The Politics of Blood

How best to manage risk involving multi-valued human biological materials is the overarching theme of this book, which draws on the sourcing and supply of blood as a case study. Blood has ethical, social, scientific and commercial value. This multi-valuing process presents challenges in terms of managing risk, therefore making it ultimately a matter for political responsibility. This is highlighted through an examination of the circumstances that led to HIV blood contamination episodes in the USA, England and France, as well as their consequences. The roles of scientific expertise and innovation in managing risks to the blood system are also analysed, as is the increased use of precautionary and legal strategies in the post-HIV blood contamination era. Finally, consideration is given to a range of policy and legal strategies that should underpin effective risk governance involving multi-valued human biological materials.

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This series of books was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law’s complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organisations such as the WHO and UNESCO now regularly address issues of medical law.

It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. Organ retention, embryonic stem cell research, physician-assisted suicide and the allocation of resources to fund health care are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and health care.

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The Politics of Blood

*Ethics, Innovation and the Regulation of Risk*

Anne-Maree Farrell
This book is dedicated to my father, Gerard Farrell

*Ar dheis Dé go raibh a anam uasal*
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Recommendation No. R (95) 15 of the Committee of Ministers to Member States on the Preparation, Use and Quality Assurance of Blood Components (adopted by the Committee of Ministers on 12 October 1995 at the 545th meeting of the Ministers' Deputies)

**European Union**


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WORLD HEALTH ORGANIZATION

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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-haemophilic factor
AIDS  Acquired immune deficiency syndrome
AP    Association des Polytransfusés (Multi-Transfused Association, France)
ARC   American Red Cross
BOT’S 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
List of abbreviations

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

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