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**Risk, Science and Blood: Politics, HIV, Hepatitis  
and Haemophilia in Ireland.**

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## Introduction

As the 1970s drew to a close, and with the alphabet of hepatitis almost exhausted, haemophiliacs in Ireland were faced with the harrowing prospect of a life-threatening virus of almost biblical proportions: AIDS.<sup>1</sup> By the 1980s virtually all of Ireland's haemophiliac population (400) had contracted hepatitis, over one hundred were HIV positive and AIDS had eclipsed bleeding as the leading cause of death. Innocent victims of a crisis that engulfed their community like a 'slow Aberfan'<sup>2</sup> their plight was compounded by the ignominy of a government unwilling to respond to pleas for financial assistance: an iatrogenic disaster had turned into a political scandal.<sup>3</sup>

As the worst treatment disaster in the history of the Irish State it has, not surprisingly, attracted the scrutiny of the media (Bowers 1997, Wren 2003, Daly & Cunningham 2003). Among political scientists in Ireland an analysis of this political crisis has been conspicuous only by its absence. Indeed, thus far only Ann-Marie Farrell's comparative account of the political scandals to emerge in Ireland, France and the United Kingdom stands out. Her work identifies as important the combined impact of a celtic tiger economy, Europeanisation and a succession of controversies involving businessmen, politicians and clergy that undermined trust in the principal pillars of society: church and state. To the Irish polity, it was a scandal too far: the traditional emphasis on altruism associated with blood acted as a 'lightning conductor' in a time of rapid social and economic change, structuring a public dynamic

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<sup>1</sup>Haemophilia is an inherited disorder of the blood that prevents coagulation. There are two forms of haemophilia; haemophilia A which results from a lack of factor VIII and haemophilia B, which is linked to a deficiency of factor IX. The symptoms are, nonetheless, identical. Mild haemophiliacs often require little or no treatment, whereas those with severe haemophilia often need daily treatment.

<sup>2</sup>Aberfan was a small mining community in Wales that lost almost an entire generation when a coal-tip collapsed, smothering 144 people, 116 of them children.

<sup>3</sup>A 1989 opposition motion to establish a trust fund became mired in moral bickering as the minority Fianna Fáil Government argued it had a responsibility to all AIDS sufferers. Although the Finlay Tribunal investigated the relationship between the Blood Transfusion Service Board (BTSB) and hepatitis infection, haemophiliacs were excluded from its remit and had to wait until 2002 (Lindsay Tribunal) for an explanation; a delay too long for over a eighty haemophiliacs who died before the tribunal had concluded.

'that led to political scandal in Ireland but not in the U.K.' (Farrell 2004, p.255).

Though far more sophisticated than the journalistic endeavours of Wren (2003), Bowers (1997), Daly and Cunningham (2003), Farrell's work is still concerned largely with what government knew (about hepatitis and AIDS) and when (the blood supply had been compromised). The origins to the blood crisis are therefore located in the failure on the part of key decision-makers to 'adequately *manage the risks* to haemophiliacs from HIV/AIDS' (Farrell 2004, p.255 emphasis added). Viewed as crucial pieces of evidence, it was knowledge that government failed to act upon: a crisis could have been averted had a precautionary stance been taken.<sup>4</sup>

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<sup>4</sup> In the U.K. a similar pattern emerged, forcing a government response. During 1987 the House of Commons Social Services Committee released its report on AIDS, suggesting that while the issues were complicated, careful consideration should be given to the plight of haemophiliacs (HCSSC Third Report 1986-87 vol. 1. para. 163). The report echoed a common sentiment: haemophiliacs, unlike homosexuals or drug users, were innocent victims. Garnering the patronage of the media and bipartisan political support, the haemophilia society initiated a lobbying campaign for financial aid (Farrell 2004, p.145). The government's response was muted. However, as Dr. P. Jones recalls: 'one day at three o'clock she (Mrs. Thatcher) suddenly said; 'we'll do it, there's the money'. Why she did, we never discovered' (Jones in Christie & Tansey 1998, p.66). Despite this success, the society's jubilation quickly turned to anger, as delay meant that at the end of 1988 only a paltry £132,000 had been paid out. Legal proceedings ensued and, amid mounting criticism, much from its own backbenchers, government agreed reluctantly to additional funds (£19 million) for the trust. It was too little too late. Rejecting the proposal, haemophiliacs continued to push for their day in court.

By the early 1990s a court case seemed imminent, raising concern among many. Regional Health Authorities (RHAs) were anxious over the time and expense spent on a defence. Fearing they would be called to give evidence against their patients, doctors warned that they would not participate. The Conservative Government moved to block the release of policy documents, claiming public interest immunity, but was overturned by the Court of Appeal. More significantly perhaps, Judge Ognall, who was to preside over the first case, was so concerned that he wrote privately to the participants urging settlement; arguing that the government had a 'moral duty to the claimants'. The letter was leaked, fuelling a media frenzy that gathered around the case (Farrell 2004, p.150). Under the leadership of John Major the Government's stance softened. In return for abandoning legal action, government offered to top up the trust by £42 million (Hansard 11<sup>th</sup> December 1990, 365). With time a priceless commodity the haemophilia society encouraged acceptance, to which its members agreed.

Nearly two decades on from Mr Major's reluctant handout to obviate court action and, with 1,700 patients deceased, haemophiliacs are still seeking answers. With crucial documents initially thought to have been destroyed re-emerging (*Review of documentation relating to the safety of blood products 1970-1985*) an independent privately funded inquiry headed by Lord Archer of Sandwell, was convened (The Archer Inquiry) in 2007 and reported in 2009.

In contrast to the focus on administrative error or inconclusive science, this book proffers a different approach. While we agree that the (mis)management of risk was important to *how* the crisis unfolded, we are concerned here with an altogether different task: an explanation of *why* the crisis emerged. Put simply, if rather too crudely for our liking, it is not how the risk was managed, but assessed. This is not semantic quibbling; it's crucial, and demands we explore the impact of the New Right on the interventionist state and how a subsequent reconfiguration of risk in politics informs a deeper understanding of a public health issue where complex scientific and technical problems are involved and powerful corporate interests are at play.<sup>5</sup>

In addressing these themes this book examines the broader milieu in which the hepatitis and AIDS crises unfolded, locating them within the context of international developments that wrought change upon the interventionist state. It contends that the blood crises were never a matter of the right or wrong science or simply administrative error, as tribunals would have us believe. Rather, it argues that blood supplies were confronted by a series of challenges (economic, virological and political) that were to prove pivotal in shaping events and where the impact of modern conservatism cannot be ignored.

If we are to understand how risk has been reconfigured under the influence of modern conservatism we need to rid ourselves of the view, a simple view in our opinion, that Irish politics is exclusively about 'what takes

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<sup>5</sup>Take for example the current banking crisis where much of the energy of economic commentators has focused upon 'attributing' blame to a failure of financial regulators to *manage* risk. It is an approach that neglects sufficient consideration of the impact of regulatory reform in the U.S.A. during the Clinton administration, which repealed the Glass-Steagall Act (1933). This act deliberately separated investment banking from retail banking, ensuring that investment bankers could not act recklessly with investors' deposits. It was part of a sustained political project forged by multi-national capital and implemented by successive administrations to reduce the burden of regulation and create conditions where the entrepreneurial spirit could thrive. For the American New Right the claustrophobic embrace of federal regulation had undermined the drive for innovation. They maintained that risk should be embraced, not feared. And, of course, those that embraced risk should be rewarded. For more detailed discussion of how these arguments apply to reform in chemical, pharmaceutical and food regulation. See 'associated files' folder on the homepage.

place in the Dáil'. While a concern with voting behaviour, patterns and the role of parliamentary institutions is an important form of political enquiry, we need to acknowledge that blood is a political issue. In so doing, our form of enquiry extends beyond the parameters of the Dáil and the media's obsession with the shenanigans of politicians. Blood is a political issue precisely because it touches upon matters that are at the heart of Irish democracy: deliberation upon the role of public and private sector provision in welfare services; the power of multinational pharmaceutical companies; the impact of regulatory reform on science. In other words, crucial areas outside of the Dáil where power is exerted, shaping the dynamics surrounding blood. In this vein, this book suggests that it is impossible to explain the crisis that enveloped Ireland's blood supply without reference to the *ideological* struggle over the nature of public service provision that took centre stage during the 1970s and 1980s.

Prior to the 1970s blood policy in Ireland had been built upon the twin pillars of voluntary donation and self-sufficiency; a policy shaped largely by the prevailing social democratically inspired view that blood, voluntarily and freely given, was both economically more efficient and safer. During this period the prognosis for those suffering from haemophilia was, to say the least, poor. A simple cut or bruise could lead to bleeding episodes. More seriously, a spontaneous bleed into the joints or the skull was potentially fatal and, consequently, most haemophiliacs never reached adulthood. By the 1960s, cryoprecipitate, a new technology that condensed the blood-clotting factor from multiple blood donations was developed and, when administered intravenously, improved coagulation.<sup>6</sup> It could be an unpleasant procedure, particularly for young boys that often had to be strapped down. However, as with any blood product, it carried a risk, a risk that increased with the number of donations.

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<sup>6</sup>Cryoprecipitate was manufactured by combining the clotting factor of multiple donors, usually 5 or 6, and was the principle technology for treating haemophiliacs until the emergence of concentrates. A fuller explanation is provided in Chapter II.

By the 1970s this policy was confronted with a triumvirate of threats (virological, political and economic) that brought into question the fabric of social democratic intervention. At this juncture an international market in blood and blood products had developed, presenting patients suffering from haemophilia with new treatment options (concentrates).<sup>7</sup> This new technology was both expensive and manufactured from large plasma pools, raising significantly the prospect of infection, especially if paid donations were used, as in the U.S.A. Crucially, the introduction of concentrates would also rupture the hermetic seal on Ireland's blood supply and introduce a new set of political actors.

The decision to import and persist with concentrates was not simply a matter of political pragmatism in a period of financial stricture: it clearly had a crucial ideational dimension. It was favourably received within the Irish medical profession, keen to avert any fabian evolution in health care and adamant that it should be left free to choose products sourced internationally. Such arguments also resonated within the Catholic Church, convinced that its hegemony in healthcare ethics had been eroded. What is important is that decisions about risk, previously refracted through the architecture of the Irish State and the preserve of ministers, civil servants and members of the medical and scientific communities, now involved U.S.A. multinational pharmaceutical companies and the United States Food and Drug Administration (USFDA): blood regulation had gone global.

The lifestyle of haemophiliacs improved dramatically with the introduction of concentrates, a technology that enhanced control of normal bleeding episodes and made medical procedures, previously considered dangerous, possible. At this early, tentative stage in their use, the medical community was aware of the prevalence of non-A, non-B Hepatitis (NANBH) in the blood supply, particularly in commercial concentrates. However, there was no test for NANBH available and little conclusive scientific evidence to

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<sup>7</sup>Concentrates were easy to store, administer and were more consistent in potency than cryoprecipitate, which had to be frozen (and thawed) and was often of uncertain potency.

persuade treating-doctors that it was anything other than a chronic disorder that might result in ill-health in a few people.

For many, the benefits of concentrates appeared to outweigh the risks, holding out the prospect of a near normal life and, with a backlog of patients awaiting corrective orthopaedic surgery, demand for concentrates escalated quickly.<sup>8</sup> It presented the BtSB with a series of problems, the most pressing of which was whether funds would be available to manufacture concentrates on a sufficient scale or allow a market in blood to develop. For government it was a thorny issue to grasp, a market in blood would undermine voluntary donation, self-sufficiency and the viability of a publicly managed blood supply. More importantly, government would be predisposed to accept the decision of the market, where a balance had to be struck between competing objectives: safety, innovation, cost, competitiveness and free trade.

For US Pharma, attempts to expand its footprint into a potentially lucrative market had been circumscribed previously by the short shelf-life of blood. The ability to 'crack' blood into its component parts therefore represented a first, crucial step in reproducing blood as an internationally tradable commodity. However, if this task was to be completed it required blood to be harvested more intensively and in significantly larger volumes, to which plasmapheresis offered a solution.<sup>9</sup> Though it was a procedure that raised concern about anaemia in the Irish and British medical communities, these were fears not shared on the other side of the Atlantic, where patients were harvested four times more often, allowing significant gains in productivity. With demand for concentrates growing, US Pharma was keen to exploit its market position, extending its blood supply network to parts of the third world, where the largest of these plasmapheresis centres (Nicaragua)

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<sup>8</sup>By the 1960s average life expectancy for haemophiliacs was 40 years, by the 1970s it was 54 and by the 1980s it had risen to 60 (Jones & Ratnoff in Leveton *et al* 1995, p.171).

<sup>9</sup>Plasmapheresis involves the extraction and separation of blood in a single operation, with the plasma siphoned off and the red cell portion of the blood returned to the donor.

bled a thousand people a day, earning the soubriquet among locals of *Casa de Vampiros* (House of the Vampires) (Starr, 2000).<sup>10</sup>

If the impact of commercial penetration attracted the attention of politicians, the gaze of the medical community was focused on evidence suggesting that hepatitis was a condition more serious than previously thought. The problem for government, both in Ireland and the U.K., was that while a risk had been identified, one assuming greater prominence in the medical journals, no risk had been proven.

With the dust not settled on such debates, a new and more terrifying threat emerged: AIDS. First identified among the gay community in the U.S.A., the swift spread of the disease was soon linked to other groups; intravenous drug users and Haitians. By early 1983, with a transfusion implicated in the AIDS infection of a newborn in the U.S.A., blood came under suspicion. Against this background, the vulnerability of haemophiliacs to this rapidly fatal disease was raised, with those such as Waterson (1983) alarmed that the few cases identified represented the 'tip of a large and rather chilling iceberg'.

Although changes to the immune system were a common feature, it did not *necessarily* suggest a causal relationship. For both haemophiliacs and treating doctors, scientific uncertainty created a complicated situation. Haemophilia societies were worried that government could impose a ban on imported concentrates, leading to shortfalls in supply. There had been only a few cases of AIDS diagnosed among haemophiliacs in the U.S.A., despite the vast quantity of blood products transfused, and none in the UK or Ireland. Vigilance and caution were important but, until *concrete* evidence could be produced, *a risk proven*, no change in treatment regimes could be advocated.

In this period of uncertainty, precautionary action was limited by the dynamics now shaping blood. The AIDS crisis had unfolded against a regulatory backdrop that had witnessed significant reform on both sides of

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<sup>10</sup>Industry defended its use of paid donors in Third World countries on the grounds that payment raised the living standards of donors (Jones 1980).

the Atlantic. In both the USA and the UK, the pharmaceutical industry had persuaded government to reduce the burden of regulatory red tape, convinced that the issue of safety could be absorbed by industry. In places such as the U.K. it meant that the Medicines Division of the Department of Health and Social Services (DHSS) was 'essentially reliant' on information provided by commercial fractionators. In was a situation replicated in Ireland, where one official candidly remarked; 'commercial companies that did seek product authorisation licenses could suggest their own standards' (*Irish Times* May 26<sup>th</sup>, 2001).

Decisions about safety, now fell largely at the doorstep of multinational companies. In some instances, such as the introduction of donor screening, they were ahead of voluntary bodies such as the American Red Cross. However, they resisted the use of surrogate tests (that indicate the *possibility* of disease from other markers) on the grounds of cost, and because a risk had not been proven. It was a window of uncertainty opened in late 1982 and closed in late 1985, as the virological threat of AIDS subsided with the introduction of heat-treatments. But, the haemophiliac community had been devastated, with HIV now the leading cause of mortality.

The sense of panic understandable in this vulnerable community did not extend to the Government or the scientific community whose imperturbability veered in the opposite direction. There was a reluctance to recommend any action until more evidence was available. The medical community was reluctant to alter treatment practise, largely because the risk of haemorrhage and its complications was deemed to outweigh the risk of developing AIDS or chronic liver disease. But critically these were decisions taken largely without consulting patients. As Mr Paul Bateman told the Archer Inquiry: 'If I had the choice to use factor VIII with the risk of infection with three life-threatening viruses, or the choice of joint damage and arthritis I would of course have chosen the latter. I was never given any choice' (Archer, 2009 p.64). Nor were patients offered information on the relative risks of treatment with different blood products, notably the comparative

risks of cryoprecipitate and factor VIII concentrate. In evidence to the Archer Inquiry, Stephen Wintle, whose wife, Colette Wintle had suffered from a mild form of haemophilia enquired as to why a 'high-risk product' had been used 'on a low-risk patient'? One Doctor, asked why a number of patients who, without consultation or informed advice, were given American products, sometimes for minor bleeds, replied that he had 'considered it worth the risk' (Archer 2009, p.64).

As the Archer Inquiry noted, it was understandable that doctors were reluctant to impose restrictions on choice without more evidence, but the danger signals might have indicated some precautions (Archer 2009, p.50). And it is this tension point, between action and inaction, where the crux of the issue lies; not in administrative failure: but how this action was shaped by the political, economic and ideological. Thus, for those that state blithely that it was a crisis that could have been averted if a precautionary stance had been taken, it is worth asking this simple question: at what point do you invoke precaution? It is a question difficult to answer at any time, but we need to recognise that policy by now was framed by an ideological commitment to reduce regulation, abandon state-led modernisation and curtail public sector involvement. Intervention, in a rapidly expanding and lucrative market, would have received short shrift from multinational pharmaceutical companies concerned about profits and market share. Modern conservatives had argued vociferously that we should embrace risk more fully, and not seek to intervene simply on the basis of spurious fears, for which there was no 'scientific proof' (conclusive evidence). And it is precisely at this point that we can begin to appreciate how the role of risk (and science) alters.

Under the influence of modern conservatism the role of expert advice is to sustain the view that risks are an attendant feature of day to day life, that what matters is how, as individuals, we make judgements about those risks. The role of science should not be 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 (think Thalidomide). These are technologies that may be contentious, possibly risky, but grounds for regulation must be founded upon a *proven risk*. It is an exercise that seeks to achieve a balance between the potential costs of regulating against risk, with other valued social objectives such as economic growth and employment.

But then again, put yourself in the place of a person who needs to use blood products that may (or may not) be compromised by hepatitis C, HIV, or for that matter new variant Creutzfeldt Jacob Disease (nvCJD). Or, a parent who must make this decision for their child and then reflect upon how these the political musings of modern conservatives, with their incessant demand to reduce intervention and embrace risk, appear so incongruous with relationships between humans at a personal level: As one mother succinctly put it, 'I thought I was a bad mum because I'd given him the injections – I'd killed him' (in Holmes, 2007).

These are not new arguments, but they have certainly fallen out of political fashion. Titmuss was always aware that the cost of medical care could not be known 'until we have consumed it'. That no distinction was made 'between services and objects,...events that are a threat to life and those that are not' (Titmuss 2002, p.251). Most damningly, healthcare was not simply another commodity. It could not be returned, undermining any notion of customer sovereignty. Titmuss would have recognised immediately that an explanation of the blood crisis could not be located in the parochial (administrative error). It was a global event and demands a global explanation; one rooted in the impact of modern conservatism on the manner in which risk, science and politics collide.

The book is divided into three chapters. The first traces the reconfiguration of risk in politics over the last three decades. Here, it describes the manner in which Conservative Governments in both the U.S.A. and U.K. initiated moves to reduce the regulatory burden upon industry, creating conditions in which the invigorating forces of the free market could

flourish. As we shall see, this political project had an important bearing upon how risk, science and politics collide.

The second chapter examines the blood crisis in Ireland and pays particular attention to the problems of political and scientific uncertainty that surrounded both NANBH and AIDS. In contrast to the Lindsay and Archer Tribunals it argues that the blood crisis cannot be attributed simply to either scientific uncertainty or administrative error. The twin pillars of voluntary donation and self-sufficiency were confronted both by escalating costs and the demand for new technologies (concentrates) during a period of severe financial restraint. The Government's response was to afford a more significant role for pharmaceutical companies, which meant that risk assessments were no longer the preserve of a forum in which public sector officials (minister, civil servants, health administrators) held sway, as risk would now be framed with market considerations to the fore.

The third chapter examines the regulation of blood in the aftermath of the blood crisis at the European level. It explores briefly the role of the principle of precaution in European decision-making and shows how this principle has become increasingly compromised by the emergence of competing principles (BATNEEC and Proportionality- the impact of modern conservative thinking). It details the 'politics' that underpinned the Blood Directive and reveals the extent to which reform has been shaped by a *particular* view of the role of risk in politics, one that accedes to the demands of multi-national capital; science that raises uncertainty cannot form the basis for intervention. For intervention to take place (a product banned, or higher regulatory/scientific standards demanded) there must be proven scientific evidence. And, even if a risk is established, any intervention must then be subject to considerations of cost, it must be proportionate.

## Chapter I

### From Titmuss to Hayek: The Reconfiguration of Risk in Contemporary Politics

One of the more enduring (if slightly disturbing) memories of my childhood was the sight of Norman Peak walking slowly up the road. It was a bemusing image of an old man moving in slow motion and one all the more perplexing because it contrasted vividly with the energy being expended in a frenetic game of football. It was not that he was injured or anything like that. On the contrary, there was a sense of presence to his gait: upright, strong, honourable. Yet, every five yards he would stop, bring out a white handkerchief and cough, a gut-wrenchingly deep cough. This occurred every five yards. To reach the pub would take something like an hour and a half; a walk that wouldn't have taken us ten minutes. A lifetime of labour at the coalface had been reduced to a struggle for oxygen. My mother would casually explain; 'it was the dust'. To the medically trained, pneumoconiosis. Despite the efforts of the National Union of Mineworkers to secure compensation for those such as Norman Peak, the National Coal Board persistently refused on the grounds of insufficient scientific evidence. Yet, as those who have lived in mining communities know all too well, it was a common condition.

The example of coal mining is cited because it reveals how risk, science and politics collide in all walks of life. We could just as easily have provided examples more familiar to our audience: the Corrib gas controversy in Mayo, nuclear power, the cigarette smoking ban in pubs, genetically modified organisms and, of course, the blood crisis. Events and issues such as these reveal that if there is a single word that captures the political zeitgeist, it is risk. And if we are to explain the blood crisis in Ireland we need to explore how risk, science and politics have been reconfigured over the latter part of the 20<sup>th</sup> century.

To those such as Beck industrial society has been supplanted by a 'risk society', where science no longer possesses an overwhelming grip upon the public's imagination. The growth of large scale technological systems" has , in Beck's opinion, meant that the *least likely* event will occur in the long run. If industrial society revolved around the distribution of goods, then risk society is about how we distribute the 'bads'. In this scenario, the security system that anticipates provision for the worst conceivable case breaks down with the advent of large-scale nuclear, ecological and genetic hazards. It involves a transformation that begins where nature ends, as we shift our concern from what nature can do to us, to what we have done to nature (Beck, 1992, p.10).

It is a set of ideas that has attracted a growing list of acolytes in political science (see MJ Smith, D Vogel; and in the field of Blood A M Farrell, Feldman and Bayer). Invoking much that has become popular in Beck's vision of a risk society, Vogel believes we now live in a *risk averse* political order, one in which 'widespread public perception of regulatory failures' have had a spill-over effect: they make both public opinion more sensitive to the risks associated with new technologies' and create a gap between public expectations and policy effectiveness. Not surprisingly, science is no longer seen as a sufficient guide to policy, curtailing 'the ability of politicians' to use 'scientific uncertainty as a justification for avoiding or delaying the imposition of more stringent measures' (Vogel, 2003).

Put simply, we need to explore how we judge risk (assess) and, more pertinently, how we respond to that risk (manage/intervene). At what point do we intervene (precautionary or not) and how do we determine the extent of that intervention? (is it proportionate? Do we balance the response to risk with other competing interests; economic and technological progress). Here we maintain that risk in politics is not an exclusively recent phenomenon, neither has the parameters of debate always been dominated by mathematical modelling and the elevation of science in the policy process. Indeed, we argue that under the influence of multinational capital and the Conservative New Right these are features that reveal the extent to which the role of risk in

politics has altered over the last three decades. More importantly, this 'reconfiguration' of risk is crucial to our explanation of the blood crisis.

In both the USA and Europe, post-war politics was dominated by a view of responsible government in which judicious intervention could rid economies of the vagaries of the free market (unemployment, poverty) and engineer a just society (education, health, housing). By the 1970s it was a view under challenge as the New Right sought to draw our critical gaze toward 'excessive' state intervention. For the leading protagonists of this period, Thatcher/Reagan, the notion of social justice that pervades government intervention was viewed as pernicious, for not only does it deny the freedom of individuals, it undermines individual responsibility: government decides what is fair, it defines just.

As part of a wider critique of social democracy that sought to redefine the relationship between the state and the individual, the New Right argued that far too much weight had been accorded to the state in deciding what is in our best interests, and far too little consideration given to the individual's capacity to respond to life's challenges (risks). It is impossible, for the state to define an acceptable level of welfare (risk), given that it involves making a balance between competing economic and social objectives.<sup>11</sup> 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.

For those of a conservative political persuasion risks are an attendant feature of day to day life, what matters is how, as individuals, we make

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<sup>11</sup> The recent court case over pesticide use in the UK is a case in point. The case turned on how exposure to pesticide spraying may affect people's health. In the original trial the campaigner secured victory on the grounds that she had produced 'solid evidence' that exposure caused harm. On appeal, however, the judge ruled that the campaigner had 'no formal scientific or medical qualifications' and that the regulatory framework for pesticides required a balance between the interests of the individual and the community as a whole'. The environment secretary said that 'in controlling pesticides, the protection of people's health is our priority. That is why we are already working to better assess bystander exposure to pesticides so that we can continue to improve our models (Guardian, 7<sup>th</sup> July, 2009). It is an example worth keeping mind as we develop the arguments of this chapter.

judgements about those risks (think the smoking ban in pubs). Here, the role of science should not be to *prevent* development on the grounds that a new technology, process or product *may* be risky (GM foods), but to establish *definitively* whether a product will be detrimental to public health, thereby establishing negligence or culpability (think Thalidomide). These are technologies that may be contentious, possibly risky, but grounds for regulation/intervention must be founded upon a *proven risk*. The objective of any risk analysis is therefore not to prevent development at all costs, but establish *how* a risk is to be *managed*, an exercise that seeks to achieve a balance between the potential costs of regulating against risk, with other valued social objectives such as economic growth and employment (think the Corrib gas dispute).

Viewed in this positive light, risk should not be feared, but embraced: it stimulates innovation and creativity (think of the new financial instruments before the credit crunch). And in this new guise, risk can be employed to define more clearly where intervention (management) *cannot* be justified across vast tracts of public policy, thereby reducing the regulatory burden upon industry.

The role of risk in politics (both nationally and internationally) is reconfigured, for science no longer underscores the regulation of the market through the state (the realm of the political/legal) but assists in the reconstruction of individual citizens as consumers of both products and *their attendant risks* (the realm of the economic/legal-producer/consumer). It articulates the extent to which individuals are exposed to risk, or defines more clearly where no *risk can be proven*. We will return to these themes in more detail and gradually tease out elements of this argument.

This chapter is divided into three sections. The first, sketches briefly the dynamic relationship between risk, science and politics as it was refracted through the political architecture of social democracy. The second and third sections examine how risk was reconfigured as big business and the

Conservative New Right sought to reverse the interventionist inclination of social democracy.

### **Risk and Social Democracy**

While social deprivation and unemployment were prominent issues that engaged European politics prior to the Second World War, few would dispute that the war provided the catalyst for establishing a new political order, founded upon new principles. Certainly, in the U.K. the effect of war was not lost on those such as Beveridge, who remarked that 'the purpose of victory' was to live in a 'better world than the old world' (Beveridge in Timmins 1996). Conceived during wartime, the Beveridge Report formed the cornerstone of a political project that appeared to achieve the impossible; satisfying all of the people, all of the time. For those on the Left it 'emphasised' a collectivist approach, one that would usher in a universal welfare state. For those on the Right, comfort could be found in the refusal to stifle 'incentive, opportunity or responsibility' (Beveridge in Timmins 1996, p.24).

In a similar vein, while the genesis of state intervention emanated from a desire to restrict monopolies, Keynes' influential work was channelled into a vision of managed capitalism. Convinced that the time of orthodox *Laissez-Faire* had passed, Keynes' advocated government intervention as a response to the most pressing problem of the inter-war years: unemployment. It is important to recognise that for Keynes it was economic, rather than social, considerations that were to the fore. Perturbed by the cyclical employment failures of the *Laissez-Faire* system, Keynes rejected the view that the unintended consequences of individual self-interested actors would result in maximising the social good. Instead, he believed that an unchecked market was inherently unstable and, therefore, required guidance to dampen its wild oscillations (think of the credit crunch). In contrast to free market thinking, which had foisted responsibility for unemployment squarely upon the

shoulders of the individual, Keynes concluded that the vagaries of the free market were not open to adjustment by any individual.

If Keynes' denunciation of an unfettered market emanated from economic rather than social considerations, the opposite could be said of Richard Titmuss. Titmuss viewed markets as pernicious and divisive, since their principal concern was profit, not welfare. Titmuss's endorsement of intervention was founded not just upon reducing the vagaries of the free market, but also on the benefit that social policy could produce: the promotion of equality, integration and community. For Titmuss, intervention (and redistribution) was not simply about correcting market failure, and providing for the disadvantaged, but was an indispensable element of policy if an individual was to be an active and equal member of society. In his opposition to liberal economists, Titmuss argued that individuals could be free only if the uncertainties of market forces were removed. Thus, he maintained that it is the responsibility of the state 'to reduce, eliminate or control the forces of market coercions which place men in situations in which they have less freedom' (Titmuss 1970, p.242).

In areas such as healthcare Titmuss disparaged the work of conservative and liberal economists alike, for they failed to consider that consumers could have no prior knowledge of their needs, the possible costs involved or the class of healthcare required. Challenging those who considered medical care to be merely another commodity, he maintained that no distinction was made 'between services and objects...events that are a threat to life and those that are not', and that the cost of medical care could not be known until 'we have consumed it' (Titmuss 2002, p.251). Most damningly, he observed that unlike other commodities, healthcare could not be returned, undermining any notion of customer sovereignty. It was a situation compounded by the customer's inability to compare products, placing the consumer in a position of 'ignorance and uncertainty', which meant that the patient had 'to trust the medical profession and the organized system of medical care' (Titmuss, 1967, p.38).

Titmuss's resistance to the unrestrained forces of the free market was defended in his seminal work the *Gift Relationship* (1970), a study of the disparities between paid and voluntary systems of blood donation that confirmed his belief that social democratic provision was not only morally, politically and socially superior, but economically more efficient. He observed, for example, that:

In terms of economic efficiency (a commercialized blood system) is highly wasteful of blood...involves heavy external costs...is administratively inefficient and resulted in costs some five to fifteen times higher...paid by the patient (Titmuss 1970, p.205).

In short, Titmuss's opposition to the free market sprung from the fact that 'diswelfares', or socially generated costs such as unemployment, ill-health and pollution, were spawned by on-going social and economic changes in society that were allowed to 'lie where they fell'. And, in the case of blood, they fell with the patient (Wilding 1995, p.153).<sup>12</sup>

The defence of state intervention offered by Titmuss carries force not only because it argues the case for efficiency, but also because it identifies legitimate state intervention, or *responsible* government, in terms of its capacity to reduce the unpredictability and uncertainty of risk to unemployment, poverty, ill-health, homelessness or ignorance. It is this, which gives the interventionist state of the post-war period the imprimatur of the public. It was not about providing the 'institutionalised pledges of safety and welfare', to which those such as Beck refer, rather it was about regulating (and thereby alleviating) the worst excesses of the free market (Beck, 1992). As Titmuss was only too well aware, consumers could not estimate in advance the nature or extent of hazards and a free market would simply

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<sup>12</sup> Titmuss's arguments were sufficiently compelling to carry weight in the U.S.A. where the U.S.A.'s Department of Health, Education and Welfare noted that: 'commercial sources of blood...contributed to a significantly disproportionate incidence of hepatitis', largely as a result of their collection 'from sectors of society in which transmissible hepatitis is more prevalent' (in Leveton *et al* 1995, p.41). In 1972 Holden observed that while: 'The Center for Disease Control in Atlanta estimates that hepatitis resulting from transfusions accounts for some 3500 deaths a year, many doctors believe that because of unreliable and inconsistent reporting, the total is closer to 35,000' (Holden, 1972.).

neglect and 'punish the indigent, the coloured, the dispossessed and the deviant' (Titmuss 1970, p.38).

One of the more prominent themes to emerge in this social democratic project was that it was predicated not upon establishing a minimum level of welfare, but rather upon an extension of social as well as civil and political rights. As a consequence, the welfare state extended beyond the realm of education, health and income maintenance to encompass full employment policies, environmental regulation, work safety, low wage councils and retraining programmes (Pfaller *et al*, 1991; Hills *et al*, 1994). It may well have been anticipated that an expansion in social rights would lead to a "general enrichment of the concrete substance of civilised life", a reduction in risk, insecurity and an "equalisation between the more or less fortunate at all levels", but it fell short of endorsing the need to establish formal equality (Bottomore & Marshall 1992, p.33). Although the alleviation of poverty was certainly a crucial consideration for any progressive democratic polity, formal equality remained an aspiration, not an explicit policy objective. As Marshall noted:

The more you look on wealth as conclusive proof of merit, the more you incline to regard poverty as evidence of failure - but the penalty of failure may seem to be greater than the offence warrants... as the social conscience stirs to life, class abatement...becomes a desirable aim to be pursued *as far as is compatible with the continued efficiency of the social machine* (Bottomore & Marshall 1992, p.20. Emphasis added).

Two themes have thus far informed our understanding of the role of risk in regulation under the auspices of the interventionist state: first, the focus upon an economic and political vision of managed capitalism; second, that state intervention acquired the imprimatur of the public because it represented a social democratic attempt to reduce the uncertainty and unpredictability of risk in a free market. However, to understand more fully the role of risk in regulation we need also to appreciate the manner in which political responsibility operates in social democracy.

From the turn of the nineteenth century to the late-1970s state regulation in both Ireland and the U.K. had been managed through a number of mechanisms: operational boards (U.K.), state-sponsored bodies (Éire), tribunals, inquiries and agencies.<sup>13</sup> As a preference for a managed, rather than mixed economy emerged, the mechanisms of intervention expanded. This deliberative element of government intervention developed as part of an evolutionary process. Recognition of a social evil called for regulation that would be backed by inspection and enforcement.

Even in this early stage in the development of an interventionist style, governments were conscious of the fact that regulations had to balance a variety of competing social, economic and environmental factors. Despite changes to the political and social structure, consultation, negotiation and compromise remained pivotal in both Irish and British politics, giving rise to the suggestion that: 'there is almost a penchant for resolving disputes by discussion, by sitting around a table and ironing out differences' (Norton 1994, p.32; Connolly & O'Halpin 1999).

The administrative apparatus of both Irish and British Governments also shared similarities. Indeed, those such as Chubb have noted that the civil service that emerged in Ireland in the 1920s was a 'British-type Civil Service in miniature' and has, in many respects, remained essentially so (Chubb 1992, p.231). Indeed, in both letter and spirit, Ireland's law-making procedure has been comparable to that of the U.K. (Coakley & Gallagher 1999, p.184). In short, as one Irish civil servant put it, we would be: 'generally on the same side as the British...looking at it against the background of broadly similar

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<sup>13</sup>Operational Boards were public bodies that managed functions, rather than regulating private actors, a compromise between full private or governmental control. In Ireland, these were termed state-sponsored bodies (a catch all categorisation that subsumed agencies) and, like their U.K. counterparts, flourished with greater state involvement (Chubb 1992). Tribunals, a form of quasi-court, also proliferated during this period and were used to adjudicate on contentious issues. Public inquiries could be either statutory or non-statutory and permitted decisions to be weighed against the views of those affected (McCudden 1990). This made public inquiries particularly suited to large-scale 'one off' decisions, where their appeal lay in the fact that they encouraged considerable 'breadth' in representation and 'depth in discussion', yet allowed ministers to retain power over the final decision (Baldwin & McCudden 1987, p.19).

administrative and implementation arrangements, and also legal arrangements' (Taylor & Horan 2001, p.376).

In the Irish case this predilection for negotiation and compromise can, in part, be attributed to its electoral system, where coalitions have now become the norm. Unlike the U.K., where first past the post and a two party system encourage political/ideological separation, or some European States where proportional representation with a list system means voter's choose along party lines, Ireland's electoral system, proportional representation by single transferable vote (PR-STV), provides a near unique political environment, one that affords fertile ground for coalitions and minority governments, often supported by independents. It produces a situation where government is not directly elected, but rather negotiated post-election.

Ministerial responsibility also has a key role to play in both Irish and British politics. As Weir and Beetham note, in the British case it is linked to the development of departments, ensuring that each minister is both 'formally in control of policy and answerable for his or her department's actions' (McCrudden, 1990; Weir and Beetham, 1999). In Ireland, it ran along similar lines and was given legislative status under the Ministers and Secretaries Act (1924). This Act established the minister as corporation sole, so that he/she could be sued as a corporate entity, rather than an as individual. Under the Act, ministers and their civil servants were indivisible, with decisions made by civil servants considered to be the same as those made by the minister (Connaughton, 2006).

There are three elements in this account to which our attention is particularly drawn: first, that the interventionist state attempted to regulate the market with regard to the social democratic virtues of altruism and solidarity. A particular understanding of state intervention therefore shaped the role of science and risk in regulation; legitimate intervention would be achieved if the risks to health, welfare and employment did not pose an excessive burden upon the free market. Second, that government always recognised the limitations of scientific advice, that political decisions always

had to be aware that science was rarely absolute and that regulations would be required to recognise this fact. Finally, the role of science in political decision making was refracted through a view of democracy that was essentially conservative, one which adhered to the maxim that 'government knows best', a tradition linked strongly to the advocacy of ministerial responsibility (Marsh *et al*, 2001).

None the less, all too often, the relationship between expert advice and politics has been presented in terms of a simple dichotomy; on the one hand scientists are responsible for risk assessment; a technical, non-political matter of gauging adverse effects on humans, plants and animals as a result of exposure to an agent. On the other hand, politicians have a responsibility for managing the risk identified by scientists, thereby setting the appropriate level of protection. (Skogstad, 2001). It is an approach that fails to consider the way in which scientific advice was refracted through the political channels of government.

Ministers place value upon expert advice largely because it carries 'weight', reassuring the public because it is not "tarnished with the political shenanigans of government" (Philips, 2000, p36.). In practice, however, the distinction between the objective pronouncements of science and the subjective interpretation of politics is often blurred. As one civil servant in evidence to the Philips Inquiry on BSE noted; in certain circumstance advice given to a minister might be affected by the experts "understanding of the Minister's current thinking" (Philips, 2000, p36.). In addition, it is recognised that while an opportunity for debate meant that a particular 'line' could be challenged, once a firm decision had been made at ministerial level: "it would have been very unusual to have advised ministers to think again, unless there was a factor which they had clearly not been able to take into account..."(Philips, 2000, p.14).

If the issue of ministerial responsibility often had an important bearing upon the 'political shape' that expert advice took, the channels through which communication travelled were also important. Policies do not evolve in a

vacuum, and to a large extent they reflect the pressure of past and present events. The manner in which issues were addressed and conveyed always required consideration of statements made by Ministers, either in opposition or office. It was hardly surprising, therefore, that civil servants and experts should very quickly take into account a “ministers’ relationships with the public and public relations”. Indeed, those that did not; “draft things in a way that emphasised the benefits of government policies”, would tend to be less popular (Philips, 2000, p.14).

If the relationship between ministers, civil servants and ‘experts’ provided a political context in which advice was shaped, the communication of that information, whether to the Dáil, Parliament or the public, was also important in the construction of policy. As Stephen Dorrell pointed out, once a minister had taken a certain line, public officials would be expected to follow suit. As a consequence, officials often proposed; “rather less than we might have done if we had thought the minister shared our perception of the seriousness of the situation... it is entirely normal for officials to shape their advice to ministers in this way: there is no point whatsoever in putting advice forward which has very little chance of being accepted” (Philips, 2000 p.10).

Given that the ‘line’ taken could involve either low politics (replying to letters or engaging local authorities) or the high politics of responding to in the Dáil or Parliament, there was always the possibility that it may; “omit important doubts and questions” (Philips, 2000 p.15). If the manner in which expert advice was refracted through the political architecture of the British State raises doubt about whether political decisions were underpinned by scientific certainty, the nature of the regulatory principles adopted during this period also provide further grounds for caution.

During the 1970s much of the legislation drafted by Irish and British Governments operated with an assessment of risk that involved a number of regulatory principles that endorsed different views. In the U.K., the 1974 Health and Safety Act, for example, the operating principle was ALARP (as low as reasonably expected) which included; “the injunction laid down in

safety law that any risk must be reduced so far as reasonably practicable, or to a level which is as ‘low as reasonably practicable’ (Philips 2000, p.42). In those areas such as the licensing of medicines, or the assessment of food additives, the preference was to adopt NOAEL: No observable adverse effects level. If it involved the regulation of food contaminants, then legislation tended to endorse the principle of either ADI or TDI; acceptable or tolerable daily intakes (Philips, 2000 p.42). In Ireland, similar principles operated. For example, the Safety/Health and Welfare at Work Act (1989) employed ‘so far as is reasonably practicable’. Indeed, in some areas such was the level of policy transfer that one civil servant recalled that:

its on record that some senator asked the minister – ‘I know that you copied subsection 1, 3, 5, 7, and 8 of the British Town and Country Planning Act. Could you ever tell us why didn’t you copy subsection 2!’ (Taylor and Horan, 2001, p.385).

Such principles were by no means new. In Ireland, for example, the Alkali Works Regulation Act of 1906, which borrowed very heavily from its British counterpart, stipulated that works should be registered with the inspectorate and that the principle of ‘best practicable means’ would inform the standards for certification (Scannell, 2005).

It was not simply that a plethora of regulatory principles existed, each with a subtle but nonetheless discernibly, different slant on risk. Rather, they were premised upon the realisation that science was *incomplete*, that a government’s defence would need to be: “bolstered by regulations that were soundly based in law, were *reasonable* themselves, were *consistent* and had been subject to *reasonable consultation* (Philips 2000, p.37). As one civil servant remarked in his evidence to the Philips Inquiry: “whatever you do you have to be able to justify it, because if you cannot justify then you are subject to judicial review...therefore, whether its scientific or other evidence you have to have justification for things you do” (Philips, 2000 p.37).

Remarkable though it may seem, political debate has been distorted by a view of risk in politics that has assumed difficulty to lie in the ability of

government to cope with inconclusive science (see Vogel, 2003; Smith, 2004). Such a view blatantly fails to recognise that in its regulation of the market the post-war interventionist state was always keenly aware of the incomplete nature of scientific knowledge and that *risk* was central to policy making environs.

The lexicon of the skilled and experienced legal draftsman was replete with concepts such as reasonable, acceptable and tolerable, not because these terms were evasive (although often they are), but because ministers, civil servants and experts recognised the imperative to consult widely with vested interest groups in order to offset the potential for a legal challenge. If we refuse to acknowledge that public servants operated within boundaries set by conflicting expert advice, and that the science was often inconclusive, we cannot begin to understand how decisions were taken, or the importance of risk within the formation of policy.

### **Risk and the New Right**

In both Europe and the USA the political landscape of the 1980s differed markedly to that of the 1960s. The positive glow of post-war economic growth had subsided, to be replaced with pessimism in political circles about escalating public sector debt, increasing inflation and rising long-term unemployment. Under the leadership of Margaret Thatcher, Helmut Kohl and Ronald Reagan, Conservative Governments extolled the virtues of competition and individual responsibility. Though far from a consistent or coherent project, this political agenda influenced profoundly the role of risk in politics in both the USA and Europe.

Much of the intellectual resource for the New Right came from Hayek's damning critique of socialism, where his antipathy rested on the fact that two of its core principles, altruism and solidarity, provide significant obstacles to sustained economic growth. Perturbed by the fact that even anti-socialists regard such concepts as virtuous, Hayek asserted that altruism can extend only to the needs of known other people and that in an extended order, its

practice is impossible (Gamble, 1996). In stark contrast to the state interventionist vision of post-war Britain, Hayek proposed that the morality of the Great Society was one constructed upon individual freedom and responsibility, the foundations of which could be found in the free 'exchange of equivalents' or, as Adam Smith once argued, 'a society in which you give me that which I want, and you shall have this which you want' (in Gamble 1996, p.29).

In Hayek's opinion, few people understood, or were prepared to accept, that an extended political order was not an expression of our fundamental moral instincts, but a denial of them. In contrast to an extended order based upon state intervention, one defended on the grounds of altruism and solidarity, Hayek proposed an alternative, spontaneous order in which there is no single directing centre and that is dominated only by the unintended consequences of all agents (Gamble, 1996). It is a societal order that explicitly rejects constructivist rationalism; that institutions and action can be based upon reason. Hayek rejected the belief in social democracy that through intervention we can engineer a 'better society'. As such, he argued that: "before we can remould society intelligently...we must realise that, even when we believe that we understand it, we may be mistaken. What we must learn to understand is that human civilisation has a life of its own, that all our efforts to improve things must operate within a working whole which we cannot entirely control" (Hayek, 1960).

Think of the issue of welfare, one that currently dominates Irish politics and where economists, politicians and media pundits alike are all too keen to draw our gaze to 'excessive welfare benefits'. As unemployment rises inexorably the debate is not about 'the contribution' (or contrition) that should be exacted from bankers and property developers, now protected through government initiatives to stave off a further collapse in property prices, but on the issue of what is an acceptable level of welfare? These are precisely the parameters of debate drawn by Hayek: should the unemployed be paid sufficiently to afford cars? Mobile phones? And where is the line to be

drawn? The struggle to define an acceptable living standard invokes necessarily a discussion of its elevated counterpart: the hardworking entrepreneur and the subsequent burden drawn in terms of increased taxes; how this impacts upon the 'motivation' to take up low-paid employment and, perhaps more importantly, the desire to consider risks for which the reward is reduced.

Not surprisingly, the notion of social justice that pervades the Keynesian Welfare State was viewed as pernicious, for not only does it deny the freedom of individuals (the state 'decides' what is fair, it defines just), but it undermines individual responsibility. In Hayek's view, liberty and responsibility were inseparable and a free society would not function or: "maintain itself unless its members regard it as right that each individual occupy the position that results from his action and accept it as due to his own action". It was, he conceded, a position: "which evokes the outright hostility of men who have been taught that it is nothing but in circumstances over which they have no control that has determined their position in life" (Hayek, 1960, p.72).

Entrenched firmly within an anti-rationalist perspective, Hayek believed that knowledge is imperfect and that the cost of any economic activity is subjective. Knowledge in a market economy is dispersed, fragmented and decentralised and any attempt at central planning or state control is flawed because it assumes that knowledge can somehow be collected by a central authority and employed to construct a more perfect market (Gamble, 1996).

It was not that Hayek was against reason *per se*, rather he opposed the possibility that reason could be harnessed to central planning, maintaining that human reason was too limited and knowledge too imperfect to allow sufficient information to be gathered to manage an economy. He was adamant that, not only was the volume of information too great, but that the temporal, contextual and subjective nature of economic knowledge would thwart any attempt to assimilate it (Tomlinson, 1995, p.18).

For the New Right, risk should be viewed in a positive light, for it stimulates innovation and creativity: it should be embraced, not feared. It was a set of political ideas that would inform significantly the reform of risk in politics in both the USA and Europe, manifest in the separation of risk assessment from its management and a corresponding elevation in the role of science so that it defines more clearly both the need and extent of regulatory intervention. These are crucial themes to our explanation of the blood crisis and, therefore, need to be teased out a little more.

From the late 1970s the impact of Federal regulation in American politics had become an increasingly controversial issue. Conservative lobby groups (such as the National Rifle Association) balked at the level of regulation to materialise from a sustained period of environmental legislation in the 1970s.<sup>14</sup> Much of this legislation, and subsequent regulatory action, drew upon emerging scientific disciplines – toxicology, epidemiology and environmental monitoring 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 (Merrill, 2003 pp1-5; see also Breyer, 1993 pp14-24).

To those such as Alvin Weinberg the difficulty lay in the fact that many of the issues that these disciplines were called upon to clarify occupied the interface between science and politics, or what he termed the realm of trans-science. In other words, while questions could be stated in scientific terms, they were beyond the proficiency of science to answer conclusively. Keen to defend science from being mired in controversies over trans-science issues, Weinberg felt that, at best, scientists could define only where: ‘science ends and trans-science begins’ (Weinberg, 1972, p.211).

It was an important contribution to a debate that for many had become shaped by an ‘overly powerful fourth branch’ of government, one that

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<sup>14</sup> The most notable were the Clean Air Act (1963), the Occupational Safety and Health Act (1970), the Clean Water Act (1972), amendments to the Federal Pesticide Law (1972) the Toxic Substances Control Act (1976) and the Resource Conservation and Recovery Act (1976).

cloaked policy choices in the science provided by an even more 'inscrutable fifth branch of technical experts' (Jasanoff 1990, p.3). Across the entire political spectrum, concerns were raised that this was an environment conducive to the production of science-policy, rather than science, a hybrid activity that had the trappings of science, but combined elements of 'scientific evidence and reasoning with large doses of social and political judgement' (Jasanoff, 1990, p.229; Epstein, 1996, p.276). As those such as Jasanoff or Breyer observe, experts within and between disciplines are often in conflict over the interpretation of data and the methods used. These are often resolved through peer-review. However, in the arena of environmental regulation such processes that legitimate science were either absent or did little to insulate findings from criticism

Uncertainty, or lacunas in knowledge, gave antagonists unlimited scope to marshal evidence and experts in support of their position (Rushefsky, 1984). Whether those involved were protesters, environmentalists, industry representatives, lobby groups or politicians, deficits in knowledge provided an opportunity to employ science to mould risk assessment guidelines consistent with their social objectives (Jasanoff, 1990, p.6).<sup>15</sup> As a consequence the role of the reviewing courts assumed an increasingly prominent role in the latter part of the 1970s.

Traditionally, the courts had deferred to experts and agency science, a view that acknowledged agencies as politically accountable and authoritative sites for resolving disputes over risk. It was a stance that had emerged forcefully in *Ethyl Corp v. EPA* (Environmental Protection Agency) (1975), one of the first comprehensive reviews of science policy in the court, where the presiding Judge ruled that an agency could act on:

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<sup>15</sup> As we write, the Corrib gas field project in Mayo run by Shell continues to court controversy and provides an interesting example of how these disputes involve the collision between risk, science and politics. Initially, the terms of dispute were framed by the threat to the areas of outstanding ecology. However, it is a dispute increasingly mired in competing interpretations of safety, where the language of risk assessment now commands centre stage. This is not by accident, and reflects the changes that have taken place in environmental regulation from the 1990s onward (see Taylor, 1998).

suspected, but *not completely substantiated*, relationships between facts, from trends among facts, from theoretical projections from imperfect data from probative preliminary data not yet certifiable as 'fact' (Jasanoff, 1990, p.50 emphasis added).

The ruling recognised that science was often inconclusive, that an agency should be permitted to engage in regulatory decision-making on *suggestive* rather than *conclusive* evidence and that universal acceptance of evidence among the scientific community was not a prerequisite for decisions. Moreover, in cases where expert interpretations differed, it was the agency that should have: 'authority to resolve the dispute consistent with its overall legal mandate' (Jasanoff, 1990, p.50).

This is a crucial matter, for at this point we can begin to identify the shift in the New Right's challenge to the role of science in politics. Keen to reduce state intervention, the New Right drew upon its anti-rationalist sentiment to criticise the role of science in justifying regulatory intervention. Its an odd turn of phrase, but important, and one that we need to tease out.

For most people, science is an entirely rational exercise; hypotheses are subject to rigorous empirical examination (on an on-going basis) in order to establish proof. And yet, much of science, recognised by scientists themselves, is concerned less with certainty and more with uncertainty. Thus, for example, there are issues upon which proof may well be impossible to establish, but upon which inferences can be made (precautionary action taken).<sup>16</sup> However, the New Right has argued vociferously that the role of science should be to establish what is known, not what *may* occur. Almost perversely, and rather confusingly, science is elevated, for it can be used to identify where intervention can be justified or, perhaps more importantly, where it cannot. In other words, the evidentiary bar has been raised, before

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<sup>16</sup>For example, Weinberg predicted that the impact of exposure to low-level radiation would probably never be fully known, given the massive volume of animal studies that would be required to demonstrate unequivocally an effect. Epidemiological studies were equally problematic, as ethical considerations precluded tests on humans, confining research to animal studies or accidental exposure. For their part, animal studies were complicated by the difficulty of extrapolating conclusions to humans, made more complex by the fact that results frequently differed depending on the species of animal tested (Weinberg 1972).

intervention can be justified. Put simply, if rather too crudely for our liking; if no risk is proven, there is no risk.

It is this demand for conclusive evidence that underpins the New Right's drive to reduce excessive intervention in vast tracts of modern life: food safety, chemicals, nuclear power or genetically modified foods. But also think of the credit crunch, the origins to which lie not in a difficulty to manage risk, but in the argument that risk should be embraced, not feared. That new financial products were beneficial to all: retail banks saw an invaluable opportunity to exploit the gains to be made from the symmetry between the retail investment arms of a bank, spreading risk across vast areas with new financial instruments reducing the possibility of systemic collapse (or that's how it came across in the risk assessment!). Higher profits and higher growth would ensure that the benefits 'trickle down' to the previously disenfranchised: welfare constructed entirely on the rewards of free market capitalism. What remains distinctive about this free market orgy is that the mathematical modelling showed that the risk was manageable, and that until a (systemic) risk could be proven, intervention (regulatory reform) could not be justified.

However, in the 1970s, in the USA, further cases reinforced the court's deferential stance to agencies. In *Dow Chemical v. Blum* (1979), which involved the emergency suspension of a suspected carcinogenic herbicide, the court upheld the use of 'action based on lower standards of proof than would otherwise be applicable' (Jasanoff, 1990, p.51). Dow Chemical criticised the EPA's methodology on a number of grounds including; data collection, statistical interpretation and suppositions over human exposure levels. However, while the court conceded that Dow Chemical had raised valid criticism, it rejected the call to overturn the EPA's decision because it had not been demonstrated that the conclusions were: 'completely without foundation or that the agency had made a clear error of judgement' (Jasanoff, 1990, p.51).

During *Hercules, Inc v. EPA* (1978), the court showed even greater deference to agency expertise, reaffirming the view that the protection of public health justified the use of: 'less elaborate procedure than may be required in other contexts'. Here again, the court ruled that where disputes arose over methodological issues, it was the: 'expert agency's function to select the appropriate analytical approach' (Jasanoff, 1990, p.52).

As the courts became increasingly embroiled in the oversight of agency decisions, other interpretations of the manner in which the oversight process should function came to the fore.<sup>17</sup> Here, the opinion of Judge Harold Leventhal (1974), had a significant impact on the development of a *Hard Look* approach. Under the *Hard Look* doctrine courts would be required to be sufficiently acquainted with technical matters in order to understand why the agency 'did what it did' (McGarity, 1984, p.100). It was a position not welcomed universally. Those such as Chief Judge Bazelon felt that scrutinising agencies in this manner required extreme care, if for no other reason than the fact that judges: 'lack the technical competence to resolve scientific controversies' (Peel, 2004, p.26). He proposed that an agency's procedures be designed to allow for public inspection and participation in areas of scientific uncertainty. While this view appeared to endorse a more open approach, it led to the adoption of 'increasingly more stringent procedural requirements to be met by agencies' (Peel, 2004, p.26). It also conceded to the court an almost unlimited capacity to impose new procedural requirements if it was dissatisfied with any element of the: 'administrator's scientific information, assumptions, or reasoning' (Jasanoff, 1990, p.56).

Though this element of court/agency interaction was ultimately overturned by the *Supreme Court in Vermont Yankee Nuclear Power Corp v. Natural Resources Defence Council* (1978), the *Hard Look* doctrine remained, and

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<sup>17</sup> In the U.S.A., the relationship between courts and agencies was subsumed under substantive statutes and the Administrative Procedures Act (1946) that empowered courts to review agency decisions. As a whole, this legislation required that they assess the agency's interpretation of its own statute, that the courts be satisfied an agency had not gone beyond its remit, that its actions were supported by substantial evidence and that agency decisions were not arbitrary, capricious or an abuse of discretion (McGarity, 1984).

courts retained the freedom to dissect the science underpinning regulatory measures. Against the backdrop of the *Hard Look* doctrine other, important challenges to agency science surfaced. In *Industrial Union Department v. American Petroleum Institute* (Benzene case), the Occupational Safety and Health Administration's (OSHA) methods became the subject of controversy. The case revolved around OSHA's decision in 1978 to slash its workplace airborne exposure standard for benzene, a known carcinogen, from ten parts per million (ppm) to one ppm.<sup>18</sup> The petroleum industry remonstrated against the new standard and initiated court action.

In 1980 the Supreme Court overturned the OSHA's decision and reproached the agency for its failure to show that the existing standard represented a significant risk, one that required replacement. In addition, the Supreme Court ruled that the agency's assessment was inadequate, and that it had failed to give due consideration to the construction of a dose-response curve for exposure that the petrochemical industry had suggested was possible on the basis of known data. Though the court acknowledged that problems often arose at the frontiers of science, and that conservative assumptions of risk were permitted, it required they be: 'supported by a body of reputable scientific thought' (Peel, 2004, p.29). More importantly, the court ruled that before any regulation was made, the agency was expected to assess the magnitude of the risk: 'based on information estimating the likely *probability* of harm in *quantitative* terms' (emphasis added, Peel, 2004, p.29). Given that industry had long sought the reform of science underpinning agency decisions, the benzene case provided ample opportunity for industry

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<sup>18</sup>In the U.S.A., carcinogens were subject to strict regulation based on a consensus among cancer experts that a safe 'threshold' level of exposure was neither possible nor practicable. Thus, regulators either had to ban a suspected substance or restrict exposure to the lowest humanly possible level. Indeed, the Delaney clause of the Federal Food, Drug and Cosmetic Act (1958) endorsed a zero-risk approach, prohibiting the 'introduction of most carcinogenic additives into food'. Though controversial, this clause remained a cornerstone of policy in the U.S.A. until the 1980s, where there was some 'wearing away' of the 'no threshold' carcinogen assumption (Jasanoff, 1986, p.11).

to argue for a separation of: 'science-based fact-finding from regulatory policy-making' (Merrill, 2003, p.2).

Determined to reduce the regulatory burden on industry, the Reagan Administration initiated reforms in the Office of Management and Budget (OMB). Here, the introduction of Executive Order (12291) was significant, ensuring that agency decisions would be subject to cost benefit analysis. With EO 12291, OMB was obliged to review agency rules and ensure any proposed action had considered: 'the condition of the particular industries affected by regulations and the state of the economy' (EO 12291). In addition, cost-benefit analysis became mandatory for major regulations, ensuring that any net benefit to society outweighed the cost (Kraft, 1998, p.198).<sup>19</sup>

Although agencies retained the authority to initiate regulations against the wishes of the OMB, such defiance would be limited, given that OMB had substantial power over agency budgets, personnel ceilings, information and 'clearance for congressional contacts and requests' (Copper & West, 1988, p.874). As one OMB Director put it: 'if you're the toughest kid on the block, most kids won't pick a fight with you' (Miller in Kargman, 1986, p.1791). Any opportunity for a fight was removed in 1983 when the Presidential Task Force on Regulatory Relief that had oversight over OMB was disbanded, leaving agencies bereft of any formal recourse to an OMB review (Olson, 1984, p.11).

Many were less concerned with OMB's clout and more troubled by its conventions. In communication with agencies the OMB avoided written contact, preferring phone calls and meetings to press home its point. Indeed, one former senior official candidly revealed that a large part of OMB's preference for oral comment on agency rules sprang from a desire not to leave fingerprints in the administrative record (Tozzi in Kargman, 1986, p.1789). In this furtive atmosphere industry representatives often used the OMB as a

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<sup>19</sup>A major regulation was one that was likely to result in: (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprise in domestic or export markets (EO 12291).

conduit to push their agenda, or for holding up regulation (Cooper & West, 1988, p.879). A significant consequence of OMB's predilection for the clandestine, and a lack of a transparent record meant that judicial review suffered 'severe handicaps for rules in which OMB had taken a major interest' (Cooper & West, 1988, p.881).

Critics of the OMB suggest that it forced agencies either to abort or delay regulations (Kargman, 1986, p.1789). Those such as Cooper and West argue that OMB's influence was such that it structured agency decisions in a manner favoured by the administration, or the interests it supported (Cooper & West, 1988, p.880). Certainly, OMB publicly acknowledged that, under EO 12291, it 'held the number of new rules to the minimum necessary', 'revised ill-conceived ones' and 'imposed long need discipline on the rule making process' (Cooper & West, 1988, p.878).

In 1985 EO 12498 extended further the OMB's power, requiring agencies to submit annually their regulatory agenda for approval, indicating how such activities were consistent with the administration's regulatory principles. This allowed the OMB to control further the regulatory process, as it could reject proposals that emerged independently of the agenda unless otherwise approved (Cooper & West, 1988, p.874).

The Reagan Administration also introduced the Ritter Bill, which required a government-wide programme of research on quantitative and comparative risk analysis. While these had been tools used by agencies, their use was extended after the Supreme Court's ruling in *Industrial Union Department v American Petroleum Institute*, which challenged successfully the OSHA's decision to reduce work place exposure to air-borne benzene without undertaking a risk analysis.

In a response to the increasingly controversial role of science in decision-making Congress requested the National Academy of Sciences to assess future options. The outcome, the National Research Council's influential report '*Risk Assessment in Federal Government: Managing the Process*' (1983; generally referred to as the Red Book) was the first, tentative step in

reform of Federal regulation. Though it fell short of recommending a formal separation between risk assessment and its management, it recognised that risk assessment should be promoted as a rational mechanism for evaluating scientific knowledge regarding potential hazards to human health or the environment and that, in the light of this assessment risk management would weigh policy alternatives and select appropriate controls. However, it did not dissipate controversy surrounding Federal agency regulation, which became increasingly the focus of challenge through the courts.

In the early 1990s Peter Huber emerged as a prominent protagonist in the long simmering debate over the validity of scientific evidence and its place in regulation and law, producing a string of publications. Promoting the phrase 'junk science' (science that cannot distinguish clearly a causal relationship; provide conclusive proof), Huber argued that the courts had become overly hospitable to claims with little scientific merit, often extending: 'equal dignity to the opinions of charlatans and Noble Prize winners' (Huber, 1991, p.123). Recommending this trend be countered, Huber called for courts to admit only testimony that was backed by a consensus among the scientific community (Dreyfuss, 1997). Industry and conservative lobby groups flocked to Huber's banner, claiming that junk science had underpinned contentious regulatory decisions.

To some, it seemed sufficient that judges insist that scientific evidence was ventilated with interested parties (Merrill, 2003). To others, more was expected of the courts; judges should be versed in the underlying science to assess an agency's competence. The findings of *Daubert v Merrell Dow Pharmaceuticals inc* (1993), a landmark case, would decide in favour of the latter, as the Supreme Court assigned a gate-keeper role to Federal judges hearing cases that involved expert testimony.

A civil product liability lawsuit, *Daubert v. Merrell Dow Pharmaceutical* centred on the charge that Bendectin, an anti-nausea medication, which it was claimed resulted in defects at birth. The plaintiff's case depended heavily

upon animal studies and unpublished epidemiological data.<sup>20</sup> *Merrell Dow* complained, arguing that only peer-reviewed studies should be admissible. In judgement, the Supreme Court cited the Federal Rules of Evidence that obliged judges to 'act as gatekeepers...keeping out any expert testimony that is not reliable as well as relevant', and the court suggested sample criteria upon which such judgements should be made (Jasanoff, 2002, p.46). 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).

Though *Daubert* was seen to encourage judges to think like scientists, it also gave considerable latitude for judges to decide how scientists think (Jasanoff, 2002). More importantly, it moved the locus of review from the scientific community to the courts, and conferred on the court the power to decide what amounted to good science. While *Daubert* endorsed the view that courts should consider the standing of evidence within the scientific community, it removed the final say over what constituted evidence to litigants and judges.<sup>21</sup> Under *Daubert*, a judge had to be satisfied that the evidence was reliable, the methods employed tested and capable of replication, rather than upon the quality of an expert (Wagner 2005; Raul and Dwyer, 2003).

Though *Daubert* related to civil rather than regulatory law, it was not long before there were calls for the extension of its principles to the regulatory arena (Raul & Dwyer, 2003). For those who advocated such a move the reason was simple. If private litigants were entitled to the rules of sound science to protect them from parochial interest, then the public: 'should be equally assured that good science was the foundation for national action' (Raul & Dwyer, 2003, p.7). Others were more reticent.

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<sup>20</sup> Animal studies have long been a source of disagreement, particularly over their extrapolation to humans. By identifying a problem as technical, industry and regulators have been able to exclude consumers or the medical profession and, 'the process of technical harmonisation in toxicology has consistently led to an overall reduction in safety-testing standards' (Abraham & Reed, 2002, p.360).

<sup>21</sup>In relying upon litigants to vet science, the legal system acts in an opposite fashion to the scientific community, where prejudiced reviews and research are shunned (Wagner, 2005).

The difficulties surrounding scientific evidence in toxic tort cases had been noted for some time, where substantial evidence was needed to satisfy the requirement that evidence indicate 'more probably than not' that a substance was harmful. Thus, despite early identification of a substance as hazardous, courts required quantification of the hazard before action could be taken (Wagner, 1986). Indeed, in the case of asbestos, some four decades elapsed between identification of the hazard and successful litigation (Wagner, 1986, p.428). To many, this meant that the court would not be satisfied until a body count was produced (Sexton 1995). In this realm of causal uncertainty agencies often depend upon weight of evidence to guide action. Put simply, WOE meant that available evidence *indicated* that a substance was either harmful or benign; what might be described in everyday language as a 'well-educated guess'. Given that WOE arguments frequently call upon studies that utilise different methods, each of which could be flawed in some manner, evaluating studies on a stand-alone basis undermines the cumulative nature of expertise and evidence (Krimsky, 2005). The application of stringent quantitative standards ran counter to both weight of evidence (WOE) arguments that agencies rely upon, and their mandate to act in a timely fashion to protect public health and safety. Here, *Daubert* is critical, since it atomised evidence into individual studies, with a judge as arbitrator of each study's relevance and reliability (Krimsky, 2005). In many instances, it allows the exclusion of expert evidence because of: 'smoke screens thrown up by artful defence councils' (McGarity, 2001, p.11).

Taken together, the 'good science reforms' in the USA do not simply qualify the actions of Federal Agencies but seek to redefine the role of science and risk in regulation. Under political administrations that favour deregulation, agencies are under direction to ensure that their science is not only of high quality, but also of sufficient magnitude or quantity to justify regulation (Wagner, 2003).

On this side of the Atlantic the British Government's interest in the complicated role of risk surfaced publicly for the first time in the public

inquiry into the Central Electricity Generating Board's (CEGB) decision to opt for the controversial Pressurized Water Reactor (PWR) for Sizewell B (in Suffolk); a technology that had been used in the ill-fated meltdown at Three Mile Island in the USA (O'Riordan, 1988). It was clear from the outset that much of the ensuing debate would be hindered by the sheer complexity (and widely contested) nature of scientific argument. It was by no means a new phenomenon. Indeed, it had been highlighted in the Inspector's report into the proposed construction of an advanced gas cooled reactor in 1971 when he observed that:

Nuclear risk is a subject so sophisticated that we, like the objectors, have no reliable grounds for framing an independent opinion, and we have been obliged to accept both the assurances given by the experts called by the generating board and those implicit in government policy...(O'Riordan, 1988, p.193).

The nature of scientific uncertainty was a recurring theme at the Sizewell B Inquiry, where debate about the reliability of nuclear technology dominated the agenda. For many, this was complicated further by the tendency to adopt risk analysis, an obscure area of science dominated by mathematical modelling which, in a nutshell, does not guarantee that an event will *not* occur, only that it is unlikely to take place. Indeed, as O'Riordan noted, terms such as acceptable risk assumed an increasing hold on policy makers, discernible in the burgeoning field of research, which sought to justify and expand its use (O'Riordan, 1988 p.193).

In an attempt to grapple with some of the difficulties of risk analysis the Chairman of the Sizewell B Inquiry, Sir Frank Layfield, criticised the concept of 'acceptable risk' because it failed to reflect the importance of the problem and in particular, the level of reluctance individuals show toward hazardous activities (Hood et al, 1992). He suggested that the term 'tolerable risk' might better reflect the true seriousness of the question, prompting the U.K's Health and Safety Executive (HSE) to argue that:

tolerability does not mean acceptability. It refers to the willingness to live with a risk to secure certain benefits and in the confidence that it is being properly controlled. To tolerate risk does not mean that we do not regard it as negligible or something we might ignore, but rather as something we need to keep under review (Hood et al, 1992 p.93).

One of a number of criticisms of risk analysis is that implementation deficits, largely related to local factors, are generally underestimated or downplayed because risk analysis assumes a rational or methodical transfer (and acceptance) of knowledge. At the same time there is not a great deal of room for competing views, conflicts of opinion or differences about how change is received. In other words, risk analysis neglects the institutional context in which there may be “different definitions of the decision problems, different perceptions of what the primary risk-generating problem is, and different kinds of relevant experience and expertise” (O’Riordan, 1988 p.14). A further problem lies in the use of comparison in fine-tuning, and yet with highly complex technologies such as nuclear power or genetically modified organisms, we simply do not know.<sup>22</sup> We have no experience to draw upon, an omission dramatically revealed at the Sizewell B Inquiry where the project Director of the pressurised water reactor at Three Mile Island was asked if he “had any comparable experience?” His response, which provoked laughter in the audience, was “No. (not) until after the accident” (O’Riordan, 1988 p.182). It seems plausible to suggest then, as O’Riordan does, that we are often left with the:

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<sup>22</sup> Wynne, has also highlighted difficulties that arise in the different frames of reference used by lay people and experts. Experts, he argues, often reduce risk to technical matters thereby accepting the view that decision-making institutions are trustworthy, natural, impartial and open minded. However, the expert framing of risk problems may include a wide array of assumptions, some of which have a crucial bearing upon problems generated. In the case of the Herbicide 2,4,5 -T (agent Orange), for example, debate about its safety was resolved only when it became apparent that the initial scientific evaluations were dependent upon the assumption that the product would be used only under stringently controlled conditions. Among agricultural workers, problems were widely recognised. However, government advisers dismissed these concerns, largely because such evidence was felt to be anecdotal or unscientific. Only at a later date did it emerge that one of the key assumptions underpinning the safety of agent orange was that the ‘real environment’ did not approximate to the laboratory conditions under which initial tests were made (Wynne, 1996).

erie conclusion that we are all busy enacting a public framework of regulation driven by certain fundamental tenets of rational knowledge that *no one* believes in. Now, there is always a certain tension between norms and actions. However, the size and nature of the gap matters, it now seems so large as to approach collective hypocrisy - even institutionalised schizophrenia - on a grand scale. The public norms of rational control and decision in regulation seem to be little more than degenerate caricatures of reasoning (O'Riordan, 1988 p.ix).

By the early 1990s the British Government was pursuing the possibility of expanding the role for risk analysis as part of its drive to reduce public expenditure and redefine government responsibility. While a concern with public finances provided the initial spur for the British Treasury's involvement in exploring the utility of risk assessment in public policy, further momentum was given by a succession of White Papers that began to sketch out a shift in the role of risk *in* politics that would bear fruition in the Deregulation Initiative.

Under the arrangements envisaged in the Deregulation Initiative a central task force of officials would check existing or new regulations initiated by a Department or Agency for their likely cost and impact upon business. From here on in, busy staff would be required to spend time identifying legislation that could be either revoked or simplified. Departments would also be required to: set out the origin and purpose of proposed regulations; identify any likely benefits; assess their impact on business; establish whether there were alternative ways of achieving the desired end and outline how they would be enforced and what this would cost. The initiative also made it more difficult to introduce new regulations, even when identified on the basis of epidemiological investigations or research findings (Philips, 2000, pp62-64).

In areas such as food safety Ministers at MAFF were certainly aware of the potential to lighten the burden of regulation. Charged with implementing change, the Enterprise and Deregulation Unit was concerned that regulators were placing burdens on industry that could not be objectively justified in terms of the risks involved. The maxim was that regulation should be aimed

at the right target and should be no more than was required to 'achieve the objective' (Philips, 2000 p.43). It was to have an important bearing upon regulation, as one of the State's veterinary service hygiene advisers observed: 'there was a wide understanding...of the standards that were required of the slaughterhouses. However, Ministers were insistent that there should be no gold-plating, and slaughterhouses should not be required to do more than was a legal requirement' (Philips, 2000, p.43). Such views were by no means uncommon, a point that emerged clearly in the testimony of a succession of witnesses to the Philips Inquiry into the BSE crisis that confirmed that government was putting out 'signals' that regulations should be enforced with a 'pretty light touch' (Philips, 2000, p.66).

The Deregulation Initiative questioned the need for complex regulations that impacted on business, prompting the establishment in April 1991 of an official group to produce guidance on risk assessment with a view to achieving greater consistency. It was to be the first of three important influences on the changing nature of risk *in* regulation. The second was a growing interest in the use of formal risk assessment techniques in developing controls on chemicals and genetically modified organisms which culminated in the formation of the Inter-Departmental Group on Risk Assessment (ILGRA). The formation of ILGRA had followed the publication of the Treasury's *Economic Appraisal in Central Government*, which was the first in a series of government documents that sought to adopt risk analysis for capital spending projects as well as to provide a 'structured thinking' framework for other policy options. Following closely in its footsteps, the DoE published its (1992) *Policy Appraisal and the Environment: A Guide for Government Departments*.

These were developments complemented by events taking place at the European level. From the early 1990s environmental policy at the EU level moved progressively away from the style of regulation where legislation was binding. The British administrative style, with its preoccupation on costs, practicalities and the standardisation of monitoring and compliance

procedures, enjoyed greater prominence as the Commission became conscious of the need to elevate 'British pragmatism' at the expense of 'continental abstraction' (Lowe and Ward, 1998, p.18). Both the Single European Act and the Maastricht Treaty accentuated this penchant for greater pragmatism, reflected in a preference for framework Directives, soft law and voluntary codes of practice (Lowe and Ward, 1998 p.24).

Few would doubt that the EU's complicated decision-making process contributed to this shift in thinking. A failure to provide a sound scientific basis to policy was often exacerbated by a tendency to invoke the principle of subsidiarity if the decision-making autonomy of Member States was threatened, ensuring that legislation was compromised (Collins and Earnshaw, 1992; Heritier, 1996). In many ways the Integrated Pollution Prevention and Control Directive (IPPC) (96/61/EC), which shapes the role of Environmental Protection agencies (EPAs), bore the hallmark of an attempt to overcome these difficulties.

Implemented in 1990, the IPPC Directive provides a framework in which a licence (to produce, but also to pollute) is granted according to whether it meets the Best Available Technology Not Entailing Excessive Cost (BATNEEC) guidelines, where the NEEC element ensures a balance between environmental benefit and financial cost (Taylor, 1998, pp53-74). To supporters, it was not simply compliance, but compliance *plus*, a guiding philosophy with a discernible hierarchy: elimination, reduction, recovery and treatment. However, critics of BATNEEC point out that EPAs refuse to be drawn on specific standards, that the guidance notes are not legally binding and that a distinction can be drawn between existing and new facilities, where the former is often treated more leniently.

Not surprisingly, the NEEC element has been particularly contentious, subject to considerable variation in interpretation. What counts as *excessive cost* depends largely upon the individual circumstances of a business, where the health of the (local) economy or the impact on international competitiveness influences negotiations (Taylor, 1998). With the fingerprints

of British pragmatism all over it, the IPPC Directive displays a preference for controls to be tailored to specific sites, avoiding different national standards emerging but, more crucially, allows '*adequate prominence ... to consideration of cost effectiveness and economic feasibility*' (Clappison, cited in Sharp, 1998).

There are two themes to draw from this brief examination of how risk in politics has experienced change in Europe and the UK. First, the extent to which environmental protection is deemed to be (only) one of a series of competing values (the others being competition, economic growth or the benefits to accrue from a new technology) to which the legislation seeks to define a balance. Here, BATNEEC is complemented by the principle of Proportionality, which requires that any action should consider balance, necessity and suitability and is generally taken to mean not using a 'sledgehammer to crack a nut'. It was adopted to assess whether national regulations impact inordinately on the free movement of goods (see Rothstein, 2004). Second, that much of the regulatory framework is concerned not with environmental protection (at any cost) but with environmental management.<sup>23</sup> The regulations assume the possibility of risk and contemplate not an absolute elimination of these risks, but their control. Once a risk analysis is complete, it becomes not a matter of *preventing* development, but *how* that risk is *managed*. It acknowledges that no environment exists in which risks are completely eliminated, or ventures that do not carry risks. These are issues not confined to environmental regulation, as they also surface in food safety reform, an area of policy where the role of risk in politics has figured prominently.

To those such as Vogel, the BSE crisis that enveloped food safety was crucial in shaping European regulatory reform, exposing a 'gap between the single market ... and the inability of European institutions to assure the safety

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<sup>23</sup>The BATNEEC principle shows that EU environmental policy is less coherent than Vogel makes out. Some pieces of EU legislation spell out the acronym BATNEEC as Best Available *Techniques* not Entailing Excessive Cost while others use Best Available Technology not Entailing excessive Cost. EU legislation is often characterised by vague compromises, open to interpretation, and contradictory approaches that add to a 'patchwork' (Heritier, 1996) rather than an overall risk averse strategy.

of the products sold within that market'. It was a crisis that made policy makers 'more comprehensive and risk averse', even in 'areas where these policies adversely affect the financial interests of important industries' (Vogel, 2003, pp569-570).

We do not wish to downplay the political significance of the BSE crisis as a catalyst for change. Indeed, elsewhere Taylor has argued that a succession of food safety scares, the most prominent and expensive of which was BSE, prompted widespread demands for reform (Taylor & Millar, 2002 & 2004). Certainly, the breadth of political support clamouring for change presented a convincing political argument for the replacement of a myriad of confusing legislative arrangements with a single authority to provide a coordinated, integrated and fully transparent approach to food safety. However, the extent to which these reforms can be understood as motivated by precaution remains open to question. Indeed, we would suggest they bear an uncanny resemblance to the choices taken in environmental protection.

In food safety, the thrust of change hinged on an elevated role for science and a reorientation in regulatory responsibility. The regime to emerge from the fallout of the BSE debacle was constructed in a manner fully cognisant of the international dynamics that were shaping food safety. This was confirmed in the formal separation of risk assessment from its management, where the European Food Safety Authority would be responsible for advancing an authoritative position on scientific advice and Member States would be responsible for risk management (Taylor and Millar, 2002 & 2004).

It is important to recognise that reform was shaped crucially by the European Union's need to consider fully the implications of international agreements negotiated under the auspices of the WTO, where the Codex Alimentarius Commission had been pushing for decisions to be based on objective, quantifiable risk analyses, a move designed specifically to reduce instances where precaution could be invoked, raising the possibility of trade disputes not founded upon sound scientific principles.

Formed in 1962 by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO), Codex has attempted to develop further its international reference status on standards, which ultimately means scientific justification is required for control measures that diverge from internationally agreed relevant standards. In the early 1990s the influence of Codex expanded significantly under the Sanitary and Phytosanitary Measure Agreement (SPS), which emerged from the Uruguayan round of trade negotiations under the General Agreement on Tariffs and Trade (GATT). The SPS operates in tandem with the agreement on Technical Barriers to Trade (TBT) and, while they recognise the sovereign right of states to provide the level of protection deemed appropriate, these measures must recognise the need to avoid constructing impediments to free trade (James *et al*, 1999 p.61).

Any disputes that arise between Member States are resolved by generalist panels, called upon to determine whether measures for managing SPS risks are maintained without sufficient scientific evidence. What remains crucial is that although flexibility in domestic risk assessment processes are permitted, and Member States have the right to establish risk regulatory measures according to their own requirements. The WTO; 'continually returns to a position that gives a privileged role to science.... in determining the proper scope of risk regulation' (Peel, 2004 p.3). While European and USA models employ different rhetoric, they take broadly similar *deferential* approaches to the review of science-based risk regulatory measures. Nowhere is this more evident than in the recent furore that broke out over research that appeared to link food additives in sweets with hyperactivity in (some) children (McCann *et al*, 2007).<sup>24</sup>

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<sup>24</sup>This research concluded that exposure to two mixtures of 4 synthetic colours plus a sodium benzoate preservative in the diet resulted in increased hyperactivity in 3-year old and 8-9 year old children in the general population. The study involved one hundred and fifty 3 year old and one hundred and forty four 8-9 year old children, selected to represent a broad range of behaviour in the general population including children with normal to high-level behavioural activity. Children medicated for ADHD were not included. A global hyperactivity aggregate (GHA) score was the main outcome of the study, based on aggregate z scores of observed

Keen to allay public concern, Diane Beckford, Head of Toxicology at the UKFSA appeared on Channel 4 news to explain the agency's position on the finding that, as a result of food additives, behaviour in some children altered dramatically, while others remained unaffected. Channel 4's anchor, Jon Snow politely enquired that; if 'children without behavioural problems had been effected by the additives', should the FSA not 'consider banning these things? Beckford's reaction was to point out that the research *also* showed that 'a significant number of ordinary children ... did not react, so 'we can't say all children will react'. Snow countered that 'no one was 'suggesting all children ... if the research shows that a significant number with no predisposition react in this way... that's a serious problem, isn't it? Altering his line of questioning, and adopting a more conspiratorial tone, he queried whether the agency was 'trying to dismiss this research'. Beckford insisted this was not the case, and that: 'it was very important research, we consider it is very important for ... a ban to take place at the *European level...because foods are transported freely, traded freely... that's why we've alerted the European Food Safety Agency (emphasis added) (<http://www.channel4.com/player/v2/player.jsp?showId=8979>)..*

What started out as an engagement with the 'findings of science', presumably to assist in our understanding of the role and impact of artificial additives, had suddenly morphed into a wider discussion of how foods are 'transported and traded freely'. Without wishing to sound glib, or downplay the importance of this issue, the white lab coat appears to have been replaced by the grey suit of management speak. But, crucially, these were lines later confirmed in the European Food Safety's hymn sheet.

Following the publication of McCann *et al's* research in *The Lancet* (2007), the European Commission asked the EFSA's panel on food additives to assess the results, taking into account, if possible, other available scientific literature. On foot of the Commission's edict, the Food Additives Panel

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behaviours and ratings by teachers, class room observers and parents, plus, for 8-9 year old children, a computerised test of attention.

issued a scientific opinion (EFSA, 2008). It noted that surveys between 2002-5 had established that the target colours were more prevalent in brightly coloured sweets, though they also occurred in soft drinks. It also acknowledged that some, but not all, of the earlier studies had also reported effects of food colours on child behaviour, although the majority of these were conducted with hyperactive children or those diagnosed with ADHD. The Panel conceded that McCann *et al*'s research was the largest of its kind, and more representative of the general population. However, it concluded that, while the research from McCann *et al* 'provides *limited* evidence that the two different mixtures of synthetic colours and sodium benzoate had a small and statistically significant effect on activity and attention in some children selected from the general population', the effects 'were *not observed* in *all* age groups and were not *consistent* for the two mixtures'. The findings may thus be relevant for '*specific individuals* within the population, showing sensitivity to food additives in general or to food colours specifically' (EFSA, 2008 p.3 emphasis added).

It was not possible, the Panel maintained, to assess the overall prevalence of such sensitivity in the general population and reliable data on sensitivity to individual additives was not available. Moreover, the clinical significance of the observed effects was 'unclear', since it was not known 'whether these small alterations in attention and activity would interfere with schoolwork and intellectual functioning' (EFSA, 2008, p.3).

However, the principal difficulties the Panel had with McCann *et al*'s research were largely methodological: the limited consistency of the results with respect to age and gender, the effects of the two mixtures of additives tested and the type of observer (parent, teacher or independent observer); the unknown clinical relevance of the novel metric (the GHA score); the fact that the study had not been designed to identify the effects of individual additives; a lack of information on dose response and finally (though not a methodological issue) the lack of a biologically plausible mechanism for induction of behavioural effects from consumption of food additives.

It seems eminently sensible to demand statistical rigour (although it is something we are unable to assess, since it falls way out of our realm of competence). However, it also seems plausible to suggest that objections to these 'demands' could be reciprocated. Those such as McGarity, for example, observe that epidemiology is a fledgling science that consists of a statistical comparison of human beings who have received a higher-than-normal exposure to a particular agent with others that have received little or none. The statistical threshold level is determined by the scientist and rests on the scientists' acceptance of what is a cause-effect relationship. The health and environmental risks posed by toxins and carcinogens cannot be proven with the certainty of mathematical reasoning and that: "if *definitive proof* is the goal, risk assessment is simply the wrong tool" (McGarity, 2003, pp165-7).

Of more import to the arguments of this chapter is that while opinions based on statistical rigour may be a welcome development on previous practice, precautionary they are not. Indeed, much of the EFSA's ruling confirms our argument that the role of risk in politics has been reconfigured. The separation of risk assessment from its management has ensured the elevation of science in defining both the need and extent of intervention. More crucially, it anticipates not *a lowering of the evidentiary bar*, but its elevation. A lack of scientific consensus, and by implication any weaknesses in statistical rigour, offer not an opportunity to invoke precaution, but form the basis from which to resist regulatory intervention. As such precaution is now more accurately understood as a tool of risk management; a temporary measure pending further scientific information and considered only after a quantifiable risk assessment has dealt with an ascertainable risk, not a theoretical uncertainty.

The role of science is therefore to articulate the extent of an individual's exposure to risk, or define more clearly where no *risk can be proven*. It is not to *prevent* development on the grounds that there may be a risk, but to establish definitively whether a product will be detrimental to public health, thereby establishing negligence or culpability. It is a regulatory framework that

assumes the possibility of risk and contemplates not its elimination, but its control. And, in the event that a risk is established, (precautionary) intervention must always be subject to considerations of economic feasibility (proportionality). Rather than perform the task of sustaining order through responsible government, science now participates in (re)constituting order through the market. The regulation of risk has shifted from the realm of the political/legal (state-citizen) to the economic/legal (producer-consumer). Nowhere is this more evident than in the Irish Food Safety Authority's recommendation that: 'parents should read food labels when buying products, so that they can identify *if* they contain these food colours and thus make an *informed purchasing* decision!' And, if we are to be liberated consumers, free to make choices, we need to establish the conditions in which free markets prosper.

The issue of food colours and 'little red sweets' slid off the media's radar rather quickly and with it, the public's gaze. Perhaps the media had concluded that the public was suffering from 'anxiety fatigue', although its blanket coverage of the credit crunch, with its addiction to the rise and fall of the FTSE 100 or the ISEQ exchange, would suggest otherwise. More likely, the answer lies in the fact that we do not need to understand the complexities of derivatives or securitised loans to grasp the core problem of the credit crunch: Toxic debt, negative equity and numbers that go up and down on our screens make for easy visual bites. Working out the basis for the EFSA's scientific opinion just doesn't make good copy.

Beneath the hysteria generated by the media after the initial publication of McCann *et al's* research lies a more nuanced understanding of a health issue where complex scientific and technical problems are involved and powerful corporate interests are at play. If we are to understand these issues we need to appreciate that, as in other areas of European regulation (chemicals, pharmaceutical products, blood) the regulation of little red sweets must observe the protocols of international trade agreements that seek to reduce spurious fears over new technologies that impede free trade.

It would be remiss to ignore the extent to which this conservative political agenda has permeated influential international bodies and how, in turn, this has shaped the manner in which risk is refracted through national polities. Here, those such as Kingsbury *et al* observe that a global administrative space has emerged, populated by a variety of international institutions and transnational networks that are increasingly significant (Kingsbury *et al*, 2005). These networks and committees have eschewed the development of law, proffering the adoption of procedural principles, codes of practice and norms: transparency, harmonisation and equivalence in order to prevent delay or arbitrary decisions. While transnational networks (OECD, WTO, CODEX) are not directly subject to control by national governments, and that the principles used are not formally binding, trade agreements give substantial incentives to conform, restricting the regulatory menu available to governments (Kingsbury *et al*. 2005a p.17; Levidow, Murphy and Carr, 2007).

It was not only in areas such as environmental regulation or food safety that the government's interest in new forms of risk assessment could be seen. By the late 1980s and early 1990s government had become increasingly interested in the role that risk assessment could perform in investment appraisal and in regulating workplace safety. This was reflected in a succession of documents emanating from the Treasury which began to develop the view that it was a mistake to regulate against *all* risks and that regulation must be seen to be proportionate to the problem. The Treasury was adamant that the principles underpinning quantitative techniques for comparing capital projects could provide a useful framework for thinking about options which could not be costed, or where uncertainty prevailed.

### **The Principle of Precaution: A Temporary but Necessary Detour**

To both academics and environmental activists alike the emergence of the principle of precaution in West German policy-making appeared to confirm a welcome trend toward ecological modernisation, offering regulation capable of surmounting the intractable problem of the trade off

between economic growth and environmental protection. Certainly, those such as Tait and Levidov (1992) maintain that regulatory intervention that required developments in technology does not necessarily come at the expense of profits (Tait and Levidov, 1992, pp219-231). Where such an approach had been adopted (for example in the German car industry) there was no evidence that it had disadvantaged the companies concerned. In other words, greater regulation of the market through state intervention did not threaten competitiveness or economic viability (Hood *et al*, 1992 p.163).

The principle of precaution has a comparatively long history in European treaties and, on various occasions, the EU has expressed a view that 'precaution should guide all community policy-making' (European Commission, 2000). Introduced first in Germany, the precautionary principle, or Vorsorgeprinzip, proved popular among northern European Leader States keen to develop domestic precautionary measures.<sup>25</sup> To advocates of the principle its ecological value lies in the way the evidentiary bar on risk is lowered, so that a lack of a scientific consensus should not *prevent* regulatory intervention. It is, as Vogel observes, a principle that 'legitimizes regulation' when 'potentially dangerous effects from a phenomenon, product or process have been identified and scientific evaluation does not allow the risk to be determined with sufficient certainty. However, it has been subject to controversy in the strained relationship between trade and environment, where the EU failed to gain its inclusion in the World Trade Organisation (WTO) agreements at either Seattle, 1999 or Doha in 2001.

Neither does the principle form an obligation under the Cartagena Protocol on Biosafety, although it has a presence in two major conventions on chemical pollutants: the 2001 Stockholm Convention on Persistent Organic

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<sup>25</sup>The literal translation of Vorsorge is precaution or foresight but, whereas in English it often suggests something that goes beyond normal caution, in the German usage it includes a notion of good husbandry, what one might call best practice. In the regulation of air pollution in Germany, for example, control legislation was understood as a means of measuring "control of emissions in accordance with the *state of technology*". Public declarations may have exhorted the importance of reducing risk, but this often meant only 'as low as possible' (Von Molke, K, 1988).

Pollutants (POPs) and the London convention on the Control of Harmful Anti-Fouling Systems on Ships (Sadeleer, 2002, p.98). More damning perhaps is the fact that international courts have been unfavourable to its application and those such as the World Trade Organisation's (WTO) Appellate body have been 'diffident at best' about its normative value (Sadeleer, 2002, pp317-8; see also Peel, 2004). More importantly, its impact on Community legislation in the 1990s has been 'only marginal', its application across Member States varied and, while it has been included in numerous texts, it has been 'vague' (Eckley and Selin, 2004).

Eckley and Selin's research into the regulation of polychlorinated biphenyls (PCBs) and brominated flame retardants (BFRS) in this regard is particularly instructive, precisely because PCBs and BFRs are compounds that have been regulated over a long period of time, are persistent, toxic, bio-accumulative, and have been subject to active domestic and international assessment. And yet, they note that while the principle of precaution was prominent in policy discussions, and debate about hazardous chemicals would have been significantly different in its absence, 'it is far less clear that the regulatory case histories of PCBs and BFRs would have developed differently in the absence of the precautionary principle'. Indeed, they suggest that it is a '*preventative, rather than a precautionary approach to regulation*' and that: '*actual regulatory decisions... do not seem to be based on a significantly lower level of proof...*' (Eckley and Selin, 2002, p.80 emphasis added). Similar sentiments emerge from policy-makers and stakeholders, where 'a lack of precaution in actual decision-making' was exacerbated by the burden on regulators to establish proof, making it difficult to move away from a risk management based system of regulation to one based on precaution (Eckley and Selin, 2002, p.97).

There are at least two further issues that raise doubt about the pre-eminence of precautionary thinking in EU policy-making. First, that it has been subject to considerable qualification from other, competing regulatory principles over the last decade that proffer a view of regulation in which a

balance needs to be struck between environmental benefit and financial cost: Best Available Technology Not Entailing Excessive Cost (BATNEEC) and Proportionality. These regulatory principles assume there are other socially valued objectives, such as economic growth, employment or technological innovation that are important, and often qualify significantly the rhetorical assurances of precaution that underpin the Community's regulatory regime.<sup>26</sup>

Second, that the principle of precaution has changed over time, 'relegated' as it is now to a tool of risk management; a temporary measure pending further scientific information and considered only after a quantifiable risk assessment has dealt with an ascertainable risk, not a theoretical uncertainty. This is a crucial issue, for it anticipates that the regulatory process involves not *a lowering of the evidentiary bar*, but its elevation. A lack of scientific consensus offers not an opportunity to invoke precaution, but forms the basis from which to resist regulatory intervention.

Despite its enthusiastic reception it is clear that by the late 1980s the principle of precaution was subject to important qualifications and open to considerable variation in its interpretation. Public declarations may have exhorted the importance of reducing risk, but this very often meant only 'as low as possible'. This was highlighted in Federal guidelines that suggested *Vorsorge* should be qualified, recognising that to go beyond the protection against risks that were identifiable would be 'excessive' and therefore not proportional.

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<sup>26</sup> Nowhere is the more evident than in the recent chemicals legislation (REACH). While substances (or technologies) of 'high concern' should be replaced by those less threatening, a process to be undertaken 'in accordance with the precautionary principle', authorisations should be granted where 'persons applying ... demonstrate... that the risks to human health are adequately controlled' or: *that the socio-economic benefits from the use of the substance outweigh the risks connected with its use ... that there are no alternative substances or technologies that are economically and technically available* (23, emphasis added). That the principle of precaution is subject further to qualification is evident in the stipulation that a substance should be substituted 'when manufacture ... causes unacceptable risk to human health or the environment 'taking into account the availability of *suitable safer alternatives and the socio-economic benefits from the substance* (REACH, 2-7, emphasis added).

## Risk and New Labour

Drawing upon the legacy of its Conservative predecessors, New Labour has sought to usher in political relations where risk assessment can assume an important role in reducing the regulatory burden upon business. It is a project inclined to let markets clear more efficiently and demands constantly that regulations are reduced, allowing the entrepreneurial spirit full reign (CM 4310, just about everywhere). Such a view emanates strongly in Tony Blair's (pre-credit crunch) tirade against the Financial Services Authority, in which he spoke of the need to question regulation that: 'inhibited efficient business by perfectly respectable companies'. Alarmed that Britain was developing a disproportionate concern about risk, and that we were encouraging an ambulance-chasing culture that inhibits risk-taking in the public sector, he argued that risk is inescapable and that too often our reflex as a society is to regulate and to introduce new rules (<http://www.number10.gov.uk/Page7562>).

New Labour's White Paper on public service reform, *Modernising Government* (CMND 4130) contains much of this political thought and sought to disarm those that saw deregulation as little more than a discredited Conservative Party policy. Here, it argued that where it considers it right to regulate, it would do so. However, it cautioned that:

regulation for its own sake is too often seen as an answer, without proper consideration being given to better ways of achieving the outcome. We will base our decision on a careful appraisal of the benefits any measure seeks to achieve, the costs it entails and the cumulative burden of regulation on business (*Modernising Government* para 2.6).

This drive for 'better regulation', and to locate a role for risk analysis in attempts to reduce the regulatory burden upon industry, has emerged in a succession of reports that include the *Review of the Regulatory Reform Act 2001* (2005), *Regulation: Less is More, Reducing Burdens, Improving Outcomes* (2005)

and *Reducing Administrative Burdens: Effective Inspection and Enforcement* (Hampton Report (2005)).

Influenced by administrative reform in Holland, *Less is More* recommended that government adopt a 'one in, one out' approach to regulation that would force departments to seek a balance between introducing new regulations and remove existing ones. Of more import to this chapter, however, was the manner in which risk assessment was identified as an important tool in attempts to reduce administrative cost and regulatory burden. For example, *Less is More* proposed *risk profiling* as an innovative way in which regulators could incentivise improved performance. In support of this argument it cited the Environment Agency's Operator Pollution Risk Assessment (OPRA), which had adopted an appraisal methodology that considered the potential hazard (location, emissions and operational complexity) and operator performance. The intention of OPRA is to allow risk assessments to determine the charge for permits, the frequency of inspections and the level of regulatory intervention. Previous 'good form' would be rewarded with a reduction in compliance assessment (earned autonomy) (*Less is More* 2005, p.60).

In a similar vein, the *Review of the Regulatory Reform Act 2001* (2005) was adamant that tangible gains could be made from adopting risk analysis and cited the case of the Regulatory Reform Fire Safety Order (2005) where a simple risk-based fire safety regime was created that applied to all public buildings and produced cost savings between £47million and £137million per year (*Review of Regulatory Reform Act 2001*, 6). Revealing though these examples are, it is with the Hampton report (2005) that risk assessment has been promoted most forcefully.

Undertaken at the behest of Gordon Brown, then Chancellor of the Exchequer, the Hampton report flagged the need for regulators to appreciate more fully the potential for conflict to arise between *prosperity and protection*. An important part of the report's argument was that regulators need to consider both the nature of the business, and the factors affecting the risk a

business poses to regulatory outcomes. The report surveyed a wide tranche of regulators, assessing the impact of inspections, demands for information and enforcement on business. As far as demands for data were concerned, the report noted that the forms sent to business did not differentiate requirements based on risk, and yet, had they done so, low-risk firms would need to provide less information, thereby reducing their administrative burden.

While the Hampton report noted that three quarters of regulators used some form of risk assessment, fewer than half those surveyed used risk assessment to reduce enforcement activity on high performing businesses and, even where risk assessment was used, patterns of enforcement activity did not alter. Indeed, the report noted that only 25 of 36 regulators included some element of earned autonomy, where good performers were visited less often, or had less onerous reporting requirements (Hampton, 2005, 26-28). The National Audit Office's study of the Environment Agency's OPRA scheme reveals the potential for glaring inconsistencies to emerge:

The Agency planned to carry out an average of 15 visits to each licensed (waste) site in 2001/2. This is more than (equivalent regulators) in France, Ireland and the United States...the Agency is required to visit all waste sites at least quarterly, and some low-risk sites are inspected even more often; *for example a pet cemetery...had been inspected eight times a year* (Hampton, 2005, p.4 emphasis added).

And yet, as the National Audit Office's study shows, when a comprehensive risk assessment was used, inspections were reduced from 125,000 to 84,000. It was by no means an isolated case. In 2002/3 local authority trading standard officers inspected 60% of high risk premises in Great Britain (35,000 inspections), yet inspected 10% of businesses classified as a low-risk (72,000). It is not just that unnecessary inspections are made, but that necessary inspections may not be carried out (Hampton, 2005, 4-5).

Overall, the Hampton report was moved to note that in parts of the regulatory system inspection was higher than necessary to achieve outcomes, and that high-cost activity inspection programmes that are inflexible divert resources away from more important areas. Not surprisingly, it was

confident that if used consistently, risk analysis should reduce the need for inspections on less risky business and identify those enterprises that require more or less inspection.

Keen to display his enthusiasm for such reform, and to expand the role for risk analysis into a wider range of public policy, Gordon Brown ploughed a similar furrow when he confirmed New Labour's commitment to remove the operating and financial review (OFR). The OFR required stock market listed companies to provide a written account of corporate governance, social values, ethical policies and the impact of their businesses on the environment and society. In his speech to the Confederation of British Industry he was adamant that New Labour would not insist on any 'gold-plating of regulations' emanating from Brussels, and that only those industries that pose a risk would be required to undertake such tasks. While he acknowledged that it was: 'best practice for companies to report on social and environmental strategies relevant to their business...that was very different from suggesting it is *right* to place on all British companies a blanket requirement to do so at the cost of millions of pounds every year in administration' (*Guardian*, 28/11/05).

Of particular import to New Labour is the detrimental impact unnecessary regulation has had upon small business, where concern has been expressed about the cumulative burden of regulations and the fact that small businesses; 'did not know what inspectors would require of them'. More disconcerting was the finding that, while small firms were keen to expand, half saw regulation as a serious barrier to growth, identifying health and safety as a significant concern (Hampton, 2005, p.25).

## Conclusion

To those such as Beck, Vogel or Smith industrial society has been supplanted by a risk society in which science has suddenly been 'found out', exposed before an incredulous public. It is a view that palpably fails to recognise that risk was always a central consideration in the regulatory principles developed by the post-war State and that politicians (and civil servants) were aware that expert advice was rarely absolute, subject to conflicting interpretation and that it was important to consult with interested parties in order to allay the possibility of any legal challenge.

In contrast, we suggest that such an approach neglects sufficient consideration of the impact of the New Right on the role of risk in politics, which has ensured that our critical gaze is drawn firmly toward the inexorable growth of the state, where a deluge in state responsibility impinges upon the individual's capacity to decide on risk. In the vernacular of the New Right, far too much weight has been accorded to the role of the state in deciding what is in our best interests, and far too little consideration given to the individual's capacity to decide on risk. It maintains that it is impossible for the state to decide what is an acceptable level of risk: there are simply too many conflicting and competing variables to consider (economic, technological and social) for a balance to be achieved.

In such a scenario, the role of expert advice is to sustain the view that risks are an attendant feature of day to day life, that what matters is how, as individuals, we make judgements about those risks. Rather than perform the task of sustaining order through responsible government, science now participates in (re)constituting order through the market. It articulates the extent to which individuals are exposed to risk, or defines more clearly where no *risk can be proven*. The role of science should not be 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. These are technologies that may be contentious, possibly risky, but grounds for regulation must be

founded upon a *proven risk*. The objective of a risk analysis is not to prevent development at all costs, but establish *how* a risk is to be *managed*, an exercise that seeks to achieve a balance between the potential costs of regulating against risk, with other valued social objectives such as economic growth and employment.

The role of risk in politics (both nationally and internationally) has been reconfigured, for science no longer underscores the regulation of the market through the state (the realm of the political/legal) but assists in the reconstruction of individual citizens as consumers of both products and their attendant risks (the realm of the economic/legal -producer/consumer).

This shift, from the realm of the political/legal (state-citizen) to the economic/legal (consumer/producer) has a crucial bearing in our analysis of the blood crisis in Ireland: the the risk from new commercial concentrates was judged and how in instances of conflicting scientific evidence, that risk was managed. This is not just about administrative error (or scientific uncertainty) but rather explores how these debates about risk were shaped by new economic and ideological circumstances: to what extent should intervention be precautionary? At what point do we make the decision for precautionary intervention? Who makes that decision? And, if the scientific information falls outside of the control of an individual state (and has no consensus on its credibility) do we have grounds to intervene? Should that intervention be balanced against other competing interests (economic and technological progress? Is it proportionate? Now that we have a more nuanced understanding of how risk, science and politics collide we can begin to explore the Irish blood crisis and reform undertaken in its aftermath at the EU level.

## Chapter II

### **Risk, Science and Blood: The Politics of the Hepatitis and HIV Crisis in Ireland.**

This is an extremely important issue...if something goes wrong with a blood transfusion...the next port of call is a coffin (Barrett *Irish Times* September 6<sup>th</sup>, 2001).

That the hepatitis C/AIDS crisis of the late 1970s and early 1980s left an indelible mark on the Irish psyche is undeniable. The infection of almost four hundred haemophiliacs with either AIDS or hepatitis C and over 1,600 women with hepatitis was not only a terrible human tragedy, but one that placed the whole Irish healthcare system on trial. As if to compound matters, there was public incredulity at the manner in which the victims were treated, as the Irish State engaged in protracted legal sparring with ailing individuals, some near death, outraging both politicians and citizens. Indeed, Brian Cowen T.D. (Fianna Fáil) captured the political mood when he argued that the state had used: 'every bullyboy legal tactic that could be devised' (Mr. Cowen Dáil Debate, 476, 1231).

Twenty years on from the onset of the blood crisis, the aftershock continues to reverberate through Irish politics. In January 2005 the Minister for Health, Mary Harney, was forced to settle a case taken by the prenatally infected son of a hepatitis C victim and, in mid-February, established a scheme to 'provide reasonable access to the insurance market' for those infected (*Irish Times* February 15<sup>th</sup>, 2005). The final bill for the crisis is now expected to exceed 1.1 billion euro (*Irish Times* February August 22<sup>nd</sup>, 2007).<sup>27</sup>

It seems rather odd that a crisis of such magnitude should attract so little attention from Irish political science. It is an omission this chapter seeks

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<sup>27</sup>As if to emphasise further the lingering impact of the crisis, in July 2007 Justice Liam McKechnie ruled against an ex-BTSB technician who sought to have charges against her relating to the infection of 7 individuals dismissed. While the defendant contended that the publicity attached to the case and delay in bringing it to trial were prejudicial to her defence, the judge ruled that the right of the public to have the case heard was 'far superior and paramount' (*Irish Times* July 7<sup>th</sup>, 2007). However, in 2009, without explanation all charges were dropped.

to redress, situating the blood crisis within the context of international developments that wrought change upon the interventionist state. It contends that any explanation of these events needs to extend beyond the view that the crisis was a consequence of administrative error, the poor implementation of policy or inconclusive science. While administrative error was important, especially in the case of the Anti-D scandal, this chapter argues that a more nuanced account needs to be taken about a triumvirate of threats that were pivotal in shaping the hepatitis/HIV blood crisis: virological, political and economic.

It maintains that the challenges presented to political arrangements, as a series of new and significant developments emerged, altered the manner in which risk, science and politics collided. Attempts to maintain the twin pillars of voluntary donation and self-sufficiency were confronted both by escalating costs and the demand for new technologies (concentrates) during a period of severe financial restraint. The Government's response was to afford a more significant role for pharmaceutical companies, which meant that risk assessments were no longer the preserve of a forum in which public sector officials (minister, civil servants, health administrators) held sway, as risk would now be framed with market considerations to the fore.

It was amid this changing political/economic climate that Ireland's blood supply faced the virological threats of NANBH and HIV. In both instances the state of medico-scientific knowledge meant that the extent of risk posed was not clearly understood. In this critical period of uncertainty options were available: a return to using cryoprecipitate (a precautionary move: the political/legal) could not be discounted. After all, this was an avenue pursued in Finland. Ireland and the UK, however, took a different stance, one wedded to concentrates and their provision by the market (economic /legal).

The focus of both the Lindsay Tribunal (Ireland) and the Archer Inquiry (England) preferred to emphasise how the surrounding uncertainty could justify the decision not to intervene; that inaction could be explained in

terms of a lack of scientific knowledge. However, it ignores the extent to which such inaction was politically driven, convinced that market driven decisions would secure the requisite level of safety and that in the absence of further information intervention in a free market could not be warranted. A risk would have to be proven. In both instances this form of public investigation fails to consider the extent to which the separation of risk assessment from risk management (a move from the public realm to the private realm) had a significant bearing upon the policy choices available.

The chapter is divided into three sections. The first section provides a backdrop to the outbreak of AIDS and covers the period prior to 1982. It begins with a short, but necessary detour for the reader: a description of the condition of haemophilia and its treatment. It sketches briefly how Ireland's blood supply was underpinned by a social democratic ethos and examines the policies enacted during the 1970s. While the pursuit of self-sufficiency and voluntary donation was laudable, it was compromised by a chronic lack of funding and insufficient attention to promoting the benefits of self-sufficiency (education); a situation compounded by a lack of a sufficient cohort to produce the plasma necessary to enjoy any potential economies of scale.

The second section explores the period from 1982 to 1986 and begins with an overview of the politicisation of AIDS in the U.S.A. Proposals to slow the spread of the disease led to remonstrations both by gay lobby groups and vested interests in the blood supply: blood bankers and fractionators. Gay lobby groups were worried about discrimination, while blood bankers/fractionators were concerned about the cost of any new proposals. However, policy responses were confronted by the lack of scientific understanding of the disease. And yet, as this section shows, the options taken were also framed by a political and ideological project opposed to intervention that did not fully consider the cost, or that would be undertaken without conclusive evidence. Intervention would have to be proportionate and should a risk not be proven then intervention could not be warranted

The final section outlines developments post-1987 and focuses on the recognition of a long-known threat to blood supplies: NANBH (which would later be termed hepatitis C). Throughout the 1970s NANBH had been recognised as a chronic condition and prevalent within Irish blood supplies. However, both the medical and scientific communities felt that it was a condition that was manageable. By the 1980s that position was abandoned, as hepatitis C was recognised as life-threatening.

### **Haemophilia and the Irish Blood supply**

Prior to the 1950s the prognosis for haemophiliacs was miserable. For severe haemophiliacs a minor knock or abrasion could produce prolonged bleeding. Of more concern, spontaneous bleeds into the joints or cranium, could corrode cartilage, bone and nerves causing excruciating pain or an untimely death. Indeed, 'most patients didn't live to grow up' (Biggs in Lee 1998, p.772). While a number of different treatments were tried, including viper venom and concentrates made from the blood of animals, treatment usually consisted of the normal procedure for bleeding; immobilisation and cooling with ice to reduce blood flow. While transfusion of whole blood was possible, it existed only in an elementary form, was itself a risky procedure and the clotting factor from a single donor was usually inadequate for the haemophiliac's needs.<sup>28</sup>

With advances from the 1960s onwards the life of haemophiliacs changed dramatically. It became possible to fractionate blood into its constituent parts and, more importantly, concentrate the clotting factor from multiple donors, producing a substance termed cryoprecipitate. As the Archer inquiry noted, it was a straightforward procedure and a significant advance because it had ten times the concentration of the factor VIII produced naturally by the body and could be injected at home and stored in domestic freezers (Archer 2009, p.13).

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<sup>28</sup>Such infusions placed a strain on the circulatory system that could induce cardiac arrest.

Nonetheless, cryoprecipitate was by no means a panacea. It was a 'clumsy procedure' and 'had to be kept at very, very low temperatures, requiring the facilities to deal with that' (in Archer 2009, p.13).<sup>29</sup> For many patients it also involved hospitalisation, often over several days. It was an unpleasant procedure, especially for young boys that had to be immobilised with straps. As one doctor recalled: 'I have a very clear memory of a ward of little boys with their legs strung up, their arms strung up' (Lee in Christie & Tansey 1998, p.3).

By the 1970s treatment had advanced to the point where haemophiliacs could live a reasonably normal life. Developments in fractionation meant that preparations of both factor VIII and factor IX, termed *concentrates*, could be stored in small containers in a fridge and could be administered either by a parent or haemophiliacs themselves.

Indeed, patients 'could hardly believe the small amount and speed of treatment compared to previous treatment with bags of cryoprecipitate' (in Archer, 2009, p.14). For haemophiliacs, it was a quantum leap in lifestyle because: 'previously we had not been able to treat these little boys who were missing their schooling, had no career to look forward to, were growing up illiterate and were growing up crippled' (Jones in Christie & Tansey 1998, p.63). What had been a debilitating disease, commonly leading to a premature death, was now considered a manageable condition.

The use of concentrates, however, was not without risk. As with any biological product, the possibility of infectious transmission existed. Although cryoprecipitate was manufactured using the plasma from a number of donors, any of which might carry infection, concentrates required the plasma of many hundreds or even thousands of donors. The risk of infectious transmission therefore increased enormously. At this stage most nation states organised blood supplies on the principles of self-sufficiency and voluntary

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<sup>29</sup> Cryoprecipitate, rich in Factor VIII, could be used to treat both haemophilia A and Von Willebrands, a congenital disease that affects both sexes, and is similar to haemophilia A, because von Willebrands factor is involved in the production of factor VIII, and a deficiency produces similar symptoms. Haemophilia B suffers derived no benefit from this advance, as cryoprecipitate did not contain Factor IX.

donation, underpinned by the belief that voluntary donation carried less risk of infection and that self-sufficiency would insulate a nation from the threat of external disease. In the case of commercial concentrates, these were manufactured by companies using *paid* donors.

Improvements in the treatment therefore provided haemophiliacs with an improved lifestyle and, not surprisingly, demand escalated. This meant that individual nations were gradually shifting away from the twin pillars of voluntary donation and self-sufficiency, allowing U.S.A. pharma to assume a more prominent role in the provision of blood products, ensuring a free market in blood supply. This was largely because the necessary volumes of plasma required were beyond the capacity of individual nation states to attain without substantial investment in donor education and recruitment or plasmapheresis.<sup>30</sup> However, this market in blood/blood products emerged from an industry that relied on paid donations, one that presented the possibility of higher rates of infectious transmission.

In the U.S.A. a plethora of studies had shown that the population of paid donors overlapped significantly with disease bearing populations; 'skid row denizens' to use Titmuss's term. So strong was the correlation between paid donation and hepatitis that in the U.S.A. a national blood policy (1973) requiring a voluntary donor system for whole blood was established, for it was recognised that commercial collection of blood: 'contributed to a significantly disproportionate incidence of hepatitis' (in Leveton *et al*, 1995, p.41). This policy, however, did not extend to commercial plasma collection or the sale of plasma derivatives such as concentrates.

In 1975 the American Blood Commission was set up to implement the majority of elements to the national blood policy and it progressed rapidly. By 1976 paid donation accounted for less than 3% of whole blood collection (US Senate Oversight Committee, 1979, p.2). Nevertheless, with concern growing over hepatitis, the F.D.A.. introduced regulations (1978) that

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<sup>30</sup> Plasmapheresis differs from whole blood collection, in that the plasma component of blood is separated and siphoned off while the red cells are returned to the donor. This prevents anaemia and allows for the donor to be harvested more frequently.

required blood to be labelled as paid or volunteer and, almost immediately, the few remaining whole blood collectors that relied on paid donation disappeared for no one would take 'blood that was implicitly inferior' (Starr 2000, p.304).<sup>31</sup> Again, this policy did not apply to source plasma or derivatives and the fractionation industry continued unabated.

By now, concern had been expressed about the increased incidence of hepatitis among paid donors, although their use was not discontinued. In 1975 two *World In Action* television programmes (UK) were broadcast that: 'alleged that paid donors, who included drug addicts and alcoholics, carried six to 13 times the risk of having hepatitis as volunteer donors' (*Irish Times* July 5<sup>th</sup>, 2000).<sup>32</sup> More importantly, perhaps, those that sold their blood, unlike voluntary donors, had a vested interest in concealing their health status and any previous infection. However, within the medical/scientific community anxiety about hepatitis was tempered by the belief that while it was a chronic condition, it was manageable. As if to confirm this as a sound decision, a new test (HBsAg), introduced between 1970/72, had led to a significant decrease in the incidence of hepatitis in concentrates tested.

Despite these improvements, 80% of haemophiliacs tested positive for the antibody to hepatitis B (the presence of the antibody indicates previous infection) by 1976, but this was not viewed as a significant concern. However, testing revealed the presence of a new pathogen: non-A, non-B hepatitis (NANBH). While it was recognised that long-term complications could follow, the long incubation period, and apparently benign nature of the virus, meant that it was considered generally to be a controllable complication

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<sup>31</sup>Despite introducing an exclusively volunteer whole blood collect system, by 1978 cracks had begun to appear in the American Blood Commission (ABC). A review by the US General Accounting Office in 1978 noted a considerable rancour between the two largest blood suppliers, the American Association of Blood Banks and the American National Red Cross, a lack of funding, resistance to regionalisation and problems obtaining data from blood banks (USGAO March 1978). The problems continued to dog the ABC and it was wound up in 1985 (Leveton *et al* 1995, p.41).

<sup>32</sup>In one of the programmes it was noted that Travenol/Baxter, the manufacturer of Hemophil a blood product used by the BTSB in 1975, would not permit filming inside one of its plasma collection centres due to 'unattractive donors'. When a BTSB official was questioned at the Lindsay Tribunal about whether haemophiliacs were aware of such practices, the response was that it was a matter for treating doctors not the BTSB (*Irish Times* July 15<sup>th</sup>, 2000).

for a potent treatment. The use of concentrates not only continued but also expanded.

### **Irish Blood Supply**

In Ireland, the blood supply was administered by the Blood Transfusion Service Board and regulated by the National Drugs Advisory Board. Though separate from each other, both organisations were agencies of the Department of Health. The establishment of the Blood Transfusion Service Board (B.T.S.B.) in 1965 was a significant step in the move to create a national blood service. The B.T.S.B. replaced the National Blood Transfusion Association (1948) and blood service centres in Cork and Limerick and had a remit to organise and administer blood services (B.T.S.B. Establishment Order 1965 (S.I. No 76/1965)). The B.T.S.B. was, to a large extent, autonomous, although the Minister for Health retained overall responsibility.

The establishment of the B.T.S.B. was clearly influenced by contemporary international debate, which revolved around the distinction between paid/unpaid donations, where the latter was accepted universally to be superior. It was a view that had a critical bearing upon the construction of a blood supply based not on paid donation from the 'denizens of skid row' to be found in the U.S.A., but on a system involving free donations by the community for the community (Titmuss, 1967). As, one of the leading titans of social democracy, Richard Titmuss, was able to declare from a position of strength that blood, voluntarily and freely given (a gift), was an expression of all that was good in social democracy. While other areas of Irish healthcare may have been subject to private or voluntary sector provision, blood remained an exemplar of the social democratic ideal, voluntary donation and national collection (self-sufficiency) became the twin pillars of policy, designed both to reduce infection and ensure the blood supply was hermetically sealed.

Unlike Canada or the U.S.A., where the blood supply was administered through voluntary organisations such as the Red Cross,

Ireland's blood provision was secured through a state agency and, though it would have been unusual for a minister to interfere directly, ultimately all decisions were made in his/her name. Indeed, in evidence to the Lindsay Tribunal, the Department of Health noted that although: 'statutory responsibility rested with health agencies...the minister carried political accountability in the area' (*Irish Times* May 16<sup>th</sup>, 2001).

Within a policy framework constructed to deliver competent regulation expert advice was refracted through political channels, where ministers and civil servants were acutely aware of the incomplete nature of scientific knowledge. It is important, therefore, to recognise that risk existed; it was just that it was refracted through political corridors of the interventionist state, ensuring that it garnered the imprimatur of the public.

Of late, debate in contemporary Irish politics has been marred with a rather odd interpretation of what we mean by the 'public'. As we struggle to come to terms with the legacy of the Celtic Tiger squandered, and with unemployment reaching stratospheric levels, conservative economists, politicians and media pundits alike are falling over themselves to attribute the roots of the credit crunch (or more pertinently the Irish economy's particular take on this orgy of free market excess) to overspending in the public sector.<sup>33</sup> In such circumstances it is all too easy to lose track of the important role that public servants *should* perform in the political process: policy gains the imprimatur of the public, precisely because public servants engage in a process of scrutiny, ensuring that important issues are debated, that different constituencies are represented, that it is open, transparent and produces a public record: it is accountable. These are crucial themes to our understanding of how risk, science and politics collide and it is to this that we now turn.

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<sup>33</sup>It's a narrative easy on the eye: the public sector party is over and the hangover (or pain) will have to be shared equally; socialism Bertie Ahern and Charlie McCreevy style. But, it is important to recognise that the 'WE' here, are not the inhabitants of the 'Galway tent', but the public sector, a cosy idyll separated from the vagaries of the capitalist economy.

Although significant differences exist in the voting systems of Ireland and the U.K: 'Ireland's law-making procedure is closely based, in the letter and in the spirit, on that of Westminster' (Coakley & Gallagher 1999, p.184). Traditionally, this has meant a view that 'government knows best' (Marsh *et al* 2001). The most important expression of this latent conservative influence in a top-down model of government was the role of ministerial responsibility. Within this concept two interrelated themes are important; a notion of a duty of care and the idea that a minister is accountable if such a duty is not performed (Weir & Beetham 1999). The former emphasises the commitment to act in the best interest of citizens, the latter stresses that such actions are open to scrutiny and penalty. In Ireland, ministers were not only accountable for appointments to boards such as the BSB, but were legally liable for the actions of those within such organisations. As Coakley and Gallagher point out:

ministers were legally responsible for everything done by their officials, from the formulation of policy to the administration of departments, and to the most basic and routine clerical duties (Coakley & Gallagher 1999, p.264).

A similar hierarchical delineation of responsibility and accountability existed with regard to the National Drugs Advisory Board (NDAB), a regulatory agency charged with overseeing the safety of medicines in Ireland, which encompassed the blood supply.<sup>34</sup>

Initially, the idea of an agency to monitor drug safety emerged as a result of the imposition of tariffs on imported drugs, a move designed to aid the Irish pharmaceutical industry (Dáil Debates, 178, 11). However, new drugs were entering the market. In many ways this was not a particularly novel problem for the Irish Government, since these were issues visited during the thalidomide tragedy, when drug regulation was especially

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<sup>34</sup>Though the NDAB was the licensing authority in Ireland for medical preparations and the minister always acted on its advice. The Lindsay Tribunal noted that: 'the general obligation and responsibility for monitoring compliance with the product authorisation code lay with the Department of Health'. In other words, responsibility ultimately lay with the minister (Lindsay 2002, p.219).

controversial. At this point politicians such as Dr. Noel Browne were anxious that an independent body, and not the 'drug houses themselves', should arbitrate on safety (Dáil Debates, 178, 12).

Discussions had begun as early as 1962, but it was not until 1966 that the NDAB was established, a delay that could be attributed largely to concern about cost, a reluctance on the part of the Minister for Health to interfere with the autonomy of the medical profession on treatment options, and prevailing international opinion that favoured a significant role for the pharmaceutical industry in testing the safety of drugs.

At a time of rapid growth in welfare provision the costs of healthcare were particularly salient. In the eight years between 1955 and 1963 the cost of healthcare in Ireland had risen by over 50% and, with funding then provided equally between the Department of Health and local authorities, it was a sensitive political issue at both a national and local level (Barrington 1987). As the Minister for Health, Mr. S. MacEntee, noted at the time, an Institute of Biological Assay would: 'require resources...at the disposal of highly developed industrial countries with large populations and considerable wealth...not available to us' (Dáil Debates, 197,1447).<sup>35</sup> Indeed, in defence of his position he observed that even if such resources were available to such a body:

it would not necessarily give a *complete assurance* of the safety as untoward complications or side-effects might not manifest themselves until a drug had been in use for a considerable period (emphasis added Dáil Debates, 197, 1447).

Moreover, the minister was reluctant to 'step on the toes' of the medical profession, sceptical as to whether his was the appropriate office to 'determine what drug should or should not be used by a properly qualified medical practitioner' (Dáil Debates, 198, 183).<sup>36</sup>

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<sup>35</sup>An Institute of Biological Assay would carry out the testing of drugs on non-human living organisms, such as animals or bacteria, in an effort to ascertain the safety of the drug for use by humans.

<sup>36</sup>A previous Minister for Health, Noel Browne, had incurred the wrath of the medical profession for among other things restricting the use of streptomycin (used in the treatment

There can be little doubt that the minister's unwillingness to 'step on the toes' of the medical profession had been influenced by the ill-fated Mother and Child scheme proposed by a previous Minister for Health, Noel Browne. The Mother and Child scheme (1948), an intended amendment to the 1947 Health Act, would provide free medical care for mothers and children up to 16 years of age. It met fierce resistance from both the medical profession, which feared a Fabian evolution in the health service, with publicly salaried positions along the lines of that in the U.K, and the Catholic Church, which controlled many hospitals and was alarmed that state interference would undermine its hegemonic position in health care ethics.

As Browne and Chadwick observe, restricting eligibility for the mother and child and school health schemes protected the private base of both doctors and public voluntary hospitals, strengthening their respective positions (Browne & Chadwick in Robins 1997, p.194). At the time the Taoiseach, John A. Costello, was reported to have said to Browne that: 'whatever about fighting the doctors, I am not going to fight the Bishops, and whatever about fighting the Bishops, I am not going to fight the doctors and the Bishops' (Barrington, 1987, p.215).

Debate surrounding the shape and remit of the NDAB also had an international dimension. In the wake of the thalidomide tragedy the safety of drugs had become a contentious issue, prompting the U.S.A. to give new powers to the U.S. Food and Drug Administration (FDA). However, as the Minister of Health at the time was aware, the U.S. F.D.A.'s regulatory ambit fell short of what had been envisaged as an Institute of Biological Assay. The U.S. F.D.A.'s new powers included inspection of factories, processes used, records, clinical trials, but not the chemical or biological testing of drugs.

In the U.K., where there had been calls for an experimental laboratory to test new drugs, an expert committee led by Lord Cohen of Birkenhead had maintained that: 'testing of new drugs...should continue to be the

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of tuberculosis) to certain hospitals, thereby curtailing its use by doctors to treat their private patients.

responsibility of the individual manufacturer,' and should not 'be transferred to a central authority'. While the committee recommended that an expert body should 'review the evidence and offer advice', Mr. MacEntee, Minister of Health, noted that neither it, nor the legislation enacted in the U.S.A., made 'mention of Institutes of Biological Assay' (Dáil Debates, 197, 1448). Defending his reluctance to establish such an Institute in Ireland, the minister noted the matter was one of such 'complexity' that the World Health Assembly (WHA) had recommended that it was best dealt with by international co-operation.

With the assistance of the World Health Organisation (WHO 1962), the WHA had resolved to set in place minimum standards for the 'clinical and pharmacological evaluation of pharmaceutical preparations' and to secure the regular reporting of safety information, particularly adverse reactions (Dáil Debates, 197, 1447). This situation altered little with Ireland's accession to the European Economic Community (1973). Indeed, the Community's 1965 Directive on medical products endorsed fully the Irish Government's stance, reinforcing the view that regulatory intervention should not inhibit the free market, insisting that:

the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health... this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community (65/65/E.E.C.).

In the area of blood and blood products, this position altered little over time. The Department of Health was unwilling to introduce primary legislation, and while there was a substantial regulatory legal infirmity regarding licences, no attempt was made to rectify this situation until 1984. Instead, the Department of Health chose to stretch the powers of the European Communities Act; 'as far as possible and even beyond' (Lindsay 2002, p.212).<sup>37</sup> Put simply, the NDAB had no standards from which to work and, in

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<sup>37</sup>The matter was not conclusively settled until 1989 when E.E.C. directives were applied to blood products under Council Directive 89/381/E.E.C.

effect, had to establish its own. In the interim this meant that because no standards were in place, commercial companies that did seek product authorisation licenses before 1984 could suggest their *own standards* (emphasis added, *Irish Times* May 26<sup>th</sup>, 2001).

The restricted powers of the NDAB, and the unwillingness of the EEC to hinder trade, were crucial factors in the development and safety of blood supplies. In Ireland, however, there was also a reluctance to challenge the autonomy of the medical profession, particularly its determination to ensure a split between the public and private sectors, all of which meant that by the 1970s government policy was increasingly predisposed to search for free market solutions, with elements of the blood supply met from international sources. This general drift in policy, with a preference toward free market provision, was cemented firmly with the emergence of blood concentrates.

Prior to the emergence of concentrates, cryoprecipitate had been the standard treatment. However, it presented problems in terms of storage and its infusion was an uncomfortable procedure that frequently required hospitalisation. The introduction of concentrates held a number of significant advantages: they were of uniform dosage/potency and could be self-administered, reducing visits to hospital. However, blood concentrates were not without problems. It was not just that they promoted a reliance on paid donors (leading to the commodification of blood), but they also carried an increased risk of infection, since a single donor could contaminate an entire batch of concentrates that had been drawn from thousands of donors. Haemophilia patients, however, were long accustomed to living with risk (hepatitis B and NANBH). As tests for the detection of hepatitis B from the early 1970s had shown; '*most haemophiliacs tested positive*' (emphasis added Krever, 1997, p.1670).

While the risk of infection from NANBH was well known, the condition was assumed manageable. Indeed, in the absence of further epidemiological information, the medical/scientific community assumed that NANBH presented a range of problems similar to that of hepatitis B, an

assumption that had an important bearing upon the assessment of risk *vis a vis* commercial concentrates.

The inability to secure sufficient supplies of blood plasma from voluntary donations was not confined to Ireland. In the U.K. during the early 1980s almost 80 percent of blood products used by haemophiliacs were imported (Krever, 1997, p.924). However, the advent of concentrates accelerated the role for pharmaceutical companies in blood provision, which meant that the international market of \$50 million (U.S. dollars) in 1975 had exploded to \$325 million by 1988 (Kimball *et al*, 2005). As a consequence, large parts of Europe became significantly dependent on: 'less protective more productive US standards to meet national therapeutic plasma needs' (Jones, 1999).

#### **Events in Ireland: Prior to mid-1982**

Although most governments in the 1970s were committed to the principals of voluntary donation and self-sufficiency it was an allegiance that became increasingly difficult to sustain. The emergence of blood concentrates, which held out the promise of an improved lifestyle, meant that in Ireland the B.T.S.B. was increasingly dependent upon fractionated products imported from the U.S.A. to augment whole blood collection. Certainly, the use of blood concentrates circumvented both the need for a significant rise in donor recruitment and the costs associated with establishing fractionation laboratories.

Given the improvements to lifestyle offered by concentrates, objections were few and far between. It was, nonetheless, a policy not without risk. Concentrate production demanded large pools, which raised the risk of infection substantially. However, scientific assessments of this increased risk remained inconclusive, and the use of concentrates escalated. Indeed, patients often infused concentrates to elevate clotting factor levels in order to prevent spontaneous bleeding episodes.

While serious cases of haemophilia required urgent treatment, for some with mild haemophilia the condition was not necessarily life-threatening, and the balance of risk between treating the patient with products carrying a danger of infection, and leaving him or her untreated varied from patient to patient. Many doctors continued to treat patients prophylactically, as opposed to administering treatment only when a bleed actually occurred. The risk of infection was assumed, even when there was no immediate necessity. As one patient recounted to the Archer Inquiry:

I had kicked my big toe, rather painful but certainly nothing that I could not have contained by just going home and sticking my foot in a cold bath of water or something. I suggest that the treatment was given not under the premise that it was a life threatening situation in any shape or form and I would suggest that many mild haemophiliacs experienced the same procedure. The only reason I was given that product, I might suggest, was that until then I had not received any commercial products so I met the criteria (Archer 2009, p.42).

Given the frequent treatments occasioned by haemophilia, it is hardly surprising that strong relationships of trust should develop between treating doctors and their patients.<sup>38</sup> However, it is also important to recognise that these decisions, decisions that reflect how risk is refracted at the micro-level through interpersonal relationships, would be shaped by a profession's preference to retain a market in blood products, ensuring that 'choice' could be retained and professional autonomy secured. As both the Lindsay (2002) and Archer Inquiry (2009) noted, 'it appears that in many cases patients were not offered the choice' and the 'practise' of doctors took little or no consideration of patients rights (Archer, 2009, p.42).

In Ireland, as elsewhere, the introduction and increased use of commercial concentrates was a matter not just for legislators, but also for those with a vested interest in the safety of the blood supply. While the BTSB was the main operator of blood services it was an arena populated by a

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<sup>38</sup>Professor Temperley, the Director of the National Haemophilia Treatment Centre in Ireland, described the anguish he felt at the death of his patients from AIDS, many of whom he had known since they were young boys, as akin to the death of his own sons (Lindsay 2002, p.148).

number of actors. Foremost among these was the National Haemophilia Services Co-ordinating Committee (NHSCC). Established in 1979 it had an assembly that included representatives from the BTSB, the National Haemophilia Treatment Centre (NHTC) and the Irish Haemophilia Society (IHS). Its function was to advise the Department of Health on service provision for haemophiliacs.<sup>39</sup>

In theory, the NHSCC provided a forum for the discussion, formation and implementation of national policy. In practise, the picture was rather more opaque. From its inception, a lack of resources had hampered the dissemination of information to both haemophiliacs and treating doctors. It was a problem compounded further by an absence of any clear policy that defined responsibilities between the national and regional centres and, as tensions emerged, attendance at meetings began to vary, resulting in a reduced input from the NHSCC (Lindsay, 2002, p.208).

In January 1980, the NHSCC produced a document for the Minister of Health that outlined protocols and responsibilities, suggesting that the BTSB retain its position as 'central purchaser and distributor' and that the NHSCC recommend products favoured for subsidy. Reinforcing the more general determination to attain self-sufficiency, it pointed out that, while commercial concentrates had benefits, home production of concentrates was '*a matter of urgency*' for supplementary treatment of patients with inhibitors, those allergic to cryoprecipitate or those who required operations (Lindsay 2002, pp369-370 emphasis added,).

Although pragmatic and prudent, the document, much like the NHSCC itself, was eclipsed both by the opinion of the BTSB and treating doctors. While the NHSCC was recognised by the Department of Health, it was bereft of both funding and departmental representation. Furthermore, despite the NHSCC's preference for an input from the NDAB on the evaluation and purchase of concentrates, little or no evidence exists that the NDAB had any

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<sup>39</sup>The main treatment centre was located in St. James Hospital Dublin. Children were treated at the National Children's Hospital because of its paediatric section and there were doctors in regional centres in Galway, Cork and Limerick that acted in consultation with the NHTC.

bearing on decisions. It appears that for much of the time the NHSCC was little more than a rubber stamp for the decisions taken by treating doctors after consultation with the BTSB (Lindsay 2002, p.207). Indeed, at the Lindsay Tribunal it was noted that: 'there was no year in which the treaters' advice was not accepted by the BTSB's former national director' (*Irish Times* October 13<sup>th</sup>, 2000).

In 1974 the concentrate Hemophil became commercially available. Initially, the BTSB was reluctant to introduce this concentrate because it signalled a shift away from a policy that involved voluntary donation and self-sufficiency. At the time, its National Director argued that a preference lay in making available a more 'acceptable and improved form of cryoprecipitate', a move that would not threaten self-sufficiency (Lindsay 2002, p.52).<sup>40</sup> The BTSB was alarmed at the prospect that Travenol, the producers of Hemophil, were 'trying to corner the market' and that the price 'could double' (*Irish Times* July 4<sup>th</sup>, 2000).<sup>41</sup>

As the use of concentrates escalated in the late 1970s, the BTSB's position shifted gradually; no longer concerned exclusively with the production of cryoprecipitate and factor IX concentrate from native blood, it had become a purchaser/distributor of concentrates. Although it was not the only organisation that could have assumed this role, it had the expertise and established distribution network, which made it the logical option. More importantly, perhaps, it had the public's trust, a factor recognised by the Lindsay Tribunal when its chairperson remarked that: 'there would have been greater reliance on the imprimatur of the BTSB in distributing the products than in the case of a commercial distributor' (Lindsay, 2002, p.48).

Although the BTSB was apprehensive about the escalating risk that accompanied commercial concentrates, risk itself was not new. However,

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<sup>40</sup>This improved form of cryoprecipitate was freeze-dried. Unlike its forerunner, wet-frozen cryoprecipitate, which was a frozen liquid that required thawing before use, freeze-dried cryoprecipitate is a powder that can be reconstituted with sterile water, making it easy to store and use. However, it was still more difficult to administer and less potent than concentrates. Ultimately, it was not until 1977 that freeze-dried cryoprecipitate was produced, by which time concentrates were in wide-spread use.

<sup>41</sup>The market at the time was estimated to be worth some £50,000 (*Irish Times* July 4<sup>th</sup>, 2000).

commercial concentrates posed a risk on a qualitatively different scale, largely because they used plasma drawn from paid donors. Hemophil, derived from skid-row types in the US and native populations in the Caribbean, jeopardised safety because these were communities that had a well-established higher risk of hepatitis transmission (*Irish Times* June 24<sup>th</sup>, 2000).<sup>42</sup>

Despite divergent opinion on the risk of concentrates, few disputed their benefits. Thus, for example, the Head of the National Haemophilia Treatment Centre, Professor Temperley, regarded the introduction of commercial concentrates as a step ahead. They were widely used in the U.K. and in his opinion; 'what was good for the people in the U.K. was good for the people in Ireland' (*Irish Times* October 13<sup>th</sup>, 2000). As far as the medical profession was concerned, haemorrhage and not hepatitis was assumed to be the greater of two evils, an assumption that would later have tragic consequences. .<sup>43</sup>

Although initially the BTSB had been against the importation of concentrates, by early 1975 its position had shifted, a move influenced not solely by the issue of provision, but also cost. .<sup>44</sup> The BTSB was operating within a fiscal straitjacket, with little prospect of developing (fractionating) its own concentrates. It was unlikely that the Department of Health would offer a public sector driven solution, given Ireland's public sector debt. Against this background of fiscal rectitude, it is hardly surprising that Travenol's offer to the BTSB that: 'it could make a 3 pence profit per unit, plus 10 percent

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<sup>42</sup>Prior to the AIDS crisis substantial amounts of plasma were collected from populations such as prisoners, which had been shown to have a high prevalence of disease transmission.

<sup>43</sup>A study published in 1983 that examined deaths among haemophiliacs in the U.K. between 1976 and 1980, attributed only 2% of fatalities to hepatitis and 29% to cerebral haemorrhage (Rizza & Spooner, 1983).

<sup>44</sup>Despite this shift it appears the matter was not without controversy. Indeed, Professor Temperley candidly admitted to the Lindsay Tribunal that the importation of concentrates was a matter of contention between Dr. O'Riordan and himself, who favoured using BTSB products (*Irish Times* October 13<sup>th</sup>, 2000). Disagreement resurfaced in 1980 when a draft version of the NHSCC's policy document recorded a divergence in opinion between: 'clinicians and the BTSB regarding the use of commercial concentrates for home therapy'. The BTSB favoured the use of its own products, though this was not recorded in the final document (Lindsay 2002, p.49).

commission by becoming a distributor', proved compelling (*Sunday Business Post* July 16<sup>th</sup>, 2000).<sup>45</sup>

Amid increasing concern about public finances, and in the absence of scientific evidence showing that NANBH posed a more serious risk than anticipated, a market solution to demand had been secured. It was a course that effectively sounded the death knell on voluntary donation and self-sufficiency as the basis of policy. While the BtSB managed to produce freeze-dried cryoprecipitate in 1977, the established free market supply of concentrates weakened the BtSB's advocacy of home produced products irrevocably. It was a position that did not improve during the 1980s, despite objections from the NHSCC.

In 1980 the NHSCC proposed that the BtSB produce a native factor VIII concentrate to replace cryoprecipitate, a proposal that would have reduced the BtSB's reliance on imported concentrates.<sup>46</sup> At this stage it was common knowledge that blood products were infected with hepatitis.<sup>47</sup> Indeed, by now, commercial concentrates carried a warning about the risk of hepatitis, both on the vial and in an accompanying information leaflet.

Further credence to the NHSCC's position was garnered from a report in 1979 on liver disease in haemophiliacs, which showed that 33 of 98 haemophiliacs (while free from hepatitis B infection) had persistently raised liver enzyme levels, an indication of the presence of NANBH infection.<sup>48</sup> In evidence to the Lindsay Tribunal, Professor Temperley agreed that: 'the majority of these would have had hepatitis C' (*Irish Times* October 13<sup>th</sup>, 2000). Despite suspicion falling on imported commercial concentrates, their

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<sup>45</sup>The BtSB withdrew Hemophil after it was linked to a hepatitis outbreak reported in the *Lancet* in August 1975 but; 'the product was later reintroduced and distributed for a mark-up' (*Irish Times* July 15<sup>th</sup>, 2000).

<sup>46</sup>In 1980 almost three times as many units of commercial concentrate were imported than in 1979.

<sup>47</sup>Such common knowledge was not always shared by patients. Although the NHSCC proposed to make available a leaflet outlining the risks of home therapy, no such leaflet was ever produced.

<sup>48</sup>The report also noted that of 41 haemophiliacs known to have hepatitis, only 24 tested positive for the B strain, which meant that the others had hepatitis A or NANBH (*Irish Times* October 13<sup>th</sup>, 2000).

importation and endorsement by treating doctors continued, a position influenced undoubtedly by the widely held view among the medical/scientific community that NANBH was a chronic, but manageable condition.

It was by no means a view universally held. In the 1979 report on liver disease, a subordinate of Professor Temperley's had warned that: 'if home treatment, using commercial concentrates, brought a definite risk of liver disease 'then risk may exceed benefit'. Moreover, in 1984 a Galway consultant expressed concern about the risk from concentrates, arguing that they should be used only for 'critical clinical situations' (*Irish Times* October 6<sup>th</sup> 2000).

The NHSCC's proposal to produce domestic factor VIII concentrates brought two issues to the fore: first, the importance of securing adequate supplies of plasma; second, whether the BTSB could undertake the fractionation of that plasma.<sup>49</sup> The BTSB's response centred on what became known as the Heparin project, one that proved controversial. The project used a process developed initially in Canada, but was a method that quickly fell out of favour.<sup>50</sup>

Whether self-sufficiency was ever a serious option, remains in doubt. Although correspondence confirms that discussions took place between the BTSB and the Department of Health, it was clear that with an estimated cost of £60 million, the option of fractionation was not high on the agenda, particularly after: 'various (financial) embargos had started to bite' (*Irish Times* July 8<sup>th</sup>, 2000). Indeed, in evidence to the Lindsay Tribunal, the BTSB's financial expert suggested that as no application for funding had been made to the Industrial Development Authority, or the European Economic Community, the Board: 'was not really serious about its introduction' (*Irish Times* September 22<sup>nd</sup>, 2000).

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<sup>49</sup>This difficulty was never faced directly. While the Heparin project attempted to overcome the first hurdle, that of securing the necessary plasma, its discontinuation meant that fractionation on a large scale was never undertaken.

<sup>50</sup> With the Heparin method blood would be collected into Heparin anti-coagulant rather than citrate anti-coagulants and subjected to a modified form of cryoprecipitation, this it was claimed would significantly increase yield.

Undeterred by the poor international standing of the Heparin method the BTSB decided bizarrely to persist with the project. It was the BTSB's final attempt to sustain a national blood policy based upon voluntary donation and self-sufficiency, and delayed any attempt to undertake fractionation. Under severe financial pressure, and with a market too small to recover the costs of fractionation, efforts to achieve self-sufficiency were, by now, little more than 'pious aspirations' (*Irish Times* June 22<sup>nd</sup>, 2000).<sup>51</sup>

The BTSB was not the only participant in the Irish blood community operating under severe financial pressure.<sup>52</sup> At the AGM of the Irish Haemophilia Society (1982), Professor Temperley suggested that money was: 'the reason for not using products made in this country' (*Irish Times* May 11<sup>th</sup>, 2000). Keen to impress upon his audience the need to retain *competition* in the supply of blood products, he warned that if the BTSB achieved a position of monopoly it could: 'have charged whatever they liked for the treatment' (*Irish Times* May 11<sup>th</sup>, 2000). Such fears were not unfounded. In 1978, for example, Professor Temperley complained to the BTSB that hospitals and the NHTC were being charged more than recipients in Northern Ireland, to which the BTSB's response was to reduce prices (*Irish Times* July 4<sup>th</sup>, 2000).

In the decade prior to the AIDS crisis, the nature of blood supply, both nationally and internationally, had undergone substantial change. In Ireland, the twin pillars upon which policy had been built, self-sufficiency and voluntary donation, were challenged both by the emergence of new technologies and the inability of the state to respond to the demand for these products. Any attempt to sustain an exclusively national approach was compromised further by the insufficient supply of plasma and the inability to recoup the massive costs of fractionation. While it may have been possible to

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<sup>51</sup> The financial pressures on the BTSB continued throughout the 1980s, complicated by its decision to change headquarters. Between 1981 and 1982 its debts escalated and, cripplingly in the red, it was bailed out by the Department of Health, with a grant of £1.6 million punts. In the opinion of one financial expert, the Board's position was the: '*pits, which couldn't but have had an effect on its decisions*' (*Irish Times* September 22<sup>nd</sup>, 2000).

<sup>52</sup> During the 1980s healthcare financing contrasted sharply with the previous decade, with a 16 per cent reduction in the proportion of GNP allocated to health expenditure (Robins 1997, p.215).

stem this shift by pursuing more vigorously enhanced donor education and recruitment, Ireland, as with other nation states, chose to meet increased demand for concentrates through the free market provision of supply. It was a move that promoted a pivotal role for the pharmaceutical industry, both in the supply of products and the *assessment of risk*.

Although calls for more stringent regulatory controls on blood products were made, these were tempered by a reluctance to hinder the market through intervention/regulation. With a shift to the free market provision of blood, and by extension the establishment of pharmaceutical companies as the arbiters of safety, what few lifeboats remained were jettisoned. The stage was set for an iatrogenic disaster that would wreak havoc on blood supplies: AIDS.

### **Risk, Politics and AIDS: June 1982 to October 1986**

In early 1983, with the incidence of AIDS in haemophiliacs on the increase, and with an epidemiological pattern similar to hepatitis B, the US Center for Disease Control gathered together the major stakeholders in the blood community, hoping to establish a consensus on tackling the disease. It was a meeting that would expose the intensely politicised nature of the AIDS crisis, for it demonstrated not only the cultural and social attitudes that surrounded the disease, but also revealed the vested interests at work in the blood supply.<sup>53</sup>

Alarmed at the threat posed by AIDS, and with diagnoses among haemophiliacs more frequent, methods to secure the blood supply were paramount. However, haemophiliacs were also anxious that the public not be panicked, either by the dissemination of misleading information or any moves that could lead to blood shortages. It was a worry shared by the blood banks, concerned that any proposals may impact upon donor motivation,

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<sup>53</sup>In Ireland, the Department of Health official responsible for informing the public of the threat of AIDS explained to the Lindsay Tribunal that he was criticised both by the gay community and the Catholic Church for his efforts. Indeed, in an unfortunate turn of phrase he remarked that: 'advocating the use of condoms to prevent sexual transmission would have caused murder' (*Irish Independent* May 23<sup>rd</sup>, 2001).

hampering the task of maintaining supply while fractionators were apprehensive about the safety of their products, their customers and the effect measures may have on competitiveness.

Unconvinced that an epidemic was imminent, public health agencies, such as the U.S.A.'s FDA and the National Institute of Health (NIH), were reluctant to become involved. For the gay community, to which the disease had initially been linked, there was considerable fear that 'scapegoats' would be sought for the spread of the disease.<sup>54</sup> As one biographer of the crisis noted, no two groups had the same agenda, and each wished to preserve their own interests, creating a situation where: 'stopping the potential spread of AIDS was secondary' (Shilts, 1988, p.220).

At this point, data on AIDS was sketchy. The incubation period of the disease was unknown, with estimates ranging from one to three years. Indeed, few were aware, or willing to contemplate, that the disease could prove terminal. In the absence of any epidemiological information, most decision makers thought that AIDS was akin to viral pathogens such as hepatitis B, an assumption that led to wildly different assessments of the risk the disease posed.

Though the incidence of AIDS among haemophiliacs had increased (from 3 to 7 in the previous 6 months) by 1983, many felt the cause of their immuno-suppression was a consequence of treatment with concentrates, since this was a known side-effect. The matter was also complicated by the fact that the number of AIDS cases among haemophiliacs appeared too few to consider blood, given the large amount of blood products now transfused. Indeed, as late as August 1983, this was the prevailing view, with Congress informed that: 'if all 20 cases under investigation by CDC finally turn out to be

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<sup>54</sup>Indeed, sensitive to the fact that gay activists and physicians were critical of the informal GRID (Gay Related Immune Deficiency) designation that had become associated with the disease, the CDC chose the neutral Acquired Immunodeficiency Syndrome, as the official name for the epidemic (Epstein 1996, p.55).

transfusion related, the incidence will be less than 1 in a million' (Bove in Feldman & Bayer, 1999, p.26).<sup>55</sup>

At the Atlanta meeting the CDC made a number of proposals. Its first was in an effort to prevent donation from high-risk populations; blood banks should question donors about their sexual behaviour. Second, surrogate tests, which sought to identify markers that occur in conjunction with a disease for which no test is available, should be employed to screen donations. In light of the lack of compelling evidence on the risk posed by AIDS, the CDC's proposals at the meeting were met with a torrent of opposition.

The gay community remonstrated forcibly against questioning that sought to identify groups at risk. It was discriminatory, constituted an invasion of privacy and would lead to further stigma (Shilts, 1988, p.222). It was blood, they argued, not donors, which should be subject to scrutiny (Bayer, 1999, p.24).<sup>56</sup>

The blood banks were also opposed to donor questioning convinced it was unethical, arguing that volunteer donors were motivated by altruism and it was inappropriate to confront them with intrusive questions. Although organisations representing haemophiliacs endorsed donor questioning, both patients and treating doctors were worried that the public might take 'flight', leading to blood and concentrate shortages.

The CDC was strongly in favour of donor questioning, arguing that it would reduce the risk of contamination. However, most groups remained hesitant, sceptical that questioning would produce honest answers about sexual preference. Indeed, it was possible that gay donors: 'might donate on purpose or out of spite' (Leveton *et al*, 1995, p.111).

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<sup>55</sup>The *Morbidity and Mortality Weekly Report*, December 2<sup>nd</sup> 1983, noted that there were 21 cases among haemophiliacs, 19 in haemophilia A patients and 2 in haemophilia B patients. In addition, there were 7 cases from outside the U.S.A. that fitted the CDC's definition of AIDS.

<sup>56</sup>During late 1982 and early 1983 donor selection procedures for hepatitis in the U.S.A. changed to exclude those from high-risk populations such as prisoners and Haitians. Though the gay community had a greater prevalence of hepatitis than prisoners they were not excluded, and no convincing rationale was offered for this decision (Dodd in Leveton *et al* 1995, p.111).

As if to compound matters further, several groups within the blood community were *suspicious* of the CDC's motivations. In line with other Federal agencies, the CDC had been a casualty of the Reagan Administration's penchant for budget cuts (mooted to be in excess of \$150 million out of \$327 million). The American Red Cross cynically suggested that:

CDC is likely to continue to play up AIDS - it has long been noted that CDC increasingly needs a major epidemic to justify its existence... especially in light of Federal funding cuts...We can *not* depend on CDC to provide scientific, objective, unbiased leadership on the topic (Cumming in Leveton *et al*, 1995, p.115).

The response from the fractionation industry was rather different, largely because it could be vulnerable to litigation should a risk against its products be proven and in late 1982 Alpha Therapeutics led the way in introducing donor questioning.

In the early stages of the crisis the gay community had an important bearing on the preventative strategy. Initially, AIDS was linked to the fast lane lifestyle of many in the gay community where multiple sexual partners, the use of recreational drugs and medical histories littered with sexually transmitted diseases were seen as significant contributing factors in the unusual immuno-suppression symptoms of AIDS. In the minds of many people the link was to stay (see Epstein, 1996).<sup>57</sup>

The gay community also differed in organisation and resources from other groups that faced exclusion. Though both Haitians and the gay community were vocal on issues such as donor questioning, in the case of Haitians it was predominately doctors residing in the U.S.A. and politicians from Haiti who protested, particularly to the notion that the disease had originated in Haiti.

A long history of discrimination toward the gay community meant that it had forged a cohesive political unit, informing its response to prejudice. In

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<sup>57</sup> As late as 1987, Jesse Helms argued in the U.S.A. Senate that: 'every case of AIDS can be traced back to a homosexual act' (in Epstein 1996, p.52).

contrast to intravenous drug users, who were on the margins, the gay community was established within the power structures of American society. As Epstein points out; 'gay communities were dominated by white, middleclass men - people with influence' (Epstein, 1996, p.65). As far as the blood banks were concerned, the gay community was a large part of its donor population and any move to exclude would have a significant impact. Indeed, estimates from the American Red Cross suggested that the gay community constituted as much as 25 percent of its donor population (Healy, 1999, p.547).

Encouraged by the American Red Cross and National Hemophilia Foundation, the public health service recommended, as a temporary measure, that high-risk groups, including gay men with multiple partners, refrain from donating. The Blood banks responded by producing a pamphlet that requested sexually active homosexual or bisexual men with multiple partners not to donate (Krever, 1997, p.230).

The CDC's second proposal at the Atlanta meeting in 1983, surrogate testing, also proved problematic. Opposition to surrogate testing was based largely, though not exclusively, on the grounds that the science was inconclusive and that the cost of introducing a test that could not prove a risk was substantial. Indeed, no less an authority than the chairman of the FDA's advisory committee on blood safety remarked that:

We are contemplating all these wide-ranging measures because one baby got AIDS after transfusion from a person who later came down with AIDS and there may be a few other cases (in Shilts, 1988, p.221).

Convinced that blood was a vector for transmission, the CDC argued that the anti-HBc test, which identified the presence of antibodies to hepatitis B, could be used as a surrogate test. The CDC claimed that an unpublished study of homosexual men displayed a strong correlation (90%) between hepatitis B and AIDS, thereby justifying the use of surrogate tests. Other

studies were more cautious, reporting a detection rate of between 25% and 40% (Leveton *et al*, 1995, p.113).<sup>58</sup>

Amid this scientific ambiguity, both the blood banks and the fractionation industry remained sceptical of the value of surrogate testing. Indeed, it was suggested that high-risk donors may donate in order to be tested, increasing the transmission of the disease via the blood supply, especially if false negatives (results indicating no infection where one exists) emerged. Moreover, given that the anti-HBc test did not specifically test for AIDS, the fear was that it may produce false positives: results that confirmed an individual with hepatitis B, but *not* AIDS. Blood banks were anxious that this could lead to the loss of non-infected blood, or that false positives would need to be explained to a donor. They were also alarmed at the prospect that tests would appear discriminatory, resulting in donor attrition. Estimates suggested this could be over 5 percent among volunteer donors and as high as 20 percent among commercial donors, leading to severe blood shortages (Leveton *et al* 1995, p.114). Not surprisingly, cost was also a significant factor, with one prominent blood banker suggesting that tests on a national scale would cost up to \$100 million (Shilts 1988, p.223).<sup>59</sup>

Unlike donor questioning, the problem of surrogate tests was not easily resolved, and remained a divisive issue until the introduction of HIV antibody tests (1984). Although a number of studies were undertaken, the results were consistently at odds with one another. Conflicting data emerged from high-risk populations in different areas. Indeed, one study, utilising the anti-HBc test by the Irwin Memorial blood bank, found ethnicity to be a better indicator of hepatitis B than homosexuality.

More disconcerting perhaps, was the lack of leadership in the area. Although a number of studies existed, no overall analysis was conducted, and

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<sup>58</sup>Although the CDC claimed a 90% correlation between AIDS and hepatitis B, the *Committee to Study HIV Transmission Through Blood and Blood Products* was unable to locate the report (Leveton *et al* 1995, p.113).

<sup>59</sup>Based on the average of 14,000,000 donations a year and \$3.00 per test, this figure might appear excessive, but when factors such as the cost of wastage due to discarding blood and replacing a donor are added, the figure appears more reasonable.

disputed results were not called into question. Indeed, it appears that: 'no one examined the evidence from all studies', or called for well-designed ones. With little in the way of conclusive science, and an administration loath to provide the substantial funding necessary to fight AIDS, the introduction of surrogate tests proved difficult (Leveton *et al*, 1995, p.113).

The Reagan Administration was both reluctant to view AIDS as an urgent health issue and antagonistic toward further regulatory intervention: its priority lay in reducing inflation and the budget deficit. If a stalled economy was to be invigorated, it was essential that 'large budget cuts and deep tax reductions' were initiated (*Time Magazine* September 21<sup>st</sup>, 1981). The administration's explicit mandate was to reduce regulation in business activity, even in areas of public safety.<sup>60</sup> As a result it promoted greater involvement for the Office of Management and Budget (OMB) in regulatory affairs, flagging its: 'determination to keep a tight lid on the cost of the nation's risk-reduction policies' (Jasanoff, 1997, p.400). It favoured 'putting the burden of proof on agencies that wanted to take leadership in regulatory affairs' (Leveton *et al*, 1995, p.125). Although the CDC was in the vanguard of the U.S.A.'s healthcare strategy, its position had been undermined by hysteria generated by its warning of a swine flu epidemic in the late 1970s that failed to materialise. On its advice, millions were immunised in a Federal Government crash programme. Both the huge cost and a number of deaths attributed directly to the vaccine, sullied the CDC's reputation.

Compounding these events it appears that considerable interagency rivalry existed between the CDC and the FDA. While such competition is undoubtedly a component of many bureaucracies, the *Committee to Study HIV Transmission Through Blood and Blood Products* (1995) was particularly struck by the significant doubts harboured by key personnel in the FDA about the scientific capabilities of the CDC (Leveton *et al*, 1995, p.125).

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<sup>60</sup>Though the Reagan Administration had set aside \$4 million for AIDS research, some scientists felt it was 'dragging its heels'. A spokesman for the gay community suggested that: 'if the same number of Boy Scouts had been dying from this, there would have been a hell of a lot more money for research' (*Time Magazine* March 28<sup>th</sup>, 1983).

Responsible for blood and blood products, the FDA also relied heavily on technical groups, one of which was the Blood Products Advisory Committee (BPAC). This group included representatives from the blood banks and fractionation industry, both opposed to surrogate testing. It was a committee that provided fertile ground on which to develop opposition to surrogate testing. The FDA's preference was for consensus backed regulation, a position that proved difficult to establish given the absence of conclusive science surrounding AIDS. In a political climate that encouraged deregulation, reduced intervention and the promotion of co-operation between government and industry, it is hardly surprising that: 'regulators were reluctant to mandate measures of uncertain efficiency and considerable monetary and human cost' (Glied, 1999, p.343).

### **Summary**

By early 1983, with the number of AIDS diagnoses increasing, the CDC moved to introduce measures it felt could act to halt the spread of the disease. Calling together stakeholders in the blood community and those affected by the disease it sought to encourage the adoption of direct questioning and surrogate tests. It proved to be a Sisyphean task. Gay groups and blood bankers blanched at the idea that donors should be asked to reveal their sexual preference, condemning it as discriminatory, or an affront to the ethos of donor motivation. On the other hand, haemophilia groups and fractionators supported the move and, in the wake of the meeting, the gay community and haemophilia groups engaged in vitriolic media attacks, until the proposal was implemented as a temporary measure in March 1983.

The CDC's second proposal, surrogate testing, received an equally cold reception. Fractionators and blood bankers argued that it could lead to blood shortages, or worse, it could increase the threat to the blood supply through false negatives. That scant support for surrogate testing emerged could also be attributed to the FDA's opposition, convinced that the CDC was exaggerating the threat in an effort to avoid the excesses of Federal

retrenchment, the cost of surrogate testing and that the evidence was far from conclusive. Surrogate testing remained a contentious issue until the development of HIV tests made it redundant.

### **Risk, Science and AIDS in Ireland: 1983**

Across Europe evidence that AIDS could infect blood products sent tremors through the medical/scientific community, since few nations, if any, had secure blood supplies. In Ireland, the Dáil's attention was first drawn to this issue in May 1983 after two cases were diagnosed, one of which proved fatal (Dáil Debates, 342, 1882).<sup>61</sup> It was a situation not alleviated by the fact that most European countries were reliant on concentrates from the U.S.A., by now responsible for 70-90 per cent of the world supply of plasma (Feldman & Bayer, 1999, p.337). With no test available, and the incidence of the disease on the increase, moves to minimise the risk came to the fore.

In Ireland, these problems were compounded by a financial crisis that had engulfed the BTSB. Funding difficulties, which had beset the BTSB from its inception, were exacerbated by the decision to move its headquarters.<sup>62</sup> It was, as the Lindsay Tribunal noted, a situation that impacted negatively on both morale and the efficiency of the BTSB and 'time which could have been valuably devoted to medical and technical matters was perforce given over to financial problems' (Lindsay, 2002, p.121).

As the AIDS crisis deepened, the Council of Ministers in Europe convened a meeting in Lisbon (1983), recommending that where possible, concentrates manufactured from large plasma pools should be avoided. In instances where this was not feasible, the committee urged that physicians and haemophiliacs be informed of any potential risk. Following the lead taken by the U.S.A., the Lisbon Committee recommended an information

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<sup>61</sup>At this point the U.S.A had recorded over 1,600 cases. In Europe, Denmark recorded 12 cases, France 92 and the U.K. 33 for 1983.

<sup>62</sup>Though the Establishment Order of the BTSB (S.I. No76/1965) had detailed accounting matters, it failed to consider how the Board would raise finances. In practice, it received capital grants from the Department of Health on an arrears basis and generated income from the sale of blood and blood products.

leaflet on AIDS be produced to educate donors and encourage self-exclusion. However, while donors from groups at risk were questioned directly in France, most European nations declined such a provocative stance.<sup>63</sup>

At this early stage of the AIDS crisis, donors in Ireland were required to complete a registration form with information on their medical history, which was then assessed by a doctor. By mid-1983 a *Message to Donors* leaflet that listed at-risk groups was added, requesting such donors to refrain from donating. It fell short of listing the symptoms of AIDS and, more disconcerting perhaps, it did not provide any means of confidential self-exclusion.

The leaflet remained un-revised until December 1985, a situation all the more remarkable when evidence emerging from epidemiological studies had influenced change in other jurisdictions. The BtSB's position was that it was confident a test for HIV would be introduced. The Lindsay Tribunal was exasperated, precisely because the absence of a test made it all the more important a comprehensive and thorough screening procedure assisted by an up to date leaflet be in place (Lindsay, 2002, p.133).

After the Lisbon meeting (1983), the Irish Haemophilia Society expressed concern about the use of American blood products, particularly in light of their donor system. However, the Lisbon Committee's recommendation that information be extended to doctors and patients was not introduced by the BtSB (Lindsay, 2002, p.65). As the body responsible for the supply and distribution of blood and blood products, the BtSB clearly had an obligation to provide such information, particularly on the relative risks associated with commercial concentrates, cryoprecipitate or BtSB factor IX.

Although cryoprecipitate varied in its potency, it was not risk free and was problematic for home therapy (self-infusion). It did, however, possess

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<sup>63</sup>Questions ranged from asking if the donor had any of the symptoms of AIDS to whether they had read and understood the information leaflet. In most, though not all nations, a signature was required to acknowledge the information had been read and a self-exclusion clause existed.

one major safety advantage over commercial concentrates: its manufacture in small plasma pools from voluntary Irish donations meant that it *carried significantly less risk than imported concentrates* produced from large pools of paid donors. It is certainly worth noting that only one haemophilia A patient was infected with HIV through treatment with cryoprecipitate, while almost one hundred were infected by the use of commercial concentrates, many of whom died before the Lindsay Tribunal had been convened. Although the plasma pools required for factor IX (haemophilia B patients) would have been larger than those used to produce cryoprecipitate, they would also have had the benefit of being manufactured from voluntary donations collected in Ireland.

The failure of the BTSB to take the lead in protecting the blood supply left a vacuum that was, alarmingly, not filled by other members of the Irish blood community. Although the BTSB would have been the main source of information on the risk to the blood supply, the NHTC was also an expert body and would have received information from organisations such as the U.K. Haemophilia Centre Directors. Indeed, with concern growing with the Irish Haemophilia Society, information was sought directly from the NHTC.

In August 1983 Professor Temperley (NHTC) explicitly attempted to allay fears, noting that the disease was rare in haemophiliacs, that the benefits of intravenous therapy were well-known and that the *balance of risk* favoured 'continuing treatment' with concentrates, a position that echoed the line taken by the Directors of the U.K. Haemophilia Centres (Lindsay, 2002, pp451-452). However, both the BTSB and the NHTC failed either to consider the balance of risk, or to make information available on the matter. This was confirmed by a Galway-based haematologist who admitted that: 'if we knew the relative risk factor of one versus the other-*and we didn't*-perhaps that could have influenced people's choice' (emphasis added *Irish Times* October 7<sup>th</sup>, 2000).<sup>64</sup>

More disconcerting perhaps is that it appears the NHSCC were no more enlightened. In testimony to the Lindsay Tribunal, Dr. Basheer, a member of

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<sup>64</sup>Professor Ernest Egan a Consultant haematologist at Galway University Hospital.

the NHSCC, pointed out that in the early-1980s AIDS was mentioned, and there was discussion that it was risky to use imported products.<sup>65</sup> However, a debate about gauging the balance of risk between concentrates and cryoprecipitate 'never took place' (*Irish Times* April 27<sup>th</sup>, 2001). It was information that was important for haematologists outside of the NHTC, and particularly crucial for treating doctors who were not haematologists, as haemophiliacs often: 'had to wait in casualty while someone phoned the NHTC for advice' (*Irish Times* April 27<sup>th</sup>, 2001).<sup>66</sup>

The absence of any leadership in response to AIDS was confirmed by the fact that, in some cases, treating doctors at the NHTC were unaware of the dangers. Thus, for example, in May 1984 a junior doctor switched a mild haemophiliac that had previously never received treatment for his condition from cryoprecipitate to factor VIII concentrate. It was an error that had tragic consequences. The patient, infected with both HIV and hepatitis C, died.

There was a striking contrast between Ireland and the U.K. In the U.K., the minutes of a U.K. Haemophilia Centre Directors meeting in October (1983) reveal that there existed a diversity of opinion on treatment options, and that the balance of risk between commercial concentrates and cryoprecipitate was vigorously discussed.

In a paper prepared in May of 1983 for the Biological Sub-Committee of the C.S.M., Dr N S Galbraith, Director of the Public Health Laboratory Service, advised that all products made from blood donation in the USA after 1978 should be withdrawn until the risk of AIDS transmission had been clarified. On 13 July 1983 the Biological Sub-Committee considered this possibility. It concluded that this would give rise to a problem of supply. The minutes declared:

Moreover the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to

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<sup>65</sup>Dr. S.M. Basheer was liaison for the Mid-Western Health Board and sat on the NHSCC between 1976 and 1986.

<sup>66</sup>Indeed, it appears that information for treating doctors was never a priority. Although Dr. Basheer had noted his concerns over the lack of guidelines for treating haemophiliacs to the NHSCC in 1980, no such information was provided (*Irish Times* April 27<sup>th</sup>, 2001).

secure UK independence of foreign supplies of clotting Factor concentrate. This should reduce markedly although not eliminate, the risks to recipients of these products (Archer, 2009, pp40-41).

However, in the absence of conclusive evidence, the U.K. Haemophilia Centre Directors were reluctant to stop treatment with commercial concentrates, since it could not be proven that these were the cause of AIDS (Lindsay, 2002, p.155). And of course, many physicians were keen to yield to 'patient demand'. However, as the Archer Inquiry (2009) noted; 'it seems clear that while patients would have been reluctant to return to the use of cryoprecipitate, in many cases they were not given an informed choice and relied on doctors for information and advice' (Archer, 2009, p.41). Nonetheless, it is also important to realise that:

There was no clear consensus among researchers and doctors, nor was there any source of authoritative advice. Virology was then a very young study, practised in hospital Pathology Departments, as a branch of microbiology. The United Kingdom Haemophilia Centres Directors Organisation (UKHCDO) had established an informal arrangement for Dr John Craske, a virologist working in Manchester, to supply advice when requested (Archer, 2009, p.49).

The U.K. Haemophilia Centre Directors' meeting was important, and one that Professor Temperley attended. Indeed, he drew upon its findings for his policy statement outlining treatment procedures to be employed at the NHTC in Ireland. However, as a document it was flawed, failing to provide a policy for naïve patients (those never before treated) or patients with haemophilia B.

The document stated that for home therapy patients had been allocated a commercial product and a batch number, a position that followed the precedent set in the U.K., where those using concentrates were advised to continue to do so until *conclusive* evidence emerged that would alter the calculation of risk.<sup>67</sup> For patients who had mild haemophilia A, or Von

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<sup>67</sup>During the Archer inquiry, Professor Ian Franklin described 'a system in use at the large teaching hospital where he served as a consultant haematologist from about August 1982. Each patient was supplied with Factor concentrate from one specific batch dedicated to that

Willebrand's disease, Desmopressin (DDAVP) and freeze-dried cryoprecipitate should be used, and, if they required hospital treatment, BTSB cryoprecipitate. The document concluded that: 'the above plan should only be disregarded in a serious emergency, if there is an allergic reaction or on the advice of the consultant on duty' (in Lindsay, 2002, pp441-442).<sup>68</sup>

In light of the failure by the BTSB to promulgate information on the balance of risk between products, a failing repeated by the NHTC, it is debateable as to what advice a consultant could provide. More perplexing, the policy made no reference to procedures for naïve patients and, while home kits were still not available for native factor IX, no reference was made to haemophilia B sufferers that could have been treated with a native product.<sup>69</sup>

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patient, until the batch was exhausted. The potential infection to which the patient was exposed was therefore limited. The system depended on careful record keeping. He explained that when he had arrived at the hospital, the system had already been in place for some time. But we have not heard evidence that this practice was widespread' (Archer 2009, p.43).

<sup>68</sup>Moreover, it appears these guidelines were only distributed to doctors in Dublin and Cork, and not forwarded to doctors in Limerick and Galway (*Irish Independent* March 1<sup>st</sup>, 2001).

<sup>69</sup>It was entirely fortuitous, and unknown to the BTSB at the time, that one of the products in use, Proplex, inactivated HIV because of a step in the fractionation process (Lindsay, 2002). While the pursuit of self-sufficiency for haemophilia A patients had been shaped by developments at both the national and international level, such factors were not as prominent with regard to haemophilia B. The treatment/production effort required for those with haemophilia B is different to that for haemophilia A, since the disorder is less common, the amount of concentrate (factor IX) needed is reduced, a situation eased further by the fact that most individuals suffer only a mild form of the condition. Moreover, the process for the production of factor IX had proved much simpler than that for factor VIII.

From 1972 the BTSB had produced a clinically acceptable concentrate from native plasma, which meant that haemophilia B patients could have been ring-fenced from the use of imported concentrates. From 1977 onwards, however, the BTSB imported and increasing quantity of commercially produced factor IX. The reason for this appears to have been a failure on the part of the BTSB to provide factor IX in a manner suitable for self-administration. As the head of the NHTC acknowledged: 'commercial Factor IX was supplied packaged in a form that made it suitable for home therapy...BTSB Factor IX was not supplied with such home treatment kits' (Lindsay, 2002, p.57).

Clearly, the social democratic policy goals of self-sufficiency and voluntary donation were compromised by the use of commercial factor IX. Although there appeared to be no 'particular difficulty' in the procurement of home-treatment kits, the BTSB failed to provide them (Lindsay, 2002, p.57). Astonishingly, the failure to ensure self-sufficiency was not rectified by mid-1984, despite the emergence of AIDS and mounting evidence that the blood products were a vector for transmission. Indeed, an entry in the May 1984 minutes of the NHSCC meeting indicates that home-kits were still not available at that time.

In this crucial period of uncertainty, the response of the Irish blood community was fragmented and hesitant, both to the threat of AIDS and to the recommendations that emerged from the Lisbon Committee of Ministers. Although a leaflet was produced, it lacked vital information and rapidly became obsolete. More alarming perhaps was the BTSB's failure to consider the balance of risk between products (commercial concentrates, cryoprecipitate, and native factor IX), a failing it shared with the NHSCC and NTHC.

Despite a lack of guidance from the BTSB the six-month period after the recommendations of the Lisbon Committee (June and December 1983) seems inordinately long for the formulation of a policy document by the NHTC. It was a failing exacerbated by the absence of any policy to address the most vulnerable sectors of a small population. In the long-term, the BTSB had pinned its hope on the Heparin project and the emergence of a HIV test. In the short-term, its solution was simply to ignore events. Indeed, at the Lindsay Tribunal Professor Temperley candidly remarked that: 'there was a certain sense in which we sincerely hoped there wasn't a problem' (*Irish Times* February 16<sup>th</sup>, 2001). A sense of aimlessness was compounded by conflicting international scientific and medical opinion on the risk posed. In the words of the chief witness for the BTSB: 'we were just small players trying to follow what was going on abroad' (*Irish Times* July 5<sup>th</sup>, 2000).

### **Hope, Fear and Dispute: 1984 to 1986**

The discovery of the HIV virus in 1984 proved pivotal in constructing a response to the AIDS crisis. While it did not form the basis for a vaccine, it allowed for the development of a test, an essential advance if the blood supply was to be protected. Moreover, shortly after the antibody test was developed, it was confirmed by the CDC that HIV was vulnerable to heat, and that heat-treatment of concentrates would inactivate the virus. These advances, while crucial if blood supplies were to be protected, arrived too late for some. In November of 1984 the Irish blood community's worst fears were

realised when a haemophiliac was diagnosed with AIDS. It was an event that was to galvanise the blood community.

By now the Heparin project had been abandoned, largely due to concerns over cost and its inability to deliver sufficient volume. The BTSB's response relied on custom-fractionation of blood plasma and, in the long run, the anticipated success of emerging technologies.<sup>70</sup> However, the BTSB was still producing some products and appeared reluctant to embrace heat-treatment. Concerned about the reduction in yield that would accompany the heat-treatment of blood products (put simply, more heat - less yield), the BTSB maintained that its products were safe, since they had been manufactured from voluntary donations. It was a stance that led to fractious relations with treating doctors that spilt over into conflict when they issued an ultimatum to the BTSB that non heat-treated products would not be used after the first of November (1985).

It was a difficult period for the BTSB, one complicated by the failure to replace key personnel. The haemorrhaging of expertise meant that a situation in which a haematologist had been inundated with managerial matters was turned into one in which a manager had become inundated with medical matters. As the Lindsay Tribunal observed, with a reduction in medical staff, the Chief Executive Officer became embroiled in decisions about blood products and, although he had 'administrative rather than medical expertise', was frequently requested to report to the board on issues relating to concentrates (Lindsay, 2002, p.126).<sup>71</sup>

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<sup>70</sup>Senior officials of the BTSB were of the opinion that, in the not too distant future, genetically engineered products would be available. Recombinant concentrates (not made from human plasma) became available in the 1990s and were introduced in Ireland for the treatment of under 12s in 1995. Their use was extended in 1997 to cover all patients with coagulation disorders. Indeed, Ireland was one of the first countries to switch to the use of such concentrates.

<sup>71</sup>With the retirement of Dr. O'Riordan the twin roles of Chief Medical Officer and Chief Executive Officer, previously administered by the National Director, were separated. While this overcame a structural weakness within the BTSB, no replacement haematologist was recruited. It was a pattern repeated with the retirement of other haematologists in subsequent years. Incredibly, for a period of two years (1986-1988) there was only one haematologist, Dr. Walsh. Dr. Walsh dealt with many of the issues that were the responsibility of the Chief Medical Officer (Dr. Barry located in Cork) without the authority

It was a situation that improved little during 1985 and 1986. The BTSB delayed both the heat-treatment of concentrates, despite indicating that the matter was being pursued, and the introduction of HIV tests. The latter had been put off because the BTSB insisted on evaluating the tests, which meant that while these were available from mid-1985, it was not until October (1985) that the Irish blood supply was secured.

When introduced, HIV tests quickly confirmed the worst - that AIDS had entered the Irish blood supply. *And yet, astonishingly, the BTSB continued to supply its own unheated blood products.* More damning perhaps, it failed to confirm to its own Board, the NDAB and the Department of Health, the AIDS seroconversions of patients, a failing that was inexcusable and bordered on negligence.<sup>72</sup>

By 1984 the BTSB had abandoned the heparin project and opted for custom-fractionation of blood products. It was a decision influenced by the cost associated with home production, the potential economic gains to be made from concentrates and the realisation that the heparin project was unsuitable for mass production. With a custom-fractionation contract in place, plasma collected from voluntary donations would be sent to a fractionator for processing in isolation (fulfilling the goal of self-sufficiency). At the time, it was a fairly novel concept and presented the BTSB with the opportunity to attain self-sufficiency without the need to invest in plant, equipment and expertise.<sup>73</sup>

Prior to the custom-fractionation contract with Travenol, the BTSB's Board had agreed in February 1983 that the sale of commercial concentrates

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vested in the position and bereft of access to the Board. In contrast, Dr. Barry had access to the Board, but was only indirectly a party to pertinent matters through communication with Dr. Walsh. This decreased circle was tightened, as Mr. Keyes the Chief Executive Officer after consulting with the relevant staff, often Dr. Walsh, was the one who reported on matters to the Board (Lindsay, 2002, p.126).

<sup>72</sup> Seroconversions occur when patients who previously test negative, return positive results in a later test, indicating infection has occurred in the interim.

<sup>73</sup> As early as January 1983 it had been noted that the costs associated with home production would be prohibitive. The BTSB's National Director had pointed out that: 'such a home-made product would make the board's financial condition worse rather than better' (*Irish Times* September 22<sup>nd</sup>, 2000).

was economically more prudent than attempts to manufacture its own concentrates (*Irish Times* September 22<sup>nd</sup>, 2000). There were also other benefits: custom-fractionation of blood meant that the BTSB would be paid not only for the plasma it supplied, it would also receive free factor VIII that could be sold to hospitals. Given the BTSB's limited finances, it was a compelling opportunity, one not lost on the financial expert for the BTSB (Mr. McStay) who pointed out that the surplus made from the contract with Travenol: 'helped to run the whole organisation' (*Irish Times* September 21<sup>st</sup>, 2000).<sup>74</sup>

While there can be little doubt that such an arrangement presented difficulties, largely because of the need to secure sufficient plasma, the BTSB was hesitant in pursuing the matter, despite the benefits. In keeping with its distracted response to the AIDS crisis, the BTSB did not establish a contract until July 1985, some eighteen months after the initial contact. At the apex of the AIDS crisis, and with the opportunity to achieve self-sufficiency within sight, the BTSB *only* pursued the matter with urgency after the November 1984 diagnoses of AIDS in an Irish haemophiliac (Lindsay, 2002, p.69). This lethargic response could also be found in its attitude to the introduction of both heat-treatments and HIV tests.

In light of the November diagnosis of a haemophiliac with HIV, Professor Temperley wrote to the BTSB, the NDAB and the Department of Health in December of 1984 recommending that only heat-treated products be purchased for 1985, urging the BTSB to heat-treat its own products.<sup>75</sup> Emphasising his concern, Professor Temperley stated that: 'unless we [treating doctors] are represented at discussion on policy from the initial phase onward' the purchase of BTSB products could not be guaranteed (Lindsay, 2002, p.373).

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<sup>74</sup>Scrutiny of the Board's income and expenditure records reveal that income from concentrate sales, as a proportion of turnover 'rose from 14 percent in 1983 to almost 20 percent in 1987 and 26 percent in 1990' (*Irish Times* September 21<sup>st</sup>, 2000).

<sup>75</sup>Under the contract with Travenol the BTSB would send plasma for processing into Factor VIII and would itself manufacture Factor IX concentrates from plasma returned by Travenol.

In his communication with the NDAB, Professor Temperley noted that, while evidence of the efficiency of heat-treatment was inconclusive, haemophiliacs were required to be: 'protected by every means possible' (Lindsay, 2002, p.216). He acknowledged that his position differed from only a few weeks before, where he had indicated that he would use both heat-treated and non heat-treated products, but emphasised that the problem required constant review. Moreover, Professor Temperley noted that the BTSB had *agreed* to heat-treat its products in the near future, and that non-heat treated products would be withdrawn over Christmas or early in the New Year (1985).<sup>76</sup> It appears, however, that the BTSB did not share the concern of treating doctors, continuing to favour its own non heat-treated products, a position that once again had tragic consequences.

In December (1984), though harbouring concerns about thrombosis, the BTSB initiated small-scale heat-treatment of its factor IX concentrate.<sup>77</sup> There was, however, a remarkable absence of records surrounding the exercise. Professor Temperley's recollection was that the BTSB had argued 'forcibly' that the balance of risk favoured home produced non-heat-treated factor IX, over commercially heat-treated products. The absence of any evidence from the BTSB that it was pursuing heat-treatment at that time lends weight to his account. Indeed, despite assurances in the Dáil in March (1985), that *only* heat-treated blood products were being used by the BTSB, it continued to supply non heat-treated products until *December* of 1985 (Dáil Debates, 357, 1002). The failure to heat-treat supplies of native factor IX led to the infection of seven haemophilia B patients with HIV, five of whom did not live to hear an explanation for their infection.

The BTSB had received a supply of heated commercial factor IX concentrates in February of 1985, yet persisted in supplying its own non-heat-

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<sup>76</sup>In December of 1984 professor Temperley had attended a U.K. Haemophilia Centre Directors meeting where policy now favoured heat-treated products and undoubtedly the first diagnosis of AIDS in an Irish haemophiliac (November 1984) was of concern to him.

<sup>77</sup>Thrombosis is the formation of blood clots, which can have serious if not fatal consequences should the clot enter the brain or heart. However, it appears the BTSB did not discuss its concerns with treating doctors, who more concerned about HIV, felt that the risk of thrombosis 'was not a major issue' (*Irish Times* October 26<sup>th</sup>, 2000).

treated product. Its view, that domestic products carried a lesser risk was, in the case of cryoprecipitate, defensible, largely because it was manufactured from small donor pools, an advantage not enjoyed by factor IX. Indeed, as early as November 1984 the Canadian Bureau of Biologics had expressed the view that: 'further reliance on AHF (concentrates) products that have not been heat-treated, cannot be justified' (Krever, 1997, p.422).

In evidence to the Lindsay Tribunal, officials from the BTSB suggested that they had simply followed events in the U.K., which accounted for the delay in the introduction of heat-treated factor IX from domestic blood supplies. However, the Lindsay Tribunal remained sceptical, concluding that there was no evidence to suggest that such an approach had been taken (Lindsay, 2002, p.74).

In late 1985 the schism between treating doctors and the BTSB widened. In August of that year Dr. Helena Daly (locum Director for the NHTC) had a meeting with senior officials of the BTSB and insisted that cryoprecipitate and factor IX be heat-treated. The BTSB informed Dr. Daly that treating cryoprecipitate was impossible and that the BTSB was against heat-treating factor IX.<sup>78</sup> The assurances given back in January of 1985 to Professor Temperley that *all BTSB products* would soon undergo heat-treatment, were clearly without substance. In the aftermath of this meeting, treating doctors issued an ultimatum to the BTSB that, unless blood products were heat-treated, they would refuse to accept them after November 1<sup>st</sup> (1985). Although the BTSB made no reply to this ultimatum, the heat-treatment of factor IX began almost immediately. However, the circumstances surrounding the heat-treatment of BTSB factor IX indicate that the BTSB both clung to its belief in the safety of its own products and harboured yield/cost concerns.

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<sup>78</sup>The Central Laboratory for Blood Transfusions in Holland developed a method for heating freeze-dried cryoprecipitate in late 1985, but it was a particularly difficult procedure. Indeed, despite the assistance of the Dutch, Finland's CLB laboratory did not develop the procedure until 1987/88.

Initially, the BTSB heat-treated its factor IX using a protocol of 68 to 70 degrees for 72 hours. However, it was quickly altered to 60 degrees for 20 hours, assumed to be effective in destroying the HIV virus. Although the Lindsay Tribunal found 'no real explanation' for this change, it seems plausible to suggest that the BTSB was anxious about the balance between yield and cost. Undoubtedly concerned about seroconversions, and aware that international opinion had converged on 60 degrees for 72 hours as the standard, the BTSB reversed its decision in mid-July 1986. The Board was informed of the change and that it would: 'lose about 10 percent of stocks as a result of this decision' (Lindsay, 2002, p.82).

Further evidence that the BTSB was reticent to heat-treat its products, was presented by its principal biochemist, who noted that the BTSB: 'had the capacity to begin heat-treating in August (1985) if not earlier'. Indeed, she was 'surprised' at how easy it was since: 'All that was required was to place the factor 9 in an incubator for the appropriate time and at the required temperature' (*Irish Times* October 26<sup>th</sup>, 2000).

The BTSB's continued use of non heat-treated products was just as controversial. Despite evidence that the blood supply had been compromised, and notwithstanding the ultimatum issued by treating doctors to cease the use of non-heat-treated products, the BTSB continued to supply non heat-treated factor IX until December of 1985. And yet, it had enough commercially heat-treated factor IX to provide for the entire requirements of haemophilia B patients (Lindsay, 2002, p.76).<sup>79</sup> Incredibly, the BTSB persisted in using these stocks of non-heat-treated native products *after* the introduction of AIDS antibody tests and the confirmation of AIDS infections within the Irish donor population.

On the 21<sup>st</sup> of October 1985 AIDS an antibody test (also known as the HTVL-III test) was introduced, a procedure that had been recommended by the WHO-sponsored international conference on AIDS in April of that year.

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<sup>79</sup> Although treating doctors had issued an ultimatum to end the use of cryoprecipitate, neither the NHTC, nor the BTSB, had informed treating doctors outside the NHTC of this change and the BTSB continued to supply existing stocks until December 1985.

While it represented an advance on surrogate tests, it was by no means conclusive, since it could not detect infection during the window period (the time between the onset of infection and the production of sufficient antibodies in the host for the test to identify). Moreover, the test could produce either false positives or false negatives. Blood banks were concerned that individuals at risk might flood the blood banks in an effort to be tested (the magnet effect), an argument used by the BTSB to defend its decision to delay the introduction of testing; a view not shared by the Department of Health, which felt sufficient sites were available.

Although the BTSB's introduction of HIV tests in October 1985 did not compare unfavourably with other nations, the Lindsay Tribunal was nonetheless critical of what it perceived to be an 'unwarranted' delay. It felt that the BTSB's decision to evaluate different tests was unnecessary, given that the information could have been gleaned from larger blood transfusion services abroad (Lindsay, 2002, p.136). The Lindsay Tribunal also noted that, despite the matter receiving increasing attention since June (1985), the BTSB did not approach the Department of Health for funding until September (1985).

The introduction of AIDS antibody tests confirmed immediately that the nightmare had arrived - within a fortnight a regular donor had tested positive. Further positive tests soon followed. However, the BTSB did not withdraw non-heat-treated products, despite the fact that further evidence had emerged confirming the blood supply had been compromised.

In mid-January (1986) the BTSB received correspondence from the Galway Regional Hospital of a patient's seroconversion. The hospital urged the BTSB to issue guidelines on blood products, replace those that had been manufactured from unscreened donations and remove those that had not undergone heat-treatment. In response the BTSB decided only heat-treated products should be used. Contact was made with the Department of Health on unscreened products and the Department decreed that: 'it is imperative that all blood products issued to hospitals, prior to the introduction of AIDS

anti-body testing, and still held in stock by them, should now be withdrawn' (Lindsay, 2002, p.78).

The BTSB responded on January 30<sup>th</sup> 1986 with a notice to hospital blood bank medical officers. However, it failed to point out that only *heat-treated* products should now be used, and that *non-screened* products be withdrawn. Under the circumstances the BTSB's conduct was indefensible. At this stage, it was fully aware that HIV had entered the Irish blood supply, was 'probably' aware of a seroconversion of a patient, and fully cognisant of international best practise that recognised the need to remove non-heated products. Indeed, only days before, on January 24<sup>th</sup>, Drogheda hospital had returned its supply of factor IX so that it could be heat-treated (*Irish Independent* July 28<sup>th</sup>, 2000).

The debacle was all the more surprising given that from January 1986 the BTSB had been supplying its own heat-treated factor IX and that there was no 'good reason' it could not have initiated a withdrawal, particularly in light of the fact that it also had available adequate supplies of heat-treated commercial concentrates (Lindsay, 2002, p.78). Incredible though it may seem, the matter was not resolved until late-June of 1986, despite a growing number of seroconversions.<sup>80</sup>

By April (1986) four seroconversions had been confirmed, although it was not immediately clear the product(s) responsible. By June, suspicion had fallen on a batch (or batches) of non-heated concentrate, forcing the BTSB to advise that only heat-treated factor IX be used and that non-heated BTSB factor IX be returned (Lindsay, 2002, p.81). Compounding this failure, BTSB officials neglected to inform its own Board of the seroconversions. More damning, it was a matter not reported to treating doctors, despite its obligation as a supplier, nor was the NDAB or the Department of Health informed of these adverse reactions. It was a set of omissions that was to turn an iatrogenic disaster into a political scandal.

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<sup>80</sup>It appears that between December 1985 and May 1986 only 318 of 517 vials were returned, leaving nearly 200 unaccounted (*Irish Independent* July 15<sup>th</sup>, 2000).

### **Risk, Science and Hepatitis: 1987 Onwards**

1987 opened with a tragic reminder of the dangers attached to the use of blood concentrates. On the 13<sup>th</sup> of January the BTSB was informed of another HIV seroconversion. In the course of treatment this patient had been infused with cryoprecipitate, Hemophil and Armour concentrate produced from both native and non-native plasma.<sup>81</sup> The prime suspect was a unit of Armour concentrate, but the evidence was far from conclusive, which meant that all blood products came under suspicion.<sup>82</sup>

It was a period of intense introspection for the BTSB as suspicion enveloped Ireland's blood supply. Although a combination of HIV antibody testing and the use of heat-treated products effectively ended the threat of HIV to the blood supplies, it was a battle hard won, and not without casualties. Respite, however, proved short-lived, as it became evident that NANBH posed a greater danger than previously thought. Between 1986 and 1988 the BTSB was preoccupied, not only with the residual consequences of AIDS, but also with the difficulties generated by the menace of NANBH.

Initially, it had been assumed to be a chronic, but manageable, condition. However, by the mid to late 1980s, it was considered a serious and insidious condition. While no symptoms were obvious with chronic infection, over time, liver cirrhosis and liver cancer could develop. Moreover, though chronic infection with hepatitis B occurs in only about 10% of infected individuals, with NANBH this figure rises to some 60% to 80% (Krever, 1997, p.39).

Of more grave concern to the Irish blood supply was that a long incubation period and capacity to remain dormant for many years meant that, even those individuals chronically infected could be asymptomatic carriers, free from signs of any liver disease. In this state, and unaware of their

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<sup>81</sup> Hemophil was a concentrate manufactured by Hyland (U.S.). As with the Armour product it would have included blood collected from a commercial system.

<sup>82</sup>The specific unit of Armour concentrate in question had been purchased directly by the National Haemophilia Treatment Centre and administered in February 1986.

infection, there was a possibility that the disease could infiltrate the blood supply, a situation complicated by a lack of clinical evidence upon which to base decisions. It was a situation made all the more problematic by the loss of key personnel and the unavailability of an accurate test for NANBH from which to evaluate competing technologies.<sup>83</sup>

These were difficulties compounded by the disappointing yields from the BTSB's arrangement with Travenol. By late-1986 the BTSB had begun exploring alternatives. Options, however, remained limited. The refusal by the USA FDA to accept the Welcome HIV anti-body test used by the BTSB for blood screening meant that native plasma could not be sent for fractionation in the U.S.A. Although this restricted the BTSB's choice of fractionator, it was offset by the development of new technologies for viral inactivation. However, the situation was far from straight-forward.

With no accurate test available for NANBH, evidence from clinical trials presented the only means by which the safety of new methods could be established. In short, trials would need to include only those who presented with no underlying liver dysfunction or markers for hepatitis. In addition, for blood testing and diagnosis specific post-transfusion testing intervals and a test for aspartate transaminase levels (an indication of damage to the liver/heart by infection) would have to be used. It was a standard set in 1984 by the International Committee on Thrombosis and Haemostasis (ICTH). However, as there was no specific test for NANBH available, trials could provide only limited assurance, a problem complicated further by the fact that most studies did not comply fully with the ICTH criteria, or the results were insufficiently conclusive. All of this meant that the effectiveness of different technologies could not be directly compared.

The scientific/medical community was placed in a precarious position; forced to make a choice primarily, though not exclusively, between competing heat-treatment technologies. Since heat-treatment had proven

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<sup>83</sup>'There was a 20 percent drop in the number of staff on the payroll at Pelican House (Headquarters of the BTSB) and a 10 percent drop in the number of staff in the Cork offices of the BTSB between 1986 and 1989 due to cutbacks' (*Irish Times* July 18<sup>th</sup>, 2000).

successful in combating HIV, most approaches in the mid-1980s focused on this method. Put simply, more heating resulted in more inactivation. However, heating also substantially reduced yield, and therefore each approach, of which there were three, offered both opportunities and problems. It was a scenario complicated further by the fact that using solvent detergents (washing with detergent) was also attracting attention. Although this technique had the significant advantage of not reducing yield, its inability to render particular viruses inactive meant it required further processing by heat-treatment.

### **Fractionation Technologies**

The process of heating concentrates in a solution (pasteurisation) was not a new technology. A German company, Behringwerke, had developed the method in the late-1970s, and was licensed to produce pasteurised concentrate in 1981. However, evidence for its capacity to inactivate NANBH did not materialise until 1987, when Schimpf published results in the *New England Journal of Medicine* that showed no infection in 26 previously untreated patients treated with pasteurised factor VIII (Schimpf, 1987). Both Armour and Cutter had been licensed to market pasteurised factor VIII in 1986, although, at that time, it was not considered viable for mass production because the intensity of the process resulted in a marked reduction in yield.

An alternative approach, developed in the early-1980s both by Alpha Therapeutics, an American company, and Immuno AG, a European manufacturer, was wet-heating. While wet-heated concentrates were effective at eliminating HIV, they did not neutralise NANBH. However, early results indicated that heating factor VIII concentrate before final lyophilisation (wet-heating) was more effective at inactivating hepatitis C than dry-heating (Krever 1997, p.512). These findings were confirmed in the *British Journal of Haematology* in 1987, although Kernoff *et al* noted that it was by no means completely effective and the method: 'still showed a significant transmission of non-A non-B hepatitis' (Lindsay, 2002, p.92).

As with any approach, the issue of cost was an important factor. In Canada, for example, Immuno AG's product was two or three times as expensive as conventional dry-heated concentrates (Krever, 1997, p.513). Indeed, the Canadian Hemophilia Society's Medical and Scientific Advisory Committee (1987) expressed concern about the cost and availability of wet-heated products. Although the Canadian Bureau of Biologics had approved some 200,000 units for use in clinical trials with naïve (previously untreated) patients in mid-1986, it was several months before the transition to such products was complete, with an estimated cost in excess of \$20 million Canadian dollars. In the interim, the committee recommended that, for patients most at risk (naïve), wet-treated products were the treatment of choice and should be made available (Krever, 1997, p.513).

While most research had focused on wet-heating, or heating in solution, laboratories in Elstree (U.K.) and Edinburgh (Scotland) began producing concentrates from dry-heating at 80 degrees for 72 hours. Such high temperatures had been avoided largely because of an anticipated loss in yield. However, modifications to the fractionation process proved successful and were: 'viewed with some astonishment by other fractionators at the time' (Lindsay 2002, p.93). Laboratory tests using the 80 degree 72 hour protocol with viruses other than HIV and NANBH confirmed an increased level of inactivation over those heated at 60 or 70 degrees. However, the procedure was *not* tested on concentrates spiked with HIV, and chimpanzees to conduct tests on were unavailable. Thus, while it may have been possible to infer that heating at 80 degrees could be more effective against HIV, the inability to test inactivation of NANBH transmission meant that clinical trials provided the only means of confirming its potential.

At symposiums in Milan, Australia and the U.K. (1986), a succession of papers were delivered that indicated dry heating at 80 degrees for 72 hours prevented post-transfusion NANBH transmission. However, the evidence was drawn from surveillance and trials that did not conform to the International Committee on Thrombosis and Haemostasis (ICTH) criteria.

Despite this, evidence continued to mount, so that by 1988 none of the 32 patients exposed to factor VIII or factor IX concentrate, dry heated at 80 degrees for 72 hours developed non-A, non-B infection as defined by accepted criteria (Lindsay, 2002, p.94).<sup>84</sup> The supply of concentrates manufactured by this method also had another advantage over commercially available concentrates; they were produced by the British National Health Service using plasma from voluntary donations.

The heat-treatment of blood plasma was not the only approach investigated. As viruses are lipid-coated they are susceptible to detergents, a technique explored in the early-1980s by the New York Blood Centre. It was a procedure that offered significant potential, since yields were not reduced. However, particular viruses such as Hepatitis A and parvovirus B19 possess no lipid envelope and are immune to the effects of detergents, which meant that the refined product would still have to undergo heat-treatment.

Early evidence from a chimpanzee study published in *Vox Sanguinis* in 1984 by Prince *et al*, found that the detergent method inactivated both hepatitis B and a strain of NANBH (Prince *et al*, 1984). While the results were encouraging, there were difficulties. The study was conducted prior to the discovery of HIV and its effect, if any, on that pathogen was unknown. Suspicion also existed about the possibility of a non-lipid coated strain of NANBH. However, in March of 1986 the *Lancet* published research that confirmed earlier results and reported that HIV (HTVL-III) spiked factor VIII concentrates were HIV inactive after the addition of the detergents in laboratory experiments. Moreover, preliminary results of clinical trials published in *Thrombosis and Haemostasis* in 1987 and the *Lancet* in 1988 confirmed no NANBH transmission.<sup>85</sup>

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<sup>84</sup>It was not until 1993 that a study complying fully with ICTH recommendations emerged.

<sup>85</sup>The non-lipid coated virus hypothesis was considered defunct at this time. Although the New York Blood Centre had approached fractionators in 1985 with a view to licensing the process for a modest fee, it was not until 1988 that the first licence for commercial fractionation method was issued to Hyland of the U.S.A. That there was such resistance to taking up the method can be explained by the fact that it was a new method and would have required re-licensing of all the products of fractionation. As one fractionator commented; 'they were already involved with heat-treated viral inactivation research, and interrupting

At this point the BTSB faced the difficulty of finding both a replacement fractionator and the technology of choice. It was a situation made all the more difficult with the depletion of key personnel, which left the BTSB with a Chief Medical Consultant who knew little about blood products (*Irish Times* July 21<sup>st</sup>, 2000). At this critical juncture, the BTSB appeared overwhelmed by events, confirmed in its erratic decision making, particularly with regard to haemophilia B patients.

There can be little doubt that the difficulties the BTSB faced were far from straight forward. In the opening months of 1987 the choice of product open to the BTSB was complicated by inconclusive results from a range of possible technologies. The effectiveness of pasteurisation had not been proven and poor yields were a serious drawback. Wet-heating presented an improved product, but there were risks associated with its use and it was costly. Although solvent detergents exhibited potential, the inability to affect non-lipid coated viruses meant that the product still had to undergo additional heat-treatment processing. The product manufactured by Elstree (80 degrees for 72 hours), one that had received positive endorsements, was clinically unproven by ICTH standards. As if this were not enough, the BTSB was also experiencing difficulties in its custom-fractionation agreement with Travenol, where yields were lower than expected for factor VIII, and plasma returned to the BTSB from which it would fractionate factor IX was, on occasion, unsatisfactory.

However, options were available to the BTSB. Although *formal* confirmation of the effectiveness of the Elstree method (80 degrees for 72 hours) had been delayed, the BTSB was alerted to its efficacy by October 1986. Indeed, a hand-written note from a meeting with Elstree representatives confirms that the BTSB was aware there was no evidence of NANBH infection after eighteen months and it was presumed safe from HIV (Lindsay, 2002,

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these research efforts...would delay licensing' (Bacich, Shanbrom in Leveton *et al*, 1995, pp86-87).

p.100).<sup>86</sup> The BTSB also knew that, while Elstree could not fractionate Irish plasma until January of 1988, it did have surplus supplies of factor IX heat-treated at 80 degrees for 72 hours (Lindsay 2002, p.100).<sup>87</sup> Testing of haemophilia B patients later revealed that three individuals had been infected with hepatitis C, by BTSB factor IX (Batch number 9885) after June 1989. It was a tragedy that could have been avoided had the BTSB acquired supplies of factor IX heat-treated by the then proven 80 degree for 72 hour protocol.<sup>88</sup>

During both April and May of 1987 reports to the Board detailed advances made in a new fractionation agreement and, while Armour were the front runner, the possibility of an arrangement with Scotland was mooted, as by now it had switched to the Elstree (U.K.) method (80 degrees for 72 hours). However, communication with Scotland ceased at this point. The explanation put forward by the BTSB was the inability of Scotland to fractionate separately Irish plasma. Although the decision would have to consider the relative risk of mixing Irish plasma with that of other jurisdictions (Scotland and the North of Ireland) against the advantages of heating at 80 degrees for 72 hours, both Scotland and the North of Ireland operated voluntary collection systems and the Lindsay Tribunal was of the opinion that this was a 'missed opportunity' and that the BTSB's failure to examine such an arrangement was 'inexplicable' (Lindsay, 2002, p.104).

Choosing to ignore these options the BTSB pursued a custom fractionation agreement with Armour in 1987, in which factor VIII was heated

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<sup>86</sup> Other possibilities were also not investigated. In November 1986 Mr. Keyes visited the New York Blood Centre to gather information on its financial and administrative organization. Although it was known that the New York Blood Centre had developed the solvent detergent method, it appears no inquiries were made as to its efficacy. It was a matter upon which the Lindsay Tribunal was moved to note that: 'the BTSB were not, at this time, actively pursuing inquiries into alternative methods of viral inactivation' (Lindsay, 2002, p.101). This lack of any serious investigation into viral inactivation technologies continued throughout 1987 and persisted into 1988.

<sup>87</sup>Discussions between Professor Temperley and Dr. Walsh indicate that while the price (20p per unit) was too high, Professor Temperley 'would be happy to take the U.K. product on a 50/50 basis with commercial product' for the following year. However, no records exist that indicate Dr. Walsh communicated the non-transmission of hepatitis status of the product to Professor Temperley and 'the Tribunal does not think it probable he did so' (Lindsay, 2002, pp100-101).

<sup>88</sup>The infections could in all likelihood have been avoided had the NHTC had a policy for the treatment of naïve haemophilia B patients in place.

at 68 degrees for 72 hours. This arrangement, however, proved to be short-lived, as dry-heating below 80 degrees was almost universally abandoned.<sup>89</sup> As a consequence of this, the BTSB was forced to review its fractionation arrangements and again failed to explore adequately the options.

In the wake of the seroconversions of six Canadian haemophiliacs with AIDS, Armour informed the BTSB in early 1988 that it intended to cease production of dry-heated concentrates and switch to a new method; the monoclonal antibody technique.<sup>90</sup> While Armour noted that it would continue its contract with the BTSB until the end of 1988, it stated that it would do so only if provided with an indemnity against: 'any liability in respect of HIV, hepatitis and other viral infection' (Lindsay, 2002, p.107).<sup>91</sup> Although the letter made no reference to the seroconversions, or withdrawal of the suspected product, the Board was aware of their existence, as Professor Temperley had informed them at a previous Board meeting. On this matter the Lindsay Tribunal was succinct; 'Armour's demand for an indemnity was a clear and worrying indication of concern on their part about the safety of the product' (Lindsay, 2002, p.107).

By June of 1988 the Department of Health and the BTSB had renegotiated a revised indemnity with Armour.<sup>92</sup> This concessionary arrangement placed the BTSB in a unique and alarming position for, as Professor Temperley noted, Armour had withdrawn its first generation products from the world market and was *only* producing first generation products for the Irish market (Lindsay, 2002, p.421).

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<sup>89</sup>Koate HT, a commercial concentrate heated at 68 degrees for 72 hours, produced by Cutter in the U.S.A. was not discontinued at this time.

<sup>90</sup>The monoclonal antibody affinity purification technique derived its benefits from the addition of monoclonal antibodies. These bind with Factor VIII molecules in cryoprecipitate and plasma and, once bound, they can be separated from the Factor proteins leaving an extremely pure concentrate. The result of which is virtually no non-factor proteins remaining that might cause infection or adverse reactions.

<sup>91</sup>Armour also stated that the indemnity 'shall be indefinite in duration and shall survive the expiration of the agreement' (*Irish Independent* June 27<sup>th</sup>, 2000).

<sup>92</sup>During September of 1988 Armour requested that the BTSB 'remove the company's trade name and labels from all products' (*Irish Times* June 28<sup>th</sup>, 2000).

Compelled by these events, Mr. Keyes compiled a review of possible options for the Board that reiterated the policy of self-sufficiency and presented three options. First, the continued production of factor VIII by conventional methods; available *only* until Armour switched to monoclonal production and still requiring the issue of product liability be addressed. Second, a switch to monoclonal concentrates. Though this would almost double the cost of factor VIII and reduce the yield, it was likely that the increased plasma requirement might be offset by the purity of the product. Crucially, however, it was believed that this product virtually eliminated any risk of viral disease transmission. Finally, there was the option of using a pasteurised product, although Mr. Keyes was of the opinion that self-sufficiency with this product was not achievable (Lindsay, 2002, p.107).

Although he was unable to attend the BTSB meeting Professor Temperley communicated that, as a result of previous HIV disasters, first generation products were being phased out. It was clear that they were also unable to inactivate NANBH. In his opinion, monoclonal concentrates carried a minimal risk of NANBH transmission; though, as yet, they were 'unlicensed' and required further clinical trials. In the case of the Armour product, he noted that it used the discredited heating protocol (60 degrees) for finishing. As far as second generation products were concerned, they had a decreased risk of NANBH infection and both a pasteurised product (Haemate P) and the NHS product (NHS 8Y, 80 degree heated) had been given adequate trials (Lindsay, 2002, p.110).

The respective costs of second and third generation products was also an issue and Professor Temperley pointed out that a *balance* would have to be struck between: 'cost and the infection dangers associated with blood products' (Lindsay, 2002, p.110). In his view, *virtually* all Irish haemophiliacs had NANBH and there was no definite evidence that crude products, such as Irish plasma/Armour factor VIII, produced immune deficiency (Lindsay, 2002, p.110). His advice, as Director of the National Haemophilia Centre, was that the Board should seek a continuation of its factor VIII contract with

Armour for 1989 and that, for naïve patients, a supply of Haemate P (a pasteurised concentrate) should be procured. After weighing up the available evidence, the Board agreed to seek a further agreement with Armour for 1989.

It was a matter upon which the Lindsay Tribunal was severely critical, particularly the failure to examine alternatives. Given that Professor Temperley had criticised first generation products, had noted the improved clinical effectiveness of 80 degree heated products and endorsed pasteurised products for naïve patients, it should have led the Board to be: 'distinctly unhappy and uncomfortable' (Lindsay, 2002, p.111). More disconcerting perhaps was the evidence presented by Mr. Keyes to the Lindsay Tribunal, when he commented that Armour had a 'clouded' reputation prior to seeking the indemnity from the BTSB and its products had been associated with HIV infections in the U.K. Although he defended the BTSB's decision on the grounds that the NDAB had approved Armour products, when asked if he had informed the NDAB of Armour's request for indemnity he noted that: 'this was not his job' (*Irish Times* October 4<sup>th</sup>, 2000).

Yet, as the Lindsay Tribunal noted, the BTSB undertook no further review of possible options. It was a position all the more unfathomable when we consider that concern about NANBH was more prominent in Europe than in the U.S.A. Indeed, given the developments taking place in Elstree (U.K.) and Edinburgh (Scotland) the BTSB's decision not to pursue this alternative was 'quite inexplicable' (Lindsay, 2002, p.108).<sup>93</sup> The Lindsay Tribunal also expressed reservations about the influence Professor Temperley's view carried with the Board in its decision to continue arrangements with Armour. While it acknowledged that, as Director of the NTHC, Professor Temperley's opinion should carry weight, it noted that his simultaneous position as a Board member created a potential conflict of interests. Indeed, Professor Temperley's position was that the doubling of costs would be difficult for *hospitals*, and not the BTSB, a stance that indicates the conflict occasioned by

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<sup>93</sup> The Lindsay Tribunal also noted that the solvent detergent method (which had been mentioned by professor Temperley) should have received some consideration.

his dual standing. This moved the Lindsay Tribunal to conclude that the Board should: 'have brought its own expertise to bear' (Lindsay, 2002, p.111). Ultimately, the issues surrounding product liability and the imminent cessation of the Armour contract proved disturbing and compelled the BtSB to investigate alternative fractionation arrangements.

Although the solvent detergent method had been sidelined in the June review (1988), it resurfaced only a matter of weeks later. Following contact with a European manufacturer (Octopharma), and encouraged by Horowitz *et al's* publication in the *Lancet* (July, 1988), plasma was sent for trial fractionation in November 1988, and returned in January of 1989. Although the yield was disappointing, this avenue was pursued until mid-1989 when the Chief Medical Consultant (Dr. Walsh) advised the Board that it 'was a better product than the one from Armour from the point of view of viral safety' and he emphasised that the Board 'could be faced with claims in respect of NANBH unless it provides a satisfactory product', a position endorsed by Dr. Flynn another member of the Board (Lindsay, 2002, p.102).

On the advice of Dr. Walsh and Professor Temperley, the Board decided in August, (1989) to enter into a contract with Octopharma. With the exception of an outbreak of hepatitis A in 1992, associated with the Octopharma product, the switch to solvent detergent inactivation ended hepatitis transmission through concentrates. Though it appreciated the difficulties faced by the BtSB, the Lindsay Tribunal was nevertheless critical of the length of time the process had taken. Under the circumstances it felt that a short-term abandonment of self-sufficiency and the use of more advanced concentrates should have been considered. Tragically, in June of 1989, three haemophilia B patients were infected with hepatitis C from a batch of BtSB factor IX, an event that could have been avoided had more advanced concentrates been used.

### **Naïve Patients**

The failure to develop and implement a policy for naïve patients, those that had little or no exposure to blood products, was heavily criticised by the Lindsay Tribunal. In general terms, this group would have included those with a mild form of haemophilia A or B (most haemophilia B sufferers have a mild form), infants and children. Although any particular treatment with concentrates carried the potential to transmit infection the limited number (sometimes as little as one) of treatments these patients require places them in a particularly vulnerable position. In other words, the assessment of risks alters according to whether a patient has been exposed to the potential for infection. In critical decisions about the cost of products to be used, higher costs could be justified for patients not exposed to risk, particularly as they were such a small population and the infrequency of their treatment would have meant the actual quantities of concentrate required would amount to very little overall. However, even if the political community wished to engage in a complicated discussion about whether these could be justified, these were decisions always informed by the state of scientific knowledge. The absence of a policy for naïve patients until December of 1988 was an area the BTSB and the NHTC appeared not to consider adequately despite developments taking place internationally.

Initially, the notion of securing a more advanced product for naïve patients appears to have been made during a meeting with Armour in June of 1987. Professor Temperley forwarded the idea, proposing that Armour might organise a small quantity of Irish plasma to be fractionated using pasteurisation by Behring. However, the matter did not 'seem to have been pursued', and although mooted in June (1988), was not put in place until December 1988 (Lindsay, 2002, p.105). This is rather surprising, as the idea was most certainly not new and, in many cases, manufacturers were eager to supply products to naïve patients, especially if they were willing to become involved in clinical trials. Furthermore, the manner in which the policy was enacted indicates clearly that it could have been in place significantly earlier.

Although the policy was formulated in June there were difficulties in securing supplies. In an effort to overcome this, the NHTC switched the use of Koate HS, a pasteurised product produced by Cutter, from a named patient basis to naïve patients. It is difficult to see any rationale for this move not being initiated earlier, a failing that generated scathing criticism from the Lindsay Tribunal, which noted that: 'such a policy should have been in place since 1987' (Lindsay 2002, p.175).

The Tribunal was even more critical of the complete absence of such a policy, specifically for haemophilia B patients. Although the issue of special products was raised in 1987 and eventually enacted in late-1988, at no time were naïve haemophilia B patients included. In light of the availability of 80 degree heated factor IX from 1986, despite its unproven potential at the time, the failure to provide such cover is a particularly damning indictment and moved the Lindsay Tribunal to note: 'the absence of such a policy was unacceptable and became increasing unacceptable from May 1988' (Lindsay, 2002, p.175).

## **Conclusion**

There can be little doubt that the infection of almost four hundred haemophiliacs with either AIDS or hepatitis C was a catastrophic event in Irish history. As details broke in the media, politicians and citizens alike were appalled. An iatrogenic disaster turned into a political scandal as the Irish state sought to deny responsibility.

Despite the impact of the crisis, any explanation has been conspicuous by its absence. While journalistic descriptions of the crisis have emerged, they have, like Ireland's two tribunals, focused primarily on issues of administrative failure/error, the poor implementation of policy or insufficient knowledge about either HIV or NANBH. These were themes that would also dominate in the proceedings of the Archer Tribunal in the U.K. While not disputing that these were important issues, this chapter has pursued a more critical examination of the crisis situating it within the context of international

developments that wrought change upon the interventionist state. It is an explanation of the blood crisis that goes beyond administrative error, the poor implementation of policy or inconclusive science. Alternatively it suggests the Irish blood supply was faced with a triumvirate of threats: virological, political and economic.

As with other nations, Ireland embraced self-sufficiency and voluntary donation as the fulcrum of policy. It was a policy under threat, as healthcare costs rose inexorably in the 1970s. In addition, the BtSB was faced with the emergence and increasing demand for concentrates. With public finances as breaking point the BtSB and government sought a free market solution to the supply of blood. It was not just about cost but, more importantly whether the Irish Government was willing to commit both financially and ideologically to a public sector response. The Irish Government's position was defended on the grounds that any decision to pursue the construction of a fractionation facility was unlikely to generate sufficient economic benefits, given the small haemophiliac population.

As the 1970s drew to a close the determination to sustain self-sufficiency and voluntary donation was compromised by a lack of funds and insufficient attention to promoting the benefits of self-sufficiency. It was a situation ultimately resolved by a marriage of the public and the private, where the BtSB moved to a custom fractionation agreement reinstating self-sufficiency based upon voluntary donation, with blood collected from volunteer donors in Ireland processed by commercial fractionators into concentrates.

However, it was a decision that cemented fractionators as the arbiters of risk. While the BtSB could choose the contractor, decisions about standards, the efficiency of inactivation methods and risk remained the preserve of fractionators and external regulatory agencies. A risk assessment was no longer the preserve of a forum in which public sector officials (minister, civil servants, health administrators) held sway, for risk would now be framed with market considerations to the fore.

### **Risk, Science and Blood: The European Blood Directive**

The HIV/hepatitis crises brought in their wake tribunals, litigation and compensation payouts on a scale not seen since the Thalidomide controversy of the 1960s, prompting a response at the EU level. Here, those such as Anne-Marie Farrell have argued that the blood scandals to sweep across Europe provided a 'touchstone through which public distrust of those in public authority was revealed', ensuring that the point of reference for policy makers in constructing a Blood Directive was not what experts deemed '*scientifically reasonable*', but that considered '*politically acceptable*' (Farrell, 2006 p.145 emphasis added). In other words, blood regulation would now be framed with precaution to the fore.

Invoking much that has become familiar within Ulrich Beck's vision of a risk society, her work appears to sit comfortably within the political fold; reform in blood can be anchored in a public's sense of vulnerability to, and anxiety about, the risk associated with modern science as governments struggle to contain the challenges presented by a complex, uncertain and unpredictable world. The problems (and responses) of blood regulation therefore mirror those to be found in other areas of contemporary politics: genetically modified organisms, bird flu or nuclear power to name but a few.

Attractive as this picture appears to an audience unfamiliar with regulatory politics in Europe, it is an account fundamentally flawed. This chapter maintains that those such as Farrell (2005, 2006) or Feldman and Bayer (1999) overstate the importance of the principle of precaution (PP), fail to accord sufficient explanatory weight to the impact of modern conservatism on European regulation and produce a confused account of the role of science (and risk) in European blood regulation. It is not just that role of PP is exaggerated, or that they neglect to consider competing principles that qualify significantly the Community's rhetorical assurances on precaution (Best Available Technology Not Entailing Excessive Cost and Proportionality) but

that they allude to a *decline* in the role of science as a guide to policy-making. More alarmingly, such accounts of *alleged* reform fail to engage seriously with the impact of competing interpretations of science, or how this conflict is refracted through the political architecture of European decision-making.

In stark contrast to those such as Farrell, Feldman and Bayer, we argue that if we are to provide a deeper understanding of reform we need to appreciate how this involved competing interpretations of complex science and technological developments and how these were shaped (and interpreted) by powerful corporate interests. Moreover, we suggest that the fingerprints of modern conservatism on the European Blood Directive are there for all to see: the separation of risk assessment from its management, and an elevated role for sound science, which defines both the *need* and *extent* of intervention. Reform was framed less by any enduring commitment to the gift relationship, or the principle of precaution, than by a determinism to retain the decision-making autonomy of Member States without compromising the drive toward a single European market.

This chapter is divided into two sections. The first section serves as an introduction for the second, providing a brief note the regulation of pharmaceuticals in the E.U. The second section details the 'politics' that underpinned the Blood Directive, where the emphasis is placed firmly upon tracing the role of modern conservative thinking in European decision-making. Crucially, it reveals the extent to which reform has been shaped by a *particular* view of the role of risk in politics, one that accedes to the demands of multi-national capital; that intervention can be legitimate only on the grounds of a proven risk and that even then it should be 'proportional'. It is a view of the role of science in politics that sits comfortably within the decision-making bodies of the WTO/Codex. Moreover, we can also see how the *role* of science has changed; science that raises uncertainty cannot form the basis for intervention. For intervention to take place (a product banned, or higher regulatory/scientific standards demanded) there must be proven scientific

evidence. And, even if a risk is established, any intervention must then be subject to considerations of cost.

### **EU Regulatory Reform**

The EU has been intensely concerned about the obstacles presented to pharmaceutical companies operating in European markets, where different registration policies increased costs for both business and government as bureaucracies had to be financed and traversed (see Oraz *et al*, 1992; Vogel 1998). Its initial response was to establish a body of European science advisers, the Committee for Proprietary Medicinal Products (CPMP 1975), and introduce a system for licensing medicines based on mutual recognition; designed both to alter the market behaviour of pharmaceutical companies and encourage inward investment by simplifying drug approval. However, the scheme proved problematic, lengthening rather than shortening drug approval times, as Member States were allowed 'too much autonomy', enabling them to raise time-consuming and 'unnecessary questions' about applications. But, the real stumbling block was that the CPMP's decisions were non-binding (see Lewis and Abraham, 2001 p.66; Jones and Jeffreys, 1994).

In a move designed to dispel further the qualms of industry the EU introduced the European Medicines Evaluation Agency (EMA), a body that would centralise the administration of drug licensing and ensure that decisions from CPMP were binding (Lewis and Abraham, 2001 p.63). Though targeted initially at the biotechnology sector, both for its economic potential and because there was a lack of regulation in this new field, its import would be far reaching (Vogel, 1998). The EMA was an important step forward, designed to 'balance' the need to ensure that individual Member States retained partial autonomy, while removing potential 'political' barriers to free trade, barriers that would also include 'spurious' fears not founded on sound scientific evidence.

Under these new arrangements Member States may refuse to recognise a new product approved by the EMEA (a marketing authorisation) *only* if a risk to public health can be established. Any challenge to an authorisation must, therefore, identify an ascertainable risk, not a theoretical uncertainty, a move that anticipates not *a lowering of the evidentiary bar*, but its elevation. The onus to establish proof therefore falls firmly at the doorstep of Member States, which are ‘under pressure to decide on their oppositional stance and to assemble evidence to support that stance quickly’. Even then, they must ‘indicate how the application could be changed to facilitate acceptance’ (Lewis and Abraham, 2001 p.66).<sup>94</sup>

### **Reform in European Blood Regulation**

To those such as the European Blood Alliance (EBA) and the European Plasma Fractionation Association (the not-for-profit sector), any reform of blood regulation in the aftermath of the blood scandals was required to acknowledge a simple and clear cut point: voluntary donation contributed significantly to blood safety (Leikola *et al*, 1992, van Aken, 1992). It was not a view endorsed universally. With substantial interests in the European market, the Plasma Protein Therapeutics Association (PPTA) (private sector) reacted

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<sup>94</sup>It is crucial to recall that most regulatory science in food, drugs and chemicals is conducted by business (private), not government (public). It is this private research that provides the basis from which regulatory agencies perform the function of ‘overseeing’. It is also important to consider that even when research is conducted by institutes or universities, bodies that would once have been seen as either independent or public, it is now increasingly financed by multi-national companies, which retain control of the data. In the event of ‘problems’ emerging, companies can invoke the all encompassing clause ‘commercially-sensitive information’. More alarmingly perhaps, in 2004 Pfizer/Warner Lambert were fined \$240 million plus \$152 million damages under a whistle blower suit taken by a former medical liaison expert, Dr. D. Franklin. During the suit, Dr. Franklin ‘detailed how the company suppressed study results, planted people in conference audiences to ask questions intended to put ‘gabapentin’ in a good light, lavished perks on doctors, used ghostwriters, gave generous “consultation fees” to “thought leaders”, and used psychological profiling of doctors in a successful bid to move gabapentin to so called blockbuster status’ (Lenzer 2004). More recently, the U.K.’s Guardian newspaper reported in 2008 that Italian researchers had revealed ‘that in some cases drug companies are rushing early, incomplete results to licensing authorities’. While the researchers suggested that such premature stoppages were an attempt to steal the march on competitors, Richard Ley, a spokesman for the Association of the British Pharmaceutical Industry disagreed, suggesting that ‘on the rare occasions that a trial is stopped it is done with the primary purpose of getting a medicine to patients as quickly as possible’ (Boseley, S. The Guardian April 9<sup>th</sup> 2008).

with alarm to calls for voluntary donation to be made mandatory, arguing that reports from those such as Van Aken (1992) and Leikola (1992) had introduced a bias in favour of the not-for-profit sector; it was simply trade protectionism by another name, designed to maintain voluntary or state monopolies (*The Source* Dec 2002-2003, p.13).

As far as the PPTA was concerned the question of payment for blood was irrelevant; the real issues were safety and supply. Indeed, defending the record of commercial products, J Bult of the PPTA pointed out that Tabor (1999) had found no transmission of hepatitis B, C or HIV following the introduction of inactivation techniques (1987), whereas in Holland, five blood-born HIV infections had occurred in 2000, despite the enforcement of non-remunerated donation (Bult 2003, p.48). Moreover, he felt it was also important to consider that even if paid donation (in theory) impacted on safety, voluntary donation was not a panacea. We should look no further than the UK, which had shown that a reliance upon a single supplier could have disastrous consequences in the event of a plant shutdown or an outbreak of new variant Creuzfeldt Jacob Disease (nvCJD) (CPMP 2002). Though keen to distance itself from efforts to reduce voluntary donation, the PPTA argued that subsidising the not-for-profit sector was contrary to the principles of European Treaties and that it would not hesitate to make it an issue for General Agreement on Trade and Tariffs (GATT). These competing 'political' interpretations of blood regulation framed the backdrop to the European Blood Directive, drawing upon different interpretations of the role of science in decision-making.

With safety a matter of on-going concern at the EU level, the opinion of the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD) of the Health and Consumer Protection Directorate was sought. Though the SCMPMD conceded that testing had greatly improved, and that donor exclusion remained an irreplaceable element, it felt it was essential to *avoid* inducement for donors: voluntary, non-remunerated donations had the

lowest residual risk, offering a higher margin of safety (SCMPMD, 2000, p.5). This was largely a precautionary position.

The EMEA's Committee of Proprietary Medical Products (CPMP) took a different stance. It warned that any move to mandate voluntary donation would create supply difficulties for many EU States and that, while those from high-risk categories in the past had contributed to infection, debate about safety had moved on. These were risk factors now largely removed by rigorous screening and/or viral inactivation. While a risk from a pathogen, including those of unknown nature could not be absolutely excluded, the application of these complementary measures meant that there was no evidence that paid donations increased the risk of viral transmission.<sup>95</sup> Indeed, the CPMP also cited the example of the UK, which had been forced to substitute the use of British plasma in the manufacture of concentrates with that of paid plasma from the U.S.A, because it was 'recognised as being at low-risk of exposure to Bovine spongiform encephalopathy (BSE)' (CPMP, 2002). Commercial manufacturers maintained (successfully) that they should be allowed to provide choice and, as in the case of drugs and food, decisions on the sale of products should be subject to protocols established in international trade agreements. Influenced by the New Right's view of risk, this is a position that recognises that risk always exists and that what is important is that we recognise that any intervention/regulation can be made only on the grounds of proven risk. That intervention needs to be proportionate and consistent to BATNEEC.

Though the Blood Directive suggests that Member States encourage voluntary donation as far as possible, this was not made a requirement (Article (20)1). While the EU acknowledges that voluntary donation is a *factor* that contributes to high standards of safety, Member States are free to impose

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<sup>95</sup>Safety had improved considerably with repeat donors (lower risk than first time donors) and inventory holds that allowed donations to be removed if the donor tested positive. This was an important consideration in the wake of the European Product Liability Directive (85/374/EEC), and the decision by Justice Burton (*A and Others v National Blood Authority and Others*, UK March 2001), that over 100 people were entitled to compensation because the NHS should have acted earlier to introduce routine screening (see RN 01/47 Scottish Parliament 2001).

more stringent protective measures, including the prohibition or restriction of imports of blood and blood components.<sup>96</sup> However, the Directive explicitly acknowledges that Member States cannot reject blood imports from elsewhere in the EU that meet the standards of the Directive ‘simply on the basis that it does not meet more stringent national regulatory standards’ (Hervey & McCale, 2005, p.247). Here, the Directive was clearly shaped by the dynamics (and ideological desire) to ‘keep matters free’ from spurious fears about risk that form the basis for ‘triple protection’.

The Directive also introduces ‘competent authorities’ at the national level, a move welcomed by those such as Farrell, who view it as a positive development, because it ‘improves the management of risk’. However, such a position fails to recognise that this move institutionalises the separation of risk assessment (EU level) from its management (Member State level), elevating the former at the expense of the latter, since a ‘competent authority’ would have to *prove* (through a risk assessment, generally undertaken at the EU level and corroborated by the EMEA) that a particular product is detrimental to public health. This clearly undermines the rhetorical assurances to precaution that underpin the EU’s general position. Furthermore, any risk assessment would also need to consider whether any (anticipated/projected) regulation was *proportionate* and that it was consistent with the principle of Best Available Technology Not Entailing Excessive Cost (BATNEEC). Intervention is, therefore, subject both to a risk assessment that establishes an ascertainable risk and not simply uncertainty and that, in the event of a risk being established, should consider the cost of intervention and whether it accords with existing protocols designed to protect free trade.

Regardless of public sentiment toward voluntary donation or self-sufficiency, commercial fractionators have successfully resisted moves to mandate the twin pillars of voluntary donation and self-sufficiency,

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<sup>96</sup>In Farrell’s opinion, this ‘gives Member States flexibility to impose higher standards in line with national priorities’ (p.169). However, what she patently fails to appreciate is that these are restrictions that have to be justified on the grounds of public health and *must* recognise both international protocols and the free movement of products that have been ratified by the EMEA.

maintaining that these were residues of an era obsessed with social engineering (the gift relationship). A welcome development (in some quarters) it may be, precautionary it is not.

## **Conclusion**

While the primary focus of this book has been the blood crisis in Ireland, as has been noted throughout, debate surrounding the interplay between risk, science and politics has been a feature of many diverse regulatory areas. Thus, it appears appropriate to conclude by reiterating the central argument that, developments, whether in the regulatory arenas of blood, food or chemicals, all reveal the enduring influence of the New Right, which has been keen to ensure that our critical gaze is drawn firmly toward the inexorable growth of the state, where a deluge in state responsibility impinges upon the individual's capacity to decide on risk. In the vernacular of modern conservatism far too much weight has been accorded to the role of the state in deciding what is in our best interests, and far too little consideration given to the individual's capacity to decide on risk. Profoundly anti-rationalist in sentiment, it maintains that it is impossible for the state to decide what is an acceptable level of risk (challenging the possibility that risk can be contained within the realm of the political/legal or state/citizen): there are simply too many conflicting and competing variables (economic, technological and social) to consider for a balance to be achieved. Any pretence to the contrary, to engineer order through intervention, is economically damaging (reduces innovation), inherently unjust (impacts upon choice and freedom) paternalistic and ideologically driven.

In a subtle, but nonetheless crucial fashion, the role of expert advice *in* blood regulation is about sustaining the view that risks are an attendant feature of day to day life: that what matters is how, as individuals, we make judgements about those risks. Science no longer underscores the regulation of

the market through the state, but actively participates in the reconstruction of individual citizens as consumers of both products and their attendant risks.<sup>97</sup> A risk assessment articulates the extent to which individuals are exposed to risk, or defines more clearly where no *risk can be proven*. And if no risk can be proven, intervention cannot be warranted.

These have been important themes to the arguments of this book, for once embedded within a regulatory framework the role of risk in politics shifts: a lack of scientific consensus offers *not* an opportunity to invoke precaution, as those such as Farrell and Feldman and Bayer would have us believe, but rather they form the basis from which to *resist* regulatory intervention. This is crucial, for it anticipates that regulation involves not *a lowering of the evidentiary bar*, but its elevation. Intervention can be justified only once a quantifiable risk assessment has identified an ascertainable risk, not a theoretical uncertainty. It is at this point that the function of expert advice in regulation is altered, for it is not to *prevent* development on the grounds that it *may* be risky but to establish definitively whether a product will be detrimental to public health, thereby establishing negligence or culpability (the realm of the economic/legal or consumer/producer).

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<sup>97</sup>In the case of food additives cited earlier, the recommendation was that if parents were concerned they 'can control what the children eat at home and if they eliminate some of the colours from what the child eats at home then that might bring about an improvement in itself' (<http://www.channel4.com/player/v2/player.jsp?showId=8979>).

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