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Wilson D. *The Making of British Bioethics*. Manchester (UK): Manchester University Press; 2014.

Chapter 6 Consolidating the 'ethics industry': a national ethics committee and bioethics during the 1990s

During the 1980s many of the individuals who were pivotal to **the making of British bioethics** sought to establish what the *British Medical Journal* identified as a 'national bioethics committee'.¹ Ian Kennedy, for one, regularly called for a politically funded committee based on the American President's Commission, and his proposals were often endorsed by newspapers and other bioethicists. They were also endorsed by senior figures at the BMA, who² believed a national bioethics committee would standardise decisions between different RECs and 'reassure the public'.² But plans for a national bioethics committee ultimately stalled in the late 1980s, after some politicians and doctors claimed that it would obstruct research and politicise bioethics.

The failure of these proposals led some bioethicists and senior scientists to argue that a national committee should have no links to government. After a series of conferences in 1990, the charitable Nuffield Foundation agreed to create an independent bioethics committee that included representatives from several professions. The resulting Nuffield Council on Bioethics embodied the belief that external oversight was vital to maintaining public confidence in biomedical research. Its establishment bolstered media support for outside involvement with³ medicine and science, leading the *Guardian* to claim that there was 'something of an ethics industry springing up'.³ But while council members believed that their independence from government secured public trust and prevented political interference, it also ensured that their advice carried little influence.

External oversight of medicine and science increased under the 'New Labour' government that was elected in 1997 and shared the neo-liberal enthusiasm for 'empowered consumers'.⁴ This arose largely in response to a public inquiry into paediatric heart surgery at Bristol Royal Infirmary. The inquiry's chair, Ian Kennedy, proposed and then chaired a Commission for Healthcare Audit and Inspection (CHAI), which he argued would empower patients by monitoring the performance of hospitals and healthcare trusts. In line with the continuing neo-liberal climate, he⁵ argued that the CHAI was needed because patients were 'not passive receivers of goods, but consumers with choices'.⁵ But criticism of the CHAI reflected a growing backlash against bioethics and the 'audit society' at the beginning of the twenty-first century, with doctors, politicians and even some bioethicists now claiming that external oversight actually damaged public trust.

Essential or obstacle? Discussing a 'national bioethics committee'⁶

Ian Kennedy was the strongest advocate of bioethics in Britain during the late 1970s and early 1980s, so it is no surprise to find that he was also the first individual to endorse a national bioethics committee. Kennedy's enthusiasm for a permanent bioethics committee arose during his spell in the United States, after he became acquainted with the Yale lawyer Alexander Capron, who was a member and later executive director of the President's Commission for the Study of Ethical Problems in Medicine.⁷ Kennedy and Capron believed that the President's Commission offered the 'perfect vehicle' for bioethics.⁸ The majority of its members were non-doctors or scientists, it had the power to suggest legal changes, while members encouraged 'extensive media coverage'⁹ of their deliberations and ensured that all meetings were recorded and open to the public.

Kennedy called for the establishment of a similar body in his final Reith Lecture, where he argued that a permanent 'board or committee' should be established to act 'as champion of the consumer's cause' in Britain.¹⁰ He suggested that this committee should issue professional guidelines and enforce sanctions when these were breached, and should also have significant lay membership to enforce 'outside scrutiny, a key principle of consumerism'.¹¹ Kennedy expanded on these plans in the book *Unmasking Medicine* and a 1983 lecture on 'Emerging Problems in Science, Technology and Medicine', where he admitted that they were modelled on the President's Commission.¹² He outlined how the British committee, like its American counterpart,¹³ 'would issue opinions, publish working papers, seek opinions, and then propose law if necessary'.

In a now familiar tactic, Kennedy promised doctors that a national bioethics committee would 'benefit the practice of medicine' by maintaining public confidence and forestalling legal challenges. He also argued that it would benefit politicians, by sparing them the time-consuming task of having to 'pass legislation on the consumer's behalf'.¹⁴ In 1981 Kennedy was uncertain 'whether such a body should be created under the auspices of a government department

or should be independently constituted', but claimed that this was a 'matter of detail' that could be settled once his proposal was accepted.¹⁵ By 1983, however, he believed that any 'standing committee should be set up by Parliament'.¹⁶

Not content with endorsing a national committee in radio lectures and books, Kennedy also discussed his plans with politicians and the chairman of the Law Commission.¹⁷ But he was not the only advocate of a government-sponsored ethics committee by the mid 1980s. In a 1984 editorial on IVF and embryo research, the *Mail on Sunday* also urged the government to establish 'a constant watchdog to involve ordinary people in the crucial decisions being made about our lives by men in white coats'.¹⁸ Like Kennedy, it argued that a 'standing committee on the practice of medicine' was vital to ensuring that 'we, the public, know our interests are being considered'.¹⁹

At the same time, senior figures within the medical profession also endorsed a national ethics committee, albeit for different reasons. In 1984 members of the CEC and the BMA's general secretary, John D. Havard, began to promote a national ethics committee to the MRC and DHSS. While Kennedy and the *Mail on Sunday* were motivated by a desire for greater public influence over science and medicine, Havard and the CEC portrayed a national committee as the solution to professional concerns. They argued that it would help prevent the uneven decisions that sometimes arose in multi-centre trials, where 'one local committee may approve a study while another may reject the project'.²⁰

In a meeting with the immunologist Sir James Gowans, secretary of the MRC, Havard endorsed a 'form of "line" relationship between the national and local ethics committees'.²¹ He claimed that a national committee would take charge of all multi-centre proposals and issue broad 'guidelines for use by RECs on various areas of research, e.g., *in vitro* fertilization'.²² The CEC expanded on this 'line relationship' in a document circulated to the DHSS and MRC, which claimed that the national committee would issue guidance for 'multi-centre or nationally based' projects, but stressed that it would 'not undermine the expertise of RECs'.²³ The CEC endorsed a more mutual relationship, where the national committee built a 'library of good practice filtering up from the RECs' and 'disseminated information on request' to local committees and researchers.²⁴

Havard sought to improve the public image of medicine during his spell as the BMA's general secretary, and both he and the CEC believed that a national ethics committee would achieve more than simply standardising local decisions.²⁵ Their proposals asserted that 'ensuring consistency in approach ... will reassure the public', with a strong network of ethical committees helping 'protect the good name of the medical profession'.²⁶ This desire to maintain public confidence led them to propose that the committee should be established and funded by the government rather than any medical organisation, since 'it is very important for the national ethical research committee to be seen to be independent'.²⁷

Several groups and individuals welcomed Havard's and the CEC's proposals. Writing to the MRC, the chair of one REC claimed that a national committee would achieve a substantial 'saving in man-hours' by ensuring that different local committees did not have to consider 'experiments which will be carried out on a nation-wide basis'.²⁸ In reply, the MRC admitted that 'there may be a need for a national ethics committee to take broad decisions of principle as to whether or not research in a particular area (e.g., research on human embryos) is desirable and permissible', although it emphasised 'the importance of local ethics committees in representing local considerations and interests'.²⁹ James Gowans also expressed cautious support for a national committee in meetings with Havard, suggesting that it 'might take the form of a standing royal commission', but he suggested that the BMA needed to learn more about other European committees before it drew up firm plans for Britain.³⁰

Perhaps most significantly, Sir Desmond Pond, then Chief Scientist at the DHSS, also expressed support for Havard and the CEC's proposal. In March 1985 Pond sent a letter to the MRC, the BMA, the GMC and prominent doctors such as Sir Douglas Black, in which he claimed that the often 'perfunctory arrangements' for ethical oversight 'point to the need for a national committee'.³¹ Pond's view of a national committee was similar to Ian Kennedy's. He argued that it could act 'firstly to set up a proper system of ethical supervision of research using human subjects (and possibly a subgroup embracing animal research); secondly to have a monitoring role to ensure that what is proposed is actually happening'. He also suggested that it might emulate the President's Commission by proposing new legislation and 'considering particular ethical issues on a case law basis'.³² Although Pond ventured no firm opinion on who should establish and fund a national committee, he proposed that the DHSS might 'take the initiative' by convening a meeting of politicians, medical figures and 'interested laymen' in order to 'get agreement on the need for a national body and general guidelines on its membership and remit'.³³

Yet while they may have agreed on the need for a national committee, these groups and individuals had differing views on its composition. Havard and the CEC believed that public trust in a national committee could be ensured by staffing

it mainly with senior doctors and scientists who were 'people of distinction in their field'.³⁴ They proposed that only two out of eleven possible members should be laymen, nominated by the DHSS, while the other nine should be professionals nominated by medical societies and the pharmaceutical industry.

Desmond Pond, on the other hand, believed that the national committee should be more 'inter-disciplinary ... with a 'lay (i.e., non science)³⁶ chairman'.³⁵ James Gowans also claimed that public trust could only be ensured through 'strong lay representation'.³⁶ In endorsing a 'lay-dominated' committee, Gowans drew on information that the MRC had obtained from France and Sweden.³⁷ In a letter to Donald Acheson, the government's CMO, Gowans claimed that documents on French and Swedish ethics committees showed that they included significant numbers of philosophers, lawyers, theologians, journalists and patient representatives,³⁸ and acted more as vehicles for confronting 'public misgivings' than for standardising professional behaviour.³⁸ These European documents also supported Havard's and the CEC's belief that a British committee should be linked to the government. They detailed how the Swedish and French committees were both organised and funded by their respective governments, with the Secretary of State for Social Affairs selecting members of the Swedish committee, and President François Mitterand and the Secretaries of State for Health and Research selecting members of the French committee.³⁹

But despite broad support from senior officials at the DHSS, MRC and BMA, as well as from some newspapers and public figures, plans for a British ethics committee never progressed beyond letter writing and 'low level informal meetings'.⁴⁰ An MRC report from October 1985 noted that Pond's calls for a meeting had received a lukewarm response and claimed that the DHSS was 'trying to hold things at arm's length'.⁴¹ This stemmed partly from scepticism towards political involvement with a national ethics committee. As the *Lancet* noted, some politicians rejected the idea of a government-sponsored committee on the grounds that it would turn ethical issues 'into party political questions, which they are not'.⁴²

These political misgivings were compounded by growing medical opposition. In a letter to Desmond Pond, one pharmacologist admitted that there 'may be a problem' with decision-making between different RECs, but claimed that he was 'not persuaded that a DHSS sponsored national committee is the right answer'.⁴³ He instead argued that existing bodies such as the Royal College of Physicians could effectively take on the role of 'a consultative body for district ethical committees'.⁴⁴ 'I am not confident', he continued, 'that a national committee containing DHSS and lay (political?) members would be more effective than the best of the existing committees.'⁴⁵ He closed the letter by predicting that since the lay members would 'face a difficult task and have themselves to acquire considerable expertise before they can give useful opinions', a national committee would achieve little more than 'slowing down the progress of clinical research'.⁴⁶

In March 1986 the *British Medical Journal* reported that the BMA's Central Committee for Hospital Medical Services (CCHMS) had also 'objected to a national committee'.⁴⁷ The CCHMS questioned who a national committee would be accountable to and claimed that the current system of ethical review could be improved by simply staffing RECs with more members who were 'in day to day contact with patients'.⁴⁸ At a BMA meeting the following month, the CCHMS argued that proposals for a national ethics committee 'did not have the support of many people actually involved in research' and criticised the CEC for not consulting widely enough.⁴⁹ Crucially, the CCHMS persuaded the BMA's governing council to withhold its support after they claimed 'we can see no effective role for a national committee that did not disenfranchise local groups'.⁵⁰

Plans for a national ethics committee had completely stalled in 1986, with the BMA withholding support, Desmond Pond retiring as Chief Scientist and the DHSS now exhibiting what the MRC called 'masterly inactivity'.⁵¹ This clearly annoyed Ian Kennedy, who complained that calls for a national committee were now 'greeted with a deafening silence'.⁵² His frustration was made clear in a 1987 letter to *The Times*, concerning cases in which judges had permitted abortions to be performed on two mentally handicapped adults who were unable to give or withhold consent. Kennedy argued that judges were 'being asked to decide questions of fundamental importance without guidance', and claimed that it was 'doubtful whether the complex arguments on both sides of such a moral dilemma can be marshalled and explored in depth' without expert advice.⁵³ He maintained it was 'increasingly hard to justify the failure to establish an appropriate body to investigate these dilemmas in a considered and detached fashion', and 'once again' urged the government to establish 'a national commission on medical law and ethics ... so that our elected politicians would have an informed basis on which to provide authoritative guidance on these fundamental questions'.⁵⁴

But Kennedy's frustration was to prove short-lived. Calls for a national ethics committee re-emerged and gained momentum in 1988, thanks to growing debates on gene therapy and the transplantation of foetal brain tissue into adults with Parkinson's Disease. Although the government convened *ad hoc* inquiries into each of these issues, politicians,

public figures and senior doctors now criticised this as a 'piecemeal' response and argued that Britain urgently needed 'a single body to which bioethical problems can be referred for assessment – and which can anticipate new ones'.⁵⁵

While foetal tissue transplants had received REC approval, MPs claimed that they should not have been undertaken without a broader debate and called for 'national control and additional guidance'.⁵⁶ Several politicians endorsed a national committee in Commons debates, and set out their views on its possible links to government. Gerard Vaughan, a former doctor and Minister of Health, believed that it should function as 'statutory body' that was 'responsible to Parliament', while the former neurosurgeon Sam Galbraith argued that it would function better as 'a quasi non-governmental organization'.⁵⁷ No politician, tellingly, spoke in favour of the current ethical and regulatory framework.

Supporters of a national committee found a high-profile ally in Mary Warnock, who claimed that public interest in 'a growing number of topics' such as gene therapy and embryo research justified the formation of 'a permanent royal commission with a rolling membership'.⁵⁸ Writing in the *British Medical Journal*, Warnock endorsed a national committee that resembled the 'monitoring body' her committee had proposed for IVF and embryo experiments. She argued that it would scrutinise professional actions in order to meet the 'growing need for public candour', with a broad membership and a 'lay chairman' ensuring it was 'sufficiently detached' from the medical profession.⁵⁹ Warnock stated that a national committee should develop guidelines and publish an annual report in which it justified its decisions to Parliament and the public – helping create 'an ethical framework widely seen to be secure and sensible'.⁶⁰

As before, and like Ian Kennedy, Warnock stressed that this 'ethical framework' would benefit science and medicine. She warned that biomedical research would suffer in the continued absence of a national bioethics committee, with the public relying on 'often partial and scaremongering items in the press to form their opinions', and Parliament likely to be 'rushed into wholly restrictive legislation'.⁶¹ Warnock asserted that a national bioethics committee would ease ongoing tensions by issuing guidance to researchers while also proving that 'research can be regulated without being banned, that knowledge can be pursued without being put to morally intolerable uses'. This, she concluded, was vital to ensuring 'that we continue, as we must, to push back the frontiers of science'.⁶²

Warnock's plans were endorsed in several letters to the *British Medical Journal*, with one doctor claiming that a national committee would 'add reassurance to the public about what was going on in research ... and would be of enormous benefit in dealing with the approval of numerous multi-centre projects, where conflicting advice is sometimes given by different local ethics committees'.⁶³ Stephen Lock, the journal's editor, also supported a permanent committee that would 'have a strategic and advisory role, dealing with broad bioethical issues as they arise and assessing their impact on our lives'.⁶⁴ Lock reported how the BMA's governing council now endorsed a national committee in their 1988–89 report, where they claimed that it was needed to 'develop guidelines on complex new areas of biomedical research' and to overcome 'widespread disagreements among local committees on multi-centre trial proposals'.⁶⁵ While the BMA council stated that their support arose from recent debates on foetal tissue transplants, they had also come under pressure from some regional divisions who 'deplored the delay' in approving Havard's and the CEC's proposals.⁶⁶

Yet despite this groundswell of support, the government again rejected claims that it should establish a national bioethics committee. This was made clear during parliamentary questions in October 1988, when the Conservative MP Sir David Price asked Margaret Thatcher if she would make it government policy to set up a permanent House of Commons Select Committee 'to study ethical problems arising out of new developments in the practice of science, technology and medicine, and to make recommendations'.⁶⁷ The Prime Minister dismissed this suggestion by claiming that consideration of ethical issues was 'already within the terms of reference of the appropriate select committees'. She warned MPs that establishing a national bioethics committee would therefore entail expensive, time-consuming and unnecessary 'changes in the existing select committee structure'.⁶⁸

The government's stance is hardly surprising given the difficulties it faced in legislative debates over IVF and embryo research. Politicians were still discussing embryo experiments and dealing with various interest groups over four years after the Warnock report had been published,⁶⁹ with supporters and opponents of research both criticising them for failing to arrive at a satisfactory solution.⁷⁰ The government was therefore reluctant to become too involved with emerging problems such as foetal tissue transplants and gene therapy, and were content to pass responsibility to *ad hoc* inquiries or, preferably, to a non-governmental ethics committee.

The government's stance was again made clear in 1989, when the *British Medical Journal* reported that civil servants at the Cabinet Office had discussed establishing a national bioethics committee, only for their plans to be 'squashed' by senior Conservatives.⁷¹ It was also made clear to attendees at a CIBA Foundation meeting held in September 1989,

where several speakers, including Ian Kennedy, spoke in support of a 'national review body to identify current and future issues'.⁷² In his closing remarks, Sir Patrick Nairne, Chancellor of Essex University and a former Chief Secretary to the DHSS, told attendees there was 'no perception in Government of the need for a national body such as a national standing commission'.⁷³ Nairne concluded that 'it may be best for those who feel the need for such a body to set a lead' and look elsewhere for support.⁷⁴ In following this advice, one speaker at this meeting succeeded where Kennedy, Havard and others had failed, and ensured that Britain gained its 'urgently needed' bioethics committee in 1991.⁷⁵

Establishing the Nuffield Council on Bioethics

The first speaker at the CIBA meeting was Sir David Weatherhall, a clinical geneticist at the University of Oxford, who had pioneered genetic testing for thalassaemic blood disorders and took a keen interest in the ethical issues associated with gene therapy techniques. In his paper, Weatherhall bemoaned the continued absence of a national forum that would stimulate public discussion and offer advice to researchers.⁷⁶ After the CIBA meeting, he took Patrick Nairne's advice and approached the charitable Nuffield Foundation to see if it would establish an advisory body on bioethics.⁷⁷

Weatherhall's lobbying led members of the Nuffield Foundation to undertake informal soundings on the need for a national bioethics committee.⁷⁸ After encouraging feedback, in April 1990 the Foundation held a two-day 'Conference on Bioethics' at Cumberland Lodge, Windsor, where thirty participants debated if 'new machinery' was needed to handle ethical issues arising from scientific and medical research.⁷⁹ Attendees were drawn from a variety of disciplines and included Margaret Brazier, Cecil Clothier, Gordon Dunstan, Anne McLaren, Stephen Lock, Patrick Nairne, David Weatherhall and Mary Warnock.⁸⁰ A conference summary detailed how they 'generally agreed that a new national bioethics body, probably in the form of a national bioethics committee or council, was needed ... to anticipate, or at least respond with speed to new bioethical problems'.⁸¹ Attendees also agreed that the 'national bioethics body' should have two main roles: providing guidance 'to those engaged in biological and clinical research', and 'placing bioethical issues higher on the public agenda, promoting fuller public understanding and confidence'.⁸²

As in earlier plans for a national committee, attendees believed that public confidence in the committee could be established by ensuring that 'a majority (however bare) of the members should be lay in the sense of being neither professional scientists nor clinically qualified' and that 'the chair should be lay in the same sense'.⁸³ They also argued, notably, that since the new committee was unlikely to have government support and 'would have no formal powers', its authority and influence would derive largely from the 'standing and quality of the individual members and the Chair'.⁸⁴

The Nuffield Foundation issued a summary of the meeting's main conclusions as a consultation document in July 1990, which it sent to organisations such as the BMA, the GMC and the MRC, to patient groups and pharmaceutical firms, as well as to sixty academics working in the biomedical sciences and bioethics.⁸⁵ The consultation noted that following 'reservations' from the GMC and the BMA, the proposed committee would not consider the ethics of clinical practice and would focus instead on 'the ethical issues posed by emerging research'.⁸⁶ As the IME's *Bulletin of Medical Ethics* noted, the consultation was greeted with 'widespread support'.⁸⁷ At the end of the consultation period, in December 1990, Patrick Nairne led a small steering group that assessed responses and sent the Nuffield trustees proposed terms of reference for the new bioethics council. The terms of reference were, broadly, that the council would identify issues raised by new technologies 'in order to anticipate public concern'; would examine these questions and 'promote public understanding'; and would set up specialist working parties to scrutinise particular issues and provide guidance for government and regulatory bodies.⁸⁸

In line with the BMA's and GMC's misgivings, the steering group maintained that the council would 'take into account the responsibilities for oversight and regulation that fall to professional and other relevant bodies' and would not investigate clinical treatment.⁸⁹ After Foundation trustees approved the steering group's terms of reference, the Nuffield Council on Bioethics was officially established in May 1991. The Nuffield Foundation was the sole source of income for an initial three-year period, estimated at £150,000 per annum, which paid for quarterly meetings and a permanent secretariat (the Wellcome Trust and the MRC joined the Foundation as co-sponsors from 1994 onwards).⁹⁰

The council's founding membership bore the hallmarks of proposals made in the April 1990 meeting and the subsequent consultation paper. First, it was weighted in favour of 'lay' expertise. Of the fifteen original members, seven were doctors and scientists, while the majority included two civil servants, two lawyers, a philosopher, a theologian, an educational consultant and a journalist. Secondly, it reflected the belief that independence from

government meant that the council's authority needed to stem from the 'public standing' of its individual members.⁹¹ The majority of the founding members were drawn from the 'Great and Good', and currently or had previously served on government inquiries into science and medicine. The inaugural chair, for example, was Patrick Nairne, who had been a renowned 'cardinal of bureaucracy' during his time as a civil servant.⁹² Scientific members included Anne McLaren, who had been 'indispensable' to Warnock's committee and now sat on the HFEA, and David Weatherhall, who had recently been appointed to a public inquiry into the ethics of gene therapy, which was chaired by Cecil Clothier.⁹³ Lay members included the lawyer Sir David Williams and Gordon Dunstan, who had both served on Home Office committees on animal experiments, as well as Ian Kennedy, who had just served on a government review of guidelines for research on fetuses and foetal tissues.⁹⁴

The Nuffield Council on Bioethics received a warm welcome from newspapers and politicians, including the new Conservative Prime Minister, John Major, who urged it to address issues raised by agriculture and environmental biotechnology in addition to biomedical science.⁹⁵ A long article in the *Independent* greeted the Nuffield Council as 'a brave attempt ... to get away from the piecemeal approach that has characterised previous British attempts to come to terms with the public policy implications of scientific advance, such as the Warnock committee on embryology and *in vitro* fertilization'.⁹⁶ The *Independent* also stated that the council would look at issues that 'concern us all and are far too important to be left to the practitioners', and welcomed the fact that its membership was 'not dominated by scientists and doctors'.⁹⁷ The *New Scientist* similarly dwelt on the council's membership and predicted that their 'eminent' backgrounds would carry 'enough authority to influence the government and Parliament'.⁹⁸

But although newspapers portrayed the Nuffield Council as Britain's first national bioethics committee, in reality it was one of many bodies dedicated to medical and scientific policymaking. This was clear from the council's first annual report, where a 'brief survey' of similar groups ran to over four pages.⁹⁹ Many of those listed were medical organisations, such as the GMC, the Royal Colleges and RECs; but others, such as the HFEA, shared the Nuffield's template of a 'lay'-dominated membership and looked at ethical issues.¹⁰⁰ The council's members and secretariat thus had to ensure that their work did not duplicate that of these existing bodies. This led them to select genetic screening as the council's first topic in 1991, closely followed by a review of the ethics of research on human tissues in 1992.¹⁰¹ The review of genetic screening was prompted by growing concerns over the possible misuse of genetic information by employers, insurers and government, while the human tissue review was prompted by medical concerns over the ownership of tissues and cells, after an American patient had argued that he was the rightful owner of a cell line that UCLA researchers had derived from his spleen.¹⁰²

These choices reflected the Nuffield Council's remit of anticipating public concerns and issuing advice for researchers in areas that lacked firm guidelines. Yet the response to both reports raised questions about its impact on policymaking. For example, the Nuffield Council's 1993 report on genetic screening argued that the government should establish an advisory committee to monitor the implementation of genetic testing.¹⁰³ But in 1995 the council's secretary, David Shapiro, noted that the government had 'not acted' on this and other recommendations.¹⁰⁴ The government only elected to form an advisory committee later in 1995, following advice from a House of Commons Select Committee on 'human genetics', which had notably been convened less than eighteen months after the Nuffield Council's report was published. This advice led to the establishment of several bodies, including an Advisory Committee on Genetic Testing (ACGT) and a Human Genetics Advisory Commission (HGAC), which both had a similar remit to the Nuffield Council but retained closer links to government.¹⁰⁵

A similar fate befell the council's 1995 report on human tissue, which Onora O'Neill claimed 'wasn't as influential as it should have been'.¹⁰⁶ The report argued that the legal status of tissue used in research was unclear and called on the government to review or update the law, 'as uncertainty may impede legitimate teaching, treatment, study or research'.¹⁰⁷ While the Department of Health responded by claiming that it would review the law in 1996, ministers did not consider the issue until 2000, following a public scandal that arose when newspapers reported that hospitals had retained organs from infant cadavers without parental permission.¹⁰⁸ When the government looked to review the law, however, it overlooked the Nuffield Council's report and convened its own inquiry, led by the lawyer Michael Redfern, and then established a 'Retained Organs Commission', led by Margaret Brazier. Like the select committee on human genetics, the Retained Organs Commission also proposed the creation of another advisory body, the Human Tissue Authority (HTA), which had a similar remit to the Nuffield Council but again enjoyed closer links to government.

The Nuffield Council's limited influence was further evident in debates on human-animal 'xenotransplants', which emerged following news that scientists had genetically modified pig organs to reduce the chance of rejection in humans.¹⁰⁹ Council members responded to concerns surrounding animal welfare and the possible transmission of

diseases by establishing a working party in January 1995. As before, they instructed the working party to formulate proposals that Patrick Nairne hoped would 'be fully considered by the Government'.¹¹⁰ But the government nevertheless convened its own inquiry into xenotransplants in September 1995 and appointed Ian Kennedy, who remained a member of the Nuffield Council, as its chairman.¹¹¹ As before, the *Bulletin of Medical Ethics* noted that the Nuffield Council's report was 'ignored by the government', which based its policies solely on the recommendations of Ian Kennedy's inquiry.¹¹²

Members of the Nuffield Council claimed that independence from government protected it from the political interference and budget constraints that affected other national committees. But it also ensured, as Onora O'Neill remarked, 'that you can't always achieve influence in government departments'.¹¹³ While the guidelines produced by national committees in countries such as the United States and France formed the basis for professional guidelines and sometimes led to new laws, the Nuffield Council's reports influenced politicians indirectly at best and were often ignored.¹¹⁴ This ensured that while the Nuffield Council on Bioethics became known for raising public awareness of certain issues, it was criticised by those who believed that a national committee should have political influence.¹¹⁵ A 1997 editorial in the *Bulletin of Medical Ethics* claimed, for instance, that it was not comparable to national committees elsewhere because 'there remains the problem of whether the government takes notice of its reports'.¹¹⁶

Bioethics under 'New Labour'

The Nuffield Council's limited impact on policymaking ensured that bioethicists continued to have greater authority as members of *ad hoc* public inquiries. This was certainly the case with Ian Kennedy, who had more policy influence as chair of the government's xenotransplants inquiry than as a member or chairman of the Nuffield Council. While Kennedy was frustrated at the Nuffield Council's lack of influence by the mid 1990s, he was also dismayed by the fact that the government only convened inquiries into new procedures such as IVF, gene therapy and xenotransplants, and left the governance of clinical treatment to doctors. This reflected the way in which the Conservative challenge to medical paternalism had 'evaporated' by the late 1980s, following claims that giving patients and outsiders a greater say in medical treatment would 'destabilise' the NHS.¹¹⁷ Medicine continued to be largely self-regulating and the far-reaching 'inspectorate' that Kennedy had championed in his Reith lectures remained conspicuous by its absence.

This, however, looked set to change following the May 1997 election of Tony Blair's 'New Labour' Party. The architects of 'New Labour' based their policies on a strategy known as the 'Third Way', which they used to differentiate themselves from the Conservatives and what Blair called 'the fundamentalist Left'.¹¹⁸ This involved rejecting the leftist assumption that a strong state was a vital component of civil society and the Thatcherite belief that freedom could only be achieved by 'rolling back the state'. Proponents of the 'Third Way' instead argued that a fair and open society could be achieved through an 'enabling' state that incorporated market incentives and encouraged 'partnership' between public services and private enterprise.¹¹⁹ This worldview led New Labour politicians to view some Conservative policies as 'necessary acts of modernization' – including the neo-liberal belief that external oversight was vital to constructing 'responsive public services to meet the needs of citizens, not the convenience of service providers'.¹²⁰

This strategy was perhaps most obvious in medicine, where the new government promised to use what it called 'clinical governance' to construct a 'healthcare service built around the patient'.¹²¹ Its enthusiasm for external oversight and 'empowered consumers' was given impetus by the disclosure of malpractice at Bristol Royal Infirmary in October 1997, which Rudolf Klein claims 'transformed the policy landscape as far as relations between the State and medicine were concerned'.¹²² The case centred on the deaths of twentynine babies and young children between 1984 and 1995, either during or shortly after surgery, which were brought to public attention after a whistleblower contacted *The Times*. A GMC hearing in May 1998 concluded that two surgeons were guilty of operating on children when they knew that death rates were unacceptably high, and also found a hospital manager guilty of failing to act after colleagues had raised concerns.¹²³ These decisions and intense media criticism led the *British Medical Journal* to conclude that the case had irreparably damaged 'the trust that patients place in their doctors'. 'British medicine', it argued, was likely to 'be transformed by the Bristol case.'¹²⁴

During May and June 1998 MPs called for a broad public inquiry that should examine not only the events at Bristol, but 'the appropriateness of professional self-regulation'.¹²⁵ Following these demands, the *British Medical Journal* predicted that New Labour would use the Bristol case to justify ending 'self regulation for doctors'.¹²⁶ Its suspicions were compounded when Frank Dobson, Secretary of State for Health, chose Ian Kennedy as chairman of a public inquiry.¹²⁷ Medical journals reprinted sections of *Unmasking Medicine* and identified Kennedy as a 'critic of vested medical interests', who endorsed oversight as 'an important check on medical standards'.¹²⁸

In many respects, Kennedy was a logical choice to chair the Bristol inquiry. He was a trusted member of the 'Great and Good' by the time New Labour won the general election, having served on several government inquiries into science and medicine. He was well acquainted with Conservative and Labour politicians, and had urged members of the new government to establish a statutory body to represent patients' interests shortly after they came to power.¹²⁹ But while some medical journals dwelt on his support for oversight, others noted that Kennedy had also been 'a good ally' to the medical profession during his time on the GMC, where he had helped doctors with 'difficult decisions and ethical dilemmas'.¹³⁰ Despite his presentation as a 'critic of vested interests', it is more likely that the government chose Kennedy because he provided an intermediary between doctors and politicians.

In addition to Kennedy, the Bristol inquiry included Mavis MacLean, another academic lawyer, as well as the doctor Sir Brian Jarman and Rebecca Howard, director of nursing for Manchester hospitals.¹³¹ Once the inquiry began formal proceedings in March 1999, it was clear that it would be a detailed and wide-ranging exercise, which the *Lancet* described as 'the largest ever independent public investigation into clinical practice'.¹³² It took place in a specially constructed hearing chamber, had a budget of over £14 million, was scheduled to hear from over 500 witnesses and was due to assess over 600,000 pages of documents.¹³³ Its terms of reference, set out by Frank Dobson, were to investigate the care of children undergoing heart surgery at Bristol and then make broad 'recommendations which could help secure high quality care across the NHS'.¹³⁴ Ian Kennedy encapsulated this ambitious remit when he told the *British Medical Journal* that 'we are not seeking to focus on individuals but rather we are looking at the whole system'.¹³⁵

Kennedy later admitted that the 'lacerating' evidence he heard during the Bristol inquiry strengthened his belief that medicine should be 'carefully monitored' by outsiders.¹³⁶ The case for external scrutiny of doctors was strengthened further by events that occurred while the Bristol inquiry was underway, including the 'retained organs scandal', reports that premature babies had been used in clinical trials without parental consent, and the trial and prosecution of the serial-killing doctor Harold Shipman.¹³⁷ Perhaps unsurprisingly, then, demands for external oversight permeated the Bristol inquiry's report when it was published in July 2001. The report, which ran to over 500 pages, began by stating that while staff at Bristol were generally 'dedicated and well motivated', they were nevertheless representative of a paternalistic 'club culture' that fostered an 'imbalance of power' between doctors and patients.¹³⁸ Most of its 198 recommendations were designed to establish 'a new culture for the NHS' in which doctors worked to 'agreed standards, compliance with which is regularly monitored'.¹³⁹ In passages redolent of *Unmasking Medicine*, the report claimed that this could be achieved by implementing 'a system of external surveillance to review patterns of performance over time and to identify good and failing performance'.¹⁴⁰

The report argued that this surveillance should be performed by two new 'overarching bodies', which would 'bring together the various bodies that regulate healthcare' in order to create a 'patient-centred' NHS.¹⁴¹ The first was a 'Council for the Quality of Healthcare' that would incorporate several of the regulatory bodies that the government had established in its first years of office, including the National Institute for Clinical Excellence (NICE) and a Commission for Health Improvement (CHI).¹⁴² The second was a 'Council for the Regulation of Healthcare Professionals', which would absorb bodies such as the GMC and the Nursing and Midwifery Council.

The report argued that these new organisations would 'ensure that there is an integrated and co-ordinated approach to setting standards, monitoring performance, and inspection and validation'.¹⁴³ Tellingly, these plans were similar to the politically funded 'inspectorate' that Kennedy had advocated throughout the 1980s. The Bristol report claimed that the government should 'establish and fund the Councils' and, crucially, that both 'must involve and reflect the interests of patients, the public and healthcare professionals'.¹⁴⁴

The Bristol report also dovetailed with New Labour's own view of a 'patient-centred' NHS. Later in 2001 ministers sought to implement its main proposal when they circulated plans for a new 'Council for the Regulation of Healthcare Professionals'.¹⁴⁵ These plans claimed that the main priority for the new council was to 'explicitly put patients' interests first'.¹⁴⁶ It would be 'open and transparent and allow for robust public scrutiny', and would ensure that professional bodies 'conform to principles of good regulation'.¹⁴⁷ While the Bristol report had proposed that the GMC should be absorbed into the new council, it was saved by reforms that introduced a scheme to regularly check doctors' fitness to practice and increased the proportion of lay members to 40 per cent.¹⁴⁸ These changes indicated that politicians did not share Kennedy's enthusiasm for disbanding the GMC, but they nevertheless argued that it should 'be accountable to a new Council for the Regulation of Healthcare Professionals, and through the Council to Parliament'.¹⁴⁹ The government closed its plans by stressing that the council should 'have a broadly based membership to ensure key stakeholder interests are represented'. This would ensure, it continued, that it 'will be representative of the regulatory bodies, health service and public'.¹⁵⁰

New Labour's plans for 'modernised regulation' here drew wholeheartedly on the Bristol report which, in turn, echoed much of Kennedy's work from the 1980s. As Rudolf Klein notes, once the government outlined plans for a new regulatory council in its 2003 Health and Social Care Act, it appeared that Ian Kennedy's 'vision for regulation was on the way to being achieved'.¹⁵¹ This body, now known as the Commission for Healthcare Audit and Inspection (CHAI), was charged with 'encouraging improvement in the provision of care by and for NHS bodies'.¹⁵² Its main task was to undertake annual reviews of the care provided by each NHS trust, using standards devised by the Department of Health to publish reports and alert ministers to failing trusts.

As part of the government's efforts to reduce the number of regulatory bodies, known as 'rationalization through amalgamation', the CHAI was scheduled to replace or assume the roles of several bodies when it formally became operational in April 2004.¹⁵³ It completely replaced the CHI, 'swallowed up' the National Care Standards Commission, which had been set up to regulate the independent healthcare sector, and took on the Audit Commission's task of assessing value-for-money in the NHS.¹⁵⁴ Given his role as chair of the Bristol inquiry, and his status as what the *Guardian* called 'the expert outsider', few people were surprised when Frank Dobson announced that the CHAI's first chairman was to be Sir Ian Kennedy – recently knighted for his 'services to bioethics'.¹⁵⁵

Following Kennedy's appointment, the *Guardian* presented him as a 'man on a mission' who would use the CHAI to 'champion patients and protect the rights of the vulnerable'.¹⁵⁶ Here, as before, Kennedy promised that the CHAI would 'look at the NHS from the patients' perspective'.¹⁵⁷ He maintained that outside scrutiny of medicine was the best way of ensuring 'social justice and fair and equal treatment for the vulnerable'.¹⁵⁸ One major difference between 2004 and the 1980s, however, was that Kennedy now held a position with considerable influence. This was made clear when the *Guardian* quoted Labour's recently departed Health Secretary, Alan Milburn, as saying: 'Ian Kennedy? He runs the NHS, doesn't he?'¹⁵⁹ Although the *Guardian* noted that this was a private joke, it claimed that others in the NHS and government wondered whether Kennedy was now 'on course to do exactly that'.¹⁶⁰

Kennedy used a guest editorial in the *British Medical Journal* to outline his vision for the CHAI, which showed how his concern with patient rights dovetailed with New Labour's neo-liberal enthusiasm for 'active citizens'.¹⁶¹ Kennedy claimed that 'a better educated population, exposed to the idea of choice and impressed by the language of rights', had ensured that patients 'were no longer passive receivers of goods, but consumers with choices who were entitled to expect good quality and to complain if they were not satisfied'.¹⁶² He argued that this shift ensured doctors alone were no longer 'the best judge of a patient's interests' – with good medical care now incorporating the views of patients, their families and professionals from other fields.¹⁶³ As he did throughout the 1980s, Kennedy stressed that involving others in setting standards was not designed to 'criticise or blame professionals', but would 'help them through the barriers that prevent them seeing patients as interactive partners'.¹⁶⁴ His goal, as set out in the Reith Lectures,¹⁶⁵ was to facilitate 'a subtle negotiation between professional and patient as to what each wants and can deliver'.

Kennedy's proposals were endorsed in the same issue by New Labour's CMO, Liam Donaldson, who claimed that the 'expert patient' had become central to the NHS.¹⁶⁶ Like Kennedy and Labour politicians, Donaldson argued that doctors benefited from treating their patients as consumers or 'experts', since it encouraged them to take responsibility for their own health rather than 'leaving it all to the doctor'.¹⁶⁷ Donaldson reiterated that this neo-liberal view of the 'empowered patient' would foster 'a new era of optimism and opportunity' by improving public trust in doctors and creating 'a new generation of patients who are empowered to take action to improve their health in an unprecedented way'.¹⁶⁸

'A Question of Trust' and the bioethics backlash

But despite the synergy between Kennedy's and the government's views of empowered patients, the CHAI was short-lived and contested. Its brief existence coincided with a backlash against external oversight, as doctors and public figures increasingly turned on the 'audit society'. Senior doctors such as Bruce Charlton, a psychiatrist at the University of Newcastle,¹⁶⁹ began to challenge the assumption that 'increased accountability is self-evidently a desirable goal'.¹⁷⁰ Charlton claimed, by contrast, that 'the meaning behind the accountability mantra is the opposite to that implied by its democratic, egalitarian, radical and "empowering" rhetoric'. He argued that the growing emphasis on accountability and oversight had simply provided a Trojan horse for new professional elites, such as lawyers, philosophers and healthcare managers, to exercise 'hierarchical domination' of doctors.

The 'ideology of accountability' also came under fire, notably from the philosopher and bioethicist Onora O'Neill. Like Kennedy, O'Neill had encountered bioethics while working in the United States during the 1970s, and was also a founding member of the Nuffield Council on Bioethics. But she held markedly differing views on the merits and

consequences of external oversight. This was clear from her 2002 Reith Lectures, entitled *A Question of Trust*, which offered a telling contrast to *Unmasking Medicine*. In her third lecture, O'Neill questioned the widespread belief that public trust could be improved through external forms of audit and regulation. She argued that externally imposed standards were 'surrogates' for professional actions, and prevented members of a profession from 'pursuing the intrinsic requirements for being good nurses and teachers, good doctors and police officers, good lecturers and social workers'.¹⁷¹ The pursuit of 'ever more perfect accountability', O'Neill concluded, had damaged rather than repaired public trust and created a 'culture of suspicion and low morale'.¹⁷²

While her Reith Lectures did not focus on specific examples, O'Neill targeted bioethics in a series of lectures at the University of Edinburgh, which were published in 2002 as *Autonomy and Trust in Bioethics*. She claimed here that:

Although the decades since the beginning of contemporary bioethics have seen a lot of effort to improve the trustworthiness of public institutions and of experts, culminating in the UK in the additional demands for accountability, audit and openness of the 1990s, this is quite compatible with a decline in public trust, and specifically with a decline of public trust in medicine, science and biotechnology.¹⁷³

O'Neill argued that bioethicists' efforts 'to improve trustworthiness' by calling for increased oversight of animal research, gene therapy and reproductive medicine had consistently failed to work.¹⁷⁴ She outlined how newspapers continued to voice unease at embryo research and gene therapy and, more seriously, how opponents of animal experiments continued to engage in 'intimidation, criminal trespass, vandalism and even terrorism'.¹⁷⁵

O'Neill believed that the authority of bioethicists was undermined by the fact that professional or social status no longer guaranteed public trust.¹⁷⁶ She argued that like their colleagues in medicine, science and politics, bioethicists could no longer rely on a place among the 'Great and Good' for their arguments to be accepted. O'Neill even claimed that bioethicists had probably damaged trust themselves, by presenting scientists and doctors as untrustworthy figures 'who pursue their own interests rather than those of patients and the public'.¹⁷⁷ She argued that their demands for increased regulation and public accountability led 'not to a restoration of trust but to claims of escalating mistrust', and caused suspicion to be 'directed inaccurately in trustworthy persons and institutions'.¹⁷⁸

O'Neill specifically claimed that the bioethical emphasis on 'empowered consumers' played a major role in escalating mistrust, by encouraging 'ethically questionable forms of individualism' and marginalising the other principles and duties that were vital to restoring confidence in professions.¹⁷⁹ 'We need', she stated, 'to identify more convincing patterns of ethical reasoning, and more convincing ways of choosing policies and action for medical practice and dealing with advances in the life science and biotechnology'.¹⁸⁰ O'Neill believed that the remedy to mistrust lay in focusing more on responsibilities instead of rights, and replacing an individualistic worldview with 'one that takes relationships as central'.¹⁸¹ She argued that this shift to a more 'principled autonomy' would provide stronger 'reasons for seeking to establish, maintain and respect trustworthy institutions and relationships'.¹⁸² This led O'Neill to conclude that encouraging doctors to be more open, asserting the obligations and duties involved in medical care or research, was a far better guarantee of public trust than simply imposing 'an audit trail'.¹⁸³

O'Neill's position differed markedly from that of Ian Kennedy, who steadfastly believed in the value of oversight and viewed 'the language of rights' as fundamental to bioethics.¹⁸⁴ But despite Kennedy's faith in 'external scrutiny', O'Neill's claims resonated with now regular criticism of the CHAI.¹⁸⁵ In a long open letter to Kennedy, Richard Horton, editor of the *Lancet*, argued that the CHAI's labelling of certain hospitals as 'poor' and 'underperforming' was 'likely to undermine public confidence in a health system that enjoys an unparalleled commitment from its doctors, nurses and allied health workers'.¹⁸⁶ Horton echoed O'Neill's work when he stated that the CHAI was damaging patient care by introducing 'an environment of prejudice, anxiety and resignation into the workplace'.¹⁸⁷ He claimed that this could only be rectified by giving the CHAI's ratings 'scientific rigour' and increasing the number of commissioners with 'daily responsibilities for front-line patient care'.¹⁸⁸

Kennedy responded that the 'current system of ratings performance has undoubtedly produced beneficial effects for patients' and reminded Horton that performance indicators were set by the government, not the CHAI.¹⁸⁹ He also dismissed Horton's belief that 'if there is a regulatory mechanism established by Parliament to monitor the performance of the NHS only healthcare professionals can operate it'. 'For real accountability', Kennedy countered, 'Horton must recognise that the voices of others, not least patients and the public, must be heard'.¹⁹⁰

But despite Kennedy's regular protests, doctors continued to argue that the CHAI was demoralising NHS workers and damaging patient care. Perhaps more significantly, it also came under fire from politicians and provided a scapegoat

when poor medical conduct was exposed. Following an outbreak of *Clostridium difficile* at the Maidstone and Tunbridge Wells NHS trust in 2007, which caused the death of ninety patients,¹⁹¹ the Health Secretary Alan Johnson criticised the CHAI for being 'slow to act' in identifying potential problems.¹⁹¹ Labour politicians remained eager to reduce the number of regulatory bodies, which was apparent when they merged the ACGT and the HGAC into a new Human Genetics Commission (HGC), and claimed that the CHAI's failings were symptomatic of a 'burdensome' regulatory sector.¹⁹² When the government announced plans to replace the CHAI and other health inspectorates with a single Care Quality Commission in 2008, Kennedy bemoaned the increasing tendency to see external oversight 'as part of the problem rather than part of the solution'.¹⁹³

This complaint could just as well have been aimed at a new generation of bioethicists, who argued that the field was undergoing 'something of a mid-life crisis'.¹⁹⁴ Angus Dawson, for one, claimed that bioethics had 'become stale and tedious' thanks to a preoccupation with 'a consumerist model of the professional-client relationship'.¹⁹⁵ Like O'Neill, Dawson argued that the 'unthinking consensus view that autonomy is the dominant value' may 'impact in a negative way' on healthcare, by ignoring evidence that suggested that patients did not necessarily want to be seen as empowered consumers but rather wanted 'to be able to trust their doctor, seeking not just *information* but *help* with sometimes complex decisions'.¹⁹⁶

Dawson claimed that bioethics could be revitalised by attending to the 'social reality of the doctor-patient relationship', which would encourage bioethicists to acknowledge the importance of values such as reciprocity and community, and appreciate that 'some forms of paternalism may be justified'.¹⁹⁷ These new arguments suggest that bioethics is already changing in a new public and political climate, and force us to reassess its history. We may well come to see the 1980s and 1990s not simply as the beginnings of bioethics in Britain, but as the high-water mark of an early incarnation: when the emphasis on oversight, public accountability and rights complemented widespread demands for audit and consumer choice.

Conclusion

Just as in the United States, where various presidents have established or closed national commissions, and staffed them with politically sympathetic figures, the debates surrounding a British ethics committee again show how bioethics is shaped by social and political factors.¹⁹⁸ The failure to establish a national bioethics committee during the 1980s stemmed partly from medical resistance but also, critically, from the government's belief that it would 'politicise' bioethics. But the continued absence of a politically sponsored national committee did not limit the opportunities for bioethicists to assist in policymaking. The government's continued preference for *ad hoc* committees on issues such as IVF, gene therapy and xenotransplants, and the subsequent creation of advisory bodies such as the HFEA, provided greater scope for official bioethics than would have arisen through a single national council. If anything, then, we might conclude that the continued growth of the 'ethics industry' during the 1980s and 1990s, which comprised several advisory bodies and the independent Nuffield Council, was due in no small part to the *absence* of a national ethics committee.

In not looking at clinical treatment, the Nuffield Council highlights how bioethics in Britain tended to examine questions raised by new biomedical technologies and neglected those issues that impact more on the day-to-day lives of patients. Yet while some criticised the Nuffield Council for not scrutinising medical care, this position was, in fact, a precondition of its establishment. As David Shapiro noted in a 1990 letter to the medical lawyer Jonathan Montgomery, transgressing on the work of bodies such as the GMC and BMA would undoubtedly have led them to oppose the council's formation. 'Our nascent body may seem a small infant', Shapiro wrote, '[and] we have to avoid at least one attempt at abortion.'¹⁹⁹

When bodies such as the CHAI did begin to monitor clinical treatment following the Bristol inquiry, sustained medical resistance and a political desire to reduce the number of 'arm's-length' bodies ensured that they were contested and ultimately short-lived. The fact that growing opposition to the 'ideology of accountability' also came from Onora O'Neill reaffirms that bioethics is not a unified field that stands apart from medicine or politics. It is, rather, a diverse set of participants and ideas whose scope and influence are constituted, and renegotiated, through relations with other disciplines and their broader sociopolitical climate.

Footnotes

- 1 Lock Stephen. Towards a National Bioethics Committee. Wanted: A New Strategic Body to Deal with Broad Issues. *British Medical Journal*. 1990;Vol. 300:1149–1150. [PMC free article: PMC1662938] [PubMed: 2346799]

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- 7 Kennedy, interview with the author (2010). See also Capron. Looking Back at the President's Commission.
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- 12 Kennedy Ian. Kennedy. Treat Me Right. *Emerging Problems in Science, Technology and Medicine*; pp. 17-18. See also Kennedy. *Unmasking Medicine*. :122-123.
- 13 Kennedy. *Emerging Problems*. :18.
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- 16 Kennedy. *Emerging Problems*. :17.
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- 29 Malcolm Godfrey to J. A. D. Cropp, 26 November 1985. National Archives: FD 7/3273.
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- 32 *Ibid*.
- 33 *Ibid*.
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- 36 Godfrey. Note for File.
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- 39 Swedish Department of Social Affairs. Appointment to the Board on Medical/Ethical Questions. 1985 March 14; National Archives: FD 7/2209. Documents sent to the MRC by the French Institute for Medical Research (INSERM) detailed how its national committee's 'recommendations have no binding [*sic*] but are made known through the Secretaries of State for Research and for Health and widely circulated to the public'. Anon. National Advisory Ethics Committee for the Life Sciences and Health. 1985 National Archives: FD 7/2209. See also Ambroselli Claire. France: A National Committee Debates the Issues. Hastings Center Report. 1984;Vol. 14:20–21. [PubMed: 6511372]
- 40 Malcolm Godfrey to Sir James Gowans, 'British Medical Association and Ethical Committees', 7 March 1985. National Archives: FD 7/3273.
- 41 Godfrey. Meeting with Dr Havard and Dr Dawson.
- 42 Lewis John. A Commons Subcommittee on Medical Ethics? Lancet. 1988;Vol. 331:1005. [PubMed: 11644348] The case for linking any committee to government was further hampered by the fate of the President's Commission, which had been disbanded in 1983 following cuts in federal funding. Senators Edward Kennedy and Al Gore eventually persuaded Congress to create a new bioethics commission in 1986, despite an attempted veto by President Reagan. See Anon. Congress Overrides Veto to Create New Bioethics Commission. The Hastings Center Report. 1986;Vol. 16:2. [PubMed: 11643919] This resulted in the formation in 1988 of a Biomedical Ethical Advisory Committee, which did not issue any reports and was disbanded by President George Bush Sr in 1990.
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- 46 Ibid. Emphasis added.
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- 53 Kennedy Ian. Call for Guidance on Medical Ethics. The Times. 1987 June 13;:15.
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- 66 Taylor. Letters to the Editor. :395.
- 67 Rt Hon. Sir David Price, quoted in *Parliamentary Debates: House of Commons*, Vol. 140 (10 November 1988) col. 254.
- 68 Rt Hon. Margaret Thatcher, quoted in *Parliamentary Debates: House of Commons*, Vol. 140 (10 November 1988) col. 255.
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- 70 Lewis. A Commons Subcommittee on Medical Ethics? [PubMed: 11644348]
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- 77 Kennedy, interview with the author (2010). Weatherhall’s role was acknowledged in a brief history of the Nuffield Council on Bioethics. See Kennedy Ian. *Nuffield Council on Bioethics: 1992–99*. London: Nuffield Council on Bioethics; 2000. Foreword; p. 3.
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- 83 Anon. Nuffield Foundation Conference on Bioethics. *The Need for a New Bioethics Body*. :3.
- 84 Ibid. See also Anon. National Ethics Committee Comes a Step Closer. :4.
- 85 O’Neill, interview with the author (2009); Shapiro. Nuffield Council on Bioethics. :263.
- 86 Anon. *The Need for a New Bioethics Body*. :3. Emphasis in original. O’Neill, interview with the author (2009); Anon. Editorial. *Bulletin of Medical Ethics*. 1990 August;(no. 61):1.
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- 89 Anon. Nuffield Council Starts Work. *Bulletin of Medical Ethics*. 1991 August;(no. 73):3–4. (p. 4).
- 90 Shapiro. Nuffield Council on Bioethics. :264.
- 91 David Shapiro, permanent secretary to the Nuffield Council on Bioethics, quoted in Vines Gail. *Research Ethics Face National Scrutiny*. *New Scientist*. 1991 March 2;:14. As Sheila Jasanoff notes, the Nuffield Foundation believed that the council would in time rely less on the reputation of its members, with authority stemming more from the quality of its reports and public consultation exercises. See Jasanoff. *Designs on Nature*. :186–187.
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- 106 O'Neill, interview with the author (2009). In addition to being a council member, O'Neill served as a member of the working party that wrote the *Human Tissue* report. See O'Neill Onora. Medical and Scientific Uses of Human Tissue. *Journal of Medical Ethics*. 1996;Vol. 22:2–7.
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- 109 Xenotransplantation was by no means a new procedure. It was the subject of professional and popular interest in the early twentieth century, thanks to tissue and gland grafting, and prompted considerable debates in the 1960s following unsuccessful attempts to transplant chimpanzee hearts into humans. For more on these earlier debates, see Nathoo. Hearts Exposed. Lederer Susan. *Flesh and Blood: Organ Transplantation and Blood Transfusion in Twentieth-Century America*. Oxford: Oxford University Press; 2008.
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- 117 Salter. *The New Politics of Medicine*. :58.

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- 119 Ibid, pp. 189–190.
- 120 Tony Blair, quoted in Ibid, p. 190. See also Marinetto Michael. Who Wants to be an Active Citizen? The Politics and Practice of Community Involvement. *Sociology*. 2003;Vol. 37:103–120.
- 121 Salter. *The New Politics of Medicine*. :59. see also Klein. *The New Politics of the NHS*. :188–205.
- 122 Klein. *The New Politics of the NHS*. :198.
- 123 Salter. *The New Politics of Medicine*. :123–124.
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- 126 Ibid, p. 1918; Klein. *The New Politics of the NHS*. :230.
- 127 Warden John. High Powered Inquiry into Bristol Deaths. *British Medical Journal*. 1998;Vol. 316:1925.
- 128 Anon. Long-Time Critic of Vested Medical Interests. *Health Service Journal*. 1999 July 8; Accessed online at <http://www.hsj.co.uk/long-time-critic-of-vested-medical-interests/30416.article> (accessed 14 February 2014).
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- 130 Anon. Long-Time Critic of Vested Medical Interests. Kennedy served as a member of the GMC between 1984 and 1993.
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- 135 Ian Kennedy, quoted in Ferriman, ‘Bristol Inquiry Appoints Doctor’, p. 283.
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- 138 Ian Kennedy (chair), *The Report of the Public Inquiry into Children’s Heart Surgery at Bristol Royal Infirmary, 1984–1995: Learning from Bristol*. London: HMSO; 2001. pp. 1–2.
- 139 Ibid, p. 435.
- 140 Ibid, p. 3.
- 141 Ibid, pp. 442, 452.
- 142 Ibid. For more on the establishment of NICE, the CHI and other regulatory bodies under New Labour, see Klein. *The New Politics of the NHS*. :199–200. , 232–2.
- 143 Ian Kennedy (chair), *Learning from Bristol*. :442.
- 144 Ibid, p. 443.
- 145 *Modernising Regulation in the Healthcare Professions: Consultation Document*. London: Department of Health; 2001. Department of Health; p. 4.
- 146 Ibid.
- 147 Ibid.
- 148 Hunter Mark. GMC Agrees New Structure. *British Medical Journal*. 2001;Vol. 323:250. [PMC free article: PMC1120877] [PubMed:

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- 149 Department of Health. Modernising Regulation. :4.
- 150 Ibid, p. 9. Emphasis in original.
- 151 Klein. The New Politics of the NHS. :231. Indeed, the consultation document only differed from the Bristol plans in one or two areas. Ministers did not believe that the GMC and other bodies should be absorbed into the new council; and they also believed that standards for doctors should be set by the Department of Health, not the new council, whose job would be to ensure that these standards were adhered to. Thanks to New Labour's drive to shrink the regulatory sector in its second term, ministers were also prepared to create only one of the two 'overarching bodies' outlined in the Bristol report.
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- 153 Klein. The New Politics of the NHS. :231.
- 154 Ibid. See also Anon. In Brief. British Medical Journal. 2003;326:464. [[PMC free article: PMC1125365](#)] [[PubMed: 12609922](#)]
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- 166 Donaldson Liam. Expert Patients Usher in a New Era of Opportunity for the NHS. British Medical Journal. 2003;Vol. 326:1279. [[PMC free article: PMC1126164](#)] [[PubMed: 12805129](#)]
- 167 Ibid.
- 168 Ibid. See also Kennedy. Patients are Experts. Kennedy. The Patient on the Clapham Omnibus. :446–447.
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- 170 Charlton. The Ideology of Accountability. :33. [[PubMed: 10192067](#)]
- 171 O'Neill Onora. A Question of Trust. Cambridge: Cambridge University Press; 2002. p. 56.
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- 173 O'Neill. Autonomy and Trust in Bioethics. :137.
- 174 Ibid, p. 139.
- 175 Ibid, p. 138.
- 176 Ibid, pp. 139–40.
- 177 Ibid, p. 3.
- 178 Ibid, pp. 144, 141.
- 179 Ibid, p. 73.
- 180 Ibid.

- 181 O'Neill. A Question of Trust. :83. Emphasis in original.
- 182 Although individual autonomy remained a component of 'principled autonomy', O'Neill argued that it should only be 'one minor aspect'. See Ibid, p. 97.
- 183 Ibid, p. 158.
- 184 See, for example, Kennedy. Preface. :vii. See also Kennedy Ian. Kennedy. Treat Me Right. Doctors, Patients and Human Rights; pp. 385–415.
- 185 Kennedy. Consumerism in the Doctor–Patient Relationship. :777.
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- 188 Ibid.
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- 190 Ibid.
- 191 Santry Charlotte. Healthcare Regulator Longed for Government's Embrace. Health Service Journal. 2008 November 12; , available online at www.hsj.co.uk (accessed 6 February 2014).
- 192 Santry Charlotte. Sir Ian Kennedy Champions "Fearless" NHS Regulator. Health Service Journal. 2009 November 12; Available online at www.hsj.co.uk (accessed 14 February 2014).
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