



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

Urgent

DATE: 13 February FAX #: 301-827-1960/1955

TO: FDA Congressional

FROM: Jeff Hamling Debbie DeLong

Tina McIntosh X Blair Simpson

RE [redacted] - it is our understanding from the Customs & Border Patrol agents that the FDA has jurisdiction over this issue raised by [redacted]. Any assistance you can give would be greatly appreciated. He needs his meds for surgery. I look forward to your quick reply. Tom

Please reply to the above fax/address or to tina.mcintosh2@mail.house.gov. Please do not share the email address with constituents - it is for agency use only. Thanks!!

There are 3 pages to this fax.

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2006-1223

TOM PRICE, M.D.
6th District, Georgia

WASHINGTON, DC OFFICE:
606 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

February 2, 2006

COMMITTEE ON FINANCIAL SERVICES
SUBCOMMITTEES:
OVERSIGHT
FINANCIAL INSTITUTIONS
DOMESTIC AND INTERNATIONAL POLICY

COMMITTEE ON EDUCATION AND THE WORKFORCE
SUBCOMMITTEES:
WORKFORCE PROTECTION
21ST CENTURY COMPETITIVENESS

ASSISTANT DEPUTY WHIP

Mr. Thaddeus Bingel
Assistant Commissioner
Office of Congressional Affairs
US Customs and Border Protection
1300 Pennsylvania Ave., NW
Washington, DC 20536

RE: Medications being held at the border for [REDACTED] (b) (6)

Dear Mr. Bingel,

Please find correspondence from our above mentioned constituents. They both need their medicine immediately; but [REDACTED] (b) (6) needs it to have surgery. Please contact us with a status on this situation and advise on how we can get their medicines released and to them as soon as possible.

If you have any questions, please contact me at 770-565-4990 or at tina.mcintosh2@mail.house.gov. Thank you in advance for your time and assistance in this matter.

Sincerely,

Tina McIntosh
Director of Constituent Services/Academy Liaison

*There are 2 pgs to this fax.
Please confirm receipt via email.
Thanks*

FEB 13 2006

[Redacted] (b) (5)

FEB. 2, 2006

CONGRESSMAN TOM PRICE
ATTENTION: TINA McINTOSH

The following medications ARE being held
in customs:

[Redacted] (b) (5)

CETIRIZINE (generic for Zyrtec)

Shipped 01/17/06

ARRIVED customs 01/19/06

TRACING Num. CE

[Redacted] (b) (5)

C.A

[Redacted] (b) (5)

LOVENOX

Shipped 01/23/06

ARRIVED Customs 01/27/06

TRACING Num. CE

[Redacted] (b) (5)

C.A

Shipped from Calgary, ALBERTA.

. Thank you.

Sincerely,
[Redacted] (b) (5)



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

MAR 15 2006

Dear Dr. Price:

Thank you for the letter of February 2, 2006, on behalf of your constituent, [REDACTED] (b) (6) regarding the policy of the Food and Drug Administration (FDA or the Agency) with respect to the importation of prescription drugs, specifically Zyrtec and Lovenox, by individuals for their own personal use (personal importation) from sources outside the United States.

Congress charges FDA with ensuring the safety and effectiveness of drugs sold in the U.S. The Federal Food, Drug, and Cosmetic (FD&C) Act prohibits the interstate shipment (which includes importation) of unapproved new drugs. Unapproved new drugs are any drugs, including foreign-made versions of U.S.-approved drugs that have not been approved by FDA for marketing in the U.S. Certain Internet websites have stated that personal importation of up to a 90-day supply of prescription medications is legal. This statement is not true.

FDA drug approvals are manufacturer-specific, product-specific, and they include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. The drugs must be produced in FDA-inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and it is legal to import these drugs. When individuals import drugs directly from foreign sources, they bypass the protections provided by FDA's drug approval process and by state regulation of pharmacies that dispense drugs within their jurisdictions.

We must emphasize that from a public health standpoint, importing prescription drugs for personal use is a potentially dangerous practice. Neither FDA nor the American public have any assurance that unapproved products from foreign sources are effective, safe, or produced under U.S. good manufacturing practices. They may not have been stored under proper

conditions, or may not be the real product, because FDA does not regulate foreign distributors or pharmacies. Foreign unapproved drugs may be contaminated, sub-potent, super-potent, or counterfeit. In addition, some foreign drug outlets offer to dispense prescription drugs without a physical examination, bypassing the traditional doctor/patient relationship. As a result, patients may receive inappropriate medications because of misdiagnoses, or fail to receive appropriate medications or other medical care, or take a product that could be harmful, or fatal, if taken in combination with other medicines.

FDA does allow Agency field personnel to use their enforcement discretion and allow entry of unapproved prescription drugs for personal use in very limited circumstances. This policy is articulated in guidance to FDA field personnel and is not a license for individuals to import unapproved, and therefore illegal, drugs for personal use into the U.S. The policy states that enforcement discretion may be exercised only if the drug is to be used for a serious condition for which effective treatment is not available in the U.S.; there is no attempt to commercialize or promote the drug to U.S. residents; and the product does not present an unreasonable risk to the patient. Because the policy does not apply to medications that are already available in the U.S., only a very few drug products available from foreign sources will meet the personal importation criteria. **Zyrtec and Lovenox are available in the U.S. and therefore do not meet the personal importation criteria.**

In addition to the new Medicare drug discount card, there are other ways for U.S. consumers to save money on domestic prescription drugs. Consumers are encouraged to shop around for price comparisons, ask their doctor or pharmacist for generic alternatives, and take advantage of prescription drug discount cards.

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

Sincerely,


for 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: _____ FAX #: 301-827-1960/1955

TO: Mr. Sachdev - FDA Cong. Unit

FROM: Jeff Hamling _____ Debbie DeLong _____

Tina McIntosh X Blair Simpson _____

RE: _____ - inquiry
Concerning bio-identical hormones.

Thank you for any assistance you can give.
Tina

* Please reply to the above fax/address or to tina.mcintosh2@mail.house.gov. Please do not share the email address with constituents - it is for agency use only. Thanks!!

There are 3 pages to this fax.

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2006-1872

FROM :

FAX NO. :

Feb. 27 2006 06:26PM P2

VIA FAX: (301) 827-6870

**Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852**

RE: Docket 2005P-0411

Dear Sir or Madam:

My name is [REDACTED] (b) (5) and I have been taking bio-identical hormones for three years. It has been a tremendous comfort to me as it alleviates all of my post menopausal symptoms, which included insomnia, severe vaginal dryness, depression, mood swings, loss of libido, and lethargy.

Since a person's hormones fluctuate, my physician evaluates my blood work at regular intervals, prescribes bio-identical hormones specifically formulated for me, and then has my pharmacist prepare them. Without this medication, my life span would be shortened and all of my symptoms would reappear causing me great stress and physical discomfort. **HORMONE THERAPY IS NOT A ONE PILL FITS ALL SOLUTION!** And taking a pill does not account for the hormonal fluctuations in one's body. Bio-identical hormones are just that...identical to what our own body produces and are not made from horse's urine or something synthetic.

The benefit of bio-identical hormone replacement therapy is that it is designed specifically for me, and I am extremely concerned that Wyeth's petition (Docket # 2005P-0411) would limit the ability of my physician and pharmacist to keep prescribing and preparing these individualized doses for me.

I have a right to choose bio-identical hormone therapy over a synthetic pill. I am urging the FDA to reject Wyeth's petition.

Sincerely,

[REDACTED] (b) (5)

FROM :

FAX NO. :

Feb. 27 2006 06:27PM P3

VIA FAX: (301) 827-6870

**Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852**

RE: Docket 2005P-0411

Dear Sir or Madam:

My name is [REDACTED] (b) (6), and I have been taking bio-identical hormones for three years. It has been a tremendous comfort to me as it alleviates all of my symptoms, which included impotence, depression, loss of libido, muscle aches and lethargy.

Since a person's hormones fluctuate, my physician evaluates my blood work at regular intervals, prescribes bio-identical hormones specifically formulated for me, and then has my pharmacist prepare them. Without this medication, my life span would be shortened and all of my symptoms would reappear causing me great stress and physical discomfort. **HORMONE THERAPY IS NOT A ONE PILL FITS ALL SOLUTION!** And taking a pill does not account for the hormonal fluctuations in one's body. Bio-identical hormones are just that...identical to what our own body produces and are not made from horse's urine or something synthetic.

The benefit of bio-identical hormone replacement therapy is that it is designed specifically for me, and I am extremely concerned that Wyeth's petition (Docket # 2005P-0411) would limit the ability of my physician and pharmacist to keep prescribing and preparing these individualized doses for me.

I have a right to choose bio-identical hormone therapy over a synthetic pill. I am urging the FDA to reject Wyeth's petition.

Sincerely,

[REDACTED] (b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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

MAR 24 2006

Dear Dr. Price:

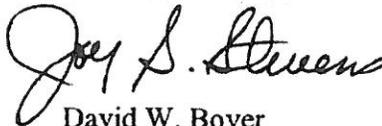
Thank you for the inquiry of March 9, 2006, on behalf of your constituents, [REDACTED] (b) (6) who wrote concerning a Citizen Petition filed with the Food and Drug Administration (FDA or the Agency) on behalf of Wyeth Pharmaceuticals. This Citizen Petition was filed at the Agency's Dockets Management Branch as Docket Number 2005P-0411 and addresses the growing, manufacturing and marketing of products known as "bio-identical hormone replacement therapies (BHRT)" that are produced and sold through various compounding pharmacies in the United States.

The compounding and use of bio-identical hormones raise complicated scientific issues of safety and efficacy as well as complicated regulatory questions that will be addressed in the Agency's response to the Citizen Petition. At this time, we can affirm that we are working to complete our evaluation in a timely manner, given the complexity of the science and policy issues raised in the petition. Once that process is concluded, FDA will provide a written response to the petitioner, which will be posted to the docket and the Agency's Internet site.

Individuals wishing to comment on this Citizen Petition can send their correspondence directly to: Dockets Management Branch, 5630 Fishers Lane, Room 1061, U.S. Food and Drug Administration, Rockville, Maryland 20852. To comment electronically, one can log on to the FDA Dockets Management page at: <http://www.fda.gov/ohrms/dockets/> and follow the instructions for "Submit Electronic Comments," then search using the Docket Number, 2005P-0411. Those comments you already have sent to FDA, we have forwarded on to Dockets Management. For comments you have received more recently, please forward them directly to the Dockets Management Branch address above.

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

Sincerely,

for 
David W. Boyer
Assistant Commissioner
for Legislation

Congress of the United States
Washington, DC 20515

August 25, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
Parklawn Building, Room 1471
Mail Stop HF-1
Rockville, MD 20857

RECEIVED
OFFICE OF LEGISLATION
2006 AUG 32 PM 2: 22

Dear Commissioner von Eschenbach:

Thank you for your leadership as Acting Commissioner of the Food and Drug Administration. The safety, efficacy, accessibility, and affordability of human drugs and biologics are of the utmost importance in protecting and improving our nation's health.

Recently, we were made aware of an application for a naturally occurring form of progesterone, 17 alpha-hydroxyprogesterone caproate or better known as 17P, to be designated as an orphan drug for an indication related to the prevention of preterm births in women with a history of preterm delivery. 17P was previously marketed in the United States for use in pregnancy as an inexpensive and generic drug by a number of manufacturers to prevent the risky and dangerous complications that stem from preterm delivery.

Preterm birth occurs in about 12% of pregnancies and costs our nation over \$6 billion annually. It is estimated that approximately 500,000 pregnant women have a history of preterm delivery in a previous pregnancy, placing them at a higher risk for another preterm delivery.

Our understanding of the intention of the Orphan Drug Act is to expand access to treatment for individuals with rare diseases and conditions. We are concerned that designating 17P as an orphan drug could have the effect of limiting access to this important and inexpensive drug for a significant number of pregnant women with a history of preterm delivery. Should this drug be afforded orphan drug status, thus possibly increasing the price and limiting access, it would be the opposite result of what was intended under the Orphan Drug Act.

The problem of preterm delivery is a devastating one; and therefore, we must ensure that all women have access to this critical prevention method at a reasonable cost. Please

2006-6897

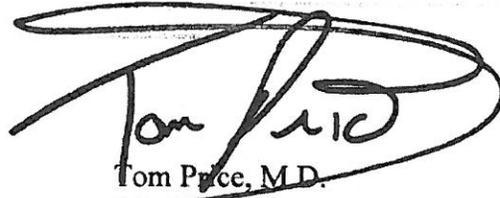
advise our offices as early as possible on the status of this application, and also please summarize the validity of the clinical trial data related to this application.

Thank you for your shared interest in ensuring affordable health care for all Americans.

Sincerely,



Phil Gingrey, M.D.
Member of Congress



Tom Price, M.D.
Member of Congress

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
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Congress of the United States
House of Representatives

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

POLICY COMMITTEE
DEPUTY WHIP

July 16, 2008

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

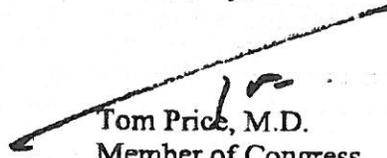
Dear Mr. Mason:

My constituent, [REDACTED], on behalf of her daughter, [REDACTED], 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 my district office at 3730 Roswell Rd., Suite 50, Marietta, GA 30062.

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

2008-4710

Fax to Tom Price - Constituent Services - (770) 565-7570

Print Document

**Congressman Tom Price
Constituent Request for Service
Privacy Act Statement**

In accordance with the Privacy Act of 1974 (5 USC 552), I hereby authorize Representative Tom Price and his designated staff to seek disclosure of all records relevant to my case from the federal agency involved. (Under the Privacy Act of 1974, we must have formal authorization from you before seeking disclosure of your records. The authorization must be signed by the person whose case is in question.)

Signature:

[Redacted Signature]

Date: 7/9/08

Description of Problem:

my daughter, age 15, is not able to get treatment for acne timely

using the drug Accutane. It is ridiculously regulated and defies reason. Please see letter attached that I sent, via the web, to the FDA. (You will notice that I did not state her name, as I understand was the proper procedure for such reporting.)

I Pledge #

Attach additional pages if necessary. Attach photocopies (no originals please) of all relevant documents.

Agency Involved: FDA

Date of Birth:

Social Security #:

Alien Card #:

Immigrant Visa #:

Veteran #:

Service Record #:

Claim #:

Mr./Mrs./Ms./Miss (please circle one)

First Name:

Last Name:

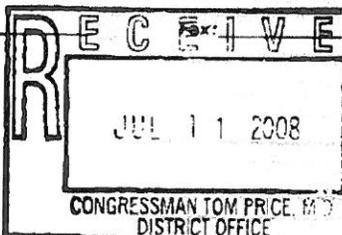
Address:

City:

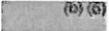
Telephone (day):

Telephone (night):

Please return this form to:
Congressman Tom Price
3730 Roswell Road, Suite 50
Marietta, GA 30062

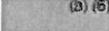


Regarding 

My daughter has done every requirement in order to begin using the acne medication Isotretinoin (Accutane). She was told on 7/3/08 that her name was not in the IPledge computer system; therefore, she cannot receive the medication until 30 more days have passed. I spoke to her dermatologist who assured me that her name had been put in the system on  but that it must have "fallen out of the system", because it was no longer there. So, the dermatologist resubmitted her information on . Her treatment will be delayed 30 days. Thirty days is a long time when you are trying to get rid of acne.

I understand that the IPledge program is used to ensure that patients do not become pregnant while on the Accutane drug. This patient is
-a virgin;
-she has undergone 2 pregnancy tests,
-and is taking the birth control pill as prescribed.
Clearly, she is not pregnant.

After speaking to , and finally Catherine Almonte, Operations Supervisor at the IPledge office (1-866-495-0654), I realized that no person there is able to make a correction to my daughter's name falling out of the IPledge system. Each person said that there were no overrides in the system. Even Catherine, the 3rd level of supervision, admitted that she could not fix a mistake that might have resulted from a computer problem, glitch, or virus. Interestingly,  stated that my situation "happens a lot". They all agreed that this IPledge program was mandated by the FDA.

Therefore, next, I talked to Ellen Wang at the FDA (301-796-3400). She, too, said that there was nothing that she could do. She said that "the rule is the rule" and "no exceptions are made", even knowing that the doctor said she had input my daughter into the system on . We will have to use the date of . She said that not even her supervisor would be able to apply reason to the situation, understand that my daughter is not pregnant, and make a phone call to  and authorize them to fill the prescription. She explained (?) that the IPledge program was written by MANY people and not ONE person could act on my daughter's behalf.

Clearly, my daughter is suffering at the hands of government bureaucracy. Acne is quite an emotional burden to carry for anyone. Each of the 5 ladies that I have spoken with was polite and "understands my frustration". Yet, none will acknowledge that my daughter has fulfilled all the IPledge requirements to begin taking Accutane. She is the victim, here in America, even having just celebrated Independence Day 3 days ago.

I would be happy to tell this story to anyone who is empowered to use their minds, apply logic and reason, and enable my daughter to begin Accutane treatment as soon as possible.





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: 16 July 2008 FAX #: 301-827-1960

TO: FDA Congressional

FROM: Jeff Hamling _____ Tina McIntosh X Sarah Vabulas _____
Jennifer Poole _____ Kyle McGowan _____

RE: Please reply to the following inquiry
As soon as possible.

Price

There are 4 page(s) to this fax.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 10 2008

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

Dear Dr. Price:

Thank you for the inquiry of July 16, 2008, on behalf of your constituent, [REDACTED] (b) (6) regarding difficulties her daughter, [REDACTED] (b) (6), has experienced with the iPLEDGE program that provides post marketing risk management for the drug Accutane (isotretinoin).

Isotretinoin is approved by the Food and Drug Administration (FDA or the Agency) for the treatment of severe recalcitrant nodular acne. It is a highly effective treatment, but has serious known side effects, such as its potential to cause birth defects in pregnant women exposed to the drug. For this reason, FDA approved the post marketing risk management program, iPLEDGE, to reduce the risk of adverse events which include birth defects and fetal death.

The iPLEDGE program is an independent program that is operated by Covance, Inc. on behalf of the Isotretinoin Product Manufacturers Group. The iPLEDGE program was implemented to ensure that all participants in the healthcare system using isotretinoin—wholesalers, prescribers, pharmacies, and patients—accept responsibility and adhere to explicit requirements to minimize the pregnancy exposures. There is no question that systems such as iPLEDGE are imperfect, particularly in leading to timely dispensing of the drug to the patient. The report by your constituent is an example of the challenges that can be encountered by any distribution system that requires participation by multiple parties.

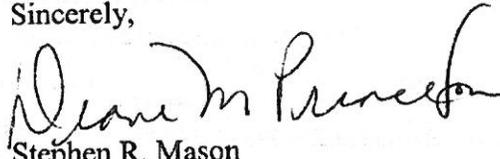
FDA works closely with Covance and the isotretinoin manufacturers to try to ensure product access is timely. In the case of your constituent, it is unclear why the “computer glitch” may have occurred nor are we aware of recurring problems of this type, particularly patient records “falling out of the system.” Reasons for delays have often times included the need for the patient to obtain contraceptive counseling, answer monthly questions, or wait for the appropriate time in her menstrual cycle to begin treatment. From the information provided we cannot determine that any of these factors were involved.

If [REDACTED] (b) (6) daughter continues to experience a delay, we recommend that her physician contact Covance to ascertain the reason.

Page 2 - The Honorable Tom Price, M.D.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen R. Mason". The signature is fluid and cursive, with the first name being the most prominent.

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

TOM PRICE, M.D.
6th District, Georgia

WASHINGTON DC OFFICE
424 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4601
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3730 HOBWELL ROAD, SUITE 50
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100 NORTH STREET, SUITE 150
CANTON, GA 30114
(678) 493-6176

www.house.gov/tomprice



Congress of the United States
House of Representatives
September 2, 2009

COMMITTEE ON
FINANCIAL SERVICES
SUBCOMMITTEES
CAPITAL MARKETS
DEPUTY RANKING MEMBER
DOMESTIC AND INTERNATIONAL POLICY

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

REPUBLICAN STUDY COMMITTEE
CHAIRMAN
DEPUTY WHIP

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, [REDACTED] (b) (6), 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 my district office at 100 North Street, Suite 150, Canton, GA 30114.

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/jp

2009-5824



PRIVACY RELEASE FORM Congressman Tom Price

Thank you for contacting my office for assistance. The provisions of the Privacy Act of 1974 require me to obtain a signed Privacy Act Release Form in order to proceed with your case. This form must be completed in its entirety before an inquiry can be made on your behalf.

Date: 8-31-09

Name: (Mr./Mrs./Ms.) [Redacted] (b) (6)

[Redacted] (b) (6)

Date of Birth [Redacted] (b) (6) AGENCY Involved FDA

Spouse/ Other Contact [Redacted] (b) (6)

Type of Immigration Petition filed N/A Date petition filed N/A

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.

FDA has ordered my thyroid hormone supplier to cease production of desiccated thyroid hormone. There is a massive nationwide shortage of this product. I depend on it to live. I cannot take synthetic T4

hormone! It makes me very sick!!!
to me, SIGN HERE [Redacted] (b) (6) Privacy Act Release Tom Price and those acting in his behalf, in order to attempt to be of assistance abate laws and regulations, information pertaining specifically to this matter. DATE 8-31-09

Once complete, please return it to: Congressman Tom Price
100 North Street, Suite 150
Canton, GA 30114
678-493-6161 FAX



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: 9/2/09 FAX #: 301-827-1960
TO: Stephen Mason
FROM: **Jennifer Poole**

RE: (b) (6)

There are 3 page(s) to this fax.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Tom Price, M.D.
Member, U.S. House of Representatives
100 North Street, Suite 150
Canton, GA 30114

OCT 30 2009

Dear Mr. Price:

Thank you for your correspondence of September 2, 2009, on behalf of your constituent, [REDACTED], regarding the shortage of desiccated thyroid hormone.

The Food and Drug Administration (FDA or the Agency) would like to note that desiccated thyroid products are not FDA-approved products even though they are on the market and available to consumers. In addition, FDA has not ordered all unapproved desiccated thyroid products off the market. Rather, FDA has urged all companies who market unapproved drug products, including desiccated thyroid products, to submit applications for approval. FDA is concerned that drugs marketed without required FDA approval have never been submitted to rigorous scientific evaluation, and therefore, may not meet required standards for safety, effectiveness, quality, and labeling. Marketers of drug products in the United States have an obligation to the public to ensure through the FDA approval process that their products meet modern standards for safety, efficacy, quality, and labeling.

Regarding possible future action against unapproved desiccated thyroid products, as a policy matter we do not discuss potential, pending, or ongoing actions, except with the firms and individuals who are the subject of those actions. Class actions against unapproved drugs are made in accordance with the priorities discussed in FDA's Compliance Policy Guide on Marketed Unapproved Drugs, which can be found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf>. Information about enforcement actions against classes of unapproved drugs is posted on the FDA Web site. For additional information regarding unapproved drugs, please access our unapproved drugs Web site at the following link: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/default.htm>

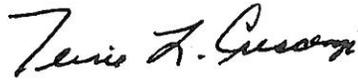
Some inquiries to FDA have cited reports of shortages of unapproved thyroid products. The manufacturer of Westroid and Nature-Throid products, RLC Labs, Inc. (also known as Western Research), reports that they are currently in backorder for all Westroid and Nature-Throid products. Major Pharmaceuticals reports that one strength of desiccated thyroid is currently available and Forest Laboratories reports that they are in backorder on all strengths

and working to restore availability. The reasons provided by the companies for the current unavailability of these products are related to raw material shortages as well as manufacturing delays.

Patients are advised to talk to their doctors about possible alternatives if they are unable to obtain their usual thyroid medication at this time. Please note that there are several approved levothyroxine products available. Examples include Synthroid, Unithroid, and levothyroxine sodium tablets. Please let our Drug Shortage program know if you have difficulty obtaining one of these alternatives listed above. The Drug Shortage e-mail account is drugshortages@fda.hhs.gov.

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

Sincerely,

fa 
Jeanne Ireland
Assistant Commissioner
for Legislation

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

WASHINGTON, DC OFFICE:
424 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
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www.house.gov/tomprice



Congress of the United States
House of Representatives

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

POLICY COMMITTEE

DEPUTY WHIP

September 30, 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

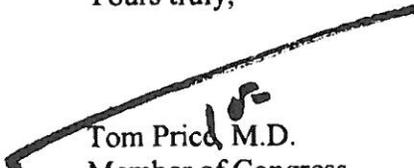
Dear Mr. Mason:

My constituent, Mr. James P. Reichmann III, 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

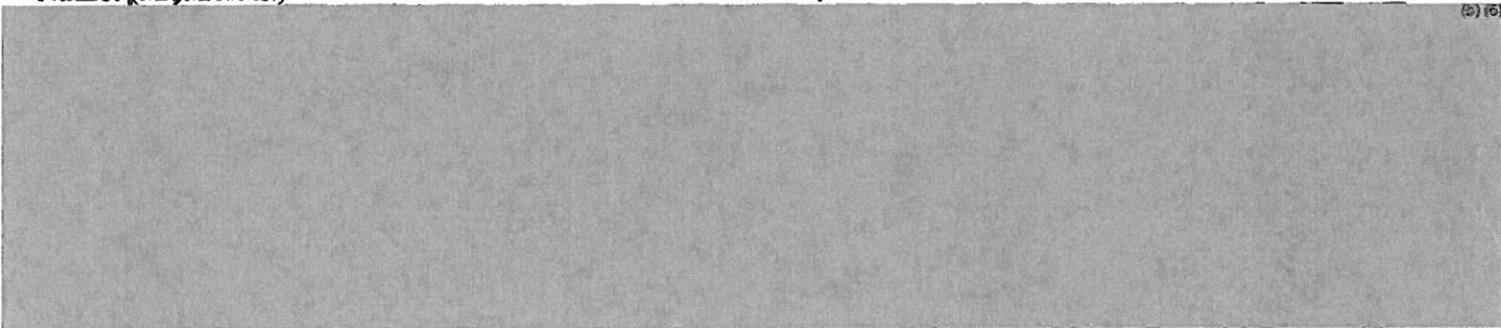
TP/tm

PRIVACY RELEASE FORM
Congressman Tom Price

Thank you for contacting my office for assistance. The provisions of the Privacy Act of 1974 require me to obtain a signed Privacy Act Release Form in order to proceed with your case. This form must be completed in its entirety before an inquiry can be made on your behalf.

Date: 9/25/2009

Name: (Mr./Mrs./Ms.) JAMES P. REICHMANN



Spouse/ Other Contact (FBI)

Type of Immigration Petition filed _____ Date petition filed _____

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.

ATTACHED FOR CITIZEN PETITION

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, to obtain in accordance with applicable laws and regulations, information pertaining specifically to this matter.

SIGN HERE James P. Reichmann DATE 9/25/2009

Once complete, please return it to: Congressman Tom Price
3730 Roswell Road, Suite 50
Marietta, GA 30062
770-565-7570 FAX



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 11 2008

James P. Reichmann

(b) (6)

Re: Docket No. 2008-P-0358

Dear Mr. Reichmann:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 18, 2008. Your petition requests that FDA (1) reclassify terbutaline sulfate from pregnancy risk category B to category C, D, or X; (2) require terbutaline manufacturers to amend labeling to reflect its change in pregnancy risk category; (3) notify obstetricians of the reclassification; (4) issue another Dear Colleague letter alerting health care professionals regarding safety concerns associated with continuous subcutaneous terbutaline pump therapy; and (5) require providers of terbutaline pumps to report to FDA all maternal deaths associated with use of a terbutaline pump.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Associate Director for Policy
Center for Drug Evaluation and Research



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 18, 2008

FILE COPY

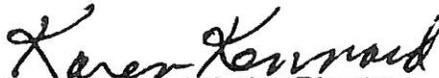
James P. Reichmann

Dear Mr. Reichmann:

Your petition requesting the Food and Drug Administration Reclassify the drug terbutaline sulfate from pregnancy risk category B to pregnancy risk category C, D, or X after evaluation of the published data (1,2), was received by this office on 06/18/2008. It was assigned docket number FDA-2008-P-0358-0001/CP and it was filed on 06/18/2008. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,


Karen Kennard, Acting Director
Division of Dockets Management
Office of Management Programs
Office of Management

FDA-2008-P-0358

ACK

James P. Reichmann

June 16, 2008

0189 8 JUN 18 P1 58

Food and Drug Administration
Division of Dockets Management
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville, MD 20852

To Whom It May Concern:

This citizen petition, filed on behalf of all the women harmed and infants injured as a result of the administration of terbutaline sulfate during pregnancy, hereby petitions the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act 21 U.S.C. Section 355(e) (3), and 21 C.F.R. 10.30, to reclassify the drug terbutaline sulfate from pregnancy risk category B to pregnancy risk category C, D, or X after evaluation of the published literature. The petitioner believes that adequate observational studies in animals and pregnant women have demonstrated positive evidence of fetal abnormalities or risk and therefore terbutaline should be pregnancy risk category X.

Additionally the petition requests the FDA require an amendment of the manufacturers' package inserts to reflect the change in pregnancy risk category, notify obstetricians of the change, issue another Dear Colleague Letter regarding continuous subcutaneous terbutaline pump reemphasizing maternal risk and adding fetal and neonatal risk, and require adverse effect reporting for patients and offspring receiving terbutaline sulfate via infusion pump.

Sincerely,



James P. Reichmann

FDA: 2008. P. 0358

CP

Citizen Petition

“Terbutaline Use in Pregnancy”

A. Action Requested

1. Reclassify the drug terbutaline sulfate from pregnancy risk category B to pregnancy risk category C, D, or X after evaluation of the published data (1,2).
2. Require terbutaline manufacturers to amend package inserts to state, “animal studies have revealed adverse effects on the fetus (teratogenic or embryocidal or other) and there are no controlled safety studies in humans.”(Risk category C) or “there is evidence of fetal risk and no proven maternal benefits.”(Risk category D) or “adequate observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities or risk” (risk category X) (3-40).
3. Notify obstetricians of the reclassification of the drug, the updated verbiage in the package insert, and that the National Asthma Education and Prevention Program recommends “Terbutaline no longer be given to women with mild or intermittent asthma while they are pregnant”(41-43).
4. Issue another “Dear Colleague” letter regarding continuous subcutaneous terbutaline pump therapy (CSQT) alerting healthcare professionals that it has not been demonstrated to be effective and is potentially dangerous to both the mother and the fetus (40, 44-47,50-53).
5. Require all providers of the “terbutaline pump” to report ALL past and future maternal deaths associated with the terbutaline pump to the Food and Drug Administration (FDA). Additionally, require long-term follow up of adverse events in the offspring of women exposed to the terbutaline pump in pregnancy.

B. Statement of Grounds

Terbutaline is one of the most commonly prescribed drugs given to pregnant women. By 1990 it was estimated that over 100,000 women with preterm labor were exposed to the betamimetic Ritodrine annually, and it is likely between 2 and 10 times as many are prescribed terbutaline. Over 260,000 pregnant women receive some form of terbutaline every year. It is available in intravenous, oral and subcutaneous formulations. Approximately 4,000 women a year are exposed to long-term continuous subcutaneous terbutaline each year (53-55).

Animal Studies Have Revealed Adverse Effects on the Developing Brain

Thirty eight scientific articles have been peer-reviewed and published from 1989-2008 that demonstrate terbutaline is a developmental neurotoxicant (3-40). These animal studies have revealed adverse effects on the fetus (teratogenic or embryocidal or other). Therefore, in light of this updated information, the FDA is required to change the pregnancy risk category for terbutaline and manufacturers must update package inserts.

There is mounting evidence that terbutaline negatively affects the vulnerable developing brain (3-40) and is closely associated with autism (38-40). Investigators at Kennedy Krieger Institute and Johns Hopkins University have begun extensive research on the link between slightly different versions of the gene (polymorphisms) that code for the Beta-2 adrenergic receptor (β 2AR) and increase the risk for autism when combined with terbutaline exposure (39). The twin study by Connors et al. published in 2005 shows that prenatal exposure to terbutaline was associated with increased risk of autism (39). Their findings were supported by an extensive genetic study by Cheslack-Postava et al. that confirmed the presence of these β 2AR gene variants in families with autism (37). In addition, Zerrate et al. demonstrated the effects of terbutaline on early brain development in an animal model using both neuropathological as well as behavioral measures (54). Prenatal modulation of the Beta-2 adrenergic receptor may alter normal brain development by delaying nervous system development and thereby contribute to autism and developmental delay (3-40). Research at Duke University, Kennedy Krieger Institute and Johns Hopkins University focuses on these childhood disorders being caused by a susceptible genetic makeup impacted by factors from outside the body (i.e. environmental), such as terbutaline. Given the absence of evidence substantiating any benefit from prolonged use of beta mimetics fetal and neonatal effects deserve a high priority (44-48, 55-58).

Human Studies Cast Doubt on the Fetal/Neonatal Safety of Tocolysis using Beta-Sympathomimetic Drugs

At least six scientific studies or case reports suggest that beta-sympathomimetic drugs, such as terbutaline, may have long lasting and significant effects on the susceptible developing fetal brain (38-40, 61-63). One published study demonstrated no difference in outcomes for seven to nine year old children exposed to ritodrine in utero (64). In the absence of any real evidence of fetal or neonatal safety and the obvious biological plausibility evidenced through the numerous animal studies, it is impossible to assure fetal or neonatal safety. Any potential benefit, though unproven despite over 30 years of use, is more than overridden by the potential catastrophic fetal and neonatal risk (44-48).

The American College of Obstetrics and Gynecology (ACOG), Agency for Healthcare Research and Quality (AHRQ) and the US Food and Drug Administration (FDA) Recommend Against Tocolysis with Terbutaline

ACOG warns against the use of terbutaline in pregnancy in a technical bulletin that states: "No studies have convincingly demonstrated an improvement in survival or any index of long-term neonatal outcome with the use of tocolytic therapy. On the other hand, the potential damages

of tocolytic therapy to the mother and the neonate are well documented" (56). ACOG further states, in practice bulletin entitled "Management of Preterm Labor", that "prolonged oral, subcutaneous, or intravenous tocolytic treatment is not effective". Instead, ACOG recommends that tocolytic drugs be used once, presumably in the hospital after accurate diagnosis, to prolong the pregnancy for two to seven days. This may allow the physician time to administer steroids to improve lung maturity of the fetus and to consider transporting the mother to a tertiary care facility (56, 57).

AHRQ, of the U.S. Department of Health and Human Services, concluded "in terms of gestational age at birth, prolongation of pregnancy, or birth weight, no benefits from maintenance treatment were uncovered". Additionally, "we graded beta-mimetics as "high" in probability of maternal risk. These drugs were shown to pose a risk to the mother of serious cardiovascular risk, minor cardiovascular risk, metabolic harms, and psychosocial harms" (59).

The use of terbutaline sulfate for treatment of preterm labor is not approved by the FDA. In 1997 the agency issued a Dear Colleague Letter that expressed concern regarding the use of terbutaline administered subcutaneously and warned of the potential dangers associated with terbutaline use for the treatment of preterm labor (44).

Despite the lack of evidence of their effectiveness and the potential for adverse effects, many physicians continue to use betamimetics. An evidence-based Cochrane Review included 11 randomized controlled trials (RCTs) with a total of 1,238 women. No differences between betamimetics and placebo, no treatment, or other tocolytics were seen for perinatal mortality and morbidity outcomes. Some adverse effects such as tachycardia were more frequent in the betamimetics group than in groups assigned to placebo, no treatment, or another type of tocolytic. Reviewers concluded available evidence does not support the use of oral betamimetics for maintenance therapy after threatened preterm labor (65).

Lastly, the National Asthma Education and Prevention Program, part of the National Heart, Lung, and Blood Institute, recommended pregnant women with mild, intermittent asthma should be prescribed short-acting inhaled beta-2 agonists rather than oral terbutaline (42).

No Randomized Controlled Trials (RCT's) Demonstrate the Efficacy of Long-term use of Continuous Subcutaneous Terbutaline

The two published and peer reviewed RCT's performed using continuous subcutaneous terbutaline therapy demonstrate no statistical difference with the intervention (45-46). Wenstrom et al. concluded, "Terbutaline by pump, saline by pump and oral terbutaline appear equivalent for the prevention of preterm delivery. The terbutaline pump should remain experimental" (45). Guinn et al. concluded, "Maintenance terbutaline therapy administered by pump does not prolong gestation in women successfully treated for suspected preterm labor"(46). The world's authority on evidence based medicine, The Cochrane Database/Library, reviewed "Terbutaline pump maintenance therapy after threatened preterm labor for preventing preterm birth" (47). The authors concluded "Terbutaline pump maintenance therapy has not been shown to decrease the rate of preterm birth by prolonging pregnancy. Furthermore, the lack of information on the safety of the pump therapy, as well as its substantial expense, argues against its role in the management

of arresting preterm labor. Future use should only be in the context of well-conducted, adequately powered randomized controlled trials" (47).

There exist at least twenty-one published observational trials and case studies that were almost *all* sponsored by companies that, at the time of publication, were providers of terbutaline administered continuously and subcutaneously via an insulin pump (Tokos, Healthdyne, PharmaThera, and Matria) (54, 66-86). As discussed in a previous National Womens Health Network citizens' petition and the official FDA response, these studies contain significant methodological flaws, not the least of which are selection and design bias (48,49). Industry sponsored observational studies can lead medicine astray, as evidenced in the example of Hormone Replacement Therapy (HRT). A decade of observational trials suggested that HRT was cardioprotective. Ultimately, when a well designed, sufficiently powered, randomized controlled trial was performed, the exact opposite was discovered: that HRT was ineffective. Despite the available findings regarding the dangers of terbutaline to the developing fetus as well as its lack of efficacy for tocolysis, the industry refuses to cease and desist providing continuous subcutaneous terbutaline and to perform a well designed, sufficiently powered randomized controlled trial (RCT).

Maternal Safety Remains Questionable

Concern regarding the safety of CSQT must be considered in light of the fact that very little, if any, therapeutic benefit has been demonstrated. (44-48) Five studies or case reports and additional information suggest concern regarding maternal safety is warranted (50-53, 60). Additional maternal injury and deaths during or shortly after CSQT administration remain unreported because there is currently no FDA reporting requirement.

When doses of terbutaline are repeated at close intervals, using continuous SQ administration, systemic levels may rapidly approach those of IV administration. It is because of these higher systemic drug levels and their known associated toxicities that intravenous terbutaline requires hospital in-patient monitoring. Similar safety concerns regarding the prolonged use of subcutaneous terbutaline, including unreported deaths while receiving or shortly after discontinuation of CSQT, is sufficient reason to issue an updated FDA Dear Colleague letter to healthcare professionals (44).

Food and Drug Administration (FDA) Position on Continuous Subcutaneous Terbutaline Therapy ("terbutaline pump")

In a November 17, 1997 letter to Cynthia A. Pearson, Executive Director, National Women's Health Network that was in response to a petition filed roughly a year and half earlier, the FDA acknowledged a lack of evidence supporting efficacy and potential adverse maternal, fetal, and neonatal health concerns from continuous subcutaneous terbutaline therapy. The letter from Janet Woodcock, MD, Director, Center for Drug Evaluation and Research and D. Bruce Burlington, MD, Director, Center for Service and Radiological Health specifically states, "The FDA agrees with your contention that there is no scientifically acceptable evidence that terbutaline administered continuously via subcutaneous infusion pump significantly prolongs pregnancy. The FDA also agrees that there is some evidence that the long-term use of subcutaneous terbutaline may adversely effect maternal, fetal, and neonatal health" (44, 48, 49).

Summary

The preponderance of evidence in animal and human studies proves biological plausibility and strongly supports fetal and neonatal safety concerns when terbutaline is administered off-label to pregnant women (3-40). There is a dearth of evidence demonstrating fetal or neonatal safety. Moreover, there is substantial evidence supporting risks for adverse neurodevelopmental outcomes in humans with genetic susceptibility, as well as in numerous studies in animal models. Maintenance therapy with tocolytics is proven to have no benefit and the potential risks to the fetus, neonate, and mother are very real. Recently, the National Asthma Education and Prevention Program recommended terbutaline no longer be given to women with mild intermittent asthma while they are pregnant (41-43). The FDA states "Moreover, there is no conclusive evidence that the use of continuous subcutaneous terbutaline produces consistent benefits in gestational age at delivery, birth weight, neonatal morbidity, or perinatal morbidity. In fact, most studies offer no evidence supporting such benefits" (48). Studies show that women receiving continuous subcutaneous terbutaline sulfate experience side effects and complications similar to those experienced by women receiving terbutaline and other beta-sympathomimetics intravenously. At least one maternal death occurred during outpatient use and one shortly after discontinuing the therapy (50, 51). Any maternal death, during or after exposure to continuous subcutaneous terbutaline, is clinically important. The FDA should reclassify the pregnancy risk category for terbutaline sulfate, require new package inserts and should issue notification of the change to the obstetricians. Additionally, in light of the side effects on the fetus, the FDA should issue another "Dear Colleague" letter regarding continuous subcutaneous terbutaline in addition to the existing letter, reinforcing maternal safety concerns as well as the potential fetal and neonatal harm (44). Lastly, the FDA should require reporting of all adverse events including maternal deaths (past and future), that have occurred among any women who were exposed to continuous subcutaneous terbutaline.

C. Environmental Impact

The requested actions would have no known impact on the environment.

D. Economic Impact

The requested actions would result in some loss of income for the manufacturers of terbutaline sulfate and for companies that supply terbutaline subcutaneously to women at risk of preterm delivery. Savings would be realized by medical consumers who are currently paying for an ineffective and harmful treatment. Additionally there would be savings for the medical consumers derived from a reduction of expenses related to management of maternal side effects and adverse neurodevelopmental outcomes in children exposed to terbutaline *in utero*.

E. Certification

The undersigned certifies that, to the best of knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that includes the representative data and information known to the petitioner that is unfavorable to the petition.



Signature

James P. Reichmann

[REDACTED]

On behalf of all of the women harmed and infants damaged as a result of the administration of terbutaline sulphate during pregnancy.

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2. Physicians Desk Reference 57th ed. Montvale, NJ: Thomson PDR; 2004: 3539
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Kennedy, Rhonda

From: Kennedy, Rhonda
Sent: Thursday, October 29, 2009 2:32 PM
To: Kennedy, Rhonda
Subject: FW: Constituent Letter - Terbutaline

*Rhonda M. Kennedy
Congressional Affairs Specialist
Office of Legislation
Food and Drug Administration
P: (301) 827-0285
F: (301) 827-1614
Rhonda.Kennedy@fda.hhs.gov*

From: Kennedy, Rhonda
Sent: Thursday, October 29, 2009 1:58 PM
To: 'tina.mcintosh2@mail.house.gov'
Subject: Constituent Letter - Terbutaline

Hi Tina,

Per our conversation earlier, here is FDA's response to Mr. James Reichmann's petition:

"As the Agency explained in its December 11, 2008, letter to Mr. Reichmann, this petition raises complex issues that require extensive review and analysis by Agency officials. Currently, FDA is working to evaluate the issues raised and provide a final response to Mr. Reichmann's petition."

I will get back to you if any new information becomes available. Please feel free to contact me if you have any additional questions or concerns.

Thanks,
Rhonda

*Rhonda M. Kennedy
Congressional Affairs Specialist
Office of Legislation
Food and Drug Administration
P: (301) 827-0285
F: (301) 827-1614
Rhonda.Kennedy@fda.hhs.gov*

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

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DISTRICT OFFICES:
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(678) 493-6176

www.house.gov/tomprice

VIA FACSIMILE



Congress of the United States
House of Representatives

January 8, 2010

COMMITTEE ON
FINANCIAL SERVICES
SUBCOMMITTEES:
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DOMESTIC AND INTERNATIONAL POLICY

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REPUBLICAN STUDY COMMITTEE
CHAIRMAN

DEPUTY WHIP

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

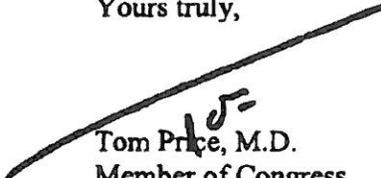
Dear Mr. Mason:

My constituent [REDACTED], 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 Tina McIntosh in my Marietta District Office at 3730 Roswell Rd., Suite 50, Marietta, GA 30062. She may also be reached by email at tina.mcintosh2@mail.house.gov or by phone at 770-565-4839.

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

2010-254

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.**

(b) (6)

(b) (6)

January 2, 2010

Representative Tom Price
Marietta Office | 3730 Roswell Road, Suite 50 | Marietta, GA 30062
phone: 770-565-4990 | fax: 770-565-7570

Dear Representative Price:

Recently, I came across a very specific problem that affects thousands of Americans when I tried to refill a prescription for a low-cost thyroid medicine that has been on the market for many years and has successfully treated millions of people. The generic name is Armour Thyroid Medicine. The Federal Government through the FDA has now either completely shut down manufacturing or severely limited the manufacturing of this drug with the excuse that "it is not consistent" with other drug manufacturers. This, in my opinion, is the Pharmaceutical Industry paying officials in Washington to shut down this competition and force patients to use more expensive drugs with more side effects.

On the same note, my insurance company of many years, (b) (6), just informed me that this year I will not be able to use "mail-in" pharmacies although I have done so for many years, (b) (6) being one of those pharmacies. It just so happens that the only limited source of Armour Thyroid Medication is from compounding mail-in pharmacies such as (b) (6). I guess I won't be able to use them either?

This Administration stated that they want to lower the costs for patients, yet, as usual they do not follow their own rhetoric.

Will you please help us look into this and protect consumers from these kinds of shenanigans? Please get Armour back on the market.

Thank you so very much. You will continue to be in our prayers. Let us know how we can help.

(b) (6)



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

MAR 05 2010

Dear Dr. Price:

Thank you for your letter of January 8, 2010, on behalf of your constituent, [REDACTED] (b) (6) of Marietta, Georgia, regarding the shortage of desiccated thyroid hormone.

The Food and Drug Administration (FDA or the Agency) would like to note that desiccated thyroid products are not FDA-approved products, even though they are on the market and available to consumers. In addition, FDA has not ordered all unapproved desiccated thyroid products off the market. Rather, FDA has urged all companies who market unapproved drug products, including desiccated thyroid products, to submit applications for approval. FDA is concerned that drugs marketed without required FDA approval have never been submitted to rigorous scientific evaluation, and therefore, may not meet required standards for safety, effectiveness, quality, and labeling. Marketers of drug products in the United States have an obligation to the public to ensure through the FDA approval process that their products meet modern standards for safety, efficacy, quality, and labeling.

Regarding possible future action against unapproved desiccated thyroid products, as a policy matter we do not discuss potential, pending, or ongoing actions, except with the firms and individuals who are the subject of those actions. Class actions against unapproved drugs are made in accordance with the priorities discussed in FDA's Compliance Policy Guide on Marketed Unapproved Drugs, which can be found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf>. Information about enforcement actions against classes of unapproved drugs is posted on the FDA Web site. For additional information regarding unapproved drugs, please access our unapproved drugs Web site at the following link:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/default.htm>.

Some inquiries to FDA have cited reports of shortages of unapproved thyroid products. The manufacturer of Westroid and Nature-Throid products, RLC Labs, Inc. (also known as Western Research) reports that they are currently in backorder for all Westroid and Nature-Throid products. Major Pharmaceuticals reports that one strength of desiccated thyroid is currently available and Forest Laboratories reports they are in backorder on all strengths and working to restore availability. The reasons provided by the companies for the current unavailability of these products are related to raw material shortages as well as manufacturing delays.

Page 2 – The Honorable Tom Price, M.D.

Patients are advised to talk to their doctors about possible alternatives if they are unable to obtain their usual thyroid medication at this time. Please note that there are several approved levothyroxine products available. Examples include Synthroid, Unithroid, and levothyroxine sodium tablets. Please let our Drug Shortage program know if you have difficulty obtaining one of these alternatives listed above. The Drug Shortage e-mail account is drugshortages@fda.hhs.gov.

Thank you again for contacting us concerning this matter. If you have further questions, 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 OFFICES:
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(770) 565-4990
FAX: (770) 565-7570

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CANTON, GA 30114
(678) 493-6176

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Congress of the United States
House of Representatives

May 17, 2010

COMMITTEE ON
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SUBCOMMITTEES:
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DEPUTY RANKING MEMBER
DOMESTIC AND INTERNATIONAL POLICY

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HEALTH, EMPLOYMENT, LABOR AND PENSIONS

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CHAIRMAN
DEPUTY WHIP

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

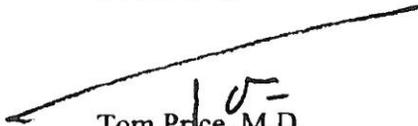
Dear Mr. Mason:

My constituent, [REDACTED] (b) (6), 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

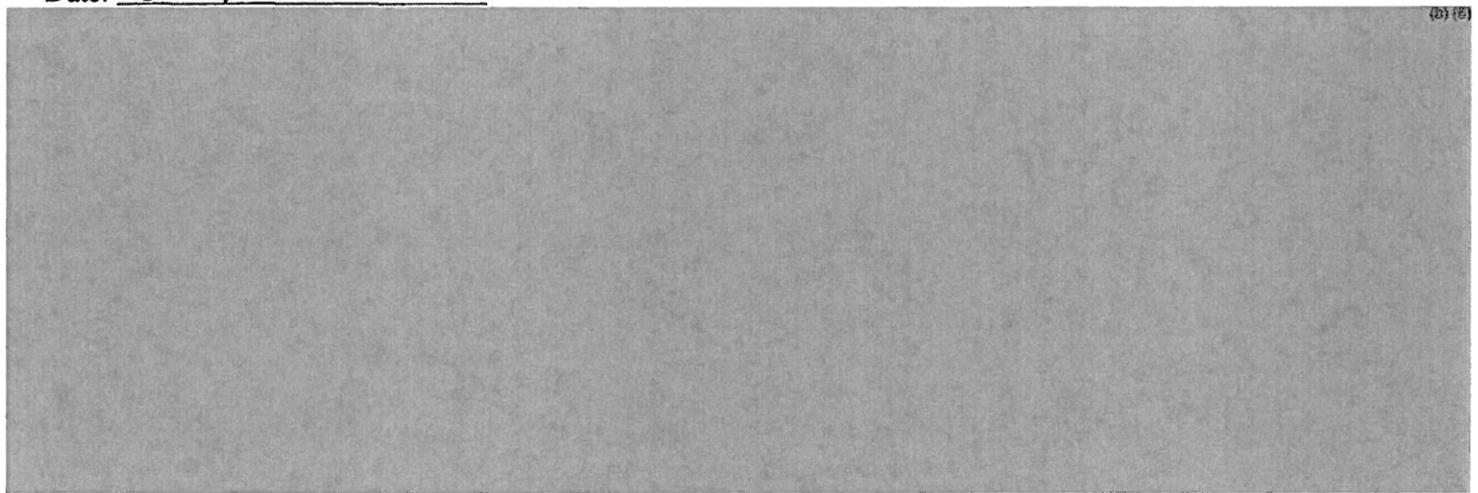
TP/tm

2010-3666

RECEIVED
MAY 17 2010
U.S. HOUSE OF REPRESENTATIVES
OFFICE OF CONGRESSMAN TOM PRICE

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

Date: 5-9-2010



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.

This is more a concern than a request
for assistance. We are concerned that
the FDA does not adequately monitor manufacture
of generic drugs especially those manufactured
in China and other third world countries.
Please see the attached sheet for our specific
problem

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, to obtain in accordance with applicable laws and regulations, information pertaining specifically to this matter.

SIGN
HERE



DATE 5-9-2010

Once complete, please return it to: Congressman Tom Price
3730 Roswell Road, Suite 50
Marietta, GA 30062
770-565-7570 FAX

For 30 years my wife has taken Librax or the generic equivalent for IBS (spastic colon). She has done well on this drug. In January 2010, her drug was switched to a generic version distributed by [REDACTED] (b) (6)

[REDACTED] She took this version for three months (yellow vs. green capsule) and began to have more problems again. Her internist said that some generics DO NOT have the same quality controls and do not have the same amounts of a drug which is a combination drug. The internist put her back on the Brand name drug (Librax 2.5) and she is doing better. We have been told that the green version of the generic (chlordiaz/clidinium) is no longer being manufactured. We were told this by [REDACTED] (b) (6). Also the price of the generic and the brand Librax has tripled in the past 3 to 4 years and is NOT covered on Medicare or our [REDACTED] (b) (6) supplement! Why! It seems unreasonable that a drug that was developed in the 1950's and is an effective treatment should be so expensive... \$300 per month is too much, and it is also NOT covered by Medicare or Medicare part D.

We feel that the FDA is NOT doing it's job of oversight and that our tax dollars are wasted as well as approving a generic drug that may come from China, according to the [REDACTED] (b) (6) website is unacceptable, particularly for senior citizens who are more easily affected by a wrong drug formula.

Being an Md/ our representative in Congress and on the Health Ways and Means Committee, we request that you look into this matter for us.

[REDACTED] (b) (6)

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

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Congress of the United States
House of Representatives

August 19, 2010

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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

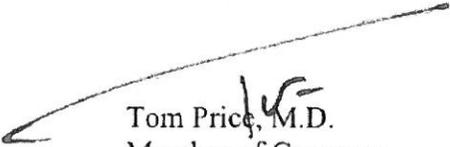
Dear Mr. Mason:

A few weeks ago I contacted your office regarding [REDACTED] (b) (5). 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. I look forward to hearing from you soon.

Yours truly,


Tom Price, M.D.
Member of Congress

TP/tm

May 17, 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, [REDACTED] (b) (6), 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

July 14, 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:

A few weeks ago I contacted your office regarding [REDACTED] (b) (6). 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



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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

AUG 24 2010

Dear Dr. Price:

Thank you for your letter of May 17, 2010, on behalf of your constituent, (b) (6), who is concerned that the Food and Drug Administration (FDA or the Agency) does not adequately monitor the manufacturing process for generic drug products made abroad. In this context, (b) (6) asked specific questions regarding the fixed-dose combination drug product marketed under the brand name Librax and the generic name chlordiazepoxide and clidinium bromide.

(b) (6) concerns touch on complex and interrelated areas of drug regulation, including an individual patient's experiences with different versions of the same drug, the quality of generic drugs, and marketed drugs that are not FDA-approved.

As a general rule, any drug or drug product that will be marketed in the United States is required under the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) to have an approved new drug application (NDA), or in the case of a generic drug product, an abbreviated new drug application (ANDA) prior to marketing a drug (21 *United States Code* (U.S.C.) 355).

FDA firmly believes that all generic drug products that have met the requirements of the approval process can be prescribed, dispensed and used with the full expectation that the consumer will receive the same clinical benefit as using the brand name product. Companies wishing to obtain approval for generic versions of approved drug products must demonstrate that their products are the same as the original drug in terms of active ingredients, strength, dosage form, route of administration and labeling. Specifically, an applicant must demonstrate that its generic product is bioequivalent to the brand name drug—that it is, in fact, biologically equivalent in terms of pharmaceutical activity, thereby delivering the same therapeutic effect as the brand name drug. However, a generic drug does not need to contain the same inactive ingredients as the brand product. Sometimes an individual will react differently to different versions of the same drug.

We encourage (b) (6) wife to discuss treatment alternatives with her physician. In addition, we suggest that (b) (6) his wife, or her physician file a MedWatch report. FDA has implemented the MedWatch program to learn of adverse experiences

that patients have encountered. FDA requires manufacturers to report adverse experiences to the Agency and accepts voluntary reports from consumers and health professionals. FDA uses these MedWatch reports to identify problems in marketed products. More specifically, the information received from a report of an adverse drug experience is added to the existing data in our Adverse Event Reporting System (AERS) database. The collected reports are monitored and observed for emerging patterns. The Agency then uses this information to initiate action as needed.

Enclosed is a copy of the MedWatch reporting form and instructions for completing it. We encourage [REDACTED] (b) (6) wife or her physician to complete this form to report the problems with the drug, and return it to the MedWatch address provided on the form. FDA also accepts reports submitted electronically at www.fda.gov/medwatch/report.htm.

Voluntary reports are essential for ensuring the continued safety of FDA-regulated products. Reports submitted to MedWatch are added to a post-marketing safety database and reviewed by FDA's post-marketing safety staff. One or two well-documented case reports may provide an early signal of unexpected safety issues and lead to additional evaluation. This may result in Agency regulatory actions that improve the safety of the products used in patient care each day. We carefully evaluate and analyze all reports that are available to us and make recommendations for possible actions if the science-based risk evaluation warrants the actions. If the report contributed to the action, the labeling change and/or public advisory will reflect the action.

Please note that FDA staff only contacts individuals who have submitted MedWatch reports if we need additional information. With the volume of reports on all issues, we are unable to provide direct feedback to each reporter, confirm whether or not a report was received for a particular individual/incident, or relate the status or outcome of a report.

To obtain specific information/documents on an issue, one can make a Freedom of Information Act (FOIA) request. One may request a printout of previously submitted reports from the AERS database. Additionally, we have the ability to do an AERS search for an individual report, provided there is enough data sufficient to enter as search parameters, i.e., date of the adverse event, type of adverse event, name and age of the patient, reporter name, and city and state where the event occurred. If we find the report in question, we would need the requester to provide authorization in writing to release the case. The reporter's name is not releasable unless it has come from the patient or Drug Company. FOIA procedures are at: <http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIRequest/default.htm>.

In regard to foreign manufacture of drugs marketed in the United States, many drug companies maintain manufacturing facilities abroad. FDA drugs (including both brand and generic) approved to be manufactured in a foreign country are manufactured in accordance with and pursuant to FDA regulations and standards, not the country of origin. Facilities that manufacture drugs for the U.S. market must meet FDA's current Good Manufacturing Practice (cGMP) requirements. cGMPs provide for systems that

ensure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations ensures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors.

FDA inspects pharmaceutical manufacturing facilities worldwide using cGMP- trained individuals whose job it is to evaluate whether or not a company is following cGMP regulations. FDA also relies upon reports of potentially defective drug products from the public and the industry. The Agency will often use these reports to identify sites for which an inspection or investigation is needed. It is of note that most companies that are inspected are found to be fully compliant with the cGMP regulations.

Complicating the situation in this instance, however, is the fact that Librax has not received full FDA approval. Between 1938 and 1962, the FD&C Act required that a sponsor demonstrate the safety of a new drug before marketing it in the United States, but the Act did not require proof of efficacy. In 1962, Congress amended the FD&C Act to require that a new drug, in order to obtain FDA approval, must be proven both safe and effective. As part of that Act, Congress mandated that FDA complete an effectiveness evaluation of drugs approved between 1938 and 1962. This process was called the Drug Efficacy Study Implementation (DESI) review.

The DESI review covered 3,400 drug products approved for safety only, as well as an even larger number of drugs identical, related, or similar to those drug products. Currently most of the 3,400 drug products and those identical, related, or similar to them have completed DESI proceedings, and those products that do not have an approved NDA, ANDA, or NDA supplement are considered to be marketed illegally in the United States. There are, however, a small percentage of products including Librax that are still pending DESI review. FDA has made an initial determination that Librax lacks substantial evidence of effectiveness. Until FDA makes a final determination, Librax can continue to be marketed.

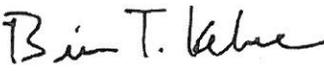
The status of Librax bears directly on [REDACTED] (b) (5) concern with the price of both the brand name and generic versions of Librax. According to the Centers for Medicare & Medicaid Services (CMS), Librax is excluded from Medicare Part D coverage because it is considered a less-than-effective DESI drug. (Please see <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf>.) We suggest that [REDACTED] (b) (5) contact CMS and his insurance provider directly to discuss the extent of coverage, as FDA does not have jurisdiction over health insurance plans or their terms of coverage. We also suggest that [REDACTED] (b) (5) contact his wife's health care professional to discuss whether or not any suitable therapeutic alternatives to Librax exist that may be covered by his insurance and Medicare.

To register general complaints concerning the price of drug products, [REDACTED] (b) (6) may wish to contact the Federal Trade Commission (FTC). FTC enforces a variety of federal antitrust and consumer protection laws. FTC seeks to ensure that the nation's markets function competitively, and are vigorous, efficient, and free of undue restrictions. FTC may be reached at the following address:

Federal Trade Commission
Bureau of Competition
Office of Policy and Evaluation
Room 394
Washington, D.C. 20580

Thank you for contacting FDA concerning this important matter. Please feel free to contact us if you have any further questions.

Sincerely,

for 
Karen Meister
Supervisory Congressional
Affairs Specialist

Enclosure

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

WASHINGTON, DC OFFICE
403 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX: (202) 275-4656

DISTRICT OFFICES
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(770) 565-4990
FAX: (770) 565-7570

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(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

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

October 14, 2011

Dear Commissioner Hamburg:

The FDA plays a critical role in ensuring the safety and efficacy of pharmaceuticals, including those known as DESI drugs. As you know, there are potentially thousands of these drugs on the market today, some with over a hundred years of commercial use. However, because there lacks a clear regulatory framework to bring DESI drugs to market legally, individuals are beginning to lose access to treatments they have relied upon for decades.

Recently, based on feedback from the FDA regarding drugs listed in the Orange Book, the Department of Veterans Affairs (VA) has begun removing drugs not currently listed from the Federal Supply Schedule (FSS) while allowing them to remain on the National Formulary. In fact, the VA has removed at least one of these drugs from the FSS even though the manufacturer has already begun the process of submitting a New Drug Application (NDA) to the FDA. As a result, not only is the VA forced to spend potentially 60% more to obtain this drug on the open market, but beneficiaries are losing access to a medication they have used, and trusted, for years. Additionally, despite the fact that this drug has been on the market for decades with no adverse event reports, the FDA is resisting the manufacturer's request that its long history of marketing be used as a substitute for some elements of the NDA.

Clinicians have been prescribing DESI drugs, and patients have been using them, for decades both in the United States and around the world. It is concerning that as DESI drugs become unavailable to veterans, millions of beneficiaries will lose access to medications they, and their clinicians, trust is their best treatment option. Because of the overall difficulty, time, and expense of bringing these drugs to market, we are starting to see the ramifications of not being listed in the Orange Book in one of our most vulnerable populations, our veterans.

The FDA should consider a more-streamlined drug approval process for DESI drugs so that access to much-needed medications is not threatened. The FDA is well within its authority in using its discretion to determine the necessary items to be included in NDAs for DESI drugs. In fact, in April 2006, the FDA indicated in correspondence that the Center for Drug Evaluation and Research is "willing to be flexible in applying statutory requirements" while working with companies who are seeking approval to market previously unapproved marketed drugs.

I appreciate that the FDA wants to guarantee the safety and efficacy of all drugs prescribed in this country. However, for the thousands of drugs on the market today with decades' worth of market history, there should be greater flexibility allowed in their NDAs. The FDA should ensure that policies it institutes do not threaten beneficiary access to much-needed medications. I look forward to hearing a response from you in the coming weeks. If you should have any questions, feel free to contact Laura Holland in my office at (202) 225-4501 or laura.holland@mail.house.gov. Thank you for your attention to this matter.

Yours truly,

A handwritten signature in black ink, appearing to read "Tom Price", with a large, stylized flourish at the end.

Tom Price, M.D.
Member of Congress
GA06



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

JAN 06 2012

Dear Dr. Price:

Thank you for your letter of October 14, 2011, regarding the marketing of Drug Efficacy Study Implementation (DESI) drugs. In your letter, you suggest that the Food and Drug Administration (FDA or the Agency) “should consider a more streamlined drug approval process for DESI drugs so that access to much-needed medications is not threatened.” In addition, you state that FDA “lacks a clear regulatory framework to bring DESI drugs to market legally.”

In responding to these and other points raised in your letter, it will be helpful to offer a brief history of the DESI program and the regulatory requirements for DESI drugs. This background information details the clear, albeit complex, regulatory framework that guides assessment of DESI drugs and should help provide context before we address your specific concerns regarding the available regulatory pathways for a DESI drug to gain approval.

When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) required that “new drugs” be approved for safety by FDA before they could be legally sold in interstate commerce.¹ To this end, the Act made it a sponsor’s responsibility, prior to marketing a new drug, to submit a New Drug Application (NDA) to FDA that demonstrated a drug product was safe for human use. Between 1938 and 1962, if a drug obtained such approval, FDA considered drugs that were “identical, related, or similar” (IRS)² to the approved drug to be “covered” by the earlier approval, and allowed IRS drugs to be marketed without independent approval.

In 1962, Congress amended the Act to require that new drugs be proven effective for their labeled indications (efficacy), as well as safe, to obtain FDA approval. This amendment also required that FDA conduct a retrospective evaluation of the

¹ A “new drug” is defined by the Act as a drug that “is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a ‘new drug’ if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use ...” (21 U.S.C. 321(p)).

² Section 310.6(b)(1) (21 CFR 310.6(b)(1)) provides: “An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties.”

effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. To comply with this requirement, FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved for safety only between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency then reviewed and re-evaluated the reports and published its findings in *Federal Register* notices. FDA's administrative implementation of the NAS/NRC reports, as you know, was called the DESI. DESI covered the more than 3,400 products specifically reviewed by the NAS/NRC, which included evaluation of some 16,000 therapeutic claims, as well as the even larger number of IRS products that had entered the market without independent FDA approval.

All drugs covered by the DESI review are considered "new drugs" under the Act. If FDA's final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for those indications and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for such indications, provided it is the subject of an application approved for safety and effectiveness.

Sponsors of drug products that are already the subject of an approved application for safety only and that have been found to be effective for one or more indications through the DESI process may rely on FDA's effectiveness determinations. As a general rule, such sponsors must update their labeling to conform to the indications found to be effective by FDA and include any additional safety information required by FDA. Those drug products with NDAs approved before 1962 for safety only, therefore, require approved supplements to their original applications, if found to be effective under DESI. In contrast, IRS drug products require an approved NDA or Abbreviated New Drug Application (ANDA), as appropriate. Furthermore, labeling for drug products classified as effective under DESI may contain only those indications for which the review found the product effective unless the firm marketing the product has received an approval for additional indication(s). Even if DESI (and IRS) products were found to be effective, they are still considered to be unapproved until applications are submitted and approved by FDA. If FDA's final DESI determination classified the drug as being ineffective, the drug product, and all drug products IRS to it, are no longer permitted to be marketed.

The Act requires that "new drugs," as defined in section 201(p) of the Act, marketed in the United States are shown to be both safe and effective prior to marketing.³ The drug approval process is essential to providing patients and prescribers with the assurance that drugs are marketed based on reliable, scientific data showing they are safe, effective, well-made, and accurately labeled. Drugs marketed without the required FDA approval have never been subjected to rigorous scientific evaluation and may not meet modern standards for safety, effectiveness, quality, and labeling. Since DESI drugs are "new

³ 21 U.S.C. 321(p)

drugs,” they are required to have an approved NDA/ANDA to be marketed in the United States.

While we recognize that the evaluation and approval process for DESI and IRS drugs has been both lengthy and complex, it was a necessary effort mandated by Congress to ensure that all drug products available to Americans are safe, effective, and meet modern scientific standards as well as current standards for labeling. In response to your suggestion that we consider a more streamlined approach to approval, and that we allow greater flexibility in approval, there is a streamlined approval pathway for drugs that are IRS to an approved DESI drug with an NDA in place. A sponsor interested in marketing such a drug may submit an ANDA and reference the approved DESI drug. In the case of an ANDA, clinical studies are generally not required because the ANDA relies on the clinical studies of the reference listed drug (RLD), if the ANDA demonstrates that the drug is bioequivalent to the RLD. For those drugs reviewed under DESI that have an NDA, sponsors would only need, in most cases, to submit a supplement to continue marketing for indications found to be effective.

In regard to Department of Veterans Affairs (VA) decisions regarding drugs listed on the Federal Supply Schedule or on the VA’s National Formulary, we are not aware of any specific guidance or direction that FDA has offered to the VA regarding the removal of drugs from its formulary. At this point, as you know, there are numerous newer drug products that post-date the DESI drug era that treat the same conditions that were treated in the past by DESI or IRS drugs. Many of these FDA-approved medicines are on the VA formulary and available for prescribing by VA clinicians.

FDA remains committed to ensuring that safe and effective drugs are available to protect and promote the health of the American people. Our initiatives reduce potential risks from products that have never been evaluated—or that have been only partially evaluated—by FDA. Please rest assured that we stand ready to assist any company or sponsor in the process of seeking approval for new drug products.

For further information on FDA’s unapproved drugs initiative, please see our website: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/default.htm>.

Thank you for your interest in this important matter. If you have further questions, please let us know.

Sincerely,


for Karen Meister
Supervisory Congressional
Affairs Specialist

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

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

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www.house.gov/tomprice



Congress of the United States
House of Representatives

April 20, 2012

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

COMMITTEE ON THE BUDGET

REPUBLICAN POLICY COMMITTEE
CHAIRMAN

DEPUTY WHIP

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

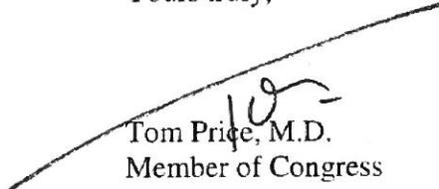
Dear Mr. Mason:

A few weeks ago I contacted your office regarding [REDACTED] (b) (6). 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. I look forward to hearing from you soon.

Yours truly,


Tom Price, M.D.
Member of Congress

TP/tm

January 27, 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:

My constituent, [REDACTED] (b) (5), 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,

Tom Price, M.D.
Member of Congress

TP/tm

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

Date: January 25, 2012

(b) (6)

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.

I have problem with my varicose veins, excruciating pain and swelling of my legs. My physician could not find any medicine sold in USA, which would have helped me.

I called my niece (MD) in Slovakia and she told me, that French pharmaceutical co. SERVIER makes wonderful medicine named DETRALEX 500mg, which also helps with cramps in legs, which bothered me much as well. She sent me small amount, and in three days my problems were gone.

Unfortunately, this medicine is not available in US, neither in Canada.

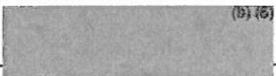
I found on Internet two countries in Europe: Ukraine and Bulgaria - where this French Co. SERVIER has also their branch in Sofia. Both countries use Russian ABC (called Cyrillic), which nobody (?) at the FDA could not read. And neither can I, even though I had to study Russian language for 2 years, while at school in Slovakia.

Yesterday I received letter from FDA, that my medicine (they called it Drug) was detained. I tried several time to call tel. & provided in letter, without any success. Then I wrote an email, copies of all, with my explanation are included. I would appreciate your help with releasing my medicine and also provide some way, that in the future they will not detain this medicine, because I need it for rest of my life. From our very modest income (we lost all our life savings) it is too much to pay for this medicine anyway. FDA needs my respond by 2/12/12. MANY THANKS!

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, to obtain in accordance with applicable laws and regulations, information pertaining specifically to this matter.

SIGN
HERE



DATE January 25, 2012

Once complete, please return it to: **Congressman Tom Price**
3730 Roswell Road, Suite 50
Marietta, GA 30062
770-565-7570 FAX

(See Reverse Side)

Copy of the original letter page 2

(b) (8)

If you have a good reason to believe that the products comply with the law and wish to discuss it with us, you may come personally to this office or write us. You must provide the reference number shown on the upper left of this notice whenever communicating with us.

Please Direct your response to:

Helen Jacobs, Compliance Officer	(718)340-7000 5681
U.S. Food and Drug Administration	(718) 662-5662 (FAX)
158-15 Liberty Avenue	<u>HELEN.JACOBS@FDA.HHS.GOV</u>
Jamaica, NY 11433	

If you do not wish to claim this shipment, you may disregard this notice and the shipment will be returned to sender without cost to you. The shipment will be returned automatically if we don't hear from you.

The shipment may contain items not included in this notice. If any portion of this shipment is refused admission, the U.S. Customs Service will cause the shipment to be returned to the sender or destroyed if the sender is unknown

Notice Prepared by: jacobsh
For the District Director, U.S. Food and Drug Administration

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

WASHINGTON, DC OFFICE:
403 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
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DISTRICT OFFICE:
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Congress of the United States
House of Representatives

January 27, 2012

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

COMMITTEE ON THE BUDGET

REPUBLICAN POLICY COMMITTEE
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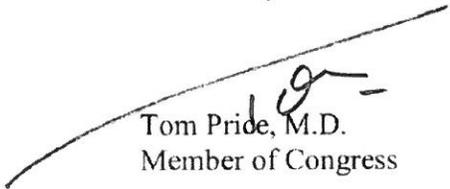
Dear Mr. Mason:

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

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

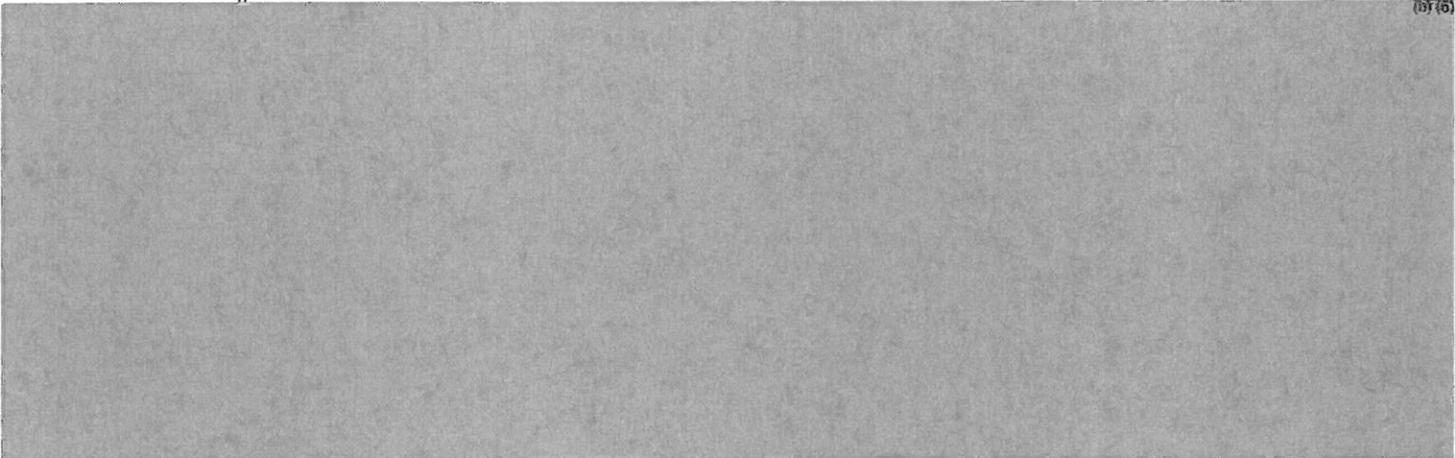
Yours truly,


Tom Price, M.D.
Member of Congress

TP/tm

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

Date: January 25, 2012



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.

I have problem with my varicose veins, excruciating pain and swelling of my legs. My physician could not find any medicine sold in USA, which would have helped me.

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I found on Internet two countries in Europe: Ukraine and Bulgaria - where this French co. SERVIER has also their branch in Sofia. Both countries use Russian ABC (called Cyrilica), which nobody (?) at the FDA could ~~not~~ read. And neither can I, even though I had to study Russian language for 8 years, while at school in Slovakia.

Yesterday I received letter from FDA, that my medicine (they called it Drug) was detained. I tried several time to call tel. & provided in letter, without any success. Then I wrote an email, copies of all with my explanation are included. I would appreciate your help with releasing my medicine and also provide some way, that in the future they will not detain this medicine, because I need it for rest of my life. From our very modest income (we lost all our life sav. mgs) it is too much to pay for this medicine anyway. FDA needs my respond by 2/12/12. MANY THANKS!

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, to obtain in accordance with applicable laws and regulations, information pertaining specifically to this matter.

SIGN
HERE



DATE January 25, 2012

Once complete, please return it to: **Congressman Tom Price**
3730 Roswell Road, Suite 50
Marietta, GA 30062
770-565-7570 FAX

(See Reverse Side)



UNITED STATES FOOD AND DRUG ADMINISTRATION
New York District Office

Notice of FDA Action

Reference Number: [redacted] (b) (6)

1/18/2012

Port of Entry 4701, JFK Airport

[redacted] (b) (6)

Shipper:

, BG

A mail shipment addressed to you from a foreign country is being held by the post office at the request of the U.S. Food and Drug Administration (FDA).

Summary of Current Status of Individual Lines

Line	FDA Product Description	Quantity	Current Status	Status Date
001	Exhibits - Other Drug Related Items N.E.C.	240 Tablets	Detained	01/17/2012

Detained

The following products are subject to refusal of admission into the United States under authority of the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to violate as indicated below:

Line	FDA Product Description	Quantity	Respond by
001	Exhibits - Other Drug Related Items N.E.C.	240 Tablets	2/12/2012
502(c); 801(a)(3)	Misbranding	The article appears to be a drug and a required label or labeling appears to not be in English, in violation of 21 C.F.R. 201.15(c)(1).	
502(f)(1); 801(a)(3)	Misbranding	The article appears to lack adequate directions for use, and does not appear to be exempt from the requirement for such directions.	

All products of this kind must meet the requirements of the Federal Food Drug and Cosmetic Act or other laws enforced by the U.S. Food and Drug Administration. These laws are designed to protect you from, among other things, unsafe or misrepresented foods, drugs, biologics, cosmetics, devices, and other articles. These products do not appear to comply with the law.

This Notice does not in any manner accuse you of violating the law.

*Invent from one of DETRALEX
 Maybe somebody in your office
 can read Russian, I already
 forgot. The medicine was
 sent from Bulgaria, when
 French Pharmaceutical Co. (DETALER)
 has their factory in Sofia,
 capital of Bulgaria.*

ЛИСТОВКА: ИНФОРМАЦИЯ ЗА ПОТРЕБИТЕЛЯ

ДЕТРАЛЕКС® 500mg

филирани таблетки

Флавоноидна фракция, пречиствена и микроинизирана
 съответствашо на флавоноиди, изразени като Хесперидин: 10%; Диосмин: 90%.

Прочетете внимателно цялата листовка, защото тя съдържа важна за Вас информация.

Този лекарствен продукт се отпуска без лекарско предписание. Независимо от това е необходимо да приемате ДЕТРАЛЕКС внимателно, за да получите възможно най-добри резултати от лечението с него.

- Запазете тази листовка. Може да имате нужда да я прочетете отново.
- Ако имате някакви допълнителни въпроси или имате нужда от съвет, попитайте Вашия лекар или фармацевт.
- Съхранете се с Вашия лекар, ако симптомите Ви се влошат или не се подобряват.
- Ако някое от нежеланите лекарствени реакции стане сериозно, или забележите други, неописани в тази листовка нежелани реакции, моля уведомете Вашия лекар или фармацевт.

В тази листовка:

1. Какво представлява ДЕТРАЛЕКС и за какво се използва
2. Преди да приемате ДЕТРАЛЕКС
3. Как да приемате ДЕТРАЛЕКС
4. Възможни нежелани реакции
5. Как да съхранявате ДЕТРАЛЕКС
6. Допълнителна информация

1. КАКВО ПРЕДСТАВЛЯВА ДЕТРАЛЕКС И ЗА КАКВО СЕ ИЗПОЛЗВА

ДЕТРАЛЕКС е венотоник (повишава венозния тонус)

2. ПРЕДИ ДА ПРИЕМИТЕ ДЕТРАЛЕКС

Не приемайте ДЕТРАЛЕКС

Ако сте алергичен (свърхчувствителен) към микро-низширана пречиствена флавоноидна фракция или към някое от помощните вещества на ДЕТРАЛЕКС.

Обърнете специално внимание при употребата на ДЕТРАЛЕКС

- Хемороиди;
- Ако хемороидите не изчезнат до 15 дни, би трябвало да потърсите Вашия лекар за съвет.

- Венозно-съдови нарушения;

Прием на други лекарства

Моля кажете на Вашия лекар или фармацевт ако вземате или наскоро сте вземали някакви други лекарства, включително и такива, получени без рецепта.

Прием на ДЕТРАЛЕКС с храни и напитки

Препоръчва се ДЕТРАЛЕКС да се приема по време на храна (вж. т. 3 КАК ДА ПРИЕМАТЕ ДЕТРАЛЕКС)

Бременност и кърмене

Пореди отсъствието на данни относно излъчването в майчиното мляко, лечението с ДЕТРАЛЕКС по време на кърменето трябва да се избягва.

Постъпвайте по съветите на Вашия лекар или фармацевт.

Ванна информация относно някои от съставките на ДЕТРАЛЕНС

Неприложимо

3. КАК ДА ПРИЕМАТЕ ДЕТРАЛЕНС

Парорално приложение.

Винаги вземайте ДЕТРАЛЕНС точно както Вашия лекар или фармацевт Ви е казал. Говорете с Вашия лекар или фармацевт, ако не сте сигурен за нещо.

Обичайната дозировка е:

- **Венозна недостатъчност:** 2 таблетки дневно, 1 таблетка на обяд и 1 таблетка вечер, по време на хранене.
- **Хемороиди:** 4-дневен курс от 6 таблетки дневно, последван от по 4 таблетки дневно през следващите 3 дни, по време на хранене.

Ако сте приели повече от необходимата доза ДЕТРАЛЕНС

Неприложимо.

Ако сте пропуснали да приемете ДЕТРАЛЕНС

Не вземайте двойна доза, за да компенсирате забравената доза.

Ако сте спрели приема на ДЕТРАЛЕНС

Неприложимо.

Ако имате някакви допълнителни въпроси, свързани с употребата на този лекарствен продукт, моля попитайте Вашия лекар или фармацевт.

4. ВЪЗМОЖНИ НЕЖЕЛАНИ РЕАКЦИИ

Като всички лекарства ДЕТРАЛЕНС може да

Описани са редки случаи на леки стомашни смущения, невровегетативни смущения (усещане за дискомфорт) и кожни реакции (обрив, силен сърбеж, уртикария), които не налагат прекъсване на лечението. Ако някоя от нежеланите лекарствени реакции стане сериозна, или ако забележите нежелани реакции, които не са описани в тази листовка, моля уведомете Вашия лекар или фармацевт.

5. СЪХРАНЕНИЕ НА ДЕТРАЛЕНС

Да се съхранява на място, недостъпно за деца.

Не използвайте ДЕТРАЛЕНС след срока на годност, отбелязан на картонената опаковка след Голден до. Срока на годност се отнася до последния ден на дадения месец.

Лекарствата не трябва да се изхвърлят в канализацията или в контейнера за домашни отпадъци. Попитайте Вашия фармацевт как да унищожите ненужните Ви лекарства. Тези марки ще спомогнат за опазване на околната среда.

6. ДОПЪЛНИТЕЛНА ИНФОРМАЦИЯ

Какво съдържа ДЕТРАЛЕНС

- Активното вещество е флавоноидна фракция, пречиствена и микроенизирана. Една таблетка съдържа 500 mg флавоноидна фракция, пречиствена и микроенизирана, количество, съответстващо на флавоноиди, изразени като хесперидин: 10% - 50 mg, динормин: 90% - 450 mg.

- Другите съставки са: натриев глицолат, микроенизирана целулоза, желатин, магнезиев стеарат, тали...

Как изглежда ДЕТРАЛЕНС и какво съдържа опаковката

ДЕТРАЛЕНС са розовооранжени, овални филмирани таблетки. Една таблетка съдържа 500 mg флавоноидна фракция, пречиствена и микроенизирана. Таблетките са налични в кутии от 30 или 60 филмирани таблетки в PVC/Алуминиеви блистри.

Не всички видове опаковки могат да бъдат налични.

Притежател на разрешението за употреба и производител

Притежател на разрешението за употреба



Les Laboratoires Servier
22, rue Garnier
92200 Neuilly-sur-Seine
Франция

Производител
Les Laboratoires Servier Industrie
905 route de Saran
45520 Gidy
Франция

и
Servier (Ireland) Industries Ltd
Borey Road
Arlow - Co. Wicklow - Ирландия

Местен представител на притежателя на разрешението за употреба
СЕРВИЕ МЕДИКАЛ ЕООД
Тел: 921 57 00

София - Sofia

My answer - copy of email

(b) (6)

(b) (6)

Tue, January 24, 2012 1:21:54 PM

To: HELEN.JACOBS@FDA.HHS.GOV

Dear Ms. Jacobs,

I tried to reach you by telephone number, provided in your letter #(718)340-7000 5681, but the machine told me, no such person exist in here. I tried several times, with no success.

I was very surprised, that this medicine I am using for varicose veins, leg swelling and pain, was detained by the FDA. I am 77 years old lady, born in former Czechoslovakia (I am from Slovak part of Country).

I had big problem with my varicose veins, extreme pain in legs and swelling, and had to stop walking, as part of my exercise regime. My doctor could not find any medication available in USA, which would have helped me.

I then called my niece in Slovakia, who is MD, told her my problems and she said, that there is a wonderful medicine made in France just for this disease. It is sold all over Europe, but not in US not Canada, and Quebec is part of Canada, where only French language is spoken.

My niece could send it to me (if you would not detain it), but I have of no way to send her money, because bank in here would charge me, then bank in Slovakia would charge for exchange from US dollars to Euro. Long story.

My son tried to find some country, which sends this medicine out of their countries, and found only two, Ukraine and Bulgaria.

Unfortunately, both Countries use Russian ABC, so you could not read, what is printed on those boxes.

Neither can I, and I had to take 8 years of Russian language at school, while Czechoslovakia was occupied by Russian. I forgot everything, except few songs.

By the way, we would not have ended in US, if not for another Russian (or Warsaw Pact) occupation of then Czechoslovakia in 1968. We waited in Austria for couple of months, went through lot of investigation by US Consulat in Vienna, until we got our Visa to enter USA.

After waiting for 5 years, that time required period, we got our USA Citizenship, and I am proud to say, that this Country is now my Country.

In those years it was required, that we renounce our Czechoslovakian citizenship, in order to receive USA Citizenship.

All this have nothing to do with my DETRALEX 500mg medicine, but I felt, that I have to write to you where I am coming from.

This medicine is expensive, I already paid 184 dollars, charged on my Visa card and would very much appreciate, if you would release it, and send it to my address, because I need it, badly.

One box is one month supply, so I would need to order from this country same medicine again, and again, until I am no longer alive.

Please, if possible, place my name in your files, or what ever you are keeping at FDA, so I can receive future shipment without delay.

I also apologize, if you will find grammar errors in this email. I am not working for a long time, loosing my hard learned English, grammar included.

I do hope, that I provided enough information for you and you would be kind to take some steps and release my medicine, where ever it is being held.

One more thing, I just wrote DETRALEX 500mg on my screen, and got among other information "What kind of diseases detralex cure?" Of course, I wrote it in English. As I mention previously, I would not be able to read Russian ABC (called Cyrilica) either.

Thank you for your understanding.

With kind regards,

(b) (6)

When I tried this medicine for the first time, 2ea in the evening, in three days my problems were over. I can not exist without it.

If you have a good reason to believe that the products comply with the law and wish to discuss it with us, you may come personally to this office or write us. You must provide the reference number shown on the upper left of this notice whenever communicating with us.

Please Direct your response to:

Helen Jacobs, Compliance Officer	(718)340-7000 5681
U.S. Food and Drug Administration	(718) 662-5662 (FAX)
158-15 Liberty Avenue	<u>HELEN.JACOBS@FDA.HHS.GOV</u>
Jamaica, NY 11433	

If you do not wish to claim this shipment, you may disregard this notice and the shipment will be returned to sender without cost to you. The shipment will be returned automatically if we don't hear from you.

The shipment may contain items not included in this notice. If any portion of this shipment is refused admission, the U.S. Customs Service will cause the shipment to be returned to the sender or destroyed if the sender is unknown

Notice Prepared by: jacobsh

For the District Director, U.S. Food and Drug Administration

From: Hamre, Gerrit
To: "tina.mcintosh2@mail.house.gov"
Cc: [Ticker, Douglas](#); [Grote, Danielle](#)
Subject: Constituent Inquiry - Import detention
Date: Monday, June 11, 2012 4:48:00 PM

Tina,

It was a pleasure speaking this afternoon. Per our conversation, I am forwarding additional information regarding FDA's personal importation policy, to assist with these matters in the future. Please see FDA's website at <http://www.fda.gov/ForIndustry/ImportProgram/ImportPolicyandInformationbyProduct/default.htm> for a comprehensive overview.

FDA may exercise enforcement discretion on importation of unapproved drugs under the following circumstances:

“When 1) the intended use is for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; 2) there is no known commercialization or promotion to persons residing in the U.S., by those involved in the distribution of the product at issue; 3) the product is considered not to represent an unreasonable risk; and 4) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply), and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country/area.”

Please let me know if you have additional questions. I hope this information has been helpful.

Take care,
Gerrit

Gerrit S. Hamre
Congressional Affairs Specialist
Food and Drug Administration
Office of Legislation - CDER/CTP Team
Tel: 301.796.8914
Fax: 301.847.8602
gerrit.hamrc@fda.hhs.gov

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

WASHINGTON, DC OFFICE:
100 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4501
FAX: (202) 225-4655

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

April 18, 2013

COMMITTEE ON WAYS AND MEANS

COMMITTEE ON THE BUDGET
VICE CHAIRMAN

COMMITTEE ON EDUCATION
AND THE WORKFORCE

DEPUTY WHIP

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, [REDACTED] (b) (6), 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 Jennifer Poole in my District Office at 85-C Mill Street, Suite 300, Roswell, GA 30075. You may also contact her by phone at 770-998-0049, by facsimile at 770-998-0050, or by email to jennifer.poole@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

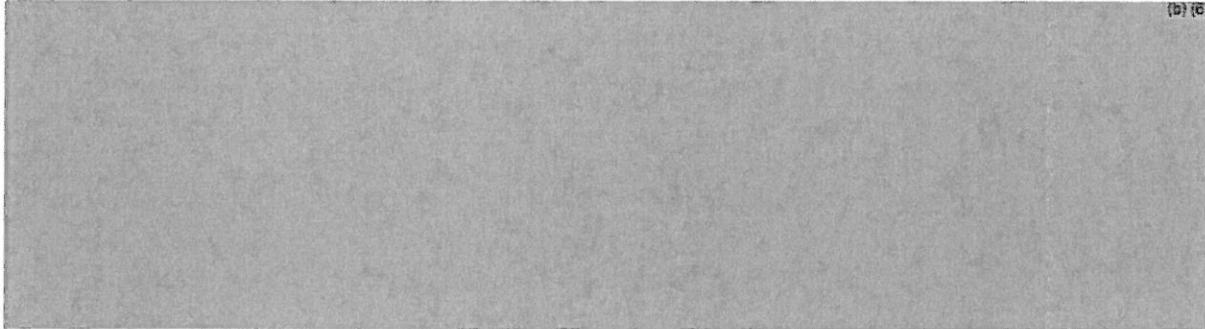
TP/jp

PRINTED ON RECYCLED PAPER

2013-2872

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

Date: 4/16/13

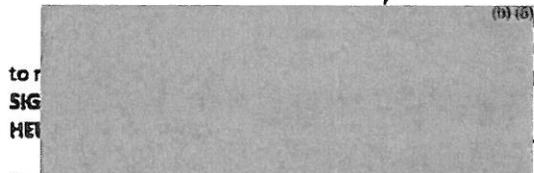


(b) (6)

Spouse/ Other Contact N/A

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.

Ever since the release of the generic
form of Lexapro 'escitalopram' I have experienced
side effects from switching to this drug.
First, within 2wks withdrawal symptoms of depression
cognitive problems. Then followed by symptoms of
PGAD, persistent genital arousal disorder, which
I am currently seeking treatment for.



(b) (6) Act Release

use acting in his behalf, in order to attempt to be of assistance
regulations, information pertaining specifically to this matter.

to r
SIG
HEI

DATE 4/16/2013

Once complete, please return it to: Congressman Tom Price
85-C Mill Street, Suite 300
Roswell, GA 30075
770-565-7570 FAX

See Attd:
There is much
literature regarding
SSRIS & PGAD.

Female Sexual Dysfunction and Persistent Genital Arousal Disorder



By Jerry Kennard, Health Guide

Wednesday, August 20, 2008

A A A

6

The term, persistent genital arousal disorder (PGAD) refers to a problem only recently identified, but which appears to affect many more women than first envisaged. Since first being described by psychiatrist Professor R. Leiblum in 2001, PGAD has attracted the attention of many hundreds of women many of whom express huge relief at finally having their situation recognized.

Originally called "persistent sexual arousal syndrome" (PSAS), Leiblum now believes the 'sexual syndrome' element is inaccurate because the problem is not sexual so much as it is an issue of unremitting genital sensations that have no particular cause and which extend over long periods of time.

But is there a difference between saying you are a nymphomaniac or saying you have PGAD? Yes, says Leiblum, who points out that so-called nymphomaniacs always identify sexual thoughts or fantasies and who experience sexual excitement. This is not the case with PGAD, which is described as an uncomfortable, unwelcome intrusion. Women with PGAD experience find no pleasure or enjoyment in their situation and actually feel quite distressed and out of control.

Emotional distress is a common theme. Women's own accounts of their situation have previously been collated and appear in the July issue of *Contemporary Sexuality*. One 65 year old talks of PGAD as like, "having a bad itch and nothing or no amount of scratching will stop it... when your every working hour feels like you are in the middle of sexual intercourse that never comes to a satisfying end it is a terrible feeling." A 53 year old woman describes how the disorder negatively affects her sexual relationship with her partner. Another 63 year old talks about being a, "case of hormonal rape." Yet others describe having "orgasmic fits" that leave them feeling uncomfortable, disturbed, embarrassed and guilty.

The causes of this distressing disorder are still unknown. MRI scans show no obvious organic pathology. To date, the women who have come forward tend to be well-educated and in long-term relationships. Some writers have speculated whether the use of selective serotonin reuptake inhibitors (SSRIs) may be responsible as accounts from some women appear to point to changes in medication as the starting point of their problem. However, this is not the case with all women. Professor Leiblum states that the only thing can be said with any certainty is the fact that PGAD appears to be a multi-factorial disorder in which neurovascular, neurochemical and psychological distress and influential.

There is no generally accepted treatment for PGAD. Certain medications can alleviate the condition but the same medications can worsen the situation in some women. Pelvic massage or stretching can be helpful. Avoidance of "heavy-handed" self-stimulation is not recommended as this simply contributes to greater genital vaso-constriction. Distraction appears to be very important as is anything which helps to provide a sense of calm.



U.S. Representative Tom Price, M.D.
Sixth Congressional District of Georgia
85-C Mill Street, Suite 300
Roswell, GA 30075
Phone: (770) 998-0049
Fax: (770) 565-7570

DATE: 4/18/13

TO: FOA
Congressional Liaison Office

FAX: 301-847-8602

FROM: Jennifer Poole, Constituent Services Director

RE: 

Thank you in advance for your assistance in this matter. If you have any questions, please do not hesitate to contact me at 770-998-0049 or by email to jennifer.poole@mail.house.gov. I look forward to hearing from you soon.

Have a Blessed day –

There are 4 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.*

Menon, Ramesh

From: Menon, Ramesh
Sent: Thursday, May 16, 2013 5:55 PM
To: 'jennifer.poole@mail.house.gov'
Subject: [REDACTED]

Attachments: MedWatch reporting form.pdf

Hi Jennifer,

As I mentioned on the phone, FDA monitors the safety of drug products, including the incidence and severity of adverse reactions, through its MedWatch program. FDA relies on the submission of MedWatch reports from health care professionals as well as consumers to help detect problems with marketed drug products. It is a voluntary system of reporting. The information received from a new report of an adverse drug experience is added to existing data in our Adverse Event Reporting System (AERS) database, and the collected reports are continually monitored for emerging patterns. In the event of a potential new safety concern, the FDA initiates action as needed.

We would encourage [REDACTED] or her health care professional to file a MedWatch report, if one has not been filed, reporting her experiences with the generic form of Lexapro. I have attached a copy of the MedWatch Reporting form and instructions for completing it. The MedWatch website can also be accessed at <http://www.fda.gov/medwatch>. [REDACTED] may also consider contacting the manufacturer of her medication, if she has not already done so.

Thanks,
Ramesh

Ramesh Menon
Congressional Affairs Specialist
Office of Legislation
U.S. Food and Drug Administration



MedWatch
reporting form.pdf (1)

Congress of the United States
Washington, DC 20515

June 12, 2015

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

Dear Acting Commissioner Ostroff:

We are writing to express our concerns regarding the Food and Drug Administration's (FDA) implementation of the *Drug Quality and Security Act* (DQSA). While we recognize the agency for its work to implement the law, we are concerned that recently released guidance documents may unnecessarily impact patient access to some compounded and repackaged drugs, which would run counter to assurances made during negotiation of DQSA. The safety of compounded and repackaged drugs is our top concern, but we must ensure that critical treatments are still available to patients who need them.

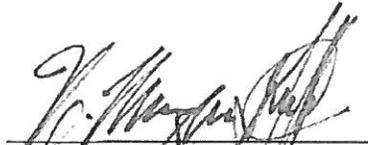
We are specifically concerned about provisions in the February 2015 draft guidance *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. We appreciate the agency's recognition of the important role these products play in the treatment of patients such as pediatric and ophthalmology patients. However, certain provisions, specifically the beyond use dates (BUD) for products covered in this guidance, could severely impact physicians' and patients' ability to access and use these products. This is especially true for biological products repackaged for office use, such as repackaged bevacizumab, for use in treating ophthalmology patients.

Unnecessarily restrictive BUDs, particularly when there is strong evidence showing the biological products can be safely mixed, diluted, or repackaged for use with longer BUDs, will essentially eliminate these products as treatment options for many patients. Physician offices will be unable to receive shipment of the products from a compounding facility before the expiration of the BUD in many cases, causing problems for physicians and patients alike. This is especially problematic for rural practices and patients. Further, we are concerned that the proposed BUDs may not allow for the required sterility testing for compounded and repackaged sterile drug products.

We urge the FDA to adhere to Congressional intent and abandon this one-size-fits-all approach to compounded and repackaged biological products and, where the evidence shows the products can be safely compounded or repackaged outside the proposed parameters, allow those products to be compounded or repackaged within parameters appropriate for that particular drug.

While we support reasonable safety measures to ensure compounded and repackaged drugs are safe and sterile, the agency must also ensure that access to essential treatments is not unnecessarily limited, as strict limitations on the compounding and repackaging process may make some treatments essentially unavailable to patients who need them.

Sincerely,



H. Morgan Griffith
Member of Congress



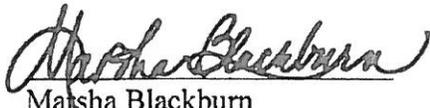
Raul Ruiz, M.D.
Member of Congress



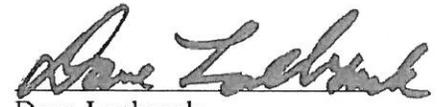
Phil Roe, M.D.
Member of Congress



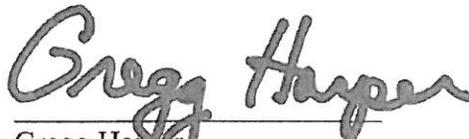
Paul Tonko
Member of Congress



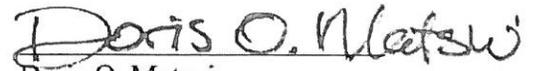
Marsha Blackburn
Member of Congress



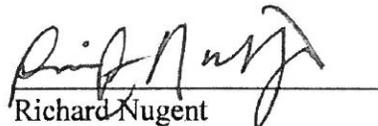
Dave Loebsack
Member of Congress



Gregg Harper
Member of Congress



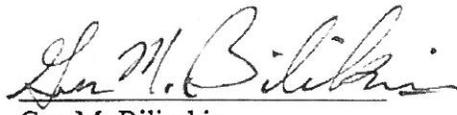
Doris O. Matsui
Member of Congress



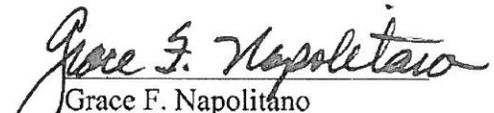
Richard Nugent
Member of Congress



Ted Deutch
Member of Congress



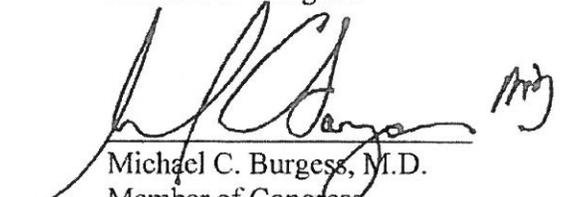
Gus M. Bilirakis
Member of Congress



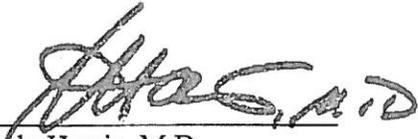
Grace F. Napolitano
Member of Congress



Joe Barton
Member of Congress



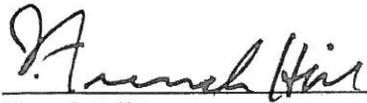
Michael C. Burgess, M.D.
Member of Congress



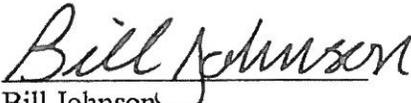
Andy Harris, M.D.
Member of Congress



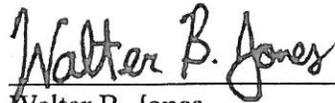
Martha Roby
Member of Congress



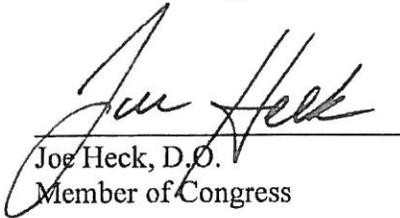
French Hill
Member of Congress



Bill Johnson
Member of Congress



Walter B. Jones
Member of Congress



Joe Heck, D.O.
Member of Congress



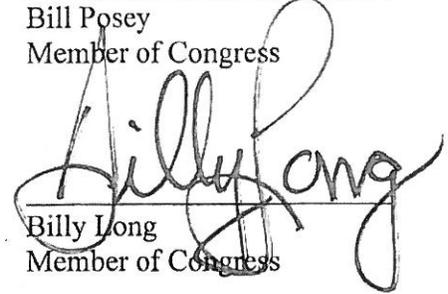
Brian Babin, D.D.S.
Member of Congress



Bob Goodlatte
Member of Congress



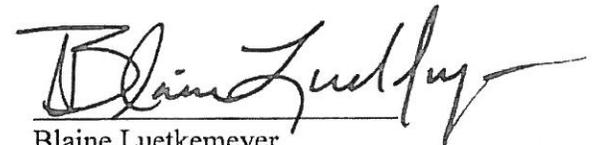
Bill Posey
Member of Congress



Billy Long
Member of Congress



Adam Kinzinger
Member of Congress



Blaine Luetkemeyer
Member of Congress



Pete Olson
Member of Congress



Renee Elmers
Member of Congress



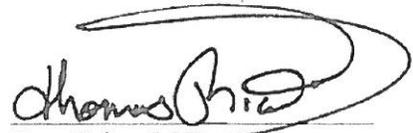
Dan Benishek, M.D.
Member of Congress



Kevin Cramer
Member of Congress



Paul A. Gosar, D.D.S.
Member of Congress



Tom Price, M.D.
Member of Congress



Matt Salmon
Member of Congress



JUL 28 2015

Dear Member:

Thank you for your letter of June 12, 2015, cosigned by several of your colleagues, concerning FDA's draft guidance document, *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (BLA)*. You expressed concerns that "certain provisions, specifically, the beyond-use dates (BUD) for products covered in this guidance, could severely impact physicians' and patients' ability to access these [compounded and repackaged] products." You also state that "[u]nnecessarily restrictive BUDs, particularly when there is strong evidence showing the biological products can be safely mixed, diluted, or repackaged for use with longer BUDs, will essentially eliminate these products as treatment options for many patients."

FDA appreciates the concerns you have raised regarding access to mixed, diluted, and repackaged products addressed in our draft guidance, and specifically the BUDs that FDA proposed. Biological products may provide a rich media for microbial growth, and as noted in the draft guidance, generally, biological products have a complex set of structural features essential to their intended effect and are very sensitive to changes to their manufacturing process, including, but not limited to, any manipulation outside their approved container-closure systems. Many biological products are particularly sensitive to storage and handling conditions and can break down or aggregate if exposed to heat and/or light, if dropped, or if shaken during storage and handling. Accordingly, diluting or mixing a biological product with other components, or repackaging a biological product by removing it from its approved container-closure system and transferring it to another container-closure system is, in the absence of manufacturing controls, highly likely to affect the safety and/or effectiveness of the biological product. Some of these effects, such as microbial contamination and interactions with the container-closure systems, can worsen over time.

The BUDs in the draft guidance reflect FDA's scientific judgment, after consultations with stakeholders, of an appropriate time within which it is reasonably likely that a mixed, diluted, or repackaged biological product could be safely used without significant risks to patients. FDA has included the BUDs in draft guidance in order to provide an opportunity for public comment.

Some of the biological products subject to the guidance, such as bevacizumab, which you reference, are sterile drugs that are manufactured without a preservative. Therefore, it is important that they be handled under conditions designed to maintain their sterility, and if they are repackaged, it is particularly important that they be placed into a suitable container and used quickly to avoid degradation of the product or proliferation of contamination, if the product is inadvertently contaminated during repackaging. Since 2007, FDA has received reports of over 100 patients with wet macular degeneration, who experienced adverse events, including blindness and serious eye infections, after injections of bevacizumab that may have been contaminated while being repackaged.

As you may be aware, the comment period on the draft guidance closed on May 20, 2015. FDA received over 350 comments, many concerning the BUDs. In addition, in April 2015, FDA held its second series of listening sessions with over 50 stakeholder groups to hear their views about FDA's efforts to implement the Drug Quality and Security Act and related activities, such as repackaging biological products. FDA intends to consider all comments on the draft guidance and input received during the recent stakeholder listening sessions before finalizing the draft guidance.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas A. Kraus', with a long horizontal flourish extending to the right.

Thomas A. Kraus
Associate Commissioner for Legislation

Grinder, Sharde

Subject: FW: [REDACTED] (b) (6) FDA inquiry
Attachments: [REDACTED] (b) (6) FDA .pdf

From: McIntosh, Tina [<mailto:Tina.McIntosh2@mail.house.gov>]
Sent: Thursday, September 24, 2015 11:22 AM
To: Jordan, Lillian T
Subject: [REDACTED] (b) (6) FDA inquiry

RE: [REDACTED] (b) (6) concern over the use of the drug Lariam

Dear Lillian -

Our above referenced constituent has contacted the Office of Congressman Tom Price, M.D. regarding a problem they are having with your agency. Please find attached a copy of their correspondence.

Please verify the status of this situation and provide our office with any information that we may use to properly assist my constituent. Please forward all correspondence to me in our District Office at 85-C Mill Street, Suite 300, Roswell, GA 30075. I may also be reached by email at tina.mcintosh2@mail.house.gov, by phone at 770-998-0049 or by fax to 770.998.0050.

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

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.

2015-6239

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

Date: 9-22-15

Name: [REDACTED] (b) (6)

Home phone

Work/Cell Phone

Social Security # [REDACTED] (b) (6) and/or A#, VA#, etc. _____
Date of Birth [REDACTED] (b) (6) AGENCY Involved Acute Care/OSHA/EOA/CDC
Spouse/ Other Contact N/A

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.

See attached.

I do however do not give permission to access any of my medical records. Use of my contact information is unacceptable.

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, to obtain in accordance with applicable laws and regulations, information pertaining specifically to this matter

SIGN HERE [REDACTED] (b) (6)

DATE 9/22/15

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

Meeting with Ryan Brooks of Congressman's Tom Price Office 9/10/15

Education

- CBS evening news segment on 12/23/2013
US troops given anti-malaria drug despite concern over side effects. [CBS.com](#)
- BBC news segment on 8/17/2015
Call for Army to stop using malaria drug mefloquine. [BBC.com](#)
- Lariam website. [Lariaminfo.org](#)
- Letter from Drs. Remington Nevin and Elspath Ritchie to Peace Corp office
- My experiences as a businessman

Requests

- Antimalarial reform at the Peace Corp
- OSHA recommendation letter. Technical Bulletin 02-04-12. Should be a legal requirement!
- FDA "Risk Mitigation Strategies" (RMS) should be emphasized for this drug
- FDA boxed warning NOT ENOUGH!!!!
- CDC warning on website should be enhanced even further



The Honorable Tom Price
Member, U.S. House of Representatives
85-C Mill Street, Suite 300
Roswell, GA 30075

DEC 30 2015

Dear Dr. Price:

Thank you for the letter of September 24, 2015, on behalf of your constituent, (b) (6), regarding the antimalarial drug mefloquine hydrochloride, previously marketed under the trade name Lariam, but no longer marketed.

Mefloquine hydrochloride is indicated for the treatment of mild to moderate acute malaria caused by specific strains of the organism, including strains that are resistant to other malaria medications. As you are aware, malaria is a serious and potentially life-threatening parasitic infection. The availability of anti-malarial drugs such as mefloquine hydrochloride is an important treatment option for patients who are infected with a resistant strain or cannot tolerate other anti-malarial drugs.

Before approving a new drug product, FDA carefully reviews safety and efficacy data and evaluates whether a drug's benefits outweigh its known risks. Adverse events reported during clinical trials are included in the drug labeling, which advises healthcare professionals and patients on safe and effective use of the product. After drug approval, additional adverse events, including infrequent and rare side effects, may become evident as the drug becomes available to a larger population. FDA requires manufacturers to report adverse experiences in accordance with regulations and tracks such information in the FDA Adverse Event Reporting System (FAERS). Additionally, FDA encourages voluntary reporting from consumers and health professionals to MedWatch, the FDA Safety Information and Adverse Event Reporting Program. FDA accepts MedWatch reports submitted by mail or electronically at: www.fda.gov/medwatch/report.htm.

As noted by (b) (6), mefloquine hydrochloride is associated with increased risk of neurologic and psychiatric adverse reactions; in July 2013, FDA strengthened warnings about this risk. This included adding a boxed warning -- FDA's strongest warning about adverse reactions -- to the label. The boxed warning states that mefloquine hydrochloride may cause neuropsychiatric adverse reactions that can persist after mefloquine has been discontinued and that it should not be prescribed for prophylaxis in patients with major psychiatric disorders. FDA also revised the Medication Guide dispensed with each prescription and the wallet card to include this new safety information and the possibility that the neurologic side effects may

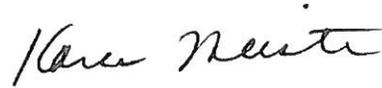
Page 2 - The Honorable Tom Price

persist or become permanent. In addition, FDA issued a Drug Safety Communication to alert patients, caregivers, and health professionals about the risks associated with mefloquine hydrochloride. More information about the Drug Safety Communication can be found at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm362887.htm>.

FDA considers mitigation and prevention of malaria a top priority and is fully engaged in scientific efforts to address this issue.

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

Sincerely,

A handwritten signature in black ink that reads "Karen Meister". The signature is written in a cursive style with a prominent dot over the 'i' in "Meister".

Karen G. Meister
Supervisory Congressional
Affairs Specialist

Mayo, Maurice

From: Jordan, Lillian T
Sent: Monday, January 11, 2016 4:24 PM
To: OC OL CDER Team
Subject: FW: [REDACTED] (b) (6)
Attachments: Fax.pdf

Importance: High

CDER Team,

The attached information is a CDER issue. Can someone please contact Tina McIntosh and let her know who will handle.

Thanks
Lillian

From: McIntosh, Tina [<mailto:Tina.McIntosh2@mail.house.gov>]
Sent: Monday, January 11, 2016 12:45 PM
To: Jordan, Lillian T
Subject: [REDACTED] (b) (6)
Importance: High

Dear Friends -

Our above referenced constituent has contacted the Office of Congressman Tom Price, M.D. regarding a problem they are having with your agency. Please find attached a copy of their correspondence.

Please verify the status of this situation and provide our office with any information that we may use to properly assist my constituent. Please forward all correspondence to me in our District Office at 85-C Mill Street, Suite 300, Roswell, GA 30075. I may also be reached by email at tina.mcintosh2@mail.house.gov, by phone at 770-998-0049 or by fax to 770.998.0050.

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

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

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Fax:

770.998.0050

Congressman Tom Price



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

Date: 12-22-2015

Name: _____



Home phone _____

Work/Cell Phone _____

Social Security _____ and/or A#, VA#, etc. _____

Date of Birth _____ AGENCY Involved U.S. Food & Drug Admin.

Spouse/ Other Contact Daughter _____

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.

I recently learned I will use a inhaler every day for life. My doctor gave me samples of Spiriva (Boehringer Ingelheim Pharmaceuticals, made in Germany) Ventolin, Bree, Advair all by Smith Clin. I wanted medicine formula made in U.S.A. As I talked to different companies I was told they could not give me that information. I have a right to use medicine from this country. Can you get this information for me? (Forget Symbicort inhaler also. All about \$305 for 30 day supply.

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, to obtain in accordance with applicable laws and regulations, information pertaining specifically to this matter.

SIGN

HERE _____



DATE 12-22-2015

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

Dear Ms. McIntosh,

Thank you for your email on behalf of Congressman Price's constituent who has concerns about obtaining medicines made in the United States. While the decision by a drug manufacturer on where to locate their business is outside the purview of the U.S. Food and Drug Administration (FDA or the Agency), I thought that the following information might be helpful.

Many drug companies have manufacturing facilities abroad. It is also common for manufacturers in the United States to manufacture at one facility and package their products at another. Please know that prescription drugs manufactured abroad for importation into and use in the United States are subject to the same legal requirements and standards as drugs manufactured in the United States.

Current FDA regulations do not require the disclosure of the actual manufacturing site or sites in the labeling of drug products. FDA regulations do require that drug product labels bear the name and place of business of the manufacturer, packer, or distributor. The statement of this place of business shall include the street address (unless it appears in a current city or telephone directory), city, state or country (for foreign addresses), and applicable mail code.

For products imported into the United States, general country of origin marking requirements are overseen by the Department of Homeland Security, U.S. Customs and Border Protection (CBP). Additional information about country of origin marking requirements can be found in CBP Publication 0000-0539, available at <http://www.cbp.gov/document/publications/terminology-and-methods-marking-country-origin-us-imports>. Specific questions regarding country of origin marking requirements should be directed to CBP.

Thank you, again, for your email on this matter. If you have further questions, please let me know.

Regards,
Michelle

Congress of the United States
Washington, DC 20515

December 21, 2015

Dr. Stephen Ostroff
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Ostroff,

As members of the House GOP Doctors Caucus, we write today to express our concerns with the FDA's implementation of the Biologics Price Competition and Innovation Act (BPCIA), and to urge the FDA to solicit and consider physicians' and patients' views in its rulemaking. At a September 17, 2015 congressional hearing, Dr. Janet Woodcock repeatedly emphasized the importance of patient and healthcare provider confidence in biosimilars to the success of this program and identified the agency's responsibility as needing to ensure that the biosimilar scientific framework is "bulletproof." We agree.

The House Doctors Caucus recently held a roundtable discussion with various stakeholders in the biosimilars debate. There was broad agreement among the panelists and the providers present that biosimilars show a great deal of promise in increasing access to treatment and reducing health care costs. The discussion also accentuated, however, that there are many unresolved questions among the patient and physician communities, and that the potential benefits of these products will only be realized when physicians feel comfortable prescribing them and patients feel safe taking them. We believe patient and provider confidence in biosimilars will be enhanced if they have a voice in the development of key policies such as labeling and interchangeability.

We believe physicians want the most accurate information possible so that they can make decisions in the best interest of their patients. Earlier this year the Alliance for Safe Biologic Medicine published a survey of physicians that reflected overwhelming support for the biosimilar label to identify the product as a biosimilar, include data used to determine that it is highly similar to the reference product, and explicitly state which indications were approved for use based on extrapolation. It is also our understanding that the majority of comments that the FDA received from patient and provider advocates in response to its February 2012 draft guidance, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," endorsed the requirement that biosimilar labels state that the product is approved as a biosimilar to a reference product for stated indication(s) and indicate the route of administration, as well as whether or not it has been determined by the FDA to be interchangeable. FDA's draft guidance stated that this information was important for providers to have in order to make prescribing decisions. However, when the FDA finalized this guidance this year, these labeling requirements were deleted without any explanation.

Additionally, during the time that the draft "Scientific Considerations" guidance was in effect, the first biosimilar was approved and the label of this product does not include any of this information. Indeed, the labeling of the first biosimilar is virtually the same as the label of the innovator product. This information is important to physicians who will make the decision of whether or not to prescribe or administer biosimilars to their patients. Why did the FDA change the labeling requirements in its "Scientific Considerations" final guidance, in seeming contradiction of both the draft guidance and the strong support from patients and physicians for these aspects of the draft guidance?

Furthermore, during her September 17 testimony, Dr. Woodcock stated that physicians could refer to the FDA's Purple Book to determine whether or not a biosimilar has been determined to be interchangeable. That seems to be contrary to FDA's own labeling regulations, as well as unnecessarily complex. Is it the FDA's expectation that all physicians know that the Purple Book exists, and that they will refer to it every time they consider prescribing a biosimilar product? What is the public health justification for referring physicians to the Purple Book rather than requiring that information on the product label?

We urge the FDA to solicit, consider, and respond to the views of patients and the physicians who care for them. We believe patients and their caregivers deserve an inclusive and transparent process for the development of BPCIA policies.

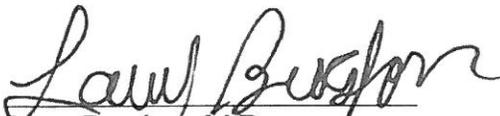
Sincerely,



Brad Wenstrup, D.P.M.
Member of Congress



David P. Roe, M.D.
Member of Congress



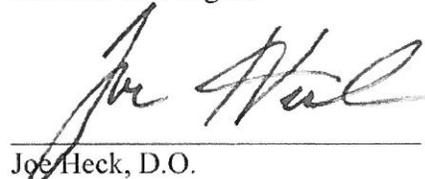
Larry Buschon, M.D.
Member of Congress



Renee Ellmers, R.N.
Member of Congress



Andy Harris, M.D.
Member of Congress



Joe Heck, D.O.
Member of Congress



Tom Price, M.D.
Member of Congress



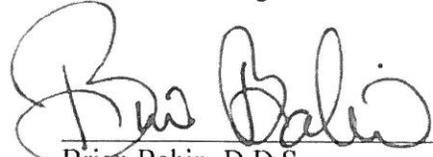
Ralph Abraham, M.D.
Member of Congress



Diane Black, R.N.
Member of Congress



Dan Benishke, M.D.
Member of Congress



Brian Babin, D.D.S.
Member of Congress



John Fleming, M.D.
Member of Congress



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

MAR 11 2016

Dear Dr. Price:

Thank you for your letter of December 21, 2015, cosigned by 11 of your colleagues, in which you expressed concerns with the Food and Drug Administration's (FDA or the Agency) implementation of the Biologics Price Competition and Innovation (BPCI) Act and urged FDA to solicit and consider physician's and patient's views in the development of key policies.

In your letter, you state that you believe patient and provider confidence in biosimilars will be enhanced if they have a voice in the development of key policies such as labeling and interchangeability. We agree. FDA is diligently working to issue guidance on issues that have been identified by FDA and stakeholders as key topics of interest including *Labeling for Biosimilar Biological Products* and *Considerations in Demonstrating Interchangeability to a Reference Product*. FDA intends to issue these draft guidances in the near future. The Agency will adhere to FDA's good guidance practices, including providing the opportunity for stakeholders to comment and taking into account the comments before issuing any final guidances.

As feasible, FDA holds listening sessions with stakeholders upon request, such as health professional and patient organizations, to hear the concerns of the patient and provider community and what educational materials they believe would be valuable to better understand biosimilars. Examples of organizations the Agency has met with include the Crohn's and Colitis Foundation and the American Medical Association.

We have restated your questions below in bold, followed by our response.

- 1. It is also our understanding that the majority of comments that the FDA received from patient and provider advocate in response to its February 2012 draft guidance, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," endorsed the requirement that biosimilar labels state that the product is approved as a biosimilar to a reference product for stated indication(s) and indicate the route of administration, as well as whether or not the product has been determined by the FDA to be interchangeable. FDA's draft guidance stated that this information was important for providers to have in order to make prescribing decisions. However, when the FDA finalized this guidance this year, the labeling requirements were deleted without any explanation.**

Additionally, during the time that the draft “Scientific Considerations” guidance was in effect, the first biosimilar was approved and the label of this product does not include any of this information. Indeed the labeling of the first biosimilar is virtually the same as the label of the innovator product. This information is important to physicians who will make the decision of whether or not to prescribe or administer biosimilars to their patients. Why did the FDA change the labeling requirements in its “Scientific Considerations” final guidance, in seeming contradiction of both the draft guidance and the strong support from patients and physicians for these aspects of the draft guidance?

FDA agrees that health care professionals should have product labeling that includes the essential scientific information about the safety and efficacy profile of a product necessary to make informed prescribing decisions for their patients. However, FDA announced that prior to finalizing this guidance, we expect to issue a separate draft guidance on labeling for biosimilar products. Therefore, FDA did not address labeling issues in its final guidance, *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*.

FDA has received citizen petitions submitted by Abbvie, Inc., the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO), requesting that FDA require the labeling of biological products licensed under section 351(k) of the Public Health Service Act (PHS Act) to include certain information including, among other things, a statement that the product is biosimilar to a particular reference product. In addition, the PhRMA/BIO citizen petition requests that FDA require the labeling to indicate whether FDA has made a determination of interchangeability for the product. FDA also has received a citizen petition submitted by a number of organizations, including the UAW Retiree Medical Benefits Trust, requesting, among other things, that a biological product licensed under section 351(k) of the PHS Act have the same labeling as its reference product. FDA is continuing to consider the issues raised by these petitions, including whether labeling of products licensed under section 351(k) of the PHS Act should contain a statement of biosimilarity/interchangeability. The public has the opportunity to comment on these Citizen Petitions and will be provided with an opportunity to comment on the draft guidance on labeling when it is published.

2. Furthermore during her September 17 testimony, Dr. Woodcock stated that physicians could refer to the FDA’s Purple Book to determine whether or not a biosimilar product has been determined to be interchangeable. That seems to be contrary to FDA’s own labeling regulations, as well as unnecessarily complex. Is it the FDA’s expectation that all physicians know that the Purple Book exists and that they will refer to it every time they consider prescribing a biosimilar product? What is the public health justification for referring physicians to the Purple Book rather than requiring that information in the product label?”

FDA created the “Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations” on its own initiative to provide a convenient source of information regarding licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. This online resource enables a user to see whether a biological product has been determined by FDA to be biosimilar to or

interchangeable with a reference product (an already-licensed FDA biological product). Biosimilar and interchangeable biological products will be listed under the reference product to which biosimilarity or interchangeability was demonstrated. The lists also serve as helpful references for industry, health care professionals, consumers and others to be able to determine the earliest date at which a biosimilar or interchangeable product could be licensed based on exclusivity determinations for the reference product.

While we intend for the Purple Book to serve as a resource for health care practitioners on whether a product has been determined to be biosimilar to or interchangeable with a particular reference product, we are continuing to consider whether the labeling of products licensed under section 351(k) of the PHS Act should include a statement indicating whether the product has been determined to be biosimilar to or interchangeable with its reference product.

Health care professionals are advised to review the labeling (prescribing information) of the biosimilar product to determine which conditions of use and routes of administration the biosimilar was approved for; the Purple Book is not intended to be a resource for this information.

FDA has initiated an outreach and education effort targeting health care professionals and consumers to increase awareness and understanding of biosimilars risks and benefits. This effort aims to increase awareness of the Purple Book. For example, FDA developed an accredited CME course to educate health care professionals (physicians, nurses, pharmacists, nurse practitioners and physician assistants) nationwide about biosimilar products. The 90 minute web-based course, which was released on February 18, 2016, provides important information about biosimilars to help health care professionals make informed decisions when considering, prescribing, or dispensing biosimilar products, and includes a web link to the Purple Book in the Resources section of the course. FDA has and will continue to conduct outreach to inform health care providers and stakeholders about the course's availability. The course is available at <http://www.fda.gov/Training/ForHealthProfessionals/default.htm>.

Thank you, again, for contacting us about this matter. The same letter has been sent to your cosigners.

Sincerely,



Dayle Cristinzio
Acting Associate Commissioner for Legislation

Brown, Akeisha

From: Legislation
Subject: FW: [REDACTED] (b) (6) /off label drug use
Attachments: ArminioPW.pdf

Importance: High

From: Poole, Jennifer [mailto:Jennifer.Poole@mail.house.gov]
Sent: Thursday, November 17, 2016 10:26 AM
To: PartsABCongressionalRO4@cms.hhs.gov; Jordan, Lillian T
Subject: [REDACTED] (b) (6) /off label drug use

Dear friends at CMS and the FDA,

One of Congressman Price's constituent's has contacted our office regarding a matter in which we believe you could be helpful. Please find attached the correspondence we received from [REDACTED] (b) (6)

Thank you in advance for your consideration and any assistance you might have to offer our constituent.

Sincerely,

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

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Privacy Act Release Form for the Office of U.S. Representative Tom Price

(adopted from Senator Perdue's Privacy Release Form)

85-C Mill Street, Suite 300

Roswell, GA 30075

770-998-0050 Fax

NOV 15 2016

~~9182 4 1 AON~~

PLEASE PRINT:

CIRCLE PREFERRED TITLE: MR. MS. MRS. DR. OTHER: MRS

NAME: (b) (6)

BUSINESS (if applicable):

ADDRESS: (b) (6)

CITY: (b) (6) STATE: (b) (6) ZIP: (b) (6)

HOME PHONE: (b) (6) WORK PHONE:

MOBILE PHONE: (b) (6) FAX:

E-MAIL ADDRESS: (b) (6)

SOCIAL SECURITY NUMBER: Will provide over phone but not on a public form DATE OF BIRTH: 01.24.1956

IDENTIFICATION NUMBER: Please provide any relevant identification number in order for the appropriate Federal Agency to identify your records pertaining to this inquiry. Not all of the following identification numbers pertain to every constituent. Please provide any number relevant to your personal case.

VA NUMBER: CSA OR CSF NUMBER:

OWCP CLAIM(S) NUMBER(S):

ALIEN IDENTIFICATION NUMBER:

IMMIGRATION RECEIPT NUMBER:

TAX ID NUMBER:

FEDERAL AGENCY OR DEPARTMENT: Please specify the name of the Federal Agency or Department involved in the space provided below.

FEDERAL DRUG ADMINISTRATION – APPROVING DRUGS FOR OFF-LABEL USE

MEDICARE – COVERING MEDICALLY-NECESSARY DRUGS FOR OFF-LABEL USE

Pursuant to the requirements of the Privacy Act, PL 93-579, I hereby grant Representative Tom Price and his staff access to my records so that they may assist me with my case.

SIGNATURE:

(b) (6)

DATE: 11-09-16

NOV 15 2016

NATURE OF PROBLEM: Below, please provide a complete statement regarding the nature of the problem and the assistance needed from this office. Please attach copies of any additional pertinent documents.

STATEMENT : Bullet points followed by full explanation

- I have a RARE auto-immune disease Neuromyelitis Optica (NMO) that attacks spinal cord and optic nerve
- There are NO FDA-approved drugs to treat NMO and no cure
- Non-FDA-approved drug Rituxan controls the disease by targeting the cells that cause the disease
- Although other insurance companies cover the cost of Rituxan when medically necessary, and Medicare HAS covered it in the past, Medicare now says it will NOT cover it
- Retirees cannot pay \$40,000 per year for this treatment but the alternative is risking paralysis, blindness, and life on a ventilator
- Drug manufacturer Genentech has a patient assistance program but the pot is getting very small with Medicare now denying coverage
- Help is needed for everyone with NMO to either get Medicare to cover Rituxan or the FDA to approve Rituxan and then Medicare would cover it

I have a RARE auto-immune chronic disease called Neuromyelitis Optica (NMO aka Devics Disease). Cells within my body create antibodies that attack the myelin sheath of my optic nerve and spinal cord, causing inflammation and creating scar tissue on the nerves, affecting my walking and my eyesight. Each attack adds to the previous damage and disability, so it's crucial to STOP THE ATTACKS! There is no cure. Its effects are like MS on steroids; its debilitation, unlike remitting/relapsing MS, is cumulative with each attack. And it is so rare (estimated 12-15,000 in the US) that drug companies have no financial interest in developing drugs and performing clinical trials to find a successful treatment. Therefore there are NO FDA-APPROVED DRUGS to treat NMO.

Rituxan, developed to treat rheumatoid arthritis, administered in twice-yearly 1g infusions, has been found kill the specific cells that create the rogue antibodies in NMO. No cells, no antibodies, no attacks. But it is an off-label use of the drug and therefore not FDA-approved, despite small-sample (because we are rare) clinical trials conducted by doctors (not the drug company) and empirical evidence that show it works. If a patient can show medical necessity, several insurance companies (BCBS, Aetna, Coventry, UHC) cover it after a patient fails on two other medications such as Imuran and CellCept (usually covered although also not FDA-approved for NMO).

I had to appeal several times but was granted coverage through my husband's employee insurance for the past four years. It saves us over \$37,000 a year since the cost of the drug alone is \$20,000 per dose. After suffering three attacks, I have been attack-free since going on Rituxan treatments three and a half years ago.

After working for over 40 years before this disease hit, I was granted SSD and became eligible for Medicare in May 2016. We thought this meant my husband at age 66 could retire because we would no longer need his employee insurance. Other patients with this disease have been covered under Medicare. But when we started looking at Supplements prior to going off employee insurance and on Part B, the Supplement insurance companies said they would only pick up balances on treatments Medicare would cover – and that Medicare wouldn't cover Rituxan for NMO use. Not believing this, and knowing other patients WERE covered for Rituxan under Medicare, I talked to Medicare but they concurred. I talked to my doctor's office, and they concurred. Then a national charitable group for NMO told me they'd been getting calls from patients all over the country that Medicare was now denying their Rituxan and that the so-called Affordable Care Act was most likely to blame. (And now, sadly, with Hillary looking like our next president, that does not appear likely to change.)

We are in a Catch-22. I have not applied for Part B or a Supplement yet because there is no point if my drug is not covered; But we don't know for sure what will happen if my provider puts through a claim to Medicare for my treatment. If I go on Medicare, my treatment is not covered, and I can't get help from the drug company, then I can't go back on the company plan. So either my husband continues to work for as long as his employer will keep him or until he or I drop dead just so I can have Rituxan. Or I go on Medicare and we take our chances that the drug company or the

NOV 15 2016

hospital where I am treated helps us with the costs, risking financial ruin and the loss of all we have responsibly worked toward for over 45 years to cover a disease I contracted through no action of my own.

Rituxan is the only reliable treatment at this time for NMO and even it is not a guarantee, but so far, it works for me. Imuran and Cellcept deplete your entire immune system, leaving you susceptible to every germ that comes down the pike. Plus the attack rate on those drugs is much higher than Rituxan. Several drug companies, under the funding of the charitable group, ARE working on drugs for NMO but they are far down the clinical trials pipeline from being FDA-approved. And they are certain to cost a lot more than Rituxan because the target audience is small. Yet Rituxan has been shown to work for not only rheumatoid arthritis and lupus, for which it is covered, but also for NMO and Multiple Sclerosis, for which it is not.

Rituxan works for NMO. It is approved in other parts of the world for treatment of NMO. It is approved for off-label use for NMO by insurance companies all over this nation (although you may still have to fight for it with some). It used to be approved by Medicare. So why the change? Yes, it's expensive, but so is the care required to manage the health issues of someone who is paralyzed and blind and on a ventilator because the disease attacked the part of the spinal cord and brain stem that regulate breathing.

The FDA needs to look at all the evidence that Rituxan works to control NMO. The risks of side effects are no different than for someone with RA or Lupus. Then approve it for NMO treatment (and MS -- their numbers are far greater than ours). Medicare needs to reconsider and approve Rituxan for medically-necessary off-label use for the same reasons.

I know this has been lengthy but it is not an issue that is easy to explain. Thank you for any help you can provide. I have many case studies that show Rituxan's effectiveness in treating NMO if you need them.

(b) (8)



Bolling, Anthony

From: Hareid, Jonathan
Sent: Tuesday, April 15, 2014 10:22 AM
To: McIntosh, Tina
Cc: Jordan, Lillian T; OC OL CDER Team
Subject: RE: [REDACTED] (b) (6)

Hi Tina,

You can reach me at 301-796-8895. I'm sorry for the confusion.

Regards,

Jonathan Hareid

Jonathan Hareid, JD/PhD
Congressional Affairs Specialist
U.S. Food and Drug Administration
Office of Legislation
White Oak Bldg. 32 Rm. 2383
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-8895
jonathan.hareid@fda.hhs.gov

From: McIntosh, Tina [<mailto:Tina.McIntosh2@mail.house.gov>]
Sent: Tuesday, April 15, 2014 10:19 AM
To: Jordan, Lillian T
Cc: OC OL CDER Team
Subject: RE: [REDACTED] (b) (6)

Lillian,

I received this message yesterday when I came in :

A Mr. Hereide from the FDA called regarding [REDACTED] (b) (6) case. You can reach him at 301-651-9172

But the number I was given is incorrect. Can I get the correct # from you or can you let them know I've tried calling?

Thank you for your continued assistance in this matter.

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

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From: Jordan, Lillian T [mailto:Lillian.Jordan@fda.hhs.gov]
Sent: Monday, March 24, 2014 2:45 PM
To: McIntosh, Tina
Cc: OC OL CDER Team
Subject: FW: [REDACTED] (b) (6)
Importance: High

Tina,

Thank you for your inquiry. I am forwarding your email to our drugs team. Someone on this team will be able to assist you.

Thank you for contacting us concerning this matter.

Lillian

*Lillian T. Jordan
Congressional Affairs Specialist
Food and Drug Administration
Office of Legislation
10903 New Hampshire Ave.
W032, Room 2341
Silver Spring, MD 20993-0002*

From: McIntosh, Tina [mailto:Tina.McIntosh2@mail.house.gov]
Sent: Monday, March 24, 2014 2:31 PM
To: Jordan, Lillian T
Subject: FW: [REDACTED] (b) (6)
Importance: High

Lillian,

We sent this last week to Elaine, but I wasn't positive she was the correct contact so I'm resending it along w/the UPS tracking information.

If additional information is needed, please let me know. Thank you in advance for your assistance in this matter.

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

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-----Original Message-----

From: McIntosh, Tina
Sent: Friday, March 21, 2014 9:43 AM
To: 'Elaine.Vining@fda.hhs.gov'
Subject: [REDACTED] (b) (6)

Elaine,

Please find attached a Privacy Release from [REDACTED] (b) (6) regarding a shipment of saline he purchased from Canada due to the shortage in the US. It was stopped in Louisville by UPS per orders from the FDA and he is requesting it be released to he can continue surgeries he has scheduled.

Any assistance you can provide would be greatly appreciated!! If additional information is needed, please let me know.

Bolling, Anthony

From: McNeill, Lorrie
Sent: Tuesday, December 16, 2014 5:09 PM
To: Stevens, Joy S; Jordan, Lillian T; Segal (Reisman), Melissa
Cc: OC OCTMA Contacts; Meister, Karen G
Subject: Contact from Congressman Price's Office

Good afternoon – below is an email contact from a staffer with Congressman Price's office to Dr. Celia Witten with a request to speak with the Congressman.

. We are forwarding the request to OL for follow up. We're happy to answer questions through OL that we are able to, but please note that we may not be able to address questions about a specific firm.

Please let us know if you have any questions. Thanks much!

Lorrie

Lorrie H. McNeill
Director
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
Email – lorrie.mcneill@fda.hhs.gov
Phone – 240-402-7800

From: Foster, Cheyenne [<mailto:Cheyenne.Foster@mail.house.gov>]
Sent: Tuesday, December 16, 2014 4:14 PM
To: Witten, Celia (CBER)
Cc: Street, Amanda
Subject: Call with Dr. Price

Dr. Witten,

I am emailing you on behalf of Congressman Price and his healthcare policy advisor, Amanda Street. Are you available to speak over the phone with the Congressman this week? It is regarding a matter with a constituent that Senator Isakson may have recently spoken with you about.

Cheyenne Foster
Executive Assistant | Congressman Tom Price, M.D. (GA-06)
Office: (202) 225-4501 | Fax: (202) 225-4656
www.TomPrice.House.Gov | [@RepTomPrice](https://twitter.com/RepTomPrice)

Bolling, Anthony

From: McIntosh, Tina <Tina.McIntosh2@mail.house.gov>
Sent: Thursday, August 06, 2015 2:25 PM
To: Jordan, Lillian T
Subject: RE: Request for Help: b(4) CCI

Woohoo!! 😊 Thanks!!

From: Jordan, Lillian T [mailto:Lillian.Jordan@fda.hhs.gov]
Sent: Thursday, August 06, 2015 2:24 PM
To: McIntosh, Tina
Subject: RE: Request for Help: b(4) CCI

Our response is in typing.

From: McIntosh, Tina [mailto:Tina.McIntosh2@mail.house.gov]
Sent: Thursday, August 06, 2015 10:20 AM
To: Jordan, Lillian T
Subject: RE: Request for Help: b(4) CCI

Lillian –

Just requesting an update on the above referenced matter. Thank you in advance for any information/assistance you can provide.

*Tina McIntosh
Constituent Services Director
Office of Congressman Tom Price, M.D. - GA06
85-C Mill St., Ste 300
Roswell, GA 30075
770-998-0049
770-998-0050 fax*

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From: Jordan, Lillian T [mailto:Lillian.Jordan@fda.hhs.gov]
Sent: Friday, July 31, 2015 3:57 PM
To: McIntosh, Tina
Subject: RE: Request for Help: b(4) CCI

Hi Tina,

Our response is in its final stage of clearance. We should have a response for you next week.

Lillian

Lillian T. Jordan

Congressional Affairs Specialist
Office of Legislation
Food and Drug Administration
10903 New Hampshire Ave.
WO32, Room 2341
Silver Spring, MD 20993-0002
Direct Line: 301-796-8912



From: McIntosh, Tina [<mailto:Tina.McIntosh2@mail.house.gov>]
Sent: Tuesday, July 28, 2015 10:34 AM
To: Jordan, Lillian T
Subject: RE: Request for Help: b(4) CCI
Importance: High

Lillian-

Just requesting an update on the above referenced matter. Thank you in advance for any information/assistance you can provide.

*Tina McIntosh
Constituent Services Director
Office of Congressman Tom Price, M.D. - GA06
85-C Mill St., Ste 300
Roswell, GA 30075
770-998-0049
770-998-0050 fax*

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From: Jordan, Lillian T [<mailto:Lillian.Jordan@fda.hhs.gov>]
Sent: Tuesday, June 30, 2015 3:23 PM
To: McIntosh, Tina
Subject: RE: Request for Help: b(4) CCI

Thanks Tina. I have forwarded this release to the appropriate office for reply.

Lillian

Lillian T. Jordan
Congressional Affairs Specialist
Office of Legislation
Food and Drug Administration

10903 New Hampshire Ave.
WO32, Room 2341
Silver Spring, MD 20993-0002
Direct Line: 301-796-8912



From: McIntosh, Tina [<mailto:Tina.McIntosh2@mail.house.gov>]
Sent: Monday, June 29, 2015 2:27 PM
To: Jordan, Lillian T
Subject: FW: Request for Help:b(4) CCI

Lillian-

Please find attached the letter that I think will suffice for FDA to speak to our office. Please forward to appropriate office for reply.

Thank you again for your time & assistance in this matter.

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

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From: b(4) CCI
Sent: Monday, June 29, 2015 2:24 PM
To: McIntosh, Tina; b(4) CCI b(6) personal privacy
Cc: DiBlasio, Carla
Subject: RE: Request for Help: b(4) CCI

Tina,

Please find the attached letter that was sent to the FDA today providing Congressman Price's office the required permission to view our dealings with the Agency over the last 18 months.

We are extremely frustrated with the speed of progress (or, lack thereof.)

b(4) CCI

From: McIntosh, Tina [<mailto:Tina.McIntosh2@mail.house.gov>]
Sent: Thursday, June 11, 2015 1:09 PM
To: b(4) CCI b(6) personal privacy
Cc: DiBlasio, Carla
Subject: RE: Request for Help: b(4) CCI

Dear All –

Carla was very sweet in her assessment of my abilities; however, I'm afraid she's placed me on a pedestal that is sure to topple. Of all the federal agencies, the FDA seems to have the strictest rules/laws/regulations when it comes to what they can share with us.

Since your request below I have been in contact the FDA again on your behalf. As you may know, our office does not have the jurisdiction to force the a federal agency to move forward with a decision nor can we coerce them down a particular path. We can simply monitor petitions but with the FDA it's not always that easy.

There are very strict laws the FDA must follow and in order for us to move any further, our office must have a letter written as outlined in the following email:

From: Jordan, Lillian T
Sent: Thursday, June 11, 2015 11:36 AM
To: McIntosh, Tina
Subject: RE: Request for Help: b(4) CCI

Tina,

FDA is prohibited by law from confirming or denying the existence of a product application or other confidential communications or submissions unless the sponsor or the manufacturer of the product publicly acknowledges the application or other material or provides FDA with written authorization to release or disclose information contained in or about their application. See generally Title 21 of the Code of Federal Regulations (CFR) Section 814.9. The letter should be written on the company's letterhead and signed by the CEO or a company employee with sufficient authority and responsibility. The letter should be as specific as possible about the information the company agrees to have FDA release to a third party (Congressional office).

For example, in the case of your constituent's company, the letter can specify that information could be released pertaining to the company's filings with FDA and any responses and/or determinations made by FDA concerning regulation of their product, if indeed, this is the information your constituent's company desires that FDA share with the Congressional office. The company can word the specifics about the material to be release any way they prefer. The letter can be sent to FDA by facsimile (301-847-8602) and should be addressed to:

*Mr. Tom Kraus
Associate Commissioner for Legislation
U.S. Food and Drug Administration
10903 New Hampshire Avenue
WO32-2346
Silver Spring, Maryland 20993-0002*

Fax 301-847-8602

Let me know if you have any further questions.

Lillian

Please fax the letter to Mr. Kraus as advised and forward a copy to us. If you have already supplied a letter as described, please forward that and we'll submit it again.

We will then follow-up with the FDA again and hopefully be able obtain some beneficial information.

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

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From: b(4) CCI b(6) personal privacy [REDACTED]

Sent: Monday, May 18, 2015 10:59 AM

To: McIntosh, Tina b(4) CCI [REDACTED]

Cc: DiBlasio, Carla;

Subject: FW: Request for Help: b(4) CCI [REDACTED]

Tina,

Could we set up a time to meet live at your convenience?

b(4) CCI [REDACTED]

From: Carla.Diblasio@mail.house.gov

To: b(4) CCI [REDACTED]

CC: Tina.McIntosh2@mail.house.gov

Subject: RE: Request for Help: b(4) CCI [REDACTED]

Date: Fri, 15 May 2015 17:49:48 +0000

b(4) CCI [REDACTED]

I hope this email finds you well. I'd like to introduce you to Tina McIntosh (copied). She's out of Dr. Price's district office and is wonderful to work with. If you don't mind filling out the attached privacy release form,

she'd be happy to continue working with you on this issue. She has more experience dealing with the FDA, so I'd love for you to get her input.

Thanks!

Carla

Carla DiBlasio, Esq.
Policy Advisor
Congressman Tom Price, M.D. (GA-06)
100 Cannon House Office Building
Washington, DC 20515 | 202.225.4501



From: b(4) CCI
Sent: Tuesday, May 05, 2015 1:01 PM
To: DiBlasio, Carla
Cc: b(4) CCI
Subject: Fwd: Request for Help: b(4) CCI

Thanks for your time on the phone today Carla. The email below was sent from our FDA attorney to Liz this morning and reflects our current status. Please let me know your thoughts. If you need us to send a release reflecting our permission to allow you to deal with our file within the FDA, please let me know. If you have any emails from Liz, even if trivial, we would appreciate a copy. I will circle back with you by Friday.

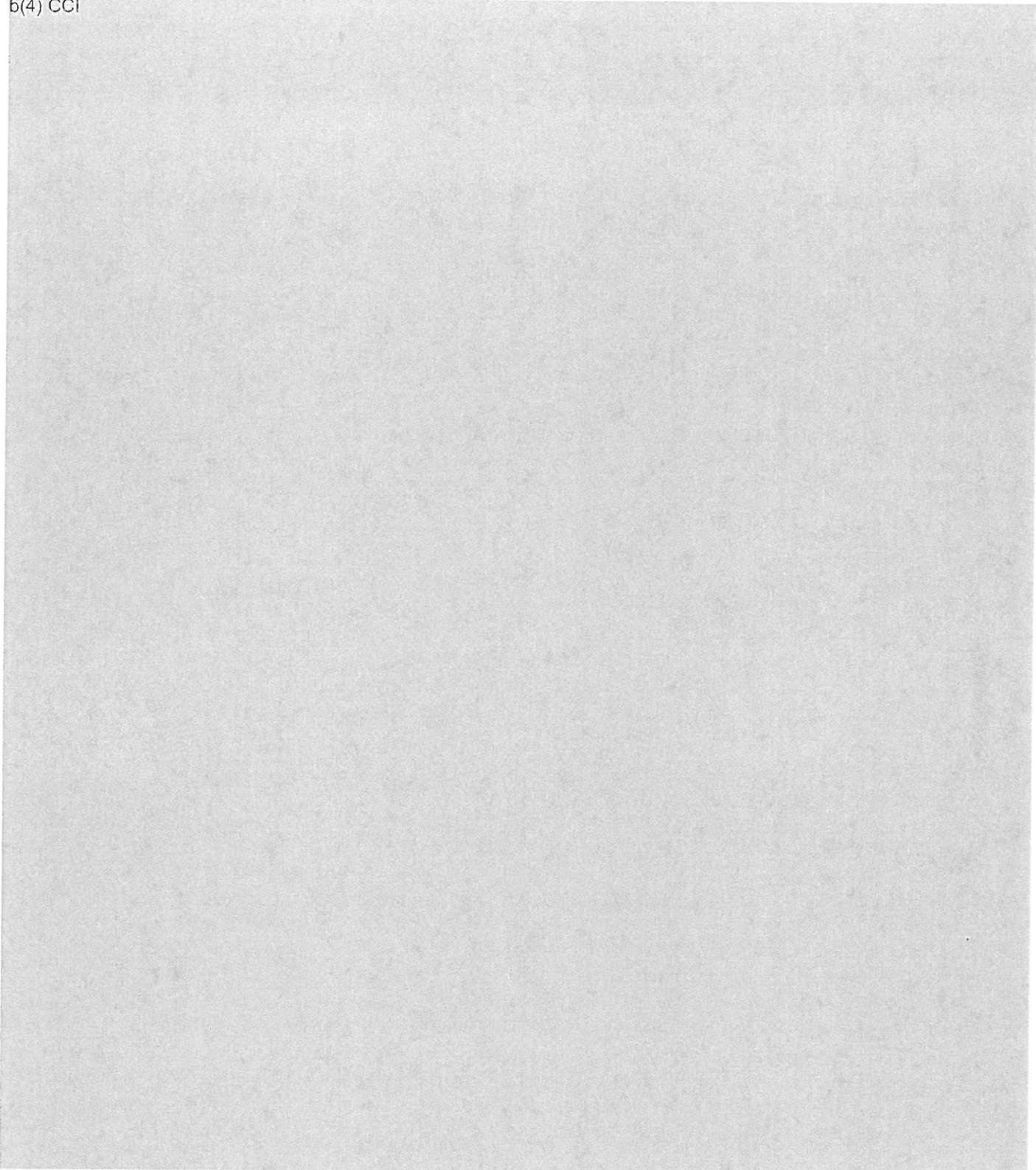
b(4) CCI

Begin forwarded message:

From: b(4) CCI
Date: May 5, 2015 at 11:47:02 AM EDT
To: "elizabeth.claverie@fda.hhs.gov" <elizabeth.claverie@fda.hhs.gov>
Subject: Request for Help: b(4) CCI

Liz, first welcome back. You've been missed! I hate to hit you with this matter so soon after returning, but we, like you, would like to put this to bed.

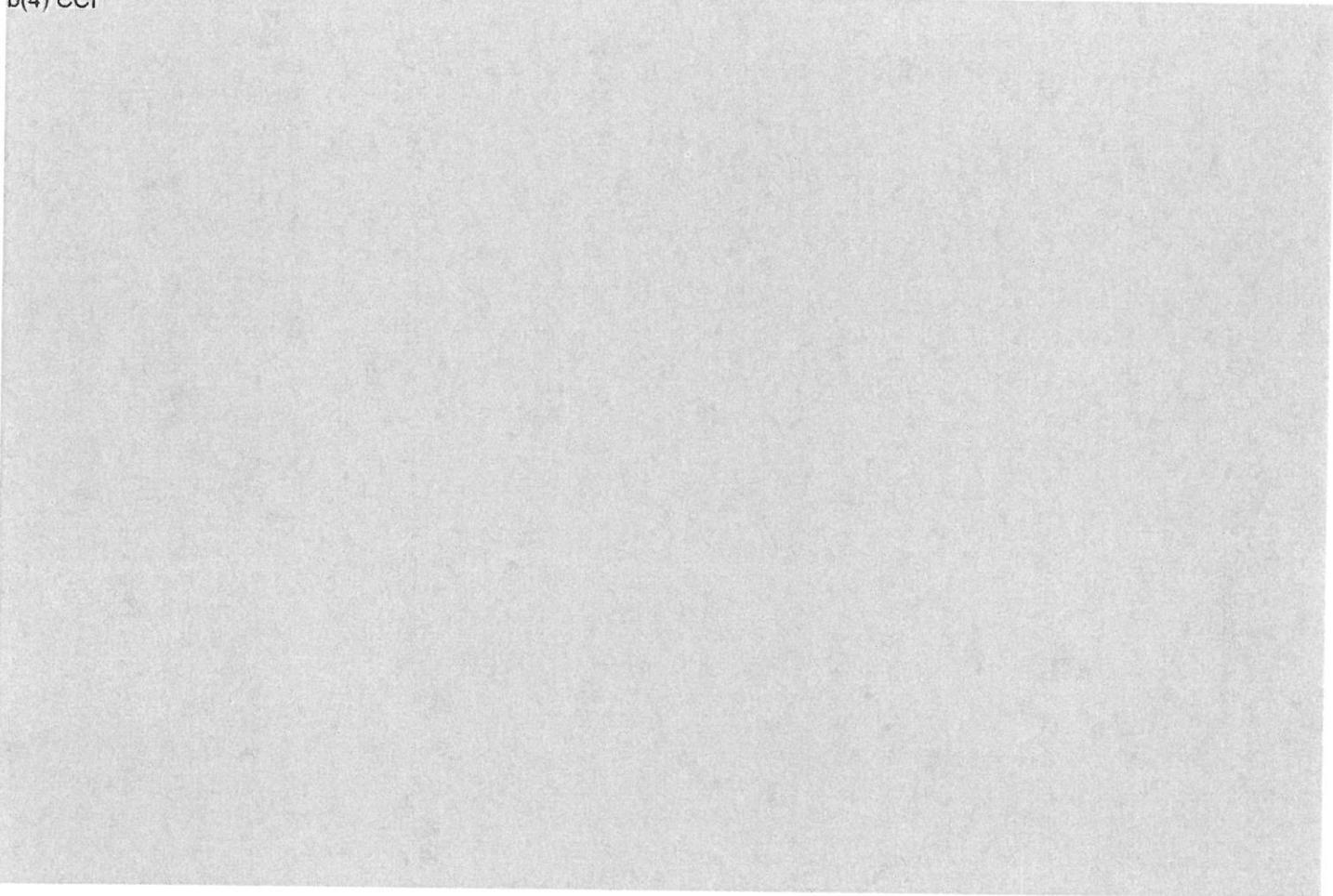
b(4) CCI



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From: b(4) CCI b(6) personal privacy
Sent: Tuesday, May 05, 2015 8:43 AM
To: b(4) CCI
Cc: b(4) CCI
Subject: Points for b(4) CCI

b(4) CCI



Sincerely,

b(4) CCI b(6)
personal
privacy

