DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tom Price, M.D.
House of Representatives
Washington, D.C. 20515-1006

FEB 26 2013

Dear Dr. Price:

Thank you for your letter of November 20, 2012, cosigned by eight of your colleagues, urging the Food and Drug Administration (FDA or the Agency) and the Environmental Protection Agency (EPA) to finalize updated fish consumption advice to pregnant women and its associated risk benefits assessment. FDA shares your interest in ensuring that pregnant women have access to sound, science-driven, and clearly understandable recommendations that enable them to make informed decisions about their diets.

Although we have not been able to issue the revised draft advice as soon as we would have liked, we have made significant progress since our latest communication with you on this matter. FDA and EPA have closely worked together to draft revised advice that includes a set of consumer-friendly questions. Both the revised advice and FDA's final risk and benefit assessment of the effects of consuming commercial seafood, which supports the advice and takes into account input from EPA, have been drafted and are currently in clearance within the Administration. As I am sure you are aware, the clearance process includes multiple agencies that have a stake in making sure we provide an inclusive, robust, and clear assessment and advice based on the best science available. We hope to issue the assessment and draft advice as soon as possible.

Please let me assure you that completing the updated advice, the questions and answers, and the risk and benefit assessment, remain a priority for the Agency. Following issuance of the updated advice in draft form for public comment, we intend to conduct focus groups to test the advice with consumers and to obtain review by the FDA Advisory Committee on Risk Communication to ensure that the messages are clear to consumers.

Thank you, again, for contacting us regarding this matter. If you have further questions or concerns, please let us know. The same letter has been sent to your cosigners.

Sincerely,

Michele Mital

Michele Mital
Acting Associate Commissioner
for Legislation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tom Price, M.D.
House of Representatives
Washington, D.C. 20515-1006

FEB 26 2013

Dear Dr. Price:

Thank you for your letter of November 20, 2012, cosigned by eight of your colleagues, urging the Food and Drug Administration (FDA or the Agency) and the Environmental Protection Agency (EPA) to finalize updated fish consumption advice to pregnant women and its associated risk benefits assessment. FDA shares your interest in ensuring that pregnant women have access to sound, science-driven, and clearly understandable recommendations that enable them to make informed decisions about their diets.

Although we have not been able to issue the revised draft advice as soon as we would have liked, we have made significant progress since our latest communication with you on this matter. FDA and EPA have closely worked together to draft revised advice that includes a set of consumer-friendly questions. Both the revised advice and FDA's final risk and benefit assessment of the effects of consuming commercial seafood, which supports the advice and takes into account input from EPA, have been drafted and are currently in clearance within the Administration. As I am sure you are aware, the clearance process includes multiple agencies that have a stake in making sure we provide an inclusive, robust, and clear assessment and advice based on the best science available. We hope to issue the assessment and draft advice as soon as possible.

Please let me assure you that completing the updated advice, the questions and answers, and the risk and benefit assessment, remain a priority for the Agency. Following issuance of the updated advice in draft form for public comment, we intend to conduct focus groups to test the advice with consumers and to obtain review by the FDA Advisory Committee on Risk Communication to ensure that the messages are clear to consumers.

Thank you, again, for contacting us regarding this matter. If you have further questions or concerns, please let us know. The same letter has been sent to your cosigners.

Sincerely,

Michele Mital

Michele Mital
Acting Associate Commissioner
for Legislation

Congress of the United States
Washington, DC 20515

November 20, 2012

Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Honorable Lisa Jackson
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Dr. Hamburg and Administrator Jackson:

We are writing to you as concerned physicians and medical practitioners regarding an issue of significant importance to ensure pregnant women in the United States and around the world receive the best medical advice. As you know, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) issued advice in 2004 to women who may become pregnant, women who are pregnant, nursing mothers and young children that recommended a reduction in already low seafood consumption levels.

Since 2004, new scientific data has found that there is now an Omega 3 deficiency in the United States based on reduced seafood consumption. Physicians, scientists, nutritionists and both the Secretaries of Health and Human Services and Agriculture agree that the 2004 advice is outdated and needs to be revised.

Members of both the House and Senate have written to the Administration nearly a dozen times calling for the completion of the risk benefit assessment and an update to the current seafood consumption advice. In each response, Members and Senators have been provided with deadlines for new advice that have been subsequently missed. Meanwhile, the new Dietary Guidelines for Americans (DGA) were jointly issued in January 2011 by the Departments of Agriculture and Health and Human Services.

Within the DGA, it specifically contradicts the 2004 advice when it stated, "the benefits of consuming seafood far outweigh the risks, even for pregnant women." It further states, "the nutritional value of seafood is of particular importance during fetal growth and development, as well as in early infancy and childhood." Ultimately, the DGA recommends women quadruple current seafood consumption during pregnancy.

As physicians and medical practitioners, we are concerned that every day the FDA delays in issuing its advice, pregnant women are receiving inaccurate, conflicting information on seafood consumption that can have a negative impact on unborn children. HHS Secretary Kathleen Sebelius has committed to issuing the risk benefits assessment and the new advice, both of which must be completed as soon as possible. We hope that both the FDA and the EPA will follow suit.

PRINTED ON RECYCLED PAPER

2012-9398

We respectfully request that both agencies provide us with an update on the status of the final risk benefits assessment and the draft new advice. This report and advice must be finalized this year. We owe it to pregnant women across the country to ensure consistency in the dietary guidelines and advice that the federal government provides to them.

Sincerely,

Phil Gingrey, M.D.
Member of Congress

John Fleming, M.D.
Member of Congress

Michael C. Burgess, M.D.
Member of Congress

Charles Boustany, M.D.
Member of Congress

Andy Harris, M.D.
Member of Congress

Bill Cassidy, M.D.
Member of Congress

Dan Benishek, M.D.
Member of Congress

Tom Price, M.D.
Member of Congress

Paul Broun, M.D.
Member of Congress

CC: Honorable Kathleen Sebelius, Secretary of the Health and Human Services
Honorable Tom Vilsack, Secretary of the U.S. Department of Agriculture
Cecilia Muñoz, Director of the White House Domestic Policy Council
Julie Moreno, White House Domestic Policy Council
Jocelyn Frye, Office of the First Lady Michelle Obama

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

January 21, 2016

The Honorable Thomas Kraus
Associate Commissioner
Office of Legislation
Food and Drug Administration
Department of Health and Human Services
Silver Spring, MD 20993

Dear Mr. Kraus:

We are forwarding a copy of correspondence we received from Congressman Tom Price on behalf of his constituent, b(6) Personal Privacy regarding a matter involving a retired Food and Drug Administration (FDA) Special Agent.

We believe it would be more appropriate for the FDA to respond to this inquiry because this matter involves an issue under the jurisdiction of your agency, rather than the Department of Justice. A copy of our letter advising Congressman Price of our referral is enclosed.

Thank you for your assistance in responding to Congressman Price's inquiry.

Sincerely,

Peter J. Kadzik
Assistant Attorney General

Enclosure

cc: The Honorable Tom Price
U.S. House of Representatives

312 7052 - EH 5

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

WASHINGTON DC OFFICE
100 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX: (202) 225-4656

DISTRICT OFFICE
85-C MILL STREET, SUITE 300
ROSWELL, GA 30075
(770) 998-0049
FAX: (770) 565-7570

www.house.gov/tomprice

COMMITTEE ON THE BUDGET
CHAIRMAN

COMMITTEE ON WAYS AND MEANS

Congress of the United States
House of Representatives

December 22, 2015

2015 DEC 28 PM 2:03

Mr. Peter Kadzik
Deputy Assistant Attorney General for Office of Legislative Affairs
Office of Legislative Affairs
US Department of Justice
950 Pennsylvania Ave., NW
Room 1145
Washington, DC 20530-0009

Dear Mr. Kadzik:

One of my constituents has contacted me regarding a matter in which I believe you could be helpful.

Please find enclosed a copy the correspondence I received from b(6) Personal Privacy I would appreciate your responding directly to Mr. Cusack.

Thank you very much for your consideration and assistance in this matter.

Yours truly,

Tom Price, M.D.
Member of Congress

TP/tm

PRINTED ON RECYCLED PAPER

November 23, 2015 - HAND DELIVERRED

U.S. Representative Price
Georgia's 6th District
85-C Mill Street, Suite 300
Roswell, Ga. 30075

Congressman Price:

I am writing this letter to your office to submit a request for assistance for a legal matter involving a retired FDA Special Agent who committed felony acts consisting of but not limited to, felony perjury. The felonies were committed during a State Court hearing this past January by invoking the FDA name and telling the court they were investigated by the Internal Affairs Department of the FDA, due to the legal matter they were giving testimony about to the court. Confirmation for the perjury was obtained in 'writing' from a Director of the FDA which was done in a very professional manner that I will always be grateful for. The document is included with this letter to **(See Attachment 'D')** your office. When a request was submitted to the FDA to have the FDA Director and manager testify to confirm the contents of the letter as required by the court in order to have a warrant issued; the request was denied by the FDA.

This request being submitted to your office for assistance was originally sent to the President and his staff at the White House explaining the situation and asking for their assistances. The request was submitted to the White House via a Certified Registered Letter on August 12, 2015 **(See Attachment P-1)** and a notice of availability sent to the White House by the USPS on August 13, 2015 **(See Attachment P-2).** Eleven days later, the White House finally accepted and received my letter. After waiting 30 days for the courtesy of a reply, an e-mail was sent using the White House Web Site **(See Attachment P-3)** asking for a reply to my letter. When no reply was received again after another 30 days, a second attempt was made using the e-mail process once again from the White House Web Site and no communications of any type has been received for the requests submitted to the White House by me.

I run a b(6) Personal Privacy business that I started after having b(6) Personal Privacy and left the corporate business environment. I started the business to be able to pay medical insurance coverage and to stay active. Attached you will find the request I submitted to Dr. Ostroff, **(See Attachment 1.0)** the Acting Commissioner for the Food and Drug Administration asking for his permission to be given for his staff to appear at a hearing and the response received **(See Attachment 2.0)** about the request. I will not document the details for what this issue and request are about since they are documented in the letter sent to the Acting Commissioner along with the supporting documentation to show the validity of the facts.

Congressman Price would you please provide your assistance and have the decision sent to me by the FDA reversed and have the FDA authorize approval for having two FDA employee's appear and testify in the Georgia Magistrate Court, in order to have a hearing scheduled and subpoenas prepared and served. The testimony will show the court, probable cause does exist and an arrest warrant should be issued for the felony acts committed by Former Federal Agent b(6) Personal Privacy during her testimony to the State court under oath and her attorney. Would you please have your

staff review the enclosed information and provide a response for this request within 14 days from delivery, so the next steps to obtain resolution for this issue can be initiated.

If there is any additional information needed to help in validating the information to determine how to address the submitted the request, please feel free to contact me at the information listed below. I apologies for having to make this written request to your office and thank you in advance for the time, effort and consideration given to address it.

Sincerely,

b(6) Personal Privacy

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, D.C. 20530*

January 21, 2016

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Price:

This responds to your letter dated December 22, 2015, on behalf of your constituent, b(6) Per b(6) Personal Privacy regarding a matter involving a retired Food and Drug Administration (FDA) Special Agent.

Upon review, we have determined that this issue falls within the jurisdiction of the FDA and have therefore referred your letter to Thomas Kraus, Associate Commissioner for Legislation. A copy of our referral letter is enclosed.

We hope that this information is helpful. Please do not hesitate to contact us if we may provide additional assistance regarding this or any other matter.

Sincerely,

Peter J. Kadzik
Assistant Attorney General

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

AUG 28 2015

The Honorable Tom Price, M.D.
House of Representatives
Washington, D.C. 20515-1001

Dear Dr. Price:

Thank you for your letter of August 4, 2015, cosigned by 13 of your colleagues, regarding the Food and Drug Administration's (FDA or the Agency) implementation of the FDA Food Safety Modernization Act (FSMA); specifically, the proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (the preventive controls for food for animals proposed rule).[1] You encourage the Agency to finalize rules that provide flexibility to allow facilities to adopt livestock feed safety practices that are practical and effective for their specific, individual operations.

Please be assured that we are working to develop final regulations that are practical for businesses and help ensure that food for animals is safe and will not cause injury to animals or humans. Since the passage of FSMA, the Agency has pursued a transparent process, engaging all stakeholders to allow us to craft final regulations that will work across the broad spectrum of food-producing operations. An unparalleled outreach effort followed the original proposal of the FSMA rules. As you know, in September 2014, FDA proposed a number of revisions to its preventive controls for food for animals proposed rule that would add flexibility and reduce burden in key areas.[2] FDA proposed the changes based on extensive outreach and feedback received during meetings with the public, industry groups, consumer groups, and livestock and poultry farmers and in the comments submitted to the Agency on the proposed rule.

We received comments during the public comment period that express concerns similar to the ones that you have raised. We are fully considering the public comments on these issues as we develop a final rule and are committed to final regulations that are reasonable and responsive to these concerns.

You may also be interested to know that while we work to finalize the rules, we are also laying the foundation for effective, efficient, and collaborative implementation of the new standards. This requires fundamentally new approaches to collaboration and oversight to achieve high rates of compliance with FSMA's prevention standards. Because we know that the vast majority of American farmers and food companies want to do the right thing on food safety and want to comply with the new rules, we are basing our FSMA implementation strategy on the principle of "educate before and while we regulate." We intend to provide guidance and technical assistance to industry so they know what is expected and are supported in doing it. For example, FDA, in

[1] *https://federalregister.gov/a/2013-25126*
[2] *https://federalregister.gov/a/2014-22445*

cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, has established the Food Safety Preventive Controls Alliance, which is developing training courses and materials on preventing hazards for both human and animal food during production.[3] These materials will help industry—particularly small- and medium-sized companies—comply with the new preventive controls rules. Our implementation strategy also calls for reorienting and retraining the FDA inspection and compliance workforce, as well as our state food safety partners, so we can provide consistent, high-quality oversight within the more preventive, systems-based, and technically sophisticated FSMA framework.

Thank you, again, for contacting us concerning this matter. If you have further questions or concerns, please let us know. The same letter has been sent to your cosigners.

Sincerely,

for Thomas A. Kraus
Associate Commissioner
for Legislation

[3] *http://www.iit.edu/ifsh/alliance/*

Congress of the United States
Washington, DC 20515

August 4, 2015

Dr. Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Ostroff,

We are writing to request your attention to a number of concerns regarding the Proposed Rule for Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Animal Food. As you know, The Food Safety and Modernization Act (FSMA) encompassed major reforms to our nation's food safety practices, and gave the FDA authority to promulgate regulations that would allow for flexibility in the production and distribution of safe animal feed and pet food. However, there remains serious concerns that the FDA's current proposed regulations are overly burdensome and costly and do not provide the intended flexibility component for livestock feed facilities.

On behalf of Georgia agribusiness, we urge the FDA to actively address several issues to ensure the final rule will allow facilities to adopt livestock feed safety practices that are practical and effective for their specific, individual operations. Our recommendations include changes to the CGMP requirement, the Risk-Based Preventative Controls process, a final cost-benefit analysis, and implementation of a staggered compliance schedule for the forthcoming final rule. We strongly request your attention to these four recommendations.

1. The proposed rule only makes one overall set of CGMP requirements. We recommend that the FDA make a clear distinction between the current CGMP for human food and another appropriate set of CGMP applicable to the livestock feed industry. The basic food composition, serving differences, and the innate differences in the level of hygienic standards between food products and animal feed products support our reasoning for establishing separate CGMP requirements.

2. We appreciate the FDA's dedication to reducing and eliminating hazards to food products through a preventative controls process. However, we ask that the FDA, again, provide a modified preventative controls process or exemption for facilities who only produce livestock feed. Specifically, we support the FDA's supplemental revision that defines a "significant hazard"

PRINTED ON RECYCLED PAPER

process of identifying significant hazards within business operations. We believe that only those hazards which rise to the level of significant hazard should be subject to the preventive control regulations which will require thorough management controls including monitoring, corrections or corrective actions, validation, and record keeping. Given the associated risks and high costs for compliance, this exemption provision seems entirely appropriate.

3. The FDA's Preliminary Regulatory Impact Analysis (PRIA) has a wide range of compliance costs, with an increasing and significant economic impact on small and very small business entities. If a final, more limited rule is created, then the cost of compliance to the animal feed and pet food industry would greatly decrease. Additionally, the PRIA does not quantify the benefits of the proposed rule. Without determining both costs and benefits, the analysis is not complete, nor does it give the associated parties confidence in the final analysis. We believe it is important to have clear evidence that the costs of implementing the proposed rule are worth the anticipated benefits.

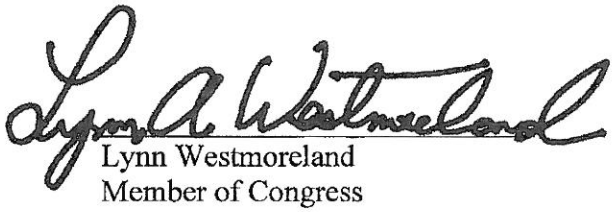
4. We request that the FDA provide a sufficient time period for facilities to meet obligations following the publication of the final regulation. Since the CGMPs regulations will establish new baseline requirements for all affected livestock feed facilities, a staggered compliance schedule would provide the necessary time for affected facilities to fully implement programs to comply with the CGMPs regulation and the preventive controls regulation. Therefore we recommend a three year compliance period for very small businesses, two year period for small business, and a one year compliance period for all other larger businesses to apply proper CGMP regulations. If affected facilities have an appropriate amount of time for CGMP compliance, then facilities will be able to lay a strong foundation of best practices which will aid facilities implementing the written animal feed and pet food safety plans required under the preventive controls regulation. As such, we recommend that FDA apply a compliance time frame for the preventative controls regulation of four years for very small businesses, three years for small business, and two years for larger businesses.

We support the FDA's efforts to ensure that all pet and animal feed are safely produced and distributed. With the recommendations that we have submitted on behalf of the livestock industry, we believe that an appropriate and safe rule can be achieved. Thank you for your consideration and thank you in advance for your response.

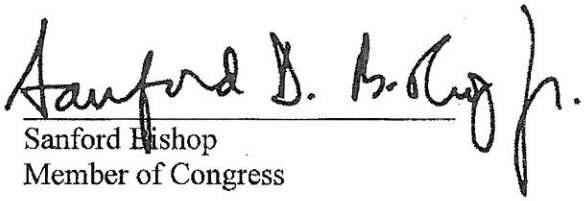
Sincerely,

Johnny Isakson
United States Senator

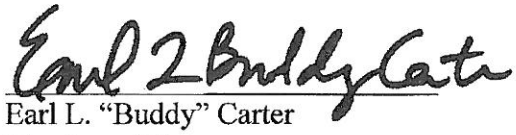
David Perdue
United States Senator



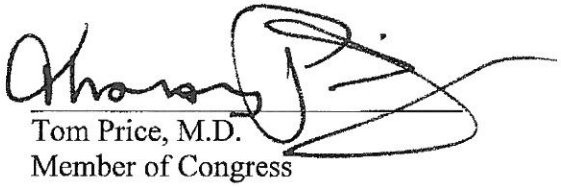
Lynn Westmoreland
Member of Congress



Sanford Bishop
Member of Congress

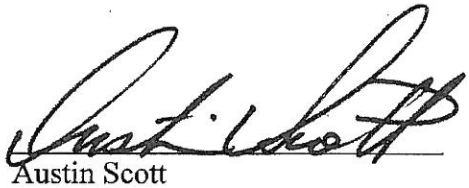


Earl L. "Buddy" Carter
Member of Congress

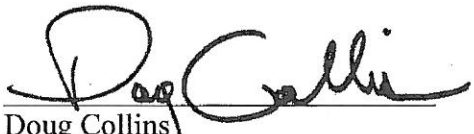


Tom Price, M.D.
Member of Congress

Rob Woodall
Member of Congress



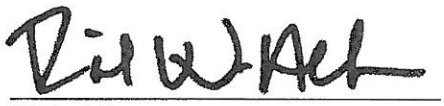
Austin Scott
Member of Congress



Doug Collins
Member of Congress

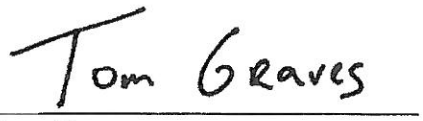
Jody Hice
Member of Congress

Barry Loudermilk
Member of Congress



Rick Allen
Member of Congress

David Scott
Member of Congress



Tom Graves
Member of Congress

Congress of the United States
Washington, DC 20515

May 30, 2014

Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

As Members of the Diabetes Caucus, we appreciate the work that FDA does to ensure that patients have timely access to safe and effective medical devices that are crucial in managing diabetes care. As you know, blood glucose monitoring test systems (BGMS) play an important role in managing diabetes in health care and assisted-use environments at the point of care, as well as in patients' homes, making appropriate regulation critical. We note that FDA issued two draft guidance documents in January of this year on BGMS. While we applaud the intent to give patients access to the most accurate and reliable products, we have concerns that the guidances could have negative impacts on access and availability of blood glucose meters.

In particular, we are concerned that the draft guidances issued by FDA impose challenging requirements for accuracy that are inconsistent with internationally recognized standards. Stakeholders, including FDA, industry, and the health care community, have worked to support the goal of improving meter performance and participated in recent updates to worldwide standards. Yet, this guidance appears to disregard those updated standards. We would encourage the FDA to continue working with stakeholders to better harmonize with worldwide regulatory requirements, rather than impose new requirements that are in excess of currently recognized standards implemented worldwide.

Additionally, we have concerns that the draft guidance on Over the Counter (OTC) BGMS contains language that seems to have the effect of placing a blanket restriction on their use in professional settings. Patients in POC facilities (hospitals, nursing facilities, etc.) can have health issues that require a timely diagnosis and treatment plan that OTC BGMS currently provide for in certain instances. Some of these care facilities are not equipped to provide alternative blood glucose testing, which may force delays in treatment, or even shift some patients off-site to receive adequate testing. Disallowing OTC BGMS use in POC settings may lead to burdensome and potentially dangerous treatment delays.

Again, thank you for your work on this important issue. We encourage FDA to carefully consider the comments of all stakeholders to ensure that any final guidance preserves timely access to safe and effective diabetes management tools.

Sincerely,

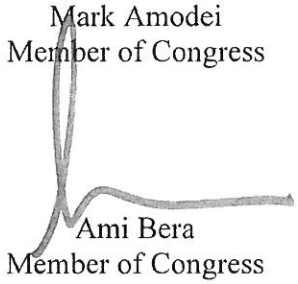
Diana DeGette
Member of Congress

Ed Whitfield
Member of Congress

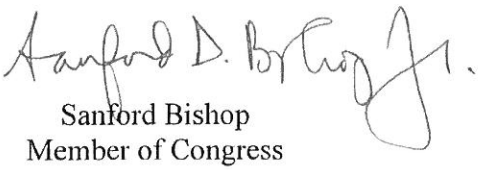
PRINTED ON RECYCLED PAPER

Mark Amodei
Member of Congress

John Barrow
Member of Congress

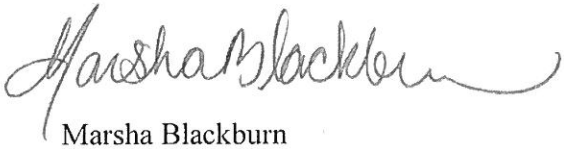


Ami Bera
Member of Congress



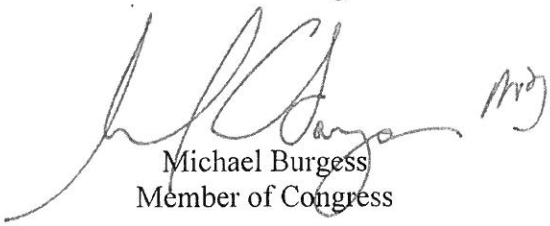
Sanford Bishop
Member of Congress

Diane Black
Member of Congress



Marsha Blackburn
Member of Congress

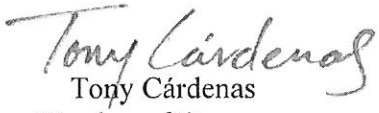
Susan Brooks
Member of Congress



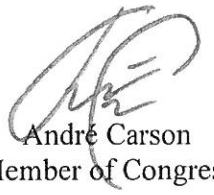
Michael Burgess
Member of Congress

Cheri Bustos
Member of Congress

G.K. Butterfield
Member of Congress



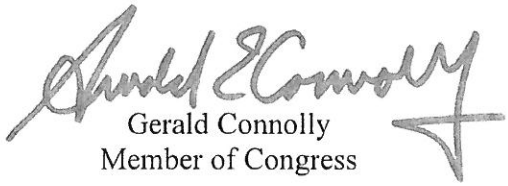
Tony Cárdenas
Member of Congress



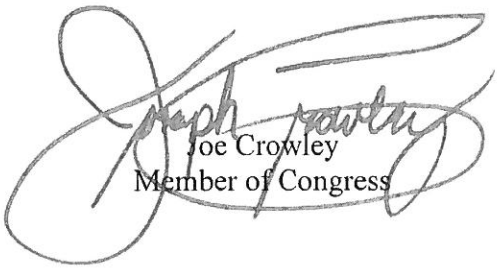
André Carson
Member of Congress

Steve Chabot
Member of Congress

Judy Chu
Member of Congress



Gerald Connolly
Member of Congress



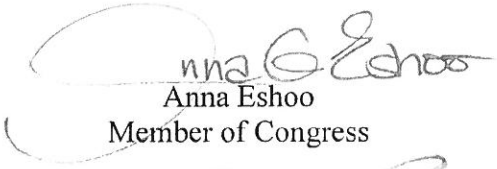
Joe Crowley
Member of Congress

Danny Davis
Member of Congress

Rodney Davis
Member of Congress

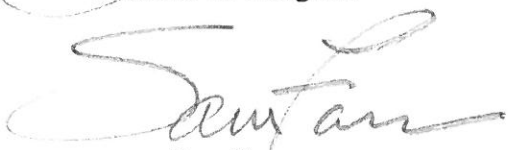
Ted Deutch
Member of Congress

William Enyart
Member of Congress

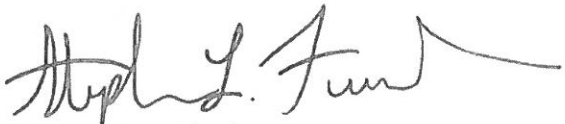


Anna Eshoo
Member of Congress

Blake Farenthold
Member of Congress



Sam Farr
Member of Congress



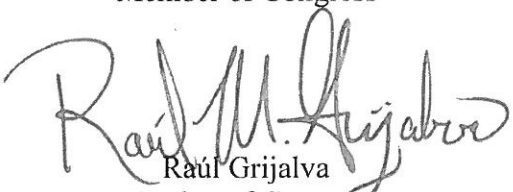
Stephen Fincher
Member of Congress

Bill Flores
Member of Congress

Joe Garcia
Member of Congress

Bob Gibbs
Member of Congress

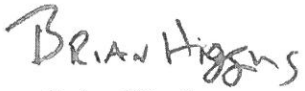
Gene Green
Member of Congress



Raúl Grijalva
Member of Congress

Brett Guthrie
Member of Congress

Joe Heck
Member of Congress

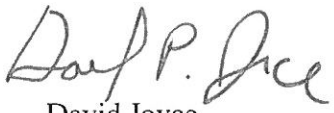


Brian Higgins
Member of Congress

Michael Honda
Member of Congress

Lynn Jenkins
Member of Congress

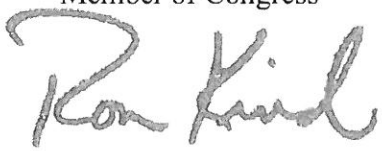
Bill Johnson
Member of Congress



David Joyce
Member of Congress

Marcy Kaptur
Member of Congress

Mike Kelly
Member of Congress



Ron Kind
Member of Congress

Adam Kinzinger
Member of Congress

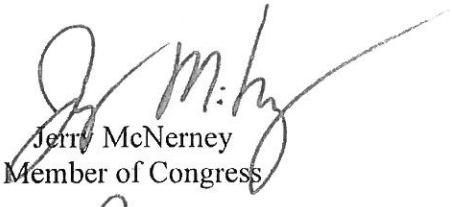
Ann Kirkpatrick
Member of Congress

Leonard Lance
Member of Congress

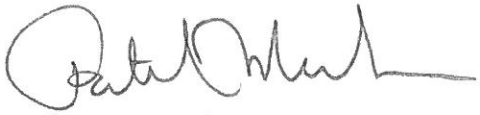
Michelle Lujan Grisham
Member of Congress

Ben Ray Lujan
Member of Congress

Betty McCollum
Member of Congress

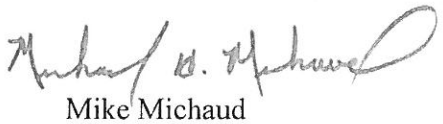


Jerry McNerney
Member of Congress

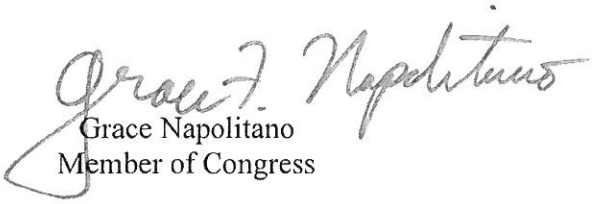


Pat Meehan
Member of Congress

Luke Messer
Member of Congress

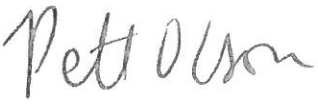


Mike Michaud
Member of Congress



Grace Napolitano
Member of Congress

Kristi Noem
Member of Congress

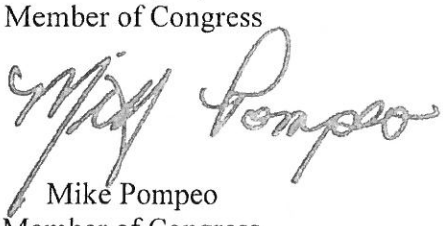


Pete Olson
Member of Congress

Erik Paulsen
Member of Congress

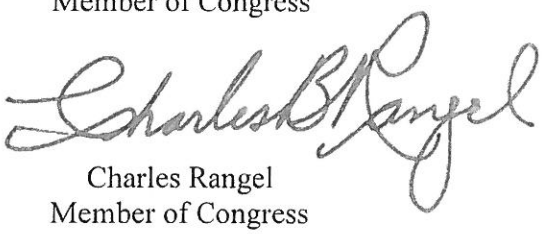
Donald Payne, Jr.
Member of Congress

Mark Pocan
Member of Congress

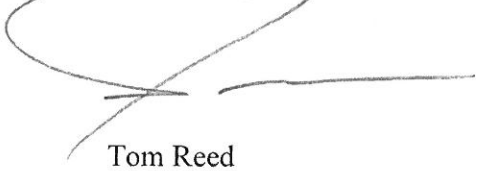


Mike Pompeo
Member of Congress

Tom Price
Member of Congress

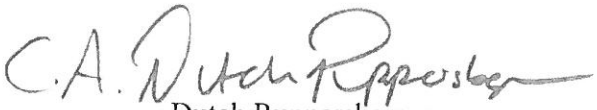


Charles Rangel
Member of Congress

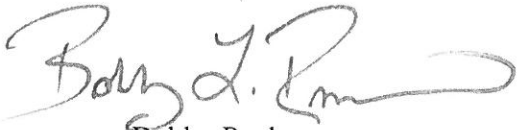


Tom Reed
Member of Congress

Dennis A. Ross
Member of Congress



Dutch Ruppersberger
Member of Congress



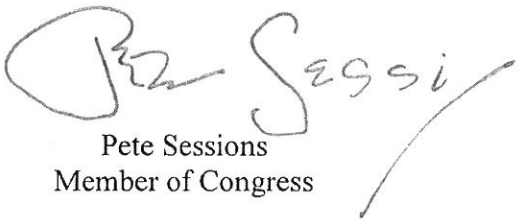
Bobby Rush
Member of Congress

Steve Scalise
Member of Congress

Brad Schneider
Member of Congress

Aaron Schock
Member of Congress

Kurt Schrader
Member of Congress

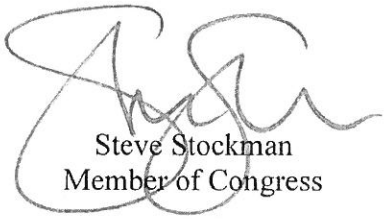


Pete Sessions
Member of Congress

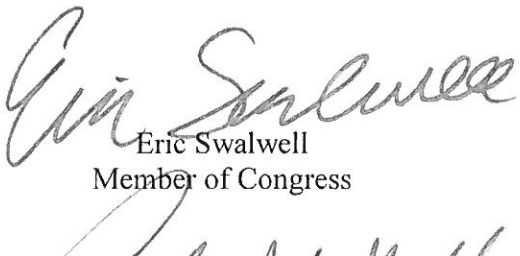
John Shimkus
Member of Congress

Adam Smith
Member of Congress

Jackie Speier
Member of Congress

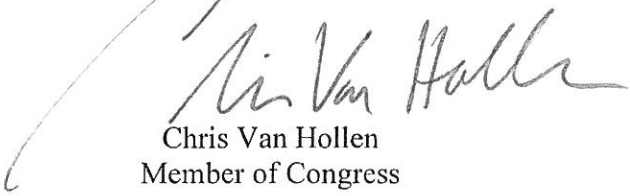


Steve Stockman
Member of Congress



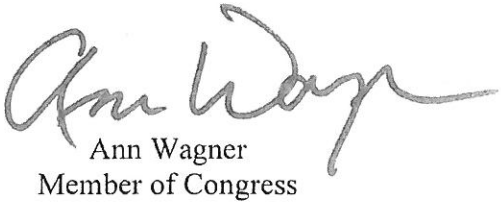
Eric Swalwell
Member of Congress

Pat Tiberi
Member of Congress

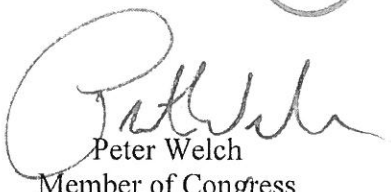


Chris Van Hollen
Member of Congress

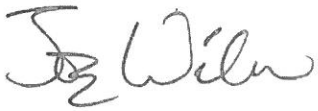
Marc Veasey
Member of Congress



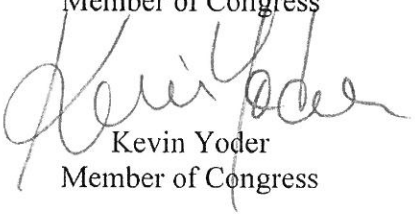
Ann Wagner
Member of Congress



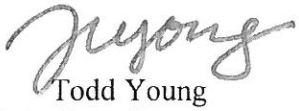
Peter Welch
Member of Congress



Joe Wilson
Member of Congress



Kevin Yoder
Member of Congress



Todd Young
Member of Congress

Joe Barton
Member of Congress

Phil Gingrey
Member of Congress

Lee Terry
Member of Congress

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

WASHINGTON, DC OFFICE:
100 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX: (202) 225-4656

DISTRICT OFFICE:
85-C MILL STREET, SUITE 300
ROSWELL, GA 30075
(770) 998-0049
FAX: (770) 565-7570

www.house.gov/tomprice

Congress of the United States
House of Representatives

COMMITTEE ON WAYS AND MEANS

COMMITTEE ON THE BUDGET
VICE CHAIRMAN

COMMITTEE ON EDUCATION AND THE WORKFORCE

DEPUTY WHIP

March 19, 2014

VIA FACSIMILE

Mr. Stephen R. Mason
Assistant Commissioner for Legislation
Food and Drug Administration
US Department of Health and Human Services
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Mr. Mason:

My constituent, Mr. Stanley Godfrey, has contacted me regarding a problem he is having. Please find enclosed a copy of his correspondence.

Please verify the status of this situation and provide me with any information that I may use to properly assist my constituent. Please forward all correspondence to Tina McIntosh in my District Office at 85-C Mill Street, Suite 300, Roswell, GA 30075. She may also be reached by email at tina.mcintosh2@mail.house.gov or by phone at 770-998-0049.

Thank you in advance for your time and assistance in this matter. I look forward to hearing from you soon.

Yours truly,

2014-2453

Tom Price, M.D.
Member of Congress

TP/tm

There are 1 page(s) to this fax. ***Confidential Notice: This facsimile, including any attachments, is for the sole use of the intended recipient (s) and may contain confidential and privileged information. Any unauthorized review; use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender immediately and destroy all copies of the original message.***

PRINTED ON RECYCLED PAPER

E-Mail Viewer

Message | Details | Attachments | Headers | Source

HTML

From: "webforms@hhws-www1.house.gov" <webforms@hhws-www1.house.gov>
Date: 3/17/2014 4:35:14 PM
To: "ga06ima@mail.house.gov" <ga06ima@mail.house.gov>
Cc:
Subject: WWWFormMail OTHER

<APP>CUSTOM
<PREFIX>(770) 623-3952</PREFIX>
<First>Stanley</First>
<Middle></Middle>
<Last>Godfrey</LAST>
<SUFFIX></SUFFIX>
<ADDR(b) (6)
<ADDR
<CITY>
<STAT
<ZIP>3
<EMAI
<PHON
<ISSUE>Need Legible Expiration Dates on Food Products</ISSUE>
<MSG>Representative Price,

Have you ever tried to locate and then read the "Use By" on a product? I'm 62 and even with glasses find it almost impossible. I'm asking you to consider legislation which requires a vendor to make this label more visible on their products.

Thank You

**********Additional Information:**********
X-URL: https://tomprice.house.gov/htbin/formproc_za/zip-auth.txt&form=/contact-me/email-me-zip-authenticated&nobase&fpGetVer=2
User Agent: Mozilla/5.0 (Macintosh; Intel Mac OS X 10_9_2) AppleWebKit/537.74.9 (KHTML, like Gecko) Version/7.0.2 Safari/537.74.9
X-Remote-Host: 99.172.118.91 X_FORWARDED_FOR:99.172.118.91, 72.246.247.23, 107.14.43.61
DATE: 03/17/2014 16:17
TRANS ID: 1403177863114681
</MSG>
</APP>

Close

Jordan, Lillian T

From: McIntosh, Tina <Tina.McIntosh2@mail.house.gov>
Sent: Wednesday, February 26, 2014 1:13 PM
To: Jordan, Lillian T
Subject: b(6) Personal Privacy
Attachments: Fax.pdf

Lillian,

Please find attached the Privacy Release from b(6) Personal Privacy regarding some b(6) Personal Privacy it as per FDA regulations state must be done.

Any assistance you can provide would be greatly appreciated. Please let me know if any additional information is needed.

Have a Blessed day-

Tina

Tina McIntosh
Director of Constituent Services/Office Manager
Office of Congressman Tom Price, M.D.
85-C Mill Street, Suite 300
Roswell, GA 30075
770-998-0049
770-998-0050 fax

***Confidential Notice:** This e-mail message, including any attachments, is for the sole use of the intended recipient (s) and may contain confidential and privileged information. Any unauthorized review; use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.*

2014-2185

PRIVACY RELEASE FORM
Congressman Tom Price, M.D.
Sixth Congressional District of Georgia

Date: 2/26/14

Name: (Mr./Mrs./Ms.) b(6) Personal Privacy

b(6) Personal Privacy

Street Address City/State/Zip

( ) b(6) Personal Privacy

Home phone Work/Cell Phone

Social Security # b(6) Personal Privacy **and/or A#, VA#, etc.** _____

Date of Birth b(6) Personal Privacy **AGENCY Involved** FDA

Spouse/ Other Contact b(6) Personal Privacy

Please provide a brief explanation of your situation with the above agency and specify how our office may be of assistance. Continue on another sheet if necessary. Send *photocopies only* of any documents you may have to support your claim. It is important for you to retain the originals for your files.

Our practice b(6) Personal Privacy They b(6) Personal Privacy required by the FDA to support them through 2017. I need to identify someone at FDA who works with b(6) Personal Privacy b(6) Personal Privacy does not respond to email or calls.

Privacy Act Release

I hereby authorize Congressman Tom Price and those acting in his behalf, in order to attempt to be of assistance to me, b(6) Personal Privacy laws and regulations, information pertaining specifically to this matter.

SIGN HERE b(6) Personal Privacy **DATE** 2/26/14

Once complete, please return it to:

Office of Congressman Tom Price, M.D.
85-C Mill Street, Suite 300
Roswell, GA 30075
770-998-0050 Fax

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tom Price, M.D.
House of Representatives
Washington, D.C. 20515-1006

APR 11 2012

Dear Dr. Price:

Thank you for your letter of February 16, 2012, on behalf of your constituent, Ms. Karen Morris of Roswell, Georgia, regarding her concerns about the regulation of New Dietary Ingredients (NDI) in dietary supplements by the Food and Drug Administration (FDA or the Agency). Specifically, Ms. Morris's concern is with the recent draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," which was published by FDA in July 2011.

The requirement for dietary supplement manufacturers to submit NDI notifications to FDA was established by the Dietary Supplement Health and Education Act of 1994 (DSHEA) and is codified in section 413 of the Federal Food, Drug, and Cosmetic Act (the Act). DSHEA requires, among other things, that a notification contain information, including any citation to published articles, that is the basis on which the manufacturer or distributor of the NDI or dietary supplement has concluded that the dietary supplement containing the NDI will be reasonably expected to be safe.

FDA issued the draft guidance in response to a statutory mandate in section 113(b) of the Food Safety Modernization Act of 2011 (FSMA).[1] Although FSMA required FDA to issue guidance on NDI issues, neither the draft guidance nor a final guidance, if adopted, creates any new rights or binding requirements with regard to NDIs; it only indicates the FDA's current thinking on the subject.

Guidance documents are not enforceable rules or requirements. The purpose of issuing guidance on NDI issues is to communicate to the dietary supplement industry FDA's interpretation of the NDI provisions of DSHEA and the Agency's recommendations on meeting the statutory requirements for NDIs. In other words, the guidance provides information and various tools to help companies meet their statutory obligation to ensure that dietary supplements containing NDIs are safe. We want to assure you that we appreciate and share your concern that the guidance be consistent with the letter and intent of DSHEA.

The draft guidance is intended to give manufacturers and distributors of dietary supplements containing NDIs information and recommendations to help them decide when an NDI notification is necessary and to improve the quality and quantity of NDI

[1] Pub. L. No. 111-353, 124 Stat. 3885, 3921.

notifications. There are an estimated 55,600 dietary supplement products on the U.S. market, and the Agency has received approximately 700 NDI notifications since we began reviewing such notifications approximately 16 years ago. Additionally, the Institute of Medicine has estimated that 1,000 new dietary supplements are introduced to the market each year. These figures, coupled with recent concern by both FDA and industry regarding the presence of undeclared active ingredients in products marketed as dietary supplements, highlight the necessity for marketers of dietary supplements to submit NDI notifications as an important preventive control to ensure that consumers are not exposed to potential unnecessary health risks in the form of new ingredients with unknown safety profiles.

The draft guidance answers frequently asked questions about NDI notifications and related issues. It also makes recommendations to industry for preparing better NDI notifications. Therefore, we believe and intend that the draft guidance may reduce the need for FDA to issue objection letters to dietary supplement manufacturers.

FDA welcomes comments on provisions that stakeholders find unclear or believe are contrary to the Act. The Agency opened a comment period on the draft guidance for stakeholders and other interested parties, which closed on December 2, 2011 (docket number FDA-2011-D-0376). FDA is currently in the process of reviewing the many comments received before publishing a final guidance document.

It has become clear from the comments we have received and from discussions that FDA has had with industry groups over the past few months that there is considerable misunderstanding about FDA's intent in parts of the guidance and that in some cases our views were not stated clearly. We intend to clarify those issues at such time as a final guidance is issued.

Leadership of FDA's Center for Food Safety and Applied Nutrition, which oversees dietary supplement safety, met with several dietary supplement trade associations in February. We believe these meetings were valuable in clarifying FDA's intent in parts of the guidance and in understanding the concerns of the industry.

Thank you, again, for contacting us concerning this matter. If you have any further questions or concerns, please let us know.

Sincerely,

Phil Brandt for

Kristina Harper
Supervisory Congressional
Affairs Specialist

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

WASHINGTON, DC OFFICE:
403 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX: (202) 225-4656

DISTRICT OFFICES
3730 ROSWELL ROAD, SUITE 50
MARIETTA, GA 30062
(770) 565-4990
FAX: (770) 565-7570

100 NORTH STREET, SUITE 150
CANTON, GA 30114
(678) 493-6176

www.house.gov/tomprice

Congress of the United States
House of Representatives

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON HUMAN RESOURCES

COMMITTEE ON THE BUDGET

REPUBLICAN POLICY COMMITTEE
CHAIRMAN

DEPUTY WHIP

February 16, 2012

Mr. Stephen R. Mason
Assistant Commissioner for Legislation
Food and Drug Administration
US Department of Health and Human Services
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Mr. Mason:

A few weeks ago I contacted your office regarding Ms. Karen Morris. In reviewing my case files, I have discovered that I have not yet heard from your office regarding this particular matter.

I would appreciate it if you would review this case and respond to my constituent's concerns. Attached is a copy of my previous correspondence for your convenience.

If my office can provide any additional information, please do not hesitate to contact Tina McIntosh in my district office at 770-565-4990 or by email to tina.mcintosh2@mail.house.gov. I look forward to hearing from you soon.

Yours truly,

Tom Price, M.D.
Member of Congress

TP/tm

2012-1593

PRINTED ON RECYCLED PAPER

November 17, 2011

Mr. Stephen R. Mason
Assistant Commissioner for Legislation
Food and Drug Administration
US Department of Health and Human Services
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Mr. Mason:

My constituent, Ms. Karen Morris, has contacted me regarding a problem she is having. Please find enclosed a copy of her correspondence.

Please verify the status of this situation and provide me with any information that I may use to properly assist my constituent. Please forward all correspondence to the attention of Tina McIntosh in my Marietta District Office at 3730 Roswell Rd., Suite 50, Marietta, GA 30062. You may also contact her by phone at 770-565-4990, by facsimile at 770-565-7570, or by email to tina.mcintosh2@mail.house.gov.

Thank you in advance for your time and assistance in this matter. I look forward to hearing from you soon.

Yours truly,

Copy

Tom Price, M.D.
Member of Congress

TP/tm

November 3, 2011

Congressman Tom Price
403 Cannon House Office Building
Washington, DC 20510

Dear Representative:

My name is Karen Morris and I am a resident of the State of Georgia. I am deeply concerned about the Food and Drug Administrations (FDA) recently issued Draft Guidance document entitled New Dietary Ingredient Notifications and Related Issues.

Dietary supplements are an important part of my and my family's health maintenance routine. We consider access to affordable supplements to be a crucial part of our healthy lifestyle to mitigate the need for expensive medical procedures and promote good health to improve and extend our lives.

The FDA's issuance of its draft Guidance is very troubling because it signals a dramatic shift in its policy towards dietary supplements and I believe the FDA is attempting to establish a system of pre-market approval for these products. It has been nearly two decades since enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Back then the industry was in a fight for its life because of the FDA's insistence on using the vague standards in the food additive provisions as a means of removing from the marketplace ingredients it disapproved of even for reasons unrelated to safety. The FDA abused its authority and through a lot of hard work we won the battle.

Now we find ourselves having to defend the very existence of this industry once again. While DSHEA purposely had drafted in it a sensible and reasonable system by which the agency must be notified of the marketing of a new dietary ingredient and the basis for which the manufacturer believes that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe, the FDA has taken positions in its draft Guidance that indicate that it intends to treat dietary ingredients as food additives once again. Even more disturbing is FDA's insistence that any change in the formula of a dietary supplement that contains a new dietary ingredient will require the submission of a NDI notification. The agency has announced its intention that all dietary supplements containing new dietary ingredients be pre-cleared by the FDA. This is contrary to Congressional intent in passing DSHEA. If the FDA deems it necessary to make such drastic changes in the way dietary supplements are regulated, I think it should have to go through Congress. This is a bureaucracy that is out of control. It would needlessly restrict access to safe dietary supplement products and is a job killer for the dietary supplement industry.

I am requesting that you do everything in your power to stop the FDA from enforcing DSHEA in a manner that is contrary to Congressional intent and in a manner that has the potential to destroy an industry that has brought so much good to so many people.

Thank you.

Sincerely,

Karen Morris

(b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tom Price
House of Representatives
Washington, D.C. 20515-1006

APR 08 2011

Dear Mr. Price:

Thank you for your letter of March 10, 2011, cosigned by fifteen of your colleagues, urging that the Food and Drug Administration (FDA or the Agency) review and update its current fish and shellfish consumption advice, referred to in your letter as the "2004 advisory," for women who may become pregnant, women who are pregnant, nursing mothers and young children. This advice was issued in 2004 by FDA in conjunction with the U.S. Environmental Protection Agency (EPA).

In your letter, you express concern that the advice communicates an overly risk-averse, precautionary principle that has led to unhealthy reductions in seafood consumption among pregnant women. You request that we inform you of our plans for updating the 2004 advice to be consistent with the 2010 Dietary Guidelines for Americans issued by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS).

The fish consumption advice issued by FDA and EPA was designed to protect developing fetuses and young children from neurodevelopmental harm due to excessive exposure to methylmercury in fish. FDA first published fish consumption advice in the mid-1990s and updated it in 2001 and 2004 in response to new information and analyses.

It is essential that this advice contains clear and balanced information that will help consumers protect against the neurotoxic effects of methylmercury in developing fetuses and young children while, at the same time, helping them to obtain the maximum neurodevelopmental benefits that fish can provide. Toward that end, FDA has been engaged in a quantitative risk and benefit assessment for commercial fish that takes into account the research germane to the subject, including research published since 2004. The 2010 Dietary Guidelines for Americans were influenced by this body of research.

The FDA risk and benefit assessment was published as a draft document[1] in January 2009. It has been under further development since that time to take into account comments from the public, other government agencies, and scientific peer reviewers, as well as to incorporate additional risk and benefit modeling as recommended by many commenters. As we complete this assessment, we will continue to consult with other

[1] *http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogens Contaminants/Methylmercury/ucm088758.htm*

scientific agencies and the public through a process in which all views can be thoroughly considered. The completed risk/benefit assessment will assist FDA in evaluating the 2004 advice and determining if updates or modifications to the advice are appropriate based on the best science available. We hope to be able to resolve these questions this year.

Thank you again for contacting us concerning this matter. If you have further questions or concerns, please let us know. The same letter has been sent to your cosigners.

Sincerely,

Jeanne Ireland

Jeanne Ireland
Assistant Commissioner
for Legislation

Congress of the United States
Washington, DC 20515

March 10, 2011

Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD, 20993

Dear Dr. Hamburg,

As you may know, on January 31, 2011, the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) released the 2010 Dietary Guidelines for Americans (DGAs). The latest DGAs are "[b]ased on the most recent scientific evidence review" and now become the new foundation for federal nutrition policy and education. In light of these new dietary guidelines, we are writing to ask the Food and Drug Administration (FDA) to consider modifications to its 2004 advice about eating seafood for women who are or might become pregnant, nursing mothers and young children, so that they might be consistent with the overall health messages contained in the DGAs.

Seafood contains healthy nutrients like omega-3s and protein with less than a couple hundred calories per 4-ounce serving. In addition to protecting heart health, omega-3s make up a major part of the brain. Recent studies show babies of moms who eat seafood 2-3 times each week during pregnancy and breastfeeding have better eye and brain development than babies of moms who limit or avoid fish.

USDA and HHS state that "the benefits of consuming seafood far outweigh the risks, even for pregnant women." The guidance emphasizes "the nutritional value of seafood is of particular importance during fetal growth and development, as well as in early infancy and childhood" and recommends "that women who are pregnant or breast-feeding consume at least 8 and up to 12 ounces of a variety of seafood per week." The guidance goes on to recommend that obstetricians and pediatricians "provide guidance to women who are pregnant or breastfeeding to help them make healthy food choices that include seafood."

These health benefits are balanced against concerns expressed in the 2004 FDA advice that certain seafood contains higher levels of methyl mercury that pose risks to an unborn baby or a young child's developing nervous system. While weighing these considerations, the new DGAs note a consistent body of evidence that "the health benefits from consuming a variety of seafood in the amounts recommended outweigh the health risks associated with methyl mercury."

We are pleased that in many ways the new Dietary Guidelines track the 2004 EPA/FDA advice. For example, they both note that fish and shellfish are an important part of a healthy diet and women and children should include appropriate amounts of seafood in their diets. The new DGAs and the 2004 advice both caution against eating four certain fish species containing higher

PRINTED ON RECYCLED PAPER

2011-2160

levels of mercury, identify fish low in mercury to include in a healthy diet, and advise women who are pregnant or breast feeding to consume up to 12 ounces of seafood per week.

However, we are concerned that the 2004 FDA advice about eating seafood did not strike the right balance of promoting the benefits of seafood while limiting intake of certain higher-mercury species. Since the FDA advice first came out in 2004, it has been widely misinterpreted as a warning for all Americans, and pregnant women in particular, to simply avoid seafood based on concerns over mercury. As a result, pregnant women have reduced their seafood consumption to an average of only 1.89 oz per week according to a 2008 FDA survey. This is less than one-fourth than the *minimum* amount of seafood now being recommended during pregnancy in the 2010 DGAs.

The DGAs emphasize the benefits babies gain when their moms eat at least eight ounces of seafood per week during pregnancy. This is an important health message that was lost in the 2004 advice. We encourage FDA to take the opportunity of the new DGAs to revise its 2004 advice to strike the proper messaging balance and support the findings of the DGAs emphasizing the net or overall health benefits of seafood consumption. When the federal government speaks in different voices about nutrition and food safety, it prevents the DGAs from achieving the full health benefits possible.

We ask you to create consistency with the current FDA advice on seafood and the DGAs as expeditiously as possible in order that federal agencies can speak in one voice to ensure that mothers and their health care providers receive the best nutrition advice for our next generation.

Sincerely,

Phil Gingrey
Member of Congress

Debbie Wasserman Schultz
Member of Congress

Charles Boustany
Member of Congress

Michael Burgess
Member of Congress

Bill Cassidy
Member of Congress

John Dingell
Member of Congress

John Fleming
Member of Congress

Barney Frank
Member of Congress

Raul Grijalva
Member of Congress

Jack Kingston
Member of Congress

Sue Myrick
Member of Congress

Tom Price
Member of Congress

Laura Richardson
Member of Congress

Peter Roskam
Member of Congress

David Scott
Member of Congress

Lynn Westmoreland
Member of Congress

CC: Honorable Kathleen Sebelius, Secretary of the Health and Human Services
Honorable Tom Vilsack, Secretary of the U.S. Department of Agriculture
Melody Barnes, White House Domestic Policy Council
Julie Moreno, White House Domestic Policy Council
Bruce Reed, Office of the Vice President Joe Biden
Robin Schepper, Office of the First Lady Michelle Obama

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DEC 20 2010

Ms. Katherine Green
(b) (6)
[redacted]

Dear Ms. Green:

Thank you for your letter of September 29, 2010, to Representative Tom Price, regarding actions taken by the Food and Drug Administration (FDA or the Agency) involving Morningland Dairy. Representative Price has asked us to respond directly to you.

By way of background, Morningland Dairy of Mountain View, Missouri, issued a voluntary nationwide recall for all cheese labeled as "Morningland Dairy" and "Ozark Hill Farms" due to potential contamination with *Listeria monocytogenes* (*L. mono*) and *Staphylococcus aureus* (*S. aureus*) on August 30, 2010, subsequent to regulatory sampling by the California Department of Food and Agriculture. Consumption of food contaminated with *Listeria monocytogenes* can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms, such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *L. mono* infection can cause miscarriages and stillbirths among pregnant women. *Staphylococcus aureus* is a bacteria that usually causes rapid food poisoning symptoms, including nausea, vomiting, retching, abdominal cramping and prostration. In more severe cases, headache, muscle cramping and transient changes in blood pressure and pulse may occur.

FDA inspected Morningland Dairy from August 30, 2010, to September 16, 2010, following this recall. Objectionable conditions were found and documented by FDA, including:

1. Failure to manufacture and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms,
2. failure to perform microbial testing where necessary, and
3. failure to transport finished food under conditions that would protect against microbial contamination.

The Missouri Department of Health and Senior Services sampled embargoed products which were subject to the recall and found *L. mono.* and *S. aureus* contaminants in some of the samples. After this discovery, that agency, not FDA, ordered the destruction of the embargoed products as a safety precaution.

We assure you that FDA is not attempting to put Morningland Dairy out of business. The

Agency will continue to work with the firm to verify that the appropriate corrective actions have been taken to prevent contamination.

Thank you again for contacting Representative Price concerning this matter. We hope this information is helpful to you.

Sincerely,

Phil Broadbent for

Kristina Harper
Supervisory Congressional
Affairs Specialist

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

WASHINGTON, DC OFFICE
424 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX (202) 225-4656

DISTRICT OFFICES
3730 ROSWELL ROAD, SUITE 50
MARIETTA, GA 30062
(770) 565-4990
FAX: (770) 565-7570

100 NORTH STREET, SUITE 150
CANTON, GA 30114
(678) 493-6176

www.house.gov/tomprice

Congress of the United States
House of Representatives

COMMITTEE ON
FINANCIAL SERVICES
SUBCOMMITTEES:
CAPITAL MARKETS
DEPUTY RANKING MEMBER
DOMESTIC MONETARY POLICY AND
TECHNOLOGY
FINANCIAL INSTITUTIONS AND
CONSUMER CREDIT

COMMITTEE ON
EDUCATION AND LABOR
SUBCOMMITTEES
WORKFORCE PROTECTIONS
HEALTH, EMPLOYMENT, LABOR AND PENSIONS
RANKING MEMBER

REPUBLICAN STUDY COMMITTEE
CHAIRMAN

DEPUTY WHIP

October 6, 2010

Mr. Stephen R. Mason
Assistant Commissioner for Legislation
Food and Drug Administration
US Department of Health and Human Services
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Mr. Mason:

One of my constituents has contacted me regarding a matter in which I believe you could be helpful.

Please find enclosed a copy the correspondence I received from Ms. Katherine Green. I would appreciate your responding directly to Ms. Green.

Thank you very much for your consideration and assistance in this matter.

Yours truly,

Tom Price, M.D.
Member of Congress

TP/tm

PRINTED ON RECYCLED PAPER

2010 - 7285

E-Mail Viewer

Message | Details | Attachments | Headers | Source

HTML

From: "Write your representative" <writerep@heoc-t2kwww1.house.gov>
Date: 9/30/2010 5:01:05 PM
To: "ga06ima" <ga06ima@mail.house.gov>
Cc:
Subject: WriteRep Responses

DATE: September 30, 2010 4:31 PM
NAM(b) (6)
ADD
ADD
ADD
CIT
STA
ZIP
PHO
EMA
msg:

I am a Georgia resident. I am writing because I am appalled by what is happening to a local famer whose product I have eaten for years. This farmer is not located in Georgia but the precedent being set by the FDA effects all Americans.

Morning land Dairy is a small family owned farm that has been in business for 30 years making the finest quality raw milk cheese. They care about the land and they care about sustainable agriculture and they care about creating safe quality food.

In the 30 years they have been in business there has never been a sickness caused by their food. They take great care in creating food in a clean environment. Because they are small they can take extra precautions to ensure they create only the best products. This is something cannot be duplicated by large industrial food producers. I feed Morningland cheese to my children without a concern. I trust them. They are quality famers and good people. Can you say the people who make your cheese are good people....do you even know who makes your food? I imagine like most Americans you might eat food that is mass produced in factories....I want more for my family and I seek out locally grown sustainable foods. I avoid processed foods and JUNK food that is perfectly legal and eaten by Americans everyday.

I feel Morningland farm is being bullied by the FDA. I understand that that the big milk lobby is waging an assault on Raw milk and Raw milk products. I am not here to debate the health principals of raw dairy. I want to tell you how concerning it is to me that this dairy was singled out and is now being put out of business by the FDA under totally false pretenses. Cheese from Morningland dairy was recently seized in a raid on a health-food store in California. REALLY Sir? A raid on a health food store? That is pretty ridiculous. Maybe the FDA should raid a 7/11 convenience store because goodness knows the junk they sell there is way more deleterious to your health that what they sell at a health-food store. But I digress.

The Morningland cheese that was allegedly tested in California had been in California for well over 4 months, and no-one seems to know how it was handled for 7 weeks between being placed in an un-iced cooler (when it was confiscated) and when it was allegedly tested. By California statutes, confiscated food is supposed to be tested right away, and that the dairy was supposed to have their own sample to test, but neither of these things was done. The FDA did test the Morningland cheese plant and milk barn by taking 100 swabs from equipment, walls, the floor, etc., and having them tested, and they found nothing. But now an inspector has told Morningland farm that they must destroy ALL of the 1000's of pounds of cheese they still have in order to get back into business. Morningland offered to, before selling any of their cheese, to have it tested, batch by batch, to confirm that it is good, but they were told that the cheese would still be 'suspect'.

This family farm will be financially devastated by having all their cheese destroyed. They will not be able to start over. I believe the FDA knows this and they are willing to destroy a family farms over false or unproven allegations to "show" other raw dairy producers that they better not "Mess" with the FDA. I think this is GARGABE POLICY! The FDA does far more harm than good in our country. I feel strongly that they are pawns of big agribusiness, but my suspicions aside, when the FDA can for all practical purposes shut down a family farm with no actual proof of food contamination... No famer is safe. Where can I buy healthy food for my family? This issue is very important to me. It affects my daily life. I will watch closely how my local senators and congressmen vote to support small farms and whether you feel that The FDA should have unfettered ability to shut down innocent famers without reasonable proof of contamination.

Finally I ask why drugs, genetically modified foods, big corporations who are massive polluters, and dairies that pump animals with hormones and antibiotics, etc. have government approval, while small companies like Morningland who try hard to make a healthful product from healthy animals, and who have harmed no-one, can be shut down as the result of one obviously faulty test. How can it be that the government has the right to choose what we eat?

With Great Concern,

Katherine Green
(b) (6)
[redacted]

Close

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Tom Price, M.D.
Member, U.S. House of Representatives
3730 Roswell Road, Suite 50
Marietta, GA 30062

MAY 11 2010

Dear Dr. Price:

Thank you for your letter of March 26, 2010, on behalf of your constituent, Mr. Marcus Geier of Roswell, Georgia, who has expressed concern about a Citizen Petition submitted to the Food and Drug Administration (FDA or the Agency); specifically, Medicure Pharma's request to ban Pyridoxal 5'-phosphate (Vitamin B6) as a dietary supplement.

FDA's regulations governing Citizen Petitions are contained in Title 21, *Code of Federal Regulations* (CFR), sections 10.25(a) and 10.30. Under these regulations, any interested party may petition the Agency to initiate an administrative proceeding to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. FDA places each Citizen Petition it receives in a public docket to enable interested members of the public to comment on the requested actions or to submit information to FDA on the requested action for FDA's consideration. FDA then considers both the information in the petition and the comments, and then determines whether to take the requested actions. Information on how to submit a comment to a petition docket can be found on our Web site at *http://www.fda.gov/ohrms/dockets/FDMS/SubmissionInformation.htm.*

The Citizen Petition your constituent is referring to, the Medicure petition, was submitted by the firm Medicure Pharma and received by FDA on November 30, 2007. The petition requests that FDA take several actions that would preclude the marketing of the substance Pyridoxal 5'-phosphate as a dietary supplement. While FDA responded to another Citizen Petition that raised similar legal and scientific issues for a different substance, this petition raises several novel and complex legal and scientific issues related to the regulatory status of this substance under the Federal Food, Drug, and Cosmetic Act that FDA had not previously considered.

FDA has not completed its evaluation of the issues raised in the petition and comments submitted to the docket established for the petition that bear on Pyridoxal 5'-phosphate's status under the Act, because of competing priorities and limited Agency resources. Your constituent can access the Medicure petition and comments in the docket for the petition on the following Web site: *http://www.regulations.gov/search/index.jsp* (docket number FDA-2007-P-0410).

Thank you again for contacting us concerning this matter. If you have any further questions or concerns, please let us know.

Sincerely,

Phil Bradbet for

Jeanne Ireland
Assistant Commissioner
for Legislation

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

WASHINGTON, DC OFFICE:
424 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX: (202) 225-4656

DISTRICT OFFICE:
3730 ROSWELL ROAD, SUITE 50
MARIETTA, GA 30062
(770) 565-4990
FAX: (770) 565-7570

www.house.gov/tomprice

Congress of the United States
House of Representatives

COMMITTEE ON
FINANCIAL SERVICES
SUBCOMMITTEES:
FINANCIAL INSTITUTIONS
DEPUTY RANKING MEMBER
DOMESTIC AND INTERNATIONAL POLICY
OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON
EDUCATION AND LABOR
SUBCOMMITTEES:
WORKFORCE PROTECTION
HEALTH, EMPLOYMENT, LABOR AND PENSIONS

POLICY COMMITTEE

DEPUTY WHIP

March 26, 2010

Mr. Stephen R. Mason
Assistant Commissioner for Legislation
Food and Drug Administration
US Department of Health and Human Services
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Mr. Mason:

My constituent, Mr. Marcus Geier, has contacted me regarding a problem he is having. Please find enclosed a copy of his correspondence.

Please verify the status of this situation and provide me with any information that I may use to properly assist my constituent. Please forward all correspondence to the attention of Tina McIntosh in my Marietta District Office at 3730 Roswell Rd., Suite 50, Marietta, GA 30062. You may also contact her by phone at 770-565-4839, by facsimile at 770-565-7570, or by email to tina.mcintosh2@mail.house.gov.

Thank you in advance for your time and assistance in this matter. I look forward to hearing from you soon.

Yours truly,

Tom Price, M.D.
Member of Congress

TP/tm

PRINTED ON RECYCLED PAPER

2010 - 2287

2287
2010 - ~~3873~~

E-Mail Viewer

Message | Details | Attachments | Headers | Source

HTML

From: "drm2g2@gmail.com" <drm2g2@gmail.com>
Date: 3/1/2010 5:01:28 PM
To: "ga06ima@mail.house.gov" <ga06ima@mail.house.gov>
Cc:
Subject: Message for Tom Price -

<APP>CUSTOM
<PREFIX>Mr.</PREFIX>
<FIRST>Marcus</FIRST>
<MIDDLE></MIDDLE>
<LAST>Geier</LAST>
<SUFFIX></SUFFIX>
<ADD(6) (6)
<CIT
<STA
<ZIP>
<EMA
<MSG>This letter is to voice my concern over Medicure Pharma's Citizen's Petition Request to Ban Pyridoxal 5'-Phosphate as a Dietary Supplement (FDA-2007P-0410).

I request that FDA reject this request and that Congress address this disturbing trend of drug companies manipulating the system and FDA.

Medicure has requested that the agency ban the marketing of dietary supplements containing pyridoxal 5'-phosphate (P5P) because Medicure has a drug in development whose active ingredient is P5P. Medicure suggests that P5P is a new dietary ingredient, which is subject to pre-market approval requirements. However, within their own documents, Medicure admits that P5P is a naturally occurring molecule part of the Vitamin B6 family. P5P has in fact been a part of the human diet well before the 1994 passage of the Dietary Supplement Health and Education Act (DSHEA); therefore P5P is exempt from the New Dietary Ingredient pre-market notification requirements. I do not believe Medicure's drug development should restrict my access to P5P as a food supplement. Vitamin B6 is essential to good health.

As an American who includes dietary supplements in my approach to health and wellness, I request that you place the rights of consumers ahead of the desires of industry and protect my freedom to access dietary supplements. Please reject Medicure's attempt to manipulate the marketplace through their Citizen's Petitions.
</MSG>
</APP>

Close

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 23 2009

The Honorable Tom Price
Member, U.S. House of Representatives
3730 Roswell Road, Suite 50
Marietta, GA 30062

Dear Dr. Price:

Thank you for your letter of October 7, 2009, on behalf of your constituent, b(6) b(6) of b(6) Personal Privacy b(6) Personal alleges impropriety in the Food and Drug Administration's (FDA or the Agency) promulgation of a regulation classifying dental amalgam products under the Federal Food, Drug, and Cosmetic Act (FD& C Act or the Act).

The accusations b(6) Personal makes in her letter regarding the Commissioner's stock holdings are without merit. Further, the Commissioner did not "personally and substantially" participate in the dental amalgam rulemaking, and therefore, complied with applicable law. Anyone wishing to mount a serious challenge to the *substance* of the Agency's dental amalgam rule may take formal steps to do so.

With respect to the Commissioner's stock holdings, b(6) asserts that Dr. Hamburg still held stock in Henry Schein when she took office. This is incorrect. As FDA made clear in an August 18, 2009, statement to FDA Web view, on May 20, 2009, six days before taking office, the Commissioner sold all of her Henry Schein stock and exercised all in-the-money Schein stock options, and sold all the resultant shares. The Commissioner fully complied with her obligations under her ethics agreement to divest her vested stock options and stock in Henry Schein within 90 days of confirmation.

Second, the Commissioner did not "personally and substantially" participate in the dental amalgam rulemaking, in full compliance with her ethics agreement. The Commissioner did not take any action with respect to the rule before it was sent to the Department of Health and Human Services (HHS); the Commissioner did not take any action with respect to the draft rule before it went from HHS to the Office of Management and Budget (OMB); and the Commissioner did not take any action with respect to the draft rule while it was at OMB – or at any other time.

Thank you for contacting us concerning this matter. If we can be of further assistance, please let us know.

Sincerely,

for Jeanne Ireland
Assistant Commissioner
for Legislation

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

WASHINGTON, DC OFFICE:
424 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX: (202) 225-4656

DISTRICT OFFICE:
3730 ROSWELL ROAD, SUITE 50
MARIETTA, GA 30062
(770) 565-4990
FAX: (770) 565-7570

www.house.gov/tomprice

Congress of the United States
House of Representatives

COMMITTEE ON
FINANCIAL SERVICES
SUBCOMMITTEES:
FINANCIAL INSTITUTIONS
DEPUTY RANKING MEMBER
DOMESTIC AND INTERNATIONAL POLICY
OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON
EDUCATION AND LABOR
SUBCOMMITTEES:
WORKFORCE PROTECTION
HEALTH, EMPLOYMENT, LABOR AND PENSIONS

POLICY COMMITTEE

DEPUTY WHIP

October 7, 2009

Mr. Stephen R. Mason
Assistant Commissioner for Legislation
Food and Drug Administration
US Department of Health and Human Services
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Mr. Mason:

My constituent, b(6) Personal Privacy, has contacted me regarding a problem she is having. Please find enclosed a copy of her correspondence.

Please verify the status of this situation and provide me with any information that I may use to properly assist my constituent. Please forward all correspondence to the attention of Tina McIntosh in my Marietta District Office at 3730 Roswell Rd., Suite 50, Marietta, GA 30062. You may also contact her by phone at 770-565-4839, by facsimile at 770-565-7570, or by email to tina.mcintosh2@mail.house.gov.

Thank you in advance for your time and assistance in this matter. I look forward to hearing from you soon.

Yours truly,

Tom Price, M.D.
Member of Congress

TP/tm

2009-6906

PRINTED ON RECYCLED PAPER

From: "Write your representative" <writerep@heoc-t2kwww1.house.gov>
Date: 8/18/2009 1:01:17 PM
To: "ga06wyr@housemail.house.gov" <ga06wyr@housemail.house.gov>
Cc:
Subject: WriteRep Responses

DATE: August 18, 2009 10:56 AM
NAME:b(6) Personal
ADDR1:b(6) Personal
ADDR2:
ADDR3:
CITY: b(6)
STATE:b(6)
ZIP:b(6) Personal
PHONE: b(6) Personal
EMAIL: b(6) Personal
msg:
Dear Honorable Tom Price,

I am writing to you today because I no longer can be silent while seemingly FDA Commissioner Dr. Margaret Hamburg misuses her position at the FDA to keep the truth about the danger of amalgam fillings covered up for personal gain and consequently allowing a specifically susceptible group of our population – pregnant women and children – to be exposed to a toxin.

After having had my own health compromised through the toxic mercury in my amalgam fillings, I had all of my amalgam fillings removed and only after a long recovery time regained my health for the most part. Given my personal experience with this toxic substance, I often have asked myself why no one ever had warned me about it even when I was sick. I owe my recovery to my own investigation and action and can tell you that I am most frustrated with the FDA and allopathic medicine. Mercury is a toxin and I am asking you, honorable Tom Price, to help investigate in Congress why Americans are still left in the dark about this toxin in amalgam. Please make sure that FDA is no longer allowed to be more responsive to industry than to human health.

Please get answers from FDA Commissioner Margaret Hamburg regarding her stock deal with amalgam distributor Henry Schein, Inc. You may want to write to Dr. Hamburg and ask her to respond to the following questions:

(1) When Senator Enzi asked Dr. Hamburg a written question about the amalgam rule, why did she not then disclose the stock and say she would be disqualified from participating?
(2) Why, when taking office as Commissioner and holding at least $250,000 of stock (says the Wall Street Journal), did she not recuse herself from participating in the rule-making right away?
(3) On what date did Margaret Hamburg recuse herself?
(4) On what date did Margaret Hamburg sell her stock in Henry Schein?
(5) Since Commissioner Lester Crawford was forced out of office in 2005 for insider stock deals, why does Commissioner Hamburg believe this situation is different, and why does she believe she should remain in office?
(6) Why is the amalgam rule so incredibly favorable to Henry Schein, giving it the right to untrammeled amalgam sales without even a requirement that patients be told of the mercury in amalgam?

Below I have listed some points that should give you insight into the cover-up situation at FDA:

1. Margaret Hamburg served on the Schein board from 2003-2009, and owned $250,000 to $500,000 of Schein stock at the time she became Commissioner, according to the Wall Street Journal, after which she participated in the amalgam rule-making.

2. The FDA's new amalgam rule has neither contraindications for children and pregnant women (as even Wall Street had predicted), nor the lesser requirement of warnings for children and pregnant women. This is in spite of the fact that FDA concedes that children and the unborn are more susceptible to mercury's neurotoxic effects and that no study indicates that mercury amalgam does not pose these known neurological risks to this subpopulation. Mercury is a substance so toxic it can cause permanent neurological damage to children and kill unborn children. However,

3. As pointed out in he Watson-Burton letter to FDA, signed by 19 Members of Congress, http://www.toxicteeth.org/Mercury%20Letter%20to%20FDA-5-2009.pdf, most consumers and parents still don't know that amalgam is mainly mercury, due to its marketing under the deceptive term "silver fillings." FDA wants to keep the mercury unknown, and has gone so far as to justify marketing amalgam as "silver fillings" because of the color. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm To its extreme discredit, FDA under Commissioner Hamburg actually pulled off the website a warning that was prudently posted by Commissioner Von Eschenbach: "Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses."

4. The only beneficiary of this secretiveness is the amalgam industry, which raises even more concerns – from 2003-2009, Commissioner Margaret Hamburg served on the board of Henry Schein Inc., the largest distributor of dental

products (including amalgam). Owning the large amount of stock in a company she would regulate, she was given 90 days to sell it, but the amalgam rule had to be finished within her first 75 days (by July 28). Clearly Commissioner Hamburg had a conflict of interest that should have prevented her from participating in the amalgam rule. Instead, she indicated her intention to work with staff on the rule in response to Senator Enzi's question about amalgam during the confirmation process last May.

5. Certainly Dr. Hamburg was aware that in 2005 Commissioner Lester Crawford was fired, then pleaded guilty to a federal crime, for issues regarding his stock holdings. However, she proceeded to promise the Senate she would clean up FDA while telling Senator Enzi she would also work on a rule where she held a quarter million dollar of stock in the largest seller of that product.

6. After she became Commissioner, Dr. Hamburg failed to recuse herself immediately despite the obvious conflict. Concerned that the Schein connection would prevent a fair rule, Consumers for Dental Choice wrote Dr. Hamburg about her conflict in early June. That first letter was ignored, but after two more letters the FDA Chief Counsel told us that her participation was not "personal and substantial." FDA's culture of corruption is maintained by such loopholes – participating in rule-making to protect your stock value is OK if you participate just a little. Not until July 24, just four days before the rule issued, did he finally advise the counsel for Consumers for Dental Choice, at this midnight hour, that Dr. Hamburg had finally recused herself due to ethical issues. (The letters to FDA are at http://toxicteeth.org/FDA_letters_JunJul2009.pdf; the Chief Counsel's letters and the Wall St Journal article about the Commissioner's stock ownership are at http://toxicteeth.org/FDA_letters2_Jul2009.pdf)

7. Commissioner Hamburg's failure to remove herself from this rule from the start is particularly reprehensible in light of the well-publicized corruption at the Center for Devices and Radiological Health (which was charged with the amalgam rulemaking).Yesterday, Center for Devices Director Dan Schultz (part of the group that has given carte blanche to amalgam sales with no disclosure) resigned "by mutual agreement" with Dr. Hamburg, amidst complaints that he pressured staff to approve devices that they did not think were safe in order to benefit industry. FDA staff believe amalgam to be one of these devices; an employee commented thusly off the record to a reporter on the amalgam rule, "Why continue to use and recommend mercury amalgam when there is safer composite alternative?...I really question FDA's motivation here. It seems to be more responsive to industry than human health." (A 'Shocking' Decision – Bias Seen in Dental Amalgams Rule, FDA WEBVIEW, 31 July 2009).

8. Considering this situation, Commissioner Hamburg's defense that she "took no action" while overseeing the rule is meaningless. Dan Schultz, was approving devices precipitously, putting unsafe devices on the market. Hamburg said in June she planned to make major changes at that dysfunctional Center. But she conveniently waited until Schultz and his Center for Devices prepared the pro-industry, anti-disclosure amalgam rule before moving Schultz out. So when Hamburg says she took "no action," she had arranged the cards in the deck so she did not need to. Near the end of the process, she could drop the case the lap of Principal Deputy Commissioner Joshua Sharfstein, confident that it was too late for him to overhaul Dan Schultz's pro-amalgam work product.

9. This rule is so pro-Henry Schein and anti-patient that in the fine print it even expresses FDA's concern about a possible decline in mercury exposure if it did not act to protect amalgam: "The daily potential exposure to mercury vapor originating from dental amalgam is expected to decrease gradually in the absence of the final rule." This concern may come as a shock to President Obama, who is negotiating a treaty to phase out all anthropogenic mercury, and who realizes that mercury is so dangerous that he wrote a law, signed by President Bush in 2008, that bans mercury exports.

10. The children of America will be mercury toxic for another generation because FDA Commissioner Hamburg put her corporate benefactor and her stock ahead of them. (Henry Schein, whose stock rose the week the rule issued, was still thanking Dr. Hamburg at a meeting pitching company stock the morning after the rule was published – months after she supposedly cut her ties with it.) The children have no voice. Don't they???

I thank you very much for taking the time to read my letter and most of all for taking the appropriate actions now.

With kind regards,

b(6) Personal Privacy

U.S. Representative Tom Price, M.D.
Sixth Congressional District of Georgia
100 North Street, Suite 150
Canton, Georgia 30114
Phone: (678) 493-6176
Fax: (678) 493-6161

DATE: 7/19/07 **FAX#:** 301-827-1960

TO: Assistant Commissioner of Legislation

FROM: Jennifer Poole

RE:

Please provide me with any information that may assist

b(6) Personal Privacy

Thank you.

There are 2 page(s) to this fax.

Confidential Notice: ***This facsimile, including any attachments, is for the sole use of the intended recipient (s) and may contain confidential and privileged information. Any unauthorized review; use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender immediately and destroy all copies of the original message.***

2007-5124

AUG-02-2002 23:39 From: To:301 443 2567 P.1/2

JUL 11 2007

b(6) Personal Privacy

Congressman Tom Price
3730 Roswell Road, Suite 50
Marietta, GA 30062

Congressman:

As a doctor, I know you are well aware of my illness, diabetes. I am a brittle Type I diabetic and have been for over 35 years.

Unaware hypoglycemia has been my problem area for the past 10-15 years. In January of this year, Medtronics developed a sensor that works with their insulin pump and can be programmed to alarm at specific high and low blood sugar levels.

The problem is the FDA hasn't issued a numeric code for the transmitter or sensors to cover the billing. The transmitter was $999.00 in January 2007 (warranted for six months, failed in five) and the new (mini-link) transmitter was on sale for $349.00 in March 2007. Sensors are $35.00 each and last 3 days.

As you can see this is not an inexpensive item, but the benefit of not experiencing unaware lows causing me to pass out is worth it.

Any assistance you can give us on this matter would be greatly appreciated. Should you require any information or help from me, please let me know. I will continue my efforts on this end.

Sincerely,

b(6) Personal Privacy

AUG-02-2002 23:39 From: To:301 443 2567 P.2/2

Congress of the United States

Washington, DC 20515

May 7, 2007

Commissioner Andrew C. Von Eschenbach
Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Buidling, Room 14-7
Rockville, Maryland 20857-0002

Dear Commissioner von Eschenbach:

We are writing to express our strong interest in seeing the U.S. Food and Drug Administration (FDA) require a national unique device identification (UDI) system for medical devices as soon as possible. We have witnessed first-hand the multiple and varied product numbering and coding systems by visiting hospitals and other health care facilities in our districts. The officials who run these facilities have expressed to us their concern about the negative impact that these multiple coding systems have on our health care system. Our provider constituents overwhelmingly believe that a national UDI would improve patient safety, reduce medical errors, enhance device recall processes, and improve device adverse event reporting. We believe that our nation's health care system will benefit by having a defined UDI with a global nomenclature that complements the FDA National Drug Code system.

In May of 2005, several of us wrote the FDA to inquire about its intentions for plans to require the bar coding of medical devices. Since that letter was sent, the FDA and the Agency for Healthcare Research and Quality (AHRQ) have commented that an urgent need exists for a unique identifier for medical devices. At the FDA's recent public meeting on October 25, 2006 the Centers for Medicare and Medicaid Services (CMS) and the Department of Defense (DoD) also voiced support for UDI.

A national UDI standard has great potential for our entire health care system. It will benefit manufacturers and improve patient safety by reducing the potential for counterfeit products being used on a patient. Also, several of us have been working with health care organizations in our districts to promote electronic health records (EHRs) and Regional Health Information Organizations (RHIOs). A UDI standard would help contribute to the success of those electronic systems and improve patient care by providing appropriate health care providers with accurate information.

PRINTED ON RECYCLED PAPER

2007-3550

We appreciate the great effort that the FDA has put into the national UDI standard issue under your leadership. As technology continues to evolve, we believe that our health care system must have the appropriate standards to help facilitate that technology and enhance patient safety and improve health care efficiency.

Sincerely,

Mike Doyle
Member of Congress

Pete Sessions
Member of Congress

Bart Gordon
Member of Congress

Lee Terry
Member of Congress

Robert Brady
Member of Congress

Tom Price
Member of Congress

Michael C. Burgess, M.D.
Member of Congress

Thaddeus McCotter
Member of Congress

Bob Etheridge
Member of Congress

Jason Altmire
Member of Congress

Todd Platts
Member of Congress

John Carter
Member of Congress

David Price
Member of Congress

Ralph Hall
Member of Congress

David Davis
Member of Congress

Stephanie Herseth
Member of Congress

Linda Sanchez
Member of Congress

Jim Moran
Member of Congress

Mike Conaway
Member of Congress

Maurice Hinchey
Member of Congress

Silvestre Reyes
Member of Congress

David Hobson
Member of Congress

Chip Pickering
Member of Congress

Diane Watson
Member of Congress

Brian Bilbray
Member of Congress

Michael Turner
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 9 2006

The Honorable Tom Price
Member, U.S. House of Representatives
3730 Roswell Road, Suite 50
Marietta, GA 30062

Dear Mr. Price:

Thank you for the inquiry of February 10, 2006, on behalf of your constituent, b(6) Personal b(6) Perso a, regarding the approval of ReSTOR intraocular lenses (IOL), manufactured by Alcon Laboratories, for a higher prescription strength.

Generally, the Food and Drug Administration (FDA or the Agency) is prohibited by law from confirming or denying the existence of an application unless the sponsor or the manufacturer of the product publicly acknowledges the application or provides the Agency with written authorization to release or disclose information contained in its application. We regret any inconvenience this may cause you. You may want to view Alcon's website (*http://www.alconlabs.com/us/eo/products/*) for information about the ReSTOR IOL.

Thank you again for contacting us concerning this matter. If we may be of further assistance, please let us know.

Sincerely,

FOR Patrick Ronan
Associate Commissioner
for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Tom Price
Member, U.S. House of Representatives
3730 Roswell Road, Suite 50
Marietta, GA 30062

DEC 5 2005

Dear Mr. Price:

Thank you for the inquiry of July 15, 2005, on behalf of your constituent, of Kennesaw, Georgia, regarding his concerns about an adverse reaction suffered by his wife that he attributes to the use of the drug Triclosan, an anti-bacterial product.

The Food and Drug Administration (FDA or the Agency) approves anti-microbial drug products, including those that contain Triclosan, under an over-the-counter (OTC) monograph system. This system is a three-phase rulemaking process, with each phase requiring publication of public notices in the *Federal Register*. The OTC drug review addresses active ingredients, rather than specific products.

The first phase of an OTC drug review is accomplished by an FDA-appointed advisory review panel comprised of scientifically-qualified individuals as voting members and non-voting members representing consumer and industry interests. The panel is charged with reviewing the ingredients and labeling of marketed OTC drug products to determine whether they can be classified as generally recognized as safe and effective for use in self-treatment. The report and recommendations of the panel are then published in the *Federal Register* as an advance notice of proposed rulemaking and public comment is invited.

The second phase of the review is FDA's evaluation of the panel's findings, consideration of public comment, and study of any new data that may have become available. The Agency then publishes its tentative conclusions as a proposed rule (tentative final monograph). A period of time is allotted for objections, requests for a public hearing, or submission of new data.

After considering any objections and new data, and processing any requests for a hearing, the Agency issues a final rule (final monograph). This process is very lengthy and, to date, the rulemaking for OTC topical anti-microbial drug products has not been finalized.

The Agency held a meeting of the Non-prescription Drug Advisory Committee on October 20, 2005, to discuss the efficacy of antiseptics intended for use by the consumer and potential risks to the individual and the general population from using these products.

Documents pertaining to this meeting can be found on our website at *http://cdernet/ACS/index.html.*

The Committee concluded that marketers of non-alcohol-based antiseptics should be required to provide data on their products effectiveness prior to marketing. Additionally, a citizen petition was submitted on October 25, 2005, requesting that FDA ban non-medical uses of Triclosan products. Those filing the petition assert that data show that bacteria will become resistant to anti-bacterial products like Triclosan, rendering the products useless to those who actually need them for medical purposes.

The Agency will now take the information presented at the meeting, recommendations made by the Committee, and information provided in the citizen petition into consideration in making our final determinations regarding the final rulemaking for these products.

may submit any information he may have on adverse skin reactions to the docket established for the citizen petition, so that we can evaluate this concern. Please know that any information submitted to our docket is public information. The Agency's non-binding goal for responding to this citizen's petition is April 23, 2006. nay send the information to the following address:

Dockets Management Branch (HFA-305)
Docket No. 2005P-0432
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Additionally, because FDA is interested in learning of any adverse experiences that patients encounter, the Agency also has implemented the MedWatch program, a voluntary system of reporting directly to FDA adverse events and product problems. Enclosed is a copy of the MedWatch reporting form and instructions for completing it. We would encourage M ; physician to complete this form to report problems, and return it to the MedWatch address. If the attending physician is not able to complete the form, the patient or a family member may do so. Reports also can be submitted electronically by accessing FDA's MedWatch homepage at: *www.fda.gov/medwatch*, click on "How to Report," then "Reporting by Health Professionals" or "Reporting by Consumers."

Thank you again for contacting us concerning this matter. Please let us know if you have further questions.

Sincerely,

for Joy S. Stevens

Patrick Ronan
Associate Commissioner
for Legislation

U.S. Representative Tom Price, M.D.
Sixth Congressional District of Georgia
3730 Roswell Road, Suite 50
Marietta, GA 30062
Phone: (770) 565-4990
Fax: (770) 565-7570

DATE: 15 July 2005

TO: FDA - Cong. Unit FAX #: 301-827-1960/1955

FROM: Jared Thomas ____ Debbie DeLong: ____ Jeff Hamling ____

Tina McIntosh X Blair Simpson ____

RE: Constituent inquiry. Thank you for your help w/ this matter! Please forward all written replies to the above address.

Tina

There are 3 pages to this fax.

Confidential Notice: This facsimile, including any attachments, is for the sole use of the intended recipient (s) and may contain confidential and privileged information. Any unauthorized review; use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender immediately and destroy all copies of the original message.

2005-4672

(b) (6)

JUL 1 3 2005

July 3, 2005

Congressman Tom Price
506 Cannon House Office Building
Washington, DC 20515

Refr: Cosmetic Product Complaint

Dear Congressman Price,

My wife was given a free sample of Dial Spring Water, Antibacterial, Clean Rinsing Body Wash, sometime during the early part of April, 2005, at one of the grocery stores where she routinely shops. She does not remember when and where she got the sample. She simply put it in her storage cabinet in our bathroom. The bottle is marked "not for individual sale" with a code number SW-5-UA-01

She came across the sample again in mid to late May, 2005 and, since it was a new product of a highly reputed brand of long standing, she decided to give it a try, without my knowledge. She did begin to experience light to moderate rashes and skin discoloration periodically, while using the product, but contributed those problems to sun exposure, since they usually occurred while of after watching our grandson play baseball. This continued until May 27, 2005, when she stepped out of a lukewarm shower, at 6:00 AM, looking like a partially boiled lobster. Most of both her arms and legs were covered by a bright red rash, which she said felt as though the skin had been scalded. I immediately applied a liberal coating of Aveeno 1% Hydrocortisone skin cream, which was the only thing we had, over the entire affected area. This alleviated the burning sensation almost immediately and after about four hours, the red rash disappeared. She has not used the product since and she has not experienced any reoccurrence of the rashes.

When I returned home from work that evening, I asked her what she was putting on her body. She handed me a half-empty bottle of Dial Spring Water, Anti-bacterial Clean Rinsing Body Wash. I immediately accessed the internet on my computer and entered the listed ingredients of the product, one by one, into the request line of the Google search engine. The listed active ingredient, Triclosan, and three of the other listed ingredients, Sodium Laureth Sulfate, PEG-8 and Fragrance, were included on Linda Chae's website (www.lindachae.com), in her list of 16 untouchable ingredients for use in cosmetic products. I verified her description of the above four ingredients on two other websites, What I learned about the nature and potential side effects of those ingredients, when included in a product advertised as beneficial to the human body, made me want to vomit.

I also learned that the FDA does not regulate or test cosmetic products prior to their release to the public, unless the product "is intended not only for cleansing but also to cure, treat, or prevent disease, or to affect the structure of any function of the human body". In that case, the product must be treated as a drug. So, please tell me, since this product is advertised to be an anti-bacterial agent, which must mean that it eliminates bacteria and thereby prevents disease, is it not both a cleansing agent and a drug? If it is a drug, that has

been tested and approved by the FDA, why doesn't it come with a listing of possible side effects, like every other drug that I have ever taken? If it is not considered a drug, I must ask myself, and you, how my government can allow a product, which contains the ingredients that this product admittedly does, to be sold indiscriminately, in the same stores where we buy our food and household supplies, without any warnings of potential side effects or instructions regarding proper use?

How can it be that our government's Food and Drug Administration will force drug manufacturers to spend millions of dollars and five or more years of time, testing and re-testing a new drug that is intended for use by a limited percentage of our total population, periodically throughout his or her life, under direction of a licensed physician, while it allows cosmetics manufacturers, who have unfettered access to the same chemicals, to formulate, advertise and sell chemical product concoctions, which can be just as deadly as any drug, for use by a great percentage of young girls and adult women in our population and a significant percentage of boys and adult men, every day of their lives, uncontrolled by any rules except their own? The only difference is that one produces chemical products which are intended for use in the body, while the other produces chemical products intended for use on the living envelope of the body. What difference does it make whether a chemical product eats up the inside of a body or the outside, or which occurs first? The logic of this seemingly accepted condition defies intelligent behavior. Is this another situation similar to the EPA's recent dramatic reversal of its previous sworn testimony before Congress regarding the toxicity and health dangers associated with mercury pollution? I have a sick feeling in the pit of my stomach which warns me that the primary problem with regulating this highly profitable industry has a great deal to do with the flow of money.

I watched last Wednesday, as my wife, who is in otherwise excellent health, suffered extreme distress, as a result of washing her body, when she stepped out of the shower and saw what the chemical industry had done to her. I watched her blood pressure soar off the charts as a result of that stress. As a citizen of this nation, I demand answers, that make sense, to the questions posed herein. I owe it to the woman I have loved, for over 50 years, to not rest or let this matter drop until I receive them.

God Save America,

Cc: Senator Saxby Chambliss
Senator Johnny Isakson
Food and Drug Administration

U.S. Representative Tom Price, M.D.
Sixth Congressional District of Georgia
3730 Roswell Road, Suite 50
Marietta, GA 30062
Phone: (770) 565-4990
Fax: (770) 565-7570

DATE: 8 Dec 2005 FAX #: 301-827-1960/1955

TO: FDA Congressional

FROM: Jeff Hamling ____ Debbie DeLong ____

Tina McIntosh ___X___ Blair Simpson ____

RE: 2nd Request - Const. Inquiry (b) (6) [redacted]

Thank you for your quick reply.

Tina

I can be reached at the above numbers or at tina.mcintosh2@mail.house.gov.

There are 4 pages to this fax.

Confidential Notice: This facsimile, including any attachments, is for the sole use of the intended recipient (s) and may contain confidential and privileged information. Any unauthorized review; use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender immediately and destroy all copies of the original message.

2005-8395

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2826
RECIPIENT ADDRESS	13018271960
DESTINATION ID	
ST. TIME	07/15 12:54
TIME USE	01'14
PAGES SENT	3
RESULT	OK

U.S. Representative Tom Price, M.D.
Sixth Congressional District of Georgia
3730 Roswell Road, Suite 50
Marietta, GA 30062
Phone: (770) 565-4990
Fax: (770) 565-7570

DATE: 15 July 2005

TO: FDA - Cong. Unit FAX #: 301-827-1960/195

FROM: Jared Thomas ____ Debbie DeLong: ____ Jeff Hamling ____
Tina McIntosh X Blair Simpson ____

RE: Constituent Inquiry. Thank you for your help w/ this matter. Please forward all written replies to the above address.

Tina

(b)(6)

JUL 13 2005

Congressman Tom Price
506 Cannon House Office Building
Washington, DC 20515

July 3, 2005

Refr: Cosmetic Product Complaint

Dear Congressman Price,

My wife was given a free sample of Dial Spring Water, Antibacterial, Clean Rinsing Body Wash, sometime during the early part of April, 2005, at one of the grocery stores where she routinely shops. She does not remember when and where she got the sample. She simply put it in her storage cabinet in our bathroom. The bottle is marked "not for individual sale" with a code number SW-5-UA-01

She came across the sample again in mid to late May, 2005 and, since it was a new product of a highly reputed brand of long standing, she decided to give it a try, without my knowledge. She did begin to experience light to moderate rashes and skin discoloration periodically, while using the product, but contributed those problems to sun exposure, since they usually occurred while of after watching our grandson play baseball. This continued until May 27, 2005, when she stepped out of a lukewarm shower, at 6:00 AM, looking like a partially boiled lobster. Most of both her arms and legs were covered by a bright red rash, which she said felt as though the skin had been scalded. I immediately applied a liberal coating of Aveeno 1% Hydrocortisone skin cream, which was the only thing we had, over the entire affected area. This alleviated the burning sensation almost immediately and after about four hours, the red rash disappeared. She has not used the product since and she has not experienced any reoccurrence of the rashes.

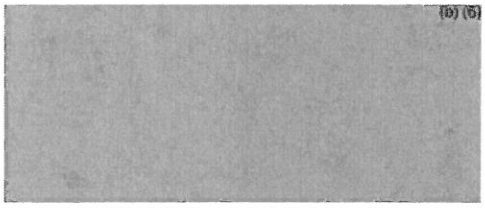
When I returned home from work that evening, I asked her what she was putting on her body. She handed me a half-empty bottle of Dial Spring Water, Anti-bacterial Clean Rinsing Body Wash. I immediately accessed the internet on my computer and entered the listed ingredients of the product, one by one, into the request line of the Google search engine. The listed active ingredient, Triclosan, and three of the other listed ingredients, Sodium Laureth Sulfate, PEG-8 and Fragrance, were included on Linda Chae's website (www.lindachae.com), in her list of 16 untouchable ingredients for use in cosmetic products. I verified her description of the above four ingredients on two other websites, What I learned about the nature and potential side effects of those ingredients, when included in a product advertised as beneficial to the human body, made me want to vomit.

I also learned that the FDA does not regulate or test cosmetic products prior to their release to the public, unless the product "is intended not only for cleansing but also to cure, treat, or prevent disease, or to affect the structure of any function of the human body". In that case, the product must be treated as a drug. So, please tell me, since this product is advertised to be an anti-bacterial agent, which must mean that it eliminates bacteria and thereby prevents disease, is it not both a cleansing agent and a drug? If it is a drug, that has

been tested and approved by the FDA, why doesn't it come with a listing of possible side effects, like every other drug that I have ever taken? If it is not considered a drug, I must ask myself, and you, how my government can allow a product, which contains the ingredients that this product admittedly does, to be sold indiscriminately, in the same stores where we buy our food and household supplies, without any warnings of potential side effects or instructions regarding proper use?

How can it be that our government's Food and Drug Administration will force drug manufacturers to spend millions of dollars and five or more years of time, testing and re-testing a new drug that is intended for use by a limited percentage of our total population, periodically throughout his or her life, under direction of a licensed physician, while it allows cosmetics manufacturers, who have unfettered access to the same chemicals, to formulate, advertise and sell chemical product concoctions, which can be just as deadly as any drug, for use by a great percentage of young girls and adult women in our population and a significant percentage of boys and adult men, every day of their lives, uncontrolled by any rules except their own? The only difference is that one produces chemical products which are intended for use in the body, while the other produces chemical products intended for use on the living envelope of the body. What difference does it make whether a chemical product eats up the inside of a body or the outside, or which occurs first? The logic of this seemingly accepted condition defies intelligent behavior. Is this another situation similar to the EPA's recent dramatic reversal of its previous sworn testimony before Congress regarding the toxicity and health dangers associated with mercury pollution? I have a sick feeling in the pit of my stomach which warns me that the primary problem with regulating this highly profitable industry has a great deal to do with the flow of money.

I watched last Wednesday, as my wife, who is in otherwise excellent health, suffered extreme distress, as a result of washing her body, when she stepped out of the shower and saw what the chemical industry had done to her. I watched her blood pressure soar off the charts as a result of that stress. As a citizen of this nation, I demand answers, that make sense, to the questions posed herein. I owe it to the woman I have loved, for over 50 years, to not rest or let this matter drop until I receive them.



Cc: Senator Saxby Chambliss
Senator Johnny Isakson
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Tom Price
Member, U.S. House of Representatives
3730 Roswell Road, Suite 50
Marietta, GA 30062

DEC 5 2005

Dear Mr. Price:

Thank you for the inquiry of July 15, 2005, on behalf of your constituent, (b) (6) , regarding his concerns about an adverse reaction suffered by his wife that he attributes to the use of the drug Triclosan, an anti-bacterial product.

The Food and Drug Administration (FDA or the Agency) approves anti-microbial drug products, including those that contain Triclosan, under an over-the-counter (OTC) monograph system. This system is a three-phase rulemaking process, with each phase requiring publication of public notices in the *Federal Register*. The OTC drug review addresses active ingredients, rather than specific products.

The first phase of an OTC drug review is accomplished by an FDA-appointed advisory review panel comprised of scientifically-qualified individuals as voting members and non-voting members representing consumer and industry interests. The panel is charged with reviewing the ingredients and labeling of marketed OTC drug products to determine whether they can be classified as generally recognized as safe and effective for use in self-treatment. The report and recommendations of the panel are then published in the *Federal Register* as an advance notice of proposed rulemaking and public comment is invited.

The second phase of the review is FDA's evaluation of the panel's findings, consideration of public comment, and study of any new data that may have become available. The Agency then publishes its tentative conclusions as a proposed rule (tentative final monograph). A period of time is allotted for objections, requests for a public hearing, or submission of new data.

After considering any objections and new data, and processing any requests for a hearing, the Agency issues a final rule (final monograph). This process is very lengthy and, to date, the rulemaking for OTC topical anti-microbial drug products has not been finalized.

The Agency held a meeting of the Non-prescription Drug Advisory Committee on October 20, 2005, to discuss the efficacy of antiseptics intended for use by the consumer and potential risks to the individual and the general population from using these products.

Documents pertaining to this meeting can be found on our website at *http://cdernet/ACS/index.html.*

The Committee concluded that marketers of non-alcohol-based antiseptics should be required to provide data on their products effectiveness prior to marketing. Additionally, a citizen petition was submitted on October 25, 2005, requesting that FDA ban non-medical uses of Triclosan products. Those filing the petition assert that data show that bacteria will become resistant to anti-bacterial products like Triclosan, rendering the products useless to those who actually need them for medical purposes.

The Agency will now take the information presented at the meeting, recommendations made by the Committee, and information provided in the citizen petition into consideration in making our final determinations regarding the final rulemaking for these products.

(b) (6) may submit any information he may have on adverse skin reactions to the docket established for the citizen petition, so that we can evaluate this concern. Please know that any information submitted to our docket is public information. The Agency's non-binding goal for responding to this citizen's petition is April 23, 2006. (b) (6) may send the information to the following address:

Dockets Management Branch (HFA-305)
Docket No. 2005P-0432
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Additionally, because FDA is interested in learning of any adverse experiences that patients encounter, the Agency also has implemented the MedWatch program, a voluntary system of reporting directly to FDA adverse events and product problems. Enclosed is a copy of the MedWatch reporting form and instructions for completing it. We would encourage (b) (6) physician to complete this form to report problems, and return it to the MedWatch address. If the attending physician is not able to complete the form, the patient or a family member may do so. Reports also can be submitted electronically by accessing FDA's MedWatch homepage at: *www.fda.gov/medwatch*, click on "How to Report," then "Reporting by Health Professionals" or "Reporting by Consumers."

Thank you again for contacting us concerning this matter. Please let us know if you have further questions.

Sincerely,

for Joy I. Stevens

Patrick Ronan
Associate Commissioner
for Legislation