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### **3. Legal Responses to Public Crisis: Tribunals of Inquiry and the Blood Crisis in the Republic of Ireland**

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#### **Abstract**

This paper will outline the national and international cases of contaminated blood which have emerged as a part of the 'risk society' of modernity since the 1980s. In particular, the paper will examine the Tribunals of Inquiry that were established in order to investigate the use contaminated blood in cases in the Republic of Ireland in that timespan. The paper will outline the key issues surrounding the 'blood crisis' that came to dominate the news agendas of the day, and will present an analysis of the legal issues which emerged from these legal responses.

#### **Introduction**

In the early 1980s, few could have predicted that the growing number of previously healthy young men in the United States that were presenting with uncommon cancers normally associated with suppression of the immune system signalled the beginning of a world-wide public health crisis - HIV/AIDS. Though HIV/AIDS remains a global concern with over 30 million people affected (WHO, 2007), the spread of the virus through blood in the early to mid-1980s led to an iatrogenic disaster that resulted in a litany of tribunals and inquires.

In Canada, where more than seven hundred haemophiliacs were infected with Human Immuno-Deficiency Virus (HIV) and many more with hepatitis C,

Justice Horace Krever (1997) sought to uncover the circumstances that surrounded an unprecedented 'public health disaster' (Krever, 1997). In Japan approximately eighteen hundred haemophiliacs were infected and the long running *Yakugai Eizu* trial led one plaintiff to commit suicide, a public apology by the Minister for Health and Welfare and, a guilty verdict against three presidents of Japan's Green Cross company for 'professional negligence causing death' (Cullinane, 2005: Feldman, 1999).

Europe experienced a similar pattern. *In France, l'affaire du sang contaminate*, saw doctors and blood bankers in the dock with custodial sentences imposed (Steffen, 1999). In Denmark the longest judicial inquiry in the history of the state developed, during which the Interior Minister Britta Schall Holberg earned the sobriquet of 'Bloody Britta' (Albeak, 1999). In Italy a civil court ruled that the Ministry of Health were solely responsible for infections from contaminated blood products (Simini, 1998). In the U.K., an inquiry (the Archer Inquiry) was not established until 2007. Led by Lord Archer of Sandwell it sought to 'unravel the facts...and help those afflicted and bereaved to come to terms with the tragedy (Lord Archer of Sandwell, opening statement: 7). However, this was an independent rather than statutory inquiry, as successive governments were of the view that a public inquiry was not justified because they did 'not believe that any new light will be shed on this issue as a result' (Lord Warner, Minister for State in the Department of Health, cited in Archer, 2009: 6). And, Government continued to maintain that 'it was not possible to effectively test for these viruses in the 1970s and 1980s' (Dawn Primarolo, Minister for Public Health in the U.K., 2009).

In Ireland, not one but two statutory inquiries were established in the aftermath of the blood crisis. The first, the *Tribunal of Inquiry into the Blood Transfusion Service Board* (Finlay, 1997), examined the events surrounding the infection of over a thousand women with hepatitis C through the use of a domestically produced contaminated blood product; Anti-D. The second, the *Tribunal of Inquiry into the Infection with HIV and Hepatitis C of persons with Haemophilia and Related Matters* (Lindsay, 2002) investigated how Ireland's

haemophiliac population had been infected by a 'medicine that was supposed to help them' (Daly & Cunningham, 2003: 205).

As the Finlay Tribunal unfolded, an iatrogenic catastrophe rapidly descended into a political scandal, as it became apparent that not only had the Blood Transfusion Service Board (BTBSB) recklessly ignored its own safety protocols and multiple indications of hepatitis infection of its primary donor, it had also attempted to ignore the matter in the 'vague and irresponsible hope that the problem might go away' (Finlay, 1997:33). Political and public concern over such revelations rapidly turned to disbelief, as it became apparent that oversight by the regulatory, the National Drugs Advisory Board, and the Department of Health had been almost non-existent for many years. As if such revelations were not shocking enough, the state sought to defend an indefensible position with 'every bullyboy legal tactic that could be devised', turning disbelief into outrage (Dáil Debates, 476, 1231).

Though the Irish Haemophilia Society was granted limited representation at the Finlay Tribunal, the tribunal's constricted terms of reference meant that its remit did not attempt to broach issues of significant concern to haemophiliacs. As a consequence, the Irish Haemophilia Society abandoned the Finlay Tribunal, walking out in protest and, continued to lobby for a Tribunal that would explain how and why haemophiliacs had been infected. The result of this lobbying was the establishment, in 2002, of the Lindsay Tribunal and, blood and politics were again in the dock.

While both tribunals focused on similar issues, such as the state of medico-scientific knowledge surrounding blood borne pathogens and, the majority of the same actors were called to account, the outcomes of the tribunals were markedly different. Hailed for reaching a speedy conclusion, the Finlay Tribunal contained the 'truth about the worst scandal in the history of the State', documenting 'with chilling clarity', the damage inflicted by the 'negligent actions of senior people with responsibility for the safety of the blood supply' (Dáil Debates, 476, 1299). Conversely, the Lindsay Tribunal was condemned for 'discovering precious little' (Dáil Debates, 556, 1038). It 'did not draw conclusions, did not find anyone guilty and did not lay the blame at anyone's door' (Dáil Debates, 556, 1038).

While the plethora of investigations into the blood crisis has been noted as reflecting a general rise in medical litigation, which increasingly sees 'judges setting the parameters' of medical practice (Cusack, 2000), the emphasis on human agency in both Irish tribunals can be seen as reflecting a forensic view of risk events. Indeed, tribunals and inquiries epitomise the forensic approach, which is driven by a rational desire to learn from past mistakes, but also has an emotional component 'enabling those who have suffered a loss to understand why it has happened, and identify and punish those responsible' (Alaszewski & Burgess, 2007: 352). Nonetheless, as Alaszewski and Burgess note, it is an approach that also 'tends to decontextualize both actors and actions from the wider systems of which they are a functional part' (Alaszewski & Burgess, 2007: 352).

If the wider context had less of an impact upon events surrounding the Anti-D scandal, it played a key part in the infection of haemophiliacs. The U.S.A. was not only the epicentre of the AIDS crisis, but was also home to the majority of pharmaceutical companies producing blood products for the treatment of haemophilia (termed concentrates). Though the U.S.A. had introduced an entirely volunteer based whole blood system during the 1970s, paid donors were extensively utilised for the harvesting of plasma from which concentrates were manufactured. Moreover, the blood crisis emerged during a period when the court system in the United States was confronting the challenges posed by an increasing trend toward mass tort litigation. Against this backdrop the relationship between expert evidence, science and the law was questioned, with some arguing that the courts were far too lenient in admitting unsubstantiated scientific claims or 'junk science' (Huber, 1991).

Given such circumstances, there can be little surprise that examinations of the blood crisis have included consideration of both meso and marco level influences that shaped the crisis and resulted in scandals. For example, Farrell (2004), who has engaged in a comparative analysis of the blood scandals in Ireland, the U.K. and France, focuses on events at the national level. Farrell identifies the interplay between professional and institution structures, the austere economic context and the social construction of HIV/AIDS, as leading to a failure to 'adequately manage' the risk to

haemophiliacs. Moreover, she suggests that the backdrop of 'socio-economic change, which was linked to the Europeanisation of the economy, institutions and values, structured the public dynamics that led to political scandal in France and Ireland', but not in the U.K. (Farrell, 2004: 255).

In contrast, Power (2007) and Taylor and Power's (2010), comparative examinations of the blood crisis in Ireland and the U.K., focuses on events at the macro level. Though not denying that the management of risk had an important bearing, they contend that the focus on risk management emulates the approach adopted by tribunals and inquiries, where concern has mainly been confined to, 'what government knew (about hepatitis and AIDS) and when (the blood supply had been compromised)' (Taylor & Power, 2010:4). For Power, Taylor and Power, this approach fails to recognise the crucial importance of the manner in which political contestation over the interventionist state at a time when a global market in blood products was developing shaped events. Dual blood systems emerged in many nations with whole blood remaining a national resource, while blood products were increasingly sourced from the market. This meant that while under the auspices of the interventionist state, risk assessment and risk management were intertwined intimately and, the preserve of blood bankers, ministers, civil servants and the medico-scientific community, the emergence of a free market in blood products introduced an ever expanding role for multinational pharmaceutical companies in decisions over risk, making them the arbiters on safety (Power, 2007; Taylor & Power, 2010). Thus, for Power, Taylor and Power risk assessment rather than risk management is to the fore in explaining the blood crisis.

At first glance this would appear to be a position supported by just such as Hughes-Jones (1995) who, in the wake of litigation against blood bankers and doctors, has suggested that the crisis could be explained by the failure to assess the risk from factor VIII concentrates, since;

If there had been continuous assessment of the risk hazards by an established authority in the 1980s, then the recent spate of litigation against individuals who carried out therapy for which there was general approval by

both physicians and patients would not have been possible (Hughes-Jones, 1995: 501).

However, this paper argues that the view put forward by Hughes-Jones fails to appreciate the complexity of the forces at play, especially the manner in which the wider deregulatory context and debates around blood, science and risk, shaped events. While Hughes-Jones adopts a not uncommonly held position within which risk assessment (science) is primarily a technical matter and risk management (politics) a political or administrative matter, such approaches pay scant attention to how the wider context has shaped the manner in which science and politics interact. In contrast to this view of a simple dichotomy between risk assessment and risk management, this paper draws upon the more nuanced explanations of Farrell, Power, Taylor and Power to inform understanding of how wider forces contributed to and, shaped events such as the blood crisis. Divided into two sections this paper begins by outlining haemophilia, the emergence of a market in blood products and events in Ireland. While concentrating on Ireland, particularly the impact of the Finlay Tribunal, it also highlights the international dimension of debate around blood and blood products. In section two, the focus of attention is switched to the wider context, specifically the manner in which the reviewing role of the courts in the U.S.A. impacted upon the regulation of risk. Here, attention is drawn to the manner in which the U.S.A. courts increasingly became the site for resolving disputes around risk and inconclusive science, an area that had previously largely been the preserve of regulatory agencies.

### **Haemophilia, blood products, and events in Ireland.**

A disorder of the blood that reduces blood's ability to coagulate, haemophilia is a hereditary condition usually passed from carrier mother to son making it an almost exclusively male condition. Though there are two types of haemophilia, A and B, the root cause is a deficiency of proteins or factors that inhibit clotting. Individuals with haemophilia A suffer from inadequate

quantities of factor VIII, while those with the B form of the disorder lack sufficient factor IX. Nonetheless, the symptoms are the same.

Whether type A or B; haemophilia can be classified as severe, moderate or mild depending upon the level of clotting factor in the blood. For those with the mild form of the disorder treatment may only be required on rare occasions, such as in the case of an accident or surgery. Individuals categorised as severe, however, need constant regular treatment, not least because unprompted cranial bleeding can be fatal. Indeed, prior to the 1950s few haemophiliacs lived to 'grow up' with many perishing in their teens or early adulthood (Biggs in Lee et al, 1998:772).

In the early post-war period limited treatment options, such as whole blood transfusions, meant that haemophiliacs were confronted by a bleak situation with often short life prospects. However, innovations in transfusion technology quickly presented haemophiliacs with the prospects of a near normal life pattern and lifespan. The first of these advances was cryoprecipitate, a sludge produced by thawing frozen plasma that allowed for the clotting factor from multiple donations (usually between five and eight) to be combined and administered intravenously.<sup>i</sup> Though a welcome advance, cryoprecipitate also exposed haemophiliacs to an increased probability of disease transmission, since any one of multiple donations could be disease bearing.

If cryoprecipitate was a significant advance in the treatment of haemophilia, factor concentrates were a quantum shift.<sup>ii</sup> Offering consistency in treatment and ease of use, concentrates afforded haemophiliacs the opportunity to enjoy a near normal life, as well as previously unimagined events, such as holidays abroad. Indeed, so successful were concentrates that prophylactic or preventative therapy became popular. Haemophiliacs would inject concentrates to raise their factor levels in order to prevent spontaneous bleeds and, the demand for concentrates increased inexorably. However, the manufacture of concentrates required condensing thousands of donations, exposing haemophiliacs to an increased probability of disease transmission, as one infected donation could contaminate an entire batch of concentrates. Where paid donations were used infectious transmission was even more likely.



However, in the arena of blood these were issues far from novel. For many years international bodies such as the World Health Organisation, Council of Europe, International Society of Blood Transfusion and the Red Cross had sought to promote blood systems based on the twin pillars of voluntary donation and self-sufficiency. Voluntary donation, it was argued, was not only morally justified but also safer. Epidemiological evidence revealed consistently that providing an incentive encouraged donations from populations, such as intravenous drug users, where disease was often rife (Titmuss, 1970; Leveton et al, 1995). Moreover, remuneration was seen to encourage donors to be less than completely truthful about any underlying condition. In a similar vein, self-sufficiency acted to prevent the importation of blood borne pathogens, isolating blood supplies and maintaining their integrity.

Though the twin pillars served as the foundations upon which blood supplies were built in many nations, in the U.S.A. both voluntary and paid systems existed prior to the 1970s. Influenced by Richard Titmuss's (1970) seminal work, 'The Gift Relationship' and the fact that paid donations frequently came from 'sectors of society in which transmissible hepatitis is more prevalent' (Leveton et al, 1995: 41) the U.S.A. moved to introduce a National Blood Policy (NBP) in 1974. This would see an entirely voluntary whole blood system established. It proved to be a difficult task however, as the two main blood banking organisations, the American Red Cross and the American Association of Blood Banks, bickered constantly and resisted co-operating with the American Blood Commission, which had been established to implement the NBP. The matter was not finally resolved until 1978 when the Food and Drug Administration (FDA) introduced regulations that required the labelling of blood as either voluntary or paid and, 'almost overnight, paid blood disappeared since no hospital would buy blood that was implicitly inferior' (Starr, 2000: 304).

However, neither the National Blood Policy nor the 1978 regulations applied to plasma or plasma derivatives. Moreover, while most nations gathered plasma from whole blood donations, commercial manufactures employed plasmapheresis; a process that allows the extraction of plasma only, returning

the red cell component of blood to the donor during the process. As a consequence of this approach, concerns around the effects of over-donation, such as anaemia could be avoided, allowing for donors to be harvested more often. This allowed pharmaceutical companies to gather quantities of plasma unavailable to most nations and a substantial global market in concentrates rapidly developed (Jones, 1980).<sup>iii</sup>

In tandem with these development Blood Shield Laws emerged in the U.S.A. as litigation over infectious transmissions increased. The Blood Shield Laws classified blood as a service rather than a product, as the seller was 'in the business of supplying the product to the consumer and it is that, and that alone, for which he is paid' (*Sheppard V. Alexian Brothers Hospital* (1973) in Westfall, 1986: 1115). As litigation over hepatitis infections continued throughout the 1970s these laws expanded to include blood banks (*Klaus V. Alameda-Contra Costa County Medical Association Blood Bank* (1976) and concentrate manufactures (*Fogo V. Cutter Laboratories* (1977)), because no test for hepatitis was available, which meant that blood and blood products were 'unavoidably unsafe', but this had to be weighted against the need for a functioning blood supply (Westfall, 1986).

The recognition that blood supplies were 'unavoidably unsafe' was far from new, as 'hepatitis transmission was a known risk from blood transfusion dating back to the 1940s' (Angelotta et al, 2007: 162). None the less, growing concern over hepatitis transmission led to the introduction of increasingly sensitive tests during the 1970s for hepatitis B, the primary culprit at the time. Though such testing markedly reduced the incidence of hepatitis B infections, the virulence of the disease meant that it remained. However, reductions in hepatitis transmission brought about by testing, soon revealed that another form of hepatitis was present. With little information and no test available, the only thing that could be said with certainty was that this pathogen was neither type A nor type B hepatitis. Thus, it was named non-A, non-B (NANBH) hepatitis (later Hepatitis C or HCV). While little was known about this new pathogen, 'all the evidence then from around the world then was that this too produced a chronic disorder which might result in ill-health in a few people (Jones in Christie & Tansey, 1998; 64). With hepatitis generally 'considered

the known 'cost of doing business' for persons with haemophilia' the importation of commercial concentrates escalated, as few nations could gather the quantities of plasma necessary to meet demand (Angelotta et al, 2007: 162).

If doctors and haemophiliacs were enthused by the advances in treatment and the availability of commercial concentrates, blood bankers were less so. Committed to the twin pillars, blood bankers frequently voiced opposition to the use of commercial concentrates. Certainly in Ireland, it was an area of longstanding, if sporadic, conflict between the Director of the BTSB, Dr. O'Riordan and, Ireland's leading haemophilia specialist, Professor Temperley (Farrell, 2004). When concentrates initially emerged in the early 1970s, Travenol a commercial concentrate manufacturer, applied to the Department of Health for a licence to market the product. The BTSB objected on the grounds that the importation of concentrates would contravene Council of Europe recommendations supporting voluntary donation and self-sufficiency and, because such concentrates were, in the words of the BTSB Director, manufactured from donations provided by 'skid row types in the US and native populations in the Caribbean' (Donnellan, 2000a).

In contrast, Professor Temperley favoured their introduction, as concentrates represented a significant 'step ahead' in the treatment of haemophilia (Humphreys, 2000a). Confronted with divergent positions the Department granted the licence and soon after the BTSB dropped its opposition and became a distributor. In part, this reversal can be attributed to the income that the role of distributor generated for the BTSB. Set up to be self-financing from the sale of blood and blood products to hospitals the BTSB struggled constantly to meet its financial obligations and had to be assisted by the Department of Health on numerous occasions. Indeed, a later examination of the BTSB's accounts would reveal that the mark-up and commission on distribution that the BTSB earned, 'helped to run the whole organisation' (Humphreys, 2000b).

In many ways the BTSB's reversal reflected the challenge that the emergence of concentrates posed to maintaining the twin pillars. Certainly, the BTSB was concerned that Travenol were attempting to 'corner the market' (Donnellan,

2000a). Committed to the twin pillars the BTSB argued that the way forward was in producing freeze-dried cryoprecipitate (Lindsay, 2002: 52). However, as Farrell suggests, such moves reflected Professor Temperley's general criticism of the BTSB as 'often too slow to recognise the technological innovations that had taken place' (Farrell, 2004: 175). Professor Temperley maintained regular contact with haemophilia specialists in the U.K., where commercial concentrates had been received favourably. Dr. Peter Jones, a leading haemophilia specialist recalled that:

We had nothing. We had enough factor concentrate to deal with the major surgery and that was really about it. Cryoprecipitate opened our eyes and then the concentrates came...We knew from the beginning that we were transmitting disease...We knew that hepatitis B was in those concentrates and the companies knew that hepatitis B was in those concentrates...Even that did not blunt the enthusiasm for treatment (Jones in Christie & Tansey, 1998: 63- 64).

While the reliance upon the revenue generated from the sale of concentrates remained a feature of the operations of the BTSB, differences of opinion over the twin pillars continued to be a bone of contention between the BTSB and treating doctors. For example, during the drafting of a policy document around home therapy in 1980 Dr. O'Riordan reiterated his preference for home produced products (Lindsay, 2002: 49). Similarly, when heat treatment to inactivate viruses in blood products was introduced in the mid 1980s the BTSB continued to maintain that domestically sourced voluntary donations were safer, despite testing revealing that HIV had entered the Irish Blood supply (Lindsay, 2002; Farrell, 2004). More importantly perhaps, while in the late 1970s the BTSB had succeeded in manufacturing a form of freeze dried cryoprecipitate and even a clinically acceptable factor IX concentrate for the treatment of haemophilia B, as Professor Temperley would point out, 'commercial Factor IX was supplied packaged in a form which made it suitable for home therapy...BTSB Factor IX was not supplied with such home treatment kits' (Lindsay, 2002: 57).

This apparent disregard for the benefits of blood products produced from domestically sourced voluntary donations serves to highlight a number of factors of importance to the narrative of the blood crisis; the general medico-scientific view that hepatitis was a relatively mild condition; the preference of treating doctors for a free market in blood products that would maintain clinical autonomy and product choice; and, the ideological tension between treating doctors and blood bankers.

As those such as Barrington (2002) and Wren (2003) have observed, the relationship between the medical profession and the Irish state has largely been antagonistic, with the medical profession keen to preserve professional autonomy and private practice. Socialised within this professional culture, it is unsurprising that those such as Professor Temperley frequently felt it necessary to preserve clinical autonomy, pursue the course of action they felt was in the best interests of patients. Indeed, Farrell notes that Professor Temperley often 'found other ways to bring his concerns to the attention of blood bankers, either through direct lobbying of civil servants at the Department of Health or through public airing of his concerns' (Farrell, 2004: 184). Professor Temperley's views, however, were not without some foundation. For example, in 1978, he drew attention to price differentials between the BTSB and the amount hospitals paid in Northern Ireland, forcing the BTSB to lower its prices (Donnellan, 2000a). He also publically aired his concerns about the BTSB gaining a monopoly on supply at a Haemophilia Society AGM in 1982 (Donnellan, 2000b). If Professor Temperley's commitment to ensuring clinical autonomy through product choice would have tragic sequences with the emergence of HIV, the BTSB's blind commitment to self-sufficiency would be largely responsible for the Anti-D scandal.

Throughout the 1970s the BTSB sought to ensure a sufficient supply of Anti-D from domestic voluntary donors in line with the twin pillars. Anti-D was a product developed to overcome the dangers associated with incompatibilities between women whose blood was RH negative but who gave birth to babies with RH positive blood. A not uncommon occurrence, it could result in antibodies remaining in the blood of the mother, impacting on subsequent pregnancies. Indeed, it was estimated that prior to the introduction of Anti-D

'over 100 babies were born dead' each year in Ireland and many more were 'born gravely handicapped or gravely injured' (Finlay, 1997: 12).

In its search to ensure an adequate supply of plasma for the production of Anti-D the BtSB pursued a number of avenues, including extracting plasma from post-menopausal women and, when this failed to produce the necessary quantities, recruiting a group of male volunteers from which to draw the necessary volumes of plasma. However, this also proved insufficient and the BtSB utilised the plasma from women undergoing plasma exchange therapy. It was an approach that flew in the face of the BtSB's own standards and the general view among blood bankers that donations should not be taken from individuals that had received a transfusion within the previous six months. While Justice Finlay observed that a number of factors had influenced this seemingly incomprehensible approach, 'for the supply of home produced Anti-D to fall short of the requirements at any time so as to involve its replacement of supplementation by imported products, would have been a major admission of failure' (Finlay, 1997: 32). Clearly keen to avert further erosion of the twin pillars the BtSB blindly pursued self-sufficiency leading to a medical disaster.

If the BtSB's irresponsible pursuit of self-sufficiency would see it, the National Drugs Advisory Board (NDAB), the Department of Health and, Ministers of Health called to account in the courts, it was the state's aggressive legal strategy that would see a medical catastrophe become a political scandal. Against a backdrop of non-cooperation, misinformation and denial by the BtSB the state adopted a hard-line adversarial position. It was a strategy that would be instrumental in ending the career of Michael Noonan, then Minister for Health. In the wake of the tragic death of Brigid McCole, Noonan, under intense opposition pressure attempted to justify the legal strategy adopted by the state, questioning whether Mrs. McCole's legal team could 'not, in selecting a test case from the hundreds of hepatitis C cases on their books, have selected a plaintiff in a better condition to sustain the stress of a High Court case? (Dáil Debates, 470, 430). An uncharacteristic remark, it nonetheless, damaged Noonan's political career irreparably. More importantly, the entire episode made politicians and civil servants 'intensely

nervous and fearful of anything related to blood' and public concern around the matter effectively meant an inquiry into the circumstances surrounding the infection of haemophiliacs, which had been side-stepped by the Finlay Tribunal, was almost inevitable (Murphy, 1999: 374; Farrell, 2004).

Indeed, Angelotta et al's (2007) examination of eight countries where haemophiliacs had been infected with HIV and HCV confirms the unique situation that was encountered in Ireland. Though in each of the countries explored the HCV infection rate was two to eight times greater than the HIV infection rate, political activism by groups seeking recompense for HCV infection did not benefit haemophiliacs, with Ireland the 'lone exception'(Angelotta, et al, 2007: 163). Indeed, the emergence of the Finlay Tribunal reflected an increasing trend toward medical litigation both in Ireland and abroad. Writing at the turn of the millennium, Cusack (2000) observed that along with the Lindsay Tribunal, there were inquiries into post-mortem practices and policies, as well as investigations surrounding the 'clinical standards of several specialist consultants' (Cusack, 2000: 1431).

If this rise in medical litigation was attributable to the emergence of a steady stream of scandals that were irreparably damaging trust in the institutions of society, it was also giving rise to the progressive encroachment of law into medicine, with judges increasingly setting the 'parameters of medical practice' (Cusack, 2000: 1432). Moreover, though the backdrop in Ireland may have been unique, this trend was increasingly apparent throughout the world (Cusack, 2000). While the rise of medical litigation in Ireland may have been the manifestation of an underlying trend toward the increasing involvement of the courts in medicine, courts in the U.S.A. had long been the site of debate over risk, medicine and science. Thus, this paper now moves to examine some of the pivotal legal developments that reflected the wider political debate and impacted upon the decoupling of risk assessment from risk management in the U.S.A.

**The wider context: law, science and risk in the United States courts.**

Throughout the 1960s and 1970s a raft of legislation that aimed to reduce health and safety risks was introduced in the U.S.A., including the Clean Air Act (1963), Occupational Health and Safety Act (1970) and the Toxic Substances Control Act (1976). Against this backdrop, agencies such as the Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) were increasingly charged with interpreting science and, setting regulations and standards based upon that interpretation. This meant that regulators were often required to engage with complex cutting edge science, where irrefutable evidence rarely existed.

It was a set of circumstances that led to increasing concern around the role of agencies and the influence of unelected 'experts' on policy (Jasanoff, 1990). Here, critics were quick to point out that experts rarely agreed and that the lack of definitive knowledge gave regulators significant latitude when making decisions. How many parts per million of a toxin represented a dangerous exposure level? What information, if any, could be extrapolated from animal studies? How often and for how long would low levels of exposure need to occur before an unhealthy level was reached? These were the types of questions that regulators were often required to answer, since in nearly every area the gold standard of science, the randomised control trial, could not be conducted. Testing on humans raised ethical questions. Animal trials presented difficulties around extrapolation to humans. Epidemiological studies could not untangle the mass of variables, such as lifestyle, environmental factors or working conditions, which could produce adverse effects for some but not for others (Weinberg, 1972). Moreover, in many cases any adverse reaction might not show up for years or even decades. Thus the impact of any advance, whether technological, pharmaceutical or chemical, could not be known or predicted with any certainty. It was a situation summed up succinctly by Majone (1978) who noted that:



Technology assessment always involves questions of a type that Weinberg termed trans-science: questions that can be stated in technical terms but that are beyond the capacity of science to answer. Hence, disagreement among experts is to be expected whenever policy-relevant scientific and technical questions are debated (52).

Given the lack of definitive knowledge and that experts or studies could be found to support any number of conflicting views it is not surprising that the courts became a battlefield upon which regular skirmishes would be fought. In the U.S.A. the Administrative Procedures Act (1946) was the primary piece of legislation governing the relationship between agencies and the courts. This legislation empowered courts to act in an oversight role, ensuring that the agencies did not stray outside their remit; that agencies set regulations and standards in line with extensive evidence; and, that agency procedures and decisions were consistent.

Concerned primarily with the manner in which agencies carried out their role rather than the decisions made, courts were initially reluctant to overturn or reject agency regulations. In large part, this was because regulatory agencies were recognised as the politically mandated appropriate forum for enacting decisions around potential hazards and risks and, as such, were obliged to interpret available data and theories in the manner they saw as most appropriate. Certainly, in the case of *Ethyl Corp v. Environmental Protection Agency* (1975), the court felt that agencies were obliged to act even where the science was not definitive and on the best available evidence. The court acknowledge that the Environmental Protection Agency could act upon 'suspected, but not completely substantiated, relationships between facts' or 'from theoretical projections from imperfect data' (in Jasanoff, 1990: 50). In a similar vein, challenges to agency decisions were rejected by the courts in *Hercules Incorporated v. EPA* (1978) and *Dow Chemical v. Blum* (1979). In both cases concerns were raised about methodological issues, with criticisms levelled at the manner in which data collection and analysis had been conducted, as well as the conclusions that had been drawn. Though the

courts acknowledged that the criticisms raised were not without foundation, they, nevertheless, reiterated the view that agencies were the appropriate authorities and, as such were entitled to select what they felt were the most appropriate analytical methods. Furthermore, as the guardians of public health they were at liberty to employ 'less elaborate procedures than may be required in other contexts' (Jasanoff, 1990: 52).

If the approach of the courts was characterised by a focus on how the agency had reached a decision rather than upon the decision itself, it was a view that would become increasingly challenged. Here, debate would centre upon whether judges should be familiar enough with the underlying technical or scientific arguments to understand not just administrative or procedural matters, but also the reasoning underpinning decisions. On the one hand, were those such as Judge Leventhal, who advocated the Hard Look approach under which judges should be familiar enough with technical and scientific debates to understand why a particular decision had been reached. On the other hand, where those that felt that judges were legal rather than scientific or technical experts and that such an approach was beyond their remit. Though complete victory could not be claimed by either side, the spirit of the Hard Look approach was adopted and judges focused more and more upon how and why agencies had reached the decisions they had. As a consequence, agencies were increasingly required to mount defences of their reasoning, methods and conclusions, as well as explaining any irregularities encountered or discrepancies between studies and sources (McGarity, 1984).

This growing encroachment of the courts into agency decisions was a reflection of both developments within the legal system and wider socio-political change. The legal system had at its core the notion that each case should stand or fall on its own merits. However, one of the consequences of modernisation and technological progress was large numbers of people could be exposed to substances detrimental to health, such as asbestos. The rise in litigation that accompanied the growth in understanding about such products and the risk they posed presented difficulties for the legal system (Jasanoff, 2002). In large part, this was because the sheer volume of individual cases

created substantial bottlenecks, effectively paralysing the courts.<sup>iv</sup> In response a trend toward mass torts or class action suits began to emerge. While this contributed to a more efficient throughput of cases, it created a potentially greater problem. In individual actions, precedents set in one court could have a ripple effect, spreading outwards to other cases and penetrating other areas of law. However, with mass torts this ripple was transformed into a tsunami, since 'a plaintiff-friendly decision in one court could start an avalanche of lawsuits around the nation' (Jasanoff, 2002: 39).

Certainly, anxiety generated by mass torts raised significant concern around the relationship between the courts, product liability and pharmaceuticals. Writing in the wake of the announcement of the first human trials in the U.S.A. of a HIV vaccine (1987), McKenna highlighted that the tort system was jeopardising 'the production of most major existing vaccines'. With some warning that 'under present legal conditions, even if [an HIV] vaccine were available tomorrow, no one would produce it', as 'worries about product-liability lawsuits could stop any company from marketing a vaccine' (McKenna, 1988: 943). Indeed, for McKenna the growth in lawsuits since the 1960s had already 'driven most manufacturers of childhood vaccines out of the market' (McKenna, 1988: 944). Though in the particular case of a HIV vaccine, the targeted rather than mass immunisation required, would markedly reduce the potential for mass lawsuits, the wider underlying issues remained.

It was not only manufacturers however, who were concerned about the impact of such developments. Keen to restore a flagging economy through the release of industry from the burden of regulation the Reagan Administration moved rapidly to ensure that regulators were not over-zealous in full-filling their remit. For example, in the early 1980s, it introduced Executive Orders 12291 and 12498, which gave the Office of Management and Budgeting (OMB) significant influence over how regulatory agencies operated (see for example Kragman, 1986; Cooper & West, 1988). In many cases, directors of agencies were also replaced by individuals more supportive of the administration's agenda (Elliot, 2003). More importantly, the Reagan Administration increasingly sought to untangle risk assessment from risk

management by requiring regulatory agencies to justify regulations with quantitative risk assessments and cost/benefit analysis (Power, 2007; Taylor & Power, 2010). As such, deregulatory reform was designed to make agencies 'more responsive, and less adversarial, to industrial interests' (Abraham & Sheppard, 1999; 830).

Against this backdrop, reviewing courts came under mounting pressure to ensure that they were conducting their 'gatekeeping' role, in relation to evidence and experts, responsibly (Edmond & Mercer, 1998). For those such as Peter Huber (1991) the problem was simple; courts were falling to separate 'junk science' from real science, extending 'equal dignity to the opinions of charlatans and Noble Prize winners' (Huber, 1991: 123). Advocating a stringent approach to admitting scientific experts and evidence, Huber argued that only evidence and expert opinion backed by consensus within the scientific community should be admissible. Those opposed to regulation were quick to popularise Huber's phrase and condemn science that contradicted their view as 'junk science'.

Debates over 'junk science' and the role of experts would come to the fore in the landmark case of *Daubert v. Merrell Dow Pharmaceuticals Incorporated* (1993). At the centre of this case was the claim that an anti-nausea medication, Bendectin, was causing birth defects. Evidence in support of the claim, however, largely relied upon extrapolation from animal studies and unpublished epidemiological studies. In almost all previous cases tried before a judge, *Merrell Dow* had been successful in defence. In contrast, in cases where a jury had been involved, judgement had frequently been in favour of the plaintiff. With such a chequered history Merrell Dow were keen to ensure that further cases did not proceed to trial where juries might rule in favour of the plaintiff and, it was argued that only studies that had passed peer-review should be admitted. In ruling on this argument the Supreme Court drew upon the Federal Rules of Evidence, which required judges to keep out 'any expert testimony that is not reliable as well as relevant' (Jasanoff, 2002: 46). Four sample criteria for making such decisions were put forward by the Supreme Court; was the science testable? Had it been subject to peer-review? Was the error rate, if any, known? Were operational standards controlled or were the

findings generally accepted within the scientific community (*Daubert*, 590, 1993).

While such criteria appear to suggest that judges should take on the traditions of science, admitting only claims backed by peer-review and consensus within the scientific community, *Daubert* had a more subtle impact. As Jasanoff observes, it gave judges the power to 'declare, case-by-case and in accordance with criteria that *they* deem appropriate, what counts as reliable science' (emphasis in original, 2002: 50). As such, judges replaced experts in deciding what amounts to valid scientific evidence. In other words, while judges were required to take into account the general view of the scientific community, they and they alone, decided what constituted admissible evidence. Moreover, by vesting such control with judges, defendants had significant scope to mount challenges against evidence or experts that may be detrimental to their case, since if experts disagreed or methodologies were challenged it was a judge rather than the scientific community which had the final say (Wagner, 2005). Summing up the post-*Daubert* world succinctly Jasanoff notes that, 'instead of calling the score as scientists: 3; charlatans:0, one might plausibly read it as judges: 3, scientists: 0' (Jasanoff, 2002: 50).

Though *Daubert* emerged after the blood crisis the consequences of *Daubert* can be explored in a striking manner through the use of an example from the HIV crisis. During the HIV crisis it was found that heating concentrates inactivated the HIV virus and manufacturers rapidly introduced a heat-treatment step into the manufacturing process. This effectively ended the threat of HIV transmission through concentrates in the mid-eighties. However, the original protocol that heat-treatment was based upon used a linear projection of viral deactivation over time. Put simply, if heating a concentrate for one hour at a specific temperature reduced viral activity by 30%, heating for two hours would kill 60% of the virus, and so on. However, Dr. Prince, a virologist conducting research for Armour Pharmaceuticals found results that were inconsistent with existing studies and which suggested that a linear relationship was unlikely. In spite of this concerning finding, Armour would not allow Dr. Prince to publish his results, As one executive put it 'this issue is not

one of regulation, but rather marketing' (in Krever, 1997: 493). Indeed, an internal memorandum by a member of Armour's plasma committee stated that:

I told Dr Prince that while our foremost concern was the safety of patients receiving these products, these data taken in isolation could only be confusing to the scientific community, the treatment community and the public. We therefore were not prepared to give him permission to publish (in Krever, 1997: 492).

In a court action under *Daubert*, the absence of published studies could be forwarded as an argument to deem such evidence inadmissible, with a judge rather than the scientific community deciding on applicability. For those such as Jasanoff (2002), such changes created circumstances where the courts were forced increasingly to behave like a state, where 'liability judgements in civil legal actions took the place of possible administrative solutions' (Jasanoff, 2002: 39). It is a view that resonates with those such as Taylor (2003) who have argued that such changes are part of a wider shift from the realm of the political/legal under the interventionist state to the economic/legal under the influence of modern conservatism. More importantly perhaps, as this paper has suggested, explanations of the blood crisis contending that the crisis could have been averted had an 'established authority' been present, fail to appreciate how broader socio-political forces shape the wider context in which such established authorities would have been a functional part.

### **Closing the book on the blood crisis in Ireland?**

If blood became an issue of intense social concern in Ireland in the wake of the Tribunals, court actions have, in contrast, petered out and faded into history. Writing in the aftermath of the Finlay Tribunal, the then National Medical Director of the Blood Transfusion Service, noted that any story, however tentatively related to blood, became front page news. Moreover, donations continued to fall, leading to the need to import blood to meet demand (Murphy, 1999). In a similar fashion, the ban on homosexuals

donating blood continued to generate controversy over two decades after the 'temporary' ban was introduced (Murphy, 2006). Conversely, in spite of an investigation by *An Garda Síochána* (Irish Police) in the wake of the Finlay Tribunal, which resulted in charges being brought against members of the BTSB in 2003 and, exploration of the possibility of the Irish state pursuing legal action against U.S.A. pharmaceutical companies, in the wake of the Lindsay Tribunal, neither action was brought to fruition.

In the aftermath of the Finlay Tribunal a Garda investigation was launched and in July 2003 charges under the *Offences Against the Person Act* were brought against Dr. Terry Walsh, a former assistant national director of the BTSB and, Cecily Cunningham who had been a biochemist at the blood bank. The passing of Dr. Walsh prevented the case against him continuing and the case against Ms Cunningham did not reach a conclusion until 2009. In 2007 Ms Cunningham went to the High Court in a bid to prevent the case against her proceeding, arguing that the deaths of senior BTSB staff, publicity surrounding the case and delays in bringing the case forward, breached her constitutional rights to a fair and speedy trial (Carolan, 2007). Justice McKechnie however, rejected the bid, contending that the 'exceptional circumstances' of the case meant that the right of the public to have the case heard was 'far superior' and 'paramount' (Carolan, 2007). Notwithstanding this decision, in January 2009 the state withdrew all charges against Ms Cunningham, though no reason was given in court (Donnellan, 2009). In the wake of the Lindsay Tribunal the suggestion that the Irish state could pursue pharmaceutical manufactures for the losses incurred in redressing the impact of the crisis was mooted. This led to explorations on both sides of the Atlantic around whether such a case was possible. In 2006, the Department of Health and Children abandoned this option after legal opinion suggested that such a case would be statute barred given the time that had elapsed and that the 'State has known about the defective blood products for many years', thus any case would be likely to be 'struck out as contravening the guarantee of a fair hearing within a reasonable period of time' (Department of Health and Children, 2006).

**Conclusion.**

There can be little doubt that the blood crisis has had a significant impact upon blood supplies both in Ireland and abroad. The instigation of tribunals and inquiries led to scandals in many developed nations, and brought the safety blood supplies into sharp focus. Ultimately this led to the introduction of more stringent regulations around blood and blood products. Legal action and scandals have therefore served to make blood supplies safer, none the less, as the emergence of new variant CJD has highlighted blood supplies continue to be vulnerable to new menaces. However, the plethora of scandals has also served to highlight that tribunals and inquiries, with their focus on human agency, are often inadequate devices for explaining events, since as Alaszewski and Burgess have observed they tend 'to decontextualize both actors and actions from the wider systems of which they are a functional part' (Alaszewski & Burgess, 2007: 352). As this paper has suggested, if we are to understand events such as the blood crisis, we need to appreciate how events such as the ideological struggle between treating doctors and blood bankers in Ireland or, debate over the relationships between risk, science, the law and politics in the U.S.A., form key elements of the wider context, shaping how risk is assessed, managed and communicated.

In the area of blood these issues re-emerged in the early twenty first century, as the European Community sought to harmonise blood policy under Directive 2002/98/EC. Though the directive acknowledged the contribution to safety made by voluntary donation, it did not make voluntary donation a requirement. In large part, this was because such a stance would run counter to free trade and because risk assessments contended that while theoretical risks could not be ruled out, advances in testing, screening and manufacturing processes meant that there was 'no evidence' of a higher risk from paid donations (Committee of Proprietary Medical Products, 2002). Given that the ability to test for a pathogen is a key element of any process of generating evidence of



the threat it may pose, it is worth remembering Dawn Primarolo's words in the wake of the Archer Inquiry in the U.K.;

Sadly, it was not possible to effectively test for these viruses in the 1970s and 1980s (Dawn Primarolo, Minister for Public Health in the U.K., 2009).

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<sup>i</sup> Though the administration of cryoprecipitate was an uncomfortable procedure it was a significant advance over whole blood transfusion, which could place a dangerous strain on the heart and circulatory system. However, cryoprecipitate was by no means a panacea. It was bulky, had to be kept at low temperatures and thawed before use and, its potency varied.

<sup>ii</sup> Manufactured by combining and distilling the plasma from hundreds, or more commonly thousands of donations, through a process of fractionation, concentrates could be produced in small vials, were of known and dependable potency and, they could be stored in a domestic fridge for injection as and when required.

<sup>iii</sup> Plasmapheresis was a technology available to organisations charged with managing national blood supplies. Though small scale testing of the process went on in many nations, its use would have necessitated investment in expertise and equipment. More importantly, however, were concerns that it would attract commercial suppliers by encouraging the setting up of paid donor centres, which could undermine the ethos of blood donation.

<sup>iv</sup> For example, in the case of asbestos, one Texan court observed that 'at a rate of 30 cases per month, it would take 6 ½ years to dispose of the 2,000 cases pending on its docket. Unfortunately, the court noted, 5,000 new cases would have been filed during that period' (Report of Mass Tort Litigation (1999) in Jasanoff, 2002: 43).

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