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ASSESSING DIGESTIVE DISEASES RESEARCH AND TREATMENT OPPORTUNITIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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CONTENTS

Page

Testimony of:
- Carron, Adam 21
- DeRose, Rodger, President and CEO, Crohn's and Colitis Foundation of America 17
- Peura, David, Digestive Disease National Coalition 24
- Spiegel, Allen M., Director, National Institute of Diabetes and Digestive and Kidney Diseases 11

Additional material submitted for the record:
- Peura, David, Digestive Disease National Coalition, response for the record 38

ASSESSING DIGESTIVE DISEASES RESEARCH AND TREATMENT OPPORTUNITIES

THURSDAY, JULY 8, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 11:05 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Upton, Buyer, Barton (ex officio), Brown, Pallone, Capps, and Rush.

Also present: Representative Kelly.

Staff present: Cheryl Jaeger, majority professional staff; Eugenia Edwards, legislative clerk; and John Ford, minority counsel.

Mr. BILIRAKIS. Good morning.

Today's hearing assessing digestive disease research and treatment opportunities addresses an important issue that is often, unfortunately, overlooked.

Digestive diseases such as ulcers, heartburn, celiac disease and inflammatory bowel disease, IBD, effect approximately 70 million Americans. Some of these diseases are minor and easily manageable while others are debilitating and extremely painful. All are increasing, unfortunately, in their frequency.

One example of IBD, Crohn's disease, was once a very rare disorder but today there are twice as many cases as there were 30 years ago, and we are not sure why.

Now, it is common to hear the personal stories about how IBD's affect an individual's family or a close friend. Members of my own family, for example, suffer from IBD.

What also troubles me greatly is that these conditions are increasingly afflicting children and teenagers. The health of our children is already in crises, especially with the skyrocketing obesity rates. Children with digestive diseases often have to live with symptoms such as pain, intestinal bleeding and weight loss. And that is why I am so honored to welcome on of our witnesses here today, Adam Carron who will speak about his personal experience with Crohn's disease. Adam, really no one should have to endure what you have experienced over the years with this terrible illness. You have my gratitude and my admiration and that of my colleagues for speaking out and educating others on Crohn's disease. It is not easy to discuss the terrible ordeals you have gone through, and we certainly thank you so very much for being here today.

We have an excellent panel of witnesses here this morning. In addition to Adam, I would like to welcome Dr. William Spiegel, Director of the National Institute of Diabetes and Digestive and Kidney Disease, NIDDK, within the National Institutes of Health.

NIDDK is the lead institute responsible for the strategic planning and priority setting of federally funded research in digestive diseases. NIDDK already has highlighted digestive diseases and specifically IBD as a priority. And we are, of course, very happy to know that. In fact, NIDDK has a center for the study of inflammatory bowel disease and a center for gastrointestinal biology and diseases which focus on IBD research.

In the 108th Congress, this subcommittee has held 5 hearings to highlight research activities and budget and priority setting at the NIH. Both Chairman Barton and I have expressed our commitment to reauthorize the NIH and assisted Director of NIH, Dr. Elias Zerhouni to implement his NIH Roadmap for Medical Research. During this process I am working to ensure that NIDDK has the resources it needs to maintain its reputation of excellence in the digestive diseases field, but also increases the transparency in the way that research is disseminated to the public. After all, what good is research if it is not in some good way disseminated to the public.

I am also excited to have representatives from two digestive disease patient advocacy groups. Rodger DeRose is the President and CEO of the Crohn's and Colitis Foundation of America, CCF. And Dr. David Peura is the Associate Chief in the Division of Gastroenterology and Hepatology and Professor of internal medicine at the University of Virginia Health Science Center. Mr. Peura is testifying on behalf of the Digestive Disease National Coalition, DDNC.

I would like to commend both of your organizations, gentlemen, on your work to improve education, access to and quality of digestive disease health care for current and future patients.

I cannot stress enough how dedicated I am to increasing research and education for digestive diseases. I was fortunate to able to speak to CCF last month and I was touched by the level of commitment there that there is in the effort to fighting these debilitating diseases. Many Members of Congress are concerned about digestive diseases, and leading that group is our colleague and friend, Congresswoman Sue Kelly and then additionally Congressman Roy Blunt and Bobby Rush have introduced bills to increase the focus on digestive diseases. Ms. Kelly is not a member of this committee, but at my invitation and I know without any objection from Mr. Brown or the other members, she is here today and is sitting up here as a member of the panel, and we certainly welcome her.

I believe it is important that we work together to find a cure and ways to prevent these very serious diseases. At the end of the day I know most of our concern is that if we do not find a solution, the prevalence of digestive diseases will continue to grow.

Again, thank you for being here today.

And I gladly yield to the ranking member of the subcommittee, my good friend from Ohio Mr. Brown for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman. Thank you all the witnesses for joining us today.

The term digestive disorder covers a wide range of illnesses, as the chairman said, several of them deadly, all of them significant from a public health perspective. Liver disease and inflammatory bowel disease or IBD, acid reflux, cancer of the stomach and pancreas, of these illnesses and many more are considered digestive disorders. More than 62 million Americans are diagnosed with one of these illnesses every year.

I was contacted by Paul Levin, who is the father of Sarah, a young woman with Crohn's disease. Crohn's is a form of IBD, it is incurable and it is insidious. It causes inflammation of the lining of the intestine. When inflamed, the lining becomes ulcerated and bleeds. It can cause severe diarrhea, abdominal pain, cramping, fever and rectal bleeding.

Sarah Levin takes 11 medications everyday. She has major surgery. She has taken steroids that stunted her growth and compromised her physical health. She has been forced to miss work again and again because Crohn's can flare up at anytime.

Regrettably there is no cure at this time. Medical treatment can only try to ease the pain and control the inflammation.

Like my digestive disorders, IBD does not get the attention it deserves given its prevalence and its disabling effects. Approximately 1 million Americans suffer from inflammatory bowel disease, and numbers keep increasing as there are about twice as many cases today of IBD as there were 30 years ago. Sarah and I hope all of us are determined to do about this. Along with her father and other advocates she has been lobbying very successfully for legislation focusing on IBD. H.R. 290 sponsored by Sue Kelly and be Jessie Jackson, Jr. would raise public awareness about IBD, jump start IBD related research and help IBD patients get the treatment that they need. I am pleased to support this bill.

I am interested in learning more about H.R. 3756 which would establish a national commission on digestive disorders. A commission was formed many years ago in 1976 to get a better handle on the prevalence of these diseases and the nature and score of available treatments. Obviously medicine has evolved significantly over these past three decades. The demographics of our nation and relevant lifestyle factors such as diet and exercise have also changed over time. If congressional action is needed to update the original commission's findings in regard to digestive disorders, reinstating the commission is a step Congress should consider.

I would add, Mr. Chairman, as you know the Bush Administration budget memo recently leaked to the Washington Post revealed the Administration's intent to cut overall funding for NIH after the election, I might add, by roughly $600 million for fiscal year 2006. If anything, this hearing has demonstrated that our national investment in medical research is more important than ever. We have no business cutting NIH. In fact, we frankly have no business in slowing down its growth and its increased spending, which this Congress has already done. And next year if President Bush gets his way, it will be much more.

We have, as I said, witnessed a slowdown in funding increase and this proposed cut that the President has suggested is absolutely going in the wrong direction. I hope, Mr. Chairman, we can learn more about that during this hearing.

Thank you.

Mr. BILIRAKIS. The Chair yields to the gentleman from Indiana, Mr. Buyer.

Mr. BUYER. I just want to note for the record, sometimes I find it breathless. The record is very clear that when Republicans took over Congress we set out as a goal, and it was to double the funding of NIH.

So I almost find it breathless whenever I hear someone "My God, Republicans may be cutting NIH."

Mr. BROWN. Would the gentleman yield?

Mr. BUYER. Mr. Brown, I just want to make clear, I have not seen this document but it makes it even better when you would testify to—you know, and I thank and appreciate the leadership the Republicans have done to double NIH funding as we push the bounds of science that improve the quality of life of people in our country. That is a good thing.

Mr. Brown, I yield to you.

Mr. BROWN. Yes. Thank you, Mr. Buyer.

I only mention that that initiative was originally President Clinton's, that the Congress then worked with in partnership bipartisanally, and now that President Bush has decided to make room——

Mr. BUYER. What initiative was Bill Clinton's?

Mr. BROWN. Well, the initiative of doubling the NIH budget, which began in——

Mr. BUYER. Boy, that is——

Mr. BILIRAKIS. Regular order. These are opening statements. We are not debating.

Mr. BUYER. I will just reclaim my time, because I am not—I do not revitalize history. I do not rewrite history.

Mr. BILIRAKIS. Let us keep our eye on the ball.

Mr. BUYER. No, no. I——

Mr. BILIRAKIS. Now all these good people have come here because they feel that we can work together for a good purpose. And then we get into partisanship——

Mr. BUYER. Mr. Chairman, yes, we can work together for good purpose.

Mr. BILIRAKIS. Well, I would repeat that I was a part of that promise that was made that we would double NIH funding——

Mr. BUYER. That is right.

Mr. BILIRAKIS. [continuing] over the next 5 years.

Mr. BUYER. That is right.

Mr. BILIRAKIS. So I do not know whether President Clinton had it in his mind to do so, whatever the case may be. I know it was the Congress that made that particular version, and we fulfilled it. We do not fulfill too many of the promises we make up here, unfortunately, but that is certainly what we will—we did do and we should be proud of it.

But I do not think we should be going into partisanship or President this or President that. Let us stick to what we are supposed to be doing here.

Mr. Buyer, please continue, sir.

Mr. BUYER. Well, part of what we are doing here is trying to improve society and take care of our people. And when private indus-

try do not make certain investment, and if we can partner with government, NIH to do that, we all benefit. And that is what all that is about.

I just want you to know that I just feel uncomfortable when we have got a very good hearing and people take shots; and that is what we just had here. So I just felt the need to correct the record.

I appreciate the witnesses being here today. And this is a very important issue. And Chairman is right, this is an issue that does not seem to get a lot of attention; you do not read on the headlines but it affects a lot of people in our society. And we appreciate you being here today.

Mr. BILIRAKIS. The Chair recognizes Mr. Pallone for an opening statement.

Mr. PALLONE. Thank you, Mr. Chairman, for holding this hearing. And as a member of the House Digestive Disease Caucus, I understand that these types of disorders are often overlooked. And my colleague, Representative Sue Kelly and all the members of the Caucus, have been working hard to raise awareness of these digestive diseases in Congress. And I appreciate that as members of the Health Subcommittee we are today affirming our commitment to recognize digestive diseases and confront their challenges.

I wanted to take a moment to specifically mention Crohn's disease. Mr. Brown has discussed the disabilities related to Crohn's disease, and so I will not repeat them. And I do not necessarily want to get into this argument about what President Bush is going to do, but I do mention that there is in fact a memo that we have expressing the fact that if he is reelected, that we will see cuts in NIH. And I hope that my Republican colleagues with us in opposing those. But I am not surprised if some members on the other side have not seen the document because I am sure that the Administration does not want anybody to know about it.

Crohn's disease affects an estimated 1 million Americans. Many victims of Crohn's are children and, unfortunately, for these children afflicted with the disease Crohn's becomes a constant feature of their lives. And I trust we will be learning much more about this and other disorders from our expert witnesses. But my point today is that Crohn's disease is about more than just numbers and biological dysfunction, as I learned a number of years ago when I met with a remarkable young man named Gideon Sofer. Gideon is a constituent of mine from Highland Park, New Jersey and a victim of Crohn's disease. When I met him he was 16 years old, and I listened to his story about the years it took him to get a proper diagnoses and how little is still known about treating Crohn's disease. Despite all of the medical and emotional obstacles Crohn's has thrown his way, Gideon has refused to sit ideally by. He founded the IBD Cure Foundation which works to raise awareness about digestive disorders.

In addition, he was the leading inspiration behind HCON resolution 455, a resolution I recently introduced that advocates from a commemorative stamp to increase awareness of and research for Crohn's. And Gideon has created an online petition for the stamp, which has garnered over 4,000 signatures in just a short time.

Since I have been privileged to know Gideon Sofer, this battle for Crohn's awareness has struck a personal cord with me. But the re-

ality is that this disorder and other diseases have always been personal because health care is about real people and real families who have been dealing with these diseases with no understanding of the cause or cure. We must work together to spread awareness, increase research and improve care. And it is for this reason that I have proposed HCON res. 455, and I hope that members of this subcommittee will also lend their support to legislation such as H.R. 290 introduced by Sue Kelly which expands research for IBD. I believe these types of legislation represent a step in the right direction.

And, again, I just want to thank the chairman and our ranking member for supporting this issue. I think this subcommittee and the Digestive Disease Caucus to work together in removing some of the harm and enormous burden placed on millions of Americans suffering from digestive diseases.

Thank you. Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Upton for an opening statement?

Mr. UPTON. Thank you, Mr. Chairman. I am going to put my full statement in for the record. I just want to say a couple of things.

I helped spearhead the bipartisan effort to double the funds for the NIH over a 5 year span, a successful effort. And I can assure anyone listening out there that there is going to be no cut in the NIH. President Bush is absolutely committed to increased funding for the NIH, and we have to thank folks like Chairman Young on Appropriations and Chairman Bilirakis and Chairman Tauzin, and now Chairman Barton for their support for the NIH as well. And let me just dispel any myth out there that the NIH is going to get cut. It ain't going to happen. My mom always told me it ain't right to say ain't, but it ain't going to happen.

I also want to welcome Sue Kelly. I am a co-sponsor of H.R. 290. It is something that needs to happen.

I have a dear friend that suffers with Crohn's disease. I am anxious to see us get a cure and to extend her lifespan and make sure that she and so many others that suffer from that disease have a great future ahead of them instead of one that is a dark shadow.

And I appreciate the efforts of Chairman Bilirakis to have this hearing. I look forward to being engaged and see legislation perhaps come out of it. And, obviously, increase the incentives and the encourage the NIH in their great work.

And I yield back my time.

Mr. BILIRAKIS. I thank the gentleman.

Ms. Capps for an opening statement?

Ms. CAPPS. Thank you, Mr. Chairman, for holding this hearing, a very important hearing. And I want to salute our colleague and welcome Sue Kelly, and thank you for your leadership in the legislation.

A particular thanks to our witnesses for appearing today, especially Mr. Carron. Yours is a very important testimony that is significant for us to have on the record here in Congress. So thank you for being here.

I did not prepare an opening statement. I look forward to the testimony.

Thank you.

Mr. BILIRAKIS. I thank the gentlelady.

By the way, the opening statement of all members of this committee have been a part of the record, obviously.

Let us see, Mr. Rush. Mr. Rush, who is co-author of one of the pieces of legislation regarding these diseases. Bobby, you are recognized.

Mr. RUSH. Thank you, Mr. Chairman.

And to members of the subcommittee, let me begin by commending the chairman and my good friend Mr. Bilirakis and the ranking member for their participation in this hearing and for the outstanding work. And I want to thank you for convening this hearing.

I have been long concerned about the devastating toll that digestive diseases and disorders have taken on our country. Each year more than 62 million of our citizens are diagnosed with a wide range of gastrointestinal disorders ranging from the inflammatory bowel disease to acid reflux disease, to GI cancers; just to name a few of them.

A study conducted by the Lewin Group in 2000 concluded that the direct and indirect costs of just 17 of these diseases exceeds $41 billion, however the human pain and suffering associated with these conditions are enormous and defy quantifying.

In the State of Illinois the screening rates for the most serious forms of GI diseases is low, and as a result the mortality and morbidity rates from these diseases are much too high.

I am encouraged by the progress that have been made in some areas of GI research and treatment. Yet, on the other hand, I find it disheartening that with respect to many of these afflictions we still lack even a basic understanding of the causes and the treatments of these dreaded diseases.

I am convinced that what we need is an energized and coordinated focus to digestive diseases research. And to this end, Mr. Blunt and I have introduced H.R. 3756, the National Commission on Digestive Diseases Act of 2004, which we urge the committee to favorably consider. This bill will direct the Secretary of HHS to convene a national commission on digestive diseases to be composed of the leading scientists in the field, physician specialists who treat patients in hospitals, clinics and offices everyday, patients who suffer from these afflictions and the National Institute of Health officials who manage the digestive disease research portfolio. This commission will survey the state of GI research and develop a long range plan with detailed recommendations by areas of research policy and programmatic development. The commission would issue its report within 18 months of it enactment.

There is precedent for what we are proposing. A little more than 25 years ago this committee approved the bill which created the original National Digestive Diseases Commission. The Commission's report issued in 1979 laid the foundation for countless important research developments and breakthroughs in the areas of digestive diseases.

Mr. BILIRAKIS. Please summarize, Mr. Rush.

Mr. RUSH. I sure will, Mr. Chairman.

But the work of this first Commission serves as a precedent, the successor national commission on digestive diseases will galvanize

the government, the research community and the public to undertake a comprehensive and cost effective campaign to end the scourge of digestive diseases.

Mr. Chairman, I look forward to the hearing today. I welcome the witnesses. And I look forward to affirmative action by this committee on the bill that Mr. Blunt and I introduced in the near future.

Thank you, and I yield back.

Mr. BILIRAKIS. Well, I assure you we will have affirmative action regarding this issue and trying to do something about it. I cannot assure that we will have affirmative action strictly on your piece of legislation.

Mr. RUSH. I am really disappointed——

Mr. BILIRAKIS. But as you and I discussed yesterday, I would like to include you in all the discussions that we have.

In any case, without objection I would yield 3 minutes to Ms. Sue Kelly who has the principal piece of legislation that has been introduced for some time for an opening statement.

Ms. KELLY. Thank you so much, Mr. Chairman. I thank you for the opportunity to be with you today.

As the sponsor of H.R. 290, the Inflammatory Bowel Disease Act, I greatly appreciate your leadership in convening today's hearing which will bring much needed attention and awareness to a disease that has long been in the shadows of society.

Crohn's disease, an ulcerative colitis collectively known as inflammatory bowel disease are chronic disorders of the gastrointestinal track that cause severe pain and suffering in the more than 1 million Americans who are affected. As you pointed out, Mr. Chairman, the IBD can cause severe abdominal pain, fever, bleeding, ulcerations and chronic diarrhea. But there are complications as well that are related to this disease; arthritis, osteoporosis, malnutrition, liver disease, colon cancer. IBD represents one of the major causes of morbidity from digestive illness, and it can be absolutely devastating.

I want to thank our witnesses for joining us today, and particularly Adam Carron, a very courageous young Crohn's disease patient from my home State who is going to share his story with us.

And I also want to recognize Bill and Shelby Modell who are here today attending the hearing. The Modells are co-founders of the CCFA.

I want to thank you, Mr. Chairman, for your interest in this issue and for your leadership in convening this hearing.

As I mentioned previously, I have introduced the Inflammatory Bowel Disease Act which would authorize an expansion of Federal support for IBD research at the National Institutes of Health and the Centers for Disease Control and Prevention.

We are at an exciting time with respect to research on these challenging diseases. A few years ago, the scientific community discovered the first gene associated with Crohn's disease. This is a landmark discovery, and other advancements in the field have opened up exciting new research pathways which have the potential to lead to better treatments and, hopefully, 1 day soon I hope a cure.

My legislation seeks to further this momentum by capitalizing on these promising opportunities. H.R. 290 builds upon recommendations put forth in a concurrent resolution on IBD, which I sponsored in the 107th Congress.

As you know, Mr. Chairman, that resolution was passed by the Energy and Commerce Committee in September of 2002.

The Inflammatory Bowel Disease Act currently has 177 bipartisan co-sponsors in the House, including 17 members of this distinguished subcommittee. I want to express my appreciation to each and everyone of these members who have co-sponsored this legislation.

Mr. Chairman, I look forward to working with you and Ranking Member Brown who is a co-sponsor of H.R. 290, to pass this important bill this year. H.R. 290 represents a landmark opportunity to help improve the quality of life for IBD patients and their families.

Thank you so much for allowing me to be here today. And I very much look forward to hearing from our witnesses.

Mr. BILIRAKIS. The Chair thanks the gentlelady.

I see that the chairman of our full committee Mr. Barton has joined us. Joe, would you like to make an opening statement.

Chairman BARTON. Thank you, Mr. Chairman. I will submit my formal statement in the record.

I want to thank you for holding this hearing. I want to thank Congresswoman Kelly for the effort that she has put into this issue for many years. And hopefully we can have a good hearing today and create a bipartisan sense of support to move some legislation.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Chairman Bilirakis, for holding this hearing today. Talking about digestive diseases is not easy. These diseases, however, are serious, painful and dramatically impact how many Americans carry out their daily lives. I am pleased that the Committee is starting a dialogue about improving our current efforts to address this problem.

In preparation for this hearing, I was informed that relatively little data exists regarding the causes, prevalence and control of digestives disease. Although scientists have made considerable progress in understanding the many complex diseases that affect the digestive system, the lack of solid data limits researcher's abilities to pinpoint the causes of these diseases and identify new treatment options. In addition, this lack of data limits our understanding of how many individuals are afflicted and whether these numbers are significantly increasing.

This lack of basic data is one more example of why I am making it a priority to reauthorize critically important public health agencies like the National Institutes of Health ("NIH") and the Centers for Disease Control and Prevention ("CDC"). As part of this effort, the Committee will explore how the CDC conducts surveys and how their data collection activities may be improved. This review should help us identify how the CDC can make improvements that will bring real benefits to patients suffering from digestive diseases, in addition to many other infectious and chronic diseases.

I am pleased that Dr. Spiegel is here to talk about how the research programs underway at the National Institutes of Health. These programs hold the potential to fundamentally improve our understanding of digestive diseases. As Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the past five years, and its scientific director for the previous 9 years, Dr. Spiegel has been at the forefront of scientific discoveries that have already improved patient outcomes.

By now, it is no secret to anyone that I am very committed to making improvements at our public health agencies, and particularly at the National Institutes of Health. Although NIH's research portfolio is largely dedicated to basic research that

transcends disease specific research, applying this research so that it directly benefits patients suffering from specific diseases is critical. I look forward to learning more about the scientific opportunities NIDDK is exploring and how we can encourage these developments by improving the organization and structure of NIH to maximize our investments in public health.

Once again, I appreciate all of the time the witnesses have taken to make this an informative hearing. Thank you for helping us to raise awareness about digestive diseases so that more Americans recognize the symptoms of these diseases and can begin treatments early.

Mr. BILIRAKIS. I thank the gentleman.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. ELIOT ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. Chairman, thank you for having this hearing today. Digestive diseases affect millions of Americans and I believe it is highly appropriate that our Committee examine the issues and the potential for moving research forward.

Mr. Chairman, I am pleased to welcome our witnesses. I appreciate all of their time and especially the testimony of Adam Carron from the Crohn's and Colitis Foundation of America. I appreciate your courage in coming before the Committee this morning to talk about your experienced with IBD. I also welcome Rodger DeRose from the Crohn's and Colitis Foundation. Both are from my home state of New York, and they have been instrumental in raising awareness about these diseases and helping patients in New York City and across the country. I am pleased to be a co-sponsor of H.R. 290, legislation focused on Crohn's disease and ulcerative colitis. This legislation has the support of 175 bipartisan members of the House. I look forward to working with the Chairman and Ranking Member to advance this important legislation in the Committee this year.

I am also interested in hearing what work the NIH is pursuing with regards to Irritable Bowel Syndrome (IBS). Obviously IBS doesn't get nearly the attention of IBD because it is a less severe condition and not life threatening but it still terribly disrupts the lives of its victims and we need to focus on this condition as well. I look forward to hearing from Dr. Spiegel about NIH's research efforts and a strategic plan regarding IBS.

Mr. Chairman, I thank you for your efforts to examine digestive disease and look forward to working with you on this important issue.

Mr. BILIRAKIS. All right. Let us go right into the testimony part of the witnesses. I have already introduced them.

Dr. Spiegel is the Director of National Institute of Diabetes and Digestive and Kidney Diseases here in Bethesda. Mr. DeRose is President and CEO of the Crohn's and Colitis Foundation of America. Adam Carron is a young man who unfortunately has been inflicted with this disease, but I think that is probably God's way of saying to Adam hey this is your opportunity to help an awful lot of people around the world by virtue of your personal experience. And Dr. Peura is here on behalf of the Digestive Disease National Coalition.

Your written statements are already a part of the record. And I would hope, I am going to set this at 5 minutes. I will not cut you off, but I would hope you would stay as close to it as you can. But hopefully you would sort of supplement and compliment your written statement.

Dr. Spiegel, let us start off with you, sir.

STATEMENTS OF ALLEN M. SPIEGEL, DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; RODGER DeROSE, PRESIDENT AND CEO, CROHN'S AND COLITIS FOUNDATION OF AMERICA; ADAM CARRON; AND DAVID PEURA, DIGESTIVE DISEASE NATIONAL COALITION

Mr. SPIEGEL. Thank you very much, Mr. Chairman and members of the committee. I am please to testify today regarding NIH efforts to combat digestive diseases.

I am accompanied today by Dr. Stephen James, who is the newly appointed Director of the Institute's Division of Digestive Diseases and Nutrition. He's an expert on digestive disease research, particularly immunologically mediated diseases including the inflammatory bowel diseases.

I have provided the written statement with a detailed account of the public health burden of digestive diseases, the vigorous research efforts NIH has underway in this area and future research directions based on our planning. I would like to just give you a brief overview this morning.

Digestive diseases research encompasses many serious, potentially life threatening illnesses. Examples, hepatitis, gastrointestinal cancer as well as highly prevalent diseases such as acute gastroenteritis, gastroesophageal reflux, the cause of heartburn, and irritable bowel syndrome. While these generally are not fatal, they cause significant morbidity.

In fiscal year 2003 the NIH invested nearly $1.2 billion in research on digestive diseases. The National Institute of Diabetes and Digestive and Kidney Disease, which I head, the National Cancer Institute and the National Institute of Allergy and Infectious Diseases accounted for 34, 32 and 17 percent of support, respectively.

During the period of the doubling of the NIH budget for which, by the way, we're extraordinarily appreciative of the bipartisan efforts of this Congress, NIDDK was able to fund a significant number of large scale digestive disease research initiatives. We were able to fund four new digestive disease development centers, a women's health center focusing on irritable bowel syndrome and to expand the number of digestive disease research centers from 12 to 16, including our newest one at the University of Virginia where another panel member, Dr. Peura, is the associate chief of the gastroenterology division.

There are active collaborations in digestive disease research among many NIH components. Just one example, NIDDK and NCI have joint efforts on Barrett's esophagus, which can be a precursor to cancer of the esophagus. Also, we collaborate on the diagnosis and treatment and prevention of liver cancer, which may be a consequence of infection with the hepatitis virus.

The NIDDK plays an important role in disseminating information on digestive disease through the National Digestive Diseases Information Clearinghouse. And this speaks to the chairman's point about the need not only to do the research, but to get the information out to the American public.

The clearinghouse develops and distributes health information for patients, the public and healthcare providers to improve under-

standing of digestive diseases. Just last week the NIH sponsored a consensus development conference on celiac disease, an immune mediated disorder that primarily affects the digestive tract. This disease affects about 1 percent of the U.S. population, but is currently recognized in only about one-tenth of patients with current medical practice. In addition to providing useful guidance to the NIH, we are hopeful this conference will raise awareness of the disease among medical practitioners and the public in order to promote early, accurate diagnosis and treatment.

As a major example of NIH digestive diseases research, I would like to give the committee a brief description of research advances in the inflammatory bowel diseases, ulcerative colitis and Crohn's disease. Many patients are diagnosed in childhood or in their teens and must cope for the rest of their lives with problems that include intestinal inflammation, abdominal pain, fever, diarrhea and rectal bleeding. We will hear momentarily from Mr. Carron whose testimony, I am sure, will be more eloquent than anything I could say about the impact of these inflammatory bowel diseases.

Now for decades there were no truly effective medications. Surgical removal of the affected parts of the intestine was often necessary, particularly in ulcerative colitis which can lead to colon cancer. Investigator initiated basic research on the immune system, however, began to illuminate the fundamental mechanisms responsible for intestinal inflammation. These discoveries set the stage for an ambitious long range plan for IBD research with the goals of improving lives with more effective treatment and ultimately, prevention. The plan, importantly, was formulated with external input from patient groups such as the Crohn's and Colitis Foundation of America and investigative groups such as the American Gastroenterological Association, both valued partners of NIDDK.

Through NIH research efforts significant improvements in therapy for Crohn's disease have resulted, notably the development of infliximab, a drug that targets an inflammation causing protein. The FDA's approval of infliximab was an important step forward in treating Crohn's disease.

Then as Congresswoman Kelly has alluded to, a major discovery occurred in 2001 when investigators announced the discovery of a gene that confers susceptibility to Crohn's disease. It is fine to find a new gene, but you need to actually then build on that to do something for patients, that is really the important part; and we have. The role of this particular gene illuminated that abnormalities in the innate immune system, the first line of defense against foreign invaders, was an important potential cause of Crohn's disease. This was translated into a clinical trial demonstrating the potential benefit of a new treatment which boosts the function of the innate immune system. Because other genes conferring susceptibility to inflammatory bowel disease remain to be discovered and could provide similar insights, the NIDDK established a new multicenter genetics consortium to speed this research.

In another example, and I think a particularly important one in terms of the crosscutting nature of research, NIDDK investigators demonstrated that the drug Rosiglitazone, currently used to treat diabetes, has anti-inflammatory effects in an animal model of IBD. Subsequently, an NIDDK sponsored multicenter clinical trial of

this drug for treatment of ulcerative colitis has been initiated and is currently in progress.

There are several promising agents in the pipeline and I hope the committee sees, as these highlights show, that progress in IBD research reflects a convergence of public health need, stakeholder input, scientific opportunity and the critical peer review system which assures that only the most meritorious proposals submitted to the NIH are funded.

On a broader level the NIH is now embarking on a new planning process for digestive diseases generally under the auspices of the statutory Digestive Diseases Interagency Coordinating Committee chaired by Dr. James. The first step in that process is the development of a liver disease research action plan, a commitment that I made to the chairman back in September of 2002. This is being done in consultation with external scientific and lay experts. We will be following a similar planning process for other specific digestive diseases. We believe this planning effort will produce useful guideposts for prioritization in NIH program development and importantly, will help synergize cross-cutting research efforts across the NIH.

Finally, let me mention that on March 9th Dr. James and I were pleased to present an overview of the digestive disease research program, recent advances and future plans to the newly created Congressional Digestive Disease Caucus. The caucus was founded through the leadership of Congresswoman Sue Kelly, and we are really appreciative of her commitment as Chair of the caucus to increase awareness of the burden of digestive diseases and to encourage research in this important area.

Mr. Chairman and members of the committee, I hope these few examples convey the firm commitment of the NIH to combatting the many digestive diseases within its research mission. Through research we seek to relieve the burden these chronic, debilitating, frustrating diseases place on individuals, families and the nation.

I appreciate the opportunity to address the committee on behalf of the NIH and the NIDDK, and we would be pleased to respond to any questions you may have.

[The prepared statement of Allen M. Spiegel follows:]

PREPARED STATEMENT OF ALLEN M. SPIEGEL, DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Committee: I am Allen Spiegel, Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the Institute that has lead responsibility for digestive diseases research at the National Institutes of Health (NIH of the Department of Health and Human Services. I am pleased to testify today regarding NIH efforts to combat digestive diseases. Through basic and clinical research studies, we can gain greater insights into the causes of these diseases, find more effective treatments, and develop prevention strategies. I am accompanied today by Dr. Stephen James, the newly appointed Director of the Institute's Division of Digestive Diseases and Nutrition. Dr. James is an expert on digestive disease research, particularly immunologically mediated diseases, including inflammatory bowel diseases.

In my testimony today, I will give you a brief overview of the public health burden of digestive diseases, the vigorous research efforts NIH has under way in this area, highlighting Crohn's disease research as an illustrative example, and closing with future directions based on our planning for research in digestive diseases. BURDEN OF DIGESTIVE DISEASES

The digestive system is critically important to human health and well being. This complex system includes the pharynx, esophagus, stomach, liver, biliary tract, pancreas, small and large intestines, and anorectum. Thus, digestive diseases research encompasses many serious and potentially life-threatening illnesses, such as cirrhosis of the liver, inflammatory bowel diseases, hepatitis, gastrointestinal cancer, ulcers, and gallstones. This constellation of diseases also includes highly prevalent diseases such as acute gastroenteritis, gastroesophageal reflux disease (the cause of heartburn), and irritable bowel syndrome that, while generally not fatal, cause significant morbidity.

Digestive diseases and their associated long-term complications have significant social and economic consequences for the Nation. According to a report published in 2002, the estimated annual total cost for digestive diseases, in 1998 dollars, was $85.5 billion (Sandler RS, Everhart JE, Donowitz M, Adams E, Cronin K, Goodman C, Gemmen E, Shah S, Avdic A, Rubin R. The burden of selected digestive diseases in the United States. *Gastroenterology.* 2002 May; 122(5):1500-11).

Digestive diseases rank second among all causes of disability due to illness in the United States. They result in an estimated 200,000 absences from work each day with a mean time lost of nine days. More than two million Americans are impaired to some degree by digestive diseases, limiting an estimated 1.2 million people in the type of occupation they can seek. Approximately 140,000 veterans receive payments for service-related disabilities due to digestive diseases.

The chronic nature of digestive diseases results in approximately 11 percent of all admissions to general hospitals in the United States and in 15 percent of all surgical procedures performed in this country. Approximately 200,000 deaths annually are caused by digestive diseases, including cirrhosis and other liver diseases, cancer of the digestive system, gallbladder disease, ulcers, and pancreatitis. Digestive diseases also complicate the treatment of other life-threatening conditions, such as cardiovascular disease.

In fiscal year 2003, the NIH invested nearly $1.1 billion in research on digestive diseases. The NIDDK, the National Cancer Institute (NCI), and National Institute of Allergy and Infectious Diseases (NIAID) accounted for 34 percent, 32 percent, and 17 percent of this support, respectively. Research mechanisms include regular research grants, cooperative clinical trials, epidemiologic studies and data systems, and cooperative consortia. In addition, during the period of the doubling of the NIH budget, we were able to expand the number of NIDDK Digestive Disease Research Centers from 12 to 16, as well as to add four new digestive disease Development Centers, plus a Women's Health Center (with the NIH Office of Research on Women's Health) focusing on irritable bowel syndrome. We are also vigorously supporting physician-scientists in digestive diseases through our research training and career development awards and the loan repayment program.

A statutory Digestive Diseases Interagency Coordinating Committee serves to coalesce and synergize the efforts of the many NIH Institutes and Centers that support research in this field, as well as the efforts of other Federal agencies. Intersecting research and active collaboration are found among many NIH components. For example, NIDDK's research on the development of islet cells of the pancreas complements the NCI's work on the cellular origins of pancreatic cancer. Similarly, NIDDK and NCI have joint efforts on both Barrett's esophagus, which can be a precursor to cancer of the esophagus, and on the diagnosis, treatment, and prevention of liver cancer, which may be a consequence of infection with hepatitis virus. Hepatitis is a shared research focus of the NIDDK, NIAID, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. The NIDDK and the National Center for Complementary and Alternative Medicine are working together to test silymarin, or milk thistle, in treatment of liver disease. These are just a few examples of the many ongoing collaborative endeavors at NIH in digestive diseases research.

The NIDDK also plays an important role in disseminating information on digestive diseases through the National Digestive Diseases Information Clearinghouse (NDDIC). The Clearinghouse develops and distributes health information for patients, the public, and health care providers to improve understanding of digestive diseases, such as Crohn's disease (http://digestive.niddk.nih.gov/ddiseases/pubs/crohns/index.htm). The Clearinghouse is available via the web (www.digestive.niddk.nih.gov), a toll-free phone line (1-800-891-5389), e-mail (nddic@info.niddk.nih.gov), mail (NDDIC, 1 Information Way, Bethesda, MD 20892-2570), and fax (301-907-8906). Each year, the Clearinghouse meets with representatives of professional and patient-advocacy groups to share information and seek feedback. The NDDIC's most recent national meeting was held on June 10, 2004, during which Michael Dolan reported on activities at the Crohn's and Colitis Foundation of America.

INFLAMMATORY BOWEL DISEASES: NEW DISCOVERIES AND PROMISE FOR THE FUTURE

As a major example of NIH digestive diseases research, I would like to give the committee a brief description of the paths that have been taken to realize research advances in the inflammatory bowel diseases (IBD), ulcerative colitis and Crohn's disease. Ulcerative colitis is characterized by inflammation and ulceration of the inner surface of the large intestine. Crohn's disease may involve any portion of the gastrointestinal tract, but most commonly affects the lower portion of the small intestine. The lesions of Crohn's disease may penetrate through the bowel wall and lead to the formation of fistulas, which are ulcerating lesions that tunnel through the intestines of patients.

The inflammatory bowel diseases are incurable, chronic, and debilitating. They affect an estimated 1 million Americans. Many patients are diagnosed in their teens and twenties and must cope for the rest of their lives with problems that include intestinal inflammation, abdominal pain, fever, diarrhea, and rectal bleeding. In children, symptoms can progress to malnutrition and growth retardation. These problems dramatically reduce quality-of-life and require lifelong, expensive medical care. For decades, there were no truly effective medications, so that surgical removal of the affected parts of the intestine was often necessary, particularly in ulcerative colitis, which can lead to colon cancer.

Investigator-initiated basic research on the immune system, however, began to illuminate the fundamental mechanisms responsible for intestinal inflammation, leading to important therapeutic advances, particularly in Crohn's disease. Mice in which certain key genes of the immune system had been knocked out unexpectedly developed inflammatory bowel disease mimicking Crohn's disease. Importantly, bowel disease did not develop in mice raised under "germ-free" conditions in which the bacteria normally residing in the bowel are absent. Thus, the immune gene knockout alone is insufficient to cause disease, but combines with the normal gut bacteria in provoking a self-destructive immune response.

These discoveries set the stage for an ambitious long-range plan for inflammatory bowel disease research with the goals of providing more effective treatment and, ultimately, prevention. The NIDDK has pursued the plan's aims to: (1) emphasize basic research on interactions between intestinal cells and bacteria; (2) augment the pool of researchers and foster interdisciplinary research; (3) establish and enhance appropriate biological resources and data collections; and (4) develop therapeutic applications and preventive approaches as basic research progresses.

This plan was formulated with external input from patient groups, such as the Crohn's and Colitis Foundation of America, and investigator groups, such as the American Gastroenterological Association. Dr. James has worked closely with these advocacy groups to maximize efforts toward accomplishing common research goals. The plan was updated at a meeting of the NIDDK-led Digestive Diseases Interagency Coordinating Committee in April 2003. In implementing the plan, the NIDDK has deployed the full range of available mechanisms, including a robust portfolio of investigator-initiated grants and pilot-and-feasibility studies, research training grants, large program project grants, and four Digestive Diseases Research Centers that focus on inflammatory bowel disease.

Through NIH research efforts, significant improvements in therapy for Crohn's disease have resulted, most notably the development of infliximab, a drug that targets an inflammation-causing protein whose role was illuminated by the mouse gene knockout experiments. The Food and Drug Administration's (FDA) approval of infliximab was an important step forward in treating Crohn's disease. A report in the *New England Journal of Medicine* earlier this year showed that it is particularly effective in healing the fistulas. An enormous new scientific opportunity emerged in 2001 when investigators announced the unprecedented discovery of a gene that confers susceptibility to Crohn's disease. This discovery represents an important payoff of the Human Genome Project. It is also a credit to the strong foundation laid by previous NIDDK research efforts—including an emphasis on targeted, interdisciplinary collaborations among researchers from different fields. Finding this gene illuminated the potential role of abnormalities of the innate immune system—the first line of defense against "foreign invaders"—as a cause of Crohn's disease. This insight was then translated into a clinical trial demonstrating the potential benefit of a new treatment, GM-CSF, a natural protein in the body which boosts the function of the innate immune system. Because other genes conferring susceptibility to inflammatory bowel disease remain to be discovered, the NIDDK established a new multi-center Genetics Consortium to speed this search. The pace of discovery in genetics of IBD is accelerating, as evidenced by the publication in April of the identification of two new candidate genes involved in Crohn's disease.

Most recently, results from a multicenter clinical trial were presented at the May 2004 meeting of the digestive diseases professional organizations. Researchers have shown that there is a benefit for Crohn's patients in the use of a monoclonal antibody targeting the cytokine IL-12. This work emanates from the intramural research program of the NIAID.

Other clinical insights are expected to emerge from an ongoing NIDDK-funded multicenter clinical trial to investigate whether the dosing of the standard, now generic, immunosuppressive drug azathioprine can be improved. Researchers are studying new testing methods for the metabolizing enzyme and toxic metabolites of the drug. This trial is an example of the vital role NIH can play in conducting clinical trials of a treatment when there is no longer any incentive for commercial interest in such research.

Other NIDDK initiatives include the detailed study of adult stem cells of the intestine that may ultimately lead to therapies stimulating gut regeneration. We are vigorously pursuing these research areas as we evaluate and monitor progress in attaining our goals. While this example illustrates how investments in investigator-initiated basic research lead to discoveries that improve the outcomes of patients with Crohn's disease, we recognize that we must take steps to accelerate the translation of basic science discoveries into patient benefits. For this reason, NIH and NIDDK are taking steps to bolster translational research.

INFLAMMATORY BOWEL DISEASES: TRANSLATIONAL RESEARCH OPPORTUNITIES

The NIH is strongly committed to spurring translational research in both Crohn's disease and ulcerative colitis. By translational research, we mean research to speed the movement of laboratory discoveries into research that holds promise of direct clinical benefits for patients—also called "bench-to-bedside" research. NIH Director Elias Zerhouni, M.D., has stressed the importance of this type of research in his initiative to develop a Roadmap for medical research, and the many Institutes and Centers of the NIH are also emphasizing translation research in their respective programs. At the NIDDK, for example, we have recently completed an assessment of drugs in the pipeline for several diseases within our mission, including the inflammatory bowel diseases—Crohn's disease and ulcerative colitis. One good example of translational research involves the drug rosiglitazone, which is used to treat diabetes. NIDDK-funded investigators demonstrated that this drug has anti-inflammatory effects in an animal model of IBD, and subsequently, a NIDDK-sponsored multi-center clinical trial of this drug for treatment of ulcerative colitis has been initiated and is currently in progress. There are approximately 10 new drugs under development for one or both of these diseases, as well as many new studies of existing agents. The novel therapies have emerged from a foundation of basic research supported by the public sector, with drug development steps pursued by the private sector. We are encouraged when industry builds upon NIH-funded basic research discoveries because such activity offers promise of new and more effective treatments for IBD.

We have identified roadblocks to translational research in IBD and steps that can be taken to address them, such as the development of surrogate markers of disease activity and better diagnostic tests. It is also essential to maximize the research investment in animal models of IBD, which can continue to provide insights into the underpinnings of the disease, and also serve as a source of potential genetic discoveries and a means of testing emerging new therapies. Research progress is often hampered by the difficulty of obtaining access to human samples. To overcome this barrier, NIDDK has recently initiated a repository that will collect and make available to investigators various types of human samples, including blood, biopsies, genetic material, and datasets. Another barrier to clinical research concerns the great complexity of modern clinical trial designs. To facilitate testing of additional new treatments under development, the NIDDK convened a meeting in January 2003 that included representatives from the FDA, industry, and the investigative community, to seek improvements in the design of clinical trials, with emphasis on improving trial endpoints. We will continue to foster such proactive partnerships with the FDA and industry, and also to pursue clinical studies in needed areas that industry does not have a commercial incentive to explore.

As these highlights show, progress in IBD research reflects a convergence of public health need, scientific opportunity, stakeholder input, and the merit of research proposals submitted to the NIH for funding. While many strides have been made, we still recognize that our currently available therapies have many drawbacks and may not provide the adequate symptom relief that patients need. At the same time, however, we are encouraged by the advances being made through research and are committed to accelerating the pace of discovery and translation.

To this end, NIDDK is fostering more cross-cutting initiatives, including emphasis on harnessing powerful new technologies in genomics, proteomics, and molecular imaging to address long-standing problems. Availability of a non-invasive imaging method to assess liver scarring or fibrosis, for example, would transform the clinical management of many liver diseases which now must rely on invasive biopsies. Such cross-cutting initiatives have broad application not only to digestive diseases, but also to a wide array of other diseases within the NIH research mission. By pursuing such endeavors, we can help to maximize NIH research investments by promoting their greatest yield and application.

ENHANCING DIGESTIVE DISEASES RESEARCH

In building the digestive diseases research portfolio, we recognize the importance of input from the scientific and lay community external to the NIH. I would like to provide just a few examples.

Stakeholder input is an important dimension of our planning and program development processes. As noted previously, our joint planning efforts with the Crohn's and Colitis Foundation of America have been very productive. Another example of input that guides NIH program development can be found in the insights and recommendations we obtain from a wide range of conferences and workshops. For example, in digestive diseases, the NIH has sponsored critically important Consensus Development Conferences on hepatitis C, and we recently submitted to the Congress a report on our implementation of the recommendations we received. Just last week, June 28-30, 2004, the NIH sponsored a Consensus Development Conference on celiac disease, an immune-mediated disorder that primarily affects the digestive tract. This disease affects about 1 percent of the U.S. population but is recognized in only about one-tenth of patients using current medical practice. In addition to providing useful guidance to the NIH, we are hopeful that this conference will raise awareness of the disease among medical practitioners and the public in order to promote early, accurate diagnosis and treatment.

On a broader level, the NIH is now embarking on a new planning process for digestive diseases generally, under the auspices of the Digestive Diseases Interagency Coordinating Committee chaired by Dr. James. The first step in that process is the development of a Liver Disease Research Action Plan, in consultation with external scientific and lay experts. An open meeting provided significant input from representatives of professional organizations, patients, and the public. Six draft chapters of the Plan have already been posted on the NIDDK website for additional public comment, and remaining chapters will be posted as they are completed by the Committee. We will be following a similar planning process for other specific digestive diseases, and we believe that this planning effort will produce useful guideposts for prioritization in NIH program development, and will help synergize cross-cutting research efforts across the NIH.

Finally, I also want to mention that on March 9, Dr. James and I were pleased to present an overview of the NIDDK digestive disease research program, recent advances, and future plans to the newly-created Congressional Digestive Disease Caucus. The Caucus was founded through the leadership of Congresswoman Sue Kelly. We are most appreciative of her commitment, as Chair of the Caucus, to increase awareness of the burden of digestive diseases and to encourage research in this important area.

Mr. Chairman and Members of the Committee, I hope that these few examples convey the firm commitment of the NIH to combating the many digestive diseases within its research mission. Through research, we seek to relieve the burden these chronic, debilitating, frustrating diseases place on individuals, families, and the Nation. I appreciate the opportunity to address the Committee on behalf of the NIH and the NIDDK, and would be pleased to respond to any questions you may have.

Mr. BILIRAKIS. Thank you very much, Dr. Spiegel.

Mr. DeRose, you are on, sir.

STATEMENT OF RODGER DeROSE

Mr. DEROSE. Well, thank you, Mr. Chairman. I appreciate the opportunity to testify on behalf of the patients across the country.

I think you all have background now in terms of the complications of this disease, so I am not going to be repetitive in that. I think when you hear Adam's story, you will understand the dilemma that so many of these patients face; that you look at a

young man like this that looks healthy and at the same time you know that on the inside they are not healthy. And that is the deceiving part about this disease. And we find this as we go across the country talking to patients that we do not get our due respect because individuals see our patients and do not recognize how debilitating this disease can be.

I just wanted to give you some background in terms of our foundation. We were founded in 1967. And, actually, two of our cofounders are here today, Mr. Chairman. I want to recognize them, Bill and Shelby Modell from New York. And, you know, they started this organization with the Rosenthals in 1967 because they had a teenager that had the disease. And a few years ago they lost their son, Michael, to not complications to Crohn's but the fact that his immune system was compromised so dramatically that other diseases set in. And they lost him. They have continued to be 100 percent committed to this organization, day in and day out.

From the time that we have started we have expanded to 42 chapters around the country. We have a mission of research, education and support. To date, we have raised nearly $300 million, $100 million of that has gone directly into research. Because we have such a high efficiency rate as an organization, the majority of the balance of that $200 million has gone into education and support to the patient community.

And I think it is fair to say, Mr. Chairman, that the organization in its 30 plus years history has an impact on every major aspect of this disease in terms of improving the quality of life of the patient community in terms of: New therapies that have been introduced because of the basic science that CCFA has supported; safer alternatives to steroids that were available, only available 25 years ago; advanced surgical techniques that have given patients their life back; improved diagnostic tools that have allowed us to detect the disease much earlier; in the area of early warning signs in terms of dysplasia and cancer, and; also in the area of nutritional therapies because many of our patients are malnourished. They cannot get the calories into their system because they're going to the bathroom so often and flushing this through their system. And importantly, education programs.

In the area of education while we run these education programs throughout the country and over 300 support groups around the country each year, we also reach out to the children with this disease in terms of running camps. We have 14 camps across the country that help children cope with the physical as well as emotional battles that they deal with with this disease. It is staffed by volunteer doctors, volunteer nurses and camp counselors 7 by 24.

So it is a community that is really based on volunteerism and has a dramatic impact in the advances that are taking place in this disease state.

I want to say one thing about the number of patients that I have talked about. We conservatively estimate that it is a million Americans, but we happen to believe that it is probably much higher than that. Anecdotally as we travel the country, as we get phone calls from patients and we talk to the professional community, it is our understanding that we are probably underestimating the size and the impact of this disease across our country. And as a re-

sult of that, the foundation 2 years actually went to the Center for Disease and Control and Prevention and we actually went to them and ask them to submit a grant request to CCFA so that we could start an epidemiology program with them, an epidemiology study to better understand the prevalence of this disease. So we funded it to the tune of three-quarters of a million dollars for those 2 years.

And our scientific advisory committee has been working very closely with the CDC, but despite repeated encouragement from your colleagues, Mr. Chairman, on the Appropriations Committee the CDC has yet to provide any financial support for this project. And now that the study has been initiated by funding from a patient group to a government agency, we are hoping that the CDC will contribute to the completion of this major study. And, of course, that is one of the aspects of the IBD bill.

With respect to research, I have to tell you that it is a real privilege for us to work in partnership with the NIH within NIDDK and in particular with Dr. James as well as Dr. Allen Spiegel. Dr. James actually sits as an ad hoc member, a nonvoting member of our national scientific advisory committee. And so we have a very close working relationship with them, and we exchange intellectual knowledge as we try to advance the state of this disease on behalf of the patient community.

I think one good example of that is the benefits that this approach has led to in terms of the discovery of the very first gene that was talked about were CCFA funded that and then the NIH came in and continued to invest the furtherance of understanding, the impact of that gene as well as other genes that may lead to getting us closer to the cure.

We are very proud of the support that we have had and that we have played with the NIH. If you talk to some of the investigators, they would say that there is probably a 20 times multiplier of fact in terms of from the time that they first get their CCFA grant from us to the time that they meet the midpoint of their career in terms of the additional funding that they get from the NIH. So you can see that there is an infusion of knowledge that is taking place here from the preliminary data that CCFA is providing with the research that the NIH is picking up and continuing.

So I am confident that working together that we can make dramatic strides here.

Mr. Chairman, I do want to thank Congresswoman Sue Kelly for introducing the bill as well as Congressman Jessie Jackson, Jr. And I thank you for taking the time out to hear our testimonies today and everything that you are doing on behalf of the patient community to advance the quality of life for our patients.

Thank you very much. And I would be happy to answer questions whenever you are ready.

[The prepared statement of Rodger DeRose follows:]

PREPARED STATEMENT OF RODGER DEROSE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CROHN'S AND COLITIS FOUNDATION OF AMERICA

Mr. Chairman and members of the subcommittee, thank you for the opportunity to testify today. I am Rodger DeRose, President and Chief Executive Officer of the Crohn's and Colitis Foundation of America.

CCFA is the nation's oldest and largest organization dedicated to finding a cure for inflammatory bowel disease. IBD (which includes both Crohn's disease and ulcerative colitis), is a chronic disorder of the gastrointestinal tract which afflicts conservatively 1 million Americans, 100,000 or 10% of whom are children under the age of 18. IBD can cause severe diarrhea, abdominal pain, fever, and rectal bleeding. Complications related to the disease include; arthritis, osteoporosis, anemia, liver disease, and colon cancer. IBD represents a major cause of morbidity from digestive illness, and although it is not usually fatal due to the major advances that have occurred in the last 30 years, IBD can be devastating. We do not know its cause, and there is no medical cure.

Founded in 1967, CCFA is headquartered in New York City and has 42 chapters that provide education and support services to patients in all 50 states. Since its beginning, CCFA has generated $300 million in revenues—$100 million of which has been directly invested in basic and clinical research related to IBD. Because CCFA prides itself on being an efficient organization, with low administrative costs, a large percentage of the remaining $200 million has been reinvested in patient education and support programs.

Through CCFA's leadership, our organization has impacted every major advancement in Crohn's and colitis over the past 30 years including: new therapies and safer alternatives to steroids, advanced surgical techniques, improved diagnostic methods to detect the disease earlier, early warning of dysplasia for the treatment of colorectal cancer in patients, nutritional therapies for struggling patients who can't get calories into their malnourished bodies, and education programs for both the patient and professional community.

In the area of education, CCFA plays a leadership role in patient based training through our 42 chapters and the 300 support groups that we offer to patients each year. Additionally, we reach out to children with IBD by sponsoring 14 camps throughout the US to help kids deal with the physical and emotional elements of this disease. We staff the camps with volunteer doctors, nurses and camp counselors that are available 24 hours a day, 7 days a week to meet the needs of the kids.

As I mentioned earlier, it is conservatively estimated that 1 million Americans suffer from either Crohn's disease or ulcerative colitis. CCFA and other leaders within the digestive disease community believe, however, that the actual number of patients is significantly higher. As a result, the Foundation has provided the Centers for Disease Control and Prevention with $750,000 over the past two years to initiate a national IBD epidemiology study to determine the true prevalence of the disease.

Gaining a better understanding of the number of patients afflicted with IBD, and their demographic characteristics, will give us invaluable clues as to the role that environmental factors play in the development and progression of the disease.

CCFA's National Scientific Advisory Committee has developed a strong working relationship with the CDC on this important study. However, Mr. Chairman, despite repeated encouragement from your colleagues on the Appropriations Committee, CDC has yet to provide any financial support for the project. Now that the study has been initiated by an investment from the patient community, we are hopeful that CDC will contribute to the continuation and completion of this major study. Mr. Chairman, we would welcome your support of this important initiative as we move forward.

With respect to research, the IBD community is encouraged by the significant progress that has been made in recent years. We are extremely grateful for the leadership of Dr. Spiegel, and his colleague Dr. Stephen James, at the NIDDK. They are strong partners in our continuing effort to combat this disease.

However, we all agree that much more needs to be done. To that end, CCFA's scientific leaders have developed a forward-thinking research agenda entitled, "Challenges in Inflammatory Bowel Disease" that outlines the many exciting opportunities that currently exist in the field. Next to the NIH, CCFA is the leading source of funding for IBD research. CCFA plays a critical role in providing "seed funding" to researchers interested in IBD. This support helps investigators gather preliminary findings which, in turn, enables them to pursue advanced IBD research projects through the NIH. A good example of the benefits of this approach is the research that led to the discovery of the first gene associated with Crohn's disease in 2001. Preliminary support for this historic research was provided by CCFA and enhanced by the NIDDK and other funding sources in subsequent years.

We are proud of the enormous impact that support from CCFA has had on Crohn's and colitis research. Some investigators estimate that there is a 20 factor multiplier effect from the time a CCFA funded investigator receives their first CCFA grant to the peak of their career. In fact, more than 80% of CCFA-sponsored

researchers have obtained subsequent funding from the NIH for further IBD research.

Mr. Chairman, I am confident that working together, with additional resources, we will develop better treatments and eventually a cure for these diseases. In 5 years, I'm hopeful that we will have approximately 5 biologic treatments available to target the disease. Today we have 1 FDA approved biologic with several pursuing or finishing stage 3 trials. In 10 years, I am hopeful that through our genetic understanding of the disease that we will have genetic treatments to alter the course of the disease. We are at an unprecedented time of optimism with respect to research on IBD. Opportunities for advancement and real progress have never been greater. An additional investment in this area has the potential to yield significant and tangible results for patients.

Mr. Chairman, I would like to take this opportunity to thank Congresswoman Sue Kelly and Congressman Jesse Jackson, Jr. for their leadership in introducing the "Inflammatory Bowel Disease Act" in the House. This landmark legislation, which addresses IBD research at the NIH and CDC, as well as other issues that are important to our community, has over 175 bipartisan co-sponsors, including 17 members of this distinguished subcommittee. On behalf of CCFA and the entire IBD community, I want to express our sincere appreciation for all of the support that this important legislation has received. Our patients and family members across the nation encourage the subcommittee to pass legislation focused on inflammatory bowel disease this year.

The chances are high that most of the subcommittee members here know someone with this disease: a co-worker, a family member, friend, acquaintance. What you may not know is the symptoms that they live with daily because most look normal outwardly but they are anything but normal on the inside.

We need your help in bringing Crohn's and colitis out of the closet so patients can get the support they need in seeking the cure through the NIH and the CCFA. You can be sure that the CCFA will do its part to end the disease.

In closing Mr. Chairman, I want to thank you for your interest in this disease and for convening this important hearing today. Our Long Island chapter was honored that you took time out of your busy schedule to join us for our annual dinner in May. Our Long Island Chapter President, Jamie Pappas and his family, send you their best. We are very grateful for your leadership and look forward to working with you to help improve the quality of life for IBD patients and their families.

I would be pleased to respond to any questions that you may have.

Mr. BILIRAKIS. Unfortunate news that we have 3 votes on the floor.

Let us go into Adam.

STATEMENT OF ADAM CARRON

Mr. CARRON. Mr. Chairman and members of this committee, thank you for the opportunity to testify today.

I am Adam Carron, an 18 year old ulcerative colitis patient from Long Island, New York and I appreciate the opportunity to share my story about living with inflammatory bowel disease with you.

My experience with IBD began at age 9. It started with bloody stools and intense abdominal pian, and my parents' nightmare came true when my doctor told us all that I was probably suffering from ulcerative colitis; the same disease that lead to the death of my uncle at age 42 and the illness my mother was struggling with.

Before I could even pronounce "inflammatory bowel disease," let alone know what it was, I knew I had something bad and was in serious trouble. I even feared that I was going to die.

I remember the insecurities affecting my everyday life; backing out of sleeping at friends' houses and going to camp; even being at school needing permission to use the bathroom frequently during the day fearful of what might happen if my teachers said no.

I was given the responsibility to remember to take my medicine every day, both orally and anally, just so that I would not have stomach cramps and blood in my stools. I resented it because in a

time when all I wanted was to fit in, none of my friends had the same issues, and therefore I did not always follow through.

But at age 11 I got very sick. The medications were no longer able to control my symptoms. I was bleeding profusely and had severe pain. I could not stop vomiting. I was forced to go into the hospital and for several weeks I lay there being given massive doses of steroids. I will never forget having to miss trick or treating with my friends and then not being able to eat the Halloween candy my sister had so graciously gathered for me because I could not eat any food.

Finally, I was released from the hospital but had to stay on the steroids for several months in order to wean my body from the harsh treatment. I could not even look at myself in the mirror, for my face had swelled up beyond relief.

A little over 1 year later, I found myself in the hospital again. This time the steroids that I was given did not help. I kept bleeding and bleeding and suffering, and constantly going to the bathroom. I was there for over one mo nth of my summer vacation and lost 25 percent of my body weight. My joints, my insides, and my psyche were all inflamed. I thought that I would never leave the hospital that month. It was at that point that my parents and doctors decided to remove my colon. After a little while, including 2 years with an ostomy, the physical pain was gone but the suffering I went through will never leave me. Several years and several surgeries later my body is, more or less, back in tact. I wake up everyday and see red lines running across my stomach, these red lines which represents the scars from the surgery provide me with a constant reminder of my struggle with IBD, yet they also serve to remind me of how lucky I am.

I am lucky because I had access to great physicians and I was able to have these successful operations and sit before you today, I hope and pray, physically cured of the disease. But not everyone with IBD gets to tell a happy ending to their story. I now spend some of my time working for the Long Island Chapter of the Crohn's and Colitis Foundation of America, helping adolescents cope with the disease, on both the individual and social fronts.

Earlier this year, I visited with a young lady, Ariana Pappas, the daughter of the CCFA Long Island Chapter President, on the weekend before her surgery. I could see in her eyes the fear that she had of the pain and the resulting scars from the surgery. I also saw the hope that she had that she would be relieved of this pain if the operation were to be successful.

I often see promising young kids forced to miss months of school at a time, causing test scores and grades to plummet from As to Cs. I have seen a young boy ridiculed everyday at school because his growth has been stunted so significantly by IBD that he looks 6 years younger than his 13 year old age. I see children so distraught and so mentally defeated, simply because they think that talking about the disease is unacceptable in today's society. Our society has inadvertently put a cap on bowel discussion, which does not usually become lifted until those days in the retirement home.

Mr. Chairman, hope for IBD patients and their families lies in the promise of better treatments and a cure through biomedical research. To that end, I want to thank Congresswoman Sue Kelly for

her leadership in introducing the Inflammatory Bowel Disease Act in the House. This landmark legislation, which addresses IBD research at the NIH and CDC, as well as other issues that are important to our community, has over 175 bipartisan co-sponsors, including 17 members of this distinguished subcommittee. On behalf of the CCFA and the entire IBD community, I want to express our appreciation for your support, and encourage you to pass this important bill this year.

In closing, I want to thank you, Mr. Chairman, for your interest in this disease and for convening this important hearing today. We are very grateful for your leadership and look forward to working with you to help improve the quality of life for IBD patients and their families. I would be pleased and honored to respond to any questions that you may have.

[The prepared statement of Adam Carron follows:]

PREPARED STATEMENT OF ADAM CARRON, MEMBER, CROHN'S AND COLITIS FOUNDATION OF AMERICA

Mr. Chairman thank you for the opportunity to testify today. I am Adam Carron, an 18 year-old ulcerative colitis patient from Long Island, New York and I appreciate the opportunity to share my story about living with inflammatory bowel disease with you.

My experience with IBD began at age nine. It started with bloody stools and intense abdominal pain, and my parents nightmare came true when my doctor told us all that I probably was suffering from ulcerative colitis; the same disease that lead to the death of my uncle at age 42 and the illness my mother was struggling with. Before I could even pronounce "Inflammatory Bowel Disease," let alone know what it was, I knew I had something bad and was in trouble. I even feared that I was going to die. I remember the insecurities affecting my everyday life; backing out of sleeping at friends houses and going to camp, even being at school, needing permission to use the bathroom frequently during the day, fearful of what might happen if the teachers said "no". I was given the responsibility to remember to take medicine everyday, both orally and anally, just so that I would not have stomach cramps and blood in my stools. I resented it because in a time when all I wanted was to fit in, none of my friends had the same issues, and therefore I did not always follow through.

At age 11 I got very sick. The medications were not controlling my symptoms. I was bleeding profusely and had severe pain. I could not stop vomiting. I had to go into the hospital. For several weeks I lay in the hospital, being given massive does of steroids. I'll never forget having to miss "Trick or Treating" with my friends and then not being able to eat the Halloween candy because I could not have any food. Finally I was released from the hospital and then had to stay on the steroids for several months in order to wean my body from the treatment. I could not even look at myself in the mirror, for my face had swelled up beyond belief. A little over one year later, I found myself in the hospital again. This time the steroids that I was given did not help. I kept bleeding and bleeding and suffering, and constantly going to the bathroom. I was there for over one month of my summer vacation and lost over 25% of my body weight. My joints, my insides, and my psyche were all inflamed. I thought that I would never leave the hospital. It was at that point that my parents and doctors decided to remove my colon. After a little while, the physical pain was gone but the suffering I went through will never leave me. Several years and several surgeries later my body is more or less back intact. The physical pain was finally gone but the suffering I went through will never leave me. I wake up everyday and see red lines running across my stomach. These scars provide me with a constant reminder of my struggle with IBD, yet, also serve to remind me just how lucky I am.

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weekend before her surgery. I could see in her eyes the fear that she had of the pain and the resulting scars from the surgery. I also saw the hope that she had that she would be relieved of her pain, if the operation were successful. I often see promising young kids forced to miss months of school at a time, causing test scores and grades to plummet from "A's" to "C's." I have seen a young boy ridiculed everyday at school because his growth has been stunted so significantly by IBD that he looks 6 years younger than his 13-year-old age. I see children so distraught, and mentally defeated, simply because they think that talking about the disease is unacceptable. Our society has inadvertently put a cap on bowl discussion, which does not usually become lifted until those days in the retirement home.

Mr. Chairman, hope for IBD patients and their families lies in the promise of better treatments and a cure through biomedical research. To that end, I want to thank Congresswoman Sue Kelly for her leadership in introducing the "Inflammatory Bowel Disease Act" in the House. This landmark legislation, which addresses IBD research at the NIH and CDC, as well as other issues that are important to our community, has over 175 bipartisan co-sponsors, including 17 members of this distinguished subcommittee. On behalf of CCFA and the entire IBD community, I want to express our appreciation for your support, and encourage you to pass legislation on IBD this year.

In closing, I want to thank you Mr. Chairman for your interest in this disease and for convening this important hearing today. We are very grateful for your leadership and look forward to working with you to help improve the quality of life for IBD patients and their families. I would be pleased to respond to any questions that you may have.

Mr. BILIRAKIS. Thank you so much, Adam, for that very moving statement.

Let us see, we have three votes on the floor. The first vote takes a few minutes and then two 5 minute votes after that. I would like to finish up maybe Dr. Peura's statement and then we can take a break.

Proceed, sir, and hopefully I will not have to cut you off. We certainly do not want to miss the first vote.

STATEMENT OF DAVID PEURA

Mr. PEURA. Thank you very much.

Mr. Chairman, members of the subcommittee, thank you for initiating this hearing on assessing digestive disease research and treatment opportunities, and particularly for allowing the Digestive Disease National Coalition to present testimony.

I am Dr. David Peura. I am Associate Chief of the Division of Gastroenterology and Hepatology at the University of Virginia. I am Professor of Medicine at that institution. I am also an active clinician, clinical researcher for over 30 years.

Established in 1978, the Digestive Disease National Coalition is a national non-profit advocacy organization comprised of the major gastrointestinal volunteer patient organization and professional societies. Currently there are 25 member organizations that belong to the DDNC. One of the original members of the coalition is the American Gastroenterological Association of which I am a member and currently serve as the President-elect.

The mission of the Digestive Disease National Coalition is to work cooperatively to improve access to and quality of digestive health care in order to promote the best possible medical outcome and quality of life for current and future patients diagnosed with digestive diseases. The founder of the DDNC was a Crohn's disease patient who saw the need for increased digestive disease research and education.

As we have heard, inflammatory bowel disease is just one of the scores of debilitating gastrointestinal conditions that afflict more than 62 million Americans. Others include hepatitis and other liver disease, irritable bowel syndrome, disease of the pancreas, ulcers, pediatric and adult gastroesophageal reflux, metabolic disorders, colon cancer, celiac disease, motility disorders, hemochromatosis and a number of other serious ailments.

A recent study, "The Burden of Gastrointestinal Disease," conducted by the Lewin Group concluded that a group of just 17 digestive disease disorders accounted for $41 billion each year in direct and indirect health costs. In some of these areas, medical research has brought us closer to developing lifesaving treatments and cures.

For example: The application of immunologic advances which have made liver transplantation a common life saving approach; the development of effective screening techniques for colorectal cancer; the genetic contributions of IBD, which we have heard about, acute and chronic pancreatitis, pancreatic and colon cancer and chronic diarrheal illnesses, these are all just on the cusp of clinical application.

Yet for every breakthrough, there is still a lack of even basic understanding of the causes, prevention, transmission and treatments of a variety of other disease.

IBD, the name given to Crohn's disease and ulcerative colitis, is a painful disrupting disorder, which currently has no cure. In Crohn's disease, the large and small intestines become inflamed. This inflammation can result in excessive diarrhea, severe rectal bleeding, anemia, fever, as well as abdominal pain and cramping, as we have heard. But I think it is important to emphasize this for the people that are afflicted with this condition.

Those battling this disorder face the trauma of multiple surgeries and the effects of toxic and potentially dangerous drugs. Ulcerative colitis attacks the large intestine, as we have heard, causing painful diarrhea, bleeding, and can ultimately lead to colon cancer, the third most common cancer among the population in the United States, difficult to diagnose and often misdiagnosed.

The goal of medical treatment of IBD is to suppress the inflammation in the large and small intestine, thereby permitting the intestines to heal and some of the symptoms to be relieved. While surgery is an option for some people, removing the segment of the small intestine of the colon, and may allow people to be symptom free for years, it is not always a cure.

Mr. Chairman, the Digestive Disease National Coalition supports the passage of H.R. 290, The Inflammatory Bowel Disease Act. In addition to being endorsed by the coalition, the bill is endorsed by 7 of the DDNC member organizations.

The DDNC commends Congresswoman Sue Kelly for her leadership in introducing this legislation. This bipartisan bill has 176 cosponsors, 17 of whom sit on this committee. The broad support of this bill reflects the tremendous potential in biomedical research related to IBD. The scientific community, led by the CCFA, has developed a long range strategic plan for the future of IBD research and is in agreement that an additional investment in IBD research

has the potential to yield greater scientific progress in clinical and general research in other areas as well.

The DDNC also supports the passage of H.R. 3756, The National Commission on Digestive Diseases Act, introduced by Congressman Roy Blunt and Congressman Bobby Rush. In 1976, Congress passed legislation that authorized the first national commission on digestive disease——

Mr. BILIRAKIS. Dr. Peura, forgive me, but I am doing something that I did not want to do. But we have less than 3 minutes left to get over and cast this vote. So you will have to forgive us. And when we get back, you will finish up. It will be probably about 20 minutes or so. As soon as we cast the third vote, we will hustle back here.

Mr. PEURA. Fine.

Mr. BILIRAKIS. Thank you.

[Brief recess]

Mr. BILIRAKIS. We are back in session.

Dr. Peura, please proceed, sir. And, again, I apologize for the interruption.

Mr. PEURA. Well, actually it was a very good place to pause, because the presentation is sort of in two halves. We have covered the issue of the IBD bill.

The DDNC also supports the passage of H.R. 3756, The National Commission on Digestive Disease Act, introduced by Congressman Blunt and Congressman Bobby Rush. In 1976, Congress passed legislation that authorized the first national commission on digestive diseases. Actually, I am probably chronologically gifted enough to have practices in the BC era, and that was before the first commission. And so I have actually seen the results of that commission.

A quarter of a century later, H.R. 3756 would authorize a contemporary commission to provide a blueprint for the digestive diseases research endeavor of the future. Like the original commission, the new commission would be charged with assessing the state of digestive diseases in the United States, identifying areas in which improvement in the management of digestive diseases could actually be achieved and creating a long range plan to recommend resources to effectively promote the GI research portfolio.

We are particularly thankful for the leadership of Congressman Blunt and Rush on this bill.

In a time of limited fiscal resources to pursue an almost boundless reservoir of scientific opportunity, it is even more imperative that the most promising avenues of research are traveled and that only the highest quality grants, trials, centers, and other programs are awarded funds. If the work of the first commission serves as a precedent, this initiative will once again galvanize the government, the research community and the expanding population of people suffering from digestive diseases in a comprehensive and cost effective national campaign to end the scourge of digestive disorders.

I would again thank you, Mr. Chairman, and this members of this subcommittee for holding this important hearing, and ask that the committee pass H.R. 290, The Inflammatory Bowel Disease Act and H.R. 2756, The National Commission on Digestive Diseases Act as soon as possible.

And I will be more than happy to answer any questions.
[The prepared statement of David Peura follows:]

PREPARED STATEMENT OF DAVID A. PEURA, DIGESTIVE DISEASE NATIONAL COALITION

Mr. Chairman and members of the subcommittee, thank you for initiating this hearing on Assessing Digestive Disease Research and Treatment Opportunities and allowing the Digestive Disease National Coalition and to present testimony. I am Dr. David Peura, Associate Chief, Division of Gastroenterology and Hepatology and Professor of Internal Medicine at the University of Virginia Health Sciences Center.

BACKGROUND ON THE DDNC

Established in 1978, the Digestive Disease National Coalition (DDNC) is a national non-profit advocacy organization comprised of the major gastrointestinal volunteer patient organizations and professional societies. Currently there are 25 member organizations that belong to the DDNC. One of the original members of the coalition is the American Gastroenterological Association (AGA) of which I am a member and currently President-elect.

The mission of the Digestive Disease National Coalition is to work cooperatively to improve access to and the quality of digestive disease health care in order to promote the best possible medical outcome and quality of life for current and future patients diagnosed with digestive diseases. The founder of the DDNC was a Crohn's disease patient who saw the need for increased digestive disease research and education.

THE IMPACT OF DIGESTIVE DISEASES

Inflammatory bowel disease is just one of the scores of debilitating gastrointestinal conditions that afflict more than 62 million Americans; others include hepatitis and other liver diseases, irritable bowel syndrome, diseases of the pancreas, ulcers, pediatric and adult gastroesophageal reflux, metabolic disorders, colorectal cancer, celiac disease, motility disorders, hemochromatosis, and other serious ailments.

A recent study, *The Burden of Gastrointestinal Diseases,* conducted by the Lewin Group, concluded that a group of just 17 digestive diseases accounts for more than $41 billion each year in direct and indirect health care costs. In some of these areas, medical research has brought us closer to developing lifesaving treatments and cures. Examples of this include:

- The application of immunologic advances which have made liver transplantation into a common life saving approach.
- The development of effective screening techniques for colon cancer.
- The genetic contributions to IBD, acute and chronic pancreatitis, pancreatic and colon cancer and chronic diarrheal diseases which are just on the cusp of recognition.

Yet for every breakthrough, we still lack even a basic understanding of the causes, prevention, transmission and treatments for other diseases.

IBD, the name given to Crohn's disease and ulcerative colitis, is a painful and disrupting disorder, which currently has no cure. We see in Crohn's disease the large and small intestines have become inflamed. This inflammation can result in excessive diarrhea, severe rectal bleeding, anemia, fever, as well as abdominal pain and cramping. Those battling this disorder have the trauma of multiple surgeries and the effects of toxic and potentially dangerous drugs. Ulcerative colitis attacks the large intestine, causing painful diarrhea, bleeding, and can ultimately lead to colon cancer, the third highest cancer population in the United States.

IBD is an unpredictable disorder, symptoms vary in nature, frequency, and intensity. I wish I could say IBD was an easy disease to diagnose, but it is not. Misdiagnosis is common. Because there is no cure for IBD, the goal of medical treatment is to suppress the inflammation of the large and small intestine and the colon. By suppressing this inflammation, intestinal and colon tissue is permitted to heal and relieve many symptoms. Surgery can be an option to remove the diseased segments of the bowel or the colon. While surgery might allow patients to be symptom-free for many years, it is not a cure.

LEGISLATIVE INITIATIVES IN DIGESTIVE DISEASES

Mr. Chairman, the Digestive Disease National Coalition supports the passage of *H.R. 290, The Inflammatory Bowel Disease Act.* In addition to being endorsed by the coalition, the bill has been endorsed by many of the DDNC member organizations.

The DDNC commends Congresswoman Sue Kelly (R-NY) for her leadership in introducing this legislation. This bipartisan bill has 176 co-sponsors, 17 of which sit on this committee. The broad support of the bill reflects the tremendous potential in biomedical research related to IBD. The scientific community, led by CCFA, has developed a long-range strategic plan for the future of IBD research and is in agreement that an additional investment in IBD research has the potential to yield greater scientific progress in clinical and general research.

The DDNC also supports the passage of *H.R. 3756, The National Commission on Digestive Diseases Act,* introduced by Congressman Roy Blunt (R-MO) and Congressman Bobby Rush (D-IL). In 1976, Congress passed legislation that authorized the first National Commission on Digestive Diseases. The Commission was charged with assessing the state of digestive diseases in the United States identifying areas in which improvement in the management of digestive diseases could be achieved, and creating a long-range plan to recommend resources to effectively deal with promoting the GI research endeavor. The Commission, because it provided a credible roadmap for research and generated enthusiasm within the biomedical community, precipitated a number of research breakthroughs.

In a time of limited fiscal resources to pursue an almost boundless reservoir of scientific opportunity, it is all the more imperative that the most promising avenues of research are traveled and that only the highest quality grants, trials, centers, and other programs are awarded funds. If the work of the first Commission serves as precedent, this initiative will once again galvanize the government, the research community, and the expanding population of people suffering from digestive diseases in a comprehensive and cost-effective national campaign to end the scourge of digestive disorders. Like its predecessor, the Commission should be directed to develop and recommend a long-range plan for the use and organization of national resources to effectively deal with digestive diseases.

I would again thank you Mr. Chairman and the members of this subcommittee for holding this important hearing and ask that the committee pass *H.R. 290, The Inflammatory Bowel Disease Act and H.R. 3756, The National Commission on Digestive Diseases Act* as soon as possible.

Mr. BILIRAKIS. Thank you very much, Mr. Peura.

I do not know whether any other members will return. Please do not think that there is a lack of interest in the subject; there is not. But it is a very hectic, frantic place, obviously, and a lot of other obligations and that sort of thing. Mr. Brown particularly extends his regrets because I know there is a group from Cleveland who—I guess they purchase from a charity, they purchase the right to have lunch with him or something. I think the Rotary Club or something of that nature. It is a critical that he has got to go. And so I know he apologizes.

I am just going to ahead.

For some time, Drs. Spiegel and Peura particularly, going back to the prior Administration in the sense that when the Democrats controlled the Congress and whatnot, we on this committee felt that we should not be determining what specific dollars should be earmarked for what specific disease. You know, the feeling was that the people at NIH know where the breakthroughs might be pretty darn close and, therefore, they are in a much better position if you will, to determine how many dollars should go to—Sue and I have talked about this. And so anyhow, it has always been our policy to not set out specific amount of dollars that will be going to research for a specific disease.

We had doubled NIH funding. We had planned to continue to increase NIH funding. And we have been hoping that they would do the job adequately in terms of allocations of dollars.

I mean, I have had Mohammad Ali come in here on behalf of Parkinson's and plead for more funding for Parkinson's. We can go on, ALS, Alzheimer's. You can just go on and on. And, of course, every group considers their disease, if you will, the highest priority

and I do not blame me. So, you know, what can we really do here? So that has always been sort of our feeling.

And I am going to ask for the two of you particularly, what your opinion is regarding that? Do you think it is right for Congress to decide what diseases deserve more attention than others or is this priority setting activity, as I have already said, best determined by the scientists and advisory counsels at the NIH.

Dr. Spiegel?

Mr. SPIEGEL. Thank you, Mr. Chairman.

Let me just say that I again want to emphasize how enormously appreciative we are both of your leadership and the bipartisan support in Congress that permitted the doubling of the NIH budget and allowed us to initiate some of these important digestive disease initiatives that I alluded to.

The reality is that science is extraordinarily complex. Because it is so complex, it is difficult often to predict where the next discovery is coming from. I gave the example of a diabetes drug which targets a receptor that turns out to be very highly expressed in the colon, and actually reduces inflammation in the colon first in animal models and then in the clinical trial, and which we are studying extensively and may become a therapy for ulcerative colitis. So for this reason we really do appreciate the flexibility in being able to set priorities.

Having said that, and having met with your staff in April, it is vital for the NIH priority setting process to be as transparent as possible. I am committed to doing the best possible job we can in making that as transparent as possible. And we do that by inviting and sharing with stakeholders such as the CCFA, the AGA, that we are hearing from, from patient groups, traveling around the country meeting with patient groups. Again, as an example, the CCFA has crafted a tremendous strategic plan in IBD which was then extensively presented at an April 2003 meeting that Dr. James chaired at our Digestive Disease Interagency Coordinating Committee. This was an opportunity for all the NIH institutes to hear this plan and work toward its implementation.

The bottom line ultimately is that, given the complexity of science, given the interrelation between things that you work on in one area that end up being very helpful to another area and the rapid pace with which these things change, we appreciate the flexibility to be able to set priorities, but in no way do we have any sense of arrogance or being isolated in saying that we are going to do this in a top down way. It has got to be transparent, it has got to have input from external groups and stakeholders, and that is what we are committed to.

Mr. BILIRAKIS. Should it have in effect mandates from Congress in terms of the amount of dollars that should be allocated to that particular disease?

Mr. SPIEGEL. Let me not be presumptuous. We are fortunate to live in an extraordinary democracy and you as the elected representatives of the people ultimately are responsible to your constituents. I view myself, as a physician, scientist and public servant, as accountable to you as the elected representative and want to work in partnership with you in each of these areas. To the extent that you offer us the flexibility to do this priority setting and

do it in the most transparent way possible, we certainly appreciate that. And I know that Dr. Zerhouni as the NIH Director, who has interacted extensively with you, does. This gives us the opportunity.

I will cite just one other example. There are many areas of both basic fundamental research as well as large projects. Take the human genome project. That was an enormous undertaking of the NIH. It was just the first step in a way, just getting all those 3 billion A, G, C and Ts, but it was the investment in that which was not specific to any disease that then allowed a tremendous acceleration in the discovery of the Crohn's susceptibility gene. That would not have happened without the investment in something that in this case was not disease specific. We have to keep that perspective in mind.

I know you have heard from Dr. Zerhouni about the NIH Roadmap. In my many ways that is another example; the idea of increasing the harmonization of clinical research practices. That has got to be a benefit to people with IBD, with ALS, with every disease where we are desperate for better treatments and preventions, and where accelerating clinical trials and really being sure that we have the public's input is vital.

Mr. BILIRAKIS. So you feel that you have adequate flexibility?

Mr. SPIEGEL. We never take it for granted and are appreciative of having that flexibility.

Mr. BILIRAKIS. Dr. Peura?

Mr. PEURA. Well, again, I want to take the opportunity again to thank you for having this hearing and allowing me to testify.

Mr. BILIRAKIS. Is the mic on?

Mr. PEURA. It is a very difficult question you ask. I mean, as a clinician I see people with lots of different disease, but I know that inflammatory bowel disease, for example, what we are discussing here is a disease that causes significant morbidity, mortality. And we have heard from Adam about the morbidity that it caused him.

Money spent for a particular disease is not just for that disease. And as Dr. Spiegel had mentioned, there are amazing outcomes that come from understanding immunology that cross many, many different disease states. Much of what we would learn by research in IBD would also be applicable to arthritis and neuro-degenerative disorders and other sorts of things. It is really not to say that anything is disease specific, because the fundamentals of research cross many disease entities.

I do know that digestive diseases as a class of disease causes significant morbidity, mortality. And as I mentioned, I practiced in the BC era. Before really—and usually when I say that it is before cimetidine which was really probably one of the first advances in pharmacology in gastroenterology where we treated ulcer disease. Endoscopy was based on ulcer disease. Colostomy was based basically on ulcer disease, but now we recognize that ulcer disease is an infectious disease and research going in there, now we can cure a chronic disease. We spent a lot of money in the past on ulcer, but we recognize that the advances in endoscopy, colostomy, surgical techniques, all of that came from ulcer disease.

So, I am obviously an advocate for money for digestive disease, but I think money is well spent on disease like IBD because of its implications for a variety of conditions.

Mr. BILIRAKIS. You both said it well, but I think you said it more like a lawyer than you did—but you know, we have these good people, people like Adam coming and testifying here and wanting us, almost pleading with us—he has not done so, but really pleading with us that X amount of dollars, should be more funding for, as I said, Parkinson's or funding for ALS. And Sue has dollars in her particular piece of legislation that would be earmarked specifically for these diseases, and whatnot.

So, you know, again the question is I mean what do we tell them? I cannot explain it the way you all have. What do we tell them? It is right for Congress to decide what diseases deserve more attention than others; and that is the question. And I think you both said in a sense that it is not right that Congress do that. At least I think Dr. Spiegel has said that in a round about way? It's important because we are met—you know, we do not have to meet with the patients just as you do. But they are pleading with us. Yes, they are pleading with you to get them well. They are pleading with us to allocate more money, which we can hope of course that more money would result in a cure. I mean, there is a hope thing there.

Anything further?

Mr. PEURA. Well, Mr. Chairman, I mean I think that if I were answering that question and somebody came into my office and said that, I would probably say I want to be as committed to supporting research. Research in one particular area, as we have mentioned, is going to effect the disease that you have, the disease that other people have, too. The problem is when we do not fund research, when we shut the faucet off and, you know, research suffers and many generations of physicians suffer. I mean, I am faced with young physicians everyday that are making a decision whether they should have a research academic career or whether they should go into private practice. Private practice is vital. There have to be people out here taking care of the Adams in this world. But there also have to be people, the best and the brightest, that are available to apply for the NIH funding and for the other funding, CCFA funding that is out there.

And to say, to sort of support that by being very positive in research and targeting those areas such as IBD that really will have an opportunity to make a major impact, not only on lives of sufferers of IBD, but patients with a variety of digestive conditions and nondigestive. I mean, I think that would be my answer, that I am committed to research. And I think it is important to have prioritization, but commitment to research and research that is going to bear fruit.

As I said, following the best and most productive avenues I think is going to be important. And that is what a digestive disease commission would also help do.

Mr. BILIRAKIS. Mr. DeRose, I believe it was you who accented maybe a lack of cooperation, lack of funding from CDC. Was it not you that made that comment? Yes. Why do you not expand on that?

Mr. DEROSE. For some time now the Appropriations Committee has had dollars allocated for an epidemiology study at the CDC, but those dollars have not been spent or focused in the area of IBD epidemiology study. And our frustration as an organization from a patient point of view has been that if the allocation is there and we can make a strong case as a patient group on the needs of this growing dilemma that we have in our country, why cannot those dollars be allocated appropriately by the CDC to move this research forward.

And so our frustration stems from that. And to the point where we said we are going to put our money where our mouth is, and that is what we believe it is important. And we will go to the CDC and ask them to submit a grant, have it peer reviewed through the same process that we use for all our grants. And if it passes, and is approved, then we will fund dollars to it.

But we felt it important enough that we take a lead on it on behalf of being able to come to you and say, Mr. Chairman, it's not a million Americans; it is 2-, it is 3-, it is 4 million Americans.

Mr. BILIRAKIS. We do not really know.

Mr. DEROSE. We do not know. The last study was done in 1991 in Olmstead, Minnesota. And that, to me, is not the best representation of every aspect of the country, nor every ethnic group of the country. And there are some high incidents of this disease in ethnic groups.

So I would say that that was our frustration with the CDC. And we still have a very positive relationship with them, and it will continue. But since they report to you as a stakeholder, I think it is incumbent on you and the Appropriations Committee to ask penetrating questions with the knowledge that you have to be able to say why are we not funding, why are we not proceeding with this study that has already been allocated.

Mr. BILIRAKIS. Okay. And you will be available for any inquires we may have to help us?

Mr. DEROSE. Sure.

Mr. BILIRAKIS. Good.

Adam, you were at the CCFA event on Long Island, were you not? You were not there?

Mr. CARRON. I do not believe I was at that particular gala.

Mr. BILIRAKIS. You were not at that particular one?

Mr. CARRON. I do not think—I am actually positive I was not there.

Mr. BILIRAKIS. Well, I was there. And I started to get tears in my eyes during your testimony, and I guarantee I had them when she, of course, had something like a half hour to share her experiences with us. And, you know, the feeling was at the time that she was basically well. She had improved so tremendously, and then she went to camp, and you have told me. What has happened since she went to camp, tell us?

Mr. CARRON. She had her first surgery, which was at Mount Sinai, and it was supposed to be her final surgery.

Mr. BILIRAKIS. Yes, she had had many surgeries. Well, she had surgeries over a period of years.

Mr. CARRON. Yes. I am sorry. This surgery at Mount Sinai was supposed to be her final surgery.

Mr. BILIRAKIS. Right.

Mr. CARRON. And it was very similar to the operation that I had where they would take the small intestine and form a pouch basically and then remove the colon. And so kind of reconnect that there.

But while she was at camp, she had an obstruction which formed by the scar tissue on the inside which had basically closed up and she was forced to come from camp and go back into the operating room to have that basically reopened up. And I believe she is currently recovering from that right now.

Mr. BILIRAKIS. Yes. Well, I notice that you counsel a lot of these young people, adolescents and whatnot on this disease. Are these young people who have the disease?

Mr. CARRON. Yes. I am serving as kind of the co-director of youth activities for the Long Island Chapter. And through that I am—I get deferred to a lot of younger kids. And I will go to the hospital to visit them or call them, and basically kind of like relax them and let them know what they are about to go through and to share my experiences with them so that—to that basically so that they will be able to deal with the IBD as best as they can and feel most confident doing so.

Mr. BILIRAKIS. Well, you are to be commended, Adam, for your courage, for your toughness, for your willingness to come here and share with us. And even though there are not other members other than Ms. Kelly here to ask our questions, a record is being taken. And I assure you it will all be very, very helpful.

I have taken more than my time, because not only be the Chair but also because nobody is here to do it, but I will yield to Ms. Kelly for her inquiry.

Ms. KELLY. I thank you, Mr. Chairman. I thank you so much for letting me here and be a part of this hearing today. I really appreciate your generosity on that.

Mr. DeRose, I want to go back to the issue about the support that CCFA has given the Centers for Disease Control. As I understand it, the CDC has not provided any support for IBD epidemiology program, that program.

The IBD Act includes the provision that will formally establish the epidemiology program, and it is really needed.

Mr. Chairman, I think it is important that we recognize organizations that contribute their own resources to projects that benefit the general public good and to promote the types of public/private partnerships in the way that the CCFA has stepped forward to do. This is an unusual organization. The members of CCFA have demonstrated that they are willing to fund research, they have put a lot of money in research and in education. And I just want to go on record as saying I feel very strongly that we in Congress owe it to organizations like that to try to at least match the amount that they have collected and put into the research on their own because it is the type of research, as both the doctors on this panel have pointed out, will extend the life of many people from many different kinds of diseases. Autoimmune disease are a very particularly interesting group of diseases. And bits of research can be put together to help others all the way along the line.

And the other thing I like to just go on record as saying is this Congress does fund specific diseases. We fund research in AIDS, we fund research in cancer and we just passed a bill to fund research on stroke. It seems to me if we do that for those three diseases where we have such a strongly committed group of people who have collected such large amounts of money on their own and offered it to the CDC, we in Congress really could help a lot of people if we would at least be able to match that by requesting of the CDC that amount of money.

I do not know, Mr. DeRose, if you would like to—I mean, I welcome this opportunity to ask you question. I would like to hear if you have got any more thoughts on this, because I think this is extraordinary? I do not know of other groups that—you are not a large groups, you are a small group and you have collected a lot of money and you have put a lot of research grants out there on your own. You have done a lot just to try to build the information base. And that is really what, I think, in part you are asking for now. And I would just like to point out that that is the reception that I got from you, and I want to know if you would like to just respond to that?

Mr. DEROSE. Well, Congresswoman, I would be echoing some of the points that you have made and think I mentioned earlier. I really do think that it is important for organizations such as ours to take a leadership role. If a government agency is not going to take action on an objective that has been laid out for them, then we are. And we will make the investments so that we can show to them, as well as to the community, that we are in position to advance knowledge and advance information so that we can get the true picture of this disease into the right hands so that you can make those kinds of decisions that are needed.

I personally feel that we as a disease state should be getting more dollars allocated to this disease. It is a complex disorder. It is not a one gene type of a disease, it is multiple genes. It is probably, depending on the literature, 10 to 20 genes that affect this disease state and we have only discovered one. And there is great activity that is taking place right now in other chromosomes. Chromosome 5 and 10 that I think once verified, and it is being verified now in independent labs around the world, we may be on the breakthrough of other genes that it may behoove us for further understanding——

Mr. BILIRAKIS. Well, but if the gentleman will yield. But do you not make that case to NIH? You made that case to CDC, and apparently they have not been cooperative. But you make that case.

I mean, who are we to make that case to? Who are we to understand the breakthrough and the complexities, as you indicated, and the technicalities and whatnot, whereas those people are the experts? And as long as we give them the funding, it seems like you should be able to make the case to them and then, hopefully, the funding would be adequate.

Mr. SPIEGEL. If you will permit me, I would like to interject something which is relevant to this point and actually harks back in a way to what Mr. Buyer I believe had said in some of his initial statements.

We work with the CCFA in a unique kind of public/private partnership which I really value, and I think that Congressman Kelly has underscored.

Mr. BILIRAKIS. I think it is terrific.

Mr. SPIEGEL. In a sense they are providing seed money to investigators who would not be able to get NIH grants without preliminary data. This is the system that we have. And it is a conservative system, but it has to be because currently under the best of circumstances only one of three applications can be funded. The reality is that we have to be extremely circumspect and we want some preliminary evidence that they can accomplish what they are setting out to do.

It is the CCFA and organizations like it, and there are some other organizations in our institute that we work with this way, who provide that seed money. As you heard from Mr. DeRose, it then leverages multifold because of the generous resources you have given us.

That is one dimension that I think is very important, and I really do value that partnership.

Let me just illuminate, and this comes to Mr. Buyer's point earlier, that we want to be extremely circumspect with every hard earned tax dollar that you give us in terms of how it is used. We do not want to reinvent the wheel. We do not want to do the work of private industry. We are not talking about nonprofit voluntary groups such as the CCFA, but industry in terms of the pharmaceutical and biotech industry. In that respect we are really now very much focused on what we call a translational emphasis for inflammatory bowel disease. We are spending at NIH as a total for fiscal year 2003 of $58.4 million on IBD. That money, though, is really targeted to areas in which we believe only NIH, only government support could really make a difference. Let me just illuminate that.

We led an almost groundbreaking kind of meeting with the FDA in January of 2003. Dr. James led that meeting, and organized that meeting. The drug industry and biotech industry were there trying to work out ways to get better indices of the disease. There's something called the Crohn's disease activity index, which is a very crude measure of disease. The fact is that you have to constantly do endoscopy, and Dr. Peura is an expert he knows how to do this, but it is invasive in a way. We need ways that are noninvasive, a simple blood test for example that could tell us how bad this disease is. These are the kinds of things, fundamental investments, which industry cannot do but which we can do; we have set these out as important goals.

Finally, just as an example, there is an interesting situation vis-à-vis ulcerative colitis versus Crohn's disease. There are actually over 10 or more new agents in the pipeline at varying stages short of approval, some of which will come through, for Crohn's disease. There is lesser activity, actually, in ulcerative colitis. Why is that? The fact is that you have this drastic maneuver of colectomy, removing the entire large bowel as a "cure." It is an alternative, but it is not the desirable outcome that we want. We want to be able to avoid that with effective kinds of treatments. For that reason we have focused extensive attention on ulcerative colitis. With this dia-

betes drug that I mentioned, there is no guarantee that is going to work, but we will not find out unless we are supporting that kind of effort.

Another example is the a drug azathioprine. It is a generic drug which is an immunosuppressant. It is now generic so there is no patent exclusivity and there is less incentive for drug companies to really be working or testing that. Again, Dr. James' leadership is involved in funding studies based at the University of Chicago and other places that are looking at the metabolism of that drug. There are wide differences among children and others in terms of the metabolism of that drug so that we need to be able to know what is the most effective dose that will suppress the disease and yet not have dangerous side effects. This is the kind of work that only NIH can support, and this is why we are so grateful for the support you are giving us to focus our attention on these areas and the translational opportunities.

Ms. KELLY. Reclaiming my time.

Dr. Spiegel, I would like to follow up with you on that because I am not really clear right now. From what you said it seems to me that we need to do the epidemiologic study that the CCFA has asked for. We have not gotten the support for that study from the CDC. And what I do not understand is are you are talking about a lot of things. There is a lot of things other there. But what I do not understand is why if NIH and CDC are connected, there cannot be some pressure from NIH on CDC to get that epidemiologic study done.

Mr. SPIEGEL. It is an excellent point. I can tell you, I am an ambitious guy, and I think an energetic guy, and I find that running my institute gives me a full time job as opposed to necessarily running other parts of the CDC. We are sensitive to what you are saying. We value colleagues at the CDC and we actually work with them in a variety of areas, often in very close partnership.

The physician and epidemiologist, I think her name is Siobhan O'Connor, at the CDC has been involved in conducting this study. She is someone we have had up to the NIH to Bethesda. We have wanted to hear from her about her methods. We are in dialog about these kinds of things. Maybe you will accuse me of not being sort of forceful enough, but I have not seen it as within my purview to dictate what they should be doing in regard to this study.

Ms. KELLY. Well, I am just a little puzzled about the money. We are giving NIH a lot of money, CDC has a lot of money. Crohn's and Colitis Foundation has given CDC a lot of money. And there is no movement on the part of CDC.

Mr. Chairman, I am wondering if perhaps it would be helpful to the CCFA if you and I wrote a letter directly to the CDC and asked them why there is no movement on that and just weigh in on the fact that it might be——

Mr. BILIRAKIS. We have been known to do that. And I have already talked to Cheryl about it. That is why I made the comment about maybe asking Mr. DeRose would be available when we might need some information toward that.

Yes, we will follow up as far as that is concerned.

Your time has basically expired.

Ms. KELLY. Thank you.

Mr. BILIRAKIS. Look, we want to do the right thing, okay. We sort of ask, you know, put yourselves in our shoes sometimes, too. You know everybody, I mean there is never enough money, No. 1. There certainly is not ever enough money for any of the diseases, and yet the squeaky wheel gets the grease and there have been some diseases that the wheels have been more squeaky than others and have gotten funding, mostly through the appropriation process. But we do want to do the right thing. And we also have to realize that money—money is significant as far as research is concerned, but there are other ways in addition to—in addition to, not in lieu thereof but obviously in addition to things that Adam have shared with us that he is doing with some of the younger people and things of that nature could be helpful.

So, to adjourn the hearing, but I would like to invite you, and I mean it sincerely and I do it every hearing, is to feed into us—well, first of all we are going to have a series of questions to you that we will submit to you in writing and we are requesting that you respond to them in a timely fashion, number. Particularly as it might involve a piece of legislation.

I am hopeful that before this year is up we are going to have some legislation on this issue. I cannot tell, I am not all powerful enough to tell Bobby Rush that his legislation will become law, and I am not powerful enough to tell Sue that her legislation will become law. But I am hoping that we will have a good piece of legislation that will combine some of the better parts of both pieces of legislation that, hopefully, will be set up in such a way that they will get the proper credit for it. Because that is important. They do not do it for credit, but I think it is obviously important that that be taken into consideration.

So taking that into consideration, respond to our questions as soon as you can. Feed into us any additional points you want to make that you have not made here today that might come to mind, any suggestions you may have to crank into the legislation, things of that nature. Let us not fight the battle of what this President did or what the previous President did, or anything of that nature. I mean, that is the wrong way to go. That is what really gets us off the track when we get into this partisanship business, and it happens unfortunately much too much up here. And we throw stones at each other rather than get our heads together and do what is right for the public out there. And you saw a little bit of an idea of that earlier today. And that is unfortunate. But I do know that all of these people are concerned, and I do know that they ultimately want to do the right thing. It is how we go about it sometimes that is maybe not the right way to go.

Adam, you come up with any ideas; first of all, if you see Ariana, give her my best, but also any ideas that you might have that would be helpful to us in order to be able to do a better job, please do not hesitate.

Thank you so very much, gentlemen.

The hearing is adjourned.

[Whereupon, at 1:07 p.m. the hearing was adjourned.]

[Additional material submitted for the record follows:]

RESPONSE FOR THE RECORD BY DAVID A. PEURA, DIGESTIVE DISEASE NATIONAL COALITION

Q. As has been stated, Congressman Blunt and I have introduced a bill that would create a temporary commission to conduct research on digestive diseases. Historically, Congress has established similar research commissions on many disease areas. Can you please comment on why it makes sense for Congress to act and create a Digestive Diseases Research Commission?

A. During the late 1990s, digestive diseases researchers and clinicians reported that there was a growing incidence in the number of patients with serious gastrointestinal diseases. In an effort to gain external validation for this growing problem, the AGA contracted with the Lewin Group in 2001 to conduct a study entitled "The Burden of Gastrointestinal Diseases." The study focused on just 17 of the scores of digestive diseases and included a comprehensive analysis of at least 5 nationally recognized health statistics data bases to determine the overall annual financial burden, in direct and indirect costs, associated with these 17 diseases. The study found that the combined direct and indirect costs to society for these diseases in 2000 were $42 billion. While the study only focused on a subset of all digestive diseases, the results have been recognized as substantive documentation that the U.S. faces a crisis in terms of the incidence of digestive diseases.

A Digestive Diseases Research Commission would focus the research community on setting priorities and research goals and address these issues in a trans-NIH and trans-scientific community fashion. This mechanism has been recognized as a successful model by scientists for over 35 years, with the first Digestive Diseases Research Commission in the 1970s as a prime example. The commission would be required to report back to Congress to ensure accountability in its deliberations.

Q. The first Digestive Diseases Research Commission was created back in the 1970s. Dr. Peura, can you comment on the benefits of creating a second Research Commission on digestive diseases?

A. A second commission would provide an important opportunity to update the work of the very successful first Digestive Diseases Research Commission. Approximately 15-18 commissioners would be appointed by the Secretary of HHS, drawing from the ranks of distinguished scientists in digestive and other diseases, representatives from research in other federal agencies, patient advocates, the pharmaceutical industry, technology experts, and industry leaders impacted by the loss of productivity related to digestive diseases. Their efforts would concentrate on the following:

- Developing a comprehensive forward-looking strategic plan for addressing the crisis in digestive diseases over the next 5-10 years;
- Addressing overarching approaches to new and effective clinical trials, specific clinical studies, refining new technologies and setting standards in these areas;
- Recommending more collaborative, inter-institute research and ways to accelerate new initiatives to more quickly and efficiently find effective treatments and cures;
- Assessing the need for more researchers in digestive diseases to meet the challenges posed by the growing incidence of digestive disorders;
- Updating the work of the first commission due to the advent of genomics and genetics research, new technologies and the discovery of new digestive diseases and how to apply this information to new research initiatives.

The efforts of the first commission led to the advent of powerful new therapies such as interferons and monoclonals and new technologies such as CT colonography and capsule endoscopy. The discovery of the H. pylori bacteria as the cause of ulcers and the IBD 5 gene's role in Inflammatory Bowel Disease are also major breakthroughs set in motion by the first commission. The first commission also recommended the establishment of the Digestive Disease Core Research Centers program which remains a model of collaborative research even today.

We still face many new challenges in the area of obesity, hepatitis and hepatomas, and the potential use of foodborne pathogens as bioterrorism agents just to name a few of many existing diseases and threats.

Q. Some critics of our bill contend that a Digestive Diseases Research Commission duplicates NIH functions already in place, such as the work done by the National Institute of Diabetes and Digestive and Kidney Diseases. Would you please tell us how a temporary research commission would supplement the work of the NIDDK and its advisory committee?

A. Actually, the NIDDK Advisory Council, which meets 3 times per year for approximately 1½ days for each meeting, operates much differently than a commission. The Council is comprised of 18 members, only 2 of which are experts in gastrointestinal diseases. The primary function of the Council is to provide second level

peer review for current research grants, grant issues and budget issues (i.e. the size of grants) which occupies approximately 50% of their meeting time. The other portion of the meeting is occupied with updates on ongoing NIH programs. As such, the NIDDK Advisory Council, as with other institute councils, does not address strategic issues or long-range research planning, but more of the "here and now" operational issues. It also does not operate as an inter-institute body. The Council serves an important operational role for the NIDDK but has a clearly distinct mission from that of a commission.

It should also be noted that one of the major outcomes of the advisory council process, scientific "consensus conferences" on specific diseases, reflect a culmination of research and not new research and, as a result, are not intended to develop new knowledge. A Digestive Diseases Research Commission would complement the Advisory Council's work by providing a forward-looking mechanism for developing a long-range plan to help accelerate research into more effective treatments and cures for digestive diseases.

Q. Can you tell us the differences between creating an internal research commission and an external commission as Mr. Blunt and I are proposing? What are the merits and/or disadvantages of each approach?

A. An internal commission would impose upon NIH to create a potentially permanent structure which is currently not in place. The logistics of creating such a body would be cumbersome, potentially disruptive of the current work being undertaken by scientists and administrators and impractical as it would require individuals to change roles and methods of operating for a defined period of time. NIH might also be required to hire more full time staff to accommodate an internal commission and, thereby, create a more permanent and costly alternative to an external commission. Digestive diseases research is also such a broad area of investigation that it lends itself more to community participation than internal deliberation. Only 10% of all research monies are designated to intramural research so the depth of expertise does not exist within the structures of NIH. Finally, due to the restrictions placed upon federal agencies, an internal commission exercise would be confined to supporting the parameters of the President's budget request and would not be conducive to creative thinking and long-range planning, thereby being more reactive in nature. In addition, the effort would not be a trans-NIH initiative and, therefore, would not be a centerpiece of other institutes' programs.

An external commission would provide an opportunity for academic gastroenterologists and other specialists to provide leadership and accept responsibility for the elements of a comprehensive long-range plan addressing digestive diseases. This exercise would also energize the digestive diseases community. Since 90% of NIH research is not conducted in Bethesda, but elsewhere in the country, it is essential to energize, and achieve buy-in, from the community that ultimately will implement the plan. This approach would also be the most effective in helping ensure any initiatives included in the plan are trans-scientific community and trans-institute.