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Keith Syrett

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Health technology appraisal and the courts: accountability for reasonableness and the judicial model of procedural justice

KEITH SYRETT*

Reader in Public Law and Health Policy, School of Law, University of Bristol, Wills Memorial Building, Clifton, Bristol, UK

Abstract: Recommendations issued by agencies undertaking appraisals of health technologies at the national level may impact upon the availability of certain treatments and services in some publicly funded health systems, and, as such, have regularly been subject to challenge, including by way of litigation. In addition to expertise in the evaluation of evidence, fairness of procedures has been identified as a necessary component of a claim to legitimacy in such circumstances. This article analyses the assessment of courts in three jurisdictions of the fairness of decision-making by such agencies and evaluates the judicial reading of procedural justice developed in this particular context against the conditions of 'accountability for reasonableness'.

1. Introduction

Recent years have witnessed the widespread establishment of national-level institutions to undertake appraisal of evidence on the clinical and cost-effectiveness of health technologies,[1] in an effort to focus finite public resources upon treatments which deliver the most effective and efficient forms of care. Although the final choice on what a health system can afford (as distinct from what is cost-effective) may reside elsewhere – such as with politicians – the recommendations which result strongly inform decision-making on access, especially to new health technologies. Thus, mandatory funding requirements may attach to appraisal recommendations (as in the United Kingdom), ministers may be precluded from listing technologies for coverage without a positive agency recommendation (as in Australia), or the agency may directly determine coverage as regards the technologies which it appraises (as in New Zealand).

*Correspondence to: Keith Syrett, Reader in Public Law and Health Policy, School of Law, University of Bristol, Wills Memorial Building, Queens Road, Clifton, Bristol BS8 1RJ, UK. Email: keith.syrett@bristol.ac.uk

1 'Appraisal' may be distinguished from 'assessment': the latter denotes the scientific/technical process of gathering and analysing information on a health technology, while the former refers to decision-making or policy advice on that technology, on the basis of a synthesis of the scientific evidence combined with other factors such as social values (Stevens and Milne, 2004).

While decisions on the availability of health services and interventions are also taken elsewhere in the system, the fact that these agencies operate at the national level endows their recommendations with especially high visibility. This is exacerbated by the nature of the technologies being appraised, which are commonly heralded as offering innovative breakthroughs in treatment for particular conditions. Consequently, the decisions reached by these agencies generate acute media and public interest and impact upon the interests of a broad range of stakeholders, including industry, patient groups, political actors and healthcare professionals.

Given such factors, the work of such institutions is highly politically and socially contentious and, as such, is especially prone to challenge by individuals, patient groups and/or industry. One mechanism through which such challenges may be articulated is litigation. Agencies undertaking technology appraisals in publicly funded health systems, while usually operating at arm's length from direct political control, nonetheless function within a statutory framework established by the legislature and exercise powers of a public nature which have been delegated to them by the executive branch of government. As such, they are susceptible to challenge through the courts, primarily through the process of judicial review of administrative action. This mechanism – which should be distinguished from an appeal on the *merits* of a decision – functions to ensure that public bodies do not exceed the scope of their allotted powers, that they understand and apply the law correctly, and that the processes of decision-making which they operate comply with certain standards of fairness.

This article considers court cases from three jurisdictions, Australia, England and Wales and New Zealand, in which recommendations issued by national-level agencies undertaking health technology appraisal functions have formed the subject matter of challenge. These systems have been selected for two reasons. First, they possess relatively mature institutional processes for appraisal, with the consequence that sufficient time has elapsed for litigation to have occurred, although the available 'data set' of case law remains small. Second, the three legal systems possess a shared legal heritage – the common law of England – which renders identification of common themes and principles a more straightforward and meaningful exercise than if the analysis were to extend more broadly: for example, to countries (such as those in continental Europe) operating within a distinct civil law tradition.

In undertaking such a study, this article seeks to contribute to two issues raised in the academic literature. First, it provides a further perspective on the question of whether the decision-making of national-level technology appraisal agencies may be regarded as fair (Mitton *et al.*, 2006) through analysis of the *judicial* approach to fairness – understood as relating to justice in decisional procedures as distinct from substantive outcomes – which has evolved in cases involving such bodies. Second, it offers comparisons between the judicial understanding of the constituent ingredients of procedural justice and the

dominant conceptual model for the legitimation of decisions on healthcare limit-setting, 'accountability for reasonableness' (Daniels and Sabin, 2008), thereby facilitating a critical reading of the latter. While the relationship between the Daniels and Sabin model and judicial review cases concerning access to treatment has been considered elsewhere (Syrett, 2002, 2007), the focus to date has been upon *local* allocative decision-making. No analysis has previously been offered in respect of litigation concerning national-level health technology appraisal agencies. Given (as previously noted) the central and growing role of this mode of decision-making within health systems and the significant controversy that it generates in view of its impact upon access, such an investigation is timely. However, prior to examination and discussion of the relevant case law, it is necessary first to understand both why procedural justice is viewed as fundamental to the legitimacy of bodies undertaking allocative functions within health systems, and why court judgements are worthy of scrutiny in this regard.

2. Limit-setting and legitimacy

Allocative decision-making in healthcare has been widely perceived to give rise to problems of legitimacy. Where choices are made in situations of scarcity, which carry significant costs in terms of human suffering, deep-seated moral conflicts are exposed and suspicion, distrust and resistance may result. Consequently, the authority of the decision-maker is called into question and the stability of the regulatory regime imperilled (Daniels and Sabin, 2008). In response to such challenges (or to pre-empt them), bodies whose work impinges upon the setting of limits to healthcare resources, including those undertaking technology appraisals, may seek to advance two broad claims to legitimacy. The first rests upon *expertise*: legitimacy derives from the methodological rigour with which the agency approaches its reviewing tasks and the capacity of its personnel to comprehend and apply the evidence which is presented. The second rests upon *procedural justice*: that is, that there is a connection between fairness of process, legitimacy and acceptance of decisions and that this may be independent of any substantive outcome.

Each of these claims to legitimacy would appear to be necessary but not sufficient. In an analysis of key stakeholder perceptions of technology appraisal processes in Australia, Canada, New Zealand and the United Kingdom, Mitton *et al.* (2006) note that "a body of experts that understands scientific evidence was … identified as essential to an effective drug review process" and that "all participants highlighted the importance of using rigorous evidence" (2006: 203). However, the authors also identify transparency as "crucial to ensuring accountability and decreasing potential controversy around formulary listing decisions", and the importance of opportunities to revisit and revise decisions made by the agencies (2006: 204, 206). Relatedly, the National Institute for Health and Clinical Excellence (NICE) in England and Wales has committed

itself to a synthesis between expertise and proceduralist approaches in order to secure legitimacy both for its 'scientific value judgements' and for those 'social value judgements', which are inherent in the distributive aspects of its work (Rawlins, 2005; NICE, 2009).

The leading model of procedural justice in healthcare priority-setting, and "arguably … the dominant paradigm in the field of health policy" (Friedman, 2008: 102), is "accountability for reasonableness", as articulated by Daniels and Sabin. This establishes four procedural conditions – publicity, relevance, revision and appeals and regulation/enforcement – with which bodies should comply, facilitating "social learning about limits" (Daniels, 2000: 1301) and enabling a process of public deliberation upon the need for limit-setting and the criteria that inform it. In short, the accountability for reasonableness model makes possible deliberative democracy in this context, the latter being seen as a sufficient condition of legitimate political decision-making (Parkinson, 2003; Lauridsen and Lippert-Rasmussen, 2009).

This model of procedural justice has been widely endorsed and applied to a variety of healthcare decision-making environments (Sabik and Lie, 2008). In the context of processes for technology appraisal, it has been assumed that compliance will satisfy the procedural component of the claim to legitimacy. Thus, NICE has contended that, absent substantive consensus upon a basis for the allocation of resources adherence to the principles of accountability for reasonableness "give[s] legitimacy to [its] guidance" (NICE, 2009: 13). Similarly, in the academic literature, the model is often "used as a sort of checklist: when the procedural conditions appear to be fulfilled, the system in place is certified as legitimate and fair" (Sabik and Lie, 2008: 75): for examples, see Mitton *et al*. (2006) and Schlander (2007).

However, this somewhat uncritical employment of the model is problematic. First, there is a risk that utilisation of the four conditions as a form of inventory downplays the significance of their function as 'connective tissue' to a deliberative democratic process, when it is by means of the latter that legitimacy is ultimately secured. Perhaps more significantly, accountability for reasonableness has been subject to a number of critiques, which mean that its application is not uncontroversial. These include arguments that bioethicists should not readily abandon the search for substantive consensus in favour of agreement on fair procedures (Ashcroft, 2008); that reasonable people are as likely to disagree about what amounts to fair procedure as upon substantive principles (Sabik and Lie, 2008); that a distinction between reasonable and unreasonable decision-making is difficult or impossible to draw and that what is 'relevant' is itself a substantive judgement (Hasman and Holm, 2005; Friedman, 2008; Lauridsen and Lippert-Rasmussen, 2009; Rid, 2009); that deliberation lacks practical feasibility (Friedman, 2008; Lauridsen and Lippert-Rasmussen, 2009); and that the model is incomplete in underplaying the value of public participation in decision-making, which may be viewed as a necessary condition for the

attainment of legitimacy (Emanuel, 2002; Martin *et al*., 2002; Friedman, 2008; Sabik and Lie, 2008; Rid, 2009).

3. Procedural justice, legitimacy and the courts

Questions of procedural justice are central to judicial review of administrative action. The centuries-old concept of 'natural justice' expresses the notion that certain procedural qualities and values are inherent in the very idea of law, particularly the rule against bias and the right to be heard. Such principles have been developed through case law and (in some jurisdictions) by legislation, and are now more commonly captured under a broader rubric of a "duty to act fairly" (Galligan, 1996: 186). Failure to give effect to this obligation provides a basis to declare a public body's decision to be unlawful, with the consequence that the decision must be retaken in accordance with procedural standards specified by the court.

Accordingly, when recommendations issued by agencies undertaking health technology appraisal are challenged by way of judicial review, the articulation of values of procedural justice will almost certainly form a central component of the judgement issued by the court. For this reason alone, any evaluation of the fairness of decision-making processes operated by such bodies is liable to be incomplete in the absence of analysis of relevant judicial pronouncements. This is not to argue that a court's view of the constituent elements of procedural justice should be regarded as definitive: while legal judgements establish parameters for future lawful decision-making (extending well beyond the parties to the instant dispute), they may subsequently be refined or overruled; furthermore, what is procedurally just in law may not equate to what is procedurally just as an ethical or moral matter. Nonetheless, as authoritative, binding and public statements of institutions accorded constitutional responsibility for the administration of justice, judgements delivered by courts clearly cannot be disregarded.

However, accounts of procedural justice in healthcare priority-setting have generally sought to downplay the judicial role. Notably, Daniels and Sabin contend that "courts are ill-equipped to deliberate about issues of limit-setting, especially about the more technical matters involved in assessing efficacy and safety" (2008: 59), arguing instead that internal dispute resolution mechanisms should be evolved so as to reduce the "threat of litigation" (2008: 58). Similarly, Friedman comments that "endless litigation" is a manifestation of distrust and that people are likely to "object and fight back with any means necessary, including litigation, whenever they are disadvantaged for reasons that they do not understand or do not agree with" (2008: 102, 111). Concerns of this type seem rooted in a view of law as an external autonomous control mechanism activated by those seeking to challenge the legitimacy of the decision-maker. The involvement of courts is seen as an unwelcome intrusion into the allocative

process, especially given the perceived judicial deficiencies in the comprehension of priority-setting, the procedural unsuitability of adversarial litigation, a relative absence of democratic credentials and – at least implicitly – a tendency for judicial inclination towards the individual, which is liable to disrupt the inherently collective task of allocation of finite resources.

While not wholly inaccurate (as noted subsequently, judges frequently admit to a lack of expertise on the technical questions entailed by technology appraisal and to limitations to their constitutional remit), this relative neglect or deprecation of the judicial role is unsatisfactory. In part this is because, as previously suggested, any account of the meaning attached by society to procedural justice is deficient in the absence of consideration of judicial pronouncements on the matter. In addition, a negative reading of judicial involvement overlooks its capacity to *facilitate*, rather than to imperil, the attainment of legitimacy. Court judgements can render the decision-making process more acceptable to stakeholders and the wider public as agencies are seen to conform to judicially articulated principles of 'good administration' on matters such as transparency, participation and accountability. These ensure fair treatment of affected parties and foster broader public understanding of – and input into – the decision reached and the criteria upon which it is based (Syrett, 2007).

On this analysis, it might plausibly be argued that a judicial review of administrative action possesses the potential to fulfil the fourth condition of accountability for reasonableness, enforcement, that is, regulation to ensure that the other procedural conditions are met (Syrett, 2002), especially if litigation is seen both as deliberative in the courtroom setting and as a catalyst for further public debate outside (Syrett, 2007). However, whether the courts *do* in fact enforce the conditions of accountability for reasonableness in relation to national-level technology appraisal agencies, or instead embrace some other version of procedural justice, will depend upon how far the three remaining conditions of the former model can be said to be embodied in the case law, to which we now turn.

4. The cases

Not all instances of litigation concerning health technology appraisal turn upon limit-setting coverage recommendations by the agency. Depending upon the nature of the powers which are legally vested in the agency, cases may concern matters such as price-setting (e.g. *Astra Pharmaceuticals (NZ) Limited vs Pharmaceutical Management Agency Limited* [(2000) NZCA 345]), the production of clinical guidelines on best practice in management of a condition (e.g. *R (on the application of Fraser) vs NICE* [(2009) EWHC 452 (Admin)], or may relate solely to issues of clinical efficacy (e.g. *Commonwealth of Australia and another vs Human Rights and Equal Opportunity Commission and others* [(1997) FCA 664] and *E vs Minister for Health and Family Services* [(1998)

HREOCA 35]). However, as Daniels and Sabin's work indicates, the question of the fairness and legitimacy of decision-making arises most acutely in the context of recommendations whose impact is to limit the availability of a medical treatment or service on cost grounds, and accordingly the (relatively few) cases in which such decisions have been challenged in court will be the focus of consideration here.[2]

4.1 Australia

Australia's centralised appraisal agency, the Pharmaceutical Benefits Advisory Committee (PBAC), was the first of the institutions surveyed here to be subject to legal challenge. In *Pfizer Pty Limited vs Birkett* ('*Pfizer*') [(2000) FCA 303/ (2001) FCA 828], the manufacturer of sildenafil (Viagra) challenged the decision of the Committee not to recommend that the product be made available on the national formulary on grounds of its cost. Rejecting the contention that PBAC was not empowered to consider questions of the overall cost of a technology (it having been argued that such considerations were for government alone), Mathews J. noted that PBAC was a 'recommendatory' rather than an 'advisory' body: hence, it was obliged to consider all relevant factors, whether medical or financial, in fulfilling its function of presenting a desirable course of action to the Minister, rather than simply offering expert clinical and health economic advice to the latter (para 88).

However, the judge's conclusion that PBAC had not acted unlawfully in taking account of information which was potentially detrimental to the interests of the manufacturer of Viagra without having informed it that it was doing so or providing an opportunity to respond, was overturned on appeal. The appeal court ruled that evidence that an alternative treatment for erectile dysfunction (alprostadil injections) was used at a considerably higher rate than had been predicted by the latter's manufacturer was not merely historical information bearing no relation to any activity of the manufacturer of Viagra and upon which it would have been difficult for the latter to make meaningful comment. Rather, it was "of central importance to the decision" (para 66). Thus, procedural fairness required that PBAC should have disclosed that it proposed to attach significance to the information on the overuse of alprostradil. Its failure to do so deprived the manufacturer of the possibility of persuading PBAC that inferences should not be drawn as to the likelihood of a similar overuse of Viagra.

In *GlaxoSmithKline Australia Pty Ltd vs Anderson* [(2003) FCA 617] ('*GlaxoSmithKline*'), a similar claim that there had been a lack of procedural fairness was rejected on the facts of the case. This case involved a revised PBAC decision on the anti-smoking aid bupropion hydrochloride which sought to minimise wastage resulting from failure to complete the full course of 120 tablets,

2 Cases were identified using legal databases (Westlaw, Lexis-Nexis and World Legal Information Institute). Searches were conducted against the name of the agency, from the date of its establishment.

recommending instead that funding be provided on the basis of an introductory prescription of 30 tablets, with the balance of 90 only made available following the issue of a second prescription. The company contended that it had been given inadequate notice of the content of certain 'anecdotal reports', which had suggested that wastage was considerable and that it had accordingly been unable to respond to these. Ryan J. held that the company did, in fact, have sufficient knowledge of the issues which were of concern to the Committee, although it was not aware of the precise details of the reports. Other arguments advanced by the manufacturer, which included claims that PBAC was not statutorily empowered to vary a recommendation that had already been issued and accepted by the Minister (since this was effectively a means of circumventing parliamentary scrutiny of any decision to cease funding), that the Committee had formed a predetermined view and had placed an unjustifiable burden on the company to displace that view, and that the recommendation had either been based upon no probative evidence or was against the weight of evidence, were also dismissed. In respect of the last of these, the judge remarked that "it is not for this court in circumstances like the present to go behind the Committee's evaluation of the preferable policy recommendation for it to make to the Minister" (para 51).

4.2 England and Wales

Despite the controversy which has attended a number of the technology appraisals conducted by the NICE on behalf of the National Health Service (NHS) in England and Wales, the first legal challenge did not take place until 2007, some eight years after the Institute's creation. In *R* (*on the application of Eisai Limited*) *vs NICE* [(2007) EWHC 1941 (Admin)/(2008) EWCA Civ 438] ('*Eisai*'), a pharmaceutical manufacturer (joined by another manufacturer and a patient group) challenged the decision of NICE to recommend that acetylcholinesterase inhibitors should only be made available for treatment of moderately severe dementia, thereby excluding the majority of patients from access to the treatment on the NHS.

As in the Australian cases, a variety of arguments were advanced. A claim that NICE had not complied with its statutory obligations to promote equal opportunities and to eliminate discrimination was accepted by the court on the basis that the guidance issued was insufficiently clear. However, a further argument that the recommendation reached by NICE was premised upon deficiencies in the understanding and application of the available evidence and reliance upon outdated data was rejected on the basis that the court was not competent to adjudicate between competing expert opinions on the evidence.

The primary ground of challenge was, however, that failure by the Institute to disclose a fully executable version of the economic model which had been developed to illustrate the cost-effectiveness of the inhibitors was procedurally unfair. In the lower court, Dobbs J. dismissed this argument, stating that the

manufacturer had not been deprived of the opportunity to advance suggestions and concerns in the light of the information which it *did* possess (para 62). However, the judge's finding on this ground was subsequently overturned by the Court of Appeal, which concluded that procedural fairness did require release of a fully executable version of the model since, without this, it was impossible to assess the reliability of the model and to make informed representations upon this matter to NICE (para 65).

Similarly, in *R* (*on the application of Servier Laboratories Limited*) *vs NICE* [(2009) EWHC 281 (Admin)] ('*Servier*'), a claim on the basis of procedural unfairness again succeeded. Here, the model had not been disclosed at all, in view of the existence of an undertaking of confidentiality given by the Institute. Holman J. nonetheless ruled that NICE was under a duty to take all reasonable steps to obtain permission to disclose the information and that, on the circumstances of the case, it had failed to discharge this duty (para 139). By contrast, those arguments which were not of a procedural nature failed. The court concluded that the failure to recommend the treatment (strontium renelate for osteoporosis) did not amount to unlawful discrimination against certain categories of disabled patients since it could be justified in light of the overall financial impact upon the NHS, and that the weight to be attached to particular data was a matter for NICE's judgement alone, while its decision as regards this data had been sufficiently and intelligibly explained to a technical reader of the guidance.

NICE's failure to disclose an economic model also formed the heart of the challenge in *R* (*on the application of Bristol-Myers Squibb Pharmaceuticals Limited vs NICE* [(2009) EWHC 2722 (Admin)] ('*Bristol-Myers Squibb*'), involving the treatment abatacept for rheumatoid arthritis. On this occasion, however, the argument was unsuccessful. While NICE had not released the modified version of the manufacturer's original economic model which had informed the final recommendation that the treatment was not cost-effective, the court ruled that the company had had full opportunity during the consultation process to make meaningful representations: as the author of the original model, it had been able to input and run alternative assumptions in a manner not open to the manufacturer in *Eisai* (paras 68–70). A further argument based upon European law (failure to communicate fully to the European Commission the cost-effectiveness criteria for exclusion of a technology from coverage by the NHS) was also rejected.

4.3 New Zealand

In *Walsh vs Pharmaceutical Management Agency Limited* [(2008) NZHC 441] ('*Walsh*'), a number of patients challenged decisions made by New Zealand's national-level health technology appraisal agency relating to the availability of Herceptin (trastuzumab) for the treatment of early-stage breast cancer.

The Pharmaceutical Management Agency (Pharmac) had recommended that the drug should not be made available on the national formulary for a 12-month period, but subsequently recommended that funding should be authorised for a 9-week period.

In the High Court, Gendall J. noted that much of the evidence filed by the patients took the form of criticism of the analysis by Pharmac of the clinical and cost-effectiveness of the treatment, upon which it was not the place of a court of law to comment. However, procedural arguments were also raised, pertaining notably to section 49(a) of the New Zealand Public Health and Disability Act 2000, which imposed an obligation upon Pharmac to consult "when it considers it appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that [in its view] may be affected by decisions on these matters". The Agency had not engaged in any such consultation in advance of its recommendation not to fund a 12-month period of treatment with Herceptin, on the basis that it was its standard practice not to consult when declining to recommend a treatment.

Notwithstanding the apparent discretion vested in Pharmac by the statute ('when it considers it appropriate to do so'), the judge concluded that such a practice prevented the Agency from properly discharging its statutory duty. Nor was this procedural deficiency 'cured' by subsequent consultation on the proposal to fund a 9-week period, since this effectively offered a choice between funding for 9 weeks or no funding at all, rather than reopening the proposal for 12-month treatment. The judge therefore ordered that a process of consultation on the proposal to decline funding for a 12-month period of treatment be instigated, while observing that it would be open to Pharmac, following consultation, to reiterate its recommendation not to provide such funding. In such circumstances, the decision to fund treatment of 9 weeks' duration – which was considered to have been lawful – would remain in place.

The process of consultation produced more than 300 responses. Following a review of these and additional clinical information, Pharmac concluded that no new information had been presented which demonstrated any additional health benefit over the 9-week period of treatment, and recommended that funding for the 12-month period should continue to be declined. However, in December 2008, the incoming National Party administration gave effect to a pre-election commitment to provide funding for treatment of 12 months' duration on New Zealand's national formulary.

5. Analysis

While one must remain attentive to the differing patterns of evolution of these legal systems (especially subsequent to independence), the principles of fair procedure are broadly shared, as is demonstrated by the citation of English precedent in each of the Australian and New Zealand cases. Given such cross-fertilisation, it is

possible to construct a judicial model of procedural justice that has resonance across all three jurisdictions. This section attempts such a task.

Perhaps the most straightforward conclusion which one might draw from these cases is that decisions reached by national-level agencies undertaking health technology appraisals are not always compliant with the principles of procedural fairness as articulated by courts. At a fundamental level, this would suggest that the answer to the question "centralised … review processes: are they fair?" (Mitton *et al.*, 2006) is "not always", at least when fairness is assessed by way of reference to judicial standards of procedural justice. However, such an assessment has certain limitations. First, the cases discussed in the preceding section represent a very small percentage of the total number of decisions taken by such agencies. It is naively reductionist to draw the inference from this small data set that the process of decision-making is unfair overall. Second, the relationship between legality and legitimacy is complex. Pronouncement by a court that the process of decision-making employed in a particular instance is procedurally unfair does not *necessarily* preclude the decision from being acceptable in the eyes of stakeholders and the general public, although it certainly renders acceptability considerably less likely.

A further, and perhaps more valuable, observation which might be made as regards these cases is that fairness or procedural justice occupies a central position both as a ground of challenge to, and as a basis of judicial appraisal of, decision-making by these agencies. It is, as noted in *Bristol-Myers Squibb*, a "general requirement of the process" (para 52). Every one of the cases discussed in the preceding section involved a claim that fair procedures had not been followed by the agency in reaching its decision, notwithstanding that a number of other bases of challenge were also enumerated. More significantly, in all four instances in which a challenge to the agency was ultimately upheld (sometimes, on appeal) – *Pfizer*, *Eisai*, *Servier* and *Walsh* – the sole argument which prevailed was that based upon lack of procedural fairness. By contrast, arguments pertaining more closely to the criteria or evidence informing a decision were routinely unsuccessful. Examples include the claim in *Pfizer* that the PBAC decision was improperly based upon the 'political' consideration of the overall cost of Viagra, the argument in *GlaxoSmithKline* that the same agency's decision rested upon inadequate or no evidence, the claims in *Eisai* that NICE's understanding and application of the evidence was defective, the Institute's alleged failure to attach weight to relevant evidence in *Servier*, and the criticisms of Pharmac's analysis of the clinical and cost-effectiveness of Herceptin in *Walsh*.

One explanation for this state of affairs is that it is simply reflective of the parameters of judicial review of administrative action. Review of the fairness of decision-making processes lies squarely within the judicial remit, but courts are not empowered to review the substance of decisions reached by administrative agencies since this would involve impermissible intrusion upon the merits of such a decision rather than a mere review of its lawfulness. This is especially

pertinent in the context of allocative decisions in healthcare, in which courts have traditionally operated a restrained approach to review, given the concerns as to lack of competence both institutionally (in that they lack expertise on matters of clinical or cost-effectiveness or the management of resources and/or the procedural capacity to deal with multifaceted allocative questions) and constitutionally (in that democratic principles require that decisions on the merits of allocative choices are entrusted to elected representatives or to unelected officials appointed by and accountable to such representatives). The limitations of the judicial role in this context were clearly articulated in *Walsh*, in which Gendall J. observed of the competing merits of the 9-week versus 12-month period of funding that:

> it is abundantly clear that there was, and remains, room for more than one view. This Court cannot sit in its judicial review capacity as though it were entertaining an appeal. It is in no position to express a view as to which side of the factual argument is correct, or to be preferred (para 154).

In view of this, it is unsurprising that procedural arguments have tended to dominate and that, correspondingly, challenges relating to the consideration of evidence or the criteria used to inform a limit-setting choice, which draw the courts more closely into an evaluation of the content of a decision, have been rejected. However, the differentiation between matters of procedure and substance is not simply a function of the delineation of appropriate judicial tasks: it can additionally be read as indicative of the courts' acceptance or otherwise of the claims to legitimacy advanced by the agency. Viewed from this perspective, the claim through expertise is regarded as possessing considerable weight, with the consequence that any aspect of the decision that rests upon the exercise of expert judgement is virtually immune to judicial intervention. The following passage from *Servier* is both illustrative of such a stance and of its interrelationship with concerns as to lack of judicial competence:

> It is important to stress at the outset that NICE is the specialist, expert body, charged with making appraisals and decisions of this type. The court is not. I have neither the right, still less the expertise, to review the decisions as to their substance (para 6).

By contrast, judicial readiness to intervene in questions of procedure indicates that the claim to legitimacy through procedural justice is regarded with greater scepticism by the courts. This brings into focus two key questions: what are the components of the judicial model of fair decision-making process as applied to agencies undertaking technology appraisals and how do these compare to the conditions of accountability for reasonableness?

The first point to be noted is that the absence of judicial scrutiny of issues relating to the substance or content of the agency's decision effectively excludes the 'relevance' condition from the ambit of the courts. In these cases, courts impose no constraints on the types of reasons, values or evidence which are advanced by agencies as the basis for coverage recommendations so as to ensure

that these are "accepted as relevant by people who are disposed to finding ways of co-operating with each other on mutually acceptable terms" (Daniels and Sabin, 2008: 51). This does not mean that we should dismiss the 'relevance' condition as a component of a fair and legitimate decision-making process, although it does lend weight to the critique that this condition is, at base, substantive rather than procedural in character. Rather, the issue of 'relevance' is, for reasons of lack of judicial competence and/or deference to expertise, left to the agency's discretion and does not form part of the judicial model of procedural justice.

Second, it is clear that the courts regard transparency as important when evaluating the procedural fairness of a decision reached by such an agency. This is perhaps most evident in the cases regarding NICE. In *Eisai*, the Court of Appeal drew attention to the "strong public interest" in the work of the Institute given its vital role in determining availability of treatments on the NHS, which NICE had recognised through "its acceptance of the need for a very high degree of transparency in the process" (para 34). The Court commended the Institute for the fact that there was "already a remarkable degree of disclosure and of transparency in the consultation process" (para 66). Likewise, in *Servier*, Holman J. stated that "NICE is always under a duty and imperative of transparency and fairness" (para 115) and observed that it must "keep firmly in mind the high importance of fairness and transparency" (para 123).

Perhaps somewhat paradoxically, it was NICE's own commitment to transparent decision-making, as evidenced in its documentation (cited in *Servier*, paras 45–47), which created a space for findings that it had acted unlawfully in failing to fully disclose the models upon which the recommendations had been premised. Thus, in *Eisai*, the Court of Appeal commented that the commitment to transparency "cuts both ways because it also serves to underline the nature and importance of the exercise being carried out. The refusal to release the fully executable model stands out as the one exception to the principle of openness and transparency that NICE has acknowledged as appropriate in this context" (para 66). Similarly, in *Servier*, the judge held that while exceptionally it might be permissible to give undertakings as to confidentiality in order to ensure the quality and robustness of the appraisal process (e.g. to enable the Institute to maximise access to information in view of the fact that some material was commercially sensitive or that its use might prejudice future academic publication rights), nonetheless, the high importance attached to transparency placed NICE 'under some duty to "press"', that is to "particularly strive to seek permission to disclose the economic model and/or the data contained therein": which duty he concluded had not been discharged (paras 121/123).

While the courts have not emphasised the importance of transparency in such explicit terms elsewhere, it is notable that non-compliance with an obligation to disclose the information upon which the decision was based also formed the rationale for judicial intervention in *Pfizer* and was cited as a ground in both

Bristol-Myers Squibb and *GlaxoSmithKline*, although the courts in the latter cases determined that sufficient information had been provided. It is also possible to construe the Pharmac practice of non-consultation in which it had reached a decision to decline to recommend the technology in question as indicative of an absence of transparency, notwithstanding that it was not conceptualised in this precise manner by the court in *Walsh*.

There is a superficial parallel between the judicial conceptualisation of fair procedures in this regard and accountability for reasonableness, which Daniels has recently characterised as requiring "transparency for all aspects of the [priority-setting] process" (2008: 330). However, it is important to identify the precise role which commitment to transparency as a principle of procedural justice serves in the Daniels and Sabin and judicial conceptions respectively. In the former, transparency primarily takes the form of the 'publicity' condition which – by allowing for public accessibility to limit-setting decisions and their rationales – facilitates consistency in decision-making by evolution of a body of 'case law' and fosters understanding of the need for limit-setting in healthcare and the criteria upon which such choices may be based, thereby opening up the prospect of a process of public deliberation. While there is some judicial acknowledgement of the latter rationale in *Servier* in which Holman J. notes that NICE must have regard to "the importance of the respective information to understanding the appraisal" (para 123), in the same case the court also observed that, while NICE should provide reasons for its guidance, they need only be sufficient to explain to a "technically informed reader" why the Institute had reached a particular conclusion (para 178). This suggests that transparency is not predominantly perceived by the courts as a value which has 'educative' utility in fostering broad understanding of the limit-setting implications of health technology appraisal as the basis for a public deliberative exercise.

Rather, the primary function of transparency in the judicial model appears to be to facilitate stakeholder participation in the initial decision-making process. This connection is, again, most readily apparent from the cases on NICE. In *Eisai*, the court held the refusal to release the fully executable version of the model to be unlawful because it limited the "ability to make an intelligent response on something that is central to the appraisal process" (para 66) of consultees (i.e. organisations invited by NICE to take part in a technology appraisal, who can submit evidence, comment on appraisal documents and appeal the final determination). Similarly, in *Servier*, the judge required NICE to disclose the economic model to all consultees and to "permit all consultees … to make further submissions or representations in response to that disclosure", noting that "NICE must give due consideration to [issues arising as a result of any such submissions] and, if it thinks fit, further revise the Final Appraisal Determinations in the light of it" (para 230). By contrast, in *Bristol-Myers Squibb*, the failure to disclose the modified model was not unlawful as this had not affected the ability of the company to make informed representations (para 71).

It might be concluded from this that participation in decision-making is regarded by courts as the dominant value of procedural justice and that transparency merely serves a secondary role in enabling such participation to be as meaningful and useful as possible. The Australian cases lend support to this view in that, as previously noted, the need for disclosure of information is not explicitly conceptualised as required in the interests of transparency, but is seen as necessary to enable the making of informed representations to the agency. Thus, in *Pfizer*, the appeal court held that the failure on the part of PBAC to inform the manufacturer that it intended to take account of the information on the usage rate of alprostadil was unlawful because (in the words of the summary of reasons attached to the court's judgement) "the Committee was obliged both to inform Pfizer that it intended to take into account certain information that was potentially detrimental to Pfizer's interests, and to allow Pfizer an opportunity to respond to that information". In *GlaxoSmithKline*, the opposite conclusion was reached on the facts, but the reasoning employed was similar, Ryan J. making the following observations:

> A Committee of experts is entitled to draw upon its own expert knowledge provided that it has properly considered the evidence before it … Nor need the content of its expert knowledge be exposed to a person affected although such a person must have an opportunity to contradict relevant material before the Committee which is prejudicial to that person's interests … The present Committee was clearly obliged to give the applicant an opportunity to respond to its concerns, however they might have arisen, and to suggest that despite the superficial attraction of the Committee's initial hypothesis as a matter of ordinary logic, there were matters which weighed against it being correct (paras 37/38).

This passage offers a clear indication of the somewhat limited conception of participation which is articulated by the courts in this context. Participation is seen in essentially adjudicative terms: it is concerned with presentation of proofs and argumentation by the parties to a decision with a view to persuading the adjudicator (decision-maker) to rule in favour of that party (Fuller, 1978). The scope of participation is narrow, being restricted to stakeholders directly affected by a decision or, in the case of NICE, to consultees who have been invited to take part. Furthermore, its function is relatively specific. The courts consistently emphasise that affected parties should be able to understand what is at issue, to present evidence and arguments and – perhaps most clearly – to respond to or rebut opposing arguments. For example, in *Eisai*, the court remarks upon the need to "check and comment on the reliability of the model", to "check whether there are variables to which the model is particularly sensitive and make informed representations accordingly" and to "challenge the reliability of the model" (paras 49/50/66); in *Bristol-Myers Squibb*, the court acknowledges that disclosure of information might be necessary in order for the company to "comment upon the … report in order to undermine the higher incremental cost-effectiveness ratios" and to "effectively examine and challenge

[the] report" (paras 59/61); in *Pfizer*, the court notes that the manufacturer "was deprived of the possibility of persuading the PBAC that the experience in respect of alprostadil injections would not be repeated should sildenafil not become available as a pharmaceutical benefit" (para 67); while in *GlaxoSmithKline*, the decision was not unlawful because "there were no factual matters relevant to the Committee's finding against the applicant upon which the applicant was denied an opportunity to comment" (para 43).

How does this compare with accountability for reasonableness? As previously noted, that model as originally conceived does not accord great significance to participation in limit-setting decisions and to this extent it may be differentiated from the judicial approach. The latter is also distinct from the model of procedural justice favoured by some of Daniels and Sabin's critics, who envisage a much broader range of direct public involvement in the process of reaching limit-setting choices. For example, Sabik and Lie call for an "open commentary" upon coverage decisions and argue that "empowerment means involving in the initial discussions both the general public and people who will be affected by the decisions, not just the decision-makers within the system" (2008: 83; see also Friedman, 2008; Rid, 2009). It is clear that the judicial approach does not go this far.

The judicial conception of participation does have some commonalities with the modified position adopted by Daniels and Sabin in recent work, in which it is contended that "consumer participation … increase[s] the likelihood that a broader range of relevant reasons and rationales will be aired in the decision-making process and thus strengthens the existing conditions of accountability for reasonableness" (Daniels and Sabin, 2008: 62). It may be argued that, similarly, the objective of the courts is to ensure that the agency is in possession of information which it might not otherwise have acquired and that it is thus able to make a balanced and, as far as possible, 'correct' decision based upon full knowledge of all relevant facts. To this end, participation connects to the 'relevance' condition in that it serves to reassure stakeholders that the decision is based upon relevant criteria, including their own responses to the evidence provided by the agency. However, there are at least two differences between the models. First, participation occupies a more central position in the judicial reading of procedural justice than is the case even in the modified version of accountability for reasonableness, where it appears as something of an afterthought: certainly, and in contradistinction to the courts, Daniels and Sabin regard participation as being of subsidiary importance to transparency. Second, whereas Daniels and Sabin are clear that engendering a "deliberative process at the point of decision-making" (2008: 63) is not a substitute for a broader process of public deliberation upon limit-setting, through which legitimacy is ultimately obtained, there is no indication in the English and Australian cases that the courts view participation as a principle which has value *outside* the original decision-making arena. It operates purely to enable reasoned argumentation, evidence and

proofs to be presented to the agency by the parties and does not function as a means of "modelling a wider deliberation [or] educating the public" (Daniels and Sabin, 2008: 63).

Only *Walsh* appears to stand as a partial exception to this narrow judicial conceptualisation of participation. Here, although Gendall J. noted that the extent of consultation was a matter lying within the discretion of the agency, he held that it was unlawful not to consult *at all* prior to reaching the decision upon funding for Herceptin, especially in circumstances where there was "known wide and continuing public interest by groups, organisations or individuals likely to be considerably affected by a decision" (para 189). He offered further indication of the meaning which he attached to the process of "wide public consultation" (para 204), which he considered should have taken place before rejection of the 12-month period of funding, in stating that:

> Consultation does not require ultimate agreement, nor does it involve negotiation. Consultation does not require or involve an ongoing dialogue over a protracted period … Consultation requires open-minded communication and hearing the voice of others who are given the opportunity, and right, to be listened to (para 207).

While it might be objected that 'consultation' differs from 'deliberation' in that a deliberative approach is more reflective and open than consultation (which is normally 'top-down' in orientation and in which scope for public reasoning and communication may be tightly constrained by a restricted range of policy options), the reference in this passage to 'open-minded communication and hearing the voice of others' and the degree of public input envisaged by the judge do suggest a broader reading of the participatory dimension of procedural justice than is apparent in the Australian and English cases. Of course, factors peculiar to the litigation in *Walsh* may explain the difference. The litigants were patients, rather than pharmaceutical companies (although it should be noted that patient groups had joined as interested parties in two cases against NICE). Furthermore, as previously noted, the particular statutory framework under which Pharmac operated imposed a duty to consult (albeit one which permitted considerable discretion in interpretation) in much clearer terms than apply either to PBAC or NICE. Nevertheless, *Walsh* does demonstrate that the potential exists for courts to adopt a more open, deliberative conception of participation in future cases of this type, should they choose to do so.

There is little by way of explicit statement which may be extrapolated from these six cases which casts light upon the judicial approach to the third condition of accountability for reasonableness, appeals/revision. Here, various models exist in practice: NICE has an internal appeals process, PBAC an independent review process, and Pharmac no formal process at all. At common law, the absence of such a process is not in itself unlawful, though if an appeal mechanism is provided, it must be procedurally fair. However, more generally, the judicial reading of transparency and participation articulated in these cases

appears precisely designed to ensure that alternative arguments and additional evidence are presented with a view to the agency revisiting (albeit not necessarily altering) its decision, as it will be obliged to do in order to comply with the court's ruling. Where litigation occurs, therefore, the court may demand internal reconsideration of the original decision on the basis of arguments and evidence which were not initially presented because of inadequacies in the realisation of transparency and participation, even where no formal appeal mechanism exists. While not as potent as the internal dispute resolution process required by Daniels and Sabin, this approach nonetheless evinces a similar judicial concern for the right to put one's case against the original decision, with the prospect of revision of the latter.

6. Conclusion

This survey of litigation in three jurisdictions demonstrates that questions of procedure occupy a dominant position in judicial scrutiny of national agencies undertaking health technology appraisals, just as they do in much of the literature on healthcare resource allocation in general. Although generally deferential to the exercise of expert judgement by such agencies, the courts cast a much more critical eye over the processes by which decisions are reached and have proved willing to declare limit-setting choices which do not comply with judicially articulated values of procedural justice to be unlawful. While it would be misleading to conclude from the small number of successful legal challenges that the decision-making processes of these agencies are generally unfair, it would be equally mistaken to ignore judicial pronouncements in light of the weight which these carry as societal yardsticks of procedural fairness and the legal obligation of compliance which attaches to them.

The judicial approach to procedural justice in cases involving national-level technology appraisal agencies differs from accountability for reasonableness in two important respects. First, the proscription of judicial intrusion into the merits of a decision largely precludes enforcement of the 'relevance' condition, except in so far as imposition of a participatory obligation connects to this condition. The judicial reluctance to regard this as a component of procedural justice lends weight to the claim that this condition is, at base, substantive in character. Second, participation plays a more prominent part in the judicial conception than it does in the original Daniels and Sabin model, with transparency being subsidiary and valued primarily for its capacity to facilitate stakeholder input. This suggests that those critiques of accountability for reasonableness which emphasise the importance of participation as a dimension of procedural fairness possess merit, notwithstanding that these appear more deliberative in orientation than the essentially adjudicative model generally adopted – at least, to date – by the courts.

While such distinctions in approach do not invalidate accountability for reasonableness (especially in view of the fact that health technology appraisal is

just one setting in which this framework has been applied), they do underline the importance of adopting a critical reading of the model and of avoiding too ready an assumption that the fairness of limit-setting decisional processes can be measured by a simple, perfunctory application of its conditions. Given the virtual inevitability of future litigation involving bodies conducting health technology appraisals, continued attention to judicial scrutiny of decision-making processes in this field will remain imperative in order to develop a comprehensive appreciation of the meaning of fairness and legitimacy in this contentious area of modern public policy.

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