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DISCUSSANTS

Thomas Pogge, Leitner Professor of Philosophy and International Affairs, Yale University, and Professorial Fellow, Centre for Applied Philosophy and Public Ethics, the Australian National University, is EPHAR 2008 AstraZeneca Lecturer on "Advanced Medicines: Must We Exclude the Global Poor?"

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ANNOUNCER: You're listening to Public Ethics Radio. I'm Matt Peterson. This podcast features conversations between our host, Christian Barry, and scholars and thinkers who engage with ethical issues that arise in public life. The show is a production of the Centre for Applied Philosophy and Public Ethics, An Australian Research Council Special Research Centre and the Global Justice Program at Yale University. You can find us on the web at www.cappe.edu.au, under the Media tab.

ANNOUNCER: Our arsenal of medicines is improving at an impressive rate. Yet thirty percent of the world's population lacks access to essential medicines. When illness strikes the poor, a lack of treatment often leads to needless suffering, disability, and even death. To many this seems inevitable because the high price of medicines puts them out of reach of the poor. As the argument goes, high prices are regrettable but necessary. Effective incentives to innovate and produce medicines can only be provided through a quite restrictive system of intellectual property protection. Professor Thomas Pogge, of Yale and the Australian National University, disagrees. He joined Christian Barry in Canberra to discuss the possibilities of pharmaceutical innovation without impeding access to essential medicines.

CB: Thomas Pogge, thank you for joining us.

TP: Very welcome.

CB: You're very concerned about the state of medical innovation or pharmaceutical innovation in the world. Can you explain how new medicines are currently developed?

TP: Currently, the main incentive to develop a new medicine comes out of the patent system. Pharmaceutical innovators get a monopoly patent for a limited period of time, twenty years from the filing of patent application and during that period they can have exclusive rights to manufacture and market the product. During that time, given that they have a monopoly, they can charge a very high mark-up and with that very high mark-up recoup the expenses that they have for researching and developing the medicine.

CB: I see. And so why exactly are patents necessary? What would happen if there weren't patents in this sense?

TP: Well if you didn't have patents, you would have very little pharmaceutical innovation. The reason is that the costs for bringing a new medicine to market are enormous; people say it is around a billion dollars. I don't know whether that figure is a slight overstatement, but it's in that ballpark between maybe half a billion and a billion dollars. What makes it expensive is not so much the actual lab work but two other factors. One is that many trials end in failure either because the medicine doesn't pan out, the molecule just doesn't do the trick or because somebody else is getting to the invention first. The other reason is that even if you have a winning molecule, you have to run through very expensive clinical trials, which are near the end of the development process and again very expensive.

CB: So you have just described how patents work and from the way you described it, it sounds like they are a pretty effective way of getting firms to enter into the market and develop new molecules and go through all these processes to try to get them approved. So what exactly is wrong with this system?

TP: There are a number of things that are wrong with this system. The most obvious one that a lot of critics have focussed on have to do with the way in which the system doesn't do much for poor people. It doesn't do much for poor people in two ways. One is that the medicines that are actually being developed during the time that they are under patent are very expensive and so poor people find it difficult to get access to these medicines. The other problem is that patent incentivised pharmaceutical companies will see very little reason to develop a remedy for diseases that are essentially concentrated among poor people. So you may have a new malaria product: it's very effective, but millions and millions of people are out there who need that product, but these people who are out there cannot afford the product at a high monopoly price. So you get stuck in either selling the product cheaply, in which case you don't make the kind of profits that you would need to make to recoup your investment in research and development; or else you keep the price high in which case you will have very few customers. Anticipating that, a patent motivated pharmaceutical company is just not going to touch the diseases of the poor, tropical diseases and so forth.

So those are problems having to do with poor people, but there are additional problems that have to do with richer kinds of people, like ourselves. And here among the problems are that if medicines are very expensive, there is a danger of counterfeiting. These are little pills that cost just a few cents to produce, if you have a fake and you can sell them for a hundred bucks or something like that.

Another problem that also concerns us is that pharmaceutical companies motivated by patent rewards will focus on symptom-relieving drugs. So the ideal patient for the pharmaceutical companies as they are now incentivised is the patient who doesn't die and also doesn't get well. That person will come back into the pharmacy every week to buy a supply of medicines and make money for the pharmaceutical companies all the way to the end of their patent lifetime.

So, it would, other things being equal, be good if we could find a way to incentivise pharmaceutical companies that didn't have that bias towards symptom-relieving drugs built-in.

CB: Maybe I can get you to focus on the first problem you pointed out, because it has been one that received a tremendous amount of attention, particularly in the last ten years because of AIDS and the development of drugs which can treat and effectively prolong the life of HIV sufferers, which are very expensive. And that is this issue of access.

Now a lot of people seem to think there is just a genuine dilemma here. That is, we have all these drugs because the companies going in there have the promise of recouping on their innovation through these monopoly patents. That's the only reason why there has been such a development of these drugs. So If we do anything to make them available to the poor, short of taxing ourselves exorbitantly so that we just pay for these drugs for these people, what's going to happen is that these companies are just not going to have any incentive to create new drugs in the future.

So the dilemma is either we continue to promote innovation through this restrictive regime, recognising that millions of these people will continue to die. Or we ensure access to the poor but we can only do that by breaking patents and eliminating incentives or by taxing ourselves to an extent that nobody seems willing to do.

TP: Yes that dilemma exists if you narrow your vision to a very limited range of options. So basically I would say it is a false dichotomy. Right, you say either we have patent rewards in which case we get new medicines but during the time of the patent the medicines are expensive or we do not have any rewards at all. If those are the two options on the table, then I agree we have a terrible dilemma. But the question is: isn't there a better way to incentivise pharmaceutical innovation, isn't there some

third option that would give us the medicines that we want and would avoid the dilemma that you so clearly outlined?

CB: Well is there another way, maybe you can discuss a little bit how you would propose to address this and some of the other problems you mentioned?

TP: Yeah the first thing to realize, I think, in finding another solution, the first idea is to separate the invention of the drug, the process of research and development on the one hand from the manufacture and sale of the product. Those two things have to be separated from each other. And you can separate them from each other, because essentially the research and development expenses are completely the same in magnitude regardless of how many people actually benefit from the drug. So if you pay for the research and development separately, then the extra cost of allowing lots of other people to participate is exactly zero. They can all then use the intellectual property if you like or the intellectual achievement that went into the development of the new drug. So that's step one of the solution. I think many people now agree that that is the correct step forward that we should do that.

The second question then is: who pays for the research and development? Who pays for that? And here I think the solution is that, again, pretty obvious, that this has to come somehow out of public funds, so you say governments are paying for it in some fashion or other. Now here we have two different questions. One is, should this be done state by state or should it be done globally. The right answer I think is doing it globally. This is much better because there is no extra cost of cutting in a lot more people by making the benefits global. If the benefits are global and can be made global at no extra cost, then why not dilute the costs as far as you can?

The second question is, how do we incentivise? How do we pay for it? One way would be for governments to get together and simply to tell certain research outfits: here is a billion dollars, we need such and such a drug. These are so called 'push programmes', and push programmes are notoriously not very successful in getting people to successfully innovate because people are already being paid and so often they don't make as much of an effort to be successful. Also because they have no competitors breathing down their necks.

An alternative that has been much discussed these days is 'pull funding'. This is where you put out a prize, sometimes in the form of cash, sometimes in the form of an advanced purchase commitment or an advanced market commitment and thereby incentivise a number of companies to compete with each other towards developing a medicine that satisfies certain constraints, meets certain specifications that are laid down in advance.

The proposal we have made is a little bit different and I think a much better proposal. Namely our proposal is that we have a generalised commitment, where we say that any medicine that works will be rewarded in proportion to how well it works.

Medicines get rewarded in proportion to their global health impact. That global health impact depends on two components. On the one hand, on the quality of the medicine, how much it helps those people who need it. Then secondly, on how many of the patients who need the medicine actually get the medicine and take it correctly in a way that makes them better. In this way you don't have to specify in advance which medicines you want companies to develop. You simply say to the companies: develop any medicine whatsoever, whatever you want to develop and then you show that it is patentable in one jurisdiction and once you have done that you can, if you like, apply for this health impact reward and for the next ten or twelve years harvest annual payments proportional to the health impact of the medicine. The only condition that registration to the health impact fund requires from the companies is that they sell the medicine at cost, no more than cost and actually companies will be very happy to do that because in this case, selling at cost gives you many more customers, many more people who can afford it and in this way companies actually make more money than they would make if they sold at a higher price.

CB: So just let me get this straight. Are you thinking that you are going to completely replace the existing system of intellectual property or this would be something that would operate in addition to the system that we now have?

TP: It would operate in addition to the system that we now have. It would be a complement that is entirely voluntary on the part of pharmaceutical innovators. So innovators would sit down beforehand and they would think about each possible research project on two separate tracks. They would say: if I develop this medicine, I could on the one hand simply take advantage of the patent system, cater to a few people and try to make a lot of money in terms of mark-up, where the difference with price and cost is very large and even with selling to a relatively small group of patients we will make our money back and then some.

The other way I could do it would be to go for the health impact reward. I would make absolutely no money on selling the drug because I am selling at cost but I would get a health impact reward which would be a certain amount of money per unit of health improvement multiplied by the number of people who experience that health improvement. Now in making this calculation, pharmaceutical companies will find that for drugs that have relatively low therapeutic benefits, like hair loss product or a skin care product or something. It would be pure insanity to park that on the health impact track because you just wouldn't get much money. Even if a million people, a billion people take your products the health benefits would be next to nil and so you wouldn't make any money. These products would simply stay on the patent stream.

Then you have products like the neglected diseases you mentioned earlier, anti-malaria product, TB products, a tropical disease product where you couldn't make any money on the patent stream. The only way to make serious money would be by registering with the health impact fund and then trying to get that drug out there in every country and really reach all the poor people who can benefit from that drug and make a lot of money that way.

Then there are a few drugs kind of in-between, that can be profitable on either track and the medicines you mentioned earlier, AIDS medicines, are a wonderful example of that, where you have a genuine choice, where you could make money by catering to a relatively small group of people who will then be charged a lot of money for AIDS medicines or catering to a much, much larger group of people who would get the medicine at cost to you, but you would then harvest the health impact reward.

And there it depends a little bit on exactly how high the reward is that would be available on the health impact fund track. It would also depend of course on the composition of the patient population but on the whole the pharmaceutical companies will have to make sometimes a difficult decision as to which of the two tracks they want to put their medicine on.

CB: Perhaps I could follow up by pressing a bit on that issue, since the question of access to HIV medication as one of the main ones that the public health people are concerned with. Since it is a voluntary initiative, that is that they can stay within the old system, isn't there a risk that companies, who are trying to develop medications for diseases that also affect rich customers in rich countries, simply won't avail themselves of this new opportunity: partly because under the present system at least they know that they have a pretty guaranteed set of customers who if they can develop a drug will get it. Whereas at least on the face of it, the health impact fund might seem to involve a lot of unclarity for them. That is, they may not know how it is going to work or they may not know how they are going to be rewarded, how much they are going to be rewarded. They don't know if people are going to come in and contest saying that perhaps they really haven't given so much benefit. How do you deal with those sorts of concerns, both about whether they will take out these patents and also the reasons behind their unwillingness to do so?

TP: These are very excellent points and we have to turn them around a little bit and ask exactly these questions in a constructive spirit and say these are the minimum requirements on how to set up the health impact scheme. Here is something where governments really have to help us. If governments

take up the idea, then of course they themselves have a very strong incentive to try to make the health impact fund successful. They want medicines to be won over to the health impact track and so they themselves will want to make that track as transparent as they can possibly make it.

For example, the one thing they absolutely have to do, is guarantee payments for 15 to 18 years into the future. This money is not just here for a year or two. This money is here for the duration, more than the duration because actually pharmaceutical companies have to decide five or six or seven years before they can hope to clear through the NIH or whatever equivalent there is, get market approval. So they have to be assured that six or seven years down the road the money will be there and then for another ten years to reward them. So governments have to come to the table and give these kinds of assurances and have to agree to a clear and transparent mechanism through which the payments will be calculated so the companies can know in advance exactly how the health impact will be measured and then can make an intelligent decision to go on to the health impact track that is the better track for them.

The other thing is of course, is that the rewards have to be large enough. Depending on how large the rewards are and you can essentially think of them in terms of dollar amount per QALY [Quality-Adjusted Life Year] or something like that. A QALY is a commonly used measure of health improvement. So depending on how much money per QALY governments are offering, of course more and more medications would fall under the health impact fund. They would become more lucrative under the health impact fund than they are under patents.

Now you will say, why don't we simply make the system mandatory? Why don't we simply take away the option of patents? There are two reasons for it, one is that there are many products that I think we want, even though the health impact is relatively minimal and products that will never be lucrative under the health impact fund. We want hair loss medication, and we want skin care medication and so there is no harm done keeping them under the patents.

The other reason is, and that's a more political reason, that if we were to deprive pharmaceutical companies of the option to patent their products and profit through monopoly prices, the pharmaceutical companies would go ballistic, they would basically veto this. They are in a position to veto it because they are extremely powerful both in the United States and also many other countries to which are essential for the success of the health impact scheme.

So in order to make headway politically, it is crucial to win the support of the pharmaceutical companies and this health impact scheme was expressly designed with the intent of trying to find something that would be palatable to these companies, by giving them two things. On the one hand, new profit opportunities in addition to the ones they already have and secondly, a way in which they can shed their rather unfavourable image that is currently becoming a major problem for them.

CP: OK, so if pharmaceutical companies are going to have new opportunities of making money without having to sacrifice any existing ways of making money, I can see why they would be on board. But of course the new ways that you are proposing that they would make money depends on somebody footing the bill and this somebody presumably is going to be the governments and ultimately the taxpayers, primarily in wealthy countries. How are you going to make this palatable to them, that is how are they going to see themselves as gaining aside from moral gain that they can recognise in helping deal with some of the health needs in poor countries? What are some of the gains that these people would see themselves as reaping that would justify the cost, and what sort of cost are we really talking about?

TB: Yes, I think it is important to see that the actual cost is very, very minimal and the reason why the cost is so minimal is because as I said earlier, spreading the benefits of a particular medicine, letting more and more people benefit by allowing the medicine to be traded in a competitive market at near cost, that cost is basically zero. So it doesn't matter whether a million people use a new AIDS medicine or a billion people use a new AIDS medicine. The cost of research and development are exactly the same. So the main thing is here by having the health impact fund regime, of course we

are paying more in taxes for research and development, that money comes back to us, in that we then pay less as patients for the drugs that we are using.

Now you ask me how much it would cost. One of the virtues of the health impact fund is that this is entirely scalable, so governments can put more money into it or less money into it by revving up and down the rate at which they pay per QALY or in other ways. We have calculated that the cheapest way you can run the fund, the very, very minimum, in order to not have excess of costs of administration and so on, would be about four billion dollars a year, which is a really quite small amount. If the fund works reasonably well, you could increase the pot and thereby incentivise and accelerate the development of new medicines for those diseases that are more lucrative under the health impact fund.

CB: The political reality of any proposal like this, is that it is competing with other ways that governments might tax their people and raise money for public purposes. So one concern I can imagine people having is that a lot of these health problems that affect poor people are problems for which there are existing medications and sometimes they are actually relatively cheap, but there just isn't the money to buy them. This counts both in terms of being concerned about these poor populations and also about the cross border affects which you mentioned. So why not just spend more money if we imagine that we have some fixed pot of money directed towards paying for the medications that already exist that can treat these people, rather than putting so much emphasis on the importance of rewarding new innovation?

TP: It is a very good question and it is something we have asked ourselves a lot as well. Basically it is true of course that there are other interventions that we could fund that would be as effective or more effective in promoting public health in the developing countries. So we could, for example, not just do off-patent medicines, as you mentioned, but also clean water initiatives, sanitation initiatives, food supplement initiatives, school lunches and so on.

All these things are proven to be extremely effective in getting the burden of disease reduced. So you might say well maybe there are more cost-effective ways of getting the global disease burden reduced. Now the problem is, in principle you are right. I don't want to take money away from any of those initiatives and divert them to something that is potentially less effective. But the reality is that not very much money is now spent on these initiatives and it is difficult to see a major increase of funding for these initiatives forthcoming. It is just not going to happen.

This project, the health impact fund, is different in that it is not an initiative that is primarily a developing world initiative, even though we hope of course that the developing countries will benefit disproportionately. It's a new way of incentivising pharmaceutical research and it is something that has enormous benefits also for the citizens in the rich countries. Think of the United States for example, where roughly 50 million people lack health insurance and know very well what it means to go to the pharmacy and be set back \$120 for a two week supply of medicines that they urgently need. So we can appeal to those people and people who are sympathetic to them and say this is something that is not just for the developing world. It is something that is better for the world at large.

So that's one thing that can be said, and the other thing is that, politically, the pharmaceutical companies may well support the scheme. They may say that even though the scheme costs lets say five, six, seven billion dollars annually which isn't much for all the rich countries together, since the pharmaceutical companies benefit, this is something that governments may well be able to willing to pay for. So again, if you think of the realities of what governments now, rich country governments in particular spent their money on, very little goes for serious poverty reduction efforts in the developing world but very, very large amounts go to what can be called corporate welfare.

We may just say to the governments: look, you know, if you pay 350 billion dollars for agro-businesses and supporting exports for cotton and so on, then why not pay a few billion dollars for

supporting the domestic pharmaceutical industry through giving them new profit opportunities and so forth.

So in other words, what you said is right. If one had a pot of money and thought carefully about how to spend it most cost-effectively on getting the global disease down, I think one might be able to do better than the health impact fund. One might, I'm not sure. But the problem with that is that you are starting with a hypothetical that just isn't true. You don't have that pot of money and getting that pot of money is a very important part of the problem. So in order to get that pot of money, one has to make a proposal of spending it in a way that mobilises at least some of the rich and mighty in support of the project.

CB: Thomas Pogge, thank you for joining us on Public Ethics Radio.

TP: It was a pleasure, thank you.

ANNOUNCER: Thanks for listening to Public Ethics Radio. We'll be back soon with another conversation about public ethics. In the meantime, you can find out more about us and the Centre for Applied Philosophy and Public Ethics on the web, at www.cappe.edu.au.

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