Domo arragato, Chairman Nishizono. Good morning, ladies and gentlemen and thank you, Prof. Singh, for the opportunity to join you here today in Melbourne. It’s an honor to be among so many distinguished professionals who play such a critical role in mental health care.

My last visit here was 10 years ago. At that time, I was the global product manager for Prozac and my role was to launch that new product in the major markets outside the United States.

I dare say that ten years ago, no one would have thought of inviting a representative of the research-intensive pharmaceutical industry to address a gathering such as this. We may not have been seen as a full partner in the field of mental health. We simply hadn’t yet earned a seat at the table.

So I appreciate the opportunity to join you at this table to discuss the economics of mental health care and the role the pharmaceutical industry plays in helping address one of the world’s most critical health care challenges. Such an opportunity is especially precious for someone in my industry.

Certainly we believe that drugs are one important and cost-effective part of the comprehensive solutions necessary to address complex mental health issues. Over the past several years, innovations in pharmacological treatments for mental illnesses have coincided with the extraordinary productivity of scientific research on the brain and behavior … a dramatic transformation of many of societies’ approaches to mental health care … and the emergence of powerful consumer and family movements.

Overlay that with a growing recognition of the role of mental illness in the global burden of disease, and it is understandable that the world is waking up to the realization that we can no longer afford to ignore the needs of millions of people who suffer, at least some time in their lives, with these illnesses.

And that is where I’d like to begin.
Estimation of the global burden of disease with disability adjusted life years (DALYs) shows that mental and neurological conditions are among the most important contributors; for instance, in 1999 they accounted for 11% of DALYs lost due to all disease and injury.

Among all the mental and neurological diseases, depression accounts for the largest proportion of the burden. Four other mental disorders figure in the top 10 causes of disability in the world: alcohol abuse, bipolar disorder, schizophrenia and obsessive compulsive disorder. The number of people with mental and neurological disorders will grow with the burden rising to 15% of DALYs lost by the year 2020.

In the face of such a crushing burden, the WHO World Health Assembly reported this year that, “the fact that countries have other health problems and that their health budgets are limited can no longer be deterrents to action. New developments persuasively indicate that cost-effective solutions are possible in all contexts.”

How are societies grappling with these growing needs and the costs that accompany them?

Here’s where the pharmaceutical industry has a critical role to play. Our fundamental role is to provide innovation – providing you with new tools to help your patients.

At Lilly, we’re looking for breakthrough drugs.

Not every drug maker elects this role. Generic manufacturers, for instance, invest almost nothing in innovation. Their pipeline is the research-intensive industry. Their role is to harvest the innovations of others when they lose patent protection and, thus, make them available at the lowest possible cost.

But for companies like Lilly that choose to build the capability for innovation, I believe we have a profound responsibility to use it to the fullest.

Yet health care payers around the world are increasingly antagonistic to scientific innovation in most aspects of medicine. They see it as a major driver of costs. And so, in various ways, they are trying to slow down the introduction of new technology.

Japan is an interesting case in point. We are still negotiating the approval of Prozac, which we hope to be able to launch in 2004 – some 16 years after we launched in Europe and the U.S. This, at a time, when Newsweek just reported in an article entitled “Japan’s Corporate Warriors are Killing Themselves in Record Numbers,” that most doctors there can’t or won’t treat mental illness, and denial prevents most patients from seeking help.

We reject that view of innovation.
Just looking into our own late-stage neuroscience pipeline, we should see regulatory submission next year for atomoxetine for attention-deficit hyperactivity disorder and duloxetine, a new antidepressant with a novel mechanism. In 2003 we plan to submit a combination of olanzapine and fluoxetine which is showing remarkable efficacy in treatment-resistant depression.

Besides their extraordinary contribution to human health, innovative pharmaceuticals actually help contain costs in the areas of health care that actually account for the biggest wedges of the health expenditures pie - doctor visits and hospital charges.

Zyprexa, Lilly’s new-generation antipsychotic, is a perfect example. While I know that the range and cost of offsetting treatments differ widely by country and are context-specific, typically in the U.S., the cost of caring for a patient with schizophrenia exceeds $100,000 a year, mainly for hospitalization. At a cost of about $10,000 a year, treatment with Zyprexa allows most patients to stay out of hospital and live more normal lives. That’s why every one of our 50 state Medicaid programs allows its use as a first-line treatment for patients with schizophrenia.

And new research documents a positive return in the health care system for innovative pharmaceuticals in general. As reported in the current issue of Health Affairs, Dr. Frank Lichtenberg, a health economist at Columbia University, has calculated that the reduction in medical expenditures from using a new drug is nearly four times greater than the added cost of that drug.

Ultimately, biomedical innovation represents the only real hope of bringing down not just the cost of care but also the vastly greater cost of disease.

You’ve seen the numbers from the Global Burden of Disease related to depression as measured in DALYs and the increases forecast over the next decades. But just think about the economic loss to society brought about by a disease like depression – which the Wall Street Journal recently estimated at $70 billion in the U.S. alone. The toll includes loss of productivity, absenteeism, poor job performance, and too often, the absolute loss of a human life. Studies have proved that employers who have programs to detect and treat depression among their employees actually get a positive return on their investment.

Armed with this knowledge, in my capacity as president of the Lilly Foundation, I worked with the International Labor Organization on a program for the recognition and referral to treatment of depression in the workplace, a program which has now been launched globally and I see picking up tremendous momentum.

Our firm conviction of the value of innovative pharmaceuticals only underscores our responsibility to innovate.

But the most important reason that the research-based pharmaceutical companies have to accept and act on this responsibility is that we are the only institutions
specifically organized to initiate, finance, assemble, and drive forward all parts of this intricate and arduous process of pharmaceutical innovation. It is not an accident that 92 percent of the drugs introduced in the U.S. from 1981 through 1990 were discovered and developed by the research pharmaceutical industry.

At the same time, true breakthroughs are rare – we test some 10,000 molecules to create a single marketed product – and the costs are high – approaching $1 billion per marketed product.

Given that reality, political decisions on pharmaceutical pricing and importation have real consequences for health care progress in general – and mental health care in particular. The wrong choices could stop the scientific revolution just as it is on the threshold of producing even more effective treatments.

If innovation is our first responsibility … it is by no means our only responsibility.

We at Lilly see ourselves in the role of a partner eager to cooperate across what we call the Mental Health Care Transaction model, which embraces a full spectrum from prevalence… to awareness… to help-seeking… to diagnosis… to evidence-based interventions… to compliance… and also to the policies that touch on these.

To better understand the prevalence of mental illnesses, Lilly supported some of the research for Chris Murray and Alan Lopez’ The Global Burden of Disease. Indeed, Lilly produced the executive summary and helped disseminate it to literally tens of thousands of health care decision makers, academics and policy makers around the world.

To foster awareness of depression, we have media trained thousands of psychiatrists to help them engage the media in a positive informational campaign and to train primary care physicians to diagnose and treat depression.

I don’t know how many millions of Zung scales and other diagnostic tools we distributed in local languages to physicians for use in their practices.

More than other areas of health and medicine, the mental health field is plagued by disparities in the availability of and access to its services. This was made abundantly clear to me a few weeks ago.

I was attending the annual fund-raising dinner for the local chapter of the “National Alliance for the Mentally Ill” a very effective family support and advocacy group in the U.S. I learned of one of their members, the father of two boys, one of whom suffered from schizophrenia while the other incredibly suffered from a brain tumor.

You can all certainly guess what I am going to tell you next! The son with the brain tumor had unlimited access to a huge range of diagnostic and treatment
interventions. His attempts to access quality care for his son with schizophrenia though were blocked at virtually every turn.

This reflects the persistent stigma that accompanies virtually everything about mental illness. The World Health Organization prescribes actions for overcoming stigma and human rights violations, for improving mental health policies and services, and for meeting the needs of special groups.

At Lilly we have empowered and in some cases organized patient and family organizations to fight stigma, raise awareness, and gain access to effective treatments. These are groups like GAMION, and the World Schizophrenia Fellowship whose members are now active in most countries of the world.

From the years I headed the Lilly Foundation, I was able to see first-hand the success of the WHO “Nations for Mental Health” program.

I worked with Jorge Alberto Costa e Silva, whom I first met in Athens on the eve of his election as president of the WPA. After he moved to the WHO as Director of the Division of Mental Health and Substance Abuse, we worked together on a major grant proposal to the Lilly Foundation that would support their efforts to launch a global initiative working at the country level to improve the mental health of underserved populations. This campaign has reached its summit through the brilliant efforts and enthusiasm of Dr. Benedetto Saraceno, current Director of the Division of Mental Health at WHO, and Mrs. Gro Harlem Brundtland, the Director General.

In the long run, successful programs such as these remind people that mental health problems are real … that their burden of pain and suffering are every bit as devastating as physical illnesses … that most of these illnesses are treatable … and that it is the right thing to do to seek treatment from mental health professionals.

There is so much progress right now in the field of mental health care. There are so many role players approaching issues from so many directions. Yet there is still a need to move this agenda to a higher level. Those with the knowledge and the ear of policy makers must exert the influence required to reform mental health care policy and to get the resources dedicated to it that it deserves.

But from where does good evidence-based mental health care policy emanate? How are best practices evaluated, scaled up, and disseminated? Who are the government policy makers qualified to implement such policies? This is the exciting area in which we have recently focused much more interest – and some very interesting things are being done right here at the University of Melbourne.

After discussing the concept of creating regional mental health policy research centers with Professor Bruce Singh here at the University of Melbourne and Professors Arthur Kleinman and Alex Cohen at Harvard University, we are pleased that we have been able to fund both programs, facilitate their cooperation, and support fellowships for
the training of up-and-coming policy experts from health ministries in Asia and the Pacific Rim. We believe this is the next big step required to building effective mental health care policies and systems around the world.

I have tried to describe the role the pharmaceutical industry plays in mental health care and the role we must all play together.

But, increasingly, we hear demands that drug companies accept the economic burden of those nations that need existing medicines but cannot pay for them.

A similar and related demand is being made on behalf of patients desperate for treatments for so-called "neglected diseases," that is, diseases that are not currently the target of pharmaceutical research.

And of course, in the United States, we must confront the issue of affordability and accessibility of vital medicines for senior citizens and others without insurance coverage.

The assumption, if not the assertion, is that the drug companies bear a central responsibility for solving these problems.

I suspect such issues were at least partially in mind when Professor Singh invited me to speak on this topic today.

So I will do my best to address them.

As I see it, the fundamental issue is precisely one of roles and responsibilities.

If indeed there is some responsibility to help those who cannot help themselves – and I firmly believe there is – then it is a responsibility shared by us all as human beings and not by one segment of private industry alone.

At the same time, I believe that companies, like individuals, do share obligations as "keepers of the commons." And at my company, we act on them.

Over the past three years, for example, Lilly has made donations for disaster relief or for ongoing humanitarian programs in roughly 100 countries, providing drugs valued at more than 25 million dollars.

Our program for poor patients in the U.S. is even more substantial. Last year we answered some 300,000 requests with medicines worth some 100 million dollars.

Many of our peers in the industry also have strong traditions of helping those in need.
But it is fair to ask, is there something more that drug companies can and should be doing for those in need?

Let’s look briefly at the specific issues I’ve mentioned.

In the U.S., the real issue is not a lack of affordable drugs. It is a lack of affordable insurance. For the majority of Americans, the costs of their drugs are substantially covered by their health plans. But seniors lack this benefit under the government run Medicare program.

Many working poor have no coverage for any needs. And I certainly realize that in many countries around the world, this constitutes the rule rather than the exception.

But this is not something that’s going to be fixed by attacking the drug companies. This is something that we must address as nation-states. We have to find better ways to help those in need get access to health insurance or public health care that includes coverage for pharmaceuticals.

As for dealing with diseases in the least developed countries, the most fundamental need is for a basic public health infrastructure, reliable measures for keeping water clean, for managing wastes, for controlling the insects that spread many diseases. There is a chronic need for the most basic medical supplies and, above all, for more people trained to use these supplies and to educate the populace about disease prevention.

Still, within that context, access to medicines is a real issue.

Despite the prevailing view in the media, patent protection is very seldom a barrier. The World Health Organization maintains a list of “essential medications” to treat diseases in the developing world. Ninety-five percent of the drugs on that list are no longer protected by patent. The problem, in many cases, is finding someone to make them and sell them at prices these nations can afford. That is a role best suited to the generics industry!

Prozac is already off-patent in virtually every country in the world and generic versions are available now at commodity prices. The pipeline has worked as it should and fluoxetine has arrived in the public sector and in the clinics of less-affluent countries to effect an echo-revolution in the treatment of patients with depression.

In other cases, where older, needed drugs are still being manufactured, many large companies do have humanitarian programs to help needy countries, as I’ve mentioned.

For example, at Lilly, we are currently working on a special project with the Soros Foundation to try to increase the availability of drugs needed to fight TB in Russia, where this terrible disease is unfortunately making a comeback. And we’re involved in other programs to help in Africa and Latin America. In one such program, we sell two drugs (cycloserine and capriomycin) required for the treatment of Multiple Drug
Resistant strains of TB to the WHO at 10% of our cost to manufacture them. While these are not innovative drugs, they are still useful and no one else is making them. The patents are long since expired, but we continue to manufacture them because there is a continuing need.

Other companies make ongoing donations of drugs that treat river blindness, elephantiasis, and other tropical diseases.

In regard to diseases that are truly neglected, that have no treatment and see none in development, this is an area where the research-based companies can play a role. But they cannot take on the whole burden. We must build broad collaborations with industry, governments, nongovernmental organizations, and charitable foundations to search for new solutions.

The issue of HIV/AIDS in the third world really has to be considered as a separate and unique problem – and time does not permit a full argument here.

Obviously, the AIDS epidemic has reached truly catastrophic proportions in some parts of the world … many of the drugs used to treat it are still under patent … and some of them are quite expensive.

What the manufacturers fear is not, as is often portrayed, the loss of revenue for one product in one afflicted and needy nation. What they fear is the “slippery slope” effect.

If a nation is justified in acquiring one drug by ignoring patents, then why not any others they may require? If one poor nation may be excused for breaching patents, why not its neighbor who is not quite so poor? And what is to restrain the pirate manufacturers from making far more than is needed in their own nation and selling the product in any market in the world that will welcome them?

Even in dealing with the devastation of AIDS in poor nations, solutions are possible without abrogating intellectual property rights.

Several of the largest manufacturers of these medicines have offered to make them available at cost, and in some quantities for free, to a number of the hardest hit areas.

But it will take much more help to acquire, deliver, and use these medicines effectively. That will take serious involvement by governments and international agencies and perhaps charitable foundations as well.

Commandeering the patents is no solution at all, actually. This approach is ultimately self-destructive.
Consider: HIV is notoriously adaptive. When a new strain with new powers breaks loose in a populace, what argument, what inducement, can these countries possibly offer to the research companies to try again?

If you can see the general principle in this specific case, you can understand better why my industry fights so hard to protect its patents. They are the foundation of all our innovation.

It is only the faith in that right that persuades investors to risk their money in biomedical research and allow us to hold it through the decades-long, high-risk struggle of bringing a product to market. Therefore, all progress in our struggle against disease is anchored in that right.

Policy must strive to find the high ground that balances the conflicting agendas of those who need answers with those who pay for the answers and with those who are expected to discover the answers.

Above and beyond these arguments, I want to develop the claim I made earlier, that trying to control costs by suppressing innovation is a poor strategy.

I set aside as a given the fact that this strategy, broadly pursued, would frustrate the hopes of millions suffering from countless diseases. Innovation is the only answer to their needs, and that has been demonstrated beyond dispute.

But let’s look more closely at the actual relation between innovation and costs. I won’t argue with the point that innovation increases therapeutic options and effectiveness, which drives utilization, which in turn drives up spending. That’s right. But that’s not the end of the story. Innovation simultaneously works to reduce costs.

The obvious case in point is the flow of intellectual property into the public domain. Today’s expensive NCE becomes tomorrow’s low-cost generic and the next day’s “essential drug.”

I have one more wide-angle view to offer. I want to explain why I think the obsession with cost control is the wrong premise for health care policy.

In part, my argument is that these policies simply have the wrong target. As many experts have noted, costs aren’t rising. Spending is. Indeed, in health care, as in any area where there is high demand, lower costs are a stimulus to greater spending. But that factor aside, better technology, broader applications, and more people reaching an age of greater need is all it takes to drive spending up.

Designing policies to try to "do something about" this displays a kind of futility akin to trying to hold back the wind.

But my concern goes beyond this.
What puzzles me is this strange habit we seem to have throughout the industrialized world of accounting for health care primarily as a cost in the grand economic equation, as something to be subtracted in the tally of each nation’s productivity. There is something fundamentally flawed in this perspective.

In an insightful, provocative essay in the *Atlantic Monthly*, Charles Morris posed it this way: "Gouging coal out of mountains to run power plants so that we can waft cool air over the brows of investment bankers is totted up as "industrial production" - an unambiguous increase in national wealth, like jet skis and video games. But new hips that allow people to walk, intra-ocular implants that restore their vision, stents that put them back to work are classified as non-productive "services" that somehow make us poorer."

Not to mention modern antidepressant drugs which salvage lives … and novel antipsychotic drugs which enable patients to be reintegrated into and make contributions to a society.

There are two points interwoven here, and they need to be stated separately.

The first is that health care is a vital, vibrant economic domain in its own right. The web of high technologies it embraces, those we broadly cover with the term "biomedicine," may well be the key technologies of the twenty-first century.

The second point is that the output of this activity, what health care does for us, is the highest kind of "good" in every sense of the term.

It is already clear that *Business Week’s* proclamation of a "biotech Century" is no mere hype.

The effect of all these technological advances -- the benefits in longer healthier lives -- represent a very basic and necessary kind of economic good.

The fact is, a healthy population appears to be a fundamental prerequisite for a healthy economy. Harvard’s Jeffrey Sachs, heading a special project for the World Health Organization, has mustered powerful evidence to show that, in Third World nations, poor health is a cause, not an effect, of ongoing poverty.

The reverse is also obvious: that much of the vibrancy of the developed world is due to our relatively good control of disease and disability in our working population. As we head into a period of greater growth, with a need for all the productive workers we can find, this contribution of health care, and especially mental health care, can only become more valuable, more essential.
Above and beyond the economic value of all this activity, there is, I believe, a social, even a moral, value to the application of the life sciences for which we should feel very positive and very proud.

Of all the things we might invest in for our society, what could be more desirable than better health? And understanding the data from the Global Burden of Disease, what area of health offers the greatest potential return on investment than mental health.

Look at what we’ve already done. Through advances in medicine and a whole host of basic but vital public health measures, life expectancy throughout much of the developed world has grown from a little over 40 years to well over 70 since 1900.

Can anyone make a case for a more important human achievement? Is there anything else we would rather have done with the money we spent to accomplish this?

This is the final role we in the research pharmaceutical industry embrace, the role of helping to shape policy in a way that recognizes these achievements, the role to assure an adequate fuel supply to the engines that have toiled to realize these achievements. It is a seat at this table for which we appeal. It is a seat at this table which we believe we have earned – and which you have so graciously offered me today.

There is a truth we must finally understand about the relation of money and medicine. They are inextricably bound up together. And on the whole, that duality serves society extremely well.

Because of the dynamic of “want” versus “need,” we may never be fully at ease with this truth.

But perhaps we can accept it in the way that Winston Churchill urged us to accept democracy, despite its flaws and irritations.

He once said, “It is the worst form of government ... except for all the others that have been tried.”