of choice for vacationers and sports enthusiasts from around the nation and the world.

His efforts on behalf of the homeless and dozens of charitable organizations ranging from the Special Olympics to the Epilepsy Foundation to the Humane Society are not well-publicized, but they point out that, when it comes to community service, Ron Book is all business. In the highest traditions of public service, he is most generous with his time and attention in helping people who cannot themselves solve the problems that they face.

I have known Ron Book since he was just a youngster, making a name for himself working on local campaigns. As is the case today, everyone who met him then was impressed with his intelligence, hard work, devotion to principle and leadership capabilities. No one was surprised that Ron served as Vice President of his High School Class, or served in the University of Florida's Student Senate, or that he started working for a Florida legislator before he even graduated from college.

Because of his interest in government and desire to develop his own considerable capabilities, law school was a natural next step for Ron, as were his service as a Special Assistant to Governor Bob Graham; his employment in two of Florida's preeminent law firms; and the creation of his own law firm.

On December 14, 1999, Ron Book's achievements will be recognized at a testimonial dinner sponsored by the American Association of Bikur Cholim Hospital, Jerusalem's first hospital and one of Israel's preeminent medical care facilities. Mr. Book will be presented Bikur Cholim's International Brotherhood Award in recognition of this outstanding contributions to both his profession and our community.

Mr. Speaker, I know that my colleagues join with me in congratulating Ronald L. Book on this great honor.

TRIBUTE TO RABBI GERSHON AND SHARENE JOHNSON

HON. BRAD SHERMAN

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, November 18, 1999

Mr. SHERMAN. Mr. Speaker, I rise today to pay tribute to Rabbi Gershon and Sharene Johnson in honor of their ''Silver Celebration'' at Temple Beth Haverim in Agoura Hills, California. This loving couple has spent 25 years as leaders in the Jewish community, both spiritually and educationally.

Rabbi Gershon Johnson has served as Rabbi at Temple Beth Haverim since 1988. He is described by many as the temple's incomparable spiritual leader. His devotion and expertise as a Rabbi are evident in his presence as a chaplain for the Southern California Board of Rabbis. He has always been extremely interested in passing on his love for and knowledge of Judaism. The Elderhostel program at the Brandeis Bardin Institute has benefited from Rabbi Gershon's knowledge, and he is one of their most popular teachers. He also has been instrumental in introducing religion to beginners through his ''Introduction to Judaism'' class sponsored by the University of Judaism.

Sharene Johnson is the wife of Rabbi Gershon, and has worked for the betterment of the Jewish community in many different ways. She has taught at several Jewish day schools throughout the United States, and has been involved in programming and consulting at Jewish resource centers as well. Her leadership has shone through as chairperson on the Principal's Council at the Bureau of Jewish Education. For the past 11 years, she has passed on her wealth of experience and knowledge as Director of Education at Temple Ner Marev in Encino, California. The Jewish community also enjoys her teaching through adult workshops and her conducting of a women's Torah Study class at Temple Beth Haverim.

In addition to their devotion to the temple, they have become a model of excellent family life and values. Rabbi Gershon teaches the ''Making Marriage Work'' program at the University of Judaism. Sharene leads several family workshops each year, and has spent much of her time working with families and children. They have been happily married for 27 years and have raised 3 wonderful children—Gavi, Rachel, and Aliza.

Mr. Speaker, distinguished colleagues, please join me in paying tribute to Rabbi Gershon and Sharene Johnson. They are both deserving of our utmost respect and praise.

HONORING EDWARD WEISS

HON. ELIOT L. ENGEL

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, November 18, 1999

Mr. ENGEL. Mr. Speaker, public service, when performed wisely and well, is the most noble of callings. I speak today to honor a man who has been in public service and who performed in just those ways. Edward Weiss is retiring from the United States Department of Justice, Immigration and Naturalization Service, after 30 years of service.

In his many capacities with the Department, Ed has received outstanding performance ratings from every United States Attorney General under whom he has served since 1981. He is well known for his ability to prepare and litigate cases. He also coordinated the Criminal Alien Program for the New Jersey District.

Ed received his BA degree from Syracuse University and graduated from Brooklyn Law School. He and his wife Susan have two daughters; Robyn, in a pre-doctorate program in Religion at Hebrew University, and Karen, studying law at George Washington University.

Ed is retiring to follow his other passions, hiking and traveling. He is a dedicated professional of who we can all be proud. I join his many friends in wishing him and his family many happy years in his retirement.

CAL BIO SUMMIT CEO SATELLITE CONFERENCE WITH MEMBERS OF THE U.S. HOUSE OF REPRESENTATIVES ON OCTOBER 26, 1999

HON. BRIAN P. BILBRAY

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, November 18, 1999

Mr. BILBRAY. Mr. Speaker, I insert the following for the RECORD:

RICHARD WILLIS. Good morning, I am Richard Willis, the Regional Manager of ComDis Co. Laboratory and Scientific Services. We are delighted to participate in this first ever BIOCOM Satellite CEO Conference. I think it is a compelling measure of the progress that is being made by so many dedicated people here in this business in San Diego over the past few years. ComDis Co. has a strong presence and a long presence in San Diego. The short commercial is that we offer services ranging from venture finance for early stage entities through to life cycle management services for more advanced companies in this business. We have a local representative here, Gail Obley who is presently working with many of you. Again, we are delighted to participate as a sponsor and wish you well in this activity. Thank you.

NARRATOR. Welcome to the Satellite CEO Conference with the Commerce Committee of the U.S. House of Representatives. In San Diego, on today's panel are: President and COO, Alliance Pharmaceutical Company, Ted D. Roth, President and CEO, IDUN Pharmaceuticals, Inc. Steven J. Mento, Ph.D., President and CEO, BIOCOM/San Diego, Joe Panetta, President and CEO, California Healthcare Institute, David L. Gollaher, Ph.D., Chairman, President and CEO, IDEC Pharmaceutical William H. Rastetter, Ph.D, Founder and CEO, INNERCOOL Therapies, Inc., John Dobak, M.D., and your moderator for today, Chairman and CEO, Alliance Pharmaceutical Company, Duane Roth.

DUANE ROTH. Let me start and just briefly introduce our panel members: First, Ted Roth who is President of Alliance Pharmaceutical, Bill Rastetter, who is Chairman, President and CEO of IDEC Pharmaceutical, Steven Mento who is President and CEO of IDUN Pharmaceuticals, David Gollaher who is President and CEO of the California Healthcare Institute, John Dobak who is the Founder and CEO of INNERCOOL Therapies, and Joe Panetta who is President and CEO of San Diego's BIOCOM. Let me suggest that we go into the issues, if that's OK with you, that we would like to have a discussion or a dialogue with you on. And for that we've got a moderator for each topic. Congressman, did you want to say anything?

Congressman BILBRAY. I need to inform you, before we get started, that the transcipt of this panel will be entered into the congressional record. So don't say anything that you don't want your grandchildren to read. But, seriously, we want for this dialogue to reflect the fact that these are issues that the biotech industry needs to have addressed and wants to have addressed. So you have been duly warned.

DUANE ROTH. We have been warned, and I guess that changes just about everything. However, let me turn to Ted and let him get the first issue on the table.

TED ROTH. Good morning Congressman, or afternoon I guess out there. Thank you for participating in this program. The issue that I would like to discuss briefly is the access to capital as the issue we are facing right now. As you know, San Diego has about 250 companies that are engaged in the various aspects of bioscience. We employ nearly 25,000 people. And spend over a billion dollars a year in research and development. We are the third largest concentration of biotech companies in the nation, or the world for that matter. All of these companies are similar in their issues to the roughly 1,300 other biotech companies in the United States.

Yesterday we had a panel of analysts who talked about the financing environment, both in the public and private markets. As most of us know, they talked about the difficulty in raising money with companies having valuations under approximately between 750 and a billion dollars. I think it is

interesting to know that the only company in San Diego that has a market valuation in excess of a billion dollars, in fact, it is greater than two billion, is IDEC Pharmaceuticals. So the vast majority, virtually all of the companies in San Diego are under this level that they talk about being difficult to finance. Most of these companies have less than two years of cash, and many have less than one year. We are currently working on about 75 products that are at a late stage clinical development. And as this development continues, the need for capital to make it through the clinical trials and prepare for commercialization will only make the financing issue more dramatic. Therefore, what we have is a situation where companies have products that are nearing approval that are running low on cash and are facing a dubious financing environment.

The federal government can take steps to help to create a better environment for us. Most of us remember what it was like in 1993 and 94 with the Clinton Health Care Plan where what was going on in Washington had quite a dramatic effect upon us. While we don't expect that there is anything that can be done now to have that kind of affect on the positive side, we think it is important for the legislators to understand that what you do in Washington really does matter to us.

What I want to do is put three issues on the table. The first is the R&D Tax Credit. And I guess that I would ask that you comment on what you think the chances are that it will either be extended or made permanent during this Congress.

The second issue is Capital Gains and taxation on increases in capital investment. Do you expect, or should we look for any legislative changes to the existing law.

The final area and the one which is relatively recent. We heard this morning about the New Jersey model whereby the biotech companies are able to transfer a part of their state NOLs to the larger pharmaceutical companies under certain circumstances. This is something that the California Legislature is looking at, they are studying a comparable bill. So I guess, the question I would pose is, what, if anything, can we anticipate at the federal level on an issue such as the NOL transfer?

Congressman BILBRAY. Well I think first of all, let me comment on the fact that you pointed out appropriately the problems that, while we may be talking politics in Washington, things like the comments that were made about the first lady's health care plan—the damage that does. Coming from you, it just shows that this is not a partisan issue, but that all of us in Washington have to be sensitive to the fact that there are more than just political games in Washington at stake here. We are talking about the breakthrough drugs and major investment, so I am glad that you bring that up because it brings credibility to the discussion on both sides.

The one thing we've got to watch out for, as you've seen in the last couple weeks, there is posturing of ''let's use the availability of drugs and pharmaceuticals to the public as some kind of political ping-pong ball which really hurts you guys right on the front line.'' And let's face it, on the other side of it, you've got to compete against other venture capital opportunities. It seems like recently we've seen that if something has a ''dot-com'' on the end of it, it is basically being perceived as a gold mine. I think hopefully we will see that moderate a bit and that BIOCOM will be on the line there.

Let me get right to your questions. The R&D Tax Credit is a very high priority. I think that it is a good possibility that somewhere down the line in the next few weeks that we will see a way to place that into a bill that the President will sign into law.

The capital gains issue: I think right now, as long as the economy is still strong, no, we won't see that move forward. I think that the Capital Gains, as the Chairman of the Federal Reserve has said, is something that will be used if we see a softening of the economy. It is the adrenaline we'll give the patient, that will stimulate the patient to get the economy moving again. So that will be incremental and will be based on when we need to stimulate the economy. What I think that you are going to find now is that the discussion coming out of DC will effect the latest numbers on inflation. So I see that as being sort of a negative.

Let me just tell you that this New Jersey model and what we are doing for California. That is totally wide open. I am basically open for suggestion on that. I couldn't tell you one way or the other. You would probably be able to tell me better about that aspect.

DUANE ROTH. Would you like to make another comment about Net Operating Loss? No? OK. Then let's move on. If we can we will move on to our second topic, and that is the Food and Drug Administration. You have been very much involved in the past in helping us with some issues with the FDA and the 1997 legislation. I'd like to turn to Bill Rastetter and ask him to make some comments regarding user fees and the modernization act. Maybe we can discuss that and then we have a second part that we'd like to talk about. Steve Mento will talk about that, and that deals with appropriations and the mission of the FDA. So, Bill, I'll let you go first.

BILL RASTETTER. Congressman, thanks for being with us here this morning. I would like to talk about PDUFA and FDAMA. For the audience here, that may not use those acronyms every day; PDUFA is of course the Prescription Drug User Fee Act under which those of us developing drugs pay certain fees to the Food and Drug Administration that helps with the hiring of reviewers and the review process. Of course, FDAMA is the FDA Modernization Act of 1997.

Congressman, I'd like to give you a little feedback from the sector. We think that PDUFA has really been an unqualified success; both for patients and for biotech companies. It has provided for very substantial funding and fast track reviews of products. I know that our own company, IDEC, has certainly benefitted from that with the 9 month approval that we obtained for Rituxan.

I think the metrics really speak for themselves. With PDIFA, the act was passed originally in 1992 and in that year there were 26 new drugs approved. By 1996, with 600 reviewers hired with user fees there was a record of 53 new drugs approved by the Food and Drug Administration. In fiscal '96, that was the year when those 600 reviewers were on board and I guess still being trained and getting into the swings of things, I&D to approval, of course I&D was many years earlier, I&D to approval for drugs approved in '96 was greater than 90 months. By '98, just two years later, that was down to less than 60 months from application to begin clinical trials to approval, a dramatic change.

So I think that it is essential that we continue to build on this momentum. It is something that came out of PDUFA and the awareness, that yes we really could do something that we could work with the FDA as a partner, something that came out of that with lots of congressional help and dialogue with the sector was FDAMA, through which Congress provided tools to improve and modernize the review process. I am delighted to tell you today, that I think that from our sector at least, the feedback is generally positive. Certainly we at IDEC view the FDA as a responsive and very active partner in drug development, where we are really jointly making drug development decisions on a real time basis with the FDA, rather than being second guessed after the fact, and this is absolutely critical. Important to being able to achieve this is absolutely critical to have a scientifically trained, well compensated and motivated and retained staff. I know that Steve will speak about that. I think that all the feedback is not positive. Some critics would say that the FDA is still failing to insure that the FDA is failing to ensure that all patients receive our technologies promptly and efficiently. I would refer you to the recent testimony of Pamela Bailey, who is the president of HIMA, or Health Industry Manufacturing Association to the Senate Committee on FDAMA that was as recently as the 21st of this month.

Of course, HIMA is the device trade association. I think that being in the biotech or the therapeutic side of the industry, I would have to ask if the device sides experience with the regulatory process might not be more positive today if they had put in place a PDUFA type act that would provided through user fees the increase staff at the regulatory agency. I'd welcome your comments on, either now if you wish, or after we wrap up.

I think though, that by and large, the FDA is more performance oriented these days, and have been really gratified to see the FDA reengineer itself and be proactive and responsive to the climate, and also pro-active to try to manage the increasingly complex workload with human resources. I think that the metrics at CBR which is the biologic side of the house at the FDA are very telling. In '86 there were 178 I&Ds, or IDE's, these are the new applications to take something into the clinic. So '86—178, by '95—452, by '99—587. If you look at the balance of those that were in Biotech, went from 87 out of 178. This year an expected 427 out of 587. So the balance is really shifting in the bureau of biologics over to biotech and the workload certainly up more than threefold in the last 13 years or so.

Yet, the operating allocation dollars to CBR have gone down. '96 was less than '95, '97 less than '96, '98 less than '97. '99 is slightly up, but it is still in constant dollars down over 10% from '95 in this environment of increased complexity, because of technology, more and more is biotech which takes more scientific review and the number of applications are way way up. So, certainly continued funding growth is essential if we are not going to lose this momentum and indeed we are going to continue to build on this momentum, and Steve will comment on these things.

Two very very important areas, and I don't want to preempt you. Trained scientific staff at salary at parity with peers in the industry, because if you can not achieve that you will never solve the problem of turnover at the Food and Drug Administration.

Number 2, information technology. I think this is the single most important factor that can contribute to increased efficiency in the food and drug administration. And we are moving from boxes and boxes, pounds and pounds of applications to single CDs that are hyper linked where the reviewers can go back and forth very quickly, gosh they can take the whole BLA home in their pocket if they want, and work on it over the weekend. An incredible efficiency to be gained if we can get the Food and Drug Administration up to speed in information technology and that will certainly require the hiring of trained motivated retained staff to put all of that in place.

Another point that I want to make is that it has been very popular in this country to

fund the National Institutes of Health. Indeed, our entire sector has come out of the enlightened funding of the NIH that we have had in this country for decades. But, we have to view the NIH and the FDA as bookends with all of our companies being the books in between. All of the books will topple off the shelf if we pull out that FDA bookend. We need to support the industry from both ends from basic science through the regulatory process, we have to be very very sure that we are buttressed from both ends.

In closing, I think that the agency got a very big boost with the appointment of Dr. Jane Henney. She has an exceptional record of leadership, both in academia and in government, an intimate knowledge of the food and drug administration having served as the deputy commissioner for operations from 1992 through 1994, I think that everybody views that the direction she has said would establish a more efficient, more responsive, more open and better understood agency. I think that from the perspective of our sector, I would like to suggest three very very important objectives for the commissioner to focus on.

Number one. To ensure that drug, biologics, and device approvals don't get sidetracked by new activities at the FDA such as tobacco and food. And Steve will comment on this. I think that one tool that should be implemented for that is a PDUFA type act for devices to increase reviewers at the FDA for the device sector.

Objective #2 is a strategic one. To continue to build a modern strategic vision for the FDA. Let me give you three objectives that CBR has identified for itself that I think are just superb and really speak to the scientific quality today within CBR. Three objectives, their own. Establish bio-markers and surrogate end points for clinical trials to make clinical trials more efficient and make approvals more streamlined. Number two. To restore protection to large segments of the adult population with biotech vaccines. The old vaccine technology is failing in many regards. Number three. The identification and use of gender specific factors that influence, or might influence drug and biologic safety and efficacy. That is the kind of strategic leadership, objective number two, the agency needs.

Number Three. A tactical counterpart to that. Building on PDUFA and FDAMA ensuring that through an inside focus on operations, efficiency and performance that the FDA continues to streamline, continues to improve its partnership with our sector. I would suggest, as Congressman, you and I have discussed on occasion, that we move toward a full time Chief Operating Officer. A partner in tactical matters with the Commissioner, to be accountable for performance for day-to-day operations for information technology systems, for hiring, training and retention of staff and that person established as a full-time person at the agency would very much complement the Commissioner who should be providing the strategic leadership.

I appreciate you being with us this morning, and I'm sorry that rambled for so long there.

Congressman BILBRAY. Well, actually there was a benefit to that, and I'll get to it in a moment. But frankly, BIOCOM was really on the cutting edge of this. Actually, I think some of you will remember—even before I was sworn in, you had me in your office and talked about how FDA reform was essential and that the institutional mind set needed to change. I am glad to know that as a result of our efforts, there has been positive movement and an evolution towards being more pro-active and cooperative on the part of the FDA. The fact is, there needs to be more. Even Henry Waxman, with whom I have often disagreed with regarding the status quo with the FDA will say that, when it comes to Biotech. The FDA regs at that time were totally inappropriate and they needed to be reformed and attitudes needed to be reformed. And frankly, somebody who has been a real leader in this and really helped us out on the Commerce Committee happens to be Richard Burr, from North Carolina.

Richard was really involved with the modernization program, he was really there. He serves not only on the Health and Environment Subcommittee, but he also serves with me on the Oversight Subcommittee, which oversees the FDA. You guys really pushed me to get on this committee because of how important this was for San Diego and it has been great working with Richard, who is somebody who has really been on the cutting edge of this, and is somebody that we can depend on to keep pushing. Like it or not, we have to admit that California does not have all the biotech industry in the world, and that North Carolina does other things besides grow something to smoke.

Let me just sort of throw it over to . . . ladies and gentlemen, I'd really like to introduce my colleague and probably one of the shining stars of not just the Commerce Committee, but of the entire Congress, and that is my classmate, Richard Burr from the great state of North Carolina. Richard.

Congressman BURR: Thanks Brian, and my apologies for my tardiness. If California is as crazy as Washington is today, you can understand the schedule that we have had as we try to wrap up this appropriations process.

I think it was appropriate that I wasn't here to make any comments. The advantageous thing for me is to hear the questions that are raised. More importantly, to hear the experiences with post-FDAMA. I think that we continually try to update ourselves on whether the modernization act is in fact executed the same way that we intended. There is no better way than to look at the amount of applications that have been filed. To look at the increase in those that have been approved. But that is not enough. Brian and I realize that, and our colleagues realize that we need to be vigilant in our watching.

I am not sure of the makeup of our panel, but I also give high marks to the FDA so far on their ability to transition. The Janet Woodcox's of the world, and certainly to the new commissioner. I think that they have made tremendous progress. I think that we still have cultural change yet to determine whether we have started. I am committed to stay involved in it until that the cultural change is evident to all of us. One of the things that we've got to watch out for I think, and when I say ''we,'' I mean members of Congress, as we address health care policy, you will hear more and more the question of pharmaceuticals and biologics come up in the discussion. We've got to make sure that the capital continues to flow to the biotechnology industry. We've got to make sure that our health care policies, as well as our approval agencies, are such that it makes Wall Street comfortable with the industry and with the investment that individuals make. It is because of that investment and the risks that each one of you take that we will experience products in the future that address both chronic and terminal illness that today we have no treatment for. We are here in hopes to listen and also to work hard to make sure that this act is carried out in a way to produce the product that it was intended to.

Congressman BILBRAY: I think you are coming from a position of strength to BIOCOM. With all the partisan bickering you see in Washington, at least on television, for you to come forward and for us to be able to say that there has been a major improvement of the situation. That the FDA has made these great leaps forward gives us more credibility when we start pointing out the shortfalls that still need to be taken care of. I think that is something that we don't do enough of in Washington. In other words, pat them on the back when they have done well, so then when you point out the shortfall, you have more credibility. That it isn't just partisan sniping. I think that is something we have been able to do on the Commerce Committee because we have acknowledged that. It is good that you guys do that. Now let's hear what we should do to improve the system more.

Believe me, when we talk about this sniping against the industry, it really worries me when I start seeing people looking to use this in the next election. I was just talking to my daughter and making the comment that I'd rather forgo the political advantage and be able to be assured that my daughters don't have to face off with the scourge of breast cancer in the next 20–30 years because we did the right thing now so that we can get these breakthroughs out on the market.

But let's hear what we can do to get it done from you guys.

DUANE ROTH. Thank you very much and thank you Congressman Burr for joining our conference.

I think what we can summarize the last discussion about is that we have done that right, and that it is moving in the right direction. But there are still issues that remain with the FDA and one of them is that it's really not uniform. There are some divisions that are performing very well, and there are others that are still lagging very far behind, and that has a lot of do with people. I am going to ask Steve to discuss appropriations in a minute, but people, and Bill made a very important point, information technology. There is no reason we should be sending truck loads of books to the FDA for review when we can send it on a CD that they can have in a matter of minutes and it is so much more efficient. I just sent a drug application last week, and the boxes and boxes and boxes of paper that went are really telling about what the FDA is still dealing with.

Congressman BILBRAY. Before we leave this, and Richard you may want to jump in on this, we've actually had an initiative called the Paperwork Reduction Act. We may want to go back and take a look at that as Members of Congress, saying how can we take the intention of that legislation and apply it to this specific issue. Rather than having to reinvent the wheel. Say, ''Look administration, we have this act that is already initiating these programs to avoid paperwork, and here you've got the industry that is ready to work with you to implement that act,'' and maybe we can plug it into this issue.

Congressman BURR. I'd also like to tell you that this is part of the cultural change that we hope to see that we haven't seen. Clearly that alarms me that we have an agency that evaluates and approves these methods that are so far technologically advanced that might not accept something on a CD-ROM has to be something cultural.

Congressman BILBRAY. My attitude is just why don't we just package it and call it the Tree Preservation Act and start going to this new high-tech.

DUANE ROTH. We could have saved a tree. Steve, why don't we turn it over to you.

STEVE MENTO. I also want to add my thanks to the other panel members and thank you Congressmen for taking the time out of your very busy schedule to listen to some of the issues that we want to present here.

I want to build my comments on both Ted and Bill's. IDUN Pharmaceuticals is one of those small companies that Ted described. We won't be filing our first I&D with the FDA until early next year. And again, I want to stress the importance that time is our enemy, so it is critical that FDA appropriations that Bill talked about are adequate, remain adequate, or are even increased, such that the gains that we have made in the last three or four years are even exceeded in the future.

It is critical to a small company with limited financing that when we submit an application, that application is rapidly reviewed, and it moves forward at an appropriate pace. As Bill said, it is key for the FDA to have sufficient personnel of the highest quality to ensure that the product review process starts and continues to move forward on a timely pace.

Critical to understand, very simple, in order to regulate a scientific industry, and biotechnology is clearly a scientific industry, we need strong scientific regulators. I will draw from a past experience I had earlier in my career when I was involved in the early days of gene therapy.

When we first started talking to the FDA about Gene Therapy, it was an industry that didn't exist. I want to commend the FDA response to our early discussions. They basically put a new group together, the Cell and Gene Therapy group, and they staffed that group with very strong scientists. I think that just looking at the safety record in that gene therapy industry over the past five or six years is not in small part due to the fact that there was strong science at both ends, both ends of the table. And even with the recent set-back in gene therapy where there was a death—the first death in a clinical trial, I think the appropriate and rapid response on both sides of the table have enabled the trials to move forward. It is very important to have strong science on both ends, and have the funding to make sure that this is possible.

And as Bill said, we are particularly concerned in our industry about so called mission creep. With funding being what it is, how will the FDA be able to respond to new initiatives that will be placed on them, new requirements with genetically modified foods, or even tobacco, with the increasing number of applications that are coming from our industry, and keep pace with the review process.

So I guess the one question I would have is, how will Congress ensure that FDA staffing, and resources are adequate to meet the ever-growing regulatory needs of the biotech industry?

Congressman BILBRAY. Well, I think, and Richard jump in, right now we are just trying to maintain appropriate oversight. Those of us on the Oversight Subcommittee are watching how these resources being allocated to the administration are being spent. We're actually able to have a substantial maintenance of our effort, and improvement of our effort even with the limits of the balanced budget, while not spending social security.

I don't see any real critical issue, in which we are going to have to reduce what is available. In fact, with you guys taking such a strong pro-active stance on user fees, which is something that Republicans often get real paranoid about, really helps us to keep this constant effort going because the industry has said that we don't mind participating in the cost as long as we get the services that we need to get these things moving along.

Richard, do you have a comment about what we need to do?

Congressman BURR. Yeah, good luck with your first application. If any agency came to me and told me that they didn't have enough money, I would be shocked. I have yet to meet one in Washington. I think that is inherent to this town. We have a very difficult job. I think that we try to work as closely as we can with the people who are on the side of the issue that where you are, and that is the applicants. Is the process working better?

Then we try to compare and look at the changes that have been made at FDA. We are all concerned with jurisdiction creep as to the issues that the FDA is involved' in. That is purely an oversight role on our part and we are going to continue to be vigilant on it. We think that when you look at the number of employees at the FDA, there has to be some change. The reduction probably frees up the slots for the talented people that all of you have expressed that they need in the process. I think that they also need to culturally address some things, such as the removal of secondary indications, where we can take that process out and possibly put that into the teaching hospitals around the country. We did part of that in FDAMA. Clearly I don't think that the FDA has moved far enough in that method. But we want to free people up so that the talented people can work on those applications that are the various breakthroughs that can happen.

We are not at a point yet that we feel that they are tied because of budget restraints, when we continue to see fifty investigators who sole job every day is to chase the tobacco industry. So we go through a little bit of a different method as to how we encourage agencies to staff up in the right places, and sometimes it takes a little longer.

Congressman BILBRAY. I think that we shouldn't move beyond this issue of what's called genetically altered food and stuff. Anybody in the BIOCOM group should not consider this to be somebody else's problem. This prejudice and this practical witch hunt against anything genetically altered is just really something that we have to confront, and we have to confront it head on.

Just because the debate is focused on foods right now, doesn't mean those of us working on medicine can allow the wolves to go after them. We need to stick together, because not only is genetic research not a threat to society, it is probably the greatest shining example of a bright future for a whole cadre of issues, from beating cancer to feeding the hungry in the world. We have to unite all of us who are well informed and understand this issue, and confront those who are the scare mongers, who will try to intimidate people with fear on this issue.

On the clinical trials issue, let me just point out a side note that the healthcare issues that were brought up last week. Every one of those managed care proposals had a clinical trials provision added to it, because Washington is finally waking up to the fact that we need to be pro-active on this issue.

DUANE ROTH. Let me move to a less controversial issue. Medicare prescription drug benefit. I am going to call on David Gollagher.

DAVID GOLLAGHER. Congressman Burr and Congressman Bilbray, we appreciate your time, you've been with us on so many issues. Both of you certainly heard, or heard right after the president's remarks yesterday about the drug industry, calling on Health and Human services to initiate a 90 day study of comparative drug prices between the United States, Mexico and Canada. The President has also rolled out his plan for providing prescription drugs for people who are uncovered in the medicare program. There are around 39 million people covered in the medicare program and around 13 million don't have any prescription drug coverage. Our industry has been very concerned that the attacks on the pharmaceutical industry will have repercussions for raising capital and for the health of the Biotechnology and the drug discovery industry so the politicalization of this issue is bad for everyone, I guess that our great concern is that looking ahead to a very contentious election in the year 2000, how can we play a constructive role in to find an approach to the prescription drug coverage for the medicare population that is bipartisan and will work? A lot of us in the past have thought that some type of premium support would provide coverage for the elderly poor would be a good way to go but we can look back as well to catastrophic coverage when the great panthers revolted and seniors refused to pay anything for additional coverage. It seems to us that this issue is very easy for the president and others to politicize by talking about new benefits that people should have and that basic support for these benefits should come out of the companies. So I guess we would like to hear some perspective on the best approach our industry can take to take some of the air out of the political balloon and help for a more bipartisan approach to what is basically a partisan issue.

CONGRESSMAN BILBRAY. Well, that's a really tough one, because we've seen people in Washington use you guys as a punching bag. It's easy to take a cheap shot, you never get thirty minutes to respond to the Administration's attacks, it's a freebie politically. We've seen the damage it can do in the early minutes, frankly, I'm concerned about the damage it's going to do now. I think that we also need to highlight this issue about how long it takes to get the product on the market, about how few percentages are able to go from R&D to the market. The things that the administration needs to do to make pharmaceuticals more cost effective is basically to stop being obstructionists. But the other issue is the tort limitation. Being on the Mexico boarded they always say ''in Mexico, we can get it for this, this, and this'' well, also you can get dental care and medical care down there, but you also have a totally different type of tort system. I wish I had the answer for how we counter this, because right now I just see it as a freebie for anyone who wants to take a political cheap shot at you and I think that we really have to take a look at how to preempt it but I don't have that answer. Maybe Richard does, he's used to his industry taking all the shots and maybe he's got some good pro-active counter offensives ready to go, Richard.

CONGRESSMAN BURR. Should you be worried? Yes. I gave a speech earlier this morning and I said had I known that the modernization act would be so successful that we would move from an average of the low teens of the applications being approved in a year to fifty or sixty or potentially seventy in future years and that the market place would have so many new drugs that were still under the recover of their R&D that it's contributed greatly to the increased cost of pharmaceuticals when we look at the entire population and especially seniors. The other thing that has come into play is that technology is a two way street and many seniors and many consumers sit at home and research their illness, they are quick to go into their physicians office. They may have been on Zantac and it treated their stomach well, today they want prylosec, and a physician is almost required to fill out that prescription, and then we move from a $10 over the counter solution to a $110 prescription solution. So the problem has ammunition and I've learned that anytime there is a box of ammunition, Henry and our good friends on the other side will continue to use it. I will tell you that most members and most people

across the country believe that there ought to be a drug benefit with medicare. The question is are we going to try to incorporate something into the existing model or are we going to do something that is politically tough but policy right and that's to create a private sector plan to compete against medicare? As I shared with people, we never complained about the post office until fed ex was created. When it gave us something to compare it to we began to ask ourselves questions about when it needs to be there, how confident do I need to be that it gets there and how much does it cost? And when you do that, if we were to create a private sector model whether it's premium support in total or another byproduct of those talks I think we get a fair comparison that seniors and the consumers can compare medicare to. What do you do? I hope that we in Congress, especially as republicans will put out some time of blueprint before we leave. Even if it's a very sketchy one on what we'd like to accomplish and how we'd like to do it on medicare restructuring and the incorporation of drug options as we come back next year. If not then the President will frame what we do and the box that we are in the State of the Union address. How can the industry help us and help themselves? It's to put the image of who you are and what you do in front of the American people. It's to take the scientists out of the lab and put them into the lecture room or the town meeting or the television. Talking about the breakthroughs that they worked on and the real lives that the breakthrough affects. The American people are willing to pay as long as they know what they're going to get and I think this is one area where the people would be willing to chip in to continue the level of research and development. If we allow the President to frame the debate and the others to set the rules, I can assure you that the number one thing I look at, which is capital, will find another industry that is more attractive in from the standpoint of their overall return and we will have a tough time in the biotechnology area.

Congressman BILBRAY. I think that you need to really focus this and be ready to do your own campaign based on things like Biotech. It's not about money, it's about lives. If you compare how much the average American family spends on a car as opposed to pharmaceuticals or breakthrough drugs it's not even comparable because you've got it packaged a certain way.

The republican proposal I'm seeing coming down, and I think that both the Senate and the House is moving, is the issue of having the needy seniors helped with this cost and really focus on them as opposed to the position that all seniors, even if they're millionaires, should be able to be subsidized by the federal government.

Congressman BURR. And I want to caution the entire group, don't fall prey to anything other than the administrations intent and the Democrats on the Commerce Committee, most of them, that the first step is to institute price control. And those price controls, whether they're instituted at the state level or whether they're instituted by the federal government, then they have the hoops to redesign the system however they want it. and clearly those price controls, being the first, thing have a great impact on where the capital goes in the future.

Congressman BILBRAY. The would initiate these prices controls and you would watch, in an industry that already has investment concerns and problems, then when it starts hurting more, it justifies Washington sticking it's nose in further. So you've got to watch these things because a lot of these crisis situations are created in Washington and not necessarily without the intention that Washington would have to step in and get involved. I know that sounds like some kind of conspiracy issue, but I think that those of you who have worked in the industry and have seen the reaction of what Washington can do would agree that this is not a Democrat or Republican issue; it's just common sense that we ought to be allies not enemies.

DUANE ROTH. We certainly will stay engaged in this issue, it's absolutely crucial to our industry and we really hate to see the way things turned yesterday. That was not helpful and puts us in a very defensive position again. We're certainly going to work on this issue and stay in touch with our constituents. Our constituents are patients. When any one tries to drive a wedge between the industry and the patients who need these products, everyone loses. I think that's what we need to be working on

Congressman BILBRAY. I think you have to point out that you've got elected officials who were on the defensive this week about Social Security. And the best defense, in a lot of their attitudes, was to go on the attack. And so, they had a position that wasn't very defensible on Social Security and so they came up with a proposal and used you guys as a punching bag and as some way to justify their agenda. They had to create an enemy and they were using you, and frankly I'm sorry to see it happen too but please understand that you should be complemented that they were on the defensive so they were going after you to take the heat off of them which is a sad fact about this.

DUANE ROTH. I'd like to move to a related issue and this is one that is very key for our industry and that's getting reimbursed once we finally get through the better behaving FDA, how do we get paid for our products and this is another major medicare issue. So I'm going to turn to John Dobak who's going to introduce the subject and get your comments.

JOHN DOBAK. Thank you and thank you folks for taking the time. I represent the medical device community. We often get lumped with Biotechnology but there are some differences between our industries as it relates to a certain issue, and I think it's important to realize that there is a difference between medical device and Biotechnology. This particular issue I think pertains to both industries. I'm going to focus on the Medical device side of these issues however. First, I'd like to note that HIMA has a seven point plan that deals with reimbursement reform and it's a very complex issue and I would encourage some review of that plan because it addresses many of the dilemmas faced by medical device companies. I'd also like to recognize that some of these issues and the solutions proposed by HIMA are addressed in a bill proposed by Orin Hatch and Jim Ramstead. The most important piece that's partly covered in this legislation is that it is trying to establish a more efficient and rapid reimbursement process for medical device companies and other life science companies after they obtain FDA approval. FDA approval is really the pinnacle of any life sciences company or medical device company, it really represents the establishment of the clinical benefit and safety of a product and one would think that with that FDA approval we would see a dissemination of the technology the profitability of the company and additional innovation of that particular company. Unfortunately, because of problems with the medicare reimbursement in particular, the technology is not utilized often times many years after the product was initially approved. I think a case in point is cardiac stints. Cardiac stints are these tubular, cage-like structures that are used to prop open the arteries. These were approved in 1994, however reimbursement was not established until 1997. At the time that the product was approved only about 15% of patients had access to this lifesaving technology. Once appropriate reimbursement was established, the use of the procedure exploded to some 85% or 90% now of interventional cardiology incorporate stinting. My concern is that I think a similar situation is going to evolve with stroke. Stroke afflicts about 700,000 patients each year in this country and that it costs the healthcare system in excess of 30 billion dollars. It's a devastating problem, it leaves people paralyzed, unable to speak and comprehend speech and even blind. Currently there's a bevy of medical device companies that are developing therapies to treat strokes. Currently there's a bevy of medical device companies that are developing therapies to treat strokes. Unfortunately the current reimbursement is only $3000–$4000 and the average length of stay in a hospital for a stroke victim is 5 days, that $3000–$4000 will not cover that hospital stay let alone new technologies that are going to prevent the devastating consequences that come from a stroke. I think this brings up a very important point about the fundamental structure of medical reimbursement and that's that medicare focuses on short term cost controls in favor of long term cost saving. I think that technology will never prove to itself to be cost efficient when the reimbursement structure focuses on this short term cost control. I would just be interested to know if there's going to be support for this bill presented by Senator Hatch and Congressman Ramstead and hear your comments about your position.

Congressman BURR. Well, I'll go first. I'm not sure about the specifics in Senator Hatch or Congressman Ramstad's bill, but it gets to the heart of what private insurance companies refer to as experimental. Those drugs or devices that have been approved by the FDA but for, some unknown definition, still have not been approved for reimbursement whether it's medicare or the private sector. I attempted, in the patients bill of rights legislation, and all the substitutes, to make sure that we had a new definition for experimental which stopped when the FDA approved it. It could no longer be experimental. It meant that medicare and companies had to specify anything that was not covered but was not under the umbrella of experimental. I don't think there's any question that the intermediaries dragged their feet sometimes companies are pushed from one entity to another, who are trying to get a new DRG code or whether they're going to be lumped in an unexisting one and in many cases the reimbursement does not represent the technological advances that have been made. I think it's clear that we're on a generation of heart stint that some of the countries of the world would look at and laugh at based on where they have progressed to. That's part of the approval process. When I look at the reimbursements I clearly don't think that it considers the technological changes that have gone into product advancements, especially in devices, and the reimbursements reflect that. I think it cries for overall medicare reform, not just in the drug model but a true competitive model. One last point, it's one that you touched on which I would call disease management. I remember when we sold for the first time the concept of medicare coverage for diabetes screening for seniors. It took 2½ years to convince some of our colleagues that it was cheaper long term to pay for this monitoring up front because it was cheaper than amputation and blindness. They now believe that and they believe it about mamograms and they believe it about PSAs. We need to start the cultural change and make people understand that

there are drugs and devices that also save money long term with a cost up front. That, again, is a cultural problem that we're going to have with this agency.

Congressman BILBRAY. It's a problem, not just with this agency, but with the entire federal system, judging what is a priority and what is a benefit. A decade ago we were bashing the private sector for looking to the next quarter. Remember we were talking about the Asians looking at the long range. The fact is, we've seen a major reform in the private sector. When Richard and I came here to Washington we were looking at this issue that the whole mentality of what we judge as a benefit or a cost is so antiquated; and it still is. You have the OMB scoring, and you have the Congressional Budget Office scoring, that is really sort of like what's here and now. A good example is, the drugs that are being used for trying to reduce the effects of strokes. I just lost a father to a stroke, so I understand. He was two years in a wheel chair—could not speak—needed to have constant service. But, the drug that may help to avoid long term damage isn't really considered a major savings because you still spend up 3 to 5 days in the hospital. So they just sort of go right over that. I think that we need to try to raise the sophistication of what we project as expenditures or savings. That could go beyond the here and now and the short term. And this town doesn't do that very well. A good example, was the question about capital gains taxes, and reducing them. In this town the projection was that it was going to be a net negative to the treasury. Well everybody knows that since we've done that there's been a huge plus up and it's been one of the biggest reasons why we have a surplus. But the town does not know to change it's institutional structures and it's institutional background to reflect reality. And I guess from a science background we would say the model here in Washington is being used to judge your industry and to judge service and cost benefit ratios. The model is a one dimensional obsolete model that we have to replace with a whole new modeling system. And maybe we can get these guys who are working on global climate change to work out a model that will be able to sell to the congress so they will have something that reflects reality better than what we have now. This thing runs deeper than just HCFA, it's the entire structure that we are trying to change.

Congressman BURR. Brian if I could, I've been asked to come back up to the Hill, and I do want to allow if there is one additional question that may or may not be on the agenda that somebody has of me before I leave, I wanted to give you an opportunity to ask it.

DUANE ROTH. Let me quickly, since you're from North Carolina, and there are some farmers there I think. Genetically modified organisms, and Brian touched on it earlier but this is an area that we do understand has a potential to creep over into the health care as well as the agriculture scare that is going on now. And I'm going to call on Joe to sort of introduce us to that mess.

JOE PANETTA. Congressman Bilbray congressman Burr, thank you very much for joining us, and on behalf of all the members of BIOCOM, I would like to thank you as well. Congressman Bilbray, over the years we know that you have been interested and involved in our issues and we've welcomed that participation on your behalf and we really look forward to working with you in the future. We haven't talked much, through BIOCOM, about the issue of genetically food, although you and I have talked about it on occasion. And it's an issue that certainly become much more in the forefront in recent weeks and months with some of the concerns been raised in Europe over the acceptability of genetically engineered foods. And it's an issue that has a direct impact on our farmers across the country here in San Diego certainly congressman Burr in North Carolina and with a lot of the research that's been going on in San Diego and North Carolina through companies that are involved in this area has a direct impact on us as well. But the two issues that I really want to touch on here are in direct relevance to you in the Commerce Committee, and those have to do with the acceptance of exports of our crops and the impact that that could potentially have on our ability to adopt this technology through our farming systems in the U.S. and also for the potential for there to be a backlash here in the United States as a result of some of the controversy that's been raised in Europe. You both know, I'm sure, that farmers have increased difficulty in adopting this technology due to the fact they've had concerns about acceptance of products in Europe and Japan. The regulations that have been implemented particularly in Europe on GM3 imports in the United States have really deterred farmers in large part from adopting this technology due to their concern. It's causing a huge headache for our farmers here in the U.S. it's raising concern with our large agricultural research companies relative to their investments in this technology in the future. And if we look at the loss in trade just last year in this area as a result of some of these negative regulations that have been implemented we're looking at $200,000,000 in crops that had to sold elsewhere as a result of European negativity on this issue. The fear that's been aroused through the activities of the activists groups in Europe could potentially end up flowing onto shore here in the U.S. and we think that what's really exacerbating these issues are the very regulations that are being created in Europe that are presumably there to deal with the issues themselves. In fact, what we are seeing instead is the reverse and the public's concerns are being raised even more. What that's causing us to see in the U.S. is that the technology is being slowed down and in fact, farmers are having to hang on to older technics as a result. I'll be brief, because Congressman Burr I know you have to get back up to the Hill. But, the concern here has more to do with the fact that we need your support in terms of any regulations that might be considered that goes beyond the already very stringent system that we have in the U.S. And the need to implement science based systems outside the U.S. as something that needs to be focused on more than the need to focus on a system that is very adequate. I think Bill Rastetter and Steve Mento both touched on the concern about the resources that we have at FDA and the need to focus these resources on the approval of some of the new pharmaceutical and device products that are in the system. The need is not there to focus those resources on a process at the FDA that is already adequate. As far as labeling goes, that's another issue that's been discussed very much recently with regard to public concern. I think from our standpoint we felt for a long time that the labeling system that the FDA adopted years ago is an adequate system to deal with any food regardless of the technology through which it's produced. And this is simply one more way of producing food, but the processes that are in place there are adequate. So, in summary we'd ask you to continue to support the efforts through FDA, USDA, and EPA to regulate these products and in terms of exports, to show strong support for our opportunity to show better crops to improve yields and to be able to export these products throughout the world to the benefit of our farmers here in the U.S. Thanks very much for your time.

Congressman BURR. Well, I appreciate the question. Yes we do have farmers in North Carolina, most of them are still under water, unfortunately. But we will bounce back and I'm hopeful that we will at least pay attention to what's happened in Europe. I've been there twice in the last twelve months. This has been one of the topics of discussion every time I've been there. Clearly this is not a trade policy breakdown, it's an attempt to continue subsidies that we tried to negotiate out. And when they finally hit on the food safety it took hold with consumers all across the EU. The concern is, and should be, what happens when that same type of campaign comes across the ocean and starts in this country and we've begun to see this already with the attempt on baby foods, where most companies have pulled many GMO products out of it. I think we've got to be very conscious of the good science that's needed. And I would hope that we would spend our time with the EU now trying to set the standards for good science and backdoor into standards that would allow us to have those markets for export purposes. I'm sure the French would be alarmed to find out today that they currently use genetically modified grapes in the majority if not all of there wine. I'm sure that they would argue that rubbing it on as opposed to injecting it in is two different things, but reality is reality. I think that this is an area of great concern not only to those of us on Commerce. I know that Senator Pat Roberts has spent a tremendous amount of time on it, and is concerned that if we are not vigilant, and if we don't watch this, that we will no longer be able to produce the world's food here in this country because of what can happen. As the member of Congress that has the Novartis agricultural headquarters for this country, it is alarming for me, and I know the impact potentially not only on North Carolina's farmers, but our ability to be the world's supplier.

Congressman BILBRAY. I think that we and everybody, there are those in the medical field that say this is an ag problem just as much as it was those to make sure you didn't go after genetic research. Remember that scare tactic, it may be good politics, but it was bad science. Just like Richard and I worked with a guy name Ganske about this issue of radiating meat, which is the safest thing you can do to stop the disease carrying potential of beef. I think we need to put together a coalition and I want to tell you this, I was on the Floor today talking to my corn growers in the Midwest. I need you to give me that information because we need to get Archer Daniels Midland and the rest of the big corners who are fighting us on other issues, that they ought to be working with us on this issue. I think that there is a flip side here too. The environmental community, rather then being your enemy should be your biggest ally, except that they don't have the facts. We're talking about the ability to use genetic research as a way of reducing the use of herbicide eliminating or reducing the substantial use of insecticide that are polluting the environment. I think that we need to talk about this. And we need to confront Europe and say, ''You want to play this game?'' We can look at the herbicide or the insecticides that you are using and say that we don't want any of your products that you are using those in. If they want to play this tough game, I think we need to get the facts out there. And I think that the pro-active approach—I propose that what we ought to be talking about up in the Northwest right now and what the administration should be pushing for is not what is genetically altered, but an international interpretation of what is organic. If you want to eat

food that was grown and processed exactly the way your great great grandfather did, 150 years ago, then I think we can find a common purpose. But the talk about genetically altered is such a ruse because the one thing that we talk about is domesticated plants. If we didn't have, quote unquote, altered plants, our corn would be about three inches long the way the Anasazi a thousand years grew their corn. And I think that we need to get this out. So the environmental community has to be confronted with the fact that rather then attacking and fearing the genetic alterations we should be moving towards it to stop all the spin off pollution that we've seen for decades. I think that we got a big question here, but we all need to pull together. I ask the medical people to take a look at the ag people because we need the ag people to help us with the medical side and with the device side. We are all in this together. We're the people with the facts. We have to stand up for them; even in the short run, politically, it doesn't seem expedient. Outside of that, I really don't have an opinion about this whole issue.

DUANE ROTH. We will certainly give you the information and keep working on this issue it's a very important one. Let met give you a chance to sign off here, I know that you have to get back to more important business. But, from our side thank you very much for taking the time, both of you, to spend with us today.

Congressman BILBRAY. Well, thank you very much for how proactive that you guys have always been. And one thing that is great about the BIOCOM people and your entire group is that rather then sit back and then complain that things didn't work out, you've been very pro-active. I think that one of the best things that we've done is to see the kinds of things that you put into it. I couldn't help but think about the device issue and our tort reform device that was named after your nephew. It's something that I think has been one of our great successes. Thanks a lot, and continue the work. One thing that I really like about it is that you can look at this panel and you can see that they go across the political spectrum, but they stick together on one issue. The well being of Americans is something that we all have to cooperate on and find answers for, rather then always pointing fingers and finding problems. So thanks again for taking the time. This was a very, very great way to be able to communicate. And hopefully Richard and I can go back and to carry your message and not just to the Commerce Committee, but to the House of Representatives. Thank you very much for the time.

DUANE ROTH. Thank you. And let me just conclude by thanking my panel members for taking time to help with this. Thank you very much.

PRESCRIPTION DRUG PRICING IN THE 20TH CONGRESSIONAL DISTRICT OF TEXAS: AN INTERNATIONAL PRICE COMPARISON

HON. CHARLES A. GONZALEZ

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Thursday, November 18, 1999

Mr. GONZALEZ. Mr. Speaker, I insert the following for the RECORD:

EXECUTIVE SUMMARY

This report, which was prepared at the request of Rep. Charles A. Gonzalez, compares prescription drug prices in Texas's 20th Congressional District with drug prices in Canada and Mexico. The report finds that senior citizens and other consumers in Rep. Gonzalez's district who lack insurance coverage for prescription drugs must pay far more for prescription drugs than consumers in Canada and Mexico. These price differentials are a form of price discrimination. In effect, the drug manufacturers are discriminating against senior citizens in Rep. Gonzalez's district by denying them access to prescription drugs at the low prices available to consumers in Canada and Mexico.

This study investigates the pricing of the five brand name prescription drugs with the highest dollar sales to the elderly in the United States. The study compares the prices that senior citizens who buy their own prescription drugs must pay for these drugs in Rep. Gonzalez's district with the prices that consumers who buy their own drugs must pay for the same drugs in Canada or Mexico. The study finds that the average prices that senior citizens in Rep. Gonzalez's district must pay are 100% higher than the prices that Canadian consumers pay and 99% higher than the prices that Mexican consumers pay (Table 1).

TABLE 1.—SENIORS IN REP. GONZALEZ'S DISTRICT PAY SIGNIFICANTLY HIGHER PRICES FOR PRESCRIPTION DRUGS THAN CONSUMERS IN CANADA OR MEXICO

Prescription drug and dosage form	Canadian price	Mexican price	20th District price	Canada-20th District price differential		Mexico-20th District price differential	
				Percent	Dollar	Percent	Dollar
Zocor: 5 mg, 60 tab	$46.17	$67.65	$113.94	147	$67.77	68	$46.29
Prilosec: 20 mg, 30 cap	55.10	32.10	129.49	135	74.39	303	97.39
Procardia XL: 30 mg, 100 tab	74.25	76.60	142.17	91	67.92	86	65.57
Zoloft: 50 mg, 100 tab	129.05	219.35	238.69	85	109.64	9	19.34
Norvasc: 5 mg, 90 tab	89.91	99.32	127.77	42	37.86	29	28.45
Average differential				100		99	

These price differences can have substantial impacts on the cost of a prescription. Prilosec, and ulcer medication manufactured by Merck, was the top prescription drug in dollar sales in the United States in 1998. An uninsured senior citizen in Rep. Gonzalez's district must pay over $70 more than a consumer in Canada and nearly $100 more than a consumer in Mexico for a one month supply of this drug. The total difference between the price a senior in Rep. Gonzalez's district would pay for a year's supply of Prilosec compared to a similar consumer in Mexico is over $1,000. The difference between the price a senior in Rep. Gonzalez's district would pay for a year's supply of Prilosec compared to a similar consumer in Canada is nearly $900.

In the case of two additional drugs considered in the study, Synthroid and Micronase, senior citizens in Rep. Gonzalez's district were forced to pay more than two times, and in one case over five times, the prices charged to Canadian or Mexican consumers.

This is the second congressional report on drug price discrimination requested by Rep. Gonzalez. the first report showed that senior citizens in Texas's 20th Congressional District are forced to pay over twice as much for their prescription drugs as the drug companies' favored domestic customers, such as HMOs and the federal government. This report shows that senior citizens in Rep. Gonzalez's district are also forced to pay twice as much for their prescription drugs than are consumers in other countries. Taken together, the two studies indicate that drug manufacturers engage in a consistent pattern of price discrimination, resulting in prices for senior citizens and other consumers who buy their own drugs that far exceed those paid by other purchasers in the United States and other countries.

I. INTRODUCTION

In the United States, drug manufacturers are allowed to discriminate in drug pricing. As the Congressional Budget Office reported in a 1998 study, ''[d]ifferent buyers pay different prices for brand-name prescription drugs. . . . In today's market for outpatient prescription drugs, purchasers that have no insurance coverage for drugs, pay the highest prices for brand name drugs.'' In 1999, the Federal Trade Commission reached the same conclusion, reporting that drug manufacturers use a ''two tiered pricing structure'' under which they ''charge higher prices to the uninsured.''

This discriminatory pricing imposes severe hardships on senior citizens. As documented in the previous report released by Rep. Gonzalez, senior citizens often have the greatest need for prescription drugs, but the least ability to pay for them. The elderly in the United States, who make up 12% of the population, use one-third of all prescription drugs, with the average senior using 18.5 prescriptions annually. They also frequently have inadequate insurance coverage or no insurance coverage at all to pay for these drugs. Approximately 75% of Medicare beneficiaries lack dependable, private-sector prescription drug coverage, and 35%—over 13 million seniors—do not have any insurance coverage for prescription drugs. As a result, many seniors cannot afford the high costs of prescription drugs. One study estimated that more than one in eight seniors were forced to choose between buying food or paying for prescription drugs.

In part to protect their citizens from these hardships, the governments of Canada and Mexico do not allow drug manufacturers to engage in price discrimination. In Canada, approximately 35% of prescription drugs are paid for by the government for beneficiaries of government health care programs. In Mexico, 30% of prescription drugs are paid for by the government under similar circumstances. The rest of the population in these two countries must either buy their own drugs or obtain prescription drug insurance coverage. To prevent drug companies from charging individual consumers excessive prices, both the Canadian and Mexican governments regulate prices for patented prescription drugs. Drug manufacturers do not have to sell their products in Canada or Mexico, but if they do, they cannot sell their drugs at prices above the maximum prices established by the government.