

## PHARMAC AND THE FUNDING OF HIGH COST PHARMACEUTICALS

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PHARMAC has asked for responses to the following questions:

- a. What are the main economic/social justice/ethical theories relevant to how decisions on funding “high cost” pharmaceuticals could be made?
- b. What if any justification is there for assessing High Cost Pharmaceuticals [HCPs] differently from other pharmaceuticals considered for public subsidisation?
- c. What might be the downsides of valuing HCPs differently?
- d. Could cost utility analysis be used more effectively when considering HCPs ? If so, how?
- e. What if any changes do you recommend PHARMAC make to its current decision making process for HCPs ?
- f. What role should rule of rescue play in assessing HCPs ?
- g. What are the arguments for and against paying a higher price (per QALY gained for example) for pharmaceuticals for those who are worse off clinically with poor quality-adjusted life expectancy, but of arguably greater need (for example the terminally ill)?
- h. Are there any general comments that you wish to make ?

In this paper I first respond to question a) and within that section briefly respond to question g). I then respond to questions b) c) and f). I end with a response to question e). I do not respond to question d) as it is not within my area of expertise to do so; and I make some general comments (question h) intermittently within the paper, and in the last paragraph.

### **a) What are the main economic/social justice/ethical theories relevant to how decisions on funding “high cost” pharmaceuticals could be made?**

There is a wide variety of substantive ethical theories and principles of distributive justice with no one theory commanding even wide acceptance let alone universal acceptance. Ruefully noting this lack of agreement in 1985, I outlined Aristotle’s still widely agreed *formal* principle of justice and five potentially mutually inconsistent *substantive* theories of justice that nonetheless could conform to the Aristotelian principle (that equals should be treated equally and unequals unequally in proportion to the relevant inequalities). These were libertarian theories, utilitarian theories, Marxist theories, Rawls’s theory and desert-based theories<sup>11</sup>. Twenty years later Lamont, in the online Stanford Encyclopedia of Philosophy<sup>2</sup> discusses a wider range of substantive principles of distributive justice, all potentially consistent with the Aristotelian formal principle but mutually inconsistent. The theories described by Lamont are those based on:

**strict egalitarianism** (in which everyone has to have the same level of material goods and services);

**the difference principle (based on Rawls’s theory of justice** in which everyone first has an equal claim to equal basic rights and liberties and secondly social and economic inequalities are considered just only if they are attached to positions and offices open to all under conditions of fair equality of opportunity and are such as to bring the greatest benefit to the least advantaged. An important application of Rawls’s theory of justice to health care is Norman Daniels’s theory of ‘Just health care’ in which ill health and disability are seen as impairing people’s fair equality of opportunity. An important variant on Rawls’s theory of justice is Nobel Prize-winning economist Amartya Sen’s theory of justice in which equality of capability to achieve what one values is the proper objective of justice);

**resource egalitarianism** (based on the notion that justice requires equality of resources but that people’s use of their resources can be justly various and that those who for example work

harder to build up their resources do not owe subsidies to those who choose to work less hard and thus obtain less income. Resource egalitarians such as Ronald Dworkin agree that compensation for natural disadvantages over which people have no control would be required by their theories of justice)- this group and the last group of principles of justice are sometimes called '**egalitarian-liberal theories of justice**;

**welfare maximisation** (based on the utilitarian basic claim that maximising people's welfare is the fundamental moral concern and that just distribution of scarce resources is whatever distribution maximises welfare- various types of welfare maximisation have been described including Bentham's 'greatest good for the greatest number' and contemporary utilitarian concern to maximise people's preference satisfaction)- **utilitarian justice**;

**people's deserts** (based on the notion that scarce resources should be distributed in proportion to what people deserve- typically because of their virtues and vices (Aristotle) or their 'toil' (John Locke) or in modern variants, their merits and demerits, their work effort and costs, their productivity and their retrospective and prospective contribution to society)- **desert-based justice**;

**libertarianism** (In Robert Nozick's libertarian theory of justice it is not outcome that is morally relevant but the moral nature of individual transactions; if a person justly acquires a holding he or she is entitled to it and when a person justly transfers a holding to which he or she is entitled then the acquirer is entitled to that holding, and no one is entitled to holdings except by such just acquisitions, and overall distributive justice is achieved by exclusion of all transactions that are not based on such just entitlements and compensation for those that have been transacted contrary to just entitlements)- **libertarian justice**;

**feminism** (Lamont points out that there is a wide range of feminist perspectives on justice but concentrates on liberal feminist perspectives that claim equal rights for women as for men, and a concern to remedy injustices against women that stem from liberal reluctance to allow the state to interfere in the 'private' sphere in which women are in practice unjustly treated. In addition feminist care and relationship perspectives such as those associated with the work of Carol Gilligan may be seen as supplanting impersonal principles such as the principle of justice)- **feminist approaches to justice**.

To these broad categories of theories of distributive justice we should add:

**Kantian theories** (in which justice is determined by application of Kant's 'categorical imperative' according to which justice is obtained when people are treated never merely as means to an end but always as 'ends-in-themselves'- as autonomous beings; when moral agents base their actions on maxims or rules of thumb that can be legitimately 'universalised' so that anyone in a similar situation could morally acceptably act on the same maxim; and when moral agents act on the basis that they are legislating for a kingdom of ends-in-themselves, or autonomous beings)- **Kantian justice**.

**Marxist theories** (in which justice is most pithily summarised in the slogan 'to each according to his need, from each according to his ability') **Marxist justice**;

**Religious theories** (in which, typically, differential concern favouring the poor, the suffering and those in need is emphasised)- various **religious theories of justice**

**Virtue theories** (in which justice is the result of and determined by the attitudes and actions of virtuous people<sup>3</sup>)- **virtue based theories of justice**

**Pluralist theories of justice** (in which a variety of potentially conflicting moral concerns are built into theories of justice)

**Anti-racism theories of justice** (in which, as with many feminist theories, emphasis is placed on remedying systematic injustices to particular groups, in this case those experienced by oppressed racial groups)

**Environmental justice** (whose emphasis is on justice based on environmental sustainability)

**Rights based justice** (in which justice, increasingly including distributive justice, is based on people's perceived human rights, and especially their human rights as enshrined in international and national conventions, declarations and laws. This approach to justice is, unsurprisingly, especially favoured in legal (as distinct from philosophical) perspectives on justice, and of course in poorer parts of the world, where so called positive rights, requiring assistance -including aid- from others, are often seen as more important than negative rights which simply require others to desist from actions (such as unjust oppression, torture, imprisonment, restriction of liberties such as political association and so on). Aspects of human rights conceptions of justice have increasingly been democratically incorporated- typically through Human Rights Acts- into national laws including those of New Zealand.

### **No single theory of justice commands widespread acceptance**

The huge range of substantive theories and principles of justice, briefly indicated above, demonstrates the fact that no one theory commands anywhere near universal acceptance. I believe that it also demonstrates the range of morally relevant concerns that an adequate substantive theory of justice would have to accommodate. In a paper<sup>4</sup> for the UK Health Equity Network I outlined criteria, broadly reflecting a range of competing theories of justice, that would be plausibly necessary for a substantive theory of distributive justice to command widespread acceptance. The paper reiterates that while an underlying acceptance that justice requires equality in some sense or another is common to all theories of justice, as Aristotle pointed out so long ago equality is not necessarily just or fair. His underlying formal requirement for justice, that equals be treated equally and unequals be treated unequally in proportion to the relevant inequality (what contemporary health economists sometimes refer to as horizontal and vertical equity) remains widely accepted. However philosophers, politicians, theologians, amongst many other groups, have been arguing ever since about what are the relevant inequalities that justify treating people unequally (vertical justice), as well as what are the relevant equalities that justify treating people equally (horizontal justice). Equality remains the central concern, but as Amartya Sen emphasises, the crucial issue is 'equality of *what?*'<sup>5</sup>.

### **Equal health care resources for equal health care need**

In health care contexts variations in levels of **health care need** are widely accepted to be morally relevant inequalities such that the greater the need the greater the presumption of a moral obligation to try to meet that need<sup>6</sup>. This of course leads to morally required *inequality* of treatment. Unequal treatment in proportion to need is built in to PHARMAC's existing overarching objective (1.1) and health needs are referred to in three of the nine decision criteria in PHARMAC's operating policies and procedures document (2.2 a,b and e). A moral obligation to benefit people differentially (ie unequally) in proportion to their need is found in a variety of moral theories including those of the major religions and of Marxism. Doyal and Gough<sup>7</sup> are contemporary exponents of a needs based system for allocation of health care resources.

Unfortunately for those who would like a relatively simple theory of distributive justice, (a) there are problems associated with the very concept of distribution of resources in proportion to health care need and (b) various other criteria morally relevant to just distribution of scarce resources can conflict with distribution in proportion to people's need for them.

## **Problems with the criterion of distribution in proportion to health care need**

These can be summarised as problems with the concepts of need in general and of health care need in particular; the potential incommensurability of different sorts of need, and of different sorts of health care need; the problems of unmeetable needs; and problems of needs that while they are meetable have either a very low probability of being met, or else can only be met at very high cost.

So far as the concept of need goes, I shall simply assert that in a highly contended arena my own working account of a need is **that without which one is harmed**<sup>8</sup>. A health need is that without which one's health is harmed, and a health care need is an element of health care without which one's health is harmed.

## **Can different sorts of needs be compared?**

The incommensurability, or non-comparability, of needs is a subclass of the general problem of incommensurability of benefits and harms. How can one say that relieving severe itching is better or worse than gaining an extra day of life, let alone how much better or worse? Like chalk and cheese we simply can't compare them- or can we? Suffice it summarily to say here that since people are in fact able to make choices between incommensurables, and indeed to give differential 'weights' to incommensurable alternatives this problem is in practice surmountable. The use of QALYs (quality adjusted life years) in the context of health care provision is one way of surmounting it. The use of QALYs is open to a variety of criticisms<sup>9,10</sup> to some of which I shall return below, but in the context of health care need the main problem is that while they may provide a way of overcoming the incommensurability problem they afford no basis for distinguishing between QALYs gained in the context of meeting needs, and QALYs gained in the absence of need. A QALY gained as a result of my going to the South of France is equivalent to a QALY gained in relieving my pain or zapping my cancer. Even within the context of QALYs gained from health care the QALY gained by the insomniac is equivalent to the QALY gained by the patient in heart failure.

## **Meetable and unmeetable needs**

Even if needs are graded in terms of severity of ill health/disability and made – at least de facto- commensurable (for example by measuring a QALY deficit from normal species functioning seen as equivalent to 'adequate health') not all needs can be met, and this would be true even were there to be unlimited resources (and of course there never are or will be unlimited resources). Thus as already noted<sup>6</sup> a person dying from a disease for which there is no known cure has a need for such a cure- but that need cannot be met. There is no point in, and in the context of scarce resources no moral justification for, providing treatments that cannot provide benefit. On the other hand, (and to respond briefly to PHARMAC's question g) above), people dying from incurable conditions remain in enormous health care need (primarily of cures for their fatal condition) and if this large degree of health care need would justify prioritising successful treatment, it seems reasonable to prioritise meeting their *meetable* health care needs even in cases when their major need for a cure for their condition can not be met. On this basis-in the context of pharmaceuticals- medications that are curative for other conditions but that are known to be ineffective for a particular patient's fatal condition should not be provided in an ineffective and often deceptive attempt to 'do something'. However medications that meet such patients' *meetable needs*, for example by alleviating their distressing symptoms such as pain, nausea and vomiting, itching and other unpleasant sensory experiences, psychological disturbances of various sorts, auditory and visual disturbances and indeed any other distressing symptom- should be prioritised.

As well as patients with very great needs that cannot be met there are also patients with very great needs for whom **treatments *might* meet those needs but with only a low probability**

**of doing so. And there are patients with very great health care needs that are clearly meetable but only at very high cost.** In both cases there is obviously a major moral tension between on the one hand providing beneficial treatment for those who greatly need it and on the other hand the opportunity costs to those denied beneficial health care resources that are spent instead on meeting very few people's needs at very high cost, either because the individual treatment though likely to be effective is very expensive or, in the case of low probability of successful treatment, because much resource will be wasted on providing non-beneficial (and possibly harmful) treatments to most recipients. I shall return to these issues when considering high cost pharmaceuticals and 'the rule of rescue'.

### **Producing sufficient, let alone maximal, benefit can conflict with meeting needs**

Clearly, however, *production of sufficient benefit, let alone production of maximal benefit* (the moral basis of utilitarian ethical theories) can conflict with distribution in proportion to need and an adequate theory of justice must surely have *some* place for a concern to produce a *sufficiency* of beneficial outcomes in the use of scarce resources. It would be, to say the least, highly counterintuitive for a theory of distributive justice to advocate the use of scarce resources on treatments that produced very little benefit, or had very low probabilities of producing benefit, any more than it could plausibly advocate using most of the available resources on producing great benefits for just a few recipients, even if those few had very great needs for such treatments. And, of course, built into PHARMAC's existing policy is exactly such an outcome concern to produce sufficient benefit per unit of resource used, notably its concern to limit the cost per unit of beneficial outcome (measured in QALYs) that it is normally prepared to pay for new pharmaceuticals. It is worth noting in this context that PHARMAC's existing policy is (implicitly) oriented to producing *sufficient* rather than *maximal* benefit and that it is explicitly concerned with benefit in relation to cost; cost-effectiveness is explicitly one of its criteria (eg OPP 2.2 (e) and 4.4), when comparing comparable outcomes: Indeed, cost utility analysis (CUA) using QALYs and direct financial costs for comparing different sorts of health interventions and outcomes (A Prescription for Pharmacoeconomic Analysis [PPA]- 1,3), is in practice probably its most important allocation criterion. Criteria for sufficiency of benefit are not specified in the current OPP and PPA, but pharmaceutical interventions that cost \$NZ10, 000 or less per QALY gained are likely to be accepted as producing sufficient benefit (see eg PHARMAC memo of Oct 2003 on High Cost Pharmaceuticals, p2) whereas those costing more than \$NZ10, 000 per QALY gained require special consideration. It is however explicitly stated that maximising beneficial outcomes as indicated by CUA is sometimes to be over-ridden by other criteria including avoidance of discrimination against the elderly and an element of preference for life-saving interventions over interventions that improve quality of life but do not extend life expectancy (PPA pp9-10). I shall return to this when considering the issue of 'the rule of rescue'.

Conceptually linked to beneficial outcome criteria are the **efficiency** criterion (avoidance of waste, or non-beneficial use, of scarce resources), and the **opportunity cost** criterion (consideration and justification of benefits that would be foregone by any proposed use of scarce resources). Both of these criteria may also conflict with allocation in proportion to need but (as a non-economist) I take it that avoidance of waste is an integral part of both cost effectiveness analysis and cost utility analysis, and that reduction of opportunity cost is its underlying moral justification.

### **Respect for people's autonomy can conflict with meeting needs**

Respect for people's autonomy is another morally relevant criterion to be included in an adequate substantive theory of distributive justice but it too may conflict with treating people equally in proportion to their needs, and it may also conflict with maximising benefit. Again PHARMAC's operational functioning at least implicitly accepts the relevance of this criterion. Thus no one is forced to submit medications to PHARMAC, or to prescribe

medications authorised by PHARMAC, or to use medications that have been prescribed for them (even if such coercion were to meet needs and provide benefit or even maximise benefit). And the autonomy of 'the people' as represented by their democratically elected Government is, arguably, respected insofar as the budget and priorities for its expenditure is accepted in PHARMAC's objectives and operational functioning.

### **Respect for autonomy does not mean accepting 'I want it so do it'**

In this context it is important to note that, at least according to standard accounts, respect for autonomy does **not** require that one does what another person autonomously requests or requires one to do- 'I want it so do it'- it simply requires that one does not interfere with the person's own autonomy (literally self-rule, probably better briefly described as deliberated, or thought out, self rule)- always with the qualification that such respect has to be compatible with equal respect for the autonomy of all potentially affected. Thus the corresponding right is the negative right of not being prevented from acting autonomously, insofar as such 'deliberated self-rule' is compatible with others' autonomy. Of course if one does do what another autonomously requests or requires one to do then that is entirely *consistent with* the principle of respect for autonomy but it is not *required* by the principle. Thus if a doctor insisted on administering to a patient some medication or other treatment despite the person's autonomous refusal that would infringe the person's autonomy and would thus infringe the principle of respect for autonomy (even if the medication or other treatment were unquestionably needed and beneficial). But if a doctor refused to comply with a patient's request or demand for a particular medication, or other treatment, that would **not** infringe that patient's autonomy and would thus not infringe the principle of respect for autonomy (even though giving the requested medication or treatment would be entirely consistent with respecting the person's autonomy and thus with the principle- and even if in some cases refusal might be immoral on other grounds- for example if it constituted failure of the doctor's duty of care). Similarly if PHARMAC refuses to authorise a medication for Government subsidy despite the autonomous requests/demands of pharmaceutical manufacturers, doctors, patients or patient advocates, such refusal does not infringe the principle of respect for autonomy even though authorisation of the medication would be entirely consistent with the principle and in some cases may be required by some other moral concern, especially provision of health benefit.

In relation to Government matters are different, for Government, on behalf of the people it democratically represents, has created PHARMAC as its/their agent equitably to manage government expenditure each year of a specified amount of money on subsidising pharmaceuticals: the sum of money and the eligible population and the type of health care expenditure (on pharmaceuticals) are specified by Government as are several criteria for equitable distribution including 'the best health outcomes' for 'people in need' (OPP 1.1) within the confines of NZ law (1.2.3 and 1.6.3), in accordance with the Treaty of Waitangi (1.6), which explicitly requires responsiveness to 'the particular characteristics, special needs and cultural values of Maori communities' (1.6.2) insofar as this is consistent with avoidance of racial discrimination and the Human Rights Act 1993 (1.6.3). The Government also reserves the right to require PHARMAC to implement the Government's 'priorities for health funding' (2.2 (h)). In respecting these obligations PHARMAC can, perhaps optimistically, be seen to be respecting the autonomy of the people of New Zealand collectively, to the extent that democratically elected governments represent such collective autonomy (and ignoring here the manifold problems of 'democratic deficit'). For PHARMAC to spend more than its allocated budget, or to spend it on unauthorised expenditure (for example on health care for people deemed by Government to be ineligible) would be to infringe the autonomy of those providing the funding as represented by their democratically elected Government. Thus this is a very different case from PHARMAC not spending its budget on treatments requested or demanded by pharmaceutical companies, doctors or patients and patient groups, where refusal would not infringe the autonomy of these stakeholders, even though expenditure in

accordance with such requests or demands would be consistent with respect for their autonomy.

### **Prioritising particular groups and relationships can conflict with distribution in proportion to need**

Another at least plausible, yet highly contentious, criterion for an acceptable theory of distributive justice is **prioritisation of the needs of certain groups on the basis of certain sorts of relationships** and their concomitant commitments. This criterion too may conflict with allocation in proportion to need.

### **Doctors prioritising the interests of their patients**

In particular, once a patient is in a professional relationship with a doctor, or other health care worker, that relationship establishes a psychological bond and an element of consequent commitment such that the doctor or other health care worker naturally gives priority to the interests of that patient over the interests of other people with whom he or she does not have a professional relationship. This psychological bond is strengthened by an explicit professional moral commitment of doctors and other health care workers to protect the health interests of **their** patients. This sort of special commitment by individual doctors and other health care workers to the health interests of 'their' patients can clearly conflict with distribution of resources according to need. But once again it would be an intuitively implausible substantive theory of distributive justice that did not accommodate *some* degree of such differential concern. In the context of distribution of pharmaceuticals this differential concern is already in practice somewhat uneasily acknowledged, in that doctors are not merely permitted but expected to give priority to their patients. Within their groups of patients doctors are expected to prioritise in relation to medical need, but they are nonetheless expected to give priority to the needs of their own patients over the medical needs- even the greater needs- of others. This expectation has fuzzy borders for in emergencies doctors are also expected to prioritise the medical needs of strangers with whom they have had no previous professional relationship, even though this may be at the expense of the lesser needs of their own patients. Furthermore within national health services doctors are increasingly expected to limit their prescription of medications, especially expensive medications, according to protocols approved by government-controlled agencies. While patient safety is an important objective of such protocols, rationing in pursuit of distributive justice is often another and increasingly doctors are expected to follow such protocols even though they may conflict with the best interests of some of **their** patients.

### **Nations prioritising the interests of their nationals and residents**

This uneasy prioritisation of the needs of their own patients while acknowledging some, but undoubtedly lesser, responsibility to meet the needs of others is reflected at a national level (and at least in the UK at regional levels too). Thus as the PHARMAC's OPP make clear (eg OPP1.1 and 2.2 (a)), it is the NZ government that decides eligibility for subsidised pharmaceuticals, and it is reasonable to presume that the bulk of such subsidy is provided for NZ nationals (and eligible Pacific Islanders) and a small part for others resident in NZ. Other people, in other parts of the world, are for the most part excluded from such subsidy, irrespective of their medical need for pharmaceuticals, though doubtless some relatively small provision is made within the NZ overseas aid budget towards meeting such needs.

However the fact that special relationships and their associated commitments are in practice an established component of systems for allocating scarce medical resources does not entail that they are morally justified. Suffice it to assert that even utilitarian justice arguments based on traditional welfare maximisation and/or preference satisfaction maximisation are likely to support such differential allocations, as are justice arguments based on respect for autonomy.

People are likely to prefer, even after autonomous deliberation, that doctors have a differential concern for their own patients (as distinct for example from requiring them to provide their services on the basis of a strict needs related egalitarianism). In national health services funded through taxation voters are likely to prefer that the bulk of the funding is distributed to their own population rather than globally on the basis of a strict needs-related egalitarianism. Theories of justice that prioritise the importance of caring relationships (for example some feminist theories) can be expected to acknowledge the importance of such relationships in the context of allocation of scarce medical resources. In all such theories the role of special relationships in distributive justice will have to be tempered by other morally relevant criteria such as those mentioned above, but in all such theories some priority is likely to be given to those in special relationships. One important practical implication of accepting the moral importance of special relationships is that once a patient is receiving subsidy for a beneficial medication, continuation of that subsidy for that patient should be prioritised, even when subsequent decisions rescind authorisation of subsidy for the medication. This does not entail continuation of subsidy for a medication after it ceases to be beneficial to a particular patient, though conditions for subsidy (eg 'so long as the medication continues to provide [objectively determinable?] health benefit') should be made clear to doctors and patients (or their representatives) before the medication is started.

### **Elimination and prevention of morally unacceptable use and distribution of scarce resources can also conflict with distribution in proportion to need**

Another criterion that would be relevant to an adequate substantive principle of distributive justice is the elimination and prevention of morally unacceptable use and distribution of scarce resources. Prevention and detection of fraud and other forms of cheating, for example, or elimination of geographical inequities of access, or prevention and detection of morally unacceptable racial or gender or other illicit discrimination, or provision and implementation of public scrutiny and accountability mechanisms can all thus be relevant to fair distribution of scarce resources but, given a fixed quantity of resource they can all, perhaps paradoxically, conflict with beneficial use of those resources in proportion to need and reduce the welfare outcome of the available resource.

I do not see any reference to this issue in the PHARMAC literature and it might be worth considering it. One approach might be to consider any such expenditure that paid for itself as always worth funding, and to set a normal limit (eg not more than x per cent of total budget- where the size of x would be a political judgment) on the amount of any other such expenditure. But opposition can be expected from those who strongly prioritise elimination of unjust distributive factors- some may well adhere to the old adage, 'let justice be done though the heavens fall'- ie discovery and elimination of unjust factors affecting allocation of PHARMAC's resources would for them take absolute precedence over other expenditure, including expenditure on health care.

All these criteria- meeting needs, producing maximal or sufficient benefit, respecting autonomy, giving preferential weight to certain 'relationship obligations' such as the health needs of a doctor's patients or a regional or ethnic group, or a country's nationals, and elimination and prevention of clearly unjust methods of allocation- are potentially relevant to a widely and morally acceptable substantive theory of justice, and no such theory has been widely accepted nor to the best of my knowledge exists<sup>11</sup>. Thus from PHARMAC's point of view it seems far preferable to acknowledge the wide range of potentially conflicting moral criteria, the lack of an agreed unifying substantive theory of distributive justice and to seek to specify the criteria that seem to it relevant in particular cases where these conflict, and to make explicit its approach to resolving such conflicts when they occur- about which I shall say more towards the end of this paper.

**PHARMAC's Questions b) c) and f):**

**b) What if any justification is there for assessing High Cost Pharmaceuticals [HCPs] differently from other pharmaceuticals considered for public subsidisation?**

**c) What might be the downsides of valuing HCPs differently?**

**f) What role should rule of rescue play in assessing HCPs ?**

In response to b) I shall assume that the bulk of pharmaceutical assessments done by PHARMAC are based on the notion that the pharmaceutical to be assessed has been licensed as effective in meeting some medical need. A cost utility assessment is carried out and if the pharmaceutical is calculated to cost less than c \$NZ10, 000 per QALY produced, the product is subsidised. The underlying rationale for this approach can be interpreted to be that a pharmaceutical treatment that effectively meets some health care need is 'affordable' if it produces health gain of one QALY for less than \$NZ10, 000, and should therefore be subsidised. It doesn't matter whether the need being met by the pharmaceutical is a minor one (the itching and soreness between two toes of a minor case of athlete's foot, for example) or a major one (the pain of a heart attack for example)- provided that meeting the need costs less than \$NZ10, 000 per QALY gained the pharmaceuticals should be subsidised. This approach incorporates the criteria of meeting health care needs, doing so effectively and doing so affordably, but takes no account of the *extent* of the needs being met. However the need criterion for distributive justice discussed above is the prima facie obligation to try to meet a patient's health care needs *in proportion to the extent of those needs*. According to this criterion, the greater the need, the greater is the prima facie obligation to meet it. Thus a pharmaceutical that fails to meet the affordability criterion of \$NZ10, 000 per QALY may nonetheless be capable of effectively meeting a severe health care need, and it is this fact that may justify 'assessing HCPs differently from other pharmaceuticals considered for public subsidisation' (question b) above). The HCP is not initially assessed differently, for all pharmaceuticals go through the same initial assessment by PHARMAC; but pharmaceuticals that would cost significantly more than \$NZ10, 000 per QALY gained require additional assessment if they effectively meet severe health care needs. The 'downside' of such additional assessment is sub-maximal health gain per unit of resource and sub-optimal reduction of opportunity cost- but as I have argued above, sufficient health gain is only one of many potentially competing criteria within a potentially widely acceptable theory of distributive justice; with effective treatment of health care need in proportion to the severity of that need being widely regarded as more morally important than maximising benefit.

Severity of health care need can itself be assessed along the two dimensions of impairment of quality of life and impairment of length of life, and advocates of cost per QALY assessments may well argue that no further assessment is justified, for QALYs are precisely designed to combine quality and length of life assessments. Unfortunately such responses encounter two major obstacles. The first is that cost per QALY gained assessments do not incorporate comparative assessments of prior health care needs- a QALY gained in treatment of athlete's foot is as valuable as a QALY gained in treating the pain of a heart attack. The need criterion requires such comparative assessments for it gives priority to treating greater needs over treating lesser needs. The second obstacle is that QALY assessments combine quality of life and length of life assessments, giving no priority to one or the other. But there are widespread human tendencies to see these assessments as fundamentally different and incommensurable- and to give moral priority to attempts to meet life- threatening needs, presumably on the grounds that it is more morally important to try to meet life threatening needs than to try to meet non-life threatening needs.

**The priority of saving life- not absolute but not just a matter of QALY assessment either**

This widespread human tendency to prioritise the saving of life over other beneficial activities for others is especially directed at saving lives that are identified and in some sense 'near'. The tendency has been dubbed 'the rule of rescue'<sup>12</sup> and summarised by Hadorn as - 'the powerful human proclivity to rescue endangered life'<sup>13</sup> -though probably 'the powerful

human proclivity to *wish* to rescue *near and identified and immediately* endangered lives' would be nearer the mark since even casual observation indicates an equally powerful human proclivity to *wish* to rescue rather than to ignore endangered lives that are not in any sense 'near', that are unidentified, and that are not in immediate danger. But even the thus qualified human tendency to wish to rescue endangered lives is of enormous moral importance in promoting the moral norm of beneficence to others in great need. However, when resources are limited, as they usually are, very expensive beneficence to some conflicts with (some of the) other moral obligations of justice identified above, and in particular with the opportunity cost to those people whose needs will not be met as a result of expenditure on very expensive rescues of those in great need. This will be the case even if we consider only life saving needs, for it hardly needs saying that within a fixed budget more lives can be saved with cheaper life saving means than with very expensive life saving means! But far more morally difficult is to try to 'weigh up' the benefits of life saving activities against the opportunity cost for people whose health care needs are not for life saving but for improvement in their quality of life.

Two polar responses are encountered, neither ultimately widely acceptable. The first is to accept that saving life must always take priority over other health care interventions that do not prolong life. The other is simply to deny that there is any morally justifiable distinction to be made- cost per unit of benefit is the only morally important criterion according to this response, with maximisation of benefit per unit of resource the guiding moral principle. Quality adjusted life years integrate the benefit of extension of life with the benefit of a healthy quality of life so maximisation of QALYs gained per unit of resource expended provides a method for maximising benefit. To start with this second response, which is essentially a simple version of the utilitarian moral criterion, it is open to objections both from within a more sophisticated utilitarian framework and from alternative moral perspectives. Sophisticated utilitarians can argue that failure to allocate additional value to life saving activities fails to acknowledge that life is the necessary condition for any sort of pleasure, satisfaction (including preference satisfaction), happiness, eudaimonia or any other sort of beneficial quality of life. Since maximisation of one or other of these is the utilitarian objective, additional value must, at least prima facie, be attributed to life prolonging activities as compared with activities that merely improve quality of life without extending it. This response acknowledges that prolonging lives of poor quality *may* produce less benefit than improving the quality rather than the length of people's lives, but emphasises that in general prolonging life is likely to take priority over merely improving quality. Moreover, since there is widespread social *desire* for attempts to be made to rescue immediately endangered lives, again a sophisticated utilitarian can argue that priority should be given to life saving activities over those that merely improve quality of life.

Non-utilitarian perspectives are likely to emphasise the intrinsic- and for some absolute- moral importance of saving life. Judaism and Islam count the saving of life as the supreme value<sup>14</sup> and while there seems less absolute an emphasis on the importance of saving life in the Christian doctrine of sanctity of life (which is more concerned with an absolute prohibition of the morally unjustified taking of life), nonetheless according to a widely seen Roman Catholic website 'ordinary means' (ie in Roman Catholic parlance morally required means) of saving life include continued provision of artificial nutrition and hydration to patients in persistent vegetative state (PVS), as in the American case of Terri Schiavo<sup>15</sup>- indicating a very strong emphasis on saving even hopelessly damaged lives. Such absolutist religious concerns may not be widely shared, but they surely reflect widespread acknowledgment of at least a strong moral commitment to preserve life. The ever-increasing medical capacity to preserve life, however, brings this commitment increasingly into conflict with the recommendations of cost-benefit and cost utility analyses.

Should we then simply accept the other polar response, that life-saving interventions should always be prioritised over non-life saving interventions? Consideration of PVS is for most

people (though of course not all) sufficient to demonstrate the moral implausibility of any such claim for it would entail that resources would have to be prioritised to keeping everyone alive, regardless of the quality of those people's lives and regardless of the opportunity cost of doing so. The extreme example of such a position would require patients in PVS to be kept alive by *any* effective life-prolonging treatment, regardless of the opportunity costs to other patients needing non-life-saving treatments. Even if we assumed that people would be allowed to refuse such life prolonging treatment in advance directives, anyone who had not refused would have to be treated with life prolonging treatment until they eventually died. These treatments would not be restricted to artificial nutrition and hydration but would include all and any potentially life-prolonging treatment, including very expensive ones. The idea that a cancer patient who went into persistent vegetative state should nonetheless continue to be treated with anti-cancer therapy, along with any other treatments that would prolong his or her life, including cardiopulmonary resuscitation, should be sufficient to illustrate the moral implausibility of accepting that life-saving interventions should always be prioritised over non-life saving interventions.

### The 'rule of rescue'

An increasingly articulated variant of the obligation to save life even at very high cost is the so-called 'rule of rescue'. This has been variously described, not just as Hadorn's 'powerful human proclivity to rescue endangered human life', or my suggested variant above, but also as Richardson and McKie summarise it, as 'the urge to rescue identifiable individuals facing avoidable death, without giving too much thought to the opportunity cost of doing so'<sup>16</sup> Richardson and McKie also report several other accounts of 'the rule', namely: 'a perceived duty to save endangered life where possible', 'the sense of immediate duty that people feel towards those who present themselves to a health service with a serious condition', 'an ethical imperative to save individual lives even when money might be more efficiently spent to prevent deaths in the larger population', 'the powerful human proclivity to rescue a single identified endangered life, regardless of cost, at the expense of many nameless faces who will therefore be denied health care', and Hadorn's 'fact about the human psyche that will inevitably trump the utilitarian rationality that is implicit in cost-effectiveness analysis: people cannot stand idly by when an identified person's life is visibly threatened if rescue measures are available'. Bioethicist Albert Jonsen, who originally coined the term 'rule of rescue'<sup>17</sup> points out in a later article that while this 'imperative to rescue endangered life' is 'undoubtedly of great moral significance'; yet he adds 'the imperative seems to grow into a compulsion, more instinctive than rational'. He recounts his puzzlement at how to resolve the impasse when 'the rational effort to evaluate the efficacy and costs, the burdens and benefits, of the panoply of medical technologies- an effort essential to just and fair allocation-encounters the straitened confines set by the rule of rescue. Even the soundest consequentialist arguments against that rule seem unable to break out of the box.'<sup>18</sup>

Various features may tentatively be discerned within the 'rule of rescue'. The first is its lack of clarity; though the differing formulations cluster around severity and immediacy of need, with need for life saving as a common (but not universal) feature- Haddorn<sup>13</sup> points out that nasty fractures can evoke the same rescue response, as indeed can any severe illness or injury, and Richardson and McKie<sup>16</sup> point out that sometimes enormous sums are spent to fly children with non-life threatening deformities or disfigurements from poor countries to wealthy countries for treatment.. In so far as some clarity can be extracted from the 'rule' (and it is noteworthy that no index entry for 'rule of rescue' is to be found in the latest 5-volume edition of the Encyclopedia of Bioethics), it seems to prioritise, as well as severe and immediate need, those needs about which *others have strong moral feelings*, generally because in some sense or another they feel '*near*' to an identified person or persons in need.

In some contexts such moral feelings may result from special and real relationships – eg those of family or friends, or the somewhat different but often nonetheless powerful feelings noted

earlier of health care workers as advocates for 'their' patients. Sometimes the feelings may arise from mere physical propinquity- the child has fallen down my well, the fire is in my road or village, the man has collapsed in front of me, and I feel I *ought* to try and help, try and *rescue*. In other cases the relationship is more 'virtual' than real, for example because a person's plight has been publicised in the media- but though the relationship may be 'virtual', the evoked feelings that the person(s) identified by the media *ought to be rescued* may nonetheless be real and powerful.

### **The rule of rescue, moral dilemmas and conflicts of moral principles**

In the context of high cost pharmaceuticals these various factors increasingly often produce genuine moral dilemmas. Strong moral reasons exist for treating the person in need, especially when the need is very great as in cases of life saving need. All the normal moral justifications for treatment are present, the patients would benefit, often greatly; they or their proper proxies autonomously request the treatment; their doctors wish to provide the treatment; the treatments are legally acceptable; the population may well be clamouring for the life-saving treatment to be provided. On the other hand provision of the very expensive but life-saving treatment in the context of a fixed budget can produce unfair opportunity costs for other patients in need, and be especially unfair to those whose needs though major are for other than life-saving treatments. Moreover provision of the high cost pharmaceutical will by hypothesis produce less overall health gain than alternative uses of the resources. What is to be done?

Unfortunately there is no widely agreed methodology for resolving moral dilemmas or conflicts of principles. Utilitarians purport to provide such a method – choose the alternative option that will maximise welfare- but a) there is sectoral repugnance for utilitarian ethics within pluralist societies and b) even within utilitarianism itself there are major disagreements about what is to count as welfare maximisation- and in particular how to balance quantity maximisation (eg Bentham's 'greatest happiness') with distributive maximisation (eg 'of the greatest number'). In the context of health, for example, is welfare maximised if a health policy maximises the total health gain, eg the total number of QALYs gained, even if higher social classes disproportionately gain more QALYs than lower social classes, or is welfare maximised if fewer QALYs are gained but more people gain them, and especially more people in greater need gain them?

### **The need for *judgement* and the need for caution about the 'mathematical model of judgement'**

It would be nice to be able to answer questions about how to deal with conflicting moral values or principles, and how to deal with moral dilemmas, with moral certainty or even with moral confidence, but alas I can't. What I am clear about is that in a democratic pluralist society policy makers ought to beware of answers to such questions that do purport to offer such moral certainty or even moral confidence. When agreed moral principles or values come into conflict *judgement* is required and unfortunately the proper approaches to carrying out such judgement are morally disputed. As the philosopher Immanuel Kant argues, 'General logic contains and can contain no rules for judgement...judgment is a peculiar talent which can be practised only, and cannot be taught'<sup>19</sup>. In his fascinating response to PHARMAC's questions Paul Hansen<sup>20</sup> suggests that PHARMAC develop an extension of a 'four step' proposal made by Hope Reynolds and Griffiths<sup>21</sup> whereby, after cost-utility assessment is undertaken against an agreed norm for funding, treatments that exceed this norm (in terms of cost per QALY or for year of life extension) are reviewed in relation to other moral concerns such as age, the 'rule of rescue', palliative care in terminal illness, severity of illness/health need, lack of available alternative treatment, and 'double jeopardy' as a result of co-morbidities. Unsurprisingly the Hope Reynolds and Griffiths proposal does not explain just *how* judgements are to be made once these various moral considerations have been addressed.

In his review Paul Hansen offers a suggestion to PHARMAC about how to carry out this last step, this moral judgement, about which I would advocate considerable 'moral caution'. Hansen notes three alternative ways for PHARMAC to deal with conflicts of value judgments: it can continue with its present policy in which value 'tradeoffs' are done by 'implicit weighting', case by case, 'in an essentially implicit and non-transparent (opaque) fashion'; it can offer some explicit criteria for 'equity weighting'; or it can develop a 'multi-criteria decision making' system such as his own in which points are agreed to be allocated in relation to an agreed range of decision criteria (such as those just mentioned). Hansen rejects the first alternative because (he implies) PHARMAC ought to be more explicit about how it comes to its funding decisions. He rejects the second because 'valid and reliable methods for estimating such weights are currently unavailable' – though he seems to approve of carrying out such equity weighting implicitly at step 4 of the four-step proposal (Hansen p21). He advocates the third alternative, the additive points system, which he points out is used internationally for a wide variety of purposes, on the grounds that such systems 'near universally. ...out-perform purely intuitive decision making approaches such as PHARMAC's current approach' (Hansen, p22).

I have two concerns, one *ad hominem*, the other substantive. First, it seems to me that Hansen's rejection of the second 'equity weighting' alternative on grounds of lack of 'valid and reliable methods for estimating such weights' is equally applicable to his preferred third alternative- indeed it seems to me that his third alternative *is* an equity weighting system. My substantive worry however is far more important. Any *weighting* system begs the question of what type of system of *judgement* is morally appropriate for dealing with conflicting moral values. One way of judging- the one recommended by Hansen-is to assign weights to the values concerned and then add up the weights of alternative approaches to particular cases and conclude that 'the weightiest' alternative is the morally correct one. Scientists and economists are particularly attracted to this sort of approach to dealing with moral conflict, (which of course is best exemplified in utilitarian thinking), presumably because it is a mathematical approach, converting as it does moral values into numerical values and then subjecting these numerical values to mathematical analysis. One problem with such an approach is the one Hansen points out to justify his rejection of 'equity weighting' approaches, notably the lack of 'valid and reliable methods for estimating' such numerical values. The other and more major problem is the Kantian problem outlined above about proposing *any* rule of judgement about conflicting moral rules or values. For such judgement may in no way resemble, or be properly convertible into, a mathematical process. It may more properly be a matter of intuition, or of 'moral perception' or of consulting one's properly informed conscience. It may be more like recognising a pattern, or a harmony or beauty. It may even involve considerations, recognitions and reflections concerning virtues and vices, and the views of virtuous (and perhaps also of vicious) people. It may even be entirely 'particularist' with every judgement unique to its particular circumstances. Or it may just be inexplicable, despite being widely recognisable when it occurs. It seems unwise for PHARMAC to prejudge these deep and contentious questions about the proper method or methods for moral judgement concerning conflicting moral principles or values by deciding that the mathematical approach is the correct approach!

### **Jim and Pedro**

A vivid and famous demonstration of the moral contentiousness of the mathematical approach to moral judgement, as exemplified by utilitarianism, is given by Bernard Williams in his story of Jim and Pedro<sup>22</sup>. Jim, a botanist travelling in South America, arrives in a small town market square, as Pedro is about to shoot 20 indigenous Indians so as to deter others from political protest. Pedro offers Jim, as an honoured visitor, the privilege of shooting one of the Indians and freeing the other 19. If Jim declines then Pedro will simply pursue his original plan and shoot all 20. The Indians and the local villagers beg Jim to take up the offer. Should he do so? One approach to dealing with this moral dilemma is the mathematical one that

utilitarianism would certainly use, concluding, Williams asserts, that the ‘obviously right answer[s]’ was that Jim should shoot one of the Indians in order to save 19. For many moral thinkers, probably including Williams, such a decision is clearly morally wrong. Yet could such rejection be morally maintained if we ‘up the ante’ so that the alternatives were to murder one person in order to save 100, or 1000, or a million lives?

While, like many others, I personally am attracted to the relative simplicity and clarity of the ‘mathematical approach’ for practical judgement in cases of moral conflict, I distrust any generalised acceptance of its use, not only because of its empirical deficit, as noted by Hansen, but also because I doubt that this sort of mathematics is **always** the morally relevant approach to moral judgment about conflicting values, even though it **sometimes** may be. Furthermore I also distrust it because I know that large numbers of conscientious moral thinkers also distrust it.

**PHARMAC’s question e): What if any changes do you recommend PHARMAC make to its current decision making process for HCPs ?**

Thus my advice to PHARMAC is to stick with a variant of the first alternative described by Hansen, namely a variant of **implicit judgement** when moral values conflict, while making **explicit** the moral values considered to be relevant and in conflict. In pursuing this course the approach recommended by Hope Reynolds and Griffiths and commended by Hansen, but without the modifications recommended by Hansen, seems morally acceptable, makes explicit the moral considerations considered to be relevant but potentially conflicting, facilitates ‘accountability for reasonableness’<sup>23</sup> (given some additional procedural developments proposed below), and avoids building into PHARMAC’s official procedures a morally contentious mathematical, computer-based, approach to moral judgement that is likely to be vigorously, vociferously and conscientiously rejected by many.

Nonetheless I would recommend that Paul Hansen’s offer of his computer programme is taken up as a **research project** with the objectives both of comparing and contrasting allocation decisions made using the Hope Reynolds Griffiths approach<sup>21</sup>, and those that would be made if the Hansen and Ombler Point Wizard multi criteria decision analysis computer programme were used; and also to experiment with the weightings or points to be given to different criteria in order to obtain judgements that were widely acceptable in a range of hypothetical (or possibly real) scenarios.

**Creation of an allocation committee**

Meanwhile I would recommend three procedural adjustments. The first is that PHARMAC creates an allocation committee, drawing on such models as a clinical ethics committee, the Oxford Priorities Forum described by Hope Reynolds and Griffiths, and the NICE Citizens’ Council. The role of this committee would be advisory to PHARMAC both in reviewing decisions already taken by PHARMAC and in giving advice about prospective decisions referred to it by PHARMAC where contentiousness is anticipated. In its deliberations a variant of the Hope Reynolds Griffiths four-step approach would be used and the conflicting values in particular cases would be made explicit even if the final judgements of individuals and the committee as a whole remained implicit, as they normally are ‘in real life’. While I would, for practical convenience, see the benefit of accepting a norm for cost per QALY below which new products would presumptively be accepted, I would recommend against having an absolute upper value as recommended by Hansen (but not by Hope Reynolds and Griffiths). It might be that on occasion an extremely expensive but effective innovatory pharmaceutical came up for consideration whose acceptance might be recommended in the short term on the understanding that further use if successful would only be authorised if the price were to come down. It seems unnecessary to preclude this possibility.

## Specifying an ethical framework

- i. In addition to instituting an allocation committee it seems wise to make more explicit the ethical framework within which PHARMAC (and its allocation committee if created) makes its allocation decisions. The Beauchamp and Childress ‘four principles’ approach<sup>24</sup> is my own preferred framework<sup>25</sup>, and has also been accepted in the UK by the National Institute for Health and Clinical Excellence<sup>26</sup> (and is not unlike the ethical framework adopted by Hope Reynolds and Griffiths<sup>21</sup>). I prefer it largely because its four prima facie moral principles (or basic values) of benefiting, not harming, respecting autonomy (so far as is compatible with equal respect for everyone’s autonomy) and justice are so obviously widely acceptable, regardless of people’s religious, social, cultural or philosophical background and commitments. An alternative approach worth considering is adoption of the more complex ethical framework recently approved by UNESCO in its Declaration on Bioethics and Human Rights<sup>27</sup>. This ethical framework has the obvious advantage of formal international approval. Unfortunately adoption of neither of these ethical frameworks will resolve the crucial problems with which I started, namely lack of agreement on a substantive theory of distributive justice. This lack of agreement in turn results from disagreement about how to deal with the conflicting moral values that, I have argued above, need to be represented in any widely acceptable substantive theory of justice; and that, as I have also argued, depends on *judgement*. It is this area of judgement that creates much, perhaps most, of the ethical controversy about resource allocation decisions, and for which I advocate at least strongly presumptive reliance on the collective judgements of an allocation group of conscientious people drawn from a variety of perspectives and committed to trying to reach agreed decisions after having explicitly considered the moral values that they believe to be relevant but in conflict in the particular cases they are asked to consider.

## Specifying the appeal mechanisms

Finally, the appeal procedures against PHARMAC’s decisions ought to be specified, as recommended in Daniels and Sabins attractive ‘accountability for reasonableness’ framework<sup>23</sup>. As I understand matters there currently exist both an informal appeal process to Government via public and media opinion and a formal appeal process through the courts. The informal process may well involve vigorous appeal, often with media amplification, to the ‘rule of rescue’ and include the use of what is sometimes called ‘shroud waving’. As indicated above my own view is that these are valid components of both the democratic process and of an acceptable substantive theory of justice. However if Government is inclined to over-rule the budget-constrained decisions of its agent PHARMAC, in response to such manifestations of public opinion, then it is surely important that Government stumps up the additional funding necessary for such ‘rescues’! Otherwise Government simply adds to the opportunity costs to those whose health care needs are less obviously appealing to ‘the rule of rescue’. The formal legal appeal process should continue to be empowered to reverse decisions by PHARMAC, but only if there has been a demonstrable failure to pursue the agreed processes, or if some relevant new evidence is adduced. The courts should continue to eschew any power to reverse an allocation decision made by PHARMAC simply because they disagree with it!

## Final comment: Be prepared for moral dissatisfaction

Finally let me reiterate the need for those involved in allocation of scarce resources to expect moral dissatisfaction with their recommendations, no matter how conscientiously and assiduously derived. The fact that resources are limited entails that not all the competing claims will be met. Those claims will often, perhaps usually, have some moral justification. Thus there is likely to be moral dissatisfaction with *any* outcome, for any outcome will generally involve the over-riding of claims that have some moral justification, in favour of

other claims judged stronger in the particular circumstances. There is, I'm pretty sure, no generally acceptable way of avoiding this dissatisfaction; indeed perhaps it would be morally worrying if there were, for absence of such dissatisfaction might well signal a loss of moral sensitivity to failure to meet morally justified claims- no matter how justified that failure is in the particular circumstances.

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## Notes and references

<sup>1</sup> Gillon R. Philosophical medical ethics. Chichester: Wiley, 1985 and 13 subsequent reprints, latest 2003.

<sup>2</sup> See entry on Distributive Justice by Julian Lamont at <http://plato.stanford.edu/entries/justice-distributive> (last accessed 27 July 2005).

<sup>3</sup> see entry on justice as a virtue by Michael Slote at <http://plato.stanford.edu/entries/justice-virtue> (last accessed 20 August 2005).

<sup>4</sup> Gillon R Value judgments about equity in health. In: Oliver A, Cookson R, McDaid D (eds): The issues panel for equity in health- discussion papers. London: The Nuffield Trust, 2001.

<sup>5</sup> For example in Sen AK. Inequality re-examined. Cambridge, Mass: Harvard University Press, 1992. As noted, Sen's preferred answer is (roughly) equality of capability to achieve what one values.

<sup>6</sup> Though I should add that some economists have made heroic efforts to oppose this norm, either by contorting the meaning of 'need' to turn it into 'capacity to benefit'- but of course people can be in enormous need and yet not have a capacity to benefit, as for example when they need a cure for their fatal disease but such a cure doesn't exist; or by arguing that 'needs assessment is based on faulty logic- the faulty logic of the imperative of "the size of the problem". That faulty logic needs to be exposed – and exposed again. It is so pervasive in health care. The fact that it is pervasive however is no reason for believing that it is in any sense right'- Devlin N, Hansen P. Allocating Health- 'Needs Assessment' and an Economics-Based Approach. Treasury Working Paper 00/4, section 2. At: [www.treasury.govt.nz/workingpapers/2000/00-4](http://www.treasury.govt.nz/workingpapers/2000/00-4). Last accessed 11.12.05. I fail to discern the 'faulty logic'- it seems rather a disagreement about the premises to be used in arguments rather than their logic. However since PHARMAC's remit is clearly acknowledged by Hansen, in his report corresponding to this one, to require a component of needs-based analysis, and since I shall be arguing that needs based analysis is not the only relevant criterion for fair allocation of PHARMAC's resources, I shall not pursue my argument against whole hearted rejection of the criterion of need any further here. See also my Note 20 below.

<sup>7</sup> Doyal L, Gough I. A Theory of human need. Basingstoke: MacMillan Press, 1991.

<sup>8</sup> This synoptic account is informed by the work of David Wiggins in his Needs, values, truth.. Oxford: Blackwell, 1987 and differs from Roger Crisp's broader account of need in which any advancement of human wellbeing can create or is a response to a need. See Crisp R. Treatment according to need: justice and the British National Health Service In: Rhodes R, Battin M, Silvers A (eds). Medicine and social justice. Oxford: Oxford University Press, 2002, pp 134-143. There is of course an elliptical sense of need in which anything can be a need if without it some prior purpose is frustrated- if I am to go to the dinner tonight I will need a dinner jacket. By my Wiggins-informed account, only if I will be harmed by not going to the dinner do I have a need for the dinner jacket- and the greater the harm the greater that need.

<sup>9</sup> One of the earliest and most trenchant critiques is given by Harris J. QALYfying the value of life. Journal of Medical Ethics, 1987; 13: 117-123.

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<sup>10</sup> A review of the debate about QALYs is given by Schwappach D. Resource allocation, social values and the QALY: a review of the debate and empirical evidence. *Health Expectations*, 2002; 5: 210-222.

<sup>11</sup> I have not in this paper considered 'desert' in the sense of merit or relative virtue, or absence of vice, as a criterion for fair allocation of scarce health care resources as my own analysis tends to eliminate this criterion as unacceptable for health care justice. Thus for example the idea that people who bring about their own ill health should not be given medication that would meet their needs because they 'don't deserve it' is hard to sustain at all, but in any case would require radical legislation before it could become relevant to PHARMAC. This does not of course rule out use of the 'sufficient benefit' criterion to prioritise, for example, provision of liver transplants to non-drinkers, including those who have given up alcohol as a demonstration of their ability and intention to stop drinking, ahead of drinkers who are unlikely to stop drinking and are thus likely to gain far less benefit from such a transplant. Similar considerations would apply to pharmaceutical treatments for which life style changes would be required for the treatment to be able to provide sufficient benefit.

<sup>12</sup> Jonsen A. Bentham in a box: technology assessment and healthcare allocation. *Law medicine and health care* 1986; 14: 172-174.

<sup>13</sup> Hadorn D. Setting Health Care Priorities in Oregon- Cost-effectiveness Meets the Rule of Rescue. *JAMA* 1991 vol 265: pp 2218-2225.

<sup>14</sup> see for example Jakobovits I. *Jewish medical ethics*. New York: Bloch Publishing Co, 1959, p45 where Dr Jakobovitz refers to both Talmudic and Koranic claims that to save a single life is equivalent to saving a whole world, or humanity as a whole.

<sup>15</sup> End of life decisions. [www.ewtn.com/expert/answers/end\\_of\\_life\\_decisions.htm](http://www.ewtn.com/expert/answers/end_of_life_decisions.htm). Last accessed 3.12.05.

<sup>16</sup> Richardson J, McKie J. The rule of rescue. [www.buseco.monash.edu.au/centres/che/pubs/wp112](http://www.buseco.monash.edu.au/centres/che/pubs/wp112). Last accessed 4.12.05.

<sup>17</sup> Jonsen AR. . Bentham in a box: technology assessment and health care allocation. *Law medicine and health care*, 1986; 14: 172-174.

<sup>18</sup> Jonsen A. Bentham in a box; technology assessment and health care allocation. *National Forum [USA]* 22/9/89.

<sup>19</sup> Kant I. Critique of pure reason A132-A133. See for example Norman Kemp Smith's translation published in London: Macmillan Press, 1973 print, pp 177-178. Kant's argument, in summary, is that since judgement is 'the faculty of subsuming under rules' there can be no general rule for judgement on pain of an infinite regress; for every time the requirement for judgement between rules arises there will be the need to judge which rule should apply, one or other of the conflicting rules or the purported rule for judgement between them – and if there were a rule for that judgement, the same problem would arise, with the need for a further rule of judgement and so on ad infinitum.

<sup>20</sup> His response deserves a full response, which I am alas unable to provide at this time. Suffice it to note that I believe his rejection of a needs based approach to resource allocation, largely implicit in his response but vigorous in his and Nancy Devlin's Treasury Working Paper 00/4, is mistaken, as I indicate in Note 6 above. To his credit he does however offer a way of accommodating such a needs based approach within a fixed budget (his value judgment 4 at p 13 of his response, corresponding to point p on his figure 2 at p11). It is an approach that I personally would be keen to see pursued, while acknowledging that it is heavily 'weighted' to the moral value of distribution in proportion to healthcare needs; and while acknowledging the general opacity of 'judgement' between conflicting moral values.

<sup>21</sup> Hope T, Reynolds J, Griffiths S. Rationing Decisions: Integrating Cost-Effectiveness with Other Values. In: Rhodes R, Battin M, Silvers A (eds). *Medicine and Social Justice*. Oxford, New York: Oxford University Press, 2002, pp 144-155.

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- <sup>22</sup> Williams B. A critique of utilitarianism. In: Smart J, Williams B. Utilitarianism for and against. Cambridge: Cambridge University Press, 1973, pp 75-155, the Jim and Pedro example at pp 98-100.
- <sup>23</sup> Daniels N, Sabin J. Setting Limits Fairly. Oxford, New York: Oxford University Press, 2002, pp43-66.
- <sup>24</sup> Beauchamp T, Childress J. Principles of Biomedical Ethics. Oxford, New York: Oxford University Press 2001 (5<sup>th</sup> ed).
- <sup>25</sup> My own use of this approach is described in reference 1 above and summarised in: Gillon R. Medical Ethics: Four principles plus attention to scope. British Medical Journal, 1994; 309: 184-188.
- <sup>26</sup> National Institute for Health and Clinical Excellence. Social value judgements – principles for the development of NICE guidance. At: [www.nice.org.uk/pdf/social\\_valuejudgement-08\\_12\\_05.pdf](http://www.nice.org.uk/pdf/social_valuejudgement-08_12_05.pdf). Last accessed on 29.12.05.
- <sup>27</sup> Universal Declaration on Bioethics and Human Rights. At: [www.unesco.org/en/ev.php-URL\\_ID=30274&URL\\_DO=DO\\_PRINTPAGE&URL\\_SECTION=201.html](http://www.unesco.org/en/ev.php-URL_ID=30274&URL_DO=DO_PRINTPAGE&URL_SECTION=201.html) - (or more easily accessed via a Google search!)- last accessed on 11.12.05.