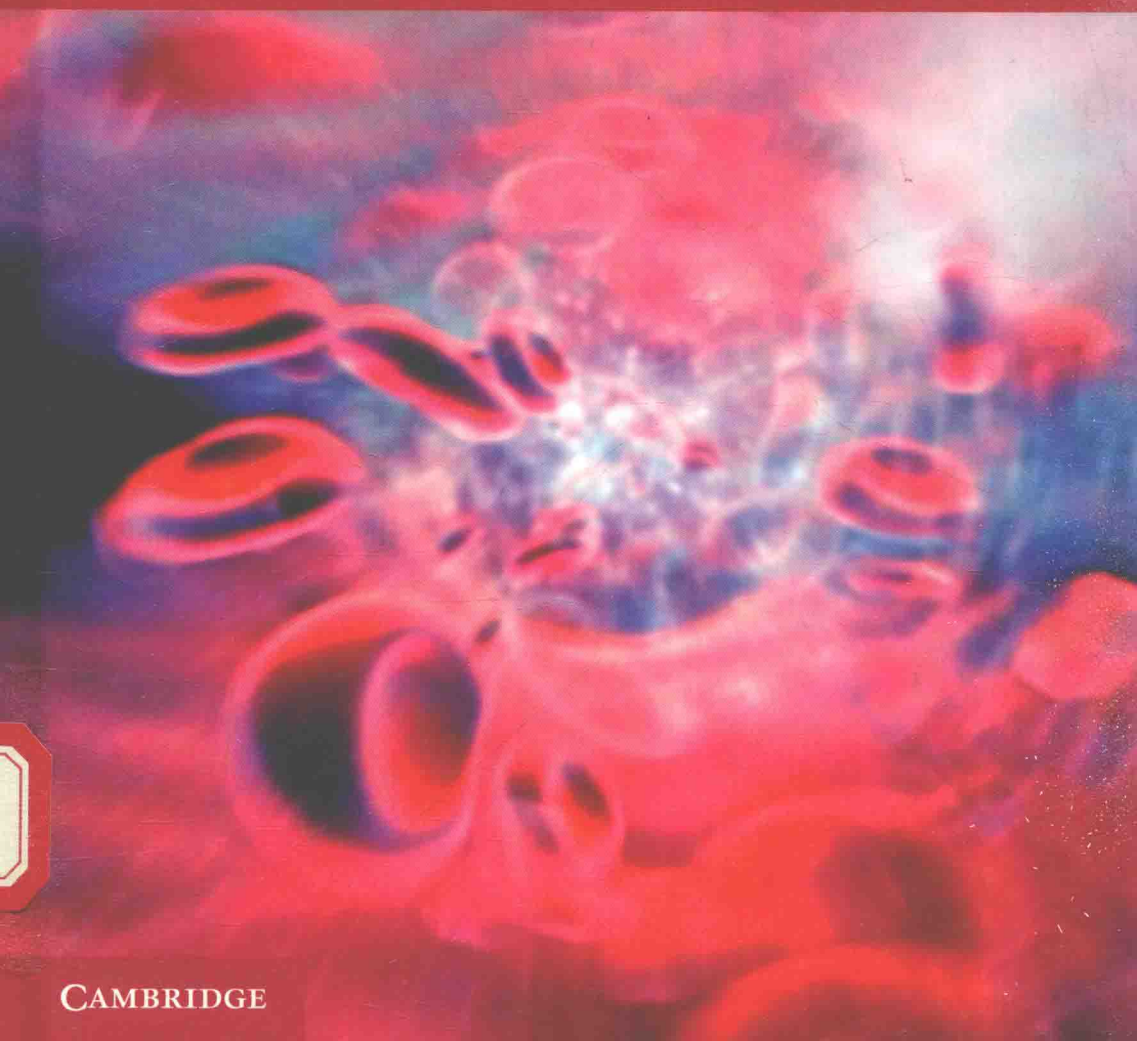
CAMBRIDGE Bioethics and Law

The Politics of Blood

Ethics, Innovation and the Regulation of Risk

Anne-Maree Farrell



CAMBRIDGE

The Politics of Blood

Ethics, Innovation and the Regulation of Risk

Anne-Maree Farrell

CAMBRIDGE
UNIVERSITY PRESS

CAMBRIDGE UNIVERSITY PRESS
Cambridge, New York, Melbourne, Madrid, Cape Town,
Singapore, São Paulo, Delhi, Mexico City

Cambridge University Press
The Edinburgh Building, Cambridge CB2 8RU, UK

Published in the United States of America by Cambridge University Press, New York

www.cambridge.org
Information on this title: www.cambridge.org/9780521193184

First published 2012

Printed in the United Kingdom at the University Press, Cambridge

A catalogue record for this publication is available from the British Library

Library of Congress Cataloguing in Publication data
Farrell, Anne-Maree, 1964–
The politics of blood : ethics, innovation, and the regulation of risk / Anne-Maree Farrell.
p. cm. – (Cambridge Bioethics and Law)
Includes bibliographical references and index.
ISBN 978-0-521-19318-4 (hardback)
1. Blood banks–Government policy. 2. Blood products–Safety measures. 3. Blood–Moral and ethical aspects. 4. Blood–Social measures. I. Title.
RM172.F37 2012
362.17'84–dc23
2012003509

ISBN 978-0-521-19318-4 Hardback

This book is dedicated to my father, Gerard Farrell
Ar dheis Dé go raibh a anam uasal

Acknowledgements

This book has been a long time coming. My initial interest in the subject matter of the book had its origins in my previous work as a lawyer in the field of blood-related litigation. Much of the in-depth reading that was required as a prelude to the writing of the book took place while I was in receipt of a Leverhulme Trust Research Fellowship, and the Trust's support is gratefully acknowledged. I also benefited greatly from a period of research leave provided by the School of Law, University of Manchester, during the writing up phase of the book. Further impetus and stimulation has been provided through my involvement in a number of research collaborations, including the Economic and Social Research Council (ESRC) research grant: *Risk, Safety and Consent in Contemporary Blood Services in the UK: Perspectives from Sociology and Law* (RES-062-23-2751) and the University of Manchester Wellcome Strategic Programme: *The Human Body: its Scope Limits and Future*. Chapter 8 drew on research done whilst in receipt of an ESRC seminar series grant: *European Law and New Health Technologies* (RES-451-26-0764). The support of both the Wellcome Trust and the ESRC is gratefully acknowledged.

I would also like to acknowledge the support and assistance I have received from Cambridge University Press in the preparation and completion of the book, in particular Finola O'Sullivan, Elizabeth Spicer and Richard Woodham. The encouragement of Margaret Brazier and Graeme Laurie, the commissioning editors for Cambridge University Press's Law, Medicine and Ethics series, was also much appreciated.

I would like to thank the anonymous reviewer who provided helpful feedback on the draft manuscript, as did colleagues including Helen Busby, John Coggon, Sarah Devaney, Julie Kent and Michael Moran. Thanks must also go to the Peek-Farrell families, colleagues and friends for their continuing support while I was writing the book, as well as to

my sons Tom and Josh for always being delightful and welcome distractions. Last but not least, this book would never have been completed without the unwavering support, patience and proofing skills of my husband, Ron – I could not have done it without you, schatje.

Chronological table of cases

Chronological table of legislation

COUNCIL OF EUROPE

EUROPEAN UNION

FRANCE

UNITED KINGDOM

UNITED STATES

WORLD HEALTH ORGANIZATION

Abbreviations

AABB	American Association of Blood Banks
ABC	America's Blood Centers
ABRA	American Blood Resources Association
ACT-UP	AIDS Coalition to Unleash Power
ACBSA	Advisory Committee on Blood Safety and Availability (USA)
AFH	Association Française des Hémophiles (Haemophilia Association of France)
AHF	Anti-haemophiliac factor
AIDS	Acquired immune deficiency syndrome
AP	Association des Polytransfusés (Multi-Transfused Association, France)
ARC	American Red Cross
BOTS WG	Blood, Organ and Tissue Safety Working Group (USA)
BPAC	Blood Products Advisory Committee (FDA-US)
BPL	Blood Products Laboratory (UK; later known as Bio Products Laboratory)
BRN	Blood Regulators Network (WHO)
BSE	Bovine spongiform encephalopathy
BSP	Biological Standardisation Programme (Council of Europe)
BWP	Biologics Working Party (EMA–EU)
CDC	Centers for Disease Control (USA; now called Centers for Disease Control and Prevention)
DGS	Direction Générale de la Santé (Department of Health, France)
DG SANCO	Directorate General for Health and Consumers (EU)
DHSS	Department of Health and Social Security (UK)
EBA	European Blood Alliance
EC	European Community

ECBS	Expert Committee on Biological Standardisation (WHO)
EDQM	European Directorate for the Quality of Medicines and HealthCare (Council of Europe)
EHC	European Haemophilia Consortium
EMA	European Medicines Agency (EU)
EPAR	European Public Assessment Reports (EMA–EU)
EU	European Union
FDA	Food and Drug Administration (USA)
GCBS	Global Collaboration on Blood Safety (WHO)
GDP	Gross domestic product
GM	Genetically modified
GMP	Good Manufacturing Practice
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HHV-8	Human herpesvirus-8
HIV	Human immunodeficiency virus
HPC	Haematopoietic progenitor cell
HTLV-III	Human T-lymphotropic virus-type III
ICH	International Conference on Harmonisation
IFBDO	International Federation of Blood Donor Organizations
IFRC	International Federation of Red Cross and Red Crescent Societies
IOM	Institute of Medicine (USA)
IPFA	International Plasma Fractionation Association
IPOPI	International Patient Organisation for Primary Immunodeficiencies
IQPP	International Quality Plasma Program
ISBT	International Society of Blood Transfusion
MASAC	Medical and Scientific Advisory Council (NHF-US)
MDL	Multi-District Litigation
MP	Member of Parliament (UK)
MSM	Men who have sex with men
NANB	Non-A non-B (hepatitis)
NAT	Nucleic acid amplification technology
NHF	National Hemophilia Foundation (USA)
NHS	National Health Service (UK)
NHSBT	National Health Service Blood and Transplant (UK)
OECD	Organisation for Economic Co-operation and Development

OMCL	Official Medicines Control Laboratories (Council of Europe)
OPEC	Organization of the Petroleum Exporting Countries
PDG	Pharmacopoeial Discussion Group (Council of Europe)
PhEur	European Pharmacopeia (Council of Europe)
PMF	Plasma Master File
PPTA	Plasma Protein Therapeutics Association
PRT	Pathogen reduction technology
PWA	People with AIDS
PWH	People with haemophilia
QALY	Quality-adjusted life years
QSEAL	Quality Standards of Excellence, Assurance and Leadership
rFVIII	Recombinant factor VIII
SaBTO	Advisory Committee on the Safety of Blood Tissues and Organs (UK)
SAC	Special Assistance Council (NHF–US)
SHOT	Serious Hazards of Transfusion (UK)
TFEU	Treaty on the Functioning of the European Union (EU)
TTI	Transfusion-transmitted infection
UK	United Kingdom
UKHCDO	United Kingdom Haemophilia Centre Doctors' Organisation (UK)
USA	United States
vCJD	Variant Creutzfeldt–Jakob disease
VNRBD	Voluntary non-remunerated blood donation
WFH	World Federation of Hemophilia
WHO	World Health Organization
WTO	World Trade Organization

Contents

1 Introduction

Throughout human history, blood has been imbued with many social and cultural meanings. It has also been used to identify and classify human beings, as well as structure social relationships.[1] The twentieth century saw a revolution in the use of blood, with scientific discoveries transforming its role in modern medicine. The sourcing and supply of blood became organised on a national basis in developed countries, underpinned by the notion of the gift relationship which promoted altruistic, non-remunerated blood donation in the context of an anonymous relationship between donors and recipients.[2] Scientific and technological developments led to the industrial production of plasma-derived medicinal products (plasma products),[3] which were predominantly sourced from individuals who received financial compensation for providing their blood (paid donors).[4] In turn, this facilitated the development of a global blood market in such products.[5]

[1] D. Nelkin, 'Cultural perspectives on blood', in E. A. Feldman and R. Bayer (eds.), *Blood Feuds: AIDS, Blood, and the Politics of Medical Disaster* (New York: Oxford University Press, 1999), pp. 274–92.

[2] R. M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy* (London: George Allen & Unwin, 1970).

[3] Plasma is the straw-coloured fluid in which blood cells are suspended. It contains a high concentration of various proteins. Through a treatment process known as fractionation, plasma proteins are separated into fractions of more or less purified proteins with different properties. Plasma products often require thousands of donations in order to manufacture a single batch. For further details, see P. Hagen, *Blood Transfusion in Europe: A 'White Paper'* (Strasbourg: Council of Europe, 1993), pp. 188–90.

[4] For the purposes of this book, the term 'paid donor' is used, although I acknowledge that the for-profit plasma products industry prefers the term 'compensated donor' on the grounds that the individual is being compensated for their time and effort in undertaking plasma donation. See Plasma Protein Therapeutics Association (PPTA), *The Facts about Plasma Collection* (www.pptaglobal.org).

[5] For an overview of the early development of the plasma products industry, see P. Hagen, *Blood: Gift or Merchandise? Towards an International Blood Policy* (New York: Alan R. Liss Inc., 1982).

In the 1980s, the acquired immune deficiency syndrome (AIDS) emerged as an epidemic in the developed world. The infectious agent responsible for the disease, which later became known as the human immunodeficiency virus (HIV), was found to be transmissible by blood.[6] Once HIV testing became available, large numbers of individuals were also found to have been infected with the virus through the use of blood. In the 1990s, revelations about the circumstances that had led to HIV blood contamination episodes caused political scandals in a number of developed countries, where it became clear that the response by those with responsibility for the blood system had been inadequate. These scandals were characterised by adverse media reaction, protracted litigation in the courts, state-sponsored tribunals of inquiry, as well as institutional and regulatory reform of national blood systems.[7] For those deemed responsible for the contamination episodes, the consequences included public excoriation and on occasion the imposition of criminal sanctions. For those individuals who were infected with HIV through blood, it was a deeply personal tragedy, resulting in serious disability and/or loss of life.[8]

Risk, public health and human biological materials

Risk governance in public health is not new, but we now live in an era of globalisation where such risks may have a rapid and wide-ranging impact with deleterious social, economic and political consequences. This is particularly true in relation to risks to public health posed by infectious diseases. In recent years, it has been recognised that there is

[6] The human immunodeficiency virus (HIV) is the virus that causes the acquired immune deficiency syndrome (AIDS). A person may be infected with the virus, but will only be considered to have AIDS once there is severe immune deficiency, or s/he is diagnosed with illnesses associated with such deficiency.

[7] For the purposes of this book, the use of the term 'blood system' is intended to refer to the collection and supply of blood components; the manufacture and supply of plasma products; and policy and regulatory processes involved in these activities. When reference is made to the term 'blood supply', it is confined to collection and supply issues involving blood and plasma products, primarily at national level.

[8] For an overview, see L. Leveton, H. C. Sox and M. A. Stoto (eds.), *HIV and the Blood Supply: An Analysis of Crisis Decisionmaking* (Committee to Study HIV Transmission through Blood and Blood Products, Division of Health Promotion and Disease Prevention) (Washington, DC: National Academy Press, 1995); The Honourable Mr Justice H. Krever, *Commission of Inquiry on the Blood System in Canada*, 3 vols (Ottawa: Canadian Government Publishing, 1997); E. A. Feldman and R. Bayer (eds.), *Blood Feuds: AIDS, Blood, and the Politics of Medical Disaster* (New York: Oxford University Press, 1999); The Right Honourable Lord Archer of Sandwell QC, N. Jones and J. Willetts, *Independent Public Inquiry Report on NHS Supplied Contaminated Blood and Blood Products* (2009).

a need for more effective global governance in this area.[9] In turn, this has fed into new initiatives in risk governance at national and regional levels to address the issue.[10] Risks to public health may often require governing entities to balance competing considerations in seeking to protect citizens' health. These may include the need to balance individual rights or entitlements to freedom of choice and liberty of the person against the need to protect the collective well-being of the population. At state level, the recognition of public health risks within national boundaries, such as those posed by infectious diseases, may result in the need to implement restrictive measures with regard to the movement of persons and goods, in order to prevent the spread of the disease. While this may have an adverse economic impact on trade and the daily lives of citizens, it is also likely to have significant political repercussions at global level.[11]

The need to engage in a similar balancing act has emerged in recent years in the context of risk governance involving the use of human biological materials, where the need to protect public health may be at stake. As a result of scientific research and technological innovation, their use in medico-scientific settings has expanded rapidly in recent years. While there has been significant political support for promoting innovation and the commercial potential of new health technologies that may result from these developments, there has also been a need in political terms to manage ethical tensions that have arisen in the public domain over their use. The aim of this book is to explore these issues in detail through examining the inter-relationship between politics, ethics and law in risk governance involving human biological materials, drawing on an in-depth qualitative study of the sourcing and supply of blood.

There are a number of reasons for choosing this case study. First, blood has socio-cultural, scientific and commercial value, and it is this multi-valuing that is likely to present challenges in terms of facilitating effective risk governance. Blood has long been recognised as

[9] L. O. Gostin, 'Meeting the survival needs of the world's least healthy people: a proposed model for global health governance', *Journal of the American Medical Association*, 298 (2007), 225–8.

[10] For example, the European Union (EU) created a legal competence in the field of public health in 1999 (see Article 152(4)(a) of the European Community (EC) Treaty, now Article 168(4)(a) of the Consolidated Version of the Treaty on the Functioning of the European Union, OJ C 83, 30.3.2010 (TFEU)). Since such time, the EU has adopted a number of policy initiatives, as well as regulatory regimes, in the field. For further details, see http://ec.europa.eu/health/index_en.htm.

[11] D. P. Fidler and L. O. Gostin, 'The new International Health Regulations: an historic development for international law and public health', *Journal of Law, Medicine and Ethics*, 34 (2006), 85–94 at 91–3.