation
- International Council for Commonality in Blood Bank Automation (ICCBBA) North American Technical Advisory Committee

PUBLICATIONS AND PRESENTATIONS

- Several scientific publications and a book chapter
- Frequently invited to represent FDA and industry at national and international meetings of such professional organizations as AABB, PPTA, ISBT, FDLI, RAPS, NATO
- Specifics available upon request

Albert Farrugia

Personal Details

Home Address: 19 Investigator Street,
Red Hill, ACT, Australia 2603

Home phone: 61) (02) 6295 7487 intl +61 2629 57487

Fax no: (61) (02) 6295 7487 intl +61 2629 57487

Mobile phone: 0413018413 intl +61413018413
+14433703081

E-mail: albertfarrugia@hotmail.com

Citizenship: Australian

Passports: Australian
European Union

Formal Qualifications

1978 Bachelor of Science, University of Malta
1984 Doctor of Philosophy, University of Edinburgh, Scotland

Recipient of a British Commonwealth Universities Association
Fellowship
Thesis title "*Studies on the Procurement of Blood Coagulation Factor
VIII*"

1988 Fellowship of the Institute of Biomedical Sciences – United Kingdom

Current appointments

2008 - current **Senior Director**, Plasma Protein Therapeutics Association
www.pptaglobal.org
Responsible for developing strategic policy options to improve
access to essential therapies in the US, Europe and Australasia
Responsible for training and teaching industry personnel,

including workshops conducted over 2010 in China, Brazil and Malaysia.
4 staff, \$US 1million budget

2008 - current **Senior Director**, ALMAR Therapeutics Pty Ltd www.almar-therapeutics.com
Providing contractual healthcare services both nationally and overseas

Current International Appointments

- Member of Advisory Group on Transmissible Spongiform Encephalopathy , Public Health Agency of Canada
- Founder member International Expert Advisory Group on Risk Modelling: Iterative Risk Assessment Processes for Policy Development Public Health Agency of Canada
- Member of Medical Advisory Board and Advisor on Blood Safety World Federation of Hemophilia
- Member European Pharmacopeia Commission Group of Experts on Plasma Products
- Member Council of Europe Committee of Experts in Blood Transfusion
- Founder and member WHO Global Collaboration for Blood Safety
- Founder and Chair WHO Working Group on Policy Issues
- Member WHO Expert Panel on Biological Standardisation
- Member United States Pharmacopeia Commission Expert Group on plasma products

Voluntary Service to the Community

- Volunteer lecturer and consultant for public health officials in developing countries in Latin America, Eastern Europe, Asia and the Middle East on public health matters related to the care of patients with blood deficiency disorders
- Volunteer lecturer for

- the World Federation of Haemophilia
- the International Patient Association for Primary Immunodeficiencies
- the Thalassemia Society of Victoria Australia

- Advisor to the Haemophilia Foundation Australia (HFA) and to its Branch in the Australian Capital Territory

- Senior Advisor and patient advocate to the World Federation of Haemophilia, writer of guidelines for best practice in care
(http://www.wfh.org/2/docs/Publications/Safety_and_Supply/GuideClottingFactor_Eng.pdf)

- Volunteer expert consultant for government agencies in Mexico, Brazil and Thailand on Best Practice in choosing therapies for blood disorders

- Senior Advisor and patient advocate to the International Patient Association for Primary Immunodeficiencies, developing advocacy materials and best practice product usage guidelines

Journal Appointments

Member on the Editorial Board for the following Journals:

- Transfusion Medicine
- Current Drug Safety
- Asian Journal of Transfusion Science

Invited Referee for the following Journals

- Lancet
- Journal of Virology
- Transfusion Medicine
- Transfusion
- Vox Sanguinis
- Biologicals
- Journal of Clinical Pharmacology

Key Research and Teaching Focus

Current research activity focuses on the evidence base of therapeutic interventions, on developing deductive methods for assessing the development of health issues and on the use of health technology assessment in developing policy. I am particularly engaged in research and international debate on conceptual frameworks for assessing public health policy developments through paradigm shifts and Popperian falsifiability (publications 119 and 120 on my list).

Publications

A complete list of publications is attached (Appendix A).

Invited Presentations

A representative list of recent invited presentations is attached (Appendix B)

Academic appointments

2005 - current **Adjunct Professor**, School of Surgery, Faculty of Medicine, Dentistry and Health Sciences, University of Western Australia

Contributions:

- Co convener of the Biotherapeutics course in the Faculty of Medicine and Surgery
- invited lecturer
- supervision and mentoring of PhD students

2005 - current **Adjunct Professor**, National Centre for Integrative Sciences, University of Canberra

Contributions:

- invited lecturer (available on <http://www.slideshare.net/albfar/science-and-policy-making-in-public-health> and <http://www.slideshare.net/albfar/emerging-infectious-threats-to-the-blood-supply>)

1990 – 1994 **Invited Lecturer with**
Royal Melbourne Institute of Technology
Victoria University
Honours student supervisor (publications 31,42,47)

Ongoing **Invited Lectures**

- Kuala Lumpur University of Malaya
- Singapore Agency for Science, Technology and Research
- Shanghai University School of Life Science
- Tel Aviv University School for Overseas Students
- University of Fiji Medical School
- University of Malta
- University of Edinburgh
- Charité - Universitätsmedizin Berlin
- University of San Paulo

Sabbatical

Jan – June 2000 Competitive award from the Australian Commonwealth to visit public health organizations in US, Canada, United Kingdom, Israel, Germany, France and the WHO in order to study international best practice in public health policy and systems related to the provision of treatment of blood disorders. Invited to speak at conferences in USA, Canada, WHO, Germany and Israel over the course of the award

Professional Affiliations

Member International Society for Cellular Therapies

Member International Society for Blood Transfusion

Member International Society for Thrombosis and Haemostasis

Member Regulatory Affairs Professionals Society

Member Australia and New Zealand Society for Blood Transfusion

Member American Association of Blood Banks

Member International Institute of Biomedical Scientists

Most Recent Achievement

October 2009 Recipient of the *Ruth Sanger Medal*, the highest award given by

the Australia and New Zealand Society of Blood Transfusion, in recognition for *“Outstanding service to blood transfusion in Australia and the Asia – Pacific”*.

Title of Ruth Sanger Oration: “Karl Popper, Thomas Kuhn and the Common Sense of Transfusion Medicine”

Previous Professional Appointments

2003 – 2008 **Senior Principal Research Scientist**
Head, Blood and Tissues Unit,
Therapeutic Goods Administration (TGA)
Department of Health and Ageing

17 staff, \$A1.9 million budget

Key Responsibilities:

As a member of the Senior Executive of the Australian Public Service, I was responsible for developing Australian Government public health policy, particularly in relation to the provision of blood and tissue therapies in Australia.

Specific duties:

- key advisor and opinion former to inter governmental jurisdictional blood committee on public health policy and associated regulation of the oversight and funding of the Australian blood system
- key advisor and instructor to the National Blood Authority in maintaining, developing and implementing public health policy for the development and funding of the blood system
- Key senior advisor and TGA representative for the development and implementation of public health policy and regulation in relation to blood, cellular and tissue products
- Managing the alignment of public health policies of New Zealand and Australia into trans-Tasman regulatory frameworks
- Collaboration with key stakeholders (including State/Commonwealth governments, academic, professional and clinical representatives and patient advocates) in order to achieve an integration of stakeholder contribution and governmental priorities into appropriate public health policy settings
- Recruitment, management and mentoring of a multi-disciplinary team of

administrative, technical and scientific staff which included oversight of quality standards and budgetary processes including cost-recovered services

Key Achievements:

- Maintaining strong academic and research activity alongside a successful senior public service career in public health, and achieving recognition as an international expert on blood safety and biological therapeutics
- Recipient of the award of the Ruth Sanger Medal by the Australia and New Zealand Society for Blood Transfusion in October 2009 for “outstanding service to blood transfusion in the Asia-Pacific Region”.
- Extensive international involvement and becoming an internationally recognized authority in the manufacture, clinical development and regulatory oversight of biotherapies and diagnostics
- Key contributor at a senior level in the Commonwealth Government to major public health policy, including contributions to the Stephens Review of the Blood System, the establishment of the National Blood Authority and the implementation (postponed) of the Australia and New Zealand Therapeutic Products Authority (ANZTPA)
- Key opinion former and decision maker in the development of Australia’s public health responses to emerging infectious risks including Severe Acute Respiratory Distress Syndrome (SARS) and Variant Creutzfeldt Jakob Disease (vCJD), in collaboration with the Chief Commonwealth Medical Officer and the Division of Population Health Department of Health and Ageing

1997 – 2003

Head (Senior Professional Officer A)

The Blood Products Group,
Therapeutic Goods Administration (TGA)
Department of Health and Ageing

8 staff, \$A0.9 million budget

Key Responsibilities:

- Managing the units responsibilities for premarket evaluation of blood and plasma-derived therapeutic products and oversight of the budget and cost recovery mechanisms
- Providing staff training and mentoring
- Collaboration with intra-agency bodies on matters of public health interest

Key Achievements:

- Leadership in international collaboration in the safety of biotherapeutics through the World Health Organisation
- Recipient of funding for a 6 month sabbatical to study best practice in public health policy and systems in US, Canada, UK, Israel, Germany, France and WHO, achieved through a competitive professional development award process of the Department of Health and Ageing - Jan - June 2000

1995 - 1997 Head (Senior Professional Officer B)

Plasma Products Stream,
Therapeutic Goods Administration
Department of Health and Ageing

7 staff, \$A0.4 million budget

Key Responsibilities

- Managing a team of seven professional and technical staff engaged in :
 - Reviewing and evaluating pharmaceutical company submissions for registration of biological drugs
 - Testing of biological drugs both pre- and post- registration and marketing
 - Development of analytical methodology for the characterisation of biologicals

- Senior advisor to the TGA on issues relating to public health and regulation of blood products for therapeutic use and responsible for:
 - Preparation of briefing reports to the Minister and ministerial responses on blood product issues
 - Senior TGA representative on departmental and other external committees
 - Senior TGA professional representative at public and professional stakeholder meetings
 - Senior international TGA professional representative on the harmonisation of drug regulation

Achievement

Significant contribution to the development public health policy principles and implementation of associated regulatory legislation for the oversight of blood components, tissue based therapies and cell therapies including stem cells for Australia

1994 - 1995 Plasma Products Evaluator, (Senior Professional Officer C)

Therapeutic Goods Administration
Department of Health and Ageing

Key responsibilities

- Evaluation of submissions for registration of drugs and drawing up of relevant reports
- Development of test methods for characterising biological drugs

1991-1994

Principal Scientist in Charge

Department of Haematology, Royal Children's Hospital,
Melbourne, Victoria, Australia

14 staff, \$A1.1 million budget

Key Responsibilities

- Management of laboratory haematology service in major teaching hospital :
 - Administering staff deployment and training
 - Allocating and monitoring budgetary outlays
 - Developing staff job descriptions and laboratory structure
- Representing the department in hospital and government policy bodies
 - Participating in the Division of Pathology Executive
 - Participating in government - sponsored external review (DeLoittes Tomasu) of pathology service delivery in Victoria
 - Interacting with patient groups including the Anti Cancer Council and the Haemophilia Foundation in optimising service delivery

Achievement

Implementation of full automation in a mainstream hospital haematology service and introduction of molecular biology techniques for screening haematological disorders in Melbourne Australia

1988-1991

Scientist in Charge

Development and Special Products,
Australian Red Cross Blood Service, Victoria, Australia

Key Responsibilities:

- Management of scientific group engaged in research and development in blood transfusion science
- Participation in Senior Managers' Group of the organisation for developing organisation's policy and interaction with key stakeholders

Achievement

Development of additive solutions for the preservation of blood components and novel red cell products for the treatment of chronically transfused patients in Melbourne Australia

1987 - 1988

Research and Development Scientist

Commonwealth Serum Laboratories (CSL) Victoria, Australia

Key Responsibilities:

- Researching optimal ways of manufacturing human plasma-derived pharmaceuticals

Achievement

Development of a generation of plasma derived therapies using new technologies permitting the use of robust viral inactivation techniques in CSL Australia

1984 - 1987

Director

Maltese National Blood Transfusion Centre, Malta
32 Staff, \$A 0.7 million equivalent budget

Key Responsibilities

- administrative and scientific direction of the blood transfusion service
 - Management of blood service operations including personnel and budget
 - Negotiation of annual government contracts for imported blood products
 - Project planning and implementation of new blood transfusion centre
- Government advisor of pathology service development
 - Advise Minister and Chief Government Medical Officer on development and resource allocation for the provision of pathology services
 - Member of Hospital management Committee for project management in chief public hospital
 - Chief Government Advisor on Acquired Immuno Deficiency Syndrome

Achievement

- Design and commissioning of a new blood transfusion centre in Malta and the introduction of the manufacture and provision of blood components in Malta
- Member and rapporteur on Viral Safety to the Council of Europe Committee of Experts on Blood Transfusion what year??

1979 - 1984

Scientist

Blood Transfusion Unit, St Luke's Hospital, Malta

Other Interests

Multicultural affairs

- Secretary, Maltese Community Council of Victoria, 1990-1993
- Secretary, Maltese Australian Association of the ACT and Queanbeyan, 1995-

1999

Philately

- Publicity Officer, Philatelic Society of Canberra 1997-1998
- President, Philatelic Society of Canberra 1999-2003
- Medals awarded for displays in National Australian Philatelic Convention 2000, 2004, 2007

Golf

Painting

Music

History, politics and current affairs

Referees

* Professor R Smallwood AO, President of the Australian Medical Council. I worked with Professor Smallwood when he was Chief Commonwealth Medical Officer 1999 - 2004, on issues such as countering the threats of SARS and vCJD and the establishment of the Australian National Blood Authority.
r.smallwood@unimelb.edu.au. 03 9822 3918

* Professor J Mathews AM, Executive Director of the Menzies Foundation. I worked with Professor Mathews when he was Head of the Population (Public Health) Division of the Commonwealth Department of Health 2001 - 2005, on the establishment of guidelines for best practice in areas such as blood usage and infectious disease transmission. mathewsj@unimelb.edu.au, ph 0411021013

* Professor Minhao Zheng of the University of Western Australia. Professor Zheng is my current collaborator in my role as adjunct Professor at UWA where I teach a biotherapeutics course and have supervised PhD students.
minghao.zheng@uwa.edu.au 0407982570

* Ms Liz Furler, CEO of Principals Australia. I worked with Liz Furler when she was head of the Population (Public Health) Division of the Commonwealth Department of Health 1998 to 2001, establishing WHO collaborations in blood safety and developing policy on blood management. lfurler@googlemail.com. 0401996643

* Mr Terry Slater, currently Chairman of Research Infrastructure Support Services (http://www.rissltd.com/About_Us.aspx) National Manager of the Therapeutic Goods Administration for 9 years during my tenure in that organisation.
Terry_slater@bigpond.com 0412631090

Publications

(P=paper, A=abstract, B=book chapter, R=Review, L=letter)

- (1) Association of ABO blood group determinants with Factor VIII. A Farrugia, M Robertson, B Griffin and C Prowse. British Society for Thrombosis and Haemostasis 1983 Meeting Proceedings, p52.[A]

- (2) Enhancement of Factor VIII:Ristocetin cofactor activity by antibodies. C Prowse, V Hornsey, A Farrugia, LR Micklem, MC McCann and J Dawes. Metchnikoff Club 1984 Meeting Proceedings, p16.[A]

- (3) Radioimmunoassay of haemostatic proteins using solid phase second antibody and sucrose separation. C Prowse, A Farrugia, B Griffin, I MacGregor and J Dawes. British Society for Thrombosis and Haemostasis 1984 Meeting Proceedings, p16.[A]

- (4) Donation procedure, fibrinopeptide A and Factor VIII. CV Prowse, H Bessos, A Farrugia, A Smith and J Gabra. Vox Sanguinis, 46, 55-57, 1984 [P]

- (5) A comparative study using immunological and biological assays of the haemostatic responses to DDAVP infusion, venous occlusion and exercise in normal men. CV Prowse, A Farrugia, FE Boulton, J Tucker, CA Ludlam, M McLaren, JF Belch, CRM Prentice, J Dawes and IR McGregor. *Thrombosis and Haemostasis*,51, 110-114, 1984.[P]
- (6) Studies on the procurement of blood coagulation Factor VIII : Selective precipitation of Factor VIII with hydrophilic polymers. A Farrugia, B Griffin, D Pepper and C Prowse. *Thrombosis and Haemostasis*,51, 338-342, 1984.[P]
- (7) Studies on the procurement of blood coagulation Factor VIII : The role of plasma freezing rate and storage conditions on cryoprecipitate quality. A Farrugia and C Prowse. *Journal of Clinical Pathology*,38, 433-437, 1985.[P]
- (8) The Acquired Immune Deficiency Syndrome - The evolving perspective. A Farrugia *Journal of the Maltese Pharmaceutical Society*, May 1986.[R]
- (9) Studies on the procurement of blood coagulation Factor VIII : In vitro studies on blood components prepared in half-citrate anticoagulant. C Prowse, Y Waterson, J Dawes and A Farrugia.*Vox Sanguinis*,52, 257-264, 1987.[P]
- (10) Incidence of Hepatitis B Surface Antigen in Maltese blood donors - Results comparing different test systems. A Farrugia. In "Clinical Gastroenterology in Malta" ed M Camilleri, Printex, Malta, 1987.[B]

- (11) What's new on Factor VIII ?A Farrugia. National Haemophilia, 18, 3-5, 1988.[R]
- (12) A microtitre plate test for assessment of in-vitro thrombogenicity in Factor IX concentrates using a chromogenic substrate. A Farrugia, A Oates, D Spiers, I Young and R Herrington. Thrombosis Research, 53, 191-196, 1989.[P]
- (13) Effects of plasma collection systems and processing parameters on the quality of Factor IX concentrate. A Farrugia, D Spiers, I Young, A Oates, R Herrington and F Damianos. Vox Sanguinis, 57, 4-9, 1989.[P]
- (14) Microtitre plate measurement of platelet response to hypotonic shock response. A Farrugia, C Hughes, S Douglas, M Neal and J James. Journal of Clinical Pathology, 42, 1298-1301, 1989[P].
- (15) Formulation of a severe-heat stable Factor VIII concentrate. A Oates, I Young, A Farrugia, E Polmear and R Herrington. Thrombosis and Haemostasis, 62, 211, 1989[A].
- (16) Use of plasma with high levels of ionised calcium in the production of model scale coagulation factor concentrates. A Farrugia, S Douglas, J James, G Whyte and R Herrington. Thrombosis and Haemostasis, 64, 374-378, 1990.[P]

- (17) Use of adenine rich washing solutions in recovering frozen red cells of improved quality. A Farrugia, J James, C Cocks, I Pietryszyn and H Piorunowski. Australian and New Zealand Journal of Medicine, 20, 393, 1990.[A]
- (18) In vitro evaluation of bedside leucocyte removal filters. J James, L Amerena, A Farrugia and G Whyte. Australian and New Zealand Journal of Medicine, 20, 393, 1990.[A]
- (19) Turbidity caused by microwave heating of stable plasma protein solution (SPPS). G Hewitson, A Farrugia, S Douglas and G Whyte. Australian and New Zealand Journal of Medicine, 20, 402, 1990.[A]
- (20) Support of high platelet counts in platelet concentrates with sodium bicarbonate. S Douglas, A Farrugia, M Neal, L Amerena and J James. Australian and New Zealand Journal of Medicine, 20, 411, 1990 [A].
- (21) A dextrose-free synthetic medium results in improved quality of platelet concentrates over storage. A Farrugia, S Douglas, S Williams, S Kellner, L Amerena and J James. Transfusion Medicine, 1, 31-38, 1991.[P]
- (22) Viral safety of coagulation factor concentrates . A Farrugia. Transfusion Science, 12, 161-162, 1991.[L]

- (23) Improved red cell concentrate quality by mixing additive into products post processing. A Farrugia, R Hill, L Rolska, S Douglas and J James. Transfusion Medicine,1, 1991.[A]
- (24) von Willebrand Factor characterisation of severe dry heat-treated Factor VIII concentrates. A Oates, E Polmear, R Herrington, A Farrugia, S Sykes, G Raines, H Aumann and A Street. Thrombosis Research, 65, 389-399, 1992.[P]
- (25) Some characteristics of blood shed into the Solcotrans post-operative orthopaedic drainage/reinfusion system. R Harrap, G Whyte, A Farrugia and C Jones. Medical Journal of Australia,157, 95-96, 1992.[P]
- (26) Controversies in haemophilia treatment - how much purity is required? A Farrugia. Newsletter of the Haemophilia Society of Victoria, 2, 12-14, 1992.[R]
- (27) Purity of Factor VIII concentrates and immune function in haemophiliacs . A Farrugia. Blood, 79, 2800,1992.[L]
- (28) Modulation of fibrinogen content in cryoprecipitate by temperature manipulation during plasma processing. A Farrugia, S Grasso, S Douglas, R Harrap, A Oates, I Young, J James and G Whyte. Transfusion, 32, 755-759, 1992.[P]
- (29) Red cell and platelet concentrates from blood collected into half-strength citrate anticoagulant : Improved maintenance of red cell 2,3 diphosphoglycerate

in half-citrate red cells. A Farrugia, S Douglas, J James and G Whyte. Vox Sanguinis, 63, 31-38, 1992.[P]

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