

**MEMORANDUM**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH**

**PID#:** D040140

**DATE:** May 17, 2005

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**THROUGH:** Gerald Dal Pan, MD., MHS. Director  
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**TO:** Solomon Iyasu, MD, M.P.H.  
Division of Pediatric Drug Development, HFD-960  
Office of Counter-Terrorism and Pediatric Drug Development

**SUBJECT:** One Year Post-Pediatric Exclusivity Post-Marketing Adverse Event Review:  
Drug Use Data – Sumatriptan (Imitrex<sup>®</sup>) Nasal Spray (NDA 20-626)  
Pediatric Exclusivity Grant Date: February 18, 2004

**\*\*This document contains proprietary data from IMS Health and Caremark which cannot be shared outside of the FDA without clearance from IMS Health and Caremark through the Office of Drug Safety.\*\***

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**EXECUTIVE SUMMARY**

This consult examines drug utilization trends for Imitrex<sup>®</sup> (sumatriptan) nasal spray in the pediatric population (0-16 years) from March 1, 2002 through February 28, 2005, with primary focus on patterns of use one year before and one year following the granting of Pediatric Exclusivity on February 18, 2004.

National outpatient total dispensed prescriptions for all 5-hydroxytryptamine (5-HT<sub>1</sub>) agonist anti-migraine products increased approximately 5% from March 2002 through February 2005 with over 11.3 million prescriptions dispensed from March 2004 through February 2005. Sumatriptan products were the most commonly dispensed products (>50%) compared to the other 5-HT<sub>1</sub> anti-migraine products during the three 12-month time periods and accounted for roughly 6 million prescriptions dispensed from March 2004 through February 2005.

Total dispensed prescriptions for Imitrex<sup>®</sup> nasal spray declined from 577,000 prescriptions dispensed from March 2002-February 2003, to 497,000 prescriptions dispensed from March 2003-February 2004, and 432,000 prescriptions dispensed from March 2004-February 2005. This represented a 14% decrease in Imitrex<sup>®</sup> nasal spray prescriptions dispensed from March 2003-February 2004 and a 13% decrease in total dispensed prescriptions from March 2004-February 2005. Dispensed prescriptions for Imitrex injectable products declined approximately 19% from March 2002 - February 2005, from almost 800,000 prescriptions dispensed from March 2002 - February 2003 to 718,000 prescriptions dispensed from March 2003 - February 2004, and 644,000 prescriptions dispensed from March 2004 - February 2005. Total dispensed prescriptions for Imitrex<sup>®</sup> oral tablets remained stable with roughly 4.8 million prescriptions dispensed during each of the three 12-month time periods from March 2002 – February 2005.

The top prescriber specialties for Imitrex<sup>®</sup> during the two 12-month time periods from March 2003 - February 2005 were family practice and internal medicine. Of all specialties, pediatricians were responsible for 1.5% of all Imitrex<sup>®</sup> prescriptions dispensed in the U.S. from March 2004 - February 2005. In general, prescribing patterns for Imitrex<sup>®</sup> dispensed in the retail outpatient setting showed no substantial change during the three 12-month time period from March 2002 - February 2005.

Among an insured population in the Caremark system, the pediatric age group (1-16 years) accounted for approximately 2% of total Imitrex<sup>®</sup> paid claims, from March 2003-February 2004. The estimated number of prescriptions for all Imitrex<sup>®</sup> products dispensed nationally to patients aged 1-16 years was approximately 110,500 during the one year period before pediatric exclusivity was granted (March 2003 – February 2005) and approximately 116,300 during the one-year period after the granting of pediatric exclusivity (March 2004 – February 2005).

The most common diagnosis associated with a mention of any form of Imitrex<sup>®</sup> in office based physician-patient encounters was “migraine, unspecified”, accounting for roughly 80% of mentions for both children and adults during the pre-exclusivity and post-exclusivity periods.

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## **INTRODUCTION**

On January 3, 2001, Congress enacted the Best Pharmaceuticals for Children Act (BPCA) to improve the safety and efficacy of pharmaceuticals for children. Section 17 of that act requires the reporting of adverse events associated with the use of a drug in children during the one year following the date on which the drug received marketing exclusivity. In support of this mandate, the FDA is required to provide a report to the Pediatric Advisory Committee on the drug utilization patterns and adverse events associated with the use of the drug on a quarterly basis. This review is in addition to the routine post-marketing safety surveillance activities the FDA performs for all marketed drugs.

Imitrex<sup>®</sup> (sumatriptan) is a selective 5-hydroxytryptamine agonist available as an injection containing 6mg of sumatriptan succinate or oral tablets containing either 25 mg, 50 mg, or 100 mg of sumatriptan succinate (NDA 20-080 and NDA 20-132, respectively). Imitrex<sup>®</sup> is also

available as a nasal spray containing 5 mg, 10 mg or 20 mg of sumatriptan base per 0.5 ml (NDA 20-626). The Imitrex<sup>®</sup> injection was approved on December 28, 1992 and is now indicated for the treatment of migraine attacks with or without aura and for the acute treatment of cluster headache episodes in adults. Imitrex<sup>®</sup> oral tablets were approved on June 1, 1995 and are indicated for the treatment of migraine attacks with or without aura in adults. Imitrex<sup>®</sup> nasal spray was approved on August 26, 1997 and is indicated for the treatment of migraine attacks with or without aura in adults. As of the date of this consult, there are no generic competitors of this product.

The Pediatric Exclusivity Board of the FDA granted pediatric exclusivity for Imitrex<sup>®</sup> nasal spray (NDA 20-626) on February 18, 2004. Imitrex<sup>®</sup> nasal spray is currently approved for the treatment of migraine attacks with or without aura in adults. Safety and efficacy in the pediatric population have not been established for any of the Imitrex<sup>®</sup> products. Other currently marketed 5-HT<sub>1</sub> agonists include: rizatriptan, zolmitriptan, eletriptan, almotriptan, naratriptan, and frovotriptan, none of which are labeled for use in the pediatric population.

We will use the term Imitrex<sup>®</sup> to refer to all forms of sumatriptan unless otherwise specified. This review describes outpatient drug usage of Imitrex<sup>®</sup> with primary focus on the nasal spray formulation in the pediatric population as compared to the adult population. Proprietary drug use databases licensed by the Agency were used to conduct this analysis.

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## DATA SOURCES

Sales data reflecting the number of bottles, vials, and tablets and/or milliliters sold by the manufacturer to various retail and non-retail channels of distribution were analyzed using IMS Health's, National Sales Perspectives™ database. Because greater than 90% of sales of these products occurred in the outpatient setting (data not shown), we focused our review on the outpatient drug utilization of these products (Table 1). Outpatient Imitrex® dispensed prescriptions were estimated by using 2 databases in concert: IMS Health's National Prescription Audit Plus™ (NPA Plus™) and Caremark (Dimension Rx™).

### *I. OUTPATIENT DRUG USE*

#### ***IMS HEALTH, NATIONAL PRESCRIPTION AUDIT PLUS™ (NPA PLUS™)***

NPA Plus™ measures the retail dispensing of prescriptions, or the frequency with which drugs move out of retail pharmacies into the hands of consumers via formal prescriptions. These retail pharmacies include chain, independent, food store, mail order, discount houses, and mass merchandiser pharmacies, as well as nursing home (long-term care) pharmacy providers. Information on the specialty of the prescribing physician can also be collected, except for in the long-term care and mail order pharmacy settings.

The number of total dispensed prescriptions is obtained from a sample of approximately 22,000 pharmacies throughout the U.S. and projected nationally. The pharmacies in the database account for approximately 40% of all pharmacy stores and represent approximately 45% of prescription coverage in the U.S.

Data for this analysis included all total prescriptions dispensed from March 1, 2002 to February 28, 2005, inclusive.

#### ***IMS HEALTH, NATIONAL DISEASE AND THERAPEUTIC INDEX™ (NDTI™)***

The National Disease and Therapeutic Index™ (NDTI™) is an ongoing survey designed and conducted by IMS Health to provide descriptive information on the patterns and treatment of disease encountered in office-based practice in the continental U.S. The data are collected from a panel of roughly 2,000 – 3,000 office-based physicians who complete and submit a survey of their practice patterns to IMS Health for two consecutive days per quarter. These data may include profiles and trends of diagnoses, patients, drug products mentioned and treatment patterns. The data are projected nationally to reflect national prescribing patterns.

NDTI™ uses the term drug uses for mentions of a drug in association with a diagnosis during an office-based patient visit. This term may be duplicated by the number of diagnoses for which the drug is mentioned. It is important to note that a drug use does not necessarily result in prescription being generated. Rather, the term indicates that a given drug was mentioned during an office visit.

For this analysis, we examined annual mentions of Imitrex® during office-based physician visits during the time period March 1, 2002 to February 28, 2005, inclusive.

### ***CAREMARK DIMENSION RX™***

Caremark is one of the largest pharmacy benefit manager (PBM) companies in the US, currently covering over 75 million participant lives, and processing over 450 million prescription claims annually. Participants whose claims are processed by Caremark are covered under various types of insurance plans, including health maintenance organizations (HMOs), employers' self-insured health plans, selected managed care plans, and other selected traditional health insurers. Caremark represents participants from all 50 states and includes special populations such as the elderly, children, and women of childbearing age. The representativeness of those included in the Caremark system to all persons receiving dispensed prescriptions in the U.S. is not known however.

For this analysis, prescription claims in the Caremark system were examined from March 1, 2002 to February 28, 2005, inclusive.

## **RESULTS**

### **I. Dispensed Prescriptions**

National outpatient total dispensed prescriptions for all 5-HT<sub>1</sub> agonist anti-migraine products increased approximately 5% from March 2002 through February 2005 with over 11.3 million prescriptions dispensed from March 2004 through February 2005. Imitrex® accounted for approximately 52% of the estimated 11.3 million prescriptions dispensed nationwide for the serotonin 5-HT<sub>1</sub> receptor agonists in the U.S. from March 2004 to February 2005 (Table 1). Total dispensed prescriptions for sumatriptan decreased approximately 2% from 6 million dispensed prescriptions from March 2003 through February 2004 to 5.9 million prescriptions dispensed during the 12-month period from March 2004 to February 2005 (Table 1). During the most recent 12-month time period (March 2004 – February 2005), Imitrex® oral tablets accounted for approximately 81.8% of all sumatriptan dispensed, followed by Imitrex® injectables (approximately 10.9%) and the Imitrex® nasal spray (approximately 7.3%).

Total dispensed prescriptions for Imitrex® oral tablets remained relatively stable accounting for 4.8 million prescriptions dispensed during the three 12-month time periods from March 2002 - February 2005 (Table 1). Total dispensed prescriptions for Imitrex® injectable products declined 19% over the three 12-month time periods (March 2002 - February 2005) from 797,000 prescriptions dispensed from March 2002 - February 2003 to 718,000 prescriptions dispensed from March 2003 - February 2004, and 644,000 prescriptions dispensed from March 2004 - February 2005 (Table 1). Total dispensed prescriptions for Imitrex® nasal spray declined 25% from March 2002 - February 2005 with 577,000 prescriptions dispensed from March 2002 - February 2003 to 497,000 prescriptions dispensed from March 2003 - February 2004, and 432,000 prescriptions dispensed from March 2004 - February 2005 (Table 1).

**Table 1: Total Number of Prescriptions Dispensed in Retail Pharmacies Nationwide for all Serotonin 5-HT1 Receptor Agonist Products (USC5 - 02112)**

	Mar 2002 - Feb 2003		Mar 2003 - Feb 2004		Mar 2004 - Feb 2005	
	N (000)	(%)	N (000)	(%)	N (000)	(%)
<b>Serotonin 5-HT1 Receptor Agonist</b>	<b>10,811</b>	<b>(100)</b>	<b>11,020</b>	<b>100.0%</b>	<b>11,311</b>	<b>100.0%</b>
<b>SUMATRIPTAN (Imitrex®)</b>	<b>6,204</b>	<b>(57.4)</b>	<b>6,010</b>	<b>(54.5)</b>	<b>5,913</b>	<b>(52.3)</b>
<b>Oral Tablets</b>	<b>4,830</b>	<b>(77.9)</b>	<b>4,795</b>	<b>(79.8)</b>	<b>4,837</b>	<b>(81.8)</b>
<b>Injectables</b>	<b>797</b>	<b>(12.8)</b>	<b>718</b>	<b>(11.9)</b>	<b>644</b>	<b>(10.9)</b>
<b>Nasal Spray</b>	<b>577</b>	<b>(9.3)</b>	<b>497</b>	<b>(8.3)</b>	<b>432</b>	<b>(7.3)</b>
<b>RIZATRIPTAN (Maxalt®)</b>	<b>1,855</b>	<b>(17.2)</b>	<b>1,792</b>	<b>(16.3)</b>	<b>1,680</b>	<b>(14.9)</b>
<b>ZOLMITRIPTAN (Zomig®)</b>	<b>1,697</b>	<b>(15.87)</b>	<b>1,618</b>	<b>(14.7)</b>	<b>1,558</b>	<b>(13.8)</b>
<b>ELETRIPTAN (Relpax®)</b>	<b>1</b>	<b>(0)</b>	<b>388</b>	<b>(3.5)</b>	<b>1,005</b>	<b>(8.9)</b>
<b>ALMOTRIPTAN (Axert®)</b>	<b>396</b>	<b>(3.7)</b>	<b>474</b>	<b>(4.3)</b>	<b>471</b>	<b>(4.2)</b>
<b>NARATRIPTAN (Amerge®)</b>	<b>552</b>	<b>(5.1)</b>	<b>456</b>	<b>(4.1)</b>	<b>390</b>	<b>(3.4)</b>
<b>FROVATRIPTAN (Frova®)</b>	<b>106</b>	<b>(1)</b>	<b>281</b>	<b>(2.5)</b>	<b>295</b>	<b>(2.6)</b>

IMS Health, National Prescription Audit Plus™, Moving Annual Totals: March-February 2002-2005, Data Extracted March 2005.  
Original file: 0503sum1.dvr

## II. Prescriber Specialty

The top three prescriber specialties for sumatriptan from March 2003 through January 2005 were family practice, internal medicine, and neurology (Table 2). Pediatricians accounted for 1.5% (85,000) -1.7% (96,000) of all sumatriptan prescriptions dispensed from March 2002 through February 2005 (Table 2). There appears to have been no substantial change in prescriber specialty for sumatriptan during the 36-month study period.

**Table 2: Total Number of Prescriptions Dispensed for all Imitrex® Products Nationwide by Physician Specialty, March 2002- February 2005**

Prescriber Specialty	Mar 2002 - Feb 2005		Mar 2003 - Feb 2004		Mar 2004 - Feb 2005	
	N (000's)	(%)	N (000's)	(%)	N (000's)	(%)
<b>*All Prescribers</b>	<b>5,820</b>	<b>100.0%</b>	<b>5,610</b>	<b>100.0%</b>	<b>5,491</b>	<b>100.0%</b>
Family Practice	1,710	(29.4)	1,659	(29.6%)	1,639	(29.8)
Internal Medicine	1,361	(23.4)	1,292	(23)	1,243	(22.6)
Neurology	881	(15.1)	824	(14.7)	775	(14.1)
Osteopathic Medicine	528	(9.1)	523	(9.3)	518	(9.4)
Obstetric/Gynecology	239	(4.1)	233	(4.2)	226	(4.1)
Other Specialties	673	(11.6%)	629	(11.2)	593	(10.8)
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<b>Pediatrics</b>	<b>85</b>	<b>(1.5)</b>	<b>89</b>	<b>(1.6)</b>	<b>96</b>	<b>(1.7)</b>

IMS Health, National Prescription Audit Plus™, Moving Annual Totals: March 2002-February 2005: Data extracted March 2005  
Original file: 0403sum2.dvr

\*(excludes Long Term Care and Mail Order Channels)

### III. Diagnosis

According to IMS Health, NDTI™, the most frequent diagnosis associated with Imitrex® for both adults and persons aged 0-16 years was migraine, unspecified (ICD 346.9), followed by headache (ICD 784.0) (Table 3). Persons aged 0-16 years accounted for 7.6% (144,000) of the 1.9 million mentions of all Imitrex® products during March 2004 through February 2005 (Table 3).

**Table 3: Top Diagnoses Associated with Mentions of Imitrex® for Adults and Pediatric Patients in visits to Office-Based Physicians  
March 2002 though February 2005**

ICD-9 CODES	Projected Number of Mentions					
	Mar 2002 – Feb 2003		Mar 2003 - Feb 2004		Mar 2004 – Feb 2005	
	N (000's)	(%)	N (000's)	(%)	N (000's)	(%)
<b>Imitrex® Products</b>	<b>1,557</b>	<b>(100)</b>	<b>1,893</b>	<b>(100)</b>	<b>1,901</b>	<b>(100)</b>
<b>Patients Age 17+ years</b>	<b>1,520</b>	<b>(97.6)</b>	<b>1,766</b>	<b>(93.3)</b>	<b>1,757</b>	<b>(92.4)</b>
346.9 Migraine Unspecified	1,206	(79.4)	1,486	(84.2)	1,444	(82.2)
784.0 Headache	220	(14.5)	200	(11.3)	169	(9.6)
346.0 Classical Migraine	12	(0.8)	22	(1.3)	45	(2.5)
346.2 Variants of Migraine	28	(1.9)	21	(1.3)	29	(1.7)
346.1 Common Migraine	18	(1.2)	16	(0.9)	28	(1.6)
Total Others (8)	35	(2.2)	21	(1)	42	(2.4)
<b>Patients Age 0-16 years</b>	<b>37</b>	<b>(2.4)</b>	<b>127</b>	<b>(6.7)</b>	<b>144</b>	<b>(7.6)</b>
346.9 Migraine Unspecified	33	(87.7)	101	(79.3)	114	(79.3)
784.0 Headache	4	(9.9)	12	(9.1)	28	(19.4)
346.1 Common Migraine	1	(2.4)	--	--	--	--
310.2 Post Concussional Syndrome	--	--	2	(1.3)	2	(1.3)
346.0 Classical Migraine	--	--	2	(1.6)	--	--
473.8 Chronic Sinusitis, Other	--	--	11	(8.7)	--	--

IMS Health, IMS National Disease and Therapeutic Index™, CD –Rom, NDTI 3 Year: March 2002-February 2005: Data extracted April 2005  
Original file: imitrexbyageddiag4.dvf

### IV. Patient Demographics

Among a large, insured patient population managed by Caremark, total paid claims for all dosage forms of Imitrex® decreased approximately 5.2% between the two 12-month time periods, March 2003 through February 2005 (calculated from Table 4). Approximately 2% (16,102) of total paid claims for Imitrex® were for persons aged 1-16 years from March 2004 through February 2005 (Table 4). Imitrex® oral tablets accounted for 82.5% (665,452) of all Imitrex® paid claims between March 2004 – February 2005, followed by Imitrex injectables 9.7% (78,248) and finally Imitrex nasal spray 7.8% (62,698) (Table 4).

Total Imitrex® nasal spray claims decreased approximately 14% (from 72,842 to 62,698 claims) between the two 12-month time periods, March 2003 – February 2005, while pediatric claims decreased 8% (from 3,364 to 3,104), during the same two 12-month time periods (calculated from Table 4).

**Table 4: Total Number of Paid Prescription Claims for all Imitrex® Products  
Caremark Dimension Rx™**

	Mar 2002 - Feb 2003		Mar 2003 - Feb 2004		Mar 2004 - Feb 2005	
	N	(%)	N	(%)	N	(%)
<b>All IMITREX®(Total)</b>	<b>873,482</b>	<b>(100)</b>	<b>851,072</b>	<b>(100)</b>	<b>806,391</b>	<b>(100)</b>
<b>Peds (1-16 yrs)</b>	<b>15,679</b>	<b>(1.8)</b>	<b>16,055</b>	<b>(1.9)</b>	<b>16,102</b>	<b>(2.0)</b>
<b>Adults (17+ yrs)</b>	<b>857,803</b>	<b>(98.2)</b>	<b>835,017</b>	<b>(98.1)</b>	<b>790,289</b>	<b>(98.0)</b>
<b>Imitrex® Oral Tablets</b>	<b>686,967</b>	<b>(78.6)</b>	<b>687,057</b>	<b>(80.7)</b>	<b>665,452</b>	<b>(82.5)</b>
<b>Peds (1-16 yrs)</b>	<b>11,602</b>	<b>(1.7)</b>	<b>12,327</b>	<b>(1.8)</b>	<b>12,628</b>	<b>(1.9)</b>
<b>Adults (17+ yrs)</b>	<b>675,365</b>	<b>(98.3)</b>	<b>674,730</b>	<b>(98.2)</b>	<b>625,824</b>	<b>(98.1)</b>
<b>Imitrex® Nasal Spray</b>	<b>85,192</b>	<b>(9.8)</b>	<b>72,842</b>	<b>(8.6)</b>	<b>62,698</b>	<b>(7.8)</b>
<b>Peds (1-16 yrs)</b>	<b>3,468</b>	<b>(4.1)</b>	<b>3,364</b>	<b>(4.6)</b>	<b>3,104</b>	<b>(4.9)</b>
<b>Adults (17+ yrs)</b>	<b>81,724</b>	<b>(95.9)</b>	<b>69,478</b>	<b>(95.4)</b>	<b>59,594</b>	<b>(95.1)</b>
<b>Imitrex® Injectables</b>	<b>101,323</b>	<b>(11.6)</b>	<b>91,173</b>	<b>(10.7)</b>	<b>78,248</b>	<b>(9.7)</b>
<b>Peds (1-16 yrs)</b>	<b>609</b>	<b>(0.6)</b>	<b>364</b>	<b>(0.4)</b>	<b>370</b>	<b>(0.5)</b>
<b>Adults (17+ yrs)</b>	<b>100,714</b>	<b>(99.4)</b>	<b>90,809</b>	<b>(99.6)</b>	<b>77,878</b>	<b>(99.5)</b>

Caremark Dimension RX™: Extracted March 23, 2005.  
File name Age\_by\_MAT-(Pediatric).xls

After applying the percentages of claims of Imitrex® oral tablets, Imitrex® injectables and Imitrex® nasal spray obtained from Caremark (Table 4) to the total projected total prescriptions dispensed nationwide obtained from IMS Health (Table 1), the estimated total number of prescriptions dispensed for all Imitrex® dosage forms in persons aged 1-16 years was approximately 112,000 during the 12-month period before granting of exclusivity, (March 2003-February 2004) and approximately 116,300 in the 12-month period after granting exclusivity (March 2004-February 2005) (Table 5).

Table 5. Estimated Nationwide Prescriptions\* Filled for Imitrex, March 2002 – February 2005.

	Mar 02 – Feb 03			Mar 03 – Feb 04			Mar 04- -Feb 05		
	Imitrex® Oral Tablets	Imitrex® Inject.	Imitrex® Nasal Spray	Imitrex® Oral Tablets	Imitrex® Inject.	Imitrex® Nasal Spray	Imitrex® Oral Tablets	Imitrex® Inject.	Imitrex® Nasal Spray
<b>Total Rx**</b>	<b>4,830,000</b>	<b>797,000</b>	<b>577,000</b>	<b>4,795,000</b>	<b>718,000</b>	<b>497,000</b>	<b>4,837,000</b>	<b>644,000</b>	<b>432,000</b>
<b>Age 1-16</b>	<b>82,110</b>	<b>4,782</b>	<b>23,657</b>	<b>86,310</b>	<b>2,872</b>	<b>22,862</b>	<b>91,903</b>	<b>3,220</b>	<b>21,168</b>
Age 17+	4,747,890	792,218	553,343	4,708,690	715,128	474,138	4,745,097	640,780	410,832

\*Estimated number of prescriptions in each age band obtained after applying percentages in each age band from Caremark to IMS Health’s total dispensed prescriptions. Figures may not add up to subtotals due to rounding.

\*\*Total Prescriptions are actual values from IMS Health (Table 1)

## LIMITATIONS

NPA Plus™ data provide an estimate of the total number of prescriptions dispensed in the U.S. However, NPA Plus™ does not include complete historical demographic information, such as age and gender. The prescriber specialty data described in this report does not include mail order and long-term care channels. This may be significant, as mail order and long-term care accounted for 13% and 7%, respectively, of sumatriptan sales in the U.S. (data not shown).

NDTI™ data provide estimates of patient demographics and indications for use of medicinal products in the U.S. Due to the sampling and data collection methodologies, the small sample size can make these data unstable, particularly when use is not prevalent in the pediatric population. These results should be interpreted with caution.

Caremark data cannot be projected to make national level estimates of use, but its large sample size can be helpful for replicating demographic findings in IMS Health’s NDTI™, where sample sizes are often small. Although the data from Caremark may not be nationally representative, they provide a useful description of prescription drug use in the U.S. for a large proportion of the population with prescription drug coverage. Estimates of the number of prescriptions dispensed nationally to pediatric populations based on the proportion dispensed to pediatric patients in the Caremark system are dependent upon the assumption that these patterns are similar across populations with and without prescription drug coverage. The accuracy of this assumption is not known at this time. In addition, reliable information for patients less than the age of 1 year is not available from this data source.

## CONCLUSION

National outpatient total dispensed prescriptions for all 5-HT1 agonist anti-migraine products increased approximately 5% from March 2002 through February 2005 with over 11.3 million prescriptions dispensed from March 2004 through February 2005. Sumatriptan products were the most commonly dispensed products (>50%) compared to the other 5-HT1 anti-migraine products

during the three 12-month time periods and accounted for roughly 6 million prescriptions dispensed from March 2004 through February 2005.

Total dispensed prescriptions for Imitrex<sup>®</sup> nasal spray declined from 577,000 prescriptions dispensed from March 2002-February 2003, to 497,000 prescriptions dispensed from March 2003 - February 2004, and 432,000 prescriptions dispensed from March 2004 - February 2005. This represented a 14% decrease in Imitrex<sup>®</sup> nasal spray prescriptions dispensed from March 2002 – February 2003 to March 2003 - February 2004 and a 13% decrease in dispensed prescriptions from March 2003 – February 2004 to March 2004 - February 2005. Dispensed prescriptions for Imitrex injectable products declined approximately 19% from March 2002 - February 2005, from approximately 797,000 prescriptions dispensed from March 2002 - February 2003 to 718,000 prescriptions dispensed from March 2003 - February 2004, and 644,000 prescriptions dispensed from March 2004 - February 2005. Total dispensed prescriptions for Imitrex<sup>®</sup> oral tablets remained stable with roughly 4.8 million prescriptions dispensed during each of the three 12-month time periods from March 2002 – February 2005.

The top prescriber specialties for Imitrex<sup>®</sup> during the two 12-month time periods from March 2003 - February 2005 were family practice and internal medicine. Of all specialties, pediatricians were responsible for 1.7% of all Imitrex<sup>®</sup> prescriptions dispensed in the U.S. from March 2004 - February 2005. In general, prescribing patterns for Imitrex<sup>®</sup> dispensed in the retail outpatient setting showed no substantial change during the three 12-month time periods from March 2002 - February 2005.

The most common diagnosis associated with a mention of any form of Imitrex<sup>®</sup> in office based physician-patient encounters was “migraine, unspecified”, accounting for roughly 80% of mentions for both children and adults during the pre-exclusivity and post-exclusivity periods.

Among an insured population in the Caremark system, the pediatric age group (1-16 years) accounted for approximately 2% of total Imitrex<sup>®</sup> paid claims, from March 2003 - February 2004. The estimated number of prescriptions for all Imitrex<sup>®</sup> products dispensed nationally to patients aged 1-16 years was approximately 112,000 during the one year period before pediatric exclusivity was granted (March 2003 – February 2004) and approximately 116,300 during the one-year period after the granting of pediatric exclusivity (March 2004 – February 2005).

**Michael C. Evans, RPh.**  
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