

Ask the Experts
Low-Cost AIDS Drugs
June 16, 2004

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Larry Levitt: . . .internetnetwork.org. Welcome to "Ask the Experts", a regular interactive web show, that provides in-depth discussion of current health policy issues and allows you to interact directly with top policy experts. Today our focus is on how to make low-cost AIDS drugs available in the developing world. There are six million HIV-positive people in developing countries who need antiretroviral medications, but just 7% of them are actually getting treated. There is no doubt lower-cost drugs would stretch existing resources. The debate continues over how to speed the distribution of these drugs while ensuring that they're safe and effective. This is especially true for so-called fixed-dose combination drugs, which combine several medications into one pill. The World Health Organization has established a pre-qualification system and has approved some generic drugs for distribution, and just last month the U.S. announced plans for a fast-track review program under the President's Global AIDS Initiative. How these systems will work is likely to be a hot topic, as the 15th International AIDS Conference convenes in Bangkok in July.

We'll spend the next hour trying to sort some of this out and answer your questions. You can reach us in two ways. E-mail your questions to ask@kaisernetwork.org or call us here at the Kaiser Family Foundation broadcast studio and ask your question on the air. You can phone toll-free at 1-888-kaiser-8.

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That's 1-888-524-7378. We'll get to as many of you as we can.

To answer your questions, we're joined by three experts who come at this issue with much experience and from a variety of perspectives. Dr. Mark Dybul is Deputy Chief Medical Officer in the Office of the U.S. Global AIDS Coordinator at the State Department. Dr. David Hoos is an assistant professor at Columbia University and has advised the Global Fund on AIDS, T.B and Malaria on drug procurement. And Jen Kates directs HIV policy for the Kaiser Family Foundation. Thank you all for being with us. Jen, let's start with you. Give us a sense of what the stakes are here. How much less expensive are these generic drugs compared to brand-name drugs, and what's the significance of these fixed-dose therapies that combine multiple drugs in one pill?

Jennifer Kates: As you mentioned, the stakes are really huge here, because the gap in who needs treatment and who is getting it is so significant and urgent to respond to. That's why the initiatives that have been announced recently embodied within the WHO's 3X5 Initiative and Pat-Phar[misspelled?] here in the U.S., the Global Fund, the President's Emergency Plan for AIDS Relief, and the Global Fund to Fight AIDS, Tuberculosis and Malaria—all of those initiatives—we all are hopeful that we'll bring treatment to more people. Of course this brings the issue of price up immediately, because price is a barrier to access in developing

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countries. The issue of generics and also fixed-dose combinations, which as you mentioned are combinations of different medications in one pill, really gets at this issue of price, because generics have helped. They're not the only factor, but they are a factor in bringing price down. For example, generics in some cases have half the prices. Now some of the fixed-dose combinations are maybe a little over 200-some dollars in some countries. Prices may go down further, so it's really been a big issue, and one that in the context of other issues like safety, efficacy, etcetera, it's a tension that exists. The other thing about fixed-dose combinations and why there's so much attention to them is not just price, but also the ease of formulation as one that's much easier to take and distribute. That's been attractive on a lot of levels.

Larry Levitt: So if you've got a healthcare system that has less infrastructure than we're accustomed to in the U.S., being able to take one pill or two pills a day rather than six pills a day makes a big difference.

Jennifer Kates: Definitely. And it also cuts down on the supply-side issues of having to supply many, many medications versus a smaller number of medications. Public health experts are also hopeful that it would cut down on drug resistance if people raised their adherence by only having to take one or two pills a day.

Larry Levitt: Adherence meaning that there's follow-

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through on their treatments?

Jennifer Kates: They're sticking with their regimen. Exactly.

Larry Levitt: David Hoos, you've been advising international organizations on drug procurement, like the Global Fund. Give us a sense of what current practice is. I mean, how is the Global Fund purchasing or providing funds to purchase these drugs, and approving them?

Dr. David Hoos: Sure. Well, I think that the tension exists of how to balance price, how to assure quality and how to assure quality in a particular context. For example, with the Global Fund where I'm part of a procurement and supply management advisory panel, the Global Fund first of all needs to make sure that the agency that would be bringing drugs into a country has good financial practices and good supply-chain practices. Then the question comes up, how do you ensure that the drugs that the country wants to purchase are of assured quality? The difficulty is often that drug regulatory authorities in developing countries may not have the sophistication to independently evaluate medications. What do you then use as the arbiter of high-quality medications?

Larry Levitt: So in the U.S. we have the USDA, that analog doesn't exist in many other developing countries.

Dr. David Hoos: Right, and the additional tension is that if you don't feel comfortable in using a developing

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country's regulatory authority, what arbiter do you use?

There's not a specific rationale for generic companies to get US-FDA approval if they're not going to market in the United States. That led to this whole process of the WHO and other UN agencies developing the pre-qualification system to create an independent arbiter of quality for drugs for AIDS, TB and malaria.

Larry Levitt: So, the Global Fund is making use of the World Health Organization, the WHO's, pre-qualification process?

Dr. David Hoos: Yes, by January 1, 2005—in a few months, basically, every Global Fund recipient will have to purchase drugs for AIDS, TB and malaria that appear on the WHO list of pre-qualified medications.

Larry Levitt: And Mark Dybul, the President's initiative, which is what you're working on, obviously that's a big stake in this now, \$15 million going in over the next 5 years. The Bush administration has been subject to some criticism, for example from former UN Ambassador Richard Holbrook that you're not moving quickly enough in purchasing generic drugs. You did just announce this new fast-track review process. How do you think that addresses the concern that some people have raised?

Mark Dybul: Well, we think it addresses them entirely. I think we need to be clear on the use of the word "generic".

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Americans in particular hear the word generic and have a connotation of a drug that has been fully vetted, cleared through regulatory agencies, and is just like taking a regular drug. That's not the case here. These are more appropriately called copies or "similar". These are not drugs that have gone through regulatory processes. I think we need to be careful about the use of the term "generic". The U.S. government policy has been from Day One, since the President announced the Emergency Plan that we would buy the lowest-possible-cost drugs, as long as they're proven to be safe and effective. What we have been struggling with is that proof of "safe and effective". A couple of weeks, about a month ago to the day, actually, Secretary Thompson announced with Ambassador Tobias, the U.S. Global AIDS Coordinator at his side, that the Food and Drug Administration would utilize authority and regulations it already had and would review drugs that would not in the immediate future be used within the United States to evaluate quality, safety and efficacy. Any of these companies would be eligible to come in through FDA processes, as they always were. We just have guidance now that helps them march them through how they would do so in an expedited way. Once we receive an application the Food and Drug Administration has stated that we will have a decision within two to six weeks. We've actually gone out and already offered technical assistance to a number of companies. We're offering pre-inspections of the plants

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before they even come in with an application to move it as quickly as we possibly can. Ambassador Tobias announced that he would accept this tentative approval for these drugs that meet these safety standards for the use of the Emergency Plan.

There are a couple of points that I would like to make about this. Cost is important, but at the moment, that's not what's preventing us from purchasing and getting people on therapy. The Global Fund, World Bank and others have had access to these knock-off or copy drugs for quite awhile. We don't see hundreds of thousands of people being put on therapy. The reason is, it's not the cost of the drugs right now; it's the human capacity that is the roadblock. Cost is certainly going to be an issue, and we want to purchase the lowest-cost drugs. But I am concerned that we emphasize the cost of the drugs, as if once we have cheaper drugs, all of a sudden everyone who needs therapy is going to be on the therapy.

Larry Levitt: When you talk about the human capacity, it's building up the—

Mark Dybul: It's building up the infrastructure, the training, and the ability of people to get the resources out. Many HIV-infected people are in rural areas that don't have any access to healthcare at this point whatsoever, and getting out to all these people is going to take time. The vast majority of people, some estimate 90%, don't know they're HIV-positive. They need to know they're HIV-positive before we can treat

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them, so there's a lot of capacity.

The other thing is that the fixed-dose combinations, we agree, is a very important step, and we are all supportive of fixed-dose combinations. What's been lost in all of this is that we're encouraging the development of new fixed-dose combinations with these announcements, we absolutely need. An example is these currently available fixed-dose combinations, the single-triple drug combination. If you look in Namibia where this is the preferred regimen, 40% of people who start drugs don't receive that because they have tuberculosis. They can't use this fixed-dose combination when people have tuberculosis. So you need all those other drugs, anyway. The requirement is going to be for full-services for HIV-infected people, not a little service. I think we need to keep all these things in mind as we talk about fixed-dose combinations.

Larry Levitt: Let me come back to something that you said. You mentioned that the generic AIDS drugs we're talking about here aren't necessarily like a generic drug that's gone through FDA approval as we're accustomed to in the U.S. But these drugs all do go through WHO's pre-qualification process?

Mark Dybul: They do, but WHO admits up-front that they are not a regulatory agency. They are not a regulatory authority, no what we call stringent regulatory authority that have been accepted as the global regulatory authorities with high standards that do the full evaluations—none of these

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authorities have looked at these drugs. We believe regulatory authorities need to look at drugs. I think today we had some example of why the regulatory authorities are so important. Drugs that had been pre-qualified were no longer able to be on the qualification list for a variety of reasons. We have the greatest respect for the WHO. We think what they've done is very important, and the individuals involved are of the highest integrity, but there is a difference between a regulatory authority and the pre-qualifications.

Larry Levitt: You mentioned the news today. You're referring to the article in the New York Times talking about the WHO removing two drugs from the pre-qualification system. We'll get to the calls and e-mails in a second, of which we have plenty, but I want to address this story in the New York Times today. David Hoos, maybe describe first of all what happened, what the WHO did, and what your sense of the significance of this is.

Dr. David Hoos: Sure. Well, two of the two-drug combinations, not the triple-drug combinations, that are manufactured by Cipla, the contracted agency that performed the bio-equivalence testing to say, if someone were to take the drug were the quantities that appeared in someone's blood at an equivalent level of taking two drugs separately? The technical processes that were described were felt to not be sufficiently well described or of appropriate technique.

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Larry Levitt: This is the documentation—

Dr. David Hoos: The documentation was felt not to be sufficient, and so the WHO had announced that those two drugs would be taken off the pre-qualification list. It was not saying that these drugs are necessarily not bioequivalent, but it could not approve that. I guess I would, however, say that, being a difference of opinion, the fast-track system that the U.S. government and the FDA have established, as far as I can tell does not significantly differ from that of the WHO pre-qualification process. And that there really hasn't been—I understand that the USDA has some hesitancy about the WHO process, but from the sort of pharmacy field, there hasn't been a significant disagreement with the WHO process. So even though it's correct to say that the WHO is not a stringent regulatory authority, it's not clear to me that there's a significant difference between what they've done through their pre-qualification process [inaudible] significant process with the fast-track you've been processing and what WHO has been doing.

Mark Dybul: Well, I want to point out that this is not a new process. The process for review has not changed. The FDA has been in existence for a very long time. This is not a new process. The process has always been there. Trizivir, which is a combination drug that has been approved by the FDA went through the same process. And so, this is not a new process. What we did is provide guidance so that companies that normally

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wouldn't enter the U.S. market for intellectual property rights now may enter. We're providing guidance to help them to enter through the process, but the process is not new. It's the same regulatory process the FDA has always had. The difference is difficult to state because for very understandable reasons the WHO process is done under a strict confidentiality. We understand that; so is the FDA process. We have a limited knowledge of how the processes were actually done. You can say we have the process, but then you need to know how things were collected and how things were done. We need a lot more information about what happened with these two drugs. Why were the drugs approved and then approval retracted? If this had happened at the FDA I think there would be an awful lot of questions asked about that. What was looked at in the first place, and what was looked at in the second place? Why wasn't it picked up the first time and why was it picked up now? Again, I do not want to in any way impugn the WHO or the WHO process. We have a great respect for the process. What we're saying though, is regulatory authorities have been in this business a long time. They have a way of doing things that we think should be maintained, and why not just use the regulatory authorities?

Larry Levitt: Some might argue the fact that the WHO did find that these processes may have been problematic for these two drugs is an indication that the system's working,

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that they actually did discover problems. Is that a reasonable argument?

Mark Dybul: I think we need a lot more information. Again, why was there approval in the first place? If I'm not mistaken, these are two drugs that were approved quite a while ago. These are not the recent drugs from last December; this was a year, a year and a half. What triggered—it would not be normal to do a second review. Why did that second review occur? There are a lot of questions around this and I think we need the answers to that to evaluate it, to see what can and should be done. I think we should look at it in the same way as what would happen in the FDA if something like this occurred, because this is an important issue. But that's not to say the WHO system shouldn't be used for certain circumstances. We're just saying we know the FDA system.

Larry Levitt: Let's move on. We have a number of e-mails coming in, and one is on pretty much this topic. It's a multi-part e-mail. I'll only ask you to answer several parts of them. The first is, and I'll read it: "Given that the World Health Assembly voted in May to assure the pre-qualification review process and the results of inspection and assessment reports of the list products, aside from proprietary and confidential information are made publicly available, would the U.S. be willing to accept WHO pre-qualification now that it has access to the underlying data?" David Hoos, let me ask you

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first, if you are familiar with the World Health Assembly vote. What is it they were actually trying to do there, making this information publicly available?

Dr. David Hoos: I think there's been a political background of the question of whether or not there should be additional requirements for assuring quality. My understanding of the WHO statement is that it's really trying to push the issue that the WHO process should be supported, that there may need to be adjustments to that process, but that it would be reasonable for adjustments to be made to that process rather than the idea that there might be an additional process, such as insisting on FDA or other stringent regulatory authority approval of a drug. In my mind, it really was an endorsement of the pre-qualification process.

Larry Levitt: Mark Dybul from the U.S. federal government's perspective, is it enough to know that the WHO information is publicly available, or do you feel like you need more in terms of—

Mark Dybul: There are two things. One is that the information is not yet publicly available. It was voted that it should be. This would be a very lengthy process. You have to redact the proprietary information before you post it. These dossiers are enormous. We don't have access to the information. The second piece of it is, what is the information that we have access to? Is the bio-equivalency information fully available?

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Is the inspection information fully available? Is the information available enough for us to say that this demonstrates the safety and efficacy? I would point out again that this is not an additive process in many ways, this is an existing review process, and again, I'm not trying to say that one should or should not be used by whomever they wish to use it, but for the U.S. government standpoint, the FDA is the mechanism by which we evaluate drug safety and efficacy. We have a process we are confident in, and so, that's the process we're using.

Larry Levitt: The second part of this question asks about the new fast-track review process, and asserted that it's only open to fixed-dose combination therapies. It asks if there's any reason why the same process could not be open to permit approval of single-dose antiretroviral drugs?

Mark Dybul: In fact, that's a misunderstanding; I think just the way it was covered. It's open to everything. We actually would expect single drugs to come in even faster than the fixed-dose combinations. It's not only for that. It's actually available for blister packs, which don't exist. We're trying to encourage the development of a blister-pack, which is a co-formulation, kind of like a pill box, with the drugs put into it, which some feel may even be better than fixed-dose combinations, if you do have to switch your drugs. I think that's a debatable point. Nonetheless, what we're trying to do

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is develop a broader market of available drugs. New fixed-dose combinations, blister packs, single drugs, whatever it takes to get us to where we need to go. I think that piece has been lost. We're trying to encourage a new generation of drugs so that we can look to the future and treat as many people as effectively as possible.

My understanding that one of the difficulties, relying on the U.S. process is under the issues of data exclusivity. How quickly can a new drug be reviewed in this process, whereas most of the current antiretrovirals can be assessed by this process, but some of the newer ones that have just very recently come on the market would actually not be able to be—a generic version of those would not be able to be reviewed, at least under the regulations governing the FDA at this point.

Mark Dybul: I guess that depends on how you look at it. The FDA would be able to review any drug for which there were adequate clinical data to show it's effective. We went through what those would be. If there's a drug that's new that hasn't been proved to be safe and effective, we would not want to use that or the generic version of it until we knew it was safe and effective, but there's nothing that I know of that could not go through this process. There are one or two drugs that would actually be excluded from this process. Tenofovir is one of them, I think, currently. There are ways to work through the process. We are working through that. I think we will be in

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the position that we can use anything that's available, and certainly in a broad enough scope.

Larry Levitt: David, this may have been what you were going to—this potentially gets into issues of intellectual property rights, and patents. Maybe we can step back a little bit. If you could just describe in very broad terms what some of those issues are, particularly as they are related to HIV medications.

Jennifer Kates: I'll defer to them as well, if they want to add to this. One thing I wanted to say, stepping back a little bit and listening to the conversation. The other reason we can have this conversation is that in the last three to four years there has been a real shift in both the feeling about providing treatment in developing countries, now that's a global goal, and now the funding that's available to do so. Some of these issues and questions hadn't really come up to the surface yet. In a way this is a good thing that all these things are happening, that people are looking at fixed-dose combinations, blister packs. Both of those are other ways of delivering drugs that make it easier in resource-poor settings, so all of this is good.

The issues around patents have to do with—at least in the United States, most of the antiretrovirals are all on patent. Patent protection would allow the price to stay at certain levels, and allows the pharmaceutical company that owns

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the patent to have rights over that. This has changed in the international context to the developing countries through a series of events, most notably the Doha declaration, which looked at something called "TRIPS", and all of these things around intellectual property and trade law. Essentially, what happened then was the beginning of a new framework allowing developing countries who have public health emergencies like HIV to approach intellectual property from a flexible perspective, allowing the purchasing and other kinds of arrangements to get generics or copies and lower-cost medications.

Larry Levitt: These are drugs that would normally still be under patent in the U.S. but could be manufactured and provided in generic form.

Jennifer Kates: In many cases. Exactly, and that's why if this happened, that's why the FDA guidance was put out in a way, to allow that to happen outside of the United States in these countries and allow the U.S. Pat-Phar[missspelled?] Initiative to actually purchase those medications.

Larry Levitt: David, this sounds like a big shift from just a couple of years ago, a shift from, "Can we provide treatment in the developing world?" to, "How do we provide treatment in the developing world?" Getting beyond the debate over patents, in some sense.

Dr. David Hoos: Right, I would certainly agree that

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there's been a major shift in terms of U.S. policy. The places where I think it's still problematic are Number 1, for countries that don't qualify as least-developed countries. In fact, they're not excluded from the patent system, so for example, the International AIDS Conference in Thailand, Thailand is not able to access the lowest prices based on the big pharmaceutical companies' antiretrovirals. Also, I think in terms of historical context, although I think it's true that we've moved on to some extent from this issue of patents, I don't think we'd be where we are if there hadn't been all this—I think challenging patents and pushing generics which had been opposed by the administration, I don't think we'd be where we are in terms of major drops in prices even by the big pharmaceutical companies if there hadn't been quite a lot of political pressure. I don't think this would have happened by itself.

Larry Levitt: Let's go back. We have a number of questions by e-mail. Mark Dybul, you had talked earlier about the infrastructure. That almost comes before you get to the issue of drug prices. We have an e-mail question that reads, "I would be obliged to know how you are going to get HIV drugs to the rural communities in Africa. Would you work directly with individuals, or through community-based organizations?" We have a very similar question asking about whether mobile medical facilities or vans would be used. Give us a sense. I don't know

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if the planning has gotten this far under the President's commission, but give us a sense how you envision getting this treatment to more rural areas.

Mark Dybul: We've already gotten that far, already doing it. Within days of the President's budget being accepted and us receiving funds, we actually were treating people by motor scooter in rural Uganda, in a program that had been started by the U.S. government already. We were able to expand rapidly. In many of the countries, Botswana, Uganda, Tanzania, we have been supporting mobile units for voluntary counseling and testing, which we hope to utilize further for care and treatment. The President announced a network system that would be utilized to ensure that we get care out. A lot has been made about that this is a model someone pulled out of the air. The network system is how healthcare is provided, whether it be in resource-limited settings in this country, or in resource-limited settings around the world. You can't, unlike our friends in New York and here in Washington, have five university-based centers in the city. You have to do what you can do within the different regions. We move from different centers out, in the urban centers, down in the rural communities to have a full reach. There has also been some talk which is a little concerning to me of centers of excellence. It's not that I don't like centers of excellence. It implies that you don't have excellent care at every step along the way.

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The President's plan will ensure excellent care every step along the way, but because of advances in our understanding of the disease, we don't need physicians at the top doing everything. Community health aides are perfectly able to provide much of this care and treatment, as they are doing already in Tururo[mispelled?]. David through Columbia University has been doing a spectacular job, doing just this, getting care out to people in the rural community. It's not in the planning stages' we're doing it.

Larry Levitt: David, talk a little bit about it. In some sense, the ability to provide treatment for AIDS which was not imaginable a decade ago, seems like it's pushing healthcare systems forward in some of these rural settings. Is that what you've found?

Dr. David Hoos: Right. I think in many settings, chronic disease management was not how the medical system responded to people's personal healthcare needs. I think similar to how it happened in this country, where HIV was an opportunity to really develop types of primary healthcare systems for poor people, I think the same thing as Mark is saying is happening in other countries. There's a huge need, and I think that we are all trying to push as quickly and as hard as possible in the context where many more people need care than may be able to receive it right now. I don't think that HIV is going to be a necessarily vertical system only

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covering one disease. I think it will be advancing the healthcare systems in other countries in concert with the national strategies of those countries.

Larry Levitt: Once you've built the infrastructure, once you've got people into treatment, there are all kinds of other things you can do with this, right?

Dr. David Hoos: And of course, there's malaria and TB and sexually transmitted infections, and reproductive health, all very intersected in the same populations. I think this will really—there are synergistic effects from the President's plan.

Mark Dybul: And I would add, from one of the questions, the question was focused on rural. We have to remember that even in large cities there are pockets that are very much like rural settings, where we have to do the same things. I think we got our budget on the 19^t of February. On March 9th we were delivering therapy on foot as opposed to on motor scooter to a slum around Kampala in a similar way. You have to get to the people where they are whether it's an urban or a rural setting. Developing these systems is going to be essential to do that.

Larry Levitt: David, before we get back to our e-mails, let me remind people, you are watching the Ask the Experts on kaisernetwork.org. You can reach us in two ways. Either by phone, toll-free at 1-888-kaiser-8, that's 1-888-524-7378, or you can e-mail to ask@kaisernetwork.org. Let me return

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to our e-mails. One issue that I think has been a thread through a lot of us has been the issue of drug-resistance. Let me ask David Hoos, one of the doctors from the panel, if you could just set the context here. Explain what drug resistance is for those of us who are non-physicians in the audience.

Dr. David Hoos: If we have a virus like HIV that causes disease, and drugs have been developed that are effective at killing that virus, that would mean that the illnesses created by that virus would get significantly better. The difficulty can be, if through difficulties in either ensuring drug supply, or people not taking their medications for various reasons, not being able to afford it, the system isn't providing them the medication, they take the medication only from time to time, that gives an opportunity for HIV, for example, for variants of that virus that are resistant to the medications to take over and basically be the dominant infection, virus. That is a lot of concern for all of us that we do this correctly so that we really ensure that people's best chance, which is their first access to therapy can really be most effective.

Larry Levitt: Mark Dybul, one of the issues the U.S. federal government has raised is issues of the quality of the drugs and the implications of that for drug resistance. Describe some of your thinking about what the problems might be there.

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Mark Dybul: I think David could explain it as well as I could. In fact, many people can nowadays. The issue is, if the drugs aren't as good as they say they are—meaning bioequivalent, and that's really what we come down to—if they're not produced in a high quality way, you increase your risk of resistance. We know that resistance is going to happen whether we have the best quality drugs or not. The question is how much more resistance will you have? And we know from years of research that David has been involved, and I have been involved, and many others have, the more often you take your drug, the more concentration, the less chance of resistance. What we're saying is, why increase the risk of resistance more? Why make the problem worse?

It really is a very substantial problem in Africa and the Caribbean and other places, more so than in the United States. In the United States we do viral loads on a regular basis. We can tell when a patient is beginning to fail. We can do a thousand dollar resistance test to identify the drug that you should substitute for, and we have 16 drugs, many of which require refrigeration and a lot of other things that we can do. We're not going to have that type of what we call "salvage therapy" available for quite a while in Africa, nor will we have the resources or capability to do such intensive laboratory analyses, so we have to do everything we can to have the highest chance of inducing the least resistance, if that

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makes sense. That's why we're so strong on this point that we need high quality drugs. I think everyone is. David and anyone in this area is saying the same thing, we're just talking about how you get to that.

Jennifer Kates: Not to minimize that concern, because I think it's clearly a very critical concern, but it's also important to note that data and experience from developing countries, Brazil especially, and Haiti, have shown that there has been little resistance, relative to what we've seen in developed countries. So what that provides is a precedent and a model that it can be done. There are certainly challenges. There are challenges in different countries that don't exist in Brazil, but I think there's a lot of hope because of those examples and those models that this can be done without increased resistance.

I don't think any of us would say that there's going to be a greater risk of resistance. That argument was made a while ago, irrespective of the drugs. All we're saying is, the drugs do matter in terms of the risks of resistance. Beginning at the same level, let's have the same quality drugs.

I guess we did talk about this already. The different systems of assuring quality of drug, WHO, FDA, There's general agreement that bioequivalence data should be sufficient. I guess I just want to underline that, whatever differences exist between the WHO pre-qualification process and the FDA, that

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both fundamentally are based on bioequivalence data, and that it exists in both systems. That's why I would feel that the WHO pre-qualification system was looking at the most key information in order to prevent drug resistance.

Larry Levitt: Mark Dybul, you'd agree that bioequivalence is the key?

Mark Dybul: Bioequivalence and good manufacturing practices, both of those. You do bioequivalency analysis once. You actually do good manufacturing practices only once, and then in the future, but those two things together give you a good sense. In the withdrawal of the pre-qualification for these drugs, they mention both the inspection and the bioequivalence. We think that's important because you do have to look at both of those. Both systems do look at that. It's just question of is it a regulatory authority that ought to be doing it or, the WHO? Different people may choose different systems.

Larry Levitt: We have one caller on the air who has been waiting patiently. Let's move on to that. It's a caller from Washington D.C. Please go ahead.

Female Speaker: I'm actually calling because you guys just discussed the synergies between HIV, TB and malaria STI's. I was calling to find out, what about the synergies between Family Planning and averting more HIV-positive infants from HIV-positive mothers.

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Larry Levitt: Thanks for the call. Jen maybe we'll start with you and could you give some perspective as to how Family Planning sort of enters this discussion?

Jennifer Kates: I think it's central. Reproductive health, more broadly speaking is just central to HIV delivery systems, to care. Certainly the impact this epidemic has had on women and girls just makes that point, and so how reproductive health systems in all of the countries that the President's initiatives are in and all over the world are integrated, bolstered and worked into the delivery of HIV care, whether it's treatment or prevention is fundamental. How that conversation could happen, let's say, in traditional Family Planning sites with women to advise them about risk, and find out if they're positive, and obviously if they are, give them and I think all of the programs that are happening are aware of that.

Larry Levitt: David Hoos, in your experience on the ground in the developing countries, do you feel that is happening, or needs to happen more?

Dr. David Hoos: I think the original programming that Columbia University has been involved in has been NTC-plus, which was the incorporation of HIV-care into the prevention of mother-to-child transmission programs. Key to that was both referral from and to Family Planning. I think some of the ideological disagreements that may be occurring in terms of

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NGO's and the administration in terms of the treatment realm, I do feel that that has not particularly impacted. The funded treatment programs are very much focused on accessing treatment and as part of that, we as a grantee for that program also have flexibility to refer back and forth to Family Planning programs.

Jennifer Kates: Just want to add to that, there's also an increasing amount of attention to the importance of including services for women that are not HIV-specific, but including HIV information, whether it's about treatment, but also about prevention, and other factors that may put women at increased risk, to include that specifically in non-traditional HIV delivery sites. That would also be important to know.

Larry Levitt: Jen, just talk a little bit. It is the case that women are now at increased risk for HIV infection.

Jennifer Kates: Women right now globally represent about half of all people living with HIV and AIDS. In sub-Saharan Africa it's a greater percentage. There are more girls infected than boys. There are a lot of reasons for that. Some of those are biological reasons, with girls being more susceptible. Most are socioeconomic, cultural, but there are a lot of things that put women at increased risk. It's a problem that unfortunately seems to be getting worse.

Larry Levitt: Let's go back to our e-mails. We have one here from all the way in New Delhi. By my clock, I think

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it's pretty late there. I don't know if he's still watching or not. If he is, he's very motivated. He's got a number of questions. Let me try to address a couple of them. The first is more of a clinical question, which I'll leave to the doctors. Would there be a difference in the criteria employed to determine when to begin HART, which I assume is Highly Active Antiretroviral Treatment. Mark Dybul, maybe talk about that a little bit. Let's start maybe back from the question a little bit. Maybe more people who are HIV-positive, living with HIV in the world, and the estimates show, need treatment. Talk about what goes into that assessment of who needs to get into treatment, and is that evolving over time?

Mark Dybul: I think it certainly is evolving over time. I used to work with Jen on the U.S. guidelines in the Department of Health and Human Services on this. This is an issue that we struggle with a lot in the United States. We base it on laboratory values in the United States. When you get to Africa or the Caribbean, in most places you're not basing it on laboratory values, you're basing it on clinical criteria, although we're moving more and more, and we want to move more and more towards the laboratory-based criteria. Basically, the reason, as you pointed out, that many people who are HIV-infected don't need therapy, is that their immune system is not at risk. It's not the virus in the end that kills you. It does, because you're infected, but it's the reduction in your immune

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system's ability to fight the virus. What we try to do is look to see at what point does the immune system require that assistance to knock the virus down so the immune system can be protected. In the ideal world, the day someone's infected we'd give them the drugs and they'd live forever, but there are difficulties with adherence. These drugs are toxic. It's not so easy. What we try to do is gauge clinically, what's the best time to help people. And in many of these settings that we deal in, those are determined by weight-loss, by things that occur early in infection, something called thrush, you can tell, in the mouth that white things occur. In many of these settings, tuberculosis is one of the key indicators that someone might be HIV-infected, so we're all working to make sure that every tuberculosis patient is tested for HIV. A lot of it is clinically based now. In some settings it's based on laboratory parameters of the health of the immune system. We're moving more and more there because we believe that that's the most effective way to identify people where it's early enough to start, but not too late that it's going to be hard to recover that patient.

Larry Levitt: Under the President's initiative or international initiatives, is the criteria for when to start someone on therapy different than in developing countries than it is currently in the U.S.?

Mark Dybul: We actually follow local guidance on this.

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We don't feel that we can come in and tell a country this is when you should start therapy. Most of the countries in which we're dealing are focus countries. May I remind you that the President's Emergency Plan has focus countries, but we actually have a hundred programs, a hundred countries in which we have bilateral assistance? It's very widespread and it's to varying degrees, but we're involved globally, not just in the focus countries. We believe, and I think David would agree that it's the local community that ought to set their standards, assuming that they're within certain guidance, and the World Health Organization has general guidance that most countries use to set their individual guidance. I actually was involved in the creation of that first set of guidelines with the World Health Organization. I think David was, too—No? We see each other in Geneva a lot, though. We basically allow the communities and the nations, as they should, because they have to have ownership for their disease.

Larry Levitt: Give a sense of the numbers here. How many people are living with HIV globally, and what are the estimates of how many people need treatment?

Jennifer Kates: There are about 40 million or so estimated to be living with HIV and AIDs. The UN is coming out with new estimates in a couple of weeks, right before Bangkok, which will probably be around the same, about 40 or so million people living with HIV and AIDS around the world. Most still in

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sub-Saharan Africa, but increasingly we're seeing epidemics emerging in other parts of the world. In terms of the estimates of who needs treatment, given all that you've heard about when to start and some of the challenges of delivering therapy, it's estimated that about six million should be on antiretroviral therapy, and only 400,000 are on antiretroviral therapy. These are just estimates, but that gives you just about a 7% coverage rate. I think the most troubling piece of that, if you look at the regions where there are the greatest numbers of people living with HIV/AIDS, particularly sub-Saharan Africa and the percent getting antiretrovirals, it's the opposite there. It's problematic. It's urgent. An estimated three million people die each year, due to HIV-related causes.

Larry Levitt: Mark Dybul, an e-mail came in as you were speaking, actually, from Los Angeles. They want to know how many HIV-positive persons are receiving antiretrovirals today paid for by the President's plan. Do you have a current estimate of—

Mark Dybul: It's hard to give an estimate because of reporting periods, which sounds like a bureaucratic answer, but you have to remember that we received our first funding at the end of February and we're now in June. What I can tell you is programs that have started. I can give you some examples. And David can give some because he's one of the recipients. Elizabeth Glaser, which is Pediatric AIDS Foundation as well,

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just informed us that they've already started 550 people on therapy and are enrolling 220 people a week. We know that within days of receiving our budget, we increased the number of people receiving antiretrovirals by motor scooter by 300 in rural Uganda. Within weeks we started therapy in a slum in Kampala of around 100 people. We've started around 300 people in rural Kenya. In South Africa we're beginning to open many sites. It's difficult to give a precise number. We have no doubt that we have begun already. Such a short period of time, having already put out \$350 million and getting ready to put out quite a bit more in just this fiscal year, we're moving at an incredibly rapid rate. We'll have numbers as reporting increases, but we've already begun getting people on therapy. That's the kind of urgency that Jen was talking about. It's not, "Let's sit around and plan," it's "Let's get the money out and start people on therapy."

Larry Levitt: Let me ask—you mentioned the Elizabeth Glaser Pediatric AIDS Fund, and we did have a number of females from the Children's AIDS Fund asking about some issues, particularly with kids. Let me read a couple of them. First is in an African setting, what are the protocols for administering ARV treatment to children as compared to adults? What are the differences in cost for providing ARV treatment to children in comparison to adults? David you've done some work on this at Columbia. Are there differences, different criteria that apply

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to kids? Are the costs different?

Dr. David Hoos: Well, I mean in general, in terms of identifying which small children acutely need antiretrovirals, the numbers used for the criteria are somewhat different. In fact, it can be more difficult to identify those small children just based on symptoms rather than on lab tests, so it's quite challenging and actually the diagnostic tests necessary are often even less available than for those who are adults. So it's quite challenging, and I think that it's important for all advocates to make sure that the needs of children are really highlighted, since in some ways they may not be prioritized because it's more difficult.

In general, administering medications to children, for anyone who has kids, if you're giving three medications all in liquid formulation to a small child via a syringe without a needle, it's very difficult for a parent. It's very difficult for a practitioner to keep changing the doses of those medications as the child increases in size. These are huge challenges that we all really need to keep on the top of our radar screen because it would be very easy to not do it because taking care of them is so difficult.

Larry Levitt: Jen Kates, one of the other challenges here, presumably, is that the AIDS epidemic has orphaned a number of kids in the developing world, and that presumably affects the ability to get kids into treatment.

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Jennifer Kates: Yeah. I mean, remember not all orphans have HIV, but a significant number do. I think the latest estimate is something like twelve million orphans—in Africa is the biggest number. There are a lot of challenges. If an orphan has HIV, he obviously doesn't have parents, might not have a support system for reaching them. You had also asked a question about price. Some of the data I've seen do show price differences between the regimens that are available for kids, and adults with adult regimens, since there tend to be more options that have been explored, being a little less expensive. That is another, in addition to prioritizing it in terms of treatment standards and protocols in how it's delivered. Price also becomes an issue there.

Dr. David Hoos: There's been no fixed-dose combinations for children, which is more difficult, and I just would want to add in terms of what can be daunting figures when we talk about the numbers of people who really need antiretroviral therapy for their health or to prevent death. In order to identify those people, it means that most of those 40 million people who are infected need to be in health care to actually know who needs that care. We're not just talking about getting a lot of people on treatment, we're actually also talking about making sure that all those people are in a healthcare system so that they can be assessed to see the severity of their illness. It starts making the magnitude quite

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impressive.

Larry Levitt: Mark Dybul, there was another story in the New York Times earlier this week about expanding routine testing in Africa. Is that something that's also part of the President's Plan, to actually get people to know their status so that you can get them into treatment?

Mark Dybul: Yeah. We believe that routine testing is an important tool. In this country, the Centers for Disease Control and Prevention have actually endorsed routine testing, in particular for pregnant women, and in medical settings. We believe that could be an important tool. Botswana has moved to have routine testing. South Africa has routine testing in a number of settings. We have had routine testing for the military and other things in this country for quite a long time. We do believe that this will increase the awareness of HIV. We think it will contribute to the decrease in stigma, although in the short term there may be some difficulties the other way with increased stigma. But it is a way to get the HIV message out, to get people informed of their status. Again, with 90% in some estimates, of people in the developing world unaware of their status, it's going to be very difficult to treat them, particularly pregnant women and young women. This is the only way we can help them to know their status. You were talking about the difference in women. In some areas young women have 60% infected, in Botswana, sometimes 70%, whereas

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young boys are 5%. One of the ways we can get to them is through routine testing in pregnancy sites. We have not issued a formal policy that we want routine testing, but we do encourage routine testing. We have certainly encouraged it in the context of pregnant women, of patients with TB, STD's and other settings.

Larry Levitt: You mentioned some of the testing what the CDC has done on the U.S. For the most part we've been talking about the developing world, but we did have several e-mails about the situation in the U.S. Let me read a part of one of them. As someone who works in the field of AIDs here in the U.S. I have to admit some anger with the constant media publicity about AIDS in other countries, while the epidemic here is being basically ignored, both by the media and government. For example, the AIDS Drug Assistance Program (ADAP) is vastly under-funded in many areas, causing waiting lists for life-sustaining drugs. What is being done about obtaining low-cost generic drugs for this country? Generally, let's step back and first describe what ADAP is and where that stands now. Presumably nothing like the rest of the world, but—

Jennifer Kates: Right. I don't think we can compare the situation in the United States to what we're talking about, although at the same time it is very important to note that not everyone in the U.S. who needs antiretroviral treatment is getting it. The AIDS Drug Assistance Program is part of the

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Ryan White Care Act. It's a very important program, because it's the federal funding primarily that goes to states, to provide medications to people with HIV who have no insurance or have limited insurance. These are individuals in the United States who cannot get their AIDS drugs any other way. It's a very, very important program, but it has struggled with funding shortages over time, and there's a lot of variation across the country. Some states have very strong programs. They have been able to offer lots of medications, provide care to a lot of people. Other states have not. What we've seen in the last couple of years especially is increasingly states are struggling. By the latest account, there were about 1500 people on waiting lists for medications across the country in about a dozen states. Not an ideal situation. People on waiting lists are either forced to go without medications or to try to piece together their care in other ways. It's definitely a global issue.

Larry Levitt: When you talk about AIDS drugs available in the U.S., what is the cost of a typical drug regimen?

Jennifer Kates: Unlike what we've been talking about, and I think it shows some of the challenges in the U.S., but also how far we've come outside of the U.S., a typical regimen in the United States is about \$12,000 or so, give or take, depending upon the regimen, for an individual for a year. That will vary by lots of factors, i.e., what insurer's paying for

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it, and all that. But it is very expensive and for those individuals who don't have insurance through an employer, or who aren't working, it's not feasible for them to pay for their own medications.

Larry Levitt: We're winding down towards the end of our hour. I wanted to look ahead a little bit with the three of you. Mark Dybul, let me start with you. You gave some examples of what the President's initiative has already been doing, and has ramped up quite quickly. Give us a sense, look at a five-year initiative, looking two, three, four, five years down the road. How many people do you expect to be treated under the initiative? How quick can we expect to see the progress?

Mark Dybul: The President's goals are five-year goals, and those are the goals we fully intend to achieve, which is two million people on antiretroviral therapy, ten million under care. As we talked about, not everyone who's HIV-infected needs therapy. Included in that 10 million are orphans and vulnerable children. To prevent 7 million new infections; the best way to arrest this disease is to prevent it. The President has enormous emphasis on the prevention of infection within this initiative. You have to have it all together, prevention, care and treatment. We talk about two, seven and ten, and those are our five-year goals. I think we are very well on our way to achieving them. We are moving very rapidly. What we have to all work on is, we're going to have immediate success, because

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there is what we call low-hanging fruit, people out there on waiting lists that we can get to and then we're going to hit the real capacity problems. That's what we're spending very much of our time on, as David and many others are, to build the capacity, to build these health systems for HIV/AIDS which can then help with other diseases as well. That's not part of our plan; we're focusing on HIV/AIDS. We are fully confident that we will achieve the goals that the President set for us in this truly extraordinarily bold vision, treating two million people. I think we can all feel good about it, as Americans that we're going to do this.

Larry Levitt: Some have suggested that 15 billion dollars isn't enough, there should be more put in the President's initiative. Is that something you could expect to see? Could you spend more?

Mark Dybul: I think there's a difference between what should be spent on HIV/AIDS and what the United States should do. Most people have said that the United States should be giving approximately a third of the world need. The President has stepped up with 15 billion dollars. In this year, in 2004, unless something miraculous happens by the end of this year, the United States will provide twice as much, twice as much as the rest of the government/donor community put together. That's an extraordinary contribution by the U.S. government. Last year, before the President's initiative, we were giving 50%,

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half of all donor aid. This year it's twice as much. So I'd say the United States government has shown the truly bold leadership to get this going. We're hoping the rest of the world understands that this is an emergency, that everyone else needs to come in and ensure that we fight the disease as a whole, but the United States has done the bold leadership to get this going.

Larry Levitt: David Hoos, we've talked a lot about the President's initiative. You've been advising international organizations about their initiatives as well. If you could look ahead two, three, four years, the World Health Organization has their 3X5 Initiative, three million people treated by 2005. The Global Fund has its own plans as well. Give a sense of, the President's plan aside, how many people might we expect to be in treatment in a few years? Where do you see those programs going?

Dr. David Hoos: Well, I don't think I can answer the question about numbers, but I think one of the important issues that really is about the intersection of the President's initiative and all these other funding sources is the increasing amount of national ownership on issues such as national strategies to confront HIV/AIDS, both in terms of treatment and prevention. Some of the ways that our programming at times is getting a little bit held up is by countries saying, "We want to establish our national framework," or "We

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want U.S. programming to fit into our national framework." The issue of sustainability and the issue of adapting treatment guidelines and approaches to local circumstances is the process that's occurring. The President's initiative, the World Bank, the Global Fund, the WHO, many of these are a combination of technical inputs and funding, and I think one of the additional important pieces is the degree in which strategies to confront HIV are really being tailored by national governments. I think it's a really important shift over time.

Larry Levitt: Do you think there's been enough of this technical assistance component to help countries ramp up?

Dr. David Hoos: Right. No, that's been increasing, but I don't think so. How to do that carefully is not always very easy to do. We're trying to figure that out. I don't think there's been enough funding so far. All these initiatives have been under-funded and we don't have the future of how much will need to be spent committed. I think that we see the extent of the problem, we don't yet have the resources, either from the U.S. or from other donors that would enable the epidemic in a really comprehensive way to be addressed, if we're talking about one, two, three, four, five years from now.

Larry Levitt: Jen Kates, we've been focused mostly on treatment, though there was some discussion about the necessity of combining and joining the issues of prevention and treatment. There was a recent report from the Prevention

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Working Group about just this issue. Looking ahead, where do you see that issue going? Is there likely to be increased tension between prevention and treatment, both for funding resources and effort, or is there an emerging consensus that these two efforts need to be joined?

Jennifer Kates: I hope there's an emerging consensus. I think it's ebbed and flowed, and there was more tension a few years ago that seemed to dissipate. Now that there's so much focus on treatment I think there's a lot of concern that that's going to divert attention from prevention, when nobody wants to pit them against each other, nor does that make any sense from a public health, or any kind of perspective at all. There have been instances of funding for prevention being reduced as funding for treatment has scaled up. The Prevention Working Group Report looks just at that question and says, "As treatment scale-up is happening globally, not only can we not forget about prevention, but this is the opportunity, and prevention both in the treatment setting, and beyond needs to be bolstered, and brought in front and center." One of the things about funding availability and how much is there, not just for treatment, it's also clearly for prevention. All of these initiatives, Pat-Phar[misspelled?], WHO's 3X5, but just these are initiatives broadly, UNAIDS, Global Fund, all of these fit together, or should fit together. While they have distinct goals, they really are global goals, so how that gets

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achieved on both the prevention/treatment front is going to be the big challenge in the next few years. One of the big issues there is the next wave countries, countries like India, China, and Russia, where really prevention is what needs to happen right now, otherwise we'll be facing the challenge of treatment down the road, not too far away.

Larry Levitt: As thousands of people convene in Bangkok this summer, I'm sure those emerging countries and epidemics will certainly be front and center. Mark Dybul, David Hoos, Jen Kates, I'd like to thank you for joining us, and all of you, thanks for watching. This has been Ask the Experts from kaisernetwork.org.

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