Influenza Prevention and Healthcare Reform: Insights for Change and Action

Featuring L.J. Tan, Ph.D. and Senator Thomas Daschle
Leaders in the biopharmaceutical industry recently convened a healthcare summit to address the future of healthcare in the United States. During this summit, thought leaders delivered speeches on topics ranging from vaccine and healthcare policy to the future of the biopharmaceutical industry. Of the many excellent speeches presented, two are especially timely and relevant to the vaccine industry.

The first of these two speeches addresses influenza immunization policy and was presented by a healthcare professional, L.J. Tan, Ph.D. The second speech, presented by Senator Thomas Daschle, a political thought leader, offers a plan for health policy reform.

CSL Biotherapies has reproduced these excerpted speeches for use by consumers, vaccine providers and healthcare professionals in the communities we serve. To view the speeches online, visit www.cslbiotherapies-us.com.

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About Influenza Prevention and Healthcare Reform

Healthcare in the United States is at a crossroads with intensification of the debate about access and quality of care. Influenza triggers 200,000 hospitalizations and 36,000 deaths in the United States each year. These are significant numbers, which prompt leading governmental agencies, advocacy groups and vaccine suppliers to increase immunization rates.

L.J. Tan, Ph.D., Director of Medicine and Public Health, American Medical Association, and Chair, National Influenza Summit, addressed pressing public policy issues associated with influenza immunization. Dr. Tan also presented options to expand immunization outreach to underserved populations.

Subsequently, Senator Thomas Daschle offered his prescription for reform. A three-term United States Senator, Senator Daschle was the Senate Democratic Leader from 1994-2004. During his tenure in the Senate, he was a central figure in debating President Clinton’s healthcare plan and President Bush’s prescription-drug benefit proposals. He also served as the campaign co-chair for President Barack Obama.

These two opinions offer perspective and a prescription for meaningful change.
CSL Biotherapies: An Unwavering Commitment to Influenza Prevention

CSL Biotherapies of Melbourne, Australia, with U.S. headquarters in King of Prussia, PA, recently marked 40 years of experience in the influenza vaccine market. During those years, the prominence of CSL Biotherapies in the marketplace has grown dramatically. The company now operates one of the world’s largest influenza vaccine production centers for global markets. Our flu vaccines are licensed and sold in 27 countries.

This heritage underpins the company’s strong commitment to safety, quality and reliability that is so critical to customers of influenza vaccines worldwide. In 2002, this commitment was reflected by the complete removal of thimerosal (a mercury-derivative) from the manufacturing process of our flu vaccines. In addition, latex was removed from our vaccine containers.

CSL Biotherapies’ recognized scientific expertise in the early prediction of influenza strain changes allows rapid improvement of our vaccine production to ensure prompt delivery to market. In 2009, CSL Biotherapies is further accelerating access for U.S. vaccine customers by opening a syringe fast-filling line in its state-of-the-art Kankakee, IL manufacturing facility.

We are extremely proud of our standing as a reliable supplier of influenza vaccine to the United States and other countries throughout the Northern Hemisphere. However, at CSL Biotherapies, we understand that our commitment to flu prevention does not stop with the delivery of quality vaccines. To communicate the importance of influenza vaccination, we also provide educational support and patient advocacy assistance.

In spite of these efforts, we still need to improve vaccine access, increase vaccination awareness, counter misinformation about flu vaccines and further prevent the spread of influenza with our existing preventative arsenal.

The CSL Biotherapies team will, therefore, continue to focus on the timely delivery of high quality flu vaccines and on relevant educational programs for vaccine recipients. Through these efforts, we are convinced that we can help stem the spread of influenza throughout the world, preserving health and saving lives.

To learn more about CSL Biotherapies and our seasonal influenza vaccine activities in the United States, visit us online www.cslbiotherapies-us.com
Influenza Vaccination: Ensuring our Future

L. J. Tan, Ph.D., Director, Medicine and Public Health, American Medical Association

Today I am going to discuss public policy issues associated with influenza immunization. In the next few years, we expect major paradigm shifts for providers of influenza vaccines. In order to continue to reduce the mortality and morbidity associated with influenza in the United States, influenza immunization rates must improve through the expansion of the influenza immunization season and continued outreach to those at high risk of complications from infection. To accomplish these goals, the influenza vaccine supply must be stable.

Prior to 2000, there were four manufacturers of influenza vaccine. The market was split fairly evenly among them. However, since the administration fee set by the Centers for Medicare and Medicaid Services (CMS) was $2.50 during that time and increased only to $3 to $5 immediately thereafter, providers and hence, manufacturers, lacked compelling incentives to increase immunization rates. Therefore, even though manufacturers had not yet reached manufacturing capacity, they were not actively promoting policy initiatives to increase influenza immunization rates. Additionally, many providers were losing money by administering influenza vaccinations. Therefore, many refused to offer this essential service.

By 2002 vaccine supplies had dwindled. Concurrently, there was a push to improve immunization rates due to the huge mortality and morbidity associated with influenza. But, as we moved to increase immunization rates, we experienced glitches in supply and distribution. These problems peaked in the 2004 and 2005 seasons. Additionally, we experienced attrition in the industry, and our four manufacturers of injectable vaccine were reduced to only two—Chiron and Sanofi-Pasteur. When Chiron failed to deliver vaccine in 2004, the United States essentially lost 50 percent of its vaccine supply. In 2005, Chiron made a significant effort to reenter the market, but was, once again, unable to deliver timely or adequate quantities of vaccine.

As a result, there was significant uncertainty among distributors and providers about the arrival of influenza vaccines and public and provider frustration when providers could not adequately immunize their patients. The Advisory Committee on Immunization Practices (ACIP) tried to alleviate the situation by making recommendations to prioritize influenza vaccine to high-risk populations, but those recommendations confused the providers even more and may have contributed to decreased immunization rates when providers turned patients away because they were not perceived as belonging to the “prioritized” group.
The good news is that in 2006-2007, through efforts to improve influenza immunization, new manufacturers entered the market, including CSL Biotherapies. During the 2006 season the United States had 120 million doses and in 2007 the country reached 132 million doses. Fees for the administration of the vaccine also increased, averaging about $18.00 nationally.

New quality improvement initiatives focused on manufacturing standards. Health Effectiveness Data and Information Set (HEDIS) compliance measures were established for adults aged 50 to 64. Long-term care facilities formulated standards and offered vaccinations to their healthcare workers while 21 states mandated immunization of residents and healthcare workers in long-term care facilities.

Currently, healthcare worker immunization rates are approximately 40 percent. These rates are unacceptable. In 2007 the Joint Commission implemented Standard IC.4.15, mandating that all Joint Commission accredited facilities must offer influenza immunization to their workers.

Furthermore, those who have chronic illnesses and are, therefore, at a high risk of complications from influenza are also not well immunized. Indeed, the Healthy People 2010 goal, and also that of the National Influenza Vaccine Summit (co-sponsored by the American Medical Association and the Centers for Disease Control) is to achieve 90 percent vaccination among these high-risk individuals. When all these regulations and requirements are instituted across the country, the demand for vaccine will surely increase.

Beyond regulations and requirements, we need to communicate to providers that the traditional paradigm of influenza vaccination is no longer valid in the United States.

What is this traditional paradigm? Providers expect complete vaccine delivery by September or early October, and without it they believe they cannot successfully immunize their patient populations. One reason for this misguided belief is the erroneous assumption that influenza vaccination should occur by Thanksgiving. Vaccination can occur anytime during the flu season. In fact, based on our current healthcare delivery system, if we intend to vaccinate all the people currently recommended to receive influenza immunization, we will need to continue offering immunizations well into January and beyond.

Unfortunately, as a result of this unwarranted desire to receive vaccine early, providers may mistakenly blame the variances in vaccine delivery on preferential distribution. Influenza vaccine distribution is a complex process. Vaccine can be obtained in many different ways. Different distributors adhere to different distribution schedules. Data indicates that preferential distribution is not causing these delays.
Policy makers also need to understand if product is delayed in distribution, prioritizing vaccine to specific patients or providers only exacerbates the problem and increases the delay. In fact, a recommendation to vaccinate a specific population may lead to vaccine wastage because of missed opportunities.

In concert with other policy makers, I have been telling providers that vaccine availability should be addressed at the production level. Distribution problems are best solved by enhancing vaccine manufacturing capacity. We need more vaccine, more manufacturers, more capacity and more production to ensure adequate supply and improve distribution.

We also need to educate providers that supply on the ground will inevitably vary until production levels are increased. After all, influenza vaccine is a biologic product produced differently every year. A manufacturer must go through strain selection and pass both licensure and potency tests. Since this is a complex and difficult process the more manufacturers involved, the more likely we will have adequate supplies in the event one manufacturer encounters production difficulties. Accordingly, it is to the benefit of the United States to have multiple manufacturers of influenza vaccines in the market.

For 2008-2009, ACIP recommends 248 million people receive influenza vaccinations. But immunization rates are low among the poor and among racial and ethnic minorities. We also know that the vaccine doesn’t work as well in the elderly. Thus, we recommend protecting the elderly by cocooning them. That is, vaccinating them and everybody around them, thereby forming a cocoon of protection. To achieve all these important public health goals, we need not only to have enough vaccine, but also to have a stable and reliable vaccine supply. In addition, the AMA believes that annual readiness equates to pandemic preparedness. If we have the capacity to produce, disseminate and administer vaccine to 248 million people in seasonal influenza, we will likely be ready to do the same in the event of a pandemic.

Given these multiple challenges and opportunities, we need to implement three paradigm shifts. First, we need to tell providers the only way to even out distribution of vaccine on the ground is to make more vaccine—increase the United States vaccine production capacity. Also, we need to recognize that additional vaccine doses would continue to arrive through December and probably beyond.

The ACIP recommendation that we vaccinate 248 million people brings us to our second paradigm shift. We need to expand the influenza vaccination season by vaccinating as soon as vaccine becomes available, capitalizing on early doses, and continuing into January and even later. If we are successful in gaining acceptance
As we continue to broaden public access and vaccinate after Thanksgiving, we will need to engage additional providers and utilize additional delivery sites for influenza immunization. Among providers and public for this revised immunization schedule, we will undoubtedly witness increased vaccination rates.

To accommodate the increased demand from expanding the vaccination period, we need to improve vaccine production capacity by increasing the number of influenza vaccine manufacturers in the United States. At the same time, we need to improve production efficiency, enhance the strain selection process, and decrease FDA approval time for completed vaccine lots. If vaccine were available in August and September, immunizers would benefit and be able to vaccinate more people earlier in the season.

Our third paradigm shift is to increase our effectiveness in vaccinating our high-risk populations. Even as we are beginning our push to expand and vaccinate throughout the influenza season, data indicates that many providers now believe they have more time to vaccinate the same high risk patients that they were vaccinating previously. As a result, last season we threw away about 27 million doses, enough vaccine to cover the entire high-risk population that presented at physicians’ offices but were not offered influenza vaccine. This is most likely because providers view an expanded season simply as time to immunize the same patients. Each year they order the same amount of vaccine and stop immunizing patients when it runs out. By not vaccinating everyone who should be vaccinated, we have significant morbidity and mortality and increased health care costs associated with influenza.

As we continue to broaden public access and vaccinate after Thanksgiving, we will need to engage additional providers and utilize additional delivery sites for influenza immunization. Many complementary providers have the ability to reach the 248 million adults recommended for vaccination, and they should be encouraged to do so. If we succeed, we will also succeed in creating an infrastructure to administer pandemic vaccine by engaging these same complementary providers in the event of an emergency.

The ACIP recommendation that all persons who want to reduce the risk of contracting or transmitting influenza should be vaccinated could be interpreted universally. Since most people want to reduce the risk of contracting influenza, perhaps we should be immunizing everyone. However, currently no universal influenza recommendation exists. We still maintain fairly complex recommendations that identify traditional populations for vaccination, namely, pregnant women, those over 50 and adults with specific chronic illnesses. We also have a new recommendation to vaccinate all children up to the age of 18, making it easier to say who should not receive the vaccine.

In closing, I emphasize that influenza can be a serious life-threatening disease. Vaccines are a strong ally in helping people prevent influenza, stay healthy and even stay alive.
Addressing the Healthcare Crisis

Tom Daschle former U.S. Senate Democratic Leader, 1994-2004

First, I want to say I am extremely moved by the CSL Biotherapies and CSL Behring mission and by the impact you have on people’s lives. And I appreciate having the chance to work with you.

Today, I will talk about the future of health policy in the United States. There is a growing chorus, a cacophony of voices, demanding meaningful health care reform. In my book, Critical: What We Can Do About the Health-Care Crisis, I describe the history of the reform movement, what went wrong—especially in the ’90s—and present some ideas about how we might address it. Already the healthcare debate is playing itself out at four different levels. The first is the Congressional level. The second is the state level. In every state, you are seeing various levels of involvement and commitment to health reform. The third is the presidential level. And, finally, we are seeing a tremendous amount of interest at the corporate and business levels.

For all these levels, health reform is gaining greater traction and far greater support than just a few years ago. So there are really two questions. The first question is, have the circumstances since the ’93-’94 healthcare reform experience changed significantly enough? And secondly, do the forces of change now exceed the forces of the status quo? There are a lot of people who currently, for good reason, want to defend what we have. And there are those who believe that even though what we have is profoundly successful in terms of saving human life, the real question is, can the framework within which we operate our healthcare system be improved?

I believe the answer to the first question is yes, circumstances have changed. Cost, access and quality have all been exacerbated. We now spend $7,500 in taxes, premiums and out-of-pocket expenses for healthcare for every person in this country. That is by far the most expensive of any country in the world. It is 40 percent more than the second most expensive country, Switzerland. But that $7,500 is really just the tip of the iceberg because costs continue to grow. It could grow to $15,000 per person. And as healthcare costs continue to escalate, there are real questions about how competitive our businesses can be when a lot of that cost is absorbed at the business level.

Business currently spends about $650 billion on healthcare, which is twice what Germany spent on healthcare last year. In 2007, Starbucks spent more on healthcare...
The real challenge is the extraordinary complexity within our healthcare system. We have virtually no transparency. And as a result of that lack of transparency, we live under a lot of myths.

than they do on coffee. General Motors spent more on healthcare than they do on steel. For most businesses, healthcare is becoming by far the single most expensive aspect of their operation. In 2007, for the first time in history, health costs for Fortune 500 companies actually exceeded aggregate profit. So regardless of which statistics we use, costs have become a very significant part of the healthcare reform debate.

Along with costs, a second issue is quality. Denis Cortese, M.D., CEO, Mayo Clinic, recently pointed out the serious quality problems we face today. For example, if a 747 were to crash in the United States it would become front page news for weeks. But we have the equivalent of a 747 crashing in our healthcare system every day-and-a-half. That many people die as a result of medical errors. And it is really remarkable that little, if any, information is ever provided to the American people about the cause.

But it is not just the number of medical errors or the number of deaths that we have to be concerned about with regard to quality. It is the overall problem we have with delivery itself. Even though the U.S. spends more on healthcare than any other country, the World Health Organization ranked the U.S. 37th in delivery, just above Slovenia and just below Costa Rica, 31st in life expectancy, and 29th in infant mortality. These are serious quality questions that we need to address.

The third issue is access. We have 47 million people with no insurance. But that is just a part of the story. Of those with insurance today, last year 37 percent did not receive the healthcare they needed because the insurance they had was inadequate. Sixty percent of the people in this country do not have dental insurance. Eighty percent do not have mental health insurance. And 95 percent do not have long-term health insurance. So even those of us who may feel we have adequate insurance assume that not having mental health or long-term health or dental health insurance is the way it ought to be; that is a given. I do not think we ought to accept that.

Access is an issue of insurance, but it goes beyond that. Every year 500,000 ambulances are turned away because of inadequate capacity in our emergency rooms. And in rural areas, we have extraordinary provider shortages. The life expectancy on Pine Ridge Indian Reservation for an Indian male today is 47 years, approximately what it is in Botswana. And so regardless of whether one looks at cost, access or quality, the value that the American people are getting today in their healthcare system needs to be addressed. And that is really what healthcare reform is all about.

The real challenge is the extraordinary complexity within our healthcare system. We have virtually no transparency. And as a result of that lack of transparency, we live under a lot of myths. One myth is that we have the best healthcare system in the
world. Well, how can we have the best healthcare system in the world with the outcomes and costs I have presented? We have what I would call islands of excellence. The Mayo Clinic and Johns Hopkins University, among teaching hospitals, and CSL Biotherapies in the biotherapeutics industry, these are extraordinary demonstrations of islands of excellence. But they exist in a sea of mediocrity.

There is also a myth that we really do not ration healthcare in this country, but other countries do. I think we ration it in the most irresponsible way. We do it on the basis of economics or pre-existing conditions. Oregon has done it in yet another way—by lottery. There are about 600,000 people in Oregon who are both uninsured and ineligible for Medicaid. Oregon could not afford to provide insurance for those 600,000 people so they started a lottery. Every year the state picks 24,000 winners to get healthcare. So if you are lucky enough to win the lottery in Oregon, you are lucky enough to get health insurance for that particular year.

There is obviously a lot of myth involving cost. Will the new system cost more? And if that is the case, where will the money come from? The answer is there is absolutely no reason why a new system needs to cost more. If it is designed appropriately, with the following ten building blocks in place, the new system will cost less, not more.

The first building block would be universal coverage. Universal coverage, with cost-containment systems in place, would provide us with efficiencies of scale that would allow us to eliminate all pre-existing conditions and access problems.

Second is complete care. Instead of segmenting or stove-piping healthcare the way we do today, we should integrate physical, mental, dental and long-term care in our healthcare delivery mechanism.

Third is wellness. We need to emphasize prevention and wellness administered through primary care physicians. If a healthcare system is structured like a pyramid with wellness at the base and the most sophisticated care at the apex, most societies administer healthcare from the base upward, not from the apex downward.

Fourth is transparency. Transparency in billing, transparency in overall quality, transparency in the degree to which healthcare is provided in any given community. This may be one of the most difficult political issues for the country to face.

Fifth is the use of best practices. We need to acquire best practices, especially in chronic care management, where most of the money is now spent. Best practices would make doctors immune from lawsuits and the need to pay exorbitant fees for
In order to reduce bureaucracy and improve decision making, we need to take the infrastructure from other sectors of our economy and apply it to healthcare. A health court would compensate those who were injured due to mistakes made in spite of the application of best practices. But doctors would no longer have to worry about defensive medicine.

Sixth is the acquisition of information technology. We spend 30 cents out of every dollar on administration in our healthcare system today. This is twice or even three times what is spent in other countries.

Seventh is the application of the Federal Employee Health Benefits Plan. This plan would pool resources in a system like we use in Congress.

Eighth, proprietary medicine needs to be addressed. Providers who own their own clinics or equipment are put in a difficult position when they need to decide about appropriate use.

Ninth, we need to use providers appropriately. We do not use nurses or alternate providers enough. We also have to encourage medical schools to teach primary care medicine more effectively and offer primary care providers better incentives.

And the tenth is the most critical of all. In order to reduce bureaucracy and improve decision making, we need to take the infrastructure from other sectors of our economy and apply it to healthcare. We need an autonomous decision-making authority or management board that would integrate the public and private systems. Today 45 percent of the American people get their healthcare from a government program while 55 percent get it from the private sector, but these systems are not integrated. If we were to apply the Federal Reserve model from our monetary system to healthcare, we would reduce bureaucracy and make better and timelier decisions. This would create more value, reduced costs, increased access and better quality.

How do we accomplish this? Politically, we need to emphasize cost reductions, coalition building and delegating details to a management board. We also need to stay on the offensive and stay focused. And, finally, we need leadership.

Nelson Mandela, one of my heroes in public life, is fond of using the following phrase: “Many things seem impossible until they are done.” Healthcare reform has always seemed impossible. But one of these days it will be done.
About the Participants

L.J. Tan, Ph.D.

Director of Medicine and Public Health, American Medical Association

L.J. Tan is Director of Medicine and Public Health at the American Medical Association. Until 2005, he was also a part-time faculty member at Columbia College’s Institute for Science Education and Science Communication. He received his M.S. in Molecular Biology from New York University, his Ph.D. in Immunology/Microbiology from Northwestern University Medical School, and completed a postdoctoral fellowship in Molecular Immunology at the University of Chicago Hospitals.

He currently serves as a member of the Scientific Advisory Board for the Immunization Action Coalition and the Coalition for Safe Needle Disposal, of the Advisory Committee for Immunization Practices (ACIP), of the Advisory Council for the Elimination of Tuberculosis (ACET), of the Steering Committees for the National Viral Hepatitis Roundtable, Voices For Vaccines, the 317 Coalition, and the Partnership to End Cervical Cancer (and on the Board for its Foundation).

He also chairs the National Influenza Vaccine Summit, co-sponsored by the AMA and the CDC, and recently organized the first National Immunization Congress. He serves on the technical advisory panel for the Joint Commission’s project on evaluating use of rapid influenza testing in outpatient settings.

He has served on numerous expert infectious disease and immunization panels and also speaks at different national meetings and media conferences. L.J. is a member of numerous professional organizations including the American Society of Microbiology, the American Association of Immunologists and the Infectious Diseases Society of America.

He lives in Oak Park with his wife, Lara, also an immunologist, three children and one dog.

Senator Thomas A. Daschle

Senior Policy Advisor, Alston+Bird LLP

Senator Tom Daschle is Special Public Policy Advisor in Alston & Bird’s Washington, D.C. office and is a member of the Legislative and Public Policy Group. As a non-attorney, Senator Daschle focused his services on advising the firm’s clients on issues related to all aspects of public policy with a particular emphasis on issues related to financial services, health care, energy, telecommunications, taxes, trade and international matters.

With more than 25 years of service in the House of Representatives and the Senate and ten years as Senate Democratic Leader, Senator Daschle has played an instrumental role in the development of U.S. legislative and regulatory policy.

Born in Aberdeen, South Dakota, Senator Daschle attended South Dakota State University and graduated in 1969.

Following college, he served for three
years as an intelligence officer in the U.S. Air Force Strategic Command. After military service, he spent five years as an aide to South Dakota Senator James Abourezk.

In 1978, he was elected to the U.S. House of Representatives, serving eight years. In 1986, he was elected to the U.S. Senate and two years later, became the first Co-Chairman of the Senate Democratic Policy Committee and the first South Dakotan to be elected to a leadership position in the U.S. Congress. In 1994, Senator Daschle was elected by his colleagues as their Democratic Leader. Senator Daschle is one of the longest serving Senate Democratic Leaders in history and the only one to serve twice as both Majority and Minority Leader.

In 2007, he joined with former Majority Leaders George Mitchell, Bob Dole and Howard Baker to create the Bipartisan Policy Center, an organization dedicated to finding common ground on some of the pressing public policy challenges of our time. He is also Co-Chair of the ONE Vote ‘08 Campaign, along with former Senate Majority Leader, Bill Frist, to address health and poverty in the developing world in a more aggressive and successful way.

He has published articles in numerous newspapers and periodicals, and is the author of the books Critical: What We Can Do About The Health-Care Crisis and Like No Other Time. He holds a number of honorary doctorate degrees.

About CSL Biotherapies

CSL Biotherapies is a subsidiary of CSL Limited which operates one of the world’s largest thimerosal-free flu vaccines manufacturing facilities for supply to global markets. CSL Limited has more than 80 years of experience in the development and manufacture of vaccines, with 40 years in flu vaccines. The focus on products for the prevention and treatment of serious diseases allowed CSL to play a key role in the collaborative work that delivered the world’s first vaccine against cervical cancer. In 2007, CSL Biotherapies’ seasonal influenza vaccine was licensed by FDA. In 2008, CSL Biotherapies received approval from the Australian Therapeutic Goods Administration for the first pandemic avian flu vaccine in Australia.