

Disclaimer

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 2 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 both medical and drug coverage was required. This is report 2 of 2. The first report contains results where only 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 both medical and 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.

Table of Contents

Glossary List of Terms Found in this Report and their Definitions

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

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

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

Figure 2b Incident 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 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

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

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

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

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

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

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)

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 | 111,363 | 126,417 | 941,812 | 6,527,209 | 6,869,628 | 17.06 | 8.46 | 1.14 | 7.45 |
| Acyclovir/acyclovir sodium | 21,079 | 26,786 | 275,316 | 6,527,209 | 6,869,628 | 3.23 | 13.06 | 1.27 | 10.28 |
| Albuterol/albuterol sulfate | 916,720 | 1,679,243 | 28,378,176 | 6,527,209 | 6,869,628 | 140.45 | 30.96 | 1.83 | 16.90 |
| Levalbuterol HCl/Levalbuterol tartrate | 149,362 | 281,339 | 4,342,037 | 6,527,209 | 6,869,628 | 22.88 | 29.07 | 1.88 | 15.43 |
| Nitazoxanide | 2,392 | 2,774 | 15,857 | 6,527,209 | 6,869,628 | 0.37 | 6.63 | 1.16 | 5.72 |
| Nizatidine | 33,402 | 94,299 | 2,851,120 | 6,527,209 | 6,869,628 | 5.12 | 85.36 | 2.82 | 30.23 |
| Oxycodone HCl | 5,171 | 6,058 | 44,890 | 6,527,209 | 6,869,628 | 0.79 | 8.68 | 1.17 | 7.41 |
| Sucralfate | 7,746 | 11,966 | 265,964 | 6,527,209 | 6,869,628 | 1.19 | 34.34 | 1.54 | 22.23 |

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

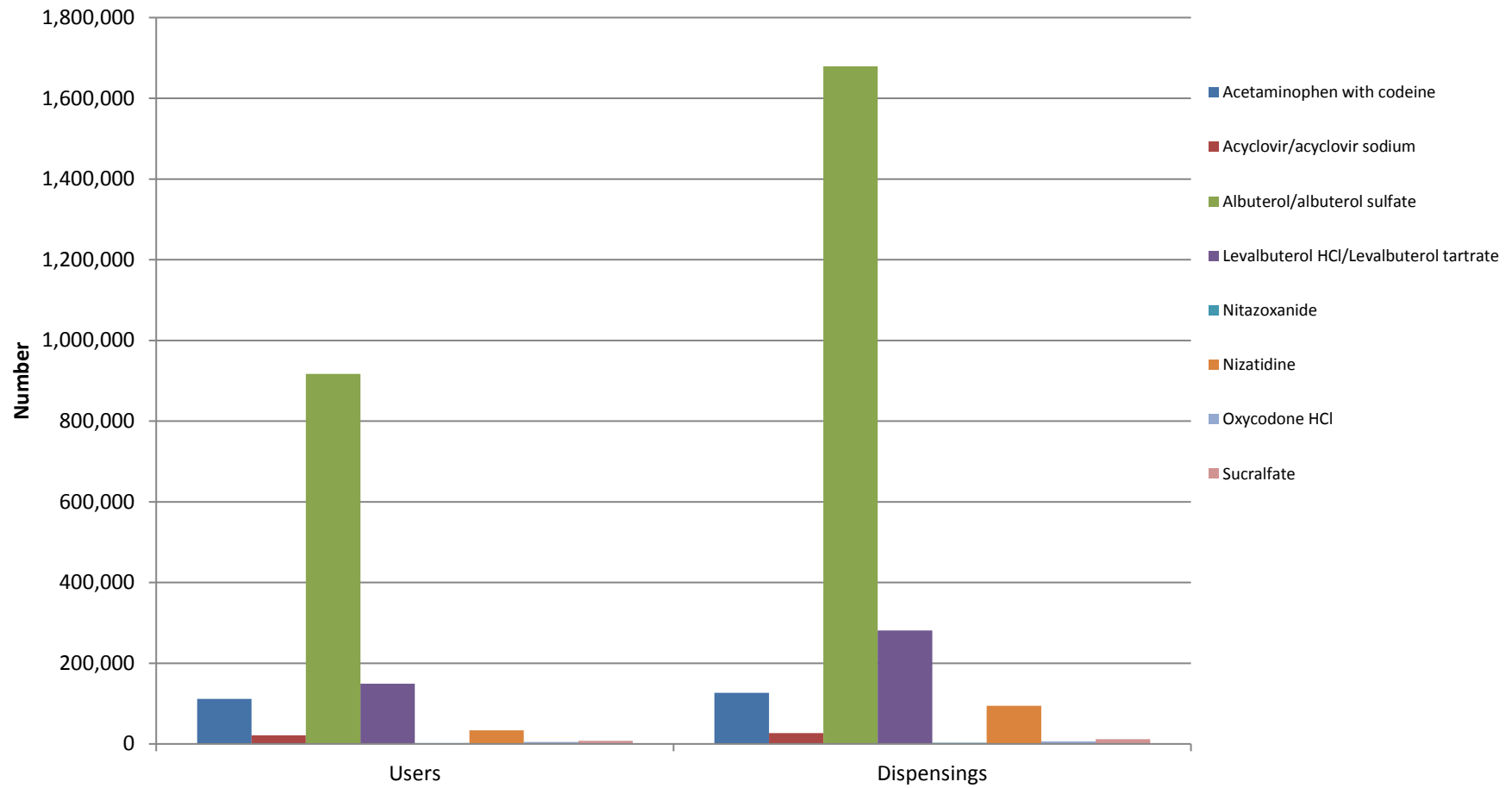


Figure 1b. Prevalent Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug Product

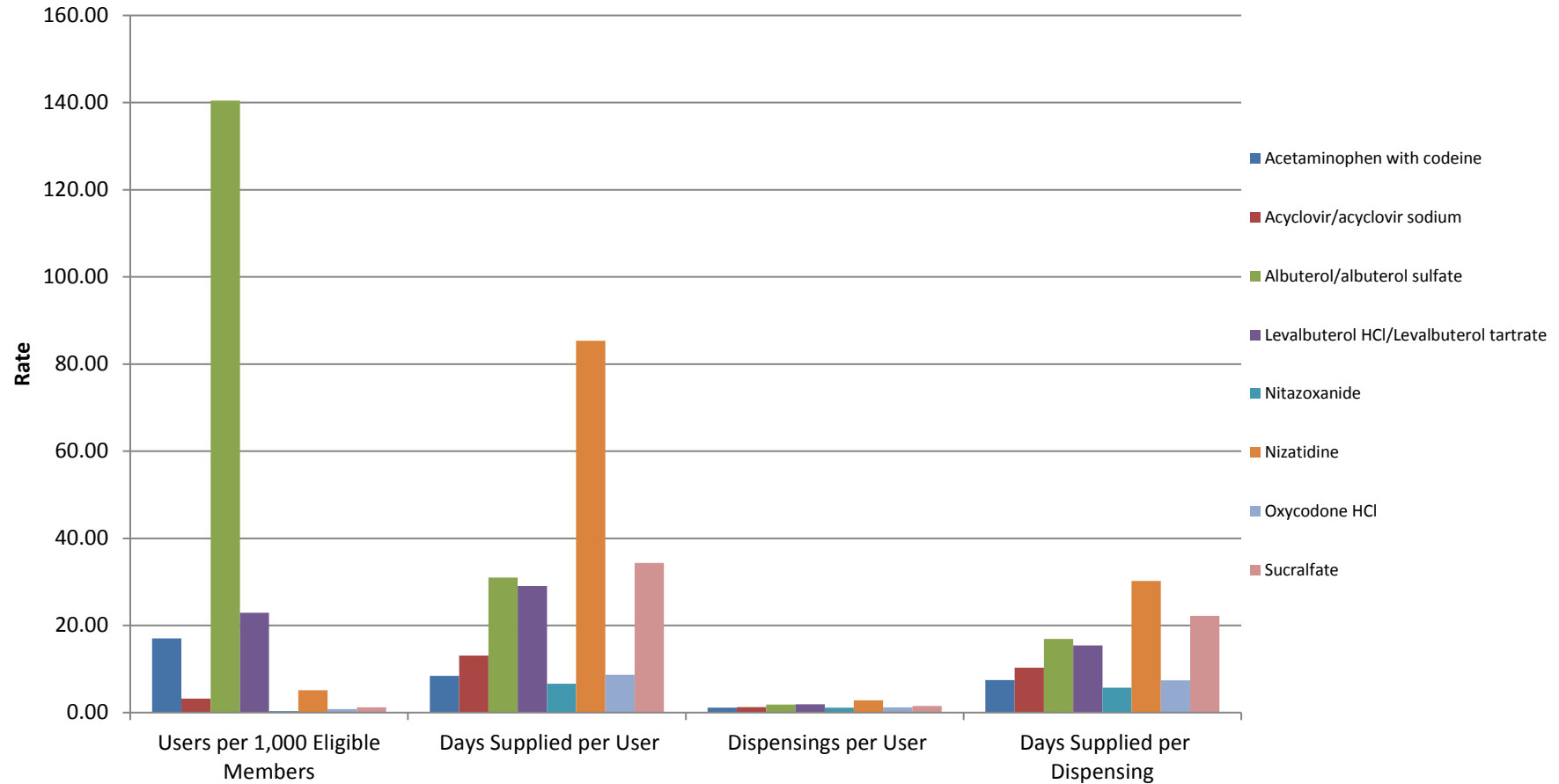


Table 2. Summary of Incident Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug

| | 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 | 111,297 | 126,342 | 941,265 | 6,515,303 | 6,780,451 | 17.08 | 8.46 | 1.14 | 7.45 |
| Acyclovir/acyclovir sodium | 21,057 | 26,755 | 274,863 | 6,515,391 | 6,839,540 | 3.23 | 13.05 | 1.27 | 10.27 |
| Albuterol/albuterol sulfate | 915,537 | 1,676,739 | 28,333,521 | 6,514,144 | 6,071,662 | 140.55 | 30.95 | 1.83 | 16.90 |
| Levalbuterol HCl/Levalbuterol tartrate | 149,178 | 280,907 | 4,334,675 | 6,515,213 | 6,717,332 | 22.90 | 29.06 | 1.88 | 15.43 |
| Nitazoxanide | 2,390 | 2,772 | 15,851 | 6,515,419 | 6,850,832 | 0.37 | 6.63 | 1.16 | 5.72 |
| Nizatidine | 33,342 | 94,103 | 2,845,212 | 6,515,353 | 6,814,133 | 5.12 | 85.33 | 2.82 | 30.24 |
| Oxycodone HCl | 5,162 | 6,014 | 44,055 | 6,515,386 | 6,848,616 | 0.79 | 8.53 | 1.17 | 7.33 |
| Sucralfate | 7,739 | 11,957 | 265,838 | 6,515,409 | 6,845,360 | 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

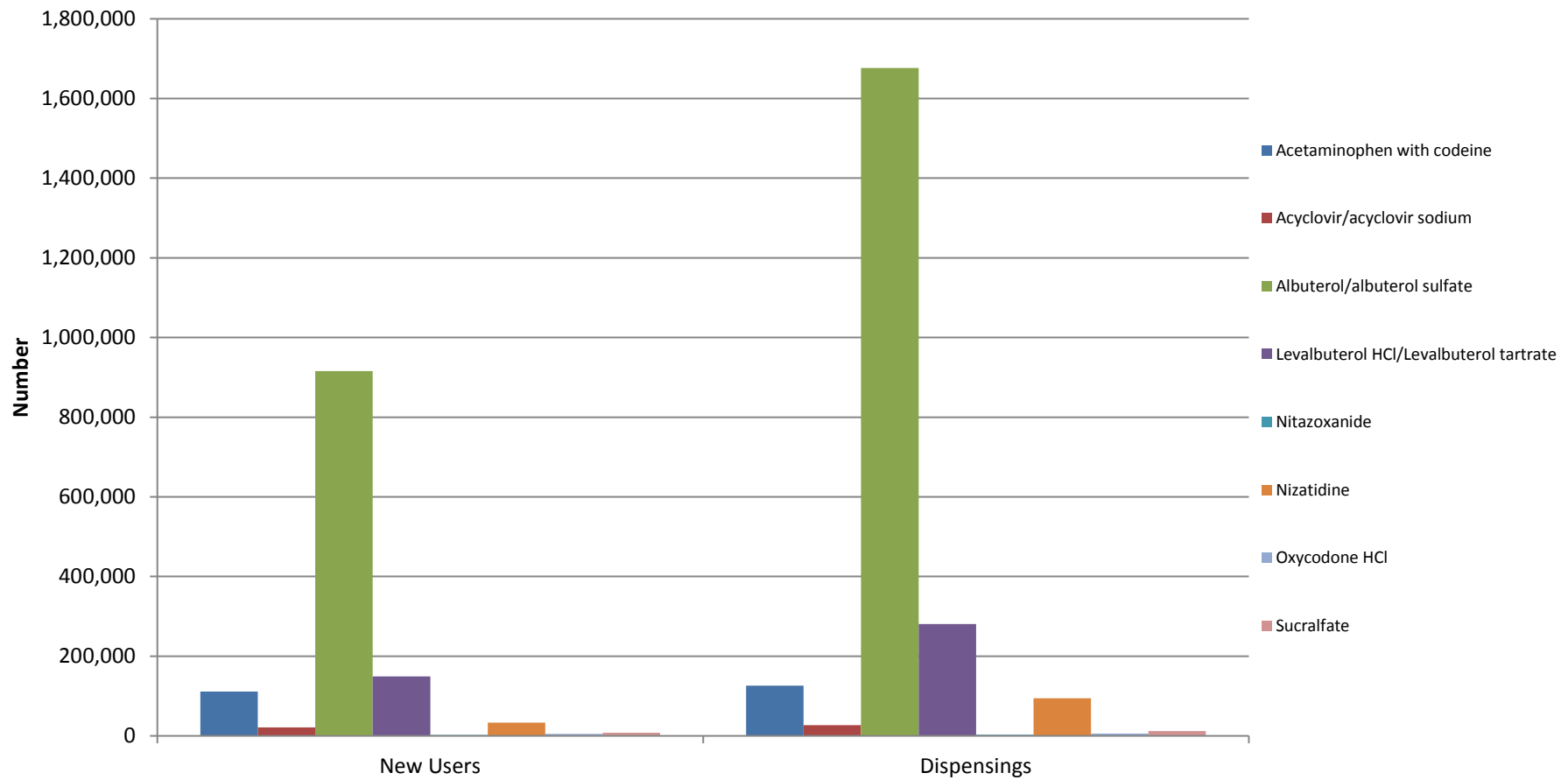


Figure 2b. Incident Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug Product

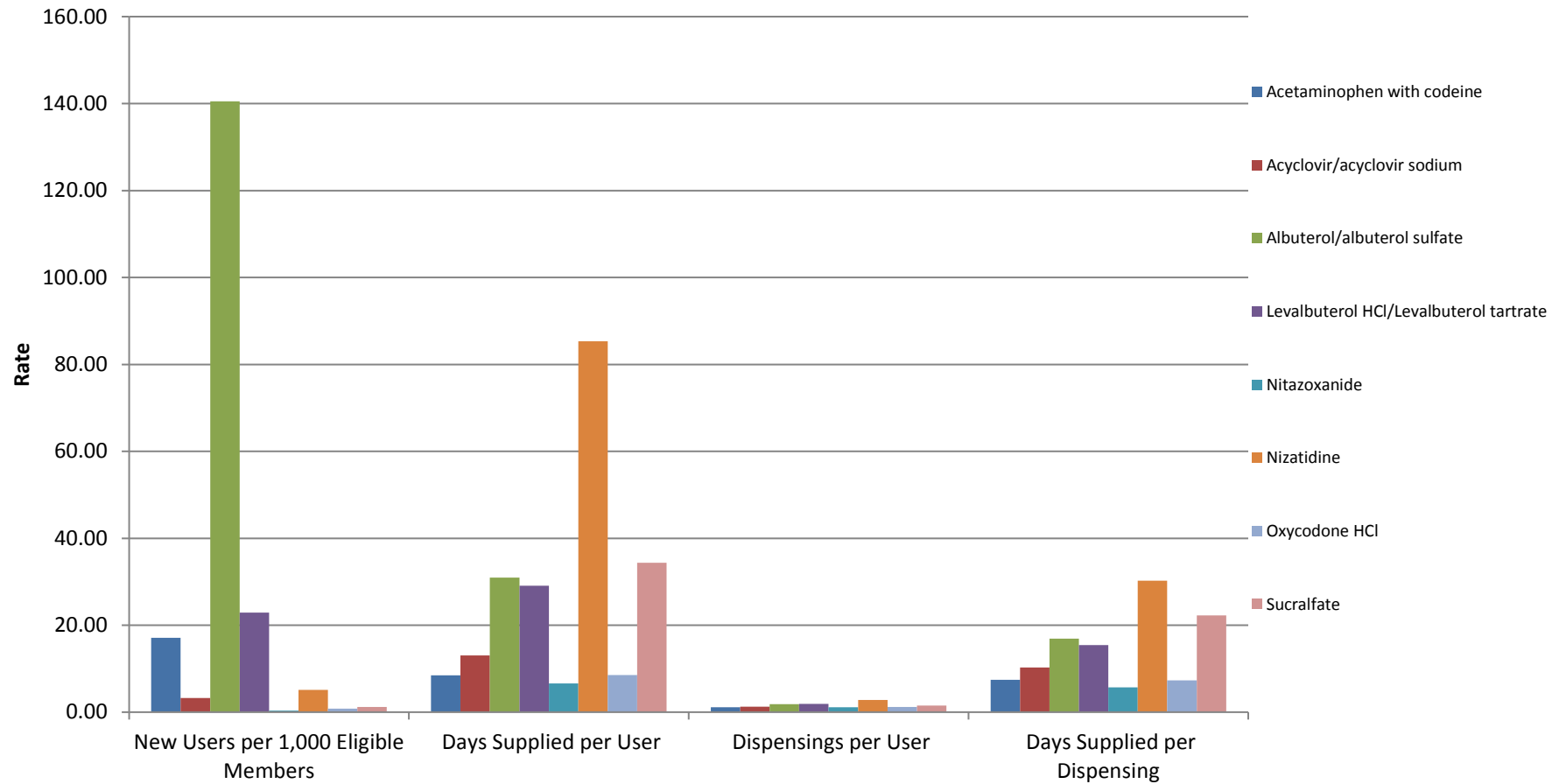


Table 3a. Summary of Prevalent Drug Use among Children 0-2 Years in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Drug and Age Group

| | Users | Dispensings | Total Days Supplied | Eligible Members | Member-Years | Users per 1,000 Eligible Members | Days Supplied per User | Dispensing per User | Days Supplied per Dispensing |
|---|---------|-------------|---------------------|------------------|--------------|----------------------------------|------------------------|---------------------|------------------------------|
| Acetaminophen with codeine | | | | | | | | | |
| 0 - < 12 Months | 35,609 | 38,730 | 288,363 | 4,711,366 | 3,179,640 | 7.56 | 8.10 | 1.09 | 7.45 |
| 0 - < 1 Month | 99 | 101 | 732 | 3,103,623 | 228,805 | 0.03 | 7.39 | 1.02 | 7.25 |
| 1 - < 3 Months | 1,490 | 1,544 | 12,797 | 3,327,518 | 499,893 | 0.45 | 8.59 | 1.04 | 8.29 |
| 3 - < 6 Months | 5,668 | 5,934 | 45,679 | 3,504,248 | 779,831 | 1.62 | 8.06 | 1.05 | 7.70 |
| 6 - < 12 Months | 29,171 | 31,151 | 229,155 | 4,191,283 | 1,725,293 | 6.96 | 7.86 | 1.07 | 7.36 |
| 12 - < 24 Months | 79,184 | 87,687 | 653,449 | 5,018,598 | 3,493,643 | 15.78 | 8.25 | 1.11 | 7.45 |
| Acyclovir/acyclovir sodium | | | | | | | | | |
| 0 - < 12 Months | 5,647 | 7,606 | 95,073 | 4,711,366 | 3,179,640 | 1.20 | 16.84 | 1.35 | 12.50 |
| 0 - < 1 Month | 112 | 114 | 2,238 | 3,103,623 | 228,805 | 0.04 | 19.98 | 1.02 | 19.63 |
| 1 - < 3 Months | 424 | 566 | 11,137 | 3,327,518 | 499,893 | 0.13 | 26.27 | 1.33 | 19.68 |
| 3 - < 6 Months | 1,079 | 1,462 | 22,713 | 3,504,248 | 779,831 | 0.31 | 21.05 | 1.35 | 15.54 |
| 6 - < 12 Months | 4,488 | 5,464 | 58,985 | 4,191,283 | 1,725,293 | 1.07 | 13.14 | 1.22 | 10.80 |
| 12 - < 24 Months | 16,026 | 19,180 | 180,243 | 5,018,598 | 3,493,643 | 3.19 | 11.25 | 1.20 | 9.40 |
| Albuterol/albuterol sulfate | | | | | | | | | |
| 0 - < 12 Months | 535,326 | 815,490 | 13,682,219 | 4,711,366 | 3,179,640 | 113.62 | 25.56 | 1.52 | 16.78 |
| 0 - < 1 Month | 2,329 | 2,435 | 43,834 | 3,103,623 | 228,805 | 0.75 | 18.82 | 1.05 | 18.00 |
| 1 - < 3 Months | 50,295 | 57,340 | 982,968 | 3,327,518 | 499,893 | 15.11 | 19.54 | 1.14 | 17.14 |
| 3 - < 6 Months | 189,266 | 237,575 | 3,972,095 | 3,504,248 | 779,831 | 54.01 | 20.99 | 1.26 | 16.72 |
| 6 - < 12 Months | 372,290 | 518,140 | 8,683,322 | 4,191,283 | 1,725,293 | 88.82 | 23.32 | 1.39 | 16.76 |
| 12 - < 24 Months | 547,398 | 863,753 | 14,695,957 | 5,018,598 | 3,493,643 | 109.07 | 26.85 | 1.58 | 17.01 |
| Levalbuterol HCl/Levalbuterol tartrate | | | | | | | | | |
| 0 - < 12 Months | 93,099 | 148,816 | 2,239,337 | 4,711,366 | 3,179,640 | 19.76 | 24.05 | 1.60 | 15.05 |
| 0 - < 1 Month | 673 | 701 | 9,894 | 3,103,623 | 228,805 | 0.22 | 14.70 | 1.04 | 14.11 |
| 1 - < 3 Months | 12,181 | 14,217 | 206,183 | 3,327,518 | 499,893 | 3.66 | 16.93 | 1.17 | 14.50 |
| 3 - < 6 Months | 35,635 | 46,145 | 684,566 | 3,504,248 | 779,831 | 10.17 | 19.21 | 1.29 | 14.84 |
| 6 - < 12 Months | 61,024 | 87,753 | 1,338,694 | 4,191,283 | 1,725,293 | 14.56 | 21.94 | 1.44 | 15.26 |
| 12 - < 24 Months | 81,754 | 132,523 | 2,102,700 | 5,018,598 | 3,493,643 | 16.29 | 25.72 | 1.62 | 15.87 |

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 | Dispensing per User | Days Supplied per Dispensing |
|----------------------|--------|-------------|---------------------|------------------|--------------|----------------------------------|------------------------|---------------------|------------------------------|
| Nitazoxanide | | | | | | | | | |
| 0 - < 12 Months | 429 | 470 | 2,989 | 4,711,366 | 3,179,640 | 0.09 | 6.97 | 1.10 | 6.36 |
| 0 - < 1 Month | 0 | 0 | 0 | 3,103,623 | 228,805 | 0.00 | --- | --- | --- |
| 1 - < 3 Months | 23 | 24 | 191 | 3,327,518 | 499,893 | 0.01 | 8.30 | 1.04 | 7.96 |
| 3 - < 6 Months | 63 | 68 | 543 | 3,504,248 | 779,831 | 0.02 | 8.62 | 1.08 | 7.99 |
| 6 - < 12 Months | 352 | 378 | 2,255 | 4,191,283 | 1,725,293 | 0.08 | 6.41 | 1.07 | 5.97 |
| 12 - < 24 Months | 1,990 | 2,304 | 12,868 | 5,018,598 | 3,493,643 | 0.40 | 6.47 | 1.16 | 5.59 |
| Nizatidine | | | | | | | | | |
| 0 - < 12 Months | 31,436 | 84,232 | 2,545,876 | 4,711,366 | 3,179,640 | 6.67 | 80.99 | 2.68 | 30.22 |
| 0 - < 1 Month | 3,761 | 3,809 | 116,728 | 3,103,623 | 228,805 | 1.21 | 31.04 | 1.01 | 30.65 |
| 1 - < 3 Months | 18,442 | 26,275 | 793,359 | 3,327,518 | 499,893 | 5.54 | 43.02 | 1.42 | 30.19 |
| 3 - < 6 Months | 15,858 | 29,873 | 901,342 | 3,504,248 | 779,831 | 4.53 | 56.84 | 1.88 | 30.17 |
| 6 - < 12 Months | 10,103 | 24,275 | 734,447 | 4,191,283 | 1,725,293 | 2.41 | 72.70 | 2.40 | 30.26 |
| 12 - < 24 Months | 3,793 | 10,067 | 305,244 | 5,018,598 | 3,493,643 | 0.76 | 80.48 | 2.65 | 30.32 |
| Oxycodone HCl | | | | | | | | | |
| 0 - < 12 Months | 2,528 | 2,851 | 20,622 | 4,711,366 | 3,179,640 | 0.54 | 8.16 | 1.13 | 7.23 |
| 0 - < 1 Month | 118 | 126 | 770 | 3,103,623 | 228,805 | 0.04 | 6.53 | 1.07 | 6.11 |
| 1 - < 3 Months | 218 | 234 | 1,816 | 3,327,518 | 499,893 | 0.07 | 8.33 | 1.07 | 7.76 |
| 3 - < 6 Months | 667 | 715 | 5,364 | 3,504,248 | 779,831 | 0.19 | 8.04 | 1.07 | 7.50 |
| 6 - < 12 Months | 1,617 | 1,776 | 12,672 | 4,191,283 | 1,725,293 | 0.39 | 7.84 | 1.10 | 7.14 |
| 12 - < 24 Months | 2,791 | 3,207 | 24,268 | 5,018,598 | 3,493,643 | 0.56 | 8.70 | 1.15 | 7.57 |
| Sucralfate | | | | | | | | | |
| 0 - < 12 Months | 4,881 | 7,657 | 186,578 | 4,711,366 | 3,179,640 | 1.04 | 38.23 | 1.57 | 24.37 |
| 0 - < 1 Month | 205 | 213 | 4,837 | 3,103,623 | 228,805 | 0.07 | 23.60 | 1.04 | 22.71 |
| 1 - < 3 Months | 1,655 | 2,011 | 50,553 | 3,327,518 | 499,893 | 0.50 | 30.55 | 1.22 | 25.14 |
| 3 - < 6 Months | 1,855 | 2,543 | 65,227 | 3,504,248 | 779,831 | 0.53 | 35.16 | 1.37 | 25.65 |
| 6 - < 12 Months | 2,050 | 2,890 | 65,961 | 4,191,283 | 1,725,293 | 0.49 | 32.18 | 1.41 | 22.82 |
| 12 - < 24 Months | 3,181 | 4,309 | 79,386 | 5,018,598 | 3,493,643 | 0.63 | 24.96 | 1.35 | 18.42 |

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 | Dispensings per User | Days Supplied per Dispensing |
|---|-----------|------------|-------------|---------------------|------------------|--------------|----------------------------------|------------------------|----------------------|------------------------------|
| Acetaminophen with codeine | | | | | | | | | | |
| 0 - < 12 Months | 35,587 | 35,587 | 38,707 | 288,111 | 4,702,381 | 3,156,691 | 7.57 | 8.10 | 1.09 | 7.44 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 75,710 | 75,710 | 82,806 | 615,609 | 4,979,581 | 3,428,065 | 15.20 | 8.13 | 1.09 | 7.43 |
| Acyclovir/acyclovir sodium | | | | | | | | | | |
| 0 - < 12 Months | 5,640 | 5,640 | 7,590 | 94,764 | 4,702,404 | 3,165,056 | 1.20 | 16.80 | 1.35 | 12.49 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 15,417 | 15,417 | 17,675 | 153,147 | 5,006,873 | 3,478,266 | 3.08 | 9.93 | 1.15 | 8.66 |
| Albuterol/albuterol sulfate | | | | | | | | | | |
| 0 - < 12 Months | 534,631 | 534,631 | 814,309 | 13,660,589 | 4,701,767 | 2,964,528 | 113.71 | 25.55 | 1.52 | 16.78 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 380,906 | 380,906 | 545,138 | 9,184,872 | 4,543,319 | 2,922,628 | 83.84 | 24.11 | 1.43 | 16.85 |
| Levalbuterol HCl/Levalbuterol tartrate | | | | | | | | | | |
| 0 - < 12 Months | 92,992 | 92,992 | 148,625 | 2,236,179 | 4,702,317 | 3,128,261 | 19.78 | 24.05 | 1.60 | 15.05 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 56,186 | 56,186 | 82,514 | 1,279,487 | 4,929,619 | 3,394,715 | 11.40 | 22.77 | 1.47 | 15.51 |

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 | Dispensings per User | Days Supplied per Dispensing |
|----------------------|-----------|------------|-------------|---------------------|------------------|--------------|----------------------------------|------------------------|----------------------|------------------------------|
| Nitazoxanide | | | | | | | | | | |
| 0 - < 12 Months | 429 | 429 | 470 | 2,989 | 4,702,415 | 3,166,521 | 0.09 | 6.97 | 1.10 | 6.36 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 1,961 | 1,961 | 2,266 | 12,627 | 5,011,559 | 3,487,969 | 0.39 | 6.44 | 1.16 | 5.57 |
| Nizatidine | | | | | | | | | | |
| 0 - < 12 Months | 31,382 | 31,382 | 84,068 | 2,540,932 | 4,702,360 | 3,148,804 | 6.67 | 80.97 | 2.68 | 30.22 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 1,960 | 1,960 | 4,249 | 125,961 | 4,989,511 | 3,470,517 | 0.39 | 64.27 | 2.17 | 29.64 |
| Oxycodone HCl | | | | | | | | | | |
| 0 - < 12 Months | 2,519 | 2,519 | 2,823 | 20,094 | 4,702,398 | 3,165,868 | 0.54 | 7.98 | 1.12 | 7.12 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 2,643 | 2,643 | 2,964 | 21,496 | 5,009,989 | 3,486,554 | 0.53 | 8.13 | 1.12 | 7.25 |
| Sucralfate | | | | | | | | | | |
| 0 - < 12 Months | 4,878 | 4,878 | 7,653 | 186,544 | 4,702,411 | 3,164,361 | 1.04 | 38.24 | 1.57 | 24.38 |
| 0 - < 1 Month | | | | | | | | | | |
| 1 - < 3 Months | | | | | | | | | | |
| 3 - < 6 Months | | | | | | | | | | |
| 6 - < 12 Months | | | | | | | | | | |
| 12 - < 24 Months | 2,861 | 2,861 | 3,602 | 60,944 | 5,008,120 | 3,484,823 | 0.57 | 21.30 | 1.26 | 16.92 |

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 1,000 Eligible Members | Days Supplied per User | Dispensings per User | Days Supplied per Dispensing |
|---|---------|-------------|---------------------|------------------|--------------|----------------------------------|------------------------|----------------------|------------------------------|
| Acetaminophen with codeine | | | | | | | | | |
| Female | 37,534 | 42,780 | 344,061 | 3,176,974 | 3,347,114 | 11.81 | 9.17 | 1.14 | 8.04 |
| Male | 73,823 | 83,631 | 597,718 | 3,349,746 | 3,522,105 | 22.04 | 8.10 | 1.13 | 7.15 |
| Unknown | 6 | 6 | 33 | 489 | 409 | 12.27 | 5.50 | 1.00 | 5.50 |
| Acyclovir | | | | | | | | | |
| Female | 10,003 | 12,580 | 128,691 | 3,176,974 | 3,347,114 | 3.15 | 12.87 | 1.26 | 10.23 |
| Male | 11,074 | 14,204 | 146,611 | 3,349,746 | 3,522,105 | 3.31 | 13.24 | 1.28 | 10.32 |
| Unknown | 2 | 2 | 14 | 489 | 409 | 4.09 | 7.00 | 1.00 | 7.00 |
| Albuterol | | | | | | | | | |
| Female | 376,166 | 650,360 | 11,015,918 | 3,176,974 | 3,347,114 | 118.40 | 29.28 | 1.73 | 16.94 |
| Male | 540,516 | 1,028,813 | 17,361,149 | 3,349,746 | 3,522,105 | 161.36 | 32.12 | 1.90 | 16.87 |
| Unknown | 38 | 70 | 1,109 | 489 | 409 | 77.71 | 29.18 | 1.84 | 15.84 |
| Levalbuterol HCl/Levalbuterol tartrate | | | | | | | | | |
| Female | 60,480 | 108,429 | 1,677,289 | 3,176,974 | 3,347,114 | 19.04 | 27.73 | 1.79 | 15.47 |
| Male | 88,872 | 172,894 | 2,664,460 | 3,349,746 | 3,522,105 | 26.53 | 29.98 | 1.95 | 15.41 |
| Unknown | 10 | 16 | 288 | 489 | 409 | 20.45 | 28.80 | 1.60 | 18.00 |
| Nitazoxanide | | | | | | | | | |
| Female | 1,025 | 1,192 | 6,688 | 3,176,974 | 3,347,114 | 0.32 | 6.52 | 1.16 | 5.61 |
| Male | 1,367 | 1,582 | 9,169 | 3,349,746 | 3,522,105 | 0.41 | 6.71 | 1.16 | 5.80 |
| Unknown | 0 | 0 | 0 | 489 | 409 | 0.00 | --- | --- | --- |
| Nizatidine | | | | | | | | | |
| Female | 15,148 | 42,515 | 1,284,571 | 3,176,974 | 3,347,114 | 4.77 | 84.80 | 2.81 | 30.21 |
| Male | 18,245 | 51,766 | 1,565,958 | 3,349,746 | 3,522,105 | 5.45 | 85.83 | 2.84 | 30.25 |
| Unknown | 9 | 18 | 591 | 489 | 409 | 18.40 | 65.67 | 2.00 | 32.83 |
| Oxycodone HCl | | | | | | | | | |
| Female | 1,729 | 2,097 | 16,923 | 3,176,974 | 3,347,114 | 0.54 | 9.79 | 1.21 | 8.07 |
| Male | 3,442 | 3,961 | 27,967 | 3,349,746 | 3,522,105 | 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 1,000 Eligible Members | Days Supplied per User | Dispensings per User | Days Supplied per Dispensing |
|-------------------|-------|-------------|---------------------|------------------|--------------|----------------------------------|------------------------|----------------------|------------------------------|
| Sucralfate | | | | | | | | | |
| Female | 3,467 | 5,228 | 115,436 | 3,176,974 | 3,347,114 | 1.09 | 33.30 | 1.51 | 22.08 |
| Male | 4,279 | 6,738 | 150,528 | 3,349,746 | 3,522,105 | 1.28 | 35.18 | 1.57 | 22.34 |
| 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 | 37,502 | 37,502 | 42,743 | 343,723 | 3,171,249 | 3315816 | 11.83 | 9.17 | 1.14 | 8.04 |
| Male | 73,789 | 73,789 | 83,593 | 597,509 | 3,343,565 | 3464229 | 22.07 | 8.10 | 1.13 | 7.15 |
| Unknown | 6 | 6 | 6 | 33 | 489 | 406 | 12.27 | 5.50 | 1.00 | 5.50 |
| Acyclovir | | | | | | | | | | |
| Female | 9,987 | 9,987 | 12,555 | 128,281 | 3,171,293 | 3332684 | 3.15 | 12.84 | 1.26 | 10.22 |
| Male | 11,068 | 11,068 | 14,198 | 146,568 | 3,343,609 | 3506448 | 3.31 | 13.24 | 1.28 | 10.32 |
| Unknown | 2 | 2 | 2 | 14 | 489 | 407 | 4.09 | 7.00 | 1.00 | 7.00 |
| Albuterol | | | | | | | | | | |
| Female | 375,707 | 375,707 | 649,335 | 10,997,097 | 3,170,807 | 3022994 | 118.49 | 29.27 | 1.73 | 16.94 |
| Male | 539,792 | 539,792 | 1,027,334 | 17,335,315 | 3,342,848 | 3048289 | 161.48 | 32.11 | 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 | 60,419 | 60,419 | 108,304 | 1,675,233 | 3,171,241 | 3284285 | 19.05 | 27.73 | 1.79 | 15.47 |
| Male | 88,749 | 88,749 | 172,587 | 2,659,154 | 3,343,483 | 3432645 | 26.54 | 29.96 | 1.94 | 15.41 |
| Unknown | 10 | 10 | 16 | 288 | 489 | 402 | 20.45 | 28.80 | 1.60 | 18.00 |
| Nitazoxanide | | | | | | | | | | |
| Female | 1,023 | 1,023 | 1,190 | 6,682 | 3,171,308 | 3338022 | 0.32 | 6.53 | 1.16 | 5.62 |
| Male | 1,367 | 1,367 | 1,582 | 9,169 | 3,343,622 | 3512402 | 0.41 | 6.71 | 1.16 | 5.80 |
| Unknown | 0 | 0 | 0 | 0 | 489 | 408 | 0.00 | --- | --- | --- |
| Nizatidine | | | | | | | | | | |
| Female | 15,123 | 15,123 | 42,435 | 1,282,230 | 3,171,281 | 3321287 | 4.77 | 84.79 | 2.81 | 30.22 |
| Male | 18,210 | 18,210 | 51,650 | 1,562,391 | 3,343,583 | 3492448 | 5.45 | 85.80 | 2.84 | 30.25 |
| Unknown | 9 | 9 | 18 | 591 | 489 | 397 | 18.40 | 65.67 | 2.00 | 32.83 |
| Oxycodone HCl | | | | | | | | | | |
| Female | 1,723 | 1,723 | 2,065 | 16,264 | 3,171,285 | 3337453 | 0.54 | 9.44 | 1.20 | 7.88 |
| Male | 3,439 | 3,439 | 3,949 | 27,791 | 3,343,612 | 3510755 | 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 | 3,464 | 3,464 | 5,223 | 115,356 | 3,171,307 | 3335635 | 1.09 | 33.30 | 1.51 | 22.09 |
| Male | 4,275 | 4,275 | 6,734 | 150,482 | 3,343,613 | 3509318 | 1.28 | 35.20 | 1.58 | 22.35 |
| 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 | 9,967 | 10,995 | 81,731 | 866,997 | 490,388 | 11.50 | 8.20 | 1.10 | 7.43 |
| 2007 | 9,769 | 10,641 | 76,570 | 938,481 | 519,735 | 10.41 | 7.84 | 1.09 | 7.20 |
| 2008 | 17,470 | 18,829 | 124,776 | 1,881,177 | 1,033,764 | 9.29 | 7.14 | 1.08 | 6.63 |
| 2009 | 15,699 | 16,896 | 113,015 | 1,764,019 | 986,151 | 8.90 | 7.20 | 1.08 | 6.69 |
| 2010 | 13,452 | 14,574 | 98,947 | 1,615,161 | 908,828 | 8.33 | 7.36 | 1.08 | 6.79 |
| 2011 | 11,064 | 11,886 | 81,053 | 1,519,620 | 855,212 | 7.28 | 7.33 | 1.07 | 6.82 |
| 2012 | 7,434 | 7,868 | 54,494 | 1,368,850 | 727,724 | 5.43 | 7.33 | 1.06 | 6.93 |
| 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 | 1,614 | 1,975 | 20,538 | 866,997 | 490,388 | 1.86 | 12.72 | 1.22 | 10.40 |
| 2007 | 1,664 | 2,068 | 20,334 | 938,481 | 519,735 | 1.77 | 12.22 | 1.24 | 9.83 |
| 2008 | 3,380 | 4,027 | 36,942 | 1,881,177 | 1,033,764 | 1.80 | 10.93 | 1.19 | 9.17 |
| 2009 | 3,128 | 3,750 | 35,187 | 1,764,019 | 986,151 | 1.77 | 11.25 | 1.20 | 9.38 |
| 2010 | 3,068 | 3,747 | 35,383 | 1,615,161 | 908,828 | 1.90 | 11.53 | 1.22 | 9.44 |
| 2011 | 2,794 | 3,437 | 33,071 | 1,519,620 | 855,212 | 1.84 | 11.84 | 1.23 | 9.62 |
| 2012 | 2,445 | 2,945 | 29,569 | 1,368,850 | 727,724 | 1.79 | 12.09 | 1.20 | 10.04 |

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 | 77,657 | 116,368 | 2,034,762 | 866,997 | 490,388 | 89.57 | 26.20 | 1.50 | 17.49 |
| 2007 | 78,138 | 117,406 | 2,035,747 | 938,481 | 519,735 | 83.26 | 26.05 | 1.50 | 17.34 |
| 2008 | 147,313 | 216,100 | 3,436,454 | 1,881,177 | 1,033,764 | 78.31 | 23.33 | 1.47 | 15.90 |
| 2009 | 146,650 | 217,429 | 3,460,468 | 1,764,019 | 986,151 | 83.13 | 23.60 | 1.48 | 15.92 |
| 2010 | 138,367 | 206,411 | 3,268,441 | 1,615,161 | 908,828 | 85.67 | 23.62 | 1.49 | 15.83 |
| 2011 | 129,795 | 193,614 | 3,016,143 | 1,519,620 | 855,212 | 85.41 | 23.24 | 1.49 | 15.58 |
| 2012 | 110,206 | 161,555 | 2,543,159 | 1,368,850 | 727,724 | 80.51 | 23.08 | 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 | 16,814 | 27,024 | 426,900 | 866,997 | 490,388 | 19.39 | 25.39 | 1.61 | 15.80 |
| 2007 | 17,820 | 27,886 | 431,287 | 938,481 | 519,735 | 18.99 | 24.20 | 1.56 | 15.47 |
| 2008 | 37,400 | 57,966 | 861,485 | 1,881,177 | 1,033,764 | 19.88 | 23.03 | 1.55 | 14.86 |
| 2009 | 32,656 | 50,674 | 792,688 | 1,764,019 | 986,151 | 18.51 | 24.27 | 1.55 | 15.64 |
| 2010 | 22,613 | 34,514 | 544,524 | 1,615,161 | 908,828 | 14.00 | 24.08 | 1.53 | 15.78 |
| 2011 | 19,338 | 29,648 | 460,739 | 1,519,620 | 855,212 | 12.73 | 23.83 | 1.53 | 15.54 |
| 2012 | 12,447 | 18,502 | 285,737 | 1,368,850 | 727,724 | 9.09 | 22.96 | 1.49 | 15.44 |

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 | 866,997 | 490,388 | 0.30 | 7.27 | 1.19 | 6.11 |
| 2007 | 254 | 296 | 1,824 | 938,481 | 519,735 | 0.27 | 7.18 | 1.17 | 6.16 |
| 2008 | 617 | 679 | 3,461 | 1,881,177 | 1,033,764 | 0.33 | 5.61 | 1.10 | 5.10 |
| 2009 | 425 | 481 | 2,658 | 1,764,019 | 986,151 | 0.24 | 6.25 | 1.13 | 5.53 |
| 2010 | 367 | 430 | 2,468 | 1,615,161 | 908,828 | 0.23 | 6.72 | 1.17 | 5.74 |
| 2011 | 255 | 294 | 1,621 | 1,519,620 | 855,212 | 0.17 | 6.36 | 1.15 | 5.51 |
| 2012 | 124 | 143 | 965 | 1,368,850 | 727,724 | 0.09 | 7.78 | 1.15 | 6.75 |
| 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 | 1,965 | 4,354 | 145,195 | 866,997 | 490,388 | 2.27 | 73.89 | 2.22 | 33.35 |
| 2007 | 3,601 | 8,634 | 269,799 | 938,481 | 519,735 | 3.84 | 74.92 | 2.40 | 31.25 |
| 2008 | 10,483 | 25,625 | 762,716 | 1,881,177 | 1,033,764 | 5.57 | 72.76 | 2.44 | 29.76 |
| 2009 | 8,078 | 19,989 | 599,525 | 1,764,019 | 986,151 | 4.58 | 74.22 | 2.47 | 29.99 |
| 2010 | 5,821 | 14,534 | 436,904 | 1,615,161 | 908,828 | 3.60 | 75.06 | 2.50 | 30.06 |
| 2011 | 4,643 | 11,974 | 362,610 | 1,519,620 | 855,212 | 3.06 | 78.10 | 2.58 | 30.28 |
| 2012 | 3,554 | 8,918 | 267,715 | 1,368,850 | 727,724 | 2.60 | 75.33 | 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 | 210 | 267 | 2,741 | 866,997 | 490,388 | 0.24 | 13.05 | 1.27 | 10.27 |
| 2007 | 261 | 316 | 2,647 | 938,481 | 519,735 | 0.28 | 10.14 | 1.21 | 8.38 |
| 2008 | 745 | 848 | 6,255 | 1,881,177 | 1,033,764 | 0.40 | 8.40 | 1.14 | 7.38 |
| 2009 | 820 | 918 | 6,488 | 1,764,019 | 986,151 | 0.46 | 7.91 | 1.12 | 7.07 |
| 2010 | 972 | 1,083 | 7,748 | 1,615,161 | 908,828 | 0.60 | 7.97 | 1.11 | 7.15 |
| 2011 | 1,032 | 1,161 | 7,954 | 1,519,620 | 855,212 | 0.68 | 7.71 | 1.13 | 6.85 |
| 2012 | 1,034 | 1,144 | 8,169 | 1,368,850 | 727,724 | 0.76 | 7.90 | 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 | 866,997 | 490,388 | 0.55 | 36.30 | 1.49 | 24.29 |
| 2007 | 611 | 876 | 19,764 | 938,481 | 519,735 | 0.65 | 32.35 | 1.43 | 22.56 |
| 2008 | 1,461 | 2,145 | 48,490 | 1,881,177 | 1,033,764 | 0.78 | 33.19 | 1.47 | 22.61 |
| 2009 | 1,320 | 1,884 | 42,108 | 1,764,019 | 986,151 | 0.75 | 31.90 | 1.43 | 22.35 |
| 2010 | 1,310 | 1,888 | 41,259 | 1,615,161 | 908,828 | 0.81 | 31.50 | 1.44 | 21.85 |
| 2011 | 1,192 | 1,790 | 39,936 | 1,519,620 | 855,212 | 0.78 | 33.50 | 1.50 | 22.31 |
| 2012 | 940 | 1,369 | 29,686 | 1,368,850 | 727,724 | 0.69 | 31.58 | 1.46 | 21.68 |

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 | 9,727 | 9,727 | 10,681 | 79,403 | 862,138 | 483,593 | 11.28 | 8.16 | 1.10 | 7.43 |
| 2007 | 9,334 | 9,334 | 10,072 | 71,853 | 930,843 | 512,188 | 10.03 | 7.70 | 1.08 | 7.13 |
| 2008 | 17,091 | 17,091 | 18,359 | 121,335 | 1,868,840 | 1,021,037 | 9.15 | 7.10 | 1.07 | 6.61 |
| 2009 | 15,140 | 15,140 | 16,227 | 108,456 | 1,752,078 | 973,748 | 8.64 | 7.16 | 1.07 | 6.68 |
| 2010 | 12,948 | 12,948 | 13,919 | 93,893 | 1,604,241 | 897,792 | 8.07 | 7.25 | 1.07 | 6.75 |
| 2011 | 10,607 | 10,607 | 11,305 | 76,897 | 1,509,978 | 845,637 | 7.02 | 7.25 | 1.07 | 6.80 |
| 2012 | 7,192 | 7,192 | 7,578 | 52,360 | 1,361,110 | 720,624 | 5.28 | 7.28 | 1.05 | 6.91 |
| 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 | 1,581 | 1,581 | 1,897 | 18,517 | 864,868 | 487,877 | 1.83 | 11.71 | 1.20 | 9.76 |
| 2007 | 1,588 | 1,588 | 1,920 | 17,663 | 935,914 | 517,439 | 1.70 | 11.12 | 1.21 | 9.20 |
| 2008 | 3,295 | 3,295 | 3,862 | 33,957 | 1,873,886 | 1,028,494 | 1.76 | 10.31 | 1.17 | 8.79 |
| 2009 | 3,011 | 3,011 | 3,483 | 30,545 | 1,760,227 | 982,140 | 1.71 | 10.14 | 1.16 | 8.77 |
| 2010 | 2,923 | 2,923 | 3,397 | 29,531 | 1,611,748 | 905,023 | 1.81 | 10.10 | 1.16 | 8.69 |
| 2011 | 2,664 | 2,664 | 3,152 | 28,842 | 1,516,379 | 851,728 | 1.76 | 10.83 | 1.18 | 9.15 |
| 2012 | 2,336 | 2,336 | 2,707 | 24,866 | 1,366,067 | 724,612 | 1.71 | 10.64 | 1.16 | 9.19 |

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 | 68,208 | 68,208 | 99,127 | 1,725,072 | 832,895 | 440,034 | 81.89 | 25.29 | 1.45 | 17.40 |
| 2007 | 63,357 | 63,357 | 90,954 | 1,563,172 | 883,312 | 461,260 | 71.73 | 24.67 | 1.44 | 17.19 |
| 2008 | 131,555 | 131,555 | 188,209 | 2,966,116 | 1,818,169 | 941,390 | 72.36 | 22.55 | 1.43 | 15.76 |
| 2009 | 120,289 | 120,289 | 171,510 | 2,715,571 | 1,668,882 | 879,293 | 72.08 | 22.58 | 1.43 | 15.83 |
| 2010 | 111,919 | 111,919 | 160,412 | 2,514,262 | 1,519,594 | 804,318 | 73.65 | 22.47 | 1.43 | 15.67 |
| 2011 | 105,466 | 105,466 | 151,262 | 2,331,795 | 1,430,697 | 759,397 | 73.72 | 22.11 | 1.43 | 15.42 |
| 2012 | 88,470 | 88,470 | 124,412 | 1,945,626 | 1,287,020 | 647,356 | 68.74 | 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 | 15,077 | 15,077 | 23,604 | 372,074 | 859,468 | 478,519 | 17.54 | 24.68 | 1.57 | 15.76 |
| 2007 | 14,352 | 14,352 | 21,421 | 324,039 | 924,911 | 505,240 | 15.52 | 22.58 | 1.49 | 15.13 |
| 2008 | 33,615 | 33,615 | 50,887 | 755,947 | 1,861,193 | 1,007,141 | 18.06 | 22.49 | 1.51 | 14.86 |
| 2009 | 26,379 | 26,379 | 39,232 | 605,385 | 1,737,957 | 958,350 | 15.18 | 22.95 | 1.49 | 15.43 |
| 2010 | 17,684 | 17,684 | 25,845 | 399,403 | 1,591,349 | 886,127 | 11.11 | 22.59 | 1.46 | 15.45 |
| 2011 | 15,534 | 15,534 | 22,905 | 350,564 | 1,501,972 | 837,281 | 10.34 | 22.57 | 1.47 | 15.31 |
| 2012 | 9,533 | 9,533 | 13,534 | 205,429 | 1,354,416 | 714,481 | 7.04 | 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 | 865,292 | 488,558 | 0.30 | 7.28 | 1.19 | 6.11 |
| 2007 | 249 | 249 | 288 | 1,778 | 936,740 | 518,307 | 0.27 | 7.14 | 1.16 | 6.17 |
| 2008 | 611 | 611 | 671 | 3,411 | 1,874,776 | 1,029,896 | 0.33 | 5.58 | 1.10 | 5.08 |
| 2009 | 416 | 416 | 467 | 2,559 | 1,761,731 | 983,714 | 0.24 | 6.15 | 1.12 | 5.48 |
| 2010 | 364 | 364 | 427 | 2,440 | 1,613,326 | 906,665 | 0.23 | 6.70 | 1.17 | 5.71 |
| 2011 | 252 | 252 | 291 | 1,608 | 1,517,886 | 853,195 | 0.17 | 6.38 | 1.15 | 5.53 |
| 2012 | 123 | 123 | 142 | 958 | 1,367,483 | 726,066 | 0.09 | 7.79 | 1.15 | 6.75 |
| 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 | 1,928 | 1,928 | 4,216 | 141,491 | 865,228 | 487,784 | 2.23 | 73.39 | 2.19 | 33.56 |
| 2007 | 3,227 | 3,227 | 7,437 | 229,869 | 935,245 | 515,738 | 3.45 | 71.23 | 2.30 | 30.91 |
| 2008 | 9,867 | 9,867 | 23,727 | 705,865 | 1,871,358 | 1,022,871 | 5.27 | 71.54 | 2.40 | 29.75 |
| 2009 | 6,670 | 6,670 | 15,628 | 467,313 | 1,753,177 | 974,357 | 3.80 | 70.06 | 2.34 | 29.90 |
| 2010 | 4,830 | 4,830 | 11,437 | 343,124 | 1,604,950 | 899,181 | 3.01 | 71.04 | 2.37 | 30.00 |
| 2011 | 3,845 | 3,845 | 9,400 | 284,155 | 1,511,857 | 847,686 | 2.54 | 73.90 | 2.44 | 30.23 |
| 2012 | 2,852 | 2,852 | 6,636 | 199,081 | 1,362,777 | 722,091 | 2.09 | 69.80 | 2.33 | 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 | 203 | 203 | 247 | 2,320 | 865,279 | 488,568 | 0.23 | 11.43 | 1.22 | 9.39 |
| 2007 | 251 | 251 | 287 | 2,215 | 936,743 | 518,295 | 0.27 | 8.82 | 1.14 | 7.72 |
| 2008 | 728 | 728 | 816 | 5,893 | 1,874,717 | 1,029,773 | 0.39 | 8.09 | 1.12 | 7.22 |
| 2009 | 784 | 784 | 868 | 5,993 | 1,761,570 | 983,415 | 0.45 | 7.64 | 1.11 | 6.90 |
| 2010 | 935 | 935 | 1,029 | 7,298 | 1,612,942 | 906,198 | 0.58 | 7.81 | 1.10 | 7.09 |
| 2011 | 998 | 998 | 1,115 | 7,503 | 1,517,401 | 852,634 | 0.66 | 7.52 | 1.12 | 6.73 |
| 2012 | 991 | 991 | 1,086 | 7,589 | 1,366,830 | 725,434 | 0.73 | 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 | 865,181 | 488,397 | 0.55 | 35.32 | 1.46 | 24.14 |
| 2007 | 581 | 581 | 815 | 18,179 | 936,518 | 517,992 | 0.62 | 31.29 | 1.40 | 22.31 |
| 2008 | 1,416 | 1,416 | 2,056 | 45,917 | 1,874,391 | 1,029,219 | 0.76 | 32.43 | 1.45 | 22.33 |
| 2009 | 1,233 | 1,233 | 1,746 | 38,467 | 1,760,964 | 982,792 | 0.70 | 31.20 | 1.42 | 22.03 |
| 2010 | 1,211 | 1,211 | 1,642 | 34,140 | 1,612,389 | 905,695 | 0.75 | 28.19 | 1.36 | 20.79 |
| 2011 | 1,117 | 1,117 | 1,639 | 36,196 | 1,516,945 | 852,240 | 0.74 | 32.40 | 1.47 | 22.08 |
| 2012 | 855 | 855 | 1,194 | 25,141 | 1,366,568 | 725,245 | 0.63 | 29.40 | 1.40 | 21.06 |

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 2.0, 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 weresplit 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 both medical and drug coverage. A second report examines 16 scenarios with differing exposures of interest that require drug coverage only. See below for a description of each of the scenarios evaluated in this report.

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