

# HB18 – 1260 - Prescription Drug Price Transparency Sponsors: Rep. J. Ginal, Rep. D. Jackson, Sen. D. Moreno March 8, 2018

House Health, Insurance, & Environment
Testimony – April Giles
President and CEO, Colorado BioScience Association

Thank you Madam Chair, members of the Committee, my name is April Giles, and I am the President of the Colorado Bioscience Association. CBSA is a nonprofit, statewide organization, representing more than 720 bioscience companies and 30,000 direct employees. Since our inception, CBSA has been actively engaged in ensuring the bioscience industry remains a strong and growing part of the state's economy, which is why we urge you to oppose House Bill 1260. As we look at our health care system as a whole, it's important to understand that the bioscience sector is not like the other sectors that comprise the health care industry. Researching and developing new cures is both resource intensive and highly unpredictable. The process can take well over a decade and cost upwards of \$2.6 billion dollars. There are also many failures seen along the way, with only one out of every ten drug candidates ultimately being approved by the FDA.

Science is not linear, determining the costs associated with the full R&D process for each product would likely be impossible or inaccurate at best. For example, the work conducted on a molecule for one disease might fail, but that research could ultimately lead to a successful new discovery within another disease later down the road.

The work underway within our industry is a painstaking endeavor, but the results achieved are invaluable to the patients we serve and the healthcare industry as a whole.

At CBSA we are dedicated to patients, ensuring people live longer, healthier lives. That's why we support true transparency. True transparency means:

- Addressing the health care system as a whole.
- Considering every player in the health care system to make meaningful changes for patients and their families.

We are committed to ensuring patients have access to therapies and needed medicines. To that end, we believe it is imperative to look at the healthcare system holistically, which would help patients understand the role manufacturers, pharmacy benefit managers (or PBM's), and insurers play in determining out of pocket costs.

Both are key to negotiating pricing and structuring rebates with each manufacturer on medicines. The Wholesale Acquisition Cost (or WAC) in the legislation does not take these factors into account. The WAC is essentially the list price, **not the net price after negotiations and rebates**. Year after year, data shows that the "net price" after rebates and discounts is 30 to 40 percent less than the list price. So, while a 10 percent increase would trigger a notice under this bill, the actual increase to a payer may only be two or three percent. And this bill does not require a health plan or PBM to notify a purchaser what the net price increase for the medication is, or if the WAC price increase will have no effect on a purchaser because a PBM negotiated price protections with the manufacturer.

This legislation also threatens a company's confidential and proprietary information, harming their ability to compete fairly in the marketplace and will chill investment into future life science innovation.

While insurers reporting details are provided CORA protection - as well as aggregation of their data - drug manufactures have not been afforded the same benefit of CORA protection and assurance of aggregated data. Why?

In closing, since the inception of the CBSA, we have worked hand-in-hand with the General Assembly to develop sound policies to advance Colorado into a top-tier cluster for the bioscience industry. To date, we all have done a phenomenal job and have had great success. House Bill 1260 sends a message to companies looking to grow or relocate here that we do not value their work.

On behalf of the bioscience industry in the state, I respectfully request that you oppose House Bill 1260. I'm happy to answer any questions.

## Other notes:

- "Every dollar invested in newer treatments saves nearly seven dollars in other costs by reducing or eliminating hospitalizations, minimizing one's inability to work at full capacity, and empowering people to live independently" – National Venture Capital Association Study
- "A new treatment delaying the onset of Alzheimer's by five years would save \$367 billion in health care services" – Changing the Trajectory of Alzheimer's Disease Report by the Alzheimer's Association
- "Retail brand and generic prescription medicines along with pharmacy costs account for about 10% of the health care spending in America today, the same percentage as in 1960"
   CMS National Health Expenditures 2014 data
- Nearly 9 out of 10 prescriptions are filled with generics, 88% in 2014 IMS Health data
- Several programs sponsored by the biopharmaceutical industry available to assist patients
  in affording their medications. One such program is the Partnership for Prescription
  Assistance, which provides a single point of access to more than 475 patient assistance
  programs. To date, PPA has helped nearly 9.5 million individuals, including roughly
  71,000 Coloradans, gain access to needed prescription medications for free or at a
  reduced cost.
- Bioscience industry is already one of the most heavily regulated industries in the health care sector. Companies are required to provide information on drug effectiveness and safety to the FDA and public companies are also required to report information on costs, sales and total R&D spending in securities filings. These filings are available to the public and listed out by company and product in aggregate.



# Please Vote No on Colorado House Bill 18-1260

#### BACKGROUND:

The bill enacts the "Colorado Prescription Drug Price Transparency Act of 2018", which requires:

- Health insurers, starting in 2019, to submit to the commissioner of insurance, as part of the health care cost reporting requirement, information regarding prescription drugs covered under their health insurance plans that were dispensed in the preceding calendar year;
- Prescription drug manufacturers, to notify state purchasers, health insurers, and pharmacy benefit
  management (PBM) firms when the manufacturer increases the price of certain prescription drugs by more
  than 10% or when the manufacturer introduces a new specialty drug in the commercial market; and
- Prescription drug manufacturers, to provide specified information to the commissioner regarding the drugs and are required to notify purchasers of a drug price increase or new specialty drug on the market.

The commissioner is then required to post the information on the division of insurance website. That data will be analyzed to determine the effect of prescription drug costs on health insurance premiums. And then the commissioner will publish a report each year. A prescription drug manufacturer that fails to notify purchasers or fails to report required data to the commissioner is subject to discipline, including a penalty of \$1,000 per day for each day the manufacturer fails to comply with the notice or reporting requirements.

#### **REASONS TO OPPOSE:**

CBSA advocates for <u>true transparency</u> to help patients understand the role of manufacturers, insurers, and PBMs in determining out-of-pocket drug costs.

- HB18-1260 would <u>negatively impact patients</u> in Colorado.
- HB18-1260 would threaten access to critically important treatments, while stifling innovation of future therapies for the patients in need.
- HB18-1260 requires reporting that is not protected, but offers protections for confidentiality to insurance companies or PBMs.
- HB18-1260 won't help lower the cost of drugs and will ultimately chill investment in future innovation through its
  requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead
  to a better understanding of pricing because the information compelled paints an inaccurate picture.
- HB18-1260 undermines free-market competition. We need transparency that would examine the entire
  healthcare sector holistically, which would help patients understand the manufacturers, insurers and PBMs role
  in determining patients' out-of-pocket costs. HB18-1260 would not accomplish this goal.
- The data and reporting that HB18-1260 requires would be difficult to capture because the R&D process is long-term and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug (or medical device). In fact, an idea intended for one product may fail in the first instance, but be incorporated into another product. Therefore, the reporting required may be misleading and is not be reflective of the total investment of getting a drug to market.

#### THE FACTS AND VALUE OF MEDICINE:

- Cost and affordability of medicines are important, and spending on medicines is not the primary driver of health care cost growth. Significant cost savings that medicines provide to the overall health care system is often ignored. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs.
- Unlike other healthcare services, there are not wide variations in regional pricing of prescription drugs. The Centers for Medicaid and Medicare Services (CMS) reported that "there exists little variation in drug ingredient



# Please Vote No on Colorado House Bill 18-1260

prices across... regions" but that reimbursement rates to providers for medical services can vary by nearly 300% across regions.1

## **CURRENT PROCESS**

- Biopharmaceuticals are among the <u>most heavily regulated industries</u> in the healthcare sector.
- From discovery through FDA approval, <u>developing a new medicine on average takes at least 10 years and is estimated to cost \$2.6 billion</u>. Less than 12% of the candidate medicines that make it into a Phase I clinical trial will be approved by the FDA.<sup>2</sup>
- When calculating the cost of research and development into one medicine, you must consider the cost of
  failures. Failure to recognize the expense associated with these results in an inaccurate calculation of the
  investment biopharmaceutical companies are making. <u>Accounting for these related discovery costs could be
  nearly impossible.</u>

#### **CBSA ADVOCATES FOR TRUE TRANSPARENCY:**

We are dedicated to patients, and we work every day to help people live longer, healthier lives. That's why we support true transparency. True transparency means:

- Examining the costs of prescription drugs, together.
- · Addressing the health care system as a whole.
- Considering every player in the health care system to make meaningful changes for patients and their families.
- It's critical to consider our complex health care holistically instead of singling out individual stakeholders.

We encourage our state legislators to consider:

- Reviewing the influential role insurers, PBMs and others play in deciding how much patients pay for medicines at the pharmacy counter.
- Considering the information patients need to make decisions about out-of-pocket drug costs when selecting their health plans.
- Tackling all areas of health care that drive up prescription costs.

True transparency requires working together. Colorado BioScience Association is talking with legislators, business leaders and patients about all of the factors that impact the price of medicines in our complex healthcare system

#### **CONCLUSION:**

Despite the challenges, our industry continues the work and investments because of the potential impact these drugs can have on people' lives. Medicines transform how we treat and cure patients, which is why our industry is committed to ensuring that our patients have access to breakthrough therapies and the needed medicine, but HB18-1260 does not help accomplish this goal. Innovative medicines save and extend lives, improve quality of life and drive value to patients and the healthcare system as a whole. Access to these innovative medicines is key to many patients' survival. HB18-1260 stifles innovation and ultimately will not help our patients most in need.

WE RESPECTFULLY URGE THE LEGISLATURE TO REJECT HB18 - 1260 SO THAT WE MAY FOCUS ON THE REAL COST DRIVERS AND TELL THE WHOLE STORY OF THE COST OF MEDICINE.

<sup>&</sup>lt;sup>1</sup> MaCurdy T, et al. Geographic Variation in Drug Prices and Spending in the Part D Program. Centers for Medicare & Medicaid Services' Office of Research, Development, and Information (ORDI). August 2009.

<sup>&</sup>lt;sup>2</sup> http://csdd.tufts.edu/news/complete\_story/pr\_tufts\_csdd\_2014\_cost\_study



# True transparency: examining the cost of prescription drugs, together

We all agree that patients need access to medicines and health care at affordable prices. That's why Colorado BioScience Association encourages true transparency.

True transparency means:

- Working together to provide patients access to affordable medicines.
- · Addressing the health care system as a whole.
- Considering every player in the health care system to make meaningful changes for patients and their families.

# Let's broaden this important conversation to create practical solutions for patients.



## How are drug prices determined?

Drug prices reflect years of research, development and clinical trials.

- One successful drug takes 10-12 years and costs up to \$2.6 billion to bring to market.
- Few medicines make it to market successfully; in fact, 90% fail.
- Manufacturers cover the costs of failed drugs with successful life-saving drugs.



Drug prices also reflect complex deals made by insurance companies and pharmacy benefit managers (PBMs).

- PBMs structure manufacturer rebates on medicines so the money goes back to the PBM or the employer, not the patient.
- Insurance companies and PBMs increasingly shift the cost of medicines to patients.
- They maintain the most control over what patients pay at the pharmacy counter.



### What solutions drive down costs?

- Competition in the market and expiring patents will produce substantial savings on medicines in coming years.
- New competition from generic and biosimilar drugs over the next five years will reduce prescription drug spending by \$143.5 billion.
- Many drug manufacturers offer medicines to low-income patients for free or at a savings through special programs.

As informed citizens and representatives of the people, let's open the dialogue and talk about a comprehensive approach to pricing transparency.

For in-depth information on contributors to drug costs, please visit www.drugcostfacts.org, or contact Jennifer Jones, Vice President of CBSA: jjones@cobioscience.com.



























March 8th, 2018

## Dear Representatives,

We are writing to urge you to vote no on HB 18-1260. As a diverse coalition that represents patients, providers, medical innovators, and businesses who care about the affordability of life-saving medicines, the development of new cures, and improving health care for Coloradans.

We are opposed to HB18-1260, the Prescription Drug Price Transparency Act of 2018, because it would not do anything to improve the patient experience, including lower their out-of-pocket costs for medications or improving access to treatment. In addition to not having any benefit to consumers, there are a number of concerning aspects of this bill.

First, mandating advanced price notification could have the unintended consequence of incentivizing secondary distributors to stockpile medicines. This could result in shortages of medicines, leading to disruption of access for patients whose health depends on those medications.

Second, prescription drugs are only one part of a much larger, complicated health care system, and HB18-1260 fails to address many of cost drivers present in that system. For example, all too often, many of the negotiated discounts and rebates for prescription drugs do not make their way to the actual patients, and instead go to others involved in the supply chain.

If Colorado policy makers want to have an impact on out-of-pocket costs and access to prescription drugs, they should instead focus on policies that would actually help to lower the cost of drugs, and this bill, simply, fails to do so. In addition, if policy makers want access to the information outlined in HB18-1260, it will be publicly available due to a similar California law passed in 2017.

We are proud of Colorado's national reputation for cutting-edge medical innovation, true consumer-friendly transparency, and bipartisan solutions to complicated policy matters. The Center for Improving Value in Health Care (CIVHC) All Claims Payer Database and Connect for Health Colorado's Plan Finder Tool have both earned national recognition for providing Colorado consumers with meaningful, searchable data to help them save money when making health care decisions. Colorado should continue to be a leader in health care through policies and innovation that provide real value for patients.

We encourage you to reject HB18-1260 and focus on bipartisan solutions that improve access to care and reduce out-of-pocket costs.

# Sincerely,

Bristol Myers-Squibb
Climbing for Carleen
Coalition of Hematology and Oncology Practices
Colorado BioScience Association
Colorado Business Roundtable
Colorado Gerontological Society
Grand Junction Chamber of Commerce
International Cancer Advocacy Network
Jefferson County Economic Development Corporation
Metro Denver Oncology Nursing Society
Pro 15
Rocky Mountain Stroke Center
Scleroderma Foundation – Rocky Mountain Chapter
Silvergate Pharmaceuticals, Inc.



## Form Letter Opposing HB18-1260

#### Subject line options:

- Silvergate Pharmaceuticals Inc. urges you to vote NO on HB18-1260: Prescription Drug Price Transparency
- Oppose HB18 1260

Dear Representative Landgraf,

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am Frank Segrave, President and CEO of Silvergate Pharmaceuticals Inc. Silvergate is leading the way in development and commercialization of innovative pediatric medications that offer dosing accuracy, safety and availability. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

Developing a biopharmaceutical drug is an incredibly challenging endeavor. Over the past 30 years, the cost of developing a new drug has grown more than ten-fold. It costs up to \$2.6 billion to bring one successful drug to market. The time for development takes 15 years on average.

Not only is the product development process long and arduous, few medicines make it to market successfully. In fact, 90% fail.

Despite the challenges, we as innovators continue the work and investments because of the potential impact these drugs can have on people' lives. Medicines transform how we treat and cure patients, cutting death rates from illnesses like heart disease by a third. They provide significant cost savings to the health care system, with fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs.

House Bill 1260 fails to reach its intended purpose and will ultimately chill investment in future innovation through its requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead to a better understanding of pricing.

Furthermore, at Silvergate Pharmaceuticals, we know too well the long-term R&D process. The data and reporting that the legislation requires is difficult to capture because the R&D process is long-term. Manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting required would not be inaccurate, and would not reflect the total investment in getting a drug to market.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency, thank you for your time and consideration. If you have any questions, I welcome a personal conversation about the potential negative impact of this legislation. I am happy to discuss why this is not good for the citizens of Colorado and companies in Colorado. Please advise if you would like to discuss further.

Frank Segrave

**Sincere** 

President & CEO



Dear Representative Buckner,

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am the CFO of Ocugen which is developing new treatments for sight threatening diseases. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

Developing a biopharmaceutical drug is an incredibly challenging endeavor. Over the past 30 years, the cost of developing a new drug has grown more than ten-fold. It costs up to \$2.6 billion to bring one successful drug to market. The time for development takes 15 years on average.

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Furthermore, at Ocugen we know too well the long-term R&D process. The data and reporting that the legislation requires is difficult to capture because the R&D process is long-term. Manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting required would not be inaccurate, and would not reflect the total investment in getting a drug to market.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency, thank you for your time and consideration. If you have any questions, I welcome a personal conversation about the potential negative impact of this legislation.

Sincerely,

Charlie Kang

Charlie Kang

Chief Financial Officer O: +1 (303) 974-7532 M: +1 (303) 550-8043

E: charlie.kang@ocugen.com



Dear Representative Kennedy,

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am the CFO of Ocugen which is developing new treatments for sight threatening diseases. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

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Sincerely,

Charlie Kang

# Charlie Kang

Chief Financial Officer
O: +1 (303) 974-7532
M: +1 (303) 550-8043
E: charlie.kang@ocugen.com

4843 Pearl E. Circle, Suite 101 Boulder, CO 80045



From: Andy Sklawer [mailto:asklawer@brickellbio.com]

Sent: Wednesday, February 28, 2018 1:29 PM

To: chris.kennedy.house@state.co.us

Subject: Brickell Biotech urges you to vote NO on HB18-1260: Prescription Drug Price Transparency

Dear Representative Kennedy:

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am the Co-Founder and COO of Brickell Biotech, Inc. a clinical stage medical dermatology company. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

Developing a biopharmaceutical drug is an incredibly challenging endeavor. Over the past 30 years, the cost of developing a new drug has grown more than ten-fold. It can cost up to \$2.6 billion to bring one successful drug to market. The time for development takes 15 years on average.

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House Bill 1260 fails to reach its intended purpose and will ultimately chill investment in future innovation through its requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead to a better understanding of pricing.

Furthermore, at Brickell Biotech we know too well the long-term R&D process. The data and reporting that the legislation requires is difficult to capture because the R&D process is long-term. Manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting required would not be inaccurate, and would not reflect the total investment in getting a drug to market.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency, thank you for your time and consideration. If you have any questions, I welcome a personal conversation about the potential negative impact of this legislation.

Si	ncerely,			
Ar	ndy			

Andy Sklawer Co-Founder & Chief Operating Officer Brickell Biotech, Inc. 305-582-4657 (c) www.brickellbio.com



# Unlocking the Potential of Blood

From: Larson, Scott [mailto:Scott.Larson@terumobct.com]

Sent: Tuesday, February 27, 2018 10:41 AM

To: chris.kennedy.house@state.co.us

Cc: April Giles <agiles@cobioscience.com>; Jennifer Jones <jjones@cobioscience.com>

Subject: HB18-1260: Prescription Drug Transparency

Dear Rep. Chris Kennedy,

I hope you remember me and Terumo BCT from the tour we had last summer. We enjoyed talking to you about our mission, showing you our campus and talking to you about your priorities. Of course, spelling "blood" with our fingers was fun too!

As you likely know, <u>HB18-1260</u>: <u>Prescription Drug Price Transparency</u> was introduced earlier this week. While I chair the Colorado BioScience Association Board of Directors and co-chair of their Policy Committee, I'm emailing you on behalf of Terumo BCT and myself. I acknowledge that as a medical device manufacturer this legislation does not directly affect us. Nevertheless, we are strongly concerned about the overall bioscience community and the impact this legislation may have on our state. The proposed legislation that requires companies to disclose proprietary information may chill investment in future innovation. At Terumo BCT, we have more than 50 years of experience in R&D and we know very well the long-term R&D process. The data and reporting that the legislation requires would be difficult to capture because the R&D process is long-term and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug (or medical device). And, in our experience, an idea intended for one product may fail in the first instance but be incorporated into another product. Therefore, the reporting required may not be reflective of the total investment of getting a drug to market and may be inaccurate.

Cost and affordability of medicines are important, but my understanding is that spending on medicines is not the primary driver of health care cost growth. The significant cost savings that medicines (and medical devices) provide to the overall health care system is often ignored. Medicines (and medical devices) can lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency. I'd invite you to talk to our team cc'd here with any questions you have about this legislation. Thank you, Representative Kennedy for your consideration and for your service to our district.

Best regards,

Scott T. Larson Sr. Vice President, Legal and General Counsel

Terumo BCT, Inc.
11158 West Collins Avenue
Lakewood, CO 80215
United States of America
Tel +1 (303) 205-2814
scott.larson@terumobct.com



# HB18 – 1260 - Prescription Drug Price Transparency Sponsors: Rep. J. Ginal, Rep. D. Jackson, Sen. D. Moreno March 8, 2018

House Health, Insurance, & Environment
Testimony – April Giles
President and CEO, Colorado BioScience Association

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Science is not linear, determining the costs associated with the full R&D process for each product would likely be impossible or inaccurate at best. For example, the work conducted on a molecule for one disease might fail, but that research could ultimately lead to a successful new discovery within another disease later down the road.

The work underway within our industry is a painstaking endeavor, but the results achieved are invaluable to the patients we serve and the healthcare industry as a whole.

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In closing, since the inception of the CBSA, we have worked hand-in-hand with the General Assembly to develop sound policies to advance Colorado into a top-tier cluster for the bioscience industry. To date, we all have done a phenomenal job and have had great success. House Bill 1260 sends a message to companies looking to grow or relocate here that we do not value their work.

On behalf of the bioscience industry in the state, I respectfully request that you oppose House Bill 1260. I'm happy to answer any questions.

# Other notes:

- "Every dollar invested in newer treatments saves nearly seven dollars in other costs by reducing or eliminating hospitalizations, minimizing one's inability to work at full capacity, and empowering people to live independently" – National Venture Capital Association Study
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- Bioscience industry is already one of the most heavily regulated industries in the health care sector. Companies are required to provide information on drug effectiveness and safety to the FDA and public companies are also required to report information on costs, sales and total R&D spending in securities filings. These filings are available to the public and listed out by company and product in aggregate.



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The commissioner is then required to post the information on the division of insurance website. That data will be analyzed to determine the effect of prescription drug costs on health insurance premiums. And then the commissioner will publish a report each year. A prescription drug manufacturer that fails to notify purchasers or fails to report required data to the commissioner is subject to discipline, including a penalty of \$1,000 per day for each day the manufacturer fails to comply with the notice or reporting requirements.

## **REASONS TO OPPOSE:**

CBSA advocates for <u>true transparency</u> to help patients understand the role of manufacturers, insurers, and PBMs in determining out-of-pocket drug costs.

- HB18-1260 would <u>negatively impact patients</u> in Colorado.
- HB18-1260 would threaten access to critically important treatments, while stifling innovation of future therapies for the patients in need.
- HB18-1260 requires reporting that is not protected, but offers protections for confidentiality to insurance companies or PBMs.
- HB18-1260 won't help lower the cost of drugs and will ultimately chill investment in future innovation through its
  requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead
  to a better understanding of pricing because the information compelled paints an inaccurate picture.
- HB18-1260 undermines free-market competition. We need transparency that would examine the entire
  healthcare sector holistically, which would help patients understand the manufacturers, insurers and PBMs role
  in determining patients' out-of-pocket costs. HB18-1260 would not accomplish this goal.
- The data and reporting that HB18-1260 requires would be difficult to capture because the R&D process is long-term and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug (or medical device). In fact, an idea intended for one product may fail in the first instance, but be incorporated into another product. Therefore, the reporting required may be misleading and is not be reflective of the total investment of getting a drug to market.

#### THE FACTS AND VALUE OF MEDICINE:

- Cost and affordability of medicines are important, and spending on medicines is not the primary driver of health
  care cost growth. Significant cost savings that medicines provide to the overall health care system is often
  ignored. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures –
  all of which translate to lower health care costs.
- Unlike other healthcare services, there are not wide variations in regional pricing of prescription drugs. The
  Centers for Medicaid and Medicare Services (CMS) reported that "there exists little variation in drug ingredient



# Please Vote No on Colorado House Bill 18-1260

prices across... regions" but that reimbursement rates to providers for medical services can vary by nearly 300% across regions.1

## **CURRENT PROCESS**

- Biopharmaceuticals are among the most heavily regulated industries in the healthcare sector.
- From discovery through FDA approval, <u>developing a new medicine on average takes at least 10 years and is estimated to cost \$2.6 billion</u>. Less than 12% of the candidate medicines that make it into a Phase I clinical trial will be approved by the FDA.<sup>2</sup>
- When calculating the cost of research and development into one medicine, you must consider the cost of
  failures. Failure to recognize the expense associated with these results in an inaccurate calculation of the
  investment biopharmaceutical companies are making. <u>Accounting for these related discovery costs could be
  nearly impossible.</u>

#### **CBSA ADVOCATES FOR TRUE TRANSPARENCY:**

We are dedicated to patients, and we work every day to help people live longer, healthier lives. That's why we support true transparency. True transparency means:

- · Examining the costs of prescription drugs, together.
- Addressing the health care system as a whole.
- Considering every player in the health care system to make meaningful changes for patients and their families.
- It's critical to consider our complex health care holistically instead of singling out individual stakeholders.

We encourage our state legislators to consider:

- Reviewing the influential role insurers, PBMs and others play in deciding how much patients pay for medicines at the pharmacy counter.
- Considering the information patients need to make decisions about out-of-pocket drug costs when selecting their health plans.
- Tackling all areas of health care that drive up prescription costs.

True transparency requires working together. Colorado BioScience Association is talking with legislators, business leaders and patients about all of the factors that impact the price of medicines in our complex healthcare system

## **CONCLUSION:**

Despite the challenges, our industry continues the work and investments because of the potential impact these drugs can have on people' lives. Medicines transform how we treat and cure patients, which is why our industry is committed to ensuring that our patients have access to breakthrough therapies and the needed medicine, but HB18-1260 does not help accomplish this goal. Innovative medicines save and extend lives, improve quality of life and drive value to patients and the healthcare system as a whole. Access to these innovative medicines is key to many patients' survival. HB18-1260 stifles innovation and ultimately will not help our patients most in need.

WE RESPECTFULLY URGE THE LEGISLATURE TO REJECT HB18 - 1260 SO THAT WE MAY FOCUS ON THE REAL COST DRIVERS AND TELL THE WHOLE STORY OF THE COST OF MEDICINE.

<sup>&</sup>lt;sup>1</sup> MaCurdy T, et al. Geographic Variation in Drug Prices and Spending in the Part D Program. Centers for Medicare & Medicaid Services' Office of Research, Development, and Information (ORDI). August 2009.

<sup>&</sup>lt;sup>2</sup> http://csdd.tufts.edu/news/complete\_story/pr\_tufts\_csdd\_2014\_cost\_study



# True transparency: examining the cost of prescription drugs, together

We all agree that patients need access to medicines and health care at affordable prices. That's why Colorado BioScience Association encourages true transparency.

True transparency means:

- Working together to provide patients access to affordable medicines.
- · Addressing the health care system as a whole.
- Considering every player in the health care system to make meaningful changes for patients and their families.

# Let's broaden this important conversation to create practical solutions for patients.



#### How are drug prices determined?

Drug prices reflect years of research, development and clinical trials.

- One successful drug takes 10-12 years and costs up to \$2.6 billion to bring to market.
- Few medicines make it to market successfully; in fact, 90% fail.
- Manufacturers cover the costs of failed drugs with successful life-saving drugs.



Drug prices also reflect complex deals made by insurance companies and pharmacy benefit managers (PBMs).

- PBMs structure manufacturer rebates on medicines so the money goes back to the PBM or the employer, not the patient.
- Insurance companies and PBMs increasingly shift the cost of medicines to patients.
- They maintain the most control over what patients pay at the pharmacy counter.



#### What solutions drive down costs?

- Competition in the market and expiring patents will produce substantial savings on medicines in coming years.
- New competition from generic and biosimilar drugs over the next five years will reduce prescription drug spending by \$143.5 billion.
- Many drug manufacturers offer medicines to low-income patients for free or at a savings through special programs.

As informed citizens and representatives of the people, let's open the dialogue and talk about a comprehensive approach to pricing transparency.

For in-depth information on contributors to drug costs, please visit www.drugcostfacts.org, or contact Jennifer Jones, Vice President of CBSA: jjones@cobioscience.com.





























March 8th, 2018

## Dear Representatives,

We are writing to urge you to vote no on HB 18-1260. As a diverse coalition that represents patients, providers, medical innovators, and businesses who care about the affordability of life-saving medicines, the development of new cures, and improving health care for Coloradans.

We are opposed to HB18-1260, the Prescription Drug Price Transparency Act of 2018, because it would not do anything to improve the patient experience, including lower their out-of-pocket costs for medications or improving access to treatment. In addition to not having any benefit to consumers, there are a number of concerning aspects of this bill.

First, mandating advanced price notification could have the unintended consequence of incentivizing secondary distributors to stockpile medicines. This could result in shortages of medicines, leading to disruption of access for patients whose health depends on those medications.

Second, prescription drugs are only one part of a much larger, complicated health care system, and HB18-1260 fails to address many of cost drivers present in that system. For example, all too often, many of the negotiated discounts and rebates for prescription drugs do not make their way to the actual patients, and instead go to others involved in the supply chain.

If Colorado policy makers want to have an impact on out-of-pocket costs and access to prescription drugs, they should instead focus on policies that would actually help to lower the cost of drugs, and this bill, simply, fails to do so. In addition, if policy makers want access to the information outlined in HB18-1260, it will be publicly available due to a similar California law passed in 2017.

We are proud of Colorado's national reputation for cutting-edge medical innovation, true consumer-friendly transparency, and bipartisan solutions to complicated policy matters. The Center for Improving Value in Health Care (CIVHC) All Claims Payer Database and Connect for Health Colorado's Plan Finder Tool have both earned national recognition for providing Colorado consumers with meaningful, searchable data to help them save money when making health care decisions. Colorado should continue to be a leader in health care through policies and innovation that provide real value for patients.

We encourage you to reject HB18-1260 and focus on bipartisan solutions that improve access to care and reduce out-of-pocket costs.

# Sincerely,

Bristol Myers-Squibb
Climbing for Carleen
Coalition of Hematology and Oncology Practices
Colorado BioScience Association
Colorado Business Roundtable
Colorado Gerontological Society
Grand Junction Chamber of Commerce
International Cancer Advocacy Network
Jefferson County Economic Development Corporation
Metro Denver Oncology Nursing Society
Pro 15
Rocky Mountain Stroke Center
Scleroderma Foundation – Rocky Mountain Chapter
Silvergate Pharmaceuticals, Inc.



### Form Letter Opposing HB18-1260

#### Subject line options:

- Silvergate Pharmaceuticals Inc. urges you to vote NO on HB18-1260: Prescription Drug Price Transparency
- Oppose HB18 1260

Dear Representative Landgraf,

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am Frank Segrave, President and CEO of Silvergate Pharmaceuticals Inc. Silvergate is leading the way in development and commercialization of innovative pediatric medications that offer dosing accuracy, safety and availability. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

Developing a biopharmaceutical drug is an incredibly challenging endeavor. Over the past 30 years, the cost of developing a new drug has grown more than ten-fold. It costs up to \$2.6 billion to bring one successful drug to market. The time for development takes 15 years on average.

Not only is the product development process long and arduous, few medicines make it to market successfully. In fact, 90% fail.

Despite the challenges, we as innovators continue the work and investments because of the potential impact these drugs can have on people' lives. Medicines transform how we treat and cure patients, cutting death rates from illnesses like heart disease by a third. They provide significant cost savings to the health care system, with fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs.

House Bill 1260 fails to reach its intended purpose and will ultimately chill investment in future innovation through its requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead to a better understanding of pricing.

Furthermore, at Silvergate Pharmaceuticals, we know too well the long-term R&D process. The data and reporting that the legislation requires is difficult to capture because the R&D process is long-term. Manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting required would not be inaccurate, and would not reflect the total investment in getting a drug to market.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency, thank you for your time and consideration. If you have any questions, I welcome a personal conversation about the potential negative impact of this legislation. I am happy to discuss why this is not good for the citizens of Colorado and companies in Colorado. Please advise if you would like to discuss further.

Frank Segrave

President & CEO



Dear Representative Buckner.

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am the CFO of Ocugen which is developing new treatments for sight threatening diseases. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

Developing a biopharmaceutical drug is an incredibly challenging endeavor. Over the past 30 years, the cost of developing a new drug has grown more than ten-fold. It costs up to \$2.6 billion to bring one successful drug to market. The time for development takes 15 years on average.

Not only is the product development process long and arduous, few medicines make it to market successfully. In fact, 90% fail.

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House Bill 1260 fails to reach its intended purpose and will ultimately chill investment in future innovation through its requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead to a better understanding of pricing.

Furthermore, at Ocugen we know too well the long-term R&D process. The data and reporting that the legislation requires is difficult to capture because the R&D process is long-term. Manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting required would not be inaccurate, and would not reflect the total investment in getting a drug to market.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency, thank you for your time and consideration. If you have any questions, I welcome a personal conversation about the potential negative impact of this legislation.

Sincerely,

Charlie Kang

Charlie Kang

Chief Financial Officer
O: +1 (303) 974-7532
M: +1 (303) 550-8043
E: charlie.kang@ocugen.com



Dear Representative Kennedy,

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am the CFO of Ocugen which is developing new treatments for sight threatening diseases. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

Developing a biopharmaceutical drug is an incredibly challenging endeavor. Over the past 30 years, the cost of developing a new drug has grown more than ten-fold. It costs up to \$2.6 billion to bring one successful drug to market. The time for development takes 15 years on average.

Not only is the product development process long and arduous, few medicines make it to market successfully. In fact, 90% fail.

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House Bill 1260 fails to reach its intended purpose and will ultimately chill investment in future innovation through its requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead to a better understanding of pricing.

Furthermore, at Ocugen we know too well the long-term R&D process. The data and reporting that the legislation requires is difficult to capture because the R&D process is long-term. Manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting required would not be inaccurate, and would not reflect the total investment in getting a drug to market.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency, thank you for your time and consideration. If you have any questions, I welcome a personal conversation about the potential negative impact of this legislation.

Sincerely,

Charlie Kang

# Charlie Kang

Chief Financial Officer
0: +1 (303) 974-7532
M: +1 (303) 550-8043
E: charlie.kang@ocugen.com

4843 Pearl E. Circle, Suite 101 Boulder, CO 80045



From: Andy Sklawer [mailto:asklawer@brickellbio.com]

Sent: Wednesday, February 28, 2018 1:29 PM

To: chris.kennedy.house@state.co.us

Subject: Brickell Biotech urges you to vote NO on HB18-1260: Prescription Drug Price Transparency

Dear Representative Kennedy:

I am writing to you today in opposition of House Bill 1260, Prescription Drug Price Transparency. I am the Co-Founder and COO of Brickell Biotech, Inc. a clinical stage medical dermatology company. My company is proud to call Colorado home, and to be part of the state's thriving bioscience sector, which is a pillar of Colorado's fast-growing economy.

Developing a biopharmaceutical drug is an incredibly challenging endeavor. Over the past 30 years, the cost of developing a new drug has grown more than ten-fold. It can cost up to \$2.6 billion to bring one successful drug to market. The time for development takes 15 years on average.

Not only is the product development process long and arduous, few medicines make it to market successfully. In fact, 90% fail.

Despite the challenges, we as innovators continue the work and investments because of the potential impact these drugs can have on people' lives. Medicines transform how we treat and cure patients, cutting death rates from illnesses like heart disease by a third. They provide significant cost savings to the health care system, with fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs.

House Bill 1260 fails to reach its intended purpose and will ultimately chill investment in future innovation through its requirement for companies to disclose proprietary information. Forcing companies to itemize costs will not lead to a better understanding of pricing.

Furthermore, at Brickell Biotech we know too well the long-term R&D process. The data and reporting that the legislation requires is difficult to capture because the R&D process is long-term. Manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting required would not be inaccurate, and would not reflect the total investment in getting a drug to market.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency, thank you for your time and consideration. If you have any questions, I welcome a personal conversation about the potential negative impact of this legislation.

Sincerely,		
Andy		
Andy Sklawer		

Andy Sklawer
Co-Founder & Chief Operating Officer
Brickell Biotech, Inc.
305-582-4657 (c)
www.brickellbio.com



# Unlocking the Potential of Blood

From: Larson, Scott [mailto:Scott.Larson@terumobct.com]

Sent: Tuesday, February 27, 2018 10:41 AM

To: chris.kennedy.house@state.co.us

Cc: April Giles <agiles@cobioscience.com>; Jennifer Jones <jjones@cobioscience.com>

Subject: HB18-1260: Prescription Drug Transparency

Dear Rep. Chris Kennedy,

I hope you remember me and Terumo BCT from the tour we had last summer. We enjoyed talking to you about our mission, showing you our campus and talking to you about your priorities. Of course, spelling "blood" with our fingers was fun too!

As you likely know, <u>HB18-1260: Prescription Drug Price Transparency</u> was introduced earlier this week. While I chair the Colorado BioScience Association Board of Directors and co-chair of their Policy Committee, I'm emailing you on behalf of Terumo BCT and myself. I acknowledge that as a medical device manufacturer this legislation does not directly affect us. Nevertheless, we are strongly concerned about the overall bioscience community and the impact this legislation may have on our state. The proposed legislation that requires companies to disclose proprietary information may chill investment in future innovation. At Terumo BCT, we have more than 50 years of experience in R&D and we know very well the long-term R&D process. The data and reporting that the legislation requires would be difficult to capture because the R&D process is long-term and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug (or medical device). And, in our experience, an idea intended for one product may fail in the first instance but be incorporated into another product. Therefore, the reporting required may not be reflective of the total investment of getting a drug to market and may be inaccurate.

Cost and affordability of medicines are important, but my understanding is that spending on medicines is not the primary driver of health care cost growth. The significant cost savings that medicines (and medical devices) provide to the overall health care system is often ignored. Medicines (and medical devices) can lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs.

I would ask you to vote NO on HB18-1260: Prescription Drug Price Transparency. I'd invite you to talk to our team cc'd here with any questions you have about this legislation. Thank you, Representative Kennedy for your consideration and for your service to our district.

Best regards,

Scott T. Larson Sr. Vice President, Legal and General Counsel

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Lakewood, CO 80215
United States of America
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scott.larson@terumobct.com