This is a preliminary transcript of a Committee Hearing. It has not yet been subject to a review process to ensure that the statements within are appropriately attributed to the witness or member of Congress who made them, to determine whether there are any inconsistencies between the statements within and what was actually said at the proceeding, or to make any other corrections to ensure the accuracy of the record.

RPTS MERCHANT

DCMN HERZFELD

MARKUP OF H.R. 1256; H.R. 1259; H.R. 1246;

H.R. 1253; H.R. 20; H.R. 307; H.R. 479;

H.R. 577; H.R. 756; and H.R. 914

WEDNESDAY, MARCH 4, 2009

House of Representatives,

Committee on Energy and Commerce,

Washington, D.C.

The committee met, pursuant to call, at 10:13 a.m., in Room 2123, Rayburn House Office Building, Hon. Henry A. Waxman [chairman of the committee] presiding.

Present: Representatives Waxman, Dingell, Boucher, Pallone, Gordon, Rush, Eshoo, Stupak, Engel, Green, DeGette, Capps, Doyle, Harman, Schakowsky, Gonzalez, Inslee, Baldwin, Ross, Weiner, Matheson, Butterfield, Melancon, Barrow, Hill, Matsui, Christensen, Castor, Sarbanes, Murphy, Space, McNerney, Sutton, Braley, Welch, Barton, Hall, Upton, Stearns, Deal, Whitfield,

Shimkus, Shadegg, Buyer, Radanovich, Pitts, Mack, Walden, Terry, Rogers, Myrick, Sullivan, Murphy, Burgess, Blackburn, Gingrey and Scalise.

Staff Present: Earley Green, Chief Clerk, Sharon Davis, Chief Legislative Clerk; Jennifer Berenholz, Deputy Clerk; Caitlin Haberman, Assistant Clerk; Phil Murphy, Assistant Clerk; Valerie Baron, Special Assistant; Alli Corr, Special Assistant; Phil Barnett, Staff Director; Kristin Amerling, Chief Counsel; David Rapallo, General Counsel; Karen Lightfoot, Communications Director and Senior Policy Advisor; Karen Nelson, Deputy Staff Director for Health; Andy Schneider, Chief Health Counsel; Sarah Despres, Senior Health Counsel; Robin Appleberry, Counsel; Naomi Seiler, Counsel; Tim Westmoreland, Counsel; Purvee Kempf, Counsel; Anne Morris, Legislative Analyst; Amy Hall, Professional Staff; Ryan Long, Minority Counsel; Aarti Shah, Minority Counsel; Chad Grant, Minority Legislative Analyst; and Lance Kotschwar, Minority General Counsel.

The Chairman. The meeting of the committee will come to order. The Chair will start with an opening statement, and the Ranking Member will be given 5 minutes as well for an opening statement, and we will then have opening statements of 2 minutes by the other members of the committee.

This is an historic day in the fight against tobacco, but it has taken us far too long to get here. I first introduced this legislation over 10 years ago and have fought every year since then to see it become law. We came close last year when the House passed this legislation by a vote of more than 3 to 1. Despite that overwhelming support, the bill did not become law, so we are back here again. I am hopeful that this year will mark the end of this long road and the beginning of great, great strides in protecting our children from tobacco.

All of us here share the goal of reducing the death and disease caused by tobacco. Tobacco is the leading preventable cause of death in our country, and every one of us has seen the devastating effects of tobacco, whether through losing someone we love, watching others grow sick, or even feeling the grip of nicotine addiction firsthand. Worst of all it is watching our children and grandchildren targeted as the next wave of casualties.

Regulating tobacco is the single most important thing we can do right now to curb the deadly toll of tobacco, and FDA is the

right agency to do this job. In fact, FDA is the only agency with the right combination of scientific expertise, regulatory experience and public health mission to effectively oversee these products. This bill will give the FDA the authority to prevent the dangerous and all too prevalent marketing and sales of tobacco to kids. It will empower FDA to prevent tobacco companies from making false and misleading claims about their products. And it will give FDA the ability to require changes to product content or design to protect the public health.

Some believe this legislation will serve only to distract FDA from its core mission. They say FDA is already facing an almost insurmountable challenge just managing its current workload. I share the concern about FDA's current ability to fulfill its mission, but it is clear to me that FDA's recent struggles are primarily a result of years of chronic underfunding. That is a failure in which both Congress and the last administration played a part.

But this unfortunate state of affairs does not mean FDA cannot and should not take on the critical role of protecting the country against the harms of tobacco. It simply means that when we give the agency this additional responsibility, we also must give it the resources necessary to handle the job and to handle it well. We have ensured that this will happen under this legislation.

The tobacco program will be fully funded through new users'

fees paid for by the industry. We have carefully crafted the legislation to ensure that the monies received from those user fees will be directed exclusively to the tobacco center. And we have ensured that the amount of user fees will be enough to permit FDA to effectively take on this task. So the new tobacco program at FDA will not impact the other programs at the agency; it will not affect the work the agency is doing in the areas of food, drug or device regulation; but it will give FDA the authority to address one of the most significant public health issues in this country.

Simply put, the bill meets the twin goals of assuring adequate funding for the tobacco program and protecting FDA's ability to fulfill its other critically important responsibilities. In short, we have everything we need to take this historic step: a comprehensive and flexible set of new authorities; a full, certain funding; and all we need now is the political will to do the right thing. I am hopeful that we have that, too.

This bill draws wide bipartisan support from all corners of the country. The breadth of support for this bill, from AARP to the American Academy of Pediatrics, from the Islamic Society of North America to the Southern Baptist Convention, just shows how critical this issue is to all Americans.

I also want to note that we have worked hard to communicate specific concerns. We have heard about the bill. The bill that

we will have before us today is identical in all substantive respects to what we passed by the House last year. In that bill we made changes to ensure fairness and flexibility for convenience stores, tobacco growers and small manufacturers. We have added provisions to ensure that FDA addresses the issue of menthol in cigarettes as one of its first priorities. And we also worked with the Minority to address many of their concerns.

I am proud that we have reached this day. I look forward to taking this step toward protecting our children from the deadly tobacco epidemic. We will be marking up some important public health bills that address issues from hearing to postpartum depression to the health care workforce. These bills all passed the House under suspension last year, and I hope to move them as expeditiously as possible.

[The prepared statement of Mr. Waxman follows:]

******** INSERT 1-1 ********

The Chairman. I want at this time to yield to Mr. Deal for an opening statement.

Mr. Deal. Mr. Chairman, I would ask if you would recognize Mr. Buyer, who has a speaking engagement. Would you recognize him first?

The Chairman. Mr. Buyer, we will recognize you now for 2 minutes.

Mr. Buyer. Thank you, Mr. Chairman.

Today is a pivotal moment, I believe, for the public health of our country. Mr. Chairman, I want to compliment you on the sincerity and your perseverance with regard to working on this issue. Although we work without the benefit of hearings, we have new members of the committee here, about nine of them that have not touched this issue before from this type of perspective, we also -- I think it would have been helpful to have the respective opinions of other experts in the field. But I do want to express my appreciation to the Chairman. We have had good discussions. And also, my sincere effort is somehow to take your position of abstinence and marry it with a pragmatic approach. And we are going to have these discussions today.

I recognize, Mr. Chairman, that you seek to actually eliminate morbidity and mortality with regard to the use of tobacco products. What I believe to be pragmatic and realistic is that people are going to continue to use tobacco products, so how

do we create the continuum of risk and make sure that people have the opportunity to make informed choices along that continuum of risk. So I believe the critical issue to be considered is how do we measurably and effectively reduce disease and death associated with tobacco use while products remain legal for over 40 million Americans who have not, cannot, or perhaps will not quit?

I believe keeping the American tobacco consumer and the public uninformed about the differences in the risks between smoking cigarettes and using nonburning forms of tobacco and other nicotine products is not in the best interest of our country. Telling current cigarette smokers to, quote, just say no, to quit now is not the most effective way to save thousands of lives. Creating a regulatory scheme that discourages or, in fact, chills the development of new lower-risk products is directly opposite of what many in the scientific and public health communities advocate, but those are the underlying tenets of the mark presented by the Chairman today.

But what do the experts say about the legislation? I shared with the Chairman and asked him to take a look at the Royal College of Physicians. They said that, quote, the current situation is perverse, unjust, and acts against the rights and best interest of smokers and the public health. Harm reduction has the potential to play a major part in preventing death and disability in millions of people who currently smoke and who either cannot or will not otherwise quit smoking. These smokers

have the right to be able to obtain and choose from a full range of safer nicotine products. And that, in fact, is the goal of this continuing risk and the discussion I would like to have with the Chairman, and I have amendments that will address that in this markup.

The Chairman. Thank you, Mr. Buyer. Your time is expired.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Recognition on this side of the aisle. Who seeks recognition for an opening statement? Ms. Eshoo, do you have an opening statement?

Ms. Eshoo. Just very briefly, Mr. Chairman.

Thank you for scheduling the markup of these bills. They are all important bills, and the American people will benefit from them, and they enjoyed broad bipartisan support, which is so important.

A bill that was supposed to be on, but isn't, was the Arthritis Prevention, Control and Cure Act, and it was removed because of opposition from the Republicans. I think Members will recall that last year the House passed the bill by unanimous consent. It enjoyed over 248 cosponsors, 70-some Republicans as cosponsors.

I want to thank you for your commitment to work with me to get this bill done. There are literally millions of Americans that suffer from arthritis, and I think something that is forgotten, and that is that children do. We have seven States in our country that don't have even one pediatric rheumatologist in the entire State, and if children go undiagnosed, they have hell to pay for that in their adulthood. So I look forward to working with you to see this bill make its way not only through the House, but the Senate and to the President's desk. Thank you.

The Chairman. Thank you very much, Ms. Eshoo.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Mr. Deal.

Mr. Deal. Thank you, Mr. Chairman.

I understand that most of the bills that will be presented are issues that have been presented to this committee before, but, as pointed out by Mr. Buyer, not everyone on the committee has gone through the full hearing process relating to them. It is my understanding, however, that several of the public health bills are reflective of bipartisan compromises passed by the House last Congress, while there are others that have been changed without the opportunity of the Members and the staff on both sides of the aisle to address these concerns. It is my hope that this markup will give us the opportunity to express those concerns in an open and fair debate.

Many of you are aware of my efforts to improve health care price transparency for millions of uninsured and self-pay patients to ensure that patients and providers have the information they need to make the best choices. Knowing the price before selecting a health care provider is important. Patients have the right to know this information, particularly given the magnitude of our current economic environment.

I also find it somewhat ironic that this committee is now considering H.R. 1256, the Family Smoking Prevention and Tobacco Control Act, given that it is less than a month ago that the Democratic Majority passed an SCHIP expansion bill that is

depending on 23 million new smokers in order to fully pay for it.

We have long been aware of the harmful and addictive effects of smoking, and I believe it is appropriate for us to look at ways to diminish the prevalence of smoking in our society. Smoking contributes to disease and death and imposes tremendous cost to our society as a whole. While I am sympathetic to the objective which this legislation seeks, ensuring that cigarettes remain out of the hands of children and encouraging adult smokers to quit, the bill's quit or die mentality simply will not work for millions of Americans addicted to nicotine.

I also have serious concerns with establishing a new regulatory responsibility under FDA at a time when Members on both sides of the aisle agree that the agency is in dire need of resources to carry out its core mission of protecting the Nation's supply of safe food, drugs and medical devices. As you will recall, former FDA Commissioner Dr. von Eschenbach provided testimony during our hearing on the bill last Congress stating the agency would be forced to shift resources from these primary missions, especially after repeated instances of contaminated food and drugs being released into the marketplace. That is a dramatic step, in my opinion, in the wrong direction.

I am also concerned about false misrepresentations or misconceptions which this legislation could produce. The FDA is tasked with ensuring products under its review are safe for the American people. By mandating FDA regulation of tobacco, we will

leave the public with a misconception that tobacco is safe. I think we all recognize that cigarettes are inherently harmful. That being the case, by granting cigarettes with an FDA seal of approval, this legislation will have the perverse effect of lowering the perceived risk of cigarettes.

I don't believe that cigarettes will ever be safe; therefore, it will be inappropriate for FDA to regulate such a product. As an appropriate alternative, I am pleased to join Representative Buyer and a number of my colleagues on both sides of the aisle in support of the Youth Prevention and Harm Reduction Act legislation, which accounts for the varying degree of risk among all types of tobacco products and would establish a new Tobacco Harm Reduction Center within the U.S. Department of Health and Human Services to regulate tobacco products without placing yet another burden on the FDA. I believe this is well-crafted legislation which would have the effect of reducing disease and death associated with tobacco use, and thereby through prevention, cessation and harm reduction.

This legislation would take bold steps as well to improve health-related information on the effects of tobacco use and ensure stringent standards for review and approval of such products that are in place. I think that this is a sensible approach to reduce the number of adult smokers and to ensure our children do not start in the first place.

Mr. Chairman, I thank you for your efforts in all of these

measures, and I look forward to working cooperatively with you as we move through this markup today.

I yield back my time.

The Chairman. Thank you very much, Mr. Deal.

[The information follows:]

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The Chairman. Mr. Dingell.

Mr. Dingell. Mr. Chairman, thank you. I commend you for this markup today.

We have a number of important bills before the committee. All these bills before us passed through this committee and passed the House overwhelmingly during the 110th Congress, so there is nothing new before us today. But then, as now, the Senate is the obstacle to getting these pieces of legislation enacted into law.

It is also, of course, true that these legislations are the result of bipartisan deliberations. The arguments for and against have been heard by most of the members of the committee. The bills before us were not enacted, as I mentioned, because the Senate failed to enact them prior to the end of the 110th Congress. I am delighted, Mr. Chairman, that you have revisited these important pieces of legislation and that you are doing so quickly this session, and I want to applaud my colleagues for their continued persistence.

We will hear today complaints that FDA does not have adequate resources to do a job, and that this is then an argument why we might not want to consider these pieces of legislation. Clearly this is erroneous, and clearly this is unwise and wrong, because if the agency lacks resources, which happens to be the case, it is the responsibility of this committee then to see to it, first, that it has the resources; second, that it has the powers; and

third, that it has the authority to address the concerns that the people have with regard to safety of matters under the jurisdiction of that committee.

And I would point out that we have legislation in this committee at this time, which I and Mr. Stupak and Mr. Pallone cosponsored, which would not only give authority, but which would give the financial resources to the Food and Drug Administration to do the job that it cannot and is not now doing. So we have two problems to address. Let us not "caval" about one while we ignore the other.

So, Mr. Chairman, I urge the favorable consideration of all of this legislation. As a matter of fact, it is so neatly done, and it has been so well handled in the committee during the previous session, that we could almost consider it en bloc by unanimous consent, but I am sure there would be somebody who would object.

Mr. Chairman, I yield back the balance of my time, and I urge my colleagues to support this legislation.

The Chairman. Thank you very much, Mr. Dingell.

[The information follows:]

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The Chairman. I should have asked unanimous consent, but we are already on track.

Mr. Stearns, do you have an opening statement?

Mr. Stearns. Good morning, and thank you, Mr. Chairman. Thank you for holding this hearing on a piece of legislation that will attempt to prevent, among other things, our young folks, young people in the next generation, from smoking by placing tobacco under the Food and Drug Administration.

The FDA is a Federal organization whose mission is to protect the public health by assuring the safety, efficacy and security of human drugs, biological products, medical devices and our Nation's food supply.

I was not supportive of this bill in the past, and I think there is a better alternative available, such as Mr. Buyer's bill, which will establish a new Tobacco Harm Reduction Center within the United States Department of Health and Human Services to regulate tobacco products. My colleague Mr. Buyer's bill will have a two-prong approach that will combine smoking-cessation programs with harm-reduction strategy and will not grant an FDA approval of cigarettes. I am cautious of the capacity of the FDA to have both the necessary staff and the proper funding to carry out the complete regulation of tobacco products in every State, city and town in America.

This legislation will require the FDA to regulate product

claims, advertising and marketing, control nicotine levels, and provide oversight to warning labels. Included in this bill is also a provision that will require the FDA to inspect every 2 years every facility that manufactures and processes tobacco at home and abroad.

Now, obviously, this bill is going to be paid for through user fees collected from the tobacco companies, but, Mr. Chairman, I think the Buyer bill is a more practical approach to doing this, and I think as we look at the marketplace today, at this point there is alternatives. And so I recommend my colleagues to look carefully at the Buyer bill.

With that, I yield back the balance of my time.

The Chairman. Thank you, Mr. Stearns.

[The information follows:]

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The Chairman. Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman.

We are marking up 10 very important public health bills today, and these various pieces of legislation represent our commitment to national public health priorities, like providing vision care for children, enhancing the primary care workforce, and protecting our children from the dangerous poisons found in tobacco products.

These bills were passed with bipartisan support in the House during the 110th Congress, and I urge my colleagues to pass these vital pieces of legislation out of this committee with the same level of urgency and vigor.

Let me just mention the tobacco bill. I don't want to use up all my time, Mr. Chairman, but I want to thank you for your tireless work on the tobacco legislation. Of course, it is the leading cause of preventable death in the United States. But it is not only dangerous to the individual, but also places a tremendous cost burden on our health care system. In President Obama's call to health care reform, he cited the need to use our resources wisely and efficiently. The costs to private and public payors are over $96 billion annually.

Regulating tobacco products is a win-win for our Nation's health and our need to be fiscally responsible in a time of economic hardship. And obviously when you talk about prevention,

that is a very important way in health care reform debate to save money, to save costs and to make sure that people live longer.

The bill gives the FDA the authority to regulate tobacco products and restrict tobacco marketing, but especially from our most vulnerable and impressionable population, our children. So I am proud to be a cosponsor of this bill along with many of my colleagues on the committee.

I am not going to talk about the other bills. I just want to make sure that we move them quickly. I know that my feeling is that because we had hearings and we had action in the subcommittee and the full committee last session, that we can bring them to the full committee today the way we are and get them passed quickly and over to the Senate. And I hope that the Senate this time does pass the bills, and they end up on the President's desk for his signature as soon as possible.

Thank you, Mr. Chairman.

The Chairman. Thank you, Mr. Pallone.

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The Chairman. Mr. Barton.

Mr. Barton. Thank you, Mr. Chairman. I appreciate you recognizing me.

Today we are going to consider a number of bills, the most important and controversial of which is the Family Smoking Prevention and Tobacco Control Act, which is a bill that you have personally introduced for a number of Congresses. Regarding that particular bill, I will say today what I said during last year's markup of what is basically the same bill: The FDA is the wrong agency at the wrong time to give this type of responsibility.

As we all know, the FDA's primary responsibility is ensuring the safety of our drugs and our food in the United States. It approves food, drugs and medical devices based on safety and efficacy. This legislation would give the FDA a new job; require it to take on something that is both enormous, completely outside its regulatory experience, and I think will divert attention from its core mission.

Since last year's markup, as you very well know, we have witnessed salmonella outbreaks in both peanut butter and peppers. We have heard criticism from both sides of the aisle. The FDA is not adequately staffed to handle its current responsibilities. Several Members of Congress have gone so far as introducing legislation to split the FDA into two separate agencies because they claim the agency is not placing the appropriate attention on

food safety. A previous Commissioner of the FDA in testimony provided to this committee stated that the agency, that is the FDA, is not the proper place for this type of responsibility, and that placing this type of regulatory authority at the FDA will divert resources from other critical areas. That seems to be, to my opinion, self-evident.

There are better ways to address the issue of tobacco, and I would hope as the bill moves forward Members will reflect on the unintended consequences. Mr. Buyer is going to offer what amounts to an amendment in the nature of a substitute, and I think it is worthy of some consideration. I am also disappointed about the process on this particular bill. I know that it passed the House in a form very similar to this last year on the suspension calendar. And I will admit that it is probably going to do so again this year. But we have a number of new members on the committee, especially on the Majority side of the aisle, and I am not aware of any special deadline or pressing reason to bypass regular order, which would and should include a hearing and perhaps even, wonder of wonders, subcommittee markup.

Lots of people are beginning to talk about the good old days when we actually had regular order, and I think there is some value in going back to it. The absence of regular order does a disservice to the members of the committee, especially the new members of the committee and the people they represent, because they have not had a chance to review the issues like some of the

grizzled veterans like yourself and myself.

Now, a few words about the nonpublic health bills. First the good news. They are bipartisan. I think a third of the bills are offered primarily by Minority Members, and I appreciate you, Mr. Chairman, for including those bills in the markup. It is a good thing when we work in a bipartisan manner.

I will say, though, that some of the bills that we are considering today, while they have passed the committee in similar form, have been changed. And I believe the bills that have been changed, it would have been nice to have had a hearing at subcommittee so we could get an idea of the consequences of those changes. We have been working at the staff level to resolve some of the issues that have been addressed that have been brought up because the bills have been changed. And I will say, Mr. Chairman, that the Majority staff has worked in good faith with the Minority staff. The more we do that, the better the process, the better the product is going to be.

Let me comment very briefly on each of these nine bills. H.R. 756, the National Pain Care Policy Act, enhances awareness of chronic pain with providers in the community. Chronic pain is an issue that many people suffer from. This bill would create an interagency coordinating committee to coordinate all the efforts within HHS and other Federal agencies relating to pain research. This effort, along with the efforts of the NIH by the Pain Consortium, will go a long way towards increasing research and

awareness of chronic pain.

H.R. 914, the Physician Workforce Enhancement Act of 2009 will assist small hospitals that serve rural or growing areas by providing them with the resources to establish a residency training program for certain high-need medical specialities.

H.R. 20, the Melanie Blocker Stokes Moms Opportunity to Access Health, Education, Research and Support for Postpartum Depression Act, is a bill in itself just in the naming of the act, Mr. Chairman. This one is from Representative Rush of Chicago, and I think it is a much-needed addition to our current law in this area.

H.R. 577 -- realize my -- I have got three more, Mr. Chairman, then I will be quiet -- the Vision Care Act of 2009, would ensure that children, especially low-income children, have access to vision screenings. We support this bill.

H.R. 479, the Wakefield Act, reauthorizes the Emergency Medical Services for Children Act. This program seeks to ensure that hospital emergency departments have the ability to care for their young patients just as they do for their adult patients. We support this act also.

The Early Hearing and Detection Intervention Act reauthorizes the newborn and infant screening program. I think this is a very important program, and we support that.

H.R. 307, the Christopher and Dana Reeve Paralysis Act, delves into the issue of paralysis. This bill would authorize

funding research on paralysis and research focusing on enhancing daily functions for persons with paralysis. We support the concept, and I believe this could be done within the NIH.

There is two more bills, but we will just simply say that we support H.R. 1253 and the Dextromethorphan Distribution Act of 2009 introduced by Congress.

The Chairman. Thank you, Mr. Barton.

[The information follows:]

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The Chairman. Mr. Green.

Mr. Green. Thank you, Mr. Chairman. I know we have a minute, and I won't take my whole minute.

I want to thank you for including the Vision Care for Kids Act, and I have a full statement I would like to place in the record. This passed the House bipartisanly, as our Ranking Member said, and there is no opposition from the Minority side, but that we would be able to pass it today.

And with that, Mr. Chairman, I yield back my time.

The Chairman. Without objection, the gentleman's statement will be put in the record.

[The information follows:]

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The Chairman. Mr. Upton, did you wish to be recognized?

Mr. Upton. Ready to get to markup, so I yield.

The Chairman. Okay. Other Members who wish to be recognized?

The gentleman from Michigan.

Mr. Rogers. Thank you, Mr. Chairman. I would like to speak in support of H.R. 756 today, the National Pain Care Policy Act. I appreciate the efforts of Majority and Minority to bring this legislation to a markup. Identical legislation was passed by this committee in the full House last year, and it reflects a bipartisan compromise developed by Mr. Dingell, Mr. Barton and Mrs. Capps, and I want to thank all of them for their work on this bill.

This year, again joined with Mrs. Capps to introduce bipartisan legislation strengthening pain research at the NIH, I would like to thank my colleague for her dedication to this issue.

Chronic pain continues to be a major public health problem in the United States, and it still is the single most common reason people seek medical care. Chronic pain continues to be a major -- excuse me. Unfortunately patients continue to struggle through a maze of uncertainty, often having to seek countless specialists before finding someone who can properly treat chronic pain.

Pain accompanies a wide range of clinical conditions, including cancer, diabetes, arthritis and HIV, yet NIH spends less

than 1 percent of its research budget on all types of pain. The legislation we will markup today improves education on chronic pain, helps patients with access to pain care and strengthens pain research at the NIH. It is certainly a culmination of 8 years of work I have spent on this very important issue. And again, I want to thank Mrs. Capps for her efforts to bring this bill forward today, and I really appreciate your dedication on this very important public health issue.

Thank you, Mr. Chairman and Mr. Barton, for your willingness to work with us on this bill. And, Mr. Chairman, I also would like, if I may, to put in the record a letter of support from 120 health organizations from across the country involved in chronic pain research, education and treatment.

And with that, Mr. Chairman, I would yield back the remainder of my time.

The Chairman. Without objection, the letter will be added to the record following the gentleman's opening statement.

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******** INSERT 1-2 ********

The Chairman. Ms. DeGette.

Ms. DeGette. Thank you, Mr. Chairman. I also will put my full statement in the record.

And I just want to commend you for your years of work on this tobacco issue. It shows a real dedication to the health of not just our children, but of all Americans.

And so I think it is one of those things when you ask the people out in the real world should the FDA regulate tobacco, they think it is already done, and so they would be very, very supportive of this.

And the other thing I will say, Mr. Chairman, I really look forward to working with you as we move along to find better ways to target advertising directed to teen smokers and to make sure that we can remove that very, very big threat. As we all know, the studies show that if you can stop somebody from smoking when they are a teenager, you can really reduce smoking in general in this country.

And I yield back the balance of my time.

The Chairman. Thank you very much, Ms. DeGette.

[The information follows:]

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The Chairman. Mr. Pitts.

Mr. Pitts. Thank you, Mr. Chairman, for scheduling the markup on several important bills dealing with very important issues, including, I want to highlight, H.R. 20, the Postpartum Depression Research and Care Act.

I support continued research on postpartum depression. I am glad to see this legislation move forward. I also support research on the emotional effects of pregnancy outcomes, such as carrying a pregnancy to term and placing the child for adoption, miscarriage, or even having an abortion. It is important that we learn more about the effects of abortion in order to provide women with the care they need. Because of the lack of research and information, postabortion depression goes widely unrecognized and untreated. Women deserve to know the long-term effects of abortion on their mental and emotional well-being. And women who have had abortions deserve to have mental health professionals who acknowledge the emotional impact of this and have the tools to treat it. And I believe that increased research on postabortion depression will lead to a greater awareness of this issue and the development of passionate outreach and counseling programs to help postabortive women. And I am pleased that this bill includes a provision that expresses the sense of Congress that NIH may conduct a longitudinal study of the long-term mental health consequences of various pregnancy outcomes for women, including

abortion. I am hopeful that NIH will pursue this recommendation.

I want to thank Mr. Rush for working with me through the years to include this language in this important bill, and I thank him for this commitment to helping women who suffer from various types of depression.

Thank you, Mr. Chairman. I yield back.

The Chairman. Thank you, Mr. Pitts.

[The information follows:]

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The Chairman. Mrs. Capps.

Mrs. Capps. Mr. Chairman, I want to commend you for bringing these several pieces of legislation up for swift action. Hopefully, unlike last Congress, we will see the Senate finally act on these important measures.

I am especially pleased to see that two pieces of bipartisan legislation I have worked on are being considered here today. The first is the Early Hearing Detection Intervention Act, which I introduced with Jo Ann Emerson this year. This bill will ensure the success of the newborn hearing screening program that is built upon so that all children will receive any necessary follow-up care.

The other bill has been mentioned already by my colleague Mike Rogers, the National Pain Care Policy Act. He and I have worked hard on this, and I want to return the compliment and thank him for his tireless work to ensure that we had a good bipartisan compromise. The bill will improve coordination of pain care and facilitate better sharing about pain across the many health disciplines.

Both of these bills are supported by, as he has mentioned, a broad coalition of health professionals, patients, biotechnology firms and researchers. I hope I can count on the support of all of us today here so that we can see these bills signed into law soon, and I yield back.

The Chairman. Thank you very much, Mrs. Capps.

[The information follows:]

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The Chairman. Mrs. Blackburn, do you wish to be recognized?

Mrs. Blackburn. No.

The Chairman. Okay. Then Mr. Gingrey.

Mr. Gingrey. Mr. Chairman, thank you. Mr. Chairman, I want to congratulate you for your work on this important issue, and I realize that work goes back at least 10 years. I am one of the new members of this committee and missed a lot of the hearings, but understand the importance of this issue, especially in trying to stop new smoking of our youth and our teenagers. I think it is extremely important.

Having said that, though, I don't plan on voting for your bill because I think there is a better plan, and that is the amendment in the nature of a substitute that Mr. Buyer is going to present, the Youth Prevention Tobacco Harm Reduction Act.

Mr. Chairman, the Family Smoking Prevention and Tobacco Control Act would add the regulation of tobacco and tobacco products to an already long list of FDA oversight responsibilities: human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation.

Over the past 2 years this committee has held numerous hearings highlighting the failure of the FDA to carry out its current responsibilities. And most recently, and I was at that hearing, in my home State of Georgia a breakdown in FDA oversight

partially contributed to the distribution of salmonella-tainted peanut products, which sickened more than 677 people in 45 States and caused at least 9 deaths.

Mr. Chairman, this committee should heed the warnings of the past. People understand the dangers of tobacco. What they don't understand is why a child should die from eating a peanut butter and jelly sandwich. We need to keep the FDA focused first and foremost on products that should be safe.

And with that, Mr. Chairman, I yield back, and I thank you.

The Chairman. Thank you very much.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Ms. Harman.

Ms. Harman. Thank you, Mr. Chairman. I believe we are going to adjourn for the Gordon Brown event. I am not sure of that.

The Chairman. If the gentlelady will permit, I won't take away your time, but for the scheduling of the Members, we will stay here, and those who want to give opening statements, we will continue with the opening statements. Then we will recess until 1:00 to continue the actual markup on the legislation. If Members want to go to the floor and still do an opening statement, let us know, and we will provide an opportunity for that. Certainly the record, without objection, will be held open for all opening statements by Members so that you will have your opening statement in the record even if not delivered orally.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. But if you wish to give an opening statement and are willing to stay here, we are willing to recognize you.

Ms. Harman.

Ms. Harman. Reclaiming my time, and I hope -- there it goes. I want to thank you for accommodating Members, including me, and commend you especially for your work, your personal work, on this FDA tobacco regulation bill, which I think is a hallmark of your career and certainly very personally important to me. I only wish it had passed when you came to Congress in 1974 because it might have saved the lives of both my parents, who died of lung cancer from smoking.

In one of the earlier comments this morning, Mr. Chairman, I think I heard a member of this committee say that this bill undermines the revenue stream for SCHIP. I believe that was the comment. And I just want to observe as a fairly long-standing member of this committee that I think that is colossally cynical and disturbing and disassociate myself from that comment.

Let me just close with the observation that this week as we act on this legislation, thousands of Americans will die from tobacco-related diseases, and thousands more will become new regular users. Approximately 4,000 children try a cigarette for the first time each day, and this cycle needs to be broken. I believe the FDA, as you said, is best qualified to enter this arena and will provide the nuanced regulation that is so

necessary. I am very pleased to support this legislation again, and on behalf of my three grandchildren who are under 3 and therefore have not had the opportunity to smoke yet, I thank you profoundly and yield back.

The Chairman. Thank you, Ms. Harman.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Mr. Scalise.

Mr. Scalise. I thank the Chairman. I know we have got a number of bills on our agenda. With the time constraint that we are dealing with, I will specifically address my comments to H.R. 1256.

I know a few things have been said about the alternative bill that is going to be filed, a substitute by Congressman Buyer, and I think have said some good comments about that. My concerns mostly revolve around the mixed messages that I think this bill would ultimately be sending by giving this FDA sanctioning to a product that many point out is a harmful product. And by having whatever regulations they are going to try to put in place, at some point in time it is going to become recognized by the public that tobacco products are, in essence, sanctioned by the FDA. And the things that go along with that, I think, don't necessarily reflect the goals that this committee might be trying to achieve. So I do think that is one concern that is going to become a bigger problem down the road.

I think most people are very familiar with the Surgeon General warning. I am not really sure what we will see in terms of advertising, or at least in the public's perception, once FDA becomes the sanctioning body for tobacco products.

There is another concern in this bill that does give legislative ability for the FDA to transfer funds as they are

starting up this new tobacco center. They can actually take money away from other parts of the FDA to move it over to set up this new agency. And as many people have pointed out, they already have shortfalls as they are trying to bring new drugs to market, make sure that our drug supply is safe. I am real concerned that for at least a 6-month period of time, they will be able to take money away from those agencies that are already strapped and backlogged and move them over to creating this new entity of dealing with tobacco. So it will take the FDA's approval ability and their sanctioning ability away from some other areas that are their primary mission.

And so with those, I will yield back the balance of my time.

The Chairman. Thank you very much.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Ms. Baldwin.

Ms. Baldwin. Thank you, Mr. Chairman. I appreciate the fact that you are bringing forward so many of these critical public health bills for consideration today. I would like to highlight just one of them.

Later today we will be considering a bill that I cosponsor with my friend and colleague Congresswoman Mary Bono Mack, and that is the Christopher and Dana Reeve Paralysis Act. This bill passed the House with strong bipartisan support last session, and we are both looking forward to it becoming law in this Congress.

I was fortunate enough to know Christopher and Dana Reeve, and I think I fairly speak for my colleague Mrs. Bono Mack when I say how inspired I know Mary was by Dana Reeve's experience. Christopher and Dana were two individuals who proved that sometimes the greatest hardships are the starting point for incredible advocacy.

Christopher and Dana Reeve, the Paralysis Act, reflects our desire to carry on their work on behalf of people living with paralysis. The bill expands research on paralysis at the NIH by encouraging increased collaboration as well as attention to the daily functioning of people with paralysis and other physical disabilities. This bill also supports programs that will improve the quality of life and health of persons with paralysis across the country.

Christopher and Dana Reeve used their visibility to work on behalf of families in all parts of this country who face the challenges of paralysis and impaired mobility. I have been honored to carry on this work, and I am honored to work on this legislation with my colleague Congresswoman Bono Mack, as well as Congressman Langevin and Congressman Bilirakis. I urge all my colleagues on the committee to join with me in supporting this legislation. And again, thank you, Mr. Chairman.

The Chairman. Thank you very much, Ms. Baldwin.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Mr. Butterfield.

Mr. Butterfield. Thank you very much, Mr. Chairman. I, too, would like to thank you for convening this very important hearing today. I know you have waited a very long time for this day.

Mr. Chairman, what you and others may not know is that I represent the largest tobacco-producing district in the United States of America. I also have a district that the poverty level for children under the age of 5 is in excess of 30 percent. I also have a district that is very high in the incidence of smoking. And so I find myself in a very precarious situation. But I want you to know, Mr. Chairman, and my colleagues to know that I am prepared to enthusiastically support this legislation.

But with that said, I need to remind all of you that the tobacco industry has changed, just as everything else in America has changed. The tobacco industry has changed dramatically in the past 20 years. It has changed for growers, for buyers, for manufacturers. But notwithstanding, I will certainly be supporting this bill because it has good policy objectives.

It is my sincere hope that the FDA will use its power, as we used to say when I was a judge, judiciously so that the modern tobacco farmer who uses the state-of-the-art technology, one who uses the best practices and hard-earned wisdom to grow their crop, that they may be allowed to continue to earn a living, just as we all earn our living, so that they can support their families and

their communities.

Thank you, Mr. Chairman, for good work on this legislation. I intend to support it.

I yield back.

The Chairman. Thank you very much, Mr. Butterfield.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Mrs. Christensen.

Mrs. Christensen. Thank you, Mr. Chairman. This promises to be a good day for the public's health in this country. The 10 bills we are marking up today, fill in longstanding gaps in our system. They increase prevention, especially in our children. They expand access to important services, and they go a long way to providing the protections that we need and expect our government to provide.

I applaud all of the sponsors of the legislation before us today, but I especially want to applaud the Family Smoking Prevention and Tobacco Control Act, which contains the strongest standard for product regulation ever given to the FDA and will help to save millions of lives. I know firsthand how difficult it was to get the support needed to pass it last year, but that was after many, many years of hard work by you, Mr. Chairman, and many organizations like Tobacco for Kids. I particularly want to join my colleagues in singling you out, Chairman Waxman, and to congratulate you and thank you for your determination, your leadership, and for being willing to look at and work with both sides throughout this effort. I look forward to continuing to support this bill and towards its passage, towards the President's signature, and especially now that we have an administration that we know we can count on to implement it as it was intended.

With that, I yield back the balance of my time, Mr. Chairman.

The Chairman. Thank you very much, Mrs. Christensen.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Ms. Sutton.

Ms. Sutton. Thank you, Mr. Chairman. Thank you for holding this hearing, this markup on these bills.

The list of health-related bills before us are important steps in addressing health care in our country, and I am a cosponsor of many of these bills and look forward to continuing my support on these initiatives.

However, today I would just like to highlight, as others have here, the Family Smoking Prevention and Tobacco Control Act, Mr. Chairman, that you have put so much work into. We all know that tobacco use in our country is a serious public mental health issue, and the Campaign for Tobacco-Free Kids estimates that 18,500 adults in Ohio die every year as a result of smoking. Even more shocking is that an estimated 293,000 kids in Ohio under the age of 18 will die prematurely from smoking.

Mr. Chairman, tobacco results in more deaths than alcohol, AIDS, car accidents, illegal drugs, murders and suicides combined. And the cost to our society does not stop with the tragic loss of life and promise. In Ohio, annual health care costs directly caused by smoking are at $4.37 billion; the portion covered by the State Medicaid program, $1.4 billion. Resident State and Federal tax burden from smoking-caused government expenditures is at $629 per household; and smoking-caused productivity losses in Ohio, $4.6 billion. So clearly the need is urgent both on a

health-related aspect, as well as it makes good economic sense.

Thank you, Mr. Chairman.

The Chairman. Thank you very much, Ms. Sutton.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. That concludes the opening statements on the legislation before us. We will now recess until 1:00, and we will reconvene with the markup.

[Recess.]

RPTS JURA

DCMN MAGMER

[1:12 p.m.]

The Chairman. The committee will come to order.

The Chair would like to call up the following bills: H.R. 1259, the Dextromethorphan Distribution Act by Representative Upton; H.R. 1246, the Early Hearing Detection Intervention Act, Representative Capps; H.R. 1253, the Health Insurance Restrictions and Limitations Clarification Act, Representative Burgess; H.R. 20, the Melanie Blocker Stokes Postpartum Moms Opportunity to Access Health, Education, Research, and Support for Postpartum Depression Act, Representative Rush; H.R. 307, the Christopher and Dana Reeve Paralysis Act, Representative Baldwin; H.R. 479, the Wakefield Act, Representative Matheson; H.R. 577, the Vision Care for Kids Act of 2009, Representative Green; H.R. 756, the National Pain Care Policy Act of 2009, Representative Capps; H.R. 914, the Physician Workforce Enhancement Act of 2009, Representative Burgess.

Without objection, all these bills will be considered as read and open to amendment at any point.

Hearing no objection, that will be the order.

[The information follows:]

******** INSERT 2-1 ********

The Chairman. I would like to ask unanimous consent to proceed on all of these bills, but before we do that I want to recognize Mr. Barton for some comments.

Mr. Barton. Thank you, Mr. Chairman.

I want to say, as I said in my opening statement, we appreciate the bipartisanship of these consent bills, the nine consent bills that are before us today. I have agreed with the motion that you just made that we consider them together so that we can move on to the tobacco bill, which will be a little bit more contentious. I do want to engage you in not necessarily a colloquy but at least something of a dialogue about the bills that deal with the NIH.

As you well know, in the stimulus package that the House and the Senate just passed and the President just signed, there is $10 billion in additional funding for NIH. This includes $8.2 billion for research, $500 million for facilities, $1 billion to renovate a university biomedical and behavioral research facility, and $300 million for instrumentation. This is a 34 percent increase in the baseline of the NIH budget.

I have no idea how this amount of funding at one time is going to impact the NIH, and I would hope that you would agree with me that, before the NIH begins to obligate these funds, we should call the NIH directors and the political appointees that have already been appointed to the NIH before this committee to do an oversight hearing and get some input on behalf of the committee

about how they intend to use this amount of funding. I am told at the staff level you agree with this approach, and I would just like to get your comments on the record on this.

The Chairman. If the gentleman would yield.

I support your concerns that we require NIH to explain how they plan to use the funds appropriated to them in the stimulus package, and I think it would be appropriate for us to have an oversight hearing on this very subject. So I look forward to working with you in that regard.

Mr. Barton. I appreciate the chairman's input and take you at your word. We will work with you to schedule that hearing at a time that is convenient for NIH and also convenient for the committee, and I appreciate your interest in this.

With that, I yield back, Mr. Chairman.

The Chairman. Thank you very much.

I evidently have taken everybody off guard by asking all these other bills to be brought up, and there are some manager amendments to some of them which have been shared and for which there is no controversy. So if there is no objection, I would like to ask -- when we asked that all the bills be considered as read, I would like to ask unanimous consent that they be considered en bloc.

Without objection, that will be the order.

I would like to ask unanimous consent that the manager's amendment to H.R. 479 be considered as read and adopted.

Without objection, that will be the order.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. To H.R. 577, the chairman has a manager's amendment in the nature of a substitute. Without objection, that will be considered as read; and, without objection, the manager's amendment in the nature of a substitute is adopted.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. On H.R. 20, there is an amendment by the chairman. Without objection, it will be considered as read and adopted.

Without hearing any objection, that will be the order.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Now I would like to ask unanimous consent that the en bloc consideration of all these bills be put to a vote. These are all very good bills.

We used to have a chairman of one of the appropriations subcommittees who used to stand up on the floor to present his subcommittee appropriations bill. He would stand up and always open his comments by saying, "This is a very good bill if I don't say so myself." And I think that was the only thing you were able to understand, because the rest of the time he mumbled.

Mr. Barton. That was Mr. Whitman.

Mr. Deal. Reserving the right to object.

The Chairman. I recognize the gentleman on his reservation.

Mr. Deal. Thank you, Mr. Chairman.

I had prepared amendments on the issue I alluded to in my opening statement, that being the issue of transparency. I do not wish to encumber these bills with that issue, and you and I have had private conversation on that. And I would just like to see if my understanding is correct, that the chairman is willing to commit that we will have a hearing on the overall issue of pricing transparency so that this may be appropriately presented to the committee without having to do so in the context of each of these individual type bills.

The Chairman. If the gentleman will permit, I do agree that we need more transparency in health care pricing. Getting

appropriate information to consumers is important; and we want to make sure that consumers have information that is timely, comprehensible, and useful in their decisionmaking.

When we address health care reform, I think it is an appropriate place for us to look at this kind of information and to have a panel to testify at one of the hearings, and I will work with you as the ranking member and Mr. Pallone as the chairman of the subcommittee in fashioning such a panel.

If the gentleman would permit, I want to yield to Mr. Pallone.

Mr. Pallone. Mr. Chairman, you said it exactly the way I had suggested it to Mr. Deal, that we definitely need to address this. It is something that is important to me, and we would either have it as part of one of the health care reform hearings over the next couple of months or consider it separately, one or the other.

Mr. Deal. Mr. Chairman, I would obviously prefer that it be dealt with separately, because I don't want the issue to be ignored by other equally important issues in a single panel. So I would ask you both to consider the possibility of a separate panel addressed to that issue.

But, with that, I withdraw my objection, and I will not object. I yield back.

The Chairman. Thank you. I appreciate your request, and we will talk further to see if we can work it out.

I was about to ask for a vote on all the bills combined, but

Mr. Stupak is here, and he wanted to be recognized. So I wish to recognize him at this time.

Mr. Stupak. Thank you, Mr. Chairman; and thank you for recognizing me. I just want to say a few words on H.R. 1253.

The legislation that we have with Mr. Burgess does one simple thing: It requires health care companies to be up front and honest on their policies when they place limitations, restrictions on benefits, prior to the point of sale of their policy.

Currently, because of the way the regulations were set up, many Americans were unaware that their health insurance may not cover injuries resulting from certain recreational activities because their policy is unclear or overly broad. This lack of clarity has created a confusing situation for individuals that may ride snowmobiles, horses, ATVs, or participate in other recreational activities. While millions of Americans enjoy these activities safely every year, when an individual is injured they often do not find out that their insurance will not cover their medical expenses until after the injuries.

Our bill, H.R. 1253, would require that any limitations and restrictions on benefits be explicit and clear. Insurance companies should be required to make available to participants and beneficiaries in an easily understandable manner a description of the limitations and restrictions included in the policy. By passing this straightforward legislation, we will protect our constituents that may ride motorcycles, horses, snowmobiles, ATVs,

or participate in other recreational activities from being caught by surprise when they thought their policy covered any possible injuries that may have resulted.

I encourage all my colleagues to once again vote for this legislation as we did last session. I ask unanimous consent to place in the record a letter of support from the American Motorcycle Association.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Stupak. I want to thank Chairman Burgess for his work on this legislation, as well as you, Mr. Chairman, Mr. Waxman, and Mr. Barton.

I yield back the balance of my time.

The Chairman. Thank you very much, Mr. Stupak.

Any further debate on the en bloc amendment?

Mr. Upton.

Mr. Upton. I would just like unanimous consent to put in my well-written statement. To save time, I will just insert it. It is bipartisan. I thank you for putting it en bloc. It is the third time. Hopefully, it is the charm for the Senate to act on it.

The Chairman. Thank you very much. Without objection, the gentleman's well-written statement will be substituted for his previous statement that he was going to put in the record and will be part of the considerations for today.

[The prepared statement of Mr. Upton follows:]

******** COMMITTEE INSERT ********

The Chairman. Mr. Burgess.

Mr. Burgess. Yes, Mr. Chairman. In the interest of time, I would also like to submit my coherent and lucidly written statements on both this bill and on 914 for the record and ask that they be considered.

The Chairman. Without objection, that will be the order.

[The prepared statement of Mr. Burgess follows:]

******** COMMITTEE INSERT ********

The Chairman. Any further discussion?

If not, the vote comes on the en bloc amendment. All those in favor say aye. Opposed, no.

The ayes have it, and the motion is agreed to, and all of those bills are duly reported with the usual instructions.

Now we will return to the tobacco legislation, H.R. 1256. Without objection, the bill will be considered as read and open to amendment at any point. That will be the order.

[The information follows:]

******** INSERT 2-2 ********

The Chairman. Let me call for amendments to the bill.

Mr. Buyer.

Mr. Buyer. Thank you, Mr. Chairman. I have a substitute amendment at the desk.

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. The gentlelady from Colorado reserves a point of order.

The clerk will report the amendment.

The Clerk. Amendment in the nature of a substitute.

The Chairman. Without objection, that amendment will be considered as read.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The gentleman from Indiana is recognized.

Mr. Buyer. Thank you, Mr. Chairman.

Due to significant concerns regarding the legislation before the committee, I took the chairman's legislation; I worked from it to develop a substitute amendment that I offer here today. My substitute amendment maintains many of H.R. 1108's provisions, while establishing a practical and workable regulatory framework which will better protect our children from the tobacco use and significantly increase the public health. Most importantly, the substitute acknowledges a continuum of risk among all tobacco products.

As the American Association for Public Health Physicians and many others have stated, a huge body of scientific literature clearly shows that smokeless tobacco products, depending on the product, range from 90 percent to 99 percent less hazardous than cigarettes in terms of risk of tobacco-related illness and death.

My substitute provides a regulatory oversight for the development of products that reduce the risk of death and disease due to tobacco use, while ensuring that all tobacco consumers are fully and accurately informed by HHS and others of the relative risks of tobacco and nicotine products. My substitute enhances tobacco prevention and cessation programs, while adding these important harm-reduction strategies which will greatly assist our efforts to encourage Americans to stop smoking.

The American Council on Science and Health has found that the established health risks associated with smokeless tobacco users are vastly lower than those of smoking. In the past 25 years, almost 80 peer-reviewed scientific and medical publications have acknowledged the differential risks between cigarettes and nonburning tobacco products. Many are concerned that encouraging the use of smokeless or nicotine products as an alternative to cigarettes is a gateway to more tobacco use. The facts, though, in the United States and Sweden do not support this.

In 1991, a national survey revealed that one-third of adult smokeless tobacco users were former cigarette users; and an earlier survey showed that young men who had smoked cigarettes and subsequently used smokeless tobacco were twice as likely to quit smoking as cigarette users only.

We must give Americans the information they need and deserve in order to make informed health decisions. In doing so, we will move them along a continuum of risk and drastically decreasing their health risk associated with tobacco use. I intend by this to create a gateway of combustion to noncombustible products.

My substitute creates a Tobacco Harm Reduction Center under the Department of Health and Human Services. This Center will house all tobacco regulation and will be streamlined and a focused agency completely committed to addressing the tobacco epidemic in our country.

H.R. 1108, on the other hand, places tobacco regulation under

the jurisdiction of the FDA, which we all know has its own challenges; and I do not want to jeopardize the FDA's focus on the safety of our drugs, devices, and food.

Furthermore, my proposal does not include many of the first amendment challenges included in the chairman's mark. Therefore, under my proposal, tobacco regulation has a better chance of going into effect immediately, while the bill before us is sure to be sent straight into years of litigation to the Supreme Court.

My substitute also ensures that Federal authorities stay off of Nation's farms. Make no mistake, under H.R. 1108, our Nation's tobacco farmers will be directly or indirectly impacted by Federal regulations. My substitute expressly prohibits the Federal Government from affecting our Nation's farming practices.

By supporting this substitute amendment, you will help to advance tobacco regulation policies to catch up with the science available on the issue today. Additionally, you will ensure the protection of our current FDA, the promotion of public health campaigns regarding tobacco, and the improved use of the States' MSA funds in the protection of our Nation's farms from government infringement.

I encourage the support of the substitute, and I yield back my time.

The Chairman. Thank you, Mr. Buyer.

The Chair recognizes himself in opposition.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. The gentlelady's point of order is withdrawn.

The Chair recognizes himself to oppose this amendment.

The fundamental approach of this Buyer substitute appears to prejudge the safety of smokeless tobacco and virtually exempts smokeless tobacco from regulation, and then the substitute uses the language of reduced harm, which doesn't require any scientific evidence to be there to show that there is a reduced harm but relies instead on an unproved assumption that if people gave up smoking and used smokeless tobacco that they would be safer.

Now, I object to this approach because I believe it would cause tremendous harm to the public health, and I believe that we should leave the important issue of harm reduction to those with scientific and regulatory expertise.

The underlying bill, H.R. 1256, takes a rational, science-based approach to promoting harm reduction. It does so by requiring that any claims of reduced risk or reduced harm from a tobacco product of any claim be supported by scientific evidence. This would ensure that claims are based on fact, not speculation; and I think it is one of the central accomplishments of the bill.

Without that kind of a provision, we could easily face another disaster like the light and low tar fraud that began decades ago. We learned from that experience that smokers are eager to take hope from claims that a new tobacco product poses less risk. We learned the tragic results, that these kinds of claims can cause smokers who might otherwise quit to delay taking

that step. And when someone decides not to quit because of claims that a new product is less dangerous, that person is not safer at all. In fact, that person is much less safe, and that is the outcome that we must prevent, and that is precisely what I think this substitute would invite.

Another major flaw of the substitute is that it would remove all the provisions in the underlying bill that limit advertising and promotion to kids. This undermines one of the most critical goals of the bill: to protect children from deceptive marketing that entices them into a lifetime of addiction and disease.

I understand that Mr. Buyer has first amendment concerns. I disagree with his perspective. I cannot accept an approach to tobacco control that does nothing to end the tremendous harm caused by the industry's continued marketing to children. It is illegal for children to buy cigarettes, and I think that we ought to ask that the advertising geared to people who are not legally able to buy the product be limited.

Another problem with the substitute is the delegation of tobacco regulation to a whole new agency instead of the Food and Drug Administration. FDA is our Nation's chief public health agency, with over 100 years of expertise and experience in setting science-based standards to protect the public health. This substitute would be a grave mistake, because they would take this important task of regulating tobacco to a new agency with no expertise or experience.

And, finally, the bill totally eliminates the user fees that would pay for the tobacco program. In these times of an extremely tight Federal budget, I don't see the wisdom of eliminating the full funding that is guaranteed under the current bill and simply hope that the government will come up with the money in some other way.

So these are my concerns about the substitute; and I, with all due respect to my friend and colleague, urge a "no" vote on the substitute.

Further debate on the substitute? Mr. Deal.

Mr. Deal. Thank you, Mr. Chairman.

I do wish to speak in favor of the Buyer approach; and there is a philosophical difference of opinion, obviously, here.

First of all, I want to commend him on the great amount of time and effort that he has put in to developing this proposal. Having watched and participated in some of the discussions that he has given to our side of the aisle, he has spent a great deal of time trying to get it right, trying to make sure that he has thought of most of the major issues as he incorporated them into this legislation.

I believe that the creation of another agency within HHS but outside of FDA gives us the best of both worlds. It keeps it within the health care community, keeps it within the jurisdiction of this committee, but it does not confuse it with the issues and the underlying obligations of the FDA.

So I am in favor of the substitute proposed by Mr. Buyer, and I would yield the balance of my time to him.

Mr. Buyer. Mr. Chairman, if I may be permitted a little bit of latitude, and then we are going to move through this really quick.

The Chairman. Would the gentleman speak into the mike?

Mr. Buyer. I ask unanimous consent that this chart be passed out to everyone, a copy of this chart.

The Chairman. Without objection.

Mr. Buyer. Everybody has it.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Buyer. The genesis for this was a very good discussion between the chairman and I, and this is a very lively discussion not only here in the United States but countries around the world. Many of them are struggling with the same challenges we have about individuals that get addicted to smoking, nicotine.

Now, there are two different specific types of approaches. You can have what Mr. Waxman has, which is sort of the abstinence-only approach; and then there is the other approach, which is really what the chairman and I were trying to do, was to come to terms on how to be pragmatic in the approach. And we are agreeing to disagree I think is what is kind of happening here.

The great debate -- and let me just share with you what the Royal College of Physicians, quote, "Harm reduction is a fundamental component of many aspects of medicine and indeed everyday life. Yet, for some reason, effective harm reduction principles have not been applied to tobacco smoking. It is very clear for most of the major health effects of tobacco smoking is as many times more dangerous than smokeless tobacco use."

Now, what I have done here is I have done something that has never been done before. I read so many treatises here since the last time we took on this legislation that I actually took the array of products that are in the marketplace and then, relative to the medical treatises, embraced this gentleman's effort to reduce the morbidity and mortality rates among our citizens. But

the real question is, his goal is to eliminate; my goal is to reduce.

So you say, okay, Steve, how do we work that out? I worked that out being very pragmatic. And the reason I offer this substitute is saying, Mr. Chairman, among all the products that are out there, I go, all right, the most dangerous is if you roll your own cigarettes or Lucky Strike. And you say, okay, those are pretty severe.

Next, you have got filtered cigarettes. And then among the filtered cigarettes there is a lot of money that has gone into the effort, and the chairman made use of this about the terminology that is in the public domain, the use of the descriptors such as light and ultra light. Well, those descriptors are out there, and I find it interesting that 85 percent of the tobacco users buy those types of cigarettes. You see, in their mind they think that they are getting a harm reduction strategy. And the chairman is right, it is not helping them with regard to their health. But if we can actually move them through an informed ability to choose among a continuum of risk from a public health standpoint, I think that is a good thing to do.

And the public doesn't know. We make these choices every day with regard to what type of automobile we want to drive or what type of food we want to eat or what we want to drink. But with regards to tobacco products, the users of these things don't know.

So we say, okay, if you don't want to use the most harmful,

which is a nonfiltered cigarette, you go to a filtered; and then, of these filtered, they have got other things they try to do.

The whole goal here is, can you have a, quote, safer cigarette? I think the chairman would say that is pretty difficult to do. Because it is not the nicotine that is harmful. It is the smoke. It is the smoke that kills. That is where all the carcinogens, that is where all the harmful health effects occur.

So how do you move them as a gateway into this continuum? And what I would submit is, you have got a couple other products out there. The reason I put question marks here between the tobacco-heated cigarette and the electronic cigarette is I think the chairman is absolutely correct. The science isn't there. But we do know that it is of less risk than with regard to actually inhaling that much smoke.

And then we have of the smokeless products --

The Chairman. The gentleman's time has expired. Do you want another minute?

Mr. Buyer. Can I have two? Give me two, and then I will go sit down. Is that a deal?

The Chairman. Two and sit down. Wow. Without objection.

Mr. Buyer. So with regard to smokeless, the reason I bring it down here to the 10 percenters is science tells us if you move them from combustion to noncombustion, you take 90 percent of the pulmonary disease and carcinogens off the map.

You say, okay, Steve, why the differential then between the smokeless and the smokeless Snus? It is because even though we move them to a smokeless product, it is fermented. So when you have a fermented product you still have some bad things occur just in the natural process of tobacco. But when you get to the smokeless Snus, it is a pasturized product. So when you look at the Swedish experiment, they don't have a lot of the great challenges in their country that other countries are dealing with because they use a lot of the smokeless Snus.

Now what we have are products that are also coming out of the market called dissolvables. These dissolvables, they don't contain the nitrosamines, and that is a good thing. Now, these types of products, whether they are dissolvables, whether they are orbs, whether they are a stick, or whether they are something, a strip you lay on your tongue that delivers nicotine, but it has a less harmful effect.

Then you have all the therapeutic, the gum, the patches, the lozenges. You have got pharmaceutical such as Chantix.

What we are trying to do -- which I would love to be able to do with the chairman and maybe in the end product -- is that we have a continuum of risk and people are able to make informed choices among the continuum of risk. And we should be driving people from smoke to smokeless. And as we drive a population into smokeless, the last thing we should be doing as policymakers is increasing taxes on these products, because we want to move a

population to make it healthier.

So when you think about the 400,000 individuals of whom are dying each year with regard to smoking and you look at the statistics, some of these leading treatises that say that if you actually took that population of 40 million users and said they are all smokeless, we reduce the mortality and morbidity rate to around 4,000. And this is a big deal.

So please take a deep breath. I know there is a lot of paper in front of you. I would be more than happy to answer any questions you may have.

Thank you for your indulgence, Mr. Chairman.

The Chairman. The gentleman's time has expired.

The Chair would like to recognize Mr. Pallone, but if you would yield to me before you get started, just to make the comment that the one thing that was not on that chart to reduce the risk would be to quit, to quit smoking. You don't have to go to a pharmaceutical at the end of the line. You could quit smoking.

And, secondly, I want to tell people that my goal is not abstinence. My goal is to discourage cigarette smoking. But I accept the fact that adults smoke, and that is the reality. And we are not going to do anything about that except to try to discourage them, but it is their decision.

Mr. Pallone for 5 minutes.

Mr. Pallone. Thank you, Mr. Chairman.

I must say, I was kind of enjoying the gentleman from

Indiana's presentation. I felt like I was back in the classroom and he was the teacher there with the chart.

But my problem with his approach and his substitute is that I don't think we should be making this decision. I mean, there is ample evidence that smokeless tobacco has some serious problems. You know, it causes cancer and various things.

And I think the chairman's reference to light cigarettes is a good one. I mean, well, actually, the fact of the matter is when tobacco -- for a long time, nobody thought there was any harm to tobacco at all, to smoking any cigarettes. And then when lights came along, even today a lot of people think that lights are less dangerous than regular cigarettes, which scientific evidence shows they are not. They actually may be worse because of the way that people inhale them and the impact on their lungs.

So I think it makes sense to leave this up to the FDA and not establish a separate standard through legislative fiat when we are not really in the position to know. So that is my basic disagreement with the gentleman when it comes to the standard for smokeless tobacco versus regular cigarettes.

In addition to that, with regard to the advertising for kids that the chairman mentioned in this substitute, to me one of the most important aspects of this legislation, is to eliminate that advertising to kids. I remember when we were initially passing this legislation last session I went to an elementary school in my district in Edison, I think, New Jersey. The teachers, the

principal had kids that were from I think kindergarten through fifth grade; and we had all the different products that were advertised that we thought were mainly trying to reach out to kids. And I was frankly surprised, because I thought those were mainly targeting teenagers, and I was amazed to see how little kids that were in first or second or third grade were actually responding to those ads. So that is a very important part of this, which the substitute I think effectively eliminates.

The other thing I would say is that, with regard to this new agency that would deal with this, I am totally convinced that the FDA is the best agency to deal with this. Now, we know that the FDA is already spread too thin, and that was brought up last year, that they have too many responsibilities, they shouldn't be given additional responsibilities. But I think the answer to that is to make sure that the FDA has the resources required to do its work -- and the legislation that the committee is considering today ensures that, with the user fees -- and to appropriate or to make sure that we have adequate revenue.

We need to do that in general, not just on cigarettes, but, in general, we need to give more money to the FDA. But that doesn't mean that we should eliminate the FDA or change who regulates things. The answer is to help them out and give them the money and the resources so they can do their job.

They are clearly the appropriate agency. They have been regulating foods, drugs, cosmetics, and even pet food. So there

is absolutely no reason why they shouldn't be the agency that regulates tobacco, and we certainly give them the money to do so in this legislation.

So I oppose the substitute for all those reasons.

Thank you, Mr. Chairman.

The Chairman. Thank you, Mr. Pallone.

Further debate? Mr. Barton.

Mr. Barton. Mr. Chairman, I rise in support of the Buyer amendment somewhat in the nature of a substitute.

I think it is clear that he has an innovative idea here. I think it is clear that he has spent a lot of time researching and perfecting it and putting it into legislative language. I also think it is clear that, to take your analogy one step further of quitting, if we prevent our children from starting in the first place, then you don't have a problem later on that you have got to convince them to quit.

Mr. Buyer's approach does things somewhat differently, substantially differently, than the base bill.

Number one, it creates this Tobacco Harm Reduction Center in the Health and Human Services Department instead of making it a part of the FDA.

Secondly, it does require more funding for tobacco cessation and also prevention. As has been pointed out, of the $52 billion that has been actually sent to the States since the tobacco settlement, only 3.5 percent of that has been spent on prevention

campaigns or cessation campaigns. And a little bit of money there would go a long, long way. Mr. Buyer's bill does that.

And I know it is late in the game. I know that you have been a tremendous advocate for trying to reduce the amount of harm that tobacco does to some of our citizens in this country and that you have been consistent and persistent on it. And I know this is a priority of yours as chairman. But I would hope you are open-minded enough to realize that there are different ways to solve the problem; and Mr. Buyer's way is a way that would be, in my opinion, much more cost-effective and probably do a better job of actually reducing smoking in the U.S. population and preventing children from starting smoking in the first place.

So I am going to support his amendment, and I hope that the -- it would really, really, really be a positive step if the committee would support this, as I know how hard you have worked on it, so it is difficult to do, but this is a better way, in my opinion, and I hope we can take it.

With that, I would yield back.

The Chairman. Thank you, Mr. Barton.

Further debate? Ms. DeGette first, and then we will get to Ms. Schakowsky.

Ms. DeGette. Thank you, Mr. Chairman.

I want to make a couple of comments about science here.

The first one I will make is I am looking at this chart, which I have only just seen just now, which Mr. Buyer gave us; and

I guess it doesn't make much sense to me from a scientific perspective because it talks about relative risk for chronic disease and then it has percentages. But relative risk is not a percentage, because it is relative. So it is one thing relative to another, and so the numbers don't really correspond to any of the research. And I want to talk about that, because that kind of thing is what we are asking this new agency to do.

What this bill or what this amendment does is it says to the administrator of the new agency that that they shouldn't take into account the impact on the population as a whole when it develops standards for tobacco products or when it sets standards for allowing a claim that one product is less hazardous than other products. Instead, what it does is it says that the administrator shall evaluate the relative health risks to individual tobacco users, which is what this chart shows. So it doesn't show the effect of a manufacturer's actions on nonsmokers or on potential quitters or the population as a whole.

So under this amendment, if a manufacturer can show that a change in a product reduces the risk of cancer for the individual tobacco user by 5 percent, for example, then the administrator would have to allow the manufacturer to make health claims; and those health claims would be like this will be safer for you than, say, smoking cigarettes. And the administrator couldn't take into account the fact that these claims could cost millions of current smokers to switch rather than to quit. Or it could cause many

young people to start smoking, thinking falsely that cigarettes or smokeless tobacco or whatever were no longer dangerous. And so the net result would be more people suffering from tobacco-related diseases.

And Mr. Buyer was talking about the marketing of these light and low-tar cigarettes. This amendment would have the exact effect that he was talking about. Because when those cigarettes were marketed, people switched to light and low-tar cigarettes instead of quitting; and others started smoking thinking that the cigarettes were no longer as dangerous as before.

That is what would happen here. People would start switching to smokeless tobacco thinking, well, since it is supposedly less risky, then they should switch to it. But, in fact, if you look at smokeless tobacco and if you look at the studies that have been done, smokeless tobacco users absorb two to three times the amount of addictive nicotine as cigarette smokers. Chewing tobacco contains 28 chemicals that are known to cause cancer. Long-term snuff users are 50 percent more likely to develop cancer of the cheek and gums. Smokeless tobacco users increase the risk of cancers of the oral cavity, throat, larynx, and esophagus when compared to people who don't use tobacco products.

But this is the kicker to me: The average age of first-time users of smokeless tobacco is 10 years old. And that is right now, even before you shift this marketing.

So if you allow manufacturers to say to people, smokeless

tobacco is relatively safer than smoking, I am afraid what you will do is you will actually have the effect of encouraging young people and children to start using smokeless tobacco, which can have a different risk to them.

So I think this is a very -- I understand what Mr. Buyer is trying to do, but it is not based in science; and, for that reason, we should reject his amendment.

I yield back, Mr. Chairman.

The Chairman. Thank you, Ms. DeGette.

Who seeks recognition? The gentleman from Illinois.

Mr. Shimkus. Thank you, Mr. Chairman. I would like to yield my time to the gentleman from Indiana.

Mr. Buyer. I would say to the gentlelady, I was very attentive to your points that you were making until you made the very last statement, and that is where your credibility just fell right off the table.

To say that this wasn't based on science, I know -- and I apologize to the members of the committee -- this is a 200-page substitute; and what had happened here is that I was working with the chairman. I would love for us to have had hearings on this. I would love for us to have been able -- we have nine members of this committee who have never touched this legislation before. I would have loved for us to have embraced regular order. I would have loved for all of you to have had a chance to read this. But please don't criticize this if you don't know what is in my

substitute.

And to say that the chart that I just put here, Ms. DeGette, is not based on science is false.

Ms. DeGette. Would the gentleman yield?

Mr. Buyer. I was painfully -- no. Hold on just a second. I will be more than happy to yield.

I was painfully accurate. Being a lawyer myself, the last thing I wanted to do was put up a chart that someone could pick apart to try to claim that somehow my argument wasn't based in some type of factual setting. I am not stupid. So it is based on the science and the treatises from which I was read. And what I did is -- this has never been done before. What I shared with the committee has never been placed before our country.

We are trying to set forth a public policy framework. And I agree with the chairman when he said, Steve, what you forgot to say is I also want them to quit. Well, you know, that is the very last thing of the continuum of risk. Maybe I should have put that: Or to quit. But what I want to be able to do is, is to make sure that people have informed choices.

You see, I have a pretty serious job on behalf of Congress here on the VA. All of you love to talk about PTSD. For the longest time, we believed that a PTSD veteran, that somehow we were helping them by permitting them to smoke. It calms them down. In reality, what the science tells us is that you take that nicotine and its impact upon the brain -- and the effect of

caffeine and nicotine both upon the brain is a counterbalance against the psychiatrists' efforts to help these PTSD patients. So I am 3 years into a smoking cessation study, and we are using therapeutic and pharmaceutical means to try to get them as we help them.

So I understand Chairman Waxman's desire. I understand the desire of many on the committee. But I am more than happy to explore with any of the members about this desire to make sure that we have informed choices among the continuum of risk.

Now, what the this bill does, it protects consumers from bad actors of smokeless products. In particular, the FDA will continue to prevent smokeless from making therapeutic claims. So I just want Ms. DeGette to know that in response to her comment. The FTC will protect individuals against false and misleading ads. There are 50 States that have consumer fraud laws with tobacco products that are subject to, and the MSA has its advertising restrictions.

So, with that, I yield to Ms. DeGette.

Ms. DeGette. First of all, I want to apologize if the gentleman took my remarks personally. I certainly meant no insinuation on your intelligence or anything else.

What I was saying is two things: First of all, as I read the substitute, which since I haven't had it for a long time like you have I haven't looked at every single part -- but it looks to me like the bill says: If a manufacturer can show that a change in a

product reduces the risk of cancer for the individual tobacco product, then the administrator would have to allow the manufacturer to make health claims.

Is that correct?

Mr. Buyer. Yes, ma'am.

Let me reclaim my time. What we are trying to do is gateway, Ms. DeGette, from smokeless to noncombustible products; and I think that is a good and healthy thing.

So what the challenge is, the base bill before us sets some unrealistic standards. So the real question out there is it sets standards that may possibly never have been able to be achieved. So that is why I called the chairman's bill an abstinence-only type approach. And what I am hopeful that we can do here is to move -- move populations from smokeless to noncombustion. When I do that, Ms. DeGette, I can take away 90 percent of those challenging health risk. As a matter of fact, the tobacco smoke is responsible for the pandemic of cancers, heart disease, respiratory disease, and other deadly results. It is the smoke.

I yield to the gentlelady.

Ms. DeGette. My second question, and perhaps the gentleman can answer, is: How can you have a continuum of relative risk based on a percentage system rather than on a comparison system?

Mr. Buyer. I am sorry. The last thing?

Ms. DeGette. If you are doing a continuum of -- relative risk is not a percentage. It is values relative to each other.

So the question is, it is not a number. For example, if smokers are five times more likely to get cancer than nonsmokers, the relative risk would be five. It is not a percentage. So I am wondering what your chart means.

Mr. Buyer. The purpose of it is I tried to take the science that was out there with regard to disease groups that result for the use of certain products. And the purpose of this chart then was really to show the pathway among choices and the fact that these users can make an informed choice among the continuum of risk. That is really the purpose of the craft.

The Chairman. The gentleman's time has expired.

Ms. Schakowsky, do you still wish to be recognized?

Ms. Schakowsky. Just a couple of comments.

The Chairman. The gentlelady is recognized.

Ms. Schakowsky. Thank you.

The substitute would exempt smokeless tobacco from virtually all regulation and places no limit on tobacco industry advertising to children. And that is the point that Ms. DeGette was saying, that 10-year-olds using smokeless tobacco -- we have had -- I can't remember if it was this committee or another committee where we have had baseball players coming before various committees of the House talking about the dangers of chewing and sniffing tobacco or whatever you call that stuff and how dangerous it is and cancer victims coming and talking about that and how this is something that we have to discourage our children from using.

In a way, it seems like we have shown that methadone treatment is something that we do for heroin users, but we are certainly not going to go advertising methadone as a preferable drug to heroin and placing no limitations on it, because there is an enormous health risk.

Allowing marketing of products as reduced risks -- and I know you challenge this, Mr. Buyer -- but, without adequate scientific evidence, restricts the government's ability to increase warning labels on cigarettes. That is in the bill, in the substitute. And eliminating user fees for the program, relying solely on discretionary appropriations for funding -- we are talking about products that kill over 100,000 people every year of known danger.

We certainly don't want to do anything in this legislation that is going to encourage young people to engage in unhealthy behaviors; and this legislation would actually allow that to be encouraged, to allow the tobacco industry now to advertise to children. And it could be a gateway then to using -- to smoking as well as to using smokeless tobacco.

So I think that this is a dangerous idea and that the idea of allowing the FDA to regulate tobacco as a drug is definitely the direction that we want to be going in. And I support Mr. Waxman's legislation.

The Chairman. Are we ready?

Mr. Walden. Mr. Chairman.

The Chairman. The gentleman from Oregon.

Mr. Walden. Thank you, Mr. Chairman. I yield to my colleague from Indiana.

Mr. Buyer. Thank you very much.

A couple things I would like to bring up as I was listening to Ms. Schakowsky speak.

It is interesting -- I brought this up with the chairman in our personal discussions. It is interesting how we get ourselves, even by political party or even ideology, on the opposite side in a paradox. And what I mean by, in the issues of teenage sex or how do we improve public health and try to stop the spread of AIDS. Now, you can have an abstinence-only approach. When conservatives talk about an abstinence-only approach with regard to teenage sex, a lot of my Democrat colleagues mock that position, and you mock that position by using a harm reduction strategy and about education.

And you also -- so their concern is, with regard to the spread of AIDS, you even advocate the needle exchange.

And so Chairman Waxman and I had a very good discussion about this; and I complimented Chairman Waxman and his leadership when he chaired the Health Subcommittee in helping the country through a difficult time in dealing with AIDS and moving in a harm reduction strategy, not only just on the spread of AIDS and doing needle exchanges but also with regard to the -- talk about another pandemic, and that is sexually transmitted diseases. And I don't want to embarrass members on this committee, but it is very easy

to pull out your statements, and I have read some of the statements that some of you have made with regard to these issues in attacking abstinence-only positions.

So my only appeal to you at this moment in time is don't lock yourself into an abstinence-only approach with regard to use on tobacco.

Ms. Schakowsky. Would the gentleman yield for just a second?

Mr. Buyer. Sure.

Ms. Schakowsky. To characterize Mr. Waxman's bill as abstinence-only would mean that we prohibit the use of tobacco. That would be to make tobacco illegal. You couldn't buy it. That is what abstinence only is. This is not -- his bill is not an abstinence-only piece of legislation.

Mr. Buyer. Reclaiming my time. His bill is an abstinence-only approach, because he sets very unrealistic standards in which can be set by manufacturers to create smokeless products to move people in a gateway along the continuum of risk to ultimately quitting. And so when you set those unrealistic standards that cannot be met --

The Chairman. Would the gentleman yield?

Mr. Buyer. -- then it becomes an abstinence-only approach.

I yield to the chairman.

The Chairman. Well, I don't agree with your designation that my approach is an abstinence-only. I am pleased to hear Republicans admit that abstinence-only programs don't work. But

give me an example. How does this bill make it difficult for someone to do anything other than use tobacco?

Mr. Buyer. One in particular, Mr. Chairman -- reclaiming my time -- is that the bill -- you hamper the ability of manufacturers to even talk about their products.

The Chairman. To make claims.

Mr. Buyer. Well --

The Chairman. They may not be valid claims.

Mr. Buyer. If we want to be able to promote and move people for which we know even now, if you look at epidemiological studies that are out there with regard to -- it is a known fact that smokeless tobacco products are less harmful than smoking. That is a known fact. And if we want to move people through that gateway, I think it is extremely important that manufacturers are able to have people make informed choices, especially if we want to move them to dissolvables. There we know that we can take away almost 98 or 99 percent of the risks.

So the -- I want to go back and say this to you personally, Mr. Chairman. I think you are right in your -- let me just read this. Here is your quote.

You said: The statistics are shocking. A few weeks ago, the CDC released data showing one in four teenage girls in the United States has a sexually transmitted infection. Thirty percent of all American girls become pregnant before the age of 20. For African American and Latino girls, the rate is 50 percent; and

thousands of teenagers and young adults in the United States become infected with HIV each year. If we are serious about responding to these challenges, we must base our policy on the best available science, evidence, and not ideology.

And that is my plea here today, is for all of us to make this public decision. Don't ground it in an ideology. Let's ground it in a framework that we can move a population along the continuum of risk and make our society healthier.

The Chairman. The gentleman's time has expired.

Are we ready for the question?

The gentleman over here.

Mr. Gingrey. Thank you, Mr. Chairman.

I just wanted to say that I am supportive of the amendment in the nature of a substitute by Mr. Buyer, his Youth Prevention and Tobacco Harm Reduction Act. And I have not read all 200 pages of his bill, but I do appreciate what he is trying to do.

Mr. Chairman, I do appreciate what you are trying to do and what you have done over the years in regard to this. Because as a physician member of the committee, clearly, I understand the goal and the need to try to eliminate smoking almost 100 percent if we could. But as my colleague right here to my right Representative Scalise said in his opening statement, the FDA is really, in my opinion, in our opinion, not the place for this, because the FDA is charged with removing from the market any harmful product. And, clearly, everybody knows at this point that cigarette

smoking, nicotine, the smoke, the tar, whatever, is harmful to one's health.

RPTS MERCHANT

DCMN BURRELL

[2:10 p.m.]

Mr. Gingrey. So as Mr. Buyer said, in contradiction to Ms. Schakowsky, that it is eventually, I think that if we pass this bill, your bill, that the FDA would have no choice but to advance cigarette smoking. And then what happens? Then my concern, Mr. Chairman, is that these people who are hopelessly addicted, the adults, will get black market cigarettes from other countries that have much more impurities and nicotine.

The Chairman. Will the gentleman yield?

Mr. Gingrey. To the chairman of course.

The Chairman. The bill specifically prohibits the FDA from banning cigarettes. That isn't going to be an option. The bill also provides that if the FDA, based on science, finds that there is some risk reduction product that they will approve that. And I am saying it without the exact language. But I would rather have the FDA make that determination than for this committee to decide we want people to use smokeless tobacco.

Mr. Gingrey. Mr. Chairman, reclaiming my time, I understand that point. But what I am saying, it seems to be an oxymoron to put the FDA in that position. And the other thing, too, if you get to the point under this bill that the amount of nicotine has been reduced so much, that these people that are, again,

hopelessly addicted, they very well might smoke twice as much cigarettes a day or three times as many cigarettes a day just to get that required amount of nicotine to satisfy the addiction. So again, I have some concerns over that.

I would say to my colleague that in comparing what Mr. Buyer is talking about in this harm reduction and smokeless tobacco, I think one of my colleagues on the majority side said that, well, oral cancer is also a bad thing. It is, no question it is. And we know some personal situations about that. But clearly it is not as life threatening as lung cancer. Lung cancer, my colleagues, unfortunately, is almost a death sentence where squamous cell cancer of the lip or tongue or cheek is not, thank goodness. But this is why I say I think the approach that Mr. Buyer has -- and at this point I would like to yield to my good friend Mr. Buyer.

Mr. Buyer. Just for a second. The chairman asked a really good question with regard to who is going to be informing whom. The reason I choose and create a harm reduction center within the Health and Human Services is so we get out of this whole debate about the FDA. We know the FDA has a lot of challenges in its present responsibilities in regulation of drugs, devices and food, and we get out of that debate. So we create a separate center, and that center then has the authority to rank the risk of tobacco products based on the sound science for which we all have a desire for it to have.

With that, I yield back to Dr. Gingrey.

Mr. Gingrey. Again, I thank the gentleman for yielding back.

Mr. Hall. Will the gentleman yield to me?

Mr. Gingrey. I will yield to the gentleman from Texas, Mr. Hall.

Mr. Hall. I have the same pangs of conscience I think that you have and that many of us have and that perhaps the chairman has. I voted with the chairman's bill last time, but I think it is of record that in World War II they furnished cigarettes to guys that were overseas and were waiting ashore in the battles over there. And there are many of them that are still alive that are hooked on cigarettes, and under this it is my understanding that they will not be able to get them. And that is the price I have paid for voting for Waxman last time. I have had a number of those people that talked to me. And there is a good many people of mid age and average age of Americans that are hooked on cigarettes.

Mr. Gingrey. Reclaiming my time.

Mr. Hall. -- that are going to be affected by not having the right to do what they want to do even though they may know the consequences. That is the only thing that worries me about it. I don't even know how I am going to vote yet, but I thank you and I thank the chairman.

Mr. Gingrey. Mr. Hall, reclaiming my time. I realize, Mr. Chairman, that my time has just about elapsed, but if I could make

one last point. And I appreciate very much what Mr. Hall said. But again Mr. Scalise earlier in his opening remarks said that if you have this tobacco under the control of the FDA, then basically people get the idea that if the FDA has given its stamp of approval, then, hey, this is okay. So I mean I think it could. But I would say, Mr. Chairman, in closing that if it wasn't for Mr. Buyer's amendment I would be very much inclined to vote for your bill because I think you are definitely trying to do the right thing, and I commend you for your heart and working toward cutting out smoking, particularly for our youth, and I yield back.

The Chairman. The gentleman's time has expired.

Mr. Gonzalez. 20 seconds, Mr. Chairman.

The Chairman. Yes.

Mr. Gonzalez. And hopefully this will be the last comment. I cannot take credit for this observation. It is really Mr. Inslee's. In speaking about abstinence, and maybe the connection Mr. Inslee made, the observation that if we did practice strict abstinence there may be less smoking. And I think I understand the connection.

The Chairman. If the gentleman -- since the gentleman has time I just wanted to make one -- well, are we ready for the vote. All those in -- the chairman will restrain himself. The vote now comes on the Buyer substitute. All those in favor of the Buyer substitute will say aye. Opposed no. The noes have it. The amendment is not agreed to.

Mr. Deal. Mr. Chairman, I would ask for a recorded vote.

The Chairman. We will proceed to a recorded vote.

The Clerk. Mr. Waxman.

Mr. Waxman. No.

The Clerk. Mr. Waxman votes no.

Mr. Dingell.

Mr. Dingell. No.

The Clerk. Mr. Dingell votes no.

Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

[No response.]

The Clerk. Mr. Pallone.

Mr. Pallone. No

The Clerk. Mr. Pallone votes no

Mr. Gordon.

[No response.]

The Clerk. Mr. Rush.

Mr. Rush. No.

The Clerk. Mr. Rush votes no.

Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

[No response.]

The Clerk. Mr. Engel.

[No response.]

The Clerk. Mr. Green.

Mr. Green. No.

The Clerk. Mr. Green votes no.

Ms. DeGette.

Ms. DeGette. No.

The Clerk. Ms. DeGette votes no.

Mrs. Capps.

[No response.]

The Clerk. Mr. Doyle.

Mr. Doyle. No.

The Clerk. Mr. Doyle votes no.

Ms. Harman.

Ms. Harman. No.

The Clerk. Ms. Harman votes no.

Ms. Schakowsky.

Ms. Schakowsky. No.

The Clerk. Ms. Schakowsky votes no.

Mr. Gonzalez.

Mr. Gonzalez. No.

The Clerk. Mr. Gonzalez votes no.

Mr. Inslee.

Mr. Inslee. No.

The Clerk. Mr. Inslee votes no.

Ms. Baldwin.

Ms. Baldwin. No.

The Clerk. Ms. Baldwin votes no.

Mr. Ross.

Mr. Ross. No.

The Clerk. Mr. Ross votes no.

Mr. Weiner.

Mr. Weiner. No.

The Clerk. Mr. Weiner votes no.

Mr. Matheson.

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

Mr. Butterfield.

Mr. Butterfield. No.

The Clerk. Mr. Butterfield votes no.

Mr. Melancon.

Mr. Melancon. No.

The Clerk. Mr. Melancon votes no.

Mr. Barrow.

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Mr. Hill.

Mr. Hill. No.

The Clerk. Mr. Hill votes no.

Ms. Matsui.

Ms. Matsui. No.

The Clerk. Ms. Matsui votes no.

Mrs. Christensen.

Mrs. Christensen. No.

The Clerk. Mrs. Christensen votes no.

Ms. Castor.

Ms. Castor. No.

The Clerk. Ms. Castor votes no.

Mr. Sarbanes.

Mr. Sarbanes. No.

The Clerk. Mr. Sarbanes votes no.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. No.

The Clerk. Mr. Murphy of Connecticut votes no.

Mr. Space.

Mr. Space. No.

The Clerk. Mr. Space votes no.

Mr. McNerney.

Mr. McNerney. No.

The Clerk. Mr. McNerney votes no.

Ms. Sutton.

Ms. Sutton. No.

The Clerk. Ms. Sutton votes no.

Mr. Braley.

Mr. Braley. No.

The Clerk. Mr. Braley votes no.

Mr. Welch.

Mr. Welch. No.

The Clerk. Mr. Welch votes no.

Mr. Barton.

Mr. Barton. Yes.

The Clerk. Mr. Barton votes aye.

Mr. Hall.

Mr. Hall. Aye.

The Clerk. Mr. Hall votes aye.

Mr. Upton.

Mr. Upton. Aye.

The Clerk. Mr. Upton votes aye.

Mr. Stearns.

[No response.]

The Clerk. Mr. Deal.

Mr. Deal. Aye.

The Clerk. Mr. Deal votes aye.

Mr. Whitfield.

Mr. Whitfield. Aye.

The Clerk. Mr. Whitfield votes aye.

Mr. Shimkus.

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Shadegg.

[No response.]

The Clerk. Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. Aye.

The Clerk. Mr. Buyer votes aye.

Mr. Radanovich.

Mr. Radanovich. Aye.

The Clerk. Mr. Radanovich votes aye.

Mr. Pitts.

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack.

[No response.]

The Clerk. Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry.

Mr. Terry. Aye.

The Clerk. Mr. Terry votes aye.

Mr. Rogers.

Mr. Rogers. Aye.

The Clerk. Mr. Rogers votes aye.

Mrs. Myrick.

Mrs. Myrick. Aye.

The Clerk. Mrs. Myrick votes aye.

Mr. Sullivan.

[No response.]

The Clerk. Mr. Murphy of Pennsylvania.

Mr. Murphy of Pennsylvania. Aye.

The Clerk. Mr. Murphy of Pennsylvania votes aye.

Dr. Burgess.

Mr. Burgess. Aye.

The Clerk. Dr. Burgess votes aye.

Mrs. Blackburn.

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

Mr. Gingrey.

Mr. Gingrey. Aye.

The Clerk. Mr. Gingrey votes aye.

Mr. Scalise.

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

The Chairman. Are there members who wish to be recorded? Mr. Boucher.

Mr. Boucher. Votes no.

The Chairman. Mr. Stupak.

The Clerk. Mr. Boucher votes no.

Mr. Stupak. Mr. Stupak votes no.

The Clerk. Mr. Stupak, no.

The Chairman. Mr. Engel.

Mr. Engel. No.

The Clerk. Mr. Engel votes no.

The Chairman. Mrs. Capps.

Mrs. Capps. Votes no.

The Clerk. Mrs. Capps votes no.

The Chairman. Yes, Mr. Gordon.

Mr. Gordon. No.

The Clerk. Mr. Gordon, no.

The Chairman. Any other member wish to be recorded? Anybody seen the light and wishes to change their vote? If not, the Clerk will announce the vote.

The Clerk. On that vote, Mr. Chairman, the ayes were 18, the nays were 34.

The Chairman. Yes 18, no 34. The amendment is not agreed to.

Are there further amendments? I will look to this side. Seeing none, let me announce that we are going to be voting pretty soon. So members please get the priority for your amendments. We will come back. But I don't think we want to spend the rest of the day on a lot of amendments. And I might also indicate even the new members have already voted on this bill, even if they didn't vote on it in committee.

So the Chair will recognize further amendments. The gentlelady from Tennessee.

Mrs. Blackburn. Thank you, Mr. Chairman. I do have an

amendment at the desk.

The Chairman. The Clerk will report the amendment.

The Clerk. Amendment offered by Mrs. Blackburn of Tennessee. Strike section 102 and insert the following.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Without objection, the amendment will be considered as read and the gentlelady is recognized to explain it. The gentlelady from Colorado reserves a point of order.

Mrs. Blackburn. Thank you, Mr. Chairman. As you are aware, I am going to offer and then withdraw this amendment. But I do think it is a good amendment. It is a good government piece of legislation. And it does focus on strengthening the Synar amendment and existing programs to prevent illegal tobacco use. And we all know that the Synar amendment was put in place in 1992. The stipulation there on Federal funds, until a State met an 80 percent compliance rate for preventing tobacco sales to minors, all 50 States have met this rate. And the work product that is being distributed now would strengthen and give the opportunity for that to be strengthened in the States because Synar has been very successful in lowering the teen smoking rate. And the amendment would seek to reduce noncompliance rates from 20 to 10 percent over the next 10 years. And it also encourages States to use their master settlement funds for tobacco control and cessation efforts. And if the State fails the Synar goals and also does not spend at least 10 percent of its MSA payments on tobacco-related projects, then the HHS Secretary could withhold those funds.

And it also requires posting of the ingredients in tobacco products to a Web site within 48 hours in order to encourage

transparency.

Now, Mr. Chairman, I am one of those members of the committee that has served as president of my local lung association board, and I have actually held cessation clinics and have worked on cutting teen smoking. I can think of nothing more harmful and nothing more encouraging to teenagers to pick up a cigarette and smoke than giving the product the FDA stamp of approval. And I am -- it is sorrowful to me that we are heading in that direction. I do not think that policy wise it is the wise step. And indeed a poll from Zogby showed that 63 percent of all Americans have concerns about what this would do to teens and teen smoking. And I think that we should be very careful as we look at giving that FDA stamp of approval.

We have a program. The Synar amendment program has worked. It has lowered teen smoking rates. This is something we want to see happen. And yes, indeed, Mr. Chairman, we join you in wanting to make certain that teens do not take up the habit of smoking. But indeed, though, it appears we are not heading that direction.

I would seek at this time to yield back my time to withdraw my amendment and thank you for your consideration of at least hearing us out on that point. Yield back.

The Chairman. The gentlelady withdraws her amendment.

Are there further amendments? The gentleman from Michigan.

Mr. Rogers. Thank you, Mr. Chairman. I have an amendment at the desk.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Without objection, the amendment will be considered as read, and the gentlelady from Colorado reserves a point of order. I would now like to recognize the gentleman to explain his amendment.

Mr. Rogers. Thank you, Mr. Chairman. Unfortunately, claims have been made about this legislation that it will not impact FDA's current mission. And I supported this bill the last time based on some of that information. Unfortunately, it just simply isn't true. While much of the bill's tobacco regulation at the FDA will be funded through user fees, there is a provision in the bill that allows FDA general funds to be diverted for tobacco regulation. That to me poses a lot of questions that we should answer before moving this bill along. At the time when the FDA is strapped for resources and failing in many of its core missions, this provision is simply unacceptable.

Mr. Chairman, you have rightly criticized the FDA's poor track record on food safety. The most recent outbreak of salmonella which sickened over 600 people and killed at least eight was the latest tragic example of the FDA's failure to protect our Nation's food supply. You and many members of this committee have correctly asserted that the FDA needs more resources to carry out its critical food safety mission.

Last year, Mr. Chairman, you were quoted as saying, and I quote, food safety is one of the most neglected functions at the

agency. The FDA is facing a funding shortfall for food safety of crisis proportions, which proves to me, Mr. Chairman, you are as wise as you are handsome. This amendment would ensure that the FDA has the resources to ramp up food safety inspections before it undertakes tobacco regulation. And I think if we are going to have a sense of priorities in this Congress we need to make sure that the things that we know are jeopardizing the lives of folks who have no control over it get taken care of. This is certainly one of them.

It would require the Secretary of HHS to certify that the FDA is able to inspect at least 10 percent of our Nation's food supplies; a reasonable goal. Last year the FDA inspected roughly 6,000 of the 189,000 food facilities under its jurisdiction. It is just about 3 percent. My amendment would ensure that the FDA increases food inspections to at least 10 percent, or about 19,000 facilities, before diverting any general funds to tobacco regulation.

And I am just going to go down the list of some of the recent ones over the last few years. And unfortunately the list is growing. There was a novo virus for green salad, lettuce and fruit; salmonella for sprouts, green salad, tomatoes and melons; E.coli for green salad; and most recently we know the peanut butter incident that left 600 sick, 8 dead.

This is a crisis. I can talk to my kids about cigarettes. It is pretty hard to say the Surgeon General warns you ought not

to eat peanut butter. I mean this is critical to the Nation's food supply. And I would strongly urge, knowing how important it is that we get people to stop smoking, it is that much more important that our food supply is safe.

I would encourage the adoption of this amendment. I think it is reasonable. It is something that we can support. And it doesn't say no to your bill, Mr. Chairman. It just says we have priorities that we must meet that impact every single household in this country.

And I would yield back the remainder of my time.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. The gentlelady withdraws her reservation. The gentleman yields back his time. The Chair recognizes himself in opposition to the amendment.

This bill provides for a user fee to provide funding for the FDA to do the job of regulating tobacco, and it does not take away money from the other FDA responsibilities, a major one of which is food safety. We are going to deal with food safety very soon and try to make sure that FDA has the resources. But that doesn't mean that FDA shouldn't be able to take on the job of regulating tobacco as under this bill. So I would urge opposition to the amendment.

Are we ready for the vote on this?

Mr. Rogers. A 30 second response, Mr. Chairman, if I may.

The Chairman. Mr. Terry. Either one of you. Do you want to

yield your time?

Mr. Terry. Yes, I will yield my time.

The Chairman. The gentleman is recognized.

Mr. Terry. Thank you, Mr. Chairman. I would like to yield time to Mr. Rogers to clarify which features are handsome.

Mr. Rogers. Thank you, Mr. Chairman. Mr. Chairman, I just want to refer to you at page 142. I am going to quote from the bill. Until such date other amounts are available to the Food and Drug Administration, excluding fees collected under this subsection, are authorized to be made available to pay for costs described. It says in your own bill that in fact money will be diverted from this bill when we pass this law. And I would strongly encourage -- I would be willing to work with the chairman to exclude that language, but obviously we haven't had much success in that cooperation. And I understand your intent. As I said, in the past I voted for it. But this bill clearly states that money from this bill will be diverted if this bill passes.

And I yield back my time to Mr. Terry.

Mr. Terry. Yield back.

The Chairman. Mr. Stupak.

Mr. Stupak. Mr. Chairman, if I may, I will be brief. For the last 3 years we have headed oversight investigations done to food safety inspections. The problem with the gentleman's amendment is a couple of things. Number one, is he talking about domestic food suppliers or is he talking about foreign? We are

really weak on foreign.

Number three, every time we have given the FDA money, like 2007, an extra $10 million, they used the money, it was for foreign food safety, they use it for bonuses for top political appointments.

Third point, in the President's budget that was just submitted to Congress there is $1 billion dedicated to food safety. So until we get an administration that is willing to put the money behind the effort that we do need in this country to inspect food facilities I think the amendment is just trying to draw us off the attention here, which is tobacco.

So I am going to oppose this amendment. We should put more money into food safety, absolutely, drug safety. The FDA needs a major overhaul. So you can throw all the money you want at it, but if you don't have proper leadership at the top nothing is going to happen. This President put forth $1 billion for food safety in its proposed budget. So I would ask that we reject this amendment.

The Chairman. The gentleman yields back his time. All those in favor of the amendment will say aye. Opposed no. The noes have it, and the amendment is not agreed to.

Mr. Rogers. Mr. Chairman, I would like a roll call vote.

The Chairman. The Clerk will proceed with a roll call vote.

The Clerk. Mr. Waxman.

Mr. Waxman. No.

The Clerk. Mr. Waxman votes no.

Mr. Dingell.

[No response.]

The Clerk. Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

Mr. Boucher. No.

The Clerk. Mr. Boucher votes no.

Mr. Pallone.

Mr. Pallone. No

The Clerk. Mr. Pallone votes no

Mr. Gordon.

[No response.]

The Clerk. Mr. Rush.

[No response.]

The Clerk. Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

Mr. Stupak. No.

The Clerk. Mr. Stupak votes no.

Mr. Engel.

Mr. Engel. No.

The Clerk. Mr. Engel votes no.

Mr. Green.

Mr. Green. No.

The Clerk. Mr. Green votes no.

Ms. DeGette.

Ms. DeGette. No.

The Clerk. Ms. DeGette votes no.

Mrs. Capps.

Mrs. Capps. No.

The Clerk. Mrs. Capps votes no.

Mr. Doyle.

Mr. Doyle. No.

The Clerk. Mr. Doyle votes no.

Ms. Harman.

Ms. Harman. No.

The Clerk. Ms. Harman votes no.

Ms. Schakowsky.

Ms. Schakowsky. No.

The Clerk. Ms. Schakowsky votes no.

Mr. Gonzalez.

[No response.]

The Clerk. Mr. Inslee.

Mr. Inslee. No.

The Clerk. Mr. Inslee votes no.

Ms. Baldwin.

Ms. Baldwin. No.

The Clerk. Ms. Baldwin votes no.

Mr. Ross.

Mr. Ross. No.

The Clerk. Mr. Ross votes no.

Mr. Weiner.

Mr. Weiner. No.

The Clerk. Mr. Weiner votes no.

Mr. Matheson.

[No response.]

The Clerk. Mr. Butterfield.

Mr. Butterfield. No.

The Clerk. Mr. Butterfield votes no.

Mr. Melancon.

[No response.]

The Clerk. Mr. Barrow.

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Mr. Hill.

Mr. Hill. No.

The Clerk. Mr. Hill votes no.

Ms. Matsui.

Ms. Matsui. No.

The Clerk. Ms. Matsui votes no.

Mrs. Christensen.

Mrs. Christensen. No.

The Clerk. Mrs. Christensen votes no.

Ms. Castor.

Ms. Castor. No.

The Clerk. Ms. Castor votes no.

Mr. Sarbanes.

Mr. Sarbanes. No.

The Clerk. Mr. Sarbanes votes no.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. No.

The Clerk. Mr. Murphy of Connecticut votes no.

Mr. Space.

Mr. Space. No.

The Clerk. Mr. Space votes no.

Mr. McNerney.

Mr. McNerney. No.

The Clerk. Mr. McNerney votes no.

Ms. Sutton.

Ms. Sutton. No.

The Clerk. Ms. Sutton votes no.

Mr. Braley.

Mr. Braley. No.

The Clerk. Mr. Braley votes no.

Mr. Welch.

Mr. Welch. No.

The Clerk. Mr. Welch votes no.

Mr. Barton.

Mr. Barton. Aye.

The Clerk. Mr. Barton votes aye.

Mr. Hall.

[No response.]

The Clerk. Mr. Upton.

Mr. Upton. Aye.

The Clerk. Mr. Upton votes aye.

Mr. Stearns.

[No response.]

The Clerk. Mr. Deal.

Mr. Deal. Aye.

The Clerk. Mr. Deal votes aye.

Mr. Whitfield.

Mr. Whitfield. Aye.

The Clerk. Mr. Whitfield votes aye.

Mr. Shimkus.

[No response.]

The Clerk. Mr. Shadegg.

Mr. Shadegg. Aye.

The Clerk. Mr. Shadegg votes aye.

Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. Aye.

The Clerk. Mr. Buyer votes aye.

Mr. Radanovich.

[No response.]

The Clerk. Mr. Pitts.

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack.

[No response.]

The Clerk. Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry.

Mr. Terry. Aye.

The Clerk. Mr. Terry votes aye.

Mr. Rogers.

Mr. Rogers. Aye.

The Clerk. Mr. Rogers votes aye.

Mrs. Myrick.

Mrs. Myrick. Aye.

The Clerk. Mrs. Myrick votes aye.

Mr. Sullivan.

[No response.]

The Clerk. Mr. Murphy of Pennsylvania.

Mr. Murphy of Pennsylvania. Aye.

The Clerk. Mr. Murphy of Pennsylvania votes aye.

Dr. Burgess.

Mr. Burgess. Aye.

The Clerk. Dr. Burgess votes aye.

Mrs. Blackburn.

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

Mr. Gingrey.

[No response.]

The Clerk. Mr. Scalise.

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

The Chairman. Other members wish to be recorded? Mr. Matheson.

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

The Chairman. Mr. Dingell.

Mr. Dingell. Votes no.

The Clerk. Mr. Dingell votes no.

The Chairman. Any other members wish to be recorded or change their vote?

The Clerk will report the vote. And while you are counting it, we will break to vote on the House floor. And then please come back after the last vote as promptly as possible because we would like to finish this bill today.

The Clerk. On that vote, Mr. Chairman, the nays were 30 and the ayes were 15, so it defeated.

The Chairman. 15 ayes, 30 noes. The amendment is not agreed

to.

The committee will stand in recess until after the last vote.

[Recess.]

The Chairman. The meeting will come back to order. I don't want to preclude anybody from offering amendments, but let me ask if any of the people here have amendments they wish to offer.

The gentleman from Michigan, Mr. Rogers. I don't want to encourage it.

Mr. Rogers. The amendment is listed as ECR 1.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Without objection, the amendment will be considered as read, and the gentlelady from Wisconsin reserves a point of order.

Ms. Baldwin. I do indeed, thank you.

Mr. Rogers. Thank you, Mr. Chairman.

Heart disease is the leading cause of death in the United States. About 700,000 people die each year from heart disease. Each year heart disease costs over $140 billion, including health care services, medications and lost productivity. Multiple new drugs designed to combat heart disease are currently being reviewed by the FDA, yet this legislation would allow FDA funds to be diverted from heart disease, drug reviews, for tobacco regulation. I think this is a dangerous precedent to set and would further handcuff the FDA's ability to carry out its core mission approving safe and effective medicines for Americans.

My amendment would simply ensure that before the FDA undertakes the enormous task of tobacco regulation current drug applications for heart disease receive a final determination. Millions of Americans rely on the FDA to bring these critical drugs to the market in order to save lives, reduce health care costs, and improve the quality of life for patients and heart disease.

I would hope the majority would accept this commonsense amendment to ensure the FDA can conduct its core mission.

And with that, Mr. Chairman, I will yield back.

Ms. Baldwin. Mr. Chairman.

The Chairman. Yes. The gentlelady from, where are you from? Wisconsin.

Ms. Baldwin. Wisconsin. Yes, not Arkansas.

The Chairman. Ms. Ross.

Ms. Baldwin. I would withdraw my reservation, Mr. Chairman.

The Chairman. The reservation is withdrawn. Further debate on the amendment? The Chair recognizes himself to speak in opposition to it.

I want FDA to deal with all applications dealing with heart disease drugs and cancer and all orphan drugs and other drugs as well. But that is not a reason to deny FDA the authority to deal with tobacco. And I would urge that this amendment be rejected.

Are we ready for the question? All in favor of the amendment say aye. Opposed no. The noes have it and the amendment is not agreed to. Do you really want a vote?

Mr. Rogers. Is there a way to roll the roll call vote, Mr. Chairman, until you have your folks here.

The Chairman. Well, if the gentleman wants a roll call vote and wants to ask that we postpone the vote until other votes are taken, you can put that as an unanimous consent request.

Mr. Rogers. I will do that, Mr. Chairman.

The Chairman. Okay. Without objection, the roll call vote on this amendment will be postponed until a time when other

amendments will be voted on by a call of the roll.

Further amendments? Yes, Mr. Burgess.

Mr. Burgess. Thank you, Mr. Chairman. I have an amendment at the desk.

[The information follows:]

******** COMMITTEE INSERT ********

Ms. DeGette. Mr. Chairman, I reserve a point of order and thank the gentlelady from Wisconsin for filling in when I was gone.

The Chairman. Without objection, the gentleman's amendment will be considered as read. The Chair notes a reservation of a point of order by the gentlelady from Colorado. And I now recognize the gentleman from Texas to explain his amendment.

Mr. Burgess. Thank you, Mr. Chairman. Just for a point of clarification, this is Burgess 031.

With this bill before us, the underlying bill, the base bill, we are going to give the FDA broad and almost limitless authority and discretion in their ability to regulate tobacco products for the protection of public health. Currently there are some provisions in the bill that would limit the FDA's authority. And one that really concerns me the most is the one that would prohibit the FDA from requiring the manufacturer to produce a cigarette that contains zero milligrams of nicotine. My amendment proposes to strike subparagraph (b) in section 907(d)(3) of the Federal Food and Drug and Cosmetic Act as added by section 101(b)(3) of H.R. 1256 and then give the FDA the power to require the reduction of nicotine levels to zero in products.

If the purpose of this bill is to reduce the harmful effects of this inherently dangerous product, then why not allow the FDA to scientifically analyze whether nicotine should be reduced and

if that reduction should be in fact reduced to zero milligrams of nicotine. It is illogical to handicap them, and that is why I am introducing this amendment.

I would note that when we did the recent reauthorization of the Consumer Protection Act last year we required reduction of lead levels down to numbers that were actually unmeasurable by current technology. I don't think it is unrealistic to ask that nicotine, we at least give the FDA the authority to regulate nicotine down to a zero milligram level.

And I will yield back the balance of my time.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. The gentlelady from Colorado withdraws her reservation.

Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman. I understand what Mr. Burgess is trying to accomplish, but I think it is not a good idea, essentially because if the FDA were to essentially abandon nicotine or say that nicotine could not be part of cigarettes it would be tantamount to an outright ban on cigarettes. And to me it is almost like the prohibition situation.

You know we went through prohibition with alcohol. You ended up with a legal black market, if you will, with alcohol, and I think the same thing would happen with cigarettes. There would become a black market with cigarettes that obviously had nicotine and we would have to deal with that whole illicit cigarette

manufacturing and chain of events.

So I think that wisely what we are doing in the underlying bill is saying that that decision about an outright ban on nicotine is left to Congress, but we allow EPA to lower the levels of nicotine to a level that would be appropriate for the protection of the public health.

I mean, I think it is a political decision more than anything else in this case, but I think it is a political decision that makes sense, and that is why I would oppose Mr. Burgess' amendment.

Mr. Burgess. Will the gentlelady yield?

Mr. Pallone. Certainly.

Mr. Burgess. And again, I know we went through this when we heard this bill the last time. But this is such an important point. We have said that we want the FDA as the premier Federal agency involved in regulation that has a basis in sound science, we want them to be at the forefront of this regulation. And then we have language in the bill that says because of the importance of a decision of the Secretary to issue a regulation requiring the reduction of nicotine yields of a tobacco product to zero, the Secretary is prohibited from taking such action under this act. But what if their science leads them in the direction that lower nicotine levels are in fact beneficial for public health and that the lowest nicotine level really should be zero, the Secretary, their hands are tied, and they cannot go to that level.

Mr. Pallone. Well, if I could reclaim my time. I mean, this is essentially what I was saying. You are a doctor, and I respect that you are looking at this from a scientific point of view. And I don't disagree that the science may very well say that no nicotine makes sense. But again, this is a political decision. The FDA is not a political body. That is our job. And I think that the fear is that if you do that, or if the FDA decided to do that for scientific reasons, it would be tantamount to prohibition. And we know what would happen. I don't have to go through American history. It was an utter failure. And if anything, it encouraged people to drink more because, you know, because now it was illegal and they could buy it on the black market and encourage all kinds of organized crime and the whole thing.

That is a political decision in my opinion, and I think that we are making that here. And I think it is a wise one based on the fact that if you just outright do a prohibition you would get all those negative consequences.

The Chairman. The gentleman from New Jersey yields back the balance of his time.

Further discussion? Mr. Barton.

Mr. Barton. I just want to ask some questions of the counsel.

Under the bill, the base bill, could the FDA without coming back to Congress set a level that for all intents and purposes was

equivalent to zero nicotine?

Mr. Westmoreland. I am sorry, sir, I am not sure if I understand. With the amendment in?

Mr. Barton. No, sir. As the bill is currently configured, absent the Burgess amendment, could the FDA set a standard for nicotine that while it allowed some minute level, some de minimis level, .0001 something, have the effect of having a zero nicotine cigarette?

Mr. Westmoreland. As I read the language, sir, it would prohibit the Secretary from requiring it to be absolutely zero.

Mr. Barton. But they could come very, very -- for all intents and purposes set a standard that was a zero?

Mr. Westmoreland. Yes, sir.

Mr. Barton. It would not be zero?

Mr Westmoreland. It wouldn't be zero.

Mr. Barton. It would be .0000001.

Mr. Westmoreland. The language as it stands prohibits reducing it to zero. It does not prohibit any positive number above zero.

Mr. Barton. Now, I want to ask the author of the bill a question. I would assume that would be the chairman. What is the chairman's take if the FDA set a standard very, very, very close to zero but which was not zero mathematically? Does the chairman think that is the same effect as a zero standard?

The Chairman. I don't know the answer to that. I think the

FDA would have to not just look at how greatly the nicotine could be reduced, but what the consequences would be of reducing it to a low amount. Somebody earlier in the debate said people might start smoking more cigarettes to make up for the drop in nicotine. I would hope the FDA would evaluate that before it made a decision. So you leave the determination to the FDA and these questions we hope would be answered by a review of the evidence and the science.

Mr. Barton. Well, the reason I ask the counsel the question and ask the chairman, who is the author of the bill, the question, the Burgess amendment is the anti-hypocrisy amendment. Either the bill should give the FDA the authority to regulate nicotine, which it does, but not to eliminate it and to put some level, minimal level, that people who choose to smoke get some nicotine value, benefit, whatever, from it, or we ought to adopt the Burgess amendment and say if they want to go to zero they can go to zero. Because apparently where we have the bill is it is very hypocritical. They can go real close to zero so there is no real impact from the nicotine, but they can't go mathematically to zero. And I think you either go one way or the other. You either give the authority to go all the way or set some minimal level beyond which they can't go, and we are not doing that.

The Chairman. Will the gentleman yield?

Mr. Barton. I will be happy to yield.

The Chairman. Well, the bill leaves it to the FDA to do what

is appropriate for the protection of the public health. And we leave them to do that. But I am very hesitant to have them ban cigarettes or remove all nicotine and let them come back to Congress if they reach a determination that is appropriate to protect the public health beyond that. But I don't think it is hypocritical to let them have the decision and not let them go all the way to ban a cigarette.

Mr. Barton. Well, reclaiming my time, what we have here is almost a dictionary definition of hypocrisy. Because you achieve the consequence without taking the consequences politically of what it is that you achieve, which to me that is hypocrisy.

Mr. Pallone. Will the gentleman yield?

Mr. Barton. Sure, I would be happy to yield.

Mr. Pallone. I think the chairman here in this legislation is recognizing the reality. I mean, some of this is science, and that is what the FDA is looking at, and some of this is, you know, us as legislators trying to figure out what works. From my perspective part of the success of getting people to reduce tobacco consumption is that it is starting to look bad. Like, you know, kids, if they think they can't smoke in a school or in a public place and the people -- Mr. Chairman, could I ask for an additional minute?

Mr. Barton. I would ask unanimous consent that I be given an additional minute so I can yield to my distinguished subcommittee chairman.

Mr. Pallone. And you don't want to get to the point where you just have an outright ban, because we know that historically if you have an outright ban you have this illicit market and sometimes it almost becomes something positive because people know it is illegal and so now they are going to do it.

I mean, I think that those kinds of decisions are really left to the legislature, not to the scientists at the FDA. And I think that is what really is sort of underlying this decision. Now, it is not perfect as to where that spectrum meets the total ban, and it may very well be that we have to come back and look at it again if the FDA decides that they want to come close to zero. But there has got to be a recognition here that we as legislators have some role and it is not purely a scientific decision. When you decide to just ban something outright you have got to think about the impact practically. And I think we are in a better position, dare I say, to look at that sort of practical aspect of it and leave the scientific aspect to the FDA.

Mr. Barton. Reclaiming my five seconds, there is growing scientific evidence that it is not the nicotine itself that is a health hazard. Nicotine is addictive, but the health hazard is the particulate matter and the smoke and all that, that transmits the nicotine. So if you do a pure health hazard apparently you can absorb a lot of nicotine without it itself being harmful to health. And I support the Burgess amendment.

The Chairman. The gentleman's time is expired. Are we ready

for the question? Yes, the gentleman from Indiana.

Mr. Hill. Thank you, Mr. Chairman. I am from Indiana and I have the eighth largest tobacco growing district in the country, which most people don't know. And I was very much involved in drafting this language because the previous language was such that it would essentially allow the FDA to go to zero, in my view. I would rather see some kind of percentage in here, but this is the best I could get by with.

The question I have though is for staff. Maybe they can answer this question. I have looked through most of this bill, but not all of it, and I am at the part right now looking at it where it talks about requiring the reduction of nicotine yields of tobacco products to zero. The Secretary is prohibited from taking such actions like that. When they determine what that percentage is going to be, is there a time period that is established in this bill when that will be actually put into practice?

Mr. Westmoreland. To do so, as I understand it, would require regulation. And regulations under the Administrative Procedures Act under normal terms would have at least a 90-day notice period for regulation.

Mr. Hill. So if there is a 90-day notice and we know exactly when it is going to be, it can always come back to Congress because we are the regulating body over the FDA. We can change that law, is my understanding, is that correct, Mr. Chairman?

The Chairman. Yes, I believe you are correct.

Mr. Hill. So I guess the scenario could come to pass that the FDA would try to take it down to near zero, but there is some legislative oversight to prevent that from happening if it in effect takes tobacco off the market. And so therefore I think that while this is not the best language that I would like to have, it at least is language that I can live with. And I think we do have a recourse if the FDA goes too far.

Thank you, Mr. Chairman. I yield back.

The Chairman. Thank you. Further discussion? The gentleman from or Oregon.

Mr. Walden. Thank you, Mr. Chairman. I yield to the gentleman from Texas for concluding comments.

Mr. Burgess. I thank the gentleman for yielding. Just on that last point, tobacco cigarettes as we all know them are the delivery device for nicotine. There is no good reason to pull tobacco smoke into your lung unless it is to satisfy the addiction to nicotine. Removing nicotine from a cigarette as a delivery device would do more to eliminate the problem of smoking than almost any single effort that we could undertake. So if our true goal is to limit the public health exposure to cigarette smoke we would eliminate the addictive component to cigarette smoke so we would not drive that behavior. And one who has watched someone train themselves to smoke, and you do have to do that, it is a very unpleasant process to go through initially because cigarette smoke is so noxious, but the reward is the nicotine that satisfies

then the craving for the nicotine addiction after it occurs. And this I think is something that likely cigarette companies have understood for some time.

My submission is that if we really want to get at the bottom of the public health issue we really will allow the FDA to allow a zero milligram nicotine cigarette to be produced, and as a consequence that cigarette would not satisfy the nicotine craving and cigarette consumption would go down.

Now, if our goal is to simply collect more taxes from the tobacco companies, then please let us be honest about what we are doing and recognize that we are satisfying our addiction to tax dollars, not trying to impact public health.

And I will yield back the balance of my time.

The Chairman. The gentleman yields back the balance of his time. Are we ready for the question?

The amendment before us is offered by the gentleman from Texas, Dr. Burgess. All those in favor of the amendment say aye. Opposed no. The noes have it, and the amendment is not agreed to.

Mr. Burgess. Mr. Chairman, can I ask that this be added to the list of votes that will be taken when the time deemed is appropriate. I would like a roll call vote on this.

The Chairman. Well, the gentleman is requesting that he have a roll call vote and it be deferred to the time when we take other roll call votes, and without objection that will be the order.

Further amendments? Mr. Deal.

Mr. Deal. I have an amendment at the desk. It is ECR 16.

[The information follows:]

******** COMMITTEE INSERT ********

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. The amendment by the gentleman from Georgia, Mr. Deal, will be considered as read. And the Chair will note that a point of order has been reserved by the gentlelady from Colorado. Mr. Deal is recognized to explain his amendment.

Mr. Deal. Thank you, Mr. Chairman. This is a little bit technical, so I hope you will try to follow what I am going to say. The last time this bill was before the committee I raised the question of whether or not we created the possibility of allowing the Secretary to approve a product that was patented as the standard, and thereby by approving a patented product as a standard create a monopoly in the hands of the company that held the patent.

Now, to the credit of the chairman, when I raised the issue of the bill that is before us today, has attempted to address it, but I personally don't feel that it has addressed it as appropriately as we should. There was no reference in the original bill as I recall to this issue last time. The change says that when determining the effective date of a new product the Secretary shall consider whether or not there is a patent that is in existence. Now, what that says to me is the Secretary establishes the standard, and then the question is, well, what effective date are we going to have for this standard to go into effect to be the standard for this new modified risk product.

Well -- and then it says he shall consider whether or not there is a patent in place on that standard. Let us say that the standard is agreed to and then he looks at it and says, well, it is a patented issue and there are 10 more years left on the patent. I think common sense is going to tell us that the Secretary is not going to defer the approval of the standard for another 10 years; he is going to approve it. And when he approves it he has then created a monopoly in the hands of the party that holds the patent.

Now, that is the way I conceive the underlying bill's language. My amendment, and I have come off of where I was last time, I simply said last time that he could not approve a standard for a new modified risk product if that standard was a patented item. I have changed it, not to make it a prohibition, but to simply say that he would consider in establishing the standard whether or not it is a patented product that meets that standard and therefore would create a monopoly by approving the standard.

Under the underlying bill he is already required to consider whether or not the new standard is technically achievable. I think it is only reasonable that he would also consider whether or not the standard is protected by a patent. And by adopting a standard that is a patented standard he has therefore created a monopoly in the hands of whatever company holds that particular patent.

I don't think that is where we want to go. That is not where

I want to go. I think that it should be a standard that a multitude of products perhaps should be able to meet that same standard. But if we allow a patented product to become the standard, then we have created a monopoly. And we are the Commerce Committee, and I don't think the Commerce Committee ought to be in favor of creating monopolies.

I appreciate your indulgence, and I would urge the adoption of the amendment. It is not an obligatory language. It just simply says in the process of setting the standard simply consider whether or not you have created a monopoly because it is already a patented product that you are basing the standard on.

I would yield back my time.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. The gentlelady from Colorado withdraws her reservation. The gentleman from Georgia yields back the balance of his time. The Chair would recognize himself.

I remember when we last considered this bill there was the issue that you had raised, and I thought we had dealt with it by saying that the Secretary would consider the technological achievability and availability of patents in setting effective dates for any new product standards. As I hear -- and we did that. But as I hear you now you want the Secretary to look at the issue of whether a patent pertains to the product before setting a standard.

Mr. Deal. Would the chairman yield?

The Chairman. Yes, sir.

Mr. Deal. You did make a change, and I think that is fine. But it only says that he shall consider when to set the effective date of the standard in light of whether or not there is a patent. In other words, he has already set the standard. If he sets the standard and the standard is a patented product that meets that standard and therefore is protected as the only product, he is then faced with the quandary of, well, I have established a standard, now I have to consider the patent life of the product that meets that standard, and I would have to delay the effective date of when the standard goes into place based on the patent. Now, he doesn't have to delay it. But if he doesn't delay it until the patent expires then he by virtue of that has created a monopoly by approving that patented product as a standard.

All I am saying is let us just require that he look at the issue of whether or not a patented product is the only one that meets the standard he is about to approve before he approves the standard, not put himself in the box of approving something that is patent protected and then having to say, well, so what, I am going let a monopoly exist for however much longer the patent life is. It is a matter of timing on it, Mr. Chairman.

The Chairman. I hear what you are saying, and I have an enormous regard for your knowledge of this area. But I am worried that if we put this into the statute that it is going to be an invitation for litigation every time there is a standard that is

established.

Let me request that you withdraw this amendment and let me think it over and see if we could agree on something. I haven't thought it through, and I don't know that I disagree with you but I feel uncomfortable accepting the amendment at this time.

Mr. Deal. If the chairman would yield. I will withdraw it, but I am serious about the issue. I don't think we intend to create this, and I am not trying to be an obstructionist on this issue, but I do think we do not want to intentionally create a monopoly, or maybe unintentionally create a monopoly.

So I would ask unanimous consent to withdraw the amendment with that understanding.

The Chairman. I appreciate that. And I certainly agree with you, we don't want monopolies just blocking progress, and there ought to be limits on monopolies. We have discussed this issue in other contexts.

So I thank you very much, and you have my word that we will try to think it through together.

Further amendments to the bill? Mr. Buyer.

Mr. Buyer. Thank you, Mr. Chairman. I have an amendment at the desk. It would be Buyer number 11.

[The information follows:]

******** COMMITTEE INSERT ********

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. Without objection, the Buyer amendment number 11 will be considered as read. The Chair will note that there is a reservation of a point of order by the gentlelady from Colorado. And Mr. Buyer is now recognized for 5 minutes to explain his amendment.

Mr. Buyer. Thank you, Mr. Chairman. I offer this amendment to address my strong concerns that the FDA is not the agency to burden with tobacco regulation today for two main reasons. First, regulation of tobacco runs counter to the FDA's expertise in providing for the safety and efficacy of the Nation's drugs and devices. Tobacco is an inherently dangerous product and the FDA has no experience regulating such product. Frankly, it is counter to their culture.

Secondly, the FDA continues to fail to perform its current duties, whether they are inspecting our Nation's food manufacturing facilities or foreign drug manufacturing facilities. As a matter of fact, I want to recognize our respected dear friend and colleague, Congressman John Dingell, for his efforts with his food and drug safety bill, and he has long championed the FDA in bringing their toes to the line. As Chairman Waxman, Congressman Dingell, Congressman Markey, Congressman Pallone, Congressman DeLauro stated, along with Senators Kennedy, Leahy, and Dodd in January 2008, quote, today the FDA is an agency that is all but

starved of resources. Experts from every affected sector agree that this desperate funding situation has rendered the FDA unable to protect the American public from even the most basic threats, including contaminated food, tainted and dangerous drugs, and faulty medical devices, end quote.

So once again I compliment John Dingell in his efforts with his food and drug safety bill, and I look forward to working with him in that endeavor. My question to my colleagues here today is, do you believe that the FDA is in a place to take on the multi-million dollar tobacco industry?

Over the past several years this committee and others have held numerous hearings to determine what needs to be fixed at FDA so we can ensure the American people that their food and their drugs and their medical devices are safe. As we talk about forcing the FDA to juggle a multi-billion tobacco industry, foreign drug manufacturing facilities are going mostly uninspected. The FDA's surveillance over the drugs on our market is inadequate. Hundreds of thousands of unregulated and potentially harmful drugs are streaming into our international mail facilities every day.

As we consider this bill, we must not forget our discussions over the past years about the FDA's lack of resources, the inability to fulfill its missions. My amendment will move all tobacco regulation responsibilities out of the FDA, but will keep it under the jurisdiction of the Department of Health and Human

Services and create the tobacco harm reduction center.

This portion which I am offering here today was in the substitute which was earlier defeated. This movement reflects the understanding that tobacco regulation is a public health issue while ensuring the protection of the FDA's current mission.

I ask for your support of my amendment and to create a dedicated Federal agency devoted solely to tobacco regulation and not further the strain on the overburdened FDA.

I note last year, the committee, we had a letter from the Secretary of Health and Human Services, dated July 20th of 2008. It was addressed to Congressman Joe Barton from Michael Leavitt. In the letter itself, in the third paragraph, it says in referencing the bill in which we are marking up here today, quote, the bill will unfortunately undermine one of the Nation's premier public health and regulatory institutions.

That is a pretty strong statement from the then -- from Michael Leavitt, who was then the Secretary of Health and Human Services.

So, Chairman Waxman, you and I have had this discussion before. I know that you are firm in your beliefs with regard to the FDA. We had a discussion on how long do we think that it would take in order to stand up an agency. So whether it is the FDA that accepts this responsibility or it is another agency within Health and Human Services, it is going to take time, and I recognize that.

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[3:52 p.m.]

Mr. Buyer. But I think it would better serve the country's interests if we had a separate agency within HHS, and for that I am asking for consideration.

I yield back.

The Chairman. The gentleman yields back his time.

Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman.

I oppose the amendment; and this is, from what I can see, taking part of your original substitute-like amendment out and just referencing the FDA part. And I sort of spoke on it before, but I want to say this.

Look, you can take various approaches to the FDA. There are some that just think the FDA should be abolished and we should get rid of it and replace it entirely. There are others, like myself, that think it is a very effective agency on many fronts because it has the kind of scientific expertise and the regulatory experience that would be effective in regulating tobacco products and that the real problem is a lack of resources.

I feel that I am not looking to get rid of the FDA or not having have them do the things that they are best at doing, and I think tobacco falls within this. They regulate foods, drugs,

cosmetics, even pet food. Tobacco is certainly something that they are perfectly capable and I think the best agency to deal with this.

The difference here is that we do provide with the user fee and the funding in this bill the resources for them to do it, which I don't think is the case, unfortunately, in some of the other areas. We do need more appropriations. We need more money for them.

Obviously, if you look at the bill that myself and Congressmen Dingell and Stupak have sponsored that deals with food safety, among other things, that is a way of doing it, effectively doing the same thing for food safety.

So I think the answer here is let's give them the resources, which we do under this legislation, let's look at what they do on food and cosmetics and other things as we do on the other bill and give them the resources. Let's not just say that we need a new agency.

In any case, the issue of whether or not there should be a new agency I think should be looked at separately. It shouldn't be done under the auspices of this bill, because we haven't had enough time to deal with it. It makes sense right now to put it under this bill and provide them with the resources, which is what this legislation does.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. The gentlelady withdraws her reservation.

The gentleman from New Jersey yields back the balance of his time.

The vote now comes on the Buyer amendment. All those in favor of the amendment will say aye; opposed, no.

The noes have it, and the amendment is not agreed to.

Are there further amendments?

Mr. Buyer. Mr. Chairman, may I have a recorded vote on that at the appropriate time?

The Chairman. The gentleman requests a recorded vote and that it be put off until the other recorded votes are taken. Any objection to that request?

Mr. Barton. Reserving the right to object.

The Chairman. The gentleman from Texas, Mr. Barton.

Mr. Barton. Reserving the right to object. And I will not object, but I was not in the room when the deal was made to roll votes. I do oppose rolling votes in committee. I think members should be here. The longer we do that, the less member participation we are going to have.

But since there was a unanimous consent request when I was out of the room, I am not going to object today. But I want the minority members to know that, as a general principle, I oppose that. And after today's markup we will have a discussion with the chairman about it. But, on this, I have no opposition to Mr. Buyer's recommendation.

The Chairman. Without objection, the unanimous consent

request is agreed to. And the Chair would also ask unanimous consent that all rolled votes take place at the end of the markup when we are ready to proceed prior to final passage.

Without objection, that will be the order.

Are there other amendments?

Mr. Gingrey.

Mr. Gingrey. Mr. Chairman, I have an amendment at the desk. I think it is amendment No. 27.

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. The Gingrey amendment will be considered as read.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The Chair notes a reservation of a point of order, and the gentleman from Georgia is recognized for 5 minutes.

Mr. Gingrey. Mr. Chairman, thank you.

This amendment, quite simply, is a postponing amendment, postponing the effective date of this Act and its amendments until the Secretary of Health and Human Services certifies that foreign facility drug inspection requirements are met.

Mr. Chairman, the mission of the FDA is to promote and protect the public health. By piling onto the FDA's plate the regulation of tobacco and tobacco products, a role for which the FDA certainly is not yet prepared, this Congress will actually weaken the overall effectiveness of the FDA and compromise consumer protections that safeguard our families, our children, and our country.

The FDA is a public health agency structured to regulate the development of products that are either intended for healing or for nourishment. Yet we have seen the FDA flounder with their charge to protect the health of consumers in this Nation. Products that should be safe -- as an example, infant formula or candy bars or, indeed, peanut butter -- have proven deadly because of breakdowns in oversight.

In light of these recent failures, I am very concerned, Mr. Chairman, at the potential for further regulatory blunders that may endanger the lives of Americans. As public servants, it

should be our duty to ensure that FDA is able to fulfill its current charge before adding a new responsibility for a product wholly different than the other products that it regulates.

In this country, a drug is not considered unapproved or adulterated if it comes from a plant that the FDA has never inspected. So my amendment before you today supports this important change, as I say, a postponing amendment.

And let me give a couple of statistics, Mr. Chairman.

The GAO estimated that FDA inspected only 8 percent of foreign drug establishments in 2007. Of the approximately 3,249 foreign drug establishments, FDA inspected only 332 of them.

As our committee's hearings on the heparin deaths showed us, FDA must focus more attention and more resources on inspecting foreign drug establishments; and it spells out on page 143 of the bill that we are actually able to take money from the primary mission of FDA to take on this new charge.

What does the chairman's bill do? It forces the FDA to use resources on building a new tobacco center instead of using the resources, as I say, to secure the safety of our Nation's drugs. This amendment will stop the FDA from using resources to regulate tobacco until the Secretary of HHS certifies the FDA has inspected every foreign drug establishment within the previous 2 years.

And, with that, Mr. Chairman, I will encourage my colleagues on both sides of the aisle to support the amendment. I yield back my time.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. Mr. Pallone.

Mr. Pallone. Well, I am sort of repeating myself here. Mr. Waxman's bill is self-funded. The resources are there to deal with the tobacco issue.

I think that the gentleman, of course, is mixing the other issue with regard to food and drug inspection, which is addressed in the FDA Globalization Act that is sponsored by Mr. Dingell, Mr. Stupak, and myself.

I would ask him, if he is concerned about that, sign on to our bill. We intend to move the bill fairly quickly. It is a -- it, again, would fund the foreign drug facilities inspection that you are looking to that you are concerned about here.

And I just don't think it makes sense to mix the two. We know the problems with the FDA. We know a lot of it has to do with resources. We are trying to address it on both fronts. But don't bring it up today and -- I know it is not your intention, but the practical consequence may be to scuttle this bill, and I think it is a mistake at this time. So I would oppose the amendment.

Mr. Stupak. Would the gentleman yield?

Mr. Pallone. I yield to the gentleman from Michigan.

Mr. Stupak. I just think it is worth repeating. All these ills that you bring up with the Waxman bill really could be resolved if you just join us in the global food and drug bill that

we have pending before this Congress. Come join, cosponsor it. We can resolve this. We have been working on this legislation for a couple years. We finally have a President who is willing to put the resources into the FDA. But you can't continue to give resources to an agency that is really broken because of the lack of leadership we have seen for the last few years.

You mentioned heparin. Heparin -- and we did the investigation. The problem there was the institutional review boards which we are going to be having hearings on because there are serious breakdowns there. So there are a number of problems there.

We are proposing legislation to address the ills that you bring up. We ask you to join us in cosponsoring that legislation so we can move forward.

But these excuses -- and that is really what these amendments are, excuses to delay the Waxman legislation -- are nothing more than excuses. And if you are serious about reforming the FDA to have them do their job, then join us. We will do it. Let's move this legislation, and then let's together strengthen and improve our FDA. There are many good, dedicated employees in the FDA, but it has been rudderless for the last few years because of lack of leadership.

The Chairman. The gentleman yields back his time.

Further discussion?

If not, let's proceed to a vote. All those in favor of the

Gingrey amendment say aye; opposed, no.

The noes have it. The amendment is not agreed to.

The next amendment. Mr. Buyer.

Mr. Buyer. Mr. Chairman, I have Buyer amendment No. 2. This is an amendment I think we can agree on, Mr. Chairman.

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. Before we talk about agreeing to the amendment, let's have it presented. The clerk will report the amendment.

The Clerk. Amendment to H.R. 1256 offered by Mr. Buyer of Indiana.

The Chairman. Without objection, the amendment will be considered as read.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The gentlelady from Colorado reserves a point of order, and the Chair now recognizes the gentleman from Indiana for 5 minutes.

Mr. Buyer. This is an amendment that I would refer to as the fire-safe cigarette amendment.

Today, 22 States plus the District of Columbia have implemented fire-safe cigarette laws. An additional 15 States have passed fire-safe cigarette laws which have not yet become effective. The amendment I offer today highlights the effectiveness of the New York fire-safe cigarette standard and sets it as a ceiling for other State fire-safe cigarette regulations.

New York was the first State to require that tobacco companies sell self-extinguishing cigarettes; and, according to the Coalition for Fire-Safe Cigarettes, deaths caused by cigarette fires declined dramatically in New York State in the first few months that fire-safe cigarettes were mandated there in 2004.

The use of cigarettes with proven reduced propensity to ignite other materials will save lives and offer the best opportunity to achieve significant improvements in fire protection. New York State has taken the lead on this important issue and has set the effective standard for others to follow.

Probably the best way to help -- I am going to hold this up, if members can take a look at this. This is a roll of tobacco

paper. And what I have done here is I took a pencil and I darkened the areas where, really, there are lines that are set. If you could look at the paper, really, where the paper is less porous. So what I did with a pencil is highlight the areas where it is less porous. So what happens is --

Hello. Look at this just for a second, please. Where the tobacco paper gets rolled like this, which means every certain point there is a less porous area of the paper of the cigarette, so when it begins to burn down, it begin to self-extinguish. It is a great standard, and I think it is one for which the States should be adopting, and I hope to set it as a ceiling. And that is the purpose of the amendment.

The Chairman. Would the gentleman yield?

Mr. Buyer. Yes, Mr. Chairman.

The Chairman. I am trying to figure this out. Because I think what you say makes sense. The New York standard is a good standard. Many States have adopted it.

If you made it as a floor, then it would require all States to abide by this standard. But you want to make it as a ceiling, and that just means States -- see, States are moving on this, maybe slower than you would like. Would you be willing to make it a floor, that at least all States must at least have the New York standard?

Mr. Buyer. Would the gentleman be willing to accept the amendment, and I will continue to work with the gentleman?

The Chairman. On the basis that I am suggesting.

Mr. Buyer. Would the gentleman be willing to accept the amendment right now, and I would be willing to work with the chairman?

The Chairman. Well, I am willing to accept that amendment if you make that change.

Mr. Buyer. Well, the New York standard is such a good standard, we shouldn't try to go beyond it. I am trying to say, let's --

The Chairman. Well, we may not.

Mr. Buyer. I want to be delicate about the Federal preemption. You brought that up to me. So I thought, well, all right, what is the best way I can draft this amendment in a manner whereby the New York standard is the standard that is utilized by the States?

The Chairman. Well, my view, generally, is if States are doing their job of adopting standards, we ought to leave them alone rather than preempt them. But your argument is that, well, a lot of States have adopted this standard; some States have not. So I could see the argument to say that we ought to at least have this standard. But if States are working on the problem, I wouldn't want to say they could never adopt a standard that is stronger. There may not be a standard that is stronger, but I don't want to preclude States from doing their job of protecting their own citizens.

So my suggestion to you is let's make this the Federal standard but not preempt the States if they go stronger.

Mr. Barton. He is advocating a California tailpipes amendment.

The Chairman. I want a floor rather than a ceiling, and you want a ceiling. Do you want a ceiling or did you want --

Mr. Buyer. If you want New York to be the Federal standard, I will go with you on the New York as a Federal standard right now. Done deal.

The Chairman. Without a preemption.

Mr. Buyer. No. Let's make that the Federal standard. Make it the Federal standard, and we will continue to work together. Henry, come on. We have had enough good discussions among ourselves that we can work this out.

The Chairman. Well, let's withdraw it and work it out before we put it in the bill. I am not ready to preempt all the States.

Mr. Buyer. If I withdraw, do you want me to redraft the amendment in which this would be -- we would use New York as the Federal standard?

The Chairman. No. I want you to withdraw it, and then you and I work on something that we both can agree on.

Mr. Buyer. We haven't agreed on much yet today.

The Chairman. You are making it hard.

Mr. Buyer. But I still want to set a ceiling. You want to set it as a floor. We are pretty far apart.

The Chairman. Then I oppose the gentleman's amendment.

Mr. Buyer. Well, now, wait a second. I am serious. We have an issue here, and I think somewhere we can find a common ground on this.

I am really surprised. I thought of all the amendments, Henry, I thought this is the one you said: Steve, thank you. We can agree on this one and let's keep on moving.

The Chairman. I hope I am not going back on some comment I made to you, but I don't recall that.

Mr. Buyer. No.

The Chairman. I don't want to preempt the States. I see what you are trying to do. If we didn't have this amendment at all, the States are moving along quite fine. They are moving to the New York standard. They may even do better than the New York standard.

What you are trying to accomplish is a worthwhile goal, and I support your goal, but I don't believe in Washington having all the answers to all the problems. I think States ought to be able to adopt laws that protect their own people.

Mr. Buyer. Wait a second.

The Chairman. The States can't adopt an FDA --

Mr. Buyer. Mr. Chairman, this is a pretty important discussion. Because when we end up doing Mr. Dingell's food and drug safety bill there will be an issue that will come before the committee regarding electronic pedigree. And the standard for

which I am working with now is the California standard. So are you about to say, Steve, with regard to electronic pedigree, if I am not going to use New York as a standard, then I guess we are not going to use California as a standard in electronic pedigree.

The Chairman. You want to discuss it now? Or do you want to pull it back and then let's see if we can work something out? Or if you want to stay with your amendment, stay with your amendment. What do you want to do?

Mr. Buyer. I want to work with you on this, because it is something you and I ought to be able to work through. I will withdraw the amendment in exchange for the pledge of the Chairman for you and I to figure this one out.

The Chairman. I accept your withdrawing of the amendment, and I will make every effort to work it out.

Mr. Buyer. All right. I accept that. Thank you.

I withdraw the amendment, ask unanimous consent to withdraw the amendment.

The Chairman. Unanimous consent is not required. The gentleman withdraws his amendment.

Are there further amendments?

Mr. Rogers.

Mr. Rogers. Thank you, Mr. Chairman.

I would move to en bloc Rogers amendments 2, 3, 4, 5, and 7.

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. The gentleman, first of all, asks unanimous

consent that those amendments be considered en bloc; and, without objection, that will be the order. And I will ask unanimous consent that all those amendments be considered as read; and, without objection, that will be the order.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The gentlelady from Colorado reserves a point of order on the en bloc amendment, and the gentleman from Michigan is recognized for 5 minutes.

Mr. Rogers. Thank you, Mr. Chairman.

And just in the effort to speed this up and at least to make at least the plea that we would do everything we possibly can not to take away from the FDA's core mission and slowing down for one minute, one day, or one dollar their effort to get a new medicine or a virus through final determination if it will, in fact, better someone's life.

The amendments which I have en bloc'd are the -- and I will give you some examples -- the HPV virus. There are some vaccines that they think they can help maybe up to the late 40s for women on HPV, which we know is one of the leading indicators that causes cervical cancer on women.

Why we would jeopardize that determination now of all times when somebody may be that close to getting a cure is beyond me. It just doesn't make sense. And that is why I think these amendments, if we work together, we can probably come to some sense of agreement.

On pediatric cancer, childhood cancers are the number one disease killer for children. Pediatric cancers are the number one disease killer for children. And what this bill does is it may take away that one dollar, that one minute. And I know -- I have

experienced this in my office, where parents call up in just the most heart-wrenching pleas you can possibly imagine about, listen, this thing is in trial. Can you get me -- we will take it out of the course of its determination. Please, this is our last effort to cure my son, my daughter, my wife. Will you please do it?

And, of course, the rules are pretty tight; and we can't do it.

So what we are proposing is maybe we slow it down. It is not right for us to do that. It is just not right to do that. And we have the opportunity here to say, listen, these things are important. Pediatric cancer is important. HPV virus, if you are infected and you are 42 years old, is important. Breast cancer, colorectal cancer, arthritis, all of the amendments deal with these issues and say, let us not take one dollar, one minute, one ounce of time from one scientist who is making these determinations that may in fact save somebody's life. That is what we are saying.

We know right now, today, that cigarettes are dangerous. That is why we are having this markup, and I thank you for it. I voted for the bill last time in hopes we could work through some of these issues. And if we can get to that determination that we are not going to take away from any other disease, then I can be there.

But, right now, I have real concerns, Mr. Chairman; and I would hope that we would consider this amendment in the spirit in

which it was intended and we could get some bipartisan support of saying: Let the scientists make cures. Put every dollar toward those cures of those people who are sick today.

And we will get to the cancer stuff. We are going to get there. We are. But let's make sure that nobody with cervical cancer doesn't have the opportunity or at least preventative with the HPV vaccination, or somebody whose child has pediatric cancer doesn't have every effort spent every day with every resource making sure that the next round of disease medicine, vaccines, whatever it is, is around to save that child's life. That is all we are saying. I hope we can work this out.

I urge the strong support of this amendment.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. The reservation is withdrawn.

Mr. Pallone.

Mr. Pallone. Mr. Chairman, I have to oppose the amendment.

I mean, we have said many times this afternoon that your underlying bill will not divert resources away from any other important programs at FDA like food safety or drug safety. It is fully funded by industry paid user fees. None of the funding for the new Center for Tobacco will be taken away from existing FDA resources.

Look, if we regulate tobacco in an effective way, it is preventative; and it may very well be that many cancers will be prevented. So I am not trying to take away from what you are

trying to achieve by saying all these other things that are both preventative vaccinations and other areas or drugs that will cure diseases that people already have are not important. But there is no reason to believe that what we are doing today would in any way inhibit those other applications from being approved; and, in fact, just the opposite. It may very well be -- in fact, I would say it is almost guaranteed that by having this regulation of tobacco that is proposed by Mr. Waxman's bill will prevent a lot of cancers, maybe even some of the ones that you mentioned.

I yield back.

The Chairman. The gentleman yields back his time.

Is there further discussion?

If not, we will proceed to a vote on the en bloc Rogers amendment. All those in favor say aye; opposed, no.

The noes have it. The amendment is not agreed to.

Mr. Rogers. Roll call vote, Mr. Chairman.

The Chairman. We have a number of pending roll call votes, and that will take time. The rules require that one-sixth of the members present request a roll call vote along with you. Do members wish to have another roll call vote? Those who wish a roll call vote will raise your hand.

A sufficient number. And, without objection, if the gentleman would permit, this will be added to the list of others whereby we are going to have a roll call vote.

Mr. Rogers. And if I may comment, Mr. Chairman, one of the

reasons I think you are seeing that, where we are trying to work with the bill and we hope make it better, we really haven't had the opportunity. And this has been a pretty rough start for trying to work together, and I know you have got your marching orders and you have got to do what you have got to do and you have got your folks who aren't really participatory in amendments, but this is our only opportunity to do that. And the longer we don't get an opportunity to work for it, this is the only option that we have to allow other Americans have the right to petition their government. And we just feel that is very, very important.

So we don't mean to be dilatory. We are not trying to be a pain in your rear. But we do believe that everybody's voice -- we may be accomplishing that, but we think and we believe that everybody's voice needs to have an opportunity to be heard in these bills. And, thus far, we have seen, candidly, Mr. Chairman, just a really poor example of how you can work together on issues where we know we have common ground.

And I don't even blame you. I think it is coming -- I think that there is directions and orders that are laid down around this Congress that I think are probably detrimental.

The Chairman. I think the gentleman makes an excellent point. I was only questioning whether we want another roll call vote, but I do want to follow the regular order here.

This was a bill that was considered in the last Congress and voted on by more than two-thirds of the House. And we are

following the regular order; and, under the regular order, the Chair would request any further amendments.

Mr. Buyer.

Mr. Buyer. Mr. Chairman, I have Buyer amendment number 1. I refer to it as the export amendment.

Ms. DeGette. Mr. Chairman, reserving a point of order.

The Chairman. The gentleman from Indiana offers an amendment which he characterizes as the export amendment; and, without objection, that amendment will be considered as read.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The gentlelady from Colorado has reserved a point of order, and the gentleman from Indiana is recognized to speak on behalf of this amendment.

Mr. Buyer. Thank you.

Mr. Chairman, I refer this to as the export amendment, but really it is a clarifying amendment. So as we went through the academics of your bill here over the last several months, this one is a new amendment. It was not considered last year.

The bill includes a significant inconsistency, I believe, with regard to the treatment of tobacco exports; and I offer an amendment to clear up that inconsistency. The purpose of this amendment is to clarify that raw leaf produced in this country or a product manufactured in this country for distribution abroad can be exported to the standards specified by the country of distribution.

For example, the European Union requires all cigarettes for sale in the EU countries to conform to the 10-1-10 product standard, which means 10 milligrams of tar, 1 milligram of nicotine, 10 milligrams of carbon monoxide. The EU also conforms to the Cooperation Center for Scientific Research relative to tobacco pesticide standards for tobacco leaf production.

However, under this bill, U.S. farmers and businesses are essentially forbidden from producing leaf or products that could be legally sold in the European Union or elsewhere. We must

ensure that products manufactured strictly for export do not have to comply with the tobacco standards expressly written for tobacco products sold within the United States. Manufacturers must be able to design their export products to the specifications of the countries to which they are exporting.

We place great demands upon importers to produce products with regard to our country's standard; and, in turn, we must give foreign nations jurisdiction over tobacco products for which they import from the United States. That is essentially the purpose of the clarifying amendment.

The Chairman. If the gentleman would yield. As I understand the basic bill, section 1031 exempts products manufactured -- maybe this is current law -- exempts products manufactured for export from the product standards and labeling and warning provisions. This would apply for standards for tobacco products export that it applies to food and drugs and already exempts those products made for export that meet the importing country's standards. So I don't see what the purpose is of your amendment.

But what I fear could happen with this is that language is so broadly written that it would also exempt manufacturers of products made for export from being required to provide FDA with the basic information FDA would need to determine the nature and extent of products being made in the U.S. that do not meet U.S. standards and would make it harder for U.S. authorities to track whether and how much of these nonconforming products intended for

export are secretly and illegally being diverted back into the U.S. market.

So I don't understand the purpose of the amendment. If it is for export, they don't have to --

Mr. Buyer. Wait a second. What we are trying to do here is we want to be in the import-export business. So to my colleague of Indiana that has got so much tobacco, you want to be able to get that tobacco into the European Union and do so in a manner that establishes or sets to their specifications or requirements. So if it is a product that is not going to be sold here in the United States, it is a product that should meet that country of origin's standards.

So I recognize that what you have here in the bill -- I just want to make sure that in your bill that no other provisions or articles within your bill have an impact with regard to a tobacco grower in Mr. Hill's district gets punished.

The Chairman. If the gentleman would further yield.

Mr. Buyer. Yes.

The Chairman. Section 1031 of the bill says: A product that is manufactured for export, that the -- if it -- it exempts the product if it is manufactured for export. Your amendment says that the Secretary shall see whether it is complying with the laws and regulations of the country of destination, instead of the laws and regulations otherwise applicable, which would mean U.S. laws.

So it seems to me we have covered it already, and I worry

about repeating it in your way for fear that it might have other consequences. But it seems to me we accomplish what you say you want to accomplish.

Mr. Buyer. Well, maybe this is a moment where you want to take a tougher approach than I do. I guess I am saying, if you are going to create -- under your bill, if it is going to be FDA, then FDA has got the jurisdiction and they can put their nose into whether or not that product complies. Who is going to make that determination with regard to it is exempt or not? Who makes that determination under your bill?

The Chairman. Well, if the law says a product is exempt from FDA approval or jurisdiction if it is meant for export, then that is the law, and that is what I understand our bill to say. You add on another part which I am not sure is required under the law, and that is that the Secretary is going to decide whether the laws of the country of destination are complied with. And -- I don't know. Do we let them decide? We wouldn't want -- it just seems hard for us to have to see whether something complies with another country's laws and regulations.

Mr. Buyer. I will tell you what I will do. This is another one. This goes back to I wish you and I would have had this meeting last week. So I will withdraw this amendment, and let's add it to the fire-safe cigarette ones, and we will work through this one.

The Chairman. All right.

Mr. Buyer. So I withdraw the amendment.

The Chairman. Thank you.

Are there further amendments? Mr. Rogers.

Mr. Rogers. Thank you, Mr. Chairman.

Here is my last ditch at what I think is the most important issue here.

The Chairman. You have an amendment?

Mr. Rogers. I have an amendment at the desk. It is 008.

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. The gentleman's amendment 008 will be considered as read.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The gentlelady from Colorado has reserved a point of order, and the gentleman is recognized to explain his amendment.

Mr. Rogers. Thank you, Mr. Chairman.

If we are serious, and I know that Chairman Pallone and yourself and others have used the argument: Listen, there is no money that comes out of this bill. That is great, except on page 142 it says, in fact, that money is coming out of the general fund for this. And my argument is, if you believe that is true and that is why you support the bill, then this is an easy amendment. I just strike that language. And it basically makes very clear that only user fee money can be used.

And let's be very, very clear on it. Let's be absolutely certain that there is no opportunity for FDA general fund money to go over to get this thing kicked off.

And, again, the reason I think that is so important is that I am the co-Chair of the cancer working group, as is Ms. Eshoo, and I tell you, sometimes those matter of days for approval do make a difference in people's lives. They do.

So I just -- I hesitate to move into this because without -- or with the understanding that they can take money out of the general fund. They will have to allocate that away from something else. And if that is your son, daughter, mother, brother, you don't want that to happen. You absolutely don't want that to

happen. And I don't think from what you are saying, Mr. Chairman, you don't want it to happen, either, because you have always argued that that doesn't happen in this bill.

So let's very clearly make the for sure and for certain statement here that no money comes out of the general fund.

My amendment is very simple. It is a prohibition against the use of other funds, and only fees collected under this section are the only funds authorized to be made available for the purposes prescribed. It strikes the section that allows general fund money and says very clearly it can only be user fees.

And I would hope that this is something that we could agree on in a bipartisan way. It is what you all have all talked about. I think it is what your intentions are. Let's make very, very clear that this is exactly what this bill will do when it comes to the most important thing, as we all know, is funding for the FDA, when you are talking about food inspections, you are talking about certification and termination of the next generation of medicine and vaccines and et cetera.

And, with that, Mr. Chairman, in a bipartisan effort here, I would yield back.

The Chairman. The gentleman yields back his time.

The Chair recognizes himself.

In the bill, while the user fees are being collected, for the first two quarters the general fund dollars can be used to carry on the purposes of regulating tobacco at the FDA. It is only for

that short period of time. And then when the user fees are collected, the money that is used must be returned.

What the gentleman would seek to do is to say, even in those first two quarters, if there is not enough money yet collected from user fees, FDA can only use the money that it has collected from user fees.

I don't understand why we would want to restrict FDA from getting started with the job, as long as FDA resources are not going to be directed to tobacco and not for other purposes, except for that very short period of time and they will get that money back.

So I would urge the gentleman to reconsider his amendment. It is only for those first two quarters while they are collecting the user fees.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. The gentleman, Mr. Walden.

Mr. Walden. I seek recognition, Mr. Chairman.

The Chairman. The gentleman is recognized.

The Chairman. In support of the gentleman's amendment, having been involved in the oversight hearings in the FDA and food safety and all and having watched in a bipartisan manner the problems at FDA and the need for every penny that is there for inspection for food safety and all; and we haven't acted on any other legislation to date, although I assume we will, it would seem prudent that before we give FDA a new challenge and then say

go start this new program, and you can draw on your existing funds to do it, and then you have to reimburse once the fees are collected. But in the language in your bill, I don't believe there is a date certain for reimbursement. Is there, Mr. Chairman? It just says they have to be reimbursed.

The Chairman. We could add a date certain if you wanted it. But it is only the startup period.

Mr. Walden. I understand that. But, so, anyway, you don't have a date certain, and that would be preferable.

But I think it still doesn't get at the underlying issues several of us have problems with. And I voted for this bill last time. In fact, I cosponsored it; and I want it to pass. But I think this is a real live issue that some of us have concern about, given the problems FDA has had, has, and continues to have.

So I intend to support the gentleman's amendment. I would prefer us to not give the FDA something new until they have the money to actually pay for what we are giving them to do, not allow them instead to go dip into other funds and pay for it.

With that, I yield to the gentleman.

The Chairman. If you would yield to me as well very briefly. I think we have a disagreement, because I don't want to delay the FDA activities for months while we are collecting the user fee. And if they can get started, I think we shouldn't delay them. So I just respectfully disagree.

You are yielding to Mr. Rogers.

Mr. Walden. I would like to, Mr. Chairman. I would yield to my colleague from Michigan.

Mr. Rogers. Several problems. We are not talking a matter of days or weeks. We are talking about a matter of months in this particular case.

And if you read the language, Mr. Chairman, this is what concerns me. It sets out the two fiscal quarters or the 6 months, but there is no prescription in here that -- it just says it has to be paid back. Okay. But now you have got commingling of funds within a department. These departments loan each other money all the time, and a lot of times it gets written off on accounting, as we all know. They don't have to necessarily have to pay it back. If it happens at the end of a fiscal year, they have to reimburse, if they do, from this year's budget, which is not likely actually to happen. So you will have a hole for an undetermined amount of time, and they can go do this through 6 months' worth of time.

In 6 months, when somebody is waiting for that determination, if you are in the final stages of trial and determination, clinical trial, human trial, you are in that final determination, 6 months is a life sentence. It is a life sentence to people. And my argument is, can't we do better?

And I understand -- before there was no use of funds in here. Well, now you are saying, well, we are just kidding. There are some use of funds, but they may have to pay it back at some time in the future. That concerns me. Because for the same FDA that

my colleague from Michigan so rightly says has got issues, I am not sure I trust them to know that that money isn't going to get back on those benches with those doctors making those determinations.

We have no way of knowing that. There is nothing in here that says they have to do that. It just says it should be reimbursed at some point. Well, if I am the director and things are happening, I don't know. It doesn't say I have to; it just says I should. That worries me a lot.

And that 6-month time that you have given them, 6 months, as I said before, can be a life sentence. I have seen it happen.

I had the most horrible case from a woman who wanted to get a drug. She had lung cancer. And I can't tell you how many conversations I had not only with her and her husband, the most heart-wrenching thing you can possibly go through, calling the company saying, please, can't you release this thing? We know you are only a matter of weeks out. Can't you -- this might actually save their lives. But the rules prohibit it, and it was pretty clear. And as she passed away, it may have, it may have not. We will never know.

But how would you like to have to pick up the phone and say, oh, by the way, it was maybe 3 weeks; now it is 6 months? It is not right for us to do that. There is so much effort and energy put into making sure that the next generation of lifesaving medicines are available, why would we make this mistake in this

bill?

And. Believe me, Mr. Chairman, I voted for this bill the last time. I want to vote for this bill. This worries me more than you can possibly imagine, because time does cost lives when you are talking about the development of the next generation of medicine.

And I yield back the time.

The Chairman. Any further discussion on the amendment?

If not, we will proceed to a vote. All those in favor of the amendment say aye; opposed, no.

It appears the noes have it.

Mr. Rogers. Roll call.

The Chairman. The gentleman requests a roll call. We will add this to the list.

Are there further amendments?

Mr. Buyer. Mr. Chairman.

The Chairman. Who seeks recognition?

Mr. Buyer of Indiana.

For what purpose does the gentleman seek recognition?

Mr. Buyer. To offer another amendment.

The Chairman. May the Chair inquire how many amendments the gentleman will be offering to this bill?

Mr. Buyer. Three, maybe four.

The Chairman. Three, maybe four. And --

Mr. Buyer. And I thought about whether I could put them

together, but I don't think I can.

The Chairman. You don't think you can put them together.

Mr. Buyer. I thought about it.

The Chairman. The gentleman will identify his amendment.

Mr. Buyer. The Buyer amendment No. 5.

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. Buyer amendment No. 5, without objection, is considered as read.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The gentlelady from Colorado reserves a point of order.

The gentleman from Indiana is recognized to speak on his amendment.

Mr. Buyer. Thank you, Mr. Chairman.

I would title this amendment the illicit tobacco trade amendment.

According to a report released last year by the House Homeland Security Committee entitled Tobacco and Terror: How Cigarette Smuggling is Funding Our Enemies Abroad, law enforcement officials estimate that in New York State alone "smuggling networks generate between $200,000 and $300,000 per week. A large percentage of the money is believed to be sent back to the Middle East where it is directly and indirectly used to finance groups such as Hezbollah, Hamas, and al Qaeda."

The findings of the bill before us state that, "Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups."

Further, one of the purposes of the bill expressly states that the bill is intended to "strengthen legislation against illicit trade in tobacco products." However, there is nothing to ensure that this bill will not exacerbate the widespread problem

of illicit tobacco trade in our country.

My amendment hopes to make sure that, before promulgating specific tobacco product standards, the Secretary must determine that such standards will not contribute to a significant increase in the demand for contraband tobacco products and the standard will not contribute to the expansion of illicit trade of tobacco products by organized crime and terror groups.

As the World Health Organization has reported, the illicit trade of tobacco products contributes to the global rise in tobacco consumption in making cigarettes cheaper and more accessible. Such products are essentially attractive to people who are price sensitive and least able to afford health care, such as the young and the poor. Illicit tobacco allows cigarettes to be sold as singles instead of packs in unregulated outlets that make it more accessible to youth. The World Health Organization reported that tobacco smuggling undermines legal restrictions and health regulations of tobacco.

I believe we must ensure that we do not create a regulatory scheme that increases illicit tobacco trade and creates an underground system by which the most harmful tobacco products are widespread and easily attainable in our country.

So I recognize, Mr. Chairman, that you asked for a study. However, I think we need to make sure that any FDA standards before they go into effect do not increase illicit trade, and that is the purpose of this amendment.

I yield to the chairman.

The Chairman. You yield to me?

Mr. Buyer. Yes.

The Chairman. Thank you.

I didn't ask for a study on our legislation. The proposal, the bill before us requires FDA to consider the impact of a proposed tobacco product standard on increasing the demand for contraband or noncompliant tobacco products before making it final. I think that accomplishes the job that we need done.

The reason I would oppose spelling it out as you have is that the more you spell out in the statute the more it becomes a basis for a lawsuit by somebody who doesn't want the FDA to act. They will say, you didn't really do this enough; you didn't follow this step and jump through this hoop and dot this "I" and cross that "T." So we ask them to -- we require them, to consider the impact, but we don't say that you cannot go forward with the regulation unless you have done all of these other things that is spelled out in your amendment.

So, I respectfully have to disagree with you and oppose your amendment.

Mr. Buyer. Reclaiming my time. And I accept the admonishment. You are right. You didn't use the word "study". But to consider -- obviously, they have to put their academic brain power together here. And I would just go ahead and require it.

And you are right. That is completely two different approaches to this, and I am trying to figure out how you and I can get on the same page at some point in time. We are going to do this, Mr. Chairman.

I yield to Mr. Pallone.

Mr. Pallone. I don't really want to take up time, so I am just -- the thing that worries me about this one, Mr. Buyer, is that -- I mean, it would be so easy for the tobacco industry or somebody who wanted to stop tobacco standards from going forward to simply manipulate things so that this illicit trade or trafficking actually began and then use that as a reason to say that we shouldn't move forward with the standard.

I mean, how you ever get to the point where you can actually certify that a standard is going to have no impact on contraband trafficking or illicit trade, I just don't see how. I know that you are well-meaning. I am not suggesting otherwise. But I would be very concerned that if you put this into place it would be very easy for someone to say that we never met that threshold, or even somehow try to make it so that the illicit traffic and the threat is there and say, therefore, we can't have a standard.

Mr. Buyer. Reclaiming my time. I know it has expired. I will take care of this, Mr. Chairman.

Mr. Pallone, I never considered what you just said. What I did is I looked at what the committee of jurisdiction has stated, along with the World Health Organization, along with what the

chairman's intent was, and I just thought it would be prudent to just go ahead and require it.

So if the chairman disagrees, I will withdraw the amendment, and we will continue to have our discussions as we do on the others.

The Chairman. The gentleman withdraws his amendment?

Mr. Buyer. Yes, I withdraw the amendment.

The Chairman. And adds to the agenda for our discussions, which I will look forward to.

Mr. Buyer. Thank you.

I also have another amendment.

The Chairman. Let me ask, do any other members have amendments?

If not, then Mr. Buyer is the last one with amendments.

Mr. Buyer. I have amendment No. 7.

Ms. DeGette. Mr. Chairman, I reserve a point of order.

The Chairman. Amendment No. 7 by Mr. Buyer will be considered as read.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. The gentlelady from Colorado reserves a point of order.

The gentleman is recognized to explain it.

Mr. Buyer. This amendment would refer to the Tobacco Product Advisory Committee.

My amendment maintains the member groups represented in the bill's Tobacco Product Advisory Committee but adds one expert in tobacco harm reduction and one expert in the illicit trade of tobacco products. These are two very important groups who really have dominated part of our discussions here today, and I think they are overlooked on the advisory council which will make recommendations to the new tobacco regulatory agency created under the bill.

So if we are serious about addressing the problems of death and disease attributed to tobacco use, I think we need experts on the committee who have studied the tobacco harm reduction and on how we move smokers away from combustible products toward less harmful nonsmoking products if they can occur or individuals cannot or will not discontinue their tobacco use.

Additionally, any actions taken by the new tobacco regulatory agency should be scrutinized from the viewpoint of an expert on illicit trade of tobacco products, the discussion for which we just had. I believe these two members will provide important and beneficial instruction to the tobacco product advisory committee,

and I urge the adoption of the amendment.

Ms. DeGette. Mr. Chairman, I withdraw my reservation.

The Chairman. Will the gentleman yield to me? Well, the gentleman yields back the balance of his time.

The Chair recognizes himself.

This amendment changes the makeup of an advisory committee which is to advise on science and health issues by taking two of the professionals in this area and replacing them with other people, including representatives from the tobacco industry. We have a disagreement about this, and I am going to oppose the amendment.

Mr. Buyer, do you want to talk again? I will yield you time.

Mr. Buyer. Thank you. Here is what I am going to do. I have got two other amendments. I am not going to offer them. Okay? I am not going to offer them.

I think what we should do, Mr. Chairman, is since we have got other issues for which we have agreed that we are going to discuss, I am going to take the other issues on pesticides and harm reduction, along with this amendment, and you and I get to have a sit-down and see what we can come to a meeting of the minds, if we can. You and I have worked on other issues together, and when you came to me and had a tough issue I was there for you. And so I think that the two of us ought to be able to figure out how we can come together on some of these issues.

So I will withdraw this amendment, I will not offer my other

two amendments, and before we get to the floor, you and I will work through this. Is that fair?

The Chairman. It is fair enough. And I accept your good faith offer to sit down and talk it through with me, and I look forward to that opportunity.

Are there any other amendments?

If not, we will proceed to a roll call vote on the pending amendments, after which, without objection, after completion of the roll call votes on the pending amendments the previous question will be automatically ordered, and we will then go to final passage.

So I want to advise all members who are sitting watching this whole proceeding on their television sets in their offices -- because what else would they be doing -- to take note that we are about to proceed to a roll call vote.

Will the clerk tell us how many amendments we are going to have a roll call vote on?

The Clerk. Mr. Chairman, there were five amendments that were postponed for roll calls, including the en bloc one.

The Chairman. Okay. The first one in order -- the clerk will tell us which one is first in order.

The Clerk. Mr. Chairman, that was the amendment offered by Mr. Rogers, 001, limitation of application.

Mr. Barton. Mr. Chairman.

The Chairman. Mr. Barton.

Mr. Barton. Strike the requisite number of words.

The Chairman. The gentleman is recognized.

Mr. Barton. I would like to point out we have never done this before, and we have lots of people who are not here. So I would recommend that the chairman have a quorum call to get members here and then do the roll call votes.

The Chairman. Why don't we do the roll call vote, and we are not going to declare the vote over unless a quorum has responded.

Mr. Buyer. Mr. Chairman.

The Chairman. Yes.

Mr. Barton. It is not fair to have roll call votes when less than half --

The Chairman. Do you want a quorum call?

Mr. Barton. I am just suggesting.

The Chairman. I am just trying to figure out the quickest way to do it. But if you want a quorum call, we can do that. Or we can call the roll and then members will come.

Mr. Barton. You are the chairman.

The Chairman. Mr. Buyer.

Mr. Buyer. Before you ask for the vote, if I may, Mr. Chairman, I ask that a letter to you from the Association of National Advertisers, the American Association of Advertising Agencies, and the American Advertising Federation be included in the record. This letter highlights the concerns the three agencies have on the constitutionality of some of the provisions

in the bill. I share this with you, and I would ask unanimous consent that this letter dated March 3, 2009, be entered into the record.

The Chairman. Without objection. Is it one letter?

Mr. Buyer. It is one.

The Chairman. Or several letters?

Mr. Buyer. No, it is one letter.

The Chairman. Without objection, the letter referred to by Mr. Buyer will be made part of the record.

[The information follows:]

******** COMMITTEE INSERT ********

The Chairman. Let's proceed on the roll call vote, and the roll will not be closed until at least a quorum. And we will give everybody a full opportunity to respond. So the clerk will call the roll.

The Clerk. Mr. Waxman.

The Chairman. No.

The Clerk. Mr. Waxman, no.

Mr. Dingell.

Mr. Barton. What are we voting on? Which amendment?

The Chairman. The clerk will tell us again the vote.

The Clerk. Mr. Chairman --

The Chairman. This is one of Mr. Rogers' amendment, not the en bloc one.

The Clerk. It is the Rogers amendment number 001 regarding limitation on application of act.

The Chairman. Please proceed with the vote.

The Clerk. Mr. Dingell.

[No response.]

The Clerk. Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

[No response.]

The Clerk. Mr. Pallone.

Mr. Pallone. No.

The Clerk. Mr. Pallone, no.

Mr. Gordon.

[No response.]

The Clerk. Mr. Rush.

[No response.]

The Clerk. Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

[No response.]

The Clerk. Mr. Engel.

[No response.]

The Clerk. Mr. Green.

[No response.]

The Clerk. Ms. DeGette.

Ms. DeGette. No.

The Clerk. Ms. DeGette votes no.

Mrs. Capps.

[No response.]

The Clerk. Mr. Doyle.

[No response.]

The Clerk. Ms. Harman.

Ms. Harman. No.

The Clerk. Ms. Harman votes no.

Ms. Schakowsky.

Ms. Schakowsky. No.

The Clerk. Ms. Schakowsky votes no.

Mr. Gonzalez.

[No response.]

The Clerk. Mr. Inslee.

Mr. Inslee. No.

The Clerk. Mr. Inslee votes no.

Ms. Baldwin.

Ms. Baldwin. No.

The Clerk. Ms. Baldwin votes no.

Mr. Ross.

[No response.]

The Clerk. Mr. Weiner.

Mr. Weiner. No.

The Clerk. Mr. Weiner votes no.

Mr. Matheson.

[No response.]

The Clerk. Mr. Butterfield.

[No response.]

The Clerk. Mr. Melancon.

Mr. Melancon. No.

The Clerk. Mr. Melancon votes no.

Mr. Barrow.

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Mr. Hill.

Mr. Hill. No.

The Clerk. Mr. Hill, no.

Ms. Matsui.

Ms. Matsui. No.

The Clerk. Ms. Matsui, no.

Mrs. Christensen.

[No response.]

The Clerk. Ms. Castor.

Ms. Castor. No.

The Clerk. Ms. Castor votes no.

Mr. Sarbanes.

Mr. Sarbanes. No.

The Clerk. Mr. Sarbanes, no.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. No.

The Clerk. Mr. Murphy of Connecticut, no.

Mr. Space.

Mr. Space. No.

The Clerk. Mr. Space, no.

Mr. McNerney.

Mr. McNerney. No.

The Clerk. Mr. McNerney, no.

Ms. Sutton.

Ms. Sutton. No.

The Clerk. Ms. Sutton votes no.

Mr. Braley.

Mr. Braley. No.

The Clerk. Mr. Braley, no.

Mr. Welch.

[No response.]

The Clerk. Mr. Barton.

Mr. Barton. Aye.

The Clerk. Mr. Barton, aye.

Mr. Hall.

Mr. Hall. Aye.

The Clerk. Mr. Hall, aye.

Mr. Upton.

[No response.]

The Clerk. Mr. Stearns.

[No response.]

The Clerk. Mr. Deal.

Mr. Deal. Aye.

The Clerk. Mr. Deal, aye.

Mr. Whitfield.

[No response.]

The Clerk. Mr. Shimkus.

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Shadegg.

[No response.]

The Clerk. Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. Aye.

The Clerk. Mr. Buyer votes aye.

Mr. Radanovich.

[No response.]

The Clerk. Mr. Pitts.

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack.

Mrs. Bono Mack. Aye.

The Clerk. Mrs. Bono Mack, aye.

Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden, aye.

Mr. Terry.

Mr. Terry. Aye.

The Clerk. Mr. Terry, aye.

Mr. Rogers.

Mr. Rogers. Aye.

The Clerk. Mr. Rogers, aye.

Mrs. Myrick.

[No response.]

The Clerk. Mr. Sullivan.

[No response.]

The Clerk. Mr. Murphy of Pennsylvania.

[No response.]

The Clerk. Mr. Burgess.

[No response.]

The Clerk. Mrs. Blackburn.

[No response.]

The Clerk. Mr. Gingrey.

Mr. Gingrey. Aye.

The Clerk. Mr. Gingrey votes aye.

Mr. Scalise.

Mr. Scalise. Aye.

The Clerk. Mr. Scalise aye.

The Chairman. Why don't you call the roll of those members who did not respond? Or do you want to just recognize them?

RPTS MERCHANT

DCMN MAGMER

The Clerk. Mr. Boucher.

Mr. Boucher. Votes no.

The Clerk. Mr. Boucher, no.

Mr. Green.

Mr. Green. No.

The Clerk. Mr. Green votes no.

Mrs. Capps.

Mrs. Capps. Votes no.

The Clerk. Mrs. Capps, no.

Mr. Butterfield.

Mr. Butterfield. No.

The Clerk. Mr. Butterfield, no.

Mr. Engel.

Mr. Engel. No.

The Clerk. Mr. Engel votes no.

Mr. Gordon.

Mr. Gordon. No.

The Clerk. Mr. Gordon, no.

Mr. Stupak.

Mr. Stupak. No.

The Clerk. Mr. Stupak votes no.

Mr. Radanovich.

Mr. Radanovich. Votes yes.

The Clerk. Mr. Radanovich votes aye.

Mr. Matheson.

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

The Chairman. Mr. Ross.

The Clerk. Mr. Ross.

Mr. Ross. No.

The Clerk. Mr. Ross votes no.

The Chairman. Have all members responded to the vote? Any member wish to change his or her vote?

If not, the clerk will tally the vote.

The Clerk. On that vote, Mr. Chairman, the ayes were 13; and the nays were 28.

The Chairman. Thirteen ayes, 28 noes. The amendment is not agreed to.

We now proceed to the second of what will be six roll call votes. The clerk will report the amendment that we are voting on, and then we will proceed to the vote.

The Clerk. Mr. Chairman, this was an amendment to H.R. 1256 offered by Mr. Burgess in section 907(d)(3) of the Federal Food, Drug and Cosmetic Act as added by section 101(b)(3) --

The Chairman. We all know that. The clerk will call the roll.

The Clerk. Mr. Waxman.

The Chairman. No.

The Clerk. Mr. Waxman, no.

Mr. Dingell.

Mr. Dingell. No.

The Clerk. Mr. Dingell votes no.

Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

Mr. Boucher. No.

The Clerk. Mr. Boucher votes no.

Mr. Pallone.

Mr. Pallone. No.

The Clerk. Mr. Pallone votes no.

Mr. Gordon.

Mr. Gordon. No.

The Clerk. Mr. Gordon votes no.

Mr. Rush.

[No response.]

The Clerk. Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

Mr. Stupak. No.

The Clerk. Mr. Stupak votes no.

Mr. Engel.

Mr. Engel. No.

The Clerk. Mr. Engel votes no.

Mr. Green.

Mr. Green. No.

The Clerk. Mr. Green votes no.

Ms. DeGette.

Ms. DeGette. No.

The Clerk. Ms. DeGette votes no.

Mrs. Capps.

Mrs. Capps. No.

The Clerk. Mrs. Capps votes no.

Mr. Doyle.

[No response.]

The Clerk. Ms. Harman.

Ms. Harman. No.

The Clerk. Ms. Harman votes no.

Ms. Schakowsky.

Ms. Schakowsky. No.

The Clerk. Ms. Schakowsky votes no.

Mr. Gonzalez.

[No response.]

The Clerk. Mr. Inslee.

[No response.]

The Clerk. Ms. Baldwin.

Ms. Baldwin. No.

The Clerk. Ms. Baldwin votes no.

Mr. Ross.

Mr. Ross. No.

The Clerk. Mr. Ross votes no.

Mr. Weiner.

Mr. Weiner. No.

The Clerk. Mr. Weiner votes no.

Mr. Matheson.

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

Mr. Butterfield.

Mr. Butterfield. No.

The Clerk. Mr. Butterfield votes no.

Mr. Melancon.

[No response.]

The Clerk. Mr. Barrow.

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Mr. Hill.

Mr. Hill. No.

The Clerk. Mr. Hill votes no.

Ms. Matsui.

Ms. Matsui. No.

The Clerk. Ms. Matsui votes no.

Mrs. Christensen.

Mrs. Christensen. No.

The Clerk. Mrs. Christensen votes no.

Ms. Castor.

Ms. Castor. No.

The Clerk. Ms. Castor votes no.

Mr. Sarbanes.

Mr. Sarbanes. No.

The Clerk. Mr. Sarbanes votes no.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. No.

The Clerk. Mr. Murphy of Connecticut votes no.

Mr. Space.

Mr. Space. No.

The Clerk. Mr. Space votes no.

Mr. McNerney.

Mr. McNerney. No.

The Clerk. Mr. McNerney votes no.

Ms. Sutton.

Ms. Sutton. No.

The Clerk. Ms. Sutton votes no.

Mr. Braley.

Mr. Braley. No.

The Clerk. Mr. Braley votes no.

Mr. Welch.

[No response.]

The Clerk. Mr. Barton.

Mr. Barton. Aye.

The Clerk. Mr. Barton votes aye.

Mr. Hall.

Mr. Hall. Aye.

The Clerk. Mr. Hall votes aye.

Mr. Upton.

[No response.]

The Clerk. Mr. Stearns.

[No response.]

The Clerk. Mr. Deal.

Mr. Deal. Aye.

The Clerk. Mr. Deal votes aye.

Mr. Whitfield.

[No response.]

The Clerk. Mr. Shimkus.

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Shadegg.

[No response.]

The Clerk. Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. No.

The Clerk. Mr. Buyer votes no.

Mr. Radanovich.

[No response.]

The Clerk. Mr. Pitts.

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack.

Mrs. Bono Mack. Pass.

The Clerk. Mrs. Bono Mack passes.

Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry.

Mr. Terry. Aye.

The Clerk. Mr. Terry votes aye.

Mr. Rogers.

Mr. Rogers. Aye.

The Clerk. Mr. Rogers votes aye.

Mrs. Myrick.

[No response.]

The Clerk. Mr. Sullivan.

[No response.]

The Clerk. Mr. Murphy of Pennsylvania.

Mr. Murphy of Pennsylvania. Yes.

The Clerk. Mr. Murphy of Pennsylvania votes aye.

Dr. Burgess.

Mr. Burgess. Aye.

The Clerk. Dr. Burgess votes aye.

Mrs. Blackburn.

[No response.]

The Clerk. Mr. Gingrey.

Mr. Gingrey. Aye.

The Clerk. Mr. Gingrey votes aye.

Mr. Scalise.

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

Mr. Radanovich.

Mr. Radanovich. Aye.

The Clerk. Mr. Radanovich votes aye.

Mrs. Bono Mack.

Mrs. Bono Mack. Aye.

The Clerk. Mrs. Bono Mack is off pass and on aye.

Mr. Rush.

Mr. Rush. How am I recorded?

The Clerk. Not recorded, Mr. Chairman.

Mr. Rush. Mr. Rush votes no.

The Clerk. Mr. Rush votes no.

Mr. Inslee.

Mr. Inslee. Votes no.

The Clerk. Mr. Inslee votes no.

The Chairman. Have all members responded to the vote?

The clerk will tally the vote.

The Clerk. On that vote, Mr. Chairman, the vote was 14 ayes and 31 noes.

The Chairman. Fourteen ayes, 31 noes. The amendment is not agreed to.

The clerk will report the next amendment.

The Clerk. This is a vote on the amendment offered by Mr. Buyer, number 011.

The Chairman. The clerk will call the roll.

The Clerk. Mr. Waxman.

The Chairman. No.

The Clerk. Mr. Waxman, no.

Mr. Dingell.

[No response.]

The Clerk. Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

Mr. Boucher. No.

The Clerk. Mr. Boucher votes no.

Mr. Pallone.

Mr. Pallone. No.

The Clerk. Mr. Pallone votes no.

Mr. Gordon.

Mr. Gordon. No.

The Clerk. Mr. Gordon votes no.

Mr. Rush.

Mr. Rush. No.

The Clerk. Mr. Rush votes no.

Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

Mr. Stupak. No.

The Clerk. Mr. Stupak votes no.

Mr. Engel.

Mr. Engel. No.

The Clerk. Mr. Engel votes no.

Mr. Green.

Mr. Green. No.

The Clerk. Mr. Green votes no.

Ms. DeGette.

Ms. DeGette. No.

The Clerk. Ms. DeGette votes no.

Mrs. Capps.

Mrs. Capps. No.

The Clerk. Mrs. Capps votes no.

Mr. Doyle.

[No response.]

The Clerk. Ms. Harman.

Ms. Harman. No.

The Clerk. Ms. Harman votes no.

Ms. Schakowsky.

Ms. Schakowsky. No.

The Clerk. Ms. Schakowsky votes no.

Mr. Gonzalez.

[No response.]

The Clerk. Mr. Inslee.

Mr. Inslee. No.

The Clerk. Mr. Inslee votes no.

Ms. Baldwin.

Ms. Baldwin. No.

The Clerk. Ms. Baldwin votes no.

Mr. Ross.

Mr. Ross. No.

The Clerk. Mr. Ross votes no.

Mr. Weiner.

Mr. Weiner. No.

The Clerk. Mr. Weiner votes no.

Mr. Matheson.

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

Mr. Butterfield.

Mr. Butterfield. No.

The Clerk. Mr. Butterfield votes no.

Mr. Melancon.

Mr. Melancon. No.

The Clerk. Mr. Melancon votes no.

Mr. Barrow.

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Mr. Hill.

Mr. Hill. No.

The Clerk. Mr. Hill votes no.

Ms. Matsui.

Ms. Matsui. No.

The Clerk. Ms. Matsui votes no.

Mrs. Christensen.

Mrs. Christensen. No.

The Clerk. Mrs. Christensen votes no.

Ms. Castor.

Ms. Castor. No.

The Clerk. Ms. Castor votes no.

Mr. Sarbanes.

Mr. Sarbanes. No.

The Clerk. Mr. Sarbanes votes no.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. No.

The Clerk. Mr. Murphy of Connecticut votes no.

Mr. Space.

Mr. Space. No.

The Clerk. Mr. Space votes no.

Mr. McNerney.

Mr. McNerney. No.

The Clerk. Mr. McNerney votes no.

Ms. Sutton.

Ms. Sutton. No.

The Clerk. Ms. Sutton votes no.

Mr. Braley.

Mr. Braley. No.

The Clerk. Mr. Braley votes no.

Mr. Welch.

[No response.]

The Clerk. Mr. Barton.

Mr. Barton. Aye.

The Clerk. Mr. Barton votes aye.

Mr. Hall.

Mr. Hall. Aye.

The Clerk. Mr. Hall votes aye.

Mr. Upton.

[No response.]

The Clerk. Mr. Stearns.

[No response.]

The Clerk. Mr. Deal.

Mr. Deal. Aye.

The Clerk. Mr. Deal votes aye.

Mr. Whitfield.

Mr. Whitfield. Aye.

The Clerk. Mr. Whitfield votes aye.

Mr. Shimkus.

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Shadegg.

[No response.]

The Clerk. Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. Aye.

The Clerk. Mr. Buyer votes aye.

Mr. Radanovich.

Mr. Radanovich. Aye.

The Clerk. Mr. Radanovich votes aye.

Mr. Pitts.

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack.

Mrs. Bono Mack. Aye.

The Clerk. Mrs. Bono Mack, aye.

Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry.

Mr. Terry. Oh, yeah.

The Clerk. Mr. Terry votes aye.

Mr. Rogers.

Mr. Rogers. Aye.

The Clerk. Mr. Rogers votes aye.

Mrs. Myrick.

[No response.]

The Clerk. Mr. Sullivan.

Mr. Sullivan. Aye.

The Clerk. Mr. Sullivan votes aye.

Mr. Murphy of Pennsylvania.

Mr. Murphy of Pennsylvania. Yes.

The Clerk. Mr. Murphy of Pennsylvania votes aye.

Mr. Burgess.

Mr. Burgess. Aye.

The Clerk. Mr. Burgess votes aye.

Mrs. Blackburn.

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

Mr. Gingrey.

Mr. Gingrey. Aye.

The Clerk. Mr. Gingrey votes aye.

Mr. Scalise.

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

Mr. Welch.

Mr. Welch. No.

The Clerk. Mr. Welch votes no.

The Chairman. All members responded to the rule?

Mr. Gonzalez. I haven't voted.

The Chairman. Mr. Gonzalez, how do you vote?

Mr. Gonzalez. No.

The Clerk. Mr. Gonzalez votes no.

The Chairman. Any other members wish to be recognized?

If not, the clerk will tally the vote.

Mr. Dingell. One more. Mr. Dingell votes no.

The Clerk. Mr. Dingell votes no.

On that vote, Mr. Chairman, the yeas were 17 and the nays were 33.

The Chairman. Seventeen ayes, 33 noes. The amendment is not agreed to.

The clerk will report the next amendment to be voted on.

The Clerk. This is an amendment by Mr. Rogers, number 002.

The Chairman. En bloc?

The Clerk. Yes, sir, that is the en bloc amendment.

The Chairman. The clerk will call the roll.

The Clerk. Mr. Waxman.

The Chairman. No.

The Clerk. Mr. Waxman votes no.

Mr. Dingell.

[No response.]

The Clerk. Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

Mr. Boucher. No.

The Clerk. Mr. Boucher votes no.

Mr. Pallone.

Mr. Pallone. No.

The Clerk. Mr. Pallone votes no.

Mr. Gordon.

Mr. Gordon. No.

The Clerk. Mr. Gordon votes no.

Mr. Rush.

[No response.]

The Clerk. Mr. Stupak.

Mr. Stupak. No.

The Clerk. I am sorry. I skipped one.

Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

Mr. Stupak. Still no.

The Clerk. Mr. Stupak votes no.

Mr. Engel.

Mr. Engel. No.

The Clerk. Mr. Engel votes no.

Mr. Rush.

Mr. Rush. No.

The Clerk. Mr. Rush votes no.

Mr. Green.

Mr. Green. No.

The Clerk. Mr. Green votes no.

Ms. DeGette.

Ms. DeGette. No.

The Clerk. Ms. DeGette votes no.

Mrs. Capps.

Mrs. Capps. No.

The Clerk. Mrs. Capps votes no.

Mr. Doyle.

[No response.]

The Clerk. Ms. Harman.

Ms. Harman. No.

The Clerk. Ms. Harman votes no.

Ms. Schakowsky.

Ms. Schakowsky. No.

The Clerk. Ms. Schakowsky votes no.

Mr. Gonzalez.

Mr. Gonzalez. No.

The Clerk. Mr. Gonzalez votes no.

Mr. Inslee.

Mr. Inslee. No.

The Clerk. Mr. Inslee votes no.

Ms. Baldwin.

Ms. Baldwin. No.

The Clerk. Ms. Baldwin votes no.

Mr. Ross.

Mr. Ross. No.

The Clerk. Mr. Ross votes no.

Mr. Weiner.

Mr. Weiner. No.

The Clerk. Mr. Weiner votes no.

Mr. Matheson.

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

Mr. Butterfield.

Mr. Butterfield. No.

The Clerk. Mr. Butterfield votes no.

Mr. Melancon.

Mr. Melancon. No.

The Clerk. Mr. Melancon votes no.

Mr. Barrow.

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Mr. Hill.

Mr. Hill. No.

The Clerk. Mr. Hill votes no.

Ms. Matsui.

Ms. Matsui. No.

The Clerk. Ms. Matsui votes no.

Mrs. Christensen.

Mrs. Christensen. No.

The Clerk. Mrs. Christensen votes no.

Ms. Castor.

Ms. Castor. No.

The Clerk. Ms. Castor votes no.

Mr. Sarbanes.

Mr. Sarbanes. No.

The Clerk. Mr. Sarbanes votes no.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. No.

The Clerk. Mr. Murphy of Connecticut votes no.

Mr. Space.

Mr. Space. No.

The Clerk. Mr. Space votes no.

Mr. McNerney.

Mr. McNerney. No.

The Clerk. Mr. McNerney votes no.

Ms. Sutton.

Ms. Sutton. No.

The Clerk. Ms. Sutton votes no.

Mr. Braley.

Mr. Braley. No.

The Clerk. Mr. Braley votes no.

Mr. Welch.

Mr. Welch. No.

The Clerk. Mr. Welch votes no.

Mr. Barton.

Mr. Barton. Aye.

The Clerk. Mr. Barton votes aye.

Mr. Hall.

Mr. Hall. Aye.

The Clerk. Mr. Hall votes aye.

Mr. Upton.

[No response.]

The Clerk. Mr. Stearns.

Mr. Stearns. Aye.

The Clerk. Mr. Stearns votes aye.

Mr. Deal.

Mr. Deal. Aye.

The Clerk. Mr. Deal votes aye.

Mr. Whitfield.

[No response.]

The Clerk. Mr. Shimkus.

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Shadegg.

[No response.]

The Clerk. Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. Aye.

The Clerk. Mr. Buyer votes aye.

Mr. Radanovich.

Mr. Radanovich. Aye.

The Clerk. Mr. Radanovich votes aye.

Mr. Pitts.

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack.

Mrs. Bono Mack. Aye.

The Clerk. Mrs. Bono Mack, aye.

Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry.

Mr. Terry. Oh, yeah.

The Clerk. Mr. Terry votes aye.

Mr. Rogers.

Mr. Rogers. Aye.

The Clerk. Mr. Rogers votes aye.

Mrs. Myrick.

[No response.]

The Clerk. Mr. Sullivan.

Mr. Sullivan. Aye.

The Clerk. Mr. Sullivan votes aye.

Mr. Murphy of Pennsylvania.

Mr. Murphy of Pennsylvania. Aye.

The Clerk. Mr. Murphy of Pennsylvania votes aye.

Mr. Burgess.

Mr. Burgess. Aye.

The Clerk. Mr. Burgess votes aye.

Mrs. Blackburn.

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

Mr. Gingrey.

Mr. Gingrey. Aye.

The Clerk. Mr. Gingrey votes aye.

Mr. Scalise.

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

Mr. Dingell. Mr. Dingell votes no.

The Clerk. Mr. Dingell, no.

The Chairman. All members having responded to the vote, the clerk will announce the vote.

The Clerk. On that vote, Mr. Chairman, the yeas were 18 and the nays were 33.

The Chairman. Eighteen ayes, 33 noes. The amendment is not

agreed to.

Have we completed all the amendments?

The Clerk. No.

The Chairman. One more.

The Clerk. I have one more, the Rogers amendment 008. A roll call was requested on that.

The Chairman. The clerk will call the roll.

This is the last amendment. Then we will proceed to final passage.

The Clerk. Mr. Waxman.

The Chairman. No.

The Clerk. Mr. Waxman votes no.

Mr. Dingell.

Mr. Dingell. No.

The Clerk. Mr. Dingell votes no.

Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

Mr. Boucher. No.

The Clerk. Mr. Boucher votes no.

Mr. Pallone.

Mr. Pallone. No.

The Clerk. Mr. Pallone votes no.

Mr. Gordon.

Mr. Gordon. No.

The Clerk. Mr. Gordon votes no.

Mr. Rush.

Mr. Rush. No.

The Clerk. Mr. Rush votes no.

Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

Mr. Stupak. No.

The Clerk. Mr. Stupak votes no.

Mr. Engel.

Mr. Engel. No.

The Clerk. Mr. Engel votes no.

Mr. Green.

Mr. Green. No.

The Clerk. Mr. Green votes no.

Ms. DeGette.

Ms. DeGette. No.

The Clerk. Ms. DeGette votes no.

Mrs. Capps.

Mrs. Capps. No.

The Clerk. Mrs. Capps votes no.

Mr. Doyle.

[No response.]

The Clerk. Ms. Harman.

Ms. Harman. No.

The Clerk. Ms. Harman votes no.

Ms. Schakowsky.

Ms. Schakowsky. No.

The Clerk. Ms. Schakowsky votes no.

Mr. Gonzalez.

Mr. Gonzalez. No.

The Clerk. Mr. Gonzalez votes no.

Mr. Inslee.

Mr. Inslee. No.

The Clerk. Mr. Inslee votes no.

Ms. Baldwin.

Ms. Baldwin. No.

The Clerk. Ms. Baldwin votes no.

Mr. Ross.

Mr. Ross. No.

The Clerk. Mr. Ross votes no.

Mr. Weiner.

Mr. Weiner. No.

The Clerk. Mr. Weiner votes no.

Mr. Matheson.

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

Mr. Butterfield.

Mr. Butterfield. No.

The Clerk. Mr. Butterfield votes no.

Mr. Melancon.

Mr. Melancon. No.

The Clerk. Mr. Melancon votes no.

Mr. Barrow.

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Mr. Hill.

Mr. Hill. No.

The Clerk. Mr. Hill votes no.

Ms. Matsui.

Ms. Matsui. No.

The Clerk. Ms. Matsui votes no.

Mrs. Christensen.

Mrs. Christensen. No.

The Clerk. Mrs. Christensen votes no.

Ms. Castor.

Ms. Castor. No.

The Clerk. Ms. Castor votes no.

Mr. Sarbanes.

Mr. Sarbanes. No.

The Clerk. Mr. Sarbanes votes no.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. No.

The Clerk. Mr. Murphy of Connecticut votes no.

Mr. Space.

Mr. Space. No.

The Clerk. Mr. Space votes no.

Mr. McNerney.

Mr. McNerney. No.

The Clerk. Mr. McNerney votes no.

Ms. Sutton.

Ms. Sutton. No.

The Clerk. Ms. Sutton votes no.

Mr. Braley.

Mr. Braley. No.

The Clerk. Mr. Braley votes no.

Mr. Welch.

Mr. Welch. No.

The Clerk. Mr. Welch votes no.

Mr. Barton.

Mr. Barton. Aye.

The Clerk. Mr. Barton votes aye.

Mr. Hall.

Mr. Hall. Aye.

The Clerk. Mr. Hall votes aye.

Mr. Upton.

[No response.]

The Clerk. Mr. Stearns.

Mr. Stearns. Aye.

The Clerk. Mr. Stearns votes aye.

Mr. Deal.

Mr. Deal. Aye.

The Clerk. Mr. Deal votes aye.

Mr. Whitfield.

Mr. Whitfield. Aye.

The Clerk. Mr. Whitfield votes aye.

Mr. Shimkus.

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Shadegg.

[No response.]

The Clerk. Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. Aye.

The Clerk. Mr. Buyer votes aye.

Mr. Radanovich.

Mr. Radanovich. Aye.

The Clerk. Mr. Radanovich votes aye.

Mr. Pitts.

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack.

Mrs. Bono Mack. Aye.

The Clerk. Mrs. Bono Mack, aye.

Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry.

Mr. Terry. Aye.

The Clerk. Mr. Terry votes aye.

Mr. Rogers.

Mr. Rogers. Aye.

The Clerk. Mr. Rogers votes aye.

Mrs. Myrick.

[No response.]

The Clerk. Mr. Sullivan.

Mr. Sullivan. Aye.

The Clerk. Mr. Sullivan votes aye.

Mr. Murphy of Pennsylvania.

[No response.]

The Clerk. Mr. Burgess.

Mr. Burgess. Aye.

The Clerk. Mr. Burgess votes aye.

Mrs. Blackburn.

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

Mr. Gingrey.

Mr. Gingrey. Aye.

The Clerk. Mr. Gingrey votes aye.

Mr. Scalise.

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

The Chairman. Have all members responded to the rule?

Mr. Murphy.

Mr. Murphy of Pennsylvania. Yes, please.

The Chairman. Mr. Murphy votes aye.

The Clerk. Mr. Murphy of Pennsylvania votes aye.

The Chairman. The clerk ready to report the vote?

The Clerk. Yes, sir. Mr. Chairman, on that vote, the yeas were 19 and the nays were 33.

The Chairman. Nineteen ayes, 33 noes. The amendment is not agreed to.

The vote now comes on reporting the bill from the committee with the usual instructions, and the clerk will call the roll for final passage.

The Clerk. Mr. Waxman.

The Chairman. Aye.

The Clerk. Mr. Waxman votes aye.

Mr. Dingell.

[No response.]

The Clerk. Mr. Markey.

[No response.]

The Clerk. Mr. Boucher.

Mr. Boucher. Aye.

The Clerk. Mr. Boucher votes aye.

Mr. Pallone.

Mr. Pallone. Aye.

The Clerk. Mr. Pallone votes aye.

Mr. Gordon.

Mr. Gordon. Aye.

The Clerk. Mr. Gordon votes aye.

Mr. Rush.

Mr. Rush. Aye.

The Clerk. Mr. Rush votes aye.

Ms. Eshoo.

[No response.]

The Clerk. Mr. Stupak.

Mr. Stupak. Yes.

The Clerk. Mr. Stupak votes aye.

Mr. Engel.

Mr. Engel. Aye.

The Clerk. Mr. Engel votes aye.

Mr. Green.

Mr. Green. Aye.

The Clerk. Mr. Green votes aye.

Ms. DeGette.

Ms. DeGette. Aye.

The Clerk. Ms. DeGette votes aye.

Mrs. Capps.

Mrs. Capps. Aye.

The Clerk. Mrs. Capps votes aye.

Mr. Doyle.

[No response.]

The Clerk. Ms. Harman.

Ms. Harman. Aye.

The Clerk. Ms. Harman votes aye.

Ms. Schakowsky.

Ms. Schakowsky. Aye.

The Clerk. Ms. Schakowsky votes aye.

Mr. Gonzalez.

Mr. Gonzalez. Aye.

The Clerk. Mr. Gonzalez votes aye.

Mr. Inslee.

Mr. Inslee. Aye.

The Clerk. Mr. Inslee votes aye.

Ms. Baldwin.

Ms. Baldwin. Aye.

The Clerk. Ms. Baldwin votes aye.

Mr. Ross.

Mr. Ross. No -- oh, aye, aye.

The Clerk. Mr. Ross votes aye.

Mr. Weiner.

Mr. Weiner. Aye.

The Clerk. Mr. Weiner votes aye.

Mr. Matheson.

Mr. Matheson. Aye.

The Clerk. Mr. Matheson votes aye.

Mr. Butterfield.

Mr. Butterfield. Aye.

The Clerk. Mr. Butterfield votes aye.

Mr. Melancon.

Mr. Melancon. Aye.

The Clerk. Mr. Melancon votes aye.

Mr. Barrow.

Mr. Barrow. Aye.

The Clerk. Mr. Barrow votes aye.

Mr. Hill.

Mr. Hill. Aye.

The Clerk. Mr. Hill votes aye.

Ms. Matsui.

Ms. Matsui. Aye.

The Clerk. Ms. Matsui votes aye.

Mrs. Christensen.

Mrs. Christensen. Aye.

The Clerk. Mrs. Christensen votes aye.

Ms. Castor.

Ms. Castor. Aye.

The Clerk. Ms. Castor votes aye.

Mr. Sarbanes.

Mr. Sarbanes. Aye.

The Clerk. Mr. Sarbanes votes aye.

Mr. Murphy of Connecticut.

Mr. Murphy of Connecticut. Aye.

The Clerk. Mr. Murphy of Connecticut votes aye.

Mr. Space.

Mr. Space. Aye.

The Clerk. Mr. Space votes aye.

Mr. McNerney.

Mr. McNerney. Aye.

The Clerk. Mr. McNerney votes aye.

Ms. Sutton.

Ms. Sutton. Aye.

The Clerk. Ms. Sutton votes aye.

Mr. Braley.

Mr. Braley. Aye.

The Clerk. Mr. Braley votes aye.

Mr. Welch.

Mr. Welch. Aye.

The Clerk. Mr. Welch votes aye.

Mr. Barton.

Mr. Barton. No.

The Clerk. Mr. Barton votes no.

Mr. Hall.

Mr. Hall. Aye.

The Clerk. Mr. Hall votes aye.

Mr. Upton.

[No response.]

The Clerk. Mr. Stearns.

Mr. Stearns. No.

The Clerk. Mr. Stearns votes no.

Mr. Deal.

Mr. Deal. No.

The Clerk. Mr. Deal votes no.

Mr. Whitfield.

Mr. Whitfield. No.

The Clerk. Mr. Whitfield votes no.

Mr. Shimkus.

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Shadegg.

[No response.]

The Clerk. Mr. Blunt.

[No response.]

The Clerk. Mr. Buyer.

Mr. Buyer. No.

The Clerk. Mr. Buyer votes no.

Mr. Radanovich.

Mr. Radanovich. No.

The Clerk. Mr. Radanovich votes no.

Mr. Pitts.

Mr. Pitts. No.

The Clerk. Mr. Pitts votes no.

Mrs. Bono Mack.

Mrs. Bono Mack. Aye.

The Clerk. Mrs. Bono Mack, aye.

Mr. Walden.

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry.

Mr. Terry. Aye.

The Clerk. Mr. Terry votes aye.

Mr. Rogers.

Mr. Rogers. No.

The Clerk. Mr. Rogers votes no.

Mrs. Myrick.

[No response.]

The Clerk. Mr. Sullivan.

Mr. Sullivan. No.

The Clerk. Mr. Sullivan votes no.

Mr. Murphy of Pennsylvania.

Mr. Murphy of Pennsylvania. Aye.

The Clerk. Mr. Murphy of Pennsylvania votes aye.

Mr. Burgess.

Mr. Burgess. No.

The Clerk. Mr. Burgess votes no.

Mrs. Blackburn.

Mrs. Blackburn. No.

The Clerk. Mrs. Blackburn votes no.

Mr. Gingrey.

Mr. Gingrey. No.

The Clerk. Mr. Gingrey votes no.

Mr. Scalise.

Mr. Scalise. No.

The Clerk. Mr. Scalise votes no.

The Chairman. All members responded to the call of the roll?

We have one more coming. We are not closing it yet. Mr. Dingell.

Mr. Dingell. Mr. Dingell votes aye.

The Clerk. Mr. Dingell aye.

The Chairman. And there is one more we understand coming on the Republican side. The clerk can do a preliminary count, and then when we find out how this next member votes then we will have the final tally.

Okay, the clerk will announce the vote.

The Clerk. On that vote Mr. Chairman the ayes were 39 and the nays were 13.

The Chairman. Thirty-nine ayes, 13 noes. The bill is reported out of the committee with the usual instructions.

That concludes our business, and we stand adjourned.

[Whereupon, at 5:24 p.m., the committee was adjourned.]