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Risk, Science and the Politics of the Blood Scandals in Ireland, Scotland, England and Finland.

Abstract

This article examines the HIV/Hepatitis C disaster that engulfed those suffering from haemophilia in Ireland, Scotland, England/Wales and Finland; the largest health scandal since the Thalidomide controversy. In its aftermath a succession of Inquiries and Tribunals focused on what government knew (about HIV/AIDS and Hepatitis C), and when (the blood supply had been compromised). The origins to the blood crisis were therefore located firmly in the failure on the part of key decision-makers to *manage* adequately the risk from HIV/AIDS and Hepatitis C. This article is concerned with an altogether different task; an explanation of *why* the crisis emerged. Put simply, it was not about how the risk was managed, but *assessed*. After a sustained period of regulatory reform, and the New Right's determination to reduce the role of state intervention, a reconfiguration of risk in politics anticipated that decisions were no longer refracted exclusively through the institutions of government, for they now involved multinational private actors, according far more emphasis to the diversity of the market.

Keywords

risk, governance, politics, science and blood.

Introduction.

A patient recalls being informed of infection by his doctor:

There was an awkward silence. He cleared his throat and said ‘something has come to my attention that I need to discuss with you. It appears that you were one of the unfortunates that has become infected’. He said, ‘you will be dead within a year.’¹

The HIV/Hepatitis C² crisis that devastated haemophiliac populations across the globe cast a dark shadow over the integrity of blood systems and brought in its wake Tribunals and compensation payouts on a scale not seen since the Thalidomide tragedy of the 1960s. In Ireland, more than half of the four hundred strong haemophilia community contracted HIV or Hepatitis C from contaminated blood products, with many not surviving the near twenty year wait for the *Lindsay Tribunal*³ to examine events surrounding their infection. In addition, the *Finlay Tribunal*⁴ investigated the infection of nearly 1,600 women with Hepatitis C through the use of a blood product, anti-D, which had been manufactured by the Irish Blood Transfusion Service Board (BTSB). The Irish state’s aggressive legal tactics generated public outrage, particularly when the minister for health, Micheal Noonan, questioned whether a

¹ Edinburgh News, ‘Hepatitis C blood transfusion victims await answers’, *Edinburgh News*, 24 March 2015.

² Hepatitis is an inflammation of the liver. Until the late 1960s the two principal forms were Hepatitis A and B. By the 1970s a further strain appeared to be the cause of infections and was labelled Non-A, Non-B Hepatitis (NANBH). Later (1989), it would be isolated and labelled Hepatitis C (HCV). Initially thought to be a chronic but manageable condition, Non-A, Non-B Hepatitis transpired to have more serious consequences, with up to one in five infections resulting in cirrhosis of the liver. The virus has a very long and often asymptomatic incubation period, which contributed both to its elusiveness and the view that it was benign. Houghton M, ‘The long and winding road leading to the identification of the hepatitis C virus’, *Journal of Hepatology*, 51 (2009), 939-948.

³ Lindsay A, ‘Report of the tribunal of inquiry into the infection with Hepatitis C and HIV of persons with haemophilia and related matters’, (Ireland, 2002). Dublin. Stationery Office.

⁴ Finlay T, ‘Report of the tribunal of inquiry into the Blood Transfusion Service Board’, (Ireland, 1997). Dublin. Stationery Office.

dying woman's solicitors could not have selected a 'plaintiff in better condition to sustain the stress of a High Court Case' from the hundreds of test cases available.⁵

In England⁶, it was only after a prolonged political struggle that a *Public Inquiry* funded by private donations and chaired by Lord Jeffery Archer was convened. The *Inquiry* did not have statutory powers, and could not compel anyone to give evidence. Those that declined to provide witnesses included the Department of Health, since it felt the *Inquiry* was 'unnecessary', though it did supply documentation. However, the crucial departmental papers of both Lord Owen and Lord Jenkin were destroyed and, in the opinion of Lord Jenkin, was done 'with intent; to draw a line under the disaster'⁷; it seemed more important to deny liability.

In Scotland, the *Penrose Inquiry*⁸ sought to bring this period to a close, providing an explanation of the reasoning behind the importation of new blood products (and their attendant risk), as well as the decision-making by general practitioners not to inform, or discuss, the risk associated with these new commercial blood products. The report was not well-received by haemophiliacs, some of whom chose to vent their outrage by publically burning copies outside the National Museum of Scotland in Edinburgh.⁹ In both Scotland and England their plight was compounded by the ignominy of successive governments that provided only paltry financial assistance, often means-tested through Trusts.¹⁰

⁵ Dáil Debates, 470, 1996.

⁶ Throughout the period under discussion the blood supplies of England and Wales fell within the same organisational structure and, for brevity, England will be used to signify both within this paper (see Department of Health (U.K.), 'Self-sufficiency in blood products in England and Wales: A chronology from 1973-1991', (U.K., 2006) Department of Health: U.K.

⁷ Archer Rt Hon Lord, 'Independent public inquiry report on NHS supplied contaminated blood and blood products', (U.K., 2009): 70. Available at www.archercbbp.com

⁸ Penrose Rt Hon Lord, 'Penrose Inquiry: Key facts and figures', (Scotland, 2015), available at <http://www.penroseinquiry.org.uk>

⁹ Peterkin M, 'Blood scandal victims condemn Penrose Inquiry', *The Scotsman*, 25 March, 2015 <http://www.scotsman.com/news/health/blood-scandal-victims-condemn-penrose-inquiry-1-3728511> (accessed 1 May 2015).

¹⁰ The All-Party Parliamentary Group for Haemophilia and Contaminated Blood found that the provisions were 'highly demeaning and onerous, and some have been reduced to tears because of it'. All-Party Parliamentary Group on Haemophilia and Contaminated Blood, 'Inquiry into the current support for those affected by the contaminated blood scandal in the UK', (U.K., 2015) Haemophilia Society. UK governments have strenuously

During the 1970s in Ireland, Scotland and England haemophiliacs were offered new forms of therapy that presented the tantalising prospect of a vastly improved lifestyle. These commercial blood concentrates were both easy to store and administer, and far more potent than previous forms of therapy (cryoprecipitate). As the evidence of one patient to the *Penrose Inquiry* attests: his treatment had begun in the 1950s with extensive bed rest (sometimes up to nine months at a time) but these new blood products were ‘like a miracle cure. Instead of going to hospital for months, you could be treated ... in days or weeks’.¹¹ (see also *Lindsay Tribunal*; *Archer Inquiry*).

Even at this early stage in the use of commercial blood concentrates the medical profession was fully aware of the prevalence of Non-A, Non-B Hepatitis (later termed Hepatitis C) and that, while concentrates offered the prospect of a near-normal life, they were pooled from thousands of paid donations, increasing the risk of infection.¹² Prince *et al.*, for example, had alerted the medical community to the potential long-term problems associated with Non-A, Non-B Hepatitis, noting that the risk of infection among recipients of blood from commercial sources was ten times higher.¹³ However, medical opinion remained convinced that Non-A, Non-B Hepatitis was a chronic, but manageable condition and that the benefits of this new therapy appeared to outweigh any drawbacks.¹⁴ However, by the mid-to-

rejected comparisons between the Irish and U.K. schemes that provide support to those infected ‘on the basis that the Irish scheme was established to compensate for wrongdoing by a government agency but that no similar wrongdoing occurred in the U.K.’ (Colthart, G., ‘*HIV and Hepatitis C infection from contaminated blood and blood products*’, Standard Note: SN/SC/5698, (U.K., 2011) House of Commons Library.

¹¹ Penrose Rt Hon Lord, ‘*The Penrose Inquiry: Preliminary Report*’, (Edinburgh, 2010): 64, available at - <http://www.penroseinquiry.org.uk/preliminary-report/>

¹² Krever H, ‘*Commission of Inquiry on the Blood System in Canada*’, (Ottawa, 1997), Canadian Government Publishing. Leveton L, Harold B, Sox C and Soto MA (eds) ‘*HIV and the Blood Supply: An Analysis of Crisis Decision-making*’, (U.S.A., 1995), National Academy of Sciences. World Health Organisation (1975) *World Health Assembly, Resolution 28.72*. (Geneva, 1975).

¹³ Prince A, Grady G, Hazzi C, Brotman B, Kuhns W, Levine R and Millian S, ‘Long-incubation post-transfusion hepatitis without serological evidence of exposure to hepatitis-B virus’, *The Lancet* 304(7875) (1974), 241-246.

¹⁴ Jones P, ‘Acquired immunodeficiency syndrome, hepatitis and haemophilia’, *British Medical Journal* 287(6407) (1983), 1737-1738: 1738.

late 1970s, further research would reveal Non-A, Non-B Hepatitis to be more dangerous than previously thought.¹⁵ This meant that by the opening of the 1980s haemophiliacs in Ireland, Scotland and England were now faced with the harrowing prospect of two life-threatening viruses: the Human Immunodeficiency Virus (HIV) and Hepatitis C. In Ireland, 240 haemophiliacs were infected with HIV and/or Hepatitis C, while in England some 1,500 haemophiliacs were infected with HIV and an estimated 30,000 people were infected with Hepatitis C. In Scotland 60 patients were infected with HIV and 478 with Hepatitis associated with blood products.¹⁶

Looking back on these events the question often raised is why, in the absence of a scientific consensus on the threat posed by HIV/AIDS/ Hepatitis C did government not err on the side of caution: it could have returned to the use of an older, established form of therapy (cryoprecipitate). After all, these were blood products drawn from smaller pools of *voluntary* donations, widely acknowledged to be far safer than commercial products drawn from extensive pools of *paid* donations, thereby reducing significantly the possibility of infection. Or, government could have increased funding for public health services to produce their own concentrates, reducing reliance upon commercially-imported products drawn from higher risk donations. This would have also ensured that the twin pillars of post-war Irish and British blood policy (self-sufficiency and voluntary donation) were maintained and that, crucially, the hermetic seal on the respective blood supplies would not have been breached.

¹⁵ Craske J, Dilling N and Stern D, 'An outbreak of Hepatitis associated with the intravenous injection of Factor VIII concentrate', *The Lancet* 306(7927) (1975), 221-223. Mannucci PM, Capitanio A, Del Ninno E, Colombo M, Paretit F and Ruggeri ZM, 'Asymptomatic liver disease in haemophiliacs', *Journal of Clinical Pathology* 28 (1975), 620-624. Mannucci PM, Ronchi R, Rota L and Colombo M, 'A clinicopathological study of liver disease in haemophiliacs', *Journal of Clinical Pathology* 31 (1978), 779-783.

¹⁶ Lindsay. *Lindsay Inquiry*. Archer. *Archer Inquiry*. Penrose. *Penrose Inquiry*.

For the Inquiries led by Lindsay, Lord Penrose and Lord Archer, the central issues appear to have been: a lack of data on demand for these new products and how this could be met (supply); the uncertain state of scientific knowledge about the virological threats posed, and the problematic tension in the paternalistic relationship between doctor and patient, with doctors, more often than not, failing to inform patients about the risk associated with these new forms of therapy.¹⁷ As one patient (among many) recalled to the *Penrose Inquiry*:

I do not remember anything ever being discussed with me about the benefits and risks of any treatment I received. I do not think this was discussed with my parents either...I, and others who attended the same hospital as me, trusted the treatment implicitly and never thought to question it.¹⁸

For those such as Farrell, Feldman and Bayer, and the Inquiries of *Lindsay*, *Archer* and *Penrose* the focus has been to identify administrative failure, underpinning an imperative to apportion blame: what government knew about HIV/AIDS and Hepatitis C, and when the blood supply had been compromised.¹⁹ It is a concern with how risk was *managed*. While we agree that the (mis)management of risk (in particular how the risk was conveyed to patients through their doctor, or whether surrogate tests²⁰ should have been introduced earlier) was important to *how* the crisis unfolded, we wish to maintain that an explanation of *why* the

¹⁷ Archer. *Archer Inquiry*.

¹⁸ Penrose. *Penrose Inquiry. Preliminary Report*: 65.

¹⁹ Farrell A, 'Is the gift still good? Examining the politics and regulation of blood safety in the European Union', *Medical Law Review*, 14 (2006), 155-179. Feldman EA and Bayer R (Eds), '*Blood Feuds: AIDS, Blood and the Politics of Medical Disaster*', (New York, 1999), Oxford University Press. Lindsay. *Lindsay Report*. Archer. *Archer Inquiry*. Penrose. *Penrose Inquiry*.

²⁰ Surrogate testing operates by identifying markers for a disease that frequently occurs in conjunction with a different disease/infection for which there is no test currently available – in this case Hepatitis B as a surrogate test for HIV. It is premised on correlations between the presence of different diseases/infections and, whilst indirect, it does provide a form of testing when no direct test is possible. The drawback of surrogate testing is that, at best, it is suggestive. Lindsay. *Lindsay Inquiry*: 207. Penrose. *Penrose Inquiry. Preliminary Report*: 68. Archer. *Archer Inquiry*: 20.

crisis emerged demands consideration not of how the risk was managed, but *assessed*. This is not semantic quibbling; it's crucial, and demands we explore how risk in politics had been reconfigured, largely as a result of the New Right's determination to reduce the role of the public sector in all forms of welfare. Once considered, we can begin to appreciate more deeply a public health issue where complex scientific and technical problems are involved and powerful corporate interests are at play.²¹ Ireland, Scotland and England were not alone in experiencing a blood crisis. As Tribunals in Canada, Australia and France (to name but a few) testify; it was a global problem.²²

This paper offers a comparative analysis, understood as a method that involves the use of 'empirical evidence ...in an attempt to compare systematically and explicitly political phenomena'.²³ We both recognise and concede that there are difficulties encountered in research in the social sciences that cannot reproduce specific experiments in the manner of the physical sciences.²⁴ However, this approach offers both the opportunity to 'sharpen' the descriptive narrative and the possibility to counter the tendency to focus on the 'uniqueness' of the national context, or what Rose terms, 'false particularisation'.²⁵

²¹ These *Inquiries* were historical investigations and, from the outset, it is important to recognise that there have been substantial improvements in the regulation of blood. Debates in the 1960s and 1970s were dominated by Titmuss's distinction between voluntary and paid donation, where the former was widely recognised to be safer. However, since that time there have been important developments, particularly with the introduction of screening and viral inactivation techniques. In addition, as the Plasma Protein Therapeutics Association (PPTA) has pointed out, even if paid donation (in theory) impacted negatively on safety, voluntary donation is not a panacea; mandatory voluntary donation and self-sufficiency could be damaging in the event of a plant shut down, or an outbreak of nvCreutzfeldt Jacob Disease (nvCJD) (See Committee of Proprietary Medical Products, 'Position statement. Non-remunerated and remunerated donors: Safety and supply of plasma-derived medicinal products', (Europe, 2002), European Agency for the Evaluation of Medicinal Products). Moreover, as J Bult of the PPTA noted, Tabor's research into commercial products found no transmission of hepatitis B, C or HIV following the introduction of inactivation techniques in 1987. And, yet, five blood-borne HIV infections had occurred in Holland (2000), despite the enforcement of non-remunerated donation. Bult J, 'Response to the review 'Paying for blood donation: Still a risk?', *Vox Sanguinis* 85 (2003): 48. Tabor E, 'The epidemiology of virus transmission by plasma derivatives: Clinical studies verifying the lack of transmission of Hepatitis B and C viruses and HIV type 1', *Transfusion*, 39 (1999), 1160-1168.

²² Angelotta C, McKoy JM, Fisher MJ, Buffie CG, Barfi K, Ramsey G, Frohlich L and Bennett CL, 'Legal, financial, and public health consequences of transfusion-transmitted hepatitis C virus in persons with haemophilia', *Vox Sanguinis* 93 (2007), 159-165.

²³ Rose R, 'Comparing forms of comparative analysis', *Political Studies*, 39(3) (1991), 446-462: 439.

²⁴ Mackie T and Marsh D, 'The comparative method', in D. Marsh and G. Stoker (eds), 'Theory and methods in political science', (Basingstoke, 1995), Macmillan/St. Martin's Press, 173-188: 173.

²⁵ Rose. *Comparing forms of comparative analysis*, 39(3): 450.

As Mackie and Marsh observe succinctly, comparative analysis can be both ‘inductive or deductive’. However, most comparative work is not deductive, largely because it recognises that concepts we use come before the theory. However, comparative work such as we see below ‘provides an insight into its ‘robustness and transferability’.²⁶ Here, a further issue of import lies in Rose’s view that the ‘presence or absence of concepts applicable to a multiplicity of countries...is the test of whether a study can be considered comparative and, for this latter reason, we use Finland as an example of a country that chose to *resist* the importation of commercial blood products, retaining the hermetic seal on its blood supply.²⁷ It was a move informed by a different interpretation of risk to that embraced in Ireland, Scotland and England.²⁸

While these debates about the role of risk in politics, and how risk has been reconfigured under the enduring influence of modern conservative ideas inform our interpretation of the blood scandals, they should also be of interest to a wider international relations audience. For example, they had a crucial bearing upon the debates that ensued over the imperative for a new European Blood Directive: whether policy should embrace a precautionary stance, mandating the adoption of both voluntary donation and self-sufficiency. To some Member States, and lobby groups such as European Blood Alliance (EBA) and the European Plasma Fractionation Association (EPFA), it seemed incomprehensible that any new Directive would not endorse the twin pillars of voluntary donation and self-sufficiency.²⁹

However, it was a view not endorsed universally, either by those Members States that relied on imported commercial products, or private companies with substantial interests in the European blood products market. The Plasma Protein Therapeutics Association (PPTA), for

²⁶ Mackie and Marsh. *The comparative message*. 176. T

²⁷ Rose. *Comparing forms of comparative analysis*, 39(3): 449.

²⁸ Rasi V, Ikkala, E, Myllyla G and Nevanlinna HR, ‘Low prevalence of antibodies against Human Immunodeficiency Virus in Finnish Haemophiliacs’, *Vox Sanguinis*, 60(3) (1991), 159-161.

²⁹ Leikola J, van Aken WG, Hogman C, Lee D, Muglia M and Schmitt H, ‘*Plasma products and European self-sufficiency: Collection, preparation and use*. Council of Europe Press (1992). van Aken WG, ‘*The role of the Council of Europe in the development of European blood transfusion*’, ISBT Science Series 2 (1993), 139-142.

example, lobbied vociferously in opposition to making voluntary donation mandatory, arguing that reports from those such as van Aken³⁰ and Leikola *et al.*,³¹ were biased; it was simply trade protectionism by another name, designed to subsidise the not-for-profit sector. The PPTA argued that this flew in the face of the principles of the EC Treaty, and that it would not hesitate to make it an issue for the General Agreement on Trade and Tariffs (GATT).³²

If these are matters that would be of particular interest to scholars of European politics, we need also to recognise how the influence of modern conservatism on the role of risk in politics has permeated influential international non-governmental organisations and trade agreements (GATT/WTO) that form a crucial consideration in policy areas beyond blood and pharmaceutical products and include food safety or chemicals regulation, to name but just two.³³ Finally, if we adjust our focus, moving beyond the realm in which risk, science and politics collide, to one that examines the impact of these ideas on how expert advice is refracted through politics, we can begin to explore its impact upon, and its contribution toward, areas as diverse as the international financial crisis or reforms in social work.³⁴

This paper is divided into three sections. The first outlines the triumvirate of threats to which the respective health services were exposed from the mid-to-late 1970s onward. The second discusses the impact of the emergence of HIV/AIDS, the scientific uncertainty surrounding this threat and how this was ‘played out’ through a new political landscape

³⁰ van Aken. *Council of Europe*. (1993).

³¹ Leikola *et al.* *Plasma products and European self-sufficiency*. (1992).

³² Lewis S, ‘European blood donation’, *The Lancet*, 339 (8799) (1992): 8-10. Hagen PJ, ‘Blood transfusion in Europe a ‘white paper’, Council of Europe Press (1993).

³³ For those such as Kingsbury *et al.*, arguments in favour of sound science have permeated new political networks that are increasingly significant (OECD, WTO, CODEX), where the preference is for the use of ‘codes of practice’ or norms, and form the element to trade agreements that give substantial incentives to conform, restricting the regulatory menu available to governments. Kingsbury B, Krisch N and Stewart R, ‘The emergence of global administrative law’, *Law and Contemporary Problems* 68 (2005), 15-62. See also – Peel J, ‘Risk regulation under the WTO SPS Agreement: Science as an international normative yardstick?’ Jean Monnet, Working Paper (2004).

³⁴ Taylor G, ‘Risk and financial Armageddon in Ireland: The politics of the Galway tent’, *Political Quarterly*, 82 (4) (2012), 596-608. Taylor G, ‘Risk, prudence and the Irish banking crisis: A comment on the Honohan Report’, *Administration*, 60 (2) (2011), 97-112.

where decisions on safety were no longer the exclusive preserve of ministers, civil servants and the medical and scientific communities. The third section examines briefly the case of Finland.

The political, economic and virological threats to the twin pillars.

The prognosis for those with haemophilia in the post-war period was miserable. Abrasions, bruises or spontaneous bleeds could lead to prolonged bleeding episodes that could be crippling or fatal.³⁵ However, during the 1960s a new technology emerged (cryoprecipitate), which condensed the clotting factor from multiple donations (commonly 5 or 6), improving coagulation dramatically. Difficulties remained, for cryoprecipitate had to be stored at very low temperatures, required thawing before use, and could be of ‘inconsistent potency’. Moreover, transfusion was in the manner of a ‘drip’, making it a slow and unpleasant procedure, particularly for young boys that would often have to be strapped down. As with any blood product, it carried a risk.³⁶

Debates about risk and the safety of blood during this period were shaped almost exclusively by the distinction between voluntary and paid donation, where the former was accepted universally to be superior. Here, Richard Titmuss was adamant that blood, voluntarily and freely given (a gift), was both more efficient and safer than in the USA, a system that drew extensively upon paid donors or, as he phrased it, the ‘denizens of skid row’.³⁷

By the mid-to-late 1970s, in Ireland, Scotland and England, a political and ideological challenge to the interventionist state that lay behind social democracy gathered pace, precisely at the moment when the United State’s pharmaceutical industry was engaged in

³⁵ Lee C, Rizza C and Tansey EM, ‘Witnessing Medical History: An interview with Dr. Rosemary Biggs’, *Haemophilia* 4 (1998), 769-777.

³⁶ Christie DA and Tansey EM, ‘*Haemophilia: Recent History and Clinical Management*. Transcript of witness seminar by Wellcome Trust’, (London: 1998), Wellcome Trust. *Penrose. Penrose Inquiry*.

³⁷ Titmuss. *The gift relationship* (1970).

efforts to extend its footprint into a potentially lucrative international market in blood products.³⁸ Previously, this move had been constrained by the short shelf-life of blood. However, the ability to ‘crack’ blood into its component parts was a first, crucial step in developing blood products that could be traded as international commodities and, keen to exploit technological advantage, USA multinationals began to collect blood more intensively. Here, new technologies (plasmapheresis) offered a solution to the issue of supply, allowing donors to be ‘harvested’ four times more often, though this was not well-received on this side of the Atlantic because of concerns about anaemia.³⁹

With medical procedures considered previously to be dangerous now possible, and with an international market anticipated to expand rapidly, the United States pharmaceutical industry was keen to exploit its market position, extending its blood supply network to parts of the third world where paid donations were used and centres, such as those in Nicaragua bled a thousand people a day, earning the soubriquet among locals of *Casa de Vampiros* (House of the Vampires).⁴⁰

Blood concentrates were not without problems. They were expensive and, as they were manufactured by pooling hundreds or thousands of donations, the risk of infection, especially if paid donations were used, was far greater. Moreover, as Peter Jones of the Newcastle Haemophila Reference Centre observed in a letter to the *British Medical Journal* in 1980: within the USA the collection of plasma was regulated by the strict rules of the United States Food and Drugs Administration (FDA), ‘what happens outside the areas of FDA surveillance is anyone’s guess’.⁴¹

³⁸ Jones. Factor VIII supply and demand. 280 (6230). Starr C, ‘*Blood: An Epic History of Medicine and Commerce*’, (London, 1998), Warner Books.

³⁹ Excessively frequent whole blood donation can deplete the body’s red blood cell count, leading to anaemia. As plasmapheresis only harvests plasma, this concern is avoided.

⁴⁰ Starr. *Blood: An epic history*: 274.

⁴¹ Jones P, ‘Factor VIII supply and demand’, *British Medical Journal* 280(6230) (1980), 1531-1532: 1531.

No one should be left in any doubt that for haemophiliacs accustomed to the problems posed with transfusion, concentrates offered a dramatic improvement in lifestyle. As one witness to the *Archer Inquiry* in the UK testified:

concentrates ...did away with the clumsiness of cryoprecipitate...it was just ...put a solution into a syringe... I clearly remember my first infusion...in 1973...I could hardly believe the small amount and speed of treatment.⁴²

While the twin pillars of voluntary donation and self-sufficiency had concentrated the minds of politicians, the medical community was, by the mid-to-late 1970s, concerned by emerging data on Non-A, Non-B Hepatitis that indicated it to be a condition more serious than previously thought. Those such as Prince *et al.* had alerted the medical community to the possible long-term problems associated with Non-A, Non-B Hepatitis and the fact that the risk of infection among recipients of blood from commercial sources was ‘ten times higher’.⁴³ Indeed, as the *Penrose Inquiry* reveals, in 1975 Dr J Garrett Allen (Stanford University Medical Centre) wrote to Dr William Maycock, Director of the Blood Products Laboratory at Elstree (BPL), expressing concern about blood donated from paid and prison donors in the USA. One product, developed by Cutter (named as Konyne), was ‘extraordinarily hazardous’ where 50-90% had developed hepatitis, ‘half of which had proved fatal’.⁴⁴ However, *The Penrose Inquiry* cautioned against this evidence, preferring to question the motive for such an argument, largely on the grounds that Dr Allen appeared to be seeking to persuade the UK to

⁴² Archer. *Archer Inquiry*.

⁴³ Prince *et al.* *Long-incubation post-transfusion hepatitis*. 304 (7875).

⁴⁴ Penrose. *Penrose Inquiry. Preliminary Report*: 148.

stop buying commercial blood products from American companies ‘on the basis that this adversely affected American attempts to set up a volunteer donation programme’.⁴⁵

Clearly, with no *conclusive* scientific evidence to persuade treating-doctors that Non-A, Non-B Hepatitis was anything other than a chronic disorder that might result in ill-health in a few people, there seemed no justifiable reason to alter treatment practise. However, these were decisions taken largely by the medical profession and, as the *Penrose Inquiry* records, ‘it was a recurring theme’ amongst both patients and their relatives that ‘they were given little or no information from their treating clinicians about the risk of infection to which they were exposed as a result of their treatment with blood or blood products’.⁴⁶ In Ireland, it was a largely similar situation and, while there was a National Haemophilia Service Co-ordinating Committee that included all stakeholders, it ‘was simply a “rubber stamp” for the decision of treating doctors in consultation with the BSB as to what products should be used’.⁴⁷

However, as the *Penrose Inquiry* notes, clinical autonomy also ensured considerable variation and, in some instances, doctors did inform patients of the attendant risks:

One of the few times I can remember being specifically warned about possible adverse consequences of using Factor IX was by a doctor...his expression comparing

⁴⁵ Penrose. *Penrose Inquiry. Preliminary Report*: 148. Prior to the mid-1970s paid donation was common in the U.S.A. However, in the wake of Titmuss’s ‘The Gift Relationship’ and with growing concerns over hepatitis transmission, in 1975 the American Blood Commission was established to implement a national blood policy founded upon voluntary donation. By 1976, less than 3% of whole blood collection in the U.S.A. was from paid donors – Senate Oversight Committee, ‘*Oversight and implementation of national blood policy. Subcommittee on Health and Scientific Resources*’, (Washington D.C., 1979). In 1978, the Food and Drug Administration (FDA) introduced regulations around labelling blood as ‘paid’ or ‘volunteer’ and paid whole blood donation effectively ended, as ‘no hospital would take blood that was implicitly inferior’ (Starr. *Blood: An epic history*).

⁴⁶ Penrose. *Penrose Inquiry. Final Report*: 1489.

⁴⁷ In late 1979 the committee did recommend the production of a leaflet for patients that outlined the risk of Hepatitis from treatment. However, no leaflet was ever produced. Lindsay. *Lindsay Tribunal*: 207.

Factor concentrates to ‘Russian roulette’ for viral risk stuck in my mind, and was responsible for my avoidance of this treatment for a number of years.⁴⁸

If the virological threat had been the focus of the medical community, politicians were concerned about cost, and how sufficient supply could be achieved. Though both the blood systems of the U.K. and Ireland had been founded upon the twin pillars of self-sufficiency and voluntary donation, and were subject to similar financial constraints, the policy choices taken were starkly different and had serious implications for their respective haemophiliac communities.

Ireland’s response to the haemophilia crisis was not shaped exclusively by political pragmatism in a period of fiscal crisis, for it was influenced by the views of both its medical profession and the Catholic Church, reluctant participants in expanded welfare provision. The former had long been opposed to the Fabian beliefs underpinning the UK’s National Health Service and, with significant interests in private practice, were determined that ‘competition’ in the supply of blood products was essential. It feared that, as a public monopoly, the Irish state’s Blood Transfusion Service Board (BTSB) could charge private patients ‘whatever it liked for their treatment’ in order to subsidise public provision.⁴⁹ The latter, which had long directed the moral compass of Irish life, was vehemently opposed to birth control and homosexuality, both of which were illegal in Ireland at the time of the HIV crisis. As a consequence, Department of Health efforts to inform the public of the threat of AIDS, and advise condom use, were severely hampered. As one official put it, ‘advocating the use of condoms to prevent sexual transmission would have caused murder’.⁵⁰ More importantly, many hospitals remained under the control of the Catholic Church, which was a substantial stakeholder in the healthcare system.

⁴⁸ Penrose. *Penrose Inquiry. Preliminary Report*: 68.

⁴⁹ Donnellan E, ‘Tribunal will hear Ireland pioneering safe clotting agents’, *Irish Times*, 11 May 2000.

⁵⁰ Melia P, ‘Church opposed AIDS campaign, says doctor’, *Irish Independent*, 23 May 2001.

In England and Scotland, operating under intense fiscal constraints imposed largely, though not exclusively, by conditions attached to loans from the International Monetary Fund (IMF), the Labour government was beginning to question openly the role of public service provision, precisely at the moment commercial concentrates had raised concerns both about cost and safety (Non-A, Non-B Hepatitis) (see *Archer Inquiry* 2009). There was little doubt that demand would increase, certainly as young children grew older and life expectancy continued to improve. Indeed, as Cash and Spencely (1976) observed, it was a complex problem that required resources urgently, and ‘should be seen by government departments as an important long-term investment’.⁵¹

It was widely acknowledged that the UK’s Blood products laboratory (BPL) had been denied capital funding over a prolonged period of time, and that it was only after determined efforts from Dr David Owen, minister for health in the Labour government, that investment was sanctioned (*Archer Inquiry*, 2009).⁵² By the mid-1970s a new fractionation plant in Edinburgh had been completed. However, issues about its capacity to supply sufficient products remained, especially as demand for these new forms of therapy continued to escalate.

Unlike the *Archer Inquiry*, The *Penrose Inquiry* Interim Report explores in significant detail these issues, noting that estimates about supply were either ‘inaccurate or outdated’, as well as difficulties encountered in the administrative relationships between various agencies in the NHS that had undergone reform.⁵³ If this was a deliberation upon the matter of demand, we are left with very little on the issue of supply: a rather limited single paragraph that reads:

⁵¹ Cash J and Spencely M, ‘Haemophilia A and the blood transfusion service: a Scottish study’, *British Medical Journal* 18 (2) (1976), 682-684: 684.

⁵² Archer. *Archer Inquiry*.

⁵³ Penrose. *Penrose Inquiry. Preliminary Report*: 105-130.

The plant had been designed to accommodate material from the UK, staff had been recruited and trained on the basis of shift working to realise the plant's production potential. *But opposition from trades' unions, allied with demands relating to terms and conditions of employment which the employers found unacceptable*, had made shift working impracticable [emphasis added].⁵⁴

It seems almost perverse to record that an *Inquiry* that cost over £11million, lasted seven years and resulted in two reports that extended to over 2,400 pages would not wish to explore in more detail the 'difficulties and associated consequences' that union-management relations had upon this crisis. It certainly raises crucial questions: for example, what were the terms and conditions of employment that employers found so unacceptable to make shift-working impracticable?

These were issues all the more important when we consider the political, economic and ideological flux of this period, where the Conservative government's antipathy toward the trade unions and public sector was a significant element to the political agenda. Indeed, its determination to 'find' alternative forms of provision (either through private sector investment or philanthropy) should not be underestimated. We need look no further than the recent revelations recording the ease with which it accepted a role for ventures proposed by those such as Jimmy Saville in Stoke Mandeville, that would draw extensively from philanthropic donations, and are now the subject of an extensive Public Inquiry.

⁵⁴ Penrose. *Penrose Inquiry. Preliminary Report*: 127.

By the late 1970s the health services in Ireland, Scotland and England were presented with a particularly difficult conundrum: either they would have to increase investment to improve production of national concentrates (sourced from supplies of voluntary donation) or choose to increase commercial imports. For Mrs Thatcher's Conservative government further investment in the public sector held little appeal, and civil servants were charged with exploring the possibility of a tie-up with industry, preferably with a British pharmaceutical company. For the Conservative government such a collaboration offered invaluable potential: the pressure on public finances would be eased, and any risk or reward associated with investment would be borne by private enterprise.

Critics of the commercial route were quick to point out that any decision to abandon NHS production of concentrates could increase the cost of haemophilia care, rupture the hermetic seal on the U.K.'s blood supply and undermine voluntary donation. While they conceded that in the short-term, a commercial route may reduce costs, over time, these could increase, since the use of both NHS produced concentrates and cryoprecipitate had provided a bulwark. Officials in the Department of Health and Social Services (DHSS) also expressed concern about the potentially negative impact on voluntary donation that could prove costly: many employers had already withdrawn support for 'time-off' to donate blood, and the emergence of 'paid donation' was likely only to exacerbate this problem.⁵⁵ If this scenario was to be avoided, a substantial increase in public investment was required to address a shortfall in the supply of plasma, assume manufacture (on an increasing scale) of concentrates, and compete with multinational pharmaceutical companies. Certainly, it is worth noting that Cash and Spencely found that there was 'no evidence to suggest that the

⁵⁵ Department of Health. Self-sufficiency from 1973 to 1991 (2006). Department of Health. Department of Health and Social Services, *Treatment of Haemophilia; Future of the Manufacture and Supply of Blood Products; Submission to Ministers with Proposals for Short-Term Measures and Examination of Long-Term Measures to Remedy Serious Defects; Discussions, Correspondence and Minutes of Meetings*. January 1st 1973 – December 31st 1980', (London, 1973). Department of Health and Social Services MH 168/144. National Archive, Kew.

voluntary donor will not respond; indeed those in the regional blood transfusion centres know that quite the reverse is true'.⁵⁶

However, it emerged that British pharmaceutical companies (with the exception of Beechams) were reluctant to be seen making a profit from voluntary donation. Moreover, civil servants in the Department of Health and Social Services cautioned that if commercialisation was introduced, 'careful public relations would be required' to offset public resistance. They were also sceptical of Beecham's expertise in fractionation and questioned its motivation, for it was felt they may simply want to use the NHS to 'learn on; a stepping stone into a lucrative world market in blood products'.⁵⁷

While a free market route was shelved, government was adamant that BPL should abandon its 'habitual service orientation' to the NHS and market products like its commercial competitors. Nonetheless, the production increases that were expected to emerge from the investment secured by Dr David Owen did not materialise until the early 1980s. What remains clear is that a crucial time-lag occurred before the increases could be realised and a 'window' had opened during which concentrates flowed inward with disastrous consequences.

In Ireland, the importation of commercial concentrates continued largely unabated. While the BTSB did focus attention on securing sufficient supplies of plasma for manufacturing concentrates, through what became known as the 'Herapin' project, it confronted challenges with both funding and expertise. Moreover, as the Herapin method had been rejected internationally, the value of such efforts seemed questionable. As one senior BTSB official later acknowledged, the whole idea was little more than 'pious aspiration', and

⁵⁶ Cash J and Spencely M. *Haemophilia A*. 18 (2): 684.

⁵⁷ Department of Health. *Self-sufficiency from 1973-1991* (2006). Department of Health and Social Services, *'Treatment of Haemophilia; Future of the Manufacture and Supply of Blood Products*. (London, 1973). Department of Health and Social Services MH 168/144. National Archive, Kew.

the Board ‘was not really serious about its introduction’, as it would have made the Board’s financial situation worse rather than better.⁵⁸ Indeed, given the austere economic situation, it is doubtful that, even if sufficient plasma was available, the funding would have been. Instead, the BTSB pursued the novel approach of custom-fractionated of Irish plasma by a commercial manufacturer. This would not only ensure self-sufficiency, but would also result in surplus blood products that the BTSB could sell to hospitals. With the BTSB in financial straits, this opportunity was ultimately taken, and as the BTSB’s financial advisor noted, the profits ‘helped to run the whole organisation’.⁵⁹ Nonetheless, reflecting the general ambivalence to the crisis, the BTSB took almost 18 months to establish the contract and only appeared to act with urgency after an Irish haemophiliac was diagnosed with HIV/AIDS.⁶⁰

Risk, Science and Haemophilia: HIV/AIDS

A witness to the *Penrose Inquiry* recalls:

My wife died of AIDS...at her funeral, her coffin was covered with a tarpaulin and the flowers were put on the floor. Following her death his sons changed their names so that their children would not be bullied because of the stigma associated with HIV and Hepatitis C. At the time of his wife’s death, he worked part-time as a mechanic. After her death he was told not to return to work because his wife had died of AIDS.⁶¹

As the 1980s opened the haemophilia communities in Ireland, Scotland and England were confronted with a new threat, for which there was little scientific knowledge;

⁵⁸ Humphreys J, ‘Profits on Factor 8 deal loomed large in BTSB decisions’, *Irish Times*, 22 September 2000.

⁵⁹ Humphreys J, ‘Debt ridden BTSB was bailed out by department’, *Irish Times*, 21 September 2000.

⁶⁰ Lindsay. *Lindsay Tribunal*.

⁶¹ Penrose. *Penrose Inquiry. Final Report*: 131.

HIV/AIDS. In the USA, the gay community had been the first group identified at risk, but HIV/AIDS was soon linked to other groups; intravenous drug users and Haitians.⁶² While changes to the immune system had been identified as important, it did not *necessarily* suggest a causal relationship, and there was no evidence to confirm that blood was a vector of transmission. In the U.S.A., only a few diagnoses had been made amongst haemophiliacs, despite the vast quantity of blood products transfused, and none in Ireland, Scotland or England. However, in late 1982, with the infection of a new-born after a blood transfusion in the USA, blood suddenly came under suspicion.⁶³

With no *conclusive* evidence that commercial concentrates carried HIV, and given the benefits associated with them, doctors were reluctant to alter treatment practise. The medical community sought to reassure patients: the mortality rate both in the U.S.A and on this side of the Atlantic was less than one percent and ‘the opinion of the majority’ was that, for haemophiliacs, the ‘risk of haemorrhage and its complications, far outweighed the risk of developing AIDS or chronic liver disease’.⁶⁴ As diagnoses among haemophiliacs became more frequent in the U.S.A., moves to secure the blood supply became paramount. The United State’s pharmaceutical industry was concerned about product safety, the issue of cost and the possibility of litigation. For haemophiliacs, there was a concern that any ‘ill-informed’ reaction could lead to blood shortages.⁶⁵

The U.S.A. Centre for Disease Control (CDC) called a crucial meeting in Atlanta (1983) that sought to introduce donor questioning and surrogate tests to reduce the spread of

⁶² Epstein S, ‘*Impure Science: AIDS, Activism, and the Politics of Knowledge*’, (U.S.A., 1996), University of California Press. Shilts R, ‘*And the Band Played on: Politics, People and the AIDS Epidemic*’, (London, 1988), Penguin.

⁶³ Centre for Disease Control, ‘*Morbidity and Mortality Weekly Report*’, 10 December 1982.

⁶⁴ Jones. Acquired immunodeficiency syndrome, hepatitis and haemophilia. 287 (6407).

⁶⁵ Department of Health. Self-sufficiency from 1973-1991 (2006). Jones. Acquired immunodeficiency syndrome 287 (6407). Leveton *et al.* *HIV and the blood supply* (1995). Lindsay. *Lindsay Tribunal*. Shilts. *And the band played on* (1998).

the disease. It would involve a major political struggle as both blood bankers and gay groups objected to the demand for donors to reveal their sexual preference. It was not just discriminatory, but an affront to the ethos of donation. As far as surrogate tests were concerned, they warned that there was the real possibility that high-risk donors may donate in order to be tested, increasing the transmission of disease through blood. Blood banks were worried that donor attrition would increase, that non-infected blood could be lost or, that tests would produce false positives; confirm an individual with Hepatitis B, but *not* HIV/AIDS.⁶⁶

Decisions about safety now fell at the doorstep of multinational companies. In some instances, such as in the introduction of donor screening, they were ahead of voluntary bodies such as the American Red Cross. However, in this period of uncertainty, precautionary action was now constrained by the national and international dynamics shaping blood. The United States government was reluctant to view HIV/AIDS as an urgent health issue and was persuaded by pharmaceutical companies that the issue of safety should be borne by industry, which was fiercely opposed toward any further regulation.⁶⁷

This was a period in which American politics was consumed increasingly with concerns about the debilitating impact of Federal regulation on industry, either by Federal agencies in the areas of health and the environment, or by the constraints imposed upon the pharma pharmaceutical and nascent bio-technology sectors (particularly genetically modified organisms) in the post -Thalidomide period. Determined to roll back the 'state', the American New Right initiated an intellectual challenge to the extended role of Federal government that was accused of deciding 'what is in our best interests', according far too little consideration to an individual's capacity to decide on risk. It was, they maintained, important to recognise

⁶⁶ Leveton et al. *HIV and the blood supply* (1995).

⁶⁷ Epstein. *Impure science* (1996). Taylor G, 'The reconfiguration of risk in the British state', *Public Policy and Administration*, 24 (2009), 379-398.

that risks were an attendant feature of day-to-day life; what matters is how, as individuals, we make judgements about those risks.⁶⁸

These were ideas that permeated debates about the role of risk and science in regulation where industry and conservative lobby groups sought to challenge Federal agency decisions that raised new issues for administrative conduct: the relevance and integrity of the science, the competence of those charged with evaluating such evidence and the role of the courts in overseeing the way in which regulatory agencies operated.⁶⁹ Others, notably Peter Huber have argued vociferously that ‘the science’ underpinning Federal intervention had been based upon ‘weight of evidence’ that amounted to little more than ‘junk science’, or science that could not establish a causal connection.⁷⁰

Profoundly anti-rationalist in sentiment, republicans maintained that government regulation was a misguided and impossible task: there are simply too many conflicting and competing variables to consider (economic, technological and social), for a balance to be achieved (see for example, Quayle Competitiveness Council, 1990). Any pretence to the contrary, to engineer order through intervention, was economically damaging (reduces innovation), inherently unjust (impacts upon choice and freedom), paternalistic and ideologically driven.

In this changing political, economic and ideological terrain the function of science in regulation alters, for it is not to *prevent* development on the grounds that a new technology, process or product *may* be risky, but to establish *definitively* whether a product will be detrimental to public health, thereby establishing negligence or culpability, for which, in the event of market failure, there is insurance. In turn, there is the firm belief that expert advice

⁶⁸ Taylor. *The reconfiguration of risk in the British state*. 24.

⁶⁹ Wagner W, ‘The bad science fiction: Reclaiming the debate over the role of science in public health and environmental regulation’, *Law and Contemporary Problems* 66(4) (2003), 63-133.

⁷⁰ Huber P, ‘Medical experts and the ghost of Galileo’, *Law and Contemporary Problems* 54 (1991), 119-128.

should articulate the extent to which individuals are exposed to risk, and be employed to define more clearly where intervention (management) *cannot* be justified.⁷¹

At this point, the burden of proof alters, for multinational pharmaceutical companies recognise only that, unless a risk is *proven*, intervention cannot be warranted. Here, we can now begin to appreciate that, if science is inconclusive, it forms not the basis from which to justify intervention, but to resist. Any determined effort to return to the use of cryoprecipitate for example, would have had to confront the clamour to resist intervention from multinational pharmaceutical companies in an ideological climate unreceptive to such calls.

It is in this context that the role of risk in politics is reconfigured, for risk was no longer refracted through the architecture of either the Irish or British state, subject to the decisions of ministers, civil servants, members of the medical and scientific communities; for *it now involved multinational pharmaceutical companies*. This new element in the political equation, and its impact on decision-making, can be seen in the evidence given to the *Archer Inquiry* by Dr Maycock when he observed that: while it ‘is always easy to look back and see what might have been done’; there was never complacency on safety: ‘the quality of this material was controlled both here and in America’.⁷² Crucially, it meant that the Irish and British governments were now predisposed to accept the decision of the market (*relocating the point at which the assessment of risk was now undertaken*).

This argument was forwarded in the contentious issue of surrogate tests, where the United State’s pharmaceutical industry maintained that there was *insufficient* scientific evidence to justify a prospective cost of \$100 million.⁷³ Opposition to precautionary intervention, which correlated strongly with the United State’s pharmaceutical industry’s

⁷¹ Taylor. *The reconfiguration of risk in the British state*. 24.

⁷² Archer. *Archer Inquiry*: 20.

⁷³ Shilts. *And the band played on* (1998).

prolonged determination to rid itself of the regulatory constraints imposed in the post-Thalidomide era, could be defended on the grounds that, at what point do you intervene in the event of scientific uncertainty? However, in this instance it seems also pertinent to ask that if a scientific consensus on the risk posed could not be established, then why was there no concerted effort to return to cryoprecipitate (even as a temporary measure)? Thus, at issue, was not simply the inconclusive nature of the science surrounding HIV/AIDS, or the extent to which concentrates posed a significant health problem, but the changing material and ideational context in which any response took place.⁷⁴

Unlike Ireland, Scotland and England, Finland chose to remain self-sufficient, resisting the clamour to embrace imported, commercial concentrates and persisted with the use of an older form of therapy (cryoprecipitate). This decision had significant benefits for its haemophilia community, where only 2 of 213 haemophiliacs contracted HIV (0.94%),⁷⁵ It was a position that correlates closely with those haemophiliacs in the U.K. that remained on cryoprecipitate (1.2% infected with HIV).⁷⁶ It seems almost perverse to record that the *Lindsay*, *Penrose* and *Archer* Inquiries ignore altogether this case study.

At this point, however, we can identify more accurately the failings of such Inquiries and Tribunals, for the origins to this crisis lie not in administrative failure, the misplaced paternalism of doctors or the inability of governments to grasp uncertainty with a complex health issue (risk management), but in the manner in which risk in politics has been reconfigured: a changing political, economic and ideological context in which the locus of decision-making surrounding risk-assessment had altered. A decade of persistent reform to

⁷⁴ The introduction from late 1985 of heat-treatment of concentrates removed the threat of HIV.

⁷⁵ Rasi V, Ikkala, E, Myllylä G and Nevanlinna HR, 'Low prevalence of antibodies against Human Immunodeficiency Virus in Finnish Haemophiliacs', *Vox Sanguinis*, 60(3) (1991), 159-161.

⁷⁶ Colvin BT, Collier LH and Craske J, 'A prospective study of cryoprecipitate administration: Absence of evidence of virus infection', *Clinical and Laboratory Haematology* 9 (1985), 13-15.

regulation in the USA, and its influence on the political narrative in Ireland, Scotland and England, had separated the relationship between risk assessment and its management, with the former elevated at the expense of the latter.

A risk assessment articulates the extent to which consumers (of health) are exposed to a risk, but acknowledges explicitly that intervention can be justified *only* once a quantifiable risk assessment has identified an ascertainable risk, not a theoretical uncertainty (or spurious fear). In such circumstances, it is absolutely imperative we understand that the evidentiary bar for intervention is raised, and any precautionary instinct is reduced. More damning is the fact that where there is a lack of political will and/or medical consensus on a potential for *systemic* health risk, the opportunity to invoke precautionary intervention is reduced, and forms the basis from which to *resist* regulatory intervention.⁷⁷

Conclusion

Post-war blood policy in Ireland, Scotland and England had been built upon the twin pillars of voluntary donation and self-sufficiency, a policy inspired largely by the work of Richard Titmuss, who maintained that blood, voluntarily and freely given, was both economically more efficient and safer.⁷⁸ As the 1970s unfolded it was a policy increasingly under threat from a triumvirate of sources (virological, political and economic) as the political fabric of social democracy became the subject of intense political debate. In this period, a market for blood products (concentrates) developed, offering haemophilia patients new treatment options. As a new form of therapy it was expensive and, because it was

⁷⁷ If this has led to confusion about the origins to the blood crises it has also contributed to a fundamental misunderstanding about the European Blood Directive that emerged, with those such as Farrell (2006) and Feldman and Bayer (1999) convinced it remains 'precautionary'. Farrell. *Is the gift still good*. 14. Feldman and Bayer. *Blood Feuds* (1999). Taylor G, 'Risk, science and European blood regulation: A pre-cautionary tale', Working Paper, Social Science Research Centre, National University of Ireland, Galway (2015).

⁷⁸ Titmuss. *The gift relationship* (1970).

manufactured from large plasma pools, raised the prospect of infection, especially if paid donations were used.

During a crucial ‘window’ in which the hermetic seal on the blood supplies of each of our case studies was ruptured, and commercial concentrates imported, (with the exception of Finland) decisions about risk were no longer subject to the decisions of ministers, civil servants and members of the medical and scientific communities, for now it involved multinational pharmaceutical companies, which meant that government was now predisposed to accept the decision of the market. Moreover, and in stark contrast to the findings of *Tribunals and Inquiries* led by *Penrose, Archer, Lindsay and Krever* (Canada) it was the *assessment*, and not the *management*, of risk that is crucial in any explanation of the blood crises that unfolded across the globe.⁷⁹

Such an explanation is crucial in understanding the reconfiguration of risk in politics as neo-liberal governments and multinational capital sought to reduce the role of the state in welfare. However, while such ideas are clearly important to explaining both the blood crisis and the European blood Directive that emerged from this debacle, they also apply to other areas of public policy, such as medicines regulation, the financial crisis and debates where there are conflicting interpretations over the role of the principle of precaution in EU decision-making, for examples chemicals, genetically modified organisms and pesticides.

⁷⁹ Penrose. *Penrose Inquiry. Final Report*. Archer. *Archer Inquiry*. Lindsay. *Lindsay Tribunal*. Krever. *Krever Commission*.