Holding back the tide: Hyper-politicization and ministerial reactions to the Herceptin Postcode Lottery Crisis

Matthew Wood

University of Sheffield Department of Politics, m.wood@sheffield.ac.uk

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Abstract

This paper argues that the literature on depoliticisation focuses too much on depoliticisation as a strategy of enhancing executive power, and not enough on how politicisation from *outside* the state impacts upon depoliticised policy spheres. Using an in-depth case study of the controversial appraisal of cancer drug Herceptin in 2005/6 by the National Institute for Health and Clinical Excellence (NICE), the paper deploys a distinctive analytical framework using three concepts of politicisation (discursive, societal and governmental) to examine how 'resilient' NICE was to external politicisation. It is argued that NICE was resilient because it was effectively 'insulated' by a form of 'institutional double glazing'. The conclusion suggests new research questions and a research agenda for examining the interaction between different processes of politicisation in a range of policy contexts, and points towards broader lessons for executive governance.

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The 'hollowing out' or evisceration of the core executive (Rhodes, 1997), declining political participation (Norris, 2011) and the supposed 'triumph' of neoliberalism in many advanced liberal democracies (Bourdieu, 2003) has led several scholars to adopt the concept of 'depoliticisation' (Roberts, 2010; Krippner, 2011). This concept describes attempts by politicians to place 'at one remove the political character of decision making' and hence retain arm's length control of decision making whilst simultaneously foregoing responsibility for policy failures or unpopular reforms (Burnham, 2001). This paper argues that although this literature has identified an important process in modern democracies, it ignores the impact of important counter-trends of *politicisation* occurring more widely within society (Moran, 2003). A key question for executive politics, it is suggested, relates to understanding how depoliticised (delegated) bodies can be *resilient* to an increasingly aggressive media and demanding public (Flinders, 2011). In order to do so, the paper breaks from existing research on depoliticisation, and its distinctive contribution is in examining the impact of *politicisation on the state* rather than the impact of *depoliticisation on society*.

Using an in-depth case study of the controversial appraisal process of Herceptin, a new biomedical drug, for early-stage HER2-positive breast cancer in 2005/6 under the British New Labour government, the paper deploys a new analytical framework based upon the operationalization of Hay's (2007) heuristic model of society-wide politicisation processes (labelled 'discursive', 'societal' and 'governmental' politicisation). It argues that the National Institute for Health and Clinical Excellence (NICE) (the 'depoliticised' body responsible for appraising Herceptin for free distribution on the National Health Service), was resilient to external pressure for ministerial intervention to approve the drug immediately, because its highly formalised and devolved decision making processes created a form of 'institutional double glazing' that protected against ministerial intervention. The study utilises a range of qualitative and quantitative empirical data gathered from semi-structured elite interviews,[1] document analysis, media coverage, parliamentary debates and a freedom of information request.

This paper is divided into six sections. The first section briefly provides a critical review of the depoliticisation literature, before the second focuses on operationalizing Hay's (2007) model. The third section introduces the Herceptin case before the fourth and fifth sections examine in detail increasing 'societal' and 'discursive' politicisation during the Herceptin crisis, and ministerial reactions within the governmental sphere. The sixth section then seeks to explain why NICE was resilient to political pressure, emphasising 'institutional double glazing'. The conclusion then argues for further research on the interrelationship between politicisation dynamics and depoliticised governance arrangements, as well as suggesting the wider implications for institutional design and executive politics in the twenty-first century.

[1] Interviews were conducted with 16 elite actors during the period of the appraisal, including senior NICE officials, former ministers, MPs, and important figures from pressure groups, media and the pharmaceutical industry. Responses have been anonymised so as to protect the identities of the interviewees.

Depoliticisation, Executive Politics and Governance

Academic work using the concept of 'depoliticisation' has blossomed in recent years, particularly in relation to governance and executive politics (Burnham, 2001; Buller and Flinders, 2005; Kettell, 2008; Newman, 2009; James, 2010). Depoliticisation, as defined by authors in this body of literature, is 'the range of tools, mechanisms and institutions through which politicians can attempt to move to an indirect governing relationship and/or seek to persuade the demos that they can no longer be reasonably held responsible for a certain issue, policy field or decision' (Flinders and Buller, 2006, pp.295-296). Examples here include delegation, institutionalising rules into policymaking or 'no alternative' arguments (Flinders and Buller, 2006). The key emphasis here is on the persistence of hierarchical power relations, even when it *appears* as if the core executive has lost power, since ministers retain arm's length control and shift blame for unpopular policies (Burnham, 2001, pp.128-129). Such an argument ties in with a range of 'critical' approaches to governance networks (Jessop, 2003; Sørensen, 2006; Bell and Hindmoor, 2009; Davies, 2011) and has inspired a wellspring of empirical research (Kettell, 2008; Rogers, 2009; James, 2010; Beveridge, 2012).

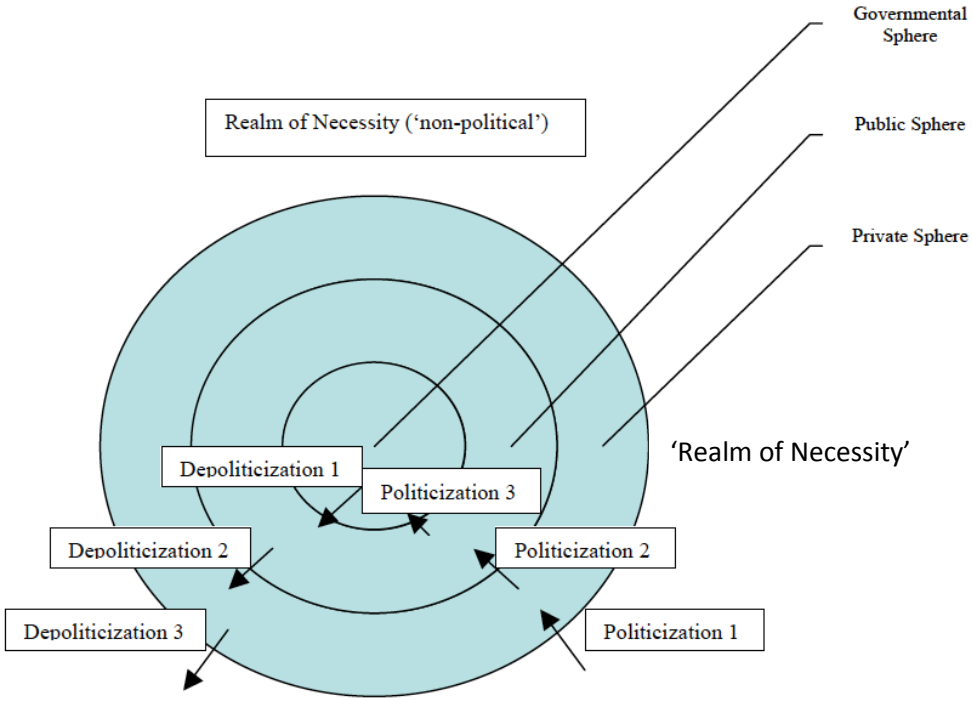
Yet, despite the welcome emphasis on power, this approach does have weaknesses, most importantly the assumption that depoliticisation is uncontested. It is often assumed that depoliticisation is an all-pervasive aspect of modern governance, and that this should form the fulcrum of scholarly enquiry (Boggs, 2000). Against this, it could be argued that the converse process to depoliticisation – *politicisation* – is actually more prevalent within contemporary societies, and thus presents a more pressing subject of enquiry. Smith (2011, p.181), for instance, argues that 'in Britain … ministers are expected to act and to do something. Policy … is often led by demand, not supply, with ministers responding to … public and media pressure'. Other authors have emphasised the prevalence of crises in which 'citizens look at their leaders … (and) expect these policy makers to avert the threat or at least minimise the damage of the crisis at hand' (Boin *et al.*, 2005, p.1) or the rise of 'pavlovian' responses to policy fiascos in which politicians feel the need to be seen to be doing something to placate media and public pressure (Lodge and Hood, 2002).

Moran (2003) even suggests that the creation of independent agencies actually creates a paradoxical form of *hyper-politicization*, where 'hyper-innovation' or attempts at improving transparency and coordination within the state, has in turn has led to 'the quango world (being) drawn inexorably into an increasingly open, partisan and juridified world' (Moran, 2003, p.139). The key point is that far from the desire to appear constrained whilst exercising greater power, it is the imperative to be seen as powerful or 'in control' whilst simultaneously being faced with a barrage of unrealistic demands for accountability from the electorate and the media that is as important a contradiction in contemporary executive politics (Flinders, 2011). A key point of this paper, then, is to examine how politicisation from *outside the state* impacts upon depoliticised policy spheres, thus examining 'the broader relationship *between* depoliticising and politicising dynamics' (Jenkins, 2011, p.158). These wider processes are precisely those stipulated by Hay (2007) in his heuristic model of (de)politicisation processes, which forms the focus of the following section.

Operationalizing the Hay Model

Colin Hay's (2007) influential book *Why We Hate Politics* provides an innocative heuristic conceptualisation of politicisation *and* depoliticisation processes operating across several spheres of the political and non-political realm. Figure 1 (below) sets out this conceptualisation.

Figure 1: Hay's (2007) Heuristic Model of Politicisation/Depoliticisation



Source: Hay, 2007, p.80

Politicization 1 refers to movements from the 'realm of necessity' where fate rules and there is no capacity for human action to the private realm as practical developments (new technology for instance) extend the capacity of humans to govern their environment. Politicization 2, movement from 'private' to 'public' realm occurs when an issue gains public acknowledgement as a salient issue of collective concern through, for instance, a public campaign. Politicization 3 then occurs when this issue becomes of legislative interest to the state and it becomes the responsibility of central departments.

The downside of this model is that it is, precisely, a heuristic model and therefore difficult to operationalize empirically. However, this task is made easier if we delimit the definition of these concepts to refer to specific, empirically identifiable social processes. So, 'Politicization 1' may be re-labelled 'discursive politicisation', as it essentially captures rhetorical attempts to make what appeared unchangeable social 'facts' contestable and a subject for public discourse. Hence, we might define 'discursive politicisation' empirically as the process

through which the governance of a particular social issue is *problematized* in societal discourse. This means that the way in which an issue is governed, for example, through the market, is seen to be problematic because new technological developments have generated problems with existing service provision and alternative approaches seem more desirable. Empirically, we may determine whether discursive politicisation is occurring by examining public and policy discourse (Hajer and Wagenaar, 2003; Fischer, 2003) for evidence of whether there is a critical assessment of existing governance practices, and proposals for alternative arrangements.

Second, we may re-label 'politicization 2' as 'societal politicisation', which captures the sense of an issue becoming an advanced topic of public debate. Hence, societal politicisation can be defined as the process through which the governance of a particular social issue is *publicized* in societal discourse. This is demonstrated by a social issue becoming a *salient* topic of public debate in media reports, online forums, radio or television programmes, legal challenges and parliamentary debates (De Wilde, 2011). The emergence of broad issue networks to replace limited policy communities (Marsh and Rhodes, 1992), engagement of pressure groups and prominence of advocacy coalitions (Sabatier and Jenkins-Smith, 1993), may also be included as evidence here.

Finally, 'Politicization 3' may be re-labelled 'governmental politicisation' as it connects with the central concern of the depoliticisation literature relating to the control and management of governance issues by the executive.[2] Governmental politicisation can hence be defined as the process through which the governance of a social issue is *conducted* predominantly by the central state. This means that the autonomy of a depoliticised body is decreased, or there is greater central coordination of an ostensibly decentralised governance network. Such a definition clearly translates empirically into the examination of levels of 'autonomy' of regulatory bodies and delegated organisations (Verhoest *et al*., 2004). However, given that the concepts of politicisation and depoliticisation tend to infer a more 'informal' notion of power (Flinders and Buller, 2006), they tend to apply more distinctively to the 'de facto' autonomy of quasi-governmental bodies (Maggetti, 2007) than to more formal legal and administrative arrangements (Gilardi, 2008). Hence, empirical assessment of autonomy will be based more upon examination of semi-structured elite interviews and data concerning communication between central department and delegated body (Maggetti, 2007), than on formal or legal rules (though these may, as we shall see, have a big effect on whether such autonomy increases or decreases).

The discussion above demarcates Hay's concepts of politicisation as relating to clear, empirically identifiable processes that involve the *problematisation* and/or *publicisation* of social issues, and the extent to which the governance of those issues is *controlled* by the executive. We are now in a place to examine how these processes interact in a particular case

[2] This paper limits the definition of governmental politicisation to control and delegation by the executive in order to gain analytical purchase on the concept. This definition ignores Hay's (2007) association of 'Politicization 3' with parliamentary debate and the movement of legislation as it is assumed that this process is better encompassed within societal politicisation, since it relates to debate and discourse in the public (albeit nominally 'state') sphere.

study of the Herceptin post-code lottery crisis during the British New Labour government, with a focus on how ministers dealt with external pressure to 'politicise' an ostensibly 'depoliticised' governance process. This may allow for a greater understanding of how resilient depoliticised institutions and procedures are to (societal and discursive) politicisation from outside the state.

NICE and the Herceptin Post-code Lottery Crisis

The regulation of new 'health technologies' (drugs, medicines, treatments, etc.) 'in a number of ways epitomises many of the features of the late-modern British regulatory state' (Brown and Calnan, 2011, p.1). In 1999 under New Labour, The National Institute for Health and Clinical Excellent (NICE) was established by Health Secretary Frank Dobson to take decision making power over the funding of drugs for free prescription on the National Health Service (NHS) away from politicians, and end the 'post-code lottery' for drugs in which only wealthy Primary Care Trusts (PCTs) could fund expensive treatments. NICE was 'intended to ensure that the lottery system under which certain treatments and drugs are available in one part of the country but not another is changed' (HoC Deb, 18 Jan 1999, 323: 592-594). NICE was hence established as a highly technocratic and devolved body, with 'considerable control over its own organization and rules of procedure' (Landwehr and Böhm, 2011, p.681). This is especially true of NICE's technology appraisal process, which is carried out in a tightly structured manner with little input from ministers over a long period up to two years (Milewa and Barry, 2005, p.506). This process can be neatly (though somewhat crudely) reduced to six bullet-pointed stages:

1. The European Medicines Agency (EMEA) licenses a 'technology' for distribution around Europe.
2. The Department of Health (DH) consults NICE and other groups, and then refers the technology to NICE for appraisal.
3. NICE identifies and consults with the policy community, produces an appraisal scope/timeline and appoints a (university-based) Technology Assessment Group (TAG).
4. The TAG writes an evaluation report of the technology's effectiveness using the methodology of cost-per Quality-Adjusted Life Years (QALYs).
5. A Technology Appraisal Committee (TAC) comprised of practitioners from outside NICE receives evidence from the TAG and submissions from other consultees (including DH) and produces an Appraisal Consultation Document (ACD)
6. The ACD is circulated around consultees for comments and a Final Appraisal Document is then sent to NICE's Guidance Executive for approval. PCTs have a short window for appeal but must then implement guidance within 3 months (see NICE, 2001; NICE, 2004a).

This process leaves little room for central intervention by ministers, with their only direct role being to delegate the initial decision (a decision which itself is usually advised on by NICE). It can hence be argued that NICE is a good example of a 'depoliticized' institution with little or no input from central government (Syrett, 2003, p.728). Yet, the area of health technology appraisal is hardly uncontroversial, and somewhat paradoxically the rise of NICE also led to 'new layers of subjectivity and policy meddling' (Brown and Calnan, 2011, p.2; cf. Klein and Sturm, 2002) as 'NICE … politicized questions of priority setting and rationing' by making issues of rationing an 'explicit' national task as opposed to an 'implicit' local task (Landwehr and Böhm, 2011, p.680). Moran (2003, p.141) argues that this is a clear example of 'hyper-politicization' – 'the breakdown of the old doctor-dominated systems of control, and the translation of rationing issues into increasingly open political argument'. This policy area hence presents a good opportunity for a case study – depoliticised decision making in a politicised societal context – and this is particularly pertinent in the case of Herceptin itself.

Herceptin (medical name 'trastuzumab') was a prominent example of a 'targeted' biomedical drug, a new breed of drugs developed in the 1980s-90s which 'provide the link between an individual's molecular and clinical profiles … allowing patients the opportunity to make informed and directed lifestyle decisions' – thus 'personalizing' the medical process (Ginsburg and McCarthy, 2001, p.491). Herceptin targeted a particular form of breast cancer – 'HER2-positive' (Petersen, 2006, p.485), which involves the faster growth of tumours and a more aggressive form of the disease. The average survival time after diagnosis for HER2-positive patients (about 20% of all cases) was approximated in 2002 to be as little as 9 months (NICE, 2002, p.2). While Herceptin had previously been recommended by NICE in 2002 for patients at the later stages of the disease, before May 2005 it had not been approved for patients at earlier stages.

However, in May 2005 new findings were announced from the Herceptin Adjuvant (HERA) trial into Herceptin's 'early stage' effects. International pharmaceutical distributor Roche claimed the drug had potentially radical, even curative effects, most significantly a 50% reduction in return of the cancer after early stage treatment. This amounted to 'the first evidence that Herceptin had the potential to reduce the risk of cancer coming back at an early stage and to prolong life for women with this aggressive form of the disease' (Roche, 2005a). Hence, although doubts persisted within the medical community over its impact upon patients with previous heart problems (Keidan, 2007) Herceptin came into public view not only as a new and effective treatment where previously there was none, but as a potentially curative treatment to an aggressive and debilitating form of breast cancer that could be given to patients with a high probability of success. As one interviewee stated:

> 'Why is Herceptin interesting? Well, because it was the first of a new type of treatment that was produced so that it was a targeted therapy. You didn't have to treat all patients, you could identify which patients would do well … the response was dramatic'

As of May 2005, however, the EMEA had not licensed Herceptin for the European market, and hence NICE could not begin its appraisal process. In the absence of guidance, PCTs were

left to make decisions based on clinicians' advice and financial viability on whether they were willing to fund individual cases. This, perhaps inevitably, led to geographical disparities in the provision of Herceptin, and hence a 'postcode lottery'. Given that the '(elimination of the) post-code lottery of care was according to political pronouncements the raison d'etre for the establishment of NICE', this presented an acute predicament (Littlejohns, 2001, p.40). In theory, Herceptin was just one example of a systemic problem which gained the moniker 'NICE blight' or 'the delay between product launch and availability of NICE guidance' (Barham, 2008, p.1037). However, several interviewees noted that the case of Herceptin is widely considered 'exceptional' or 'defining' due to the extent of political and media interest. In this case, we saw the explosion of an 'institutional crisis' in which NICE's processes were brought into question, and ministers were under substantial pressure to intervene in the appraisal process. The next section examines the empirical evidence for societal and discursive politicisation, going through the key stages of media and public pressure.

Playing out the post-code lottery: Societal and discursive politicisation

The Herceptin post-code lottery crisis was played out in the public sphere from roughly 19 May 2005 when Roche first presented evidence to the American Society of Clinical Oncologists' (ASCO) Conference, up until the final NICE appraisal was released on 23 August 2006. There were three key periods: 'crisis emergence', 'crisis peak' and 'crisis diffusion'.

1. *Crisis emergence*

In the first period Roche's high profile presentation of the HERA trial findings at the ASCO Conference initiated an international clamour for access to Herceptin. As one former employee in the pharmaceutical industry recounted:

> "It was a very emotional period; people were astounded that the results were better than anyone had ever anticipated. That got reported by the press in the UK as it did in every country in the world that this was the breakthrough cancer that for the first time had shown these dramatic results, and patients wanted to get hold of it".

The presentation created an almost euphoric atmosphere, which generated significant positive media interest. Whereas only 13 Herceptin articles had been published in national newspapers since November 2003, May 2005 produced 10 articles alone, all of which had a positive slant towards Herceptin. Importantly, the first 'case study' of a patient, Barbara Clark, who was eligible for Herceptin but denied treatment by North Somerset PCT was also highlighted (BBC News, 8 June 2005) and raised by her MP in parliament (HoC Deb, 30 June 2005, 435: 1543). Already, there was pressure to conform to international trends and circumvent existing regulatory processes. Societal politicisation at this stage, however, was not substantial. Domestic pressure was largely unorganised and local in nature, and, as Figure 2 (see appendix) shows, national press coverage was relatively low.

2. Crisis peak

However, as is clear from Figure 2, from mid-September to late-November there was a much more sustained period of media pressure. National interest became an almost daily occurrence, with 24 pieces in September, 87 in October and 49 in November. One NICE member of staff recalled the intensity of this pressure:

> "Herceptin gave some particular difficulties for us because NICE generally wouldn't comment until we were formally working on a piece of guidance. The queries from journalists and others were coming in well before we got to that stage, putting the NICE press office and DH press office under quite a lot of pressure … It was on a daily basis, the NICE press office took around 60 calls a week from journalists just about our work, it was a really busy press office and a significant proportion of those were about Herceptin for the whole period it was going on. So Herceptin did put real pressure on the press office"

Interviewees from both DH and NICE agreed that this pre-assessment period was the most intensely 'difficult' period of media pressure. Here, there was an intensification of pressure group activity, particularly from long-campaigning cancer charities such as Breakthrough Breast Cancer and Cancer BACUP (Hind *et al*., 2011, p.24) but also a more temporary pressure group, Women Fighting for Herceptin (WFH).[3] Having featured on Radio 4's Women's Hour programme in August, the small group of Staffordshire patients took their campaign to the national level, aided by public relations firm Porter Novelli (*Guardian*, 29 March 2006) and Roche's own media campaign accompanying the publication of the HERA results in October (Roche, 2005b). WFH submitted a petition to Downing Street signed by 34,000 people, and were given a meeting with Health minister Rosie Winterton. The event gained national media coverage leading *The Sun to* launch its own appeal urging Patricia Hewitt (Health Secretary) to 'make Herceptin available immediately' (*The Sun*, 29 September 2005) and parliamentary motions to speed up the process (HoC Deb, 21 October 2005, 437: 1270W; HoC Deb, 22 November 2005, 439: 1358). As one interviewee remarked: '(t)here was a lot of stuff in the media, a lot of activity and these groups became very prominent and somehow struck a chord with society, i.e. it was cancer, it was women, it was breast cancer, it was a disease that many people could relate to'. This influence is further confirmed by the shortlisting of 'Fighting for Herceptin' for the 2006 Chartered Institute of Public Relations Excellence Awards (Wilson *et al*., 2008, p.131).

Moreover in the legal sphere several patients challenged PCT decisions to deny them treatment. The earliest of these was Barbara Clark, who, having threatened to take her case with North Somerset PCT to the European Court of Human Rights, was designated an 'exceptional case' and supplied with the drug. The importance of this event is clear, as 3 October marked the first peak in media interest (see Figure 2), and Clark would become the

[3] This was initially a small local campaign group from Staffordshire comprising four women who had been diagnosed HER2-positive but denied treatment with Herceptin and leader Dorothy Griffiths who had previously campaigned for access to the drug in 2001 and set up the Dot Griffiths Cancer Foundation, which helped to fund the local campaign.

most mentioned patient in national media (Wilson *et al*., 2008, p.128). As various patients challenged their PCTs on legal grounds following this reversal, 'the Herceptin campaign rose to fever pitch' (Keidan, 2007). Most prominently in November, Elaine Barber, a patient at North Stoke PCT and member of WFH threatened legal action after being denied Herceptin on grounds of cost. She appealed against this decision but was rejected (Mayor, 2005). Barber's subsequent legal threat led to the PCT agreeing to reverse its decision, on the grounds of her 'exceptional circumstances' (Mayor, 2005). These mounting legal challenges, driven by the involvement of expert solicitors Irwin Mitchell, provided a focal point for media attention on the Herceptin issue, as one legal expert noted:

> 'The main media interest was around when the cases were being issued or the hearings or decisions. So the media tried to work the story around the cases as opposed to around the general public campaign'

3. *Crisis diffusion*

In February, media coverage peaked as Anne Marie Rogers, a patient at Swindon PCT, became the first to take her appeal to the High Court. When Rogers' case was rejected (Dyer, 2006), a storm of negative media coverage followed (e.g. BBC News, 15 February 2006, see Figure 2). The percentage of negative articles criticising the 'post-code lottery' reached its highest since May 2005 (77.9%), and there was only one 'positive' article towards the ability of patients to access Herceptin published in the entire month, out of a total of 68. This negativity was furthered by a high profile Panorama programme entitled 'Wanting the Wonderdrug', which emphasised the personal experiences of participants in the WFH campaign (BBC Panorama, 7 February 2006).

By now however, the appraisal process was already underway, as NICE had appointed the Evidence Review Group (ERG) for assessing Herceptin, based around a new 'Single Technology Appraisal' (see below) that started the appraisal process in line with, rather than after the licensing decision. On 7 February NICE hence received a submission of evidence on Herceptin from Roche and on 17 February Roche applied to the EMEA for a European license. Significant media coverage and Parliamentary debate on the topic continued through to April (Hind *et al*., 2011, p.42), as the Court of Appeal's 'landmark judgement' on 12 April overturned the High Court's ruling on Anne Marie Rogers (*Independent*, 12 April 2006). However, because the regulatory process was already underway, with licensing expected by late-May and a NICE decision a matter of weeks later, the issue declined in salience.

This diffusion of pressure continued through to the later stages of the regulatory and assessment process, as Hind *et al*. (2011, p.42) and Abelson and Collins (2009, p.e120) show. Although in late July Newbury and Community PCT appealed against NICE's draft guidance published on 9 July (Wells and Cheong-Leen, 2006 p.1), this was swiftly rejected by a NICE review panel (NICE, 2006a) and final NICE guidance was issued on 23 August recommending Herceptin for treatment 'for women with early-stage HER2-positive breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable)' (NICE, 2006b, p.4).

The above analysis suggests evidence of both 'societal' and 'discursive' politicisation during the Herceptin post-code lottery crisis. It is clear that there was a substantial increase in the salience of Herceptin as an issue, with the coalescence of a long-term 'advocacy coalition' of patient, charity and pharmaceutical organisations (Sabatier and Jenkins-Smith, 1993) with more short term ad hoc 'issue networks' of legal, medical, political, journalistic and marketing groups (Marsh and Rhodes, 1992). Moreover we can also observe 'discursive politicisation' in the sense that most public discourse was critical of existing governance arrangements and implored ministers to get involved. This amounts to a two-pronged form of politicisation from outside the state, which put substantial pressure upon ministers to intervene in NICE's appraisal and 'fast track' the drug. The remainder of this paper shows, however, that such intervention did not happen, and explains why NICE was resilient to political pressure.

Maintaining Depoliticisation

The publicly declared actions of ministers developed roughly in line with the intensity of political pressure. In the 'emergence' crisis period the primary government action was to refer Herceptin to NICE. On 21 July Herceptin was referred outside the normal referral 'waves' of health technologies (NICE, 2005b). At this early stage, however, Herceptin was not referred to as an 'exceptional' case. In fact, DH referred Hercerptin alongside Velcade, another high profile drug used to treat Multiple Myeloma. Under-Secretary for Health Liam Byrne was thus able to respond to controversy surrounding Barbara Clark by stating that existing processes would remain:

> ''It is perhaps inappropriate for NICE to determine the clinical effectiveness and cost-effectiveness of a drug while its safety and efficacy are still under consideration … we cannot override the drug licensing process' (HoC Deb, 30 June 2005, 435: 1548-1549).

At this stage DH was seen as performing its primary function within the governance system, namely, to refer drugs to NICE for appraisal, and nothing more.

More crucial is the 'peak' stage, in which ministerial activity increased significantly. The most important action here was a press release on 5 October, at the first peak of media pressure, in which Patricia Hewitt was quoted as saying:

> 'Herceptin has the potential to save many women's lives and I want to see it in widespread use on the NHS ... I want the licence for Herceptin to be granted as quickly as possible … and to be available within weeks of the licence being given. I share the huge frustration of many women about the delays in getting Herceptin

licensed. I am determined to take action, and this represents a major step forward in our fight against cancer' (DH, 2005)

This announcement was to lead to further 'interventions' on Herceptin. On 25 October the Health Secretary made similar remarks to the Breakthrough Breast Cancer Fly-in, this time though compelling PCTs to fund Herceptin outside of NICE recommendations:

> 'I have shared the huge frustration of many women about the delays in accessing cancer drugs … it has the potential to save as many as 1000 lives a year … I want to make it clear that PCTs should not refuse to fund Herceptin solely on the grounds of cost … I have asked (NICE) to start on a fast-track appraisal' (Hewitt, 2005).

Prime Minister Tony Blair even suggested PCTs should 'go ahead and allow people to use (Herceptin)' (*BBC News*, 3 November 2005).

Given the 'unusual and exceptional' amount of ministerial activity, as one interviewee commented, it could be argued that ministers were essentially pre-determining the assessment process (Mayor, 2005). Such arguments only gain greater salience when we consider that shortly after Blair and Hewitt's statements NICE introduced the Single Technology Appraisal (STA) process as a way to 'enable single new drugs, and existing drugs with new indications to be rapidly assessed' (NICE, 2005a). Herceptin was the first drug to go through this quicker process which ran alongside, rather than beginning after, the licensing decision by the EMEA, hence aiming to close the gap in which a 'postcode lottery' could exist (for a full description see NICE, 2006c). That the introduction of the STA followed shortly after ministerial statements about a desire to 'speed up' the appraisal process certainly intimates some form of 'political' influence on NICE's decision making, and perhaps even suggests ministers leaning on NICE officials to achieve a positive appraisal for Herceptin. However, a close analysis of documents provided via a freedom of information request for all correspondence between NICE and DH regarding Herceptin between 1 May 2005 and 1 September 2006 suggest this is not the case.[4] This data is presented in table 1.

Table 1: Email communications between DH and NICE referring to Herceptin (1 May 2005-1 September 2006)

		Subject			
Month	No. of Email Communications	Referral	Press handling	Consultation	Other
May 2005	1	1	-	-	-
June 2005	1	1	-	-	-
July 2005	3	2	1	-	-
August 2005	1	1	-	-	-
September 2005	0	-	-	-	-
October 2005	3	-	3	-	-

[4] The Freedom of Information request was submitted to DH on 1 August 2012 and responded to on 30 August 2012.

November 2005	5	-	5	-	-
December 2005	2	-	-	2	-
January 2006	0	-	-	-	-
February 2006	0	-	-	-	-
March 2006	2	-	-	-	2
April 2006	1	-	-	1	-
May 2006	1	-	-	1	-
June 2006	2	-	1	1	-
July 2006	1	-	-	1	-
August 2006	2	-	-	2	-

Table 1 shows that the number of emails exchanged between NICE and DH explicitly mentioning Herceptin is very small. Even during the most intense periods of political pressure in October and November only a total of 8 emails explicitly mentioning Herceptin were sent. The email subjects provided in columns 3-7 from the left also suggest that the nature of this email communication was largely formalistic in nature. Emails from May-August focused largely upon the formal referral of Herceptin, specifically NICE advising DH within a Joint Planning Group (JPG). There is a significant exchange around the end of October regarding the coordination of the STA launch (would it be a joint DH and NICE statement or separate ones?) and a 'Q&A' of stock responses for media questions on Herceptin. The clear theme, however, is not the decision to implement STA itself, but *coordination* – who will say what, how will the image of NICE independence be maintained and how will Herceptin be downplayed as a driver of the new process. This press handling subsides as the STA appraisal for Herceptin begins, and the majority of communication from December 2005-August 2006 relates to DH's formal role as a consultee in the STA.[5]

The data presented above suggests that contact (in email) was limited mainly to formal communication in terms of DH's referral and consultation roles. This finding is strongly supported by a NICE response to a House of Commons Select Committee report on its activities:

> 'There has never been any direct or indirect attempts by ministers to influence our guidance once topics have been referred for consideration. Sometimes we are asked to consider issues that generate significant public interest and comment; and ministers may give interim advice to the NHS on how to manage such issues while we are developing formal recommendations. While our independent advisory committees are aware of interim advice from ministers, this advice does not influence the formal recommendations that they develop' (NICE, 2008, p.2).

[5] The only exceptions being communications in March referencing Herceptin in relation to future STA referrals and scoping reports for the '12th wave' of appraisals, and a press handling communication in June around the date of the FAD release.

This argument is reinforced by the evidence of interviewees from both DH and NICE. As one interviewee from NICE closely involved with the Herceptin appraisal bluntly stated:

> 'what happened in the appraisal itself … is, I'm being perfectly honest here: business as usual. We carried out our appraisal in exactly the same way as we carried out any other appraisal. No interaction with ministers or DH in terms of what we should/shouldn't be finding'

It may hence be suggested that although Herceptin generated societal and discursive politicisation, this did not apparently translate to governmental politicisation in the sense that ministers did not seek to exert informal influence on NICE's appraisal process. This evidence is limited in the sense that it does not account for informal phone calls or face-to-face meetings, but what evidence there is does not strongly support a counter-argument. One NICE insider recalled informal teleconferences with DH officials about upcoming recommendations, but this was to manage media responses not discuss appraisal substance. A couple of interviewees also suggested DH may have contacted NICE by phone once specifically about Herceptin, but was flatly rebuffed. The question, then, is why was NICE apparently resilient to external pressures?

Institutional Double Glazing

This section argue that ministerial intervention in NICE was avoided mainly due to the presence of institutional constraints reinforced by prevalent cultural norms – 'institutional double glazing'. This argument relates to the notion that 'public organisations that are endowed with certain structural features … enjoy higher survival chances than those without these birth characteristics' (Boin *et al*., 2010, p.385). In particular Lewis (2003, p.143) argues that 'political insulation' or formal bureaucratic autonomy 'decrease(s) the impact of changing administrations and changing majorities on the policies implemented by administrative agencies'. The notion of 'insulation' is particularly useful here, as it can be argued that the formal institutional design of NICE provided extra protection for scientific decision makers, in a form of 'institutional double glazing' that acted as an effective barrier to ministerial intervention.

Importantly, the appraisal of any health technology is not technically carried out by NICE but by the TAC *appointed by NICE*. Put simply, it can be argued that the decision making process is not 'one-step' removed from the central state but *two steps removed*. DH appoints the chair of NICE, and meets senior NICE officials in high level quarterly reviews, but NICE appoints the TAC, which *independently* assesses evidence, and senior NICE officials do not get involved with TAC decisions. As one NICE member bluntly put it: 'if Andrew (Dillon, Chief Executive) went to the committees, they would all resign'. Although it is important not to overstate the formal independence of TACs - NICE is legally responsible for the final decisions - in terms of their 'de facto' levels of independence from senior NICE officials,

TACs are highly autonomous. The appraisal process is hence highly 'insulated', as one NICE official stated:

> 'Once we have established a programme, it insulates the decision making from influences that are outside of the process to formulate the recommendations. There's no way DH or government can influence a decision that NICE are in the process of appraising'

Ministers hence have very little (if any) opportunity to influence TAC decisions. One former NICE official even suggested the whole point of NICE was to act as an insulator for the TAC:

> 'We're not the ones who make the decisions, we're not in the room … On Herceptin, the decisions were made by a TAC sitting in a room, experts from throughout the health service. Obviously they're human beings who to some extent are influenced by what they see and read and [their] experience. But actually what we saw one of our jobs as being … was to (we used to use a rude word for it!) catch a lot of the rubbish and form a protective barrier around the committee so they could actually focus on the evidence and looking at the decision. In my time there I never went to a TAC meeting, it wasn't part of my role. My role was… to handle [the pressure] on their behalf and make sure that they could sit in a kind of bubble with all the evidence and look at it'

On top of this formal 'barrier', the appraisal process is highly routinized and formalised, and TAC procedures for evidence submission by stakeholders and methods of appraising evidence are specified in substantial detail in several governance documents (NICE, 2001; NICE, 2004a, b). The effect of this highly formalised process was that once Herceptin had been referred, DH became just one of several 'consultees', and, as Table 1 shows, was contacted predominantly in that capacity once the process began. One civil servant in the NICE liaison unit within DH described their role as one of wearing different 'hats':

> 'As well as the sponsor department, with a slightly different hat on we are a legitimate consultee in its work … once the topic has been referred we become a consultee in the development of that. Almost at the moment of that referral we swap hats … our primary focus was on making sure that NICE did as timely a job as possible doing what we needed to do as quickly as possible but in the appraisal itself it wasn't any different to what we would do for anything else.'

This point suggests that the role of DH was heavily circumscribed by official procedures, which required it to fulfil specific roles at different points. Although DH officials tried to rush the referral of Herceptin through as quickly as possible, any room for influencing NICE informally was squeezed out by rule-based procedures. As one NICE official put it:

> 'the advisory bodies receive an evidence base from NICE and interpret it according to standard NICE guidelines … All of the comments that come in/responses are made

> public on the website. You can't do something and then hide it, without having to explain yourself to someone else'

Of course, formal procedures are often followed because they coincide with informal norms or ideas about 'good practice' (Helmke and Levitsky, 2004). Here, the views of interviewees clearly portray a highly developed norm of deference to and trust in NICE's clinical/scientific expertise, related to its long-serving senior management team and deference to medical expertise more generally. As one former senior DH advisor noted:

> 'Two very strong features of NICE were credibility of the senior team and their stability over a long period of time, which is quite unusual … they secured the confidence of ministers and others, because in the end ministers appoint the chairman. There was a long period of stability with Sir Michael Rawlins and Sir Andrew Dillon and although there was always criticism (and this was the sort of thing that ministers would get involved in) … All those debates were going on but they were about the framework within which NICE operated rather than the decisions it was making … on the whole ministers left NICE to get on with it, and actually as its reputation built that became easier and easier to do

The elite interviews further reflect a culture within Whitehall of deference to scientific/medical expertise, particularly NICE's reputation as an international leader in reviewing evidence, as the same former advisor put it:

> 'The honest truth is what do ministers know about these things? It was an area of professional expertise'

Beyond formal and informal institutions, there is also evidence that ministers and NICE officials enacted explicit strategies to deflect blame and prevent the crisis from escalating (Boin *et al.*, 2009). For example, ministers blamed PCTs and clinicians for not supplying Herceptin sooner, as Hewitt (2005) argued that 'As with other unlicensed drugs, it is down to individual clinicians to decide whether or not to fund Herceptin … PCTs must also be involved and will have to decide whether to support the clinicians' decisions and pay for Herceptin'. Similarly, Health Minister Jane Kennedy asserted that 'it is for clinicians to decide, in discussions with patients, whether herceptin is appropriate … the NHS … need(s) to make arrangements to provide herceptin' (HoC Deb, 22 November 2005, 439:1359 and 1362). Moreover, as several interviewees noted, NICE was also developing its own 'story' about responding to the issue of 'timeliness'. For example, NICE Chair Andrew Dillon commented in a press release:

> "We are aware of the need for timely advice on the use of new medicines, particularly for life-threatening conditions such as cancer. The proposals we have set out mean NICE can deal with the current backlog much quicker than planned and that we will be able to issue guidance to the NHS rapidly in the future, once a drug is licensed" (NICE, 2005a, p.2)

This ‘timeliness’ issue was identified by interviewees as an important theme within NICE at the time, and a factor in speeding up the introduction of the STA. These ‘narratives’ or ‘stories’ contributed to deflecting and diffusing the ‘blame risk’ associated with crisis situations (Hood, 2011). Yet, they can principally be interpreted as methods for containing the crisis or stopping escalation to encompass wider issues of institutional legitimacy, rather than efforts to prevent intervention in this specific case.

Conclusion

This paper has attempted to make a distinctive contribution to the literature on depoliticisation by expanding the empirical focus beyond the state sphere, focusing on the impact of *politicisation on the state* rather than *depoliticisation on society*. In doing so, it has made a preliminary effort to operationalise Hay’s (2007) model of (de)politicisation processes to examine how NICE was resistant to external politicisation during the Herceptin postcode lottery crisis. This article has important implications for further research on depoliticisation, namely, shifting the agenda towards examining how organisations successfully maintain their depoliticised status in the face of politicising pressures, rather than non-reflexively assuming depoliticisation as a non-contested ‘act’ (Burnham, 2001). The argument here has been that depoliticisation succeeded because of tight procedural rules and ‘double delegation’ not only from ministers to NICE executives, but from executives to the independent TAC.

Future research might examine a variety of other policy areas (perhaps ones less reliant on scientific evidence) to examine how (if at all) depoliticised bodies resist external politicisation. In this regard, the analytical framework deployed in this article (societal, discursive and governmental politicisation) may be applied in a range of policy areas and countries. This analytical framework also opens up a variety of other research questions. For example, are societal and discursive politicisation intimately linked (as implied in this paper) or can they exist separately, and how influential are they in such situations? How might we more quantitatively ‘measure’ the interactions between these variables both in case studies and in more longitudinal and comparative studies? Are there other politicisation processes that have been missed out of this framework? Is there any way of examining the interaction between politicisation processes *and depoliticisation processes* beyond the state (see Figure 1)? These questions are not necessarily new, but they do at least address age-old dilemmas of public administration and political science from a new perspective, establishing a distinctive research agenda that brings together questions of discourse, political participation and executive governance.

From a more general perspective, this paper has provided evidence on how governance structures can be resilient to external political pressure. Through an institutional design that created a highly formalised and technocratic decision making process, reinforced by a longstanding, respected leadership team NICE was effectively insulated from external

political pressure. This finding chimes with longitudinal research that emphasises formal organisation as an important aspect of agency autonomy (Gilardi, 2008; Hanretty and Koop, 2012). Perhaps more importantly, however, it presents a good case study of how, in the context of an increasingly over-stretched and under-resourced central state (Lodge, 2013), organisations may be designed to be resilient to the push and pull of crisis politics. Although clearly one case cannot make for wide-scale generalisation, it can offer important contextual pointers, for instance the importance of stability in terms of personnel, to future plans to create NICE-type organisations in different policy areas (HM Government, 2013). Further research might deploy the analytical framework developed in this paper to examine how other delegated bodies in other policy areas and countries manage (successfully or unsuccessfully) political pressure, and what lessons can be taken for governance in the twenty-first century.

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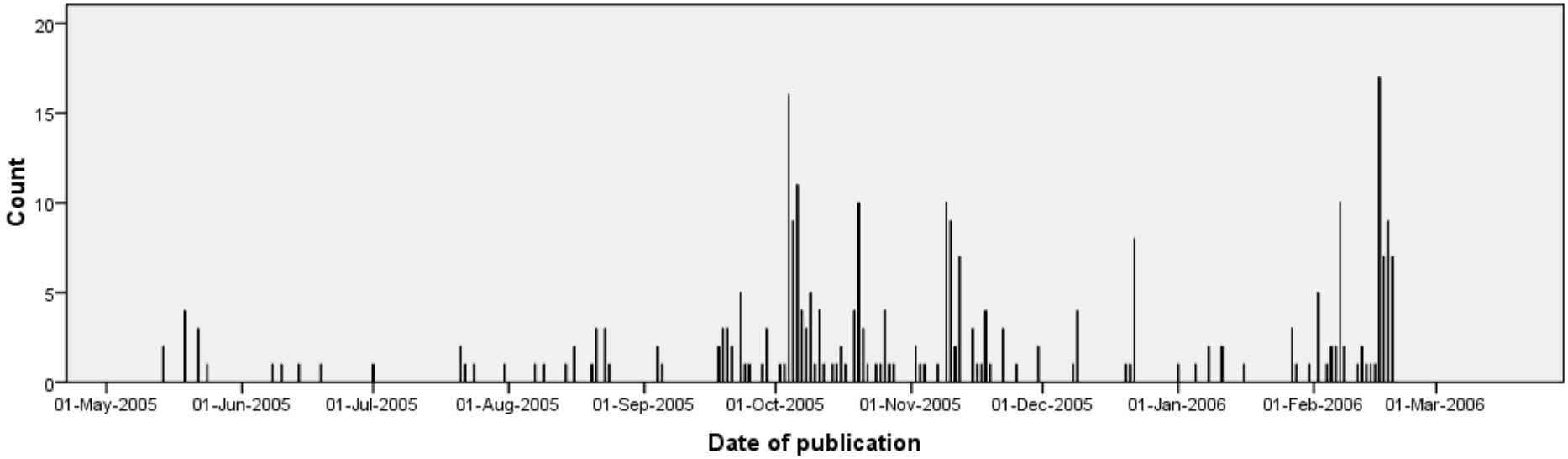
Appendix

Figure 2: National Newspaper articles published on Herceptin (14 May 2005-19 February 2006)



Graph computed from data supplied by Wilson et al, 2008.