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S. HRG. 111–595

THE COST OF BEING SICK: H1N1 AND PAID SICK DAYS

HEARING

BEFORE THE

SUBCOMMITTEE ON CHILDREN AND FAMILIES

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

ON

EXAMINING H1N1 AND PAID SICK DAYS

NOVEMBER 10, 2009

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: http://www.gpoaccess.gov/congress/senate

U.S. GOVERNMENT PRINTING OFFICE

53–648 PDF WASHINGTON : 2010

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

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THE COST OF BEING SICK: H1N1 AND PAID SICK DAYS

TUESDAY, NOVEMBER 10, 2009

U.S. SENATE,
SUBCOMMITTEE ON CHILDREN AND FAMILIES,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:35 a.m. in Room SD–430, Dirksen Senate Office Building, Hon. Christopher J. Dodd, chairman of the subcommittee, presiding.

Present: Senators Dodd, Murray, Casey, Hagan, Merkley, and Enzi.

OPENING STATEMENT OF SENATOR DODD

Senator DODD. Order.

Let me welcome all of you here this morning for this hearing. I am delighted to see such a good turnout this morning, and some wonderful people that we're going to hear from as our witnesses here to talk about the Healthy Families Act and the related matters affecting H1N1 flu, as well. Let me thank everyone for being here. We meet in the midst of an American emergency. According to the Centers for Disease Control, H1N1 flu has reached to 48 States and affected as many as 5.7 million Americans. Overall, 672 Americans have died, including at least 129 children.

In my State of Connecticut, along with my first witness, Congresswoman DeLauro, our State, and across the country families are anxious about this pandemic and are frustrated that vaccines remain unavailable even to pregnant women, schoolchildren, and the elderly. For those at greater risk, H1N1 represents a serious health threat that forces changes in daily routines. I hope, by the way, that today we can finally get some answers for the folks who have asked me—and, I'm sure, many others—why it is taking so long to produce enough vaccines.

But, I've called this hearing today because the impact that a pandemic like H1N1 cannot be solely measured by the number of people infected or the tragic lives that are lost. H1N1 is causing an emergency for workers and families across our country, as well. Again, in my State of Connecticut, we have had at least 10 schools close. We've even had entire school districts close. Some 600 schools across the country have closed their doors for at least some period of time. This, in turn, forces, of course, working parents to care for sick children or find ways to ensure that children whose schools have closed are supervised.

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Yesterday, I hosted a roundtable discussion in Connecticut on H1N1. A woman by the name of Jane Grady from Middletown, CT, told me about one Monday when she got a call from her school that more than 350 children were sick and another 100 got sick during that day. When she came to pick up her son, as she described it, it looked like an emergency room in a hospital.

Meanwhile, small businesses, of course, are losing productivity because of worker illnesses. And for the 57 million private-sector workers who do not have paid sick leave available, coming down with H1N1 means you have to make a choice; either you go in to work sick and risk infecting your co-workers or stay home and lose, of course, a very important day's pay.

The Center for Disease Control has strongly recommended that you stay home until your fever has ended, and for at least another 24 hours after that. This isn't just a workers' rights issue, it's a public health emergency. Families shouldn't have to choose between staying healthy and making ends meet. But, if staying home means you don't get paid, that's an impossibility, especially for families struggling to make ends meet in this very tough economy. The more infected Americans who go to work, the more Americans who will be exposed to H1N1.

According to the CDC, an individual who comes to work with H1N1 will infect 10 percent of his or her coworkers. That's worth repeating. According to the Center for Disease Control, an individual who comes to work with H1N1 will infect 10 percent of his or her coworkers. What's troubling is, more than three-quarters of food service and hotel workers do not have paid sick days. Childcare, retail, nursing home workers are also less likely to have paid sick days. Some 80,000 school cafeteria workers cannot stay home when they are sick, and they come to work to serve approximately 10 million schoolchildren every day.

I'm told virtually 100 percent of schoolbus drivers are without paid sick leave across the country. Now, that number maybe not quite 100 percent, but that's the number I've been given, it's close to 100 percent. This is simply dangerous, for all of the obvious reasons.

Those most in need are also the least likely to have paid sick days. Only one in four low-wage workers have paid sick days, and they're often most likely to have jobs requiring frequent contact with the public. According to the Bureau of Labor Statistics, only 22 percent of the lowest-income workers have paid sick days, compared with 86 percent of some of the highest 25 percent of wage earners.

I'm introducing emergency legislation to help keep Americans safe from the H1N1 virus. The bill that I introduce will guarantee paid sick days that workers can use to take care of themselves and loved ones if they are affected by H1N1 or seasonal flu. Workers should have paid sick leave as a matter of basic fairness, in my view.

The FMLA, the Family Medical Leave Act, was an important step toward helping people balance work and family. For those who still have to make that impossible choice every day, and so many do, it's not nearly enough. That's why 145 nations around the globe guarantee paid leave, and why our friend, Senator Ted Kennedy,

introduced the Healthy Families Act almost 7 years ago, in 2003 or 2004, along with Congresswoman DeLauro, to guarantee it to workers in this country, and why I'm very proud to carry that legislation forward in his name and the name of Congresswoman DeLauro.

Now sick leave is a matter of keeping Americans safe from this pandemic, and from the next one or whatever it may be. Experts estimate that if workers simply followed the CDC guidelines and stayed home, the number of people affected by pandemic flu would be cut by up to one-third. If paid sick leave had been the reality when this pandemic began, we would be in far better shape across the Nation.

So, I want it in place immediately to help parents and workers, and I want it in place before the next pandemic, which will come. I guarantee it will. And once again we'll be sitting here asking ourselves the same questions once again. It's a matter of fairness for workers, in my view, and it's a matter of safety for all others.

I welcome our witnesses this morning, and thank them for their time, and hope that we can help families not only in our individual States, but across the Nation, who are worried about this pandemic and anxious for some answers.

Our first witness is Congresswoman Rosa DeLauro, who is no stranger, having worked with me a number of years ago as my chief of staff in the U.S. Senate when I first came here. She knows this side of the Hill as well as anyone, and has been a remarkable Member of Congress now for a number of years, and has been the author of this legislation on the House side for many, many years

Rosa, it's a pleasure to have you back in the committee.

Ms. DELAURO. Thank you.

Senator DODD. You used to sit on this side, back here.

Ms. DELAURO. I did, indeed, Senator. Senator Enzi, it's a pleasure to see you this morning. If you just bear with me, what a wonderful opportunity for me to be able to testify before the subcommittee today.

Senator DODD. I'm going to have Mike Enzi make an opening——

Ms. DELAURO. Fabulous.

Senator DODD [continuing]. Statement.

Ms. DELAURO. Go ahead, Senator.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. I would have been happy to wait until——

Senator DODD. No, no, no.

Senator ENZI [continuing]. Others gave theirs, but, in keeping with the tradition—Mr. Chairman, today Americans across the country are trying to protect themselves and their families from the threat of the flu pandemic that's threatening the lives of children and pregnant women around the world. Yet, when they show up at the doctor, they're being told that there are no more vaccines and that due to shortages in supply, they'll have to be put on a waiting list until the next shipment arrives. Mr. Chairman, they're learning that their government has failed to prepare the country for the threat of a flu pandemic that was foreseeable and preventable, with better coordination and preparedness.

The 2009 H1N1 virus was first detected in Mexico in March 2009; a month later, in the United States; today it's spread to 48 States including my home State of Wyoming. Yet, most Americans who want to protect themselves by vaccination have been left in the lurch and told that a supply of vaccines may not even be available before the pandemic is over.

Now, in light of the bill that we're considering, some employers might wonder if the vaccine isn't there, shouldn't the Federal Government reimburse the employer for the time that he has to provide paid sick leave, and perhaps even the parent be reimbursed for the inconvenience?

I do have to mention a good program that's happening in my State. One of the problems people face is when you have your child in daycare, and they get sick. They don't want to infect the rest of the daycare ones, so the parents have come and pick them up. In Gillette, WY, the hospital has a sick-child daycare, where you can then take your child, and they'll get care, as well as being taken care of during the day. I think it's a rather innovative approach to it.

This summer, the Administration promised Americans that 80 to 120 million doses of the vaccine would be distributed by mid-October, yet here we are a month past that deadline, and only 36 million doses are available. As for the doses that are available, the Administration appears to be taking inadequate precautions to ensure fair and appropriate distribution. The media's full of stories of vaccines going to populations that don't fit the high-risk profile, such as terrorism suspects being held at Guantanamo Bay, instead of those populations at risk, such as small children and pregnant women.

With death tolls rising and almost no access to the vaccine, it's no wonder that we're concerned. Every person left unvaccinated is an opportunity for H1N1 to spread exponentially and to mutate into a more deadly strain.

I'm pleased that we have a representative of the Center for Disease Control here today to shed light on what's gone wrong and to tell us what improvements can be made. I also want to welcome Dr. Scott Gottlieb to the committee today to discuss some of the policies that have contributed to the vaccine shortage and provide recommendations for ways to improve our response to pandemic flu in the future.

Some of these issues include the decision of the Department of Health and Human Services to order single-dose instead of the more efficient multidose vials. Multidose vials are produced more quickly and can out-produce single dose vials 10 to 1. We have also yet to approve the use of adjuvants in flu vaccines, which decrease the amount of vaccine needed in a single dose, which would allow us to vaccinate more people with the same amount of vaccine. Adjuvants are currently used in the flu vaccine sold in Europe, but not yet approved for use in flu vaccines in the United States.

Another shortfall we face is regarding the production process. Today the United States still depends on chicken eggs for their vaccine production. All other nations are using more advanced cell-based manufacturing processes that are not dependent on a supply of eggs and can more quickly increase vaccine production. One way

the Federal Government can improve our production capability is through increases in funding for BARDA. We also need to approve the cell-based manufacturing process for the flu vaccine so that manufacturers will not need to wait for FDA approvals the next time our Nation faces the threat of a pandemic flu.

It is imperative that the United States increase its capabilities to produce better technology that will increase our preparedness in the future.

Today's hearing will focus on the impact that H1N1 has on sick and healthy Americans every day, but let us not lose sight of the opportunity for Congress to learn from this experience and continue to force our Nation to increase our preparedness capabilities.

The alarm that the H1N1 virus has raised in many households also translates to our workplaces. Employers recognize that an outbreak of the epidemic among their employees could shut down a business for weeks and longer. And in the absence of widespread access to the vaccine, they're taking steps to protect their employees. They're providing information about flu prevention, hand sanitation tools, and similar products. They're preparing for telecommuting and running their operations with smaller staff.

One of today's witnesses, Ms. Elissa O'Brien, will testify about her company's vigorous H1N1 flu prevention efforts. Her company has also adopted a leave policy which generously provides a starting level of 26 days of paid leave and short-term disability coverage, enough to accommodate the flu needs of every employee, but which would be up-ended if the one-size-fits-all Healthy Families Act became law.

Reading through her testimony, I was reminded that Washington does not have a monopoly on good ideas, and that whenever we act prescriptively, we also decrease flexibility and creativity. What works in one place of business may not work in another. And what we inflexibly mandate may not be best for all.

I think sometimes Congress has a union mentality that the employer is out to hurt the employee, and the mistaken idea that they won't do the right thing unless they're forced to.

As we all remember, the Healthy Families Act was a priority of our late chairman, Senator Kennedy. Before I entered public service, I was a small-business owner, so I'm speaking from experience when I say the goal of the legislation is something we all share. In a small business, employees are like family members. The smaller the business, the more like family members.

Employers know that if they want to attract and keep good employees, they must give them the flexibility they need to care for their own health and their loved ones. Indeed, in the most recent member benefit survey conducted by the Society for Human Resource Management, some 86 percent of the respondents reported that their companies provided sick leave either under a separate sick leave program or as part of a general paid-time-off plan. Over 80 percent of the respondents also indicated they provide both short-term and long-term disability insurance coverage, and an increasing number utilize even more creative approaches, such as paid time off and sick leave banks or pools.

The beauty of these creative approaches is that they're responsive to the needs and wants of employees, the changing costs of

providing different benefits, and the ability of the employer to provide such benefits while staying in business. I remember lots of times, when I was in business, that you'd have that "sit up in the middle of the night and wonder how you're going to make payroll the next day." You never considered laying off people. That was absolutely a last choice. Sometimes you did without in order to be able to pay them.

In contrast, the type of leave mandate by this and similar bills would create complete inflexibility. It also would add to the practical problems human resource officers deal with every day by importing intermittent leave and medical verification rules which have proven problematic in other statutes.

In addition, this bill provides no deterrents for abuse of the leave entitlements, and raises privacy concerns, two issues that employers have found innovative ways to resolve in the absence of a mandate. Most employers provide sick leave benefits both because they know that a healthy workforce benefits their business, and because they know that in a competitive labor market, they must address this issue to attract and retain quality employees.

Today, the average cost of employee benefits for all employers in the private sector is nearly $8.02 an hour. Average benefits now comprise 30 percent of total payroll costs. While the number of employers finding ways to provide paid leave as part of their benefit package continues to increase, there are some employees who do not have paid sick leave available to them at their place of work. The bulk of these individuals are employed by smaller employers who, especially in the challenging times like these, are struggling to maintain current payrolls. And that's getting harder and harder.

Friday's job numbers showed we lost another 190,000 jobs last month, and the unemployment rate reached a 26-year high of 10.2 percent.

Hitting small business and startups with new costs and unfunded mandates is never advisable, and it's even more irresponsible during a time when job creation should be a top priority.

I notice that whenever we hold a hearing on small businesses, I'm always asked by the media, "How come more small businesses didn't show up?" I know the reason for that. It's that if they had an extra employee so that they could come and listen to a hearing, they'd fire one person, because they'd have one too many people. They just don't have any extras, so the flexibility isn't there that's in the bigger businesses.

It's a simple fact, whenever we impose unfunded mandates on employers, the money necessary to pay those increased costs must come from somewhere. They can't just print it, the way Washington does. No matter how desirable the goal, one cannot simply dismiss the cost as unimportant or inconsequential.

Here, the costs are decidedly not inconsequential, particularly for the smaller businesses. The pool of available labor dollars is not infinite, and when we mandate their expenditure for a specific purpose, we always run the risk of unintended consequences, such as adding to the growing pool of unemployed workers.

A dollar that must be spent here often results in a dollar that will not be spent elsewhere. Imagine the irony of an employee

who's granted sick leave under this bill, but whose employer decides to eliminate or reduce health plan benefits.

The H1N1 pandemic has raised concerns for Americans looking to protect themselves and their families, as well as for employers seeking to keep their businesses going and their employees healthy. These concerns, however, are layered on top of the economic worries that have recently plagued us and the unemployment numbers, which continue to rise. Now, more than ever, we should be lifting up America's small businesses where the growth starts and create sustainable jobs. This is not the time to compound problems. Small businesses are facing another unfunded, inflexible mandate from Washington.

I thank the Chairman and look forward to hearing from the witnesses.

Senator DODD. Well, I thank you, Mike, for that statement.

We're now going to ask for the Congresswoman to express some views.

I should have pointed out, Rosa has been a Member of Congress since 1990, and it seems like only yesterday, when you were sitting here and introduced the Healthy Families Act, 5 years ago, same time Senator Kennedy did, as well. You've been a tireless advocate on behalf of working families.

Thank you. Your testimony and any supporting documents, Congresswoman, will be included in the record.

STATEMENT OF HON. ROSA L. DELAURO, U.S. REPRESENTATIVE FOR CONNECTICUT

Ms. DELAURO. Thank you very much, Mr. Chairman. I might just say, it was in 1990 that I had the pleasure of having you stand next to me as I campaigned for this job. So much, much appreciated. As I say, I'm grateful to see you, Senator Enzi, this morning, delighted to come before this committee.

I have wanted to say something when the Senator—Senator Enzi didn't speak first, because there's always that sense, as a staff person—you know, I was a staff person for so many years, so I sympathize with the folks behind the chairs there. Once a staff person, always a staff person.

I am so grateful to be here today. And to you, Senator Dodd, I want to just say it, because I did have the opportunity of working with you as you put together—which was a fundamental change in public policy in the United States at a time when most people were not thinking about the problems and the concerns of working families, and that produced the Family Medical Leave Act. It also produced the Childcare Development Block Grant and other countless measures that have helped American workers and their families. As I say, it was groundbreaking and visionary public policy to meet the needs that people were facing in their lives, and we are all grateful to you for that effort.

Today, I speak not only of a issue of basic fairness, but one of growing importance to our economy, particularly given the experience with the H1N1 virus this year, and an issue to which my friend and your colleague, the late Senator Kennedy, was passionately committed to, and that is paid sick days.

I believe that paid sick days are a basic question of right and wrong, as Senator Kennedy did. Yet, as you pointed out, Senator Dodd, unlike 145 other nations, including 19 of the 20 most economically competitive countries in the world, that is to say everyone but us, everyone but the United States, does not guarantee a single paid sick day to workers. Not one day. The Family and Medical Leave Act, which covers 60 percent of the workforce, is, as we all know, unpaid leave. As such, right now 57 million Americans cannot take time from work when they are sick or when they need to stay home to care for an ailing child or an elderly relative. And yes, it is a good thing to have a program that takes care of sick children while you're working. I think we all know, and we could talk to the medical profession, about how much quicker kids recover from an illness if they have their parent or parents with them as they're going through whatever the illness is.

In fact, almost half of all private-sector workers—79 percent of low-income workers—do not have a single paid day off.

The numbers are particularly galling in the food service industry, where only 15 percent of workers have paid sick days. Food service is not an industry where we want employees showing up to work with contagious viral infections. All of these workers are forced to put their jobs on the line every time they take a day off.

According to a 2008 study, one in six workers report that they or a family member had been fired, suspended, punished, or threatened with firing for taking time off due to personal illness or to care for a sick relative. This is unacceptable. It goes against who we are as a Nation.

Even if you do not agree that providing paid sick days is a question of basic American values, there is more to the issue. Establishing paid sick days is also about economic competitiveness, income security for families, and, as HINI has proved to us this past year, primarily the public health. In fact, presenteeism, the practice of coming to work sick, costs our national economy more than it would cost to provide paid sick days. According to one study, $180 billion is lost annually; meaning that right now employers pay an average of about $255 per employee per year in lost productivity, more than the cost of absenteeism and medical and disability benefits.

The argument that we cannot afford to institute paid sick days right now does not hold water. In fact, the opposite is true. Passing paid sick days would boost productivity.

For all of these reasons and more, Senator Kennedy and I first introduced the Healthy Families Act, 5 years ago. Our bill would require employers with 15 or more workers to provide 7 days of earned paid sick leave annually for their own medical needs or to care for a family member. For every 30 hours worked, a worker earns 1 hour of paid sick leave. It's up to a maximum of 56 hours. That's 7 days.

We re-introduced the bill last May. We have 120 cosponsors in the House, 21 cosponsors in the Senate. The legislation is supported by a broad coalition of over 130 State and national groups, including the National Partnership for Women and Families, the American Association of University Women, MomsRising, and Business and Professional Women.

Paid sick days has always been a good and common sense idea. But, in light of the recent H1N1 epidemic, it has also become a necessary one. Since H1N1 was first diagnosed and the dangers posed by widespread infection have been recognized, we have seen countless public health officials, even the President of the United States—they're on the television, they're on the radio to ask folks to follow a simple guideline: If you get sick, stay home from work or school, limit contact with others to keep from infecting them.

Well, it may be all right for the President and others to be on TV saying that that's what folks ought to do. Yet, following this critical advice is virtually impossible for far too many Americans right now. The President has wisely called a national emergency to deal with H1N1, but in this economy too many workers cannot answer the call. When more and more workers are feeling economically vulnerable and afraid to even miss 1 workday, we face an extraordinarily serious health risk that spreads much more quickly if the sick do not stay at home.

Which is why I'm happy to be working with you, Mr. Chairman, on emergency legislation that will address the need to act now on this issue. Our emergency legislation would reflect the core principles of the Healthy Families Act. It would allow workers, not employers, to decide when they are too sick to work and when they are healthy enough to return. It would cover caregiving, so that parents can stay home with sick kids without risking their family's economic security. It would provide job security for workers who are too sick to come to work.

Passing the Healthy Families Act or emergency legislation that reflects its core principles would finally give American workers and their families the freedom to care for themselves or a sick relative when they need to. It would save employers money, encourage productivity, help to boost our economy. Most importantly, right now it would protect the public health by helping to stop the spread of dangerous viral infections like H1N1.

I hope that we, in the Congress, can honor Senator Kennedy's legacy by finding the strength and the will to get this legislation passed for America's workers and families. They have already waited too long.

I thank you again for the opportunity to be here this morning to testify.

[The prepared statement of Ms. DeLauro follows:]

PREPARED STATEMENT OF HON. ROSA L. DELAURO

Good morning. Thank you, Chairman Dodd, for the opportunity to testify before the subcommittee today, and for all your leadership on behalf of the American people. Through your hard work and tireless advocacy, we now have the Family and Medical Leave Act, the Child Care Development Block Grant, and countless other measures that help American workers and families. I thank you for your continued commitment to this cause.

I speak today not only on an issue of basic fairness, but one of growing importance to our economy, particularly given our experience with the H1N1 virus this year. And an issue to which my friend and your colleague, the late Senator Kennedy, was passionately committed: paid sick days.

I believe that paid sick days are a basic question of right and wrong, as did Senator Kennedy. Yet, unlike 145 other nations, including 19 of the top 20 most economically competitive countries in the world—that is to say, everyone but us—the United States does not guarantee a single paid sick day to workers—not one day.

The FMLA, which covers 60 percent of the workforce, is, as we all know, unpaid leave.

As such, right now 57 million Americans cannot take time off work when they are sick, or when they need to stay home to care for an ailing child or elderly relative. In fact, almost half of all private sector workers—and 79 percent of low-income workers—do not have a single paid day off. The numbers are particularly galling in the food service industry, where only 15 percent of workers have paid sick days. Suffice to say, food service is not an industry where we want employees showing up to work with contagious viral infections.

All of these workers are forced to put their jobs on the line every time they take a day off. According to a 2008 study, one in six workers report that they or a family member had been fired, suspended, punished or threatened with firing for taking time off due to personal illness or to care for a sick relative.

To my mind, this is completely unacceptable. It goes against who we are as a nation. But, even if you do not agree that providing paid sick days is a question of basic American values, there is more to this issue. Establishing paid sick days is also about economic competitiveness, income security for families, and, as H1N1 has proved to us this past year, primarily the public health.

In fact, "presenteeism"—the practice of coming to work sick—costs our national economy more than it would cost to provide paid sick days. According to one study, $180 billion is lost annually, meaning that, right now, employers pay an average of $255 per employee per year in lost productivity, more than the cost of absenteeism and medical and disability benefits. So, the argument that we cannot afford to institute paid sick days right now does not hold water—In fact, the opposite is true: passing paid sick days would boost productivity.

For all of these reasons and more, Senator Kennedy and I first introduced the Healthy Families Act 5 years ago. Our bill would require employers with 15 or more workers to provide 7 days of paid sick leave annually for their own medical needs or to care for a family member.

We re-introduced the bill last May, and have almost 120 co-sponsors in the House and 21 co-sponsors in the Senate. This legislation is also supported by a broad coalition of over 130 State and national groups, including the National Partnership for Women and Families, the American Association of University Women, Moms Rising, and Business & Professional Women.

Paid sick days has always been a good, common sense idea, but, in light of the recent H1N1 epidemic, it has also become a necessary one. Since H1N1 was first diagnosed and the dangers posed by widespread infection have been recognized, we have seen countless public health officials, and even the President, take to the airwaves to ask folks to follow a simple guideline: If you get sick, stay home from work or school and limit contact with others to keep from infecting them.

And yet, following this critical advice is virtually impossible for far too many Americans right now. The President has wisely called a national emergency to deal with H1N1, but in this economy, too many workers cannot answer the call. In fact, the convergence of a deadly contagion like H1N1 spreading in this economic climate could well be catastrophic. Right when more and more workers are feeling economically vulnerable and afraid to even miss 1 workday, we face an extraordinarily serious health risk that spreads much more quickly if the sick do not stay at home.

That is why I am also happy to be working with the Chairman on emergency legislation that will address the need to act now on this issue. Our emergency legislation would reflect the core principles of the Healthy Families Act. It would allow workers, not employers, to decide when they are too sick to work and when they are healthy enough to return. It would cover care-giving, so parents can stay home with sick kids without risking their family's economic security. And it would provide job security for workers who are too sick to come to work.

Passing the Healthy Families Act, or emergency legislation that reflects its core principles, would not only do right by American workers and families, and finally give them the freedom to care for themselves or a sick relative when they need to. It would save employers money, encourage productivity, and help boost the economy. And, most importantly right now, it would protect the public health by helping to stop the spread of dangerous viral infections like H1N1.

It would also give us one more chance to honor the life's work of a true champion of working people, Senator Kennedy. I wish he could have been here today to help make this case. He cared very deeply about this issue, and I know his passion and his eloquence would have steered us all to action. Now that he has left us, I very much hope we in Congress can honor his legacy once more, by finding the strength and the will to get this legislation passed for America's workers and families. They have already waited too long.

Thank you.

Senator DODD. Well, Congresswoman, thank you very, very much. Once again, eloquent testimony, and well researched, as well. We thank you for your commitment, going back so many years, on this issue.

I always, at times like this, like to thank colleagues, as well. Dan Coats and Kit Bond, who were my cosponsors of the Family Medical Leave Act, in a bipartisan effort in those days. Orrin Hatch was my cosponsor on the Childcare Development Block Grant Program, going back 25 years ago, now, in those areas.

We exempt, of course, a lot of small businesses, because obviously—and I agree with Senator Enzi in that point, that when—the smaller the business, the greater the likelihood there's an understanding; as the numbers grow larger, they become far more difficult for people to accommodate those concerns and interests.

The statistic in my own opening statement, that still sort of stunned me when I kept on reading it over and over again—the fact that a person with H1N1 going to work, according to the CDC, could contaminate or affect 10 percent of that person's workforce, is rather breathtaking. So, beyond the question of the impact, obviously, the idea that we would allow a situation to persist that poses that much of a threat to our country—and we're going to get these over and over again. Now, this is—we'd like to think these are rare occasions. I only wish they were. But, the reality of our world in which we live today is that these kinds of issues will happen with great frequency. We need to get smartened up and realize it's here, and begin to deal with it in a comprehensive fashion, or we're going to find ourselves stumbling through these issues, year after year, without having the kind of national policy as to how we address these questions.

We've always talked about a sick person in the family, or you being sick—today we're looking at at least 600 school districts closed across the country, or the ones we've had in our home State of Connecticut. A lot of cases, that child that's leaving school is not sick, you're not sick—so, we talk about, normally, whether—when someone is ill. We've got a new situation emerging. Today, with so many parents both holding jobs, there isn't anyone at home. The neighborhoods that we grew up in—I certainly did in the 1950s and 1960s, where there was always someone around there who could take on the responsibility, there was always the next-door neighbor, there was always the aunt, there was the grandparent, all those things—that's a bygone era. They don't exist anymore. They're not there, in most neighborhoods.

When you're coming back, and your child all of a sudden is being told, "Go home," there isn't anyone home. As Jane Grady pointed out yesterday, when you've got an 11-year-old, and you're sending him home, where there's no one there. These situations demand far more creative thinking than we've been able to provide. Well, we're going to find more serious problems with it.

Anyway, you've answered the question, to some extent, in your testimony but, the question is, How can the need for paid sick days, that we're seeing during the H1N1 situation, point to a need for a broader Federal policy? That's one question I'd ask you to address.

And, second, this notion, again, that, in a competitive environment, where we're going to—we now spend three times that of our major global competitors, economically, to run healthcare, and obviously to a significant disadvantage as we try to compete globally in a more competitive global economy. The fact that we're in the company—and I say this respectfully of these countries, but Lesotho, Liberia, Papa New Guinea and Swaziland——

Ms. DELAURO. They can do it.

Senator DODD [continuing]. Those are the four other countries that we're—and the United States—the fifth. Those are the five countries that don't have paid sick leave in the world. That's nice company—that say this—five nations, four of whom are struggling economies, barely surviving as nation-states, along with the richest, most affluent country in the world. The arguments we hear about this are the one's we've heard historically. When it comes to work hours, occupational safety standards, it's always the same argument, in a sense. We would be in a very different place in this country had we not had the imaginative and forceful legislation of Senator Kennedy and others over the years to try and make it possible and understand the value of having an American worker that can produce and be productive.

I wonder if you might comment on that, as well as on the idea of looking for a broader national Federal policy.

Ms. DELAURO. Oh, I would be happy to. I think what has really focused people's attention on the whole issue of paid sick days—because Senator Kennedy and I have been talking about this, and others have been talking about it for last 5 years—but, what I think has crystallized the issue for all of us is the H1N1 crisis. The admonition to people is, "Stay home. Be home." What does that mean for a single parent? What does that mean for a two-family parent? Yeah, when I got sick, my mother worked, Dad worked. I went to my grandmother's pastry store, and I had great care and great pastry. That is not the circumstance for 57 million people who work in the private sector. They don't have that advantage.

Now, I think, given that, as you have pointed out, one needs to deal with the underlying issue, the more fundamental issue of uniformity of a policy, a national policy, that is uniform. We could all come up with—you could have 50 States coming up with a particular plan to meet a need.

Emergencies will continue to occur. The basic underlying fact is that 57 million people in the United States of America—one, as you pointed out, of four countries, certainly not amongst the industrialized countries, all of whom are experiencing, quite frankly, economic difficulties—find that this is basically the right thing to do, to allow for paid sick days. Let us have a national policy that meets the needs of working families today.

Also, in terms of that competitive edge, that study that I made reference to was done by Cornell University, that talked about, in fact, that it was better, in terms of bottom line, because of the loss in productivity, the loss of potentially—an average, over $250 per employee, that if that person had paid sick days, and you were dealing with both disability and benefits, that you would not be losing as much by not having any paid sick policy at all.

I understand the comment about small businesses, and there's a real awareness in the legislation with regard to small business. The Healthy Families Act includes a small-business exemption. If a company has fewer than 15 employees, HFA does not apply. There was a recognition that small businesses have challenges that others may not have. The threshold is consistent with title VII and other labor laws.

Let me just also mention this to you, that if—because, Senator Enzi, as you said—that there are others who have a more generous policy. Well, as a matter of fact, what the legislation says is that employers who already provide at least 56 hours of paid leave, paid sick time, paid time off, do not have to change their existing policies, as long as the time can be used for the purposes that are set out in the Healthy Families Act.

We want to recognize that there are people and employers who have made accommodations and understand the needs of their employees. But, you can't fly in the face of 57 million people who work in the private sector who do not have that opportunity.

I'll make one other comment. You know, we work in the public sector. We go to the head of the line when we're ill, and probably when our families are ill. We can take as much time as we want. There is no one saying, "Your job isn't going to be there," "Your salary isn't going to be there," or, "You can't do it."

I'll end with this—and Senator Dodd may not be pleased with me for saying this—but I had a direct experience 23 years ago. Diagnosed with ovarian cancer, I went to my employer at that time—Senator Christopher Dodd—and explained my situation. I was about to take leave from the Senate office to head up a re-election campaign in 1986. Senator Dodd said to me, "Rosa, go get yourself well. Don't worry about your job as chief of staff, don't worry about the campaign. It's there. It begins when you get back."

That's not the situation for 57 million people in this country. We are not special. We don't live in a rarified air. We need to walk in the shoes of the millions of Americans who work hard every day to support their families. Yes, they get sick, whether they're in a large business or in a small business. And my view is that we do have moral obligations and responsibilities as Members of Congress to help people meet the challenges that they face in their lives. That's why I hope we can, in fact, pass emergency legislation and the Healthy Families Act.

I thank you again for the opportunity to testify.

Senator DODD. Thank you very much, Congresswoman. Thank you for that story. By the way, we won that election when you came back.

[Laughter.]

Ms. DELAURO. Yes we did.

Senator DODD. Senator Enzi.

Senator ENZI. Mr. Chairman, in keeping with the tradition of the committee, I won't have a question for the Congresswoman. But, I will raise a few points in response to some of the things that have been said here.

[Laughter.]

Numbers aren't telling the whole story in this case. No doubt there are small businesses who are not able to have a paid leave

policy in place officially. But, I guarantee you that they handle those people's situation on a case-by-case basis. They can't have sick people at work. Customers can tell if somebody's sick. They don't want sick people around them. Those people are taken care of, and if they want to keep them, they're taken care of in a method that provides them with some pay.

Now, every employer won't be able to do that. I would tell you that I think the small employers probably want to do it more than the big employers. To the small employer, the employee is really a person. To the big employers, it's a number out there, and if you've got to make the bottom line come out right, you move the numbers around to where it fits. But, that doesn't happen in small business, for the most part. There are always exceptions.

I have some real-life examples, too. I have a daughter that has one of my grandchildren. And she has a babysitter. If one of the kids at the babysitter is sick, all of them get sent home. That means that my daughter has to take off from work and go home and be with the baby. There's a leave policy, but it's not a paid leave policy. I understand this, and I suppose some would assume I ought to really be rooting for it on the basis of my daughter. She really likes the flexibility that she gets in her job, and she likes what she gets paid, and so, it is worth it to her to accommodate that.

It's been mentioned that we can take as much time as we want here. I couldn't, when I had a small business. If I got sick, I had to show up, because there wasn't anybody that was going to do what I did. If I was really sick, and I couldn't show up, the business suffered.

I'm a little surprised at your statement that your mom sent you to the bakery.

[Laughter.]

We're going to be handling food safety here, pretty quick.

Ms. DELAURO. But I didn't handle the food.

Senator ENZI. This bill takes the small business definition down from 50 employees that are presently covered by FMLA, which is not paid leave, down to 15. And the smaller the business is, the less flexibility with spare employees there is. We're in an economy now, where if I'm the guy that has 15 employees, do you think I'd hire a 16th one, with us considering this piece of legislation? I wouldn't be able to. That would force me into a situation. As a small business employer we had paid sick leave, so I know the problems that come with sick leave, as well. You have some employees that never take it, and you have others that don't have a half a day of earned sick leave available to them because the minute they do, they take it, for whatever purpose. It's pretty hard to question those purposes.

I'll be interested in reviewing, in the bill, what the exceptions are. I'm curious as to whether it can be accrued, whether it carries over from year to year, and whether you get compensated for unused sick leave if you leave the business? Those are all questions that the employers have to deal with, plus the part-of-an-hour times that people are gone, for whatever medical reason. A lot of bookkeeping things are involved in this and the more of these things that you add to business, the less likely they are to be able

to expand and hire other employees, in a time when we need to be hiring other employees. We need to be getting people employed.

People are waiting now on startups on business, waiting to see what kind of rules and regulations they're going to have to have when they start up. They are concerned we could take away their flexibility and make all businesses the same in this area. I don't think that'll help the employment situation.

I don't have any questions.

Senator DODD. Rosa, we thank you immensely. I don't know if Congressman Merkley or—I said Congressman—Senator Merkley—Jeff, I apologize—it was Congresswoman DeLauro.

Senator Murray, welcome, as well. Do you have any questions for the Congresswoman?

Senator MERKLEY. Thank you very much, Mr. Chair. I'd just like to give the Congresswoman a chance to elucidate on some of those questions on carryover, or compensation for unused sick leave, or any of those other details that might be helpful to understanding how this would work when the rubber hits the road.

Ms. DELAURO. The legislation is silent on those issues, and those are the details that can get worked out.

I just might add that I can recall very similar kinds of conversations when we were going through the Family and Medical Leave, that we were going to, really—that American business was going to go to hell in a hand basket, quite frankly. That it was going to end—our small businesses—it was going to bring that to a crashing halt. I think we haven't seen that to be the case with Family and Medical Leave. I think there are lots of the details obviously to get sorted out and worked out, which is the way they did with Family and Medical Leave, and how it can proceed forward.

I will give you another example of where I found this to be so poignant. I had the opportunity to meet with the families of some of our troops overseas, in Iraq and Afghanistan, and, as it turned out, most of the families were young women with small children. I will tell you that it was a real awakening, in terms of talking about emergencies and so forth, of what comes up. We think about H1N1.

These young women were really frightened. Obviously, they're frightened on a whole variety of issues that have to do with the survival of a spouse. But, they were working women. They did have their kids in daycare, or where ever they had them during the day. They didn't have paid sick time—they got sick, their kids got sick. I know, personally, because we had a case in our office, where we went to bat for a young woman who was told, her job was coming to an end because she took 3 days off with a child.

This is a real issue for working men and women in this country. If we don't believe we have to address it, as we have other public policy issues that directly affect working families, we're not going back to an economic situation where you have someone who is home all day, and who is waiting for children to come home or can stay there. That's not what our opportunity is. I think we can get to sorting out what the details are, and making sure that we're not putting—the goal is not to put people out of business. The goal is to try to make sure we have a public policy that ensures that peo-

ple have adequate kinds of assistance when they get sick, or their kids get sick, or an elderly relative gets sick.

Senator DODD. Thank you very much, Congresswoman.

Thank you, Senator Merkley.

Senator MERKLEY. Thank you.

Ms. DELAURO. Thank you, Senator.

Senator DODD. Senator Murray.

Senator MURRAY. Mr. Chairman, I do not have a question for Representative DeLauro. I do thank you for being here.

I really want to thank you for having this hearing. This is such a dilemma for families today, with the current H1N1 issue. Families are having to decide between a tough economy, where they don't have income, and following the regulations of staying home that CDC has issued. We shouldn't put families in that bind. We should make sure that they stay home when they're sick, so that they don't spread the flu, but they don't lose their ability to put food on the table and pay their mortgage at the same time. I really appreciate your holding this hearing today.

Senator DODD. Thanks very much. Thank you, Senator, very much.

Congresswoman, we thank you immensely.

Ms. DELAURO. Thank you Mr. Chairman, thank you Senator Enzi. Thank you.

Senator DODD. Let me invite our second panel to come on up and join us.

Welcome Deputy Secretary Seth Harris to the subcommittee today. I look forward to his testimony on behalf of the Department of Labor. Mr. Harris was nominated to be Deputy Secretary of Labor on February 23, 2009. Prior to his position at DOL, Mr. Harris was a professor of the law at New York Law School, and director of its labor and employment law programs. He's also a member of the National Advisory Commission on Workplace Flexibility. He also served at the Department of Labor during the Clinton administration. And is a graduate of NYU and Cornell University.

We thank you, Mr. Harris, for joining us.

I'd also like to welcome Rear Admiral Anna Schuchat. Did I pronounce that correctly, the last name? Doctor, we welcome you very much. Dr. Schuchat first joined the CDC in 1988. She has done extensive work in preventing infectious diseases in children. She has worked in a variety of countries, on topics including meningitis and pneumonia vaccine studies, surveillance, and prevention; and SARS emergency response and epidemiological studies. Dr. Schuchat attended Swarthmore College, Dartmouth Medical School, and now serves as CDC's deputy director for science and program.

We welcome you, Doctor, to the committee, as well.

Why don't we begin with you, Secretary Harris, and then we'll go right to Dr. Schuchat.

STATEMENT OF HON. SETH D. HARRIS, DEPUTY SECRETARY, U.S. DEPARTMENT OF LABOR, WASHINGTON, DC

Mr. HARRIS. Thank you very much, Chairman Dodd, Senator Enzi, Senator Murray, and Senator Merkley. I appreciate the op-

portunity to testify about workplace flexibility and paid leave in the context of the 2009 H1N1 flu pandemic.

Mr. Chairman, I'd like to begin by acknowledging your outstanding leadership on these most critical issues. You're the father of the Family and Medical Leave Act, and one of the Nation's most important advocates for America's working parents and their children. Whether fighting to ensure that children receive the H1N1 vaccine, or to extend the Family and Medical Leave Act to our military heroes, you've shown over and over again your deep and abiding commitment to Americans who are struggling to perform their jobs while also caring for themselves and their loved ones at home. It's essential work, and we're fortunate to have you leading the way, sir.

I'd also like to acknowledge Congresswoman DeLauro for her comments this morning, and for her continuing and tireless work on behalf of our Nation's hardworking families.

Mr. Chairman, we live in a time of pandemic. Much has been done to prepare for the 2009 H1N1 public health emergency, but more must be done to protect the economic security of working families when illness strikes. Our current system forces too many sick workers to go to work, and too many working parents to send sick children to school or daycare. This system poses a threat to our public health, our economic future, and a social system that depends heavily on people caring for themselves and their family members.

Full economic security for workers who must tend to their own illnesses or the illnesses of their family members requires two assurances. First, workers who take leave must not lose their jobs or suffer some other form of discipline from their employers. And second, they must have a source of income during any leave period. Under our existing legal regime, millions of workers get neither of these two assurances. Current Federal law does not mandate employers to provide paid, job-protected leave to their workers.

The Family and Medical Leave Act has helped millions of workers take unpaid leave without fear of firing or discipline, but the FMLA protects only those workers employed by employers with more than 50 employees, and only if the employees meet certain eligibility criteria. Even if both the employer and the employee are covered by the FMLA, leave is available only for serious health conditions, which would not include a large percentage of cases of the 2009 H1N1 flu, the seasonal flu, and other common and contagious diseases. Equally important, many workers simply cannot afford to take the unpaid leave provided by the FMLA.

In 2008, the Bureau of Labor Statistics found that only 61 percent of private sector employees are offered paid sick leave for their own illness or injury, and high-wage workers were more likely to have paid leave than low-wage workers; only 49 percent of low-wage workers have access to paid sick or personal leave. Other Federal laws and programs also do not provide workers with job security or income when they're sick or need to take time off to care for their family members.

Unemployment insurance and disaster unemployment assistance cover workers only if they are able and available to work. A worker who cannot work because of illness or caregiving responsibilities

would not be eligible. The bottom line for sick workers and workers with sick family members is that taking leave risks their jobs and their ability to support their families.

The situation is a concern for employers as well as employees. The CDC reports—as you said, Mr. Chairman—on average, that an individual who comes to work with the H1N1 flu will infect 10 percent of his or her coworkers. Instead of one sick worker staying home, an employer could end up with dozens of sick workers, who are unproductive, making their coworkers unproductive, and potentially spreading a contagious disease to their families and friends. It is common sense and good business sense. Workers should be able to stay home if they are ill.

On August 19, 2009, Secretary Solis joined the Secretaries of Health and Human Services, Commerce, and Homeland Security in announcing the CDC's updated guidance to employers on how to respond to the 2009 H1N1 pandemic. The guidance notes that, "Employers play a key role in community mitigation." That is, efforts by all of us to limit the pandemic's effects. Central to community mitigation is that all people with influenza-like illness should stay home and away from the workplace.

That's why this Administration strongly supports the Healthy Families Act. This legislation would ensure that millions more of working Americans will be able to earn up to 56 hours of paid sick time for family care or self care. Simply, the Healthy Families Act provides the assurances that workers need. It assures them job security when they take sick leave or leave to care for a family member, it provides short-term continuation of the workers' income, while they recuperate from illness or provide needed care to a family member.

Mr. Chairman, the current system is broken. We welcome the opportunity to work with you and the other members of this committee to fix it.

Once again, thank you very much for inviting me to testify today. I look forward to your questions.

[The prepared statement of Mr. Harris follows:]

PREPARED STATEMENT OF SETH HARRIS

Good morning Chairman Dodd, Ranking Member Alexander, and members of the committee. I am pleased to join you and share the regards of Secretary Solis.

The vision of the Department of Labor (DOL) is **good jobs for everyone**. One important component of this vision is ensuring workplace flexibility for family and personal care-giving. While much has been done to help prepare for a public health emergency like the current 2009 H1N1 pandemic, the Administration believes that more must be done to help protect the economic security of working families who often must choose between a pay check and their health and the health of their families.

Today, I will address current Federal leave law and regulations as they pertain to the private sector, the challenges which arise during times of widespread illness, such as H1N1, and the Administration's support for paid leave and increased workplace flexibility policies such as the proposal introduced earlier this year by Senator Kennedy, the Healthy Families Act.

Current Federal law does not mandate that employers provide paid leave to their workers. Rather, the only Federal law on leave, the Family and Medical Leave Act (FMLA), requires employers with 50 or more employees to provide unpaid leave to eligible workers under a limited set of circumstances. Under FMLA, covered and eligible employees are entitled to take up to 12 workweeks each year of job-protected, *unpaid leave* for the "serious health condition" of the employee or of the employee's son, daughter, spouse or parent where the reason for the leave meets the strict re-

quirements of the FMLA. In many instances of leave needed in response to a widespread public health emergency, such as the 2009 H1N1, the FMLA will simply not provide protections. An estimated 60 percent of the workforce is covered and eligible for *unpaid* leave but only when the leave is for reasons that qualify pursuant to the strict FMLA standards.

Other Federal laws and programs generally do not provide much assistance to workers needing job security and income when they are sick or need to take time off to care for family members.

Unemployment Insurance (UI) and Disaster Unemployment Assistance (DUA) do not cover workers who may lose their jobs and are not "able and available to work" (with a limited exception under DUA for workers injured by a disaster). During a pandemic, individuals who are laid off because their work site is closed or because business has declined due to an outbreak would be eligible for regular UI as long as they are able to, available for, and actively seeking work. The UI program does not cover individuals who are sick, are caring for someone who is sick, are caring for well children dismissed from school, or are otherwise not available and actively seeking work.

Individuals ineligible for regular UI who lost their jobs as a direct result of a major disaster declared due to severe pandemic flu and individuals who are unemployed because they contract the flu and are unable to work might qualify for DUA. However, individuals who are unemployed because they are caring for sick family members, are caring for children whose schools have been closed, or are quarantined, are generally not "able and available" and would not be eligible for DUA. DUA would also not be payable to individuals whose unemployment is only indirectly related to the severe pandemic flu outbreak and is only available if there is a disaster declaration.

In 2008, the Bureau of Labor Statistics (BLS) surveyed private sector employers about their leave policies. While approximately 7 in 10 employees received paid leave to attend jury duty and funerals, only 61 percent of private sector employees were offered sick pay for their own illness or injury. Thirty-seven percent of employees were offered paid time off for personal reasons, and 8 percent were offered paid leave for family reasons. Federal, State and local government employees' access to paid and unpaid leave is greater than private sector employees' for all types of leave.

A variety of factors are associated with the availability of paid leave. In its March 2008 National Compensation Survey, the BLS found that the availability of paid leave increases with income. Eighty-three percent of the highest-paid workers (wages in the top 10th percentile and above) had access to paid sick leave, compared to just 23 percent of the lowest paid workers (bottom 10th percentile). In addition, 54 percent of the highest paid workers were able to access paid leave for personal reasons compared to 17 percent of the lowest paid workers.

Low-wage workers have less access to paid leave, and thus are more likely to go to work even if they are sick or their child is sick. Only 49 percent of low-wage workers have access to paid sick leave or personal leave or family leave or vacation.[1] Particularly vulnerable are the 3.7 million working adults in households with children under 14 years old and no other adult or older child to share child caring responsibilities. Single parents and low-wage workers can find it challenging to stay home even for a few days.

The lack of paid leave and other workplace flexibilities has significant impacts on the Nation's workforce. This lack of access to paid leave forces many workers to choose between taking care of their health and the health of their families and paying their bills. This is made even more troublesome when the illness is contagious, like seasonal and pandemic influenza, given that the consequences of employee's decisions to go to work when ill or to send a sick child to school can adversely affect many others.

Flu activity is now widespread in 48 States. According to the CDC, of all visits to doctors nationally, the proportion that are for influenza-like-illness continues to increase steeply and is now higher than what is seen at the peak of many regular flu seasons. In addition, flu-related hospitalizations and deaths continue to rise nationwide and are above what is expected for this time of year.

In the context of the current 2009 H1N1 pandemic, FMLA job protections may be available to relatively few workers who need leave. For example, healthy workers who stay at home to care for their healthy children while schools are closed would not be covered. Additionally, FMLA leave would only be available if the covered and

[1] Low-wage workers are defined as workers earning less than $7.25 an hour in March 2008. Iris S. Díaz and Richard Wallick, "Leisure and illness leave: estimating benefits in combination," *Monthly Labor Review*, February 2009, Volt. 132, No. 2.

eligible employee's or family member's medical condition meets the definition of a "serious health condition." For example, where the individual with 2009 H1N1 is not hospitalized, the employee or family member would have to receive in-person treatment from a health care provider within 7 days of the onset of incapacity and have a second in-person treatment visit within 30 days or otherwise meet continuing regimen of treatment requirements for the illness to qualify as a "serious health condition," a requirement that may be difficult to meet if public health officials recommend that the majority of sick individuals not seek medical treatment absent complications. Moreover, even where an employee's leave is covered by FMLA, this law does not address the problems associated with employees lacking access to pay while on leave. Even in the rare instances when the illness is serious enough to meet these qualifications, this law does not help those who cannot afford to take time off because their employer does not offer paid leave or if they have used whatever paid leave they have. It also does not help those who need to care for their extended family members.

Employer-provided workplace flexibilities could help workers who need time off during a pandemic—as well as in ordinary times. However, according to BLS, private industry employers offer formal flexible workplace arrangements[2] to only 5 percent of workers. Like paid sick leave, eligibility for flexible work arrangements is higher for full-time workers than part-time and increases with income.

Given the lack of Federal laws regarding paid leave, five States have used temporary disability insurance programs to provide income to workers who experience non-occupational illnesses or injuries. California and New Jersey have implemented paid leave programs in addition to their temporary disability insurance programs. In addition, several cities have passed ordinances requiring certain employers to provide paid sick leave to their employees, though these plans were established many years ago—not necessarily in response to current conditions.

The scope of the current 2009 H1N1 public health emergency demonstrates the need for paid leave and flexible workplace policies. The goal of the U.S. Government and its State and local partners to date has been to slow the spread of a pandemic and mitigate its social and economic impact through the use of antivirals and non-pharmaceutical interventions, often referred to as community mitigation strategies. The Federal Government adopted community mitigation as Federal policy in 2007.[3]

On August 19, 2009, Secretary Solis joined the Secretaries of Health and Human Services, Commerce and Homeland Security in issuing a letter announcing the Centers for Disease Control and Prevention's (CDC) updated guidance to employers on how to respond to the 2009 H1N1 pandemic. CDC notes in their guidance that businesses and other employers play a key role in protecting employees' health and safety, as well as in limiting the negative impact of influenza outbreaks on the individual, the community, and the Nation's economy. I would like to share a few highlights from this guidance that are most relevant to the question before the subcommittee today.

First, the guidance recognized that all employers must balance a variety of objectives when determining how best to decrease the spread of influenza and lower the impact of influenza in the workplace. They should consider and communicate their objectives, which may include one or more of the following: (a) reducing transmission among staff, (b) protecting people who are at increased risk of influenza-related complications from getting infected with influenza, (c) maintaining business operations, and (d) minimizing adverse effects on other entities in their supply chains.

Second, the guidance noted that during an influenza pandemic, *all* **people with influenza-like illness should stay home** and away from the workplace. If the severity of illness increases, employers should be ready to implement additional measures and public health officials may recommend a variety of methods for increasing the physical distance between people (called social distancing) to reduce the spread of disease. These could include school dismissal, child care program closure, canceling large community gatherings, canceling large business-related meetings, spacing workers farther apart in the workplace, canceling non-essential travel, and utilizing work-from-home strategies for workers who can conduct their business remotely.

CDC recommends that people with influenza-like illness remain at home until at least 24 hours after they are free of fever (100° F [37.8° C]), or signs of a fever without the use of fever-reducing medications to reduce the number of people infected. In most cases, this means staying home 3 to 5 days.

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[2] Flexible workplace arrangements are "the ability to work an agreed-upon portion of a work schedule at home or some other approved location, such as a regional work center."

[3] See *Community Strategy for Pandemic Influenza Mitigation* (CMG).

CDC has asked employers to allow sick workers to stay home without fear of losing their jobs and to develop other flexible leave policies to allow workers to stay home to care for sick family members or for children if schools dismiss students or child care programs close.

While the Federal Government has been working diligently to provide guidance and implement community mitigation strategies, these strategies often do not help address the economic conditions facing families without leave.

For example, during a severe pandemic, compliance with community mitigation measures, including home isolation, quarantine and school closures (particularly extended school closures), would have a negative economic impact on many workers and their families. As I mentioned previously, a significant number of workers do not have access to sufficient paid or unpaid job-protected leave, nor do many have access to other workplace flexibilities, such as telework, which would allow them to stay home when sick or when exposed to someone who is sick (self-quarantine), to care for a family member who is sick, or to care for a child dismissed from school.

Staying home from work in compliance with community mitigation will cost workers income because they are on unpaid leave—or could cost them their jobs if they are laid off because they cannot come to work. These issues are of particular concern for low-wage, part-time and otherwise vulnerable workers. Such single parents and low-wage workers will find it particularly challenging to care for a child dismissed from school for an extended period of time during a severe pandemic.

The economic cost to working families associated with the lack of paid leave is significant not only during times of influenza pandemics. These are decisions that working families must make daily—choices between keeping their jobs and taking care of their health and the health of their children.

In addition, paid leave represents a relatively small share of total compensation costs. In its June 2009 Employer Costs of Employer Compensation survey, BLS calculated the costs of paid leave borne by employers. All types of paid leave for private industry add up to 6.8 percent of total compensation costs, or $1.85 per employee hour out of $27.42. BLS also reports employer costs for paid leave across different occupational groups. Workers in the highest paid category—management and professional—earn a total of $48.96 per hour and their paid leave equals 8.4 percent of total compensation. The lowest paid occupational group—service workers—earn on average $13.15 per hour, only slightly more than 25 percent of the rate for management and professional. Paid leave for this group accounts for only 4.2 percent of their total compensation.

The Healthy Families Act offers an important opportunity to provide workers with economic security by assuring that they have the ability to stay home if they are sick without fear of losing their jobs or being forced to go to work sick because they cannot afford to stay home. We support this bill and look forward to working with you on it as it moves through the legislative process.

As mentioned, the vision for the Department of Labor is *good jobs for everyone*. And one of the key components of a good job is having workplace flexibility for family and personal caregiving. We believe that work-life balance includes policies such as paid leave, flexible work schedules and teleworking, employee assistance programs, childcare, and elder-care support. Jointly with our colleagues in the Cabinet, DOL is working to improve work-life policies, and efforts are underway to see how we can better meet the needs of modern working families.

Finally, an important part of helping families stay healthy and ensuring employers have a productive workforce is health insurance reform. Health insurance reform can relieve the burden of rising health care costs on small businesses, increase accessibility for young adults, increase transparency and accountability in the insurance industry, empower consumers, lower costs, reform the delivery system, improve the quality of care, simplify the administrative bureaucracy, and give consumers more knowledge and more bargaining power. We encourage the Senate to pass health insurance reform.

In conclusion, it is clear that while much has been done to help prepare for a national health emergency like 2009 H1N1, more is needed to help protect the economic security of working families who must choose between a pay check and their health and the health of their families. That is why the Administration supports the Healthy Families Act and other proposals that advance workplace flexibility and protect the income and security of workers. I appreciate your time today, and I am happy to answer any questions you may have.

Senator DODD. Thank you very much, Secretary Harris.

Doctor, we welcome again. You've been before the committee in the past, so we welcome you here again.

STATEMENT OF ANNE SCHUCHAT, M.D., ACTING DEPUTY DIRECTOR FOR SCIENCE AND PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION AND ASSISTANT SURGEON GENERAL, U.S. PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ATLANTA, GA

Dr. SCHUCHAT. Thank you, Mr. Chairman, and thank you, Senator Enzi and members of the committee. It's a pleasure to update you on the Administration's response to the H1N1 virus, and comment on the impact this pandemic is having on work, school, and our society.

Many millions of Americans have already been infected with the 2009 H1N1 strain. Thousands of hospitalizations and more than 1,000 deaths have occurred already. The virus is widespread now, in 48 States. So far there is no change in the illness pattern caused by the virus.

This is disproportionately a younger person's disease. It disproportionally affects adults with chronic conditions such as asthma, diabetes, conditions that are far too common in 2009 in America. It also disproportionally affects pregnant women, who have suffered hospitalizations and deaths to a great extent.

So far, our CDC scientists have found no change in the virus. There's been no genetic change that would make this—escape the protection that vaccines will afford, and no change to rapidly increase the proportion of strains that are resistant to our medicines, like TAMIFLU. However, influenza is unpredictable, and it is unpredictable what trajectory this virus will have in the weeks and months ahead. Only time will tell.

CDC's role in this H1N1 response has been aggressive and science-based. I'd like to thank the Congress and this committee for the many years with which you have recognized that public health is integral to public safety. The investments that Congress has made in preparedness over the past several years mean that we are far better prepared for this response than we would have been. I shudder to think how we would be doing had H1N1 hit our shores 4 or 5 years ago.

We rapidly identified this new virus and characterized it; we developed a candidate vaccine strain and handed it off to industry to develop vaccines; we carried out epidemiologic and laboratory surveillance in the United States and abroad. We have had an aggressive, comprehensive, and science-based response, rapidly deploying CDC assets, like life-saving anti-viral medicines that were part of our strategic national stockpile. Laboratory kits that were rapidly developed through pandemic flu investments were shipped to all of the public health labs in the United States and to more than 150 other countries so we cold track the spread of this virus and understand whether it was changing, and make sure that the vaccines under development would still work.

We deployed field teams to provide technical assistance at home and abroad. We've issued a series of science-based guidance that we have updated as the science has changed or come to light. We've shared these with key sectors, including the healthcare system. We've focused on prevention for schools, businesses, and healthcare workers, and on treatment with antivirals, focusing on

outreach to providers, to pharmacies, and to the public. We have had an aggressive and multifaceted communication strategy, using traditional media and new media. We have focused on the shared responsibility each of us plays in responding to the H1N1 virus, stressing that ill people should stay home from school or work, and avoid spreading the virus to others. We have launched a voluntary immunization program.

The vaccination effort has been unprecedented, from developing the strain virus for vaccine development, the exquisitely expert clinical trials that the NIH carried out, issuing science-based recommendations for use of these vaccines. It is a public-private partnership.

We are very disappointed in the initial production of the vaccine. These are made using biologic processes, egg-based technology that is tried and true, but that is fragile. We are, to some extent, a victim of a slow-growing virus that has not cooperated. Now the production is accelerating and we are seeing substantial amounts of vaccine becoming available. We are receiving, ordering, delivering, rapidly, the vaccine doses. As of today, 41.1 million doses of H1N1 vaccines are available for the States to order. Three-fourths of this is in the form of injectable vaccine and one-quarter is the nasal spray. The pace of our progress is truly picking up.

We have prioritized five groups for early use of the vaccine, the groups that are at highest risk for disease or its complications or most likely to spread infection. The State and local health authorities are in the position of making decisions on the best ways to reach these priority populations. It is important for us to use every dose of vaccine as it becomes available to slow the spread of this pandemic and to protect the most vulnerable parts of our population.

We have developed this vaccine in record time without any shortcuts on safety. We have also enhanced our vaccine safety system to be ready for concerns, to try to make sure that if there are unanticipated problems, we find them quickly and respond appropriately. We are working hard across Health and Human Services and with all of the Federal Government to manage this response, but fundamentally we are relying on State and local public health to direct the vaccination efforts in their communities.

This pandemic did not come at a good time for our economy, and the public health infrastructure around the country has been frayed. But, H1N1 does highlight the need for long-term investing in that infrastructure. This hearing, though, highlights the human and economic impact of influenza and other illness on the workplace and on business continuity. Our CDC guidance has recommended that individuals stay home when they are sick and not spread infection in the workplace. We've asked businesses to be flexible about leave policy, and, where appropriate, to encourage issues, like telecommuting, that would reduce spread in the workplace.

It's really important to have the right policies in place and to plan for contingencies, but our goal really is to make it easy for people to make the right choices, to make the healthy choices. I really applaud the committee for taking this issue seriously.

My colleagues and I at CDC and across Health and Human Services are committed to sustaining communication and to answering your questions going forward.

[The prepared statement of Dr. Schuchat follows:]

PREPARED STATEMENT OF REAR ADMIRAL ANNE SCHUCHAT, M.D.

Chairman Dodd, Ranking Member Alexander, members of the committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza.

CDC and our colleagues throughout the Department of Health and Human Services (HHS) are working in close partnership with many parts of the Federal Government, as well as States and localities, under a national preparedness and response framework for action that builds on the efforts and lessons learned this previous spring and from past influenza preparedness trainings. Working together with governors, mayors, tribal leaders, State and local health departments, the medical community and our private sector partners, we have been monitoring the spread of H1N1 and facilitating prevention and treatment, including starting to implement a vaccination program.

Influenza is probably the least predictable of all infectious diseases, and the 2009 H1N1 pandemic has presented considerable challenges—in particular the delay in production of a vaccine due to slow growth of the virus during the manufacturing process. Today I will update you on the overall situation, provide an update on vaccination status, and discuss other steps we are taking to address these challenges.

This hearing is also an important opportunity to consider the impact this pandemic has had on work, school, and society. And although we are focused this year on the impact of the H1N1 pandemic, it is important to remember that even in a normal year, individuals and institutions are impacted by illnesses, as reflected in lost work and school days and lower productivity. Data from our National Center for Health Statistics in 2008 show, for example, that employed adults 18 years of age and over experienced an average of 4.4 work-loss days per person due to illness or injury in the past 12 months, for a total of approximately 698 million work-loss days.

TRACKING AND MONITORING INFLUENZA ACTIVITY

One major area of effort is the tracking and monitoring of influenza activity, which helps individuals and institutions monitor and understand the impact of the 2009 H1N1 virus. Since the initial spring emergence of 2009 H1N1 influenza, the virus has spread throughout the world. H1N1 was the dominant strain of influenza in the southern hemisphere during its winter flu season. Data about the virus from around the world—much of it collected with CDC assistance—have shown that the circulating pandemic H1N1 virus has not mutated significantly since the spring, and the virus remains very closely matched to the 2009 H1N1 vaccine. This virus also remains susceptible to the antiviral drugs oseltamivir and zanamivir, with very rare exception.

Unlike in a usual influenza season, flu activity in the United States continued throughout the summer, at summer camps and elsewhere. More recently, we have seen widespread influenza activity in 48 States; any reports of widespread influenza this early in the season are very unusual. Visits to doctors for influenza-like illness as well as flu-related hospitalizations and deaths among children and young adults also are higher than expected for this time of year. We are also already observing that more communities are affected than those that experienced H1N1 outbreaks this past spring and summer.

Almost all of the influenza viruses identified so far this season have been 2009 H1N1 influenza A viruses. However, seasonal influenza viruses also may cause illness in the upcoming months—getting one type of influenza does not prevent you from getting another type later in the season. Because of the current H1N1 pandemic, several additional systems have been put in place and existing systems modified to more closely monitor aspects of 2009 H1N1 influenza. These include the following:

Enhancing Hospitalization Surveillance: CDC has greatly increased the capacity to collect detailed information on patients hospitalized with influenza. Using the 198 hospitals in the Emerging Infections Program (EIP) network and 6 additional sites with 76 hospitals, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group and monitor the clinical course among persons with severe disease requiring hospitalization.

Expanding Testing Capability: Within 2.5 weeks of first detecting the 2009 H1N1 virus, CDC had fully characterized the new virus, disseminated information to researchers and public health officials, and developed and begun shipping to States a new test to detect cases of 2009 H1N1 infection. CDC continues to support all States and territories with test reagents, equipment, and funding to maintain laboratory staff and ship specimens for testing. In addition, CDC serves as the primary support for public health laboratories conducting H1N1 tests around the globe and has provided test reagents to 406 laboratories in 154 countries. It is vital that accurate testing continue in the United States and abroad to monitor any mutations in the virus that may indicate increases in infection severity, resistance to antiviral drugs, or a decrease in the match between the vaccine strain and the circulating strain.

Health Care System Readiness: HHS is also using multiple systems to track the impact the 2009 H1N1 influenza outbreak has on our health care system. HHS and CDC are in constant communication with State health officials and hospital administrators to monitor stress on the health care system and to prepare for the possibility that Federal medical assets will be necessary to supplement State and local surge capabilities. To date, State and local officials and health care facilities have been able to accommodate the increased patient loads due to 2009 H1N1, but HHS is monitoring this closely and is prepared to respond quickly if the situation warrants.

Implementing a Flu-related School Dismissal Monitoring System: The Centers for Disease Control and Prevention (CDC) and the U.S. Department of Education (ED), in collaboration with State and local health and education agencies and national non-governmental organizations, have implemented a flu-related school dismissal monitoring system for the 2009–2010 school year. This monitoring system generates a verified, near-real-time, national summary report daily on the number of school dismissals by State across the 130,000 public and private schools in the United States, and the number of students and teachers impacted. The system was activated August 3, 2009. This has helped us to calibrate our messages and guidance and may have contributed to the smaller number of school closings seen in the fall relative to those seen in the spring.

PROVIDING SCIENCE-BASED GUIDANCE

A second major area of effort in support of individuals and institutions is to provide science-based guidance that allows them to take appropriate and effective action. Slowing the spread and reducing the impact of 2009 H1N1 and seasonal flu is a shared responsibility. We can all take action to reduce the impact flu will have on our communities, schools, businesses, other community organizations, and homes this fall, winter, and spring.

There are many ways to prevent respiratory infections and CDC provides specific recommendations targeted to a wide variety of groups, including the general public, people with certain underlying health conditions, infants, children, parents, pregnant women, and seniors. CDC also has provided guidance to workers and in relation to work settings, such as health care workers, first responders, and those in the swine industry, as well as to laboratories, homeless shelters, correctional and detention centers, hemodialysis centers, schools, child care settings, colleges and universities, small businesses, and Federal agencies.

With the holidays coming up, reducing the spread of 2009 H1N1 influenza among travelers will be an important consideration.

CDC quarantine station staff respond to reports of illness, including influenza-like illness when reported, in international travelers arriving at U.S. ports of entry. Interim guidance documents for response to travelers with influenza-like illness, for airline crew, cruise ship personnel and Department of Homeland Security port and field staff have been developed and posted online. As new information about this 2009 H1N1 influenza virus becomes available, CDC will evaluate its guidance and, as appropriate, update it using the best available science and ensure that these changes are communicated to the public, partners, and other stakeholders.

In preparation for the upcoming months when we expect many families and individuals to gather for the holidays, we are preparing to launch a national communications campaign to encourage domestic and international travelers to take steps to prevent the spread of flu. Plans are to display public advertisements with flu prevention messages in ports of entry and various other advertising locations, such as newspapers and online advertisements, both before and during the upcoming holiday travel season.

SUPPORTING SHARED RESPONSIBILITY AND ACTION THROUGH ENHANCED COMMUNICATION

A third major area of effort is to support shared responsibility and action through enhanced communication to individuals. Our recommendations and action plans are based on the best available scientific information. CDC is working to ensure that Americans are informed about this pandemic and consistently updated with information in clear language. The 2009 H1N1 pandemic is a dynamic situation, and it is essential that the American people are fully engaged and able to be part of the mitigation strategy and overall response. CDC will continue to conduct regular media briefings, available at flu.gov, to get critical information about influenza to the American people.

Some ways to combat the spread of respiratory infections include staying home when you are sick and keeping sick children at home. Covering your cough and sneeze and washing your hands frequently are also effective ways to reduce the spread of infection. Taking personal responsibility for one's health will help reduce the spread of 2009 H1N1 influenza and other respiratory illnesses.

CDC is communicating with the public about ways to reduce the spread of flu in more interactive formats such as blog posts on the Focus on Flu WebMD blog, radio public service announcements, and podcasts.

Through the CDC INFO Line, we serve the public, clinicians, State and local health departments and other Federal partners 24 hours/day, 7 days/week, in English and Spanish both for phone and e-mail inquiries. As of midnight November 4, CDC–INFO had responded to 98,377 phone calls and 38,628 e-mails from the general public, and 14,782 inquiries from clinicians, for a total of 151,700 inquiries since the onset of the H1N1 response in April.

Our information is updated around the clock so we are well-positioned to respond to the needs and concerns of our inquirers. Our customer service representatives get first-hand feedback from the public on a daily basis. In addition to the H1N1 response, we continue to provide this service for all other CDC programs.

PREVENTION THROUGH VACCINATION

A fourth major area of effort is prevention through vaccination. Vaccination is our most effective tool to reduce the impact of influenza. Despite rapid progress during the initial stages of the vaccine production process, the speed of manufacturing has not been as rapid as initially estimated. CDC characterized the virus, identified a candidate vaccine strain, and our HHS partners expedited manufacturing, initiated clinical trials, and licensed four 2009 H1N1 influenza vaccines all within 5 months. The speed of this vaccine development was made possible due to investments made in vaccine advanced research and development and vaccine manufacturing infrastructure building through the office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) over the past 4 years, and in collaboration with CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). The rapid responses of HHS agencies, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by pandemic preparedness efforts for influenza pandemics set in motion by the H5N1 virus re-emergence in 2003, and the resources Congress provided for those efforts.

Pandemic planning had anticipated vaccine becoming available 6–9 months after emergence of a new influenza. 2009 H1N1 vaccination began in early October—5 months after the emergence of 2009 H1N1 influenza. Critical support from Congress resulted in $1.44 billion for States and hospitals to support planning, preparation, and implementation efforts. States and cities began placing orders for the 2009 H1N1 vaccine on September 30. The first vaccination with 2009 H1N1 influenza vaccine outside of clinical trials was given October 5. Tens of millions of doses have become available for ordering, and millions more become available each week. Although significant delays in vaccine production by manufacturers have complicated the early immunization efforts, vaccine will become increasingly available over the weeks ahead, and will become more visible through delivery in a variety of settings, such as vaccination clinics organized by local health departments, healthcare provider offices, schools, pharmacies, and workplaces.

CDC continues to offer technical assistance to States and other public health partners as we work together to ensure the H1N1 vaccination program is as effective as possible. Since September 30th, although the number of H1N1 vaccine doses produced, distributed, and administered has grown less quickly than projected, States have begun executing their plans to provide vaccine to targeted priority populations. Although we had hoped to have more vaccine distributed by this point, we are working hard to get vaccine out to the public just as soon as we receive it.

H1N1 vaccines are manufactured by the same companies employing the same methods used for the yearly production of seasonal flu vaccines. H1N1 vaccine is distributed to providers and State health departments similarly to the way federally purchased vaccines are distributed in the Vaccines for Children program. Two types of 2009 H1N1 vaccine are now available: injectable vaccine made from inactivated virus, and nasal vaccine made from live, attenuated (weakened) virus.

CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that 2009 H1N1 vaccines be directed to target populations at greatest risk of illness and severe disease caused by this virus. On July 29, 2009, ACIP recommended targeting the first available doses of H1N1 vaccine to five high-risk groups comprised of approximately 159 million people; CDC accepted these recommendations. These groups are: pregnant women; people who live with or care for children younger than 6 months of age; health care and emergency services personnel; persons between the ages of 6 months through 24 years of age; and people from ages 25 through 64 years who are at higher risk for severe disease because of chronic health disorders like asthma, diabetes, or compromised immune systems. These recommendations provide a framework from which States can tailor vaccination to local needs.

Ensuring a vaccine that is safe as well as effective is a top priority. CDC expects that the 2009 H1N1 influenza vaccine will have a similar safety profile to seasonal influenza vaccine, which historically has an excellent safety track record. So far the reports of adverse events among H1N1 vaccination are similar to those we see with seasonal flu vaccine and not unexpected, but we will remain alert for the possibility of rare, severe adverse events that could be linked to vaccination. CDC and FDA have been working to enhance surveillance systems to rapidly detect any unexpected adverse events among vaccinated persons and to adjust the vaccination program to minimize these risks. Two primary systems used to monitor vaccine safety are the Vaccine Adverse Events Reporting System (VAERS), jointly operated between CDC and FDA, and the Vaccine Safety Datalink (VSD) Project, a collaborative project with eight managed care organizations covering more than nine million members. These systems are designed to determine whether adverse events are occurring among vaccinated persons at a greater rate than among unvaccinated persons. CDC has worked with partners to strengthen these vaccine safety tracking systems and we continue to develop new ways to monitor vaccine safety, as announced earlier this week by the Federal Immunization Safety Task Force in HHS. In addition, based on the recommendation of the National Vaccine Advisory Committee (NVAC), HHS established the H1N1 Vaccine Safety Risk Assessment Working Group to review 2009 H1N1 vaccine safety data as it accumulates. This working group of outside experts will conduct regular, rapid reviews of available data from the Federal safety monitoring systems and present them to NVAC and Federal leadership for appropriate policy action and follow-up.

More than 36,000 people die each year from complications associated with seasonal flu. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all people 50 years of age and over and all adults with certain chronic medical conditions, as well as infants and children. As of the fourth week in October, 89 million doses of seasonal vaccine had been distributed. It appears that interest in seasonal flu vaccine has been unprecedented this year. Manufacturers estimate that a total of 114 million doses will be brought to the U.S. market.

REDUCING THE BURDEN OF ILLNESS AND DEATH THROUGH ANTIVIRAL DISTRIBUTION AND USE

In the spring, anticipating commercial market constraints, HHS deployed 11 million courses of antiviral drugs from the Strategic National Stockpile (SNS) to ensure the Nation was positioned to quickly employ these drugs to combat 2009 H1N1 and its spread. In early October, HHS shipped an additional 300,000 bottles of the oral suspension formulation of the antiviral oseltamivir to States in order to mitigate a predicted near-term national shortage indicated by commercial supply data. In addition, the Secretary authorized the release of the remaining 234,000 bottles of pediatric Tamiflu® on October 29. We will continue to conduct outreach to pharmacists and providers related to pediatric dosing and compounding practices to help assure supplies are able to meet pediatric demand for antiviral treatment. Finally, CDC and FDA have also worked together to address potential options for treatment of seriously ill hospitalized patients with influenza, including situations in which physicians may wish to use investigational formulations of antiviral drugs for intravenous therapy. The FDA issued an emergency use authorization (EUA) on October 23, 2009, for the investigational antiviral drug peramivir intravenous (IV) to be used for certain hospitalized adult and pediatric patients with confirmed or suspected

2009 H1N1 influenza infection. Physician requests for peramivir to be used under the EUA are managed through a CDC web portal.

CLOSING REMARKS

CDC is working hard to limit the impact of this pandemic, and we are committed to keeping the public and the Congress fully informed about both the situation and our response. We are collaborating with our Federal partners as well as with other organizations that have unique expertise to help CDC provide guidance to multiple sectors of our economy and society. There have been enormous efforts in the United States and abroad to prepare for this kind of challenge.

Our Nation's current preparedness is a direct result of the investments and support of Congress over recent years, effective planning and action by Federal agencies, and the hard work of State and local officials across the country. We look forward to working closely with Congress as we address the situation as it continues to evolve in the weeks and months ahead.

Again, Mr. Chairman, thank you for the opportunity to participate in this conversation with you and your colleagues. I look forward to answering your questions.

Senator DODD. Well, thank you very much, Doctor.

Let me jump right in on some of the questions. Senator Enzi raised some of them in his opening comments, and they're a lot of questions we're getting, as well, on a regular basis. I know you probably get them all the time, as well.

I understood, by the way, that there are basically five companies that are producing the vaccine, and all but one of them are located outside of the United States. Is that correct?

Dr. SCHUCHAT. Yes, that is right.

Senator DODD. Well, how did that happen?

Dr. SCHUCHAT. Well, I think one good feature is that we have contracts with five companies, and that was intended to reduce our risk that one company or another would have a problem. Our problem, of course, is this slow-growing virus has been a problem for four of the companies.

We are in better shape than we were a few years ago. At 2004, we only had one company producing vaccine for the United States, and now we have five companies with license to produce influenza vaccine for seasonal use. Most of those companies, as you say, produce overseas. There have been investments in encouraging manufacturing here in the United States and expanding that capacity, but this is not an issue that changes overnight.

Senator DODD. Now, one of the issues I've heard raised is that, in some of these countries, the political community have passed legislation prohibiting the exportation of the vaccines outside until all of their needs are being met domestically. Is that true?

Dr. SCHUCHAT. There are contracts in place in different countries, and some of them do have those policies. The global capacity to produce influenza vaccine is not large. It's much larger than it was 5 years ago, but it's not sufficient for the entire world's population. We are vulnerable. We were lucky that the HHS had gotten contracts in place with these five companies and that our contracts, for the most part, are being honored.

Senator DODD. What are the lessons we've learned about—I appreciate the fact that you say this is—and by the way, let me commend you and others and the people who work at CDC. You do a remarkable job. I should have begun my comments by thanking you and others for the tremendous efforts that are made. I don't want these questions to be seen as just the critical questions, but the questions we're getting——

Dr. SCHUCHAT. Sure.

Senator DODD [continuing]. All the time. What have we learned in this phase of it? I appreciate that we're better off today than we were 4 or 5 years ago, but we're constantly learning. What have we learned here, given the anticipation, last summer, of having—I forget the exact numbers we were anticipated to have of vaccines—obviously came way short of that number. Now we're trying to catch up with it. What have we learned as a result of that, that we would now close that kind of a gap?

Dr. SCHUCHAT. Right. I think that we've learned some things about technology. Of course, you can't change this overnight, there are long-term investments needed to strengthen our technology for vaccine production, particularly for influenza.

I think we've also learned something about managing expectations. The companies have produced a lot of vaccine in a record time, but I think the expectations that were set have been difficult to meet. We tried to let people know that bumps could happen, that manufacturing of influenza vaccine is always unpredictable. Yet, I think we didn't get that message out sufficiently.

Senator DODD. So the expectation we set earlier on was unrealistic.

Dr. SCHUCHAT. Well, I think that we tried to qualify it, but perhaps we didn't achieve—it wasn't as well absorbed as we would have liked.

Senator DODD. Talk to me a bit about—I had a meeting yesterday—I don't know if you were in the room when I mentioned, yesterday—I had a roundtable conversation with my department of health in the State of Connecticut and others and the chief epidemiologist in the State. He pointed out to me, we're going to face a third wave, as he described it—Dr. Carta did—of H1N1 probably in late December, January, February—and that at the height, I guess it would be the flu season, as well. Share with us what we can anticipate.

Dr. SCHUCHAT. It's impossible to predict exactly what course we'll see. We do look to history. In 1957 there was a pandemic that did occur early in the fall, like what we're seeing right now, and things got better in December, and then, after the first of the year, there was a second wave of increase in deaths around the country. We're very mindful that that has happened in the past.

We, of course, had disease in the spring, are seeing much more disease now in the fall, just as we had expected, and hope that our vaccination effort will blunt the impact that this virus is having. We like to say that the influenza season typically lasts until May, and so, I think we need to be on alert through that period.

Senator DODD. Again, there have been these reports, obviously, of detainees in Guantanamo receiving the vaccines. There were reports last week that Wall Street, for instance, got a dose of vaccine. Now, again, those headlines alone can provoke their own almost predictable responses. Tell me what the thinking was in both those cases.

Dr. SCHUCHAT. Yes. I think that communication is vital, and misinformation is rampant in any kind of 2009 health emergency. My understanding is that the Department of Defense has vaccine for

Active Duty personnel and that the information about the detainees was not correct.

The issue with Wall Street—let me explain, again, that CDC distributes vaccine to places that the State or city health departments designate. The States and cities are in much better shape than CDC in Atlanta, or HHS in Washington, to know how best to reach priority populations in their midst. They are primarily directing this vaccine to hospitals, to private providers, to local health departments, to schools, and to some employee-based clinics.

Many adults are vaccinated with seasonal flu in the workplace. It's a very convenient place to be vaccinated. I believe this is what was going on with the New York City area. Apparently their initial distributions were to hospitals, private providers, schools, and health departments, and it was only in their second tier that they started to ship vaccine to employers.

Senator DODD. Again, we're talking about—our priority populations here are pregnant women, children, and the elderly.

Dr. SCHUCHAT. No, oh, I'm sorry.

Senator DODD. No, I'm sorry, go ahead, you correct me.

Dr. SCHUCHAT. For seasonal flu that's absolutely right. For the H1N1 virus, it is disproportionately affecting younger people. The five priority groups that our advisory committee recommended be vaccinated early in the response were pregnant women, children and young adults from 6 months to 24 years of age, adults that are working age who have chronic health conditions—diabetes, asthma, cancer and so forth—adults 25 to 64 with those conditions—and parents of newborns under 6 months, as well as healthcare workers or emergency medical service personnel. Many adults—either because they're parents of a newborn, because they have a common disease, like diabetes or asthma, or those adults in the healthcare or emergency medical service personnel, and then adults who are pregnant, who are in the workforce—could easily be reached through employer clinics. We really look to the cities and States, who are directing the implementation of vaccine, to know how best to get vaccine into the path of priority populations. We want it to be convenient, accessible, and available, and we all really do want pregnant women and other adults with risk conditions, to be vaccinated promptly.

Senator DODD. Last two questions I'll have for you here is—tell me about the coordination between CDC, HHS, Department of Labor. How is that working?

Dr. SCHUCHAT. It has been a real privilege to be part of the Federal team that's responding to H1N1 since the early days in April. I would say that there's tremendous coordination within HHS—daily phone calls, actually multiple times a day. We have liaisons at different parts of HHS. Extreme close cooperation with the Department of Labor, Department of Education, Commerce, and, of course, the Department of Homeland Security.

Pandemics do not know borders, and they don't respect sectors. Pandemics do not restrict themselves to the health sector. We have really looked to Labor to help with the flexible leave policy, to Education to help with updated school guidance, as well as a surveillance system that is giving us vital information.

Senator DODD. And last, on the issue—what recommendations does CDC make to employers to help them limit the spread of H1N1? What specific guidelines do childcare facilities and schools use to prevent the spread? And when it comes to H1N1 virus, what are the biggest challenges you hear from employers and schools, State and local public officials?

Dr. SCHUCHAT. Our guidance to schools, childcare centers, and business all stress the importance of staying home when you're sick, or keeping your child home if they are sick. We have updated the guidance, based on the spring, learning from the course of this virus, to suggest staying home for 24 hours after your fever is gone without taking antifever medicines, and that you could return to school or the workplace at that point. We've stressed to businesses the importance of having flexible leave policies so it's easy for your employees to do the right thing.

The Secretaries of Labor and Health and Human Services sent letters out to business. I've spoken with the U.S. Chamber of Commerce. We've really tried to get that message out, to make it easy for people to do the right thing.

Senator DODD. What's the period of time we're talking about—is it 2 days, 3 days? Roughly. I realize this is a tough question. Roughly, what do you anticipate?

Senator DODD. Right. For most people, the recommendation to stay home 24 hours after the fever is gone would mean 3 to 5 days. Of course, if you get sick on a Friday, you wouldn't miss so much.

Senator DODD. Right.

Dr. SCHUCHAT. In the spring our guidance was to stay home for 7 days, and that was very disruptive to schools, and also disruptive to the workplace.

Senator DODD. Of course you're—then, with the inconsistency, in a way, obviously, of recommending these policies, and yet we don't really have an overall strategy. We kind of lurch from pandemic to pandemic on these matters. That'll be another question.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman. I'll just do a few followup questions on what you asked.

The first one being on this apparent confusion over the Department of Defense. Shouldn't the DOD's Guantanamo vaccine order be canceled and re-directed to the CDC, so that you can be sure that every child and pregnant woman that would have the vaccine that wants it can have it? Shouldn't that be the first priority?

Dr. SCHUCHAT. The Department of Defense purchase of H1N1 vaccine is directed for Active Duty personnel and for the dependents and others affiliated with the DOD. That would be carried out through the CDC central distribution effort, so, I think that the DOD was really trying to make sure that Active Duty personnel could be vaccinated promptly. Really, force readiness is a vital factor for them.

Senator ENZI. I think anybody that's infected with it considers it a very vital factor.

Now, the Administration announced ambitious goals for the vaccine production, claiming that the United States would have access of 80 to 120 million doses of the H1N1 vaccine by mid-October. We're now in November, and we only have 36 million vaccines.

What went wrong at CDC or HHS? What caused such a drastic overestimation?

It's my understanding that the manufacturers did not report similar targets. Is that true?

Dr. SCHUCHAT. The estimates for vaccine projections for this fall were given by manufacturers to Health and Human Services. We shared those estimates with the State and local health departments, who were keenly needing information in order to be able to plan the school clinics and the other mass clinics. As information changed, we updated the information.

Every time we've talked about influenza vaccine production, really from June onwards, we've talked about how unpredictable it can be. Many may remember 2004 and 2005, when, October 5th, we learned that half of the U.S. vaccine supply was lost because of manufacturer challenges. I think that while we have tried to qualify projections, it's been difficult to get that message out. It is extremely frustrating and disappointing to everyone, I think, that we have had this delayed start.

That said, we have twice as much vaccine right now as we had about 2 weeks ago, and the pace is really picking up. We are seeing the ability, more and more every day, to meet the incredible demand that we have for vaccine.

Senator ENZI. Of course, I'm hearing from the people that are standing in line for clinics, and then getting up to the front of the line and finding out that there isn't enough vaccine there to take care of them and their children, some waiting in line for more than 1 or 2 hours.

Dr. SCHUCHAT. Absolutely. It's difficult to see that, and especially pregnant women, people with their children, children with these disabilities. It's very hard. The good news is, a poll recently showed that 9 out of 10 people who looked for vaccine and were not able to get it plan to look again, that they understand that the supply is limited right now, but do hear that more is coming. I wish it were much easier, more convenient for everyone who wants to be vaccinated to be vaccinated. I think the next several weeks will be a delicate effort to really try to reach these priority groups, and after that, the others in need.

Senator ENZI. I'm also hearing from some people who, at their clinic, have been asked if they wanted the vaccine. They said, "Well, I thought that was in short supply, and I'm not in that eligible group." And their answer from the clinic was, "We don't have enough people in that eligible group, but we have vaccines."

Is there anything being done to cause a redistribution there? Those people that realize they shouldn't have it are still getting it, and somebody else is not getting it.

Dr. SCHUCHAT. You raise a really important issue about the challenges of supply and demand at that very local level. Our advisory committee on immunization practices thought carefully about how to prioritize vaccine when it was in short supply—again, learning from the 2004–2005 experience. At that point, a very narrow set of priorities were given, and people did step aside, as you say, and we ended up having to throw out vaccine. Our advisory committee came up with a pretty broad priority population—it's about half of the U.S. population—but said, at any level—at local, at the pro-

vider level, at the county level—the decisions about when to expand beyond the priority groups should be made, rather than at the national level, really locally, because the local attitudes about vaccine, whether people are concerned about the disease or are really seeking the vaccine, are different, area to area. We may see differences, week to week, and our advisory committee wanted there to be a very low threshold for providers to be able to continue to offer vaccine to others, especially as it's continuing to be produced each day.

Senator ENZI. You keep referring back to that 2004–2005 incident. I can remember when Senator Byrd and Senator Dodd and Senator Kennedy and I were in a room trying to work out some of the problems of this.

Can you point to any internal barriers at the Department of Health and Human Services that have contributed to the vaccine shortage? Or are there positions that haven't been filled that would exacerbate the vaccine shortage? Are there some things we need to do?

Dr. SCHUCHAT. You know, I think the key barrier to our vaccine immunization—or, to our immunization effort—is really the fragility of the public health infrastructure, that even with the doses that are coming out, we are dependent on the local and State public health system to direct these doses to providers, to local clinics, to hospitals. You know, there have been about 15,000 jobs lost in that sector over the last 2 years. The emergency funds for pandemic have helped a lot, but the core is really eroded.

Senator ENZI. Are there any positions, though, in the Federal Government, that we haven't filled yet, that need to be, to work on this?

Dr. SCHUCHAT. I'm not aware of there being, but we could get back to you on that.

[The information referred to may be found in Additional Material.]

Senator ENZI. Thank you.

Senator DODD. Thanks.

I am receiving a note, by the mayor's office in New York, that Goldman Sachs requested 5,400 H1N1 doses, but received 200, which was consistent with the average number of employees who may be pregnant. That's the note I'm reading.

The other problem they manage—that, for instance, they report an average of 23 percent of parental consent rate for vaccines in school-age children in New York City, and they're attributing that to the fact that New York City has a relatively low rate of H1N1. Therefore, the parents may be less reluctant to be asking for it. Parental consent is critical, obviously, for those things. That's a pretty low number, that 23 percent.

Dr. SCHUCHAT. Yes. Parental consent is a vital part of successful school-located immunization. We have success stories around the country, and we have some areas that have seen more challenges. In some areas, this is something that parents are used to. You know, they've been offering seasonal flu vaccine in the schools, and the consents are higher—more in the 30-, 40-, or 50-percent range. We got fantastic results from Maine recently about very high acceptance rates. The logistics of school-located clinics are pretty

tricky, and we really applaud the hard work that the States and cities have been doing to carry them out.

Senator DODD. Senator Murray.

Senator BROWNBACK. Were children vaccinated without parental consent?

Dr. SCHUCHAT. I believe there may have been one or two situations like that, but I don't have the details. There's a consent form that's provided. In fact, CDC developed draft consent forms this summer, so States could be ready. And we really wanted, working with the Department of Education, to raise that awareness on the part of the schools and the parents about when the vaccine gets there, there won't be that much time to get all the ducks in a row, so let's work on everything we can up front. You know, this is an enormous undertaking, and there will be aberrations.

Senator BROWNBACK. And there were.

Senator DODD. Senator Murray.

Senator MURRAY. Thank you very much.

Dr. Schuchat, first of all, thank you so much. I know everybody's working really hard. Expectations were high. We have all watched, with frustration, long lines at home, in many places where parents with young kids, and pregnant women, have stood in line and found out, at the end of the day, there wasn't enough for them. I heard your explanation, that manufacturing didn't happen as soon as possible, some distribution.

A two-part question. First of all, when will we see those lines gone, so that people will be able to get access to the vaccination, so we can give them that assurance? Second, what are the lessons learned in distribution, so we know, next time, for December–January, or for several years from now?

Dr. SCHUCHAT. Yes, thank you, those are both really important issues. You know, I think that more and more doses are getting out to providers, and the health departments are also directing vaccine for these mass clinics and school clinics. I think the pressure will be decreasing. Things could change very quickly if demand changes. Right now there's very high demand for vaccine in most, but not all, communities.

I can't tell you an exact day when things will be better in any one community. I can say that the supply is much more reliably increasing now, and that demand could change quickly. It's really when you reach that sweet spot of supply and demand.

I can't give you a number of doses by which everything will be fine. But, certainly when there's more doses out there in the school-located clinics and the doctors' offices, the numbers who need to attend the mass clinics will be reduced.

The second question was about lessons learned, and I think a critical lesson is about communication. We have really been trying to support the State and local health departments and give them information in order to be able to do their planning and their outreach. As the supply changed, their planning had to really change, and they had to recommunicate information. I think the American public has been great about this, but I think if they understood, in any one locality or State, how vaccine is being distributed, there would be a lot easier time. Many States and cities are doing that,

but to say we're initially shipping to hospitals, then we're starting these school programs——

Senator MURRAY. But that's a State decision as to whether it goes to hospitals or schools.

Dr. SCHUCHAT. Yes, that's right. What CDC does is set national guidance about priority populations. States and cities are in the best position to know their community, to know their provider capacity, to know their health system, to know the partners—the church and faith-based communities, to know, How can we reach these people who need to be vaccinated most effectively?

We are letting the State and local health departments direct the vaccine. I think there are some places where the State-to-local health department communication could be better, but, fundamentally, I think public health at the local and State level have been doing a phenomenal job. Fundamentally the problem has been less vaccine than we all expected.

Senator MURRAY. Right.

Mr. Harris, I wanted to ask you—as I said in my opening remarks, I am very concerned that CDC has issued these guidelines, they want people to stay home, it's absolutely the right thing to do, to stop the spread of this and to make sure that we're doing the right thing. We're doing this right at a time when our economy is really struggling, and many workers today can't take sick leave, or they lose income.

Obviously we're looking at legislation today to impact that for paid sick leave. I think that that is the right thing to do. Can you tell us today what some of the best practices you're giving to employers today so that they can make sure their workforce remains healthy?

Mr. HARRIS. We can, and we share the concern that you just expressed, Senator. We've been working very closely with Dr. Schuchat and our friends at HHS, as well as the Commerce Department and the Department of Homeland Security, to provide that kind of guidance to employers and other institutions that are large gathering places.

The philosophy of community mitigation is to avoid illness, to the extent possible, using social distancing and other strategies. What we've encouraged employers to do—the most important principle, is that if someone is sick, they shouldn't come to work; if they arrive at work sick, they should be sent home. The goal should be for sick people to stay away from healthy people so that we don't spread the illness.

For a lot of workers, as you said, that's a difficult thing to do, because they give up a day's pay, they risk their job in some cases. There's no protection against discipline for a large percentage of workers. We may well have reached the stage where—or we believe we have reached the stage where we need legislation that makes it easier for employers to—in this tightly competitive environment—to make that choice, to make that decision for workers to stay home; for workers to make that decision for themselves to stay home.

Senator Enzi mentioned that in a lot of businesses you have employers who would like to have workers stay home, and make informal arrangements. In the tough competitive environment we're ex-

periencing right now, it's hard for employers to make that kind of an individual arrangement. They need the added help. If we make all competitors comply with a basic labor standard, that kind of decision—that social distancing, staying home if you're sick—becomes easier.

Senator MURRAY. Thank you very much, I appreciate it.

Thank you both.

Senator CASEY. Mr. Chairman, thank you very much.

Doctor, I want to thank you for your work, and your commitment to public service, especially under difficult circumstances.

Deputy Secretary Harris, great to have you here.

Doctor, first of all—and this is by way of repetition, but that's important around here. I know you've testified to this, one way or the other. I just want to be clear, in terms of some of the numbers here, to the extent that you can answer this question.

The gap, or the disconnect, between the demand or the need for treatment, as opposed to what is in the pipeline for the vaccines—can you give me a general sense of those numbers?

Dr. SCHUCHAT. Yes. Today, 41.1 million doses of H1N1 vaccine are available for the States to order. It's about twice what we had 2 weeks ago.

We don't have a precise number of doses that we think will be enough. We don't know the long-term demand. We have some baselines or background to use. With seasonal influenza, about one out of three people for whom it's recommended actually gets the vaccine. We do a bit better with seniors; about 70 percent of seniors get the vaccine. In the younger age groups, we don't do very well. If one out of three people in this recommended group of 159 million actually sought the vaccine, we'd be pretty close to where we needed to be right now. We know, though, that demand is higher than that right now.

What I have been saying is that exactly where demand will be in the weeks ahead is difficult to predict. We're grateful that 9 out of 10 people who sought vaccine and couldn't find it plan to look again. They may get frustrated, and we hope they don't. We're hopeful that we can address the concerns that some people have about the safety of the vaccine, or about the threat of the virus, so that they take seriously the benefits the vaccine can offer when it's available to them.

We don't know exactly what week or day in any particular area we will have that perfect mix of supply and demand. This actually happens every year with seasonal flu vaccine. We have more than we want, or not enough. People think the pharmacy's got it before the doctors' offices. It's very challenging. It's just something that—seasonal flu vaccine is pretty much a private-sector enterprise. This H1N1 program, of course, is publicly directed, and we're really stressing the importance of communication to let people know what to expect and how to protect themselves.

Senator CASEY. With regard to H1N1, you're saying 41.1 million doses are available.

Dr. SCHUCHAT. As of today.

Senator CASEY. OK. And when you say "available," what does that mean?

Dr. SCHUCHAT. That's right. "Available" means that it's come from the manufacturers to our central distributor. It's been checked in, and it wasn't damaged. It didn't need to be quarantined or set aside. It is ready for the States to order. The States have a pro-rata share of the vaccine, based on their population, and every day the States or the big city health departments are putting in orders for vaccine to be shipped to the sites that they designate.

We have the capacity to ship to up to 150,000 sites. We're not shipping to that many yet. As supply increases, we can ship to many places directly. The 41.1 million is the doses that, this morning, the States were offered—the cumulative total that they were able to order from.

Senator DODD. That is exactly the question—it is cumulative? That's the number available now?

Dr. SCHUCHAT. This is the total that have become available since the program began on September 30.

Senator DODD. What do you have available now?

Dr. SCHUCHAT. I would have to get that back to you.

[The information referred to may be found in Additional Material.]

Dr. SCHUCHAT. Basically, a key point is that the States are ordering every day, and most of the States are ordering the vast majority of what's allocated to them, so there's not a lot sitting around. This is in and out.

We've really, over the past couple weeks, sped things up. You know, once we understood it was a trickle that we were getting, we said, "Well, we'd better speed up every drop of vaccine that we get, focusing on overnight shipment." To 90 percent of the sites, or a guarantee that it we will reach the provider site within 24 hours for 90 percent of deliveries, focusing on shipping the needles and syringes at the same time as the vaccine doses. Initially we were going to ship the needles the day before, so you'd be sure you got them. We've really sped up everything we can speed up, and have been offering outreach to States that are having trouble keeping up with their orders.

Senator DODD. No, I understand. No, I apologize for interrupting, I just wanted that cumulative——

Senator CASEY. No, that's OK. You're the Chairman.

[Laughter.]

With regard to H1N1, what have you learned—or what have we learned—not just you, but all of us—and, I guess, what have you learned—just on this topic: distribution or delivery of the vaccines—what have we learned, and what are the biggest challenges in the next couple of weeks and months on this? Just on the distribution challenge.

Dr. SCHUCHAT. We have been learning how best to manage the central distribution and support of the State and local health departments. Some of our systems were ready, because we had transitioned to a central distributor system for our childhood vaccination program, the Vaccine for Children Program. Eighty million doses of routine vaccines goes in and out of this system every year.

This is a large-scale, short-term influenza program on top of that, and some of our systems weren't ready. We are in the process of upgrading the information system by which providers order vac-

cine. In the future, we hope that providers can just order right in their own offices, without having to go through the State and local health departments, but that system wasn't yet ready.

The weeks ahead, the second thing we've learned is how fragile the State and local public health system is. I can't tell you how many times in our outreach to our counterparts we got messages back—automatic messages—"It's Friday, we're furloughed." Or, "No one is here today." You know, really a hard time for public health to mount this kind of response. They've been really rising to the occasion in a tremendous way.

In the weeks ahead, anything can happen. This can be unpredictable, although many of the things that have happened, we had contingency plans for. I think, in the weeks ahead, we're going to reach a point where, instead of not having enough vaccine, we have vaccine that's not being used. It's critically important that we are ready with aggressive outreach, particularly to the vulnerable populations that may not be in the mainstream, getting the messages, to make sure that we're able to protect people who want to be protected, and that we can address the concerns that they have.

Senator CASEY. Well, I think I'm over time. I've got a couple more, but I'll hold.

Senator DODD. Thank you, Bob.

Senator Hagan.

Senator HAGAN. Thank you, Mr. Chairman.

In response to your last statement, when you said, "In the weeks ahead, we will probably have an oversupply," what is your strategy to try to be sure that people are educated that they really do need to come in and get the H1N1 vaccination?

Dr. SCHUCHAT. Yes. We've been working with a comprehensive communications strategy with public service announcements, with partners, lots of outreach to local trusted partner groups. The White House has organized a whole set of outreach to the faith-based and community-based organizations to help us reach people who may not trust, certainly, the government in Atlanta or Washington, but not necessarily even their State or local government, so that we are able to raise demand where demand is just a function of lack of information.

There's been this tricky period, right now, where we'd like to make sure that we have sufficient supply before we raise demand further, because we don't want people even more frustrated about the lines and inability to access vaccine. We've been really holding frequent discussions about when do we turn on that part of the strategy, rather than it being so early that it backfires, but not too late to benefit the people who could take advantage of protection.

Senator HAGAN. I wanted to ask a question on individuals that don't have paid sick leave. It's my understanding that in many places, schoolbus drivers don't have access to that. I think that's a shocking fact. I know that the CDC strongly recommends that anyone who is ill should stay at home. Have there been any particular efforts made to ensure compliance among those professions that are most likely to cause the spread of disease, such as teachers, bus drivers, healthcare workers?

Mr. HARRIS. We've been engaged, working with CDC and working with HHS and the Commerce Department. We're doing out-

reach into the business community, through the Chamber of Commerce and other organizations; not targeted to particular occupations, but targeted to particular industries. You highlight a very important fact, and that is that a lot of workers, particularly low-wage workers in service-based industries, who have a tremendous amount of customer contact, are among the least likely workers to have paid leave, to be able to take time off from work. Exactly the opposite of what you would want. From a public health perspective, you have workers in contact with people who are coming in to work sick—food service workers, hotel workers, childcare workers, bus drivers, and others, the Chairman mentioned cafeteria workers in schools—exactly the situation that we don't want to have. One in four low-wage workers has paid leave. And in those service industries, about 78 percent have no leave. That's the reason why we're advocating for the Healthy Families Act, to try and address that problem.

Senator HAGAN. I know there's a lot of concern lately regarding the healthcare professionals who have decided not to get vaccinated—or to get the vaccine. Is that prevalent? Is that causing distress and problems within medical offices and hospitals?

Dr. SCHUCHAT. You know, it's a sad feature of this pandemic that some vocal healthcare workers have not wanted to be vaccinated, or have discouraged their patients from being vaccinated. As a doctor and a public health expert, it's just vital to me to do no harm, to not spread flu to my patients, and to protect myself and those around me. I believe that we will have a greater uptake of influenza vaccine in healthcare workers, both the seasonal and the H1N1, over the course of this season and the future ones, because I think people are beginning to realize that the flu can be serious and that the influenza vaccines, while not perfect, offer better protection than risking the disease. I do expect, in the years ahead, we'll be making more progress with that. It's gotten a lot of attention this year, and we certainly strongly promote healthcare worker vaccination. It's been less than half of healthcare workers, in the past several years of surveys, that have taken advantage of the vaccine.

Senator HAGAN. Thank you.

Senator DODD. Senator Hagan, thank you very much.

I appreciate you raising the issue of the schoolbus drivers. Earlier today, I raised the issue, as well. I was told 100 percent of school bus drivers do not have any sick leave pay. That number, obviously, is a pretty staggering number. I'm told, unlike other areas, it's just almost universal in that area.

That question that Senator Hagan has raised is one that—because, here again, we're talking about this fact situation, and Senator Enzi pointed out that, we first became aware of this in March, and obviously we had numbers that predicted a certain amount of dosages being available this summer. We didn't reach that. What's quite clear to all of us is that we're living in a world today where, because of the interconnectibility, these kinds of conditions are going to become more common. It's not the rarity any longer, it's the predictable. To what extent, then—whereas, as we did after 9/11, began thinking about how we deal with this in a comprehensive way, as part of a Federal policy, to deal with these issues—whether

it's sick leave, or whatever other aspects of this, I think it will be very, very important so that we don't find ourselves, kind of, lurching and having dramatic hearings and asking questions of why didn't we know better this time around than the next time? I think all of us, in the midst of everything else, would love to get some thoughts and ideas from the CDC, obviously HHS, and others—private sector, Department of Labor—all of the pieces that come together, as to how we can frame a structure, an architecture that would allow us to be able to respond to these fact situations, when they emerge, in a way with far greater predictability, so they become, while important events, ones that we're structurally capable of responding to in a thoughtful manner. I certainly would welcome that kind of suggestion, as well.

I just have one question, for you Mr. Harrison—I apologize that, due to the time, and so forth, I didn't get to ask—I'll submit some questions. I have several of them for you.

[The information referred to may be found in Additional Material.]

Senator DODD. Is it the Administration's view that you would support the Healthy Families Act? Is that true?

Mr. HARRIS. Yes.

Senator DODD. I appreciate that.

We're also working on some emergency legislation to deal with this kind of a situation, and we don't have it framed yet, but we'd very much welcome the Administration's participation. In fact, we welcome anyone's participation in this, to help us put together something that might help us respond to this situation.

With 600 school districts closing their doors across the country because of H1N1—I've had 10 in my State alone. It isn't just the sick parent or the sick child, it's the healthy parent and healthy child that find themselves all of a sudden with no one watching out for them, with working parents. How do we accommodate that? We've got to try to think about a structure, here, that can be more acceptable. We look forward to working with you on that.

Mr. HARRIS. Thank you, sir.

Senator DODD. I'll leave the record open for some additional questions, as well.

I thank our two witnesses, very, very much.

Let me, if I can now, move to our third panel. Let me introduce our witnesses. Debra Ness is a good friend. I'll acknowledge, at the outset, is president of the Partnership for Women and Families.

Ms. Ness, welcome again, to this committee. We appreciate your taking the time to talk to us today about paid sick days and Healthy Families Act.

Ms. Ness has been president of the National Partnership for Women and Families for 5 years, was previously the executive vice president of the National Partnership for 13 years. She's worked for over two decades in the areas of social justice, health and public policy, attended Drew University and Columbia University School of Social Work. She draws upon years of work in areas important to women and working families.

We're happy to have you with us.

Desiree Rosado is a constituent of mine and—delighted to have you here, Desiree. Thank you for coming down—welcome to the

Children's and Family Subcommittee—from Groton, CT, taking the time to be with us. Ms. Rosado lived in Groton, with her husband and three children, for 12 years. She works as a special education assistant in the Groton public schools, very active in the community, is a member of the MomsRising. She and her husband led the praise and worship department in their church.

We thank you very much for joining us, as well.

Elissa O'Brien is active. She's the director of human resources for Wingate Healthcare, in Massachusetts, which has 4,000 employees. Ms. O'Brien is also an active volunteer for the Society for Human Resources and Management and is currently serving a 2-year term as director for the Rhode Island State Council of the organization.

We thank you, for joining us here, as well, Ms. O'Brien.

We have with us Scott Gottlieb. Dr. Scott Gottlieb is a fellow of the American Enterprise Institute. Dr. Gottlieb—welcome to the committee—is a fellow of the American Enterprise Institute, as well as a practicing physician, has served in several capacities at the Food and Drug Administration, as well as a senior policy advisor at the Centers for Medicare and Medicaid Service—CMS.

And we thank you, for joining us, as well, this morning.

We'll begin in the order that I've introduced you. We'd ask you to keep your remarks to about 5 minutes, if you could, so we can get to some questions.

Debra, nice to see you. Thank you for being here.

STATEMENT OF DEBRA NESS, PRESIDENT, NATIONAL PARTNERSHIP FOR WOMEN AND FAMILIES, WASHINGTON, DC

Ms. NESS. Thank you.

Good morning, Chairman Dodd, Ranking Member Enzi, Senator Casey. Thank you, for inviting us all here to talk about the policies that America's workers urgently need during this H1N1 flu emergency.

I'm Debra Ness, president of the National Partnership for Women and Families, a nonprofit, nonpartisan, advocacy group. I'm here to testify in support of the Healthy Families Act, groundbreaking legislation that is tremendously important to working people across the Nation, especially during this national emergency.

The National Partnership leads a very broad-based coalition in support of paid sick days. I'm testifying here today on behalf of the millions of individuals represented by civil rights, women's, disability, children's, faith-based, antipoverty, labor, health, and research communities. We all urge you to quickly pass the Healthy Families Act, the bill now before Congress that offers the best solution to this problem.

What is the problem? Quite simply, that millions of hardworking people in this country have no paid sick days. Almost half of private-sector workers and more than three-quarters of low-wage workers, most of them women, don't have a single paid sick day. At a time when the H1N1 virus has infected millions and is widespread in 48 States, our failure to provide a minimum standard of paid sick days is exacting a terrible toll. Over the past few months, as this national emergency has progressed, experts and public officials from the CDC to the President of the United States have told

us all: Be responsible, stay home, keep sick children home, to prevent the spread of the virus. It's excellent advice. Unfortunately, as the Congresswoman pointed out earlier today, taking that advice is simply not an option for millions of workers. They want to do the right thing. No one wants to spread the flu. Frankly, what's responsible when staying home means risking a paycheck or a job that your family depends on?

Working people need paid time off to recover from H1N1, to care for sick family members, to prevent spread of the virus. This is particularly true for those who do the caregiving. The highest H1N1 virus attack rate is among children and youth, many of whom need a parent to care for them when they get sick. That's why the lack of paid sick days is especially challenging for working women, who often have primary responsibility for a child as well as eldercare in their families.

Our failure to provide a minimum standard of paid sick days also is putting our public health at risk. Only 22 percent—less than a quarter—of food service and public accommodation workers have paid sick days. Workers in childcare centers, in nursing homes, disproportionately lack paid sick days. They are forced to work when they're sick, and, in so doing, they put their coworkers, the people they care for, and the public at risk.

While the need for paid sick days is particularly compelling during this H1N1 flu emergency, the reality is that working families struggled without paid sick days prior to this emergency, and they will continue to do so until Congress acts. Every year the seasonal flu and other illnesses strike millions of us, and every year the failure to let workers earn paid sick days puts the economic security of millions of families at risk.

Senators, I certainly don't need to tell you how devastating the current economic crisis has been for families. Many families that once relied on two incomes are managing now with just one or none. A survey commissioned last year by the Public Welfare Foundation found that one in six workers reported that they or a family member had been fired, suspended, punished, or threatened with being fired, simply for taking time off due to personal illness or to care for a sick relative. That was before H1N1 and the recession. The pressures now, are even worse.

Another survey, conducted just a month ago, found that five in six workers say that the recession is creating added pressure to show up for work even when they're sick. In a humane and rational society, that's just not a choice workers should be forced to make.

Furthermore, we know that paid sick days are good for businesses. Responsible employers know that. They know that when they take care of workers, workers stay on the job. They know that workers with paid time off are more loyal and productive. They know that keeping trained workers on the job is less expensive than replacing them. They know that paid sick days reduce presenteeism—people going to work sick and getting other people sick. They know that paid sick days are not only the right thing to do, but the smart thing to do.

In conclusion, just like the minimum wage, America needs a Federal minimum standard of paid sick days that protects all employees. The Healthy Families Act will provide that standard. It would

let workers earn up to 7 paid sick days a year to recover from short-term illness, to care for a family member, to seek routine medical care, or to seek assistance related to domestic violence, sexual assault, or stalking. Congress should waste no time in passing this bill.

I thank you for the opportunity to testify here today. We look forward to working with you to pass the Healthy Families Act.

Senator Dodd, I want to echo what Congresswoman DeLauro said and recognize your leadership that has spanned more than three decades on behalf of working families, understanding, to your core, that it is time for our Nation's workplace policies to catch up with the realities that families struggle with, day in, day out.

[The prepared statement of Ms. Ness follows:]

PREPARED STATEMENT OF DEBRA L. NESS

Good morning Chairman Dodd, Ranking Member Alexander, members of the subcommittee and my distinguished fellow panelists. Thank you for inviting us to talk about the policies our Nation's workers urgently need during this H1N1 flu emergency.

I am Debra Ness, President of the National Partnership for Women & Families, a non-profit, non-partisan advocacy group dedicated to promoting fairness in the workplace, access to quality health care, and policies that help workers meet the dual demands of work and family. I am here to testify in support of the Healthy Families Act, groundbreaking legislation that is tremendously important to working people across the Nation—especially during this national H1N1 flu emergency. The National Partnership for Women & Families leads broad-based coalitions that support the Healthy Families Act. These coalitions include children's, civil rights, women's, disability, faith-based, community and anti-poverty groups as well as labor unions, health agencies and leading researchers at top academic institutions. They include 9 to 5, MomsRising.org, the Leadership Conference on Civil Rights, the AFL–CIO and SEIU, the Family Values @ Work Consortium, the National Organization for Women and dozens of other organizations. Together, we urge Congress to pass the Healthy Families Act.

WORKERS NEED PAID SICK DAYS DURING THIS H1N1 FLU EMERGENCY

In recent months, much attention has focused on the H1N1 virus and the best ways to contain it—and with good reason. H1N1 is a novel flu virus that experts predict may result in many more illnesses, hospitalizations and deaths this year than would be expected in a typical flu season.[1] Forty-eight States had "widespread flu activity" as of Oct. 24, according to the Centers for Disease Control and Prevention (CDC).[2] The CDC recorded nearly 26,000 hospitalizations and more than 2,900 deaths related to H1N1 flu between Aug. 30 and Oct. 24.[3] The virus is now so widespread that the CDC and World Health Organization are no longer keeping track of the number of individual cases. Officials estimate if 30 percent of the population contract the virus, it could mean approximately 90 million people in the United States could become ill, 1.8 million may need to be hospitalized, and approximately 30,000 could die.[4] As a result, President Barack Obama declared the H1N1 flu outbreak a national emergency, allowing hospitals and local governments to quickly set up alternate sites for treatment and triage procedures if needed to handle any surge of patients.[5]

Week after week, government officials urge sick workers to stay home and keep sick children at home to prevent the spread of the H1N1 virus. Commerce Secretary

[1] U.S. Dept. of Health and Human Services, "About the Flu," *http://pandemicflu.gov/individualfamily/about/index.html*.

[2] Centers for Disease Control and Prevention, 2009–2010 Influenza Season Week 42 ending October 24, 2009, *http://www.cdc.gov/flu/weekly/*.

[3] CDC, 2009 H1N1 Flu U.S. Situation Update, 10/2/09, *http://www.cdc.gov/h1n1flu/updates/us/*.

[4] The President's Council of Advisors on Science and Technology. "Report to the President on U.S. Preparations for 2009—H1N1 Influenza", 8/7/09, *www.whitehouse.gov/assets/documents/PCAST_H1N1_Report.pdf*.

[5] New York Times, "Obama Declares Swine Flu a National Emergency", *www.nytimes.com/aponline/2009/10/24/health/AP-US-Obama-Swine-Flu.html?scp=3&sq=obama%20national%20emergency%20swine%20flu&st=cse, 10/24/09*.

Gary Locke said that "if an employee stays home sick, it's not only the best thing for that employee's health, but also his co-workers and the productivity of the company."[6] Health and Human Services Secretary Kathleen Sebelius said that "one of the most important things that employers can do is to make sure their human resources and leave policies are flexible and follow public health guidance."[7]

The CDC has also issued recommendations: "People with influenza-like illness [must] remain at home until at least 24 hours after they are free of fever . . . without the use of fever-reducing medications."[8] In addition to the guidance for workers, officials have stated that schools and child care providers will need to rely on parents to keep children at home if they are feverish.[9] This is excellent advice, as far as it goes, but unfortunately, taking this advice isn't an option for millions of workers. They may want to do the right thing and do all they can to prevent the spread of the H1N1 virus. But for many, doing their part means risking their paychecks and even their jobs, because they lack job-protected paid sick days.

Working people need *paid time off* from their jobs to recover from the H1N1 flu and care for sick family members—and prevent further spread of the virus. Yet, the reality is that nearly half (48 percent) of private-sector workers lack paid sick days.[10] The same is true for nearly four in five low-wage workers—the majority of whom are women.[11] Women also are disproportionately likely to lack paid sick days because they are more likely than men to work part-time, or to cobble together an income by holding more than one part-time position. Only 16 percent of part-time workers have paid sick days, compared to 60 percent of full-time workers.[12]

Especially during this epidemic, workers with caregiving responsibilities in particular have an urgent need for paid sick days. The highest H1N1 virus attack rate is among 5- to 24-year-olds, many of whom need to stay home from school when sick—often with a parent to care for them.[13] That's why the lack of paid sick days is particularly challenging for working women—the very people who have primary responsibility for most family caregiving. In fact, almost half of working mothers report that they must miss work when a child is sick. Of these mothers, 49 percent do not get paid when they miss work to care for a sick child.[14]

OUR FAILURE TO ESTABLISH A PAID-SICK-DAYS STANDARD IS PUTTING THE PUBLIC HEALTH AT RISK DURING THE H1N1 EMERGENCY

Our Nation's failure to provide a minimum standard of paid sick days is putting our public health at risk. Many of the workers who interact with the public every day are without paid sick days. Only 22 percent of food and public accommodation workers have any paid sick days, for example. Workers in child care centers and nursing homes, and retail clerks disproportionately lack paid sick days.[15] Because the lack of paid sick days forces employees to work when they are ill, their coworkers and the general public are at risk of contagion.

Research released this year by Human Impact Partners, a non-profit project of the Tides Center, and the San Francisco Department of Public Health, found that providing paid sick days to workers will significantly improve the Nation's health. This groundbreaking study found that guaranteeing paid sick days would reduce the spread of pandemic and seasonal flu. More than two-thirds of flu cases are transmitted in schools and workplaces. Staying home when infected could reduce by 15 to 34 percent the proportion of people impacted by pandemic influenza.

The Human Impact Partners analysis also found that if all workers had paid sick days, they would be less likely to spread food-borne disease in restaurants and the number of outbreaks of gastrointestinal disease in nursing homes would reduce. The researchers provided evidence that paid sick days may be linked to less severe illness and shorter disability due to sickness, because workers with paid sick days are 14 percent more likely to visit a medical practitioner each year, which can translate

[6] Associated Press, "Government enlists employers' help to contain flu," 8/19/09.

[7] HHS News Release, 8/19/09, *www.hhs.gov/news/press/2009pres/08/20090819a.html*.

[8] CDC, Recommendations for the Amount of Time Persons with Influenza-Like Illness Should be Away, *www.cdc.gov/h1n1flu/guidance/exclusion.htm*.

[9] Center for Infectious Disease Research & Policy, Univ. of Minn., *www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/aug0709schools3.html*.

[10] Vicky Lovell, Institute for Women's Policy Research, Women and Paid Sick Days: Crucial for Family Well-Being, 2007.

[11] Economic Policy Institute, Minimum Wage Issue Guide, 2007, *www.epi.org/content.cfm/issueguides_minwage*.

[12] Vicky Lovell, Institute for Women's Policy Research, No Time to be Sick, 2004.

[13] CDC, Novel H1N1 Flu: Facts and Figures, *www.cdc.gov/h1n1flu/surveillanceqa.htm*.

[14] Kaiser Family Foundation, "Women, Work and Family Health: A Balancing Act," Issue Brief, April 2003.

[15] Vicky Lovell, Institute for Women's Policy Research, No Time to be Sick, 2004.

into fewer severe illnesses and hospitalizations. They also found that parents with paid time off are more than five times more likely to provide care for their sick children.

Recent data on the impact of the H1N1 virus in Boston, MA shows that the outbreak has hit certain mostly low-income communities harder than other communities. The Boston Public Health Commission reported that more than three in four Bostonians who were hospitalized because of H1N1 were black or Hispanic.[16] Boston's experience is not unique. Communities of color all across the country face similar health disparities and they may be due, in part, to the fact that low-wage workers are less likely to have paid sick days.

BEYOND THE H1N1 EMERGENCY

While the need for paid sick days may seem particularly compelling during the H1N1 emergency, the reality is that working families struggled without paid sick days prior to this emergency, and they will continue to struggle after this emergency unless Congress takes action. Paid sick days aren't just about protecting the public's health—they are also about protecting the economic security of millions of workers and their families. One in six workers report that they or a family member have been fired, suspended, punished or threatened with being fired for taking time off due to personal illness or to care for a sick relative, according to a 2008 University of Chicago survey commissioned by the Public Welfare Foundation. To put a face on some of those statistics, I'd like to share with you a few stories from working people:

- Heather from Cedar Crest, NM told us:

  "In October, I got very sick with diverticulitis. My doctor put me on bed rest for 2 weeks. While I was out, my boss hounded me to come back, but I was way too sick. I told him I would be back as soon as I could. I was not receiving sick pay at all. When I did go back to work early, he fired me and told me he needed someone he could count on. I worked for this man for 2 years. I was shocked. Sometimes things happen and you get sick. How are you to foresee these things?"

- Noel from Bellingham, WA wrote to us:

  "I had to work while having bouts of awful bronchitis and walking pneumonia. I got no time off at all even when I was in severe pain, coughing up phlegm or vomiting. Instead I had to act like I wasn't sick, and keep up the same standards and smiling face . . . I couldn't take unpaid days off from work because I couldn't afford to do that. I needed the money to pay for things like rent and food. When my quality of work suffered substantially from having to go to work while so sick, I was fired from my job because according to my then-supervisor, I did not create a happy environment for the customers."

The H1N1 outbreak has come during a painful recession, and both have exacerbated the need for paid sick days. I don't need to tell you that the economic crisis has been devastating for working families. More than 11.6 million workers have lost their jobs, and millions more are underemployed. In October, the unemployment rate was 10.2 percent—the highest level since December 1983. The unemployment rate for African-Americans was 15.7 percent, the rate for Hispanics was 13.1 percent, and the rate for whites was 9.5 percent in October 2009.[17] For many families that once relied on two incomes, this crisis has meant managing on one income or no income at all. As a result, families are not only losing their economic stability, but their homes: one in nine mortgages is delinquent or in foreclosure.[18]

Five out of six workers (84 percent) say the recession and the scarcity of jobs are creating more pressure to show up for work, even when they are sick.[19] Workers are understandably anxious about their job security, and many are unable to take any risk that might jeopardize their employment—even if they are stricken with H1N1. Especially now, when so many workers are suffering terribly, we must put in place a minimum labor standard so taking time off for illness doesn't lead to financial disaster. Workers have always gotten sick and always needed to care for

[16] Cases of swine flu higher among city blacks, Hispanics, Stephen Smith, Globe Staff, August 18, 2009, *http://www.boston.com/news/local/massachusetts/articles/2009/08/18/cases_of_swine_flu_higher_among_bostons_blacks_hispanics?mode=PF*.

[17] U.S. Bureau of Labor Statistics, Economic News Release, Employment Situation Summary, Nov. 6, 2009, *http://data.bls.gov/cgi-bin/print.pl/news.release/empsit.nr0.htm*.

[18] Center for American Progress, *www.americanprogress.org/issues/2009/03/econ_snapshot_0309.html*, March 2009.

[19] Angus Reid Strategies for Mansfield Communications online survey of 1,028 workers, conducted 9/10–9/12/09. Margin of error: +/-3.1% points.

children, family members and older relatives—and they have always managed to be productive, responsible employees. But without a basic labor standard of paid sick days, families' economic security can be at grave risk when illness strikes.

In addition, as our population ages, more workers are providing care for elderly parents. When working people have to take unpaid time off to care for a parent, spouse or sibling, they face often-terrible financial hardship. More than 34 million caregivers provide assistance at the weekly equivalent of a part-time job (more than 21 hours per week), and the estimated economic value of this support is roughly equal to $350 billion[20]—a huge contribution to the health and well-being of their families. Caregivers contribute more than time; 98 percent reported spending on average $5,531 a year, or one-tenth of their salary, for out-of-pocket expenses.[21] Yet, many lose wages each time they must do something as simple as taking a family member to the doctor.

BUSINESSES BENEFIT FROM PAID SICK DAYS POLICIES

Research confirms what working families and responsible employers already know: when businesses take care of their workers, they are better able to retain them, and when workers have the security of paid time off, their commitment, productivity and morale increases, and employers reap the benefits of lower turnover and training costs. Furthermore, studies show that the costs of losing an employee (advertising for, interviewing and training a replacement) is often much greater than the cost of providing short-term leave to retain existing employees. The average cost of turnover is 25 percent of an employee's total annual compensation.[22]

As mentioned previously, paid sick days policies also help reduce the spread of illness in workplaces, schools and child care facilities. In this economy, and during this time of a national health emergency, businesses cannot afford "presenteeism," which occurs when, rather than staying at home, sick employees come to work and infect their co-workers, lowering the overall productivity of the workplace. "Presenteeism" costs our national economy $180 billion annually in lost productivity. For employers, this costs an average of $255 per employee per year and exceeds the cost of absenteeism.[23] In addition, paid sick days policies help level the playing field and make it easier for businesses to compete for the best workers.

Already, many savvy employers have responded to the H1N1 outbreak by expanding or improving their paid sick days policies. For example, Medtronic Inc. has reacted by granting all its employees, including hourly workers, 3 additional paid sick days. Best Buy has instructed its managers to send employees home if they arrive at work sick, and to pay them for the remainder of the day, even if they do not have any sick time.[24] Texas Instruments, Inc. has relaxed its sick days policy, allowing workers to take as many days as they need to recover, by granting them the option of borrowing against future leave.[25] These businesses and many others know that it is in their best interest to make sure that they do not have masses of sick workers on the job. They know that paid sick days must be part of their operating plans if they are going to keep their doors open and their businesses thriving during these difficult economic times.

THE NATION NEEDS POLICIES THAT ALLOW WORKERS TO MEET THEIR JOB AND FAMILY RESPONSIBILITIES

Our Nation has a proud history of passing laws that help workers in times of economic crisis. Social Security and Unemployment Insurance became law in 1935; the Fair Labor Standards Act and the National Labor Relations Act became law in 1938, all in response to the crisis the Nation faced during the Great Depression. Working people should not have to risk their financial health when they do what

[20] Gibson, Mary Jo and Houser, Ari, "Valuing the Invaluable: A New Look at the Economic Value of Family Caregiving." AARP, June 2007.

[21] Jane Gross, "Study Finds Higher Costs for Caregivers of Elderly," *New York Times*, 11/19/07.

[22] Employment Policy Foundation 2002. "Employee Turnover—A Critical Human Resource Benchmark." HR Benchmarks (December 3): 1–5.

[23] Ron Goetzal, et al, Health Absence, Disability, and Presenteeism Cost Estimates of Certain Physical and Mental Health Conditions Affecting U.S. Employers, Journal of Occupational and Environmental Medicine, April 2004.

[24] Next test: Flu 101, Suzanne Ziegler, Minneapolis Star Tribune, September 23, 2009 *www.startribune.com/lifestyle/health/60463767.html?elr=KArksi8cyaiUo8cyaiUiD3aPc:__Yyc:aUU.*

[25] Sick Time: Employers Gear Up for Swine Flu, Betsy McKay and Dana Mattioli, Wall Street Journal, November 2, 2009, *http://online.wsj.com/article/SB20001424052748704746304574508110025260366.html.*

all of us agree is the right thing—take a few days to recover from contagious illness, or care for a family member who needs them. Now is the time to protect our communities and put family values to work by adopting policies that guarantee a basic workplace standard of paid sick days.

At present, no State requires private employers to provide paid sick days. The cities of San Francisco, the District of Columbia and Milwaukee have passed ordinances requiring that private employers provide paid sick days. This year, more than 15 cities and States have considered paid sick days laws to ensure that this basic labor standard becomes a right for all workers. This is a National movement now, and we expect it to expand to more than 25 campaigns next year. But illness knows no geographic boundaries, and access to paid sick days should not depend on where you happen to work. That's why a Federal paid sick days standard is so badly needed.

Like the minimum wage, there should be a Federal minimum standard of paid sick days that protects all employees, with States and individual employers given the freedom to go above the Federal standard as needed to address particular needs of their residents or workers. The Healthy Families Act would create just that: a Federal floor that allows workers to earn up to 7 paid sick days a year to recover from short-term illness, to care for a sick family member, for routine medical care or to seek assistance related to domestic violence, sexual assault or stalking.

Congress should waste no time in passing the Healthy Families Act so that working people can earn paid time off and help prevent the spread of the H1N1 virus and other illnesses—without jeopardizing their economic security.

Chairman Dodd and members of the subcommittee, I thank you for the opportunity to participate in this important discussion, and we look forward to working with you to ensure that America's workers have a basic right of paid sick days.

Senator DODD. Well, thank you, as well. I appreciate those kind comments, and I thank you for your work over the years, as well. You've been a great asset and help in helping us craft these ideas. I thank you. A pleasure to have you with us today.

Ms. Rosado, we welcome you. It's nice to have a constituent from Connecticut come on down and be with us. You can give us some valuable information. We welcome your comments this morning.

STATEMENT OF DESIREE ROSADO, WORKER, GROTON, CT

Ms. ROSADO. Thank you.

First of all, I want to thank you, Senator Dodd and members of the subcommittee, for holding this hearing on the costs of being sick. It is an issue that matters deeply to families like mine, in Connecticut and around the country. Thank you also for giving me the opportunity to testify here today.

Like Senator Dodd said, my name is Desiree Rosado. I've been married for 13 years. I have three children, ages 12, 10, and 6. My oldest daughter, Isabella, is in the seventh grade, in middle school. My middle daughter, Alicia, is in the fifth grade. And my son, David, is in the second grade.

Like most, we are a working family. I've lived in Groton, CT, for 12 years, and I've worked in the Groton public school system for the last 3 years. My job is in special education, and I work as a one-on-one assistant in the school that Alicia and David attend. My husband works as a security guard, third-shift supervisor, at the Groton Naval Submarine Base. He's been working there for about 5 years. We are members of a church called International Family Worship Center, where my husband and I head the Praise and Worship Department.

In our community, I can't even tell you how many sick kids we've seen sent home from school or kept home due to illness, these last several weeks. I think it's fair to say that just about every family

has either been affected by the illness or is worried that their children will be infected.

Mine were. All three of my children were sick this fall. They've been healthy for about a week and a half now. It was rough going, for a while. First, Alicia, my middle daughter, got a terrible headache, followed by fever of about 102 that lasted for almost a week. She had stomach pain, dizziness, and body aches. I had to miss work to stay home and take care of her for that week. The very day Alicia was able to go back to school, I went back to work, and I had been in class for about 1 hour when the school nurse called to tell me that my son, David, had a fever of 101 and he had to go home. My daughter, my oldest daughter, Isabella, she fell ill that same day, and she and David were both sick for about a week. And then Isabella developed a sinus infection and bronchitis, as well, after the flu.

In all, I missed about 2 weeks of work to care for my kids. I get no sick pay from my job, so my paycheck for that period was almost nothing. That caused tremendous hardship for my family.

My husband and I live paycheck to paycheck right now, because we have no choice. We're trying to pay down our debts and make our family financially stable, but it is a hard road. And it's made a lot harder because, whenever we get sick or our children get sick, we have to decide whether to stay home without pay or to disregard doctor's orders and risk getting sicker and infecting others by going to work or school.

When I don't get paid, it wreaks havoc on our family budget. My husband handles the finances, and he is able to juggle things around so we can make ends meet. Sometimes we end up having to borrow from our rent money that we've put aside, and we hate to do that, but sometimes we have no choice.

That's one of the reasons I joined MomsRising, a wonderful million-member online organization that represents mothers like me across the country. MomsRising supports the Healthy Families Act because families like mine need to be able to earn paid sick days so we don't have to borrow from our rent money and go deeper into debt every time our kids get sick.

When I was asked if I would come here and share my story and tell you how my family's been affected by this, I was more than willing, because having no paid sick days has really hurt our family's finances and economic stability. I'm speaking not only for myself, but for many other moms and families who are dealing with the same thing right now, and who really need relief.

Being able to earn paid sick days would help so many parents and families I know through my work, church, and my community, and many more people that I don't know personally, but who are struggling with these same issues.

I'm honored to be here today to take part in this hearing and to have a chance to tell you my story. I hope it will make a difference and convince you to pass the Healthy Families Act so all workers will be able to earn paid sick days.

Thank you.

Senator DODD. Well, we thank you very much, Ms. Rosado. It takes a lot of courage to come and tell a personal story.

Ms. ROSADO. Thank you.

Senator DODD. And with that thing spreading through your family, which is not uncommon.

Ms. ROSADO. Yes.

Senator DODD. I'm learning about—I used to understand this issue intellectually.

[Laughter.]

Now that I have a 4-year-old and an 8-year-old, I've learned about it personally. Living with a Petri dish is usually a fascinating experience. I'm told I can anticipate having six colds a year, I think is what they anticipate, anyone with young children in school age, not to mention a time now, when obviously there's a heightened degree of problems with these issues.

Anyway, we thank you very, very much, and honored that you're here.

Ms. ROSADO. Thank you.

Senator DODD. Ms. O'Brien.

STATEMENT OF ELISSA C. O'BRIEN, VICE PRESIDENT OF HUMAN RESOURCES, WINGATE HEALTHCARE, ON BEHALF OF THE SOCIETY OF HUMAN RESOURCE MANAGEMENT, NEEDHAM, MA

Ms. O'BRIEN. Chairman Dodd, Ranking Member Enzi, and distinguished members of the subcommittee, my name is Elissa O'Brien. I'm vice president of Human Resources at Wingate Healthcare, which operates and manage skilled nursing facilities and assisted living residents throughout Massachusetts and in New York.

I appear today on behalf of the Society for Human Resource Management, or SHRM. As one of SHRM's more than 250,000 members, I thank you for this opportunity to be here today to examine our Nation's response to H1N1 and paid sick leave proposals.

Most employers and HR professionals are doing their part to respond to the current H1N1 flu pandemic by educating employees and taking common sense steps to prevent the spread of the virus in the workplace while maintaining critical business functions.

I will briefly outline what Wingate Healthcare is doing to protect its facilities and employees, and then discuss a broader issue of mandated paid leave.

At Wingate, we offer a very generous paid-time-off plan, which we like to call PTO. That provides our 4,000 employees with paid leave to use for any reason. Providing care to the sick, disabled, and elderly on a 24/7 basis requires that we make every effort to prevent the spread of illness in our facilities and to our patients. Therefore, Wingate's policy encourages employees to stay at home if they are experiencing any flu-like symptoms, and advises them to stay at home until they are free from fever. Wingate also offers alternative scheduling and telecommuting options for some employees to care for their sick family member.

Wingate has taken other specific measures to protect our employees and patients. For example, we have provided our staff with the seasonal flu vaccines, although we are experiencing some backlogs. We are also working to obtain the H1N1 vaccine, although this, too, has proven very difficult.

Obviously, the current H1N1 threat has thrust the issue of paid leave into the national debate. Employers and HR professionals have long understood the value of providing voluntary paid leave plans to employees as a recruitment and retention tool. Paid sick leave, mandated, however, could negatively impact those organizations who are already providing generous paid leave benefits.

SHRM has a strong concern with a one-size-fits-all mandate encompassed in S. 1152, the Healthy Families Act, or HFA. I would like to note four significant challenges with the bill, from an HR professional's perspective.

First, the HFA, like the current FMLA, proscribes a series of vague and ill-defined qualifying events that may trigger leave eligibility for an employee.

Second, the HFA would likely disrupt current employer paid leave offerings. For example, it is unclear how the HFA's paid sick leave requirement would impact paid time-off plans.

Third, the HFA would not pre-empt any State or local laws that provide a greater paid leave and leave rights, thus forcing employers to comply with a patchwork of varying Federal, State, and local leave laws.

And finally, the HFA inflexible approach could cause employers to reduce wages and other benefits to pay for the leave mandate and associate a compliance cost, thereby limiting employees' benefits and compensation options.

SHRM believes we need to adopt a different approach to all leave policies, an approach that reflects the needs of today's more mobile, diverse and flexible 21st-century workforce.

Based on HR's years of experience on the front line in implementing leave statutes like FMLA, we believe Congress should offer incentives for employers to do more, not to risk unintended consequences of another government mandate.

SHRM has developed a set of five principles to help guide the creation of this new leave policy. Briefly stated:

First, SHRM believes that a new workplace leave policy must meet the needs of both the employees and employers.

Second, employees should be encouraged to voluntarily provide paid leave to help employees meet work and personal life obligations through a safe-harbor leave standard.

Third, a new policy should encourage maximum flexibility, creativity, and innovation for both employees and employers.

Fourth, this policy must avoid a mandated one-size-fits-all approach and instead recognize that paid leave offerings should accommodate the increasing diversity of the workforce needs and environments.

And fifth, the policy must support a variety of work options, such as telecommuting, flexible work arrangements, job sharing, and compressed and reduced schedules.

SHRM is committed in working with Congress to determine a workplace flexibility policy that will lead more organizations to offer this type of paid leave and other benefits that make the most sense for employees and families.

I thank you for your time today, and I look forward to your questions.

[The prepared statement of Ms. O'Brien follows:]

PREPARED STATEMENT OF ELISSA O'BRIEN, SPHR

Chairman Dodd, Ranking Member Alexander and distinguished members of the subcommittee, my name is Elissa O'Brien. I am the Vice President of Human Resources for Wingate Healthcare, a privately owned health care provider that operates and manages high quality, skilled nursing facilities and assisted living residences throughout Massachusetts and New York.

I appear today on behalf of the Society for Human Resource Management (SHRM), the world's largest association devoted to serving the needs of human resource professionals and to advancing the HR profession. On behalf of SHRM's more than 250,000 members, I thank you for the opportunity to appear before the subcommittee to examine our Nation's response to H1N1 and paid sick leave proposals.

Clearly, the top-of-mind issue for this committee is the current H1N1 flu pandemic and what Congress can do to help Americans deal with a potential health care crisis. A national health emergency such as H1N1 comes along extremely infrequently, and few institutions, public or private, can be fully prepared—as we cannot predict the severity of the impact. Despite this uncertainty, employers must take every precaution to educate our employees and take common-sense steps to prevent the spread of the virus in the workplace. Our efforts must focus both on ensuring the well-being of our employees, and making sure plans are in place to maintain critical business functions. In my testimony today I will briefly outline what Wingate Healthcare is doing to protect its facilities and employees, the efforts SHRM has undertaken to educate our members and the profession on H1N1, and discuss the broader issue of mandated paid sick leave.

At Wingate, we offer a very generous paid time off (PTO) plan that provides our 4,000 employees with paid leave to use for any reason. The nature of our business—providing care for the sick, disabled and elderly on a 24–7 basis—requires that we make every effort possible to prevent the spread of illness in our facilities and to our patients. Wingate policy, therefore, encourages employees to stay home if they are experiencing any flu-like symptoms such as fever, cough, or fatigue and advises them to remain at home until they are free from fever. Our policies are designed to provide maximum flexibility for our workers, and include a PTO bank consisting of 26 days of paid leave for new employees, growing to 33 days for those who have been with Wingate for 7 years or more. A flexible PTO policy such as ours supports and encourages employees to stay home for their illness, or if needed, to stay home to care for a close family member with an illness. Wingate also offers alternative schedules and a telecommuting option for some employees to use to care for a sick family member.

In addition to encouraging sick workers to use their paid time off and recuperate at home, Wingate has taken other specific measures in our facilities to protect our employees and patients from the spread of illness. This includes distribution of a "Wingate Bag" that includes Lysol, tissues, hand sanitizer and information on how to keep healthy. These bags have been distributed organization-wide to our employees who work in an office setting. We have also installed hand sanitizer throughout our facilities. As part of our proactive measures, as we do every year, we have provided our staff with the seasonal flu vaccine at the company's expense, although we are experiencing some backlogs in obtaining the vaccine this year. In addition, Wingate is working to obtain the H1N1 vaccine for our employees, although this too has proven difficult.

As I stated, no institution can be fully prepared—but we are confident that we are doing everything we can to protect our facilities from the H1N1 virus. We are also proud that our efforts have been recognized by SHRM as an example to employers and human resource professionals on how to best prepare for a health emergency such as H1N1. SHRM's leadership in the employer community on this issue has been extremely beneficial, and I believe will help lessen the impact of the H1N1 pandemic in workplaces throughout the country.

With the early outbreak in 2008 of H1N1 influenza, SHRM and HR professionals across the country began to prepare for a more serious and widespread pandemic in 2009. In preparation, SHRM and the Center for Infectious Disease Research & Policy (CIDRAP) at the University of Minnesota partnered together to host a 2-day summit, "Keeping the World Working During the H1N1 Pandemic: Protecting Employee Health, Critical Operations, and Customer Relations." Leaders and presenters of four breakout sessions encouraged candid sharing among attendees, keeping the focus on practical tools, tips, and resources that can be put into action right away.

Following the summit, SHRM consulted with the government's leading health authorities—the Centers for Disease Control and Prevention (CDC), and the U.S. Occupational Safety and Health Administration (OSHA)—to compile information for

employers to prepare for and respond to a widespread influenza pandemic in the workplace. In collaboration with CIDRAP, we created the toolkit, *Doing Business During an Influenza Pandemic: Human Resources Policies, Protocols, Templates, Tools, & Tip*.

From SHRM's perspective, most employers and HR professionals are responding appropriately and proactively during this national emergency. While Wingate's flexible paid time off policy may be an example of an "effective practice"—other employers are doing what they can by relaxing attendance or absenteeism policies, allowing more alternative schedules, promoting telecommuting, or simply addressing employee needs as required. In a poll of its members conducted last May, 67 percent of SHRM members indicated that they either planned to, or were currently sending employees home if they came to work with flu- or cold-like symptoms. As the national focus on H1N1 has grown in recent months, we believe that it is highly likely that an even larger percentage of employers have adopted a similar approach.

FLEXIBLE PAID TIME OFF PROGRAMS

Obviously, the H1N1 pandemic has thrust the issue of paid sick leave into the national debate. Employers and HR professionals have long understood the value of providing paid leave to employees. For example, according to the *SHRM 2009 Examining Paid Leave in the Workplace Survey*, 81 percent of responding SHRM members reported that their organization offered some form of paid leave while 88 percent offered paid vacation leave. In addition, 2008 data from the Bureau of Labor Statistics suggests that 83 percent of private sector workers had access to paid illness leave. Because many employers already offer generous paid leave, efforts to mandate paid sick leave would likely result in unintended consequences that could negatively impact both employers and employees, as discussed later in my testimony.

The current flu pandemic illustrates the need for a 21st Century workplace flexibility policy that adapts to emergency situations, reflects the nature of today's workforce, and meets the needs of *both* employees and employers. It should enable employees to balance their work and personal needs while providing predictability and stability to employers. Most importantly, such an approach must encourage employers to offer greater flexibility, creativity and innovation to meet the needs of their employees and their families.

At Wingate, our flexible PTO program allows our employees to schedule their time off to meet personal and individual needs, including observing holidays, caring for a family member, illness or injury, vacation, or tending to personal matters. For most employees, unused days are automatically rolled into an employee's "Extended Illness Bank," which ensures compensation for illness and injury that last more than 5 days. After an absence of more than 15 days, our Short Term Disability benefit is available for employees, providing much-needed assistance. I have attached a copy of Wingate Healthcare's Paid Time Off Policies and Procedures for the record.

Wingate's PTO program reflects the principles for paid leave that the Society for Human Resource Management advocates. Both SHRM and Wingate believe that any Federal leave policy should:

- Provide certainty, predictability and accountability for employees and employers.
- Encourage employers to offer paid leave under a uniform and coordinated set of rules that would replace and simplify the confusing—and often conflicting—existing patchwork of regulations.
- Create administrative and compliance incentives for employers who offer paid leave by offering them a safe-harbor standard that would facilitate compliance and save on administrative costs.
- Allow for different work environments, union representation, industries and organizational size.
- Permit employers that voluntarily meet safe harbor leave standards to satisfy Federal, State and local leave requirements.

I have attached a copy of SHRM's Principles for a 21st Century Workplace Flexibility Policy for the record.

The collective membership of SHRM represents the professionals who develop and implement human resource policies in organizations throughout the country and, as such, are responsible for administering employee benefit plans, including paid time-off programs. Our members are also constantly looking for ways to adapt and design workplace policies that improve employee morale and retention—two essential elements in developing and maintaining a productive workforce. It just makes sense that offering a solid benefits program makes it easier for organizations to attract and retain great employees.

Given the practical experience SHRM and its members possess, we believe we are uniquely positioned to provide insight on a sensible Federal leave policy that ensures fairness and balance for employees and employers and we urge Congress to take a serious look at adopting policies that will encourage employers to adopt the type of flexible paid time off program that has worked so well for Wingate Healthcare and its employees.

FAMILY AND MEDICAL LEAVE ACT

As Congress considers workplace leave policy, I'd like to take a moment to point out the pitfalls that can accompany a new government mandate. Since its enactment in 1993, the Family and Medical Leave Act (FMLA) has helped millions of employees and their families, yet not without consequences. Key aspects of the regulations governing the statute's medical leave provisions, however, have drifted far from the original intent of the act, creating challenges for both employers and employees.

As you know, the FMLA provides unpaid leave for the birth, adoption or foster care placement of an employee's child, as well as for the "serious health condition" of a spouse, son, daughter, or parent, or for the employee's own medical condition.

From the beginning, HR professionals have struggled to interpret various provisions of the FMLA. What began as a fairly simple 12-page document has become 200 pages of regulations governing how the law is to be implemented. This is the result of a well-intentioned, but counter-productive attempt to anticipate and micromanage every situation in every workplace in every industry—without regard for the evolving and diverse needs of today's workforce.

Among the problems associated with implementing the FMLA are the definitions of a serious health condition, intermittent leave, and medical certifications. Vague FMLA rules mean that practically any ailment lasting 3 calendar days and including a doctor's visit, now qualifies as a serious medical condition. Although we believe Congress intended medical leave under the FMLA to be taken only for truly serious health conditions, SHRM members regularly report that individuals use this leave to avoid coming to work even when they are not experiencing serious symptoms. This behavior is damaging to employers and fellow employees alike.

However well-intended the original FMLA legislation was, proscriptive attempts to micro-manage how, when and under what circumstances leave must be requested, granted, documented and used are counter-productive to encouraging flexibility and innovation. This is an especially important lesson when considering legislation that would mandate paid sick leave.

HEALTHY FAMILIES ACT

SHRM has strong concerns with the one-size-fits-all mandate encompassed in S. 1152, the "Healthy Families Act" (HFA). The bill would require public and private employers with 15 or more employees for 20 or more calendar workweeks in the current or preceding year to accrue 1 hour of paid sick leave for every 30 hours worked. Under the HFA, an employee begins accruing the sick time upon commencement of employment and is able to begin using the leave after 60 days. The paid sick time could be used for the employee's own medical needs or to care for a child, parent, spouse, or any other blood relative, or for an absence resulting from domestic violence, sexual assault or stalking.

We share the goal that employees should have the ability to take time off to attend to their own or a close family member's health, and that the leave should be paid. However, at a time when employers are facing unprecedented challenges, imposing a costly paid leave mandate on employers could easily result in additional job loss or cuts in other important employee benefits. While the HFA presents a host of practical concerns, I would note four significant challenges with this bill from an HR professional's perspective.

First, the HFA, like the current FMLA, prescribes a series of vague and ill-defined qualifying events that may trigger leave eligibility for the employee. Under the current FMLA, employers and employees alike must make a determination if the requested leave is eligible for coverage as a qualifying event. While in many instances this determination of leave eligibility under the FMLA can be made easily, in others it requires the employer and employee to make a rather subjective, sometimes intrusive determination to determine leave eligibility—often leaving both parties frustrated and distrustful of each other. Unfortunately, we anticipate that employers and employees will have a similar experience under the HFA in trying to determine leave eligibility.

Second, although it may not be the intention of the bill sponsors, the HFA would disrupt current employer paid leave offerings. For example, if an employer's existing paid leave policy fails to meet *all* the requirements of the act, the employer's plan

would need to be amended to comply with the HFA requirements. In addition, it is unclear how the HFA's paid "sick" leave requirement would impact paid time off plans, programs that are growing in popularity. In fact, more and more employers have begun to offer Paid Time Off plans, similar to the one offered at Wingate Healthcare, in lieu of other employer-sponsored paid leave programs because these types of plans are preferred by employees and employers. According to the *SHRM 2009 Examining Paid Leave in the Workplace Survey*, 42 percent of employers offer PTO plans to their employees. Congress should build on the progress that is already being made by offering incentives for employers to do more—not risk the unintended consequences of an onerous government mandate that could very well result in decreased benefits and fewer new jobs.

Third, the HFA specifically states that the act does not supersede any State or local law that provides greater paid sick time or leave rights, thus forcing employers to comply with a patchwork of varying Federal, State and/or local leave laws—as well as their own leave policies. As it stands now, employers consistently report challenges in navigating the various conflicting requirements of overlapping State and Federal leave and disability laws. The HFA would only add to the already complex web of inconsistent but overlapping leave obligations under Federal and State laws.

Finally, the HFA's inflexible approach could cause employers to reduce wages or other benefits to pay for the leave mandate and associated compliance costs, thereby limiting employees' benefit and compensation options. This is because employers have a finite pool of resources for total compensation. If organizations are required to offer paid sick leave, they will likely "absorb" this added cost by cutting back or eliminating other employee benefits, such as health or retirement benefits, or forgo wage increases, a potential loss to employees who prefer other benefits rather than paid sick leave.

SHRM believes the Federal Government should encourage paid leave—without creating new mandates on employers and employees. As has been our experience under the FMLA, inflexible mandates and proscriptive regulations are counter-productive to encouraging flexibility and innovation. As a result, the focus is on documentation of incremental leave and the reasons for the leave, rather than on seeking innovative ways to help employees to balance the demands of both work and personal life. Another rigid Federal mandate would be more of the same.

CONCLUSION

SHRM and the 250,000 human resource professionals it represents believe that it is time to give employees choices and give employers more predictability when it comes to a Federal leave policy. We believe employers should be encouraged to provide the paid leave their workforces need—and let *employees* decide how to use it. From our perspective, a government-mandated approach to providing leave is a clear example of what won't work—particularly during a time of economic crisis.

It is clear that the H1N1 pandemic presents extreme challenges to business, government and non-profit organizations of all types. SHRM and its members are focused on keeping their workforces as safe and healthy as possible and keeping their businesses running until this public health threat has run its course. In the meantime, we caution against rushing to impose new mandates that will do more harm than good. Rather, we welcome the opportunity to work with Congress to develop a more modern workplace flexibility policy. Thank you for the opportunity to testify before the committee and I welcome your questions.

ATTACHMENT 1.—WINGATE HEALTHCARE, INC.

PAID TIME OFF POLICIES AND PROCEDURES

EFFECTIVE DATE

This document describes the Wingate Healthcare Paid Time Off (hereinafter referred to as "PTO") policy in effect as of January 1, 2005.

DISCLAIMER

This policy supercedes all prior "time off" policies and procedures, including any representations or interpretations of "time off" policies or procedures that are inconsistent with this memorandum.

ELIGIBLE USES OF SCHEDULED PAID TIME OFF

The Company's PTO policy provide employees with the flexibility to schedule their time off to meet personal and individual needs, including observing holidays, caring for a family member, illness or injury, vacation, or tending to personal matters.

ELIGIBILITY

Full and part-time employees that are regularly scheduled to work at least 24 hours per "Pay Period" (defined as Sunday through Saturday) accrue PTO on a weekly basis. Pay-in-lieu of benefits, per diems and temporary employees are ineligible for PTO benefits.

PTO does not accrue during the first 90 days of employment. Upon successfully completing 90 days of employment, employees will be credited with PTO from the first day of employment. Employees who cease employment prior to 90 days are not entitled to any PTO benefits.

ACCRUAL PERIOD

PTO accrues and resets every 12 months, beginning on each employee's employment "Anniversary Date" (defined as the employee's date of hire). Such 12-month period is referred to herein as an "Employment Year". PTO balances will reset to zero annually, on the employee's Anniversary Date and unused PTO balances do not carry forward to the following Employment Year for hourly non-exempt employees. However, unused PTO will automatically transfer to the employee's Extended Illness Bank. Please see the section on Extended Illness Bank below, for bank maximums and details. Management and exempt-level employees are allowed to carry over a maximum of 1 week PTO time into the following year and any outstanding unused PTO will automatically transfer to the employee's Extended Illness Bank. Please see the section on Extended Illness Bank below, for bank maximums and details.

ACCRUAL RATES

PTO accrues on a weekly basis, based on the number of hours an employee works in a Pay Period. PTO does not accrue on any hours worked in excess of 40 in a Pay Period. The amount of PTO employees accrue is based on their position and seniority with the Company, as detailed in the following chart.

Position Level	0 through 3 Years of Service	4 Years of Service	5 and 6 Years of Service	7 or More Years of Service
	Maximum Weekly Accrual	Maximum Weekly Accrual	Maximum Weekly Accrual	Maximum Weekly Accrual
Administrators, DNS, Department Heads, Managers, Including Exempt Level Staff.	5.08 Hrs/ Week (33 Days/Year).	5.08 Hrs/ Week (33 Days/Year).	5.39 Hrs/ Week (35 Days/Year).	5.54 Hrs/ Week (36 Days/Year).
All Other Staff	4.00 Hrs/ Week (26 Days/Year).	4.77 Hrs/ Week (31 Days/Year).	4.92 Hrs/ Week (32 Days/Year).	5.08 Hrs/ Week (33 Days/Year).

This chart reflects accruals based on a full-time, 40-hour-per-week position. Part-time employees accrue PTO on a prorated basis.

REQUESTING AND USING PTO

To use PTO, employees must complete a Time Off Request Form at least 2 weeks in advance, typically before the applicable work schedule is posted. Though we attempt to accommodate employees' PTO requests, approval is based on the needs of the facility. In the event of scheduling conflicts, PTO will be granted on the basis of seniority and/or the date of request. Scheduling and approving PTO requests is the responsibility of the Department Head or Supervisor and is subject to final approval by the Administrator.

PTO may be taken as it accrues and in increments of one (1) hour. No more than forty (40) hours may be taken in a Pay Period. PTO request over 2 weeks will not be approved. Facilities reserve the right to limit PTO request on no more than a week in peak time off months. Employees who need to take an extended time off must apply for a Leave of Absence. Policy is detailed in the Company's Employee Handbook.

PTO balances must be used during the Employment Year in which it accrues. PTO balances do not carry forward to the following Employment Year except for

management and exempt-level personnel who are allowed to carry over no more than 1 week of PTO (maximum 40 hours) in an Employment Year. Please refer to the Accrual Period section of this policy for details.

APPROVAL PROCESS

In order to assist staff in planning for time-off, approval or denial of PTO requests will be completed within 2 weeks of the request.

BUYING BACK PTO DAYS

Hourly, non-exempt employees may buy back up to 24 days of their accrued PTO in any Employment Year. However, employees may not buy back more than one (1) day per pay period and two (2) days in any single month.

PTO time may be bought back on accrued time only. Employees cannot borrow time for buy back purposes.

Employees must complete the Buy Back Section of the Time Off Request Form and submit it to their Supervisor for approval. Every attempt will be made to process your request within the next payroll cycle following approval.

BORROWING PTO

Employees may borrow up to 1 week (5 days) of *un*accrued PTO for time off purposes only and not for buy back purposes, as long as the employee is able to accrue the borrowed PTO within their employment year. Borrowing PTO is subject to the Administrator's approval. If an employee terminates employment prior to accruing the borrowed days, the Company will deduct the cash value of the borrowed time from the employee's final paycheck at their rate of pay in effect at the time of their termination.

PTO ADVANCE

As a convenience to our employees who may have difficulty accessing their banks during travel on a vacation lasting 5 or more consecutive days, the Company will advance (pre-pay) up to 5 days of *accrued* PTO pay. The employee must give the Payroll Department 2 weeks prior written notification. Advances are subject to the Administrator's approval. The Company will not advance *un*accrued PTO time. Unfortunately, for administrative reasons, we are unable to process PTO advances for employees who use direct deposit for their paycheck.

MAJOR HOLIDAYS

The company recognizes Fourth of July, Thanksgiving, Christmas and New Year's Day as major holidays. These days are hereinafter referred to as "Major Holidays".

Working A Major Holiday

All hourly regular, non-exempt, per diem, pay-in-lieu of benefit, temporary and new employees (still within their first 90 days of employment) will be paid "Holiday Premium Pay", equal to one-half (½) their regular base rate of pay for hours worked on a Major Holiday in addition to their regular base hourly pay.

Major Holiday Unscheduled Day Off

If an employee works a Major Holiday, but takes an **unscheduled** day off the day before or the day after the Major Holiday, they will be paid their regular hourly rate of pay for hours worked on the Major Holiday, therefore, losing any Holiday Premium Pay.

If an employee does not work on a Major Holiday and takes an **unscheduled** day off the day before or the day after the Major Holiday, they will not receive PTO pay for the Major Holiday observed unless approved by the Administrator.

UNSCHEDULED DAYS

Attendance and Tardiness

It is understandable that unexpected circumstances arise which may make it difficult for an employee to provide appropriate advance notice to request time off. However, employees are expected to comply with the Company's Attendance and Tardiness policies detailed in the Company's Employee Handbook and the Attendance Policy contained within the Employee Performance Improvement Program.

If more than three (3) incidents of unscheduled time off occur during a 12-month period, the employee may be subject to disciplinary action up to, and including, termination of employment.

No Call No Show

If an employee is a no call no show they will not be able to use PTO time for that day. Additionally, the employee will be subject to disciplinary measures as outlined in the No Call No Show policy detailed in the Company's Employee Handbook and in the Attendance Policy contained within the Employee Performance Improvement Program.

EXTENDED ILLNESS BANK

Employees must use their PTO balance during the Employment Year in which it accrues. PTO balances do not carry forward to the following Employment Year. However, the Company will deposit any accrued, unused PTO days at the end of the Employment Year into the employee's Extended Illness Bank for use in the event the employee becomes ill or injured for 5 or more consecutive days. The maximum number of Extended Illness Bank hours is 120 hours.

Extended Illness Bank days are ineligible for payment upon termination, unless the employee has been employed for 10 or more years.

Employees who have been employed with the company for ten (10) or more years are eligible to be paid for a portion of their Extended Illness Bank days when they leave the company, as follows:

Years of Service	% of Extended Illness Bank Eligible For Payment
10–14 Years	50%
15–19 Years	75%
20 or More Years	100%

BENEFITS UPON TERMINATION

Upon termination of employment, the Company will pay employees for a portion of their accrued PTO balance based on the "vacation time" value of their PTO balance and the employee's position, as follows:

Position	% of PTO considered "Vacation Time" Upon Termination of Employment
Administrators and Directors of Nursing Managers/Department Heads, and Exempt Level Staff	35%
All Other Staff	25%

Employees may not take PTO days during their resignation period unless approved by the facility Administrator. If approved, time off taken during the resignation period will be deducted from the employee's PTO balance.

If you have questions regarding this policy, please contact your Human Resources Representative in the Business Office.

ATTACHMENT 2—SOCIETY FOR HUMAN RESOURCE MANAGEMENT (SHRM) [1]

PRINCIPLES FOR A 21ST CENTURY WORKPLACE FLEXIBILITY POLICY

The Society for Human Resource Management (SHRM) believes the United States must have a 21st century workplace flexibility policy that meets the needs of *both* employees and employers. It should enable employees to balance their work and personal needs while providing predictability and stability to employers. Most importantly, any policy must encourage—not discourage—the creation of quality new jobs.

Rather than a one-size-fits-all government approach, where Federal and State laws often conflict and compliance is determined under regulatory silos, SHRM ad-

[1] The Society for Human Resource Management (SHRM) is the world's largest association devoted to the human resource profession. Founded in 1948, SHRM represents 250,000 human resource professionals in thousands of small and large employers representing every sector of the U.S. economy.

vocates a comprehensive workplace flexibility policy that, for the first time, responds to the diverse needs of employees and employers and reflects different work environments, union representation, industries and organizational size.

For a 21st century workplace flexibility policy to be effective, SHRM believes that all employers should be encouraged to provide paid leave for illness, vacation and personal days to accommodate the needs of employees and their family members. In return, employers who choose to provide paid leave would be considered to have satisfied Federal, State and local leave requirements. In addition, the policy must meet the following principles:

Shared Needs—Workplace flexibility policies must meet the needs of both employees and employers. Rather than an inflexible government-imposed mandate, policies governing employee leave should be designed to encourage employers to offer a paid leave program (i.e., illness, vacation, personal days or a "paid time off" bank) that meets baseline standards to qualify for a statutorily defined "safe harbor." For example, SHRM envisions a "safe harbor" standard where employers voluntarily provide a specified number of paid leave days for employees to use for any purpose, consistent with the employer's policies or collective bargaining agreements. In exchange for providing paid leave, employers would satisfy current and future Federal, State and local leave requirements. A Federal policy should:

• Provide certainty, predictability and accountability for employees and employers.

• Encourage employers to offer paid leave under a uniform and coordinated set of rules that would replace and simplify the confusing—and often conflicting—existing patchwork of regulations.

• Create administrative and compliance incentives for employers who offer paid leave by offering them a safe harbor standard that would facilitate compliance and save on administrative costs.

• Allow for different work environments, union representation, industries and organizational size.

• Permit employers that voluntarily meet safe harbor leave standards to satisfy Federal, State and local leave requirements.

Employee Leave—Employers should be encouraged voluntarily to provide paid leave to help employees meet work and personal life obligations through the safe harbor leave standard. A Federal policy should:

• Encourage employers to offer employees with some level of paid leave that meets minimum eligibility requirements as allowed under the employer's safe harbor plan.

• Allow the employee to use the leave for illness, vacation, personal and family needs.

• Require employers to create a plan document, made available to all eligible employees, that fulfills the requirements of the safe harbor.

• Require the employer to attest to the U.S. Department of Labor that the plan meets the safe harbor requirements.

Flexibility—A Federal workplace leave policy should encourage maximum flexibility for both employees and employers. A Federal policy should:

• Permit the leave requirement to be satisfied by following the policies and parameters of an employer plan or collective bargaining agreement, where applicable, consistent with the safe harbor provisions.

• Provide employers with predictability and stability in workforce operations.

• Provide employees with the predictability and stability necessary to meet personal needs.

Scalability—A Federal workplace leave policy must avoid a mandated one-size-fits-all approach and instead recognize that paid leave offerings should accommodate the increasing diversity in workforce needs and environments. A Federal policy should:

• Allow leave benefits to be scaled to the number of employees at an organization; the organization's type of operations; talent and staffing availability; market and competitive forces; and collective bargaining arrangements.

• Provide pro-rated leave benefits to full- and part-time employees as applicable under the employer plan, which is tailored to the specific workforce needs and consistent with the safe harbor.

Flexible Work Options—Employees and employers can benefit from a public policy that meets the diverse needs of the workplace in supporting and encouraging flexible work options such as telecommuting, flexible work arrangements, job sharing, and compressed or reduced schedules. Federal statutes that impede these offer-

ings should be updated to provide employers and employees with maximum flexibility to balance work and personal needs. A Federal policy should:

• Amend Federal law to allow employees to balance work and family needs through flexible work options such as telecommuting, flex-time, part-time, job sharing and compressed or reduced schedules.

• Permit employees to choose either earning compensatory time off for work hours beyond the established workweek, or overtime wages.

• Clarify Federal law to strengthen existing leave statutes to ensure they work for both employees and employers.

Senator CASEY [presiding]. Thank you very much.

We're down to two of us now, Senator Enzi and I. I'm standing in for Senator Dodd.

Dr. Gottlieb.

STATEMENT OF SCOTT GOTTLIEB, M.D., RESIDENT FELLOW, AMERICAN ENTERPRISE INSTITUTE, WASHINGTON, DC

Dr. GOTTLIEB. Thanks a lot. I want to thank the members of the committee for having me here today.

I also have a longer written statement I'd like to submit for the record.

This flu has taken a substantial toll on Americans, and I believe our focus should be on ways we can mitigate these risks in the future if more Americans can benefit from vaccination earlier in the course of these kinds of pandemics.

The good news is that we're much better prepared to deal with this flu than we would have been as recently as 5 years ago. This owes to steps taken by the current Administration to start development of an H1N1 vaccine early last spring, and other steps that they took to make the development processes easier when the virus first emerged. It also owes, in addition, to extensive pandemic planning undertaken by the Bush Administration, which left us with a much better capacity to deal with this crisis.

There are still gaps in our preparedness, and nagging vulnerabilities. Too many of our policy choices, with respect to development of this vaccine, forced us to sacrifice on the speed and reliability of the vaccine production in order to assuage concerns about vaccine safety.

With the right tools and investments, going forward, we should be able to have more effective vaccines and predictable supply while maintaining our very high degree of safety, and this should be our focus.

Having an adequate domestic capacity for developing pandemic vaccines is a matter of national security. European countries share our regulatory standards and our focus on safety, but they are far ahead of us in using new and more reliable technology in their production of new flu vaccines.

One step for improving our readiness for the future is to better integrate the use of vaccine additives called adjuvants into our pandemic planning. First, FDA should write formal guidance on the development of adjuvants as part of pandemic vaccines.

The United States should also consider stockpiling pre-approved vaccine preparations that could be used in public health emergencies. The European strategy of having pandemic vaccines pre-approved as mockups was a prudent step.

We also need to invest in new manufacturing. Using cell cultures instead of chicken eggs cuts 3 to 4 weeks from the time required to mass-produce a vaccine. The biggest advantage of cell-based manufacturing is its more rapid scale-up and its, potentially, better predictability.

We also need to make sure that an adequate proportion of the worldwide influenza vaccine production capacity is domiciled in the United States. It's hard to envision other nations allowing limited supply of vaccine raw material to be shipped outside their borders in the event of a lethal pandemic. This was already made clear to us, as Senator Dodd commented on earlier, and this isn't even a truly lethal pandemic. It's a very serious virus, but it could have been far worse. Yet, already we saw the Australian government pressure vaccine-maker CSL to keep its vaccine home, in Australia, instead of fulfilling its contract for 36 million doses for the United States. In Canada, where GSK maintains one of its two flu vaccine production facilities, the other being in Germany, but the Canadian facility is the one that supplies the U.S. market, the company had to assure the Canadian government that the Canadians would be served first from that facility before the United States could receive its H1N1 orders.

This risk is compounded by the fact that all but one of the vaccines production facilities we depend on is located outside the United States. There are also significant limitations in global fill/finishing capacities, and also there aren't enough facilities domiciled here in the United States.

There are business impediments to building new facilities. Production sites require large investments, and the financial return of flu vaccine is typically small. If the same company produces flu vaccines at two different facilities, completely separate clinical trials and separate approvals are required for each vaccine. This drives developers to expand existing facilities rather than create new ones. There may be better ways to enable more cooperation between requirements set forth by different regulators, or make use of studies that could bridge between products from a single manufacturer's different manufacturing lines, to incentivize manufacturers to build redundant facilities.

Other measures that would help create more domestic capacity include guaranteed markets for seasonal flu vaccines. This would create additional incentives for building U.S. manufacturing capacity, especially if the tender process favored domestic manufacturers.

In closing, some of our policy choices contributed to the limited availability of vaccine this season. These trade-offs can be reduced in the future if we take steps today to increase our capacity for timely development of safe, effective, and innovative vaccines in the future.

Thank you very much.

[The prepared statement of Dr. Gottlieb follows:]

PREPARED STATEMENT OF SCOTT GOTTLIEB, M.D.*

INTRODUCTION

Mr. Chairman and members of the committee, I wish to thank you for the invitation to appear before you today to address issues related to our preparedness for H1N1 flu. While this influenza is, so far, proving less virulent than once feared, it is still a very dangerous virus.[1] This is especially true for vulnerable populations such as pregnant woman,[2] young children, and those with compromised immune systems or lung disease.[3] [4] H1N1 infections are expected to decline in November and December 2009 but then peak again with higher mortality from March to May 2010. In this respect, some experts believe H1N1 may emulate the 1957 pandemic—decreasing late this year only to pick up again in the spring.[5]

As we are here today to discuss, this flu has taken a substantial toll on Americans. It has affected their health but also their financial security, whether it's through lost wages, missed workdays, or increased job insecurity during a deep recession. But legislation creating employment benefits specifically targeted to this flu doesn't appear to be the right focus for our resources or response. It would be hard to administer. There also doesn't seem to be a compelling public policy case for singling out this particular flu from others—many of which have actually hit the older and working age populations harder in the past.

Instead, I believe our focus should be on ways we can mitigate these risks in the future, if more Americans were able to benefit from vaccination earlier in the course of a pandemic.

The good news is that we were much better prepared to deal with this flu than we would have been as recently as 5 years ago. This owes to steps taken by the current Administration to contract for development of an H1N1 vaccine early last spring, when the virus first emerged. Collaborative steps to speed vaccine production were undertaken immediately, even before it was clear a vaccine would be needed, including work between U.S. Government agencies, international partners, and drug firms to provide viral reference strains and reagents needed for vaccine production. These tasks were accomplished in record time despite technical challenges. In addition, extensive pandemic planning undertaken by the Bush administration[6] left us with much better capacities to deal with this crisis. But there are still significant gaps in our preparedness, and nagging vulnerabilities.

Too many of the policy choices we were confronted with in this crisis forced us to sacrifice on the speed and reliability of vaccine production in order to assuage concerns about vaccine safety. Vaccine supplies are increasing, but we still do not have the quantities we expected, in the time frame that we needed.[7] Among other things, we chose to forgo the use of vaccine additives that could[8] boost effectiveness and might have helped us stretch our limited supply of vaccine raw material over more shots. We are compelled to rely on old, unpredictable manufacturing technology because we haven't developed the necessary capacities with more modern tools. We also lack domestic vaccine manufacturing facilities. In at least two cases we know of, this put the United States behind other countries in getting vaccine orders filled.

The bottom line is we have relied for too long on outdated capacity for our flu vaccines, in part because of our cultural reluctance to embrace new methods. This is not simply a regulatory issue, but reflects the public mood when it comes to vaccine products.

There are good reasons why the regulation of vaccines is distinct. Vaccines are given to millions of otherwise healthy people, and administered over a compressed time period. This is especially true for flu vaccines. That rapid and widespread administration limits the ability to uncover "latent" risks after products are approved and marketed. It means that, by the time we intervene to prevent exposure to an emerging side effect, millions of people might have already received a seasonal product. This is a unique risk. For these reasons, a strong pre-market regulatory process is imperative. New vaccine technology, like any innovation, invariably brings some new uncertainties—heightening regulatory caution.

For all of these reasons and many others, we are slow to embrace change to flu vaccine production. But with the right tools and investments, we should be able to mitigate any reasonable risk. We can have more effective vaccines, and more pre-

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dictable and timely supply, while maintaining our high degree of safety. This should be our focus.

Right now, our decisions to stick with safe and familiar methods also obligate us to embrace too much uncertainty about product supply. In the setting of a pandemic, these tradeoffs are simply not acceptable. While manufacturing problems at the drug firms contributed to delays in vaccine availability this year, the bottom line is that the policy choices we made also played a role. The drug makers are easy targets in our political culture and have recently received the brunt of official criticism from some public officials. But fault for today's shortages don't rest with them alone, any more than it rests with the public health officials overseeing our pandemic response. These are problems of biology and technology. Still, I worry that too much time spent finger pointing obscures the mission we should be focused on. Fixing blame will not improve our readiness. It will not increase our vaccine supply.

These issues are matters of national security. The fact is that European countries share our regulatory standards and our focus on vaccine safety. But they are far ahead of us in using new and more reliable technology into their production of new flu vaccines. It's true we remain farther ahead with other vaccine products, such as our adoption of conjugate vaccines or live attenuated approaches. But when it comes to pandemic planning, and response to flu, there is more we need to be doing.

Understanding the tradeoffs made by our policy choices, the gaps in the technology we use, and the steps we must take to improve future readiness—these things should be our focus.

USE OF VACCINE ADDITIVES TO IMPROVE YIELD AND EFFECTIVENESS

One step to improving our readiness for the future is to better integrate the use of vaccine additives called adjuvants into our pandemic planning.

An adjuvant is a substance incorporated into a vaccine that enhances or directs the immune response of the vaccinated patient. Adjuvants are designed to bring the vaccine's antigen into contact with the immune system and, therefore, enhance the magnitude of immunity produced as well as the duration of the immune response.

Novartis[9] and GSK, among other drug firms, have done innovative work incorporating new generations of adjuvants into vaccines marketed in Europe this fall for H1N1. A lot of the recent activity in Europe to deploy adjuvants was based on "mock up" preparations of pandemic vaccines that those nations had been preapproved and stockpiled.

In the United States, our decision to forgo use of adjuvants, that can work to increase the protective effects of a given quantity of vaccine, limited our ability to stretch our already limited stock of H1N1 vaccine raw material (the vaccine antigen).[10] It is worth noting that no country has had earlier large supplies of vaccine, including in Europe. The three countries first out with substantial vaccine (the United States, Australia and China) all used non-adjuvanted egg-based vaccines. So the capacity issues, and challenges are a global problem. But to improve for the future, we need to be better prepared to embrace these new methods.

In 2008, GSK became the first company to obtain a European license for an adjuvanted prepandemic vaccine, Prepandrix. This vaccine is designed to raise immune protection against several strains of the H5N1 (Avian) flu virus.[11] GSK also recently became the first drug manufacturer to get U.S. Food and Drug Administration (FDA) approval for a modern adjuvant that is used in conjunction with a vaccine distributed domestically. That vaccine, Cervarix is administered to prevent cervical cancer and precancerous lesions caused by human papillomavirus (HPV) types 16 and 18. Cervarix contains the adjuvant ASO4, which is a combination of aluminum hydroxide[12] and monophosphoryl lipid A (MPL).[13] It is the first vaccine licensed by the FDA that includes MPL as an adjuvant. ASO4 is a close cousin of the adjuvants that are already in wide use in Europe, and shares some similarities[14] to adjuvants included in some of the versions of H1N1 vaccine being used around the world.

There is no adjuvant approved for use in a flu preparation in the United States and no adjuvanted H1N1 vaccine available in this country. Integrating an adjuvant into the United States. H1N1 vaccine would not have been as easy as borrowing the data used by Europe.

For one thing, the European approvals for pandemic vaccines, and most of the clinical data that were reviewed by the European Medicines Agency (EMEA) to support them, are not with the identical vaccine antigens or from same facilities from which the United States H5N1 vaccines are manufactured. There are differences that potentially can occur when different antigens are mixed with different adjuvants. So it's not a sure bet that the antigen available for the U.S. vaccine could be effectively used in conjunction with the same adjuvants being used in the Euro-

pean vaccines. The safety profile of vaccines can also be affected by minor changes in how a protein is presented. Nonetheless, there is good reason to believe that for most patients, these adjuvants (one is already used in a U.S. stockpiled vaccine that targets pandemic avian flu)[15] could boost our present supply of a H1N1 vaccine as much as fourfold,[16] or even more when an adjuvant is used in a vaccine for children.[17] [18]

U.S. public health authorities laid some groundwork toward the use of adjuvants in the event that the H1N1 vaccine proved to be ineffective in the absence of these components. It was with the strong urging of the FDA that studies by vaccine manufacturers and National Institutes of Health (NIH) included both adjuvanted and non-adjuvanted formulations of H1N1 vaccine. The Department of Health and Human Services (HHS) also purchased and filled and finished a large stockpile of adjuvant in case it was needed.

In addition, U.S. public health authorities asked for data that could inform the effects of adjuvants and whether they would be beneficial and needed for H1N1 vaccine. The studies that regulators around the world relied on to evaluate the immunogenicity of both non-adjuvanted and adjuvanted vaccines are largely the result of requests for this data by FDA. The United States worked to keep an adjuvant option "on the table" were it to be needed.

Despite the foundational work done by FDA and others, the United States might not have been prepared to license an adjuvanted H1N1 vaccine through our customary regulatory process should it have been necessary. In all likelihood, if we had to incorporate adjuvant this fall, we would have been forced to make an adjuvanted H1N1 vaccine available under an Emergency Use Authorization (EUA),[19] which is an authority that authorizes use of a product for treatment or prevention of well-defined, public health emergencies when the relevant product has not already been approved for this specific use by the FDA.[20] A vaccine supplied through such an expedited authorization would have surely raised public concerns about its safety, perhaps reducing vaccination rates and offsetting any public health gains achieved by the use of the adjuvant. As a result, while the option of using an adjuvant was kept on the table, it was set on the very edge of the table.

Ultimately, the U.S. decision to not employ adjuvants was based on clinical data that showed an excellent response to standard doses of the licensed vaccines in the absence of any adjuvants. But that meant that the H1N1 vaccine required much higher quantities of vaccine raw material (antigen) than would have been required if adjuvants had been incorporated.[21] [22] While the amount of antigen in the U.S. H1N1 vaccine is equivalent to the quantity used in the seasonal flu vaccine distributed around the world each year, in this case, we had very limited quantities of H1N1 antigen. Stretching supply was imperative. In the United States, we were compelled to spread a limited supply of vaccine antigen across fewer shots than Europeans.

In a future pandemic, we may not have this same opportunity. Even today, the decision to forgo the use of adjuvant has to be considered as one of the tradeoffs contributing to our current H1N1 vaccine shortage. This kind of tradeoff doesn't need to exist in the future.[23]

What measures can be taken to improve our process for evaluating vaccine adjuvants? First, FDA should consider creating formal guidance on the development and use of adjuvants to help guide product developers. The EMEA developed formal guidance on adjuvants 3 years ago. The document is available on that agency's Web site.[24] FDA doesn't have a similar guidance document, and while it hasn't indicated it plans to write one, the FDA held a meeting on the topic in December 2008. Its workshop could serve as a prelude to the development of formal guidance-writing process.

The United States should also consider stockpiling pre-approved vaccine preparations that could be used in a public health emergency. There is now ample experience in Europe on which we can draw.[25] Adjuvants are not approved as stand alone substances because they do not always perform the same with different vaccines or types of vaccines or, at times, even with different versions of the same antigen.[26] Nonetheless, the European strategy of having pandemic vaccines pre-approved, as mock-ups, was a prudent step.

UPGRADING OUR MANUFACTURING TECHNOLOGY

Seasonal flu vaccines and the H1N1 vaccine are still made by the same process that has been used for 50 years: they are grown inside chicken eggs.[27] This process is unpredictable, slow, and difficult to scale. It is also expensive, costing more than $300 million to build a new plant and requiring more than 5 years to bring an egg-based production facility online.

Here is how the egg-based process works: Flu, as with any virus, will grow only in living cells. In the case of flu vaccine, production of the vaccine components has used the cells of embryonated (fertilized) hens' eggs. The success of this system is primarily dependent upon the availability of adequate flocks of chickens. These flocks must be hatched about 6 months in advance to achieve maturity at the time that the eggs are needed. A bipartisan investment that helped improve our readiness was support of year-round flocks. Nonetheless this egg-based process requires long lead times and has other risks.

The flocks, for example, are susceptible to their own diseases.[28] Another challenge of the egg-based process is virus yield. This refers to the number of viral particles that come out of an egg that could be used to make the vaccine. As a rule of thumb, one to three eggs are needed to produce each individual shot of the seasonal flu vaccine. Eggs are typically low-yield factories for the production of vaccine components.

This was certainly true this year. The H1N1 virus that was adapted by the Centers for Disease Control (CDC) for growing inside the chicken eggs, and sent to the manufacturers as the "seed" stock[29] (for jumpstarting manufacturing lines) was slow in being shipped to the drug firms owing to the difficulty in developing this template strain. Once it arrived, it was not well-suited to the production lines, and yielded low quantities of vaccine antigen.[30 31] Manufacturers spent several weeks before they realized this seed stock was yielding low vaccine quantities. It took still more weeks for the drug firms to re-engineer the seed stock to come up with a more effective template for growing vaccine antigen in the chicken eggs.[32 33] This experience underscores the unpredictable qualities of our present flu vaccine manufacturing process, and how vulnerable we are as a result of our dependence on it.

Because of the uncertainties and delays inherent to this production process—and because the emergence of pandemic strains of influenza virus may occur outside the normal timeframe for vaccine production (when chicken flocks are not at peak availability) we need alternative production systems for flu vaccine. The principal alternative to the egg-based process is tissue culture cell lines that can be used as incubators for viral replication.[34]

Using cell cultures instead of chicken eggs cuts 3 to 4 weeks from the time required to mass-produce a vaccine. But the biggest advantage of cell-based manufacturing is its more rapid scale-up and is potentially better predictability. These attributes are typically more variable using older egg-based processes. Moreover, the use of hundreds of thousands of eggs can be a more dirty process, making it prone to production glitches.[35]

There are many approved cell culture vaccines made in the United States—this includes most of our viral vaccines such as Measles, Mumps and Rubella (MMR) as well as vaccines for polio and Zoster, among others. An issue for flu vaccines has been getting good yield and a good clinical response using cell cultures. Only in recent years has there been real progress on these steps. As a result, the United States has recently begun to scale up work on cell-based manufacturing for influenza vaccines. More needs to be done. Our current vulnerabilities are too significant to be satisfied with merely incremental progress.

The Biomedical Advanced Research and Development Authority (BARDA) awarded one Federal contract for $487 million last spring to Novartis for the construction of the first U.S. facility to manufacture cell-based flu vaccine.[36] That facility is scheduled to open this year, but it won't be producing licensed vaccine until 2014.[37 38] GSK and Sanofi-Aventis are also working on cell-based production of influenza vaccine.[39] Baxter recently became the first company to gain marketing authorization by the European Commission for a cell-based vaccine.[40] That cell-based vaccine product is not available in the United States.[41]

Cell-based vaccine production is not without its own obstacles, and risks. In addition to issues around getting adequate yields from cell-based production processes, there are also challenges with immunogenicity[42] and reactogenicity.[43] All of these problems have come up in past attempts to scale cell-based production processes. There is also a remote and theoretical safety concern around the ability of genetic material to jump from the cell lines, into the vaccine, and then integrate into human tissues. FDA has issued a guidance to provide a pathway for safe use of novel cell substrates that tries to address the proper testing that flu vaccine manufacturers should undertake in order to rule out these risks.

Given the strategic advantages of the cell-based process, we need to invest in developing this capacity more quickly. BARDA should support development of similar facilities to the one being constructed in North Carolina. A typical cell-based facility costs as much as $600 million and would only be able to produce about 40 million doses of seasonal "trivalent" flu vaccine a year. The Novartis facility will be able to produce around 150 million doses of "monovalent" vaccine—containing just one

viral strain, as opposed to the seasonal flu vaccine, which contains three different viral strains—in the event of a pandemic.

All of this illustrates the more challenging economics of vaccine production, for which significant upfront expenditures are required to build facilities capable of producing largely fixed capacities of vaccine. So long as seasonal flu vaccines remain commoditized products, with slim margins and little product differentiation (public health agencies want vaccines coming from different manufacturers to be largely interchangeable) then there will not be large enough private profits to support substantial new investments in manufacturing infrastructure. Getting additional facilities on-line will require Federal investment. This capacity, however, is a matter of national strategic security and should be a U.S. priority.[44 45]

ENSURING DOMESTIC PRODUCTION CAPABILITIES

We also need to make sure that an adequate proportion of the worldwide influenza vaccine production capacity is domiciled in the United States—enough to adequately supply a reasonable portion of the U.S. market in the event of a pandemic.

It is hard to envision other nations allowing limited supply of vaccine raw material to be shipped outside their borders in the event of a full-blown pandemic with a very dangerous flu. More likely, nations would take steps to nationalize their domestic production capacity.

The drawback to relying on foreign plants was made clear recently when foreign countries claimed priority for the H1N1 vaccine produced in their own countries. That was the case in Australia, where the government pressured vaccine manufacturer CSL to keep its vaccine at home instead of fulfilling its contract for 36 million doses of swine flu vaccine for the United States.[46 47 48] In Canada, where GSK maintains one of its two flu vaccine production facilities, the company had to assure the Canadian government that the Canadian population would be served first from that facility before any other countries that rely on that manufacturing site—including the United States—received fulfillment of their H1N1 vaccine orders.[49]

This risk is compounded by the fact that all but one of the vaccine production facilities we depend on is located outside the United States.[50] There are five companies licensed to sell seasonal flu vaccine in the United States. But only one, Sanofi-Pasteur, has a domestically located plant. The others—GlaxoSmithKline, Novartis, CSL Ltd. and MedImmune—use plants in England, Germany and Australia.

After the U.S. firm MedImmune was acquired by AstraZeneca, additional production capacity was located in Cambridge, UK in 2008. Novartis, based in Switzerland, operates a cell-culture vaccine production facility in Marburg, Germany. The cell culture facility maintained by Baxter for production of flu vaccine is located in the Czech Republic.

There also appears to be significant limitations in global fill and finishing capacities for flu vaccine. This also limits supply. In addition, concerns about trace amounts of the mercury-containing vaccine preservative thimerosol, found in multidose vials of flu vaccine, prompted public health officials to request drug firms manufacture more single-dose syringes. This took longer and added delays to vaccine availability.

There are lingering concerns that thimerosol is linked to autism, despite well-conducted studies that show that the vaccine preservative is safe. If we are going to let these kinds of theoretical fears drive decisions about how vaccines are packaged, then we ought to invest in better finishing capacity or safe and effective preservatives that wont so easily fall prey to theoretical risk. Ideally, we also need more of the companies that produce flu vaccines to locate new filling and finishing facilities in the United States.

There are business impediments to building new facilities—these production sites require substantial investments and the financial return on flu vaccine, in particular, is small. Flu vaccines generate modest margins relative to other vaccines and drug products.

One of the additional business impediments companies face in making investments in multiple, differently situated vaccine production facilities stems from how these facilities are regulated. The vaccine produced from each facility needs to be separately licensed by both the FDA and the EMEA. That means that if the same company produces flu vaccine at two different facilities (even in cases where it uses the same processes at each facility) the company often has to conduct separate clinical trials for each vaccine. While FDA has approved vaccines where little or no United States-specific data was available, there remain many situations where redundant trials were required or European data was not fully leveraged.

This drives developers to expand existing facilities rather than create new ones. Since the clinical trials require substantial investments of time and money, it is far

more economical to maintain a few very large vaccine production facilities. After all, each facility's vaccine will be treated as a completely new product with its own expensive clinical trials. There are good scientific reasons why biologicals coming from distinct facilities are treated independently by drug regulators. But there may be better ways to enable more cooperation between requirements set forth by different regulators or make use of studies that could bridge between products from a single manufacturer's different manufacturing lines.

The ability to conduct these kinds of bridging studies, if they could streamline the requirements for entirely separate clinical trials, could save time and money. It would also reduce the economic impediments firms face to creating redundant manufacturing capacity.

Other measures that would help create more domestic capacity include guaranteed markets for seasonal flu vaccines. This would create additional incentives for building U.S. manufacturing capacity, especially if the tender process favored domestic manufacturers.

OTHER AREAS FOR IMPROVEMENT

We also need to develop new types of vaccines. BARDA has made grants available to fund research into completely new platforms for vaccinating against flu. Just this past June, BARDA awarded a research and development contract for work on a recombinant flu vaccine. We are making incremental but meaningful progress. We should be undertaking a more robust process to put substantial resources behind these scientific efforts.

The complexity of developing a vaccine against pandemic flu is similar to the problems posed by development of the seasonal flu shots. The vaccine needs to be adapted to match each specific strain of the flu virus. In the case of the seasonal flu, we have to develop a new vaccine each year to guard against that season's circulating strains of influenza.

It also means that we depend on just-in-time delivery when it comes to flu vaccine. This owes to the fact that the vaccine targets proteins on the surface of the flu virus that itself undergo easy mutation. Since these proteins change easily, a new vaccine must be developed to target the unique proteins found on each particular strain of influenza.

Better technologies can enable development of vaccines that require much shorter development timelines, or that protect against a broader range of flu strains.

On the first point, for example, Virus Like Particles (VLPs) have been suggested as a promising platform for new viral vaccines. In the light of a pandemic threat, VLPs have been recently developed as a new generation of non-egg-based cell culture-derived vaccine candidates against influenza infection.[51]

Influenza VLPs are formed by a self-assembly process incorporating structural proteins of the flu virus.[52] These particles resemble the virus from which they were derived but lack viral nucleic acid, meaning that they are not infectious. VLPs used as vaccines are often very effective at eliciting both T cell and B cell immune responses. The human papillomavirus and Hepatitis B vaccines are the first VLP-based vaccines approved by the FDA.

Research suggests that VLP vaccines could provide stronger and longer lasting protection against flu viruses than conventional vaccines.[53] Production may begin as soon as the genetic sequence of the virus is published online, without an actual sample of the agent, and it may take as little as 12 weeks, compared to 9 months for traditional vaccines.[54] The VLP may be grown in either plants or insect cells. As it contains no genetic material, some ingredients of traditional vaccines such as formalin and detergent treatments, are not needed.[55] In some recent clinical trials, VLP vaccines appeared to provide complete protection against both the H5N1 avian influenza virus and the 1918 Spanish influenza virus.

There is also opportunity to create a vaccine that protects against a broader variety of influenza strains, reducing the need to tailor a new vaccine to each individual strain of circulating flu. A universal vaccine would target more "conserved" regions of the flu virus's structural proteins—parts of the flu virus architecture that do not undergo much mutation and, therefore, are unlikely to change, regardless of the particular strain of flu.

Right now, our vaccines target proteins that are on the outer surface of the flu virus. Since our immune systems attack these proteins, the proteins themselves undergo adaptation, mutation, and change in order to evade our immune response. But structural proteins that are core components of the architecture of all flu viruses would be less likely to undergo mutation, regardless of the pressure from nature to change in order to survive.

Theoretically, to target these core proteins, a universal vaccine would need to recruit our T cells to attack the flu virus, as opposed to today's vaccines, which recruit an antibody response. For that reason, some suggest that such a "universal" vaccine would more likely be a therapeutic tool, as opposed to a protective vaccine. There is some literature to suggest that a T cell response alone may not be sufficient to protect us fully from flu, but work continues, and a universal vaccine is at least possible.

Drug firms sometimes complain that there is a disconnect between the advice and goals of different government agencies, especially between those charged with trying to develop new technologies (BARDA) and those charged with ensuring their safety (FDA).

It remains important for FDA to preserve its distinct mission to assure product safety and effectiveness and for the agency to remain independent. But when it comes to areas of critical public health need, where the government is engaged in a substantial effort to fund development of new technology, there's more we can do. FDA meets early with academic and industry developers of novel technologies especially for critical public health needs like flu and terrorism. But there may be more opportunities to create clearer pathways to market by also engaging FDA more closely in the government procurement process.

One opportunity is to couple BARDA funding of new technology with regulatory programs that provide additional, early feedback to sponsors developing those new methods. Multiple studies have shown that early and frequent FDA feedback helps sponsors avoid mistakes and results in timelier access to safe and effective products. This kind of regulatory effort is time and labor intensive, however, and would need to be funded inside FDA.

Finally, we also need to spend time examining how limited vaccine has been distributed during this pandemic, and take steps to put in place a better process for the future. My own view is that we should have relied more on the clinical community as a way to target the vaccine to high risk Americans. Doctors who treat high-risk patient populations—for example obstetricians that see pregnant women or pulmonologists who treat people with lung disease—in many cases had no access to the vaccine in many States. To target these populations of patients, we need to work through, and target, the doctors that care for them.

CONCLUSION

The Obama team deserves credit for ordering vaccines early last spring when H1N1 first emerged and for acting quickly to support their development. It wasn't clear, at that moment, whether H1N1 would emerge as a pandemic or fade into the summer and fail to re-emerge in the fall. The Administration's decision to undertake a crash effort to field vaccine saved lives.[56] Moreover, many of the shortcomings in our current preparedness are not the product of policy choices, but are challenges that relate to biology and the inherent complexity of targeting viruses that change rapidly and frequently. The fact that the United States has quickly fielded a program with high quality licensed vaccines despite the old technology and processes we relied on is a substantial public health accomplishment.

This shouldn't, however, obscure the fact that at many points we made deliberate decisions to rely on those old methods rather than adapt new ones because of our concerns about safety and our comfort with the tried and true approaches. Some of our policy choices did have consequences, and contributed to the limited availability of vaccine. These tradeoffs can be reduced in the future if we make a concerted effort today to increase our capacity for timely development of safe, effective and innovative vaccines.

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2. Pregnant women are among the groups of people who have been hit particularly hard by the swine flu, and officials recommend they be vaccinated. Since the H1N1 virus was first discovered in April, more than 100 pregnant women have been hospitalized and 28 have died, according to the most recent government figures.

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4. In contrast to seasonal influenza, elderly persons have proven less likely to contract the virus; nevertheless, many elderly persons who do contract the virus have had serious complications.

5. Dr. Paul Auwaerter, clinical director of the division of infectious diseases at Johns Hopkins University, noted that most or all of the H1N1 vaccine doses will be delivered by early December. He added that H1N1 infections will likely decline in November and December 2009 but then peak again with higher mortality between March to May 2010. Redd added that the infections may decrease by late this year and pick up again in the spring, similar to the 1957 pandemic.

6. Under the HHS Pandemic Influenza Plan (November 2005), the Department's key goals for vaccine preparedness were: Stockpile enough pre-pandemic influenza vaccines to cover 20 million persons in the critical workforce; Develop sufficient domestic manufacturing capacity to produce pandemic vaccine for the entire U.S. population of 300 million persons within 6 months of pandemic onset.

7. J Norman. H1N1 Flu Vaccine Supply Expected to Increase Soon. Congressional Quarterly Healthbeat, November 6, 2009.

8. It is not clear from past or current data, including with H1N1, whether clinical effectiveness of vaccine will be increased by adjuvants, although it is clear our supply could have been stretched by incorporating these additives, making a smaller quantity of vaccine as effective as a larger dose. The human immunogenicity data for the H1N1 vaccine do not show a difference so far in the antibody response to the vaccine for the majority of the populations studied. Inclusion of an adjuvant may be most substantive in truly immunologically naïve situations, for example with H5N1, or in young children, where there is no pre-existing immunologic memory. This is still a potentially important contribution.

9. John Carroll, "Novartis Readies Key Adjuvant for Swine Flu Use," Reuters, April 30, 2009.

10. The antigens are basically components of the virus that have lost their property to infect people but remain similar to wild-type virus. When injected as part of a vaccine, they stimulate our immune systems to develop antibodies that will target the natural, "wild-type" virus.

11. I. Leroux-Roels et al., "Antigen Sparing and Cross-Reactive Immunity with an Adjuvanted rH5N1 Prototype Pandemic Influenza Vaccine: A Randomised Controlled Trial," The Lancet 370, no. 9,587 (August 18, 2007): 580–89.

12. Gupta RK. Aluminum compounds as vaccine adjuvants. Adv Drug Deliv Rev. 1998 Jul 6;32(3):155–172.

13. FDA News Release. FDA Approves New Vaccine for Prevention of Cervical Cancer, October 16, 2009. Available at *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm187048.htm*.

14. MPL works differently than oil in water, another adjuvant, although the two do have in common novelty.

15. Steve Usdin and Erin McCallister, "Opportunity in Crisis."

16. For example, an adjuvanted H1N1 vaccine being used in Europe contains 3.75 micrograms of vaccine stock. The same vaccine in the United States, without the adjuvant, requires 15 micrograms of vaccine for equal potency.

17. Data shows the adjuvanted vaccine produced by GlaxoSmithKline can produce close to 100% protection in children with 1.9 microgram of vaccine antigen whereas 15 micrograms are required for the U.S. licensed vaccine that doesn't contain adjuvant.

18. We may see a pattern where the effects of adjuvants may not be as profound when there is some background immunologic memory in the population. But data are either not readily available or are pending, many of the studies do not examine lower levels of non-adjuvanted vaccines. In some, lower levels of non-adjuvanted may also turn out to be immunogenic in some select populations.

19. The Project BioShield Act of 2004 (Public Law 108–276), among other provisions, established the comprehensive EUA program. EUA permits the FDA to approve the emergency use of drugs, devices, and medical products (including diagnostics) that were not previously approved, cleared, or licensed by FDA or the off-label use of approved products in certain well-defined emergency situations. Issuance of an EUA is predicated on a Declaration of Emergency that justifies the authorization of the EUA by the Secretary of HHS. Following the HHS Secretary's Declaration, the FDA commissioner may issue an EUA if he or she concludes that: (1) the agent listed in the emergency declaration can cause a serious or life-threatening disease or condition; (2) on the basis of the totality of scientific evidence available, it's reasonable to believe that the medical product may be effective in diagnosing, treating or preventing this disease or condition or a serious or life-threatening disease or condition caused by another EUA-authorized product or an otherwise approved or licensed product; (3) the known and potential benefits of the med-

ical product outweigh the risks, both known and potential; and (4) no adequate, approved, alternative medical product is available.

20. SL Nightingale, JM Prasher, and S Simonson. Policy Review: Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States, Emergency Infectious Diseases. Volume 13, Number 7. July 2007.

21. FC Zhu, H Wang, HH Fang, JG Yang, et al. A Novel Influenza A (H1N1) Vaccine in Various Age Groups. Published at *www.nejm.org,* October 21, 2009 (10.1056/NEJMoa0908535). Available at *http://content.nejm.org/cgi/content/abstract/NEJMoa0908535v1*.

22. ME Greenberg, MH Lai, GF Hartel, CH Wichems, et al. Response after One Dose of a Monovalent Influenza A (H1N1) 2009 Vaccine—Preliminary Report. Published at *www.nejm.org*, September 10, 2009 (10.1056/NEJMoa0907413). Available at: *http://content.nejm.org/cgi/content/full/NEJMoa0907413*.

23. It's important to note that it isn't clear how much of the U.S. reluctance to embrace adjuvants is a function of our caution, and how much is a function of sponsors. More likely, it's an element of both. One reason Novartis' older adjuvanted vaccine hasn't been approved in the United States is that they acquired it from Chiron, which wasn't able to implement a formal U.S. regulatory or commercial strategy. The adjuvanted vaccine was approved in Italy in 1997, although only for the elderly and using antigen from a specific EU facility. Apportioning blame between FDA and the drug firms would be clearer if Novartis or GSK had filed an application to license an adjuvanted vaccine in the United States and FDA had rejected it, but they haven't. It's hard to know if this is because FDA has discouraged it or for other reasons. But none of these facts change the steps we should be focused on.

24. Available at *www.emea.europa.eu/pdfs/human/vwp/13471604en.pdf*.

25. See European Medicines Agency, "Guideline on Adjuvants in Vaccines for Human Use," EMEA/CHMP/VEG/.

26. As one example, aluminum compounds—which are the only adjuvants used widely with routine human vaccines and are the most common adjuvants in veterinary vaccines—do not work with influenza vaccine.

27. C Gerdil, "The Annual Production Cycle for Influenza Vaccine," Vaccine 21, no. 16 (May 1, 2003): 1,776–79.

28. DJ Alexander, "A Review of Avian Influenza in Different Bird Species," Veterinary Microbiology 74, nos. 1–2 (May 22, 2000): 3–13.

29. N. Bardiya and J.H. Bae, "Influenza Vaccines: Recent Advances in Production Technologies," Applied Microbiology and Biotechnology 67, no. 3 (May 2005): 299–305.

30. Virus yield is increased substantially by using strains of the virus that are specially tweaked to make them produce more viral particles and survive better in the eggs. That is because the "wild-type" viruses that are isolated from patients do not grow well in the eggs that are used for their manufacture. Therefore, the wild-type viruses need to be altered or re-assorted to grow well in eggs while still retaining the ability to make the viral antigens that are needed for an effective vaccine. But this process of making re-assortant strains takes time. At present, there are not many labs that are capable of working on developing these re-assortants.

31. Both CDC and FDA used the state-of-the-art technology, called reverse genetics, as their method to create pandemic H1N1 reference viruses, which were provided to manufactures to develop their own seed viruses for vaccine production

32. B McKay, C Simpson and J Whalen. Obama Targets Swine-Flu Response. The Wall Street Journal, October 26, 2009. A1

33. J Burns. Health Officials Frustrated by H1N1 Vaccine Shortage. The Wall Street Journal, November 4, 2009. B1

34. M.G. Pau et al., "The Human Cell Line PER.C6 Provides a New Manufacturing System for the Production of Influenza Vaccines," Vaccine 19, nos. 17–19 (March 21, 2001): 2,716–21.

35. Steve Usdin and Erin McCallister, "Opportunity in Crisis," BioCentury, May 4, 2009.

36. Dr. Bruce Gellin, director of the HHS National Vaccine Program, recently noted publicly that other Federal collaborations with private companies for expedited development of new vaccine technologies are also underway, although he has not cited the names of other companies.

37. U.S. Department of Health and Human Services, "HHS Awards $487 Million Contract to Build First U.S. Manufacturing Facility for Cell-Based Influenza Vaccine," news release, January 15, 2009, available at *www.hhs.gov/news/press/2009pres/01/20090115d.html* (accessed May 6, 2009).

38. It's also worth noting that the North Carolina Novartis plant will also produce an adjuvant, MF59.

39. 21. Bruce Japsen, "Flu Vaccines No Easy Remedy: Low Sales Mean Lack of Incentive for Drugmakers," Chicago Tribune, April 29, 2009.

40. Baxter's Celvapan H1N1 pandemic vaccine using Baxter's Vero cell technology. Celvapan H1N1 is the first cell culture-based and non-adjuvanted pandemic influenza vaccine to receive marketing authorization.

41. Baxter Receives European Commission Approval for CELVAPAN H1N1 Pandemic Influenza Vaccine, October 07, 2009. *http://www.baxter.com/about_baxter/press_room/press_releases/2009/10_07_09-celvapan.html*. Press Release.

42. Immunogenicity is the ability of a particular substance, such as an antigen or epitope, to provoke an immune response.

43. Refers to the ability of some biologics to cause unwanted immunological reactions.

44. The margins made on flu vaccines are also narrow by drug-industry comparisons. Flu vaccine doses cost about $3 each to manufacture, according to industry insiders. This does not include the depreciated costs of the capital needed to invest in manufacturing facilities. Each vaccine ultimately sells for $10–12 for each dose. The fixed costs related to quality assurance, administration, and depreciation are estimated to account for 60 percent of total production costs.

45. "After Decades of Malaise, the Vaccine Industry Is Getting an Injection," Knowledge@Wharton, November 2, 2005, available at *http://knowledge.wharton.upenn.edu/article.cfm?articleid=1306* (accessed Nov 4, 2009).

46. J Norman. H1N1 Vaccine Delayed for Priority Groups Until January. CQ Healthbeat. November 4, 2009.

47. One CSL Biotherapies' vaccine manufacturing facility (which it shares with CSL Behring) is located in King of Prussia, PA. It has been supplying vaccine in the United States since the 2007–2008 flu season. Its parent company, CSL Limited, is located in Melbourne, Australia. On August 18, 2009 FDA licensed CSL's new vaccine filling and packaging facility, located in Kankakee, IL. CSL Biotherapies may use it to fill and package H1N1 vaccine if requested to do so by HHS. CSL Biotherapies' contract for bulk antigen with HHS is $180 million.

48. DG McNeil. Nation Is Facing Vaccine Shortage for Seasonal Flu. New York Times, November 4, 2009. A1

49. GSK maintains two flu vaccine production sites, in Germany and the other in Canada. The German facility is licensed to supply vaccine to Europe while the Canadian facility supplies other countries, including the United States.

50. That domestic facility, operated by Sanofi, was supported by grants from HHS/BARDA that significantly increased its capacity. FDA licensed an additional production line this May at that facility. See *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149577.html*.

51. SM Kang, JM Song, FS Quan, RW Compans RW. Influenza vaccines based on virus-like particles. Virus Res. 2009 Aug; 143(2):140–6. Electronic publication 2009 Apr 15.

52. They are assembled into budding particles composed of the hemagglutinin (HA), neuraminidase (NA) and M1 proteins, and may include additional influenza proteins such as M2.

53. TP Luo, Z Yang, M Gao, Z Pan. Virus-like particle vaccine comprised of the HA, NA, and M1 proteins of an avian isolated H5N1 influenza virus induces protective immunity against homologous and heterologous strains in mice. Viral Immunology 2009 July;22(4):273–81.

54. New Vaccine Strategy Might Offer Protection Against Pandemic Influenza Strains. American Society for Microbiology. 5–18–2009. *http://gm.asm.org/index.php?option=com_content&task=view&id=217&Itemid=1*.

55. Dobbs, David (October 22, 2009). "Delivering a Virus Imposter Quicker." Technology Review. *http://www.technologyreview.com/biomedicine/23782/*.

56. S. Gottlieb. Why You Can't Get the Swine Flu Vaccine. The Wall Street Journal, October 28, 2009. A22.

Senator CASEY. Thank you very much.

I wanted to, first of all, thank each of our witnesses for appearing today and for your testimony and for the work you're doing on these issues.

I'll be rather brief, and I know that our Ranking Member, Senator Enzi, might have questions, as well.

First of all, I wanted to just say, we're happy everyone's here. Ms. Rosado, we're especially grateful that you're here, in light of what you've been through the last couple of weeks in your own

family. I was noting, each of your children that you mention in your testimony—Isabella, Alicia, and David—should be very proud of the testimony you gave. I know it's not something every parent likes to do, which is to catalog the sickness that has run through your home, and the consequences for your family, but we're grateful that you brought your own story to Washington. I know it's not easy to get all the way down here. We won't ask you about the travel.

At the risk of starting a big argument here—I don't want to do that—but, some constructive debate and dialogue is important. I guess I wanted to start with Debra Ness, in terms of what you heard from Ms. O'Brien. And if you could provide, if you want to, some rebuttal. There's somewhat of a conflict here between your testimony and hers, in terms of what we should be doing, and I want to give you that opportunity, and then, Ms. O'Brien, you certainly can provide your own rebuttal. Just with regard to the legislation. I'm a cosponsor of this. I obviously support it very strongly. We also want to hear the competing arguments.

Ms. NESS. Well, I want to start by saying that we would welcome the opportunity to work with all of you, members of this panel and this subcommittee, to ensure that this is, at the end of the day, legislation that works for both employers and employees. I wish we lived in a world where we all did the right thing all the time. The bottom line is that today there are at least 100 million workers in this country who wouldn't be able to take a paid sick day to stay home with a sick child. There are many workers—and we heard the stats over and over again today—three-quarters of low-wage workers—we're talking about workers in food service, workers in public accommodations, nursing-home workers, school workers, etc.—they don't have a lot of flexibility. They don't have much opportunity to innovate. When they need to take the time to take care of themselves or their family, they need the protection of basic labor standard that would allow for them to do that without losing their pay or part of their paycheck or putting their job on the line. And today, that's what happens for millions of workers in this country.

It would be terrific to work to fashion this legislation in a way that works for both. We do believe that the Healthy Families Act is actually good for the bottom line, that it would actually help employers. All the research shows that it actually makes more sense to give workers the time that they need to get better, as opposed to having them come to work sick, and particularly for those workers who interface with the public or who take care of our elderly or our children; even more important that we give them the time to be home when they're sick, or take care of their kids.

I think while we're all for flexibility and innovation, we need a basic standard to ensure that, at a minimum, when somebody is sick, when a worker is sick, they can take care of themselves or take care of their family member.

Senator CASEY. Ms. O'Brien, I wanted to give you equal time, in the time remaining that I have. I also wanted you to think about this and respond to it in the context of what Ms. Rosado provided—not in just in a particular sense, but in a—her family being representative of some of the challenges many families face. I mean,

I'm reading from her testimony, "Alicia gets a terrible headache, followed by a fever of 102 that lasts for almost a week." Then her mom has to miss work to stay at home and take care of her. Then she's able to get Alicia back to school, and then her son David is sick.

How do we——

Ms. O'BRIEN. Right.

Senator CASEY [continuing]. Deal with those real-world—not theoretical, but real-world—situations?

Ms. O'BRIEN. Well, first of all, I can empathize with you. Currently, my son was diagnosed with the swine flu, last week, and my daughter has that right now. I understand the challenges of being a working mom and a two-family working mom. I understand that, I do truly understand that. However, I also understand that we need flexibility in the workplace. We need—not a one-size-fits-all type of mandated government regulatory compliance issues that we need to juggle. We juggle with many, many different aspects of different laws, like FMLA and HIPAA, and we can go on and on in how those all interact with something like the Healthy Families Act.

One thing I do want to go back to—Ms. Ness specified nursing-home facilities. Workers do not get paid time off for sick time. I have to say, I have to disagree with that. We employ 4,000 employees. We are not a publicly held company, we are a privately owned company, nursing home facility. We offer PTO time, which we feel is more flexible for our employees, because not only are they able to take time off if they want to take care of a sick parent, sick loved one, or want to, maybe, go on vacation, or may want to take care of a personal situation, or, by any chance, maybe they're not Catholic, so maybe they don't recognize Christmas, so maybe they want to work on Christmas, or different types of holidays that they'd rather save up that PTO time to do something to care for, maybe, a sick loved one or—what we find is paid-time-off policies actually give more flexibility to employees.

I might add, as well, that we also give out buy-backs. That's very, very critical in today's environment. If our employees do not use all their PTO time, or don't choose to use their PTO time, we actually give out paybacks for those PTO times. Financially, they even gain better under a PTO flexible workplace.

Again, one-size-fits-all—we are very, very different industries. We are a 24/7 facility. We are mandated to have a certain number of staff on our floors. If our patients are not being cared for, we suffer, they suffer, and we could actually, potentially, close down. Which, from what I understand, is a constant struggle, especially in my industry, because we've seen so many cuts, on a State level, with Medicaid. We had not seen Medicaid cuts in over 25 years. Those are the struggles that we are facing on a day-to-day basis.

When you impose a mandate to employers, OK, they have to choose. There's only a finite amount of resources that we have to pay for employees' pay, comp, and benefits. It's about 30 percent of our operating costs. Again, it's going to be stretched. We're going to have to make very difficult decisions—very difficult decisions. Like, we were faced, this year, when we had to make a very, very difficult decision whether or not to lay off people or not give pay

raises. I know that that's a different discussion. Again, you have to understand the day-to-day challenges we face as employers. My employer is very different than in manufacturing or from a public-sector employer.

Senator CASEY. Thank you very much. And thank you, for bringing your personal story, as well.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman.

I want to thank everybody for testifying.

I'm not going to have time to ask all of the questions that I'd like to ask, so I will be submitting some of them to you in writing, in hopes of getting back an answer that will help us as we move through the legislation.

[The information referred to may be found in Additional Material.]

Senator ENZI. Now, I've been going through the HELP Committee markup on the health bill, and then the group of six negotiations—days and days and days of that, from morning until night—and then the Finance markup. During that time, we got to meet with the Congressional Budget Office a number of times to find out what the cost of the bill was. Some of these costs that we are putting on business—the question that we always asked was, Will the cost of that benefit be passed on to the employee? In every instance, they said, "Yes, it would be, in the way of reduced salary later, which spreads the cost to the employee, but it's still a cost of the benefit." We have to be real careful on that.

This bill does have "use it or lose it" in it. What I found out from being an employer is that most employees won't pay any attention to that. If they're sick, they'll use what they have. But you always have some that, if it's "use it or lose it," that last week, if they still have a week—and they usually don't, they usually have half a day, because they take half a day or an hour every chance that they accumulate it, they will take the rest of the time, feeling that if it's something the government said that they should get, that they certainly don't want to lose any of that paid leave time. That's going to be a real problem with the bill.

Dr. Gottlieb, I really appreciate your testimony. You may have noticed that in my opening remarks I used some of it to emphasize what you had said. I still have a lot of questions on vaccines, but I want to take advantage of Ms. O'Brien while she's here.

I was a member of the Society of Human Resource Management.

Ms. O'BRIEN. Yes.

Senator ENZI. I'm, I think, the only Senator that's been a registered professional in human resources.

Ms. O'BRIEN. I remember when you were first elected.

Senator ENZI. That's how I wound up on this committee, a little encouragement from that organization. I joined that organization because, as a small businessman, I had trouble interpreting a lot of the Federal regulations. And, I've got to say, that hasn't eased any. That's an organization that can help you to understand what the stuff that we write actually says. I am particularly concerned about the H1N1 pandemic, at the moment.

Ms. O'Brien, how helpful have the Federal and State Government resources been as you prepared for this flu season? Do you

have any suggestions on what the government could do to be more helpful? And have you run into any legal barriers as you've been preparing?

Ms. O'BRIEN. Well, again in my testimony, we have been trying—first of all, we need to get more of the seasonal vaccines, not only for our employees, but for our residents, as well. For some reason, we are experiencing a huge backlog on the vaccinations that we have ordered. We ordered those early. We are also trying to get our hands on the H1N1 vaccine, as well.

Now, New York State, which we do operate in, required all healthcare facilities to have the H1N1 and the seasonal flu vaccine, I believe. They have now lifted that requirement. They lifted that requirement because they—grassroots effort—there was a huge complaint that we couldn't get our hands on it. Even though our intent is to pay for the vaccines for our employees, because we feel it is the right thing to do, we can't get our hands on the vaccines. If you're asking me if the government has been very helpful in that, no, they have not.

Senator ENZI. OK.

Ms. O'BRIEN. No, they have not.

Senator ENZI. We'll do some more questions on the——

Ms. O'BRIEN. However, I must say, I do visit the Center for Disease Control, and they have given us a lot of good information to pass on to our employees.

Senator ENZI. Now, you mentioned a little bit of a conflict with the State. I'm going to move back over into the Healthy Families Act.

Ms. O'BRIEN. Oh, yes.

Senator ENZI. And your company has facilities in two States, one of which is New York, and it already mandates paid leave through an insurance scheme.

Ms. O'BRIEN. That's correct.

Senator ENZI. Can you describe the multiple levels of mandates that you'd be required to comply with, should this bill go into effect?

Ms. O'BRIEN. Sure. We operate in New York and Massachusetts, so we have the New York insurance fund and we also have, in Massachusetts, the Small Necessities Leave Act. Now, I'm not too sure of how that—I would really have to kind of study it a little bit to find out how that would interact with that.

I used to be an HR practitioner in Rhode Island. I actually live in the State of Rhode Island.They also have a different type of leave. We are a company that is growing, and we are growing into different States.

My concern is the administrative burdens, the headaches, and the time that is spent to patchwork all these different leaves. It gets very, very confusing when you are trying to administer. Because we want to do the right thing. It becomes very, very difficult.

I'm also very concerned about—with the Healthy Families Act and the recent GINA and also HIPAA. My understanding is, from this act, we are going to have to ask people why they are out. We don't want to get into a situation we're on the other side of the law on those very important Federal regulations. We are struggling with that, and it is a constant struggle for us, as HR professionals.

Senator ENZI. Thank you.

I'll be asking some questions of you about some of the misuses and the way that the law fits in with that. I'll want some more detailed answers on that, so I'll send that to you——

Ms. O'BRIEN. OK.

Senator ENZI [continuing]. In writing.

Again, I've been one of those small businessmen in that position of trying to decide what additional benefits to give and what raises to give, and have been in those times when you have to decide whether you're going to have to let some people go.

Ms. O'BRIEN. The worst decision.

Senator ENZI. I'm really worried about—I'm curious as to why this legislation is changing the number from 50 people down to 15 people, when we never have corrected the things that we've held numerous hearings on in this committee that are problems with administering the 50 level.

Ms. O'BRIEN. Right.

Senator ENZI. And the employers with 15 people are going to have a whole lot less capability of doing it than the people with 50 or more employees. I think we probably ought to make all those corrections. Those are some of the things we'll have to consider.

Again, I thank all the members of the panel. I will have specific questions, for each of you and will appreciate your answer.

Ms. O'BRIEN. Thank you.

Senator CASEY. Thank you, Senator Enzi.

Before we go, I just have one or two questions for Ms. Ness, and then we'll conclude.

And, Dr. Gottlieb, you'll be, I guess, answering a lot of questions in writing. I don't know whether that's good or bad.

[Laughter.]

You'll be getting a lot of those.

Ms. Ness, two questions. One is, what's your sense, based upon your work and observation of how sick leave policies have been implemented, with regard to two issues: First, how have cities done when they've implemented sick leave policies—to the extent that you can tell us that. And second, if you could amplify or summarize what you had said before with regard to the positive business impact of having this legislation in place.

Ms. NESS. I don't have specific statistics on how cities are doing, compared to States or private-sector employers, but, in general, public-sector employers are doing a better job on this front than the private sector. And, as we all know, the Federal Government makes 13 paid sick days available per year to workers.

I do want to say, in response to Ms. O'Brien's comments—first, I commend her. It sounds like you are a model employer and the kind of employer that we need more of.

I think that there are some misunderstandings about the legislation, because it sounds to me, from what you've described, that this legislation wouldn't require you to change anything.

One of the things we've tried to do, in working with members of this subcommittee in crafting this legislation, is to keep it as simple as possible and as easy for employers to implement as possible. Again, we want to make this be something that works well for both employers and employees. And we believe that it should. As I said

earlier, it's good business sense. It makes sense to give people time off when they're sick. All the research shows that the costs of presenteeism—people going to work sick—is actually higher than the cost of giving people the time they need to get better, because—it's common sense. People take longer to get better, they get other people sick, there's more absenteeism. It also costs more, generally, to recruit and hire and train a new employee than to give somebody a few days to get better.

No matter how you look at it, it generally is common sense and good for the bottom line for businesses to do this, as well as essential to working families' economic security.

I want to underscore, we're in the middle of a major healthcare debate in this country, and one of the challenges that we're all grappling with is the terrible disparities we see in health outcomes and health status in this country. There's this clear evidence that the lack of paid sick days is something that falls disproportionately hard on low-income workers and communities of color. And there's growing evidence that the H1N1 virus is hitting communities of color harder than other communities.

We recently saw some information from the Boston Public Health Commission that made it clear that in the African-American community and the Hispanic community, the incidence of H1N1 was much higher, and the percentage of hospitalizations was much higher in those communities. There's a correlation between that and people not being able to stay home when they're sick, not being able to get to a doctor because they don't have the time to do so.

All of these issues interrelate, as we think about this as an economic security issue for workers and families. It's a serious public health issue. It is related to our quest to eliminate the terrible disparities we face in this country when it comes to health outcomes.

Senator CASEY. Well, thank you very much.

I do want to say, as we conclude here, that at the end of the hearing we need to emphasize that the record will be open for 10 days for anyone who would like to submit statements. Of course, as I mentioned, there will be further questions submitted.

I do want to thank our witnesses for your presence here, and especially for both the Rosado and the O'Brien families, who have particular challenges right now. We hope that it all works out and everyone stays healthy. We're grateful for that.

I want to thank Senator Dodd for chairing this hearing, Senator Enzi for being here with us today. And we're grateful.

This hearing is adjourned.

Thank you very much.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR HARKIN

Recently President Obama declared the H1N1 outbreak to be a national emergency. This important step will allow us to speed up the government's response to this disease and make better use of our public health resources.

But fighting H1N1 isn't just a task for the government—each and every American has to do their part. That means taking preventive measures to avoid illness and—if you do become sick—following proper guidelines to avoid spreading the disease to others.

These guidelines are simple: If you get sick, stay home from work or school and limit contact with others. Indeed, the CDC strongly recommends that people with H1N1 stay home at least 24 hours after their fever ends.

Unfortunately, too many Americans cannot follow this common sense prescription. Almost half of all private sector workers—including 79 percent of low-wage workers—have no paid sick days they can use to care for themselves or a sick family member. For these workers, taking a day off means losing a much-needed paycheck, or even putting their jobs in danger. In this tough economy, workers without paid sick days effectively have no choice: they have to go to work. Even if they're sick, even if they're contagious, even if they have a sick child at home, they have to go to work.

The lack of paid sick days is a crisis for public health that will make the H1N1 outbreak worse. Studies show that a single sick worker who is infected with a highly contagious disease like H1N1 is likely to infect almost 20 percent of the coworkers they come into contact with. The likelihood of transmission is even greater for workers who handle food or provide hands-on care to children, elderly, or disabled Americans. Unfortunately, these are the workers least likely to have paid sick days.

Lack of paid sick days is also a crisis for America's working families. Parents forced to choose between a job and caring for a child often have no choice but to leave sick children home alone. These children are unable to see their doctors for diagnosis or medication and are at serious risk if their condition worsens. They are also unlikely to recover as quickly. There is strong medical evidence that sick children have shorter recovery periods, better vital signs, and fewer symptoms when their parents share in their care, but for parents without paid sick days staying home just isn't an option.

That's unacceptable. As President Obama has said, "Nobody in America should have to choose between keeping their jobs and caring for a sick child."

That's why I am glad that Senator Dodd has called this hearing today, and why I am a proud supporter of the Healthy Families Act. This critical legislation allows workers to earn up to 7 days of paid sick leave each year. Employees can use this time to stay home and get well when they are ill, to care for a sick family member, to obtain preventive or diagnostic treatment, or to seek help if they are victims of domestic violence.

The Healthy Families Act would be a common sense policy even in normal times. Every worker has to miss days of work because of illness. Every child gets sick and needs a parent at home to take

care of them. Every person needs to see a doctor on occasion for preventive care. Hardworking Americans deserve the chance to take care of these needs without putting their jobs on the line.

But this bill is even more critical when we are facing a public health crisis. Now more than ever, workers want to do the responsible thing and stay home when they're sick. And they want to be able to protect their health and their family's health by taking the time they need to get vaccines and treatment.

The Healthy Families Act is an essential part of our national response to the H1N1 outbreak. It will protect our families, and protect our nation. Experts estimate that if workers followed the CDC's guidance and stayed home from work when they are sick, it could reduce the number of people infected by a pandemic flu by 15–34 percent. Passing this bill will, quite literally, save lives, both now and in the future.

I hope all of my colleagues will join me in supporting the Healthy Families Act.

PREPARED STATEMENT OF SENATOR MURRAY

Thank you, Senator Dodd, for holding this hearing.

I appreciate the witnesses who have taken the time to be here today to discuss how we can help protect our workers, families, businesses, and communities from illness.

This is especially important now as we see H1N1 spread across the Nation.

I would like to start by saying once again just how much we miss our dear friend Ted Kennedy—especially as we discuss this issue. He was such a strong champion for paid leave in the workplace, and his hard work has moved us closer to that goal.

And that goal is so critical.

Since my time as a State Senator and a working mother I have been fighting to ensure that working Americans can take care of themselves and their families when they are sick—and not have to worry about losing their jobs.

I was so proud to stand with Senator Dodd in my first year as a U.S. Senator as we passed the Family and Medical Leave Act.

That was a great step forward—but the work is far from done.

Our families are facing the toughest economic environment since the Great Depression. Too many are asking themselves how they're going to pay their rent, their health care premiums, or how they will put food on the table.

But one thing they should never have to worry about is losing their jobs or their paychecks just because they or a family member gets sick.

That's why I am proud to be an original co-sponsor of the Healthy Families Act that would allow workers to earn up to 56 hours of paid leave to care for themselves or their family.

This problem is not new, but the current H1N1 crisis has demonstrated so clearly the consequences and costs of employees coming into work sick—and the very real need for a policy that will allow them to stay home.

This is not just good for workers—it is critical for businesses that want to keep their workforce healthy and productive during a national health care crisis like H1N1.

The CDC has issued guidance to help employers plan for and respond to H1N1. This guidance urges employers to allow sick workers to stay home without fear of losing their jobs and to allow workers to care for sick family members or for children if schools dismiss students.

We've been told by the CDC that on average, an individual who comes to work with H1N1 will infect 10 percent of his or her coworkers.

Those workers could then infect even more workers—including those who are particularly vulnerable to the flu, such as those with underlying health conditions or women who are pregnant.

Workers and businesses have a responsibility to each other and to the public to prevent the spread of serious illnesses like H1N1.

Ensuring that workers have paid leave makes the decision to stay home much easier for employees who are struggling to pay the bills.

Let's also not forget that our health care professionals, who will be the front line for all Americans in tackling this crisis, are employees as well.

And good leave policies will help them choose to care for themselves without being concerned about keeping their job.

I encourage my colleagues to pay close attention to this health crisis.

To consider the value of guaranteed paid leave not only for our workers and businesses, but to help keep illnesses like H1N1 under control.

And to support the Healthy Families Act.

Thank you.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF UNIVERSITY WOMEN (AAUW)

Thank you for the opportunity to submit testimony for the subcommittee's hearing on paid sick days and the H1N1 flu.

Founded in 1881, the American Association of University Women (AAUW) is a membership organization founded in 1881 with approximately 100,000 members and 1,300 branches nationwide. AAUW has a proud 128-year history of breaking through educational and economic barriers for women and girls, and continues its mission today through education, research, and advocacy. AAUW believes that creating work environments that help employees balance the responsibilities of work and family is good public policy. In fact, AAUW's 2009–2011 member-adopted Public Policy Program is committed to "greater availability of and access to benefits and policies that create a family-friendly workplace environment," which are critical for women to achieve "equitable access and advancement in employment."[1]

Despite the Family and Medical Leave Act (FMLA) and a patchwork of State laws and employer-based benefits—many of which AAUW members helped to pass—family and personal sick leave remain elusive to many working Americans. Further, despite the relative wealth of the United States, our family-oriented workplace policies lag dramatically and embarrassingly behind those in much of the rest of the world—including all high-income countries and many middle- and low-income countries as well.[2]

This year particular attention must be paid to workplace policies which shape how families and workplaces respond to an outbreak of pandemic flu. As we all know, the H1N1 flu has become widespread, and many employers are working toward developing plans to help employees avoid presenteeism[3] and ensure that business continues. AAUW supports the Healthy Families Act (S. 1152) as the solution to keeping families healthy and economically secure—and businesses solvent and open—during this and future flu seasons.

EMPLOYEES NEED PAID SICK DAYS, ESPECIALLY WOMEN

AAUW has long supported flexible workplace policies to address the family responsibilities of employees. Offering workers the option of taking time off when they or a family member is sick is not just good for families, it's good for business. At least 145 countries worldwide provide paid sick days, with 127 providing a week or more annually. More than 79 countries provide sickness benefits for at least 26 weeks or until recovery.[4]

But many hardworking Americans do not have access to the important benefit of paid sick leave. In fact, just under half (43 percent) of the private sector workforce has no paid sick days.[5] Low-wage workers are especially hard hit, with about half receiving no paid sick days.[6] In the industries that employ the most women—retail trade and accommodations/food service, which coincidentally have immense public health implications due to their accompanying contact with the public—almost 9 million women do not have paid sick days.[7] Further, 27 percent of low-income women put off getting health care because they cannot take time off from work and 18 percent of women at all income levels face this situation.[8] More than 22 million working women do not have paid sick days,[9] and as a result half of working mothers report that they must miss work and often go without pay when caring for a sick child.[10]

Paid employment should not be at odds with family responsibilities. In fact, finding solutions so that the two roles might better coexist is in the best interest of businesses. Current models of benefits are out of touch with the realities of the 21st century workforce, where households are often headed by dual-earning couples out of necessity, or a single parent whose juggling act can be particularly difficult. Furthermore, elder care responsibilities affect nearly 4 in 10 adults, and this number is likely to grow higher as nearly two-thirds of Americans under age 60 expect to be responsible for the care of an elderly relative in 2008.[11] But work is not a choice for the majority of Americans, and most cannot afford to forfeit their paycheck or their job when a family member is sick; the Healthy Families Act provides a reasonable solution to this everyday crisis faced by families nationwide.

THE HEALTHY FAMILIES ACT

Without paid sick days, employees often come to work sick, decreasing productivity and infecting co-workers. We've seen increased attention to this community health issue during the recent H1N1 flu pandemic, with CDC officials urging schools to close and workers presenting symptoms to stay home.[12] In addition, the CDC guidance recommends that employers institute flexible workplace and leave policies for sick workers, those who stay home to care for ill family members, and those who must stay home to watch their children if dismissed from school. The lack of available paid sick days forces families with children to confront difficult choices that impact not only their families but potentially their communities as well. Such decisions can become a catch–22. For the 86 million Americans who do not have paid sick days,[13] a decision to stay home to care for a sick child or family member jeopardizes their family income or even their job in an economy where it is difficult to find another. In addition, employees themselves are unable to make smart decisions to stay home to prevent infecting others because they cannot go without a day's wages.

The Healthy Families Act would require employers with at least 15 or more employees to guarantee workers 7 days of accrued paid sick leave annually. By ensuring that hard working Americans have access to a minimum number of paid sick days that can also be used to care for sick dependents, employees will no longer have to make the difficult choices between caring for loved ones—or themselves—and losing much-needed income. In these challenging economic times, that decision is an especially difficult one for families to make.

In the 111th Congress, the Healthy Families Act was introduced with an important new provision. The bill's paid sick days would be available for use for treatment, recovery, and activities necessary to deal with an incidence of domestic violence. This includes, but is not limited to, activities such as filing a restraining order, making a court appearance, moving into a shelter, and seeking medical treatment. We know that the aftermath of domestic violence costs employers, at a minimum, between $3 billion and $5 billion annually in lost time and productivity.[14] And even more importantly, victims of intimate partner violence lose 8 million days of paid work each year.[15] Paid sick and safe days are a necessity to victims and AAUW supports this new provision in the bill.

This Congress, the Health Family Act ensures employees paid sick days through a mechanism that is business friendly. Employees now accrue up to 7 paid sick days a year based on the hours they work—a method that is similar to the allocation of

other benefits employers may already have in place. This is also a method that ensures that part-time workers are included.

Not only is offering paid sick days a positive step for businesses to stay in tune with the makeup and needs of the 21st century workforce, paid sick days produce savings for businesses through decreased turnover and increased productivity. The Institute for Women's Policy Research estimates that the Healthy Families Act would result in a net savings, after covering costs of paid leave, of $8 billion per year. In addition, we are fortunate to be able to examine the policy already in place in San Francisco, where it was shown that implementing paid sick days resulted in a minor impact on employers and strong job growth in relation to the region.[16]

CONCLUSION

The recent H1N1 flu pandemic has brought long overdue attention to the tenuous balance a majority of workers and families seek to establish between a paycheck and their own health needs. Families cannot go without a paycheck when one member is sick, but presenteeism in the workplace will only serve to increase the public health risk and spread of disease. The Healthy Families Act is a long-term workable solution that contains principles necessary to any paid sick days legislation—ensuring that workers are economically secure, protected in their jobs, and able to care for their families and themselves when illness strikes. For these reasons, AAUW strongly urges passage of the Healthy Families Act.

Thank you for the opportunity to submit testimony.

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PREPARED STATEMENT OF THE CENTER FOR LAW AND SOCIAL POLICY (CLASP)

The Center for Law and Social Policy (CLASP) is a nonpartisan national nonprofit that develops and advocates for policies at the Federal, State, and local levels that improve the lives of low-income people. CLASP's mission is to improve the economic security, educational and workforce prospects, and family stability of low-income parents, children, and youth, and to secure equal justice for all.

CLASP strongly encourages passage of the Healthy Families Act (H.R. 2460/S 1152). The Healthy Families Act would allow those who work for businesses with 15 or greater employees to earn up to 7 paid sick days per year. These days could be used for: an absence related to a physical or mental illness, injury, or medical condition; obtaining professional medical diagnosis or care, or preventive medical care for the employee; obtaining the same types of care for a family member; and seeking services to recover from domestic violence.

Having paid sick days is a basic labor standard that needs to be legislated because the lack of a mandate has resulted in about half of all private-sector workers having no ability to take a day off when sick without losing pay. Too many are at risk of losing jobs as well. The lack of paid sick days disproportionately affects low-income people, heightens public health risks, and creates an uneven playing field for businesses.

The lack of paid sick days particularly hurts low-income workers: Nearly half of all private-sector U.S. workers (47 percent) do not receive *any* sick time and 70 percent do not have sick days to care for sick children. It's worse for low-income workers. Fully 77 percent of workers in the bottom wage quartile—nearly 24 million—do not have any paid sick leave.[1] When these workers fall ill, or their children or other family members get sick, they are forced to choose between their badly needed pay check and often their job security, and their health. Parents with paid time off are more than five times as likely as other parents to stay home with sick children, which helps with recovery, yet only 41 percent of working mothers have paid sick days consistently.[2] Many workers who do have paid time off are permitted to use it only for their own illness, not to care for a sick family member.

The lack of paid sick days threatens our public health: President Obama has declared the H1N1 flu outbreak a national emergency, and the Centers for Disease Control and Prevention has issued guidelines recommending that employees experiencing flu-like symptoms stay home from work or school and limit contact with others. Employees are unable to heed these warnings if they do not have paid sick days and cannot afford to stay home from work or risk losing their jobs.

The danger resulting from the spread of viruses and disease is especially acute in the service industry, where workers interact regularly with the general public. Because service workers earn low wages, they usually cannot afford to miss a day of work during an illness. Further, workers in the food and accommodation industry are least likely to have access to paid sick days.[3] Without paid sick days, some employees continue to go to work and interact with patrons while sick, which creates a public health concern.[4]

While some businesses may have responded to the recent flu outbreak by providing time off for employees to protect public health, many businesses have not changed their policies. A government policy that sets a labor standard floor is essential.

Providing paid sick days is good for business: A minimum labor standard on paid sick days is critical to ensure that businesses, especially small businesses, have a level-playing field. Competition with other firms that do not offer paid sick days discourages many businesses from voluntarily offering paid sick days to their employees, even when they would like to do so.[5] A small firm that wants to provide paid sick days to its employees typically cannot afford to do so unless the firm's competitor provides them as well. The smaller a firm's profit margin, the greater the need for a level-playing field.

Costs associated with high rates of turnover are substantial. Paid sick days would reduce the incentive for employees to leave one firm for another with better working conditions. Unhealthy workers also are unproductive workers. "Presenteeism," or the cost incurred when sick employees go to work but perform under par due to illness, constitutes a "hidden" loss in productivity for businesses. Health conditions of sick employees often worsen when they do not rest at home or seek medical care, thereby exacerbating the loss in productivity. And, sickness is spread easily in the workplace from one employee to another.[6] Flu contagion in the workplace costs our

national economy $180 billion annually in lost productivity.[7] For employers, this costs an average of $255 per employee per year and exceeds the cost of absenteeism and medical and disability benefits.

There is some concern that mandated paid sick days legislation would lead to job loss and raise the unemployment rate. But a recent study has found that there is no statistically significant effect of mandated paid sick days or leave on national unemployment rates.[8] However, paid sick days could pay off by restricting the costly spread of contagious diseases.

The public supports a minimum standard; other nations already provide it: Because paid sick days are critical to public health and are good for business, it is not surprising that 21 of the world's 22 highly ranked countries in terms of economic and human development provide paid sick days. The United States is the only country among that group that has failed to adopt a national policy guaranteeing that workers receive paid sick days or paid leave.[9]

There is widespread public support for paid sick days as a basic labor standard. According to a survey conducted for the Public Welfare Foundation, 82 percent of respondents considered paid sick leave for themselves a "very important" employee benefit. In addition, 75 percent of respondents "strongly favored" a law guaranteeing all workers a minimum number of paid sick days.[10]

The Healthy Families Act provides our Nation with an opportunity to provide paid sick days to workers, including the many low-wage workers who cannot afford to do without them. CLASP strongly urges passage of the Healthy Families Act.

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PREPARED STATEMENT OF DEBORAH L. FRETT, CEO, BUSINESS AND PROFESSIONAL WOMEN'S FOUNDATION

INTRODUCTION

Thank you for this opportunity to submit testimony on behalf of Business and Professional Women's Foundation in support of the Healthy Families Act (S. 1152/H.R. 2460).

Business and Professional Women's Foundation (BPW Foundation) works with women, employers and policymakers to create successful workplaces that practice and embrace diversity, equity and work-life balance. Through our groundbreaking research and our unique role as a neutral convener of employers and employees, BPW Foundation leads the way in developing and advocating for polices and pro-

grams that "work" for both women and businesses. A *successful workplace* is one where women can succeed and businesses can profit.

BPW Foundation has a network of supporters in every community across the country which includes both employers and employees. Both our employee and employer members support paid sick days because they know it's good for business **and** workers.

THE CHANGING WORKFORCE

One of the most significant trends of the past 50 years has been the movement of women, especially mothers, into the paid labor force and the growth of women-owned businesses. Women now make up half of the U.S. workforce and are projected to account for 49 percent of the increase in total labor force growth between 2006 and 2016.[1] Women-owned firms represent 30 percent of all U.S. businesses and between 1997 and 2004 the number of women-owned firms increased by 17 percent nationwide—twice the rate of all firms.[2]

Achieving a sustainable work-life balance is of paramount concern for working women and their families. One-third (⅓) of women believe that the difficulty of combining work and family is their biggest work-related problem, and nearly three-fourths (¾) think the government should do more to help.[3] Many women business owners say they left their previous employer to start their own businesses to have greater work-life balance, and therefore they are more likely to offer that flexibility to their employees. Women-owned firms in the United States are more likely than all firms to offer flex-time, tuition reimbursement, and profit sharing to their employees.[4]

Despite the current economic downturn, there is ample evidence that we are headed toward a workforce shortage. There will be more jobs than workers and the jobs of the future are going to call for more education, more critical thinking and more compassion—all skills at which women excel. The number of jobs requiring either an associate's degree or a post secondary vocational credential will grow by 24.1 percent during this decade. By 2020 it is estimated that there will be 15 million new U.S. jobs requiring college preparation; yet at the current rates there is the potential for 12 million unfilled skilled jobs.[5]

The make-up of the workforce has changed. Women account for 51 percent of persons employed in management, professional and related occupations categories; 63 percent of sales and office occupations; and, 45 percent of workers in public administration.[6] Other data shows that businesses with more women in senior positions are more profitable, women make a majority of the buying decisions within a family and younger workers are demanding more flexibility in their workplaces.[7] **Investing in policies that support working women is simply good for business.**

The increasing work commitment of American families and the changing workforce is putting new pressure on employers and policymakers to address the problem of work-life balance. BPW Foundation believes that greater attention to work-life policy initiatives, such as paid sick days, is good for business and will result in improved employee retention, positive human capital outcomes, a more productive workforce and healthier and happier families.

BPW Foundation supports the Healthy Families Act (S. 1152/H.R. 2460) because it is an important and necessary step towards achieving work-life balance.

HEALTHY FAMILIES ACT (S. 1152/H.R. 2460)

BPW Foundation supports the Healthy Families Act and its goal to guarantee full-time workers seven (7) paid sick days each year to recover from an illness, care for a sick family member, seek routine medical care, or seek assistance related to domestic violence.

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Women make up half of the U.S. workforce. Currently there are no State or Federal laws that guarantee all workers a minimum number of paid sick days. Nearly half (48 percent) of private-sector workers don't have a single paid sick day to care for their own health or that of a family member.[8] The lack of this benefit has forced millions of Americans to choose between their paychecks and their health or the health of a family member. The Healthy Families Act is much needed change.

The lack of paid sick days particularly hurts working women, who still bear a disproportionate responsibility for care of the family. According to the National Compensation Study, more than 22 million working women self report that they do not have paid sick days.[9] Half of all working mothers report that they have had to miss work to care for an ailing child and of those half reported that they lost wages in the process.[10]

The following story was shared with us on the condition of anonymity. The author is a mother who works as a security guard for a large corporation and feared recrimination just for talking about her struggles due to a lack of paid sick leave.

> I would love to have paid sick leave. I'm a mother of two girls, 3 and 13. When I was pregnant with my first child I had no clue what to expect. Being pregnant, you have to go to the doctor a lot. My job didn't provide any leave at all. If you do not work, you do not get paid. Every time I had a doctor's appointment, I had to check my calendar and make sure I could afford to take off. I worked up to my 32d week and it took 3 months to get back to work. In that time with no income I had to go on welfare and food stamps.
>
> With a child, I had to leave work for emergencies more frequently because any problem with your child is top priority. It would be great to be able to take leave to handle such things and not feel guilty or scared about missing work!
>
> With my second child I was a little more prepared, but it was the same story: miss work and you don't get paid. Well, this time around I was put to the test; I had rent, electric, gas and transportation bills. I lost my apartment because I had no income while out with a new child. I'm not saying that having paid sick leave would have saved my apartment, but I would have had better options and managed my time off better. I currently work M–F 7 a.m.–3 p.m. and overtime whenever possible. If I need to take my children to annual check-ups, I have to take unpaid leave. There would be a lot less stress in those situations if I had time I could take with no reprimand.
>
> Being a single mother is hard enough. A few days of sick leave could mean a great deal to anyone out here trying to raise a family and be a responsible parent.

The lack of paid sick days also hurts men. Thirty percent of working fathers report having had to take unpaid leave to care for themselves or a family member.[11] More than 2 million fathers are the primary caregivers of children under 18, a 62 percent increase since 1990.[12] Due to lingering stereotypes about gender roles, some men report having been denied leave to care for a family member.

The lack of paid sick days hurts families. It hurts moms and dads, kids and grandparents and singles—everyone gets sick. This fact has been driven home by the spread of the H1N1 flu virus. **It is difficult for many families to heed the government warning to stay home from work and to keep sick children home from school when they lack job-protected paid sick days.** Many workers will risk their paychecks and even their jobs if they stay home when they or their children contract the flu. Unpaid time impacts the entire household because of the lost income. And not taking sick time impacts your health and ability to do preventive and wellness care. Without paid sick days, workers and families face financial difficulty in cases of illness or family health emergencies like H1N1 flu virus.

The American family has changed dramatically in the last 50 years. Employee benefits should reflect the way we live now. In the 1960s, the overwhelming majority—70 percent—of American families with children had a mother who stayed

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[8] Vicky Lovell, Institute for Women's Policy Research, "Women and Paid Sick Days: Crucial for Family Well-Being," 2007.

[9] Institute for Women's Policy Research analysis of the March 2006 National Compensation Survey, the November 2005 through October 2006 Current Employment Statistics, and the November 2005 through October 2006 Job Openings and Labor Turnover Survey.

[10] Kaiser Family Foundation, "Women, Work and Family Health: A Balancing Act," Issue Brief, April 2003.

[11] Kaiser Family Foundation, "Women, Work and Family Health: A Balancing Act," Issue Brief, April 2003.

[12] Business and Professional Women's Foundation, "The State of Work-Life Effectiveness," June 2006, PP. 4 & 20.

home to provide around-the-clock childcare. Today, that statistic is reversed: *two-thirds* of families with children have either two employed parents, or a single employed parent, most of whom now work full-time.[13]

If we are really committed to the American family, leave policies must be created so that everyone can achieve the work-life balance that is so frequently talked about. It is not enough for a few companies to offer paid sick days; it must be widely recognized as key to a successful workplace. In this economic climate many working women are backing off from their flexible work schedules and not taking sick days for fear of losing their jobs. A benefit that employees are afraid to take advantage of **is no benefit.** If we are truly interested in fostering a strong and productive workforce and strong families, then we must ensure that there are workplace policies that support employee success. And paid sick days is such a policy.

Paid sick days are good for business. The lack of paid sick days leads to what is known as "presenteeism." Presenteeism is the practice of employees coming to work sick, being unproductive and infecting their co-workers. That is bad for business. Ultimately, it costs businesses less to allow a sick person to stay home with pay than it does if the sick worker causes the illness of others in the workplace. The American Productivity Audit and studies in the Journal of Occupational and Environmental Medicine, the Employee Benefit News, and the Harvard Business Review show that presenteeism is a large drain on productivity—larger than that of either absenteeism or short-term disability.

Companies that provide paid sick days tend to have lower job turnover rates, lower recruitment and training costs, lower unnecessary absenteeism, and a higher level of productivity than firms that do not offer this benefit.[14] The stock market is showing favorable signs to support work-life policies as well. A recent Harvard Business article cited a research study of stock market reaction to the announcement of Fortune 500 firms adopting work-family programs. The results showed a positive swing of the stock—on average 0.48 percent.[15]

The Healthy Families Act also contains important protections for business. To meet the concerns of small businesses, **companies with 15 employees or fewer are exempted**. And if a company already provides paid sick days, nothing changes. In addition, paid sick days will be calculated using an accrual method so an employee will earn those days over time rather than getting them all at once. At first glance, many business owners thought that offering paid sick days would be a burden, but the numerous who have initiated this benefit have found that it is an easy adjustment and the pay-offs in productivity and happy employees are well worth it.

Business research firms have calculated the ROI (Return on Investment) of companies who execute work-life effectiveness policies to those that do not and found that there are positive business profits for those who do. For example, companies on "best companies to work for" lists (e.g. excellent HR practices) produced four times the bottom line gains as compared to other indexes such as the S&P 500.[16]

CONCLUSION

BPW Foundation believes in a three-pronged approach to creating a successful workplace.

1. Legislation like the Healthy Families Act;
2. Working with businesses to proactively implement and update their own workplace policies; and
3. Empowering women through education.

Paid sick days are important to BPW Foundation because they are important to the health and well-being of women, families and workplaces. The Healthy Families Act will start us on the road toward successful workplaces for employers and employees.

Thank you.

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[13] U.S. Census Bureau, "America's Families and Living Arrangements: 2006," *http://www.census.gov/population/socdemo/hh-fam/cps2006/tabFG1-all*; Bond, et al., "Highlights of the National Study of the Changing Workforce," 2002.

[14] Jane Waldfogel, "The Impact of the Family Medical Leave Act," Journal of Policy Analysis and Management, vol. 18, Spring 1999; Christine Siegwarth Meyer, Swati Mukerjee, and Ann Sestero, "Work-Family Benefits: Which Ones Maximize Profits?" Journal of Managerial Issues, 13(1):28–44, Spring 2001; Families and Work Institute, Business Work-Life Study, 1998, available at *http://www.familiesandwork.org/summary/worklife.pdf*; Children's Defense Fund, "Minnesota, Parental Leave in Minnesota: A Survey of Employers," Winter 2000; and "Limits of Family Leave," Chicago Tribune, May 4, 1999.

[15] Freek Vermeulen, "The Case for Work/Life Programs," Harvard Business blog, April 2009.

[16] Business and Professional Women's Foundation, "The State of "Work-Life Effectiveness," June 2006, pp. 2 & 12.

NATIONAL FEDERATION OF INDEPENDENT BUSINESS (NFIB),
NOVEMBER 23, 2009.

Hon. TOM HARKIN, *Chairman,*
Senate Committee on Health, Education, Labor, and Pensions,
428 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. MIKE ENZI, *Ranking Member*,
Senate Committee on Health, Education, Labor, and Pensions,
428 Dirksen Senate Office Building,
Washington, DC 20510.

DEAR CHAIRMAN HARKIN AND RANKING MEMBER ENZI: On behalf of the National Federation of Independent Business (NFIB), the Nation's leading small business advocacy organization, I am writing in opposition to the proposed paid leave mandate to combat the spread of the H1N1 virus. NFIB believes that short-term problems cannot be solved by long-term mandates, especially when unemployment is at a 26-year high of 10.2 percent.

NFIB's opposition to mandated paid leave to prevent the spread of contagious illnesses does not mean we do not take this issue seriously. A one-size-fits-all mandate may not prevent the spread of contagious illnesses, like the H1N1 virus, but will certainly be burdensome for small businesses. NFIB is educating small business owners via our Web site and through cooperation with Federal agencies (for example, at *http://www.nfib.com/business-resources/business-resources-item/cmsid/50072/* and *http://www.nfib.com/small-business-legal-center/compliance-resource-center/compliance-resource-item/cmsid/49902/*). After all, small businesses cannot afford to lose employees to any illness and small employers make every effort to accommodate their workers' leave requests. According to the NFIB 2004 *Small Business Poll on Family and Medical Leave*, 82 percent of small employers handle family and medical leave requests on a case-by-case basis, and 95 percent granted the most recent request for short-term leave for important personal matters. This type of flexibility is essential for small businesses. Unfortunately, the proposed mandate's vague language would impinge upon the employer's ability to offer flexible leave policies for his/her workers, creating more hurdles for small business. This is especially harmful as our economy continues in its struggle to recover.

The proposal severely lacks clear guidance regarding employee classification, compensation, the definition of "illness" and how it impacts current policies and requirements. Despite the inclusion of a "sunset" provision, history assures us that this will be anything but temporary. And although the bill attempts to provide a safe harbor for firms with fewer than 15 employees, the language does not clearly define the terms of coverage for part-time employees, temporary or contract employees. It also does not take into account Paid Time Off plans or make clear the requirements for disqualification from the safe harbor provision. Under the Family Medical Leave Act, employees need a certificate from a doctor stating that they can return to work following an illness. There is no similar provision in this bill, forcing the employer to play doctor. As a result, it is unclear whether the employer will be held liable should they not demand that an employee go home at the first possible sign of illness.

The mandate is clear, however, in dissuading employers from hiring more than 15 employees. This proposal will make it more difficult for small firms to expand and create jobs. Small business owners will delay creating jobs or expanding their business when faced with additional Federal mandates. At a time when unemployment hovers at 10 percent, now is not the time to discourage small businesses—America's job creators—from creating new jobs. According to NFIB's Small Business Economic Trends (SBET) survey, small business owners continue to have a negative view of the economy, although their optimism has risen slightly each month since the lowest point reported, in March 2009. In the last 3 months, 8 percent of small business owners increased employment, but 19 percent reduced employment (seasonally adjusted). NFIB strongly believes that small business owners should be free to create policies that work best for their employees and their business—especially given current economic conditions.

NFIB opposes paid sick leave mandates in general and we oppose H.R. 3991, Emergency Influenza Containment Act, which was recently introduced in the House of Representatives.

Sincerely,

SUSAN ECKERLY,
Senior Vice President, Public Policy.

NATIONAL SMALL BUSINESS ASSOCIATION (NSBA),
NOVEMBER 24, 2009.

Hon. CHRIS DODD, *Chairman,*
Senate HELP Committee, Children and Families Subcommittee,
428 Dirksen Senate Office Building,
Washington, DC 20510.

Hon. LAMAR ALEXANDER, *Ranking Member,*
Senate HELP Committee, Children and Families Subcommittee,
428 Dirksen Senate Office Building,
Washington, DC 20510.

DEAR CHAIRMAN DODD AND RANKING MEMBER ALEXANDER: On behalf of the National Small Business Association (NSBA), I am writing to provide comments for the Nov. 10 hearing, "The Cost of Being Sick: H1N1 and Paid Sick Leave." The following comments focus on proposed H1N1 sick leave policies, suggested roles for the Federal Government to address the H1N1 flu season, and efforts already underway by small businesses to ensure a healthy workforce.

NSBA is the Nation's oldest small-business advocacy group representing employers in every State. As an organization, we represent all sectors and industries of the U.S. economy from retail to trade to technology—our members are as diverse as the economy which they fuel. More than one in two people in the U.S. private workforce—an estimated 70 million—work for or run a small business, according to data from the U.S. Small Business Administration Office of Advocacy and U.S. Census Bureau. Small business comprises 99.7 of all U.S. private employers, or 29.6 million businesses, and creates more than half of U.S. gross domestic product.

There is no doubt that H1N1, or swine flu, is a potential threat to our Nation's small businesses. The Centers for Disease Control and Prevention have acknowledged that flu activity is widespread in 48 States. The CDC also notes a significant increase in flu-related hospitalizations and deaths thus far this year vis-à-vis this time last year. NSBA shares the goals of employers, employees, and the government in protecting the workforce and the public from the impact of H1N1. However, current proposed sick leave policies would do more harm than good for small businesses, their employees, and their families; thus, Congress must take a deliberative approach in developing a Federal Government role in combating the impact of H1N1 that does not implement costly, unfunded mandates on small employers.

HOUSE AND SENATE PROPOSED LEGISLATION FOR HINI PAID SICK LEAVE

Currently, the only Federal law providing employee leave is the Family and Medical Leave Act (FMLA), which requires employers with 50 or more employees to provide unpaid leave to eligible workers meeting certain requirements. FMLA provides employees who meet these requirements up to 12 work weeks a year of job-protected, unpaid leave. Anticipated H1N1 paid sick leave legislation would fundamentally alter the nature of employee leave policy that has existed since 1993 to the detriment of small businesses.

Representative George Miller introduced the *Emergency Influenza Containment Act of 2009* (H.R. 3991), which would require employers who send employees home, or tell them to stay home due to symptoms of a contagious illness, or because they have been in close contact with a person who has a contagious illness, to pay the employees sick leave for each workday the employee is out of work, up to a maximum of 5 work days during a 12-month period. The bill would apply to any employer with more than 15 employees, and to all full- and part-time employees. The act would take effect 15 days after it is signed into law and would expire in 2 years.

Indications from the Nov. 10 hearing and Chairman Dodd's office note that he will be introducing similar legislation with significant modifications, including a provision that would provide 7 paid sick days instead of 5 for employees to take leave for "flu-like symptoms, medical diagnosis or preventive care, to care for a sick child, or to care for a child whose school or child care facility has been closed due to the spread of flu." In addition, the discretion on the need for sick leave would be left to the employee, although medical certification could be required through regulation by the Department of Labor.

In lieu of implementing costly mandates on small businesses in the form of required sick leave, Congress should consider other areas of Federal support to employees and employers that do not put restrictive, nationalized, one-size-fits-all standards on small businesses. In addition, Congress should recognize and account for small businesses' existing paid time off (PTO) programs and workplace flexibility initiatives that are already under way before hastily passing legislation without proper deliberation.

FEDERAL SUPPORT

Despite the clear signs of a pending pandemic that emerged in spring 2009, our public health infrastructure is insufficiently meeting the needs of our society. Only certain individuals have had access to H1N1 vaccinations, and even those often waited hours in line to get vaccinated. While vaccination production and distribution have improved in recent weeks, individuals that are outside of the "high-risk" populations—many of which work for small businesses—remain vulnerable in the early stages of this year's flu season.

There are more suitable and efficient Federal public policies to pursue rather than mandated sick leave. First, greater focus and attention should be paid to the education and preparation for the flu season. Publicizing personal hygiene best practices and other public health-related information can go a long way to prevent the spread of H1N1 in the workplace. NSBA has been working to provide this kind of critical information to our members via our Web site for the past several months. Second, the Federal Government has a direct role in ensuring that the public health infrastructure is prepared and capable to meet the needs of our society. Timely vaccinations for small-business employees and their families can shield them from the impact and spread of contagious diseases. Small businesses should not have to pay the price for the Federal Government's inability to protect the public through our public health system.

FLEXIBILITY AND PAID TIME OFF

In the wake of the current economic recession, small businesses need to maintain flexibility in order to survive, grow and provide jobs. In addition, small employers are already taking steps to address the potential impact of H1N1 on employees and their families. Many employers are addressing H1N1 threats by considering workplace flexibility options, including telecommuting, job sharing, schedule changes, shift swapping and other PTO arrangements for employee's own illness or to care for ill family members.

Proponents of paid sick leave proposals often cite the lack of dedicated paid sick leave benefits offered to employees as the impetus to pass Federal legislation. However, this data does not take into account the flexible benefit arrangements small businesses design to meet the needs of their business, their employees, and there families, including the PTO benefit arrangement. In fact, the vast majority of employers voluntarily offer generous paid leave benefits. According to the Department of Labor, 82 percent of private employers currently offer some form of paid leave to their workforce. Nevertheless, PTO does not account for the individual by individual agreements that small-business owners frequently make with their employees to accommodate each parties' needs.

More importantly, NSBA recently provided comments to a Senate work group on workplace flexibility, and is strongly supportive of their efforts to develop consensus-based, bipartisan solutions that work for both employers and employees. Flexible scheduling can ease the burden of unpredictable illness of employees and family members, and PTO can undermine the potential for abuse of dedicated paid sick leave policies.

CONCLUSION

Similar to any other flu season, small-business employers are sensitive to the threats of H1N1. In fact, the old cliché of small-business owners and their employees being a family is never truer than in times of an employee's ill-health. An employer's greatest asset is their employees, and it doesn't take a public health official to tell a small-business owner that the flu can spread and cripple their business. There are pragmatic solutions to address the threats presented by H1N1, but the current paid sick leave proposals are not the answer.

With so much economic pressure on the shoulders of our Nation's small businesses, it is unfathomable that Congress would consider legislation mandating additional costly requirements on small businesses. Proposed H1N1 sick leave mandates comes on top of 10 percent unemployment rates and economic challenges that, in combination with mandated sick leave, pose dire consequences for the job-creation role of small businesses.

NSBA looks forward to the opportunity to work with you so as to explore policy alternatives to the currently proposed sick leave policies. Meanwhile, NSBA welcomes the opportunity to work with you in continuing our role of educating small-

business owners, their employees, and their families in preparation for the pending flu season.

Sincerely,

TODD O. MCCRACKEN,
PRESIDENT.

RESPONSE TO QUESTIONS OF SENATOR DODD BY SETH HARRIS

Question 1. The Federal Government, through the CDC, has issued several important guidances to employers for utilization during the H1N1 pandemic. These guidances generally encourage employers to be flexible in their leave policies and permit workers to stay home without risking their jobs. While some employers have adjusted their leave policies, many haven't—and unfortunately many of those employ low-income workers who are least likely to have access to paid leave to begin with. Many people argue that employers are capable of addressing their employees' needs and the Federal Government does not have a role to play here. Why is it not enough to encourage employers to be flexible in their leave policies? Why is further direction from the Federal Government needed?

Answer 1. The Department applauds the efforts of responsible employers who adjust their leave policies in response to the public health threat of the 2009 H1N1 pandemic; however, not all employers have heeded the CDC guidance and many workers have only unpaid leave available to them.[1] Since only 49 percent of low-wage workers have access to paid sick leave or personal leave or family leave or vacation, *unpaid* leave may provide job security but not the income they must have to keep paying for basic necessities. Low-wage workers cannot afford to go unpaid even for a few days, and therefore will go to work when they are sick—infecting others and spreading disease.

Further direction is needed because in spite of the guidance and encouragement from the Federal Government, some workers did not have access to the leave they needed during the 2009 H1N1 outbreak. In addition, many workers do not have access to paid sick leave for ordinary illnesses and injuries that are not a public health threat but still can endanger their job or income.

Question 2. You mentioned in your testimony that several States and cities in the United States have implemented either temporary disability insurance programs or paid sick days laws. Has the Department of Labor heard of any ill effects on employers that these leave policies have imposed? Is a piecemeal, State-by-State or city-by-city provision of paid sick days an effective or adequate way of providing employees with the leave they and their families need?

Answer 2. I am not aware of any studies done on the impact of temporary disability insurance (TDI) programs (other than the impact on working parents regarding maternity leave) or paid sick leave laws on employers in those States or cities that require them. It should be noted that only the programs in Hawaii and Puerto Rico are funded by employers, so the TDI programs in California, New Jersey, Rhode Island and Washington would have no direct monetary impact on employers.

Secretary of Labor Hilda L. Solis' vision is **Good Jobs for Everyone.** One of the key components of a good job is having workplace flexibility for family and personal caregiving. The Department believes that work-life balance is enhanced by policies such as paid leave and must be available to *all* workers.

Question 3. My staff recently spoke with the owner of a restaurant in West Hartford, CT who provides his employees with paid sick and vacation time. This owner provides his employees with paid leave because he says it increases morale, drastically reduces turnover, saves his business money, and helps him maintain loyal customers. Some argue that providing paid sick leave is detrimental to employers' bottom lines. Is this true or is the restaurant owner in CT correct in saying that this benefit can save businesses money? Can paid leave benefit businesses?

Answer 3. We believe it is common sense *and good business sense* that workers are able to stay home if they are ill without fear of losing their job, and do not have to work when ill simply because they do not have paid leave. Keeping employees with infectious illnesses home can help businesses reduce the spread of illness in

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[1] *New York Times* "Lack of Paid Sick Days May Worsen Flu Pandemic" November 2, 2009; Washington Post "H1N1 exposes weak leave policies" November 9, 2009; *CNNMoney.com* "Swine flu—and no paid sick leave" October 4, 2009; *AP* "Millions Without Sick Leave Fear Swine Flu" November 1, 2009; *AP* "Swine Flu or Not, Many Workers Can't Stay Home" May 4, 2009; *Christian Science Monitor*" Swine Flu: With No Paid Sick Leave, Workers Won't Stay Home" November 14, 2009.

their workplace and keep more employees working—which will help employers' productivity. Some studies have found a relationship between work-life benefits and *positive employer outcomes* although the Department is not aware of any recent studies updating these findings.

Question 4. You said in your testimony that workers can jeopardize their job security by having to stay home from work because they are sick. Is this especially true during the current economic downturn? If so, why is that?

Answer 4. Some employers have policies that penalize employees for absences from work, resulting in some cases with the employee being fired. The Department is not aware of any studies regarding changes to these types of leave policies during economic downturns. Of course, during an economic downturn with a high unemployment rate, it can be harder for workers who are fired to find new jobs.

Question 5. The CDC guidances also tell workers and families not to go to work if they are sick and to keep their children home from school if their children are sick. Secretary Sebelius and Secretary Locke, among others, have repeated these instructions. I have been listening to these recommendations over the last several months and I can't help but feel that they are ignoring what is a reality for far too many workers—that many employees don't have the economic ability to take time off of work without pay, and they don't have access to paid leave. There seems to be a significant inconsistency between what the Federal Government is telling employees will be most effective in slowing the epidemic and what people are actually able to do. Do you agree that this discrepancy exists? Would the Healthy Families Act help to fill this gap?

Answer 5. We have not seen any studies yet quantifying the number of employers who heeded the advice of Secretaries Sebelius, Locke and Solis to allow workers with influenza-like illness to stay home and away from the workplace. Even if some employers are providing leave to their employees who are ill with the H1N1 virus, the Healthy Families Act would ensure that many more employees could stay home when they are sick without fear of losing their job or losing income.

Question 6. In your testimony you mentioned that DOL has been working with other agencies on the H1N1 flu pandemic. Can you describe this collaboration and why it is important on an issue such as this one?

Answer 6. The Department strongly supports the interagency efforts led by the White House and the Departments of Health and Human Services and Homeland Security in responding to the 2009 H1N1 pandemic. DOL has been involved since 2005 in the Federal planning to prepare our Nation for a possible pandemic. All our efforts acknowledged that a severe pandemic would have enormous human and economic consequences. DOL's involvement ensured that choosing the right response, one that would minimize the overall negative impact on our society, took into account the specific effects on workers and workplaces. All Federal partners brought similar program and policy expertise to the planning process so that our guidance anticipated all possible consequences.

The release of the *National Implementation Plan* in 2005 was just the start of the interagency work. Since then, DOL has been an integral part of the ongoing planning efforts as well as the continual assessment of Federal, State and local readiness. DOL's involvement in developing the 2007 *Community Strategy for Pandemic Influenza Mitigation* and in subsequent guidance documents ensured that policies and plans that affected workplaces, and particularly the safety and health of workers, was addressed. For example, DOL, along with the Equal Employment Opportunity Commission, published FAQs on the workplace issues to be considered by employers in writing and implementing their pandemic plans. DOL's Occupational Safety and Health Administration (OSHA) also provided guidance to workers and employers on how to keep workers safe and healthy during a pandemic. (*see http://www.osha.gov/dsg/topics/pandemicflu/index.html.*)

With the onset of the 2009 H1N1 outbreak, DOL has worked very closely with our partner agencies in helping our Nation respond to this novel virus. We worked with CDC and others on the *Guidance for Businesses and Employers to Plan and Respond to the 2009–2010 Influenza Season* and released new resources specific to H1N1 (*see http://www.osha.gov/h1n1/index.html*). Through the Federal Advisory Council on Occupational Safety and Health (FACOSH), the Assistant Secretary for OSHA who chairs FACOSH, convened a subcommittee of Federal agencies and labor representatives to address the challenges of responding to the 2009 H1N1flu pandemic within the Federal community. FACOSH's recommendations, which appear in its final report, "Recommendations for Consideration by the Secretary of Labor on Pandemic-H1N1 Influenza Protection for the Federal Workforce," are being evaluated for further action. This coordination has allowed the Federal agencies to speak

clearly and with one voice to help individuals, communities and businesses respond quickly and effectively to this novel virus.

RESPONSE TO QUESTIONS OF SENATOR DODD, SENATOR REED, SENATOR ENZI AND SENATOR HATCH BY ANNE SCHUCHAT

QUESTIONS OF SENATOR DODD

Question 1. Can you talk about what you expect to see happen with H1N1 as we head into the traditional flu season? How is CDC preparing for it?

Answer 1. It is possible that the pandemic will wane over time as the season progresses. However, there are also possibilities for worsening that we should consider as we head into the traditional flu season: (1) Seasonal H3 influenza arrives in strength in the winter, and (2) 2009 H1N1 influenza has increased activity. Either possibility might occur alone, or together.

HHS' CDC has had systems in place to monitor changes in virus circulation for many years including tracking of influenza-like illness, geographic spread, hospitalizations and deaths due to influenza, and changes in the virus itself that may make it more lethal or resistant to antiviral medications. We also routinely track changes in the relative circulation of influenza strains, and monitor for new strains that may be different from the current vaccine strains. We have enhanced these systems during the pandemic by augmenting our relationships with State and local health departments in the area of virus testing (subtype characterization and antiviral resistance monitoring), expanding collaborative agreements with key medical centers nationwide (identifying and tracking trends in disease severity), increasing our interaction with laboratories across the country (subtype monitoring), and adding a number of electronic data sources to track illness spread, antiviral use, school closures, and impact on communities.

Question 2. Dr. Schuchat, with respect to the response to this pandemic, could you also talk about the level of coordination between CDC/HHS and other Departments, especially the Department of Labor?

Answer 2. CDC/NIOSH (National Institute for Occupational Safety and Health) has coordinated with the Department of Labor (DOL)/Occupational Safety and Health Administration (OSHA) on several matters related to worker safety and health during the course of this pandemic, and DOL/OSHA has been a partner with CDC in reaching out to labor unions to keep them informed of CDC guidance related to worker safety and health. In particular, OSHA played a significant role in the development of HHS/CDC's interim infection control guidance for healthcare settings for the 2009–2010 influenza season, as well as in the development of a companion piece to this document which focused on strategies to mitigate the impact of shortages of appropriate respiratory protection for healthcare workers. OSHA has also been a partner with CDC/NIOSH on a regular series of conference calls with a wide array of labor unions, in which updates are provided about the current status of the pandemic, and questions are fielded from the labor audience.

During the summer of 2009, CDC/NIOSH staff participated as subject matter experts in the DOL/OSHA-sponsored Federal Advisory Council on Occupational Safety and Health (FACOSH) emerging issues workgroup, which was convened to review agency experience in protecting Federal employees from 2009 H1N1 influenza. FACOSH advises the Secretary of Labor on issues related to the occupational safety and health of the Federal workforce. The workgroup gathered information from Federal agencies and labor organizations representing Federal employees. It also sought insight from technical experts who provided perspective on the occupational safety and health-related gaps that exist in pandemic planning within the Federal Government and provided recommendations for the Secretary of Labor, including providing better all-around pandemic-related training within Federal agencies and facilitating the coordination of 2009 H1N1 influenza information to improve consistency and clarity.

Question 3. In your testimony you mentioned what individuals can do to prevent the spread of illness. What recommendations does the CDC make to employers to help them limit the spread of H1N1? What specific guidelines should child care facilities and schools use to prevent the spread of H1N1?

Answer 3. In a guidance document titled, "CDC Guidance for Businesses and Employers To Plan and Respond to the 2009–2010 Influenza Season," CDC outlines the measures which businesses can take to help protect their workforce and to maintain business continuity during this pandemic. The recommendations are framed for two scenarios: the first aimed for pandemic conditions similar to those experienced during the Spring wave of 2009 H1N1 influenza; and the second targeted for a pan-

demic more severe, based on the level of illness typically caused by the virus. Under current conditions, the guidance recommends that businesses take the following steps to keep staff from getting sick with the flu.

- Ensure that sick workers stay home,
- Monitor employees for illness and send sick workers home,
- Practice good hand and cough hygiene,
- Clean surfaces and items that are frequently touched by many people,
- Encourage employees to get vaccinated for both seasonal and 2009 H1N1 influenza,
- Take measures to protect employees who are at higher risk for complications of influenza,
- Make plans to maintain business continuity in the face of rising absenteeism, and
- Advise employees on proper measures to take when traveling overseas.

Should pandemic conditions become more severe, based on increased virulence of the 2009 H1N1 virus, further measures which CDC recommends include:

- Consider active screening of employees for illness,
- Provide alternative work environments for employees at higher risk of flu complications,
- Increase social distancing in the workplace,
- Cancel non-essential business travel, and
- Prepare for the effects that school closures could have on work absenteeism.

CDC recommends that schools and early childhood programs take the following steps to help keep students, teachers, and staff from getting sick with influenza. These steps should be followed all the time and not only during a flu pandemic.

- Encourage all school and early childhood program staff and students to get vaccinated for seasonal flu and 2009 H1N1 flu.
- Educate and encourage staff and students to cover their mouth and nose with a tissue when they cough or sneeze and provide easy access to tissues and trash cans. Teach children to cover coughs or sneezes using their elbow instead of their hand when a tissue is not available.
- Remind staff and students to practice good hand hygiene and provide the time and supplies for them to wash their hands with soap and water as often as necessary. Help younger children wash their hands properly and frequently.
- Remind staff to stay home and parents to keep a sick child at home when they have flu-like symptoms. Sick people should stay at home until at least 24 hours after they no longer have a fever or signs and symptoms of a fever (has chills, feels very warm to the touch, has a flushed appearance, or is sweating) without the use of fever-reducing medicine.
- Send sick students, teachers, and staff home and advise them and their families that sick people should stay at home until at least 24 hours after they no longer have a fever or signs of a fever (without the use of fever-reducing medicine). Early childhood program staff should perform a daily health check of children and make sure that contact information for parents is up-to-date so they can be contacted if they need to pick up their sick child.
- Move sick students and staff to a separate, but supervised, space until they can be sent home. Limit the number of staff who take care of the sick person and provide a surgical mask for the sick person to wear if they can tolerate it. Have surgical masks available for school nurses and others who care for sick people at the school or early childhood program.
- Routinely clean surfaces and items that children frequently touch with their hands (or mouths in early childhood programs) with the household disinfectant that is usually used, following the directions on the product label. Additional disinfection beyond routine cleaning is not recommended.
- Encourage early medical evaluation for children and staff at higher risk of complications from flu. They will benefit from early treatment with antiviral medicines if they are sick with flu.
- Stay in regular communication with local public health officials. It may be necessary to temporarily close an early childhood program or selectively dismiss a school with a large proportion of children at higher risk for influenza complications if flu transmission is high in the community. Local public health officials will also know if the influenza starts to cause more severe disease, calling for additional strategies to be implemented.

Question 4. The Advisory Committee for Immunization Practices (ACIP) has identified children 6 months to adults 24 years of age to be among the vaccine priority groups. Can you talk about the adequacy of vaccines, equipment and other medica-

tions to treat children? Do you believe that our Nation's emergency departments and emergency medical personnel are adequately trained and equipped with proper medicines and devices suitable for children?

Answer 4. We expect the 2009 H1N1 influenza vaccine to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. Over the years, hundreds of millions of Americans including children have received seasonal flu vaccines. HHS/CDC and HHS' Food and Drug Administration (FDA) will be closely monitoring for any signs that the vaccine is causing unexpected adverse events and we will work with State and local health officials to investigate any unusual events.

For pediatric patients the antiviral drugs available are Tamiflu oral suspension and Tamiflu (30 mg and 45 mg) capsules. Relenza may also be used for treatment of influenza for children 7 years of age and older. There are adequate supplies of Tamiflu capsules and Relenza in the commercial supply chain. There were limited supplies of Tamiflu oral suspension available however, as of November 30, 2009, the manufacturer of Tamiflu has announced they are increasing the supply of Tamiflu pediatric oral suspension in the commercial supply chain. This product is now being made available.

For children who are too young to use Relenza or who can not swallow capsules, if commercial Tamiflu oral suspension product is not available, pharmacies may compound Tamiflu suspension using adult capsules. In addition, Tamiflu 30 and 45 mg capsules may be mixed into a sweetened liquid by a caregiver.

The training of personnel for management of infectious patients should not be very different between adult and pediatric care. Compared with training and equipment, staffing and space limitations are likely to be more challenging in these settings. In case of shortages in resources, HHS/CDC's Strategic National Stockpile contains supplies, equipment, and medications to support children as well as adults should there be a need to supplement locally available resources.

Question 5. When it comes to the H1N1 virus, what are the biggest challenges you hear from employers? Schools? State and local public health departments?

Employers

Answer 5. In the Spring when the 2009 H1N1 influenza virus first emerged, the biggest challenge for employers was adapting their pandemic plans to a pandemic that was milder than most plans had anticipated. Additionally, employers found that the WHO pandemic phases, which were planned to be utilized as triggers for further actions, were not actionable based on actual pandemic conditions. In response to these concerns and the key roles that businesses play in protecting the health of the workforce, CDC issued guidance for businesses and employers, encouraging them to develop pandemic plans that are flexible and sensitive to changes in the pandemic severity. Businesses and employers needed specific guidance regarding measures to use and advice on the timing of their implementation. In August, CDC updated that guidance and included recommendations for both the current level severity of pandemic and a more severe pandemic scenario.

Schools

Since the beginning of the pandemic in Spring of 2009, schools have been concerned with decreasing exposure to regular seasonal flu and 2009 H1N1 flu, implementing school closure guidance where necessary, and mitigating the effects that can come with closure. The decision to dismiss students should be made locally and should balance the goal of reducing the number of people who become seriously ill or die from influenza with the goal of minimizing social disruption and safety risks to children sometimes associated with school dismissal. While dismissal can be an effective means of decreasing the spread of disease in a community, it can also lead to negative consequences, including interruption of students' education, students being left home alone, workers missing shifts when they must stay home with their children, and low-income students missing free or reduced price meals.

State and Local Health Departments

One of the biggest challenges we hear about from State and local public health officials is vaccine availability and the impact that it has had on State and local vaccination planning efforts. Many State and local health departments have reported that demand for vaccine has been greater than vaccine supply in their jurisdictions. In addition, challenges related to the limited ability to project future vaccine supply as well as concerns about inaccurate or unpredictable vaccine allotment numbers have complicated State and local long-term planning efforts. State and local public health departments are concerned about their ability to sustain very high workload due to the pandemic while maintaining the ability to respond to other

public health events in their jurisdictions. The State laboratories have been especially impacted by the demand for testing for the 2009 H1N1 virus. Other challenges include additional personnel needs, particularly for administrative, vaccinator, and support staff personnel. A related challenge is the need for improved hiring processes to address recruiting difficulties. State and local health officials also have indicated a desire for more streamlined data collection and reporting requirements.

QUESTIONS OF SENATOR REED

Question. I am deeply worried that Rhode Islanders, especially those at high risk of contracting H1N1 influenza, will not have access to adequate protection. In addition to the 160,631 doses of ANTIVIRALS that will be provided to Rhode Island at no cost to the State, the CDC recommended that the Rhode Island purchase an additional 112,981 doses of the H1N1 vaccine in order to immunize residents. The Federal Government offered to subsidize 25 percent of the cost of purchasing these additional doses. However, the current economy has hit Rhode Island particularly hard, and the State was only able to allocate sufficient resources for the purchase of 38,849 additional doses. Similarly, due to the State's budgetary constraints, I have heard concerns that there will be inadequate levels of personnel to staff preparedness activities and respond to the surge in illness. How does the CDC plan to address the need for additional vaccines and personnel in States that have been hardest hit by the current economy, and, as such, unable to adequately prepare to protect residents from the H1N1 influenza?

Answer. HHS pandemic influenza preparedness plans includes having enough antiviral drugs to treat 25 percent of the U.S. population (75 million courses) with additional product available to support containment efforts (6 million courses). The goal is for the Federal Government to procure 50 million courses of antiviral drugs, and for project areas to procure 31 million courses which would be made available for purchase of HHS subsidized contracts. Of the 31 million courses, approximately 25.5 million courses have been procured by project areas.

In the spring, approximately 11 million regimens of antiviral drugs were deployed from the Strategic National Stockpile (SNS) to the 62 project areas. We understand that there was only modest use of this product at the State level. Thirteen million regimens of antiviral drugs were purchased to replenish the SNS assets deployed and have been incorporated into SNS inventory over the summer. HHS has also made an additional purchase of 16 million regimens of antiviral drugs that are anticipated to be delivered through February 2010 into SNS inventory, offsetting the gap that is present in State stockpiles (5.5 million regimens).

Release of additional SNS antiviral drugs to States is determined based on multiple factors including disease progression, demand for product, and changes in product supply (commercially and within State stockpiles).

Furthermore, all 2009 H1N1 vaccine is being purchased by HHS at no cost to the States, local health departments or other vaccinators.

CDC has taken several steps to help alleviate State and local 2009 H1N1 staffing needs, including temporarily assigning Federal staff to State and local health departments to provide support of State and local 2009 H1N1 response activities on a short-term basis. These temporary 2009 H1N1 field staff augment existing Federal field staff already fully involved in the 2009 H1N1 pandemic response, including preparedness and immunization field staff, career Epidemiology Field Officers, and Epidemic Intelligence Service officers. CDC will consider the requests based on Federal staff availability to meet anticipated needs.

In addition, CDC's 2009 H1N1 Public Health Emergency Response (PHER) grant funds may be used to hire State personnel needed for 2009 H1N1 response activities. Of the 62 PHER awardees, 40 reported spending an estimated $15.7 million on personnel and fringe benefits through October 31, 2009. These funds paid in part or in full for 3,944 positions. The majority of personnel hired were nurses (38 percent), vaccine administrators (10 percent), and preparedness and response specialists (7 percent). An additional 20 percent of personnel expenditures supported "other" positions, including support staff, translators, data collection/entry personnel, contract nurses and call center support staff.

Last, PHER funds may be used to support more long-term State and local health department staff. Many awardees already have requested direct assistance positions, for which CDC is currently in the process of recruiting and hiring.

QUESTIONS OF SENATOR ENZI

Question 1. We continue to hear reports about schools closing across the country. Can you describe the vaccination programs at public schools? How many or what

proportion of schools have vaccination programs? For those schools without vaccination programs, do they have plans to refer students and parents to local clinics that have access to the H1N1? What are we doing to assist the schools that have closed to vaccinate the children when they return or when they are at home because of the closing? Finally, when you calculate the allocation of vaccine that you distribute to communities, do you include in that calculation the schools in that community?

Answer 1. During the week of November 23, 2009, there were no school closings reported to the CDC. There is no national program to vaccinate children through schools, although CDC has posted materials to assist State and local health departments with their programs at (*http://www.cdc.gov/h1n1flu/vaccination/slv/*). Because CDC does not collect data nationally on the number of schools that participate in such programs, there is not a mechanism to describe the proportion of schools offering vaccination programs. There is also no way to determine, at least on a national level, whether or not schools are referring students and parents to local clinics where the 2009 H1N1 vaccine is being offered. Since every State varies in its approach to vaccine distribution, there is no comprehensive mechanism to collect this type of information.

The 2009 H1N1 vaccine is allocated on a pro rata basis. Once allocated to project areas, there may be State and local decisions to further distribute vaccine on the basis of the number of school clinics. Again, each project area varies in its approach to vaccine allocation.

Question 2. In light of the barriers that have been exposed with the H1N1, including our country's limited capacity to produce flu vaccine and the impact of not approving adjuvants in the flu vaccine, what specific steps will the Administration take to better prepare our country for the next flu pandemic?

Answer 2. HHS is in the third year of implementing a comprehensive program to better prepare our country for the next influenza pandemic. This program supports the advanced development of improved influenza vaccines using both cell-based and recombinant and molecular technologies to produce vaccines that are not dependent on egg supplies. The advanced development program also supports the development of adjuvant technologies so they may be licensed for use with influenza vaccines in the coming years and be available as licensed vaccine for use during the next influenza pandemic.

This program supports the building and expansion of domestic manufacturing infrastructure for influenza vaccine production. HHS supported the construction of the first U.S. cell-based facility that opened on November 24, 2009 and is expected to be operational by 2011, producing a significant portion of the U.S. pandemic vaccine needs within 6 months of the onset. HHS also has plans to support the construction of a second facility for production of cell-based or recombinant influenza vaccine with similar manufacturing surge capacity. Further, the domestic infrastructure program supported the expansion and upgrade of existing egg-based vaccine facilities in the United States.

Last, this program supports stockpiling of pre-pandemic H5N1 vaccine antigens and adjuvants. These stockpiles of antigens and adjuvants will allow the United States to more rapidly respond to an emerging pandemic by using these stockpiles to produce vaccines for an initial response.

Question 3. The United States has historically low flu vaccinations rates. What is the Administration doing to improve these rates? How are you expanding public awareness about the different types of vaccines and why it is important for certain populations to be vaccinated?

Answer 3. The objective of the 2009–2010 influenza vaccination communication campaign is to support the public health goal of protecting as many people as possible from both seasonal influenza and 2009 H1N1 flu, with minimal social and economic disruptions. The primary goals of the 2009 influenza vaccination communications efforts are to provide timely and accurate information about the Federal influenza and pneumococcal vaccination recommendations, the benefits and risks of vaccination, and information about vaccine supply that helps individuals protect themselves and their families from influenza, including helping them make vaccine choices.

A crucial element of the combined 2009 H1N1 and the 2009–2010 seasonal influenza communications campaign involves engaging key stakeholders to help support and further vaccination messages. These stakeholders, including healthcare workers, pharmacists, employers, labor organizations and colleges and universities, are integral in furthering CDC's recommendations and disseminating these messages to as many people as possible. Working in concert with its traditional public health

partners, we are also utilizing other outreach mechanisms to spread the word about influenza vaccines.

We have developed various print products, social media, and audio/video tools available in English, Spanish, and additional languages. Products include messages for both seasonal and 2009 H1N1 influenza. Print products include posters, flyers, brochures, and fact sheets, like Vaccine Information Statements. Social media products and activities include web banners, buttons, and badges that enable partners and external organizations to provide a link back to CDC on their Web site, a weekly blog on WebMD, and webinars for bloggers. We also are employing audio and video tools such as public service announcements (PSAs), podcasts and videos. These are available for State and local public health partners to use in healthcare settings. New information and materials are posted regularly on flu.gov and cdc.gov/h1n1flu.

HHS/CDC is producing messages and materials for all of the groups recommended for seasonal and 2009 H1N1 flu vaccines, as well as messages for the general public, including hard-to-reach populations. However, because we know that the 2009 H1N1 virus affects certain population groups more severely than others, we have crafted targeted communication to reach those at the highest risk. For example, pregnant women, parents of children aged 18 and under, and adults ages 25 through 64 years. We have also created plain language materials and products tailored for specific ethnic and racial groups.

CDC is conducting outreach to health care providers through multiple channels to educate them on the importance of vaccination among their patients and to help address the challenge of low vaccination rates among health care personnel. Some examples of this outreach include a teleconference with leaders from the Nation's healthcare provider and healthcare personnel organizations and HHS Secretary Kathleen Sebelius and a partnership with Medscape to produce a weekly video series to provide updated information to physicians, nurses, pharmacists, and other healthcare professionals.

CDC has invited minority media outlets, particularly African-American and Hispanic media to hear from experts about the seriousness of the seasonal flu virus and 2009 H1N1 influenza virus, as well as to learn the importance of receiving both immunizations. Agenda topics for these briefings have included: flu season overview, importance of vaccinations, impact of influenza on specific ethnic and minority populations especially children, prevention and treatment, perspectives and attitudes of these specific populations. There is also time allotted for open discussion and one-on-one interviews, as requested.

Question 4. The Administration projected that the United States would have access to 80–120 million doses of the H1N1 vaccine by mid-October, but we all know that those goals were way off the mark. In your opinion, do you think that it would have been possible to produce that many vaccines within the timeframe that was given to manufacturers?

Answer 4. Theoretically it would have been possible to produce the projected number of doses within the targeted time period. However, the realities of production posed unanticipated and unforeseeable delays. Potential production delays such as manufacturers changing delivery schedules due to country prioritization, extremely low production yields, prolonged seasonal influenza vaccine manufacturing campaigns, and day-to-day logistical and production line problems were not incorporated into our projections. These vaccine production capacity numbers were developed in July 2009.

HHS has been transparent throughout the process, providing estimates and projections of vaccine manufacturing capacity availability based on our most current knowledge of vaccine delivery logistics and information from vaccine manufacturers, with the necessary caveats that vaccine manufacturing has numerous variables, many of which are inherent in the science of the virus and beyond our control. Changes in projections reflected delays in vaccine availability and not reductions in the total amount that will be available.

Development of the 2009 H1N1 influenza vaccine began in late May 2009 when the five U.S.-licensed manufacturers received virus reference strains from CDC and began making virus seed stocks. Commercial scale manufacturing of the vaccine began in late June to early July. The U.S. Government began receiving shipments of vaccine in late September with shipments expected every week at least through January 2010.

QUESTIONS OF SENATOR HATCH

Question 1. The Biomedical Advanced Research and Development Authority (BARDA) was set up to provide incentives for companies to manufacture new products that could aid the United States in responding to biological, chemical and radi-

ological threats. This mechanism helps companies bear the costs associated with moving products through the research and development pipeline by assisting with that financial burden. This system has worked well for incenting new products but was not intended for existing products or technology. The current pandemic has highlighted the uncertainties.

Answer 1. The success of our response to a Public Health Emergency depends most of all on medical countermeasures for treatment and prevention of disease to help reduce the spread of infections, reduce health consequences, and ultimately save lives.

Secretary Sebelius has asked the Assistant Secretary for Preparedness and Response to lead a review of its entire public health and emergency medical countermeasures enterprise, to be completed in the first quarter of 2010. The goal of this review is a modernized countermeasure production process that promotes promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices.

The U.S.-pandemic preparedness strategy for establishing a domestic manufacturing surge capacity to produce sufficient pandemic vaccine for the entire United States within 6 months of pandemic onset involves an integrated approach utilizing vaccine development and U.S.-based manufacturing facility building. Advanced development of new influenza vaccines using tissue culture, recombinant DNA, and molecular technologies is the foundation for providing more flexible, robust, and less-vulnerable ways to manufacture influenza vaccines. Further, advanced development of antigen-sparing technologies for existing and new influenza vaccines using adjuvants provides opportunities to expand the vaccine manufacturing base multifold at different points towards the final surge capacity goal. Coupling the enhancement of existing U.S.-based manufacturing facilities that produce egg-based influenza vaccines with the building of new domestic facilities that will manufacture cell-, recombinant-, or molecular-based influenza vaccines is the natural extension to vaccine advanced development and should achieve the U.S.-pandemic vaccine surge capacity goal.

The seeds planted since the investments were initiated in 2006 have thus far generated the trees that will bear fruit in the next several years. Specifically, the HHS cell-based influenza vaccine program supports the advanced development of six cell-based programs. Two of these vaccines are nearing completion of final clinical testing and are expected to seek U.S.-licensure in 2010–11. One of these two companies has started to build a plant for the production of cell-based vaccines here in the United States with assistance from HHS. This facility may be available for vaccine production in less than 2 years in a pandemic emergency. Other cell-based vaccine candidates are earlier in the development pipeline.

In June 2009, HHS made its first award for advanced development of a recombinant vaccine. Recombinant and molecular technologies do not depend on the ability to grow the virus in an egg or a cell to manufacture vaccine and thus may be available much sooner after pandemic onset. It is projected that this first program will be licensed for use in the United States in 3 years. A second request for proposals (RFP) was released in September 2009 to support additional recombinant and molecular influenza vaccine candidates; multiple proposals were received for review and contract awards are expected early in 2010.

In early 2007 HHS made awards for three antigen-sparing technology programs. These technologies reduce the amount of vaccine needed to vaccinate a person and thus increase the total supply. These technologies are in late stage of development with 2009 H1N1 vaccines and are expected to seek U.S.-licensure in 2010.

Additional influenza vaccine manufacturing facilities in the United States would augment existing and nearly completed influenza vaccine manufacturing facilities implementing new cell-, recombinant-, or molecular-based technologies and is consistent with HHS' pandemic influenza preparedness activities. HHS plans to issue RFPs in 2010 to support the construction of a new cell-based manufacturing facility in the United States and to expand the domestic fill-finish vaccine manufacturing network.

Additionally, new vaccine production technologies and technologies that expedite the vaccine production and delivery process will be pursued, such as new and faster ways to measure how vaccine potency, which will provide better estimates of vaccine production.

Together, these programs of advanced development and building domestic manufacturing infrastructure will enable the United States to meet its pandemic preparedness vaccine goals in the next 3 years.

RESPONSE TO QUESTIONS OF SENATOR DODD AND SENATOR ENZI BY DEBRA NESS

QUESTIONS OF SENATOR DODD

Question 1. Some critics have expressed concern about the impact that passing a bill like the Healthy Families Act would have on American businesses and our global economic competitiveness. However, you testified in opposition to that claim. What do both international experiences and our early experiences with the San Francisco paid leave ordinance tell us about the impact that the Healthy Families Act would have on businesses and our Nation's economic competitiveness?

Answer 1. Based on research on international experiences and early experiences with the San Francisco paid sick days ordinance, we conclude that the availability of paid sick time does not negatively impact economic competitiveness and employment.[1]

The U.S. lags far behind other countries in paid sick day standards. In fact, a global consensus exists around the guarantee of job-protected paid sick days: 163 nations guarantee paid leave for workers to recover from their own health conditions. The United States and the Republic of Korea are the only industrialized nations that lack a standard of paid sick days.[2]

The World Economic Forum, which brings together the top business leaders from around the world, ranks the most competitive national economies. The United States is alone among the 20 most competitive countries in not guaranteeing workers paid sick days. Eighteen of these countries provide 31 or more sick days with pay. In fact, the countries which are most economically competitive are *more likely* to guarantee paid sick days for employees' own health and to care for the health needs of children and adult family members. According to the researchers, by guaranteeing paid sick days, these nations are guaranteeing a healthy workforce, which is essential to competition.[3] [4]

While San Francisco became the first jurisdiction in the United States to guarantee workers paid sick days in 2007, their early experiences have been similar to those internationally. Economic indicators do not show that San Francisco's paid sick days law had an adverse affect on the city's economy. In fact, in the 12-month period following the effective date of the policy, employment in San Francisco expanded by 1.1 percent, the same rate as neighboring Marin and San Mateo counties and substantially above the rate of employment change in Alameda, Contra Costa and Santa Clara counties.

According to a statement to the House Education and Labor Committee's Subcommittee on Workforce Protections by Donna Levitt, Manager of San Francisco's Office of Labor Standards Enforcement:

> "I am not aware of any employers in San Francisco who have reduced staff or made any other significant changes in their business as a result of the sick leave ordinance. While San Francisco, like every community, has suffered in the current recession, to my knowledge no employers have cited the sick leave requirement as a reason for closing or reducing their business operations in the city."[5]

Question 2. Has the FMLA been unduly burdensome on employers to implement?

Answer 2. No; in fact, the FMLA has demonstrated conclusively that family-friendly workplace policies are good for businesses as well as good for workers and families. Since 1993, workers have used the FMLA more than 100 million times to take the unpaid time off that they need to care for themselves or their families, without sacrificing their jobs and long-term economic stability.[6] During the efforts

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[1] Earle, Alison and Jody. Heymann. 2006. "A Comparative Analysis of Paid Leave for the Health Needs of Workers and their Families Around the World." Journal of Comparative Policy Analysis. 2006; 8 (3): 241–257.

[2] Heymann, Jody. *Raising the Global Floor*. 2009.

[3] Heymann J., A. Earle, & J. Hayes. (2007). *The Work, Family, & Equity Index: How Does the United States Measure Up*?. Boston/Montreal: Project on Global Working Families. *www.mcgill.ca/files/ihsp/WFEIFinal2007.pdf*.

[4] Earle A. & J. Heymann. (2006). A comparative analysis of paid leave for the health needs of workers and their families around the world. *Journal of Comparative Policy Analysis* 8(3):241-257.

[5] Donna Levitt, Statement for the Record to the House Subcommittee on Workforce Protections, 6/25/2009.

[6] Dept. of Labor. The Family and Medical Leave Act Regulations: A Report on the Department of Labor's Request for Information 2007 Update at 129. We based this estimate on multiplying the Employer Survey Based Estimate by 15. Unfortunately, the data we have on FMLA leave use is quickly becoming out of date. The Dept. of Labor last surveyed employers and em-

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to pass the FMLA, advocates withstood, and overcame, relentless scare tactics from businesses that claimed the law would be the end of them. Over 15 years later, the FMLA is well established, and businesses have flourished with it in place. Data from the most recent national research on it, conducted by the U.S. Department of Labor, show that the vast majority of employers in this country report that complying with the FMLA has a positive/neutral effect on productivity (83 percent), profitability (90 percent), growth (90 percent), and employee morale (90 percent).[7] The act benefits employers in numerous ways, most notably from the savings derived from retaining trained employees, from productive workers on the job, and from a positive work environment.

The Department of Labor agrees that the FMLA is working well. According to its 2007 Report:

> Department is pleased to observe that, in the vast majority of cases, the FMLA is working as intended. For example, the FMLA has succeeded in allowing working parents to take leave for the birth or adoption of a child, and in allowing employees to care for family members with serious health conditions. The FMLA also appears to work well when employees require block or foreseeable intermittent leave because of their own truly serious health condition. Absent the protections of the FMLA, many of these workers might not otherwise be permitted to be absent from their jobs when they need to be.[8]

QUESTIONS OF SENATOR ENZI

Question 3. The Healthy Families Act covers small employers that employ 15 or more employees. This is a much lower threshold than the Family and Medical Leave Act of 1993 (FMLA), which set a 50 employees threshold. As we heard from Ms. O'Brien's testimony, the FMLA has been extremely burdensome to administer for the employers it governs. Now, you are advocating multiplying that burden and extending it to more than 600,000 new employers who may not have sophisticated HR departments. Why is it appropriate to include employers who are exempted from the FMLA?

Answer 3. The Healthy Families Act uses an employer-size threshold different from the FMLA because its scope and purpose is entirely different. The FMLA provides unpaid, job-protected leave for up to 12 weeks a year to care for a newborn, newly adopted or foster child, to care for a seriously ill family member, or to recover from an employee's own serious illness. The Healthy Families Act offers leave that is for a much shorter time—7 days. The FMLA does not address many workers' day-to-day health needs. FMLA coverage for illnesses is limited to serious, longer-term illnesses and the effects of long-term chronic conditions. The law does not offer time off to workers to deal with common illnesses that do not meet the FMLA standard of "serious" or for routine medical visits for themselves and their families. The Healthy Families Act aims to offer leave for common, short-term illness like the cold or the flu.

Unlike the FMLA, the need for paid sick days is largely based on public health concerns: to prevent the spread of contagious illness within our workplaces, schools and communities. Workers in jobs that involve the most interaction with the public are among those least likely to have paid sick days. Only 22 percent of food and public accommodation workers have any paid sick days, for example. Workers in child care centers, retail clerks, and nursing homes also disproportionately lack paid sick days.[9] To fulfill the purpose of safeguarding public health, a 15-employee threshold makes more sense than a larger, 50-employee threshold, which would exempt 40 percent of the workforce. Any higher threshold for the Healthy Families Act would be tantamount to creating holes in mosquito netting.

Question 4. The nonpartisan Congressional Budget Office estimated that this bill will cost private employers $11.4 billion over 5 years. A substantial amount of that will fall on smaller employers that are already struggling to make payroll in these difficult economic times. Indeed, as we can see from the current 10.2 percent unemployment rate, many are not able to maintain current payrolls. If this bill is enacted, won't employers be forced to adjust somewhere—either by reducing current

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ployees on the FMLA in 2000. Since then, the Dept. has not conducted any national survey on the FMLA. The Department needs to conduct scientifically sound survey research on the FMLA so that policy decisions can be made based on that information, rather than on selected employers' complaints.

[7] Dept. of Labor. FMLA Survey Report. 2000. *www.dol.gov/whd/fmla/chapter6.htm.*

[8] Dept. of Labor.2007 Report.

[9] Vicky Lovell. Institute of Women's Policy Research. Valuing Good Health: An Estimate of Costs and Savings for the Healthy Families Act, 2005.

healthcare or retirement benefits, or by downsizing their number of employees and adding to the ranks of the unemployed?

Answer 4. Paid sick days policies can be implemented without negative impacts for employers. For a case in point, we can examine efforts to raise the Federal minimum wage, which set off a wave of similar business claims. According to a 2006 statement from 650 economists, increasing the minimum wage "can significantly improve the lives of low-income workers and their families, without the adverse effects that critics have claimed"[10] and result in higher productivity, lower turnover and improved worker morale. While a paid sick days policy would impose modest costs, economists predict that is also likely to help business by reducing turnover and improving worker productivity.

It is also important to consider San Francisco's experience. The city's labor enforcement official has publicly stated that she is not aware of any employers in San Francisco who have reduced staff or made any other significant changes in their business as a result of the sick leave ordinance. Furthermore, despite an economic slowdown affecting employment in all counties in the Bay Area in 2007, after passing paid sick days, San Francisco maintained a competitive job growth rate that exceeded the average growth rate of nearby counties. In the 12-month period following the 2007 effective date of the new policy, employment in San Francisco expanded by 1.1 percent, substantially above neighboring areas without this ordinance.

Question 5. The Healthy Families Act "employers with existing policies" section only applies to employers that offer leave "under the same conditions outlined" in the bill. Would an employer that offers 5 days of paid leave per year but allows unused leave to carry over annually qualify? Would undesignated leave that could be used for sick leave or any other purpose qualify if an employee made the decision to use all available leave for vacation leave? Does the term "same conditions" include the terms of enforcement and remedies?

Answer 5. The Healthy Families Act is aimed to address the needs of workers who have no paid time off to deal with their own health needs or the health and well-being of their families. Employers who offer paid leave policies that allow employees to use the leave in the same method and for the same purpose as the paid time off offered by the Healthy Families Act will not be required to change their policies. We expect that administrative details will be fleshed out through the Federal regulatory process. During that time, both the employer and employee communities will have an opportunity to weigh in.

Question 6. Some smaller local governments that rely on part-time and seasonal employees for services such as mowing the grass in public spaces are concerned that mandating paid sick leave for these employees will impose high cost and bureaucratic burdens. These local governments would be forced to consider shifting their employment practices away from part-time work. But working part-time is an option many employees seek because of the flexibility it provides, particularly teenagers looking for after-school work and parents who can only work during school hours. Do you understand the value work opportunities like these provide and do you think they are worth preserving?

Answer 6. While we understand the value of part-time and seasonal work opportunities, we also understand workers' need for paid sick days. Part-time workers are more likely to work in industries that require frequent contact with the public, and without paid sick days, are more likely to put the public's health at risk. For example, two in five food-service workers are employed part-time, about twice the proportion of workers across all industries.[11] These workers not only directly interact with customers, but also come into contact with food and drink, which may facilitate the spread of contagion. The accrual system in the Healthy Families Act allows part-time workers to accrue paid sick days, but to address the needs of employers, part-time workers will earn less time annually than full-time workers. Similarly, to accommodate the needs of employers with seasonal employees, the Healthy Families Act permits employees to use their earned paid sick time only on the 60th day of their employment.

RESPONSE TO QUESTIONS OF SENATOR DODD BY ELISSA O'BRIEN

Question 1. You mentioned in your testimony that earlier this year 67 percent of SHRM members indicated that they either planned to or were currently sending employees home if they came to work with flu- or cold-like symptoms. However, this

[10] See the economists' statement at *www.epi.org/minwage/epi—minimum—wage—2006.pdf*.

[11] Bureau of Labor Statistics. Food Services and Drinking Places. *www.bls.gov/oco/cg/cgs023.htm#emply*.

still leaves a large proportion of SHRM employers, which do not of course encompass all employers, who do not employ such practices. This isn't good enough—we cannot just provide these worker protections to some Americans and not others. Why do the remaining 33 percent of SHRM members not provide this kind of policy during an epidemic and how can we ensure that they do—both for the public health and for families—economic well-being?

Answer 1. The 67 percent response cited in my written statement came from a survey of SHRM members conducted in May of 2009, many months before the Federal Government declared the H1N1 virus a public health emergency. In a more recent poll of SHRM members conducted October 15, 2009, 74 percent of HR professionals indicated their organization was informing their workforce not to come to work if they have flu- and cold-like symptoms. In addition, many employer policies already direct employees to stay home if they are experiencing these symptoms, so the number of organizations that adhere to this type of policy is much higher than 74 percent.

Organizations have also employed other policies and tactics to help reduce the spread of the H1N1 virus in the workplace. In the October 15, 2009 SHRM poll, HR professionals cited the following as the top strategies and programs currently being implemented:

- Educating employees on flu prevention measures=89 percent.
- Monitoring the H1N1 virus situation by following guidance from the CDC, WHO, etc.=84 percent.
- Making hand sanitizer, other disinfectants, masks and other flu prevention tools readily available across the organization=84 percent.
- Developed an employee communication strategy related to the H1N1 virus=75 percent.

Question 2. As you correctly note, because Wingate Healthcare provides care for sick, elderly, and disabled Americans, it is particularly crucial that your company have policies in place to ensure that sick workers stay home. Unfortunately, not all health care workers have these critical benefits. According to BLS, only 77 percent of health care workers in the private sector have any paid sick days at all. Do you think that businesses that provide health care services to vulnerable populations should provide paid sick days to ensure that their workers don't spread illness? Do you think it would harm your business if you stopped providing this basic benefit to workers?

Answer 2. SHRM believes that employers should voluntarily provide paid leave to their employees. These benefits are incredibly important recruitment and retention tools for employers. In my experience, providing generous paid leave benefits and programs has provided Wingate with a competitive advantage over similar entities in which we compete for talent. It is true that not all health care organizations are able to provide paid sick leave to their employees, and it would be helpful to know from a public policy perspective what type of financial barriers or other obstacles prevent these organizations from offering these benefits.

Question 3. You stated that we should "encourage" employers to provide adequate paid leave policies for their employees. I agree. However, "encouragement" is clearly not enough. There continue to be many employers who, *despite encouragement*, still offer no paid sick time for their employees. We know that this inequity disproportionately impacts those workers in low-wage jobs who cannot afford to take unpaid time off when they are sick or to care for an ill family member. What should be done about these employees? How can we be satisfied when a large proportion of our workforce has inadequate workplace rights and benefits?

Answer 3. According to the Bureau of Labor Statistics, 83 percent of all private sector employees have access to paid illness leave. Unfortunately, as you point out, this means that a small percentage of employees are left without access to paid time off to address their health needs or those of their family members. Rather than pursue a one-size-fits-all paid leave mandate that ultimately penalizes those employers who are already providing generous paid leave benefits, public policy should do more to encourage employers to offer paid leave.

As it stands today, unlike other areas of Federal law, there is no Federal law or statute that incentivizes employers to provide this type of benefit. For example, the government provides real incentives to homeowners to make their homes more energy efficient by providing them tax credits for replacement windows. Struggling employers need encouragement in the form of real incentives too. That's why SHRM has proposed a set of principles for a 21st Century Workplace Flexibility Policy that encourages employers to provide paid leave by allowing them to meet a safe harbor standard of leave. By voluntarily meeting this safe harbor leave standard, an em-

ployer would opt out of other Federal, State and local leave requirements. Additionally, tax credits for small employers and/or those organizations that can least afford to offer paid leave benefits would be another way to incentivize employers to offer paid leave.

Question 4. I applaud your efforts at Wingate to provide employees with the tools they need to balance work and family, and you argue that paid time off offers a flexible option for employers that should be encouraged. A concern you raise is that the Healthy Families Act could cause employers to reduce wages or other benefits, and therefore limit flexibility. While research does not support this claim, how would providing a Federal floor from which employers, such as Wingate, could offer more generous benefits to their employees cause costs different than offering paid time off policies? What evidence do you have that employers will scale back other benefits if this law passes? Why would employers respond in that way to a law that will ultimately save them money?

Answer 4. As you know, employers have only a finite pool of resources to devote to employees' total compensation, which includes wages and other important benefits such as health care and retirement plans, educational assistance, and paid time off. When the government imposes a Federal floor or mandate, it confines or restricts employers' discretionary spending on other benefits and current benefit offerings are often scaled back to meet that minimum requirement given compliance costs incurred as a result of the mandate. Since enactment of the Family and Medical Leave Act (FMLA), SHRM members have reported during focus groups and other venues that they have in fact scaled back leave benefits to meet the added costs and minimum requirements of the FMLA.

Question 5. You state that the Family and Medical Leave Act (FMLA) has been difficult for employers to implement and that the Healthy Families Act would be similarly difficult. Employers are already required to keep track of the hours that their employees work and our paid sick days bill would simply require them to provide 1 hour of paid sick time for every 30 hours worked. Employers have the option to require medical certification for an absence of more than 3 days, but even that option—which is entirely the employer's choice—imposes minimal burdens. In a survey, 60 percent of employers said that the FMLA took less than 30 minutes per case to request and review. How, in your view, would the Healthy Families Act impose an undue burden on employers?

Answer 5. It is true that requests for FMLA leave for the birth, adoption or foster care placement of a child impose minimal burden on HR professionals and employers and SHRM data supports this assertion. In the *2007 SHRM FMLA and Its Impact on Organizations Survey*, only 13 percent of HR professionals reported challenges in administering leave under the FMLA for the birth or adoption of a child.

On the other hand, administering medical leave under the statute can prove challenging. Among the problems associated with implementing the FMLA are the definition of a serious health condition, intermittent leave, and medical certifications. In fact, 47 percent of SHRM members responding to the *2007 FMLA Survey* reported that they have experienced challenges in granting leave for an employee's serious health condition as a result of a chronic condition (ongoing injuries, ongoing illnesses, and/or non-life threatening conditions). Medical certifications that allow for intermittent leave for a chronic, episodic condition make managing absenteeism extremely difficult. Moreover, vague FMLA rules mean that practically any ailment lasting 3 calendar days and including a doctor's visit, now qualifies as a serious medical condition. Under the HFA, eligible employees could use paid sick leave for many broader purposes than the FMLA's serious health condition standard.

As you mention, employers may request a medical certification under the HFA, but only if the leave extends for more than 3 consecutive workdays. This then would enable an employee to use paid sick leave every other day for 2 weeks, without notice, forcing the employer to either forgo production or shift that employee's workload to another employee.

Many of the HFA provisions, including intermittent leave, are modeled on the FMLA. For example, employees would be able to use HFA leave on an intermittent basis, in small increments of time. During the Department of Labor's multi-year review of the FMLA regulations, the Department reported an explosion in sporadic, unscheduled leave—particularly the inappropriate use of medical leave—which was never envisioned by FMLA's authors. This unfair use of leave created enormous challenges for managers of time-sensitive operations such as emergency responders, public safety and public health operations run by State and local governments, as well as for employers in the transportation and communications industries. Allowing paid sick leave to be used on an intermittent basis would only exacerbate these

challenges, especially given that some employees would be eligible to use both HFA and FMLA leave on an intermittent basis.

Question 6. You have raised concerns about the impact of the Healthy Families Act on businesses with existing policies that provide paid time off that can be used for a variety of purposes. However, the Healthy Families Act contains specific language addressing this concern, stating that: "Any employer with a paid leave policy who makes available an amount of paid leave that is sufficient to meet the requirements of this section and that may be used for the same purposes and under the same conditions—as leave provided under the act does not have to change their existing policies. This language says that as long as an employer provides leave that can be used for illness, caregiving, or preventive care—and as long as there are not excessive restrictions on when or how employees can use that leave—the employer is not impacted by this law at all. Why would responsible businesses with paid time off policies object to this law if it requires no change in their existing rules?

Answer 6. SHRM appreciates the efforts the sponsors of the Healthy Families Act have made to alter the bill language to address concerns regarding paid time off (PTO) plans. As you know, paid time off plans are a growing trend among many of the nation's top employers (many of which are recognized by Working Mother Magazine and others) because they allow for maximum employee flexibility while providing employers with certainty and predictability. Yet, despite the above stated changes to the HFA, SHRM members are concerned that the HFA could be interpreted by regulators in a manner that would disrupt current PTO programs, and ultimately force these plans to meet additional requirements.

For example, many employer PTO plans include "no-fault attendance" policies, whereby an employer may take disciplinary action against an employee for failure to adhere to the employer's notice requirements for using PTO leave. The HFA, however, prohibits employers from taking any negative action that would impact an employee's ability to take leave under the act, so it is unclear whether these types of PTO plans would meet the HFA requirements.

QUESTIONS OF SENATOR DODD TO SCOTT GOTTLIEB

Question 1. In your written testimony you said that there does not seem to be a compelling public policy case for singling out this particular flu from others and then you go on to say other flus have hit older working-age populations much harder in the past. You also said that employment policy does not appear to be the right focus of our resources and response. There are 2.1 million births each year to women in our workforce. As you know, children have been disproportionately affected by this pandemic and most are too young to care for themselves. In light of your testimony, what do you think is an appropriate response for working parents whose children have become infected with H1N1?

Question 2. You talk in your testimony about vaccine production. Can you address what you see as the underlying reasons why the Federal Government has continued to rely on older egg-based technology for vaccine manufacturing? What obstacles do you see at the Federal level to moving to more modern vaccine development process such as cell-based, recombinant technology?

[Editor's Note: The response to the above questions was not available at time of print.]

RESPONSE TO QUESTIONS OF SENATOR ENZI BY SCOTT GOTTLIEB

Question 1. Dr. Gottlieb, can you please provide the committee with specific ways in which Congress can act to improve vaccine production capabilities? How can Congress help our manufacturers to increase the number of cell-based manufacturing facilities producing flu vaccine?

Answer 1. First, we need to invest—through Federal grants if necessary—in additional facilities for manufacturing flu vaccine, in particular cell-based facilities. These plants could be scaled more quickly than current manufacturing processes (that depend on culturing virus in specially-hatched chicken eggs) to enable rapid production of a pandemic vaccine. A certain amount of this production capacity needs to be maintained domestically. In a full-blown pandemic, with a very deadly strain of flu causing mass casualties, it is hard to envision that foreign nations would allow limited supplies of potentially life-saving vaccines to be shipped outside their borders. The reaction to H1N1 demonstrated how quickly international panic can set in, prompting governments to take extraordinary and sometimes severe measures. Canada and Australia effectively nationalized the facility that the United States relied on for its vaccine. In the case of Australia, the government pressured

vaccine maker CSL Limited to turn over 36 million doses of H1N1 vaccine contracted for by the United States and produced in an Australian-based manufacturing plant. Meanwhile, in Canada, where British drug maker GlaxoSmithKline maintains its U.S.-focused flu vaccine facility, the company had to assure the local government that Canadians would be served from that manufacturing plant before Americans could receive any of their vaccine orders. In a full-blown pandemic, we can expect vaccine-manufacturing facilities to be nationalized. Yet much of the flu vaccine production capacity exists outside the United States. The creation of more domestic capacity for rapid vaccine production should be viewed as a strategic asset that we need to develop and maintain. But ultimately, we need to move away from the current process that relies on the direct culturing of the virus for production of vaccine (in order to develop the vaccine antigen) to a process that relies on the direct development of the antigen. For example, new processes such as recombinant technologies allow the manufacture of small fragments of virus (called virus-like particles or VPLs rather than relying on collecting and culturing whole copies of the virus. This and similar innovations (that don't rely on direct culture of the virus itself) can yield more vaccine in shorter periods of time—about 10–12 weeks to scale up a big production run of VPLs, compared with 26 weeks using an egg-based vaccine or 16 for a cell culture. The newer methods give us a better chance to intervene with vaccine during the first wave of a pandemic.

Question 2. Dr. Gottlieb, what would the impact be of approving the use of adjuvants in flu vaccines in the United States in terms of spreading the supply of the vaccine to reach more people? What are the barriers to approving the use of adjuvants in vaccines sold in the United States?

Answer 2. One step to improving our readiness for the future is to better integrate the use of vaccine additives, called adjuvants, into pandemic planning. An adjuvant is a substance incorporated into a vaccine that enhances or directs the immune response of the vaccinated patient. Adjuvants are designed to bring the vaccine's antigen into contact with the immune system and, therefore, to enhance the magnitude of immunity produced as well as the duration of the immune response.

Novartis and GlaxoSmithKline (GSK), as well as other drug firms, completed innovative work incorporating new generations of adjuvants into vaccines for H1N1 marketed in Europe during the H1N1 outbreak last year. Much of the activity in Europe that enabled countries to deploy adjuvant as part of HIN1 vaccines was based on mock-up preparations of pandemic vaccines that Europe countries had pre-approved and stockpiled. In the United States, our decision to forgo the use of adjuvants, which can work to increase the protective effects of a given quantity of vaccine, limited our ability to stretch our already constrained stock of H1N1 vaccine raw material (the vaccine antigen). Ultimately, because the HIN1 virus ended up being less virulent and widespread then feared, that limited the vaccine supply that we have available, and its delayed availability, does not appear to have triggered public health consequences. Indeed, it proved sufficient. But in the future, with a more virulent pandemic, we may not be so lucky. To improve our readiness, we need to be better prepared to embrace new methods. What measures can be taken to improve our process for evaluating vaccine adjuvants? First, the FDA should consider creating formal guidance on the development and use of adjuvants to help guide product developers. The EMEA developed formal guidance on adjuvants 3 years ago. The document is available on that agency's Web site. The FDA does not have a similar guidance document. The United States should also consider stockpiling pre-approved vaccine preparations that could be used in a public-health emergency. The country can draw on Europe's ample experience to inform this process. Adjuvants are not approved as stand-alone substances because they do not always perform the same way with different vaccines, types of vaccines, or, in some circumstances, with different versions of the same antigen. Nonetheless, the European strategy of having pandemic vaccines pre-approved, as mock-ups, was a prudent step.

Question 3. Dr. Gottlieb, you discussed the impact that ordering single-dose shots had on our vaccine supply. Can you think of any other country that has ordered both multi-dose and single-dose flu vaccines? Why would the U.S. Government order both?

Answer 3. Each country, as well as the United States, ordered both single-dose and multi-dose vaccine. But it has been argued that the United States asked manufacturers to shift production toward the development of more single-dose vials. Developing these single-dose vials required more time, and is blamed for at least some of the delay in making available the supply of H1N1 vaccine. One of the concerns around the multi-dose vials that led to an apparent decision to pursue more single-dose shots, was that the multi-dose vials require the use of some preservatives that

contain thimerosal, a mercury-containing vaccine preservative that continues to stir concern that it can trigger childhood autism, even though this association has been firmly disproven.

Question 4. BAKDA was set up to provide incentives for companies to manufacture new products that could aid the United States in responding to biological, chemical and radiological threats. This mechanism helps companies bare the costs associated with moving products through the research and development pipeline by assisting with that financial burden. This system has worked well for incenting new products but was not intended for existing products or technology. The current pandemic has highlighted the uncertainties associated with flu vaccine production and you have testified about the importance of developing newer technologies for producing influenza vaccines if we are to be prepared for future epidemics. Is there a need to create some incentives for companies that are producing traditional products such as influenza vaccine so that we can ensure an adequate and timely domestic supply when needed and that the United States can compete favorably with other countries when vaccine supplies are needed?

Answer 4. The technology for developing improved influenza vaccines is in development. The stumbling block has always been the demand for these products. Vaccines are purchased by public, health entities that value lower cost over the kinds of innovation that can lead to improved production processes. In addition, they favor vaccines that are commoditized and can be used interchangeably, since differentiated vaccines are harder to deliver over large populations—for example, requiring public health agencies to match a specific vaccine to certain groups of patients. We would see more investment in improved vaccines and better production processes if we had a predictable demand for these products. To these ends, the government should also guarantee the annual purchase of a certain amount of seasonal flu vaccine. This would enable the industry to reliably forecast demand, spurring investment in new facilities that could also be used to produce vaccine in a pandemic. The annual procurement should favor vaccines produced in U.S. plants and with newer, cell-based methods. The procurement process could also favor vaccines with certain technological improvements that align with better pandemic preparedness—for example vaccine derived from processes that don't require the direct culturing of the virus. Purchased vaccine could be distributed domestically, or better still, donated to Asian nations such as Vietnam. Flu strains often originate in Asia and we rely on local Asian governments to undertake vigorous surveillance and share emerging virus strains. Giving them free shots would encourage vaccination to reduce spread and give nations more skin in global efforts to stem outbreaks.

Question 5. The FDA is charged with ensuring the safety of drugs, devices and medical products. It does so through a variety of mechanisms culminating in approval of these products after careful review using an external advisory committee as well as internal safeguards. This process was shortened during the recent pandemic using a mechanism called Emergency Use Authorization so that drugs that had not yet completed the process of review but which had a sufficient body of evidence to be presumed safe could be released for use in treating people hospitalized in intensive care units with pandemic influenza. In your testimony you suggested that for novel technologies for critical public health needs a closer working relationship might need to be developed between FDA and manufacturers to ensure that we have timelier access to safe and effective products when we need them. Could you elaborate on how that closer working relationship might be structured and what hurdles might need to be overcome to put such a process in place?

Answer 5. Often times, FDA has found itself placed in uncomfortable roles in moments of public health emergency—where there is a political effort to expedite the availability of medical products to respond to a crisis. FDA's feedback about the process for validating the safety and effectiveness of medical products is vital to the rapid development of any countermeasure. At the same time, the FDA believes that its role as an independent arbiter of the science places constraints on how much it should be involved in discussions and efforts to expedite the availability of products, even in moments of crisis. We could benefit from a more formal consideration of how this process should work—where there is a need for FDA to play a very hands-on role in guiding the development of product, but where the agency needs to maintain some impartiality in order to maintain its regulatory independence. One consideration might be the formalization of a process that maintains very separate FDA teams for just such scenarios: one team for working with product makers for expediting the development of countermeasures, and another team for evaluating the safety and effectiveness of any resulting products. If there were a pre-established SOP in place, this would provide transparent assurance that components of FDA

could be engaged in helping to expedite development of a product, while other elements in the agency remained far enough removed to maintain their impartiality But the bottom line is we should consider how best to structure a formal process in advance of the next public health crisis, since this challenge exists in perpetuity.

[Whereupon, at 12:04 p.m., the hearing was adjourned.]

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