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Paying for patented drugs is hard to justify: an argument about time discounting and medical need

Abstract

Drugs are much more expensive whilst they are subject to patent protection than once patents expire: patented drugs make up only 20% of NHS drugs prescriptions, but consume 80% of the total NHS drugs bill. This paper argues that, given the relatively uncontroversial assumption that we should save the greater number in cases where all are equally deserving and we cannot save both groups, it is more difficult than is usually thought to justify why publicly funded healthcare systems should pay for patented treatments. The claim to medical treatment of those who will be sick with a given condition once the patent runs out is just as strong as those who are sick with it now, but we will be able to treat more people with the same unit of resource in the future. Hence, when resource constraints entail that both cannot be funded, publicly funded healthcare systems ought to wait until patents expire before approving drugs for general use in the publicly funded system.

1 Introduction

It is often taken for granted that publicly funded single-payer health systems such as the UK's NHS and Canada's Medicare should ensure that those covered by the system have as wide access as possible to patented drugs. When new drugs for treating

life-threatening conditions such as cancer are withheld because they are not cost-effective enough, there are frequently complaints and negative media coverage, with the result that politicians have become very wary of making the case for cost-effectiveness.

This paper presents a fundamental challenge to such views. Given the relatively uncontroversial assumption that we should save the greater number in cases where all are equally deserving and we cannot save both groups, I argue that where resource constraints entail that both cannot be funded, publicly funded healthcare systems ought to wait until patents expire before approving drugs for general use in the publicly funded system. The claim to medical treatment of those who will be sick with a given condition once the patent expires is just as strong as those who are sick with it now, but we will be able to treat more people with the same unit of resource.

There are four main types of argument which could be deployed by those who wish to claim that despite the fact that we should save the greater number when we are dealing with two groups of strangers and cannot save both, we should spend our money now on patented drugs rather than saving more people in the future. None is plausible. The first is that we should discount future health benefits. I argue that the health benefit that a drug provides will in general be the same once the patent expires as it is now,[1] and so it would be wrong to apply a discount rate to these future health benefits unless we think that the mere fact that a benefit is further away makes it legitimate to discount it. I argue that such pure time discounting is implausible: whilst it is obvious that different people require medical treatment at different times, there is no justification for thinking that the time at which a medical need occurs should make a difference to its moral

weight.

Second, someone might appeal to contextual features which make it appropriate to give priority to those who are ill now, even if their needs are objectively no more important than those of people in the future. As in a rescue situation, it might be argued that it is appropriate to respond with whatever materials are at our disposal, despite the fact that doing so will use up resources that could have been used to save other lives more cost-effectively. I argue that this objection rests on a morally mistaken framing of the situation. We are invited to think of the people who are now in need of treatment as exceptional. However when viewed from a public policy perspective, people getting sick and dying is not exceptional or unprecedented. Performing expensive ‘rescues’ is indefensible as an approach to public policy where the foreseeable cost of so doing is that many more will not be rescued when they become sick in the near future.

The third objection appeals to equality. Healthcare is a good which is widely considered to be of special moral status; and so it might be argued that there is something worryingly unequal about a healthcare system where the vast majority are deprived access to the latest life-saving medicines, whilst the rich few can afford them. I agree that there is something morally troubling about people dying who could have been saved. But given the agreed common ground that there are not enough resources to meet all healthcare needs, whatever we do people will die who could have been saved under a different allocation of resources. So the fact that people will die under my proposal who would not die under our current system does not militate strongly against my proposal: the relevant question is which distribution of resources provides the fairest prioritisation of treatments.

The final and most important objection appeals to the role of patents in incentivising development of new drugs. If publicly funded healthcare systems withdrew from funding patented drugs, this would lead to fewer new drugs being produced. This worry is a very real one, but it can be addressed in two ways, depending on the viability of non-patent based approaches to drug development. First, squarely within the current patent system, publicly funded healthcare systems can adopt a system of value-based pricing, which adds an additional weighting for pharmaceutical innovation to cost-effectiveness calculations. Applying such a weighting would bring additional new medicines within the confines of what would be supplied. Second, both the fairness and the effectiveness of the patent system as a way of incentivising drug development are increasingly being called into question. If it is correct to suppose that alternative approaches would provide fairer or more effective ways to fund drug development, then an obvious solution would be for publicly funded healthcare systems to support drug innovation by making a proportionate contribution to such schemes.

2 Drug patents, drug development and drug prices

Formulae for making drugs are, unless subject to intellectual property regulation, public goods: they are nonrival in use, and nonexcludable. Standard economic theory tells us that, unless we do something to incentivise their production, we should expect a shortfall of public goods. The basic problem is that it will tend to be irrational (in self-interested terms) for an agent to expend his own time and money creating a public good, given that everyone else will be able to benefit from the public good as much as he will. It is better for him to allow someone else to do the hard work, and then take a

free ride on others' efforts. But of course, it will tend to be irrational for anyone else to put the effort in either.

The patent system aims to solve the problem of the production of public goods by making ideas excludable. It creates an incentive to innovative work, by providing a temporary monopoly over the commercial exploitation of the product as stated in the patent claim. By allowing the inventor a monopoly, the patent system allows him to recoup his development costs and return a profit by charging a price much higher than the price he could charge if there were open competition.

Drug discovery is an expensive process. If we include the costs of pharmaceutical companies' failures and marketing, the cost of bringing a new drug to market is estimated to be in the order of $800 million.[2] Whilst the patent term is 20 years, companies file their patent claim early in the drug development process. It takes between 8-13 years from the filing date to the point at which the drug actually becomes available for sale.[3] The net result is that once a new drug comes onto the market and is available for sale, the effective patent term will be somewhere between 7-12 years.

A generic drug is one that is identical in action (or to use the technical term, *bioequivalent*) to a patented drug, and hence is "identical…to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use."[4] After the expiry of the patent, anyone can produce a generic version of the drug using the same process as claimed in the patent, without having to pay any licence fees to the company which developed it. Developing generic drugs is much cheaper than developing New Chemical Entities for two reasons. First, the search costs are minimal: the chemical structure of the branded drug can easily be

reverse-engineered by chemists (who additionally have the disclosures in the original patent application to rely on). Second, the testing costs are also vastly reduced as generics manufacturers have only to show that their drug is bioequivalent to the branded drug, rather than to complete the full schedule of clinical trials.

From the point that a generic is available, the branded drug will become much less profitable for the company who developed it. Hence pharmaceutical companies aim to recoup the costs of drug development and earn their profits in the effective patent time window. Inevitably the prices of patented drugs are vastly greater than the price would be under competition from multiple generics.

Costs savings are considerable when generics become available: for instance a recent EU competition inquiry into the pharmaceutical sector found that, in the period 2000-07, generic medicines were introduced an average of seven months after the expiry of the patent (four months with the most popular drugs).[5] Initial cost savings were around 25% of the former cost of the branded drug. After generics had been on the market for two years, prices were on average 40% cheaper than the branded drug had been.[6] And as more competitors enter the market, generics prices continue to fall.[7] According to the Generic Pharmaceutical Association (GPhA), generics account for only 16% of costs, but 69% of all prescriptions dispensed in the United States, whilst branded drugs account for 84% of the costs of drugs, and a mere 31% of prescriptions.[8] In the UK's NHS it is estimated that generics account for 80% of the prescriptions, but only 20% of the overall drugs budget. Branded drugs take up the remaining 80% of the overall drugs budget, but yet only account for only 20% of the number of prescriptions.[9] In Europe as a whole, generics amount to more than 50% of the prescriptions filled, but

only 18% of the costs.[10]

3 How Generics Allow us to Save the Greater Number

I shall assume that under conditions of resource scarcity, our distribution should adhere to the following schematic principle: *moral choices about which of two groups should get a scarce resource that cannot be provided to both should be determined both on the strength of the moral claim each individual in each of the groups has to the good, and the number of individuals in each group*. Where the moral claims of the individuals in each group are all equally strong, we should give the resource to the more numerous group.[11] Where two groups are of the same size, we should give the resource to the group with the strongest moral claim.[12]

I take it that consequentialist positions will find the schematic principle congenial – seeing as all forms of consequentialism are simply ways of filling out this schema. Most nonconsequentialist positions (and commonsense morality) should also agree with the principle: to oppose it, one would have to be either a sceptic about saving the greater number, or a sceptic about saving the more deserving. I am not aware that anyone has defended scepticism about saving the most deserving, as it is a position of doubtful coherence: it would amount to the claim that *despite* the fact that group A is more deserving (according to whichever metric of deservingness is the correct one) of the resource than group B and at least as numerous, there is no duty to award the resource to group A in preference to group B.

Scepticism about saving the greater number is more reputable: John Taurek argues

that there is no moral duty to save the group with the greater number in the following kinds of case:[13]

1. The agent can save either a smaller or a larger group of innocent people from (equally) serious harm.
2. The costs of saving either the smaller or the larger number will be the same.
3. The agent has a duty to save at least one of the groups.
4. If the agent acts to prevent harm, then the harm they prevent would not have been prevented if they had done nothing.
5. All other things are equal.[14]

I shall not argue against numbers scepticism here.[15] My argument is in this sense hypothetical: *if* we should reject numbers scepticism, then we should accept my more general principle for allocation of scarce resources.

Assuming that the schematic resource allocation principle is accepted, it follows straightforwardly that we should prefer to fund the generic to its patented equivalent. This is because, for a given unit of resource, buying the branded drug would allow the healthcare system to provide treatment for *n* people whose claim to treatment is *s*. Buying the generic drug would allow the healthcare system to provide treatment for *n* people whose claim to treatment is *s*, and an additional *m* persons with a claim to treatment of s.

The same principle, when combined with a claim about the wrongness of time-discounting which I shall defend shortly, entails that publicly funded healthcare systems should often wait until drugs come of patent before making them generally available:

1. We should not discount claims to treatment solely because they are in the future.
2. If we buy the patented drug now, then for $X we will be able to provide treatment for *n* people whose claim to treatment is *s*.
3. If we buy the generic version in ten years' time, then for $X we will be able to provide treatment for *n+m* people whose claim to treatment is *s*.
4. When choosing between two different groups composed of individuals who each have an equal claim to treatment, we should give preference to treating the larger group.
5. Therefore, treating the larger number with the generic drug in ten years should have a higher priority than treating the smaller number now.

I acknowledge that it is artificial to suppose that publicly funded health care systems have hypothecated sums of money for different drugs, and that it is also unrealistic to expect that governments would set up a large number of bank accounts and leave $X in each account until a given drug patent ran out. But I hope that this does not obscure the moral point of the argument, which is simply that if a government has a responsibility to use scarce resources fairly, it is morally unjustifiable to spend money now to meet a number of needs of a certain moral urgency if that precludes meeting a greater number of needs of the same moral urgency in the future.

Depending on the size of a given healthcare budget and our theory of the urgency of medical need, it may be that *both* providing the patented drug now to *n* people, *and* providing it to *n+m* people once the patent expires are of sufficiently high priority that

both should be provided.[16] On many substantive accounts of the moral urgency of medical need, some new patented drugs will come higher up the list of priorities than some already funded *non*patented treatments: if the new patented drug allows us to provide treatment to *n* people with a moral urgency of need of *s*, whilst another nonpatented treatment we are currently funding allows us only to provide treatment to *n-m* people with a moral urgency of need of *s*, then providing the patented drug should be prioritised over this nonpatented treatment.[17]

So the argument does not establish the claim that publicly funded healthcare systems should never fund patented treatments, but rather that they should not do so at the expense of providing treatments to larger groups of individuals whose individual claims to treatment are or will be equally strong as those who are now sick. However, this does not mean that the argument is toothless: the fact that we cannot meet all healthcare needs with current budgets, and think that there is no reason to make current healthcare budgets radically larger is a strong reason to think that some, perhaps many, patented treatments would not reach the cutoff point.[18]

Patents on antibiotics

The effectiveness of some drugs (for example statins) will remain constant over tens or

hundreds of years of wide use. However, antibiotics diminish in effectiveness as their usage increases because the pathogens they target tend to acquire resistance.[19]

Where a drug can be expected to decline in effectiveness over time, it will not provide precisely the same level of health benefit once the patent expires as it did previously. But this does not provide a reason to think that we should use more of the drug whilst it is under patent, for two reasons. First, the sharp change in legal status between in patent and out of patent has no effect in itself on the level of resistance to a particular drug.[20] Second, the main factor that increases antibiotic resistance is use of antibiotics. Hence the situation is not like one in which the freezer breaks down and one is forced to eat one's way through several tubs of ice cream to stop them from going to waste, but more like discovering an oil reserve, which could equally as well be used some time in the indefinite future.

Where there are are no worries of spoilage, the fact that if we use more of a limited resource now, there will be less of it in the future, does not provide a reason for using more of the limited resource now. Rather, it provides a reason for thinking that this limited resource should be distributed in a way that gives priority to those who have the strongest overall claim to it. I argue elsewhere that ownership of a patent on a particular antibiotic does not bring with it a moral entitlement to use up the underlying resource of the effectiveness of the antibiotic.[21] Assuming this argument is sound, the key question (just as in cases where the effectiveness of a drug does not decline over time) is whether people who need treatment now have systematically stronger claims than those who will require treatment in the future, a question I examine in the next section.

4 Time discounting and future benefits

I claim that the point in time at which we can provide a treatment does not make a difference to the moral urgency of providing that treatment. However, such a position can be challenged. It can be argued that we should subject future benefits to a discount rate—that is, to treat them as less valuable the further away they are. We can distinguish between two different types of discounting: discounting of commodities, and pure discounting.

It is standard in economics to apply a discount rate to commodities. The price of most commodities falls over time relative to the return we could get on an investment at a bank, so buying a commodity today has the opportunity cost of the greater amount of the same goods we could buy in the future. The price of commodities falls over time relative to the return on a bank investment both because we become more efficient at manufacturing commodities over time, and because natural resources such as forests grow naturally if we wait before harvesting them. Broome dubs this the fertility of technology: as he puts it, “present commodities can be converted into a greater quantity of future commodities, if we choose”.[22] Given these facts it makes sense to employ a discount rate for commodities because we will be able to buy more of those same commodities for our money in the future.

Patented drugs are commodities whose price falls over time, so it might be thought that we should discount the future value of the health benefits they produce. However,

this does not follow: the economists' discounting model assumes that the increased number of commodities we would be able to buy in the future have the same value for wellbeing as the smaller bundle we can buy now. However not all commodities vary in this way relative to wellbeing: some commodities contribute a constant amount to wellbeing whenever they occur. Broome's example is saving a life:

> Lifesaving in the future will make the same contribution to well-being as lifesaving in the present. Certainly, future lifesaving is cheaper than present lifesaving, but this is not a reason for valuing it less. The market prices of commodities only have a role in valuations because they measure the relative values of commodities to people. In equilibrium, they will do so... But if lifesaving produces constant well-being and yet is cheaper in the future, we evidently do not have an equilibrium.[23]

In short, just because we could create health benefits more cheaply in the future, there is no reason to think that the health benefits thus created should be subject to commodity discounting.

Pure discounting means discounting the value of benefits and harms in the future solely for the reason that they are in the future.[24] I shall attempt to argue that pure discounting is implausible; however, I shall conclude this section by arguing that even if we do adopt a pure discount rate, it would not provide a cogent justification for paying for patented treatments.

Suppose we have two ambulance drivers, Prometheus and Epimetheus. Prometheus,

like his mythic namesake, has the power of foresight: he can tell (within narrow confidence intervals) what is going to happen in the near future. He can predict with great accuracy at the start of his shift how many emergencies there will be, and the number of people who will be harmed (and how severely harmed) in each. Epimetheus has no such superpowers. For Epimetheus, the moral demands of the job are straightforward: he is to go to where people need urgent medical attention, as soon as he is called.

However Prometheus's greater knowledge gives him greater possibilities. He could act just in the same way as Epimetheus does—waiting till people require rescuing, and then heading over to them as quickly as possible. However, doing this is likely to have large opportunity costs. Given that (we stipulate) he is the only ambulance driver in the town, it will often be the case that if he prioritises whoever needs saving *now*, he will not then be able to save a larger group of no less deserving people who are not yet in distress, but who (he correctly predicts) will shortly require rescue.

Given the knowledge that Prometheus has, I think it would be wrong for him to prioritise those who need saving now, where that would have the predictable effect that more people who are equally as deserving of rescue will not be saved. My reason for saying this is simple: the time at which one becomes morally needy ought not to make a difference to the strength of one's moral claim. At the point when each person needs rescuing he or she is equally as needy as any of the others when he or she requires rescue. It is just that different people reach the point at which they need to be rescued at different times. Relying on a "first-come, first-served" model would be morally arbitrary, and where applying it would lead us to save less people that we otherwise

could, it is morally indefensible.

The future benefits reductio

It might be thought that this argument is subject to a reductio ad absurdum. Drugs continue to fall in price once they have come off patent, and other medical procedures will also be able to be performed more cheaply in the future. If the argument establishes that publicly funded health care systems should not pay for patented drugs, then it must also establish that publicly funded healthcare systems should not pay for drugs *at all*, for these same treatments will always be available more cheaply in the future. Call this the *future benefits reductio.*[25] The claim that we should not provide treatment to anyone now appears to be clearly false; so it would follow that the argument which establishes that publicly funded health care systems should not pay for patented drugs must be unsound.

This objection relies on a misunderstanding of my argument. I have proposed that our theory of the moral urgency of providing treatment – what ever other features it should have – should be atemporal. In other words, we should rank indviduals for moral urgency of treatment by a criterion which does not invoke temporal priority. The *future benefits reductio* is the worry that given that we will be able to provide treatments much more cost-effectively in the distant future, anyone now alive will come towards the bottom of the list when it comes to prioritisation, and so would not be treated now.

However, this conclusion does not follow from the atemporal approach. The atemporal approach tells us only which claims to treatment should appear higher up the list when we are trying to answer the question “which treatments should we fund when

we cannot afford to fund them all". The fact that there is a group Y who will in the future have the condition that Group X now have, and that Y will be able to be treated much more cost-effectively than X is a reason not to treat X now only if we cannot both treat X now and treat Y in the future. If medical treatments are getting more cost effective over the long term that is a reason for thinking that treatments which seem affordable now, given our current health budget, will be ranked high enough on the atemporal list for it to be reasonable to provide them.[26]

Nonzero Pure Discount Rates

Even if my argument against pure discounting is rejected, it is difficult to see how adopting a nonzero pure discount rate could provide a cogent reason to prefer using drugs whilst still on patent. In order for pure discounting to do so, it would need to be the case that the larger medical benefit to be gained in the future, when depreciated by the pure discount rate, becomes less than the smaller medical benefit obtainable whilst the drug is on patent. Given that patents typically have only another 10 years to run once the drug reaches the market, and that the prices of generic drugs will be much cheaper than patented ones, the pure discount rate would have to be high to justify using the money to buy a patented drug now rather than providing a treatment for more people once the patent expired. In order for it to be better to put the money into a patented drug now, the pure discount rate would need to be at least 3%.[27] If we adopted this pure discount rate, then a benefit 30 years in the future would be worth only 40% of what that same benefit would worth now, one 60 years would be worth 16%, whilst a benefit in 100 years would be worth less than 5% of one now.

But if such a pure discount rate were correct for health harms and benefits, then it would (unless there is some distinguishing feature) have to be true for other future harms and benefits, such as those due to climate change.[28] If we adopted such a high pure discount rate, it would not be wrong to make things much worse for people as little as ten years in the future, because we would be able to legitimately discount greatly the important of their future wellbeing. This seems clearly unacceptable. So even if we should adopt a nonzero pure discount rate, it is implausible to think that the pure discount rate would be high enough to provide a reason to reject my argument.

5 The Rule of Rescue

Another objection focuses on the moral importance of the fact that the people who currently need treatment are sick *now.* When a child falls down a well, or miners get trapped below ground, hardly anyone thinks it a bad thing if a massive rescue operation is mounted, even if the money spent on this rescue could save rather more lives if devoted to more cost-effective ways of improving human lives. So, appealing to the same considerations, we could argue that the *presentness* of current need allows us to legitimately prioritise it, even though we could treat more citizens with medical conditions of the same moral urgency if we were to prioritise our resources atemporally. Albert Jonsen christened our response to such cases the Rule of Rescue.[29]

I do not want to deny the emotional force of rescue cases of this kind, but it would be mistaken to use such emotions as a basis for public policy. Our intuitions about rescue are heavily affected by factors which are morally arbitrary. For instance, they are more

likely to be triggered by a large percentage of a small group in peril than a smaller percentage of a larger group.[30] They are triggered by identifiable individuals rather than statistical lives. And they are more likely to be triggered by a sudden drop in wellbeing for someone than by a gradual drop, or by the fact that someone has been in a bad way for a very long time. But none of these seem like very cogent moral reasons.[31]

More importantly, the psychological effects of the impulse to rescue depend on us framing the situation as an *exceptional* one in which a sudden and unexpected calamity is avertible by swift action. But it is doubly mistaken to view the design of publicly funded healthcare systems through this lens. First, patterns of morbidity and mortality are not unexpected when we ascend to a policy level. Whilst for any given person, a stroke or a road traffic accident may be a sudden and unexpected catastrophe, we have a great deal of epidemiological research which will allow us to predict—within fairly narrow confidence intervals—the expected number of strokes and road traffic accidents in a country each year. It is simply a dereliction of a government's duty if it does not collect such data, and plan policies on the basis of the expected statistics for each disease. Given the availability of epidemiological data, publicly funded healthcare systems are in a situation like Prometheus rather than Epimetheus, and so they too should be unmoved by concerns of presentness.

Second, from a policy level it is mistaken to assume that each case where death is imminent should be treated in accordance with the rule of rescue. Getting sick and dying is the rule, not the exception. It is the human condition, and will be with us for as long as there are human beings.[32]

6 Arguments from equality of access

Healthcare is a good which is widely considered to be of special moral status.[33] It might be thought that there is something worryingly unequal about a healthcare system in which poorer citizens are deprived of access to the latest life-saving medicines. My suggestion, it might be argued, would create a two-tier system: those who have to stick with the generics they can get from the publicly funded healthcare system, and those who are rich enough to privately purchase expensive patented drugs for their condition.

I agree that this is a genuine worry, but we should notice that problems of unequal access are endemic to any attempt to contain drug costs. As things stand, some patented drugs are already excluded from being funded in public healthcare systems because they are not cost-effective enough. Given a limited budget, publicly funded healthcare systems must choose either (1) to fund *all* drugs, regardless of their cost-effectiveness, or decide that some drugs are not cost-effective enough to fund. If they decide that some drugs are not cost-effective enough to fund, they can either (2) prevent those drugs being made available to those who want to buy them privately, or (3) allow those drugs to be bought privately. Option (1) is a denial of the problem, rather than a plausible solution to it. Cost containment strategies have been introduced in healthcare because we do not have enough resources to meet everyone's healthcare needs. It is perverse to respond to this scarcity by insisting that all drugs should be provided, regardless of their expense. Publicly funded healthcare systems should adopt either option (2), or option (3): my argument here does take a stance on which is to be preferred.

Cost containment of patented drugs is not new. What my argument provides is a different, and more morally compelling argument for withholding access to some

patented treatments. Whether healthcare systems persuaded by my argument would allow systematically less access to patented treatments than current systems will depend both on the size of the allocated healthcare budget, and on the specifics of the account of the moral urgency of medical need the healthcare system chooses to adopt.

7 Funding future drug development

The purpose of the patent system is to incentivise innovation by providing a return on investment for patentholders, and so any proposal that reduces the amount of patented drugs bought will by the same token weaken this element of incentivisation. If many countries were to opt out of buying patented drugs in their publicly funded healthcare system, then this would lead to a decline in the number of new drugs being developed, and would be deleterious to those who were then unable to benefit from new drugs in the future.

This worry is a very real one. Given that the main claim I am arguing for is that systems of resource allocation for public healthcare systems should take future claims to treatment seriously, it would be a very serious problem if these concerns could not be answered.[34]

The first point to make in response is that my argument has been against *over-valuing* present patented treatments. It does not follow that healthcare systems that were persuaded by my argument would fund *no* patented drugs: whether they fund a particular patented drug will depend both on their available budget, and on how morally urgent they think the good which can be done by the patented drug for a given unit of

resource is. So it is possible that, consistent with my proposal, a wealthy healthcare system might choose to fund a considerable number of patented drugs. Moreover, it would be consistent with the scheme that I am proposing for publicly funded healthcare systems to add an additional weighting to health gains produced by highly innovative medicines. Applying such a weighting would bring additional new medicines within the confines of what would be funded.[35]

A second and deeper point is that both the fairness and the effectiveness of the patent system as a way of incentivising drug development are increasingly being called into question. The poor conversion rate of R&D spending into New Chemical Entities and the disturbing trend for much research to go into “me too” drugs has received much press.[36] There are also fundamental questions of fairness in the diseases which commercial companies target: diseases which are prevalent only in poorer countries get far less than the share of research money dictated by their contribution to the global burden of disease.[37]

In the light of these problems, it would be premature to think that the viability of any proposal for the purchase of pharmaceuticals should be judged by its ability to support the patent system as it currently exists. There are a number of alternative ways in which research into new drugs can be funded that have been argued to be both fairer and more efficient than the current system, including sponsoring more research into neglected diseases, compulsory licensing as standard in developing countries,[38] offering prizes for drug inventions,[39] and contributing to a mechanism like Thomas Pogge and Aidan Hollis's proposed Health Impact Fund.[40] If it is correct to suppose that such alternative approaches fairer or more effective ways to fund drug development, then an obvious

solution would be for publicly funded healthcare systems to support drug innovation by making a proportionate contribution to such schemes.

8 Conclusion

I have argued that it is much more difficult for publicly funded healthcare systems to justify paying for patented drugs than is usually thought. Whatever substantive account of moral urgency of medical needs a healthcare system adopts, it should prioritise providing treatment to $n+m$ people with a moral urgency of need of s in ten years' time over providing treatment to n people with a moral urgency of need of s now.

However, my argument in this article establishes only that *where we have to choose* between providing the treatment now and providing it once the patent expires, we should provide it after the patent expires. Depending on the size of a given healthcare budget, it may be that we can afford *both* to provide the patented drug now to n people, *and* to provide it to $n+m$ people once the patent expires. In such cases I would of course advocate that we supply it now. But not all cases are of this sort. Publicly funded healthcare systems face genuine scarcity of resources: they cannot fund all the treatments for all the medical needs. Given this situation, one thing they should definitely not do is to provide patented treatments now at the expense of providing more morally urgent treatments in the future.[41]

[1] The effectiveness of antibiotics declines as they are used. However, as I argue in Section 3, the fact that antibiotic effectiveness is a limited and non-renewable resource does not support the claim that we should prioritise using antibiotics now.

[2] This figure is from a widely cited report by Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, "The price of innovation: new estimates of drug development costs" *Journal of Health Economics* 22.2 (2003): 151–185. Christopher P. Adams and Van V. Brantner found a wide variance between $500 million to over $2 billion, depending on product drug developed, and the developing firm, in "Estimating The Cost Of New Drug Development: Is It Really $802 Million?" *Health Affairs* 25.2 (2006): 420–428.

[3] This period is composed of the clinical research and development phase (2–10 years), with an average of 5 years, and gaining approval from the relevant national drug regulator such as the FDA, or MHRA (2 months–7 years), with an average of 2 years. For an overview, see Michael Dickson and Jean Paul Gagnon. "Key factors in the rising cost of new drug discovery and development", *Nature Reviews Drug Discovery* 3.5 (2004): 417–429.

[4] U.S. Food and Drug Administration, *Generic Drugs: Questions and Answers*. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm. Last accessed 20 June 2011.

[5] See EU Competition Commission Pharmaceutical Sector Inquiry, *Fact Sheet 1 - Prices, time to generic entry and consumer savings*, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_1.pdf. The full reports from this commission can be found at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

[6] EU Competition Commission Pharmaceutical Sector Inquiry, *op cit.*.

[7] Whilst my argument does not depend on this occurring, it is worth noticing that there would be potential for much greater cost savings on prices of generics if there were a political will to ensure a more competitive market. The patent system is designed to allow the patent holder to charge an economic rent. Where there are only one or two generics manufacturers in the market, each can create a market for themselves by charging only a moderate amount less than the price previously charged by the manufacturer of the branded drug. In this period, the price that the early entrants are charging will usually still be wildly disproportionate to the marginal cost of production of the drug. HIV/AIDS drugs provide an interesting case study of the startling effects that political lobbying and real competition between generics manufacturers can have on prices: "In May 2000, the price of a brand-name antiretroviral (ARV) drug cocktail was $US10,400 per patient per year. It was only in October 2000 when a generic producer offered to sell a triple combination cocktail at $US800 that things began to change. Within a UN-led initiative to cut prices of AIDS cocktails for a small number of developing countries, pharmaceutical companies dropped their price to $US931. In February 2001, the generic price dropped again to $US350, which set off a price war between branded

and generic drug makers, reducing the prices of both brand-name and generic drug cocktails. In October 2001, the best world price for a triple-combination drug cocktail had come down to $US295." Médecins Sans Frontières, *A Matter of Life and Death: The Role of Patents in Access to Essential Medicines*, November 2001. Available from http://www.doctorswithoutborders.org/publications/reports/2001/doha_11-2001.pdf. Last accessed 6 January 2011.

[8] http://www.gphaonline.org/about-gpha/about-generics/facts. Last accessed 20 June 2011.

[9] Jennifer Dixon, *Making progress on efficiency in the NHS in England: options for system reform*. Nuffield Trust, 2010, p. 7. Available from: http://www.nuffieldtrust.org.uk/members/download.aspx?f=/ecomm/files/Making_progress_on_efficiency_in_the_NHS_in_England.pdf. Last accessed 20 June 2011.

[10] http://www.imshealth.com/imshealth/Global/Content/Document/Market_Measurement_TL/Generic_Medicines_GA.pdf Last accessed 20 June 2011.

[11] The principle remains silent on how we should rank the priority of individual moral claims to resources: possibilities include doing so on the basis of well off or badly off the person who will be receiving the benefit is; the person's capacity to benefit from the resource; or that each person has an equal claim to the resource. It would also be compatible with the principle to hold a pluralist account. The only thing that the principle requires is that we have some nonarbitrary way of deciding what I shall call the *moral urgency* of providing the scarce resource to any given individual: who should be higher priority, who lower, and who the same priority.

[12] The principle remains silent on how, if at all, we should aggregate individual moral claims into the moral claims of groups: possibilities include simply aggregating, or a more complex methodology of pairwise comparison, such that we compare the highest priority person in the first group with the highest priority person in the second group and so on. The principle presupposes merely that there is some nonarbitrary way of deciding which of two groups composed of the same number of individuals has the greater claim to the limited resource, and when both groups have an equal claim.

[13] John Taurek, "Should the numbers count?," *Philosophy and Public Affairs*, 6(4) (1977): 293-316.

[14] This way of setting up the problem is Michael Otsuka's in "Scepticism About Saving the Greater Number", *Philosophy and Public Affairs* 32.4 (2004): 413–426 at p. 413. However, instead of my (2) and (3) Otsuka has the requirement that the saving can be performed "at trivial cost to yourself". Otsuka's premiss attempts to perform two tasks: first to make plausible the claim that there is a duty to save at least one group, and second, that the costs of saving should not make a difference. In my reconstruction I have explicitly separated these.

[15] Prominent nonconsequentialists who have argued in favour of saving the greater number in these kinds of cases (though for somewhat different reasons) include T.M. Scanlon, *What We Owe To Each Other* (Cambridge, Mass.: Harvard University Press, 1998), Frances Kamm, 'Aggregation and Two Moral Methods', *Utilitas*, 17 (2005): 1-23, Otsuka, *op cit.*, Rahul Kumar, "Contractualism on Saving the Many", *Analysis* 61.270: 165-170.

[16] In addition, as Section 7 examines, there might be reason to apply a weighting to particularly innovative drugs that would allow them to be reimbursed at a level more than proportionate to the immediate healthcare benefit they provide.

[17] Of course, depending on a particular substantive account of moral urgency of medical need, some drugs will come fairly low down on the list of priorities even once they are out of patent: it may be that the drug provides very little medical benefit, and is intrinsically costly to produce, for instance.

[18] Which treatments those would be depends of course on our particular substantive account of the moral urgency of medical treatments.

[19] For an accessible introduction to this problem, see Karl Drlica and David S. Perlin, *Antibiotic Resistance: Understanding and Responding to an Emerging Crisis* (New Jersey: FT Press, 2011).

[20] Though it may have indirect effects if, for example, the availability of generic versions of a drug makes the drug cost-effective to use in a wider variety of contexts.

[21] James Wilson, "Drug Resistance, Patents and Justice: Who Owns the Effectiveness of Antibiotics?" in *Global Health, Global Goods, and International Community* ed. John Coggon and Swati Gola (London: Bloomsbury Academic, 2012).

[22] John Broome. "Discounting the Future", *Philosophy & Public Affairs* 23.2 (1994): 128–156, at p. 139.

[23] John Broome, *op. cit.*, p. 150.

[24] Most philosophers have followed Ramsey's lead in thinking that pure discounting is "is ethically indefensible and arises merely from the weakness of the imagination". Frank P. Ramsey. "A Mathematical Theory of Saving", *The Economic Journal* 38 (1928): 543–559, at p. 543. Arguments for pure discounting have mostly come from economists. For an overview of this debate, see John Broome, *Counting the Cost of Global Warming* (Bristol: White Horse Press, 1992), chapter 3; and Grégory Ponthière, "Should we discount future generations' welfare? A survey on the "pure" discount rate debate," *CREPP Working Papers* 0302, Centre de Recherche en Economie Publique et de la Population (CREPP) 2003. Available from http://ideas.repec.org/p/rpp/wpaper/0302.html.

[25] For an interesting analysis of this argument, see Dan Moller, "Should we let people starve – for now?" *Analysis* 66:291 (2005): 240-247.

[26] Despite the increase of cost-effectiveness of treatments over time, we should not expect that all possible treatments we have available now would be ranked high enough up the atemporal list to be funded. The fact that we cannot meet all healthcare needs with current budgets, and think that there is no reason to make current healthcare budgets radically larger is a strong reason to think that some current treatments would not reach the atemporal cutoff point. Which treatments those would be depends of course on our particular substantive account of the moral urgency of medical treatments.

[27] Assuming, conservatively, that after 12 years prices for the generic drug will be 40% less than the branded drug is at the beginning of its patent period. In fact, the pure discount rate would have to be considerably in excess of 3%, given that we could take our initial sum of money and invest it in the bank for the period of the patent.

[28] It is hard to see how there could be any such distinguishing feature, especially (as is well argued by Anthony

Costello et al. “Managing the health effects of climate change”, *The Lancet* 373.9676 (2009): 1693–1733), many of the bad effects of climate *are* effects on human health.

[29] Albert R Jonsen, “Bentham in a Box: Technology Assessment and Health Care Allocation”, *Law, Medicine and Health Care* 14 (1986): 172-4, at p. 174.

[30] Karen Jenni and George Loewenstein, “Explaining the Identifiable Victim Effect”, *Journal of Risk and Uncertainty* 14.3 (1997): 235–257.

[31] John McKie and Jeff Richardson, “The Rule of Rescue” *Social Science & Medicine* 56.12 (2003): 2407–2419. Mark Sheehan has recently argued in this journal that a more cogent moral justification for the rule of rescue is available: “the fact that we are strongly inclined to use large amounts of resources (or otherwise risk great cost to ourselves) in order to save an identifiable individual suggests that we have a *prima facie* agent-relative obligation to those in need of rescue.... we stand in a special relationship, perhaps a relationship of circumstance, to those in need of rescue and as such have a *prima facie* obligation to save them.” Mark Sheehan, “Resources and the Rule of Rescue”, *Journal of Applied Philosophy* 24.4 (2007): 352-366, at p.359. However, such an argument is unconvincing. The psychological propensity to rescue favours the existence of this moral duty only if the existence of the moral duty would provide a more convincing explanation of the psychological propensity to rescue than other accounts. Sheehan does not provide an argument for why this should be.

[32] As Richard Cookson, Christopher McCabe and Aki Tsuchiya put it, “Human beings are mortal. Sooner or later, all lives will pass through the stage (however defined and operationalised) where death is “imminent”. ... It is problematic to regard falling within this window as constituting something “exceptional” and being worthy of special consideration.”, “Public Healthcare Resource Allocation and the Rule of Rescue”, *Journal of Medical Ethics* 34.7 (2008): 540 –544, at pp. 543-4.

[33] See for example, Norman Daniels, *Just Health: Meeting Health Needs Fairly* (Cambridge: Cambridge University Press, 2007). I provide a critique of Daniels's account in James Wilson, “Not so special after all? Daniels and the social determinants of health,” *Journal of Medical Ethics* 35.1 (2009): 3-6.

[34] Thanks to the referees for pushing me to be clearer on this point. It has also been objected (by some of the audiences to whom I gave the paper) that any publicly funded healthcare system that followed my argument would be free-riding unfairly on those who do pay for patented drugs. This argument is weak. Even if a healthcare system did completely stop using patented drugs on the basis of my argument, it is less than clear that they would be acting unfairly. The main rationale of a patent system is to enlarge the public domain: to incentivise people to make public their inventions so that everyone can benefit from them once the patent period has elapsed. Waiting until an existing drug comes off patent before starting to use it is not wrongful. See for example, James Boyle. *The Public Domain: Enclosing the Commons of the Mind* (New Haven: Yale University Press, 2008); and James Wilson, “Could There be

a Right to Own Intellectual Property?" *Law and Philosophy*, 28.4 (2009): 393-427.

[35] The UK government has recently consulted on proposals to introduce such an innovation premium into drug pricing, as part of a move towards a scheme of value-based pricing. See http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_128226. It should be mentioned, however, that it is not clear that such an innovation premium would be a cost-effective way of pharmaceutical innovation. For this argument, see Karl Claxton, Mark Sculpher and Stuart Carroll, "Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS", *CHE Research Paper 60* pp. 15-16 available from http://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP60_value_based_pricing_for_pharmaceuticals.pdf

[36] For good overviews, see Merrill Goozner, *The $800 Million Pill* and Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* (New York, Random House, 2004).

[37] For this argument, see for example James H. Flory and Philip Kitcher. "Global Health and the Scientific Research Agenda", *Philosophy & Public Affairs* 32.1 (2004): 36–65; Julian Reiss and Philip Kitcher, "Biomedical Research, Neglected Diseases, and Well-Ordered Science," *Theoria* 24.3 (2009): 263–282; Thomas W. Pogge. "Human Rights and Global Health: A Research Program", *Metaphilosophy* 36 (2005): 182–209.

[38] See Sean Flynn, Aidan Hollis and Mike Palmedo, "An Economic Justification for Open Access to Essential Medicines in Developing Countries" *Journal of Law, Medicine and Ethics* 37.2: 184-208.

[39] See for example, James Love and Tim Hubbard, "The Big Idea: Prizes to Stimulate R&D for New Medicines", *Chicago-Kent Law Review*, 82.3 (2007): *1519-1554.*

[40] See Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* (Incentives for Global Health, 2008).

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