

Deirdre Connelly
President, North America Pharmaceuticals
CED Conference
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Thank you, Jack, for that kind introduction, and thank you, Governor Perdue, for your remarks. It's great to hear such support for the biopharmaceutical sciences from the Chief Executive of the state.

This is really a very remarkable gathering and a testament to the importance of the life sciences to the RTP area, the state of North Carolina and to the Southeastern United States.

While this session is the "official" opening of the conference, I understand that the Venture Day session this morning stimulated a lot of good discussion. I'm sure that will continue throughout the rest of the meeting, and my colleagues from our R&D group are really looking forward to exchanging ideas with all of you later today and tomorrow.

Because the biopharmaceutical industry is so critical to this area and to our society, it's important for us to talk about some of the challenges we face. Some of those challenges are fueled by the evolving expectations and demands of the society we serve. Some we've created for ourselves. Others are simply part of the changing nature of our business.

But all are challenges we must meet – as an industry and as a society – if we are to continue to advance medicine, create valuable jobs and help patients.

So what are those challenges?

- First, of course, is healthcare reform and all its downstream effects.
- Second is the evolving policy and regulatory environment.
- And third, is a decline in research and development productivity at a time when society is demanding proof of value for money and science is advancing significantly.

Let me start with healthcare reform.

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With passage of the Patient Protection and Affordable Care Act last March, our industry entered into a significantly different operating environment with much higher costs.

We agreed to pay ninety billion dollars over ten years toward healthcare funding as part of the agreement PhRMA reached with the Senate Finance Committee and the White House.

On the up-side, by 2014, medical coverage will be expanded for the under-insured and will be extended to the uninsured – so more patients will have access to medical treatment.

Yet, that care will be delivered in a market where the majority of funding and purchasing is no longer driven by the private sector, but by the public sector – and that means a greater focus on cost-containment.

Even in the private market, patients, providers and payers are demanding greater value and more cost-effective care – and changing their practices to achieve it.

So we are seeing healthcare practices consolidate and decision-making centralize.

Physicians are consolidating into medical centers, group practices and integrated delivery networks.

Hospitals are consolidating, as well – with 500 fewer hospitals now than there were just three years ago.

As a result, decision-making is more centralized, with formularies rather than doctors dictating the choice of medicines for patients.

This is all before the health care reform bill is fully implemented. In the coming years, how care is delivered and paid for will have the greatest impact on healthcare in this country.

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Three key tools will be critical in shaping the future of healthcare delivery and payment:

- first, health information technology
- second, comparative effectiveness research, and third
- quality standards.

If used badly, these tools will focus on cost, limit patient access to medicines, and shrink the market for innovation even further. If used well, these tools will help coordinate care among providers and move us to a true “healthcare system,” where delivery and payment will be based on quality of outcomes, not on quantity of services provided.

So, now is a critical time for all of us to work to ensure that the thousands of pages of the healthcare reform bill are translated into regulations in a way that focuses on quality and outcomes.

At GlaxoSmithKline, we have advocated for healthcare reform based on a “Triple Solution” of prevention, intervention and innovation to improve health and rein in costs. Consider these facts:

- Approximately 75% of our healthcare spending today goes to treating chronic diseases
- Almost half of all Americans have at least one chronic disease
- Chronic diseases cost our country over a trillion dollars in lost productivity every year.

Fortunately, many chronic diseases that harm health and drive healthcare spending are preventable and treatable.

Looking just at prevention, if just one in ten people started a walking program, we could potentially save 5.6 billion dollars on heart disease treatments each year.

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In the area of intervention, if we could adequately screen for diabetes and appropriately treat diabetic patients, we could significantly reduce the burden of Type 2 diabetes, and reduce the 80,000 amputations done each year due to poor treatment.

And, in terms of innovation, think about what has already been accomplished. In the last 20 years, overall survivor rates for cancer in the US have increased by 25% and the death rate from HIV/AIDS has fallen by 70% since 1990 – thanks to the medical innovations our industry has delivered.

Health information technology, comparative effectiveness research and quality standards, if applied appropriately, could help significantly improve prevention and treatment of disease and even lead to future innovation.

If health information technology is used to better coordinate care, we can make sure people get the screening and the appropriate treatment they need – including access to innovative medicines that will prevent more significant illness and expense later. If not, health information technology will become a tool to focus on short-term costs and further shrink the market for innovation and return on R&D investment.

If comparative effectiveness research is used to assess the relative benefit of different medicines, we can demonstrate the value of our innovations. If not, comparative effectiveness will focus primarily on cost and not outcomes and limit access to innovative medicines.

If we use quality standards to pay providers for truly improving the health of their patients, society can get real value for the money – and we can demonstrate our contribution to improving health while lowering the long-term cost of care. If not, quality standards will focus more on cost and volume of services provided rather than patient benefit.

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So this is a critical time for us to demonstrate our value to society in meeting customer demand for innovative treatments that reduce the long-term cost of care – while also ensuring that we are rewarded for that innovation. And we must do business in an ethical way that increases confidence in us as valued partners with patients, providers and payers for improved patient health.

Earlier, I talked about other ways healthcare reform is affecting our operating environment, specifically, the provider and payer consolidation we are seeing. As a consequence, those we serve are challenging us to meet their needs in a different way.

In response, we're transforming how we market and sell our medicines at GSK to demonstrate our value to our customers. And we are doing that in a way that is consistent with our ethical values – focused on the best interests of the patient, transparent about our working relationships, operating with integrity, and respecting those we work with and serve.

Let me give you a few examples:

As more healthcare providers move into large health systems or integrated delivery networks, where decisions on purchasing and prescribing are made from a central office, sales professionals can offer more value to healthcare providers by operating more as business-to-business partners.

So, we've moved to a customer-centric model that aligns with the desire of our customers to have one point of contact for GSK who understands what they need and can deliver the right information at the right time for the improved health of their patients.

That way, instead of having multiple sales reps calling on a health system to present information on different GSK medicines, a single individual is now responsible for managing that account and bringing in specialists to meet specific customer requests and needs.

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For instance, at one time we had 50 representatives calling on the University of Virginia Medical Center. Today we have one person responsible for that customer who brings in specialists as needed to answer questions, provide support and solve problems.

Customers are also asking for more disease education information and support for improving patient outcomes. In response, rather than organizing our marketing and selling efforts around our brands, we're organizing and deploying our resources around our customers and their therapy needs.

So, for example, to better support our customers in asthma and COPD, we have created a new group of respiratory care specialists who are themselves healthcare professionals – physicians, pharmacists, physician assistants and nurses.

This team does not sell medicines. Instead, they work with healthcare providers and payers to provide in-office education on treatment guidelines, how to assess disease severity, and what disease management tools to use to improve care for asthma and COPD.

Clinicians see real value in this approach, especially as payers increasingly link health outcomes to pay.

Our representatives also work in a different way with cancer specialists.

Oncology creates special issues for patients. As we all know, cancer is frightening, and the medicines used to treat it have serious side effects.

The drugs themselves can be complicated. Every cancer drug delivered by IV has a different infusion rate.

Arzerra, one of our cancer drugs, can take 12 hours to infuse in a patient the first time – possibly longer if the patient has a reaction to the drug.

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Those IVs are given in the office. That way a health care professional can talk to the patient during the infusion and help them understand how to manage their side effects. Our clinical educators – who are all oncology nurses - work with cancers centers to teach nursing staff how to appropriately and safely infuse patients, and how to counsel the patient on managing side effects so they adhere to their treatment schedule.

But half of our cancer medicines are tablets – a lower cost innovation for patients who don't have to spend a day in an IV chair every week. But no infrastructure exists to support those patients in the clinic. They get a prescription for a cancer pill and leave the office. Then they go home and deal with the side effects on their own. As a result, adherence rates for oral cancer medicines are very low.

Our clinical educators help the cancer center nursing staff understand what the touch points are for the patients, so they can help the patients know what to expect and help them adhere to their oral treatments.

I said before that we must demonstrate our value, but in a values-based way so that our customer can trust us to work with them in the best interests of our patients. Oncologists see that our representatives can provide significant value, given their extensive training and knowledge of our products and their labels.

But because of the demands on cancer center staff, they depend on us to provide detailed, accurate, up-to-date and balanced information about our medicines. That means we have to earn their trust by showing every day that our interest is in what's best for the patient. That we respect them as our business partner. That we are transparent with them in our business dealings and in describing both the benefits and the risks of our medicines. And that in all things we act with integrity.

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Those are some of the ways we are responding to the need to demonstrate our value to our customers while meeting the challenges of healthcare reform and the evolving needs of the marketplace.

The second challenge I mentioned was the policy arena and the changing regulatory environment. Clearly, this is an area where we don't control the agenda, but where we all need to work with policymakers and our elected representatives to ensure balance on issues such as innovation, safety and cost.

Let me give you a couple of examples.

In late January, the U.S. Department of Health and Human Services announced that, to help bring more new medicines to market, it was creating a billion-dollar government drug development center to advance new drug discovery.

Then, last week the President submitted his initial 2011 budget to Congress. One proposal was to reduce data exclusivity for biologics from 12 to 7 years.

One announcement supports innovation; the other takes it away.

As a nation, we all agree that we must improve access to healthcare and lower its cost. Generics have an important role in holding down costs. But people forget that today's generics were yesterday's innovation.

We must constantly remind the policy-makers that our value to society comes from rewarding the long-term, costly and risky investments necessary to bring new drugs and biologics to market. Without those rewards, society's goals for overcoming diseases like Alzheimer's, Parkinson's or cancer will not be met.

Given that 10,000 baby boomers turn 65 every day, the future costs of treating diseases such as Alzheimer's will be staggering. Future innovation could significantly reduce the direct and indirect costs of Alzheimer's, which alone adds up to one hundred forty eight billion dollars for Medicare, Medicaid and private payers.

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Here's another example to consider.

The regulatory landscape is changing significantly, particularly as a result of the FDA Amendments Act passed in 2007, which expanded FDA authority to look at drug safety throughout the entire product life cycle. FDA can require drug sponsors to conduct post-approval studies to assess a known, or a potential risk. That's the case even for medicines that have been on the market for a decade and have a long history of safe use if FDA believes a safety signal must be explored.

FDA may also require a "REMS" – or Risk Evaluation and Mitigation Strategy – if the Agency determines one is necessary to ensure that the benefits of the drug outweigh the risks. And FDA can impose distribution and use restrictions.

The FDA is using these tools more and more often. Most medicines now can expect a REMS of some sort at approval. In fact, all six biologics approved in 2010 had REMS.

Of course we support ensuring that our medicines are safe for patients. As tools for analyzing side effects get more sophisticated, even weak signals of potential risk need to be investigated. But we have to recognize that all medicines have benefits and risks and the two have to balance in relation to the severity of the disease. That balance requires context so that we don't overstate either the benefit or the risk. Studies to clarify level of risk have to have an achievable outcome that is relevant to improved patient care.

For example, one ongoing scientific debate has been the potential risk of death associated with long-acting beta-agonists used in treating asthma. The rate of asthma-related death is extremely low in the US. Depending on the specific clinical trial design, research to further quantify that risk could require hundreds of thousands of patients, many years to complete, and force patients to discontinue successful therapies to test this hypothesis about safety.

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In this regulatory environment, such hurdles to investment in development may be too high for smaller biotech companies to clear. Even large companies are choosing to give up on research if the cost is too high to pay for an outcome impossible to achieve or of limited patient benefit.

So, what does this mean for the biopharmaceutical industry?

First, we must be guided by what is in the best interest of the patient. We must be transparent in studying, understanding and communicating all the information we have on a medicine – before and after approval so that regulators, payers and healthcare providers can make the best treatment decisions for their patients.

At GSK we make an effort to publish all our data. Even if our papers are rejected by the medical journals, we post data on our clinical trials website to ensure public visibility of both our safety and efficacy data.

We also have to plan for the inevitable. At GSK, even as we formulate our clinical development programs, we plan for post-marketing surveillance.

In the future, development partnerships between biotech and big pharma will become increasingly important as a way to share costs for innovation.

And we must continue to work with the FDA to find the appropriate level of investigation to determine clinical risk for patients balanced against the benefit of the medicine.

By taking this approach to working with the FDA, and being transparent in how we conduct our clinical development programs, we will be able to demonstrate the value of our medicines in a way that is consistent with our values.

[Pause]

Now, I'd like to address the third factor affecting our industry, research productivity and the potential that significant scientific breakthroughs could hold.

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Between 2000 and 2009, annual spending on research and development in our industry increased from 26 billion dollars to almost 46 billion dollars. Yet the number of new molecular entities approved has not kept pace with the investment made.

In 2010, the FDA approved only 21 new drugs. This was near the record low of 17 approvals in 2002, and down significantly from an average of 32 new drugs approved by the agency between 1992 and 2001.

If the trend continues, we may see investors move away from the sector and we will see biopharmaceutical companies continue to look at acquisitions as a way to invigorate their pipelines.

The decline in new drug approvals by the FDA has been attributed to various factors – including a more conservative FDA as I've just outlined. But another factor is a decrease in R&D productivity.

Scientific advances such as mapping of the human genome and the advent of personalized medicine hold great promise for continued advancements in the search for new treatments.

But R&D timelines are long, the costs are high, and failure is more common than success. So research and development into new drugs must be more productive if it's going to be sustainable. And, we must be able to generate a fair return on our investment for the benefit of society.

But with approximately three quarters of the prescriptions in this country now written for generics, the biopharmaceutical industry has a much smaller market in which to compete. And even to compete in that shrinking market, we have to prove we have a value proposition better than the competition, or payers won't pay.

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Gone are the days when payers would accept marginal improvements on existing drugs. We must understand that the old model that covered the inefficiency of our research by producing “me-too” drugs and reformulations is over. And, as we generate clinical data on new drugs, payers have made it clear that placebo isn’t on the formulary. They want to see value demonstrated versus the current standard of care.

For big companies like mine, as we increased our investment in research and development, we also built larger and larger research organizations. In the process, we created a lot of bureaucracy and became overly reliant on process.

So, to make sure that our research organization is being productive and capitalizing on advances in science, we’ve made a move to re-personalize R&D. We’ve created about 40 early-stage research teams, with between 5 and 70 scientists in each.

We call these discovery performance units, or DPUs. And each one focuses on a particular disease or pathway.

And when I say re-personalizing R&D – we really are. In most cases, the people who work in our DPUs are co-located so they can easily communicate with one another and share ideas.

We’re getting away from having researchers on a project scattered in different buildings, in different cities or even on different continents.

And, we operate the DPUs like small biotech companies. They submit a 3-year business plan with overall budget and clearly defined objectives.

At the end of the three year period, the results for each DPU will be evaluated and we will make a determination if the unit should continue its work or be disbanded.

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It's through this process that we are working to bring greater productivity and accountability to our internal research efforts.

We are also very open to partnering with others to find the best science, wherever it exists. We currently have partnerships with more than 50 companies.

And that's why conferences like this one can be so useful.

As most of you know, North Carolina is ranked as the number three state in the nation for biotechnology, which not only includes pharmaceuticals, but also agricultural products and research, testing and medical labs.

And for us, having our U.S. headquarters in the Research Triangle Park is a significant opportunity.

I find it very interesting that in 1959 a group of business, government and academic leaders had the foresight to establish a research park here, as a way to address an economic outlook for the area that did not hold much promise. An economic future that forced many graduates of the area's universities to leave the region to find good jobs.

Twenty five years later, once again leaders from business, academia and government demonstrated remarkable vision and foresight when they created the North Carolina Biotechnology Center and the Council for Entrepreneurial Development – two organizations that have been critical in establishing this area as a leader in the life sciences.

These groups met the challenge and their plans worked. Today more than 170 research and development related organizations call RTP home.

And that's a great environment for a company like ours, whose focus is finding the best science and the best new ideas wherever they may come from.

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I've outlined some of the challenges we face as an industry. I've shared with you some of the approaches my company, GSK, is taking to address these.

I've given you my thoughts on how we need to engage as we move forward to make sure that, as an industry, we address the challenges we've created for ourselves and work constructively with other stakeholders to address the challenges they have for us.

I'm hopeful that we have the foresight, the intelligence and the resolve to meet the challenges we face, just as those who created the Research Triangle Park did.

In closing, I want to leave you with one final thought.

And that is: remember that, in the end, what we're all trying to do is deliver better health to the patients who depend on us.

Often times the challenges we face as an industry seem to push and pull in conflicting directions. Yet, in order for us to succeed in delivering to society what is needed and expected, we must all work together to reach a point of equilibrium that will serve the long-term interests of society.

I trust that through your combined efforts, your work will make a difference in healthcare.

Thank you.