

## Report to the Vermont Legislature on Pharmaceutical Drug Cost Transparency In Accordance with 18 V.S.A. § 4635

Submitted to: Committee, General Assembly, etc.

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## Attorney General's Report on Prescription Drug Cost Transparency Pursuant to 18 V.S.A. § 4635 December 1, 2023

#### **OVERVIEW**

This report is submitted pursuant to 18 V.S.A. § 4635 ("Prescription Drug Cost Transparency"). The statute requires that the Attorney General's Office ("AGO") provide a report to the General Assembly on an annual basis. This report focuses on information provided to the AGO by the Department of Vermont Health Access ("DVHA"), Blue Cross and Blue Shield Vermont ("BCBSVT") and MVP Health Care ("MVP") for calendar year 2022.

## I. <u>Information Provided by the Department of Vermont Health Access</u>

Pursuant to 18 V.S.A. § 4635, DVHA and health insurers with more than 5,000 covered lives in Vermont for major medical health insurance (referred to below as "Health Insurers") are required to provide certain information annually about the increase in the price of prescription drugs.

The statute requires that DVHA annually create two lists. The first, required by 18 V.S.A. § 4635 (b)(1)(A), is comprised of 10 prescription drugs (at least one generic and one brand name) on which the State "spends significant health care dollars" and for which the wholesale acquisition cost ("WAC") <sup>2</sup> has increased by 50 percent or more over the past five calendar years or by 15 percent or more during the previous calendar year. DVHA must rank the drugs on the

<sup>&</sup>lt;sup>1</sup> The AGO's 2019 report was prepared after discussing with Legislative leaders the challenges of complying with the reporting requirements of the statute. The same format is used in this report as was used from 2019 to 2022. The AGO looks forward to working with the Legislature to address the compliance challenges presented by, among other things, federal law which prohibits Medicaid from providing drug-specific net cost information.

<sup>&</sup>lt;sup>2</sup> WAC is defined under federal law as a manufacturer's "list price" for a drug to wholesalers or other direct purchasers but does not reflect any prompt pay or other discounts, rebates, or reductions in price. 42 U.S.C. § 1395w-3a (c) (6).

list from those with the largest to smallest increase, and state: whether it considers any of the drugs to be specialty drugs; whether the drugs were included based on their price increase over one year, five years or both; and provide DVHA's total expenditure for each drug.

The second list, required by 18 V.S.A. § 4635 (b)(1)(B), is comprised of 10 prescription drugs (at least one generic and one brand name) on which the State "spends significant health care dollars" and for which DVHA's net cost<sup>3</sup> has increased by 50 percent or more over the past five years or 15 percent or more during the previous calendar year. DVHA must rank the drugs on the list from those with the largest to smallest increase, state whether it considers any of the drugs to be specialty drugs, and whether they were included based on their price increase over one year, five years or both. (18 V.S.A. § 4635 (b)(1)(B)).

DVHA's WAC list, Net Cost list, and an explanation of the drug selection criteria it used for each are attached as Exhibit A.

## II. <u>Information Provided by Vermont Health Insurers</u>

Pursuant to 18 V.S.A. § 4635 (b)(1)(C), the Health Insurers are also required to create a list of 10 prescription drugs (at least one generic and one brand name) on which the insurance plan "spends significant health care dollars" and for which the insurance plan's net cost<sup>4</sup> has increased by 50 percent or more over the past five years, 15 percent or more during the previous calendar year, or both. Each Health Insurer must rank the drugs on the list from those with the largest to smallest increase and state whether it considers any of the drugs to be specialty drugs. BCBSVT and MVP are the two health insurers who have made annual submissions. The public

<sup>&</sup>lt;sup>3</sup> "Net cost" is defined in 18 V.S. A. § 4635 (b)(1)(B) as the cost to DVHA net of rebates and other price concessions.

<sup>&</sup>lt;sup>4</sup> "Net cost" is defined in 18 V.S. A. § 4635 (b)(1)(C) as the cost to the insurance plans net of rebates and other price concessions.

versions of the 2022 net cost lists provided by BCBSVT and MVP are attached hereto as Exhibits B and C, respectively. Health Insurers also provide the AGO with a list that includes the insurer's actual net dollars spent on each drug. That list is exempt from public inspection pursuant to 18 V.S. A. § 4635 (b)(1)(C)(ii).

## III. Factors That Influence Manufacturers' Drug Pricing

As observed by the AGO in previous Prescription Drug Cost Transparency reports, manufacturers have identified several factors they consider in making pricing decisions, although the weight they place on those factors seems to vary. The factors commonly mentioned as impacting manufacture's decisions to increase prices are listed below, in no specific order:

- the value of innovative medicines;
- cost effectiveness (meaning the economic value to patients given the effectiveness of the drug, compared to other drugs in the same class);
- the size of the patient population for the drug;
- investments made (including in research and development) and risks undertaken;
- return on investment;
- fiduciary responsibilities;
- post-marketing regulatory commitments and ongoing pharmacovigilance (safety surveillance);
- creation and maintenance of manufacturing facilities and capabilities, including the
   ability to address drug shortages caused by production issues;
- cost of ingredients;
- competition, including for drugs in the same class;
- the rate of inflation; and

percentage of sales in commercial versus Medicare or other government channels, and
the funds expended on assistance programs for people with limited resources or without
insurance which, in some measure, offset drug sales income.

## IV. Analysis of Cost Information Submitted by DVHA and Health Insurers

As mentioned above, the Health Insurers provide the AGO with their net dollar expenditures on a confidential basis. Because federal law prevents DVHA from disclosing the net prices it pays for individual drugs, it is unable to provide the AGO with the prices actually paid, even on a confidential basis. 42 U.S.C. § 1396r-8(b)(3)(D). DVHA has provided the gross dollar amount (WAC) it paid for individual drugs, as depicted in Exhibit A, but those figures do not exclude any rebates or other price concessions it receives. As a result, it is not possible to compare DVHA's net drug costs to the Health Insurers' net drug costs.

## A. How DVHA and the Insurers Selected the Drugs on the Lists

As mentioned above, 18 V.S.A. § 4635 permits DVHA and the Health Insurers to compile their lists based on either drug price increases of 50 percent or more over the past five years or 15 percent or more during the previous calendar year. To be consistent and to maximize comparison of the lists, DVHA and the Health Insurers selected their 10 drugs based on an increase of 15 percent or more during calendar year 2022.

## B. DVHA and the Health Insurer Drug Price Increases

## 1. <u>DVHA</u>

Since DVHA is prohibited from revealing drug-specific net cost information, its Net Cost list ranks the drugs from 1 through 10 but reflects the gross amount paid for those drugs. As DVHA observed in its footnote to the net cost chart, the gross amount paid "may not align in rank order with the net cost of the drug to the State." Ex. A., p.3.

The drugs on DVHA's WAC and Net Cost lists did not overlap. DVHA listed eight brand and two generic drugs on its Net Cost list. DVHA's WAC list was composed of one brand and nine generic drugs. One generic drug, Prednisolone Sodium Phosphate, was on its WAC list last year, manufactured by a different company. Humalog, on both BCBSVT's and DVHA's Net Cost current list, was on DVHA's list last year.

On its Chart #3, DVHA provided a summary of the last three years of data on WAC prices increases. DVHA Report, p.5. In its summary of the 13,946 drugs analyzed in 2022, DVHA said that 195 NDCs<sup>5</sup>( representing 1.4%) exceeded the 15% statutory threshold. Of those 195,153 were generics. The average generic increase of 42.1% represented an average increase of \$0.27. The average 24.91% brand increase represented an average increase of \$12.79.

DVHA made a number of observations about the drug price trends it experienced from 2020 to 2022.

-Compared to 2020 and 2021, there was an increase in the total number of drugs that exceeded the 15% per year threshold.

-Compared to 2020 and 2021, there was an increase in the number of generic NDCs that exceeded the 15% threshold. In 2020, 109 generic drugs exceeded the threshold and in 2021 only 56 generic drugs exceeded the threshold. 153 generic drugs exceeded the 15% threshold in 2022.

-In 2022, generic drug prices rose at a higher rate than brand drugs. In 2022, the average increase for generic drugs was 42% compared to the 25% average increase in brand drugs.

DVHA Report, p.4.

<sup>&</sup>lt;sup>5</sup> The NDC refers to the National Drug Code, a unique number assigned to each human drug in the U.S.

## 2. Health Insurers

BCBSVT selected two generic drugs for inclusion on its current list and MVP selected no generic drugs. In its report (Ex. C), MVP said that none of its generic drugs have increased 15% over the previous calendar year or alternatively, 50% or more over the past year. BCBSVT's largest percentage increases were for the two generics (at 124% and 315%), but they represented the smallest net drug spends of the drugs listed. BCBSVT's brand name drug increases ranged from 17 % to 71%. MVP's brand name drug increases ranged from 15.1% to 57.7%. None were common to MVP's 2021 and 2022 lists. As discussed below, one was common to BCBSVT's 2021 and 2022 lists.

## C. Specialty Drugs

The statute requires that DVHA and the Health Insurers identify any "specialty drugs" that appear on their lists. "Specialty drugs" are used to treat chronic, serious, or life-threatening conditions and are often far more costly than traditional drugs.<sup>6</sup>

The single brand drug on DVHA's WAC list is a specialty drug. Of the eight brand drugs on DVHA's Net Cost list, five are specialty drugs. Two of the specialty drugs (Stelara and Xolair) were on DVHA's Net Cost list last year. Stelara is also on MVP's list this year.

Specialty drugs represented six of the ten brand drugs on MVP's list versus four on its previous list. Specialty drugs represent eight of the ten drugs on BCBSVT's list (including both

<sup>&</sup>lt;sup>6</sup> They can cost thousands of dollars per month and may exceed \$100,000 per year. There are few or no low-cost generics. "Although there is no accepted definition of *specialty pharmaceuticals*, they generally are drugs and biologics (medicines derived from living cells cultured in a laboratory) that are complex to manufacture, can be difficult to administer, may require special patient monitoring, and sometimes have Food and Drug Administration (FDA)-mandated strategies to control and monitor their use." <a href="https://www.healthaffairs.org/do/10.1377/hpb20131125.510855/full/">https://www.healthaffairs.org/do/10.1377/hpb20131125.510855/full/</a>. They may require specialized and temperature-controlled shipping, storage and handling.

generic drugs), while four of the drugs on BCBSVT's previous list were specialty drugs. Humira is on both the MVP and BCBSVT lists this year. It was on BCBSVT's list last year as well.

## Conclusion

Pharmaceutical drug pricing is extraordinarily complicated. Each party in the drug distribution chain (which includes manufacturers, wholesalers, pharmacy benefit managers, pharmacies, health/plans/payers) is governed by myriad requirements, and their interests vary. While it is clear there are ongoing sizeable drug price increases in both brand and generic drugs, the process of preparing this report has again demonstrated the challenges to providing the public with useable information about pharmaceutical pricing.

Respectfully Submitted,

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## Exhibit A



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## 18 V.S.A. § 4635- Pricing Transparency Drug List-DVHA Methodology

Date: June 1, 2023

Vermont law <u>18 V.S.A.</u> § <u>4635</u>, entitled "Prescription Drug Cost Transparency" requires the Department of Vermont Health Access ("DVHA") to create two lists of 10 prescription drugs each per the following statutory language:

(b)(1)(A) The Department of Vermont Health Access shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more during the previous calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall include the percentage of the wholesale acquisition cost increase for each drug on the list; rank the drugs on the list from those with the largest increase in wholesale acquisition cost to those with the smallest increase; indicate whether each drug was included on the list based on its cost increase over the past five years or during the previous calendar year, or both; and provide the Department's total expenditure for each drug on the list during the most recent calendar year.

(B) The Department of Vermont Health Access shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the cost to the Department of Vermont Health Access, net of rebates and other price concessions, has increased by 50 percent or more over the past five years or by 15 percent or more during the previous calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall rank the drugs on the list from those with the greatest increase in net cost to those with the smallest increase and indicate whether each drug was included on the list based on its cost increase over the past five years or during the previous calendar year, or both.

DVHA's Pharmacy Unit prepared data on drugs that meet the criteria per the following methodology.

## Methodology used for selection of drug list for 18 V.S.A. § 4635:

To be consistent with other payers and allow the Attorney General's office to maximize comparisons of the list among payers, DVHA developed the list based on the one-year increase in wholesale acquisition cost (WAC) and net cost. The data was supplied by DVHA's Pharmacy Benefits Manager (PBM), Change Healthcare, based on criteria supplied by DVHA with a list of active drugs that exceeded a 15% increase in gross and net cost to DVHA over the previous calendar year. The final list of the top 10 drugs in each category was derived by reviewing these lists in detail, taking into consideration the previous year's lists, brand, generic, specialty status, and total spend. Net spend was also considered when generating the ranking of the drugs in the "net cost" list.

#### 10 PRESCRIPTION DRUGS WHOLESALE ACQUISITION COST INCREASE (Chart 1)

This list contains drugs for which the wholesale acquisition cost (WAC) increased by 15 percent or more in calendar year 2022. The WAC unit price for all drugs with utilization was pulled as of December 31<sup>st</sup> calendar year 2022. The data was averaged and grouped at the product name level and then broken down to include ten drugs, considering total gross cost to DVHA and % increase.

	TOP 10 BASED ON WAC INCREASE-2022 (Chart 1)										
Therapeutic Category	PRODUCT NAME	GENERIC NAME	LABELER NAME	Brand or Generic (B/G)	Highest	PERCEN T_INCRE ASE(AVG )		Specialt	Drug Appeared on Previous Year List		
Corticosteroids	EMFLAZA	Deflazacort Tab	PTC THERAPEUTICS, INC.	В	10	19%	\$ 230,224	YES	NO		
Stimulant/ADHD	AMPHETAMINE/DEXTROAMPHET	Amphetamine-Dextroamphetamime	AMNEAL PHARM. OF NEW YORK	G	4	55%	\$ 56,775	NO	NO		
Laxative	GAVILAX	Polyethylene Glycol 3350	LUPIN PHARM., INC.	G	5	50%	\$ 30,737	NO	NO		
Salicylate	ASPIRIN LOW DOSE	Aspirin	MAJOR PHARM.	G	8	25%	\$ 15,355	NO	NO		
Vitamin	AQUEOUS VITAMIN D INFANTS	Cholecalciferol	LANNETT COMPANY, INC.	G	2	104%	\$ 13,727	NO	NO		
Corticosteroids	PREDNISOLONE SODIUM PHOSP	Prednisolone Sol 15MG/5ML	PAI	G	7	31%	\$ 11,602	NO	YES (diff mfr)		
Opioid/pain	ACETAMINOPHEN/CODEINE	Acetaminophen w/ Codeine Tab	SPEC GX, LLC	G	3	100%	\$ 7,197	NO	NO		
Antihistamine	BANOPHEN	Diphenhydramine	MAJOR PHARM.	G	9	25%	\$ 3,669	NO	NO		
Laxative	GAVILYTE-G	PEG 3350-KCI-Sod Bicarb-Sod Chl-Sod Sulf	LUPIN PHARM., INC.	G	6	50%	\$ 10,337	NO	NO		
Sedative	TEMAZEPAM	Temazepam Cap	AMNEAL PHARM LLC	G	1	112%	\$ 1,369	NO	NO		

#### **TOP 10-NET AMOUNT PAID (Chart 2)**

This list contains drugs for which the net cost to DVHA increased by 15 percent or more in calendar year 2022. DVHA net cost was calculated as wholesale acquisition cost minus manufacturer federal rebates. The total net cost for each NDC was divided by the total quantity (ex. tablets or capsules) of the drug reimbursed by DVHA for that NDC to obtain the Net Unit Cost for each drug. This list is NDC-based. In cases where multiple NDCs of the same drug appeared on the list the total gross spend was combined and the percent increase averaged. The data was pulled by calendar year and ranked based on highest to lowest net paid amount for each drug.

TOP 10 NET AMOUNT PAID-CY 2022(Chart 2)											
Therapeutic Category	PRODUCT NAME	GENERIC NAME	LABELER NAME	Brand or Generi c (B/G)	Rank by Net Amount Paid 1= Highest Net Spend	_	_	OUNT	Specialt y (YES/NO )	On Previous	Appeared on this year's GROSS (WAC) COST LIST
Antipsoriatics	STELARA	Ustekinumab	JANSSEN BIOTECH, INC	В	1	27%	\$	5,824,224	YES	YES	NO
Hormone related	LUPRON DEPOT-PED	Acetate (3 Month) Inj Pediatrio	ABBVIE INC	В	2	19%	\$	862,028	NO	NO	NO
Antiasthma - Monoclonal	XOLAIR	Omalizumab	GENENTECH, INC.	В	3	19%	\$	560,541	YES	YES	NO
Insulin	HUMALOG KWIK INJ 200/ML	Insulin Lispro	ELI LILLY AND COMPANY	В	4	24%	\$	564,722	NO	YES	NO
Anticonvulsants	VIMPAT	Lacosamide	UCB, INC.	В	5	23%	\$	355,402	NO	NO	NO
Multiple Sclerosis Agents	COPAXONE INJ 40MG/ML	Glatiramer Acetate	TEVA NEUROSCIENCE, INC.	В	7	35%	\$	292,892	YES	NO	NO
Anticonvulsants	TOPIRAMATE ER	Topiramate	UPSHER-SMITH LAB., LLC.	G	6	127%	\$	74,082	NO	NO	NO
Inflammatory Bowel Agents	CIMZIA	Certolizumab Pegol	UCB, INC.	В	8	127%	\$	187,774	YES	NO	NO
Contraceptives IUD	MIRENA	Levonorgestrel (IUD)	BAYER HEALTHCARE PHARM, INC	В	9	19%	\$	59,103	YES	NO	NO
Hypnotics - Tricyclic Agents	DOXEPIN HYDROCHLORIDE	Doxepin HCI (Sleep)	CURRAX PHARM., LLC.	G	10	41%	\$	8,970	NO	NO	NO

<sup>\*</sup>DVHA is prohibited from publishing drug-specific net cost information. The gross cost to DVHA for each drug listed is provided as a benchmark. This will not align in rank order with the net cost of the drug to the State.

Both drug lists were further refined to assure that at least one generic and one brand appeared on each list, and specialty drugs were identified. Specialty drugs were defined as per DVHA's posted list of specialty drugs on the DVHA website at: <a href="DVHA Specialty Drug List">DVHA Specialty Drug List</a>. Since DVHA is prohibited from publishing drug-specific net cost information, the gross cost to DVHA for each drug listed is provided as a benchmark. This may not align in rank order with the net cost of the drug to the State.

## **DRUG PRICE TRENDS**

- Chart #3 below is a summary of the last three years of data on WAC price increases. The NDCs included in this comparison only include NDCs for which DVHA had utilization. Compared to 2020 and 2021 there has been an increase in the total number of drugs reaching the 15% increase per year threshold.
- Compared to 2020 and 2021, there is an increase in the number of generic drug NDC's exceeding the threshold. In 2020 there were 109 generic drugs exceeding the threshold and in 2021 there were only 56 generic drugs exceeding the threshold. Compared to 153 in 2022 which is evident in chart 1 where 9 out of 10 drugs on the list are generic drugs.
- Again, this year, generic drug prices consistently rose at a higher rate than brand drugs. In 2022 the average increase for generic 42% vs average increase brands were 25 %.

## CHART #3

2020 GROSS									
Category	Total # NDC's Evaluated	# of NDCs Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC>= 15% last 1Yr	13,066	122	0.93%	109	89.34%	131.52%	20.51%	\$0.43	\$36.45
2021 GROSS									
Category	Total # NDC's Evaluated	# of NDCs Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC>= 15% last 1Yr	13,323	99	0.74%	56	56.57%	110.67%	26.69%	\$0.20	\$7.09
2022 CDOCC									
2022 GROSS  Category	Total # NDC's Evaluated	# of NDCs Exceeded Threshold	% of Total	Number of generic NDCs exceeding threshold	Generic % of total NDCs exceeding threshold	Avg % increase Generic	Avg % increase Brand	Avg \$ Inc Generic	Avg \$ Increase Brand
WAC>= 15% last 1Yr	13,946	195	1.40%	153	78.46%	42.10%	24.91%	\$0.27	\$12.79

## Exhibit B

# **BCBSVT List of Drugs with Largest Net Price Increase Impact**

Pursuant to 18 V.S.A. § 4635 (b)(C)(i)

2021

Ranking	NATIONAL_DRUG_CODE	DRUG_NAME	MANUFACTURER	Brand/Generic	Specialty?	1-yr % Increase
1	00074433902	HUMIRA PEN INJ 40MG/0.8	ABBVIE	Brand	Υ	24%
2	61958250101	BIKTARVY TAB	GILEAD SCIENCES	Brand	N	31%
3	00024591401	DUPIXENT INJ 300/2ML	SANOFI PHARMACEUTICALS	Brand	Υ	23%
4	00078060715	GILENYA CAP 0.5MG	NOVARTIS	Brand	Υ	17%
5	57894064001	TREMFYA INJ 100MG/ML	JANSSEN BIOTECH	Brand	Υ	55%
6	55513013760	OTEZLA TAB 30MG	AMGEN	Brand	Υ	34%
7	00002751001	HUMALOG INJ 100/ML	LILLY	Brand	N	71%
8	50474071079	CIMZIA PREFL KIT 200MG/ML	UCB PHARMA	Brand	Υ	36%
9	00093763056	IMATINIB MES TAB 400MG	TEVA PHARMACEUTICALS USA	Generic	Υ	315%
10	72205003092	ABIRATERONE TAB 250MG	NOVADOZ PHARMACEUTICALS	Generic	Υ	124%

# Exhibit C

# MVP List of Drugs with Largest Net Price Increase Impact Pursuant to 18 V.S.A. § 4635(b)(1)(C)(i) 2022 to 2021

Ranking	National Drug Code(s) (NDC)	Drug Name	Manufacturer	Brand/ Generic	Specialty?	1 Year % Increase
1	00074055402	HUMIRA PEN INJ 40/0.4ML	ABBVIE	Brand	YES	15.9%
2	57894006103	STELARA INJ 90MG/ML	JANSSEN BIOTECH	Brand	YES	16.2%
3	00169633910	NOVOLOG F/P PEN 100U/ML	NOVO NORDISK	Brand	NO	25.9%
4	00074210001	SKYRIZI PEN INJ 150MG/ML	ABBVIE	Brand	YES	51.3%
5	00597015230	JARDIANCE TAB 10MG	BOEHRINGER INGELHEIM	Brand	NO	19.5%
6	00069050130	XELJANZ XR TAB 11MG	PFIZER U.S.	Brand	YES	26.5%
7	72618300002	NURTEC ODT 75MG	BIOHAVEN PHARMACEUTICALS	Brand	NO	21.1%
8	61958200201	DESCOVY TAB 200/25MG	GILEAD SCIENCES	Brand	YES	15.1%
9	00002143611	EMGALITY PEN 120MG/ML	LILLY	Brand	NO	57.7%
10	58406002104	ENBREL INJ 50MG/ML	AMGEN	Brand	YES	32.6%

Note: Price increases were calculated after applying any manufacturer rebates and administrative fees.

Note: No generic drugs have increased 15% over the previous calendar year or alternatively, 50% or more over the past 5 years