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Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request cder_mpl1r_wp158

Request ID: cder_mpl1r_wp158_nsdv_v01

Request Description: We examined the utilization and switching patterns of N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) contaminated valsartan products, as well as angiotensin-converting enzyme inhibitors (ACEI), other angiotensin II receptor blockers (ARBs) excluding valsartan, and calcium channel blockers (CCB) in the Sentinel Distributed Database (SDD). This is report 1 of 2. Report 2 examined the utilization of incident NDMA and NDEA contaminated valsartan products, ACEI, ARBs, and CCB users in the SDD.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1

Data Source: The study period spanned from January 1, 2010 to April 30, 2019. We distributed the analytic package to 16 Data Partners (DPs) on October 9, 2019. Please see Appendix A for a list of the dates of available data for each DP included in this report.

Study Design: We identified individuals with prevalent use of valsartan, ACEI, other ARBs, and CCB and evaluated the occurrence of drug switches for the valsartan specific products including either contaminated, uncontaminated, or recalled and not contaminated exposure episodes. This is a Type 2 analysis in the Query Request Package (QRP) documentation.

Exposures of Interest: We defined the exposures of interest as valsartan, ACEI, other ARBs, and CCB using outpatient dispensing data and National Drug Codes (NDCs). Valsartan NDCs were separated into several groupings: any valsartan, recalled valsartan NDCs, recalled valsartan NDCs that tested negative for contamination, contaminated valsartan (tested positive) NDCs, NDMA-contaminated valsartan (tested positive for NDMA) NDCs, NDEA-contaminated valsartan (tested positive for NDEA) NDCs, uncontaminated (tested negative) or non-recalled valsartan NDCs, uncontaminated valsartan (tested negative) NDCs, and non-recalled valsartan NDCs. Cohort re-entry was allowed. Please see to Appendix B for a list of generic and brand names of medical products used to define switches in this report.

Outcomes of Interest: We examined switches from contaminated or recalled valsartan as outcomes of interest using outpatient dispensing data and NDCs:

- 1) Contaminated valsartan NDCs who switched to uncontaminated or non-recalled valsartan NDCs
- 2) Contaminated valsartan NDCs who switched to non-valsartan ARBs
- 3) Contaminated valsartan NDCs who switched to ACE inhibitors
- 4) Contaminated valsartan NDCs who switched to CCBs
- 5) Uncontaminated valsartan or non-recalled valsartan NDCs who switched to contaminated valsartan NDCs
- 6) Recalled valsartan NDCs that were not contaminated who switched to uncontaminated or non-recalled valsartan
- 7) Recalled valsartan NDCs that were not contaminated who switched to other ARBs
- 8) Recalled valsartan NDCs that were not contaminated who switched to ACE inhibitors
- 9) Recalled valsartan NDCs that were not contaminated who switched to CCBs
- 10) Uncontaminated valsartan or non-recalled valsartan NDCs who switched to recalled valsartan NDCs that were not contaminated

Please see to Appendix B for a list of generic and brand names of medical products used to define switches in this report.

Cohort Eligibility Criteria: We included the following age groups in the cohorts: 18-44, 45-64, and 65+ years. Certain cohorts included the following exclusion criteria on the index date (date of first dispensing):

- 1) In cohorts examining users of contaminated valsartan NDCs, we excluded users with evidence of any other ARBs on their index date
- 2) In cohorts examining users of uncontaminated valsartan or non-recalled valsartan NDCs, we excluded users with evidence of any other ARBs on their index date
- 3) In cohorts examining users of recalled valsartan NDCs that were not contaminated, we excluded users with evidence of any other ARBs on their index date

Overview for Request cder_mpl1r_wp158

Follow-up Time: Follow-up time began on the day of first dispensing and continued for the duration of the exposure episode. Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a treatment episode of continuous exposure. Exposure episodes were considered continuous if gaps in days supplied were 15 days or less. An episode extension of 15 days was added to the end of each exposure episode. Follow-up continued until the first occurrence of any of the following: 1) outcome occurrence; 2) disenrollment; 3) recorded death; 4) end of exposure episode; 5) end of query period.

Please see Appendix C for the specifications of parameters used in this request.

Limitations: Algorithms used to define exposures, outcomes, inclusion and exclusion criteria, and covariates are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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**Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Tool***

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1a. Baseline Characteristics for Members Dispensed Valsartan in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Characteristic¹	Number	
Number of episodes	12,427,541	
Number of unique patients	4,608,091	
Demographics	Mean	Standard Deviation
Mean Age (Years)	68.5	11.2
Age Group (Years)	Number	Percent
18-44	643,408	5.2%
45-64	3,457,733	27.8%
65+	8,326,400	67.0%
Sex		
Female	2,688,027	58.3%
Male	1,919,975	41.7%
Other	89	0.0%
Race		
Unknown	1,344,423	29.2%
American Indian or Alaska Native	8,820	0.2%
Asian	139,464	3.0%
Black or African American	527,901	11.5%
Native Hawaiian or Other Pacific Islander	5,121	0.1%
White	2,582,362	56.0%
Hispanic Origin	128,977	2.8%
Year		
2010	2,542,856	20.5%
2011	1,549,358	12.5%
2012	1,380,609	11.1%
2013	1,395,275	11.2%
2014	1,153,390	9.3%
2015	1,098,571	8.8%
2016	1,171,403	9.4%
2017	1,195,131	9.6%
2018	932,484	7.5%
2019	8,464	0.1%
Distribution of index-defining generic names:	Number	Percent
Recalled valsartan	3,000,878	24.1%
Contaminated valsartan: tested positive	713,696	5.7%
N-Nitrosodimethylamine (NDMA)-contaminated valsartan: tested positive	442,818	3.6%
N-Nitrosodiethylamine (NDEA)-contaminated valsartan: tested positive	353,982	2.8%
Recalled valsartan not contaminated	2,302,457	18.5%
Uncontaminated valsartan OR non-recalled valsartan	9,415,759	75.8%
Uncontaminated valsartan: tested negative	1,954,834	15.7%
Non-recalled valsartan	7,463,392	60.1%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique members.

Table 1b. Baseline Characteristics for Members Dispensed Angiotensin-Converting-Enzyme (ACE) Inhibitors in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Characteristic¹	Number	
Number of episodes	77,730,586	
Number of unique patients	27,676,077	
Demographics	Mean	Standard Deviation
Mean Age (Years)	65.1	12.2
Age Group (Years)	Number	Percent
18-44	7,008,593	9.0%
45-64	26,621,237	34.2%
65+	44,100,756	56.7%
Sex		
Female	13,788,108	49.8%
Male	13,887,354	50.2%
Other	615	0.0%
Race		
Unknown	8,753,970	31.6%
American Indian or Alaska Native	118,419	0.4%
Asian	486,178	1.8%
Black or African American	2,616,393	9.5%
Native Hawaiian or Other Pacific Islander	56,550	0.2%
White	15,644,567	56.5%
Hispanic Origin	788,578	2.8%
Year		
2010	11,629,835	15.0%
2011	8,324,897	10.7%
2012	8,324,721	10.7%
2013	9,056,620	11.7%
2014	8,872,991	11.4%
2015	8,646,331	11.1%
2016	8,441,299	10.9%
2017	7,762,365	10.0%
2018	6,527,171	8.4%
2019	144,356	0.2%
Distribution of index-defining generic names:	Number	Percent
Amlodipine besylate/benazepril HCl	2,888,988	3.7%
Benazepril HCl	3,349,210	4.3%
Benazepril HCl/hydrochlorothiazide	687,950	0.9%
Captopril	457,228	0.6%
Captopril/hydrochlorothiazide	36,476	0.0%
Enalaprilat dihydrate	68	0.0%
Enalapril maleate	4,379,031	5.6%
Enalapril maleate/hydrochlorothiazide	318,325	0.4%
Fosinopril sodium	526,531	0.7%
Fosinopril sodium/hydrochlorothiazide	37,693	0.0%

Table 1b. Baseline Characteristics for Members Dispensed Angiotensin-Converting-Enzyme (ACE) Inhibitors in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Distribution of index-defining generic names:	Number	Percent
Lisinopril	48,044,184	61.8%
Lisinopril/dietary supplement	*****	*****
Lisinopril/hydrochlorothiazide	12,095,475	15.6%
Moexipril HCl	76,248	0.1%
Moexipril HCl/hydrochlorothiazide	68,765	0.1%
Perindopril arginine/amlodipine besylate	232	0.0%
Perindopril erbumine	45,163	0.1%
Quinapril HCl	1,415,845	1.8%
Quinapril HCl/hydrochlorothiazide	165,606	0.2%
Ramipril	3,049,515	3.9%
Trandolapril	144,818	0.2%
Trandolapril/verapamil HCl	45,700	0.1%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique members.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1c. Baseline Characteristics for Members Dispensed Calcium Channel Blockers in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Characteristic¹	Number	
Number of episodes	55,264,878	
Number of unique patients	20,904,589	
Demographics	Mean	Standard Deviation
Mean Age (Years)	68.6	12.4
Age Group (Years)	Number	Percent
18-44	3,497,349	6.3%
45-64	14,838,239	26.8%
65+	36,929,290	66.8%
Sex		
Female	11,859,546	56.7%
Male	9,044,620	43.3%
Other	423	0.0%
Race		
Unknown	5,303,206	25.4%
American Indian or Alaska Native	77,210	0.4%
Asian	519,227	2.5%
Black or African American	2,823,141	13.5%
Native Hawaiian or Other Pacific Islander	40,204	0.2%
White	12,141,601	58.1%
Hispanic Origin	529,724	2.5%
Year		
2010	7,499,901	13.6%
2011	5,142,382	9.3%
2012	5,439,201	9.8%
2013	6,189,740	11.2%
2014	6,101,913	11.0%
2015	6,272,345	11.3%
2016	6,383,686	11.6%
2017	6,260,347	11.3%
2018	5,857,980	10.6%
2019	117,383	0.2%
Distribution of index-defining generic names:	Number	Percent
Amlodipine besylate	40,961,035	74.1%
Clevidipine butyrate	*****	*****
Diltiazem HCl	6,890,203	12.5%
Felodipine	648,456	1.2%
Isradipine	42,816	0.1%
Nicardipine HCl	24,589	0.0%
Nicardipine in sodium chloride, iso-osmotic	*****	*****
Nifedipine	3,671,821	6.6%
Nimodipine	8,165	0.0%
Nisoldipine	122,847	0.2%
Verapamil HCl	2,981,000	5.4%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique members.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1d. Baseline Characteristics for Members Dispensed Angiotensin II Receptor Blockers (ARBs) (Excluding Valsartan) in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Characteristic¹	Number	
Number of episodes	35,091,786	
Number of unique patients	13,764,196	
Demographics	Mean	Standard Deviation
Mean Age (Years)	67.5	11.1
Age Group (Years)	Number	Percent
18-44	2,107,544	6.0%
45-64	10,281,629	29.3%
65+	22,702,613	64.7%
Sex		
Female	7,888,841	57.3%
Male	5,875,043	42.7%
Other	312	0.0%
Race		
Unknown	4,163,607	30.2%
American Indian or Alaska Native	46,563	0.3%
Asian	444,285	3.2%
Black or African American	1,345,795	9.8%
Native Hawaiian or Other Pacific Islander	34,607	0.3%
White	7,729,339	56.2%
Hispanic Origin	381,585	2.8%
Year		
2010	3,405,407	9.7%
2011	2,867,247	8.2%
2012	3,192,388	9.1%
2013	3,957,642	11.3%
2014	4,112,064	11.7%
2015	4,198,240	12.0%
2016	4,260,245	12.1%
2017	4,194,752	12.0%
2018	4,814,103	13.7%
2019	89,698	0.3%
Distribution of index-defining generic names:	Number	Percent
Amlodipine besylate/olmesartan medoxomil	562,170	1.6%
Azilsartan medoxomil	92,618	0.3%
Azilsartan medoxomil/chlorthalidone	91,616	0.3%
Candesartan cilexetil	330,517	0.9%
Candesartan cilexetil/hydrochlorothiazide	106,843	0.3%
Eprosartan mesylate	6,871	0.0%
Eprosartan mesylate/hydrochlorothiazide	3,194	0.0%
Irbesartan	1,753,087	5.0%
Irbesartan/hydrochlorothiazide	549,596	1.6%
Losartan potassium	19,580,498	55.8%

Table 1d. Baseline Characteristics for Members Dispensed Angiotensin II Receptor Blockers (ARBs) (Excluding Valsartan) in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Distribution of index-defining generic names:	Number	Percent
Losartan potassium/hydrochlorothiazide	6,398,708	18.2%
Olmesartan medoxomil	2,449,831	7.0%
Olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	255,834	0.7%
Olmesartan medoxomil/hydrochlorothiazide	1,680,063	4.8%
Telmisartan	755,602	2.2%
Telmisartan/amlodipine besylate	14,556	0.0%
Telmisartan/hydrochlorothiazide	481,655	1.4%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique members.

Table 2a. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Episodes (Number)	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Exposures with No Washout							
Recalled valsartan							
4,539,013	2,166,462	156,816,286	138.15	20,694,994	20,725,824	1,092,229,142	1,136,375,549
Recalled valsartan NOT contaminated							
3,506,291	1,745,481	156,816,286	111.31	15,437,754	15,463,647	809,384,911	854,148,791
Contaminated valsartan (tested positive)							
1,274,402	666,083	156,816,286	42.48	5,282,231	5,283,868	284,281,800	283,725,384
N-Nitrosodimethylamine (NDMA)-contaminated valsartan (tested positive)							
837,752	495,977	156,816,286	31.63	3,318,829	3,319,324	184,325,535	184,095,835
N-Nitrosodiethylamine (NDEA)-contaminated valsartan (tested positive)							
720,748	393,954	156,816,286	25.12	2,590,456	2,591,115	133,555,645	133,405,031
Uncontaminated valsartan (tested negative) OR non-recalled valsartan							
10,389,440	3,962,322	156,816,286	252.67	57,890,712	58,024,121	2,491,702,084	2,638,620,505
Uncontaminated valsartan (tested negative)							
2,558,668	1,129,190	156,816,286	72.01	12,992,899	12,994,436	554,520,342	553,546,039
Non-recalled valsartan							
8,597,826	3,498,852	156,816,286	223.12	45,196,264	45,328,330	1,949,576,387	2,097,568,687
Angiotensin-converting enzyme (ACE) inhibitors							
77,730,586	27,676,077	156,816,286	1,764.87	454,241,945	454,951,646	22,392,100,876	25,383,834,325
Calcium channel blockers							
55,264,878	20,904,589	156,816,286	1,333.06	354,334,795	355,093,995	16,797,112,863	18,261,475,338
Angiotensin II receptor blockers (ARBs) (excluding valsartan)							
35,091,786	13,764,196	156,816,286	877.73	212,268,837	212,556,895	10,702,493,697	11,113,316,697
Valsartan							
12,427,541	4,608,091	156,816,286	293.85	78,234,929	78,394,906	3,568,347,637	3,758,999,161

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Table 2b. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Exposures with No Washout								
Recalled valsartan								
2010	0	0	56,773,854	0.00	0	0	0	0
2011	0	0	56,751,065	0.00	0	0	0	0
2012	141,695	136,213	58,626,613	23.23	1,011,834	1,012,259	48,192,784	48,726,700
2013	424,351	320,055	63,428,088	50.46	2,485,560	2,487,363	130,315,678	131,958,730
2014	378,758	275,801	66,622,663	41.40	1,649,852	1,651,538	90,525,908	91,463,326
2015	758,370	587,968	68,672,365	85.62	4,070,973	4,079,730	208,663,389	217,412,331
2016	1,150,194	877,379	71,314,156	123.03	6,223,041	6,233,011	340,763,178	358,204,912
2017	1,000,403	755,184	71,393,475	105.78	3,846,273	3,852,501	202,667,421	213,733,138
2018	682,002	567,809	66,747,713	85.07	1,404,147	1,406,104	71,042,517	74,815,461
2019	3,240	3,236	6,162,065	5.25	3,314	3,318	58,267	60,951
Recalled valsartan NOT contaminated								
2010	0	0	56,773,854	0.00	0	0	0	0
2011	0	0	56,751,065	0.00	0	0	0	0
2012	137,276	131,805	58,626,613	22.48	923,289	923,664	43,332,427	43,876,438
2013	383,804	288,954	63,428,088	45.56	2,139,031	2,140,514	111,147,905	112,819,986
2014	319,821	233,569	66,622,663	35.06	1,342,981	1,344,366	72,687,604	73,680,730
2015	550,072	431,649	68,672,365	62.86	2,826,986	2,834,529	145,463,686	153,853,938
2016	846,636	651,530	71,314,156	91.36	4,362,067	4,370,420	238,071,848	255,742,906
2017	753,140	575,916	71,393,475	80.67	2,797,920	2,803,075	146,472,250	157,922,563
2018	513,336	430,486	66,747,713	64.49	1,043,211	1,044,806	52,168,680	56,208,836
2019	2,206	2,202	6,162,065	3.57	2,269	2,273	40,511	43,394
Contaminated valsartan (tested positive)								
2010	0	0	56,773,854	0.00	0	0	0	0
2011	0	0	56,751,065	0.00	0	0	0	0
2012	4,726	4,691	58,626,613	0.80	17,960	17,960	1,500,094	1,494,116
2013	54,407	44,607	63,428,088	7.03	270,283	270,323	14,176,281	14,127,610
2014	74,974	57,644	66,622,663	8.65	262,164	262,228	15,336,600	15,268,992

Table 2b. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Contaminated valsartan (tested positive)								
2015	252,434	197,449	68,672,365	28.75	1,259,775	1,260,082	64,466,286	64,480,612
2016	356,977	275,572	71,314,156	38.64	1,867,440	1,868,013	103,099,143	102,852,261
2017	312,398	238,171	71,393,475	33.36	1,167,920	1,168,410	62,879,656	62,746,954
2018	217,374	182,709	66,747,713	27.37	435,562	435,724	22,804,211	22,735,433
2019	1,112	1,112	6,162,065	1.80	1,127	1,128	19,529	19,407
N-Nitrosodimethylamine (NDMA)-contaminated valsartan (tested positive)								
2010	0	0	56,773,854	0.00	0	0	0	0
2011	0	0	56,751,065	0.00	0	0	0	0
2012	0	0	58,626,613	0.00	0	0	0	0
2013	20,328	16,798	63,428,088	2.65	121,493	121,493	5,880,877	5,859,537
2014	31,211	25,048	66,622,663	3.76	114,804	114,805	6,271,896	6,247,404
2015	121,555	99,228	68,672,365	14.45	546,017	546,051	29,494,537	29,600,626
2016	265,220	212,128	71,314,156	29.75	1,375,117	1,375,367	78,761,167	78,594,411
2017	245,376	191,312	71,393,475	26.80	875,060	875,218	48,106,275	48,016,199
2018	154,046	137,505	66,747,713	20.60	286,322	286,374	15,810,546	15,777,413
2019	16	16	6,162,065	0.03	16	16	237	245
N-Nitrosodiethylamine (NDEA)-contaminated valsartan (tested positive)								
2010	0	0	56,773,854	0.00	0	0	0	0
2011	0	0	56,751,065	0.00	0	0	0	0
2012	4,726	4,691	58,626,613	0.80	17,813	17,813	1,487,761	1,481,813
2013	54,407	44,607	63,428,088	7.03	268,468	268,505	14,068,111	14,019,500
2014	74,974	57,644	66,622,663	8.65	257,894	257,947	15,091,662	15,025,156
2015	194,952	150,575	68,672,365	21.93	822,497	822,681	40,708,067	40,783,288
2016	148,097	114,007	71,314,156	15.99	591,802	591,982	29,873,692	29,823,569
2017	120,530	94,403	71,393,475	13.22	392,344	392,498	20,261,070	20,242,969
2018	121,949	105,147	66,747,713	15.75	238,510	238,560	12,045,573	12,009,144
2019	1,113	1,113	6,162,065	1.81	1,128	1,129	19,709	19,593

Table 2b. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Uncontaminated valsartan (tested negative) OR non-recalled valsartan								
2010	2,542,856	1,700,588	56,773,854	299.54	23,048,027	23,131,679	927,179,788	970,986,832
2011	1,549,358	977,537	56,751,065	172.25	8,715,020	8,730,790	358,871,783	374,385,470
2012	1,353,057	868,232	58,626,613	148.10	7,045,474	7,057,058	299,295,040	313,773,606
2013	1,224,957	822,317	63,428,088	129.65	6,009,194	6,017,738	274,980,958	288,437,593
2014	1,023,934	697,840	66,622,663	104.75	4,266,930	4,272,435	197,205,880	205,824,561
2015	911,314	661,599	68,672,365	96.34	3,325,234	3,328,711	164,288,080	171,811,483
2016	649,741	501,555	71,314,156	70.33	2,233,606	2,235,693	109,455,364	122,427,891
2017	560,506	440,755	71,393,475	61.74	1,996,210	1,997,936	101,642,511	118,989,484
2018	566,646	456,516	66,747,713	68.39	1,243,790	1,244,850	58,662,559	71,817,433
2019	7,071	7,069	6,162,065	11.47	7,227	7,231	120,121	166,152
Uncontaminated valsartan (tested negative)								
2010	616,762	423,980	56,773,854	74.68	4,795,106	4,795,838	189,664,594	189,268,046
2011	410,808	270,900	56,751,065	47.73	2,180,034	2,180,265	87,925,008	87,635,483
2012	382,153	262,324	58,626,613	44.74	1,814,576	1,814,766	76,414,544	76,091,961
2013	305,998	214,546	63,428,088	33.83	1,402,851	1,402,963	63,588,838	63,403,180
2014	217,341	156,623	66,622,663	23.51	769,754	769,839	34,774,468	34,659,753
2015	242,029	188,260	68,672,365	27.41	915,323	915,409	44,670,784	45,005,752
2016	157,591	123,292	71,314,156	17.29	529,355	529,411	27,020,763	27,011,405
2017	115,697	92,570	71,393,475	12.97	371,206	371,234	19,847,703	19,880,143
2018	109,048	92,717	66,747,713	13.89	213,443	213,460	10,592,950	10,569,667
2019	1,241	1,241	6,162,065	2.01	1,251	1,251	20,690	20,648
Non-recalled valsartan								
2010	2,045,878	1,397,944	56,773,854	246.23	17,326,216	17,407,103	699,985,765	742,969,835
2011	1,244,240	804,922	56,751,065	141.83	6,668,595	6,684,877	275,286,342	291,297,320
2012	1,122,423	751,425	58,626,613	128.17	5,630,475	5,642,615	238,987,786	254,103,381
2013	1,002,230	684,798	63,428,088	107.96	4,719,843	4,728,606	214,020,623	227,822,606
2014	912,161	645,132	66,622,663	96.83	3,637,759	3,643,422	168,309,109	177,138,551
2015	791,143	589,454	68,672,365	85.84	2,716,009	2,719,526	133,598,737	141,163,058

Table 2b. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Non-recalled valsartan								
2016	537,593	422,168	71,314,156	59.20	1,794,844	1,796,891	87,325,459	100,403,658
2017	462,315	365,984	71,393,475	51.26	1,647,718	1,649,430	82,956,513	100,308,801
2018	473,866	380,645	66,747,713	57.03	1,048,694	1,049,745	49,004,338	62,213,637
2019	5,977	5,975	6,162,065	9.70	6,111	6,115	101,715	147,840
Angiotensin-converting enzyme (ACE) inhibitors								
2010	11,629,835	7,950,555	56,773,854	1,400.39	111,284,494	111,501,929	5,074,347,825	5,887,960,000
2011	8,324,897	5,516,440	56,751,065	972.04	53,220,916	53,299,147	2,511,684,462	2,878,836,855
2012	8,324,721	5,540,616	58,626,613	945.07	51,886,221	51,958,943	2,533,682,676	2,883,112,515
2013	9,056,620	6,134,729	63,428,088	967.19	54,805,583	54,884,594	2,845,414,192	3,230,558,107
2014	8,872,991	6,031,845	66,622,663	905.37	50,644,354	50,711,913	2,593,950,731	2,918,012,619
2015	8,646,331	5,918,850	68,672,365	861.90	46,138,547	46,200,666	2,383,250,801	2,657,185,196
2016	8,441,299	5,863,649	71,314,156	822.23	40,184,844	40,245,260	2,090,779,189	2,322,021,445
2017	7,762,365	5,511,316	71,393,475	771.96	30,292,551	30,345,507	1,583,353,091	1,750,261,250
2018	6,527,171	4,861,403	66,747,713	728.33	15,632,174	15,651,284	772,206,381	852,151,961
2019	144,356	143,703	6,162,065	233.21	152,261	152,403	3,431,528	3,734,377
Calcium channel blockers								
2010	7,499,901	5,283,771	56,773,854	930.67	85,873,759	86,127,994	3,797,389,771	4,147,151,625
2011	5,142,382	3,487,524	56,751,065	614.53	37,198,117	37,273,619	1,693,950,624	1,847,535,148
2012	5,439,201	3,728,568	58,626,613	635.99	39,127,265	39,202,739	1,837,411,443	1,998,568,030
2013	6,189,740	4,305,221	63,428,088	678.76	42,543,228	42,628,976	2,115,945,450	2,299,927,201
2014	6,101,913	4,249,181	66,622,663	637.80	38,394,735	38,463,461	1,886,348,189	2,048,507,964
2015	6,272,345	4,399,705	68,672,365	640.68	37,081,333	37,147,848	1,831,679,006	1,983,110,562
2016	6,383,686	4,536,088	71,314,156	636.07	33,039,852	33,101,879	1,646,004,177	1,781,627,738
2017	6,260,347	4,530,001	71,393,475	634.51	26,249,866	26,297,615	1,305,761,089	1,413,771,694
2018	5,857,980	4,400,680	66,747,713	659.30	14,703,667	14,726,700	680,168,511	738,579,217
2019	117,383	117,002	6,162,065	189.87	122,973	123,164	2,454,603	2,696,159

Table 2b. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Angiotensin II receptor blockers (ARBs) (excluding valsartan)								
2010	3,405,407	2,304,265	56,773,854	405.87	32,165,912	32,201,644	1,449,373,683	1,499,720,394
2011	2,867,247	1,942,938	56,751,065	342.36	22,544,251	22,565,695	1,082,471,844	1,123,134,949
2012	3,192,388	2,177,409	58,626,613	371.40	24,304,495	24,328,955	1,200,557,535	1,247,329,602
2013	3,957,642	2,732,049	63,428,088	430.73	28,419,427	28,451,907	1,489,783,443	1,546,310,262
2014	4,112,064	2,847,796	66,622,663	427.45	27,121,717	27,153,463	1,412,218,230	1,471,733,700
2015	4,198,240	2,919,721	68,672,365	425.17	25,462,946	25,497,772	1,339,122,755	1,395,277,298
2016	4,260,245	3,014,590	71,314,156	422.72	22,537,995	22,593,329	1,191,757,081	1,234,110,216
2017	4,194,752	3,044,227	71,393,475	426.40	17,676,271	17,710,520	941,788,000	976,763,597
2018	4,814,103	3,792,358	66,747,713	568.16	11,941,255	11,958,983	593,410,072	616,840,653
2019	89,698	89,362	6,162,065	145.02	94,568	94,627	2,011,054	2,096,026
Valsartan								
2010	2,542,856	1,700,588	56,773,854	299.54	25,060,309	25,148,788	1,023,365,087	1,070,722,704
2011	1,549,358	977,537	56,751,065	172.25	9,696,091	9,713,111	406,547,857	423,522,868
2012	1,380,609	878,164	58,626,613	149.79	8,723,472	8,736,821	383,311,230	400,195,390
2013	1,395,275	914,212	63,428,088	144.13	8,592,268	8,603,405	422,262,674	439,649,487
2014	1,153,390	760,019	66,622,663	114.08	6,597,798	6,605,697	326,339,995	339,115,225
2015	1,098,571	748,882	68,672,365	109.05	6,369,725	6,376,795	327,282,440	341,912,920
2016	1,171,403	823,009	71,314,156	115.41	6,124,549	6,131,445	321,532,694	344,636,982
2017	1,195,131	859,415	71,393,475	120.38	4,906,704	4,912,678	253,644,332	279,474,231
2018	932,484	729,604	66,747,713	109.31	2,155,252	2,157,397	103,912,074	119,572,868
2019	8,464	8,458	6,162,065	13.73	8,761	8,769	149,254	196,486

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Table 2c. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Sex

Sex	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Exposures with No Washout								
Recalled valsartan								
Female	2,672,940	1,251,972	82,088,203	152.52	12,370,787	12,389,975	648,025,252	675,723,208
Male	1,865,999	914,449	74,720,604	122.38	8,323,904	8,335,546	444,189,401	460,637,883
Other	74	41	7,479	54.82	303	303	14,489	14,459
Recalled valsartan NOT contaminated								
Female	2,090,768	1,022,479	82,088,203	124.56	9,344,445	9,361,030	485,961,335	513,998,837
Male	1,415,467	722,972	74,720,604	96.76	6,093,096	6,102,404	323,413,033	340,139,412
Other	56	30	7,479	40.11	213	213	10,543	10,543
Contaminated valsartan (tested positive)								
Female	724,101	373,489	82,088,203	45.50	3,040,221	3,040,969	162,859,140	162,558,116
Male	550,282	292,581	74,720,604	39.16	2,241,920	2,242,809	121,418,714	121,163,352
Other	19	13	7,479	17.38	90	90	3,946	3,916
N-Nitrosodimethylamine (NDMA)-contaminated valsartan (tested positive)								
Female	478,861	280,651	82,088,203	34.19	1,927,361	1,927,591	106,347,769	106,236,504
Male	*****	*****	74,720,604	28.82	1,391,414	1,391,679	77,975,447	77,857,012
Other	*****	*****	7,479	10.70	54	54	2,319	2,319
N-Nitrosodiethylamine (NDEA)-contaminated valsartan (tested positive)								
Female	413,661	223,748	82,088,203	27.26	1,497,296	1,497,583	76,971,121	76,910,700
Male	307,073	*****	74,720,604	22.78	1,093,121	1,093,493	56,582,793	56,492,630
Other	14	*****	7,479	10.70	39	39	1,731	1,701
Uncontaminated valsartan (tested negative) OR non-recalled valsartan								
Female	6,274,729	2,338,493	82,088,203	284.88	36,867,788	36,962,695	1,563,951,463	1,650,478,008
Male	4,114,477	1,623,753	74,720,604	217.31	21,022,168	21,060,670	927,717,582	988,109,121
Other	234	76	7,479	101.62	756	756	33,039	33,376
Uncontaminated valsartan (tested negative)								
Female	1,537,342	671,628	82,088,203	81.82	8,222,792	8,223,715	345,299,264	344,797,026
Male	1,021,263	457,541	74,720,604	61.23	4,769,970	4,770,584	209,216,050	208,743,985
Other	63	21	7,479	28.08	137	137	5,028	5,028

Table 2c. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Sex

Sex	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Non-recalled valsartan								
Female	5,215,929	2,073,648	82,088,203	252.61	28,794,159	28,888,225	1,224,914,670	1,311,989,797
Male	3,381,720	1,425,138	74,720,604	190.73	16,401,485	16,439,485	724,633,676	785,550,512
Other	177	66	7,479	88.25	620	620	28,041	28,378
Angiotensin-converting enzyme (ACE) inhibitors								
Female	39,067,815	13,788,108	82,088,203	1,679.67	234,717,009	235,092,120	11,369,844,623	12,926,701,992
Male	38,660,864	13,887,354	74,720,604	1,858.57	219,518,015	219,852,598	11,021,901,208	12,456,745,878
Other	1,907	615	7,479	822.30	6,921	6,928	355,045	386,455
Calcium channel blockers								
Female	32,230,132	11,859,546	82,088,203	1,444.73	212,296,560	212,765,078	9,894,608,061	10,799,468,061
Male	23,033,531	9,044,620	74,720,604	1,210.46	142,032,880	142,323,541	6,902,255,934	7,461,741,252
Other	1,215	423	7,479	565.58	5,355	5,376	248,868	266,024
Angiotensin II receptor blockers (ARBs) (excluding valsartan)								
Female	20,598,493	7,888,841	82,088,203	961.02	128,411,302	128,575,471	6,415,212,068	6,672,296,703
Male	14,492,391	5,875,043	74,720,604	786.27	83,853,470	83,977,353	4,287,089,748	4,440,822,075
Other	902	312	7,479	417.17	4,065	4,071	191,881	197,919
Valsartan								
Female	7,432,609	2,688,027	82,088,203	327.46	49,053,705	49,165,477	2,203,545,344	2,317,563,685
Male	4,994,668	1,919,975	74,720,604	256.95	29,180,210	29,228,415	1,364,757,836	1,441,390,712
Other	264	89	7,479	119.00	1,014	1,014	44,457	44,764

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 2d. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Age Group

Age Group (Years)	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Exposures with No Washout								
Recalled valsartan								
18-44	182,420	91,166	71,679,345	12.72	702,655	703,697	27,470,087	28,243,143
45-64	1,207,311	585,969	55,500,433	105.58	5,382,401	5,389,742	238,694,672	245,448,643
65+	3,149,282	1,527,943	47,737,287	320.07	14,609,938	14,632,385	826,064,383	862,683,763
Recalled valsartan NOT contaminated								
18-44	144,751	75,706	71,679,345	10.56	544,608	545,372	21,192,411	21,958,351
45-64	928,149	469,384	55,500,433	84.57	4,041,694	4,047,198	178,490,268	185,278,497
65+	2,433,391	1,228,211	47,737,287	257.29	10,851,452	10,871,077	609,702,232	646,911,943
Contaminated valsartan (tested positive)								
18-44	44,869	23,460	71,679,345	3.27	155,361	155,485	6,163,824	6,169,559
45-64	334,066	173,160	55,500,433	31.20	1,338,119	1,338,897	59,984,722	59,945,361
65+	895,467	478,927	47,737,287	100.33	3,788,751	3,789,486	218,133,254	217,610,465
N-Nitrosodimethylamine (NDMA)-contaminated valsartan (tested positive)								
18-44	26,459	15,438	71,679,345	2.15	87,046	87,075	3,454,133	3,462,759
45-64	203,375	119,101	55,500,433	21.46	773,085	773,290	35,168,496	35,185,122
65+	607,918	366,203	47,737,287	76.71	2,458,698	2,458,959	145,702,906	145,447,954
N-Nitrosodiethylamine (NDEA)-contaminated valsartan (tested positive)								
18-44	25,735	13,936	71,679,345	1.94	81,644	81,698	3,180,443	3,181,499
45-64	194,022	103,663	55,500,433	18.68	694,542	694,886	30,251,564	30,217,493
65+	500,991	281,767	47,737,287	59.02	1,814,270	1,814,531	100,123,638	100,006,040
Uncontaminated valsartan (tested negative) OR non-recalled valsartan								
18-44	524,339	205,672	71,679,345	28.69	2,122,828	2,125,444	75,572,227	79,070,925
45-64	2,811,239	1,101,560	55,500,433	198.48	13,589,522	13,608,326	530,970,576	556,225,366
65+	7,053,862	2,764,383	47,737,287	579.08	42,178,362	42,290,351	1,885,159,281	2,003,324,215
Uncontaminated valsartan (tested negative)								
18-44	117,893	49,967	71,679,345	6.97	442,876	442,962	15,689,565	15,689,229
45-64	701,061	307,219	55,500,433	55.35	3,116,449	3,116,923	120,443,761	120,208,106
65+	1,739,714	796,343	47,737,287	166.82	9,433,574	9,434,551	418,387,016	417,648,704

Table 2d. Summary of Valsartan, Angiotensin-Converting Enzyme (ACE) Inhibitor, Calcium Channel Blocker, and other Angiotensin II Receptor Blocker (ARB) Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Age Group

Age Group (Years)	Episodes	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied
Non-recalled valsartan								
18-44	430,241	180,438	71,679,345	25.17	1,682,309	1,684,836	59,939,958	63,438,323
45-64	2,290,148	958,014	55,500,433	172.61	10,581,855	10,600,256	414,559,057	440,000,716
65+	5,877,437	2,446,171	47,737,287	512.42	32,932,100	33,043,238	1,475,077,372	1,594,129,648
Angiotensin-converting enzyme (ACE) inhibitors								
18-44	7,008,593	2,636,915	71,679,345	367.88	29,129,751	29,175,616	1,125,503,445	1,232,478,664
45-64	26,621,237	9,789,512	55,500,433	1,763.86	140,003,993	140,224,694	6,086,494,016	6,785,797,742
65+	44,100,756	16,359,833	47,737,287	3,427.06	285,108,201	285,551,336	15,180,103,415	17,365,557,919
Calcium channel blockers								
18-44	3,497,349	1,469,734	71,679,345	205.04	14,386,673	14,423,505	534,840,626	593,533,796
45-64	14,838,239	5,796,364	55,500,433	1,044.38	81,812,542	81,992,272	3,416,899,838	3,698,791,151
65+	36,929,290	14,297,472	47,737,287	2,995.03	258,135,580	258,678,218	12,845,372,399	13,969,150,391
Angiotensin II receptor blockers (ARBs) (excluding valsartan)								
18-44	2,107,544	859,010	71,679,345	119.84	9,381,401	9,403,890	359,365,438	370,221,505
45-64	10,281,629	4,190,778	55,500,433	755.09	56,038,734	56,150,055	2,437,224,185	2,518,655,995
65+	22,702,613	9,134,560	47,737,287	1,913.51	146,848,702	147,002,950	7,905,904,074	8,224,439,197
Valsartan								
18-44	643,408	247,284	71,679,345	34.50	2,902,873	2,906,425	106,223,341	110,581,071
45-64	3,457,733	1,315,692	55,500,433	237.06	19,067,714	19,092,814	776,884,469	809,299,206
65+	8,326,400	3,176,623	47,737,287	665.44	56,264,342	56,395,667	2,685,239,827	2,839,118,884

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Table 3a. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Episodes (Number)	Total Users	Eligible Members¹	Users per 10,000 Eligible Members	Years at Risk	Adjusted Dispensings	Raw Dispensings
Exposures with No Washout						
Contaminated valsartan (tested positive), switch to non-recalled OR uncontaminated valsartan (tested negative)						
850,441	460,913	156,541,584	29.44	498,961.9	3,201,485	3,202,626
Contaminated valsartan (tested positive), switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)						
850,441	460,913	156,541,584	29.44	495,107.2	3,201,485	3,202,626
Contaminated valsartan (tested positive), switch to angiotensin-converting enzyme (ACE) inhibitors						
1,222,530	637,219	156,417,299	40.74	794,202.7	5,053,331	5,054,896
Contaminated valsartan (tested positive), switch to calcium channel blockers						
779,677	438,381	156,492,819	28.01	419,129.7	3,100,896	3,101,968
Non-recalled OR uncontaminated valsartan (tested negative), switch to contaminated valsartan (tested positive)						
9,438,809	3,703,788	156,574,939	236.55	6,700,359.8	53,607,475	53,730,560
Recalled valsartan NOT contaminated, switch to non-recalled OR uncontaminated valsartan (tested negative)						
2,600,571	1,365,498	156,542,912	87.23	1,567,537.2	10,427,325	10,438,523
Recalled valsartan NOT contaminated, switch to ARBs (excluding valsartan)						
2,600,571	1,365,498	156,542,912	87.23	1,572,900.5	10,427,325	10,438,523
Recalled valsartan NOT contaminated, switch to ACE inhibitors						
3,353,476	1,653,505	156,417,294	105.71	2,259,429.9	14,736,710	14,761,135
Recalled valsartan NOT contaminated, switch to calcium channel blockers						
2,704,197	1,380,901	156,492,819	88.24	1,694,276.0	11,768,090	11,786,580
Non-recalled OR uncontaminated valsartan (tested negative), switch to recalled valsartan NOT contaminated						
9,438,809	3,703,788	156,574,939	236.55	6,631,420.5	53,607,475	53,730,560

Table 3a. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Episodes (Number)	Days Supplied	Amount Supplied	Episodes with an Event Switch	Switches among Episodes (Percent)	Switching Events per 1,000 Years at Risk
Exposures with No Washout					
Contaminated valsartan (tested positive), switch to non-recalled OR uncontaminated valsartan (tested negative)					
850,441	172,793,958	172,316,366	145,426	17%	291.46
Contaminated valsartan (tested positive), switch to ARBs (excluding valsartan)					
850,441	172,793,958	172,316,366	120,859	14%	244.11
Contaminated valsartan (tested positive), switch to ACE inhibitors					
1,222,530	272,414,890	271,838,503	15,430	1%	19.43
Contaminated valsartan (tested positive), switch to calcium channel blockers					
779,677	165,612,252	165,086,250	122,104	16%	291.33
Non-recalled OR uncontaminated valsartan (tested negative), switch to contaminated valsartan (tested positive)					
9,438,809	2,290,366,102	2,424,217,063	311,979	3%	46.56
Recalled valsartan NOT contaminated, switch to non-recalled OR uncontaminated valsartan (tested negative)					
2,600,571	547,268,916	574,242,204	450,908	17%	287.65
Recalled valsartan NOT contaminated, switch to ARBs (excluding valsartan)					
2,600,571	547,268,916	574,242,204	316,607	12%	201.29
Recalled valsartan NOT contaminated, switch to ACE inhibitors					
3,353,476	775,077,950	817,242,530	38,855	1%	17.20
Recalled valsartan NOT contaminated, switch to calcium channel blockers					
2,704,197	617,409,102	645,255,505	217,037	8%	128.10
Non-recalled OR uncontaminated valsartan (tested negative), switch to recalled valsartan NOT contaminated					
9,438,809	2,290,366,102	2,424,217,063	869,817	9%	131.17

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes (Number)	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Years at Risk	Adjusted Dispensings	Raw Dispensings
Exposures with No Washout							
Contaminated valsartan (tested positive), switch to non-recalled OR uncontaminated valsartan (tested negative)							
2010	0	0	56,439,847	0.00	0.0	0	0
2011	0	0	56,024,805	0.00	0.0	0	0
2012	2,389	2,374	57,701,906	0.41	2,052.1	9,093	9,093
2013	34,827	28,390	62,395,417	4.55	24,774.4	156,825	156,852
2014	46,732	36,636	65,335,708	5.61	26,015.9	158,166	158,209
2015	154,085	119,765	67,234,158	17.81	98,785.5	681,594	681,813
2016	232,017	176,717	69,740,332	25.34	172,588.8	1,096,102	1,096,471
2017	226,201	167,458	69,582,517	24.07	126,200.7	793,952	794,311
2018	153,470	128,040	64,706,547	19.79	48,510.9	305,026	305,149
2019	720	720	5,649,978	1.27	33.5	727	728
Contaminated valsartan (tested positive), switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)							
2010	0	0	56,439,847	0.00	0.0	0	0
2011	0	0	56,024,805	0.00	0.0	0	0
2012	2,389	2,374	57,701,906	0.41	2,154.6	9,093	9,093
2013	34,827	28,390	62,395,417	4.55	25,634.2	156,825	156,852
2014	46,732	36,636	65,335,708	5.61	27,113.0	158,166	158,209
2015	154,085	119,765	67,234,158	17.81	101,013.0	681,594	681,813
2016	232,017	176,717	69,740,332	25.34	171,804.0	1,096,102	1,096,471
2017	226,201	167,458	69,582,517	24.07	123,240.1	793,952	794,311
2018	153,470	128,040	64,706,547	19.79	44,115.0	305,026	305,149
2019	720	720	5,649,978	1.27	33.2	727	728
Contaminated valsartan (tested positive), switch to angiotensin-converting enzyme (ACE) inhibitors							
2010	0	0	56,161,747	0.00	0.0	0	0
2011	0	0	55,256,344	0.00	0.0	0	0
2012	4,521	4,488	56,872,725	0.79	4,097.6	17,201	17,201
2013	51,874	42,576	61,504,862	6.92	39,033.4	257,081	257,120
2014	72,179	55,559	64,426,821	8.62	43,242.5	251,714	251,776
2015	242,110	189,300	66,275,618	28.56	179,705.1	1,207,060	1,207,356

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes (Number)	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Years at Risk	Adjusted Dispensings	Raw Dispensings
Contaminated valsartan (tested positive), switch to ACE inhibitors							
2016	343,101	264,630	68,722,194	38.51	285,495.6	1,790,395	1,790,943
2017	299,492	227,615	68,602,260	33.18	176,479.9	1,112,999	1,113,468
2018	208,211	174,794	63,772,159	27.41	66,099.1	415,824	415,974
2019	1,042	1,042	5,416,855	1.92	49.5	1,057	1,058
Contaminated valsartan (tested positive), switch to calcium channel blockers							
2010	0	0	56,338,268	0.00	0.0	0	0
2011	0	0	55,593,741	0.00	0.0	0	0
2012	3,006	2,987	57,273,071	0.52	2,323.5	10,949	10,949
2013	34,891	28,838	61,941,374	4.66	21,862.2	165,141	165,165
2014	47,840	37,356	64,891,274	5.76	24,795.8	163,683	163,723
2015	158,426	125,183	66,782,442	18.74	98,448.8	751,416	751,602
2016	212,222	166,001	69,231,416	23.98	141,575.7	1,053,379	1,053,749
2017	191,632	148,950	69,123,643	21.55	93,315.5	694,306	694,641
2018	131,009	111,593	64,296,535	17.36	36,778.8	261,361	261,478
2019	651	651	5,565,922	1.17	29.4	661	661
Non-recalled OR uncontaminated valsartan (tested negative), switch to contaminated valsartan (tested positive)							
2010	2,492,035	1,665,935	56,522,564	294.74	2,612,999.8	22,509,713	22,589,734
2011	1,505,398	945,777	56,286,911	168.03	1,013,720.8	8,323,440	8,337,636
2012	1,315,583	840,986	57,976,006	145.06	853,811.0	6,791,308	6,801,909
2013	1,140,854	760,530	62,643,228	121.41	743,287.6	5,511,752	5,519,316
2014	913,752	612,619	65,566,834	93.43	506,810.7	3,719,459	3,724,131
2015	753,849	542,650	67,393,035	80.52	391,641.7	2,699,173	2,701,853
2016	510,585	390,964	69,828,080	55.99	251,520.3	1,737,124	1,738,693
2017	406,478	312,165	69,607,167	44.85	205,351.5	1,418,897	1,420,071
2018	394,742	309,871	64,734,962	47.87	120,962.3	890,947	891,552
2019	5,533	5,532	5,666,610	9.76	254.2	5,662	5,665

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes (Number)	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Years at Risk	Adjusted Dispensings	Raw Dispensings
Recalled valsartan NOT contaminated, switch to non-recalled OR uncontaminated valsartan (tested negative)							
2010	0	0	56,439,847	0.00	0.0	0	0
2011	0	0	56,024,805	0.00	0.0	0	0
2012	69,913	66,180	57,714,476	11.47	52,633.3	417,497	417,648
2013	280,176	207,388	62,421,475	33.22	211,432.9	1,410,902	1,411,640
2014	249,298	179,507	65,381,694	27.46	157,172.5	1,031,931	1,032,594
2015	358,768	276,741	67,292,837	41.12	241,034.0	1,661,936	1,663,491
2016	607,847	462,919	69,819,723	66.30	439,737.6	2,856,273	2,859,898
2017	619,476	467,458	69,691,479	67.08	337,673.3	2,201,514	2,204,822
2018	413,634	347,572	64,811,558	53.63	127,776.9	845,758	846,914
2019	1,459	1,456	5,652,374	2.58	76.5	1,514	1,516
Recalled valsartan NOT contaminated, switch to ARBs (excluding valsartan)							
2010	0	0	56,439,847	0.00	0.0	0	0
2011	0	0	56,024,805	0.00	0.0	0	0
2012	69,913	66,180	57,714,476	11.47	54,214.4	417,497	417,648
2013	280,176	207,388	62,421,475	33.22	219,056.8	1,410,902	1,411,640
2014	249,298	179,507	65,381,694	27.46	162,919.6	1,031,931	1,032,594
2015	358,768	276,741	67,292,837	41.12	247,764.4	1,661,936	1,663,491
2016	607,847	462,919	69,819,723	66.30	440,261.5	2,856,273	2,859,898
2017	619,476	467,458	69,691,479	67.08	331,679.9	2,201,514	2,204,822
2018	413,634	347,572	64,811,558	53.63	116,927.3	845,758	846,914
2019	1,459	1,456	5,652,374	2.58	76.6	1,514	1,516
Recalled valsartan NOT contaminated, switch to ACE inhibitors							
2010	0	0	56,161,740	0.00	0.0	0	0
2011	0	0	55,256,346	0.00	0.0	0	0
2012	132,806	127,487	56,872,744	22.42	121,179.5	894,471	894,822
2013	370,411	278,660	61,504,869	45.31	310,105.7	2,059,772	2,061,196
2014	309,713	225,942	64,426,817	35.07	205,661.1	1,294,392	1,295,696
2015	531,183	416,290	66,275,615	62.81	408,539.7	2,726,210	2,733,344
2016	809,937	621,291	68,722,190	90.41	658,669.3	4,158,978	4,166,871

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Episodes (Number)	Total Users	Eligible Members ¹	Users per 10,000 Eligible Members	Years at Risk	Adjusted Dispensings	Raw Dispensings
Recalled valsartan NOT contaminated, switch to ACE inhibitors							
2017	711,866	541,058	68,602,267	78.87	405,620.9	2,619,903	2,624,740
2018	485,492	406,106	63,772,162	63.68	149,550.8	980,853	982,332
2019	2,068	2,064	5,416,857	3.81	102.8	2,131	2,134
Recalled valsartan NOT contaminated, switch to calcium channel blockers							
2010	0	0	56,338,273	0.00	0.0	0	0
2011	0	0	55,593,739	0.00	0.0	0	0
2012	105,795	101,536	57,273,064	17.73	89,991.6	707,443	707,719
2013	298,854	225,781	61,941,367	36.45	230,122.9	1,640,612	1,641,627
2014	249,975	183,540	64,891,288	28.28	154,269.4	1,043,419	1,044,456
2015	428,311	336,998	66,782,439	50.46	307,532.1	2,173,207	2,178,529
2016	652,162	503,533	69,231,417	72.73	489,944.8	3,299,197	3,305,156
2017	578,823	444,165	69,123,639	64.26	308,137.8	2,115,887	2,119,604
2018	388,624	327,100	64,296,533	50.87	114,196.6	786,624	787,787
2019	1,653	1,649	5,565,914	2.96	80.7	1,701	1,702
Non-recalled OR uncontaminated valsartan (tested negative), switch to recalled valsartan NOT contaminated							
2010	2,492,035	1,665,935	56,522,564	294.74	2,594,954.7	22,509,713	22,589,734
2011	1,505,398	945,777	56,286,911	168.03	1,007,080.4	8,323,440	8,337,636
2012	1,315,583	840,986	57,976,006	145.06	843,695.5	6,791,308	6,801,909
2013	1,140,854	760,530	62,643,228	121.41	733,674.7	5,511,752	5,519,316
2014	913,752	612,619	65,566,834	93.43	499,237.7	3,719,459	3,724,131
2015	753,849	542,650	67,393,035	80.52	383,938.9	2,699,173	2,701,853
2016	510,585	390,964	69,828,080	55.99	246,247.2	1,737,124	1,738,693
2017	406,478	312,165	69,607,167	44.85	202,404.5	1,418,897	1,420,071
2018	394,742	309,871	64,734,962	47.87	119,932.8	890,947	891,552
2019	5,533	5,532	5,666,610	9.76	254.0	5,662	5,665

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Days Supplied	Amount Supplied	Episodes with an Event Switch	Switches among Episodes (Percent)	Switching Events per 1,000 Years at Risk
Contaminated valsartan (tested positive), switch to non-recalled OR uncontaminated valsartan (tested negative)					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	752,599	749,366	*****	*****	339.16
2013	8,820,178	8,788,568	10,852	31%	438.03
2014	9,229,729	9,181,931	16,868	36%	648.37
2015	34,595,993	34,576,674	43,680	28%	442.17
2016	60,088,903	59,912,261	34,978	15%	202.67
2017	43,121,237	42,984,073	24,306	11%	192.60
2018	16,172,378	16,110,605	14,038	9%	289.38
2019	12,941	12,888	*****	*****	238.81
Contaminated valsartan (tested positive), switch to ARBs (excluding valsartan)					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	752,599	749,366	52	2%	24.13
2013	8,820,178	8,788,568	1,073	3%	41.86
2014	9,229,729	9,181,931	1,408	3%	51.93
2015	34,595,993	34,576,674	7,888	5%	78.09
2016	60,088,903	59,912,261	25,932	11%	150.94
2017	43,121,237	42,984,073	36,613	16%	297.09
2018	16,172,378	16,110,605	47,876	31%	1,085.25
2019	12,941	12,888	17	2%	512.05
Contaminated valsartan (tested positive), switch to ACE inhibitors					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	1,438,189	1,432,211	*****	*****	10.98
2013	13,504,082	13,455,886	770	1%	19.73
2014	14,742,927	14,676,853	713	0	16.49
2015	61,855,233	61,858,929	3,014	1%	16.77

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Days Supplied	Amount Supplied	Episodes with an Event Switch	Switches among Episodes (Percent)	Switching Events per 1,000 Years at Risk
Contaminated valsartan (tested positive), switch to ACE inhibitors					
2016	98,981,536	98,728,211	4,460	1%	15.62
2017	60,039,541	59,903,328	3,804	1%	21.55
2018	21,834,354	21,764,178	2,620	1%	39.64
2019	19,028	18,906	*****	*****	80.81
Contaminated valsartan (tested positive), switch to calcium channel blockers					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	912,482	907,314	308	10%	132.56
2013	8,728,181	8,689,680	4,707	13%	215.30
2014	9,402,622	9,349,737	5,146	11%	207.54
2015	38,316,714	38,280,031	21,362	13%	216.99
2016	57,414,944	57,202,083	36,553	17%	258.19
2017	37,154,542	37,033,220	34,220	18%	366.71
2018	13,670,953	13,612,453	19,771	15%	537.57
2019	11,814	11,733	37	6%	1,258.50
Non-recalled OR uncontaminated valsartan (tested negative), switch to contaminated valsartan (tested positive)					
2010	906,738,476	949,591,769	24,266	1%	9.29
2011	342,868,255	357,562,423	12,515	1%	12.35
2012	288,835,198	302,720,096	21,233	2%	24.87
2013	252,711,792	265,210,192	38,710	3%	52.08
2014	170,872,254	178,708,219	52,518	6%	103.62
2015	132,552,784	138,691,520	72,945	10%	186.25
2016	85,165,892	95,654,530	52,213	10%	207.59
2017	69,780,242	84,259,765	26,649	7%	129.77
2018	40,743,446	51,678,273	10,915	3%	90.23
2019	97,763	140,276	15	0%	59.01

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Days Supplied	Amount Supplied	Episodes with an Event Switch	Switches among Episodes (Percent)	Switching Events per 1,000 Years at Risk
Recalled valsartan NOT contaminated, switch to non-recalled OR uncontaminated valsartan (tested negative)					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	18,510,678	18,695,686	20,142	29%	382.69
2013	75,376,820	76,533,756	69,524	25%	328.82
2014	55,612,599	56,324,285	63,280	25%	402.61
2015	85,115,676	88,680,202	93,526	26%	388.02
2016	153,773,108	163,732,604	89,649	15%	203.87
2017	116,112,595	124,299,826	75,614	12%	223.93
2018	42,738,008	45,944,276	39,134	9%	306.27
2019	29,432	31,569	39	3%	509.80
Recalled valsartan NOT contaminated, switch to ARBs (excluding valsartan)					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	18,510,678	18,695,686	2,283	3%	42.11
2013	75,376,820	76,533,756	8,747	3%	39.93
2014	55,612,599	56,324,285	7,160	3%	43.95
2015	85,115,676	88,680,202	17,832	5%	71.97
2016	153,773,108	163,732,604	61,388	10%	139.44
2017	116,112,595	124,299,826	94,970	15%	286.33
2018	42,738,008	45,944,276	124,194	30%	1,062.15
2019	29,432	31,569	33	2%	430.81
Recalled valsartan NOT contaminated, switch to ACE inhibitors					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	42,001,690	42,512,755	*****	*****	13.43
2013	107,330,782	108,902,540	4,756	1%	15.34
2014	70,219,318	71,153,543	2,971	1%	14.45
2015	140,667,827	148,649,483	5,397	1%	13.21
2016	227,807,305	244,479,017	9,418	1%	14.30

Table 3b. Summary of Valsartan Episodes and Event Switches in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Year

Year	Days Supplied	Amount Supplied	Episodes with an Event Switch	Switches among Episodes (Percent)	Switching Events per 1,000 Years at Risk
Recalled valsartan NOT contaminated, switch to ACE inhibitors					
2017	137,685,338	148,376,538	8,510	1%	20.98
2018	49,326,545	53,126,721	6,168	1%	41.24
2019	39,145	41,933	*****	*****	68.09
Recalled valsartan NOT contaminated, switch to calcium channel blockers					
2010	0	0	0	.	.
2011	0	0	0	.	.
2012	32,992,819	33,313,847	7,619	7%	84.66
2013	85,415,446	86,480,491	24,418	8%	106.11
2014	56,179,117	56,803,925	18,139	7%	117.58
2015	112,172,423	117,316,142	32,497	8%	105.67
2016	179,978,736	190,844,969	55,877	9%	114.05
2017	111,142,003	118,409,233	49,903	9%	161.95
2018	39,497,292	42,054,057	28,529	7%	249.82
2019	31,266	32,840	55	3%	681.54
Non-recalled OR uncontaminated valsartan (tested negative), switch to recalled valsartan NOT contaminated					
2010	906,738,476	949,591,769	103,022	4%	39.70
2011	342,868,255	357,562,423	57,364	4%	56.96
2012	288,835,198	302,720,096	107,272	8%	127.15
2013	252,711,792	265,210,192	113,302	10%	154.43
2014	170,872,254	178,708,219	120,754	13%	241.88
2015	132,552,784	138,691,520	159,942	21%	416.58
2016	85,165,892	95,654,530	118,805	23%	482.46
2017	69,780,242	84,259,765	62,420	15%	308.39
2018	40,743,446	51,678,273	26,916	7%	224.43
2019	97,763	140,276	20	0%	78.74

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4a. Descriptive Statistics of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Episodes (Number)	Mean	Standard Deviation	Minimum	1%	5%	10%	25%	50%	75%	90%	95%	99%	Maximum
Exposures with No Washout													
Contaminated valsartan (tested positive), switch to non-recalled OR uncontaminated valsartan (tested negative)													
145,426	208.03	242.64	1	5	25	29	60	102	267	524	730	1,145	2,149
Contaminated valsartan (tested positive), switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)													
120,859	358.51	321.56	1	6	25	40	96	248	559	827	948	1,274	2,105
Contaminated valsartan (tested positive), switch to angiotensin-converting enzyme (ACE) inhibitors													
15,430	191.84	251.40	1	1	4	10	30	86	253	554	771	1,117	1,952
Contaminated valsartan (tested positive), switch to calcium channel blockers													
122,104	124.27	191.56	1	1	2	5	16	47	141	354	541	914	2,028
Non-recalled OR uncontaminated valsartan (tested negative), switch to contaminated valsartan (tested positive)													
311,979	489.00	571.98	1	9	28	36	89	247	685	1,363	1,849	2,322	3,251
Recalled valsartan NOT contaminated, switch to non-recalled OR uncontaminated valsartan (tested negative)													
450,908	255.54	301.34	1	5	23	29	63	136	340	653	890	1,462	2,292
Recalled valsartan NOT contaminated, switch to ARBs (excluding valsartan)													
316,607	343.25	328.59	1	6	22	35	90	227	529	808	941	1,446	2,301
Recalled valsartan NOT contaminated, switch to ACE inhibitors													
38,855	195.56	272.46	1	1	5	10	28	80	246	574	792	1,219	2,265
Recalled valsartan NOT contaminated, switch to calcium channel blockers													
217,037	154.84	238.78	1	1	2	6	19	56	182	448	665	1,137	2,289
Non-recalled OR uncontaminated valsartan (tested negative), switch to recalled valsartan NOT contaminated													
869,817	481.63	540.33	1	8	28	36	90	263	711	1,230	1,707	2,295	3,266

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), switch to non-recalled OR uncontaminated valsartan (tested negative)												
Total	145,426	100%	*****	*****	10,852	100%	16,868	100%
0-30	17,556	12%	*****	*****	1,295	12%	1,968	12%
31-60	19,223	13%	33	5%	1,719	16%	2,562	15%
61-90	24,172	17%	54	8%	1,490	14%	3,494	21%
91-120	16,582	11%	54	8%	1,106	10%	2,346	14%
121-150	5,938	4%	15	2%	358	3%	652	4%
151-180	9,093	6%	38	5%	444	4%	948	6%
181-210	8,006	6%	76	11%	428	4%	852	5%
211-240	3,791	3%	31	4%	192	2%	406	2%
241-270	5,643	4%	55	8%	294	3%	614	4%
271-300	5,058	3%	56	8%	260	2%	530	3%
301-330	2,354	2%	*****	*****	163	2%	184	1%
331-360	3,008	2%	*****	*****	232	2%	226	1%
361+	25,002	17%	*****	*****	2,871	26%	2,086	12%
Non-recalled or uncontaminated valsartan (tested negative), switch to contaminated valsartan (tested positive)												
Total	311,979	100%	24,266	100%	12,515	100%	21,233	100%	38,710	100%	52,518	100%
0-30	21,540	7%	0	0%	0	0%	*****	*****	1,106	3%	1,909	4%
31-60	25,008	8%	0	0%	0	0%	*****	*****	1,520	4%	2,736	5%
61-90	34,708	11%	0	0%	0	0%	306	1%	2,079	5%	4,212	8%
91-120	24,998	8%	0	0%	0	0%	209	1%	1,770	5%	3,198	6%
121-150	10,461	3%	0	0%	0	0%	150	1%	1,018	3%	1,846	4%
151-180	15,609	5%	0	0%	0	0%	503	2%	1,232	3%	3,046	6%
181-210	14,526	5%	0	0%	0	0%	413	2%	1,155	3%	3,167	6%
211-240	7,094	2%	0	0%	0	0%	343	2%	648	2%	1,733	3%
241-270	10,222	3%	0	0%	0	0%	799	4%	882	2%	2,505	5%
271-300	9,499	3%	0	0%	*****	*****	562	3%	769	2%	2,333	4%
301-330	5,587	2%	0	0%	*****	*****	409	2%	457	1%	1,707	3%
331-360	7,208	2%	0	0%	54	0%	434	2%	512	1%	2,104	4%
361+	125,519	40%	24,266	100%	12,425	99%	17,022	80%	25,562	66%	22,022	42%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)												
Total	120,859	100%	52	100%	1,073	100%	1,408	100%
0-30	8,319	7%	*****	*****	*****	*****	183	13%
31-60	10,045	8%	*****	*****	*****	*****	160	11%
61-90	9,643	8%	*****	*****	*****	*****	130	9%
91-120	7,827	6%	*****	*****	*****	*****	92	7%
121-150	6,063	5%	*****	*****	42	4%	*****	*****
151-180	6,823	6%	*****	*****	40	4%	*****	*****
181-210	6,732	6%	*****	*****	37	3%	*****	*****
211-240	4,019	3%	0	0%	24	2%	13	1%
241-270	3,979	3%	*****	*****	26	2%	*****	*****
271-300	3,672	3%	*****	*****	24	2%	*****	*****
301-330	2,937	2%	0	0%	*****	*****	*****	*****
331-360	3,246	3%	0	0%	23	2%	16	1%
361+	47,554	39%	*****	*****	449	42%	655	47%
Contaminated valsartan (tested positive), switch to angiotensin-converting enzyme (ACE) inhibitors												
Total	15,430	100%	*****	*****	770	100%	713	100%
0-30	3,944	26%	*****	*****	221	29%	211	30%
31-60	2,411	16%	12	27%	136	18%	134	19%
61-90	1,562	10%	*****	*****	*****	*****	92	13%
91-120	1,113	7%	*****	*****	58	8%	*****	*****
121-150	730	5%	*****	*****	*****	*****	29	4%
151-180	663	4%	*****	*****	*****	*****	25	4%
181-210	570	4%	*****	*****	23	3%	*****	*****
211-240	388	3%	*****	*****	18	2%	*****	*****
241-270	448	3%	0	0%	24	3%	20	3%
271-300	348	2%	*****	*****	20	3%	*****	*****
301-330	287	2%	*****	*****	12	2%	*****	*****
331-360	286	2%	*****	*****	13	2%	*****	*****
361+	2,680	17%	*****	*****	131	17%	*****	*****

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), switch to calcium channel blockers												
Total	122,104	100%	308	100%	4,707	100%	5,146	100%
0-30	47,175	39%	*****	*****	1,666	35%	2,056	40%
31-60	20,878	17%	48	16%	817	17%	863	17%
61-90	12,576	10%	*****	*****	495	11%	557	11%
91-120	7,753	6%	30	10%	278	6%	318	6%
121-150	4,514	4%	16	5%	167	4%	156	3%
151-180	4,027	3%	11	4%	142	3%	135	3%
181-210	3,503	3%	15	5%	137	3%	116	2%
211-240	2,472	2%	*****	*****	95	2%	*****	*****
241-270	2,253	2%	*****	*****	65	1%	*****	*****
271-300	2,053	2%	*****	*****	81	2%	83	2%
301-330	1,581	1%	*****	*****	56	1%	62	1%
331-360	1,410	1%	*****	*****	54	1%	49	1%
361+	11,909	10%	61	20%	654	14%	595	12%
Recalled valsartan NOT contaminated, switch to non-recalled OR uncontaminated valsartan (tested negative)												
Total	450,908	100%	20,142	100%	69,524	100%	63,280	100%
0-30	53,018	12%	*****	*****	7,607	11%	6,661	11%
31-60	52,603	12%	*****	*****	7,594	11%	7,667	12%
61-90	65,131	14%	1,988	10%	8,340	12%	10,322	16%
91-120	44,736	10%	1,741	9%	5,761	8%	6,541	10%
121-150	18,730	4%	899	4%	2,330	3%	2,671	4%
151-180	26,907	6%	1,724	9%	2,779	4%	3,949	6%
181-210	23,732	5%	1,546	8%	2,714	4%	3,434	5%
211-240	11,694	3%	554	3%	1,414	2%	1,632	3%
241-270	15,879	4%	601	3%	1,823	3%	2,325	4%
271-300	14,923	3%	619	3%	1,772	3%	2,267	4%
301-330	7,975	2%	308	2%	1,220	2%	1,023	2%
331-360	10,312	2%	335	2%	1,707	2%	1,217	2%
361+	105,268	23%	5,343	27%	24,463	35%	13,571	21%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, switch to ARBs (excluding valsartan)												
Total	316,607	100%	2,283	100%	8,747	100%	7,160	100%
0-30	25,758	8%	*****	*****	1,565	18%	1,134	16%
31-60	28,478	9%	*****	*****	1,271	15%	977	14%
61-90	25,970	8%	*****	*****	687	8%	634	9%
91-120	21,711	7%	*****	*****	503	6%	436	6%
121-150	16,227	5%	148	6%	295	3%	233	3%
151-180	17,554	6%	114	5%	315	4%	238	3%
181-210	16,625	5%	72	3%	307	4%	201	3%
211-240	10,671	3%	59	3%	221	3%	117	2%
241-270	10,614	3%	48	2%	218	2%	109	2%
271-300	9,633	3%	38	2%	215	2%	100	1%
301-330	8,065	3%	37	2%	169	2%	75	1%
331-360	8,389	3%	22	1%	156	2%	82	1%
361+	116,912	37%	670	29%	2,825	32%	2,824	39%
Recalled valsartan NOT contaminated, switch to ACE inhibitors												
Total	38,855	100%	*****	*****	4,756	100%	2,971	100%
0-30	10,503	27%	*****	*****	1,451	31%	944	32%
31-60	6,249	16%	216	13%	734	15%	512	17%
61-90	3,784	10%	158	10%	408	9%	299	10%
91-120	2,827	7%	158	10%	324	7%	208	7%
121-150	1,692	4%	96	6%	214	4%	113	4%
151-180	1,620	4%	77	5%	170	4%	119	4%
181-210	1,337	3%	60	4%	140	3%	95	3%
211-240	952	2%	40	2%	115	2%	45	2%
241-270	939	2%	31	2%	115	2%	60	2%
271-300	818	2%	36	2%	104	2%	49	2%
301-330	614	2%	*****	*****	79	2%	32	1%
331-360	580	1%	*****	*****	78	2%	38	1%
361+	6,940	18%	327	20%	824	17%	457	15%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, switch to calcium channel blockers												
Total	217,037	100%	7,619	100%	24,418	100%	18,139	100%
0-30	76,789	35%	*****	*****	8,362	34%	7,081	39%
31-60	35,009	16%	*****	*****	3,868	16%	2,937	16%
61-90	20,942	10%	*****	*****	2,135	9%	1,759	10%
91-120	13,555	6%	514	7%	1,304	5%	1,041	6%
121-150	8,454	4%	373	5%	903	4%	572	3%
151-180	7,438	3%	306	4%	712	3%	504	3%
181-210	6,626	3%	253	3%	678	3%	462	3%
211-240	4,819	2%	154	2%	515	2%	317	2%
241-270	4,451	2%	136	2%	513	2%	299	2%
271-300	3,994	2%	142	2%	453	2%	274	2%
301-330	3,278	2%	120	2%	346	1%	206	1%
331-360	2,955	1%	*****	*****	307	1%	187	1%
361+	28,727	13%	*****	*****	4,322	18%	2,500	14%
Non-recalled OR uncontaminated valsartan (tested negative), switch to recalled valsartan NOT contaminated												
Total	869,817	100%	103,022	100%	57,364	100%	107,272	100%	113,302	100%	120,754	100%
0-30	61,855	7%	0	0%	0	0%	2,617	2%	8,166	7%	6,677	6%
31-60	67,732	8%	0	0%	0	0%	4,584	4%	9,004	8%	7,077	6%
61-90	88,764	10%	0	0%	0	0%	7,024	7%	10,777	10%	10,210	8%
91-120	65,576	8%	0	0%	0	0%	5,892	5%	8,258	7%	7,720	6%
121-150	29,288	3%	0	0%	0	0%	4,115	4%	3,708	3%	4,208	3%
151-180	41,856	5%	0	0%	0	0%	6,330	6%	3,954	3%	6,084	5%
181-210	38,847	4%	0	0%	0	0%	6,458	6%	3,486	3%	6,170	5%
211-240	20,198	2%	0	0%	0	0%	4,305	4%	2,077	2%	3,583	3%
241-270	30,049	3%	0	0%	*****	*****	7,953	7%	2,549	2%	5,338	4%
271-300	28,320	3%	0	0%	*****	*****	6,404	6%	2,582	2%	4,966	4%
301-330	16,350	2%	0	0%	1,223	2%	2,931	3%	1,525	1%	3,616	3%
331-360	20,646	2%	0	0%	1,775	3%	2,982	3%	1,786	2%	4,633	4%
361+	360,336	41%	103,022	100%	53,775	94%	45,677	43%	55,430	49%	50,472	42%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), switch to non-recalled OR uncontaminated valsartan (tested negative)										
Total	43,680	100%	34,978	100%	24,306	100%	14,038	100%	*****	*****
0-30	5,132	12%	4,480	13%	2,581	11%	2,034	14%	*****	*****
31-60	5,738	13%	4,413	13%	2,569	11%	2,189	16%	0	0%
61-90	7,161	16%	5,152	15%	3,578	15%	3,243	23%	0	0%
91-120	4,910	11%	3,372	10%	2,566	11%	2,228	16%	0	0%
121-150	1,877	4%	1,195	3%	1,004	4%	837	6%	0	0%
151-180	3,213	7%	1,635	5%	1,663	7%	1,152	8%	0	0%
181-210	2,718	6%	1,364	4%	1,453	6%	1,115	8%	0	0%
211-240	1,344	3%	667	2%	775	3%	376	3%	0	0%
241-270	2,007	5%	1,100	3%	1,123	5%	450	3%	0	0%
271-300	1,795	4%	992	3%	1,124	5%	301	2%	0	0%
301-330	776	2%	528	2%	637	3%	*****	*****	0	0%
331-360	849	2%	797	2%	840	3%	*****	*****	0	0%
361+	6,160	14%	9,283	27%	4,393	18%	*****	*****	0	0%
Non-recalled or uncontaminated valsartan (tested negative), switch to contaminated valsartan (tested positive)										
Total	72,945	100%	52,213	100%	26,649	100%	10,915	100%	15	0%
0-30	6,230	9%	6,506	12%	3,567	13%	2,167	20%	*****	*****
31-60	7,567	10%	7,508	14%	3,585	13%	2,049	19%	*****	*****
61-90	10,191	14%	10,516	20%	4,640	17%	2,764	25%	0	0%
91-120	7,418	10%	7,236	14%	3,369	13%	1,798	16%	0	0%
121-150	3,428	5%	2,201	4%	1,341	5%	477	4%	0	0%
151-180	4,932	7%	2,999	6%	2,240	8%	657	6%	0	0%
181-210	4,500	6%	2,821	5%	2,051	8%	419	4%	0	0%
211-240	2,167	3%	1,224	2%	845	3%	134	1%	0	0%
241-270	3,099	4%	1,752	3%	969	4%	216	2%	0	0%
271-300	3,263	4%	1,520	3%	912	3%	*****	*****	0	0%
301-330	1,854	3%	651	1%	*****	*****	49	0%	0	0%
331-360	2,515	3%	916	2%	622	2%	51	0%	0	0%
361+	15,781	22%	6,363	12%	*****	*****	*****	*****	0	0%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)										
Total	7,888	100%	25,932	100%	36,613	100%	47,876	100%	17	0%
0-30	778	10%	936	4%	879	2%	5,401	11%	17	0%
31-60	566	7%	709	3%	567	2%	7,925	17%	0	0%
61-90	357	5%	513	2%	439	1%	8,107	17%	0	0%
91-120	259	3%	357	1%	274	1%	6,773	14%	0	0%
121-150	119	2%	219	1%	202	1%	5,437	11%	0	0%
151-180	132	2%	189	1%	166	0%	6,258	13%	0	0%
181-210	109	1%	179	1%	420	1%	5,954	12%	0	0%
211-240	69	1%	120	0%	2,470	7%	1,323	3%	0	0%
241-270	71	1%	119	0%	3,329	9%	411	1%	0	0%
271-300	80	1%	96	0%	3,263	9%	186	0%	0	0%
301-330	47	1%	71	0%	2,741	7%	*****	*****	0	0%
331-360	57	1%	74	0%	3,036	8%	40	0%	0	0%
361+	5,244	66%	22,350	86%	18,827	51%	*****	*****	0	0%
Contaminated valsartan (tested positive), switch to angiotensin-converting enzyme (ACE) inhibitors										
Total	3,014	100%	4,460	100%	3,804	100%	2,620	100%	*****	*****
0-30	827	27%	1,042	23%	924	24%	707	27%	*****	*****
31-60	462	15%	567	13%	562	15%	538	21%	0	0%
61-90	281	9%	402	9%	332	9%	382	15%	0	0%
91-120	199	7%	266	6%	223	6%	315	12%	0	0%
121-150	149	5%	196	4%	137	4%	197	8%	0	0%
151-180	105	3%	157	4%	147	4%	203	8%	0	0%
181-210	96	3%	129	3%	133	3%	171	7%	0	0%
211-240	69	2%	93	2%	149	4%	45	2%	0	0%
241-270	81	3%	113	3%	176	5%	34	1%	0	0%
271-300	53	2%	104	2%	142	4%	18	1%	0	0%
301-330	47	2%	87	2%	123	3%	*****	*****	0	0%
331-360	52	2%	77	2%	133	3%	*****	*****	0	0%
361+	593	20%	1,227	28%	623	16%	*****	*****	0	0%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), switch to calcium channel blockers										
Total	21,362	100%	36,553	100%	34,220	100%	19,771	100%	37	0%
0-30	7,698	36%	12,643	35%	13,537	40%	9,470	48%	*****	*****
31-60	3,300	15%	5,617	15%	5,931	17%	4,302	22%	0	0%
61-90	1,975	9%	3,330	9%	3,566	10%	2,620	13%	*****	*****
91-120	1,326	6%	2,242	6%	2,235	7%	1,324	7%	0	0%
121-150	776	4%	1,369	4%	1,379	4%	651	3%	0	0%
151-180	701	3%	1,265	3%	1,220	4%	553	3%	0	0%
181-210	572	3%	1,135	3%	1,080	3%	448	2%	0	0%
211-240	493	2%	792	2%	826	2%	182	1%	0	0%
241-270	413	2%	801	2%	758	2%	128	1%	0	0%
271-300	408	2%	701	2%	714	2%	*****	*****	0	0%
301-330	289	1%	576	2%	575	2%	*****	*****	0	0%
331-360	267	1%	567	2%	459	1%	*****	*****	0	0%
361+	3,144	15%	5,515	15%	1,940	6%	0	0%	0	0%
Recalled valsartan NOT contaminated, switch to non-recalled OR uncontaminated valsartan (tested negative)										
Total	93,526	100%	89,649	100%	75,614	100%	39,134	100%	39	0%
0-30	11,313	12%	10,777	12%	7,767	10%	6,607	17%	*****	*****
31-60	11,626	12%	9,625	11%	7,333	10%	6,521	17%	*****	*****
61-90	14,478	15%	10,322	12%	10,464	14%	9,217	24%	0	0%
91-120	10,163	11%	7,262	8%	7,587	10%	5,681	15%	0	0%
121-150	3,853	4%	2,825	3%	3,678	5%	2,474	6%	0	0%
151-180	5,810	6%	3,738	4%	5,771	8%	3,136	8%	0	0%
181-210	4,837	5%	3,431	4%	5,123	7%	2,647	7%	0	0%
211-240	2,424	3%	1,916	2%	2,833	4%	921	2%	0	0%
241-270	3,307	4%	2,929	3%	3,903	5%	991	3%	0	0%
271-300	3,091	3%	2,838	3%	3,743	5%	593	2%	0	0%
301-330	1,444	2%	1,730	2%	2,060	3%	190	0%	0	0%
331-360	1,546	2%	2,705	3%	2,670	4%	132	0%	0	0%
361+	19,634	21%	29,551	33%	12,682	17%	24	0%	0	0%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, switch to ARBs (excluding valsartan)										
Total	17,832	100%	61,388	100%	94,970	100%	124,194	100%	33	0%
0-30	2,037	11%	2,868	5%	2,798	3%	15,061	12%	*****	*****
31-60	1,282	7%	1,941	3%	1,732	2%	20,974	17%	*****	*****
61-90	865	5%	1,295	2%	1,118	1%	21,125	17%	*****	*****
91-120	600	3%	979	2%	912	1%	18,015	15%	*****	*****
121-150	340	2%	566	1%	520	1%	14,125	11%	0	0%
151-180	293	2%	515	1%	465	0%	15,614	13%	0	0%
181-210	253	1%	454	1%	1,157	1%	14,181	11%	0	0%
211-240	170	1%	291	0%	6,489	7%	3,324	3%	0	0%
241-270	183	1%	305	0%	8,714	9%	1,037	1%	0	0%
271-300	164	1%	247	0%	8,432	9%	437	0%	0	0%
301-330	108	1%	220	0%	7,265	8%	191	0%	0	0%
331-360	104	1%	199	0%	7,728	8%	98	0%	0	0%
361+	11,433	64%	51,508	84%	47,640	50%	12	0%	0	0%
Recalled valsartan NOT contaminated, switch to ACE inhibitors										
Total	5,397	100%	9,418	100%	8,510	100%	6,168	100%	*****	*****
0-30	1,457	27%	2,229	24%	2,211	26%	1,830	30%	*****	*****
31-60	796	15%	1,386	15%	1,311	15%	1,294	21%	0	0%
61-90	541	10%	763	8%	722	8%	893	14%	0	0%
91-120	330	6%	575	6%	528	6%	704	11%	0	0%
121-150	212	4%	352	4%	308	4%	397	6%	0	0%
151-180	204	4%	299	3%	288	3%	463	8%	0	0%
181-210	179	3%	262	3%	243	3%	358	6%	0	0%
211-240	126	2%	211	2%	293	3%	122	2%	0	0%
241-270	129	2%	213	2%	329	4%	62	1%	0	0%
271-300	96	2%	184	2%	324	4%	25	0%	0	0%
301-330	70	1%	133	1%	257	3%	*****	*****	0	0%
331-360	63	1%	112	1%	257	3%	*****	*****	0	0%
361+	1,194	22%	2,699	29%	1,439	17%	0	0%	0	0%

Table 4b. Summary of Time to Switching between Valsartan and Switch Product Episodes in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, switch to calcium channel blockers										
Total	32,497	100%	55,877	100%	49,903	100%	28,529	100%	55	0%
0-30	10,379	32%	17,434	31%	18,310	37%	13,114	46%	*****	*****
31-60	4,696	14%	8,045	14%	8,375	17%	6,111	21%	*****	*****
61-90	2,823	9%	4,919	9%	5,143	10%	3,470	12%	*****	*****
91-120	1,900	6%	3,321	6%	3,312	7%	2,163	8%	0	0%
121-150	1,141	4%	2,267	4%	2,083	4%	1,115	4%	0	0%
151-180	1,137	3%	2,053	4%	1,816	4%	910	3%	0	0%
181-210	996	3%	1,789	3%	1,704	3%	744	3%	0	0%
211-240	734	2%	1,365	2%	1,336	3%	398	1%	0	0%
241-270	723	2%	1,313	2%	1,220	2%	247	1%	0	0%
271-300	644	2%	1,155	2%	1,182	2%	144	1%	0	0%
301-330	504	2%	1,089	2%	931	2%	82	0%	0	0%
331-360	481	1%	952	2%	864	2%	*****	*****	0	0%
361+	6,339	20%	10,175	18%	3,627	7%	*****	*****	0	0%
Non-recalled OR uncontaminated valsartan (tested negative), switch to recalled valsartan NOT contaminated										
Total	159,942	100%	118,805	100%	62,420	100%	26,916	100%	20	0%
0-30	13,705	9%	15,846	13%	9,204	15%	*****	*****	*****	*****
31-60	16,128	10%	17,261	15%	8,619	14%	*****	*****	*****	*****
61-90	20,047	13%	23,350	20%	10,708	17%	6,648	25%	0	0%
91-120	15,295	10%	16,092	14%	7,814	13%	*****	*****	*****	*****
121-150	7,372	5%	5,176	4%	3,470	6%	1,239	5%	0	0%
151-180	11,463	7%	7,192	6%	5,358	9%	1,475	5%	0	0%
181-210	10,583	7%	6,376	5%	4,715	8%	1,059	4%	0	0%
211-240	5,368	3%	2,775	2%	1,790	3%	300	1%	0	0%
241-270	7,317	5%	3,912	3%	2,502	4%	*****	*****	0	0%
271-300	7,838	5%	3,376	3%	2,215	4%	*****	*****	0	0%
301-330	4,384	3%	1,611	1%	*****	*****	*****	*****	0	0%
331-360	5,887	4%	2,176	2%	1,327	2%	80	0%	0	0%
361+	34,555	22%	13,662	11%	*****	*****	*****	*****	0	0%

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5a. Descriptive Statistics of Time to Censoring, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Episodes (Number)	Mean	Standard Deviation	Minimum	1%	5%	10%	25%	50%	75%	90%	95%	99%	Maximum
Product Discontinuation													
Contaminated valsartan (tested positive), DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
584,215	207.65	226.56	15	44	44	44	74	104	254	508	734	1,046	2,174
Contaminated valsartan (tested positive), DID NOT switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)													
610,527	177.47	190.92	15	44	44	44	52	104	200	390	567	944	2,084
Contaminated valsartan (tested positive), DID NOT switch to angiotensin-converting enzyme (ACE) inhibitors													
1,021,242	229.81	247.84	15	44	44	44	78	104	284	569	807	1,139	2,264
Contaminated valsartan (tested positive), DID NOT switch to calcium channel blockers													
557,724	202.10	223.51	15	44	44	44	74	104	230	477	720	1,054	2,186
Non-recalled OR uncontaminated valsartan (tested negative), DID NOT switch to contaminated valsartan (tested positive)													
8,075,326	240.76	340.70	15	44	44	44	44	104	268	620	974	1,754	3,284
Recalled valsartan NOT contaminated, DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
1,787,347	200.39	227.12	15	44	44	44	59	104	226	478	690	1,072	2,283
Recalled valsartan NOT contaminated, DID NOT switch to ARBs (excluding valsartan)													
1,925,634	192.13	223.39	15	44	44	44	44	104	207	464	650	1,123	2,282
Recalled valsartan NOT contaminated, DID NOT switch to ACE inhibitors													
2,809,550	235.67	268.76	15	44	44	44	74	104	285	589	826	1,275	2,303
Recalled valsartan NOT contaminated, DID NOT switch to calcium channel blockers													
2,104,732	224.72	259.07	15	44	44	44	74	104	284	561	795	1,225	2,303
Non-recalled OR uncontaminated valsartan (tested negative), DID NOT switch to recalled valsartan NOT contaminated													
7,530,378	221.10	312.47	15	42	44	44	44	104	231	554	857	1,628	3,284
End of Available Data													
Contaminated valsartan (tested positive), DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
52,436	315.86	336.72	1	3	14	25	63	179	471	818	1,015	1,392	2,217
Contaminated valsartan (tested positive), DID NOT switch to ARBs (excluding valsartan)													
50,107	297.93	320.61	1	3	13	24	61	167	443	782	982	1,344	2,181
Contaminated valsartan (tested positive), DID NOT switch to ACE inhibitors													
85,410	347.44	365.79	1	3	13	25	63	200	525	903	1,087	1,431	2,255

Table 5a. Descriptive Statistics of Time to Censoring, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Episodes (Number)	Mean	Standard Deviation	Minimum	1%	5%	10%	25%	50%	75%	90%	95%	99%	Maximum
Contaminated valsartan (tested positive), DID NOT switch to calcium channel blockers													
44,702	312.42	345.96	1	3	12	22	56	166	468	833	1,042	1,402	2,218
Uncontaminated valsartan (tested negative), DID NOT switch to contaminated valsartan (tested positive)													
255,330	386.32	560.55	1	3	13	24	66	185	457	959	1,483	3,202	3,307
Recalled valsartan NOT contaminated, DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
148,873	343.63	383.59	1	3	14	26	67	200	495	870	1,088	1,820	2,319
Recalled valsartan NOT contaminated, DID NOT switch to ARBs (excluding valsartan)													
141,455	328.05	379.00	1	3	13	25	63	182	464	835	1,078	1,824	2,319
Recalled valsartan NOT contaminated, DID NOT switch to ACE inhibitors													
215,744	386.90	425.95	1	3	13	26	67	226	569	979	1,229	2,015	2,319
Recalled valsartan NOT contaminated, DID NOT switch to calcium channel blockers													
160,804	367.54	411.29	1	3	13	25	64	206	537	943	1,176	1,964	2,319
Non-recalled OR uncontaminated valsartan (tested negative), DID NOT switch to recalled valsartan NOT contaminated													
249,672	368.06	524.39	1	3	13	24	63	180	444	907	1,396	2,919	3,307
End of Enrollment													
Contaminated valsartan (tested positive), DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
108,001	253.02	285.09	1	3	11	21	53	148	345	657	863	1,306	2,217
Contaminated valsartan (tested positive), DID NOT switch to ARBs (excluding valsartan)													
106,553	243.69	273.27	1	3	11	21	53	143	336	628	830	1,258	2,181
Contaminated valsartan (tested positive), DID NOT switch to ACE inhibitors													
165,954	281.04	311.85	1	3	12	22	57	161	396	728	954	1,365	2,255
Contaminated valsartan (tested positive), DID NOT switch to calcium channel blockers													
89,836	250.31	290.43	1	2	10	19	49	138	343	659	880	1,326	2,218
Uncontaminated valsartan (tested negative), DID NOT switch to contaminated valsartan (tested positive)													
869,992	320.01	430.58	1	3	11	21	56	166	387	795	1,145	2,113	3,307
Recalled valsartan NOT contaminated, DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
323,026	273.21	321.60	1	3	12	21	56	156	360	696	933	1,482	2,319

Table 5a. Descriptive Statistics of Time to Censoring, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019

Episodes (Number)	Mean	Standard Deviation	Minimum	1%	5%	10%	25%	50%	75%	90%	95%	99%	Maximum
Recalled valsartan NOT contaminated, DID NOT switch to ARBs (excluding valsartan)													
319,890	266.87	317.76	1	3	11	21	55	152	352	675	913	1,484	2,319
Recalled valsartan NOT contaminated, DID NOT switch to ACE inhibitors													
447,911	307.87	357.36	1	3	12	23	60	172	433	800	1,036	1,673	2,319
Recalled valsartan NOT contaminated, DID NOT switch to calcium channel blockers													
342,395	292.77	343.34	1	3	12	22	57	163	406	754	997	1,570	2,319
Non-recalled OR uncontaminated valsartan (tested negative), DID NOT switch to recalled valsartan NOT contaminated													
858,849	312.22	412.92	1	3	11	21	55	164	380	775	1,104	1,972	3,307
Death													
Contaminated valsartan (tested positive), DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
8,915	230.54	244.63	1	4	14	24	57	140	327	587	750	1,086	1,942
Contaminated valsartan (tested positive), DID NOT switch to ARBs (excluding valsartan)													
8,924	229.29	243.53	1	4	14	24	57	140	325	577	743	1,097	1,715
Contaminated valsartan (tested positive), DID NOT switch to ACE inhibitors													
14,278	258.09	263.83	1	5	15	27	64	163	366	647	812	1,140	1,868
Contaminated valsartan (tested positive), DID NOT switch to calcium channel blockers													
6,617	232.45	253.60	1	4	14	23	55	138	324	603	774	1,101	1,942
Uncontaminated valsartan (tested negative), DID NOT switch to contaminated valsartan (tested positive)													
176,073	399.75	461.25	1	5	15	27	71	222	568	1,050	1,389	2,022	3,281
Recalled valsartan NOT contaminated, DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)													
28,021	239.22	269.61	1	4	13	23	53	139	335	602	794	1,250	2,086
Recalled valsartan NOT contaminated, DID NOT switch to ARBs (excluding valsartan)													
28,071	239.87	271.48	1	4	13	23	53	139	335	602	797	1,278	2,086
Recalled valsartan NOT contaminated, DID NOT switch to ACE inhibitors													
42,429	271.62	294.96	1	4	14	25	61	164	386	676	865	1,349	2,237
Recalled valsartan NOT contaminated, DID NOT switch to calcium channel blockers													
28,133	256.16	284.12	1	4	13	24	57	151	362	642	832	1,293	2,225
Non-recalled OR uncontaminated valsartan (tested negative), DID NOT switch to recalled valsartan NOT contaminated													
174,283	391.92	448.35	1	4	15	27	70	220	559	1,029	1,361	1,941	3,281

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	Overall		2010		2011		2012		2013		2014	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)												
Total	584,215	100%	*****	*****	21,352	100%	26,253	100%
0-30	2,442	0%	*****	*****	*****	*****	81	0%
31-60	131,450	23%	107	7%	5,292	25%	7,060	27%
61-90	42,281	7%	38	3%	1,542	7%	2,007	8%
91-120	157,069	27%	*****	*****	5,582	26%	8,122	31%
121-150	20,449	4%	24	2%	631	3%	722	3%
151-180	12,542	2%	*****	*****	*****	*****	403	2%
181-210	59,585	10%	231	16%	1,981	9%	2,454	9%
211-240	10,202	2%	*****	*****	*****	*****	274	1%
241-270	7,018	1%	*****	*****	*****	*****	206	1%
271-300	29,161	5%	129	9%	1,093	5%	1,012	4%
301-330	7,253	1%	*****	*****	225	1%	212	1%
331-360	4,167	1%	*****	*****	154	1%	90	0%
361+	100,596	17%	358	25%	3,882	18%	3,610	14%
Non-recalled or uncontaminated valsartan (tested negative), DID NOT switch to contaminated valsartan (tested positive)												
Total	8,075,326	100%	2,219,602	100%	1,357,942	100%	1,183,268	100%	1,002,392	100%	783,159	100%
0-30	63,198	1%	14,142	1%	10,504	1%	8,600	1%	9,084	1%	7,462	1%
31-60	2,410,653	30%	588,240	27%	461,109	34%	381,681	32%	300,092	30%	237,572	30%
61-90	752,555	9%	192,305	9%	138,214	10%	115,681	10%	91,375	9%	71,823	9%
91-120	1,437,465	18%	284,311	13%	211,079	16%	197,544	17%	187,013	19%	159,000	20%
121-150	343,814	4%	89,840	4%	58,130	4%	51,839	4%	42,622	4%	34,528	4%
151-180	224,080	3%	64,266	3%	37,929	3%	33,785	3%	25,917	3%	21,450	3%
181-210	532,022	7%	122,500	6%	74,206	5%	75,130	6%	67,213	7%	58,260	7%
211-240	171,166	2%	49,660	2%	27,677	2%	26,628	2%	20,042	2%	16,986	2%
241-270	130,668	2%	40,392	2%	21,002	2%	20,821	2%	14,718	1%	12,650	2%
271-300	279,837	3%	72,601	3%	37,343	3%	42,819	4%	35,560	4%	29,643	4%
301-330	121,143	2%	37,220	2%	19,776	1%	18,009	2%	14,569	1%	12,342	2%
331-360	88,179	1%	29,405	1%	14,710	1%	12,949	1%	9,760	1%	8,817	1%
361+	1,520,546	19%	634,720	29%	246,263	18%	197,782	17%	184,427	18%	112,626	14%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), DID NOT switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)												
Total	610,527	100%	*****	*****	31,052	100%	41,639	100%
0-30	3,065	1%	*****	*****	*****	*****	126	0%
31-60	150,417	25%	*****	*****	7,362	24%	10,115	24%
61-90	51,078	8%	43	2%	2,524	8%	3,769	9%
91-120	170,589	28%	*****	*****	7,402	24%	12,541	30%
121-150	23,203	4%	25	1%	932	3%	1,301	3%
151-180	14,195	2%	*****	*****	*****	*****	746	2%
181-210	60,005	10%	342	16%	2,663	9%	3,998	10%
211-240	10,809	2%	*****	*****	*****	*****	548	1%
241-270	7,874	1%	*****	*****	*****	*****	410	1%
271-300	29,543	5%	256	12%	1,530	5%	2,063	5%
301-330	7,766	1%	11	1%	339	1%	366	1%
331-360	4,356	1%	*****	*****	*****	*****	209	1%
361+	77,627	13%	573	28%	6,600	21%	5,447	13%
Contaminated valsartan (tested positive), DID NOT switch to angiotensin-converting enzyme (ACE) inhibitors												
Total	1,021,242	100%	*****	*****	46,984	100%	65,360	100%
0-30	4,952	0%	*****	*****	*****	*****	204	0%
31-60	199,785	20%	*****	*****	10,260	22%	13,724	21%
61-90	72,862	7%	68	2%	3,921	8%	5,935	9%
91-120	264,730	26%	*****	*****	11,379	24%	21,076	32%
121-150	35,995	4%	41	1%	1,507	3%	2,058	3%
151-180	22,739	2%	13	0%	997	2%	1,117	2%
181-210	104,222	10%	645	16%	3,905	8%	6,111	9%
211-240	18,960	2%	16	0%	694	1%	813	1%
241-270	14,031	1%	*****	*****	*****	*****	624	1%
271-300	56,024	5%	462	12%	2,198	5%	3,396	5%
301-330	13,877	1%	15	0%	547	1%	545	1%
331-360	8,407	1%	*****	*****	*****	*****	289	0%
361+	204,658	20%	1,142	29%	10,514	22%	9,468	14%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), DID NOT switch to calcium channel blockers												
Total	557,724	100%	*****	*****	27,864	100%	39,038	100%
0-30	2,950	1%	0	0%	77	0%	134	0%
31-60	126,796	23%	128	5%	6,927	25%	9,076	23%
61-90	43,451	8%	42	2%	2,532	9%	3,736	10%
91-120	151,106	27%	*****	*****	6,937	25%	12,496	32%
121-150	19,956	4%	27	1%	893	3%	1,255	3%
151-180	12,304	2%	*****	*****	*****	*****	679	2%
181-210	54,829	10%	388	16%	2,292	8%	3,569	9%
211-240	9,789	2%	*****	*****	*****	*****	523	1%
241-270	7,131	1%	*****	*****	*****	*****	393	1%
271-300	28,237	5%	288	12%	1,235	4%	1,906	5%
301-330	6,886	1%	11	0%	298	1%	283	1%
331-360	4,190	1%	*****	*****	*****	*****	178	0%
361+	90,099	16%	593	25%	5,185	19%	4,810	12%
Recalled valsartan NOT contaminated, DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)												
Total	1,787,347	100%	41,748	100%	184,138	100%	162,954	100%
0-30	9,730	1%	*****	*****	800	0%	750	0%
31-60	439,473	25%	*****	*****	50,170	27%	47,084	29%
61-90	142,250	8%	3,660	9%	14,661	8%	14,059	9%
91-120	452,066	25%	*****	*****	42,673	23%	42,353	26%
121-150	69,573	4%	1,764	4%	6,488	4%	5,741	4%
151-180	42,476	2%	1,239	3%	3,997	2%	3,427	2%
181-210	166,132	9%	3,489	8%	15,520	8%	13,829	8%
211-240	34,112	2%	1,074	3%	2,976	2%	2,522	2%
241-270	23,335	1%	709	2%	2,115	1%	1,760	1%
271-300	81,319	5%	1,444	3%	8,238	4%	6,575	4%
301-330	23,643	1%	549	1%	2,090	1%	1,824	1%
331-360	14,599	1%	427	1%	1,342	1%	1,122	1%
361+	288,639	16%	7,769	19%	33,068	18%	21,908	13%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time	Overall		2010		2011		2012		2013		2014	
Days	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, DID NOT switch to ARBs (excluding valsartan)												
Total	1,925,634	100%	59,407	100%	243,799	100%	218,290	100%
0-30	11,578	1%	*****	*****	1,030	0%	988	0%
31-60	486,027	25%	*****	*****	58,405	24%	55,501	25%
61-90	163,305	8%	4,798	8%	18,418	8%	18,458	8%
91-120	493,339	26%	*****	*****	53,401	22%	55,237	25%
121-150	76,337	4%	2,342	4%	8,309	3%	7,528	3%
151-180	46,761	2%	1,769	3%	5,181	2%	4,667	2%
181-210	176,724	9%	6,204	10%	19,686	8%	20,300	9%
211-240	35,889	2%	1,554	3%	3,930	2%	3,570	2%
241-270	25,300	1%	1,027	2%	2,899	1%	2,514	1%
271-300	87,116	5%	2,437	4%	10,852	4%	10,600	5%
301-330	25,254	1%	826	1%	2,886	1%	2,758	1%
331-360	15,617	1%	664	1%	1,924	1%	1,608	1%
361+	282,387	15%	12,785	22%	56,878	23%	34,561	16%
Recalled valsartan NOT contaminated, DID NOT switch to ACE inhibitors												
Total	2,809,550	100%	114,179	100%	327,359	100%	277,168	100%
0-30	17,295	1%	*****	*****	1,513	0%	1,417	1%
31-60	586,334	21%	*****	*****	71,426	22%	65,531	24%
61-90	206,542	7%	7,286	6%	23,442	7%	23,137	8%
91-120	685,834	24%	*****	*****	72,011	22%	73,240	26%
121-150	103,355	4%	4,134	4%	10,857	3%	9,155	3%
151-180	65,247	2%	2,973	3%	6,823	2%	5,530	2%
181-210	271,923	10%	13,870	12%	26,432	8%	26,291	9%
211-240	53,780	2%	2,819	2%	5,295	2%	4,318	2%
241-270	38,759	1%	1,855	2%	4,095	1%	3,042	1%
271-300	141,313	5%	5,883	5%	14,930	5%	13,885	5%
301-330	39,354	1%	1,596	1%	4,129	1%	3,360	1%
331-360	25,195	1%	1,230	1%	2,815	1%	1,949	1%
361+	574,619	20%	30,286	27%	83,591	26%	46,313	17%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	Overall		2010		2011		2012		2013		2014	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, DID NOT switch to calcium channel blockers												
Total	2,104,732	100%	85,209	100%	245,626	100%	209,471	100%
0-30	12,840	1%	*****	*****	1,169	0%	1,095	1%
31-60	466,386	22%	*****	*****	57,546	23%	52,533	25%
61-90	160,202	8%	5,742	7%	18,352	7%	18,030	9%
91-120	521,202	25%	*****	*****	54,974	22%	55,538	27%
121-150	77,426	4%	3,102	4%	8,226	3%	6,999	3%
151-180	48,372	2%	2,193	3%	5,075	2%	4,183	2%
181-210	200,889	10%	10,116	12%	19,640	8%	19,532	9%
211-240	39,359	2%	2,070	2%	3,946	2%	3,165	2%
241-270	28,393	1%	1,337	2%	3,028	1%	2,272	1%
271-300	102,674	5%	4,367	5%	10,896	4%	9,949	5%
301-330	28,387	1%	1,153	1%	2,993	1%	2,451	1%
331-360	18,041	1%	898	1%	2,067	1%	1,428	1%
361+	400,561	19%	20,986	25%	57,714	23%	32,296	15%
Non-recalled OR uncontaminated valsartan (tested negative), DID NOT switch to recalled valsartan NOT contaminated												
Total	7,530,378	100%	2,143,237	100%	1,314,001	100%	1,098,596	100%	929,083	100%	715,947	100%
0-30	60,728	1%	14,142	1%	10,504	1%	8,500	1%	8,620	1%	7,109	1%
31-60	2,354,823	31%	588,240	27%	461,109	35%	376,461	34%	290,076	31%	231,660	32%
61-90	723,259	10%	192,305	9%	138,214	11%	111,803	10%	86,397	9%	68,735	10%
91-120	1,366,154	18%	284,311	13%	211,079	16%	189,308	17%	175,839	19%	150,963	21%
121-150	325,124	4%	89,840	4%	58,130	4%	48,334	4%	39,649	4%	32,362	5%
151-180	210,977	3%	64,266	3%	37,929	3%	30,722	3%	24,194	3%	19,900	3%
181-210	492,621	7%	122,500	6%	74,206	6%	66,670	6%	63,185	7%	53,481	7%
211-240	158,987	2%	49,660	2%	27,677	2%	23,138	2%	18,801	2%	15,281	2%
241-270	121,081	2%	40,392	2%	21,002	2%	17,739	2%	13,719	1%	11,251	2%
271-300	250,245	3%	72,601	3%	37,099	3%	33,036	3%	32,919	4%	25,623	4%
301-330	110,749	1%	37,220	2%	18,934	1%	15,239	1%	13,553	1%	10,715	1%
331-360	80,964	1%	29,405	1%	13,717	1%	11,330	1%	9,123	1%	7,669	1%
361+	1,274,666	17%	558,355	26%	204,401	16%	166,316	15%	153,008	16%	81,198	11%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)										
Total	96,460	100%	165,907	100%	170,769	100%	102,014	100%	*****	*****
0-30	464	0%	568	0%	620	0%	654	1%	*****	*****
31-60	25,853	27%	35,193	21%	35,552	21%	22,393	22%	0	0%
61-90	7,937	8%	11,225	7%	11,422	7%	8,110	8%	0	0%
91-120	23,437	24%	38,177	23%	42,438	25%	38,764	38%	*****	*****
121-150	3,446	4%	5,279	3%	5,645	3%	4,702	5%	0	0%
151-180	2,101	2%	3,251	2%	3,300	2%	3,045	3%	0	0%
181-210	8,104	8%	13,980	8%	15,463	9%	17,372	17%	0	0%
211-240	1,590	2%	2,579	2%	3,034	2%	2,447	2%	0	0%
241-270	1,229	1%	1,747	1%	2,786	2%	840	1%	0	0%
271-300	4,012	4%	7,246	4%	12,256	7%	3,413	3%	0	0%
301-330	1,143	1%	1,974	1%	3,475	2%	*****	*****	0	0%
331-360	639	1%	1,173	1%	2,083	1%	*****	*****	0	0%
361+	16,505	17%	43,515	26%	32,695	19%	31	0%	0	0%
Non-recalled or uncontaminated valsartan (tested negative), DID NOT switch to contaminated valsartan (tested positive)										
Total	619,648	100%	405,070	100%	301,051	100%	203,166	100%	28	0%
0-30	4,466	1%	3,092	1%	2,829	1%	*****	*****	*****	*****
31-60	175,355	28%	117,072	29%	81,596	27%	67,919	33%	17	0%
61-90	55,756	9%	38,458	9%	27,550	9%	*****	*****	*****	*****
91-120	145,739	24%	110,327	27%	76,813	26%	*****	*****	*****	*****
121-150	26,740	4%	17,209	4%	13,617	5%	9,289	5%	0	0%
151-180	16,768	3%	10,119	2%	8,521	3%	5,325	3%	0	0%
181-210	53,488	9%	32,363	8%	29,022	10%	19,840	10%	0	0%
211-240	13,122	2%	7,147	2%	6,526	2%	3,378	2%	0	0%
241-270	9,441	2%	5,151	1%	4,702	2%	1,791	1%	0	0%
271-300	26,939	4%	14,907	4%	15,378	5%	4,647	2%	0	0%
301-330	9,264	1%	4,672	1%	4,600	2%	691	0%	0	0%
331-360	6,316	1%	3,115	1%	2,926	1%	181	0%	0	0%
361+	76,254	12%	41,438	10%	26,971	9%	65	0%	0	0%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), DID NOT switch to angiotensin II receptor blockers (ARBs) (excluding valsartan)										
Total	132,061	100%	175,373	100%	159,158	100%	69,159	100%	*****	*****
0-30	730	1%	770	0%	730	0%	634	1%	*****	*****
31-60	32,886	25%	40,737	23%	38,286	24%	20,908	30%	*****	*****
61-90	11,359	9%	13,691	8%	12,744	8%	6,948	10%	0	0%
91-120	32,353	24%	43,969	25%	46,732	29%	26,904	39%	*****	*****
121-150	5,155	4%	6,340	4%	6,459	4%	2,991	4%	0	0%
151-180	3,376	3%	4,000	2%	3,814	2%	1,624	2%	0	0%
181-210	12,710	10%	15,959	9%	17,759	11%	6,574	10%	0	0%
211-240	2,721	2%	3,039	2%	3,241	2%	833	1%	0	0%
241-270	2,266	2%	2,123	1%	2,393	2%	353	1%	0	0%
271-300	6,860	5%	8,772	5%	8,869	6%	1,193	2%	0	0%
301-330	1,991	2%	2,401	1%	2,505	2%	153	0%	0	0%
331-360	1,033	1%	1,471	1%	1,356	1%	29	0%	0	0%
361+	18,621	14%	32,101	18%	14,270	9%	15	0%	0	0%
Contaminated valsartan (tested positive), DID NOT switch to angiotensin-converting enzyme (ACE) inhibitors										
Total	214,534	100%	289,482	100%	251,396	100%	149,489	100%	*****	*****
0-30	1,168	1%	1,215	0%	1,111	0%	1,138	1%	*****	*****
31-60	43,876	20%	52,756	18%	47,219	19%	31,772	21%	*****	*****
61-90	16,215	8%	18,505	6%	16,011	6%	12,207	8%	0	0%
91-120	50,075	23%	63,898	22%	60,370	24%	56,530	38%	*****	*****
121-150	7,737	4%	8,970	3%	8,437	3%	7,245	5%	0	0%
151-180	5,292	2%	5,547	2%	5,031	2%	4,742	3%	0	0%
181-210	22,087	10%	23,442	8%	23,080	9%	24,952	17%	0	0%
211-240	4,387	2%	4,343	2%	4,941	2%	3,766	3%	0	0%
241-270	3,891	2%	3,118	1%	4,561	2%	1,321	1%	0	0%
271-300	12,314	6%	13,392	5%	18,928	8%	5,334	4%	0	0%
301-330	3,418	2%	3,457	1%	5,533	2%	362	0%	0	0%
331-360	1,844	1%	2,234	1%	3,526	1%	69	0%	0	0%
361+	42,230	20%	88,605	31%	52,648	21%	51	0%	0	0%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Contaminated valsartan (tested positive), DID NOT switch to calcium channel blockers										
Total	123,635	100%	150,941	100%	133,892	100%	79,961	100%	*****	*****
0-30	688	1%	737	0%	671	1%	643	1%	0	0%
31-60	29,017	23%	33,042	22%	29,544	22%	19,062	24%	0	0%
61-90	10,179	8%	10,879	7%	9,325	7%	6,758	8%	0	0%
91-120	29,928	24%	36,035	24%	34,409	26%	30,410	38%	*****	*****
121-150	4,511	4%	5,012	3%	4,534	3%	3,724	5%	0	0%
151-180	2,966	2%	3,061	2%	2,750	2%	2,275	3%	0	0%
181-210	12,220	10%	12,017	8%	12,281	9%	12,062	15%	0	0%
211-240	2,440	2%	2,213	1%	2,512	2%	1,704	2%	0	0%
241-270	2,072	2%	1,519	1%	2,221	2%	631	1%	0	0%
271-300	6,656	5%	6,674	4%	9,017	7%	2,461	3%	0	0%
301-330	1,818	1%	1,668	1%	2,631	2%	177	0%	0	0%
331-360	991	1%	1,116	1%	1,627	1%	30	0%	0	0%
361+	20,149	16%	36,968	24%	22,370	17%	24	0%	0	0%
Recalled valsartan NOT contaminated, DID NOT switch to non-recalled OR uncontaminated valsartan (tested negative)										
Total	230,221	100%	436,758	100%	459,875	100%	271,641	100%	12	0%
0-30	1,296	1%	2,087	0%	2,354	1%	2,261	1%	*****	*****
31-60	62,667	27%	98,185	22%	102,830	22%	67,232	25%	*****	*****
61-90	19,226	8%	32,323	7%	33,938	7%	24,383	9%	0	0%
91-120	55,528	24%	98,829	23%	109,779	24%	94,755	35%	*****	*****
121-150	7,952	3%	15,451	4%	17,128	4%	15,049	6%	0	0%
151-180	4,907	2%	9,255	2%	10,142	2%	9,509	4%	0	0%
181-210	18,464	8%	36,126	8%	38,898	8%	39,806	15%	0	0%
211-240	3,687	2%	7,215	2%	9,309	2%	7,329	3%	0	0%
241-270	2,646	1%	5,332	1%	7,987	2%	2,786	1%	0	0%
271-300	8,907	4%	18,593	4%	29,903	7%	7,659	3%	0	0%
301-330	2,606	1%	5,790	1%	10,141	2%	643	0%	0	0%
331-360	1,576	1%	3,485	1%	6,493	1%	154	0%	0	0%
361+	40,759	18%	104,087	24%	80,973	18%	75	0%	0	0%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, DID NOT switch to ARBs (excluding valsartan)										
Total	305,329	100%	466,503	100%	442,870	100%	189,423	100%	13	0%
0-30	1,831	1%	2,584	1%	2,672	1%	2,199	1%	*****	*****
31-60	76,373	25%	109,244	23%	109,960	25%	62,550	33%	*****	*****
61-90	25,948	8%	37,411	8%	37,999	9%	20,273	11%	0	0%
91-120	73,900	24%	110,174	24%	122,113	28%	67,768	36%	*****	*****
121-150	11,292	4%	17,892	4%	19,796	4%	9,178	5%	0	0%
151-180	7,265	2%	10,850	2%	12,219	3%	4,810	3%	0	0%
181-210	26,831	9%	40,857	9%	47,055	11%	15,791	8%	0	0%
211-240	5,667	2%	8,524	2%	10,185	2%	2,459	1%	0	0%
241-270	4,270	1%	6,483	1%	7,041	2%	1,066	1%	0	0%
271-300	13,765	5%	22,573	5%	24,091	5%	2,798	1%	0	0%
301-330	4,070	1%	7,189	2%	7,162	2%	363	0%	0	0%
331-360	2,457	1%	4,571	1%	4,272	1%	121	0%	0	0%
361+	51,660	17%	88,151	19%	38,305	9%	47	0%	0	0%
Recalled valsartan NOT contaminated, DID NOT switch to ACE inhibitors										
Total	467,491	100%	682,431	100%	598,369	100%	342,532	100%	21	0%
0-30	3,046	1%	3,711	1%	3,620	1%	3,573	1%	*****	*****
31-60	96,707	21%	128,102	19%	121,692	20%	83,945	25%	*****	*****
61-90	34,650	7%	44,982	7%	42,033	7%	31,012	9%	0	0%
91-120	108,981	23%	146,538	21%	141,152	24%	120,990	35%	*****	*****
121-150	16,152	3%	22,182	3%	22,343	4%	18,532	5%	0	0%
151-180	10,844	2%	13,691	2%	13,756	2%	11,630	3%	0	0%
181-210	46,543	10%	55,582	8%	54,116	9%	49,089	14%	0	0%
211-240	8,549	2%	10,986	2%	12,894	2%	8,919	3%	0	0%
241-270	6,943	1%	8,444	1%	10,897	2%	3,483	1%	0	0%
271-300	23,880	5%	31,503	5%	41,112	7%	10,120	3%	0	0%
301-330	6,629	1%	9,383	1%	13,353	2%	904	0%	0	0%
331-360	3,997	1%	6,147	1%	8,830	1%	227	0%	0	0%
361+	100,570	22%	201,180	29%	112,571	19%	108	0%	0	0%

Table 5b. Summary of Time to Product Discontinuation, in Days, among Valsartan Episodes which DID Not Switch in the Sentinel Distributed Database (SDD) between January 1, 2010 and April 30, 2019, by Length Category and Year

Time Days	2015		2016		2017		2018		2019	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Recalled valsartan NOT contaminated, DID NOT switch to calcium channel blockers										
Total	351,852	100%	507,888	100%	448,728	100%	255,941	100%	17	0%
0-30	2,241	1%	2,744	1%	2,709	1%	2,552	1%	*****	*****
31-60	76,906	22%	102,357	20%	96,782	22%	64,895	25%	*****	*****
61-90	26,833	8%	35,084	7%	32,661	7%	23,500	9%	0	0%
91-120	83,641	24%	112,077	22%	107,169	24%	90,238	35%	*****	*****
121-150	12,182	3%	16,698	3%	16,693	4%	13,526	5%	0	0%
151-180	8,062	2%	10,216	2%	10,164	2%	8,479	3%	0	0%
181-210	34,750	10%	41,073	8%	40,005	9%	35,773	14%	0	0%
211-240	6,402	2%	7,975	2%	9,381	2%	6,420	3%	0	0%
241-270	5,155	1%	6,188	1%	7,909	2%	2,504	1%	0	0%
271-300	17,563	5%	22,826	4%	29,867	7%	7,206	3%	0	0%
301-330	4,860	1%	6,717	1%	9,598	2%	615	0%	0	0%
331-360	2,888	1%	4,347	1%	6,252	1%	161	0%	0	0%
361+	70,369	20%	139,586	27%	79,538	18%	72	0%	0	0%
Non-recalled OR uncontaminated valsartan (tested negative), DID NOT switch to recalled valsartan NOT contaminated										
Total	533,920	100%	339,634	100%	266,794	100%	189,144	100%	22	0%
0-30	4,003	1%	2,622	1%	2,433	1%	*****	*****	*****	*****
31-60	164,704	31%	103,794	31%	74,851	28%	*****	*****	*****	*****
61-90	49,664	9%	32,358	10%	24,258	9%	*****	*****	*****	*****
91-120	132,719	25%	92,763	27%	68,543	26%	60,629	32%	0	0%
121-150	22,951	4%	13,857	4%	11,495	4%	8,506	4%	0	0%
151-180	13,816	3%	8,179	2%	7,065	3%	4,906	3%	0	0%
181-210	43,764	8%	25,815	8%	24,256	9%	18,744	10%	0	0%
211-240	9,966	2%	5,729	2%	5,523	2%	3,212	2%	0	0%
241-270	7,233	1%	4,144	1%	3,913	1%	1,688	1%	0	0%
271-300	20,094	4%	11,497	3%	13,019	5%	4,357	2%	0	0%
301-330	6,716	1%	3,683	1%	4,049	2%	640	0%	0	0%
331-360	4,553	1%	2,404	1%	2,590	1%	173	0%	0	0%
361+	53,737	10%	32,789	10%	24,799	9%	63	0%	0	0%

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Appendix A. Start and End Dates for Each Data Partner (DP) up to Request Distribution Date (October 9, 2019)

DP ID	Start Date ¹	End Date ¹
DP01	01/01/2010	02/28/2019
DP02	01/01/2010	07/31/2018
DP03	01/01/2010	03/31/2019
DP04	01/01/2010	11/30/2018
DP05	01/01/2010	12/31/2018
DP06	01/01/2010	12/31/2017
DP07	01/01/2010	12/31/2018
DP08	01/01/2010	12/31/2018
DP09	01/01/2010	04/30/2018
DP10	01/01/2010	03/31/2018
DP11	01/01/2010	01/31/2019
DP12	01/01/2010	04/30/2019
DP13	01/01/2010	01/31/2019
DP14	01/01/2010	06/30/2018
DP15	01/01/2010	06/30/2018
DP16	01/01/2012	06/30/2017

¹The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of Generic and Brand Names of Medical Product Used to Define Exposures, Exclusion Criteria, and Outcomes in this Request

Generic Name	Brand Name
Recalled valsartan	
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
amlodipine besylate/valsartan	Amlodipine-Valsartan
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
Valsartan/Hydrochlorothiazide	Valsartan/Hydrochlorothiazide
Amlodipine/Valsartan/Hydrochlorothiazide	Amlodipine/Valsartan/Hydrochlorothiazide
Recalled valsartan not contaminated	
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
amlodipine besylate/valsartan	Amlodipine-Valsartan
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
Valsartan/Hydrochlorothiazide	Valsartan/Hydrochlorothiazide
Amlodipine/Valsartan/Hydrochlorothiazide	Amlodipine/Valsartan/Hydrochlorothiazide
Contaminated valsartan	
amlodipine besylate/valsartan	Amlodipine-Valsartan
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
N-Nitrosodimethylamine (NDMA)-contaminated valsartan	
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
amlodipine besylate/valsartan	Amlodipine-Valsartan
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
N-Nitrosodiethylamine (NDEA)-contaminated valsartan	
amlodipine besylate/valsartan	Amlodipine-Valsartan
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
Uncontaminated valsartan (tested negative) or non-recalled valsartan	
amlodipine besylate/valsartan	Amlodipine-Valsartan
valsartan	Diovan
valsartan/hydrochlorothiazide	Diovan HCT
amlodipine besylate/valsartan	Exforge
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
nebivolol HCl/valsartan	Byvalson
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge HCT
aliskiren/valsartan	Valturna
sacubitril/valsartan	Entresto

Appendix B. List of Generic and Brand Names of Medical Product Used to Define Exposures, Exclusion Criteria, and Outcomes in this Request

Generic Name	Brand Name
Uncontaminated valsartan	
amlodipine besylate/valsartan	Amlodipine-Valsartan
valsartan	Diovan
valsartan/hydrochlorothiazide	Diovan HCT
amlodipine besylate/valsartan	Exforge
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
Non-recalled valsartan	
neбиволоl HCl/valsartan	Byvalson
valsartan/hydrochlorothiazide	Diovan HCT
valsartan	Diovan
amlodipine besylate/valsartan	Exforge
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge HCT
aliskiren/valsartan	Valturna
sacubitril/valsartan	Entresto
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
valsartan	Valsartan
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
amlodipine besylate/valsartan	Amlodipine-Valsartan
Angiotensin-converting enzyme (ACE) inhibitors	
lisinopril	Lisinopril
captopril	Capoten
lisinopril/hydrochlorothiazide	Lisinopril-Hydrochlorothiazide
ramipril	Ramipril
enalapril maleate	Enalapril Maleate
enalapril maleate/hydrochlorothiazide	Enalapril-Hydrochlorothiazide
captopril	Captopril
benazepril HCl	Benazepril
fosinopril sodium	Fosinopril
quinapril HCl	Accupril
ramipril	Altace
benazepril HCl/hydrochlorothiazide	Benazepril-Hydrochlorothiazide
quinapril HCl	Quinapril
moexipril HCl	Moexipril
moexipril HCl/hydrochlorothiazide	Moexipril-Hydrochlorothiazide
benazepril HCl	Lotensin
lisinopril	Zestril
amlodipine besylate/benazepril HCl	Lotrel
quinapril HCl/hydrochlorothiazide	Quinaretic
lisinopril/hydrochlorothiazide	Zestoretic
trandolapril	Trandolapril

Appendix B. List of Generic and Brand Names of Medical Product Used to Define Exposures, Exclusion Criteria, and Outcomes in this Request

Generic Name	Brand Name
fosinopril sodium	Monopril
trandolapril	Mavik
enalaprilat dihydrate	Enalaprilat
benazepril HCl/hydrochlorothiazide	Lotensin HCT
fosinopril sodium/hydrochlorothiazide	Fosinopril-Hydrochlorothiazide
amlodipine besylate/benazepril HCl	Amlodipine-Benazepril
perindopril erbumine	Perindopril Erbumine
enalapril maleate	Vasotec
captopril/hydrochlorothiazide	Captopril-Hydrochlorothiazide
moexipril HCl	Univasc
moexipril HCl/hydrochlorothiazide	Uniretic
perindopril erbumine	Aceon
trandolapril/verapamil HCl	Tarka
lisinopril/dietary supplement,comb.10	Lytensopril
lisinopril/dietary supplement,comb.10	Lytensopril-90
trandolapril/verapamil HCl	trandolapril-verapamil
enalapril maleate/hydrochlorothiazide	Vaseretic
lisinopril	Prinivil
lisinopril/hydrochlorothiazide	Prinzide
quinapril HCl/hydrochlorothiazide	quinapril-hydrochlorothiazide
enalapril maleate	Epaned
quinapril HCl/hydrochlorothiazide	Accuretic
lisinopril	Qbrelis
perindopril arginine/amlodipine besylate	Prestalia
Calcium channel blockers	
verapamil HCl	Covera-HS
felodipine	Felodipine
nicardipine HCl	Cardene IV
diltiazem HCl	Cardizem LA
verapamil HCl	Calan
amlodipine besylate	Amlodipine
diltiazem HCl	Cardizem
diltiazem HCl	Diltiazem HCl
nifedipine	Nifedipine
nicardipine in dextrose, iso-osmotic	Cardene IV in Dextrose
diltiazem HCl	DILT-XR
amlodipine besylate	Norvasc
felodipine	Plendil
verapamil HCl	Verapamil
verapamil HCl	Calan SR
nicardipine in sodium chloride, iso-osmotic	Cardene IV in Sodium Chloride
isradipine	Isradipine

Appendix B. List of Generic and Brand Names of Medical Product Used to Define Exposures, Exclusion Criteria, and Outcomes in this Request

Generic Name	Brand Name
nifedipine	Procardia XL
diltiazem HCl	Cardizem CD
nicardipine HCl	Cardene SR
nicardipine HCl	Nicardipine
isradipine	DynaCirc CR
diltiazem HCl	Tiazac
diltiazem HCl	Dilacor XR
diltiazem HCl	Taztia XT
diltiazem HCl	Cartia XT
diltiazem HCl	Diltia XT
verapamil HCl	Isoptin SR
nifedipine	Nifediac CC
nifedipine	Procardia
nisoldipine	Nisoldipine
nifedipine	Adalat CC
clevipidine butyrate	Cleviprex
nisoldipine	Sular
verapamil HCl	Verelan
nimodipine	Nimodipine
verapamil HCl	Verelan PM
diltiazem HCl	DILT-CD
diltiazem HCl	Diltzac ER
diltiazem HCl/dextrose 5 % in water	Diltiazem in Dextrose 5 %
nifedipine	Afeditab CR
nifedipine	Nifedical XL
diltiazem HCl in 0.9 % sodium chloride	Diltiazem HCl in 0.9% NaCl
nicardipine in 5 % dextrose in water	Nicardipine in 5 % Dextrose
nicardipine HCl in 0.9 % sodium chloride	Nicardipine in 0.9 % NaCl
nimodipine	Nymalize
diltiazem HCl	Matzim LA
Angiotensin II receptor blockers (ARBs)	
losartan potassium	Cozaar
irbesartan	Avapro
candesartan cilexetil	Atacand
irbesartan/hydrochlorothiazide	Avalide
losartan potassium/hydrochlorothiazide	Hyzaar
telmisartan/hydrochlorothiazide	Micardis HCT
candesartan cilexetil/hydrochlorothiazide	Atacand HCT
losartan potassium/hydrochlorothiazide	Losartan-Hydrochlorothiazide
losartan potassium	Losartan
eprosartan mesylate/hydrochlorothiazide	Teveten HCT
eprosartan mesylate	Teveten

Appendix B. List of Generic and Brand Names of Medical Product Used to Define Exposures, Exclusion Criteria, and Outcomes in this Request

Generic Name	Brand Name
irbesartan/hydrochlorothiazide	Irbesartan-Hydrochlorothiazide
irbesartan	Irbesartan
candesartan cilexetil/hydrochlorothiazide	Candesartan-Hydrochlorothiazid
azilsartan medoxomil/chlorthalidone	Edarbyclor
azilsartan medoxomil	Edarbi
telmisartan	Micardis
telmisartan/hydrochlorothiazide	Telmisartan-Hydrochlorothiazid
telmisartan	Telmisartan
candesartan cilexetil	Candesartan
telmisartan/amlodipine besylate	Telmisartan-Amlodipine
eprosartan mesylate	Eprosartan
telmisartan/amlodipine besylate	Twynsta
amlodipine besylate/olmesartan medoxomil	Azor
olmesartan medoxomil	Benicar
olmesartan medoxomil/hydrochlorothiazide	Benicar HCT
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Tribenzor
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil	Olmesartan
olmesartan medoxomil/hydrochlorothiazide	Olmesartan-Hydrochlorothiazide
amlodipine besylate/olmesartan medoxomil	Amlodipine-Olmesartan

Appendix C. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool, version 8.1.1, to examine switching patterns of N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) contaminated products in the Sentinel Distributed Database (SDD).

Query period: January 1, 2010 - April 30, 2019
Coverage requirement: Medical and drug
Pre-index enrollment requirement (days): 0
Post-index enrollment requirement (days): 0
Enrollment gap (days): 45
Stockpiling: Default
Age groups (years): 18-44, 45-64, 65+
Stratifications: Year, age group, sex
Additional output: Censoring table; Distribution of Index Codes Output Indicator
Time to switch categories (days): 0-30, 31-60, 61-90, 91-120, 121-150, 151-180, 181-210, 211-240, 241-270, 271-300, 301-330, 331-360, 361+

Exposure

Scenario	Exposure Group	Cohort definition	Washout Period (Days)	Episode Gap (Days)	Episode Extension (Days)	Censoring Criteria
1	Recalled valsartan	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
2	Recalled valsartan NOT contaminated	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation

Appendix C. Specifications Defining Parameters for this Request

Scenario	Exposure Group	Cohort definition	Exposure			Censoring Criteria
			Washout Period (Days)	Episode Gap (Days)	Episode Extension (Days)	
3	Contaminated valsartan (tested positive)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
4	N-Nitrosodimethylamine (NDMA) contaminated valsartan (tested positive)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
5	N-Nitrosodiethylamine (NDEA)-contaminated valsartan (tested positive)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
6	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation

Appendix C. Specifications Defining Parameters for this Request

Scenario	Exposure Group	Cohort definition	Exposure			Censoring Criteria
			Washout Period (Days)	Episode Gap (Days)	Episode Extension (Days)	
7	Uncontaminated valsartan (tested negative)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
8	Non-recalled valsartan	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
9	Angiotensin-converting enzyme (ACE) inhibitors	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
10	Calcium channel blockers	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation

Appendix C. Specifications Defining Parameters for this Request

Scenario	Exposure Group	Cohort definition	Exposure			Censoring Criteria
			Washout Period (Days)	Episode Gap (Days)	Episode Extension (Days)	
11	Angiotensin II receptor blockers (ARBs) (excluding valsartan)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
12	Contaminated valsartan (tested positive)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
13	Contaminated valsartan (tested positive)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
14	Contaminated valsartan (tested positive)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation

Appendix C. Specifications Defining Parameters for this Request

Scenario	Exposure Group	Cohort definition	Exposure			Censoring Criteria
			Washout Period (Days)	Episode Gap (Days)	Episode Extension (Days)	
15	Contaminated valsartan (tested positive)	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
16	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
17	Recalled valsartan NOT contaminated	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
18	Recalled valsartan NOT contaminated	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation

Appendix C. Specifications Defining Parameters for this Request

Scenario	Exposure Group	Cohort definition	Exposure			Censoring Criteria
			Washout Period (Days)	Episode Gap (Days)	Episode Extension (Days)	
19	Recalled valsartan NOT contaminated	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
20	Recalled valsartan NOT contaminated	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
21	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation
22	<p><u>All valsartan:</u> A) Recalled valsartan, B) Contaminated valsartan (tested positive), C) NDMA contaminated valsartan (tested positive), D) NDEA contaminated valsartan (tested positive), E) Recalled valsartan NOT contaminated, F) Uncontaminated valsartan (tested negative), G) Non-recalled valsartan</p>	Cohort includes all valid exposure episodes during query period	0	15	15	*Death; *Data Partner End Date; *Query End Date; *Disenrollment; *Product discontinuation

Appendix C. Specifications Defining Parameters for this Request								
Scenario	Exposure Group	Exclusion			Event Outcome			Baseline Characteristics
		Event	Evaluation Window	Exclude	Event	Blackout Period (Days)	Period (Days)	
1	Recalled valsartan	N/A
2	Recalled valsartan NOT contaminated	N/A
3	Contaminated valsartan (tested positive)	N/A
4	NDMA contaminated valsartan (tested positive)	N/A
5	NDEA contaminated valsartan (tested positive)	N/A

Appendix C. Specifications Defining Parameters for this Request								
Scenario	Exposure Group	Exclusion			Event Outcome			Baseline Characteristics
		Event	Evaluation Window	Exclude	Event	Blackout Period (Days)	Period (Days)	
6	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	N/A
7	Uncontaminated valsartan (tested negative)	N/A
8	Non-recalled valsartan	N/A
9	ACE inhibitors	See Table 1b
10	Calcium channel blockers	See Table 1c

Appendix C. Specifications Defining Parameters for this Request								
Scenario	Exposure Group	Exclusion			Event Outcome			Baseline Characteristics
		Event	Evaluation Window	Exclude	Event	Blackout Period (Days)	Period (Days)	
11	ARBs (Excluding valsartan)	See Table 1d
12	Contaminated valsartan (tested positive)	All ARBs except contaminated valsartan	Index date	Dispensing date OR days supplied	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	1	0	N/A
13	Contaminated valsartan (tested positive)	All ARBs except contaminated valsartan	Index date	Dispensing date OR days supplied	ARBs (Excluding valsartan)	1	0	N/A
14	Contaminated valsartan (tested positive)	.	.	.	ACE inhibitors	1	0	N/A
15	Contaminated valsartan (tested positive)	.	.	.	Calcium channel blockers	1	0	N/A

Appendix C. Specifications Defining Parameters for this Request								
Scenario	Exposure Group	Exclusion			Event Outcome			Baseline Characteristics
		Event	Evaluation Window	Exclude	Event	Blackout Period (Days)	Period (Days)	
16	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	All ARBs except uncontaminated or non-recalled valsartan	Index date	Dispensing date OR days supplied	Contaminated valsartan (tested positive)	1	0	N/A
17	Recalled valsartan NOT contaminated	All ARBs except recalled valsartan that is not contaminated	Index date	Dispensing date OR days supplied	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	1	0	N/A
18	Recalled valsartan NOT contaminated	All ARBs except recalled valsartan that is not contaminated	Index date	Dispensing date OR days supplied	ARBs (Excluding valsartan)	1	0	N/A
19	Recalled valsartan NOT contaminated	.	.	.	ACE inhibitors	1	0	N/A
20	Recalled valsartan NOT contaminated	.	.	.	Calcium channel blockers	1	0	N/A

Appendix C. Specifications Defining Parameters for this Request								
Scenario	Exposure Group	Exclusion			Event Outcome			Baseline Characteristics
		Event	Evaluation Window	Exclude	Event	Blackout Period (Days)	Period (Days)	
21	Uncontaminated valsartan (tested negative) OR non-recalled valsartan	All ARBs except uncontaminated or non-recalled valsartan	Index date	Dispensing date OR days supplied	Recalled valsartan NOT contaminated	1	0	N/A
22	<p><u>All valsartan:</u></p> <p>A) Recalled valsartan, B) Contaminated valsartan (tested positive), C) NDMA contaminated valsartan (tested positive), D) NDEA contaminated valsartan (tested positive), E) Recalled valsartan NOT contaminated, F) Uncontaminated valsartan (tested negative), G) Non-recalled valsartan</p>	See Table 1a

National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."