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**Kaiser Conversations on Health  
With Sidney Taurel  
Kaiser Family Foundation  
May 10, 2006**

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**MATT JAMES:** Welcome to today's Kaiser Conversation on Health. I am Matt James, senior vice president for Media and Public Education at the Kaiser Family Foundation. The Kaiser Conversation on Health is an event that we started to try to bring health policy newsmakers to Washington, here in the Barbara Jordan Conference Center in the Kaiser Family Foundation building in Washington, to explain what they are working on and the issues that they are concerned with.

This is our latest in a Kaiser Conversation on Health series. It is also broadcast live on [kaisernetwork.org](http://kaisernetwork.org). Past guests have included Virginia Governor Mark Warner, CMS administrator Mark McClellan, AETNA CEO Jack Rowe, former HHS Secretary Tommy Thompson and Irish activist and sometimes musician, Bono.

Today's guest is Sidney Taurel, who is the CEO and chairman of Eli Lilly Company. Now before we get into a heavy duty policy discussion, let me tell you a little bit about Mr. Taurel. First, it is important for you to know that he has held just about every job I think you can hold at Eli Lilly at one time or another. He began there in 1971, right out of Columbia Business School, and worked his way steadily up the ladder until he became the CEO and chairman in 1999.

That is the public history that some of you may know. Let me tell you just a little bit more about Mr. Taurel that

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you may not know. First of all, he was born in one of the great cities in the world - Casablanca. He has lived virtually all over the world. As a profiling in pharmaceutical executive mentioned, they wrote, "He speaks French, English, Portuguese and Spanish. He married a native of Brazil. Taurel proposed to his wife in Heidelberg, Germany, they became officially engaged in Casablanca, they legalized their union in a civil ceremony in Columbus, Ohio, and they took part in a religious ceremony in Paris, France. Taurel noted, 'Home has always been wherever I am living at the moment.'"

Now just to stick with the international theme for just a moment, he has taken his international flavor and brought a lot of that to Indiana. He has established the International School of Indiana, which emphasizes language emersion and he has three kids who were born in three different countries. The best I could do was have one child born in a red state and one in a blue state.

Sidney Taurel is our only guest - or at least I thought this. I have to apologize. I thought he was our only guest, who is a chevalier of the French Legion of Honor, which is in effect like being knighted. But then I did a little bit of checking and I am sorry to say that Bono also has that honor. But that is not bad company to be in.

In just a moment, I am going to turn this over to Jackie Judd, our vice president, who is going to ask questions

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of Mr. Taurel and about what he has been working on. But just a reminder again for those who are watching this on kaisernetwork.org, if you have a question and you would like to have it read to Mr. Taurel, you can e-mail that question to [conversations@kff.org](mailto:conversations@kff.org). That is [conversations@kff.org](mailto:conversations@kff.org).

Let me add one more last housekeeping item, if you will. Our next Kaiser Conversation on Health is going to be on June 13<sup>th</sup> and we are going to, on that day, have Kenneth Cole come in and talk about AIDS activism and celebrity activism in this 25<sup>th</sup> Anniversary of the HIV/AIDS epidemic.

Let me also offer just one last offer, if you will, to Mr. Taurel. One of the things we noticed when we were doing our research also is Eli Lilly Company has been sort of a breeding ground for public servants and politicians, so as some of you know, Randall Tobias became our AIDS coordinator and is now looking at running USAID. Mitch Daniels of course, is now the Governor of Indiana. So if you want to use the vast resources of Kaiser Network and make any major political announcements, we offer the stage to you. And with that, I will turn it to Jackie.

**JACKIE JUDD:** [Inaudible]

**SIDNEY TAUREL:** First of all, I think the Medicare drug benefit is a great addition to the Medicare program. I think the enrollment has been going well, according to the figures that CMS has been releasing - more than 30 million, maybe 31

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million people have enrolled and there are another six million or so who have another form of coverage. That is out of a total of 42 million. Where we are affected is in terms of the sales and therefore the pricing and as has been published by CMS, the average discount that CMS has obtained from manufacturers has been 27-percent versus an estimated last year of 15-percent. So [inaudible], if you will, is working.

In terms of the effect on us, we are getting access to these plans more or less at the same level as we do in the private sector. I think that there might be some slight benefit initially in terms of volume. We have not seen that yet; it is too early. But there may be because there are some people who simply did not have access and have access now to drug coverage. But over time, I expect that the impact will be one of very tough pricing negotiation over time. And of course, there is always the risk of government price control at some point in time.

**JACKIE JUDD:** As you say, it is early. And I know the original expectations were for a sales bump of about two to three percent of what you were selling. Does that feel about right?

**SIDNEY TAUREL:** We have never quantified really what impact would be because there were some countervailing aspects here. For some products, probably lower price because of the negotiating power of the health plans. For other products, a

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bit of an increase in volume. But some products, like our biggest product, Zyprexa, is not really affected in volume too much because the great part of our market is Medicaid patients and dual eligibles and those already had coverage.

**JACKIE JUDD:** You talk about the price pressure. Some analysts say that in the next two to three years, that price pressure will become even greater, as drug plans look at what is being charged and decide to drop certain drugs from their lists. How do you anticipate something like that? What do you do to prepare?

**SIDNEY TAUREL:** Fortunately, some of our drugs - the key products - are among the six categories that CMS has designated as needing to have essentially all products available on the formulary because people react differently to those drugs. For example, antipsychotics like our Zyprexa, which is the number one product, antidepressants - this applies also to anticancer drugs, to I think HIV drugs, to I think asthma compound and one other category. So for those, both for '06 and '07, CMS has basically determined that the health plans could not just eliminate some products from their formulary.

**JACKIE JUDD:** But beyond 2007, it is an unknown.

**SIDNEY TAUREL:** It is an unknown, absolutely. And for other therapeutic areas, clearly companies have to compete the way we compete in a private sector, which is to demonstrate that you have a better cost benefit ratio than your

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competitors.

**JACKIE JUDD:** Lilly, and many other drug companies, had patient assistance programs for people unable to afford to buy the drugs. Part D put those programs pretty much in a state of flux. And I understand that Lilly now, in a limited way, wants to reinstitute a part of the program for the duration. Fill us in on that.

**SIDNEY TAUREL:** Okay, let me explain it. We have several different patient assistance programs - some that we have had for a very long time. In total, the value of those programs went from \$150 million in 2001, to \$425 million in 2005. That is five percent of the total Lilly sales. About half of that is for low-income patients, period. That is called "Lilly Cares." Then in 2002, we introduced "Lilly Answers," which was meant to be a bridge towards the Medicare drug benefit for Medicare-eligible patients - elderly and disabled.

This program was terminated for the enrollment at the end of 05, as patients were enrolling into Medicare. What we have found is that for some products, particularly the more expensive products, or those for whom continuative care is very important, such as antipsychotic - even with a drug benefit, low-income people, who did not qualify for the low-income subsidy - in other words, people about 135-percent of the federal poverty level - were still going to have difficulty

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paying for the drug.

We are doing three things right now, which we are announcing today. One is that we will continue the overall program for all products until the end of the year for people who are not enrolled in Medicare yet, and we will encourage those people to enroll in Medicare. Two, we will, for our two key products for which there is a problem of access, Forteo for osteoporosis and Zyprexa for schizophrenia and bipolar disease, offer a bridge program for people enrolled in Medicare. We want to make sure that people do not use this towards the true out-of-pocket calculation, so this would be consistent with the overall guidance that the OIG has given. And at the same time, we are asking the Inspector General for specific approval of our plan, which we would hope then would continue over time.

**JACKIE JUDD:** So the two drugs you selected, you did that because of the cost?

**SIDNEY TAUREL:** Yes.

**JACKIE JUDD:** Cost barriers.

**SIDNEY TAUREL:** And the importance of continuing the treatment for those patients because if you are on an antipsychotic and you go to another one, you can have a tremendous relapse.

**JACKIE JUDD:** If somebody is paying full freight for Forteo, several hundred dollars a month I understand?

**SIDNEY TAUREL:** Yes.

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**JACKIE JUDD:** Six hundred, six-fifty a month?

**SIDNEY TAUREL:** Yes, I do not know the exact number, but when I look at last year's Lilly Answers program, Forteo represented almost half of the total. I mentioned about \$200 million for Lilly Answers and Forteo was 90 of that. So the two products that we have selected are really the bulk of what has been the Lilly Answers program so far.

**JACKIE JUDD:** And so how many people do you think will be able to take advantage of it, if the Inspector General says okay?

**SIDNEY TAUREL:** I do not have the calculation. I know that the Lilly Answers program has covered, I believe, 210,000 patients last year, but a large majority of those are now enrolled in Medicare and a portion of those are above the 200-percent of federal poverty level, which is a criterion to be eligible for the patient assistance program.

**JACKIE JUDD:** I know the question for a lot of people in our audience here and on the web as well, because we have received e-mails already, is, why are the drugs so expensive?

**SIDNEY TAUREL:** It is a large question obviously. First, it takes 12 to 15 years to bring a drug from the wild and twinkle in a researcher's eye all the way to the patient. This is a risky and expensive and lengthy proposition. I am sure you have seen some of the studies which have been done over time, showing that on average a drug costs about \$800+

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million. Those are the published studies. I think if you look at the reality inside the mAbs, the figure is actually higher than that.

That cost covers obviously the risk. In other words, it covers all of the failures, as well as a time value of money, because it takes 12 to 15 years. So that is a big reason. And so today's prices and profits of pharmaceutical companies help pay for the research that we are doing to cover unmet medical needs.

This being said, I think the current model as it exists, is probably not sustainable. So we are all about doing two things. One is we use our cost base and try everything we can throughout the value chain to reduce the cost of bringing drugs to market in the current, what I would call, one size fits all model.

And secondly, we are, at the same time, exploring a new model of more tailored therapies. Let me explain that a little bit. Today, the value proposition that we have for patients, for payers and for providers, is not an optimal value proposition because we test products for a given disease and then we go to a provider and say, "Try it on your patients with that disease." In the best case, it is going to work on eight patients out of ten. The worst cases, it may work on one out of ten or two out of ten. And it may hurt one out of 100 or one out of 1,000.

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Today, we are not really able to precisely tell providers, "Use it on this patient, not on that patient. It may hurt this one." But science is moving progressively in that direction with technologies like biomarkers, pharmacogenomics, bioimaging and so on. We are progressively moving towards this future of more personalized medicine.

That is the sort of challenge for the pharmaceutical industry and what we are really all about in our strategy is to make the current model more cost-effective and at the same time, make the investments in technologies necessary to move into this earmark.

**JACKIE JUDD:** How does that model affect the cost? Does it affect the actual R&D cost? Does the \$800+ million figure go down in that scenario?

**SIDNEY TAUREL:** Time will tell. Initially, probably not. But over time, we hope that it will because biomarkers and pharmacogenomics will help us target better the patients who will participate in clinical trials. So instead of having a shotgun approach, as we do today, have a large population of patients with a given disease who will test it on a much less smaller population.

We might also have more products that way because today, we kill very early, some molecules when we find that there is a problem. But if we, through pharmacogenomics, can identify a subset of the population for whom that problem does

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not exist, then the product will be allowed to continue and develop. At the other end, on the sales side, you might argue that this will be smaller molecules in terms of sales. So how the economic model will work out, nobody can tell you today. But this is the direction to which we are working.

**JACKIE JUDD:** Then it is a very, very long range plan.

**SIDNEY TAUREL:** Yes.

**JACKIE JUDD:** I think the people who, today, ask the question, "Why are they so expensive?" want some more immediate help. And for some, the second part of that question is usually this, "Why shouldn't the government begin to set prices, to negotiate prices?" particularly now, since it has become a much larger purchaser than ever before.

**SIDNEY TAUREL:** As Matt said, I have lived in several countries around the world and many of them have price controls and government price controls. And what we have seen has been that over time, this kills the incentives for innovation. When you look at the amount of R&D which was done in Europe 30 years ago versus today, Europe went from something like 60-percent of the R&D for pharmaceuticals and new products, to something like 25-percent today. So 30 years of price controls have really caused a lot of the R&D of the new products to move to the United States, which has a freer market.

On the other hand, they do not necessarily save a lot on their drug bill because the price controls apply also to

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products once they are off patent. In this country - and we were discussing this just before we came in - once a patent expires, the inflow of generic competitors brings the prices down extremely quickly. In countries with price controls, not so - they may have a price approved by the government at 20 or 30-percent below the original price. The prices of generic products and off patent products are much higher outside of the U.S. than they are in the U.S. The system that we have really forces us to stay on our feet and ensure that once a patent expires for a product, we have something else to replace it and hopefully more innovation.

**JACKIE JUDD:** I suspect the audience will have some follow-up questions on that point, so I will not pursue it here. I do want to ask this question - The pricing issue has made so many people in America so cynical about your industry. You have been in this business since 1971, as Matt said. Do you ever stand back and ask yourself, how did the pharmaceutical industry, that improves lives, saves lives, sometimes be talked about in the same sentence as the tobacco industry? How did we land there?

**SIDNEY TAUREL:** I ask myself that question very, very often. I think one fundamental issue is, I would say, the difference between the psychology of want and the psychology of need. If you want something, you are prepared to pay the price for it and not argue. If you want a car and you want a

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convertible and you want it red, you will pay the price it takes to get that car. But the gasoline which goes into that car, is something that you need, but not necessarily want. And so when the price goes up, you get mad because it is imposed on you.

Health care belongs in the category of things that you need and do not particularly want. And so that makes you suspicious of whoever makes a living out of health care and mad at companies which seem to have a high level of profitability. The solution to that, over time, is really to ensure better access for better insurance. And frankly, the image of the pharmaceutical industry in Europe, where there is better access, is better than the image we have in this country. This is not the whole problem. I think there are some issues of perceived business practices that needed to be addressed and I think have been addressed. In every other industry, if you take your customer to lunch, is that an acceptable practice? It is no longer an acceptable practice in our industry, and so we have changed as an industry our ways of working.

**JACKIE JUDD:** And the new guidelines direct to consumer advertising.

**SIDNEY TAUREL:** Same thing. I think the direct to consumer advertising is something that meets an overall societal trend of people wanting to understand better about their own health care and take their destiny in their own

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hands, if you will. There are many diseases for which people do not seek treatment, so if you can educate, through direct to consumer, people about the fact that this can be treated, you would get the better outcome for everyone. There is also issues of compliance with treatment, especially on diseases for which you do not have symptoms, people generally do not comply with the treatment. But direct to consumer communication, not just mass advertising, but other means, help remind people of the need to take their medicine.

I think in spite of these potential benefits of direct to consumer, it has been criticized because it sort of has trivialized a little bit the perception of the industry. We do not sell detergents, we sell products which save lives or prolong the lives or improve the quality of lives.

**JACKIE JUDD:** Does it frustrate you that you even need to say something like that?

**SIDNEY TAUREL:** Yes. Of course it does. Of course it does. So to address this second area of business practices, I think we have, in the last few years, the industry has come together to adopt codes of practice. There has been some, both for good promotion practices vis-à-vis physicians, direct to consumer advertising, there was criticism also of the research that we do and conflicts of interest for investigators, whether they are results of studies that were published or not. And we have brought a lot of transparency to this - and Lilly was a

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leader in this area - by creating a registry where, at the beginning of any clinical trials, it is registered in this website which is publicly available that people can check once the study results have been published that indeed all the studies which were started are being published, whether the result is positive or not. So again, those are the two key areas I think - access and business practices. I think we are addressing both.

**JACKIE JUDD:** Before we turn it over to the audience, I want to talk to you about your vision for health care reform. I have heard you talk about it before and you break it down into three interesting parts: The metabolic disorder, the autoimmune disorder and the cognitive disorder. Explain.

**SIDNEY TAUREL:** Okay. Metabolic disorder - I think what we are seeing in the health care system is a dysfunctioning [misspelled?] market. For a market to function, you need to have any kind of mixed signal between buyer and seller, where price is arrived at through a negotiation and quality is known and transparent. We do not have that in the health care system because people do not realize the cost of what they buy. Most people get their insurance through their employer. They do not see the bills. These are after-tax dollars so they do not have a feel for what it costs and that is particularly true, by the way, for pharmaceuticals but that is beside the point. That is the metabolic disorder. It is

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over-consumption because we do not realize the cost of what we consume.

The second one is the autoimmune, and that is the effect of all the government regulations, which surely intended to protect consumers, very often have perverse consequence. For example, all the state regulations of insurance, which makes the provision of insurance a very complex and more costly proposition than it needs to be because you have to abide by 50 different state regulations. Of course our tort system is part of this as well, and calculations have been made to the extra cost of tort is probably in the range of \$90 billion a year.

**JACKIE JUDD:** And there are people, I should say, who would disagree with that. And then the final part is the cognitive.

**SIDNEY TAUREL:** This is basically a factor of all the information which is available out there and that we do not allow ourselves to take advantage of. We have all the tools in information technology that we need to make the system much more effective to improve quality. And yet, it is not deployed in health care in the same way as it is deployed in other services, such as financial services. We have our own, as consumers, version of a cognitive disorder by knowing what hurts us and still engaging in behaviors that do, like smoking and so on and so forth.

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Physicians have their own version of that by not keeping up-to-date with best treatments. We should have information on the best practices that are being used everywhere and that is not happening. So those are three symptoms, if you will, of a disease and the disease is high cost and escalating costs, problem of quality and problem of access.

**JACKIE JUDD:** That is the diagnosis. What is the prescription?

**SIDNEY TAUREL:** There are many ideas obviously.

**JACKIE JUDD:** If you could pick one, what do you think would have the most significant impact on the way the health care system currently works?

**SIDNEY TAUREL:** I am going to cheat and take two.  
Okay?

**JACKIE JUDD:** Okay, it is a deal.

**SIDNEY TAUREL:** All right. I think the first one is one where there is a very strong bipartisan support, and that is to better use information technology, to have systems which are more interoperable, to have common standards and to eventually have, on a chip, patient records that patients can carry with them so that you can avoid all of the duplication of tests and so forth. That would have a tremendous impact and some calculations have been made as to how much could be saved through that.

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The other one is to address the needs of the uninsured. Besides the problem of equity, which is a serious problem, you have also an economic problem because people who do not have access to health care insurance, end up in the emergency room and do not have access to preventive care, which is much more cost effective, so we see tremendous costs shifting. Because when they end up in the emergency room, they are treated and the cost ends up on somebody else's bill.

There are about 45 to 48 million uninsured in this country and they are divided in about three more or less equal groups. One is a group of people who are eligible for some kind of government program and have not enrolled. So an outreach program to make sure that those people enroll, I think, needs to be engaged in. And I think the experience that CMS, the health plans have had with Medicare enrollment, with a lot of grassroots efforts, a lot of learning has occurred that can help address the needs of those people.

Then you have a group of people who simply are not eligible, but simply can not afford it. And I think those people need some help of some kind.

**JACKIE JUDD:** In what form?

**SIDNEY TAUREL:** One of the options is health savings accounts, but with a refundable tax credit for the low-income people that would basically, if you will, a sort of voucher system that would be offered by the government. A lot of

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studies show that this can be paid for by the savings that you have by getting the uninsured actually covered.

And then you have another group of people who can afford health insurance but do not think they need it. Very often, young people, young professionals who do not feel it is worth spending money in health care. And there, I think we have got to experiment with some thoughts of using sticks or carrots to get people to buy some health insurance. So if you increase the pool of people who are insured, which reduces the cost for everyone.

There is a very interesting experiment going on as you know in Massachusetts, which I think we need to monitor very, very carefully, which uses that sort of stick and carrot approach. I think it is a very interesting experiment. Now, not to say that it can be used throughout the country because I think the conditions in Massachusetts are specific, but I think it is a very positive study.

**JACKIE JUDD:** Getting back to the use of health savings accounts - and right after this question, I am going to ask you to start taking questions from the audience - one of the central criticisms of health savings accounts are that the people who can least afford the high deductibles would be given these or expected to have them in some way. How do you answer that?

**SIDNEY TAUREL:** I am not sure, why...

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**JACKIE JUDD:** That the people in the low-income category can not afford the high deductibles that often come with health savings accounts.

**SIDNEY TAUREL:** I think the people in the lowest income categories need help. I would think that a means tested subsidy would make sense.

**JACKIE JUDD:** Okay, let's get you to the audience. I always say this and the joke is probably old to some of you who have returned, but it is our inside the after studio moment. Who would like to get the first question? Yes? This lady up here and if you could stand, identify yourself and your affiliation, I would appreciate it.

**JILL WEXLER:** I am Jill Wexler [misspelled?], I am the Washington editor of *Pharmaceutical Executive Magazine*. You mentioned earlier the need to develop new ways of developing drugs and getting drug approvals, and certainly the Food and Drug Administration plays a central role in that. The Agency has been without strong leadership for quite some time and the prospects are not very good. But I have not seen leadership in the pharmaceutical industry saying very much about this or being very visible in perhaps putting pressure on policymakers to do something about this situation. Are there more things that industry could do or should do and is this a big concern for you?

**JACKIE JUDD:** I would add a second part to that

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question. Has the lack of permanent commission affected your business?

**SIDNEY TAUREL:** Right. I think things are changing and are improving. One of the key priorities for the FDA is the so-called critical part initiative, which is geared at exactly developing the biomarkers and other technologies that we need for the development of personalized medicines and defining a regulatory path for drugs developed that way.

We are also in the process, since the NIH is also very involved with this so-called roadmap initiative, with the same goal. We are talking about forming a consortium actually between NIH, pharma and FDA to collaborate on the development of biomarkers in a sort of pre-competitive area.

Yes, the lack of a commissioner has hurt the industry. In many ways, I think the FDA is in a tough position. They never get credit for the things they do right and they get blamed when something goes wrong. With all the debates around the withdrawal of Cox-2 inhibitors or Vioxx, and other, like suicidality [misspelled?] with antidepressant and other issues surrounding side effects, we have seen the Agency become a little bit more susceptible to pressures. The number of black box warnings has tripled between 2003 and 2005. What I find needs to be changed is the basic belief in the general public that there is such a thing as risk-free drugs. A risk-free drug is a placebo. Drugs should be evaluated on the basis of

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benefit versus risk. And we need to find a better way, more transparent, more objective, and more standard, to assess all drugs along those lines. I believe that is one of the important things that the FDA would be doing with a new leadership.

**JACKIE JUDD:** What were you alluding to when you said that they were susceptible to pressures?

**SIDNEY TAUREL:** The press and people in Congress jump on issues of a side effect for a given drug and, again, forget the benefit aspect. That has I think caused the FDA to be more cautious, to have those black box warnings, perhaps be a little bit more cautious in approving drugs if you look at the number of applications which do not result in an approval in the first cycle, those have increased. The FDA's role is, yes, to protect public health, but part of protecting public health is to insure that innovative drugs that can help people in need, get to the market on a timely basis. There is progress to be made in that area. I am very confident that the new commissioner is committed to the balance in this approach.

**JACKIE JUDD:** We have an e-mail question. Please comment on the emerging research on, what this writer says, disease mongering and what short and long-term consequences this may have for your industry. And I presume by 'disease mongering', he means the creation of disease, or the creation of need where there may actually not be much.

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**SIDNEY TAUREL:** That is a very controversial area.

**JACKIE JUDD:** Yes it is.

**SIDNEY TAUREL:** And we had our own experience. We launched a product called Sarafem, which was for PMDD, Premenstrual Dysphoric Disorder, which is an extreme form, if you will, of PMS. Women who suffer from that were helped by this product and doctors would treat and gynecologists felt that there was a need for that product. This is a true disease. But since there had been no product for it before, and often women were not seeking treatment, there has been a cover in the press that this was a disease which was invented.

Take the issue of Attention Deficit Hyperactivity Disorder in children - again, there are different views in Europe and in the U.S. about is this a disease at all? How many kids are affected by that? And so what we need is better education, better standards. Again, what I was talking about earlier, we do not have sufficiently well defined standards of care for diagnosis and care for disease.

**JACKIE JUDD:** But does that leave an opening for what the writer calls 'disease mongering'?

**SIDNEY TAUREL:** There are some diseases which are under-diagnosed and are treated. Frankly, before Prozac and the other SSRI products and other antidepressants were launched, the estimate was that only 30-percent or so of people in this country who had depression were actually diagnosed and

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treated. So it has helped, if you will, this disease to sort of come out of the closet and be accepted and people to be treated. A lot of suicides and ruined lives have been avoided thanks to these products. We should avoid under-diagnosis and early treatment, as we should avoid over-diagnosis and over treatment and I am sure there are some cases where the person who asks the question is right and there may have been some extra news products.

**JACKIE JUDD:** Yes?

**JOHN ROKOV:** John Rokov [misspelled?] from the Baltimore Sun. I have a question going back to the critical path. There are a lot of different views on what sort of regulatory reforms are needed. For example, some folks go so far as to argue for dropping the efficacy requirement. I was wondering what you think would spur drug development and speed up approvals and improve patient access?

**SIDNEY TAUREL:** Again, if you talk about critical path and therefore this refers typically to products which are more tailored. For those, almost by definition, as I was discussing earlier when discussing the potential cost of this research, we will be able to show efficacy in a smaller number of patients than we do today because we are going to be able to target the population in the clinical trials of people who are the most likely to respond positively to the drug. That is how I see the future.

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Now, in the current model - what I call the one-size-fits-all - I think there is also room for reducing what has been an incredible inflation over the last two decades of number of cases to approve a new drug. Part of it is FDA regulations, part of it is over cautious [inaudible] on the part of the industry to make sure that the drug is really approved. But this has added to the cost and we need to address that.

**JACKIE JUDD:** The lady back here.

**HALESH DEVY:** Halesh Devy [misspelled?] CNBC. You touched on this in the beginning, but if you could sum up for me how Medicare Part D is going to hurt and help your business.

**SIDNEY TAUREL:** I will repeat what I said. I think first, it is helping patients. Some people who did not have access to drugs and drug coverage will today and this in turn will result in some increase in the overall volume for the pharmaceutical industry. On the other hand, there will be more negotiation of prices and some people who were buying on the free market will buy through the Medicare program and taking advantage of the negotiations that the health plans who administer the program have engaged in. What I see is, over time, pressure on the prices of the industry.

**JACKIE JUDD:** Yes, over here.

**JAN HEINRICH:** Hello. My name is Jan Heinrich [misspelled?]. I am with Health Policy R&D. I would like to

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ask you about post-marketing surveillance. There have been lots of questions, as you say, as a result of the Vioxx being withdrawn. But what would you recommend be the policy so that we can more accurately monitor the response to drugs once it is more broadly distributed to the population?

**SIDNEY TAUREL:** I think regulatory agencies, including the FDA and the industry I think, do a pretty thorough job of assessing risk versus benefits of products prior to the launch and prior to the approval. But once a product is on the market, the only thing which is being monitored is the adverse events. The continuing assessment of efficacy does not occur. And as I mentioned earlier, I think you cannot divorce one from the other; it is always a question of balance. And that balance defers from product to product and very importantly from disease to disease.

Going forward, I think we need to be able to tap the incredible amount of data that is available in day-to-day usage. CMS will have a treasure trove of data on how drugs are actually working, both efficacy and side effect wise once in the market. Health plans, like Kaiser Permanente or United Healthcare, et cetera, have also a lot of data that hopefully will find a way one day to mine so that we can continue to assess the efficacy which is safety profile of drugs. There is so much we can do before we launch a drug. We find a lot of things after it is on the market, both positive and negative.

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**JACKIE JUDD:** In the back there.

**DEIDRE HENDERSON:** This is a follow on question.

Deidre Henderson [misspelled?] with the Boston Globe. You may not have heard, but last night there was an amendment that was added to a House Appropriation bill that the FDA will give them mandatory rights to demand that drug makers do postmarketing studies and if those postmarketing studies are not completed, the agency can begin proceeding to take a drug off the market. This was driven by a GAO report that found that two-thirds of the postmarketing studies that drug companies say that they are going to do, do not get completed. I was curious - I know it is sort of off-the-cuff - if you have any sense of what implications that legislation may have?

**SIDNEY TAUREL:** Again, not having seen the particular proposal, it is hard to comment on the details. But on the principles, I believe that companies should abide by their commitments to do postmarketing trials when agreed upon with the FDA. We have been very, very assiduous in doing this, if you look at the record of Eli Lilly.

Now, as to the stick, if you will, to be used, I would think that taking a product off the market would hurt patients in many cases and that does not seem to me to be the right approach to take. But somehow to have some strong incentive for companies to abide by their commitments makes sense to me.

**JACKIE JUDD:** You are actually going up to Capitol Hill

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tomorrow to meet with the leaders of the Senate Finance Committee, some of them anyway - you and other of your counterparts to talk about the patient assistance programs. What message do you intend to bring to them and what do you think they are going to ask of you?

**SIDNEY TAUREL:** In terms of what they are going to ask is pure speculation, but I think they have expressed some concern that with the adoption of the Medicare drug benefit, some of the patient assistance programs, that companies were offering, are being discontinued and that leaves some patients - low-income patients, but again, above 135-percent of federal poverty level - with difficulty paying for some drugs that they were receiving for free before.

The reason why we could not help, as an industry, those patients, was an OIG opinion back in November of last year, saying that you could not be at the same time enrolled in a Medicare program and receive patient assistance. This has been clarified now in April by the OIG giving approval to one company's proposal to have this program outside of Part D. In other words, they would continue to get access to the product, but could not claim either the fee that they pay for this access or the cost of the drug itself as part of their expenditures in Medicare, which would count towards the donut hole and so forth.

I believe that the discussion will be around what can

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be done to continue to have programs which help patients of low income. And obviously this will have to take place within the constraints of anti-trust because we can not discuss, between pharmaceutical companies, even with senators present, specific company programs.

**JACKIE JUDD:** I know you are only announcing today the letter that went over to the OIG to ask if the two drugs can be sold. But is there any possibility that that list, at some point, will get longer?

**SIDNEY TAUREL:** Oh yes...

**JACKIE JUDD:** Just let me finish - there is an e-mail from a lady in Detroit who works in a free clinic and she says, "...for example, why has Lilly cut off all four Medicare patients from obtaining free insulin through their prescription assistance program?"

**SIDNEY TAUREL:** First of all, we continue to have our Lilly Cares program covering insulin for low-income people. Secondly, for the Medicare enrolled people, insulin is a low-cost product and the co-pay that they would have under Medicare is actually lower than the \$25.00 that we charge a month for access.

**JACKIE JUDD:** She said these were people who could not even afford to go into Part D.

**SIDNEY TAUREL:** Oh, who could not afford to go to Part D? Then she is wrong because we are continuing, until the end

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of this year, our Lilly Answers program for people who have not enrolled in Part D.

**JACKIE JUDD:** Are there questions on the side that I have not gotten to? Yes?

**SHALAZAY NASHWAY:** My name is Shalazay Nashway [misspelled?]. I am from the International Trade Administration. I want to [inaudible] to the international side and wonder if you could speak about the image of pharmaceutical companies internationally and this philosophy of need versus want. One of the things we hear a lot when we talk to foreign governments, especially in developing countries, is going to the need aspect, they sometimes ask why can't the pharmaceutical companies provide more access by subsidizing those countries and taking the weight off of the governments. I wondered if you could address that issue and also talk a little bit more about Lilly's MDR-TB program.

**SIDNEY TAUREL:** Okay. First of all, I think there are some major differences in price levels between developing and developed countries and that exposes the industry frankly to criticism inside this country to say, how can you subsidize these other countries, because we do. A price of many of our products in Brazil might be a third of what it is in the U.S.

How can we afford to do that? We have already spent the money on the R&D. It is a sunk cost. So at that point going forward, we look at this on a marginal basis and the cost

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at that point is only the cost of manufacturing the drug. We can make those drugs available at the lower cost. But obviously, if we were to do that everywhere, we could not continue to fuel our research.

In terms of the MDR-TB, this is a Multi-drug Resistant Tuberculosis program that Eli Lilly engaged in about three years ago. We found that, first, this was a very serious health care need in a number of developing countries. And that we had two older products that were very useful in the treatment of MDR-TB and that use was actually discovered by Dr. Farmer.

We first looked for generic companies which would want to manufacture that drug and could not find any there. Those two drugs are particularly difficult to manufacture. What we eventually did, was actually make investments in companies in China, South Africa, India and Russia in their capacity, with the help of Purdue University, we have transferred the technology to them and trained their technicians. We have also, with the help of Harvard Medical School, made sure that the drugs were being used appropriately and monitoring the development of resistance and so forth. The whole program is being coordinated under the egos of the WHO, which has a goal of so many thousands of patients treated by 2010 for MDR-TB, and also it made sense [inaudible] who has been involved in that. It is a different approach, very integrated and it sort

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of follows the philosophy that if you want to feed a man a meal, you give him a fish. If you want to feed him for a lifetime, you teach him how to fish.

This program is something which has cost Eli Lilly maybe \$70 million or so over a three-year period, but the value that it is creating by being self-perpetuating is several times that value.

**JACKIE JUDD:** Back here.

**LIZ CAMMANTI:** Hi, good afternoon. My name is Liz Cammanti [misspelled?] and I am with the Center for Economic and Policy Research. I had a question about one of the things you said in your talk regarding price controls in Europe and the fact that because of the price controls, the companies are doing less research in Europe. It occurs to me that it may not be a direct effect of the price control, so there is less money to do the research, but the companies actually are rewarding the U.S. by not having price controls and so they left. It is less of a cause and effect of Europe having the price controls, but wanting to reward the U.S. So I was wondering what your opinion is of that statement.

And then secondly, in terms of savings for R&D, it seems like a lot of savings could come out of the investments you are making in China and India and other developing countries that have highly skilled populations. I am wondering if you foresee a lot more of the cutting edge R&D going abroad

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in the future. Thank you.

**SIDNEY TAUREL:** To answer the first part of your question, I would quote a study done by the U.S. Department of Commerce at the end of 2004, which showed that the effect of price differences between the U.S. and other countries and which concluded that if Europe had the same level of prices as the U.S., we would have another \$5 billion, I believe was the number, invested in R&D and that would result in 06 and 07, new innovative products, which would benefit citizens of all the countries.

And another point I would make is that the system that we have here of free pricing not only rewards innovative drugs, but also once the patent expires, the economic viability of the drug goes away immediately because of free competition, because of the entry of generics. So this keeps companies like mine on their toes to continuously innovate so that we can come up with the new innovation when we lose patents. And when we lost our Prozac patent, we had redoubled our efforts in R&D and had nine products that we launched over the following three years.

The second part of your question - yes, as I mentioned earlier in the one-size-fits-all model, we are trying to improve our cost structure and the productivity of our R&D by looking at every aspect of the value chain. Part of it includes doing more R&D in countries like in China where there is a lot of talent. We are to be careful about potential

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intellectual property issues. So what we have done so far is to sort of separate our R&D activities between what we would call judgment-based activities and rules-based activities. For example, today in China, 20-percent of all our chemists in the world are now in China and they work more on the latter, on the rules-based activities.

But we are exploring those models and in India, we have been very encouraged by the fact that after the adoption of patents last year, finally, we are seeing a lot of the generic companies trying to change their business model to a maybe low-cost research-based model and there are some things that perhaps we can learn and co-op several of those through partnerships. We have already announced a couple of those.

**JACKIE JUDD:** I just have a quick follow-up to the first half of her question. And that is, there are people who say that given the profits that the pharmaceutical industry make, innovation is not as strong as it should be, that what the focus has been on in the past several years has been the 'me too' drugs.

**SIDNEY TAUREL:** I wanted to give you the list of the products - the nine products that I mentioned - that Eli Lilly has launched. One was Xigris, the first product ever for the treatment of severe Sepsis. One was Strattera, the first non-stimulant product for ADHD. One was Alimta, which was the very first product for treatment of mesothelioma. Another one was

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Cymbalta, which was the first product approved for treatment of diabetic neuropathic pain.

**JACKIE JUDD:** I will trust you on the others.

**SIDNEY TAUREL:** Okay. [Laughter] Forteo was the first product which...

**JACKIE JUDD:** Would you say that is true though of the larger industry? If you look outside of what Lilly has done, is it a fair criticism?

**SIDNEY TAUREL:** I do not really think so. I think there are a few examples, which have been very well publicized, that may have created that impression. And also I think innovation goes in cycle. If you look at the overall level of new products which have been approved by the FDA over the last five years, it was 40-percent less than the previous five years. So the cycle has been down. But, if you look at a recent study by Tuft University, they are looking now at products which are in the development pipeline and there, we have seen over the last three years, a significant uptake. I think there is hope that there is more new innovation.

One of the reasons perhaps why the productivity went down for the industry as a whole, is that I think companies are actually looking more and more for breakthrough drugs because with the current cut-throat competition that exists in the private sector and also the difficulty of getting reimbursement in the public sector. Unless you have a drug which is

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significantly better than existing drugs, or bring it to the market at the much, much lower cost, you are not going to have a success. And that is why companies are trying to really bring drugs which are better than whatever exists.

**JACKIE JUDD:** We have time for one more really quick question from the audience. Back her?

**LOREEN GROPPY:** Laureen Groppy [misspelled?] with Gannett News Service. Back on Medicare Part D - is the pressure that Chairman Grassley and other senators put on drug companies, is that a factor in Lilly's decision to extend Lilly Answers and is it possible that you will extend Lilly Answers even further beyond the end of this year?

**SIDNEY TAUREL:** I would say, no. We have been, since August of 2005, desirous to have an extension of our Lilly Answers program. We submitted to the OIG, at that time, we were the first company to submit a request for an opinion on a program which was around Part D. We have not heard back from the OIG. Since that other company got the positive approval for their program, we got some better guidelines as to what is likely to be approved and what is not and that prompted us to immediately come up with this program. And this is separate from any political pressure.

**JACKIE JUDD:** Okay, we started with Part D and we ended with Part D. That was the final word. Thank you so much for your time and your thoughts. [Applause] For our audience here

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and on the web, just another reminder that June 13<sup>th</sup>, we will be having Kenneth Cole here to talk about AIDS and the 25<sup>th</sup> anniversary. Thank you all.

[END RECORDING]