

Subject: RE: Generics - Meeting Request HB 631
From: Camille Fesche <cfesche@alexander-cleaver.com>
Date: 4/11/2017 2:05 PM
To: Mat Palmer -GOV- <mat.palmer@maryland.gov>

Thanks!

Camille G. Fesche, Esq.
Government Relations Consultant | Attorney
[Alexander & Cleaver, P.A.](#)
cfesche@alexander-cleaver.com | Cell: 410-935-7721

From: Mat Palmer -GOV- [mailto:mat.palmer@maryland.gov]
Sent: Tuesday, April 11, 2017 12:57 PM
To: Camille Fesche <cfesche@alexander-cleaver.com>
Subject: Re: Generics - Meeting Request HB 631

Let me check my calendar and I will send you some dates. Thank you.
On Tue, Apr 11, 2017 at 12:45 PM Camille Fesche <cfesche@alexander-cleaver.com> wrote:

Hi Mat –

Now that HB 631 has passed out the Senate and is up for the Governor's consideration, I checking in again to see when you have time to talk with Lupin and the Generic Pharmaceuticals regarding our concerns with this bill.

Thanks!
Camille

Camille G. Fesche, Esq.
Government Relations Consultant | Attorney
[Alexander & Cleaver, P.A.](#)
cfesche@alexander-cleaver.com | Cell: 410-935-7721

From: Camille Fesche
Sent: Friday, April 07, 2017 8:55 AM
To: Mat.palmer@maryland.gov
Subject: Generics - Meeting Request HB 631

Hi Mat –

It was a pleasure meeting you in person the other day in Senator Hershey's office. Lupin Pharmaceuticals, a generic drug manufacturer located in the Inner Harbor, is seeking a meeting or call with you in the Governor's Office to express their concerns about HB 631. I know this is last minute, but are you available today or Monday?

Subject: Re: Generics - Meeting Request HB 631
From: Mat Palmer -GOV- <mat.palmer@maryland.gov>
Date: 4/14/2017 4:13 PM
To: Camille Fesche <cfesche@alexander-cleaver.com>

Camille,

I do understand your clients are opposed to the bill and asking the Governor to veto. Let me be clear we have the bill on a list of bills which have concerns and will not be signed at the bill signing on 4/18. I can meet with your clients on Wednesday, I am free from 10 am to 1 pm. Please let me know what time would work for your clients.

Thanks.

Mat

On Fri, Apr 14, 2017 at 1:38 PM Camille Fesche <cfesche@alexander-cleaver.com> wrote:

Hi Mat -

I'm checking in again. My client is getting rather anxious to get something on the books.

Also, wanted to be very clear that my client is seeking a veto of HB 631. I believe they are sending a veto letter early next week. Is there anything else that we need to do?

Thanks!

Camille

Camille G. Fesche, Esq.

Government Relations Consultant | Attorney

[Alexander & Cleaver, P.A.](#)

cfesche@alexander-cleaver.com | Cell: 410-935-7721

From: Camille Fesche
Sent: Thursday, April 13, 2017 3:06 PM
To: Mat Palmer -GOV- <mat.palmer@maryland.gov>
Subject: RE: Generics - Meeting Request HB 631

Subject: RE: Generics - Meeting Request HB 631
From: Camille Fesche <cfesche@alexander-cleaver.com>
Date: 4/19/2017 2:22 PM
To: Mat Palmer -GOV- <mat.palmer@maryland.gov>

Hi Mat –

Thank you very much for meeting with the Generic Pharmaceuticals. We really appreciated your listening to our grave concerns. Please do not hesitate to reach out to me if you need any additional information, arguments, or clarification.

Thanks!
Camille

Camille G. Fesche, Esq.
Government Relations Consultant | Attorney
[Alexander & Cleaver, P.A.](#)
cfesche@alexander-cleaver.com | Cell: 410-935-7721

From: Camille Fesche
Sent: Thursday, April 13, 2017 3:06 PM
To: Mat Palmer -GOV- <mat.palmer@maryland.gov>
Subject: RE: Generics - Meeting Request HB 631

Hi Mat –

I'm checking in again to see you have some dates/times. I'm hearing rumors that Governor Hogan is considering vetoing HB631.

Thanks!
Camille

Camille G. Fesche, Esq.
Government Relations Consultant | Attorney
[Alexander & Cleaver, P.A.](#)
cfesche@alexander-cleaver.com | Cell: 410-935-7721

From: Mat Palmer -GOV- [<mailto:mat.palmer@maryland.gov>]
Sent: Tuesday, April 11, 2017 12:57 PM
To: Camille Fesche <cfesche@alexander-cleaver.com>
Subject: Re: Generics - Meeting Request HB 631

Let me check my calendar and I will send you some dates. Thank you.
On Tue, Apr 11, 2017 at 12:45 PM Camille Fesche <cfesche@alexander-cleaver.com> wrote:

Hi Mat –

Now that HB 631 has passed out the Senate and is up for the Governor's consideration, I checking in

Subject: FW: HB 631- Generics
From: Camille Fesche <cfesche@alexander-cleaver.com>
Date: 5/8/2017 1:36 PM
To: "cara.sullivan@maryland.gov" <cara.sullivan@maryland.gov>

Hi Cara –

Thank you very much for taking my call. Please see my email to Mat below and do not hesitate to let me know if you need anything.

Thanks!
Camille

Camille G. Fesche, Esq.
Government Relations Consultant | Attorney
Alexander & Cleaver, P.A.
cfesche@alexander-cleaver.com | Cell: 410-935-7721

From: Camille Fesche
Sent: Monday, May 08, 2017 12:50 PM
To: Mat Palmer -GOV- <mat.palmer@maryland.gov>
Subject: HB 631- Generics

Hi Mat –

Hope you are doing well on this sunny morning. After our meeting, the generic manufacturer members of AAM have sent the governor's office letters requesting a veto of HB 631. Below is a list of all the entities that sent letters. They were directed to send the letters directly to you, but since I don't have control over that, I wanted to make sure you had a list. If you are missing any letters, please let me know, I'll get you a copy.

Update:

- Alvogen
- Amneal
- Apotex
- Aurobindo
- Dr. Reddy's
- Intas
- Lupin
- Mayne
- Momenta
- Mylan
- Pfenex
- Sandoz
- Sagent
- Sun
- Glenmark
- Teva
- West-Ward
- Zydus

And:

- AAM (attached)
- American Consumer Institute
- Council for Citizens Against Government Waste
- 8 consumer groups signed on to this letter. <http://www.theamericanconsumer.org/wp-content/uploads/2017/04/Coalition-letter-HB-631-FINAL.pdf>

Please don't hesitate to let me know what else you need. I'm happy to set up additional meetings and get additional support.

Thank you!
Camille

Camille G. Fesche, Esq.

Government Relations Consultant | Attorney
cfesche@alexander-cleaver.com | cell: 410-935-7721



Attorneys at Law

54 State Circle
Annapolis MD 21401
p. 410-974-9000

<http://www.alexander-cleaver.com>

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RISING STARS 2016



Your Generics & Biosimilars Industry

May 12, 2017

The Honorable Lawrence J. Hogan, Jr.
Governor of Maryland
State House
100 State Circle
Annapolis, Maryland 21401

Re: House Bill 631

Dear Governor Hogan:

I am writing to follow up on our recent request that that you veto House Bill 631. As you know, the Association for Accessible Medicines (AAM) improves access to safe, affordable, effective medicines by representing the leading manufacturers of generic and biosimilar drugs. Generic medicines continue to be a success story in the U.S. health care system, comprising 89% of all prescriptions but only 27% of total prescription costs. Based on data from IMS Health, **the use of generic drugs saved the State of Maryland and private insurers over \$4.1 billion last year.**

As we have discussed with your Chief Legal Counsel, while the stated intent of H.B. 631 is laudable, Attorney General Brian Frosh's bill would harm patients in Maryland, and it is likely unconstitutional for several reasons, including: (i) that the definition of "unconscionable increase" renders the provision unconstitutionally void for vagueness and (ii) that the bill violates the dormant commerce clause of the Constitution by regulating the sale of medicines in other states. While we believe that you already have the authority to increase public awareness and transparency about prescription drug spending in Maryland, should you choose to veto this unconstitutional bill, AAM pledges to work with you on a constitutional method for increasing the transparency of drug prices and punishing price-gougers such as Turing Pharmaceuticals, which manufactures an off-patent branded drug that saw massive increases in the list price of its drug.

H.B. 631 is unconstitutionally void for vagueness, because it does not provide clear notice to manufacturers regarding the legal limits of prices that are subject to penalty and legal actions under the bill. Under the procedural due process guarantees of the Fourteenth Amendment, a state statute cannot be enforced if it is "so vague as to leave an individual without knowledge of the nature of the activity that is prohibited"; the Supreme Court has held that to be constitutionally viable, a statute "must give a person of ordinary intelligence a reasonable opportunity to know what is prohibited and provide explicit standards for those who apply it to

avoid arbitrary and discriminatory enforcement.”¹ Maryland courts apply similar concepts in void-for-vagueness cases.²

Manufacturers repeatedly asked the Maryland General Assembly and Attorney General Frosh himself to include in the bill clear standards by which to determine whether a price increase was deemed to be an “unconscionable increase” or “excessive.” Yet legislators refused to link the clear standards that govern whether the Attorney General may request information from manufacturers in the bill (e.g., an 80% increase in the wholesale price) to the definition of an “unconscionable increase,” which gives rise to penalties and liability under the bill. Rather, the Attorney General has asserted that there is no need to define “unconscionable” or “excessive” pricing that gives rise to liability under H.B. 631.

H.B. 631 would also violate the commerce clause of the Constitution by regulating drug pricing outside of Maryland’s borders. Under the dormant commerce clause, it is a violation of the interstate commerce clause of the Constitution for any state or locality to (i) blatantly discriminate against interstate commerce; or (ii) impose a burden on interstate commerce that is clearly excessive in relation to the putative local benefits.³ State statutes that directly regulate commerce, and specifically prices, beyond the boundaries of a state have been held to be per se invalid.⁴

In this case, H.B. 631 regulates pricing in a way that would affect prices outside of Maryland. In our national health care market, drug pricing is inherently a multi-state phenomenon, because it involves multiple parties (manufacturers, drug wholesalers, pharmacy benefits managers, retail pharmacy chains, nationwide HMOs, Medicaid and Medicare contractors, and others) operating in multiple states. For example, under the Medicaid program, manufacturers must enter into a national agreement in order to obtain Medicaid coverage for their medicines.⁵ The restrictions established in H.B. 631 would have the effect of regulating prices under Maryland’s standards wherever there is a national sales agreement. Moreover, H.B. 631 does not even have a geographical restriction requiring a sale in Maryland to trigger liability.

¹ See *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317-18 (2012) (FCC guidelines relating to obscenity were void for vagueness because the regulated broadcasters had not been afforded constitutionally sufficient “fair notice” of the allegedly proscribed conduct at issue). See *generally* 16B Am. Jur. 2d Constitutional Law § 972 (2017); 82 C.J.S. Statutes § 86 (2017).

² See, e.g., *McCree v. State*, 105 A.3d 456 (Md. 2014); *Finucan v. Md. Bd. of Physician Quality Assurance*, 846 A.2d 377 (Md. 2004).

³ Art. I § 8, cl. 3, of the U.S. Constitution. See *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 390 (1994).

⁴ See *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989); *Brown –Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 579 (1986).

⁵ See U.S. Department of Health and Human Services, Medicaid Drug Rebate Program, *available at* <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (“The program requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer’s drugs.”)

The Honorable Lawrence J. Hogan, Jr.

Page 3

Indeed, the legislation states that a person alleged to have violated the law "may not assert as a defense that the person did not deal directly with a consumer residing in the State." 2-803(F). For both of these reasons, the bill would be subject to a per se challenge on dormant commerce clause grounds.

* * *

H.B. 631 will harm more than help patients and taxpayers in Maryland. It will provide an incentive for generic drug companies to avoid the higher risk and legal uncertainty of selling affordable medicines in the state. Moreover, Attorney General Frosh's bill would exempt three-quarters of prescription drug spending in Maryland, the branded pharmaceutical sector, and thus the bill will not have any significant impact on skyrocketing drug prices or the co-pays affecting the tax-payers of Maryland.

You have the opportunity to take leadership on this issue and pass a bill that is constitutional and will cover all of the drug spending in Maryland. If you veto H.B. 631, AAM pledges to work with you to achieve this shared goal.








Thank you for your continued consideration on this important issue. If you have any questions, please do not hesitate to contact me.

Best regards,



Chester (Chip) Davis, Jr.
President and Chief Executive Officer

Thank you

Subject: Thank you
From: Chip Davis <chip.davis@accessiblemeds.org>
Date: 5/13/2017 5:21 PM
Attachments:  image001.jpg (857 bytes),  image002.jpg (854 bytes),  image003.jpg (859 bytes),
 image004.jpg (852 bytes),  image005.jpg (1.0 KB),  image006.png (6.7 KB),
 Larry Hogan should veto Maryland's drug-pricing bill - The Washington Post.pdf (71.3 KB)
To: <Sam.Malhotra@Maryland.gov>

Sam-

Wanted to send a brief message to thank you for taking the time to catch up last evening. It was indeed a pleasure, and I greatly appreciate your counsel, feedback and perspective on the current state of HB 631. Governor Hogan could not have been more generous with his time and consideration, and based upon both of your collective input, rest assured we will continue our ongoing outreach and education efforts to highlight the inherent flaws and significant downside risk associated with this legislation. As we discussed, this is not a policy issue where it benefits Maryland to be first in the nation.

On a related note, wanted to make sure you saw the op-ed from former Democratic Kentucky Attorney General that just ran in the Washington Post. I can assure you, from prior experience, that during his term in office General Conway was not known as an industry advocate or champion; so the fact that he believes this bill is bad law, and bad precedent, is particularly noteworthy. For convenience I have attached the piece below.

The Governor referenced that both he, and your team, will continue to evaluate the consequences of this bill - intended and unintended - between now and the May 26th deadline. To that end, please do not hesitate to let me know if you have any additional questions, or if we can provide any additional information or context. While I work in Washington, I live in Annapolis, and can make myself available on short notice should any need arise.

Congratulations on a successful evening, and thanks again for your time.


Best,

Chip

Chester (Chip) Davis, Jr., J.D.
ASSOCIATION FOR ACCESSIBLE MEDICINES
PRESIDENT & CHIEF EXECUTIVE OFFICER
O • 202-249-7150 MAIN • 202-249-7100
777 SIXTH STREET, NW • SUITE 510 • WASHINGTON, DC 20001



Thank you letter for Governor Hogan

Subject: Thank you letter for Governor Hogan
From: Chip Davis <Chip.Davis@accessiblemeds.org>
Date: 5/15/2017 12:25 PM
Attachments:  Davis Letter to Gov. Hogan 05.15.17.pdf (61.0 KB)
To: "Kara.Bowman@Maryland.gov" <Kara.Bowman@Maryland.gov>

Hi Kara-

It was a pleasure to meet you on Friday evening at the wonderful event on the Eastern Shore. Very much appreciate your efforts to ensure we had time to meet with Governor Hogan to discuss HB 631. To that end, if you would be so kind to ensure that he gets the attached follow up letter I would be most appreciative.

Thanks again, and I hope to see you this Saturday at Preakness for the RGA event.

Best,

Chip

Chester (Chip) Davis, Jr., J.D.
PRESIDENT & CHIEF EXECUTIVE OFFICER
ASSOCIATION FOR ACCESSIBLE MEDICINES
O • 202-249-7150 MAIN • 202-249-7100
777 SIXTH STREET, NW • SUITE 510 • WASHINGTON, DC 20001



Your Generics & Biocellulose Industry



Your Generics and Biosimilars Industry

May 15, 2017

The Honorable Lawrence J. Hogan, Jr.
Governor of Maryland
State House
100 State Circle
Annapolis, Maryland 21401

Dear Governor Hogan,

Thank you very much for taking the time to meet on Friday afternoon. For me it was both an honor and pleasure. I greatly appreciate your counsel, feedback and perspective on the current state of HB 631. You could not have been more generous with your time and consideration, and based upon your input, and that from members of your team, I can assure you we will continue our ongoing outreach and education efforts to highlight the inherent flaws and significant downside risk associated with this legislation. As we discussed, this is not a policy issue where it benefits Maryland to be first in the nation.

As you and your team continue to evaluate the consequences of this bill - intended and unintended - between now and the May 26th deadline, please do not hesitate to let me know if you have any additional questions, or if we can provide any additional information or context. While I work in Washington, I live in Annapolis, and can make myself available on short notice should any need arise.

Congratulations on a successful event Friday evening and thank you again for your time. It was a privilege to be a part of it. I look forward to seeing you this coming Saturday at the RGA event.

Best regards,

Chester (Chip) Davis, Jr.
President and Chief Executive Officer

Re: Thank you letter for Governor Hogan

Subject: Re: Thank you letter for Governor Hogan
From: Kara Bowman -GOV- <kara.bowman@maryland.gov>
Date: 5/16/2017 10:35 AM
To: Chip Davis <Chip.Davis@accessiblemeds.org>

Mr. Davis,

It was a pleasure to meet you as well last Friday evening, and thank you very much for following up. I connected with both Sam Malhotra and Chris Shank following our meeting to ensure we were all on the same page, and I believe you may have had an opportunity to meet with our Chief of Staff as well. I have shared this with the Governor and will ensure that our team circles back with you.

I look forward to seeing you on Saturday as well - it should be a great day! In the meantime, please don't hesitate to let me know if there is anything else that I can do.

All the best,
Kara

On Mon, May 15, 2017 at 12:25 PM, Chip Davis <Chip.Davis@accessiblemeds.org> wrote:

Hi Kara-

It was a pleasure to meet you on Friday evening at the wonderful event on the Eastern Shore. Very much appreciate your efforts to ensure we had time to meet with Governor Hogan to discuss HB 631. To that end, if you would be so kind to ensure that he gets the attached follow up letter I would be most appreciative.

Thanks again, and I hope to see you this Saturday at Preakness for the RGA event.

Best,

Chip

Chester (Chip) Davis, Jr., J.D.

PRESIDENT & CHIEF EXECUTIVE OFFICER

ASSOCIATION FOR ACCESSIBLE MEDICINES

RE: Thank you letter for Governor Hogan

Subject: RE: Thank you letter for Governor Hogan
From: Chip Davis <Chip.Davis@accessiblemeds.org>
Date: 5/17/2017 11:55 AM
To: Kara Bowman -GOV- <kara.bowman@maryland.gov>

Kara-

Thank you for the response, and for sharing my letter with Governor Hogan. Your efforts in that regard are greatly appreciated.

I did have the opportunity to connect with Sam as well at the event. He was similarly generous with his time and perspective, and I committed to keeping him informed around our ongoing efforts.

Definitely look forward to seeing you and the Governor on Saturday at Preakness. The forecast sounds very promising; but no matter the weather it will once again be a terrific day for Maryland to shine on the national stage.

On a separate note, I understand that the Governor and First Lady have been invited to a concert tomorrow evening at Maryland Hall for the Creative Arts, entitled "In the Light," that will feature a number of special musicians partnering with Anne Arundel County Public School's Performing and Visual Arts Magnet Program ("PVA") to raise awareness and funds for the Musical Autist nonprofit organization. My 17 year old daughter Caroline, who was diagnosed with autism back when she was 2 years old, will be singing in the finale with the Broadneck High School orchestra and chorus, so if the Governor's schedule allows him to attend will do my best to catch up there and say hello.

Continued thanks.

Best,

Chip

Chester (Chip) Davis, Jr., J.D.
ASSOCIATION FOR ACCESSIBLE MEDICINES
PRESIDENT & CHIEF EXECUTIVE OFFICER
O • 202-249-7150 MAIN • 202-249-7100
777 SIXTH STREET, NW • SUITE 510 • WASHINGTON, DC 20001



Your Generics & Biosimilars Industry

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From: Kara Bowman -GOV- [mailto:kara.bowman@maryland.gov]
Sent: Tuesday, May 16, 2017 10:36 AM

Subject: AAM Information on HB 631

From: Chris Bowlin <Chris.Bowlin@accessiblemeds.org>

Date: 5/23/2017 4:39 PM

CC: "sam.malhotra@maryland.gov" <sam.malhotra@maryland.gov>

To: "christopher.shank@maryland.gov" <christopher.shank@maryland.gov>

Chris Bowlin has shared a OneDrive for Business file with you. To view it, click the link below.

 HB-631-Alternative-TPs-5-23-17 (004).docx

Chris,

Let me introduce myself. I'm Chris Bowlin, SVP for Government Affairs at AAM.

I know you've met with Chip Davis, our CEO on a number of occasions over the past several weeks. And you've heard from a number of members about the negative implications of HB 631 on the tremendous savings provided the generic industry.

As you've rightly pointed out, that despite our constant efforts during the legislative session to limit the negative impact of the bill, we were not able to overcome the lobbying by the AG, and his allies, to gain new legal authority to intervene in the market against the business practices of companies whose prices he disagrees with. This new unprecedented authority for an attorney general creates tremendous business risk for generic manufacturers and will undoubtedly limit patient choices and chill competition. Lupin, one of our largest member companies, and with US headquarters in downtown Baltimore, is one of our loudest advocates against the bill. We hope you will advise the governor to veto the bill on the merits because of its provision of new authority to the AG and because it will undermine the great efforts the Governor is making to turn around the MD economy and reinforce that the state is "open for business."

You've heard our arguments, and those of our members, encouraging the Governor to veto the bill. And I realize the consideration of our position is based on more than the merits, or lack thereof, of the bill. The bill was passed overwhelmingly in both chambers and a veto has the very real possibility of being overridden if the revote tracks the vote on passage.

In the hopes that the Hogan Administration agrees with the criticisms of the bill, we would suggest that there is a strong, compelling public case to be made that there is a

better way to address drug pricing. Right now, the AG and the democrats appear to be the prevailing public voice on doing something on drug pricing. But that doesn't have to be the case. HB 631 will jeopardize generic drug savings and make the drug spending problem worse, not better. Giving the AG new authority to sue companies and set drug prices from the AG office is, respectfully, not the answer. The good news is, and our polling backs this up, that no politician owns the issue of drug pricing. And a veto of the bill with market-friendly, workable alternative would be supported if an education campaign were launched.

Over the weekend, Chip had the chance to speak to the governor again. And I happened to speak with him at a gathering on Sunday as well. (I also had a brief conversation with Sam Malhotra and he asked me to copy him as well.) Of course we urged him to veto the bill. But we also discussed that the issue is not going away this year or next. And that he could veto the bill and capitalize on the issue using his voice to lead a conversation about addressing drug pricing from a more workable perspective – not one that cedes new authority to the AG. But one that uses a two part approach to address the problem: 1) use his own existing authority to address certain aspects of the problem and 2) commit to addressing the problem and pledge to work with the legislature on an alternative approach that respects the market, encourages more competition and preserves the \$4.1 billion that Maryland saves due to generics.

The governor urged Chip to share with you any recommendations that we may have. By way of this email, I'm sharing a set of talking points detailing what we believe is wrong with the bill and a short set of principles that the Governor could support in next year's session, giving him the platform to lead on this issue. We would work with you all to build out the principles so that drug spending is addressed, but not in a way that targets the one industry saving all the money

I've talked with Steve Hershey and an effort to educate the Senate about a better way may require a lot of work and strong message, but it is doable with enough time.

I am not unaware of the legislative challenge the Governor would face by vetoing the bill. But, a veto with an alternative that he could talk about going into next year would give him the right message with the public.

I'd like to have a conversation with you about the attachment if you would have a few minutes.

Thank you for your consideration.

Warm regards,

Chris Bowlin
202-669-5369

Chris Bowlin

ASSOCIATION FOR ACCESSIBLE MEDICINES

Senior Vice President, Government Affairs



777 SIXTH STREET, NW • SUITE 510 • WASHINGTON, DC 20001

O • 202-249-7124 CELL • 202-669-5369



Your Generics & Biosimilars Industry

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Subject: Draft Letter and PR if Governor Hogan Declines to Veto
From: Chris Bowlin <Chris.Bowlin@accessiblemeds.org>
Date: 5/25/2017 10:06 AM
Attachments:  Draft Hogan Letter re H.B. 631 No-Sign-v2.docx (37.4 KB),
 Draft Language re H.B. 631 No-Sign-v2.docx (36.7 KB)
To: "christopher.shank@maryland.gov" <christopher.shank@maryland.gov>,
"sam.malhotra@maryland.gov" <sam.malhotra@maryland.gov>

Chris and Sam,

Chris Bowlin here from AAM.

You should have received my email on Tuesday with principles for an alternative bill to HB 631 that you all could announce along with a veto. We are still strongly encouraging a veto.

If the governor is not going to veto the bill, attached is a draft letter the governor could write a letter to the assembly and issue a press release with some suggested messages.

Please let me know if you have any questions.

Chris
Bowlin

Chris Bowlin

ASSOCIATION FOR ACCESSIBLE MEDICINES
Senior Vice President, Government Affairs
777 SIXTH STREET, NW • SUITE 510 • WASHINGTON, DC 20001
O • 202-249-7124 CELL • 202-669-5369



Your Generics & Biosimilars Industry

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May 26, 2017

The Honorable Thomas V. Mike Miller
President of the Senate
State House
Annapolis, Maryland 21401

The Honorable Michael E. Busch
Speaker of the House of Delegates
State House
Annapolis, Maryland 21401

Dear Mr. President and Mr. Speaker:

I write to explain the rationale for my decision not to sign House Bill 631 -- *Public Health -- Essential Off Patent or Generic Drugs -- Price Gouging -- Prohibition*.

Although the stated intent of the bill is laudable — to curtail and punish specific bad actors responsible for outrageous increases in certain prescription drug prices — House Bill 631 inexplicably targets the manufacturers of lower cost generic drugs, which have saved Maryland patients and taxpayers billions of dollars every year. And it does so in a manner fundamentally at odds with the limitations of the United States Constitution by regulating drug pricing and commerce at the national level rather than focusing on consumers and sales here in Maryland.

Sensible regulation of prescription drug prices in the state of Maryland is something that I support and which can be done in a targeted manner consistent with the Constitution. But I cannot endorse legislation, even bipartisan legislation, that contravenes the boundaries of federalism enshrined in the Commerce Clause and which does not provide sufficient guidance to manufacturers as to what conduct is prohibited.

House Bill 631 appears to suffer from serious constitutional infirmities, because the bill would directly regulate interstate commerce and prices by prohibiting and penalizing manufacturer pricing behavior occurring at the national and interstate wholesale level, and thereby impacting pricing beyond the boundaries of the state of Maryland. *See PhRMA v. D.C.*, 406 F. Supp. 2d 56, 69-70 (D.D.C. 2005), *aff'd sub nom. BIO v. D.C.*, 496 F.3d 1362 (Fed. Cir. 2007) (“PhRMA”). Under Supreme Court jurisprudence, a state statute “directly regulat[ing]” commerce occurring beyond the boundaries of that state is *per se* invalid and “generally struck down ... without further inquiry.” *Brown–Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see also Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (“[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid....”); *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (noting that “[t]he Commerce Clause ... precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State”).

Indeed, the bill prohibits *any* “unconscionable” increase in the price of an essential off-patent or generic drug so long as the drug is “*made available* for sale in the State,” H.B. 631 §2-801(B)(IV), (C), and (F) (emphasis added), meaning that price increases are prohibited even

without the occurrence of an actual intrastate sale. Moreover, the bill contains an express limitation, H.B. 631 §2-803(D), that in an action brought by the Attorney General, a person alleged to have violated the statute “may not assert as a defense that the person did not deal directly with a consumer residing in the State.” H.B. 631 §2-803(G). Based on these provisions, the bill as written appears unequivocally to target pricing and sales that occur out-of-state, and at a minimum, the bill can be viewed as having the practical effect of controlling manufacturers’ conduct beyond the boundaries of the state, because the pricing prohibition would reach national wholesale pricing and the sale of products well beyond the borders of Maryland. *PhRMA*, 406 F. Supp. 2d at 69-70; *Healey*, 491 U.S. at 336.

H.B. 631 also appears to suffer from serious “vagueness” problems under the procedural due process concepts of the Due Process Clause of the Fourteenth Amendment. *See, e.g., FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012) (“A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required.”). The Supreme Court has long held that “a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law,” *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926), and that the requirement of clarity in regulation is essential to the protections provided by the Due Process Clause, *see United States v. Williams*, 553 U.S. 285, 304 (2008). A fair reading of the bill indicates that it provides little real guidance to manufacturers as to what conduct they are permitted to engage in and what market forces might permissibly justify price increases. The bill, for example, leaves entirely unstated what price increases might be unconscionably “excessive,” and what types of increases might be “justified” by the “cost of production” or “the cost of appropriate expansion of access.” H.B. 631 §2-801(F). These are precisely the types of information that fair notice requires the State to provide to manufacturers before any prohibition or enforcement action may be undertaken.

Given the large legislative majorities that supported this bill, I have determined that a veto will not serve the interests of the citizens of Maryland in efficient government. I have no desire to waste the time of the General Assembly or the public. But I do believe this bill will be struck down by the courts as transgressing the fundamental limits of federalism in the United States Constitution and I cannot sign a bill I strongly believe to be unconstitutional.

For these reasons, I have decided not to endorse H.B. 631.

Sincerely,

Lawrence J. Hogan, Jr.
Governor

DRAFT LANGUAGE FOR GOVERNOR HOGAN RE NON-SIGN OF H.B. 631

**GOVERNOR LARRY HOGAN DECLINES TO ENDORSE UNCONSTITUTIONAL
GENERIC DRUG PRICING LEGISLATION**

May 26, 2017

Well Intentioned But Fatally Flawed, Bill Would Unconstitutionally Regulate Commerce and Prices Beyond the Boundaries of Maryland And Fails To Provide Basic Notice To Manufacturers Regarding Prohibited Conduct

ANNAPOLIS, MD – Governor Larry Hogan today declined to sign House Bill 631, which would directly regulate interstate commerce in and national pricing of generic drugs in violation of the Interstate Commerce Clause of the United States Constitution. The bill is also likely to be found unconstitutionally vague under the Due Process Clause of the Fourteenth Amendment.

“Although the stated intent of the bill is laudable -- to curtail and punish specific bad actors responsible for outrageous increases in certain prescription drug prices -- House Bill 631 inexplicably targets the manufacturers of lower cost generic drugs that save Maryland patients and tax payers billions of dollars every year” said Governor Hogan. “And it does so in a manner fundamentally at odds with the limitations of the United States Constitution by regulating drug pricing and commerce at the national level rather than focusing on consumers and sales here in Maryland.”








“Sensible regulation of prescription drug prices in the state of Maryland is something that I support and which can be done in a targeted manner consistent with the Constitution. But I cannot endorse legislation, even bipartisan legislation, that contravenes the boundaries of federalism enshrined in the Commerce Clause and which does not provide sufficient guidance to manufacturers as to what conduct is prohibited.”

The governor detailed several fatal flaws in the legislation, such as the bill’s—

- targeting of pricing at the national manufacturer and wholesaler level occurring outside the state of Maryland without any requirement that an actual sale be made within the state;
- express limitation on a manufacturer’s ability to demonstrate that it did not engage in transactions with consumers in the state; and
- vague prohibition on unconscionably “excessive” price increases that provides little to no information to manufacturers as to what free market behavior is acceptable and what is not.

“Given the large legislative majorities that supported this bill, I have determined that a veto will not serve the interests of the citizens of Maryland in efficient government. I have no desire to waste the time of the General Assembly or the public. But I do believe this bill will be struck down by the courts has transgressing the fundamental limits of federalism in the United States Constitution and I cannot sign a bill I strongly believe to be unconstitutional.”

Thank you

Subject: Thank you
From: Chip Davis <chip.davis@accessiblemeds.org>
Date: 5/13/2017 5:21 PM
Attachments:  image001.jpg (857 bytes),  image002.jpg (854 bytes),  image003.jpg (859 bytes),
 image004.jpg (852 bytes),  image005.jpg (1.0 KB),  image006.png (6.7 KB),
 Larry Hogan should veto Maryland's drug-pricing bill - The Washington Post.pdf (71.3 KB)
To: <Sam.Malhotra@Maryland.gov>

Sam-

Wanted to send a brief message to thank you for taking the time to catch up last evening. It was indeed a pleasure, and I greatly appreciate your counsel, feedback and perspective on the current state of HB 631. Governor Hogan could not have been more generous with his time and consideration, and based upon both of your collective input, rest assured we will continue our ongoing outreach and education efforts to highlight the inherent flaws and significant downside risk associated with this legislation. As we discussed, this is not a policy issue where it benefits Maryland to be first in the nation.

On a related note, wanted to make sure you saw the op-ed from former Democratic Kentucky Attorney General that just ran in the Washington Post. I can assure you, from prior experience, that during his term in office General Conway was not known as an industry advocate or champion; so the fact that he believes this bill is bad law, and bad precedent, is particularly noteworthy. For convenience I have attached the piece below.

The Governor referenced that both he, and your team, will continue to evaluate the consequences of this bill - intended and unintended - between now and the May 26th deadline. To that end, please do not hesitate to let me know if you have any additional questions, or if we can provide any additional information or context. While I work in Washington, I live in Annapolis, and can make myself available on short notice should any need arise.

Congratulations on a successful evening, and thanks again for your time.

Best,

Chip

Chester (Chip) Davis, Jr., J.D.
ASSOCIATION FOR ACCESSIBLE MEDICINES
PRESIDENT & CHIEF EXECUTIVE OFFICER
O • 202-249-7150 MAIN • 202-249-7100
777 SIXTH STREET, NW • SUITE 510 • WASHINGTON, DC 20001

