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SLIDE: Technology Convergence/Title

Good evening, and thank you for that warm introduction. I'm pleased to be here tonight with so many thought leaders in medical technology. And I'm excited by the possibilities our collective skills portend for the advancement of health care in the service of patients.

After all, that is what we do. We can debate how much more challenging the regulatory environment has become, how much more costly and difficult it is to bring new products to market, how the imbalance of perceptions of benefits and risks has affected our willingness to blaze new frontiers.

No matter how spirited the debate, we will all arrive back at the point where we began: we are absolutely compelled to chart a course for that next frontier, to apply all that we know about science and technology to treatments and, yes, cures, for some of the world's most devastating and persistent medical conditions.

It is true that much progress has been made. We should be proud of the contribution we have and will continue to make to better the lives of people around the world. But consider this.

SLIDE: Charting a Course for the Future

Healthcare today is a \$4 trillion marketplace. Even Johnson & Johnson, with \$53 billion in assets the world's most broadly based health care company, represents less than one percent of this opportunity...fulfills less than one percent of that need.

So the challenges are still in front of us, and, despite so many advances, these challenges continue to grow in complexity and with many confounding factors.

SLIDE: Increasingly Competitive Environment

Why? Well, among other things, we operate in an increasingly challenging external environment with respect to public perceptions of our industry. We face intense global competition and challenges to intellectual property. As populations age, we experience increasing pricing pressures and attempts by payors to reduce the cost of health care. Finally, the regulatory requirements we must meet to bring products to market are ever higher hurdles.

This is, arguably, the most challenging public environment in the history of the life sciences. Our industry is among those under the heaviest media scrutiny, and that coverage is more times than not negative.

In the public debate, the level of cynicism grows toward claims of innovation, in part because innovation claims alone without concurrent demonstrations of value represent to policymakers little more than the potential for higher costs.

Add to this an extremely risk averse physician and patient base, and you will conclude that advancing science is only one of many steps in a long process toward innovation. With credit to the indomitable spirit of researchers, however, I am glad to say that we press on.

In fact, our industry has continued to grow in the face of this environment. True innovators are bigger and better today because we have brought new products to the marketplace – products that have changed millions of lives for the better.

It goes beyond encouraging innovation. It is a mandate. In the environment in which we operate, we simply have no choice but to be on the cutting edge of change. “Innovate or die” is the maxim within an industry that’s as fiercely competitive, fast-moving and publicly examined as ours.

SLIDE: Increasing Demand for Health Care

Beyond the business imperative, there is the far more compelling human imperative as to why we must innovate. That's the increasing demand for quality health care due to an aging population... many areas of unmet need... the unabated incidence of major diseases affecting broad segments of the population, such as cancer, cardiovascular disease, obesity and diabetes... the mandate for early treatment and prevention... and emerging markets where rising GDP and urbanization are leading to expanding access to care.

SLIDE: Revolution

This century ushered in the age of Biology. And the revolution in biology, converging with the revolution in technology that closed the last century...provides opportunities for healthcare innovation and value creation.

Nano-technology...microelectronics and micro-electro-mechanical systems, or MEMS... neurostimulation... mechanism based, targeted therapies... regenerative medicine, biologics and cell therapy... genomics... health information technology... and technology convergence and personalized medicine... once seemingly disparate technologies and disciplines, they are being brought together to drive further innovation.

SLIDE: Technology Convergence

Technology convergence is the merging of med tech and info tech with biotech, giving us new possibilities in the treatment of serious medical conditions that until now have been inadequately treated. Perhaps more important, this convergence may get us to our dream of preventing and curing diseases like cancer, heart disease and diabetes. Technology convergence may also enable truly personalized medicine – targeted treatment for patients with specific characteristics and disease subtypes – which rather than being a threat to our industry, will open new doors to innovation and value creation.

Fortunately, there are concurrent efforts to create a smoother regulatory pathway to get these products to market more quickly, such as the creation of the FDA Office of Combination Products.

SLIDE: FDA White Paper

You may recall the FDA White Paper of March 2004 entitled “Innovation or Stagnation.” A key observation of that paper was that “only a concerted effort to apply the new biomedical science to medical product development will succeed in modernizing the critical path.” The FDA made some important observations in its white paper, but it did not crack the code of how to bring these together.

SLIDE: What does it take to succeed?

The truth of the matter is that complexity demands a broadness of approach and a willingness to collaborate across traditional boundaries. Success requires breaking down barriers within companies, between companies, within universities and in partnership with universities, in strengthened government agencies, and in collaboration with payors along the way.

The opportunity lies within the divergent sciences that shape the field of medicine. To realize its full potential, we need to put the people together who have these areas of expertise...free flow of ideas, people and money across traditional boundaries to bring forward innovation with greater speed and success.

If we are successful, we will continue the wave of innovation that has ushered in the newest combination products.

SLIDE: Technology Convergence – Combination Products

Two examples in the Johnson & Johnson family are the Cypher stent, where a drug improves a device, and the Ionsys drug delivery system, where a device improves a drug.

While the drug-eluting stent category has been challenged on many fronts over the past year or so, one thing that's indisputable is that the very existence of the product is illustrative of the importance of collaboration.

SLIDE: Coronary Stent History

The history of coronary stent development demonstrates the critical factors needed for success in combination products... innovation through technology convergence, collaboration and partnership.

Johnson & Johnson's efforts began with bare metal stent technology which was developed based on an early concept licensed from two physicians, Julio Palmaz and Richard Schatz, and culminated in the approval of the first coronary stent, the Palmaz-Schatz stent. But because of the problem of restenosis, or the renarrowing of the coronary artery within the first six months after stent placement, which was seen in anywhere from 15 to 35 percent of patients, scientists and engineers from Cordis collaborated with their R&D colleagues in our pharmaceuticals group to find an answer.

The complexity of the problem required not only collaboration between our internal organizations, but also partnerships with outside companies to come up with a solution that has virtually eliminated restenosis – the drug-eluting stent.

Beyond our own resources, we developed Cypher by aggregating technologies from Wyeth, for the drug sirolimus, and SurModics, for the polymer matrix, which provided just the right amount of drug over just the right amount of time.

The Cypher experience also demonstrated the importance of working in partnership with government agencies.

SLIDE: CYPHER Regulatory Process

Cypher was the first combination drug-device for the cardiovascular branch at FDA. Questions for them included how to regulate Cypher...was it a drug or a device?

Ultimately, because the primary mode of action was as a device, it was regulated by the device branch, but the rules from the drug side of FDA also applied!

The rules were evolving and only became clear fairly late in the game. This was a collaborative learning experience for both Cordis and the FDA, especially because new complex manufacturing requirements made product supply a challenge.

Just as important as establishing a good working relationship with FDA was Cordis' effort to work closely with CMS to make sure that ICD 9 codes and DRG

assignments were established before approval, thereby ensuring access and reimbursement for the patients who would benefit from the technology...

Cypher is just one example of important combination products, and there are many others on the horizon at Johnson & Johnson, some more distant than others. I'd like to review just a few other areas of promise that illustrate how convergence of ideas, technologies and people are driving innovation.

SLIDE: Chronic Illness

I think you would agree that the key strategic issue in health care is reducing chronic illnesses worldwide. Simple, yet sophisticated diagnostic tests can help us do this.

SLIDE: Diagnostics: Critical First Step in Healthcare

In-vitro diagnostics examine material from the body... generally blood... to determine the absence or presence of disease... to assess the status of medical conditions... and to guide therapy.

Sixty to 70 percent of medical decisions are based on laboratory test results. Yet in-vitro diagnostic testing is responsible for less than 2 percent of all healthcare costs. This makes in-vitro diagnostics a key player in the management of patients.

SLIDE: Yesterday, Today, Tomorrow

Today, the in-vitro diagnostics industry is focused on improving laboratory operations. Tomorrow, the in-vitro diagnostics industry will focus on improving patient outcomes.

Our healthcare systems around the world are overburdened with chronically ill patients. As this problem increases, it creates economic and medical risk for most nations.

Advanced biologic technologies can provide a solution to the mounting crisis in healthcare... by identifying patients in the earliest stages of disease... and moving them on a path to health.

Ortho-Clinical Diagnostics, J&J's in-vitro diagnostics company, is transforming its business from a focus on instruments, and improving lab operations... to a business that will drive improved patient outcomes through evidence-based medical solutions that enable personalized medicine and drive highly profitable growth for our business.

In these efforts, they are collaborating internally with our pharmaceutical and device companies and externally with researchers and leading universities.

Slide: Advanced Diagnostics

Two examples. First - CellSearch, which detects circulating tumor cells that have detached from solid tumors and entered the blood stream. This information can be linked to determine the best treatment for the patient. And the second example, GeneSearch, available outside the US and pending imminent approval by the FDA, is designed to determine if a woman's breast cancer has spread into the lymph nodes, again helping to determine appropriate therapy. Because this is a real-time intra-operative diagnostic, it can save many women a more extensive surgical procedure if the cancer has not spread; or a second operation when indeed the cancer has spread.

Both these technologies show the power of combining diagnostics with therapeutics to improve patient outcomes.

SLIDE: The Evolution of Biosurgicals

Another example of combination products transforming healthcare is in biosurgicals.

The first manufactured hemostat, a gauze-like fabric used to stop surgical oozing, was introduced in the late 1940s. For the last several decades, however, there has been limited innovation in this area... that is, until now.

Today, Ethicon, a Johnson & Johnson medical device company, is driving innovation with a new line of hemostats, and again illustrating the power of collaboration and partnership.

Products like Surgiflo Hemostatic Matrix, a flowable hemostat, are excellent for stopping bleeding on uneven surfaces and in hard-to-reach places.

The newer generation of hemostats is biologically based combination products.

Slide: Advanced Hemostats

They include Evicel Fibrin Sealant, which Ethicon launched in partnership with Omrix Biopharmaceuticals, as an adjunct to hemostasis in patients undergoing either liver or vascular surgery.

Human plasma-derived biologic components are mixed and applied directly to the bleeding site, providing a clotting mechanism to stop bleeding.

With Omrix, we are also developing an exciting next generation biologic hemostatic dressing, or fibrin patch.

It's a unique combination product that marries Ethicon's novel biodegradable matrix with Omrix's proprietary biologic.

In surgery, it forms a seal over the wound, to stop brisk bleeding.

What's its application? Well, uncontrolled bleeding is the leading cause of death due to injury around the world. In the US alone, accidents, stabbings, gunshot wounds and other trauma cause more than 160 thousand deaths a year.

This fibrin patch, now in early clinical trials, can rapidly manage the whole spectrum of bleeding, from mild to life-threatening.

Slide: Success Through Collaboration

Our success so far with this product has been driven through internal collaborations between Ethicon and the biologics manufacturing experts at Centocor, another Johnson & Johnson company, and close external collaboration with our partner, Omrix Biopharmaceuticals.

SLIDE: Big Risk, Big Reward

A few earlier stage examples of collaborations across technology disciplines demonstrate big opportunities but also high risk. We recognize that at the cutting edge of technology we won't always succeed, but when we do, we'll make an enormous contribution to healthcare.

One project based on biotech advances promises an array of “smart” consumer products. The technology involves tiny molecules, or linkers, that stick substances like sunscreen wherever they’re needed on the body.

The substances stay on, and can be pulled off quickly and easily when desired... something like a “molecular Post-It note.”

This could mean make-up that doesn’t melt off... anti-aging creams and sunscreens that don’t rub off... semi-permanent cosmetics or colorizers that don’t wash out.

This technology promises to transform skin, hair, dental, wound care and other consumer product categories. And while our heritage consumer business is taking the lead, scientific contributions come from Centocor and an outside partner, as well as our Corporate Office of Science and Technology and Johnson & Johnson Development Corporation, which invests in new ventures.

SLIDE: To Succeed with Combination Products We Must...

These are just some examples of how we are applying technological know-how to combination products. But we believe that to succeed with combination products, we must also understand the external environment.

To do so requires that we understand the medical need, recognize the regulatory complexity of drug-device, biologics-device and diagnostic-drug or diagnostic-device combinations, and define the value proposition for key stakeholders, including patients, physicians and payors.

SLIDE: Imagine, Collaborate, Innovate

Finally, we must imagine our success, collaborate across disciplines, and continue to innovate.

We cannot, and will not, succeed without constantly fueling the fire of imagination, passion and energy... a flame that will illuminate our path into the future.

But, no one company, organization or institution can succeed alone. We must also harness the power of the leading universities... the emerging and already strong technology companies... the large and well-established pharmaceutical and medical device companies... and create partnerships, consortiums, and new business models for creation, collaboration and innovation.

And we must remember that innovation goes beyond the technologies themselves to our capabilities to create new ways to make innovative medicines, devices, and diagnostics accessible and affordable to all who need them.

If we don't, we jeopardize the opportunity we have in our grasp as the next wave of medical innovators.

Ultimately, we must maximize the value of science, of technology, of human assets, for the benefit of patients. In this room is the know-how, the proprietary technology, the capabilities of diverse, entrepreneurial companies. In this room are the passion and commitment of people who recognize the unique and noble calling of health care... pioneers blazing a trail to a future of promise.

We are at a point of inflection, I believe... where tentative efforts to bring together disparate disciplines give way to confidence in the power of collaboration and convergence... and patients will be all the better for it.

Thank you.