

THE EMBRYONIC STEM CELL FIGHT

Interview #3

Monday, October 18, 2004

RITCHIE: The last time I saw you, you were on your way to Egypt.

LUDLAM: That's right!

RITCHIE: Was that a successful trip?

LUDLAM: Completely fabulous. We were with an Australian group on a camping trip. We spent five days with Bedouins in the Western Desert, camping in the oases. Then we spent three days sailing with the Nubians on the Nile on a traditional felucca. We saw most of the ancient sites as well. We took a balloon ride, rode on donkeys, camels, and a train, took a carriage ride, and walked endlessly. It was very low to the ground, the way that two former Peace Corps volunteers like to travel! [Laughs]

Since then we spent three weeks in Idaho in August. I took a five-day hiking trip supported by llamas, and we took a six-day whitewater raft trip on the Middle Fork of the Salmon. Then we went horseback riding for what was supposed to be five days, except that my wife, Paula, got thrown off a horse and we had to medivac her out with a helicopter. She's okay now, but it was harrowing. And we're about to take off to Palau and Yap in the South Pacific for New Year's.

These islands are near the Philippines, and we'll be sea kayaking and snorkeling. Palau is the top-rated snorkeling site in the world. We'll also spend three days on Peleliu, where my wife's uncle fought in the Second World War. His unit had fourteen hundred killed and fifty-seven hundred wounded in the two hundred hours they were on Peleliu. This puts our losses in Iraq in perspective.

This is a typical trip for us. We love to sea kayak. I've sea kayaked in the Queen Charlottes, Nova Scotia and Newfoundland, Belize, Baja, Iceland, Prince William Sound, and Turkey. I've also hiked in the Himalayas, Andes, Atlas, Owen Stanley Range, Brooks

Range, and Rockies. I also love whitewater rafting and have rafted a hundred rivers ranging from the high arctic in Alaska to the Yukon Territory, British Columbia, Arizona, Maine, Idaho, West Virginia, Chile, and New Guinea. I applied twice to be on Survivor, but never even got an interview. Now that was a disappointment!

For twenty years I organized rafting trips on the Gauley River in West Virginia, a world class whitewater run. We rafted it so often that we decided to jazz it up one year by wearing costumes. Everyone else was white knuckles, and we came out in Santa Claus outfits with a blown up gorilla. It freaked everyone out. Our outfitter, Class VI River Runners, was then asked to supply a poster for a local Wendy's and the picture it chose was of our costumed group. This spoofs the pictures donated by all the other outfitters, which are pictures of hair raising flips. All of these trips put this political work in context and give me a great way to release the tensions. My wife and I take some great trips. I believe in working hard and playing hard.

RITCHIE: I'd say you do some pretty exotic trips.

LUDLAM: Well, that's our style. We need escapes from all the seriousness of this desk-bound town.

RITCHIE: Yes, people say that travel can be dangerous but actually, staying around here could also be dangerous.

LUDLAM: My office is immediately above the [Tom] Daschle mail room where the October 15, 2001, anthrax attack occurred, so you're absolutely correct.

RITCHIE: You've also mentioned your plans to rejoin the Peace Corps. Have you proceeded any further on that?

LUDLAM: Well we should hear more next week. We have applied. We've been accepted. But now they have to match us up with a program in Africa and that's proving to be a little bit complicated. It's always more complicated to match up couples than to match up singles. We expect we're on track to leave next September

So the timing of these interviews is perfect. I'm wrapping up my career and when I

leave to go into the Peace Corps that will be the end, I believe, for my government career. I hope at that point never again to work at a desk. So these interviews provide me with a chance to tell all these stories and get them on the public record.

RITCHIE: Do you have any place in Africa that you'd like to go to if you had the opportunity?

LUDLAM: We've put in a preference for Mali, Niger, and Senegal. Over on the east side of Africa, we've requested Uganda and Tanzania. Down in the south, we're requested Zambia and Madagascar. In West Africa, we've also requested Benin, and Ghana, and Cameroon. So we've actually given the Peace Corps quite a few possibilities.

RITCHIE: You also suggested that the Stanford program might use these oral histories, and I wondered what you had in mind for that.

LUDLAM: I've asked myself why I am providing this oral history. Obviously, it might be of interest to researchers. Maybe what I say can provide them with information about how this institution really operates, and how people really win and lose in the trenches.

Primarily, however, I am telling these stories for the Stanford students who might be considering a public service career. They can read this and see what a public service career can accomplish and what it's like day-to-day. I'm in very close touch with the Stanford in Government (SIG) program. This program focuses on summer internships, and then there's the Stanford in Washington (SIW) program that brings students here for an academic program over the winter. I helped to establish the SIW program based on my experience with SIG. My great hope is that some of these students will not just come and experience Washington, and learn a little bit about it, but I hope some of them will spend thirty or forty years in a public service career.

What I can show them with my stories is what a public service career can encompass. Why is it that people win or lose in politics? How complicated are the fights? How tough and nasty can they be? Is this fun or is this drudgery? How can you handle it in terms of the daily grind? How do you handle failures? I'm talking here about fights that I lost, not just the victories. The students need to know that also. We need young blood and we need staff who can manage a whole career, not just a few years, which is the average.

RITCHIE: We can make the interviews available on disk as well as in hard copy and since they are in the public domain, you can reproduce the interviews as often as you want for the Stanford students. It seems to me these interviews will serve as a very good introduction for them.

LUDLAM: Some of them will like what they read here and some of them won't.

RITCHIE: Some may be discouraged, some may be inspired.

LUDLAM: Who knows?

RITCHIE: You never can tell. In our previous interviews we've focused before on your work in the 1970s and '80s, from the Senate Legal Counsel to the Hart-Scott-Rodino to patent reform. Today, can we start with the history of the role you played in the fight over embryonic stem cell research? As an introduction to that, could you tell me again how you became the principal lobbyist for the biotechnology industry?

LUDLAM: I was working in the Senate in 1993 as chief tax counsel of the Senate Small Business Committee with Dale Bumpers and I had gotten to know the lobbyist for the Biotechnology Industry Organization (BIO), Lisa Raines. Lisa was killed in the Pentagon plane on 9/11. She was flying out to California to work on something for the biotech company for which she then worked. She was a highly energetic advocate for the biotech industry, both when she was the principal lobbyist at BIO and then with this company.

Back in the 1991-1993 timeframe, Lisa was interested in a capital gains incentive I'd championed for Senator Bumpers.¹³⁰ She was leaving BIO and they were looking for a new vice president for government relations. She asked me to apply, I applied, and I got the job. It was a dilemma for me because I was eighteen months short of the age of fifty. I already had twenty years of government service so—

RITCHIE: Eighteen months short of fifty years?

LUDLAM: Yes, that is the magic formula. Age fifty with twenty years of government service is the minimum for retiring. If you have twenty years of service, and you are age fifty, you can start drawing your pension then, not having to wait until you're sixty-

five. When the BIO offer came, I was forty-eight and a half. So leaving the Hill to go down to be a lobbyist was a difficult decision financially, but it was too interesting a client to pass up. BIO, in effect, paid me the pension I was foregoing, so that helped me to justify the move. I became the principal lobbyist for a thousand biotech companies and for a very controversial industry. It was a great deal of fun

RITCHIE: Before we get to the cloning fight, just in general as a lobbyist, how different does Capitol Hill look from the outside than it does after all those years working inside?

LUDLAM: I think the answer is not at all different. The only difference was that my client was a group of companies and up here your client is one individual, a chairman or individual member. Other than that, everything you do day to day is almost exactly the same. The way you talk to people is the same. The way you identify issues is the same. The way you do research is the same. I'm on Senator Lieberman's staff now, but I'm definitely a lobbyist. I'm constantly pressing others to join me in an effort, to join a coalition, or to move in one direction or another. So I don't think that day to day there is much difference between being a staffer and being a lobbyist.

RITCHIE: That's an interesting way of looking at it. Well, how did you get into the whole embryonic stem cell issue, which is now a hot issue in this presidential election?

LUDLAM: The issue has come a long ways since 1997. The fight today couldn't be more different than the fight in the first round of the fight back then. It was far and away the most complicated and intensified fight I have ever been involved with in my entire forty years in politics. And perhaps the most satisfying.

I would characterize it this way: if you're going to pursue a career in politics for forty years, all of that time you are developing the skills that you hope to apply in one titanic fight where you are the critical person leading on a monumental issue. If you've prepared well, you can win, vindicating all the years of investment in developing those skills. That's what the stem cell fight was all about for me.

Every skill I have ever developed in any context in the Hart-Scott-Rodino fight or the Senate Legal Counsel fight or in the Airline Noise bill or the patent reform bill, all of those

fight, all of those skills, came to bear on the cloning fight in 1997 and 1998. I was in the perfect position to lead the effort, and I won. That's what you hope for in a public service career. In my view, if the only thing I had ever done was the human cloning fight, that would probably justify my whole public service career.

The stakes back in 1997 and 1998 were large. With embryonic stem cells, it could be that we have a special cell that can be transplanted into a patient to repair any cell in the body—cells for your eyes, heart, liver, kidneys, muscles, or nerves. We could have a special cell that could repair the damage that disease and aging do to these cells and organs. We could secure a stem cell that could regenerate the patient's organs, make them young and viable again.

Half of health-care costs arise from the degeneration of organs. This includes degeneration of the skin, nerves, eyes, internal organs, and brain, and it includes damage from aging and disease. If we can transplant a stem cell that could regenerate the damaged organs, it potentially could revolutionize human life and medicine. This is a far-off dream. It will take at least ten or fifteen years to know how much of this dream is real. It's already been seven years from the original legislative fight over whether to curtail or ban this research.

The stakes in this fight were and remain potentially very high, the highest. This is what the fight was about. We won't know for many years whether or not embryonic stem cells can do any or all of this, but the potential is so great that it's worth fighting to continue this research. That, at least, is my perspective. I don't believe it is wise policy to ban scientific research that could revolutionize human medicine.

This was a complicated fight to lead in part because I'm a lawyer. Leading this fight meant that I had to understand oocytes, zygotes, embryos, blastocysts, mitosis, haploid and diploid cells, somatic cell nuclear transfer, enucleated eggs, spare embryos, totipotent cells, pluripotent cells, differentiated cells, customized stem cells, histocompatibility, and a whole variety of other incredibly complicated scientific and medical concepts.

I became sufficiently familiar with all of these concepts so that I could lead this fight without being challenged by any expert. I can say that I never once misstated the status of the science or what it might lead to. I never engaged in hype. I fought very hard to preserve my

credibility on these very complicated issues.

It's typical of a Senate career that you are constantly being dragged into fights where you initially know nothing about the subject matter, and all of a sudden you have to assemble a degree of expertise sufficient so that you can explain things to people and persuade people about how they should act and vote. I have never been in a fight where the issues, technically speaking, were as complicated as they were in the embryonic stem cell fight.

What was even more amazing about this fight was that everyone was obfuscating the issues—both sides. Nobody was telling the whole truth about what this debate was about. Basically it was a conspiracy between the right and the left to claim that the issue was something other than what it was. The Republicans and the Right to Life community thought cloning was the political slogan that would win the day. They don't want to admit that they were trying to criminalize medical research. Now [George W.] Bush comes along and says he will provide some government funding for some stem cell research at the same time he is trying to criminalize other stem cell research. All of it based upon the idea that life begins at conception.

RITCHIE: When you said cloning, you meant that they were going to use the slogan of "human cloning" as something to use in campaigning, because cloning had a negative connotation.

LUDLAM: Yes, correct. Most polls find that people oppose "human cloning."

RITCHIE: Okay. You could explain everything in that way because it was an easier concept for the public to understand.

LUDLAM: That was a slogan that Republicans believed would work best for their side. The Democrats used "stem cell research" as their slogan of choice. They don't want to admit that they are willing to destroy human embryos for medical research purposes. They don't want to admit that they don't believe that life begins at conception. In short, both sides were playing very fast with what is really at stake as a matter of science.

For the Right to Life community, the effort to ban embryonic stem cell research has been a radical departure from its traditional agenda. It had been making great progress in

seeking to ban third trimester abortions, where you might be aborting a viable fetus. I think that almost everybody is squeamish about third trimester abortions. This revulsion is what led to enactment of the ban on partial birth abortions.¹³¹ I think this ban will turn out to be unconstitutional,¹³² but it was quite a big political effort and they secured the enactment of a ban on some kinds of abortions.

In the stem cell fight, the Right to Life community has changed the focus from a third trimester fetus to a zygote or embryo that is smaller than the head of a pin. This is a totally different focus, visually, emotionally, and politically. It isn't clear to me whether or not this fight to criminalize embryo research will ever prove to be an effective one for the Right to Life movement. I can't imagine they will get as much political traction opposing embryo research as they have gotten with opposing third trimester abortions.

It's a bit strange that the Right to Life community came out opposed to this research. These zygotes or embryos—from which the embryonic stem cells are extracted—are not created by conception or artificial insemination. In fact, there's no sperm involved. There is no father. These zygotes or embryos are laboratory constructs, completely unnatural. As I will explain, the process of deriving stem cells starts with oocytes, eggs that have not been fertilized. Then the nucleus of the zygote is extracted and the diploid nucleus of a patient is inserted. Then the stem cells are harvested and the zygote or embryo is effectively destroyed.

The oocytes that are used for this procedure are those that are left over in invitro fertilization (IVF) clinics. For IVF to work, the technicians harvest many more oocytes than they eventually use. Harvesting oocytes involves inserting a needle into the vagina and the ovaries to extract oocytes from a follicle. They use suction to extract the oocytes.

If IVF—that is reproduction—is the goal, the technicians fertilize all the oocytes with the father's sperm and see which zygotes or embryos look to be the healthiest—a sort of "beauty contest." Only the healthiest zygotes or embryos are implanted to induce a pregnancy. The rest of the unfertilized oocytes are frozen for possible later use by the couple.

There are hundreds of thousands of these frozen oocytes and embryos in IVF clinics around the world. The vast majority will never be used and eventually they'll be discarded. It makes sense to me to use these spare oocytes and embryos to develop embryonic stem treatments for patients rather than let them sit in freezers or discard them. I find it interesting

and a little strange that the Right to Life movement has switched its focus to these laboratory creations. I guess, even if there's no sperm and no father, the fact that we end up with a zygote or embryo makes this similar enough for them to fertilization so that they find it abhorrent. Apparently, they believe that all of these zygotes or embryos have all the constitutional rights of you and me and that none of them can be destroyed or used as the means by which we develop stem cell treatments for sick patients. I don't know if this makes any sense medically or politically.¹³³

For the biotech industry, the medical research community, and the patient advocates, the cloning/stem cell fight was the first fight over criminalizing some basic biomedical research—a watershed event. It's the first major conflict between those groups and the Right to Life community. I predict it'll be the first of many fights. If you think about it, all of the genetic tests that women perform during pregnancy—and eventually there will be thousands of them for every type of disease and condition you can imagine—might be connected to abortions. Eventually people might want to use these tests to select for size, intelligence, and lots of other characteristics—not just for diseases.

Eventually we are going to have a massive conflict between the medical insurance community, the biotech community, the pharmaceutical industry, and the patients, and the Right to Life community. This was the first of those fights. Now, seven years later, we can see the embryonic stem cell fight in a little more focus. But back in 1997 and 1998 the industry, patient, and medical research community was totally and completely unprepared. It is no exaggeration to say that because of this lack of preparation to defend embryonic stem cell research, the Congress was poised to set criminal penalties on this research. By all rights, those of us who were defending this research should have lost this fight. We were totally on the defensive. We were caught by surprise. Basically the story I will tell is how we managed, against all odds, to win a stunning victory.

It all began with Dolly, a Scottish ewe. Dolly was born on July 5 of 1996 as the result of an experiment, Ian Wilmut's experiment, at the Roslin Institute in Scotland. Dolly was the first mammal cloned from another mammal. Her DNA was exactly the same as the DNA of another lamb, another ewe. The reason why she was called Dolly is the cell that was used to create her was a mammary cell from the other lamb. Wilmut associated mammary cells with Dolly Parton. That mammary cell was Dolly's starting material. So Dolly was genetically identical to another ewe.

I think most people understand that there are good reasons why we want animal clones. There's a lot of value in cloning animals. I'll talk about that in a minute. One of the strangest things about the Dolly case was that when her existence was announced, that was February 19 of 1997 in the *New York Times*, nobody talked about animal cloning. They skipped right over that and talked about human cloning! This was one of many strange twists and turns in this debate. We've still not had a debate about animal cloning.

The way they created Dolly is truly fantastic, and I am really quite surprised that a Nobel Prize has not yet been awarded to Wilmut for his experiment. I think he'll probably get one at some point. Wilmut started with a lamb oocyte, an unfertilized egg which has only half of the DNA of a fertilized egg. It's a haploid cell. Normally, when you want to take this egg to term—to birth—you combine the egg with a sperm. You use IVF to secure a fertilized egg or a zygote. This is an embryo that has a full complement of DNA, a diploid cell. When you introduce the sperm, you get a fertilized egg that has different DNA from either of the parents. You get a mixture of their DNA, and therefore it's not a clone. That's where you get variety, and that's where you get the possibility of evolution.

Dolly's egg was not fertilized and there is no mixture of DNA. Her DNA is exactly the same as that of the ewe from which the mammary cell was extracted. The way Wilmut did this was completely amazing. He started with the unfertilized egg. He took the nucleus out of that egg. The nucleus he extracted was a haploid nucleus—with half the DNA of an adult cell. This yielded an enucleated egg, an egg with no nucleus. Then he took the mammary cell, extracted its full, diploid nucleus and introduced it into the enucleated egg. Then we had an egg with a diploid nucleus that is identical to the nucleus in the other ewe.

Wilmut had created the equivalent of a fertilized egg. It wasn't a fertilized egg, but it is the equivalent of a fertilized egg because it has the full compliment of DNA, a diploid nucleus. This process of extracting the nucleus and introducing a new nucleus is called "somatic cell nuclear transplant."¹³⁴

Wilmut then implanted that "fertilized" egg into a ewe, brought it to term, and Dolly was born. And Dolly's DNA was the same as the DNA of the mammary cell from which the diploid nucleus was taken and implanted into the cell. She was a clone. The thing that is really bizarre here is that the nucleus that they brought in from the other ewe was a differentiated cell. There's a difference between a differentiated cell and an undifferentiated

cell. An egg or a sperm is an undifferentiated cell. It is a cell that could become any cell in the body. There are approximately two hundred and ten different types of cells in the human body. The egg and sperm, once combined, first become an embryo and then later they differentiate into all these different types of cells. Some of the cells become eyes, teeth, or whatever. We don't fully understand the process by which the fertilized eggs differentiate into a full blown human being. There are apparently regulatory genes that control cell differentiation, telling one cell to become one type and another to become another type of cell.

In this case, Ian Wilmut took a differentiated cell that had become a mammary cell, extracted its nucleus, inserted this nucleus into an enucleated egg, and caused the DNA to de-differentiate to the point where he had the equivalent of a fertilized egg that had not differentiated. Getting this differentiated cell to de-differentiate was the key, the act of genius for which Wilmut deserves a Nobel Prize. So Dolly was a clone. Clone means copy. Wilmut started with a mammary cell of one ewe and created a whole new ewe with the same DNA.

In terms of cloning animals, it's clear that there is value in growing copies of a cow that is a fantastic producer of milk. At some point, Churchill Downs is going have to decide whether or not a clone of Secretariat is eligible to run in the Kentucky Derby, and Westminster is going to have to decide whether a clone of Mick is going to be able to compete.¹³⁵ At some point we'll have controversy about animal clones, but nobody is trying to ban them at the moment. But human cloning has been and continues to be a fantastic fight.

It is possible to legislate a ban on human reproductive cloning saying that anybody who creates Dolly in human form is a criminal. The law can say that you cannot create a duplicate, an artificial twin if you will, of an existing person using somatic cell nuclear transfer, and de-differentiation of a diploid cell, to create a clone of an existing human being.

One question in such a law is whether the woman who carries that clone to term is the criminal or whether it's only the scientist and the medical people who are the criminals. That's a question the Right to Life movement by and large has dodged with regard to abortions—they do not propose to make the woman who has the abortion the criminal but only her doctor. I'm assuming they might want to dodge this issue in regard to cloning as well.

Instead of wanting to ban human reproductive cloning, however, the Right to Life community wanted to ban embryo research. Even if the constructed embryo was never implanted, even if the embryo was never brought to term, the Right to Lifers wanted to ban the research itself, to ban the creation of an embryo with the same DNA as someone else.

One of the strange twists here is that the Right to Life community only wanted to ban some embryo research and not all embryo research. It probably wants to ban all embryo research, but its legislative proposal would only be to ban some embryo research. This is another strange twist. This is where we get to embryonic stem cells. Perhaps you thought I'd never get to them! The question is what does embryo research have to do with stem cells?

RITCHIE: Right, why make the distinction?

LUDLAM: I'll explain. It gets very strange. If we start with a zygote, our early stage embryo, it begins to divide and you get daughter cells. After about the fourth day the organism, the zygote or the early stage embryo, begins to differentiate into a fetus with arms and legs and all of the organs. But for the first four days it is simply dividing and every cell is identical to every other cell. We don't fully know what happens that starts differentiation, and we don't fully understand how the differentiation occurs. Apparently there are some signaling genes that say: you're going to become skin; you're going to become liver; and the organs begin to develop into a fetus. The embryo goes from being a blob of identical cells to a fetus of differentiated cells.

During those first four days, these cells are embryonic stem cells. They're dividing but not differentiating into different types of cells. It remains possible that any of these cells can become any type of cell. Once you have extracted the stem cell, you have what's called a "totipotent" cell, meaning it is a cell that could become any cell in the body. It could also become a person if it's implanted and brought to term. It's either the equivalent of a fertilized egg or just a specialized differentiated cell, depending on what you manipulate it into being. Unfortunately, in order to extract a stem cell from an embryo, you have to destroy the embryo.

The reason we want these stem cells is because if we could control differentiation, we could tell this stem cell to become cardiac muscle cells to treat heart attack victims, or skin cells to treat burn victims, or spinal chord neuron cells for treatment of spinal chord

injuries, or pancreatic cells to treat diabetes. We would transplant those cells into a diseased person or an aged person to regenerate an organ that had been damaged.

Strangely, the Right to Life movement was not trying to ban all of this research. What it was trying to ban was the creation of a certain specialized kind of stem cell, which is a stem cell that has the same DNA of an existing person, a cloned stem cell. It was not trying to ban the extraction of stem cells from embryos that are created through normal fertilization or IVF where the DNA is not the clone of any other's DNA.

These two types of stem cells are critically different. What researchers want to do is create a customized stem cell with the DNA of the patient they want to treat. The reason they want to do it is because that stem cell will not be rejected through histoincompatibility.¹³⁶ This is the problem with organ transplants because the organ comes from somebody else who doesn't have the same DNA as the patient. Rejection is a huge problem with these transplants. In order to make these transplants work, they have to suppress your immune system to ward off rejection of the new organ.

This explains why with stem cells, they want the stem cell to have the same DNA as the patient. What they take is an adult differentiated cell from the patient (like taking the mammary cell Wilmut used to create Dolly); they use somatic cell nuclear transfer to create an embryo which has the same DNA as the patient; they extract a stem cell from that control differentiation; they transplant that cell into that patient; and the cell is not rejected by the patient's immune system. That is the kind of stem cell that was the subject of this debate, not stem cells generally and not embryo research generally. Only the creation of customized embryos and customized stem cells for the treatment of patients was at risk.

The reason why it became so controversial is because that same embryonic stem cell could be implanted in a woman and brought to term as a clone of the other person, of the patient. That isn't the purpose of this research, but it could be done, theoretically. As I said earlier, it's possible to enact a ban on implanting a cloned, customized stem cell that has DNA that is identical to the DNA of an existing person. So you can permit the research but not the implantation. It is also possible to ban the creation of customized stem cells without banning the creation and even the implantation of other embryonic stem cells. There are two issues here; the debate only focused on one of them.

RITCHIE: The Right to Life group was willing to admit that there were two categories?

LUDLAM: No, they didn't admit that they were only attacking one type of stem cells and they didn't admit that they were attacking the creation of these stem cells, not the implantation of them. They would be happy to ban all embryo research, I'm sure, but they only proposed to ban some of it. They only proposed to ban the stem cell research that is the most important and the most useful.

They were not proposing to ban embryo research to create non-compatible stem cells. They only wanted to ban research that created customized stem cells that could avoid tissue rejection. The implication is that tissue rejection is a good thing and suppression of the immune system is an effective strategy!

Another strange twist in this story—and this is why it's fun to be in public service—was that in 1997 and 1998 we had not yet isolated a human embryonic stem cell. These stem cells didn't exist in the laboratory. So this entire fight about stem cells in 1997 and 1998 was about something that didn't yet exist. Embryos existed, and we thought we could use somatic cell nuclear transfer to create cloned stem cells, but it hadn't yet been done. So this was a theoretical debate, charged up with all kinds of emotions.

On November 6, 1998, researchers announced that they had isolated a human stem cell. James Thompson of Wisconsin and John Gearhart at Johns Hopkins announced that each of them had separately isolated human stem cells. They are now generally available, but at the time of this debate, they didn't yet exist.

Another bizarre chapter in this story occurred in 1997 when the existence of Dolly was announced. My boss at BIO, without consulting me, immediately went on the television to announce that BIO would support criminalizing human cloning. My immediate reaction was absolute horror because I knew, instantly, that the Right to Life community was going to use this as a vehicle and excuse to ban embryo research. I knew that they would mislead people about the nature of legislation. I knew that they would call it cloning, and actually attempt to ban customized stem cells. I didn't know all the details but I had a clear vision that if BIO supported criminalizing human cloning, we would give the Right to Life community a clear shot at banning vital biomedical research.

It so happened that a week later, BIO had a board of directors meeting in San Diego. I challenged my boss in front of the board of directors. I said that we should oppose any criminal ban on human cloning because it would be used by the Right to Life community to ban embryo research. The board backed me and my boss threatened to fire me. He was enraged at my embarrassing him in front of the BIO board. He didn't fire me but he threatened to. So this whole initiative at BIO started off with a bang.

RITCHIE: He took that position presumably because he thought that a ban on human cloning would protect him. In other words, give on one side, and he'd be free on the other. But your position was if you give in on one side, you're vulnerable on the other side?

LUDLAM: Correct. He thought it would be popular for the industry to oppose human cloning. He wanted to look good and try to get out in front of what he viewed as a tidal wave. I knew instantly that human cloning wasn't what the fight was really going to be about. It was going to be about embryo research, not human cloning. At any rate, as I ventured into this brawl in the Congress, I had a very skittish board and an enraged boss.

One key issue in this town that goes to the heart of these fights is when you risk your job. I was almost fired at the Carter White House. Here I was almost fired at BIO. In my view, if you don't stand up for your views, you shouldn't play this game. It can be a tough game. And there are victors and vanquished. You have to take risks and you have to be willing to lose and be fired. Simple as that. If this isn't your constitution, you should play a more gentle game. In this case, my view of the matter turned out to prescient.

Exactly as I feared, Vern Ehlers [R-Michigan] in the House introduced a bill that used broad and fuzzy language to ban stem cell research generally and not just ban human reproductive cloning. There were hearings on that bill in the Connie Morella subcommittee over on the House Science Committee. Three or four days of hearings. I had about 150 biotech companies located in Montgomery County, her district. So we expected that she would help us defend this research. She was regarded as a moderate and independent Republican. James Sensenbrenner, who was the chairman of that committee, was a Right to Life supporter. I was sitting in a meeting with Connie Morella's top staffer when Jim Sensenbrenner's top staffer came in and, in front of me, told the Morella folks that they would cede jurisdiction over this bill, it would move to and through the full committee, and they would report a broad ban on this research. Without uttering a peep of objection, Connie

Morella let that happen.

To be clear, I always thought Morella was a member who rarely did anything. This was explicit and graphic confirmation of that impression. Later, when Ira Shapiro, among others, ran against her in the next election, I would have loved to have "outed" Morella for selling us out on stem cell research. Ira was an old friend of mine from the Senate Legal Counsel and Ethics in Government Act bill, and I was a big backer of Ira, but I couldn't come out and tell this story because I was then employed by Senator Lieberman. What I would have said is that Connie Morella sold us out to the Right to Life community, without a whimper or peep.

So, the Ehlert bill went to the full committee. For the full committee markup, I didn't even go to Morella's office for help. I went to Lynn Rivers from Michigan. She offered several amendments, and lost them all. The committee reported out the Ehlert bill on August 1, 1997. It was referred to the House Commerce Committee and things were fairly quiet the rest of 1997.

I knew that 1998 was going to be worse. I had seen that the Catholic Bishops were organizing the whole effort in the House. So I went to all of the patient groups warning, "They're going to try to criminalize some stem cell research." I made multiple attempts to organize the patient community and the medical research community in defense of this research, and none of them agreed to do anything. I had no coalition. I had no supporters. We were completely disorganized.

In January of 1998 the entire fight went nuclear. We still had no coalition, no followers, no troops. I had just hired a new staffer who joined me on January 5, Nancy Bradish, an Irish redhead who turned out to be a brilliant fighter. She came out firing and running. She was a passionate advocate and crucial to our success in this brawl. I absolutely loved my time in the trenches with her. I have enormous respect for her brains, her fire, and her love of battle. She's also a zany and delightful person to be around.

Two days after Nancy arrived at BIO, Richard Seed in Chicago announced on National Public Radio that he was going to clone a human being.¹³⁷ Can you imagine finding a provocateur named "Seed" as the guy who wants to clone a human being? It's right out of central casting.

That day, [Senate Majority Leader] Trent Lott said that the first action of the new session of Congress was going to be to pass a criminal ban on human cloning. I knew what that meant. I knew that meant that they would criminalize embryo research.

So January 7 through February 12 were the thirty-seven days from hell for me and Nancy. It is the most intensive legislative work I've ever done. Much more intensive than Hart-Scott-Rodino or anything else I've ever worked on. Absolute pandemonium for thirty-seven days. Nancy and me against the entire Right to Life community.

Kit Bond was the leader of the whole cloning ban for Lott. Their ban was not a ban on reproductive cloning. It would criminalize the creation of an embryo that could be implanted, even if it was never implanted, but only if that embryo was one that had the DNA of an existing person.

I have a day-by-day chronology of what Nancy and I did during those thirty-seven days. I'm going to put it into the appendix to these interviews because it is a chronology of what a fight looks like from the trenches. It reveals an absolute frenzy of activity.

My strategy was simple. I was going to leave the trench and see if anybody would follow me. It was like World War I. Someone rises up and goes over the parapet and takes the bullets or the gas. Sometimes others follow and sometimes they don't. I said, "To hell with it. I'm going." I had no idea if anyone—my board, my boss, or any coalition—would follow me. I only knew Nancy would.

I knew that my board of directors was skittish and confused. My boss had already threatened to fire me once on this subject. I had no coalition. I knew that I was taking BIO into the teeth of the Right to Life movement, into the teeth of Trent Lott, and ultimately into the teeth of the House Republicans. I knew this would be bloody. If that meant the end of my career at BIO, so be it.

To be honest, I didn't go to my board and ask them whether they wanted to engage in a frontal confrontation to defend embryo research, to fight the Right to Lifers, or to fight the Republicans. I didn't go to my boss to alert him about what this would look like. I had a vivid imagination about how bloody it would be, but I did not share that with my board or boss. I had Nancy, who was born to fight. That was it.

As you'll see in the chronology, Nancy and I divvied up seventy-five meetings on the Hill in those thirty-seven days. We held massive briefings for patient groups and for Hill staffers. In the end we organized a coalition of seventy patient groups. We had dozens of Nobel laureates decry this ban on stem cell research.

At one point I held a seven-hour conference call with the researchers from Roslin so that I would technically understand what the hell this research was about. I had to learn all of this science. I didn't want to make any misstatements about the science. They hadn't yet isolated a stem cell. I didn't want to make any claims about what was or wasn't at stake, and what could or couldn't happen from stem cells, unless it was entirely accurate.

I'm happy to say despite the frenzy of the process, I can look back at the documents, look back at the testimony, look back at the statements, and I think I did not misstate anything even once. I'm very proud of that because the pressure on us was just phenomenal. Every day was pandemonium. Like kickboxing. Every appendage flailing

On February 3, Trent Lott and Kit Bond introduced their version of the ban. Just as I suspected, it said it shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, to use human somatic cell nuclear transfer to create an embryo. It wasn't a ban on reproduction; it was a ban on research. This research would yield a ten-year criminal penalty plus civil fines. The term "human somatic cell nuclear transfer" was defined to mean taking the nuclear material of a human somatic cell and incorporating it into an oocyte from which the nucleus has been removed or rendered inert and producing an embryo.

RITCHIE: Do you have any suspicions as to why they came out so focused on creating the embryo when they could have separated the cloning issue from embryo research?

LUDLAM: I don't. I'm not a party to their decision-making process. The Catholic Bishops have always opposed embryo research. They believe that a fertilized embryo is the equivalent of a human being.¹³⁸ This was a chance for them to use "human cloning" as a subterfuge to enact a criminal penalty for some research involving embryos.

RITCHIE: To start with the broadest possible attack on the issue?

LUDLAM: Well, they apparently made the calculation that they couldn't seek an across-the-board ban on embryo research, that they could only seek a ban on a certain type of research they could call "cloning." I don't know why it was so limited.

It strikes me as unprincipled, opportunistic. I think they must have calculated that the public might not support a general ban on all embryo research, but they could potentially seek an enactment of a legislative ban on human cloning embryo research. I don't know. The Catholic Bishops made a corporate decision that that's what they would go after.

Complicating this situation was that Kit Bond was running for reelection at the time and Missouri is well known as a having a very strong Right to Life movement. In the middle of all of this, we knew that we needed an alternative to what we anticipated would be the contents of the Bond/Lott bill. I had days, and days, and days of negotiation with Diane Feinstein's and Ted Kennedy's staffs so they would propose an alternative to the Bond-Lott bill, which is a ban strictly on reproductive cloning and not on embryo research. It was very difficult to draft.

My great hope was that Bill Frist would be our champion because he was a transplant surgeon and he understands organ rejection. He understands histoincompatibility. We made sure that he and his staff understood that the only research that was going to be banned was customized stem cells, and that the only purpose for creating customized stem cells was to avoid cell transplant rejection. There is absolutely no doubt in the world that he and his staff knew exactly what the science was all about, and exactly what was at stake. But Frist joined Bond and Lott.

He is still joined to Bond and Lott on this issue. It's clear that the reason for this is that he has ambitions in the Republican Party, and that's the only position he can take. But given what he knows about the science, his support for a criminal ban on this science is absolutely unconscionable. There's nobody who has ever served in the House or Senate who knows more about what is at stake in this fight than Frist. The whole purpose of stem cell research is to avoid transplanting organs, whole organs.

When you know what's going on in a fight, and you know what somebody knows, and you know what they finally choose to do, you take the measure of the person. I admire Frist in many other respects, but in this one I think what he did was absolutely

unconscionable. His personal knowledge that we were banning the most useful stem cells is unquestionable, so I believe he was giving priority to his political position over his Hippocratic Oath.

On February 11 we finally got to the cloture vote on the Bond and Lott bill. Lott needed sixty votes to get cloture. He got forty-two. Twelve Republicans defected to join us, including Strom Thurmond. We had others who would have joined us if we ever needed them. We crushed him. We absolutely humiliated Trent Lott.

RITCHIE: Do you think he had any inkling that it was going to turn out that way?

LUDLAM: Only some. My goal in this fight was not simply to win. It was to crush Lott, and the Republicans, and the Right to Life movement, because I did not think my side had the power to sustain a year-after-year-after-year fight with the Right to Life community. My effort was not simply to win, but it was to crush them, because I thought that they would eventually win a war of attrition. It's now seven years later and they still haven't won and I think they will never win.

RITCHIE: Did you focus most of your attention on Republicans, assuming Democrats were on your side on this issue?

LUDLAM: Yes, I personally had meetings with the Right to Life staffers in about twenty-five Senate offices. This was a very interesting cross-cultural experience for me. I went in and said, "You're on a high moral plane and so am I. You are not on a higher moral plane than I am." I knew we probably couldn't get many of them, although we did get Thurmond and eleven others. He had, I think, a granddaughter or a niece who had diabetes.

Connie Mack was an absolute hero in this process. His family is rife with cancer. He stood up and was our leader for our side of the debate. Mack was ambiguous until the end, but then he came out for our side. I am told that there was a screaming confrontation between Mack and Bond, after Mack came out in favor of our side of the debate. I was not a witness. Bond is well known for being nasty.

RITCHIE: I think a lot of people were quite surprised because Mack had been so conservative in the House of Representatives. He hadn't been quite as ideological in the

Senate as he had been in the House, but still that was a remarkable break for him. At one point Senator Lott said to him, "Well, with you of course this is personal." And he said, "Of course it's personal."

LUDLAM: Sometimes politics is personal. In the middle of our massive preparation for this cloture vote in the Senate, the House Commerce Committee was scheduling a hearing for the next day, February 12, on this issue. In addition to lobbying the Senate, I was also lobbying every member of that subcommittee, lining up my witnesses, and drafting their testimony. More pandemonium.

Mike West was my witness. He's a fantastically interesting, almost totally uncontrollable human being, who would love to talk about Catholic theologians in the Middle Ages, or lots of other stuff, rather than stick to a script. I drafted Mike's testimony very tightly, to talk absolutely accurately without speculating about anything. I had a four-hour briefing of him the day before where I told him on about forty occasions, "Do not leave the script. Do not talk about that. Do not talk about that. Do not talk about that. Do not talk about that." I just went on and on and on trying to keep him under control.

RITCHIE: Did he stay under control?

LUDLAM: He did. I was sitting behind him. I was going to kick him if he didn't stick to the script. All but two members of that subcommittee backed us. There were only two members on that subcommittee who supported the ban. So I crushed the Republicans in the Senate on February 11, and I crushed them in the health subcommittee in the House on February 12.

As you would expect, on February 17 we were invited—compelled is the better word for it—to what we all refer to as the "woodshed meeting." The Republican leadership in the Senate and House called us all in—BIO and our allies—to scream at us about how we had embarrassed them. They accused us of lying and misrepresenting the facts, which was absolutely not true. We sat and took their invective for forty-five minutes, and then we said to them, "If you ever try to ban medical research again, we will do exactly the same thing." We didn't blink or back off an inch.

RITCHIE: Who were the leaders who called you in?

LUDLAM: Lott's staff, Bond's staff, Frist's staff, and who was the majority leader in the House?

RITCHIE: Dick Arme y?

LUDLAM: Arme y's staff, all of them. We looked them in the eye and said, "We do not regret a thing. We never misstated a fact. And if you do it again, you'll get exactly the same response." If you don't stand up to your friends in this game, they'll run all over you.

You have to stand up and tell them that you stand for certain things, and there are certain things that you will never support even when it is your friends who support them. Of course, the Republicans are much more the industry's friends than the Democrats. They didn't like our defiance, of course, but I think they had some respect for the fact that we didn't give an inch. If people think you can be intimidated, you're finished.

RITCHIE: It seems that their position was not an effort to see where there was room for compromise. It was to establish a position and to force it on you.

LUDLAM: Sure.

RITCHIE: They weren't consulting with you to see what you were seeking.

LUDLAM: No.

RITCHIE: They were imposing a decision to ban some research.

LUDLAM: Absolutely. That forced us to fight and embarrass them. I view this as entirely their fault, not ours. We were on the defensive. They were the offenders. We'd warned them and we'd given them expert and accurate information about the medical value of the research they were banning. Frist could not have been better positioned to understand these points.

To make matters even more strange, on February 13, two days after I had won the cloture fight in the Senate and one day after I had won the day in the House Commerce Committee, the chairman of the board of directors at BIO announced to my boss that I had

to be fired. He went to my boss and said, "Ludlam has to go." The reason for this was that he was a die-hard Republican, and he had gotten calls from his Republicans friends on the Hill saying, "Your little boy here has embarrassed us and we want him out of BIO. He's persona non grata here." That came from a staffer of [Congressman Tom] Bliley at House Commerce who was well known as a bully.

So instead of being able to celebrate one of the greatest victories, probably the single greatest victory of my entire career in politics, I spent the next six months defending my job. It was brutal. It was surreal. It was vicious. It was nasty. It was ugly. And I survived it.

This was just what happened with the Regulatory Flexibility Act fight when immediately after my victory Frank Moore tried to fire me. In this town, winning is just the beginning. Before you start celebrating, you need to watch out for retaliation! People who lose get pissed and try to get even. That's this game at its essence.

This proposal to fire me was never discussed by the board. I don't know if he ducked or just cooled off or he was fearful we had the votes to beat him. We attended two board and two executive committee meetings not knowing if he'd bring this up. I had to be totally prepared to defend myself. It was very tense and uncomfortable.

My boss was backing me. He knew that if one member company with a partisan political interest in an issue could get the top lobbyist fired, the trade association would be forever vulnerable to that kind of intimidation. And if it got public, it would be even more embarrassing to BIO. It would look like it was bought and sold to the Republicans and had become their toady.

As far as I'm concerned, this fight was absolutely worth the price. If they had fired me, I could have handled that. I made a decision in San Diego the year before to challenge my boss in front of the board of directors and got them to oppose a ban on cloning. I'd almost gotten fired then. Then I made a decision to leave the trench to fight the Bond bill and almost got fired. In both cases, if I had been fired, so be it. I could live with myself and be proud of the risks I had taken and the skill with which I'd won the day.

RITCHIE: Do you think after the six months of battles, did they begin to realize what a victory they had won? Or were they more worried about their continuing relations

with the leadership on the Capitol Hill?

LUDLAM: I don't think the board understood the importance of this fight, that it was a rite of passage for BIO, that it said a lot about BIO's values. In terms of relations with the Hill, this fight had no negative impact on the industry's relations with the Republicans. Adults move on in this political game.

Since then, the embryonic stem cell fight has devolved into a fight that is trench warfare between the patient community and the medical research community and the Republicans, but not BIO particularly. At the time it was only me and Nancy. We were the only people out front, but eventually we had allies and they've carried on the cause. Dan Perry is the key guy, with the Alliance for Aging Research.

I think it is a rite of passage for a trade association to have an experience like this. Trade associations tend to be risk averse. They don't like to make enemies, especially with the people who tend to be their best friends. I don't think my board or boss felt they were adequately consulted by me about how nasty this was going to get. The truth of the matter is that I didn't consult with them because I didn't want them to stop me. [Laughs]

It's clear that I led them into something where I knew how grim it would be and they didn't. But my personal judgment was that it was worth the risk, and that they had to stand on our principles. We could never support criminalizing of any medical research. Even trade associations have to stand for something. So I didn't and won't apologize for what I did for a second. The risks that I took were totally and completely justified and in the best interest of BIO, its members, and the entire biomedical community.

Since then, we have seen Ron Reagan testifying at the Democrat National Convention. We have Nancy Reagan involved. It's now an issue in the presidential campaign. We have seen Proposition 71 in California where they are going to set aside three billion dollars for stem cell research. And the administration has just backed off its attempt to secure a UN resolution banning cloning worldwide. Now it is hard to imagine how close we got in 1997 and 1998 to a criminal ban on this research.¹³⁹

RITCHIE: You talked about how complicated the issue was for you. It's always hard to sell a complicated issue to a public audience but if the "cloning" slogan had worked, that

would have been a nice way of presenting it because it would have been a very simple way for people to understand. But it seems to me that the response in return has been to explain the benefits of this type of research. That's what's made Nancy Reagan's stand and Ronald Reagan, Jr.'s stand a remarkably popular one. It's also remarkable that there have been very few internally divisive issues like that within the Republican Party, which has been fairly cohesive in recent years.

LUDLAM: We were selling hope. We had to speculate about what we could do with embryonic stem cells. Hope is an important commodity in politics. The problem was that we hadn't even isolated a stem cell, which was why this debate was so dangerous for our side. Now that we have stem cells and there's a huge coalition favoring this research, it's an even fight. Back in 1997-1998 it was a very unfair battle where by all rights we should have been annihilated. The other side was peddling fear of human clones, a very powerful argument.

I think all politics has devolved into a debate about emotions and values. It is no longer just issues. Everybody is selling hope or fear and I think that's part of why politics has become so nasty. I think it's the advertising profession that has taught us how to segment and motivate people, and they segment and motivate you with hope or fear. Politics has learned to play the same game.

In terms of the Stanford students, let me say that one hopes in a career that when something like this happens you have the skills to lead a fight and win. This is when we can apply all that we've learned in all our years in the trenches, so we know instantly, minute by minute, what we have to do to win. We know who we have to meet with. We know what's coming next. We know how to persuade people. We know how to explain the facts and concepts. We know the parliamentary situation. We know how to draft bills and amendments. We know how to make our arguments, position ourselves, and organize a coalition. We have *all* of those skills that enable us to fight with the best in a fight that is very emotional, very fast paced, and very important.

I'm very proud of the risks that I took, and the result that we got, but it took all of what I've learned over the previous decades to win. You can't engage in politics for a few years and assemble those skills.

RITCHIE: Now when you're starting on a project like this, and you've got an issue

that has a deadline as a bill is being called off the calendar and coming down the pike, is there an existing network on Capitol Hill on an issue like medical issues that you can begin to plug in and get active and get on your side? Do you know staffers and senators and representatives who were likely to be your allies?

LUDLAM: Yes to some extent we had a network, but of all of the people I worked with on this issue who were on the Hill, I probably only knew one or two of them before the fight started. We had relationships with some members, but this was a whole new fight, and a whole new issue. We were really starting from scratch. The pace of it was so phenomenal, and the issues were so complicated, that even though I worked on this a little bit the year before, we were caught essentially flatfooted at the time this hit us.

RITCHIE: You mentioned the senators that disappointed you, but were there any senators who really came through on the issue?

LUDLAM: Feinstein and Kennedy took the lead on the other side. They introduced the alternative bill and did a very effective job of organizing the other side of the debate. I have great respect for both of them—they are talented members who are willing to fight. Connie Mack was critical.

When we started, essentially nobody on the Hill understood what the issue was about. They didn't understand what stem cells were or could become. They didn't understand the process of somatic cell nuclear transfer. Literally I had to walk several hundred people through all of what I have explained here, which is not easy stuff for anyone to understand.

We were always careful to explain that the Republicans and the Right to Lifers were not trying to ban all stem cell research. We're trying to be honest, and fair, and factual. They were only banning some stem cell research. Well, of course that confused people the most. They'd ask, "Why aren't they trying to ban all stem cell research?" Then we tried to explain why the research they were banning was so valuable. It was so strange and we hadn't yet isolated stem cells. It was surreal, it was completely surreal. There was so much misleading information. There were so many emotions. There were so many charges. It was just absolutely pandemonium for those thirty-seven days.

RITCHIE: I heard Senator [John] Cornyn of Texas give a talk recently in which he

said the big problem on Capitol Hill is that senators rarely read the bills that they vote on. The implication on that is that people don't bother to learn a lot, but learn only what they need to know. Is that an accurate account? Or did senators and staff go out of their way to try to figure out this complicated issue? If twelve Republican senators bucked their party, they had to have had some motivation and understanding of the issue.

LUDLAM: Well, both sides in the debate were offering misleading information for different reasons. The Democrats did not want to say that they were willing to destroy human embryos for medial research purposes. The Republicans didn't want to explain that they wanted to throw scientists in jail and ban research on the most useful type of stem cell.

We had both sides misleading everybody, and neither side being honest, which makes it especially difficult for an outsider who has a commercial interest to try and set things straight. In the end, I think we were able adequately to explain that these were artificial embryos that were not fertilized, that they could be implanted, could be brought to term, and could yield a clone, but that we had an entirely different use in mind.

I understand the other side's problem with our argument. But I also believe that the only way to get totipotent stem cells, and customized totipotent stem cells, is to use somatic cell nuclear transfer to bring in the DNA from a patient to create an embryo, and destroy it to harvest that stem cell.

Sometimes in a debate like this, you are tempted to just throw up your hands in frustration. We had here a conflict that was completely derivative of your beliefs about embryos and human life and when human life begins. I infuriate some of my liberal friends when I explain that the Right to Life community has values and principles that are akin to anti-war principles of the '60s or liberals who oppose the death penalty. I don't happen to agree with them that life begins at conception, but I think that they come to this point of view with high moral principles. If it is true that an embryo is a human being, then killing it should be a crime. I don't happen to believe that embryos are human beings, but I respect the Right to Life movement for raising issues about embryo research. The Choice community has vilified the Right to Life community in ways that are completely unfair. I was an anti-war protestor, I don't like the death penalty, and I don't like third trimester abortions. I don't happen to oppose embryo research because I don't think at that point the fetus is viable. For me that's the dividing line between what's moral and what's not moral. But I do respect the

Right to Life community for their views and commitment.

RITCHIE: In this campaign were you able to get the press involved? Did you direct much of your effort towards the media?

LUDLAM: The answer is "not much" because we didn't have time. My view was that the only way to win this fight was to explain it one-on-one to the members and their staff. We didn't have enough time to bring in the press. I thought the press was never going to understand the issue and would constantly be creating more problems. Every time they wrote an article, they would include seven or eight misstatements. This made everything even more difficult to explain. So my strategy was, "I want to be the only one to explain these things on the Hill and it won't be helpful if the press tries to do the same."

RITCHIE: Did the press get it wrong or did they —

LUDLAM: They have never gotten it right. They have never explained to this day what this fight is all about. I don't know why Bush isn't being accused of proposing to throw scientists in jail. I don't know why he's been so successful with his ploy of funding some stem cell research at NIH. Why can't people understand the concept of "customized" stem cells? Why can't Bill Frist?

RITCHIE: Well the end of the story, by the way, is that you did keep your job. You were not forced out of the BIO operation. They sort of swallowed that situation.

LUDLAM: I was widely respected in some quarters for how I handled this fight. I think people even enjoyed the woodshed meeting.

RITCHIE: Did the Clinton administration play any part in all of this battle?

LUDLAM: Yes, it was helpful. It made a series of statements during this debate which were helpful. My friend at the White House, Rachel Levinson, did a wonderful job of working with us as we fought in the trenches on the Hill. For several decades she's one of the leading advocates for life sciences research.¹⁴⁰

RITCHIE: It probably didn't help that the president was being impeached in the

middle of all of this.

LUDLAM: In most respects, I think Clinton was a worthless president. After the reconciliation bill and the health care bill in '93, he never led again. I don't think we should elect presidents to a second term unless they're going to lead. He never led in his second term. His dysfunction came naturally to him because his mother married a series of alcoholics who beat her. So Bill Clinton was a classic adult child of an alcoholic. His lifelong sex addiction came from that. All of us who worked for Dale Bumpers in the '80s knew all about it, and none of us were surprised when this happened.

In fact, I think what Clinton should have done, once he was caught with [Monica] Lewinsky, was to say that he was going to resign for the good of the country, and the good of the Democratic Party, make Al Gore the incumbent, let Al Gore select a vice president to be confirmed in the Senate and the House. Then Al Gore would have run as an incumbent, and would have won.

Unfortunately, Bill Clinton thought he was more important than the country. In fact, if you remember back at the time when [Richard] Nixon was facing a similar decision, Barry Goldwater went to Nixon and said he must resign for the good of the country, and Nixon did. I think Dale Bumpers should have gone to Bill Clinton and told him to resign for the good of the country. I've said that to Dale Bumpers, who acknowledged that I might have a point here. But the Democrats all lined up to defend Clinton, which was stupid. Clinton never fought for the congressional Democrats. He betrayed the African American Democrats when he signed welfare reform, yet they all loved him. If Clinton had resigned, everything would have been different in the 2000 election. But Bill Clinton thought he was more important than you, and me, and everybody else. He fought even though he knew full well that he'd screwed Lewinsky and lied under oath. He knew he was defending his office based upon lies.

RITCHIE: You are now back here on Capitol Hill after your seven plus years with BIO. You are working with Senator Lieberman. Were you very much involved in the 2000 election?

LUDLAM: I had no involvement in the 2000 campaign, and I had as little involvement with his 2004 run as possible. I don't like electoral politics. During the 2004 campaign I had endless fights with the campaign policy staff, who I thought were much too

focused on pandering to the liberal Democratic primary voters.

RITCHIE: What have you been working on with Senator Lieberman?

LUDLAM: Well, as I explained, the way I got back here was that I've known Bill Bonvillian, Senator Lieberman's brilliant LD [Legislative Director], and Senator Lieberman since '89, when they first arrived here. Lieberman was appointed to the Small Business Committee where I was a staffer with Dale Bumpers. They were intensely interested in high technology, industrial policy. They were intellectually curious about all of these things, so one of the first things they did when they first got here was to come over to talk to me at the Small Business Committee. I've always had tremendous respect for Bill and Senator Lieberman.

After I left BIO in 2000, I was free, and they had an opening, so I came up to my natural home, which is back here in the Senate. What is so attractive about both of them is that both Bill and Senator Lieberman are incredibly curious about all of the ways in which the economy works and they are incredibly entrepreneurial. Senator Lieberman and Bill both are kind people, and it is hard in politics to find people who are both skilled and kind. They are both. They also love to focus on the big issues. The issues that I have focused on with Lieberman are the three biggest threats that I see to our country. One of them is bioterrorism, another is debt, and the third is China.

RITCHIE: Tell me about the bioterrorism initiative.

LUDLAM: When I left BIO in 2000, I had no intention of working on the biotech issues again. I was finished with that. I had immersed myself in those issues for seven years and I came here to move back to my old portfolio focused on economic policy. I was not assigned to work on health care, Medicare, FDA, patents, bioethics, or any of the BIO issues. They were not any part of my portfolio. I was focused on economics, budget, tax, fiscal policy, high-technology policy.

All this changed on October 15, 2001, when we got hit in the Hart Building with weapons grade anthrax. My office is located immediately above the Daschle mailroom, where the anthrax letter was opened. After we were evacuated to the Dirksen Building, Bill and I were talking about what we could do about the attack, and he said, "You know this

industry. Why don't we work out a set of incentives to try to get the industry to help us to get ready for a bioterror attack?"

I undertook a crash project and on December 4, 2001, Senator Lieberman introduced a bill I drafted that provides incentives to persuade the biopharma industry to help us develop medicines as countermeasures for bioterror pathogens.¹⁴¹ The problem addressed in the bill is that we have essentially none of the medicines we need to respond to an attack. In the summer of 2000 the Defense Science Board put out a study that found that we have one of the fifty-seven medicines we would most want in the case of bioterror attack—only one. The board didn't think relying on an eighteenth century smallpox vaccine was good enough. It didn't think that relying on a six-shot over eighteen-months anthrax vaccine was good enough. Those vaccines got yellow, not green lights on the DSB "stoplight" chart. This list of fifty-seven medicines does not begin to deal with all of the exotic hybrid threats or genetically modified pathogens or infectious disease generally. The list of threats that we could face is truly frightening.¹⁴²

If we get hit with a bioterror or infectious disease attack and we don't have medicines, the public will flee. We will see panic. We need to be able to tell the public that we have a diagnostic, so we know what pathogen we're dealing with. We need to tell them that we have a safe and effective therapeutic or a vaccine. We need to tell them that they will not die and their children will not die. If, instead, we have to tell them that we don't know what it is, that it's a highly contagious pathogen, and we have no medicines to protect them, we'll see mass panic and we will have to impose quarantines.

When SARS hit in China, Beijing, Shanghai, and Hong Kong were closed down for months. Nobody went to work. We have to avoid that situation here. We have to secure development of these medicines. We have to have good medicines that work, with a minimum of side effects.

The biopharma industry has no interest in this research because of what happened to Bayer Company, a good Connecticut company. Bayer had secured an anthrax label indication for its antibiotic Cipro in 1999 or 2000, a year before the Daschle attack. It had done so at the request of CDC and FDA. These agencies wanted one antibiotic that was "on-label" for anthrax in case we got hit with an anthrax attack. Bayer said they would do it, and did it, and paid the money to get the label indication for anthrax based upon animal studies.

Then we got hit with the attack, and Bayer donated four million doses of Cipro to the government. The government said it would like to buy several million more doses of Cipro. Chuck Schumer and Tommy Thompson threatened the patent of Bayer if it wouldn't sell Cipro at one-fourth the market price. Bayer had no choice and it was forced to sell Cipro to the government at one-fourth the market price. Then all of its other customers for Cipro demanded this discount. It was basically an attack on Bayer's patriotism and stock price and Bayer had no leverage to resist.

The biopharma industry looked at this and said, "I understand this. If I have the perfect product to deal with a bioterror attack, and the government needs it, it will steal it." This is exactly what they had suspected would happen and then the Bayer incident proved that this fear was justified. Their fears were shown to the world in Technicolor.

Another major problem is that there is no market for many of these bioterror countermeasures other than the government. The industry hates the government. They hate Medicare. They hate FDA. They have problems with NIH. The government is not their friend. So the idea that there is only a government market is a disaster. It's second to only having no market at all, from the industry point of view.

I know all of this because I've represented the industry. The industry doesn't want to spend its capital on this bioterror countermeasure research. So the question is this: what incentives can you put in front of them that might change their mind? So that's what we did, we introduced the bill that provides these incentives.

Drafting this bill put me in a strange situation because BIO did not support the legislation, nor did PhRMA.¹⁴³ They didn't support it because they do not want to do the research, and therefore they do not want to support incentives that might make it more difficult for them not to do the research.

So pushing this legislation put me in an antagonistic relationship with my former employer. I knew this would be the case before we introduced the bill. I knew the industry wouldn't support this legislation. I didn't go to it for technical support. I did all the drafting of the legislation myself.

Strangely, Ralph Nader—my old nemesis on the Airline Noise bill—wrote a book

during the presidential campaign, with Charles Lewis. It was a book called *The Buying of the President, 2004*. It was an attack on the ethics of all the candidates.¹⁴⁴ There is a long section in the book attacking me by name for shilling for my former employer in proposing these bioterrorism incentives. The report didn't lead to anything. No other press source picked it up.

Back in 1978 when we enacted the revolving door rules in the Ethics in Government Act, it never occurred to us that anyone would come back to the Hill—taking massive pay cuts like the 75 percent pay cut I took. So the revolving door restrictions we drafted—the one year cooling off period—only applies when a Capitol Hill person leaves the Hill to work in a private firm downtown. The restrictions don't apply if someone from K Street comes back to the Hill!

Even though the revolving door rules didn't apply to me, I observed the one year cooling off period after leaving BIO. And in Lieberman's office I've never handled the issues that form the core of the biotech industry's legislative agenda—healthcare policy, FDA, Medicare, bioethics. I only got involved with the bioterrorism issue after the anthrax attack. So, I find it ironic that I've been accused of violating the revolving door restrictions given that I had helped write and enact them!

The allegations in the Nader/Lewis book are fundamentally bogus because I am not doing something my old clients want me to do. In fact, they have privately told me to shut up. But this subtlety was lost on Nader and Lewis, who just looked at the surface and concluded that I was trying to help my former clients. In fact, I'm trying to force the industry to spend its capital on research that we need for the public defense. We need to create a market for these medical products, and a motive for these companies and their investors so they will invest their capital in this research and so we will not face public panic and quarantines.

Nothing in our bill is a giveaway to the industry. The industry is rewarded only if it expends its own capital to fund the research and successfully develops the medicines we need. If it tries and fails, it gets nothing. So I'm trying to shift the risk to the industry, not give it a windfall. Interestingly, this model is exactly the model that industry would most prefer. It doesn't want the government to fund the research because then the government will then own the product's price and the patent. This is a cost-plus market and it's a business

model the industry will never accept. It's willing to take the risk, and spend its own capital to develop the products, if there's a sufficient reward at the end if they succeed. That's the economic model I've proposed we work with in the Lieberman bill. This is no sweetheart deal for the industry.

In the same bill, I've taken the opportunity to propose a fundamental reform of NIH. I've long believed NIH was a massively unproductive organization that's become little more than a pork barrel funding source for academics. NIH could not care less about maximizing its role in the development of medicines for patients.

In this bill, we've proposed to protect NIH patents from erosion due to FDA delays, the corollary to the reforms we enacted for PTO delays in the Patent Reform Act. I loved working on this with Dave Schmickel. He's a prince, an expert, and a dear friend. I'm now trying to land him a job up here on the Hill with the HELP Committee, so he can help us pass these critical reforms.

RITCHIE: Did the bill get anywhere?

LUDLAM: In February of 2003 President Bush in his State of the Union address announced that he wanted to pass what he called "Project BioShield." This was his version of my idea. We heard that he'd proposed it because he feared that Lieberman, who was running for president, might be the Democratic nominee. So Bush was working to preempt us and protect their right flank. Their proposal came straight out of our bill, but it was only one of the twelve titles in our bill. In July of this year, we enacted Project BioShield.¹⁴⁵ It's a down payment on my comprehensive plan.

I am now in the process of drafting BioShield II, and doing everything I can to persuade the administration to steal that also. I'm arguing that a bioterror attack or infectious disease outbreak could well ruin Bush's second term. And there are many Richard Clark's around—like me—who can say they warned the administration again and again.¹⁴⁶

I've been blessed to work with some of the top professionals in the Senate on this initiative. Bruce Artim, now Senator Hatch's chief of staff on the Senate Judiciary Committee, is my lead partner. I've known Bruce for many years and always found him to be extremely knowledgeable, dedicated, and lighthearted. I love working with him, and with

the rest of Senator Hatch's health policy team, especially Patty DeLoatche. I've known Patty since the stem cell fight and she's a delight to work with. Dedicated, and also lighthearted. Senator Gregg's staff is also first rate: Vince Ventimiglia and Steve Irizarry. They're pros.¹⁴⁷

There's actually a lovely little story in the middle of all of this, which ties up into an earlier story in this oral history. I was redrafting the bill, second version of this bill in December of 2002. I knew that the procurement titles of our first bill, introduced in December 2001, were not well drafted. The Senate Legislative Counsel had done its best, but I knew that we were falling far short of the radical procurement reforms I needed.

I remembered Gil Cuneo, with whom I had worked on the organizational conflict of interest issue back in 1978. He had died, but I went to his old firm to ask them whether they would give me some pro bono help in redrafting the bill. The firm had changed names several times, but it was still the top government contracts firm in the city. Eventually I found a partner of the firm, Frank Rapoport, who gave me considerable pro bono time to help in redrafting the procurement titles of the bill. Just as Frank and I were about to introduce the new bill, in January of 2003, President Bush announced Project BioShield, and suddenly we were off to the races. The tie with Gil Cuneo had me well prepared for this surprise.

Frank was suddenly a hot commodity. He had drafted what became Project BioShield. He immediately landed a few clients, including Aventis, the big vaccine manufacturer. Then Frank and I and a few others hired by Aventis waded in to fix and enact BioShield. John Clerici and Dack Dalrymple were skilled players on Frank's team. Aventis Pasteur was critical because it was the only large pharmaceutical firm that wanted to fix and pass BioShield.

The administration's draft bill was miserable, absolutely miserable, and we had to rewrite it in the House. We had twelve amendments we needed, and we got ten of them adopted. The bill went to three committees and every single committee improved the bill. That is unheard of! We had no help from the administration. Then when we'd fixed the bill in the House, we persuaded the Senate to adopt the House bill. Vince and Steve were crucial to this transaction. The bill we enacted is a fairly functional product. I give Gil Cuneo some credit for this; it was his pro bono help for me back in 1978 on the organizational conflict of interest legislation that set this whole process in motion.

We will introduce BioShield II in February.¹⁴⁸ It is the most ambitious set of incentives ever proposed for any economic activity, and I'm not sure if it's enough. The industry is incredibly skeptical of this research. It has no interest at all. I'm not sure if the incentives we're proposing—as ambitious as they are—will be sufficient. The incentives include the whole tax code, patent system, the tort system, and lots of other incentives, and that might not be sufficient to entice the industry to play. If we don't get the industry interested in this research, we are never going to get the medicines that we need to prepare ourselves for an attack. We're going to see panic, and we're going to see quarantines. It is a very desperate situation, and a very difficult challenge in terms of incentives.

I've been working on different types of economic incentives my entire career, and I've never run into a problem of incentives as difficult as this one or as critical. If we're not prepared for a bioterror attack, millions, or even tens of millions could die. We could see a SARS attack that would kill 100 million people.

We could see an avian flu attack that would kill a couple hundred million people. The 1918 flu epidemic, which killed at least 20 million people and perhaps 100 million, had a lethality rate of 1.8 percent. The avian flu we're now seeing has a 55 to 70 percent lethality rate. SARS had a 40 percent lethality rate. It's possible to see a billion or more people dying in a new pandemic flu outbreak. This would give us Cambodias and Rwandas all over the world.

I have taken the lead to apply BioShield II to the development of medicines for all "infectious diseases," not just for bioterror pathogens. I am assembling a coalition of all of the international public health groups, including those focused on research to develop drugs and vaccines for AIDS, Malaria, TB, and other third world diseases. They will back these incentives and press to apply them to all infectious diseases. So what we might secure here is enactment of a very aggressive set of incentives for research on medicines for all infectious diseases. This could have an unbelievable impact on hundreds of millions of people. This is a big idea.¹⁴⁹

My fear was that we would pass BioShield and the natural course would be for the Congress and administration to sit on their laurels for several years waiting to see how it worked. I knew BioShield wouldn't be sufficient. So four months before we passed BioShield in July of 2004, I started talking about "BioShield II." I just invented the term. I

had a good idea of what would be in it but there was no such bill. Basically it would be everything that wouldn't make it into BioShield, all the stuff on the cutting room floor. The Lieberman bill had twelve titles and BioShield was only one of them.

RITCHIE: President Bush announced that in his State of the Union message and then rarely mentioned it again. It didn't seem to be a big initiative of his administration. Were they pushing it hard or was it something that they were being pushed into?

LUDLAM: We were told by a high ranking administration official that the only reason Bush proposed it was because he felt Lieberman would be the Democratic nominee. So Bush was putting BioShield to make sure that we couldn't outflank him on the right on biodefense. Then when the legislation was introduced, the biopharma industry hadn't been consulted, was silent, had no interest in it, wasn't trying to fix it, and wasn't trying to pass it. The legislation got bogged down in a variety of ways. Lieberman's campaign languished, and the president lost interest. In the end, we got it passed and the president had a big signing ceremony at the White House on the eve of the Republican convention.

On October 6, 2004, the Senate Judiciary Committee and the Senate Health Committee held a joint hearing on "BioShield II." The hearing was chaired by [Orrin] Hatch and [Judd] Gregg. They are totally convinced that BioShield is not enough. They heard deafening silence from the industry while we were working to pass it. The hearing clearly implied that enacting BioShield wasn't remotely enough. The fact that we had any hearing at all was remarkable. The fact that we had a joint hearing was very unusual.

The hearing was my idea. It was my idea that it be a joint hearing. I selected all the witnesses. I mostly wrote the testimony of all the witnesses. I wrote the questions that the committee asked for the witnesses, and I wrote the answers that the witnesses gave to the questions. I have rarely been so involved in manipulating a legislative product.

Now I am having endless meetings with everybody in the administration trying to persuade them to try and start a process to look at BioShield II. I'm trying to play on their fears about how a bioterror attack, or SARS or avian flu, could ruin their second term.¹⁵⁰

This is a big issue and the enactment of BioShield is an accomplishment. But BioShield II would be the Holy Grail for research on a whole host of neglected and

dangerous diseases. The day before the October 6 hearing, we had the debacle with Chiron and their flu vaccine production in England. My immediate reaction was this mess was manna from heaven. This is the perfect event to show that we have no vaccine industry in the United States. Part of what we're trying to do in this bill is to recreate a vaccine industry, almost from scratch. Government policies basically destroyed our vaccine industry. We also need to create a biodefense industry, and in the middle of all of that, we need to create what I call a research tool industry.¹⁵¹

The research tool industry would be an industry that wouldn't be trying to create actual diagnostics, therapeutics, and vaccines, but would focus on developing tools that would give us the power to create new diagnostics, therapeutics, and vaccines on a crash basis. So if we get hit with something new for which we are not prepared, either from a terrorist or from Mother Nature, we can develop a new medicine in the middle of an epidemic to try to quell the damage. This is a visionary idea. We want to stockpile as many things as we can for the things that we can't anticipate, but it's the nature of bioterrorism and the nature of Mother Nature that we will never be prepared for everything.

The bill attempts to create a vaccine industry, a bio-defense industry, and a research tool industry. Rather ambitious. So far, with the enactment of BioShield, I've only secured about 5 percent of what I've proposed. Now that BioShield II will focus also on third world diseases, I have a huge personal interest. I'm going to be vulnerable to these diseases when I get to Africa in the Peace Corps. I've seen people die of these diseases and I've had some of them myself.

This bioterror and infectious disease initiative is the kind of issue that Lieberman can handle. He's a man of stature, and a man of vision, a man who knows how to lead, and a man who can handle the complexities of this bill.¹⁵²

RITCHIE: What is the second initiative you mentioned?

LUDLAM: The second big threat is government debt, both explicit and implicit. We are seeing a convergence of two titanic forces. One of them is demographics, which is overwhelming, and the other one is an upending of the alignment of our political parties. These two forces are now colliding in very dangerous ways.

In terms of demographics, everybody has a general sense that the baby boomers are going to retire and it's going to be costly in terms of our social insurance programs, Medicare and Social Security. In April, I forced the Social Security trustees to issue new estimates on the shortfall in funding for Medicare and Social Security. They had previously estimated that on a present value basis that the programs were \$18 trillion short.

Present value estimates tell you how much money you need to set aside today to pay the bills you know that are going to be due tomorrow. It is a methodology that all businesses use, but which the government does not use. The government operates on a cash accounting basis. The old trustees' estimate was \$18 trillion short, present value. I forced them to change their methodology and this yielded the new estimate that we are \$72 trillion short. To put this in perspective, the net worth of the United States is \$42 trillion. The annual GDP is \$10 trillion. Every year we fail to set aside \$72 trillion, that figure grows by about \$2 trillion.

Two brilliant economists, Kent Smetters and Jagadeesh Gokhale, laid the intellectual groundwork for these new estimates.¹⁵³ They'd worked at Treasury and prepared landmark studies on the present value of the government's long-term commitments, particularly Social Security and Medicare. I have been working closely with both of them for several years on this issue and enjoyed every minute of the experience.

The point is simple: these programs are catastrophically underfunded, ruinously underfunded. Yet nobody seems to know and recognize this fact—because the cash accounting system which dominates the congressional budget process disguises the shortfall. The cash flow approach, focusing on yesterday and today, is the perfect system to enable politicians to make irresponsible promises today to secure their reelection and not acknowledge the costs of these promises over the long term. As a result, there's no political will to deal with this shortfall. Demographics is a force of nature on a par with global warming and SARS.

The other force that is converging with that funding shortfall is the realignment of our political parties. For fifty years the Republicans were the Castor Oil party and actually believed in fiscal responsibility. Because of the entrepreneurial vision of a few members, in 1978 the Republicans started espousing supply-side economics. A certain congressman from Buffalo, Jack Kemp, and a few other people, and a famous drawing on a napkin in a restaurant down on Connecticut Avenue, and we had supply-side economics.¹⁵⁴

As a result, Republicans in 1981 passed the most irresponsible tax bill in the history of the United States, the Reagan tax cut. This involved the infamous "Lear Jet weekend" when every lobbyist in the country flew in to get something into that bill. It took us seventeen years from 1981 to 1998 to get back to a balanced budget. It took one of the greatest economic booms of all time and also three major tax increases. The second of these ended the first Bush presidency when he broke his no-tax pledge. It took the massive tax increase in 1993 under Clinton, and the high-tech boom of the late '90s, to finally undo the damage of the 1981 tax cut. Democrats passed a tax cut in 1993 and then they lost their majority in the House.

Since George Bush has come into office, we have passed four tax cuts in four years and again—like those we saw starting in 1982—we are running catastrophic budget deficits. These tax cuts include almost three hundred "sunsets," put there by Republicans. Every single one of those sunsets could result in a vote which the Republicans will characterize as a vote to "raise taxes" or "cut taxes." The Democrats are totally and completely on the defensive. They had absolutely no strategy to stop these tax cuts. There is no indication that Republicans will back off the tax cuts.

In 1982 Reagan backed off his tax cuts and passed what was to that date the largest tax increase in history. [That's when I won my victory on tax exempt bonds.] He took back about a third of the tax cuts from 1981. I have no sense that the Republicans in this era will back off the 2001 tax cut, or the 2002 or the 2003 or the 2004 tax cuts.

These tax cuts and deficits coincide with the baby boomer retirements, which start in just seven years. Just to give you a sense of what this crunch looks like, Senator Lieberman is about to put out a study, which we put together with the Urban Institute, which finds that in eight years if we fund only the tax cuts, Defense and Homeland Security, Medicare and Social Security, and interest on the national debt, and have a balanced budget, we will not have a single dollar left for anything else—zero. We would just need to cut out all these other programs; we'd have to eliminate them. We would have no Congress, no courts, no White House, no State Department, no Education Department, no Transportation Department. Zero, absolute and complete zero. No parks. And, most important of all, no Peace Corps!

If we keep running the deficits, it is quite clear to me that we will see a crash of the dollar. The only reason why the dollar hasn't crashed is the Chinese and the Japanese are

intervening to keep it strong so they can steal our manufacturing jobs. We're already paying a very big price for these deficits and this irresponsibility. At some point the Japanese may not be able to sustain their massive intervention and the Chinese may repeg the yuan. We've already seen a big depreciation of the dollar against the euro. I think we will see an even bigger depreciation against all the other currencies, because I think that not only do we have the government debt, we have unprecedented consumer debt, and we have unprecedented current account debt.

At some point our lenders will extract a premium on interest rates, because they will begin to think that we are a banana republic. And they don't even know about the \$72 trillion shortfall! Our country is living completely and totally beyond our means, and it's all being financed by borrowing and intergenerational transfers of debt.¹⁵⁵

For me the issue is: how do you get a handle on this problem? I figure that the only thing that I can do about this problem is to try and change the government accounting system and the budget process. The current cash accounting process gives you no handle on what's going on in the future. It tells you what happened yesterday, and maybe what's happening today. It gives you no clue about what's happening tomorrow. The budget process is totally broken. Republicans and Democrats have learned how, with sunsets and other gimmicks, to disguise the cost of their programs and move the costs outside the budget window so that politicians can pander.

This goes to the fundamental flaw that even Tocqueville understood about the United States when he said that "America will endure until the politicians learn they can bribe the people with their own money." What we get with politicians—I think it is the fatal flaw of democracies—is that they make promises today and then ask for the public to pay for them after the next election, but not before. We have that now with the tax cuts. We have that now with the entitlement spending, and the budget process does absolutely nothing to indicate how irresponsible it is.

Lieberman has introduced a bill, S.1915 (November of 2003), which would move us to a present value accounting system, and force us to recognize the cost of government programs into the future. I drafted this bill with a team of twelve economists over a period of a year. We went through forty drafts. We had two hundred e-mails on some of the key sentences in the bill. It was the most intensive drafting process I have ever been through, and

it is a phenomenally complicated bill.¹⁵⁶ Kent and Jagadeesh were key members of our drafting team.

It would keep the cash accounting system but supplement it with a present value system, where all of the future costs are known today. It would establish points of order that would change the day-to-day operation on the floor. We also need to amend the Byrd Rule. It is a very tough and complicated bill. It's an attempt to deal with the demographics and the irresponsibility of Republicans. Democrats have always been irresponsible on spending, and sometimes even on tax cuts, so they have no credibility on fiscal responsibility. They deserve some credit for being fiscally responsible, but they're ineffective in stopping or slowing the Republican juggernaut on tax cuts. Republicans have got it down to a formula and can pass any tax cut they want to pass. The timing of all of this, with the baby boom demographics, could not be worse or more dangerous.

It's been a massive struggle on this initiative with the budget process establishment. The CBO [Congressional Budget Office] issued a major report on long-term fiscal measures and went out of its way to piss on our proposal. It was a first rate hatchet job. It set up phony straw men, gave nothing but the most negative possible spin on every issue, and put none of the issues in context. We've sent a very nasty letter with a long list of probing questions to the CBO to try to mitigate the damage. At the same time, the Center on Budget and Policy Priorities [CBPP], one of the most effective liberal think tanks, showed us a draft report of theirs on our bill and it was even more biased and contrived. I had a very rough meeting with them about it. I argued that if we don't reform the entitlements, particularly the non-means tested Medicare program, everything CPBB believed in would be in dire jeopardy. I'm not sure if the report will be revised.¹⁵⁷

My point about both the CBO and CBPP reports is that the current budget process, which focuses on short-term cash flow, is a disaster and we all have to move towards new measures that will give us a vision of the fiscal future. The battles with CBO and CBPP are distractions and part of the guerilla warfare that goes with nearly any legislation.

Again, as has been so common in my career, I have teamed up with some first rate professionals, in this case Jen Olson¹⁵⁸ with Senator Lindsay Graham and Maya MacGuineas of the New American Foundation.¹⁵⁹ They're both so practical and visionary advocates for fiscal responsibility. So the threat is either bugs or debt. Take your pick. Both can kill us.

Both can kill our economy. Both can ruin this country. Both can ruin the second term of George Bush. I think bioterrorism and debt are just about the most dire threats I can think of. Either one of them could destroy us completely.

RITCHIE: How active has Senator Lieberman been in all of this? Has he taken the bit and run with it, or has he had to be persuaded to come on board on this?

LUDLAM: He trusts me. [Laughs] He listens to me and he has done everything I've asked him to do. He's introduced three bioterror bills and is about to introduce BioShield II. He's introduced the fiscal responsibility bill. He's given some speeches on these issues. Mostly, he's turned me loose. He obviously was very busy during his campaign, which took him out of pocket for a year. But he's given me pretty much everything I need from him. These are the kinds of issues that are so technical that it's hard for members to actually carry the ball. These really are the kinds of things staff needs to pursue. I've pursued them relentlessly, but the beginning in both cases was a very ambitious bill.

I guess what I've learned in my career is that big ideas are easier to pass than small ideas. Most people, I think, have reached the opposite conclusion, that because the process is so complicated, and so bitter, and so partisan, that you have to salami slice your ideas in order to get anything done. I believe exactly the opposite. I think the only way you can galvanize the political system is to go with massive ideas that deal with massive problems that people cannot avoid. That's what I'm doing on the bioterrorism and debt initiatives.

RITCHIE: That's very interesting. I've always thought that on appropriations issues that members can't fathom trillions of dollars, but the smaller the appropriation, when it gets down to a little bit of money, they have the big fights over that because they can understand that amount of money. They'll argue over a few hundred thousand dollars and then pass a trillion dollar bill without a fight.

LUDLAM: What I'm trying to do is change the entire budget process so all of them will have difficulty pandering that way. Democracy is fine, but it's got a fatal flaw which is pandering.

RITCHIE: That and the fact that the public doesn't pay attention when they need to pay attention.

LUDLAM: The cash accounting system purposely disguised the consequences of pandering. The deficits are not great, the deficits are bad, but they are about 2 percent of the fiscal problem. It's the commitments that are outside of the budget window that are going to ruin us. The real issue is the excessive, profligate, and irresponsible commitments we've made to the baby boomers. Those are the commitments we need to know about and manage. Instead of worrying about \$100 billion or \$500 billion, we need to focus on the \$72 trillion shortfall in funding for Social Security and Medicare. Focusing on hundreds of billions compared to tens of trillions, that is the choice. The commitments to the baby boomers are what is completely obscured by the cash accounting system. In fact, I think the cash accounting system is perfectly designed to enable politicians to pander. That's why they support it. I'm trying to pass a system that will make it vastly more painful for members to be irresponsible, to make commitments that come due after the next election.

RITCHIE: What chance do you think the bill has of passing at this stage?

LUDLAM: I think we will first have to face a budget or international financial crisis. We've already had a rather stupid and wide-ranging budget process debate in the House, which unfortunately was entirely focused on tinkering with the cash accounting system. I think a real debate might be precipitated by a run on the dollar.

A declining dollar helps our exports. It hurts imports. Given our trade deficit, this is a good thing. But a decline in the dollar hurts Europe's exports, and its growth. The U.S. is the only vibrant economy in the world now, except for China, and we need Europe and other industrialized countries to generate growth. Germany is still mired in deflation and experiencing double digit unemployment. Relying only on the U.S. to stimulate the world economy is dangerous. If the dollar decline undermines growth in Europe, it hurts world GDP growth.

Japan is holding the Yen down with its massive currency intervention, but it might not be able to do this for long. As the Yen rises, it'll dampen Japan's growth. After a decade in deflation, its economy has only recently shown any signs of life. We need Japan to help grow the world economy.

China is not moving quickly to repeg the yuan. It may repeg the yuan soon, but it probably won't be a big shift. If it repegs, it's not clear that that will be enough to prevent

the bursting of a bubble and a plunge in its economy. Its central bank is weak and inflation and energy shocks are huge worries.

The imbalances in the world economy are massive. The U.S. and China are basically the only bright spots. Overall, China is running a trade deficit, but it's sucking in huge amounts of imports—the only bright spot for Japan. It's the U.S. that is living wildly beyond its means and it's all being financed by foreigners. This is dangerous.

If the U.S. sucks in fewer imports, there's less competitive pressure on the prices of U.S. products, which might lead to inflation. If the dollar declines, foreigners investing in Wall Street and other U.S. assets face currency losses that make these investments unattractive even if the investments themselves appreciate. The currency losses offset that appreciation. If the dollar declines, there's pressure on oil prices, which are all paid in dollars. And U.S. purchases of oil from abroad get more expensive. If the dollar declines, foreigners are less likely to buy our government debt. Again, they may face currency losses that exceed the interest income.

If U.S. interest rates go up, we dampen growth in our economy and increase the budget pressure—with financing charges becoming the fastest growing government program and squeezing out other spending. It's possible all of this leads to a political crisis next year—with a focus on the budget deficits. If that happens, it's a perfect opening for the Lieberman fiscal responsibility initiative. It's the only proposal around that focuses on the real problem, the entitlements.

That's what I'm getting ready for. That's how I'm positioning Senator Lieberman. It's the same with regard to the bioterror bill. If there's a bioterror attack, we couldn't be better positioned to respond. In either case, we can propose our bills on the floor and force members to walk the plank.

The point of our bill is simple: the current budget process is a fraud. Its focus on cash flow disguises and ignores the long-term challenge. Until we update this process to focus on the long term, there's much less pressure on the Congress to deal with the long-term challenge before it's too late. So I'm anticipating that there might eventually be an "Oh my God, the sky is falling" debate about the deficits. The deficits are not the problem; the real problem is the debt, the long term debt, and the entitlements. But we can use the budget

deficits debate to focus on budget process. I think the Senate will do budget process before it can deal with budget substance. They can't possibly deal with Medicare reform or even Social Security reform without changing the budget process first.

I have met with the White House, with OMB, with Treasury. I have a coalition of eight or ten fiscal responsibility groups on the outside that were very interested in what I'm proposing. I'm attempting to work with the staffs of Senator Mitch McConnell, Lindsay Graham, and Judd Gregg—the new Budget Committee chairman. I think Gregg might forego debate on a budget resolution to focus on budget process.

So the answer to your question is that the odds that the Lieberman bill will be enacted are long, but that was true of the Gramm-Rudman-Hollings law enacted in 1985. It came up when we had the massive Reagan deficits and didn't have the votes to raise the debt ceiling. Wall Street was screaming. International markets were unstable. So they drafted G-R-H on the Senate floor. Unfortunately, it was a cash accounting proposal, and not a very well designed one.

I'm trying to anticipate the next crisis and be ready to pass a responsible reform that's focused on the long term, not just the cash flow. I am working very effectively with a bunch of Republicans who are fiscally responsible. There aren't many Republicans who are and there are essentially no Democrats who are fiscally responsible.

Frist is interesting because he thinks of himself as a citizen-legislator. I hear he might propose a "Twenty-first Century Senate Reform" that might include budget process elements. It might focus on such issues as the committee system, floor debate procedures, the discontinuity between authorizers and appropriators, and other issues. I am pressing his staff to include my present value accounting ideas.

Because of the flu vaccine debacle, the bioterrorism initiative is further along. We had the joint hearing on BioShield II, and I've got very solid Republican champions. Again, I can't find any Democrats who are interested.

RITCHIE: And the third threat? China?

LUDLAM: Yes, China. I took a staff trip to China in April [of 2004]. It's obvious

when you go to China that the twenty-first century is going to be dominated by us and them—and maybe just by them. China is both a threat and an opportunity.

It's overwhelming what is happening in China. The political revolution there, which got started in 1978 under Deng Xiaoping, is one of the greatest transitions in the history of any country in the world.¹⁶⁰ From the Dark Ages of the Great Leap Forward and the Cultural Revolution, China is emerging as an entrepreneurial, free enterprise economy.

So I'm drafting a bill, which Lieberman has agreed to introduce next year, that sets up the mother of all exchange programs. And I mean the mother of all exchange programs. Basically, everybody who can organize exchanges with China under any auspices—young people, businessmen, defense people, patent lawyers, anybody—we'll support. We will provide massive funding for Mandarin language study in the United States. We will authorize \$1.3 billion for a whole series of interrelated programs, which is one dollar for each Chinese. It's a very interesting bill, a very interesting concept, and very futuristic.

We're having a meeting with the Chinese Embassy on Friday about it, and we're roping in lots of other people who understand that the twenty-first century is all about the United States and China.¹⁶¹

RITCHIE: When you say exchange, would you also be funding Chinese to come to this country?

LUDLAM: Yes, it's fully reciprocal.

RITCHIE: Well that raises a question, because right now it's very hard, because of the security issues, to get visas. Visas are becoming an increasing problem for academic scholarship. Universities are finding that people who are coming here with scholarly credentials are having their visas denied. How would you deal with something like that?

LUDLAM: We have a whole title of the bill dealing just with visas. We'll propose visa reforms on a grand scale, applied first to China. Every other country has got visa problems with the U.S. now with our new emphasis on homeland security, but this bill would set up all kinds of new mechanisms, new resources, and new priorities to get the visas for Chinese processed much more quickly, with better results.

Some people would probably look at that and ask why we're only focused on China. Our answer is that China warrants such prominence and the reforms we propose provide a model for reforming all of our visa programs. We understand that visas are a big part of the problem.

So I've had the good fortune to be ending my career focusing on three overriding threats—bugs, debt, and China. It couldn't be a more stimulating agenda and it shows just how much fun it can be to serve in the Congress for a great member like Joe Lieberman.

RITCHIE: Well it looks like you're retiring on a high point.

LUDLAM: We'll see if that's true. This is a fickle and tough game. Timing is everything. Actually I have to end this interview so I can go to a security briefing on how we can protect ourselves against a radiological or an anthrax attack in the Senate.

RITCHIE: Maybe later this week we can meet again?

LUDLAM: That would be fine. It's recess. But the cloning fight was a fabulous opportunity.

RITCHIE: Well, thank you very much.

End of the Third Interview

Endnotes

¹³⁰ The first version of this bill was introduced on April 7, 1987 (S. 931). It provided a preferential capital gains tax rate for direct, long-term investments in the stock of small entrepreneurial firms. The capital gains had been repealed in the 1986 Tax Reform Act. This bill restored the preference for certain high risk investments. The bill was reintroduced as S. 348 on February 7, 1989; S. 1932 on November 7, 1991 (cosponsored by forty-seven senators), and S.368 on February 16, 1993. This last bill provided a special capital gains tax rate for individual and corporate taxpayers who make high-risk, long-term, growth-oriented venture and seed capital investments in startup and other small enterprises. For ten-year holdings of the qualifying stock investment, the tax rate was set at zero. This concept became law as part of the 1993 Clinton tax bill, but it was gutted with restrictions.

¹³¹ When President Bush signed the Partial-Birth Abortion Ban Act (S. 3) into law on November 5, 2003, pro-lifers saw the culmination of an eight-year struggle by congressional pro-lifers. The bill represents the first direct national restriction on any method of abortion since the Supreme Court legalized abortion on demand in 1973. The Partial-Birth Abortion Ban Act was introduced by Congressman Charles Canady (R-Fl.) on June 14, 1995. The House first passed the bill on November 1, 1995, 288-139. The Senate first passed the bill on December 7, 1995, 54-44. In the 104th and 105th congresses, Congress approved the ban but President Clinton vetoed the bills; in both of those congresses, the House overrode but the Senate sustained. In the 106th Congress, both the House and Senate passed similar bills, but no final bill was approved. In the 107th Congress (2002), the House passed the ban, but the Senate Democratic leadership blocked it from coming to the Senate floor. In 2003 the bill won final approval in the House on October 2, 281-142, and in the Senate on October 21, 64-34.

¹³² In the case of *Stenberg v. Carhart* in 2000, by a 5-4 vote, the Supreme Court struck down a Nebraska law banning partial-birth abortions, holding that *Roe v. Wade* guarantees the right of an abortionist to use the method whenever he thinks it is preferable to other methods.

¹³³ The Catholic Church view on zygotes and embryos focuses on ensoulment, the point in time where it is animated by a spiritual soul. The process of development of a zygote into an embryo and then into a fetus is medically very complicated and little understood. We don't know precisely when fertilization has, in fact, occurred: when the spermatozoon docks with the oocyte, at penetration of the oocyte, or at the initial interaction of DNA, or when the DNA fuse together? For the Church, however, ensoulment undoubtedly occurs at the moment of fertilization, whenever that is deemed to have come to pass. Given that there is no fertilization and no conception in the creation of embryonic stem cells, it's hard to say why ensoulment must necessarily occur when the nucleus of the patient is inserted into the

oocyte.

¹³⁴ A somatic cell is any diploid cell of a plant or an animal other than a germ cell. Also called body cell and somatic cell nuclear transfer—moving a cell nucleus and its genetic material from one cell to another.

¹³⁵ Mick is the Kerry blue terrier who won best in show at Westminster in 2003 and was the biggest British import since the Beatles, strutting his stuff and winning best in show at more than two hundred shows in the U.S. for two and a half years before he won at Westminster.

¹³⁶ Histoincompatibility is the incompatibility in which one person's tissue cannot be transplanted to another person. Incompatibility (immunology) is the degree to which the body's immune system will try to reject foreign material (as transfused blood or transplanted tissue).

¹³⁷ At first sight, Richard Seed seemed to be a serious contender in the race to produce the first human clone. He trained as a physicist, but turned to reproductive technology twenty years ago when he founded a company to transfer embryos from prize cows to surrogate mothers. Then, in the 1980s, he launched a company called Fertility and Genetics to apply the technique to people, using it to move fertilized eggs from healthy women, inseminated several days before, to those with fertility problems. That effort resulted in publications in *The Lancet* and *The Journal of the American Medical Association*, with one 1984 JAMA paper (vol. 251, p. 889) reporting the birth of a healthy child. At the time, this embryo transfer was a competing technology to IVF, but it never caught on. "Seed has enough credentials to make you listen," says Lori Andrews, an expert on the legal issues surrounding reproduction at Chicago-Kent College of Law. "But so many people are far ahead of him." In interviews right after his announcement, Seed did not acknowledge that cloning a person would pose a far greater challenge than his previous work. This is in character, says Maria Bustillo of the South Florida Institute for Reproductive Medicine in Miami, a coauthor on some of his papers. "He was always kind of eccentric with a lot of grandiose ideas, but I'm not worried. He's not capable of pulling this off." While Seed provided money for the research on which she collaborated, Bustillo notes, his scientific input was limited. Unfortunately, he had sufficient credibility to spur a nuclear explosion in the Congress on the "human cloning" issue.

¹³⁸ If a fertilized embryo is the equivalent of a human being, it would follow that any IVF clinic that discards an embryo that a couple decides not to use for IVF is committing murder. In the IVF process, dozens of embryos are created and only a few are implanted. The rest are

saved or discarded. Estimates are that there are hundreds of thousands of these fertilized embryos in IVF clinics. The idea that it should be a crime to discard any of them is not likely to find a positive response in Congress.

¹³⁹ Despite President Bush's veto threat, the House voted on May 24, 2005, in favor of a bill (H.R. 810) sponsored by Reps. Mike Castle, R-Delaware, and Diana DeGette, D-Colorado, to lift Bush's 2001 ban on federal funding for new research using stem cells from embryos that had not been destroyed before August 2001. Bush called the bill a mistake and said he would veto it. The House approved it by a 238-194 vote, far short of the two-thirds majority that would be needed to override a veto. Supporters of the measure said many embryos that would be studied would otherwise be discarded rather than implanted in the wombs of surrogate mothers. The moral obligation, they argued, rested on Congress to fund research that could lead to cures for diseases like Parkinson's and Alzheimer's. The House vote on the Castle-DeGette bill was intended mostly as a show of force to help propel it through the Senate and, the sponsors hope, into compromise talks with the White House. It's not clear what Senator Frist will do with the measure, but it's clear that the Congress is not poised to enact a criminal penalty for embryonic stem cell research. To show how the political climate on stem cell research has changed, the July 2005 issue of *National Geographic* features an article on stem cells with titles such as "With more and more countries aggressively developing stem cell therapies, the United States is in real danger of being left behind," "A five-day old embryo is smaller than the period at the end of this sentence [and] has no identifying features or hints of a nervous system," and "proponents say it's immoral not to use leftover embryos to save lives...."

¹⁴⁰ Rachel is currently director, Office of Government and Industry Liaison, The Biodesign Institute, Arizona State University. Previously Rachel was with the White House Office of Science and Technology Policy handling life sciences issues including biotechnology under the administrations of George H. W. Bush, Clinton, and George W. Bush. She was on detail from NIH. At NIH, she'd worked on establishment of the NIH component of the Human Genome Project, and in the Office of Technology Transfer and the Office of Recombinant DNA Activities, now called the Office of Biotechnology Activities.

¹⁴¹ See S. 1764 introduced by Senator Lieberman on December 4, 2001.

¹⁴² See the testimony of Senator Lieberman at an October 6, 2004, hearing of the Senate Judiciary and HELP Committees.

¹⁴³ PhRMA is the Pharmaceutical Research and Manufacturers Association, which represents the large pharmaceutical firms. BIO represents the small biotechnology companies. There's

a complicated relationship between the two.

¹⁴⁴Charles Lewis and the Center for Public Integrity, *The Buying of the President, 2004: Who's Really Bankrolling Bush and His Democratic challengers—And What They Expect in Return* (New York: Perennial, 2004).

¹⁴⁵ Public Law 108-276.

¹⁴⁶ Richard A. Clark was the former White House anti-terrorism leader for the Clinton and Bush administrations. On March 24, 2004, he testified before the National Commission on Terrorist Attacks Upon the United States (the 9/11 Commission) that the Bush administration had not taken the threat of terrorism seriously.

Subsequent to this interview I became aware that the Senate Republicans were drafting their own bioterror/infectious disease bill to be included in the Senate Republican leadership bills introduced on January 24, 2005. I had circulated my draft BioShield II bill widely, including sending it to many Republicans and administration officials. The result was that the Republican leadership bill for the 109th Congress, S. 3, was taken largely verbatim from my draft.

I managed to persuade the Republicans to steal my draft for one good reason—they know I am an expert on these issue and they can have confidence following me. They did not apologize for stealing my work product, or for not asking permission to do so, but I have no concern about that. They know they are indebted to me and I find that they are coming back again and again to me for more substance.

When the Republican bill was introduced, I sent out the first word to my master email list, praising the Republicans, but also pointing out that they'd "borrowed" our bill. I also emphasized that Senators Lieberman and Hatch were shortly to introduce the real deal, the refined and upgraded version of our BioShield II bill, and that everyone should look to that for the real substance.

In order to persuade the Republicans to steal or borrow more of my work product, to take our BioShield II bill and substitute it for the text of S. 3, I conducted a quasi-public drafting process on BioShield II. The Republicans had worked off my December 15, 2004 draft and I proceeded to vet additional drafts in February and March and April. I sent out my drafts to my entire "bioterror" email list—six hundred experts. The recipients probably forwarded the draft to one thousand more experts. Not a single one of them leaked my drafts to the press. I did all of this in plain view of the Republican staffers, who are all on the same list.

In doing this, I was making the point that I was drafting the penultimate bill, that I had access to experts that they couldn't match, and that they would be fools not to steal or borrow more of my work. I wanted to show them that I was way out in front of them and running at full speed. I wanted to freeze any effort on their part to drafting their bill and wanted to force them to wait for my final bill to be introduced. I'm trying to control the

process indirectly, through my command of the substance.

Part of my thinking here is that Senator Lieberman is not a member of any of the key committees that will consider this legislation. So the high water mark of our influence may well be when BioShield II is introduced. I was also thinking about my planned retirement to go serve in the Peace Corps, so I wanted to maximize my influence early in the process.

The new Lieberman bill, S. 975, was introduced on April 28, 2005. It is 360 pages long with 29 titles. It's an aggressive, serious, and comprehensive bill. It challenges the Republican leadership, particularly Senator Frist, to be serious about the issue. It's also a challenge to the administration.

I invented a very interesting way of organizing this effort. All of the e-mails I sent out were sent to people on a blind copy, BCC, basis, so that no one could "reply all" and use my list. I kept total control of it. They didn't know who else was on the list. They couldn't post a message contradicting mine. They were quite captive and dependent. This gave me great power to propagate my views. I would send out the most frightening information—all attempting to motivate people to back my aggressive proposals. I began to get everyone feeding me very up-to-date information that everyone wanted to see. So many people came to me asking to be placed on the list. I have enlisted the top six hundred experts in the world and given them an incredibly aggressive bill to follow.

The biggest problem is that the bill falls within the jurisdiction of so many Senate Committees. S. 3 has provisions for HELP, Judiciary, Finance, and Banking. BioShield II adds Agriculture, Homeland Security, Environment and Public Works, Foreign Relations, and perhaps Commerce. I've proposed to the leaders of the HELP Committee that it report out a bill including the architecture for a comprehensive bill, and whenever a provision falls within another committee's jurisdiction, it should insert brackets and name the committee of jurisdiction, e.g. "[Finance Committee]." This will put tremendous pressure on Senator Frist to organize all of the committees to contribute their elements of the comprehensive bill. I've said to the HELP Committee leaders that this is the only way they can show that they are attempting to secure a comprehensive bill and won't be left holding the bag on a narrow, unimpressive bill. I've also said to Senator [Richard] Burr, chairman of the Public Health Subcommittee, that if he handles this well, he is perfectly positioned to be the vice presidential nominee on the next Republican ticket. If there's an attack or an outbreak, and he's been the leader in attempting to prepare us for it, he'd be the perfect choice. He's also smart, telegenic, and geographically correct.

The introduction of the Republican bill, S. 3, was a massive victory for me because now there is little doubt that the Congress will, in fact, enact BioShield II. The details are in doubt, but I am confident we'll enact an aggressive and significant bill based very much on my concepts and drafting. How this all turns out will not be known until after this oral history is finalized.

On my last day in public service, I sent out one last email to the six-hundred-person mailing list I'd developed. It stated in part: "It is urgent that you maintain the pressure on Senator Frist and the Administration. The fate of this legislation lies almost entirely in their hands. Senators Lieberman, Hatch, Brownback, Enzi, Burr, and Gregg have provided superb leadership, but there are severe limits on what they can accomplish without the

leadership of Senator Frist and the Administration. Only Senator Frist can bring together all of the Senate Committees with jurisdiction over elements of BioShield II. Here's the cite to his recent speech on bioterrorism, which is long on analysis and painfully short on prescriptions for action: http://frist.senate.gov/_files/060105manhattan.pdf. Compare it to Lieberman's speech, printed below, which is long on both. Also, nothing will happen until the Administration finally states unequivocally that we need to enact something like BioShield II. . . . Thank you all again for your support. This is your legislation to win or lose. It's yours to win now. My role is over. I wish you the best and will be forever grateful for your support. Bless you all."

¹⁴⁷ Kira Bacal joined Senator Hatch's staff and Wendy Shelton joined the Lieberman staff in 2005 and they have proven to be incredibly helpful. Kira has a PhD, an MD, and an MPH and Wendy is a veterinarian, so they actually understand all the science. Working with professionals like them, with their knowledge and sense of humor, makes this work an easy job.

¹⁴⁸ It was actually introduced in late April.

¹⁴⁹ I successfully recruited support for the bill from a wide ranging coalition of groups focusing on AIDS, TB, and malaria research. It all started with Bob Guidos of the Infectious Diseases Society of America (IDSA). Bob is another former Peace Corps volunteer, so we tend to look at the world the same way. I worked with Bob and IDSA for over a year and it determined that the only serious proposal for developing these countermeasures—principally new antibiotics—was mine. Bob is a first-class professional and a delight to work with. So IDSA became leaders in fighting for my ideas. Then Bob led me to Peg Willingham who represents the International AIDS Vaccine Initiative (IAVI), which has now endorsed my bill. Peg is also a first-class professional and a delight to work with. That led me to other groups and voila, we have an infectious disease coalition. This white hat endorsement puts the left wingers—like Kennedy and Schumer—very much on the defensive. It's perfectly appropriate that I will now be headed off to Senegal, where AIDS and many of these infectious diseases are a major problem. I've had the great pleasure to work with a brilliant group in developing this legislation: George Poste, the preeminent expert on bioterrorism in the world; Richard Danzig, a neighbor and former navy secretary; Frank Rapoport and John Clerici with Gil Cuneo's old firm; Dack Dalrymple, world class expert on procurement and vaccine issues; Jeff Kushan, my patent guru and ally on the PTO utility guidelines; Jim Rafferty, my tax expert; Dave Schmickel, my dear friend; Bruce Artim, Patty DeLoatche, and Kira Bacal with Senator Hatch's staff; Anne Solomon of CSIS; Steve Lawton of BIO and NABI; Leighton Read of Alloy Ventures; Susan Geiger of Preston Gates; Tara O'Toole and Brad Smith of the BioSecurity Center; Mike Hopmeier of Unconventional Concepts; Val Giddings of BIO regarding bioag terrorism; Rachel Levinson, a world class expert on life sciences issues; Klaus Schafer of DoD; Cynthia Schneider and Mike McDonald at Georgetown. I consider

all of them to be friends and supporters. They're visionaries who care deeply about these critical issues. If the nation knew them, they'd feel safer and very grateful.

¹⁵⁰ Following is an argument I have been circulating widely in the administration: "The flu vaccine debacle is just the tip of a massive vulnerability for the Bush Admin. in the second term. A Bioterror attack or contagious disease outbreak (SARS, avian flu) would make 9/11 look trivial. The President almost lost the election because of the flu debacle. His second term will be a mess if it's marred by a failure of leadership to prepare for an infectious disease. That would lead to another 9/11 Commission! And there would be multiple 'Richard Clarks' to expose the Administration's indifference to the threat. Lieberman proposed what became BioShield. He's now drafting BioShield II. He wants to work with the Admin. He's got Hatch, Gregg, and Enzi on it. Reports are that he's trying to get Clinton! BioShield is the Admin.'s brand. Proposing BioShield II is the right moniker for this new initiative. Getting ready for infectious disease is worthy of a mention in the State of the Union address. It's important enough to be mentioned in the Inaugural Address. The policy issues here are very complex, but the key problem is that the biopharma industry is not interested in this research—to develop drugs and vaccines to deal with an outbreak. If we don't have drugs and vaccines, we'll get quarantines—which are very ugly. The industry does not trust the government—AT ALL. So we have to overcome this suspicion with incentives. These incentives will drive some liberal Democrats nuts, but that's probably a desirable thing from the Admin.'s point of view (witness Cleland and Carnahan). If the Admin. waits for Tony Fauci to develop these medicines, we'll never get ready. At a minimum the Admin. has to make some bold gestures at solving this problem and getting us ready. We won't be ready for many years to come, but it's imperative that the Admin. show that it's taking this threat very seriously. There is zero political risk of proposing bold incentives. The risk comes from not leading and not pushing the Congress to take decisive steps."

¹⁵¹ We will never be able to anticipate all of the pathogens that might be utilized by terrorists. Our medicine chest will never have all the medicines we need for all the possible terrorist pathogens. The ultimate and only effective bioterror defense are "research tools" powerful enough so that we can develop and deploy new countermeasures quickly after an attack has occurred. We need this power to respond to Mother Nature's new concoctions, like SARS, but it's also the only defense against exotic terror pathogens we'll never see in advance of an attack As stated by the leading biodefense think tank, "The process of moving from 'bug to drug' now takes up to ten years. The U.S. biodefense strategy must have as one of its key strategic goals the radical shortening of this process." The development of research tools is a central focus of the bills that Senator Hatch and I have introduced and it will be a central focus in BioShield II and all of the incentives in BioShield II will apply to the development of research tools.

¹⁵² *CQ Homeland Security* published an article regarding my retirement on May 20, 2005, "The Gods Must Be Crazy: Biodefense 'Visionary' Chuck Ludlam Is Off to Africa," By Eileen Sullivan and Sean Madigan, CQ Staff.

¹⁵³ Kent is associate professor of insurance and risk management. He's served as economist, Congressional Budget Office, 1995-98; faculty research fellow, Aging Program, National Bureau of Economic Research, 2000-present; research associate, Public Economics, National Bureau of Economic Research, 2001-present; deputy assistant secretary of Economic Policy, U.S. Treasury: 2001-2002; member, Blue Ribbon Advisory Panel on Dynamic Scoring, U.S. Congress (JCT), 2002-present; member, National Academy of Social Insurance, 2002-present; research associate, Michigan Retirement Research Center, 2000-present. Among his seminal writings on fiscal issues are, "Measuring Social Security's Financial Problems" (with Jagadeesh Gokhale), (December, 2004); "Fiscal and Generational Imbalances: New Budget Measures for New Budget Priorities" (with Jagadeesh Gokhale); Testimony before the Subcommittee on the Constitution, House Judiciary Committee (March 2003). Jagadeesh now operates out of the Cato Institute. He's a former senior economic adviser to the Federal Reserve Bank of Cleveland. He served in 2002 as a consultant to the U.S. Department of Treasury (working with Kent) and in 2003 as a visiting scholar with the American Enterprise Institute. He has coauthored many of key fiscal policy studies with Kent. At Cato he's authored, "The Impact of Social Security Reform on Low-Income Workers" and coauthored "Social Security Privatization: One Proposal" (with David Altig).

¹⁵⁴ Supply-side economics was born in an igloo shaped curve drawn on a cocktail napkin by economist Arthur Laffer at a meeting at a restaurant in the late 1970s as Laffer and Robert Mundell described the concept to Jude Wanniski. The curve was used by Republicans to justify tax cuts. The Laffer curve and supply side economics inspired the Kemp-Roth Tax Cut of 1981. Supply-side advocates of tax cuts claimed that lower tax rates would generate more revenue because government was operating on the right-hand side of the curve. Conventional economic paradigms acknowledge the basic notion of the Laffer curve, but argue that government was operating on the left-hand side of the curve, so a tax cut would thus lower revenue. The central question is the elasticity of work with respect to tax rates.

¹⁵⁵ For a frighteningly realistic projection of how our country could experience a "meltdown" see "Countdown to a Meltdown," by James Fallows, *Atlantic Monthly* (July-August 2005) at 51.

¹⁵⁶ Three of the provisions of this bill illustrate the complexity of this issue. One requires the president to submit new estimates of the long-term shortfall in funding for the government. Here is what the bill requires of the president: "For the 75-year horizon under clause (i)(I), each calculation shall take each year's expenditures minus revenues, divide this difference

by the projected discount factor for that year, and add the resulting 75 annual discounted flows to obtain the program's net present value imbalance. The long-term discount and growth rates utilized in these calculations shall be discussed in the report and consistent with those utilized by the Department of Treasury and other government agencies with regard to other long-term financial calculations. For purposes of the calculations in clauses (iii), (iv), and (v) of subparagraph (A), revenues will include payroll taxes as allocated by law to the respective Trust Funds (currently the case for OASI, DI, and HI), participant premiums (for SMI), general revenue receipts from the taxation of benefits, as currently allocated by law to the OASI, DI, and HI Trust Funds, and funding for the Federal retirement and health insurance systems, both civil and military. For purposes of this calculation, revenues will not include interest income on Trust Fund and transfers of general revenue to SMI, Social Security, or Medicare."

Another provision calls for the president to submit estimates for the long-term cost of legislation he proposes. Here's what the bill requires of him: "If the net present value of the Government's overall liabilities and commitments of a legislative recommendation or recommendations is found to have an adverse impact greater than 0.25 percent of the present discounted value of all future payrolls over 75 years or an indefinite horizon, the President shall submit a plan to accompany such recommendation or recommendations that reduces the total of debt held by the public added to the calculation of the net present value of the Government's overall liabilities and commitments published, as required by section 331(e)(3)(A)(i) of title 31, United States Code, to a level that exceeds 1.25 percent of the present discounted value of all future payrolls as of September 11, 2011. Such plan shall be submitted with regard to calculations based both on a 75-year horizon and an indefinite horizon."

Another provision sets up a point of order against legislation that has a negative long-term fiscal impact. Here's how the legislation defines this point of order and how it sets up strict rules of construction in scoring the proposal: "It shall not be in order in the House of Representatives or the Senate to consider any bill or resolution (or amendment, motion, or conference report on that bill or resolution) that changes direct spending or revenues that would, when considered together with any other legislation passed by that House or enacted prior to such consideration during that calendar year, cause an adverse impact on the net present value of the Government's overall liabilities and commitments incurred by that measure over 75 years or an indefinite time horizon that is greater than 1.25 percent of the present discounted value of all future payrolls. The calculation required by this subsection shall assume that the legislative measure subject to the point of order will be a permanent change in law and disregard any changes in the terms of the legislative measure and any formula or mechanism for adjustments in the recommendations beyond the date of enactment to the extent that such change, formula, or mechanism decreases the net present value of the Government's overall liabilities or commitments over 75 years or an indefinite time horizon."

¹⁵⁷ In early 2005, CBPP decided not to issue its report and began to negotiate a new budget process bill based on mine. If CBPP and my conservative economist allies reach an

agreement, we'll have a left-right coalition that might be quite powerful.

¹⁵⁸ Jen is legislative director for Senator Lindsey O. Graham, R-South Carolina. She specializes in Social Security, tax, and budget policy. Prior to joining Senator Graham's staff, she served as legislative assistant for Congressman Jim Kolbe, R-Arizona, where she focused on Social Security and health care issues. Before coming to the Hill, she was a research assistant at the American Enterprise Institute and Pension Policy Analyst at the American Academy of Actuaries.

¹⁵⁹ Maya serves as president, Committee for a Responsible Federal Budget & Director, Fiscal Policy Program at the New America Foundation. Before coming to New America, MacGuineas served as a Social Security advisor to the McCain for President campaign. She has also worked at the Brookings Institution, the Concord Coalition, and on Wall Street. She received her master in public policy from the John F. Kennedy School of Government at Harvard University and serves on the boards of a number of national, nonpartisan organizations.

¹⁶⁰ Deng was born in Sichuan province in 1905. In the '20s he commanded communist guerrillas against Chinese Nationalists. In 1956 he was appointed general secretary of Communist Party, but then he was purged by Mao from 1966 to 1969 during China's Cultural Revolution. In 1975 he surfaced as the vice premier and vice chairman of Communist Party. By 1976 he was expected to advance as premier, but he was again purged. In 1978 he won a power struggle against Mao's successor and became China's paramount leader. He remained the paramount leader until 1987 and died in 1997 of Parkinson's disease. He will go down as one of the most important political leaders of the twentieth century and his legacy may dominate the twenty-first century.

¹⁶¹ The bill was introduced as S. 1117, the U.S.-China Cultural Engagement Act, on May 25. Paul Brand and Hassan Tyler in my office did most of the work and managed a glorious rollout event, with lots of American students speaking in Chinese about how important it is to engage with China and learn its language. The timing for the introduction couldn't have been better; Tom Friedman has just published a fascinating book about the flat world, which argues that China is critical to the twenty-first century. Paul and Hassan could not have been more effective in developing my idea into a practical, ambitious and visionary bill. We named the titles of the bill after famous Chinese, specifically Du Fu, Wang Xizhi, Zheng He, Sun Yat-sen, Zhou Xinfang, Cai Lun, Ieoh Ming Pei, and Wang Wei. We printed a short history of each of them in the bill. We tried valiantly to persuade the Rules Committee to permit us to print these names in Chinese script, arguing that that this was consistent with the theme of the bill. We failed to persuade them. If they had agreed, it would have been the first time any bill was printed with non Latin script. I'm constantly thinking of new ways to

accomplish things in the Senate. In drafting the bill, we reached out—as is always our routine—to the various groups with expertise or interest in the matter. We approached the Embassy of China and they came in for a meeting. We explained that we wanted their views, would keep all of our conversations off the record, and would not imply that they were endorsing the bill. This type of consultation was something they'd apparently never encountered, so it took some months for them to become comfortable with what we were asking of them. Then they began to open up about their concerns about our draft, which centered on two issues. First they were concerned that any funding of programs in which any of the participants were from Taiwan would imply U.S. recognition of Taiwan. We emphasized that we were only focused on cultural exchanges, not political ones. But this was not sufficient to allay their fears, so we eventually limited the bill to U.S.-P.R.C. exchanges. Second, they were concerned that any bill might become a vehicle for opponents of the P.R.C. We emphasized that in a democracy we could not stop anyone from offering such an amendment, but that we and the administration would oppose any such amendments, and we were confident those amendments would fail. These discussions were quite fascinating. They were, in effect, cross-cultural exchanges, exactly what we intend to spur in the bill, and they revealed just how important it is for the United States to learn more about the Chinese and their culture. Just prior to my retirement, the embassy hosted a farewell dinner for me, a truly gracious gesture by embassy staff we'd come to respect.