

Shaping Innovation in Healthcare

Keynote Address by Roche Chairman Christoph Franz at the Annual Gala Dinner of the American Swiss Foundation

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Good evening, ladies and gentlemen. Ms. Williams, thank you for your kind introduction. Madame President, Patricia Schramm, your invitation to speak at this 73rd Annual Gala of the American Swiss Foundation is an honor for me. It's good to be here with you to continue the tradition of celebrating and deepening the American-Swiss relationship.

Let me start by saying how saddened I, too, was to hear about the serious illness of Ambassador Whittlesey, Chairwoman Emeritus of this foundation. Her esteemed reputation precedes her -- she was the heart and soul of this foundation, inspiring us all with her mission to strengthen the understanding and ties between our two countries to create a better world.

It is precisely for patients like Madame Whittlesey (and their families) that we, at Roche, have this enormous privilege to go to work for every day. They are what inspire and drive our work. And in the pharmaceutical industry, innovation is the key to ensuring ever-better outcomes for patients.

So there are good reasons why I'd like to focus my remarks this evening specifically on "*Shaping Innovation in Healthcare*".

Interesting to note: The global top 10 in pharma has always been dominated by US and European companies, and two of those companies are from Switzerland – a country with less people than the city of New York! And Roche spends more than 10 billion US dollars a year on research and development – 27 million dollars each day worldwide – more than any other healthcare company.

Roche's strength today is partly due to our early and significant investments in the US. Our ties with the US go way back. We've been operating in America since 1905, when we set up a trading operation right here in New York City, downtown at 90 John Street. Today, Roche has a hefty American footprint, extending from Manhattan to the Midwest to the Bay Area. And we employ 25,000 employees in the US.

When Roche was founded in 1896 - 122 years ago -, life expectancy was below 50 years. Since then it has risen by thirty years / 40% to roughly 80 years; around half of

this is due to better medical care. For example, our antibiotic Bactrim, has saved more lives than the two world wars destroyed!

I think it's impressive that anti-infectives from Roche – discovered in the last century – have helped to save several billions of human lives! An early example is a Roche drug called Rimifon – an important treatment for tuberculosis introduced in 1952. It reduced the death rate of the highly infectious disease 50-fold! - Rimifon's effectiveness against tuberculosis, by the way, was discovered in our US labs by an immigrated German scientist and his American colleague, while they were doing research into an entirely different area – and interestingly two other pharmaceutical companies (Squibb and Bayer) were developing the same compound at the exact same time!

And, not long afterward, the great Roche medicinal chemist Leo Sternbach – a transfer from headquarters in Basel to the US – also made a discovery on a hunch, which led to a new class of medicines known as the benzodiazepines. The most famous of the group was Valium, which continues to be used today to treat anxiety.

That's the way innovation often was shaped back then: perseverance of the scientists paired with serendipity, leading to one-size-fits all treatments. It was like finding the needle in the haystack.

Now, one fundamental issue for the industry was: Patients typically vary in their response to medicines. Differences in genes and their expression (generally proteins) can help explain these different responses, i.e. People are genetically different, but medicines were not differentiated according to the genetic profile of patients.

Then, a great idea made history. Half a century ago, the Basel Institute for Immunology was established. It was funded by Roche, but otherwise independent. Scientists there investigated fundamental aspects of the immune system. Three of them won the Nobel Prize in 1984 - Niels K. Jerne, Georges J.F. Köhler and César Milstein - for inventing a technique for producing at large scale a new category of medicines, called monoclonal antibodies. They were not created from a mix of chemical compounds, but from biological organisms, so essentially bacteria which are bio-engineered to serve as little chemical factories! Monoclonal antibodies have since revolutionized biological research.

This invention (by the way) brought together Roche and Genentech – the pioneering Bay Area biotech firm, founded in 1976 – and led to the first targeted therapies. This was the beginning of the new era of personalized healthcare – for Roche and for the entire medical field.

In the late 90s, Herceptin was the first such gene-based medication to be developed. It was for a particularly fierce form of breast cancer. The women who responded to Herceptin all produced too much of a protein called HER2, which accounted for the relentless growth of their tumors. – The combination of a diagnostic test to identify patients with the over-production of HER2, along with the targeted Herceptin treatment, proved life-saving for countless women who'd previously had no hope. Five-year breast cancer survival rates are now more than 90%, and Herceptin played a major part in that progress.

Since then, our company alone has introduced eight personalized cancer medicines with what we call “companion” diagnostic tests that identify patients likely to respond to them.

But cancer is a complex disease, with over 250 forms that we know about so far. Some still have a very poor prognosis. So, despite these successes, the battle against cancer and other devastating diseases is not over.

Fortunately, the next big advance seems to have arrived and it has the potential to deliver the next wave of innovation. It's called the digitization of healthcare.

(Digitization of healthcare)

There is a huge potential – to give you an example:

- It took 13 years up until 2003 and cost roughly 3 billion USD to sequence the first human genome and its 3 billion base pairs.
- Today, anyone can have their genome sequenced within a few hours for about 1,000 USD. This cost will further decrease in the coming years.
- The availability of data is absolutely exploding!

Our highly regulated research-driven pharma industry has always been heavily data-driven. Data, after all, enable us to prove the efficacy and safety of new medicines in clinical trials. In fact, there's an old saying that goes, “*In God we trust. All others bring*

data!” What’s new for us today is the availability of “real-world data” and the ability to process it with increasing speed and precision.

Broadly speaking, digitization in the field of healthcare started with the transition from hand-written paper files to electronic medical and health records. The next step is using information technology to capture, systematize and analyze these large volumes of data generated in real-world clinical practice, and link these real-world data with "internal" data that companies like Roche obtain from clinical trials.

Think about it. Today, some 96% of patients are NOT involved in tightly controlled clinical trials. Their experience represents a much, much larger body of data in circumstances that are much closer than clinical trials to actual, everyday treatment conditions. This is invaluable information, because things are seen in large volumes of data that are not evident in smaller-scale clinical trials. This promises to be another enormous boost for the increasingly individualized treatment of patients.

We at Roche already have a wealth of health data in-house. But we’re not an IT company. So collaboration with specialized companies is key.

Partnerships in general are nothing new for us. Partnerships in digital health are. And once again, US companies are largely the ones we’re joining together with.

Three years ago, Roche acquired a majority shareholding in Foundation Medicine in Cambridge, Massachusetts, a leader in advanced genome sequencing. Our work with them is bringing us closer to our goal of finding targeted treatments for all patients – especially those with rare forms of cancer.

Two years ago, we formed a partnership with Flatiron Health, located right here in Manhattan. Flatiron was founded by a couple of brilliant young men. They observed a situation that deeply troubled them. They saw a fragmented, siloed, disconnected maze of highly relevant patient data out there in the healthcare system that was resistant to the kind of coordinated collection and analysis that they believed were the keys to improved therapy and care.

In response, they formed Flatiron, which Roche recently acquired. So far, it’s already given us access to anonymized data on cancer patients from a wide range of clinics and academic research centers – data of high enough quality to satisfy the requirements of both research and health authorities.

But that's enough about science, technology and big data. Let me now bring things back to their rightful focus – on patients.

I want to tell you about a specific patient who's benefitting from a medicine in the new field of immunotherapies – treatments that use the patients' own immune systems to fight diseases. For the first time, there is now justified hope that we can also cure patients with advanced cancer. This is a truly remarkable development.

Teams at Roche and Genentech are working on a novel cancer medicine to treat metastatic colorectal cancer, the third most common cancer in men and the second in women. I'd like to take a moment to read from a letter a trial participant wrote us. It begins:

“My Dearest Friends at Genentech and Roche,

“I was given the remarkable opportunity to go on a phase 1 Genentech/Roche trial studying combination immunotherapy. My CEA on the day I began the trial was 188. That's a very high number and it indicated a significant amount of cancer in my body.

Today, when I went in to see my oncologist, he announced that my CEA had dropped from 188 to 40! To have this significant of a drop, well, it completely took me and my doctor by surprise. We high-fived and neither of us could stop grinning.

“Knowing that companies like yours are working tirelessly to come up with cures means the world to us. I may even get to see my 8th grade twins graduate from high school, the likelihood of which was slim to none when I first began my cancer journey.

“Thank you for everything you do. I am so very, very grateful.”

Ladies and gentlemen, personal stories like this one are a daily source of motivation to everyone at Roche and Genentech to do everything we can to improve patients' lives.

Let me conclude with a few points I'd ask you to keep in mind, especially as you and your family and countless others whose lives depend on medical innovation consider policies that will affect the future of the research-driven healthcare industry.

- Far too many diseases are still resistant to effective treatment, and the research-driven healthcare industry is the only hope of changing that. – But medical innovation happens in incremental steps; only rarely in major leaps. It takes time and stamina and requires the mindset of a long-distance runner, not a sprinter.
- Medical innovation also entails huge risks. Many of our projects will fail but not to try would be to ensure total failure. I like how Samuel Beckett put it: “Ever tried. Ever failed. No Matter. Try again. Fail again. Fail better.” Nurturing curiosity and perseverance is a must, and learning from failure is a costly but essential part of the business model of the research-driven pharmaceuticals industry.
- Innovation is a delicate and difficult plant that only bears fruit in the right environment. It needs a macroclimate – one that provides a reliable legal framework, with proper protection of intellectual property, as well as a rich educational foundation; independent basic research; an inter-connected ecosystem of partnerships among academia, government, pharmaceutical companies, technology firms and data enterprises; along with sufficient financial resources and social acceptance to help it flourish. The US is still the nation that best rewards innovation. America’s precious macroclimate must be protected to ensure it remains as conducive to future health innovation as possible.

So, shaping the future of innovation is still about finding the needle in a haystack. And while the haystack is becoming increasingly large, we now have much better tools (such as artificial intelligence and machine learning) to find it!

Ladies and gentlemen, the next decade will be a very exciting time for patients and their families. I know that with our strong footholds of Roche in Switzerland and Genentech in the US, we will be part of that future -- improving quality of life, prolonging life and, in the best case, curing patients. I feel very privileged to be part of this journey.

Thank you so much for this opportunity to share my perspectives with you this memorable evening.