



Modular Program Report

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 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	
<u>Request Description</u>	FDA has requested execution of Modular Program #1 (MP1) to investigate prevalent and incident use of acetaminophen with codeine, acyclovir, albuterol, nizatidine, and sucralfate among children ages 0 to 2 years. This involved one run of MP1. The time window for the request was January 1, 2000 –December 31, 2011.
<u>Request Description</u>	<p>FDA requested use of MP #1 to investigate prevalent and incident use of acetaminophen with codeine, acyclovir, albuterol, nizatidine, and sucralfate among children ages 0 to 24 months. The query was run against the Mini-Sentinel Distributed Database for the time period 1/1/2000 to 12/31/2011 (query period). The package was distributed to Data Partners on October 19, 2012.</p> <p>Results provide counts of new users, dispensings, total days supplied, eligible members, and member-days. Total days supplied are from the MSCDM outpatient pharmacy table for records identified using valid NDCs (for any form, e.g., tablet, vial, topical). A "minimum" washout type for the exposure was used, meaning that the program only considered the first incident exposure (dispensings/procedures) for each member over the member's entire enrollment history. A 1-day washout period was used to define incident use, meaning that a user was considered a new user if he/she was not exposed to the drug of interest in the prior one day.</p>
<u>Request ID</u>	msy4mpr02
<u>Requester</u>	FDA/CDER

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<u>Table 1b</u>	Table displaying the number of incident users, new starts, dispensings, total days supplied, eligible members, member-days, new users per 1,000 eligible members, days supplied per user, dispensings per user, and days supplied per dispensing by drug product - January 1, 2000 - December 31, 2011.
<u>Figure 1b</u>	Two figures displaying the information in the prior tab.
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<u>Table 4a</u>	Table displaying the number of prevalent users, dispensings, total days supplied, eligible members, member-days, users per 1,000 eligible members, days supplied per user, dispensings per user, and days supplied per dispensing by drug product and year - January 1, 2000 - December 31, 2011.
<u>Table 4b</u>	Table displaying the number of incident users, new starts, dispensings, total days supplied, eligible members, member-days, new users per 1,000 eligible members, days supplied per user, dispensings per user, and days supplied per dispensing by drug product and year - January 1, 2000 - December 31, 2011.

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<u>Appendix A</u>	List of ingredients included in each of the five drug product groups (acetaminophen with codeine, acyclovir, albuterol, nizatidine, and sucralfate) presented in this report.
Notes:	Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications for Query ID MSY4MPR02

FDA has requested execution of Modular Program #1 (MP1) to investigate prevalent and incident use of acetaminophen with codeine, acyclovir, albuterol, nizatidine, and sucralfate among children ages 0 to 23 months. The query period was from January 1, 2000 to December 31, 2011. The enrollment gap was set at 45 days; the washout was set to 1 day; and the washout type was set to minimum. Age groups were split as follows: 00-<01M, 01-<03M, 03-<06M, 06-<12M, 12-<24 months. In total, 5 different scenarios were examined. See below for a description of each of these scenarios.

Drug/Exposure Criteria				
Scenario	Prevalent/Incident exposure	Incident w/ respect to (incidence criteria):	Washout (days)	Washout type*
1	Acetaminophen with codeine	Acetaminophen with codeine	1	Minimum
2	Acyclovir	Acyclovir	1	Minimum
3	Albuterol	Albuterol	1	Minimum
4	Nizatidine	Nizatidine	1	Minimum
5	Sucralfate	Sucralfate	1	Minimum

*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.

**Modular Program 1 will consider those members with at least drug coverage.

Glossary of Terms in Modular Program 1*

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

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

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled”

Member-Days (incidence-based cohort) - Sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period.

Member-Days (prevalence-based cohort) - Sum of all days members are enrolled with drug and medical coverage** during the query period.

New Starts- Number of incident exposures during the query period. User must have no prior exposures in the washout period. For a minimum washout type, an individual may have no more than one new start. For a multiple washout type, an individual may have more

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

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

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.

*all terms may not be used in this report

**in cases where only NDCs are used to identify exposure, only drug coverage is required

Table 1a. Summary of Prevalent Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine	114,767	130,614	949,375	6,568,952	2,479,284,305	17.47	8.27	1.14	7.27
Acyclovir	22,711	29,516	301,044	6,568,952	2,479,284,305	3.46	13.26	1.30	10.20
Albuterol	991,375	1,913,731	31,584,054	6,568,952	2,479,284,305	150.92	31.86	1.93	16.50
Nizatidine	30,553	85,129	2,553,750	6,568,952	2,479,284,305	4.65	83.58	2.79	30.00
Sucralfate	7,397	11,382	252,863	6,568,952	2,479,284,305	1.13	34.18	1.54	22.22

Figure 1a1. Number of Prevalent Users and Dispensings among Children 0-2 Years between January 1, 2000 and December 31, 2011, by Drug Product

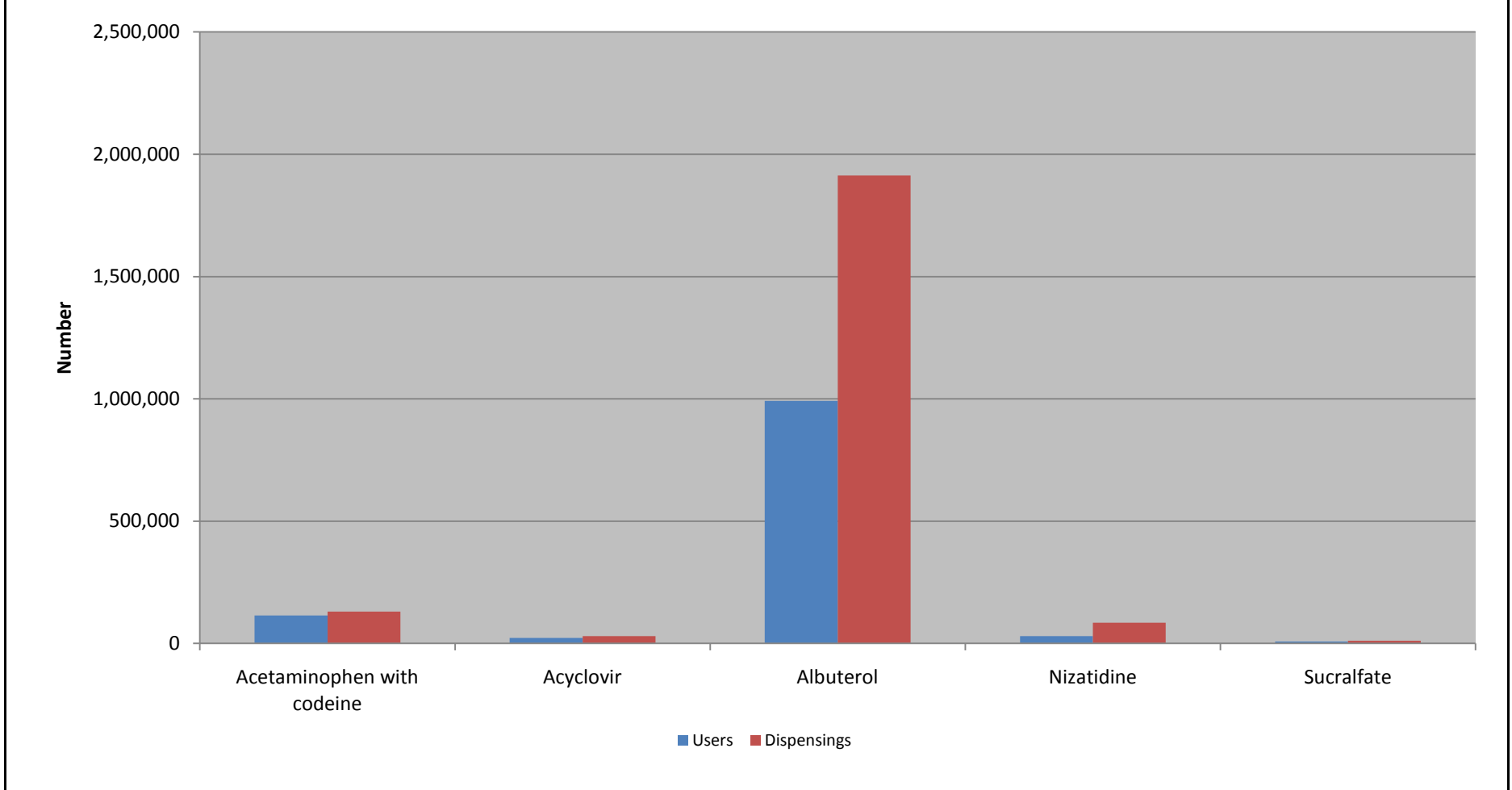


Figure 1a2. Prevalent Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplide per Dispensing among Children 0-2 Years between January 1, 2000 and December 31, 2011, by Drug Product

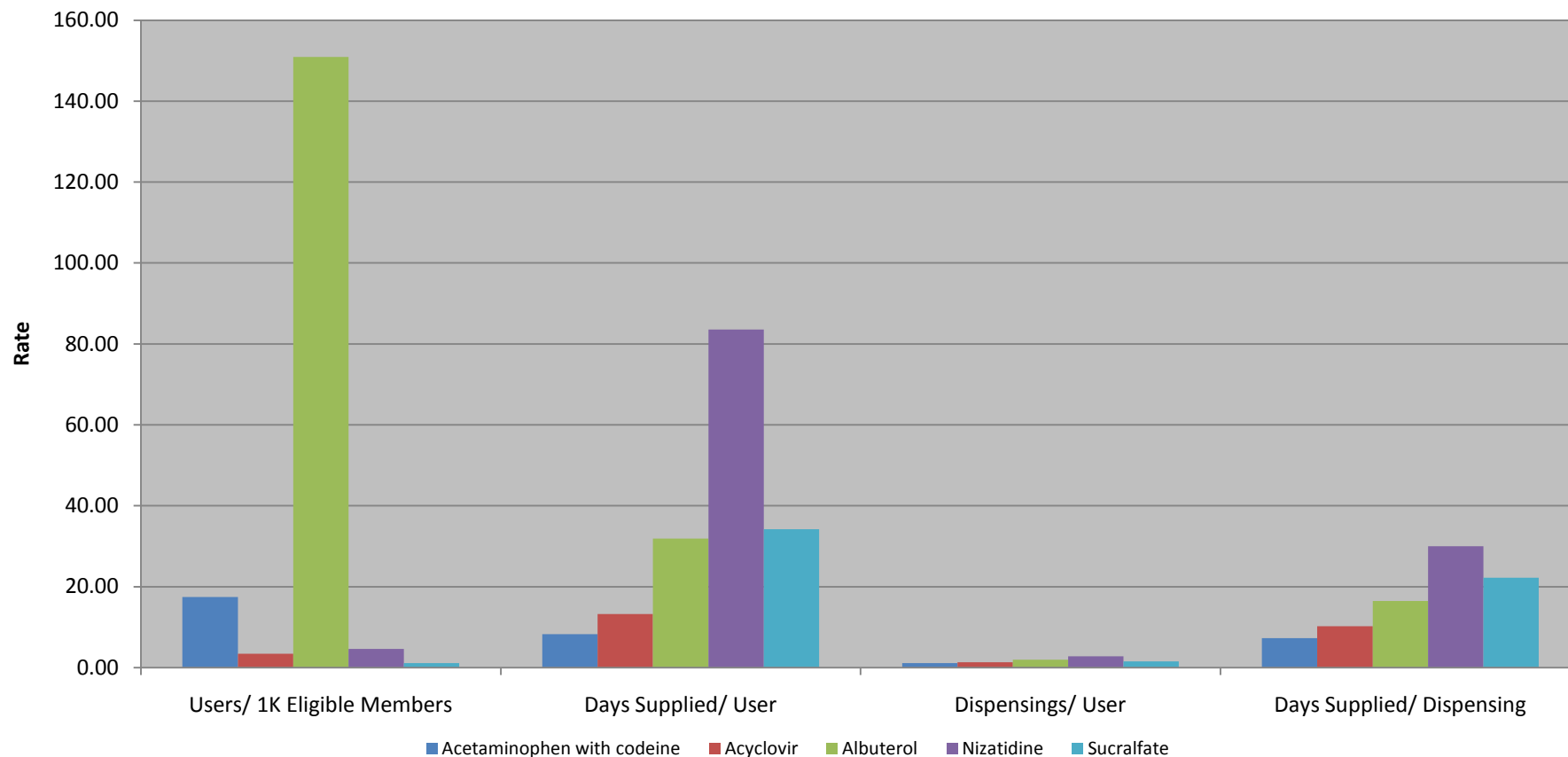


Table 1b. Summary of Incident Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine	114,683	114,683	130,505	948,714	6,556,089	2,445,956,184	17.49	8.27	1.14	7.27
Acyclovir	22,685	22,685	29,455	299,739	6,556,296	2,467,888,182	3.46	13.21	1.30	10.18
Albuterol	989,556	989,560	1,909,824	31,516,304	6,554,546	2,160,012,101	150.97	31.85	1.93	16.50
Nizatidine	30,496	30,496	84,960	2,548,670	6,556,285	2,460,334,582	4.65	83.57	2.79	30.00
Sucralfate	7,390	7,390	11,374	252,727	6,556,335	2,470,504,350	1.13	34.20	1.54	22.22

Figure 1b1. Number of New Users, New Starts, and Dispensings among Children 0-2 Years between January 1, 2000 and December 31, 2011, by Drug Product

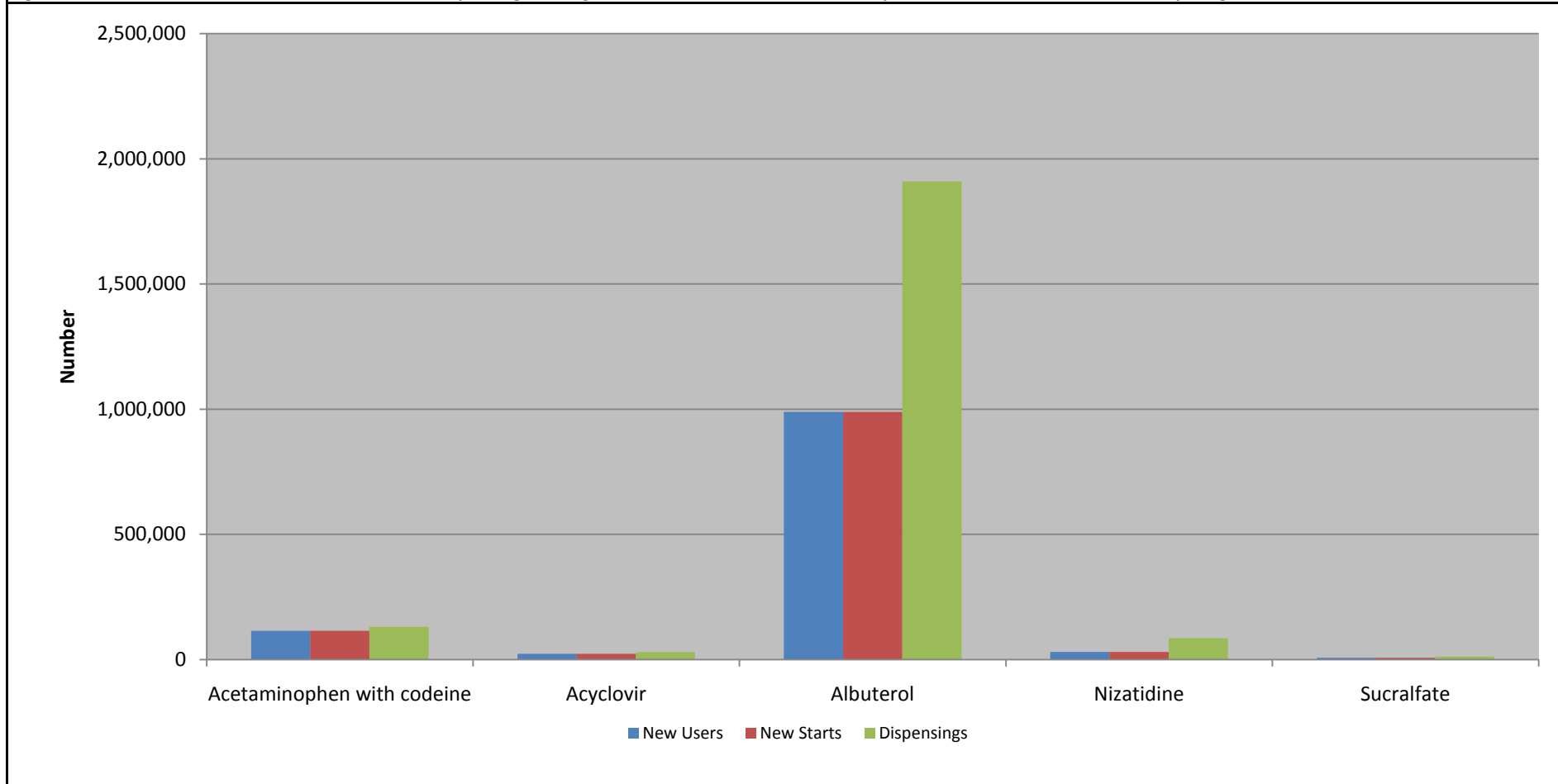


Figure 1b2. Incident Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplide per Dispensing among Children 0-2 Years between January 1, 2000 and December 31, 2011, by Drug Product

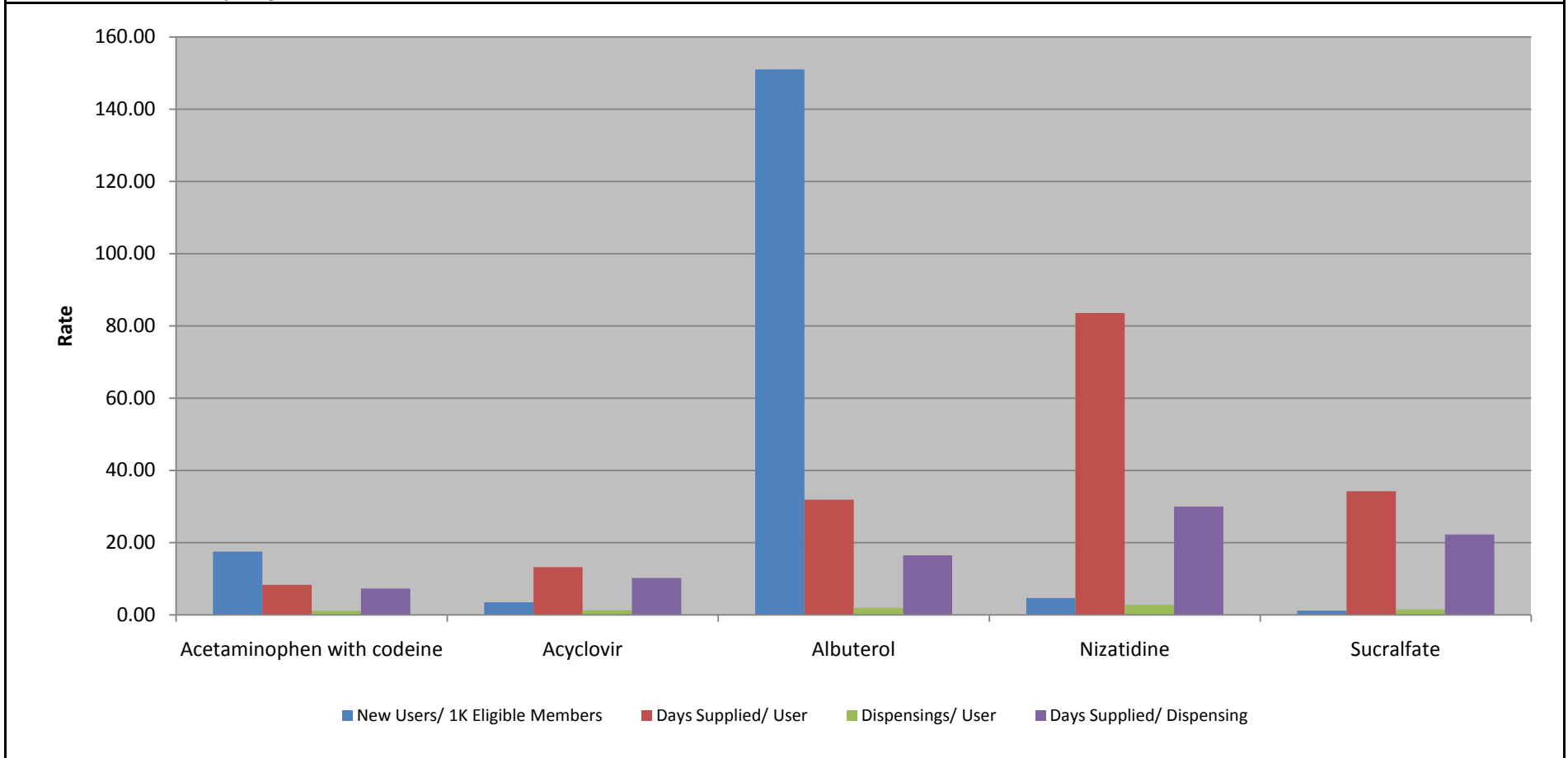


Table 2a. Summary of Prevalent Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Age Group

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine									
0 - < 1 Month	151	159	983	2,956,658	81,369,864	0.05	6.51	1.05	6.18
1 - < 3 Months	1,525	1,580	12,729	3,196,867	179,594,904	0.48	8.35	1.04	8.06
3 - < 6 Months	5,823	6,086	46,076	3,387,003	281,491,599	1.72	7.91	1.05	7.57
6 - < 12 Months	29,980	32,066	230,475	3,885,586	589,636,010	7.72	7.69	1.07	7.19
12 - < 24 Months	81,736	90,723	659,112	5,042,752	1,269,461,066	16.21	8.06	1.11	7.27
Acyclovir									
0 - < 1 Month	118	123	2,201	2,956,658	81,369,864	0.04	18.65	1.04	17.89
1 - < 3 Months	429	555	10,364	3,196,867	179,594,904	0.13	24.16	1.29	18.67
3 - < 6 Months	1,149	1,536	21,613	3,387,003	281,491,599	0.34	18.81	1.34	14.07
6 - < 12 Months	4,851	6,043	64,354	3,885,586	589,636,010	1.25	13.27	1.25	10.65
12 - < 24 Months	17,267	21,259	202,512	5,042,752	1,269,461,066	3.42	11.73	1.23	9.53
Albuterol									
0 - < 1 Month	2,977	3,132	53,096	2,956,658	81,369,864	1.01	17.84	1.05	16.95
1 - < 3 Months	60,688	70,898	1,162,856	3,196,867	179,594,904	18.98	19.16	1.17	16.40
3 - < 6 Months	215,178	278,493	4,518,711	3,387,003	281,491,599	63.53	21.00	1.29	16.23
6 - < 12 Months	411,551	592,926	9,700,910	3,885,586	589,636,010	105.92	23.57	1.44	16.36
12 - < 24 Months	592,152	968,282	16,148,481	5,042,752	1,269,461,066	117.43	27.27	1.64	16.68
Nizatidine									
0 - < 1 Month	3,392	3,437	104,034	2,956,658	81,369,864	1.15	30.67	1.01	30.27
1 - < 3 Months	16,729	23,721	709,894	3,196,867	179,594,904	5.23	42.43	1.42	29.93
3 - < 6 Months	14,461	26,957	807,635	3,387,003	281,491,599	4.27	55.85	1.86	29.96
6 - < 12 Months	9,223	21,982	661,267	3,885,586	589,636,010	2.37	71.70	2.38	30.08
12 - < 24 Months	3,440	9,032	270,920	5,042,752	1,269,461,066	0.68	78.76	2.63	30.00
Sucralfate									
0 - < 1 Month	193	201	4,659	2,956,658	81,369,864	0.07	24.14	1.04	23.18
1 - < 3 Months	1,565	1,906	47,911	3,196,867	179,594,904	0.49	30.61	1.22	25.14
3 - < 6 Months	1,774	2,438	62,328	3,387,003	281,491,599	0.52	35.13	1.37	25.57
6 - < 12 Months	1,980	2,787	63,531	3,885,586	589,636,010	0.51	32.09	1.41	22.80
12 - < 24 Months	3,010	4,050	74,434	5,042,752	1,269,461,066	0.60	24.73	1.35	18.38

Table 2b. Summary of Incident Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Age Group

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine										
0 - < 1 Month	146	152	146	958	2,931,761	78,320,612	0.05	6.56	1.00	6.56
1 - < 3 Months	1,518	1,573	1,518	12,673	3,190,802	179,177,597	0.48	8.35	1.00	8.35
3 - < 6 Months	5,718	5,958	5,718	44,904	3,379,790	280,665,915	1.69	7.85	1.00	7.85
6 - < 12 Months	29,200	31,074	29,200	222,643	3,873,611	585,467,920	7.54	7.62	1.00	7.62
12 - < 24 Months	78,101	85,580	78,101	620,362	5,002,426	1,244,886,655	15.61	7.94	1.00	7.94
Acyclovir										
0 - < 1 Month	113	118	113	2,066	2,931,759	78,320,457	0.04	18.28	1.00	18.28
1 - < 3 Months	383	474	383	7,787	3,190,777	179,196,988	0.12	20.33	1.00	20.33
3 - < 6 Months	1,017	1,219	1,017	13,300	3,380,777	280,926,327	0.30	13.08	1.00	13.08
6 - < 12 Months	4,592	5,327	4,592	48,511	3,878,770	588,282,955	1.18	10.56	1.00	10.56
12 - < 24 Months	16,580	19,615	16,580	174,686	5,030,183	1,263,485,112	3.30	10.54	1.00	10.54
Albuterol										
0 - < 1 Month	2,923	3,076	2,923	51,922	2,931,734	78,305,171	1.00	17.76	1.00	17.76
1 - < 3 Months	60,001	70,001	60,001	1,148,187	3,188,222	177,762,336	18.82	19.14	1.00	19.14
3 - < 6 Months	199,248	254,081	199,249	4,126,470	3,325,766	268,356,122	59.91	20.71	1.00	20.71
6 - < 12 Months	328,682	449,127	328,682	7,343,480	3,652,197	519,461,245	90.00	22.34	1.00	22.34
12 - < 24 Months	398,702	586,127	398,705	9,670,413	4,516,645	1,043,224,833	88.27	24.25	1.00	24.25
Nizatidine										
0 - < 1 Month	3,382	3,426	3,382	103,761	2,931,755	78,299,393	1.15	30.68	1.00	30.68
1 - < 3 Months	15,131	21,229	15,131	635,190	3,187,948	178,580,866	4.75	41.98	1.00	41.98
3 - < 6 Months	6,614	10,468	6,614	312,663	3,365,719	279,350,559	1.97	47.27	1.00	47.27
6 - < 12 Months	3,547	6,807	3,547	202,244	3,860,340	585,252,133	0.92	57.02	1.00	57.02
12 - < 24 Months	1,822	3,884	1,822	113,863	5,015,389	1,261,692,934	0.36	62.49	1.00	62.49
Sucralfate										
0 - < 1 Month	193	201	193	4,659	2,931,763	78,320,197	0.07	24.14	1.00	24.14
1 - < 3 Months	1,517	1,837	1,517	46,254	3,190,719	179,161,954	0.48	30.49	1.00	30.49
3 - < 6 Months	1,378	1,787	1,378	44,203	3,379,711	280,809,425	0.41	32.08	1.00	32.08
6 - < 12 Months	1,574	2,024	1,574	42,265	3,877,485	588,253,898	0.41	26.85	1.00	26.85
12 - < 24 Months	2,728	3,450	2,728	58,749	5,032,065	1,266,286,632	0.54	21.54	1.00	21.54

Table 3a. Summary of Prevalent Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Sex

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine									
Female	38,849	44,380	347,751	3,191,984	1,205,909,233	12.17	8.95	1.14	7.84
Male	75,594	85,848	599,561	3,363,179	1,268,443,013	22.48	7.93	1.14	6.98
Unknown	324	386	2,063	13,789	4,932,059	23.50	6.37	1.19	5.34
Acyclovir									
Female	10,813	13,892	140,733	3,191,984	1,205,909,233	3.39	13.02	1.28	10.13
Male	11,829	15,521	158,749	3,363,179	1,268,443,013	3.52	13.42	1.31	10.23
Unknown	69	103	1,562	13,789	4,932,059	5.00	22.64	1.49	15.17
Albuterol									
Female	406,967	739,217	12,230,488	3,191,984	1,205,909,233	127.50	30.05	1.82	16.55
Male	583,004	1,172,107	19,314,716	3,363,179	1,268,443,013	173.35	33.13	2.01	16.48
Unknown	1,404	2,407	38,850	13,789	4,932,059	101.82	27.67	1.71	16.14
Nizatidine									
Female	13,798	38,212	1,145,920	3,191,984	1,205,909,233	4.32	83.05	2.77	29.99
Male	16,705	46,798	1,404,254	3,363,179	1,268,443,013	4.97	84.06	2.80	30.01
Unknown	50	119	3,576	13,789	4,932,059	3.63	71.52	2.38	30.05
Sucralfate									
Female	3,267	4,927	108,774	3,191,984	1,205,909,233	1.02	33.29	1.51	22.08
Male	4,110	6,429	143,411	3,363,179	1,268,443,013	1.22	34.89	1.56	22.31
Unknown	20	26	678	13,789	4,932,059	1.45	33.90	1.30	26.08

Table 3b. Summary of Incident Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Sex

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine										
Female	38,810	38,810	44,329	347,420	3,185,861	1,194,133,526	12.18	8.95	1.14	7.84
Male	75,557	75,557	85,800	599,272	3,356,560	1,247,025,230	22.51	7.93	1.14	6.98
Unknown	316	316	376	2,022	13,668	4,797,428	23.12	6.40	1.19	5.38
Acyclovir										
Female	10,800	10,800	13,870	140,375	3,185,936	1,200,451,808	3.39	13.00	1.28	10.12
Male	11,820	11,820	15,508	158,489	3,356,626	1,262,539,935	3.52	13.41	1.31	10.22
Unknown	65	65	77	875	13,734	4,896,439	4.73	13.46	1.18	11.36
Albuterol										
Female	406,273	406,276	737,771	12,205,135	3,185,306	1,076,163,616	127.55	30.04	1.82	16.54
Male	581,951	581,952	1,169,788	19,275,313	3,355,700	1,079,415,532	173.42	33.12	2.01	16.48
Unknown	1,332	1,332	2,265	35,856	13,540	4,432,953	98.38	26.92	1.70	15.83
Nizatidine										
Female	13,773	13,773	38,140	1,143,789	3,185,932	1,197,103,712	4.32	83.05	2.77	29.99
Male	16,673	16,673	46,701	1,401,305	3,356,605	1,258,336,576	4.97	84.05	2.80	30.01
Unknown	50	50	119	3,576	13,748	4,894,294	3.64	71.52	2.38	30.05
Sucralfate										
Female	3,264	3,264	4,923	108,684	3,185,956	1,201,768,614	1.02	33.30	1.51	22.08
Male	4,106	4,106	6,425	143,365	3,356,632	1,263,824,134	1.22	34.92	1.56	22.31
Unknown	20	20	26	678	13,747	4,911,602	1.45	33.90	1.30	26.08

Table 4a. Summary of Prevalent Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine									
2000	5,469	6,286	61,099	394,966	84,928,063	13.85	11.17	1.15	9.72
2001	5,290	6,021	59,704	388,229	85,015,541	13.63	11.29	1.14	9.92
2002	5,299	6,014	57,946	372,681	81,020,143	14.22	10.94	1.13	9.64
2003	5,258	6,031	56,630	367,059	79,468,747	14.32	10.77	1.15	9.39
2004	10,581	11,648	71,898	862,331	175,714,902	12.27	6.80	1.10	6.17
2005	10,130	11,071	74,632	895,801	181,847,227	11.31	7.37	1.09	6.74
2006	10,546	11,628	81,317	942,754	192,873,839	11.19	7.71	1.10	6.99
2007	10,304	11,235	78,109	1,017,563	204,069,230	10.13	7.58	1.09	6.95
2008	17,371	18,737	123,995	1,951,597	387,598,710	8.90	7.14	1.08	6.62
2009	15,687	16,881	112,931	1,802,043	367,547,910	8.71	7.20	1.08	6.69
2010	13,263	14,385	98,066	1,639,760	335,077,502	8.09	7.39	1.08	6.82
2011	9,937	10,677	73,048	1,491,045	304,122,491	6.66	7.35	1.07	6.84
Acyclovir									
2000	582	727	10,164	394,966	84,928,063	1.47	17.46	1.25	13.98
2001	634	799	10,610	388,229	85,015,541	1.63	16.74	1.26	13.28
2002	698	887	11,367	372,681	81,020,143	1.87	16.29	1.27	12.82
2003	693	927	12,977	367,059	79,468,747	1.89	18.73	1.34	14.00
2004	1,882	2,375	21,199	862,331	175,714,902	2.18	11.26	1.26	8.93
2005	1,743	2,219	23,307	895,801	181,847,227	1.95	13.37	1.27	10.50
2006	1,966	2,471	24,915	942,754	192,873,839	2.09	12.67	1.26	10.08
2007	1,982	2,557	24,574	1,017,563	204,069,230	1.95	12.40	1.29	9.61
2008	3,813	4,674	44,798	1,951,597	387,598,710	1.95	11.75	1.23	9.58
2009	3,507	4,271	41,183	1,802,043	367,547,910	1.95	11.74	1.22	9.64
2010	3,369	4,227	42,129	1,639,760	335,077,502	2.05	12.50	1.25	9.97
2011	2,747	3,382	33,821	1,491,045	304,122,491	1.84	12.31	1.23	10.00

Table 4a. Summary of Prevalent Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Albuterol									
2000	50,515	84,885	1,666,195	394,966	84,928,063	127.90	32.98	1.68	19.63
2001	51,661	86,689	1,666,971	388,229	85,015,541	133.07	32.27	1.68	19.23
2002	49,376	82,893	1,587,637	372,681	81,020,143	132.49	32.15	1.68	19.15
2003	48,203	81,142	1,518,812	367,059	79,468,747	131.32	31.51	1.68	18.72
2004	88,241	141,211	2,208,495	862,331	175,714,902	102.33	25.03	1.60	15.64
2005	92,182	146,626	2,381,444	895,801	181,847,227	102.90	25.83	1.59	16.24
2006	97,275	153,596	2,503,155	942,754	192,873,839	103.18	25.73	1.58	16.30
2007	99,076	155,700	2,567,780	1,017,563	204,069,230	97.37	25.92	1.57	16.49
2008	176,787	273,414	4,295,503	1,951,597	387,598,710	90.59	24.30	1.55	15.71
2009	173,059	268,399	4,263,050	1,802,043	367,547,910	96.03	24.63	1.55	15.88
2010	154,186	237,765	3,780,261	1,639,760	335,077,502	94.03	24.52	1.54	15.90
2011	132,121	201,411	3,144,751	1,491,045	304,122,491	88.61	23.80	1.52	15.61
Nizatidine									
2000	0	0	0	394,966	84,928,063	0.00	---	---	---
2001	0	0	0	388,229	85,015,541	0.00	---	---	---
2002	1	1	14	372,681	81,020,143	0.00	14.00	1.00	14.00
2003	1	1	30	367,059	79,468,747	0.00	30.00	1.00	30.00
2004	44	60	1,709	862,331	175,714,902	0.05	38.84	1.36	28.48
2005	390	801	21,501	895,801	181,847,227	0.44	55.13	2.05	26.84
2006	2,323	5,187	156,607	942,754	192,873,839	2.46	67.42	2.23	30.19
2007	4,128	9,965	302,445	1,017,563	204,069,230	4.06	73.27	2.41	30.35
2008	10,259	25,160	748,852	1,951,597	387,598,710	5.26	72.99	2.45	29.76
2009	8,011	19,793	592,966	1,802,043	367,547,910	4.45	74.02	2.47	29.96
2010	5,651	14,122	426,324	1,639,760	335,077,502	3.45	75.44	2.50	30.19
2011	4,018	10,039	303,302	1,491,045	304,122,491	2.69	75.49	2.50	30.21

Table 4a. Summary of Prevalent Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Sucralfate									
2000	87	128	2,560	394,966	84,928,063	0.22	29.43	1.47	20.00
2001	90	126	2,702	388,229	85,015,541	0.23	30.02	1.40	21.44
2002	141	194	4,334	372,681	81,020,143	0.38	30.74	1.38	22.34
2003	191	295	6,173	367,059	79,468,747	0.52	32.32	1.54	20.93
2004	569	843	18,383	862,331	175,714,902	0.66	32.31	1.48	21.81
2005	440	660	14,757	895,801	181,847,227	0.49	33.54	1.50	22.36
2006	492	749	17,287	942,754	192,873,839	0.52	35.14	1.52	23.08
2007	636	903	20,097	1,017,563	204,069,230	0.63	31.60	1.42	22.26
2008	1,450	2,121	47,986	1,951,597	387,598,710	0.74	33.09	1.46	22.62
2009	1,328	1,881	41,655	1,802,043	367,547,910	0.74	31.37	1.42	22.15
2010	1,296	1,859	40,542	1,639,760	335,077,502	0.79	31.28	1.43	21.81
2011	1,099	1,623	36,387	1,491,045	304,122,491	0.74	33.11	1.48	22.42

Table 4b. Summary of Incident Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Acetaminophen with codeine										
2000	5,456	5,456	6,269	60,933	394,203	83,779,654	13.84	11.17	1.15	9.72
2001	4,982	4,982	5,596	56,125	384,470	83,551,478	12.96	11.27	1.12	10.03
2002	5,010	5,010	5,626	54,560	368,781	79,577,721	13.59	10.89	1.12	9.70
2003	4,921	4,921	5,516	52,305	363,224	78,068,777	13.55	10.63	1.12	9.48
2004	10,252	10,252	11,173	68,990	857,127	173,141,790	11.96	6.73	1.09	6.17
2005	9,679	9,679	10,511	70,372	888,162	179,016,865	10.90	7.27	1.09	6.70
2006	10,157	10,157	11,135	77,763	935,029	189,982,515	10.86	7.66	1.10	6.98
2007	9,845	9,845	10,636	73,235	1,008,985	201,111,566	9.76	7.44	1.08	6.89
2008	16,983	16,983	18,258	120,495	1,938,701	382,871,852	8.76	7.10	1.08	6.60
2009	15,127	15,127	16,212	108,376	1,789,796	362,974,156	8.45	7.16	1.07	6.68
2010	12,770	12,770	13,738	93,094	1,628,780	331,062,667	7.84	7.29	1.08	6.78
2011	9,501	9,501	10,121	69,072	1,482,084	300,817,143	6.41	7.27	1.07	6.82
Acyclovir										
2000	579	579	719	9,962	394,213	84,465,514	1.47	17.21	1.24	13.86
2001	610	610	729	8,805	387,367	84,695,109	1.57	14.43	1.20	12.08
2002	676	676	844	10,765	371,883	80,704,250	1.82	15.92	1.25	12.75
2003	652	652	776	9,993	366,231	79,143,074	1.78	15.33	1.19	12.88
2004	1,845	1,845	2,276	19,785	860,093	174,759,194	2.15	10.72	1.23	8.69
2005	1,648	1,648	2,008	19,594	893,328	181,011,456	1.84	11.89	1.22	9.76
2006	1,892	1,892	2,307	21,443	940,186	191,986,149	2.01	11.33	1.22	9.29
2007	1,882	1,882	2,354	21,219	1,014,508	203,113,472	1.86	11.27	1.25	9.01
2008	3,718	3,718	4,482	41,414	1,943,938	385,562,426	1.91	11.14	1.21	9.24
2009	3,373	3,373	3,984	36,419	1,797,856	365,988,026	1.88	10.80	1.18	9.14
2010	3,210	3,210	3,857	36,031	1,636,097	333,610,343	1.96	11.22	1.20	9.34
2011	2,600	2,600	3,091	29,497	1,488,147	302,849,169	1.75	11.35	1.19	9.54

Table 4b. Summary of Incident Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Albuterol										
2000	50,004	50,004	83,875	1,648,483	394,035	75,374,667	126.90	32.97	1.68	19.65
2001	40,021	40,021	63,752	1,239,916	355,030	70,538,643	112.73	30.98	1.59	19.45
2002	37,243	37,244	59,494	1,148,126	334,448	66,280,185	111.36	30.83	1.60	19.30
2003	36,501	36,501	58,333	1,092,034	330,323	65,525,844	110.50	29.92	1.60	18.72
2004	76,996	76,996	119,674	1,851,591	824,716	154,850,307	93.36	24.05	1.55	15.47
2005	73,205	73,205	110,862	1,793,649	834,445	157,151,921	87.73	24.50	1.51	16.18
2006	78,337	78,337	118,627	1,921,803	877,508	166,720,215	89.27	24.53	1.51	16.20
2007	78,296	78,297	117,091	1,915,734	946,360	177,286,555	82.73	24.47	1.50	16.36
2008	155,543	155,543	234,007	3,650,425	1,873,555	346,899,202	83.02	23.47	1.50	15.60
2009	138,410	138,410	205,437	3,238,831	1,686,301	320,973,454	82.08	23.40	1.48	15.77
2010	121,134	121,135	178,586	2,802,824	1,527,331	291,720,652	79.31	23.14	1.47	15.69
2011	103,866	103,867	151,733	2,343,674	1,392,758	266,690,456	74.58	22.56	1.46	15.45
Nizatidine										
2000	0	0	0	0	394,215	84,541,551	0.00	---	---	---
2001	0	0	0	0	387,703	84,846,758	0.00	---	---	---
2002	1	1	1	14	372,287	80,860,824	0.00	14.00	1.00	14.00
2003	1	1	1	30	366,695	79,310,442	0.00	30.00	1.00	30.00
2004	44	44	60	1,709	860,540	175,069,155	0.05	38.84	1.36	28.48
2005	376	376	745	20,096	894,438	181,359,007	0.42	53.45	1.98	26.97
2006	2,231	2,231	4,884	147,987	940,894	191,977,776	2.37	66.33	2.19	30.30
2007	3,681	3,681	8,514	258,219	1,013,690	202,404,875	3.63	70.15	2.31	30.33
2008	9,623	9,623	23,197	690,454	1,941,084	383,594,600	4.96	71.75	2.41	29.76
2009	6,598	6,598	15,414	460,393	1,790,967	363,222,601	3.68	69.78	2.34	29.87
2010	4,677	4,677	11,058	333,420	1,629,522	331,584,006	2.87	71.29	2.36	30.15
2011	3,264	3,264	7,687	231,311	1,483,997	301,562,987	2.20	70.87	2.36	30.09

Table 4b. Summary of Incident Drug Use among Children 0-2 Years in the MSDD between January 1, 2000 and December 31, 2011, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Sucralfate										
2000	87	87	128	2,560	394,215	84,527,782	0.22	29.43	1.47	20.00
2001	88	88	116	2,402	387,648	84,822,278	0.23	27.30	1.32	20.71
2002	136	136	183	4,084	372,215	80,828,916	0.37	30.03	1.35	22.32
2003	175	175	234	4,451	366,592	79,264,046	0.48	25.43	1.34	19.02
2004	555	555	813	17,619	860,368	174,946,584	0.65	31.75	1.46	21.67
2005	415	415	614	13,574	894,027	181,252,522	0.46	32.71	1.48	22.11
2006	464	464	686	15,597	940,832	192,256,752	0.49	33.61	1.48	22.74
2007	604	604	842	18,486	1,015,263	203,381,441	0.59	30.61	1.39	21.95
2008	1,401	1,401	2,025	45,203	1,944,631	385,908,033	0.72	32.26	1.45	22.32
2009	1,240	1,240	1,743	38,022	1,798,850	366,306,323	0.69	30.66	1.41	21.81
2010	1,204	1,204	1,646	34,458	1,636,942	333,923,825	0.74	28.62	1.37	20.93
2011	1,021	1,021	1,475	32,804	1,488,899	303,085,848	0.69	32.13	1.44	22.24

Appendix A. List of Ingredients included in each Drug Product Group in this Report

The drug product group "Acetaminophen with codeine" included all NDCs that contained ingredients of both acetaminophen and codeine.

The drug product group "Acyclovir" included all NDCs that contained ingredients of Acyclovir or Acyclovir Sodium.

The drug product group "Albuterol" included all NDCs that contained the ingredients Albuterol, Albuterol Sulfate, Levalbuterol HCL, or Levalbuterol Tartrate.

The drug product group "Nizatidine" included all NDCs that contained the ingredient Nizatidine.

The drug product group "Sucralfate" included all NDCs that contained the ingredient Sucralfate.