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The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-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 the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries

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 MSY4_MPR59_v1, Report 1 of 2

Request ID: MSY4_MPR59_v1

Request Description: This request estimates prevalent and incident use of acetaminophen with codeine, acyclovir/acyclovir sodium, nizatidine, albuterol/albuterol sulfate, levalbuterol HCl/levalbuterol tartrate, oxycodone HCl, nitazoxanide, and sucralfate among children aged 0-2 years. This report contains the results where only drug coverage was required. This is report 1 of 2. Report 2 contains results where both medical and drug coverage was required.

Modular Program Tool Used: Modular Program #9 (MP9) version 2.0

Data Source: We distributed this request on September 10, 2013 to 18 Data Partners contributing to the Mini-Sentinel Distributed Database (MSDD). The study period included data from January 1, 2000 - December 31, 2012. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We identified prevalent and incident users of acetaminophen with codeine, acyclovir/acyclovir sodium, nizatidine, albuterol/albuterol sulfate, levalbuterol HCl/levalbuterol tartrate, oxycodone HCl, nitazoxanide, and sucralfate, among a cohort aged 0-2 years.

Exposure of Interest: We identified exposures of interest using valid National Drug Codes (NDCs) identified from outpatient pharmacy dispensing recorded in the Mini-Sentinel Common Data Model (MSCDM). We defined incident use as no prior evidence of exposure drugs in the day prior to the first qualifying exposure (index). Cohort re-entry was not allowed. Only the first incident exposure for each member over the member's entire enrollment history was included. Please see Appendix B for a list of generic and brand drug names used to define exposures in this request.

Cohort Eligibility Criteria: We required members to be continuously enrolled in health plans with drug coverage, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in this cohort: 0-12 months and 12-24 months. The 0-12 month age group was further stratified by 0-<1, 1-<3, 3-<6, and 6-<12 months.

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

Limitations: Algorithms to define exposures may be imperfect and therefore, 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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Appendix B List of Generic and Brand Drug Names Used to Define Exposures in this Request

Appendix C Specifications Defining Parameters for this Request

Glossary of Terms in Modular Program 9*

Amount Supplied - Number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the Mini-Sentinel Common Data Model (MSCDM).

"Incident with Respect to" Codes - NDC and/or procedure and/or diagnosis codes to be used to refine the incident definition for the exposure(s) of interest. For example, if a requester is examining exposure to DRUG A but wants incidence of DRUG A to be defined with respect to DRUG A and DRUG B, the Incident with Respect to Code fields would include both DRUG A and DRUG B codes.

Care Setting - Contains the care settings considered for the individual diagnosis or procedure codes of interest. The following are valid entries:

IP: inpatient hospital stays

IS: non-acute institutional stays

ED: emergency department visits

AV: ambulatory visits

OA: other ambulatory visits.

Days Supplied - Number of days supplied for all dispensings encountered by individuals in the prevalent or incident cohort. The number is reported by the pharmacist as the number of days that the medications supports, based on the number of doses. (To be included in the incident-based cohort, a member must have a dispensing that meets the criteria specified for incidence type and washout period. However, if a member has more than one dispensings claim on the index date, all claims identified on that date will be included in the number of dispensings. Claims identified any time after the index date are not included in dispensings.)

Dispensings - Total number of dispensings for members included in the prevalent- or incident-based cohort. To be included in the incident-based cohort, a member must have a dispensing that meets the criteria specified for incidence type and washout period. However, if a member has more than one dispensings claim on the index date, all claims identified on that date will be included in the number of dispensings. Claims identified any time after the index date are not included in dispensings.

Eligible Members (incidence-based cohort) - Number of members eligible for incident diagnosis (defined by the washout period) with drug and/or medical coverage during the query period.

Eligible Members (prevalence-based cohort) - Number of members with at least one day of drug and/or medical coverage during the query period.

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

Exposure - NDC and/or procedure and/or diagnosis code values for the exposure(s) of interest.

Incidence Type (incidence-based cohort) - *Minimum incidence type* will only consider the first claim in the query period as long as it is the first claim in the user's entire available history. *Single incidence type* will consider the first claim in the query period that satisfies the washout period criteria. That is, incidence is defined as the first claim during the query period with no evidence of a prior claim during the previous washout period days. *Multiple incidence type* will use the washout period to establish incidence and consider all qualifying incident claims.

Incident Only Care Setting - Contains the care settings considered for the individual diagnosis or procedure codes included as "Incident with Respect to" codes.

Member-Years (incidence-based cohort) - Sum of all years of enrollment with drug and/or medical coverage in the query period preceded by a washout period.

Member-Years (prevalence-based cohort) - Sum of all years members are enrolled with drug and/or medical coverage during the query period.

New Starts- Number of incident dispensings during the query period. Patient must have no prior dispensings of interest in the washout period. For a single and minimum incidence type, an individual may have no more than one new start. For a multiple incidence type, an individual may have more than one new start.

New Users - Number of members with incident claims during the query period. Member must have no evidence of claims of interest (defined by incidence criteria) in the prior washout period. A patient may only be counted once in a query period.

Query Period - Period in which the modular program looks for diagnoses of interest.

Washout Period (incidence-based cohort) - Number of days a patient is required to have no evidence of prior claim of interest and continuous drug and/or medical coverage.

*all terms may not be used in this report

Table 1. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Acetaminophen with codeine	111,557	126,617	943,040	6,545,401	6,887,561	17.04	8.45	1.13	7.45
Acyclovir/acyclovir sodium	21,104	26,815	275,607	6,545,401	6,887,561	3.22	13.06	1.27	10.28
Albuterol/albuterol sulfate	918,260	1,681,910	28,416,870	6,545,401	6,887,561	140.29	30.95	1.83	16.90
Levalbuterol HCl/Levalbuterol tartrate	149,601	281,786	4,347,997	6,545,401	6,887,561	22.86	29.06	1.88	15.43
Nitazoxanide	2,397	2,780	15,905	6,545,401	6,887,561	0.37	6.64	1.16	5.72
Nizatidine	33,485	94,522	2,857,915	6,545,401	6,887,561	5.12	85.35	2.82	30.24
Oxycodone HCl	5,182	6,069	44,974	6,545,401	6,887,561	0.79	8.68	1.17	7.41
Sucralfate	7,759	11,988	266,377	6,545,401	6,887,561	1.19	34.33	1.55	22.22

Figure 1a. Number of Prevalent Users and Dispensings among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug Product

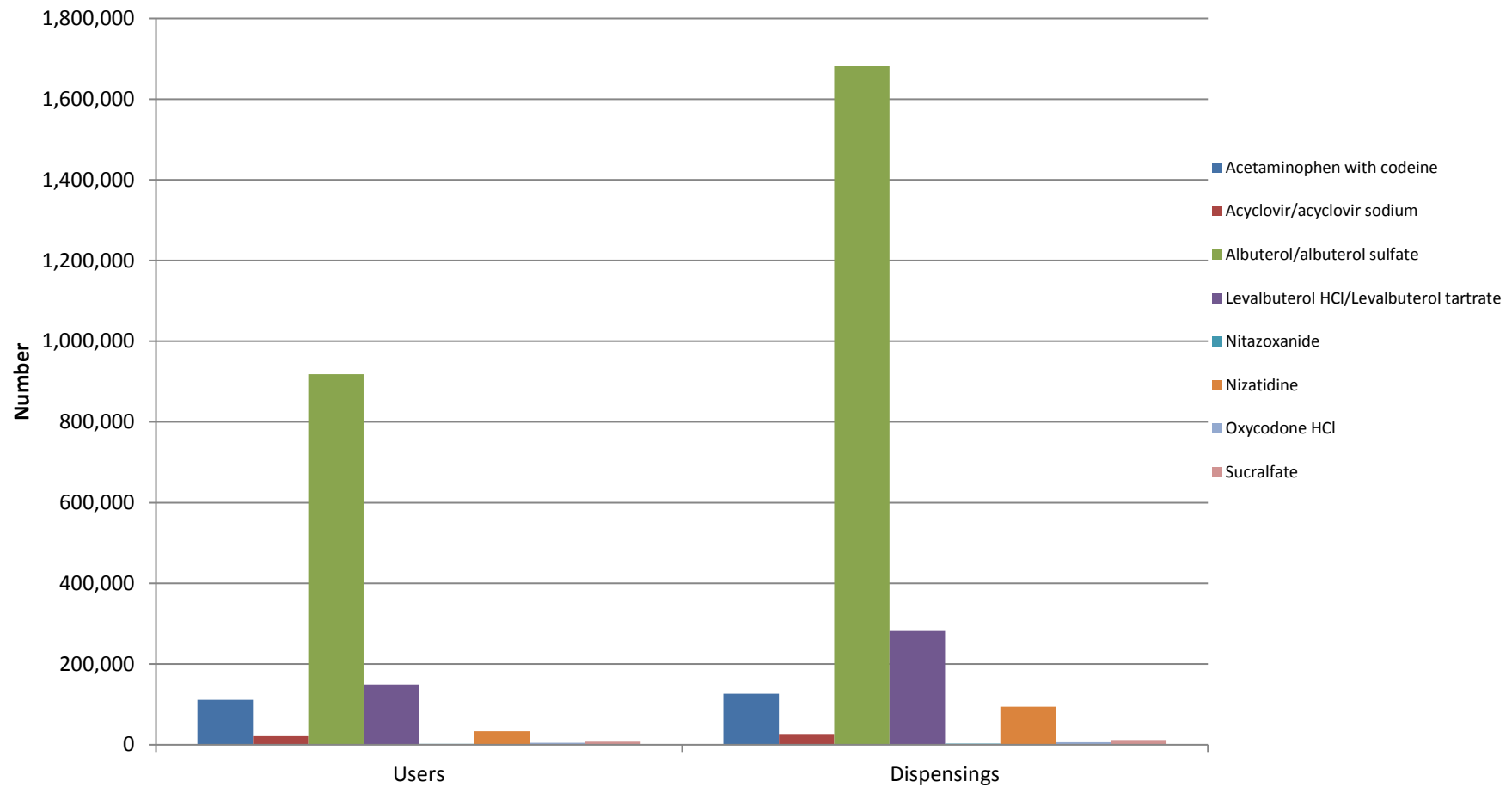


Figure 1b. Prevalent Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug Product

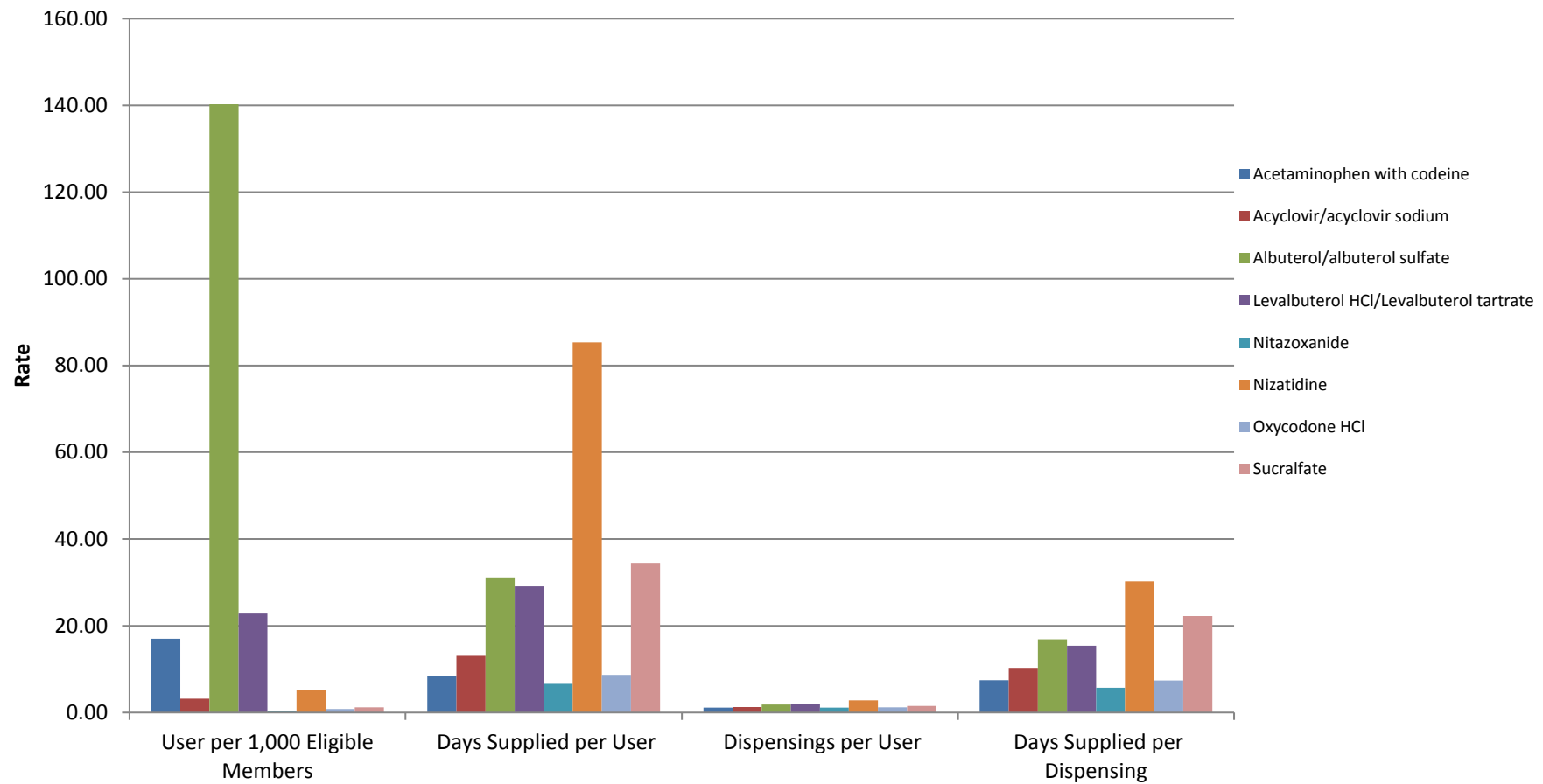


Table 2. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug

	New Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Acetaminophen with codeine	111,491	126,542	942,493	6,533,506	6,798,210	17.06	8.45	1.13	7.45
Acyclovir/acyclovir sodium	21,083	26,785	275,159	6,533,596	6,857,403	3.23	13.05	1.27	10.27
Albuterol/albuterol sulfate	917,076	1,679,404	28,372,217	6,532,346	6,088,145	140.39	30.94	1.83	16.89
Levalbuterol HCl/Levalbuterol tartrate	149,417	281,354	4,340,635	6,533,417	6,734,937	22.87	29.05	1.88	15.43
Nitazoxanide	2,395	2,778	15,899	6,533,623	6,868,711	0.37	6.64	1.16	5.72
Nizatidine	33,425	94,326	2,852,007	6,533,557	6,831,880	5.12	85.33	2.82	30.24
Oxycodone HCl	5,172	6,024	44,135	6,533,589	6,866,488	0.79	8.53	1.16	7.33
Sucralfate	7,752	11,979	266,251	6,533,613	6,863,229	1.19	34.35	1.55	22.23

Figure 2a. Number of New Users and Dispensings among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug Product

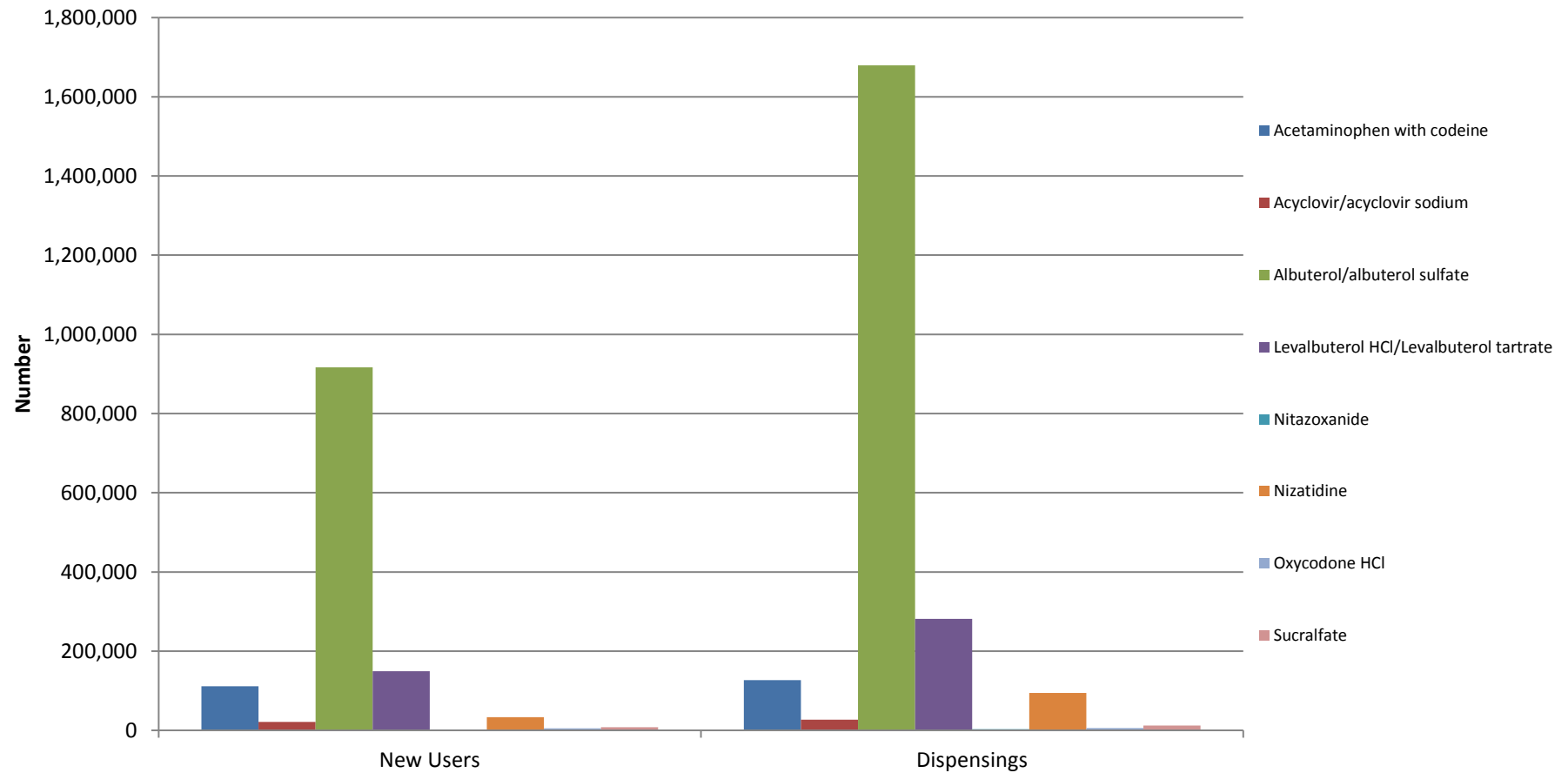


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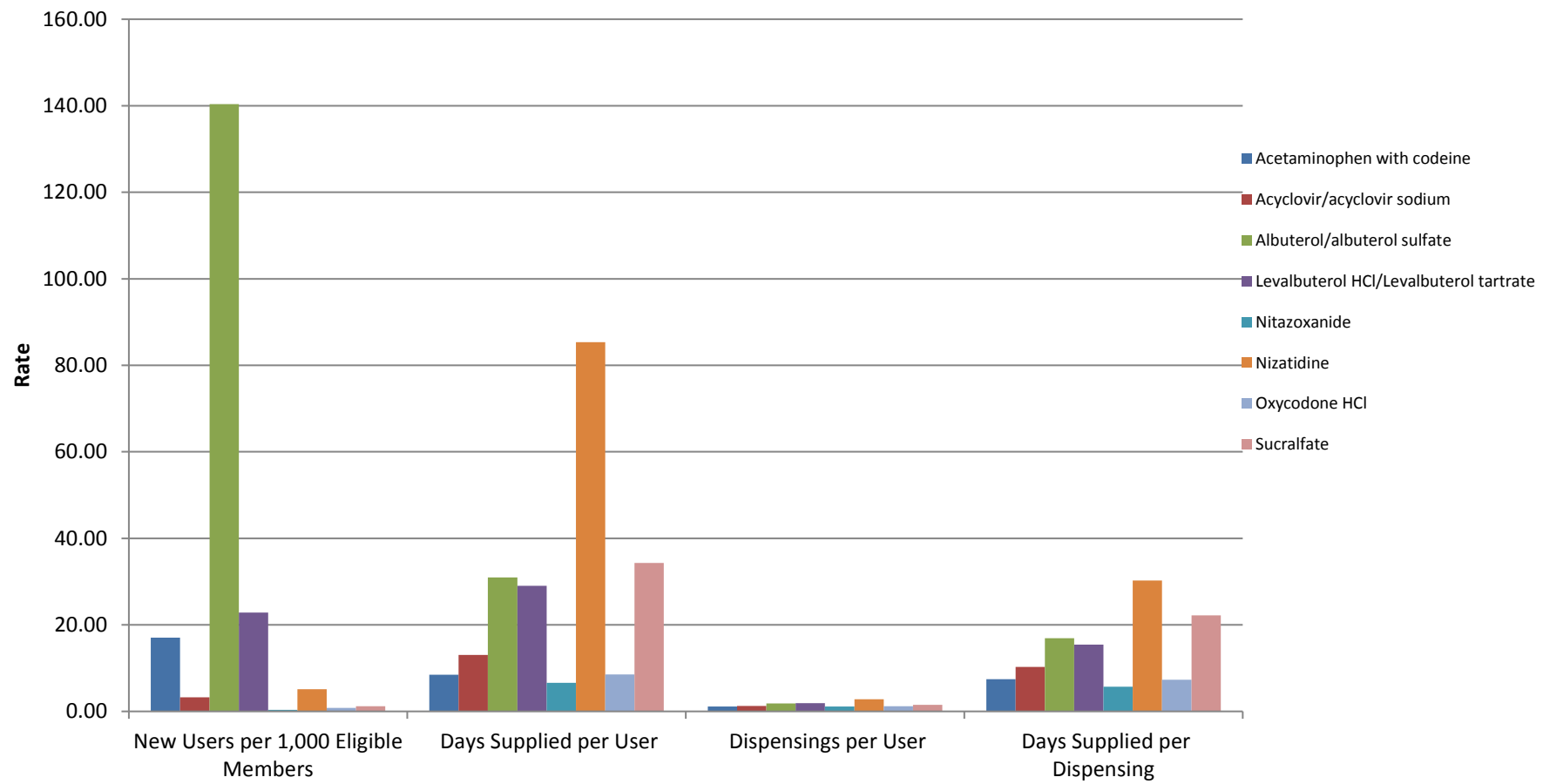


Table 3a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Age Group

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Acetaminophen with codeine									
0 - < 12 Months	35,672	38,796	288,759	4,723,020	3,187,299	7.55	8.09	1.09	7.44
0 - < 1 Month	99	732	101	3,110,100	229,328	0.03	1.02	7.39	0.14
1 - < 3 Months	1,496	12,827	1,550	3,334,791	500,985	0.45	1.04	8.57	0.12
3 - < 6 Months	5,676	45,754	5,942	3,512,627	781,644	1.62	1.05	8.06	0.13
6 - < 12 Months	29,221	229,446	31,203	4,202,064	1,729,542	6.95	1.07	7.85	0.14
12 - < 24 Months	79,315	87,821	654,281	5,034,108	3,503,854	15.76	8.25	1.11	7.45
Acyclovir/acyclovir sodium									
0 - < 12 Months	5,652	7,612	95,118	4,723,020	3,187,299	1.20	16.83	1.35	12.50
0 - < 1 Month	112	2,238	114	3,110,100	229,328	0.04	1.02	19.98	0.05
1 - < 3 Months	424	11,137	566	3,334,791	500,985	0.13	1.33	26.27	0.05
3 - < 6 Months	1,081	22,727	1,464	3,512,627	781,644	0.31	1.35	21.02	0.06
6 - < 12 Months	4,491	59,016	5,468	4,202,064	1,729,542	1.07	1.22	13.14	0.09
12 - < 24 Months	16,046	19,203	180,489	5,034,108	3,503,854	3.19	11.25	1.20	9.40
Albuterol/albuterol sulfate									
0 - < 12 Months	536,200	816,776	13,699,906	4,723,020	3,187,299	113.53	25.55	1.52	16.77
0 - < 1 Month	2,337	2,443	43,948	3,110,100	229,328	0.75	18.81	1.05	17.99
1 - < 3 Months	50,375	57,437	984,110	3,334,791	500,985	15.11	19.54	1.14	17.13
3 - < 6 Months	189,549	237,931	3,976,934	3,512,627	781,644	53.96	20.98	1.26	16.71
6 - < 12 Months	372,901	518,965	8,694,914	4,202,064	1,729,542	88.74	23.32	1.39	16.75
12 - < 24 Months	548,300	865,134	14,716,964	5,034,108	3,503,854	108.92	26.84	1.58	17.01
Levalbuterol HCl/Levalbuterol tartrate									
0 - < 12 Months	93,235	149,036	2,242,119	4,723,020	3,187,299	19.74	24.05	1.60	15.04
0 - < 1 Month	674	702	9,900	3,110,100	229,328	0.22	14.69	1.04	14.10
1 - < 3 Months	12,202	14,240	206,467	3,334,791	500,985	3.66	16.92	1.17	14.50
3 - < 6 Months	35,684	46,208	685,388	3,512,627	781,644	10.16	19.21	1.29	14.83
6 - < 12 Months	61,107	87,886	1,340,364	4,202,064	1,729,542	14.54	21.93	1.44	15.25
12 - < 24 Months	81,895	132,750	2,105,878	5,034,108	3,503,854	16.27	25.71	1.62	15.86

Table 3a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Age Group

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Nitazoxanide									
0 - < 12 Months	429	470	2,989	4,723,020	3,187,299	0.09	6.97	1.10	6.36
0 - < 1 Month	0	0	0	3,110,100	229,328	0.00	---	---	---
1 - < 3 Months	23	24	191	3,334,791	500,985	0.01	8.30	1.04	7.96
3 - < 6 Months	63	68	543	3,512,627	781,644	0.02	8.62	1.08	7.99
6 - < 12 Months	352	378	2,255	4,202,064	1,729,542	0.08	6.41	1.07	5.97
12 - < 24 Months	1,995	2,310	12,916	5,034,108	3,503,854	0.40	6.47	1.16	5.59
Nizatidine									
0 - < 12 Months	31,513	84,432	2,551,955	4,723,020	3,187,299	6.67	80.98	2.68	30.22
0 - < 1 Month	3,771	3,819	117,029	3,110,100	229,328	1.21	31.03	1.01	30.64
1 - < 3 Months	18,484	26,332	795,023	3,334,791	500,985	5.54	43.01	1.42	30.19
3 - < 6 Months	15,896	29,945	903,592	3,512,627	781,644	4.53	56.84	1.88	30.18
6 - < 12 Months	10,127	24,336	736,311	4,202,064	1,729,542	2.41	72.71	2.40	30.26
12 - < 24 Months	3,803	10,090	305,960	5,034,108	3,503,854	0.76	80.45	2.65	30.32
Oxycodone HCl									
0 - < 12 Months	2,533	2,856	20,661	4,723,020	3,187,299	0.54	8.16	1.13	7.23
0 - < 1 Month	118	126	770	3,110,100	229,328	0.04	6.53	1.07	6.11
1 - < 3 Months	218	234	1,816	3,334,791	500,985	0.07	8.33	1.07	7.76
3 - < 6 Months	668	716	5,367	3,512,627	781,644	0.19	8.03	1.07	7.50
6 - < 12 Months	1,621	1,780	12,708	4,202,064	1,729,542	0.39	7.84	1.10	7.14
12 - < 24 Months	2,797	3,213	24,313	5,034,108	3,503,854	0.56	8.69	1.15	7.57
Sucralfate									
0 - < 12 Months	4,889	7,671	186,886	4,723,020	3,187,299	1.04	38.23	1.57	24.36
0 - < 1 Month	206	214	4,867	3,110,100	229,328	0.07	23.63	1.04	22.74
1 - < 3 Months	1,658	2,014	50,641	3,334,791	500,985	0.50	30.54	1.21	25.14
3 - < 6 Months	1,858	2,547	65,311	3,512,627	781,644	0.53	35.15	1.37	25.64
6 - < 12 Months	2,054	2,896	66,067	4,202,064	1,729,542	0.49	32.17	1.41	22.81
12 - < 24 Months	3,187	4,317	79,491	5,034,108	3,503,854	0.63	24.94	1.35	18.41

Table 3b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Age Group

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000 Eligible Members	Days Supplied per User	Dispensing per User	Days Supplied per Dispensing
Acetaminophen with codeine										
0 - < 12 Months	35,650	35,650	38,773	288,507	4,714,038	3,164,295	7.56	8.09	1.09	7.44
0 - < 1 Month	96	96	98	694	3,086,003	220,781	0.03	7.23	1.02	7.08
1 - < 3 Months	1,493	1,493	1,547	12,793	3,329,012	499,890	0.45	8.57	1.04	8.27
3 - < 6 Months	5,577	5,577	5,817	44,622	3,505,695	779,454	1.59	8.00	1.04	7.67
6 - < 12 Months	28,484	28,484	30,275	222,080	4,189,929	1,717,839	6.80	7.80	1.06	7.34
12 - < 24 Months	75,841	75,841	82,940	616,441	4,995,027	3,438,155	15.18	8.13	1.09	7.43
Acyclovir/acyclovir sodium										
0 - < 12 Months	5,645	5,645	7,596	94,809	4,714,062	3,172,679	1.20	16.80	1.35	12.48
0 - < 1 Month	110	110	112	2,193	3,086,005	220,781	0.04	19.94	1.02	19.58
1 - < 3 Months	380	380	486	8,567	3,328,991	499,939	0.11	22.54	1.28	17.63
3 - < 6 Months	932	932	1,100	12,627	3,506,661	780,149	0.27	13.55	1.18	11.48
6 - < 12 Months	4,223	4,223	4,750	42,392	4,195,425	1,725,914	1.01	10.04	1.12	8.92
12 - < 24 Months	15,438	15,438	17,699	153,398	5,022,374	3,488,442	3.07	9.94	1.15	8.67
Albuterol/albuterol sulfate										
0 - < 12 Months	535,505	535,505	815,595	13,678,289	4,713,424	2,971,794	113.61	25.54	1.52	16.77
0 - < 1 Month	2,303	2,303	2,407	43,051	3,085,975	220,748	0.75	18.69	1.05	17.89
1 - < 3 Months	49,924	49,924	56,870	973,764	3,326,948	496,768	15.01	19.50	1.14	17.12
3 - < 6 Months	177,619	177,619	220,258	3,678,499	3,460,025	750,736	51.33	20.71	1.24	16.70
6 - < 12 Months	305,659	305,659	406,248	6,790,733	3,979,366	1,548,320	76.81	22.22	1.33	16.72
12 - < 24 Months	381,571	381,571	546,079	9,199,662	4,558,019	2,931,783	83.71	24.11	1.43	16.85
Levalbuterol HCl/Levalbuterol tartrate										
0 - < 12 Months	93,128	93,128	148,845	2,238,961	4,713,975	3,135,820	19.76	24.04	1.60	15.04
0 - < 1 Month	670	670	698	9,821	3,086,003	220,773	0.22	14.66	1.04	14.07
1 - < 3 Months	12,048	12,048	14,036	203,911	3,328,470	499,139	3.62	16.92	1.17	14.53
3 - < 6 Months	32,485	32,485	41,407	613,540	3,495,333	773,982	9.29	18.89	1.27	14.82
6 - < 12 Months	47,925	47,925	65,334	988,822	4,153,892	1,694,587	11.54	20.63	1.36	15.13
12 - < 24 Months	56,289	56,289	82,676	1,281,792	4,944,976	3,404,698	11.38	22.77	1.47	15.50

Table 3b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Age Group

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000 Eligible Members	Days Supplied per User	Dispensing per User	Days Supplied per Dispensing
Nitazoxanide										
0 - < 12 Months	429	429	470	2,989	4,714,073	3,174,147	0.09	6.97	1.10	6.36
0 - < 1 Month	0	0	0	0	3,086,006	220,783	0.00	---	---	---
1 - < 3 Months	23	23	24	191	3,329,093	499,982	0.01	8.30	1.04	7.96
3 - < 6 Months	58	58	62	498	3,507,064	780,330	0.02	8.59	1.07	8.03
6 - < 12 Months	348	348	374	2,195	4,196,689	1,727,249	0.08	6.31	1.07	5.87
12 - < 24 Months	1,966	1,966	2,272	12,675	5,027,065	3,498,159	0.39	6.45	1.16	5.58
Nizatidine										
0 - < 12 Months	31,459	31,459	84,268	2,547,011	4,714,018	3,156,370	6.67	80.96	2.68	30.23
0 - < 1 Month	3,759	3,759	3,806	116,684	3,085,997	220,716	1.22	31.04	1.01	30.66
1 - < 3 Months	16,693	16,693	23,540	711,025	3,325,785	498,066	5.02	42.59	1.41	30.20
3 - < 6 Months	7,177	7,177	11,472	345,446	3,489,795	775,377	2.06	48.13	1.60	30.11
6 - < 12 Months	3,830	3,830	7,410	221,907	4,173,085	1,715,689	0.92	57.94	1.93	29.95
12 - < 24 Months	1,966	1,966	4,266	126,454	5,004,943	3,480,635	0.39	64.32	2.17	29.64
Oxycodone HCl										
0 - < 12 Months	2,523	2,523	2,827	20,129	4,714,055	3,173,491	0.54	7.98	1.12	7.12
0 - < 1 Month	110	110	117	671	3,086,000	220,781	0.04	6.10	1.06	5.74
1 - < 3 Months	212	212	225	1,677	3,329,039	499,964	0.06	7.91	1.06	7.45
3 - < 6 Months	646	646	682	4,901	3,506,867	780,234	0.18	7.59	1.06	7.19
6 - < 12 Months	1,555	1,555	1,677	11,421	4,195,896	1,726,620	0.37	7.34	1.08	6.81
12 - < 24 Months	2,649	2,649	2,970	21,541	5,025,489	3,496,738	0.53	8.13	1.12	7.25
Sucralfate										
0 - < 12 Months	4,886	4,886	7,667	186,852	4,714,069	3,171,981	1.04	38.24	1.57	24.37
0 - < 1 Month	206	206	214	4,867	3,086,005	220,779	0.07	23.63	1.04	22.74
1 - < 3 Months	1,601	1,601	1,936	48,816	3,328,918	499,838	0.48	30.49	1.21	25.21
3 - < 6 Months	1,437	1,437	1,848	45,789	3,505,518	779,799	0.41	31.86	1.29	24.78
6 - < 12 Months	1,642	1,642	2,097	43,488	4,193,892	1,725,669	0.39	26.48	1.28	20.74
12 - < 24 Months	2,866	2,866	3,607	61,001	5,023,619	3,495,007	0.57	21.28	1.26	16.91

Table 4a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Sex

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,00 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Acetaminophen with codeine									
Female	37,590	42,837	344,457	3,185,843	3,355,798	11.80	9.16	1.14	8.04
Male	73,961	83,774	598,550	3,359,069	3,531,354	22.02	8.09	1.13	7.14
Unknown	6	6	33	489	409	12.27	5.50	1.00	5.50
Acyclovir									
Female	10,012	12,591	128,760	3,185,843	3,355,798	3.14	12.86	1.26	10.23
Male	11,090	14,222	146,833	3,359,069	3,531,354	3.30	13.24	1.28	10.32
Unknown	2	2	14	489	409	4.09	7.00	1.00	7.00
Albuterol									
Female	376,750	651,343	11,029,721	3,185,843	3,355,798	118.26	29.28	1.73	16.93
Male	541,472	1,030,497	17,386,040	3,359,069	3,531,354	161.20	32.11	1.90	16.87
Unknown	38	70	1,109	489	409	77.71	29.18	1.84	15.84
Levalbuterol HCl/Levalbuterol tartrate									
Female	60,574	108,608	1,679,542	3,185,843	3,355,798	19.01	27.73	1.79	15.46
Male	89,017	173,162	2,668,167	3,359,069	3,531,354	26.50	29.97	1.95	15.41
Unknown	10	16	288	489	409	20.45	28.80	1.60	18.00
Nitazoxanide									
Female	1,027	1,195	6,700	3,185,843	3,355,798	0.32	6.52	1.16	5.61
Male	1,370	1,585	9,205	3,359,069	3,531,354	0.41	6.72	1.16	5.81
Unknown	0	0	0	489	409	0.00	---	---	---
Nizatidine									
Female	15,181	42,606	1,287,281	3,185,843	3,355,798	4.77	84.80	2.81	30.21
Male	18,295	51,898	1,570,043	3,359,069	3,531,354	5.45	85.82	2.84	30.25
Unknown	9	18	591	489	409	18.40	65.67	2.00	32.83
Oxycodone HCl									
Female	1,734	2,102	16,953	3,185,843	3,355,798	0.54	9.78	1.21	8.07
Male	3,448	3,967	28,021	3,359,069	3,531,354	1.03	8.13	1.15	7.06
Unknown	0	0	0	489	409	0.00	---	---	---

Table 4a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Sex

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,00 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Sucralfate									
Female	3,472	5,236	115,614	3,185,843	3,355,798	1.09	33.30	1.51	22.08
Male	4,287	6,752	150,763	3,359,069	3,531,354	1.28	35.17	1.57	22.33
Unknown	0	0	0	489	409	0.00	---	---	---

Table 4b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Sex

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Acetaminophen with codeine										
Female	37,558	37,558	42,800	344,119	3,180,122	3324442	11.81	9.16	1.14	8.04
Male	73,927	73,927	83,736	598,341	3,352,895	3473362	22.05	8.09	1.13	7.15
Unknown	6	6	6	33	489	406	12.27	5.50	1.00	5.50
Acyclovir										
Female	9,997	9,997	12,567	128,355	3,180,168	3341335	3.14	12.84	1.26	10.21
Male	11,084	11,084	14,216	146,790	3,352,939	3515661	3.31	13.24	1.28	10.33
Unknown	2	2	2	14	489	407	4.09	7.00	1.00	7.00
Albuterol										
Female	376,290	376,290	650,316	11,010,889	3,179,679	3031116	118.34	29.26	1.73	16.93
Male	540,748	540,748	1,029,018	17,360,219	3,352,178	3056649	161.31	32.10	1.90	16.87
Unknown	38	38	70	1,109	489	380	77.71	29.18	1.84	15.84
Levalbuterol HCl/Levalbuterol tartrate										
Female	60,513	60,513	108,483	1,677,486	3,180,115	3292830	19.03	27.72	1.79	15.46
Male	88,894	88,894	172,855	2,662,861	3,352,813	3441705	26.51	29.96	1.94	15.41
Unknown	10	10	16	288	489	402	20.45	28.80	1.60	18.00
Nitazoxanide										
Female	1,025	1,025	1,193	6,694	3,180,182	3346680	0.32	6.53	1.16	5.61
Male	1,370	1,370	1,585	9,205	3,352,952	3521623	0.41	6.72	1.16	5.81
Unknown	0	0	0	0	489	408	0.00	---	---	---
Nizatidine										
Female	15,156	15,156	42,526	1,284,940	3,180,155	3329887	4.77	84.78	2.81	30.22
Male	18,260	18,260	51,782	1,566,476	3,352,913	3501596	5.45	85.79	2.84	30.25
Unknown	9	9	18	591	489	397	18.40	65.67	2.00	32.83
Oxycodone HCl										
Female	1,727	1,727	2,069	16,290	3,180,158	3346109	0.54	9.43	1.20	7.87
Male	3,445	3,445	3,955	27,845	3,352,942	3519971	1.03	8.08	1.15	7.04
Unknown	0	0	0	0	489	408	0.00	---	---	---

Table 4b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Sex

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Sucralfate										
Female	3,469	3,469	5,231	115,534	3,180,181	3344289	1.09	33.30	1.51	22.09
Male	4,283	4,283	6,748	150,717	3,352,943	3518531	1.28	35.19	1.58	22.34
Unknown	0	0	0	0	489	408	0.00	---	---	---

Table 5a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000			
						Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Acetaminophen with codeine									
2000	5,442	6,258	60,919	381,038	222,808	14.28	11.19	1.15	9.73
2001	5,259	5,986	59,506	369,094	219,915	14.25	11.32	1.14	9.94
2002	5,281	5,991	57,993	367,403	218,640	14.37	10.98	1.13	9.68
2003	5,222	5,983	56,535	364,082	216,014	14.34	10.83	1.15	9.45
2004	4,335	4,769	35,990	391,249	229,889	11.08	8.30	1.10	7.55
2005	5,135	5,741	40,283	408,029	240,560	12.58	7.84	1.12	7.02
2006	9,977	11,006	81,798	867,671	490,845	11.50	8.20	1.10	7.43
2007	9,774	10,647	76,607	938,790	519,964	10.41	7.84	1.09	7.20
2008	17,512	18,871	125,030	1,886,174	1,036,664	9.28	7.14	1.08	6.63
2009	15,738	16,936	113,231	1,769,159	989,118	8.90	7.19	1.08	6.69
2010	13,487	14,610	99,222	1,621,757	912,745	8.32	7.36	1.08	6.79
2011	11,092	11,916	81,230	1,526,090	858,836	7.27	7.32	1.07	6.82
2012	7,469	7,903	54,696	1,376,892	731,563	5.42	7.32	1.06	6.92
Acyclovir									
2000	511	629	9,233	381,038	222,808	1.34	18.07	1.23	14.68
2001	556	698	9,747	369,094	219,915	1.51	17.53	1.26	13.96
2002	625	780	10,437	367,403	218,640	1.70	16.70	1.25	13.38
2003	612	796	12,010	364,082	216,014	1.68	19.62	1.30	15.09
2004	723	930	10,385	391,249	229,889	1.85	14.36	1.29	11.17
2005	764	1,004	12,480	408,029	240,560	1.87	16.34	1.31	12.43
2006	1,615	1,976	20,543	867,671	490,845	1.86	12.72	1.22	10.40
2007	1,664	2,068	20,334	938,790	519,964	1.77	12.22	1.24	9.83
2008	3,384	4,031	36,971	1,886,174	1,036,664	1.79	10.93	1.19	9.17
2009	3,133	3,756	35,224	1,769,159	989,118	1.77	11.24	1.20	9.38
2010	3,074	3,754	35,459	1,621,757	912,745	1.90	11.54	1.22	9.45
2011	2,799	3,442	33,126	1,526,090	858,836	1.83	11.83	1.23	9.62
2012	2,450	2,951	29,658	1,376,892	731,563	1.78	12.11	1.20	10.05

Table 5a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000			
						Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Albuterol									
2000	49,794	83,597	1,645,674	381,038	222,808	130.68	33.05	1.68	19.69
2001	50,814	84,484	1,636,337	369,094	219,915	137.67	32.20	1.66	19.37
2002	48,011	78,846	1,536,386	367,403	218,640	130.68	32.00	1.64	19.49
2003	45,382	73,235	1,415,922	364,082	216,014	124.65	31.20	1.61	19.33
2004	40,279	62,029	1,122,387	391,249	229,889	102.95	27.87	1.54	18.09
2005	43,908	68,169	1,226,296	408,029	240,560	107.61	27.93	1.55	17.99
2006	77,709	116,438	2,035,695	867,671	490,845	89.56	26.20	1.50	17.48
2007	78,162	117,443	2,036,235	938,790	519,964	83.26	26.05	1.50	17.34
2008	147,645	216,586	3,443,876	1,886,174	1,036,664	78.28	23.33	1.47	15.90
2009	146,939	217,854	3,466,454	1,769,159	989,118	83.06	23.59	1.48	15.91
2010	138,802	207,083	3,277,715	1,621,757	912,745	85.59	23.61	1.49	15.83
2011	130,086	194,047	3,022,731	1,526,090	858,836	85.24	23.24	1.49	15.58
2012	110,579	162,099	2,551,162	1,376,892	731,563	80.31	23.07	1.47	15.74
Levalbuterol HCl/Levalbuterol tartrate									
2000	241	371	5,614	381,038	222,808	0.63	23.29	1.54	15.13
2001	905	1,621	20,685	369,094	219,915	2.45	22.86	1.79	12.76
2002	1,983	3,635	48,420	367,403	218,640	5.40	24.42	1.83	13.32
2003	4,122	6,958	99,452	364,082	216,014	11.32	24.13	1.69	14.29
2004	6,093	9,847	168,438	391,249	229,889	15.57	27.64	1.62	17.11
2005	7,302	12,693	196,068	408,029	240,560	17.90	26.85	1.74	15.45
2006	16,846	27,088	427,641	867,671	490,845	19.42	25.39	1.61	15.79
2007	17,825	27,893	431,356	938,790	519,964	18.99	24.20	1.56	15.46
2008	37,502	58,134	863,609	1,886,174	1,036,664	19.88	23.03	1.55	14.86
2009	32,741	50,803	794,422	1,769,159	989,118	18.51	24.26	1.55	15.64
2010	22,648	34,561	545,270	1,621,757	912,745	13.97	24.08	1.53	15.78
2011	19,354	29,673	461,137	1,526,090	858,836	12.68	23.83	1.53	15.54
2012	12,453	18,509	285,885	1,376,892	731,563	9.04	22.96	1.49	15.45

Table 5a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000			
						Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Nitazoxanide									
2000	0	0	0	381,038	222,808	0.00	---	---	---
2001	0	0	0	369,094	219,915	0.00	---	---	---
2002	0	0	0	367,403	218,640	0.00	---	---	---
2003	6	10	113	364,082	216,014	0.02	18.83	1.67	11.30
2004	32	38	248	391,249	229,889	0.08	7.75	1.19	6.53
2005	82	94	610	408,029	240,560	0.20	7.44	1.15	6.49
2006	260	309	1,889	867,671	490,845	0.30	7.27	1.19	6.11
2007	254	296	1,824	938,790	519,964	0.27	7.18	1.17	6.16
2008	621	683	3,503	1,886,174	1,036,664	0.33	5.64	1.10	5.13
2009	425	481	2,658	1,769,159	989,118	0.24	6.25	1.13	5.53
2010	367	430	2,468	1,621,757	912,745	0.23	6.72	1.17	5.74
2011	255	294	1,621	1,526,090	858,836	0.17	6.36	1.15	5.51
2012	125	145	971	1,376,892	731,563	0.09	7.77	1.16	6.70
Nizatidine									
2000	0	0	0	381,038	222,808	0.00	---	---	---
2001	0	0	0	369,094	219,915	0.00	---	---	---
2002	1	1	14	367,403	218,640	0.00	14.00	1.00	14.00
2003	1	1	30	364,082	216,014	0.00	30.00	1.00	30.00
2004	15	21	546	391,249	229,889	0.04	36.40	1.40	26.00
2005	112	248	6,066	408,029	240,560	0.27	54.16	2.21	24.46
2006	1,971	4,373	145,759	867,671	490,845	2.27	73.95	2.22	33.33
2007	3,602	8,639	269,889	938,790	519,964	3.84	74.93	2.40	31.24
2008	10,501	25,667	764,198	1,886,174	1,036,664	5.57	72.77	2.44	29.77
2009	8,085	20,012	600,199	1,769,159	989,118	4.57	74.24	2.48	29.99
2010	5,843	14,587	438,466	1,621,757	912,745	3.60	75.04	2.50	30.06
2011	4,660	12,015	363,828	1,526,090	858,836	3.05	78.07	2.58	30.28
2012	3,573	8,958	268,920	1,376,892	731,563	2.59	75.26	2.51	30.02

Table 5a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Years	Users per 1,000			
						Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Oxycodone HCl									
2000	36	41	291	381,038	222,808	0.09	8.08	1.14	7.10
2001	43	44	278	369,094	219,915	0.12	6.47	1.02	6.32
2002	35	38	306	367,403	218,640	0.10	8.74	1.09	8.05
2003	40	42	384	364,082	216,014	0.11	9.60	1.05	9.14
2004	46	61	801	391,249	229,889	0.12	17.41	1.33	13.13
2005	77	95	828	408,029	240,560	0.19	10.75	1.23	8.72
2006	212	269	2,756	867,671	490,845	0.24	13.00	1.27	10.25
2007	261	316	2,647	938,790	519,964	0.28	10.14	1.21	8.38
2008	746	849	6,260	1,886,174	1,036,664	0.40	8.39	1.14	7.37
2009	821	919	6,491	1,769,159	989,118	0.46	7.91	1.12	7.06
2010	973	1,084	7,751	1,621,757	912,745	0.60	7.97	1.11	7.15
2011	1,037	1,166	8,010	1,526,090	858,836	0.68	7.72	1.12	6.87
2012	1,035	1,145	8,171	1,376,892	731,563	0.75	7.89	1.11	7.14
Sucralfate									
2000	78	114	2,402	381,038	222,808	0.20	30.79	1.46	21.07
2001	87	123	2,642	369,094	219,915	0.24	30.37	1.41	21.48
2002	140	193	4,304	367,403	218,640	0.38	30.74	1.38	22.30
2003	182	284	6,143	364,082	216,014	0.50	33.75	1.56	21.63
2004	248	336	7,140	391,249	229,889	0.63	28.79	1.35	21.25
2005	161	245	4,628	408,029	240,560	0.39	28.75	1.52	18.89
2006	481	719	17,462	867,671	490,845	0.55	36.30	1.49	24.29
2007	612	878	19,784	938,790	519,964	0.65	32.33	1.43	22.53
2008	1,465	2,151	48,630	1,886,174	1,036,664	0.78	33.19	1.47	22.61
2009	1,321	1,885	42,142	1,769,159	989,118	0.75	31.90	1.43	22.36
2010	1,313	1,895	41,389	1,621,757	912,745	0.81	31.52	1.44	21.84
2011	1,195	1,793	40,005	1,526,090	858,836	0.78	33.48	1.50	22.31
2012	943	1372	29706	1376892	731563	0.68	31.50	1.45	21.65

Table 5b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Acetaminophen with codeine										
2000	5,429	5,429	6,241	60,753	380,291	219,689	14.28	11.19	1.15	9.73
2001	4,951	4,951	5,561	55,927	365,358	215,952	13.55	11.30	1.12	10.06
2002	4,992	4,992	5,603	54,572	363,525	214,707	13.73	10.93	1.12	9.74
2003	4,885	4,885	5,470	52,210	360,255	212,194	13.56	10.69	1.12	9.54
2004	4,128	4,128	4,496	33,217	387,493	226,494	10.65	8.05	1.09	7.39
2005	4,873	4,873	5,394	37,473	404,636	236,796	12.04	7.69	1.11	6.95
2006	9,737	9,737	10,692	79,470	862,812	484,044	11.29	8.16	1.10	7.43
2007	9,339	9,339	10,078	71,890	931,158	512,413	10.03	7.70	1.08	7.13
2008	17,133	17,133	18,401	121,589	1,873,823	1,023,906	9.14	7.10	1.07	6.61
2009	15,179	15,179	16,267	108,672	1,757,169	976,679	8.64	7.16	1.07	6.68
2010	12,983	12,983	13,955	94,168	1,610,803	901,673	8.06	7.25	1.07	6.75
2011	10,635	10,635	11,335	77,074	1,516,418	849,233	7.01	7.25	1.07	6.80
2012	7,227	7,227	7,613	52,562	1,369,135	724,431	5.28	7.27	1.05	6.90
Acyclovir										
2000	509	509	622	9,046	380,301	221,585	1.34	17.77	1.22	14.54
2001	535	535	632	7,966	368,277	219,106	1.45	14.89	1.18	12.60
2002	610	610	746	9,899	366,649	217,819	1.66	16.23	1.22	13.27
2003	575	575	658	9,067	363,298	215,175	1.58	15.77	1.14	13.78
2004	702	702	880	9,470	390,446	228,983	1.80	13.49	1.25	10.76
2005	728	728	896	10,021	407,157	239,559	1.79	13.77	1.23	11.18
2006	1,582	1,582	1,898	18,522	865,542	488,332	1.83	11.71	1.20	9.76
2007	1,588	1,588	1,920	17,663	936,234	517,668	1.70	11.12	1.21	9.20
2008	3,299	3,299	3,866	33,986	1,878,872	1,031,379	1.76	10.30	1.17	8.79
2009	3,015	3,015	3,488	30,577	1,765,342	985,097	1.71	10.14	1.16	8.77
2010	2,929	2,929	3,404	29,607	1,618,337	908,927	1.81	10.11	1.16	8.70
2011	2,669	2,669	3,157	28,897	1,522,842	855,339	1.75	10.83	1.18	9.15
2012	2,342	2,342	2,714	24,960	1,374,106	728,435	1.70	10.66	1.16	9.20

Table 5b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Albuterol										
2000	49,612	49,612	83,183	1,637,505	380,121	196,927	130.52	33.01	1.68	19.69
2001	39,401	39,401	62,240	1,219,321	336,228	180,812	117.19	30.95	1.58	19.59
2002	36,354	36,354	56,921	1,116,709	329,751	179,103	110.25	30.72	1.57	19.62
2003	34,444	34,444	52,772	1,021,598	328,200	179,082	104.95	29.66	1.53	19.36
2004	31,560	31,560	46,523	831,497	357,284	196,171	88.33	26.35	1.47	17.87
2005	34,902	34,902	51,858	931,678	376,736	206,521	92.64	26.69	1.49	17.97
2006	68,260	68,260	99,197	1,726,005	833,569	440,464	81.89	25.29	1.45	17.40
2007	63,376	63,376	90,982	1,563,584	883,595	461,455	71.73	24.67	1.44	17.19
2008	131,880	131,880	188,685	2,973,335	1,823,122	944,096	72.34	22.55	1.43	15.76
2009	120,524	120,524	171,836	2,720,317	1,673,755	881,979	72.01	22.57	1.43	15.83
2010	112,293	112,293	160,993	2,522,263	1,525,908	807,865	73.59	22.46	1.43	15.67
2011	105,686	105,686	151,585	2,336,683	1,436,853	762,734	73.55	22.11	1.43	15.42
2012	88,784	88,784	124,845	1,952,065	1,294,819	650,938	68.57	21.99	1.41	15.64
Levalbuterol HCl/Levalbuterol tartrate										
2000	241	241	371	5,614	380,303	221,702	0.63	23.29	1.54	15.13
2001	824	824	1,452	18,096	368,391	219,027	2.24	21.96	1.76	12.46
2002	1,719	1,719	3,003	39,290	366,298	217,009	4.69	22.86	1.75	13.08
2003	3,653	3,653	5,853	83,198	362,252	213,383	10.08	22.78	1.60	14.21
2004	5,046	5,046	7,851	132,478	387,386	225,102	13.03	26.25	1.56	16.87
2005	5,521	5,521	9,207	140,335	402,329	233,969	13.72	25.42	1.67	15.24
2006	15,109	15,109	23,668	372,815	860,142	478,960	17.57	24.68	1.57	15.75
2007	14,353	14,353	21,411	323,950	925,209	505,455	15.51	22.57	1.49	15.13
2008	33,717	33,717	51,055	758,071	1,866,172	1,009,975	18.07	22.48	1.51	14.85
2009	26,441	26,441	39,318	606,478	1,742,988	961,216	15.17	22.94	1.49	15.42
2010	17,709	17,709	25,878	399,874	1,597,851	889,969	11.08	22.58	1.46	15.45
2011	15,548	15,548	22,928	350,916	1,508,398	840,868	10.31	22.57	1.47	15.31
2012	9,536	9,536	13,537	205,500	1,362,445	718,302	7.00	21.55	1.42	15.18

Table 5b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Nitazoxanide										
2000	0	0	0	0	380,303	221,764	0.00	---	---	---
2001	0	0	0	0	368,576	219,473	0.00	---	---	---
2002	0	0	0	0	367,011	218,204	0.00	---	---	---
2003	6	6	10	113	363,719	215,581	0.02	18.83	1.67	11.30
2004	32	32	38	248	390,833	229,380	0.08	7.75	1.19	6.53
2005	81	81	93	604	407,621	240,027	0.20	7.46	1.15	6.49
2006	256	256	305	1,863	865,966	489,014	0.30	7.28	1.19	6.11
2007	249	249	288	1,778	937,060	518,537	0.27	7.14	1.16	6.17
2008	615	615	675	3,453	1,879,763	1,032,782	0.33	5.61	1.10	5.12
2009	416	416	467	2,559	1,766,845	986,674	0.24	6.15	1.12	5.48
2010	364	364	427	2,440	1,619,918	910,573	0.22	6.70	1.17	5.71
2011	252	252	291	1,608	1,524,352	856,810	0.17	6.38	1.15	5.53
2012	124	124	144	964	1,375,526	729,892	0.09	7.77	1.16	6.69
Nizatidine										
2000	0	0	0	0	380,303	221,764	0.00	---	---	---
2001	0	0	0	0	368,576	219,473	0.00	---	---	---
2002	1	1	1	14	367,011	218,204	0.00	14.00	1.00	14.00
2003	1	1	1	30	363,718	215,581	0.00	30.00	1.00	30.00
2004	15	15	21	546	390,836	229,390	0.04	36.40	1.40	26.00
2005	106	106	232	5,666	407,627	240,013	0.26	53.45	2.19	24.42
2006	1,934	1,934	4,235	142,055	865,902	488,236	2.23	73.45	2.19	33.54
2007	3,227	3,227	7,440	229,899	935,562	515,963	3.45	71.24	2.31	30.90
2008	9,885	9,885	23,769	707,347	1,876,340	1,025,741	5.27	71.56	2.40	29.76
2009	6,676	6,676	15,650	467,974	1,758,273	977,297	3.80	70.10	2.34	29.90
2010	4,852	4,852	11,489	344,656	1,611,518	903,057	3.01	71.03	2.37	30.00
2011	3,861	3,861	9,435	285,192	1,518,282	851,265	2.54	73.86	2.44	30.23
2012	2,867	2,867	6,664	199,924	1,370,793	725,896	2.09	69.73	2.32	30.00

Table 5b. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
Oxycodone HCl										
2000	36	36	41	291	380,303	221,750	0.09	8.08	1.14	7.10
2001	41	41	42	270	368,550	219,444	0.11	6.59	1.02	6.43
2002	35	35	38	306	366,982	218,174	0.10	8.74	1.09	8.05
2003	39	39	41	378	363,692	215,555	0.11	9.69	1.05	9.22
2004	46	46	61	801	390,809	229,362	0.12	17.41	1.33	13.13
2005	75	75	87	588	407,606	240,015	0.18	7.84	1.16	6.76
2006	205	205	249	2,335	865,953	489,022	0.24	11.39	1.21	9.38
2007	251	251	287	2,215	937,062	518,524	0.27	8.82	1.14	7.72
2008	729	729	817	5,898	1,879,704	1,032,660	0.39	8.09	1.12	7.22
2009	785	785	869	5,996	1,766,686	986,374	0.44	7.64	1.11	6.90
2010	936	936	1,030	7,301	1,619,531	910,104	0.58	7.80	1.10	7.09
2011	1,003	1,003	1,120	7,559	1,523,865	856,245	0.66	7.54	1.12	6.75
2012	991	991	1,086	7,587	1,374,869	729,259	0.72	7.66	1.10	6.99
Sucralfate										
2000	78	78	114	2,402	380,303	221,732	0.21	30.79	1.46	21.07
2001	85	85	113	2,342	368,527	219,410	0.23	27.55	1.33	20.73
2002	135	135	182	4,054	366,940	218,117	0.37	30.03	1.35	22.27
2003	166	166	223	4,421	363,615	215,456	0.46	26.63	1.34	19.83
2004	234	234	306	6,376	390,670	229,200	0.60	27.25	1.31	20.84
2005	155	155	227	4,206	407,412	239,866	0.38	27.14	1.46	18.53
2006	473	473	692	16,704	865,855	488,852	0.55	35.32	1.46	24.14
2007	582	582	817	18,199	936,838	518,221	0.62	31.27	1.40	22.28
2008	1,420	1,420	2,062	46,057	1,879,376	1,032,104	0.76	32.43	1.45	22.34
2009	1,233	1,233	1,746	38,471	1,766,077	985,750	0.70	31.20	1.42	22.03
2010	1,214	1,214	1,649	34,270	1,618,979	909,599	0.75	28.23	1.36	20.78
2011	1,119	1,119	1,641	36,256	1,523,407	855,853	0.73	32.40	1.47	22.09
2012	858	858	1,197	25,161	1,374,609	729,070	0.62	29.33	1.40	21.02

Appendix A. Dates of Available Data for Each Data Partner (DP) in the Mini-Sentinel Distributed Database (MSDD) as of Request Send Date (September 10, 2013)

DP ID	DP Start Date*	DP End Date*
DP0001	1/2/2008	11/30/2012
DP0002	1/2/2000	12/31/2012
DP0003	1/2/2000	6/30/2012
DP0004	1/2/2000	12/31/2012
DP0005	1/1/2000	4/30/2012
DP0006	6/2/2007	10/31/2012
DP0007	1/2/2005	12/31/2012
DP0008	1/2/2008	9/30/2012
DP0009	1/2/2000	12/31/2012
DP0010	1/31/2000	12/31/2012
DP0011	1/2/2000	12/31/2011
DP0012	1/1/2000	12/31/2012
DP0013	1/2/2000	6/30/2012
DP0014	1/1/2000	12/31/2012
DP0015	1/31/2000	12/31/2012
DP0016	1/1/2000	12/31/2011
DP0017	1/2/2006	12/31/2012
DP0018	1/31/2004	12/31/2012

*The 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 Drug Names Used to Define Exposures in this Request

Generic Name	Brand Name
Acetaminophen with Codeine	
Acetaminophen with Codeine	Acetaminophen W/Codeine
Acetaminophen with Codeine	Sk-Apap W/Codeine
Acetaminophen with Codeine	Panadol W/Codeine No.3
Acetaminophen with Codeine	Panadol W/Codeine No.4
Acetaminophen with Codeine	Phenaphen W/Codeine
Acetaminophen with Codeine	Tylenol W/Codeine
Acetaminophen with Codeine	Tylenol-Codeine
Acetaminophen with Codeine	Tylenol W/Codeine No.2
Acetaminophen with Codeine	Tylenol-Codeine No.3
Acetaminophen with Codeine	Tylenol W/Codeine No.3
Acetaminophen with Codeine	Tylenol-Codeine No.4
Acetaminophen with Codeine	Tylenol W/Codeine No.4
Acetaminophen with Codeine	Anacin-3 With Codeine
Acetaminophen with Codeine	Anacin-3 W/Codeine
Acetaminophen with Codeine	Codaphen
Acetaminophen with Codeine	Acetaminophen-Codeine
Acetaminophen with Codeine	Proval No.3
Acetaminophen with Codeine	Empracet W/Codeine No.3
Acetaminophen with Codeine	Empracet W/Codeine No.4
Acetaminophen with Codeine	Capital W/Codeine
Acetaminophen with Codeine	Copan
Acetaminophen with Codeine	Capital W-Codeine
Acetaminophen with Codeine	Steraphen W/Codeine
Acetaminophen with Codeine	Acetaminophen With Codeine
Acetaminophen with Codeine	Aceta W/Codeine
Acetaminophen with Codeine	Coastaldyne
Acetaminophen with Codeine	Papa-Deine No.4
Acetaminophen with Codeine	Ty-Pap W/Codeine
Acetaminophen with Codeine	Ty-Tab W/Codeine
Acetaminophen with Codeine	M-Gesic
Acetaminophen with Codeine	Tylagesic 3
Acetaminophen with Codeine	Codaca No.3
Acetaminophen with Codeine	Codaca No.4
Acetaminophen with Codeine	Vitapap W/Codeine
Acetaminophen with Codeine	Stopayne
Acetaminophen with Codeine	Cocet Plus
Acetaminophen with Codeine	Cocet
Acetaminophen with Codeine	Umi-Apap
Acetaminophen with Codeine	An-Abate
Acetaminophen with Codeine	Mi-Code
Acetaminophen with Codeine	Acetaminophen W-Codeine
Acetaminophen with Codeine	Vopac

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures in this Request

Generic Name	Brand Name
Acyclovir	
Acyclovir	Acyclovir
Acyclovir	Zovirax
Nizatidine	
Nizatidine	Axid
Nizatidine	Nizatidine
Nizatidine	Axid AR
Albuterol	
Albuterol	Albuterol
Albuterol Sulfate	Albuterol Sulfate
Albuterol Sulfate	Proventil
Albuterol	Proventil
Albuterol Sulfate	Proventil Hfa
Albuterol	Ventolin
Albuterol Sulfate	Ventolin
Albuterol Sulfate	Ventolin Rotacaps
Albuterol Sulfate	Ventolin Hfa
Albuterol Sulfate	Arm-A-Med (Albuterol Sulfate)
Albuterol Sulfate	Proair Hfa
Albuterol Sulfate	Accuneb
Albuterol Sulfate	Airet
Albuterol Sulfate	Albuterol Sulfate Hfa
Albuterol	Respirol
Albuterol Sulfate	Albuterolsulfate
Albuterol Sulfate	Volmax
Albuterol Sulfate	Vospire Er
Levalbuterol	
Levalbuterol Hcl	Levalbuterol Hcl
Levalbuterol Hcl	Levalbuterol Concentrate
Levalbuterol Tartrate	Xopenex Hfa
Levalbuterol Hcl	Xopenex
Levalbuterol Hcl	Xopenex Concentrate
Oxycodone	
Oxycodone Hcl	Roxicodone
Oxycodone Hcl	Roxicodone Intensol
Oxycodone Hcl	Oxycodone Hcl
Oxycodone Hcl	Oxycodone Concentrate
Oxycodone Hcl	Oxycontin
Oxycodone Hcl	Eth-Oxydose
Oxycodone Hcl	Oxyir
Oxycodone Hcl	Oxyfast
Oxycodone Hcl	Oxecta
Oxycodone Hcl	Endocodone
Oxycodone Hcl	Percolone
Oxycodone Hcl	Dazidox

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures in this Request

Generic Name	Brand Name
Oxycodone Hcl/Acetaminophen	Sk-Oxycodone W/Acetaminophen
Oxycodone Hcl/Acetaminophen	Tylox
Oxycodone Hcl/Acetaminophen	Oxycodone-Acetaminophen
Oxycodone Hcl/Acetaminophen	Roxicet
Oxycodone Hcl/Acetaminophen	Oxycodone W/Acetaminophen
Oxycodone Hcl/Acetaminophen	Percocet
Oxycodone Hcl/Acetaminophen	Oxycodone Hcl-Acetaminophen
Oxycodone Hcl/Acetaminophen	Magnacet
Oxycodone Hcl/Acetaminophen	Endocet
Oxycodone Hcl/Acetaminophen	Xolox
Oxycodone Hcl/Acetaminophen	Primlev
Oxycodone Hcl/Acetaminophen	Oxycodone/Apap
Oxycodone Hcl/Acetaminophen	Primalev
Oxycodone Hcl/Acetaminophen	Perloxx
Oxycodone Hcl/Acetaminophen	Alcet
Oxycodone Hcl/Acetaminophen	Lynox
Oxycodone Hcl/Acetaminophen	Narvox
Oxycodone Hcl/Aspirin	Oxycodone Hcl-Aspirin
Oxycodone Hcl/Aspirin	Endodan
Oxycodone Hcl/Aspirin	Percodan
Oxycodone Hcl/Oxycodon Ter/Asa	Sk-Oxycodone W/Aspirin
Oxycodone Hcl/Oxycodon Ter/Asa	Roxiprin
Oxycodone Hcl/Oxycodon Ter/Asa	Oxycodone W/Aspirin
Oxycodone Hcl/Oxycodon Ter/Asa	Percodan
Oxycodone Hcl/Oxycodon Ter/Asa	Oxycodone-Aspirin
Oxycodone Hcl/Oxycodon Ter/Asa	Endodan
Oxycodone/Aspirin	Oxycodone W/Aspirin Half-Str
Oxycodone/Aspirin	Percodan Demi
Nitazoxanide	
Nitazoxanide	Alinia
Sucralfate	
Sucralfate	Carafate
Sucralfate	Sucralfate

Appendix C. Specifications Defining Parameters for this Request

Modular Program #9, version 2, was used to investigate prevalence and incidence of eight drug products in the infant population. The query period was from January 1, 2000 to December 31, 2012, and the enrollment gap was set at 45 days. Age groups were split as follows: 0-<12 and 12-<24 months. The 0-<12 month group was further stratified by months: 0-<1, 1-<3, 3-<6, 6-<12 months. This report examines 16 scenarios with differing exposures of interest that require drug coverage only. A second report examines 16 scenarios with differing exposures of interest that require both medical and drug coverage. See below for a description of each of the scenarios evaluated in this report.

Scenario	Incident exposure	Drug/Exposure Criteria			
		Coverage Requirement	Incident with respect to (incidence criteria):	Washout (days)	Washout Type*
Age Group = 0- <12, 12-<24 months					
1	Acetaminophen with codeine	Drug Only	Acetaminophen with codeine	1	MIN
2	Acyclovir/acyclovir sodium	Drug Only	Acyclovir/acyclovir sodium	1	MIN
3	Nizatidine	Drug Only	Nizatidine	1	MIN
4	Albuterol/albuterol sulfate	Drug Only	Albuterol/albuterol sulfate	1	MIN
5	Levalbuterol HCl/Levalbuterol tartrate	Drug Only	Levalbuterol HCl/Levalbuterol tartrate	1	MIN
6	Oxycodone HCl	Drug Only	Oxycodone HCl	1	MIN
7	Nitazoxanide	Drug Only	Nitazoxanide	1	MIN
8	Sucralfate	Drug Only	Sucralfate	1	MIN
Age Group = 0-<1, 1-<3, 3-<6, 6-<12 months					
9	Acetaminophen with codeine	Drug Only	Acetaminophen with codeine	1	MIN
10	Acyclovir/acyclovir sodium	Drug Only	Acyclovir/acyclovir sodium	1	MIN
11	Nizatidine	Drug Only	Nizatidine	1	MIN
12	Albuterol/albuterol sulfate	Drug Only	Albuterol/albuterol sulfate	1	MIN
13	Levalbuterol HCl/Levalbuterol tartrate	Drug Only	Levalbuterol HCl/Levalbuterol tartrate	1	MIN
14	Oxycodone HCl	Drug Only	Oxycodone HCl	1	MIN
15	Nitazoxanide	Drug Only	Nitazoxanide	1	MIN
16	Sucralfate	Drug Only	Sucralfate	1	MIN

*A "minimum" washout type for the exposure will only consider the first incident exposure (dispensings/procedures) for each member over the member's entire enrollment history. There can be at most one incident exposures (dispensings/procedures) per member. The enrollment requirement is based on the number of days in the washout.