

**MEMORANDUM**

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

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**TO:** Solomon Iyasu, MD, MPH  
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Office of Counter-Terrorism and Pediatric Development

**SUBJECT:** One Year Post-Pediatric Exclusivity Postmarketing Adverse Event Review: Drug Use Data  
Methylphenidate (Concerta®, NDA 21-121)  
Pediatric Exclusivity Grant Date: December 4, 2003

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

**EXECUTIVE SUMMARY**

This consult examines the drug use for methylphenidate in the pediatric population (0-16 years), with primary focus on patterns of use one year before and one year following the granting of Pediatric Exclusivity on December 4, 2003. Proprietary drug use databases licensed by the Agency were used to conduct this analysis. The IMS Health, National Sales Perspectives™ was used to determine the various retail and non-retail channels of distribution. Since the majority of use for this product occurs in the outpatient setting, we further examined the utilization patterns for methylphenidate focusing on the outpatient setting. Outpatient use was measured by two IMS Health audits, the National Prescription Audit *Plus*™ (NPA *Plus*™) and the National

Disease and Therapeutic Index™ (NDTI™), along with prescription claims for a 36-month period of time from Caremark (Dimension Rx™).

We examined prescriptions dispensed for Concerta®, its generic product (methylphenidate) as well as other single ingredient or combination analeptic products to compare Concerta® use relative to other products of the same therapeutic class.

There was an overall increase in the estimated prescriptions dispensed for single ingredient and combination analeptic products from 25 million prescriptions in year 2002 to over 29 million prescriptions dispensed in year 2004. This represented a 16.6% increase from year 2002 to year 2004. The single ingredient analeptic products accounted for approximately 17.7 million (60.8%) of the analeptics market in year 2004. The combination analeptic products accounted for approximately 11.4 million (39.2%) of the entire analeptics market in year 2004.

Methylphenidate products had the highest market share for the single ingredient analeptic products accounting for approximately 80% of the single ingredient market for all three years surveyed. Among all the methylphenidate products, Concerta® retained about half of the market share during all three years. During 2004, approximately 7.8 million prescriptions (55.1% of the prescriptions dispensed for methylphenidate) were dispensed for Concerta®. This represented an 11.1% increase in dispensed prescriptions for Concerta® from year 2003 or a 24% increase in dispensed prescriptions from year 2002.

Pediatricians were the most frequent prescribers for Concerta® in year 2004 with over 2.7 million (37%) dispensed prescriptions, followed by psychiatry specialty with 2.3 million dispensed prescriptions (31%) and family practice specialty with 866,000 dispensed prescriptions (11.7%). Together, these specialties accounted for nearly 80% of the dispensed prescriptions for Concerta® in year 2004.

Of the total prescription claims for Concerta® among an insured population managed by Caremark, the majority of the prescription claims for Concerta® were for persons aged 1-16 years, representing, on average, approximately 80% of all claims for all three years. Based on this percentage, over 6 million prescriptions for Concerta® are estimated to have been dispensed nationwide for persons aged 1-16 years in the U.S. during year 2004.

Pediatric male patients represented the majority of claims for Concerta®, accounting for approximately 75% of all pediatric prescriptions from year to year. In the adult population, males accounted on average for approximately 56% of adult claims for Concerta®.

According to IMS Health, NDTI™, the indication most frequently associated with Concerta® use in the pediatric population (0-16 years) for years 2002 through 2004 was “attention deficit disorder” (ICD-9 code 314.0), accounting for over 96% of the total Concerta® mentions during office-based physicians visits.

Overall, the majority of use for Concerta® in the outpatient setting as observed through the Caremark system as well as in IMS Health, NDTI™ appears to be in the pediatric population, and use has been increasing in both pediatric and adult populations over the past three years.

## 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 Subcommittee of the Anti-Infective Drugs 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.

Concerta® (NDA 21-121) is an oral central nervous system stimulant product consisting of methylphenidate HCl. The product was approved on August 1, 2000, for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The safety and efficacy Concerta® have not been established in children under six years of age. Concerta® extended-release tablets are available in 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths. The product is administered orally once daily in the morning.

The Pediatric Exclusivity Board of the FDA granted pediatric exclusivity for Concerta® Extended-release Tablets (NDA 21-121/S-008) on December 4, 2003.

This review describes outpatient drug use patterns for methylphenidate and Concerta® in the pediatric population as well as in the adult population in the years prior to and subsequent to the granting of pediatric exclusivity. Proprietary drug use databases licensed by the Agency were used to conduct this analysis.

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## METHODS

IMS Health, National Sales Perspectives™ data were used to determine the setting in which the product was sold. Sales of this product by number of tablets sold from the manufacturer to various retail and non-retail channels of distribution were analyzed (Table 1). Since the majority of use for this product occurs in the outpatient setting (93% of all tablets sold were to outpatient pharmacies during year 2004), we further examined the utilization patterns for methylphenidate focusing on the outpatient setting only. Outpatient use was measured by two IMS Health audits, the National Prescription Audit *Plus*™ (NPA *Plus*™) and the National Disease and Therapeutic Index™ (NDTI™), along with prescription claims for a 36-month period of time from Caremark (Dimension Rx™).

We examined prescriptions dispensed for Concerta®, its generic product (methylphenidate) as well as other single ingredient and combination analeptic products to compare Concerta® use relative to other products of the same therapeutic class. The single ingredient analeptic products included: methylphenidate, modafinil, dextroamphetamine, dexmethylphenidate, pemoline, methamphetamine. The combination analeptic products included amphetamine and

dextroamphetamine containing products such as Adderall®, Adderall XR® and amphetamine salts.

**Table 1. Sale of Concerta® Tablets (Extended Units) Sold to U.S. Distribution Channels, IMS Health, National Sales Perspectives™, 2004**

<b>U.S. Distribution Channels</b>	<b>Extended Units (000)</b>	<b>%</b>
<b>Total</b>	<b>291,152</b>	<b>100.0</b>
Retail Distribution Channel	271,375	93.2
Non-Retail Distribution Channel	19,778	6.8

IMS Health, National Sales Perspectives™, Year 2004, Extracted February 2005. Original File: 0502con3.dvr.

### ***OUTPATIENT DRUG USE - DATA SOURCES***

#### ***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 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 include prescriptions dispensed for Concerta® and other analeptic agents from January 1, 2002 – December 31, 2004, inclusive.

#### ***CAREMARK, DIMENSION RX™***

Caremark is one of the largest pharmacy benefit manager (PBM) companies in the US, currently covering over 70 million lives, and processing over 545 million prescription claims annually. FDA has access to Caremark's Dimension Rx™ database consisting of a subset of total Caremark paid claims, representing 350 million claims per year for prescriptions filled in 57,000 pharmacies across the country. These patient-level claims are available for 36 rolling months at the time they are accessed on-line. 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's Dimension Rx™ system 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 Caremark's Dimension Rx™ system to all persons receiving dispensed prescriptions in the U.S., however, is not known.

For this analysis, prescription claims in the Caremark Dimension Rx™ system were examined from January 1, 2002 to December 31, 2004, 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 diagnosis 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 Concerta® during office-based physician visits during the time period January 1, 2002 – December 31, 2004, inclusive.

## **RESULTS**

### **I. Dispensed Prescriptions**

There was an overall increase in the estimated prescriptions dispensed for single ingredient and combination analeptic products from 25 million prescriptions in year 2002 to over 29 million prescriptions dispensed in year 2004 (Table 2). This represented a 16.6% increase from year 2002 to year 2004. The single ingredient analeptic products accounted for approximately 17.7 million (60.8%) of the analeptics market in year 2004. The combination analeptic products accounted for approximately 11.4 million (39.2%) of the entire analeptics market in year 2004.

Methylphenidate products had the highest market share for the single ingredient products accounting for approximately 80% of the single ingredient market for all three years surveyed. Among all the methylphenidate products, Concerta® retained about half of the market share during all three years. During 2004, approximately 7.8 million prescriptions (55.1% of the prescriptions dispensed for methylphenidate) were dispensed for Concerta®. This represented an 11.1% increase in dispensed prescriptions for Concerta® from year 2003 and a 24% increase in dispensed prescriptions from year 2002.

**Table 2: Total Number of Prescriptions Dispensed (in thousands) for Concerta® and Analeptic Agents in Retail Pharmacies, IMS Health, National Prescription Audit Plus™, 2002 - 2004**

	2002		2003		2004	
	Prescriptions (000)	%	Prescriptions (000)	%	Prescriptions (000)	%
<b>Total Analeptic Products</b>	<b>25,013</b>	<b>100.0</b>	<b>26,320</b>	<b>100.0</b>	<b>29,176</b>	<b>100.0</b>
<b>Single Ingredient Products</b>	15,968	63.8	16,249	61.7	17,735	60.8
Methylphenidate	12,955	81.1	13,103	80.6	14,136	79.7
<b>Concerta</b>	<b>6,278</b>	<b>48.5</b>	<b>7,013</b>	<b>53.5</b>	<b>7,794</b>	<b>55.1</b>
<b>18MG</b>	<b>1,848</b>	<b>29.4</b>	<b>1,646</b>	<b>23.5</b>	<b>1,564</b>	<b>20.1</b>
<b>27MG</b>	<b>166</b>	<b>2.6</b>	<b>705</b>	<b>10.0</b>	<b>1,027</b>	<b>13.2</b>
<b>36MG</b>	<b>2,705</b>	<b>43.1</b>	<b>2,707</b>	<b>38.6</b>	<b>2,874</b>	<b>36.9</b>
<b>54MG</b>	<b>1,558</b>	<b>24.8</b>	<b>1,955</b>	<b>27.9</b>	<b>2,330</b>	<b>29.9</b>
Other Methylphenidates	6,677	51.5	6,090	46.5	6,342	44.9
Modafinil	1,095	6.9	1,427	8.8	1,933	10.9
Dextroamphetamine	1,510	9.5	1,246	7.7	1,151	6.5
Dexmethylphenidate	164	1.0	280	1.7	349	2.0
Pemoline	222	1.4	171	1.1	143	0.8
Methamphetamine	23	0.1	22	0.1	23	0.1
<b>Combination products</b>	9,045	36.2	10,071	38.3	11,440	39.2
*Amphetamine/ Dextroamphetamine	9,045	100.0	10,071	100.0	11,440	100.0
Adderall XR®	4,324	47.8	6,434	63.9	7,791	68.1
Amphetamine Salts	2,098	23.2	2,717	27.0	3,081	26.9
Adderall®	2,623	29	920	9.1	569	5.0

IMS Health, National Prescription Audit Plus™, Years 2002 - 2004, Extracted January 2005.

Original file: 0501con1.dvr

\*Amphetamine/Dextroamphetamine Combination products include Adderall®, Adderall XR®, and amphetamine salts

Pediatricians were the most frequent prescribers for Concerta® in year 2004 with over 2.7 million (37%) dispensed prescriptions, followed by psychiatry specialty with 2.3 million dispensed prescriptions (31%) and family practice specialty with 866,000 dispensed prescriptions (11.7%) (Table 3). Together, these specialties accounted for nearly 80% of the dispensed prescriptions for Concerta® in year 2004. In general, prescribing patterns for this product showed relatively little change across provider specialties from year 2000 - 2004 (data not shown).

**Table 3: Total Number of Prescriptions Dispensed (in thousands) for Concerta® by Physician Specialty, IMS Health, National Prescription Audit *Plus*™, 2004\***

Prescriber Specialty	Prescriptions (000)	%
<b>All prescribers</b>	<b>7,426</b>	<b>100.0</b>
<b>1 Pediatrics</b>	<b>2,752</b>	<b>37.1</b>
2 Psychiatry	2,300	31.0
3 Family Practice	866	11.7
4 Osteopathic Medicine	420	5.7
5 Neurology	252	3.4
6 Nurse Practitioner	219	2.9
7 Unknown	158	2.1
8 Internal Medicine	155	2.1
9 General Practice	45	0.6
10 Internal Med/Pediatrics	41	0.5
Other Specialties	218	2.9

IMS Health, National Prescription Audit *Plus*™, Year 2004, Extracted January 2005.

Original file: 0501con2.dvr

\* Excluding Long-Term Care and Mail Order Pharmacies

## II. Patient Demographics

Among an insured population managed by Caremark, the total number of claims for Concerta® has also increased from 807,843 in year 2002 to 963,715 in year 2004 (Table 4). The increase in that population was consistent with IMS Health data sources.

The majority of the prescription claims for Concerta® (approximately 80%) during the three years were for persons aged 1-16 years, and the remaining 20%, were for persons aged 17 and older.

The number of prescription claims for the pediatric population (age 1-16 years) increased from 660,421 claims in year 2002 to 749,881 claims in year 2004. The pediatric male patients represented the majority of pediatric claims (approximately 75%) for Concerta® during all three years.

Similar to the prescription claims for the pediatric population, the number of prescription claims for adults also increased from 147,422 to 213,834 over that same time period, representing a 45% increase from 2002 to 2004. Unlike the pediatric population, however, the adult male claims represented on average about 56% of all adult prescription claims for Concerta®.

Overall, the majority of use for Concerta® in the Caremark system as well as in IMS HEALTH's NDTI appears to be in the pediatric population, and use has been increasing in both pediatric and adult populations over the past three years.

**Table 4: Total Number of Claims for Concerta® by age groups and gender from Year 2002 - 2004 from Caremark Pharmacy Benefit Manager Database**

Characteristics	2002		2003		2004	
	Claims (N)	%*	Claims (N)	%*	Claims (N)	%*
<b>Age (years)</b>						
1-16	<b>660,421</b>	<b>(81.8)</b>	<b>709,686</b>	<b>(80.1)</b>	<b>749,881</b>	<b>(77.8)</b>
Female	157,930	23.9	172,195	24.3	190,494	25.4
Male	502,491	76.1	537,491	75.7	559,387	74.6
17+	<b>147,422</b>	<b>(18.2)</b>	<b>176,221</b>	<b>(19.9)</b>	<b>213,834</b>	<b>(22.2)</b>
Female	63,971	43.4	76,515	43.4	97,005	45.4
Male	83,451	56.6	99,706	56.6	116,829	54.6
<b>TOTAL</b>	<b>807,843</b>	<b>(100)</b>	<b>885,907</b>	<b>(100)</b>	<b>963,715</b>	<b>(100)</b>

Caremark Dimension Rx™, Extracted February 2004

\* Percent in parentheses represents percent of the total number of claims for **Concerta®**

Since IMS Health, NPA Plus™ does not include demographic information on patients for the entire time period of interest, we applied the proportions for demographic subgroups from Caremark's Dimension Rx™ to IMS Health, NPA Plus™ data in an effort to approximate the number of prescriptions dispensed for Concerta® nationwide to children (Table 5). Using this approach, over 6 million prescriptions for Concerta® are estimated to have been dispensed for persons aged 1-16 years in the U.S. during year 2004.

**Table 5: Estimated Nationwide Prescriptions Dispensed for Concerta® in the Pediatric Age Group (1-16) During Year 2004**

	Total Number of Prescriptions* Dispensed for All Age Groups <i>(from Table 2)</i>	% Pediatric Claims** (Ages 1-16 yrs) <i>(from Table 4)</i>	Estimated Number of Prescriptions Dispensed to the Pediatric Population (Age 1-16 yrs)
<b>TOTAL</b>	7,794,000	77.8%	6,064,628

\*IMS Health, National Prescription Audit Plus™, Year 2004, Extracted January 2005.

Original File: 0501con1.dvr

\*\*Caremark Dimension Rx™, Extracted February 2005.

### III. Indication for Use

According to IMS Health, NDTI™, the diagnosis, or indication, most frequently linked to Concerta® use in the pediatric population (0-16 years) for years 2002 through 2004 was “attention deficit disorder” (ICD-9 code 314.0), accounting for over 96% of the total Concerta® mentions during office-based physicians visits (Table 6). In the adult population (17 years and over), nearly two-thirds of the mentions (66.0%) were for “unspecified disturbance of conduct” followed by “attention deficit disorder” which accounted for over 25% of all mentions in this age group during year 2004.

**Table 6: Indications Associated with Mentions of Concerta® (in thousands) During Office-Based Physician Visits by Patient Age Groups, IMS Health, National Disease and Therapeutic Index™, 2002 – 2004**

	2002		2003		2004	
	N	%	N	%	N	%
<b>Concerta® Total Mentions</b>	<b>2,978</b>	<b>100.0</b>	<b>4,154</b>	<b>100.0</b>	<b>3,986</b>	<b>100.0</b>
<b>Patient Age 0-16</b>	<b>2,387</b>	<b>80.1</b>	<b>3,574</b>	<b>86.0</b>	<b>3,340</b>	<b>83.8</b>
314.0 Attention deficit disorder	2,303	96.5	3,455	96.7	3,258	97.5
312.9 Unspecified disturbance of conduct	33	1.4	20	0.6	19	0.6
313.8 Other or mixed emotional disturbances of childhood or adolescence	---	---	4	0.1	15	0.4
299.0 Infantile autism	14	0.6	21	0.6	12	0.4
299.8 Other specified early childhood psychoses	---	---	14	0.4	11	0.3
<b>Patient Age 17+</b>	<b>591</b>	<b>19.9</b>	<b>580</b>	<b>14.0</b>	<b>646</b>	<b>16.2</b>
312.9 Unspecified disturbance of conduct	347	58.7	389	67.0	426	66.0
314.0 Attention deficit disorder	200	33.8	142	24.5	166	25.7
311.0 Depressive disorder, not elsewhere classified	4	0.7	6	1.0	13	2.0
296.3 Major depressive disorder, recurrent episode	5	0.9	3	0.5	10	1.5
799.9 Other unknown and unspecified cause	3	0.4	---	---	10	1.5

IMS Health, National Disease and Therapeutic Index™, Years 2002 – 2004, Extracted February 2005.  
Original File: 0502Concerta AgDx.dvf

## DISCUSSION

Based on the databases that were used for this consult, the use of analeptic products has been on the rise in the past three years, 2002 to 2004. Dispensed prescriptions for Concerta® in both adult and pediatric populations have been continuously increasing during the time period surveyed.

There was relatively little change in the prescribing patterns for Concerta® dispensed in outpatient retail pharmacy settings across provider specialties from year 2002 through 2004. Pediatricians were the most frequent prescribers for Concerta® followed by psychiatry and family practice. Together these specialties accounted for nearly 80% of the prescriptions dispensed in year 2004. Approximately 37.1% of the prescriptions dispensed in the outpatient retail pharmacy settings derived from pediatricians, consistent with the observation that the majority of use of this product appears to be in the pediatric population.

Findings from this consult should be interpreted in the context of the known limitations of the databases used. NPA Plus™ data provide an estimate of the total number of prescriptions dispensed in the U.S. The data, however, do not include historical demographic information, such as age and gender. The inclusion of prescriber specialty data in this report does not include the mail order and long-term care channels.

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 participants 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 participants less than the age of 1 year is not available from this data source.

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.

## **CONCLUSION**

There was an overall increase in the estimated prescriptions dispensed for single ingredient and combination analeptic products from 25 million prescriptions in year 2002 to over 29 million prescriptions dispensed in year 2004. This represented a 16.6% increase from year 2002 to year 2004.

Methylphenidate products had the highest market share for the single ingredient products, accounting for approximately 80% of the single ingredient market for all three years surveyed. Among all the methylphenidate products, Concerta® retained about half of the market share during all three years. During 2004, approximately 7.8 million prescriptions (55.1% of the prescriptions dispensed for methylphenidate) were dispensed for Concerta®. This represented

an 11.1% increase in dispensed prescriptions for Concerta® from year 2003 and a 24% increase in dispensed prescriptions from year 2002.

Of the total prescription claims for Concerta® among an insured population managed by Caremark, the majority of the prescription claims for Concerta® were for persons aged 1-16 years, representing, on average, approximately 80% of all claims for all three years. Pediatric male patients represented the majority of pediatric claims at approximately 75% from year to year. In the adult population, males accounted on average for approximately 56% of claims,

Overall, the majority of use for Concerta® in the outpatient setting as observed through the Caremark system as well as in IMS Health, NDTI™ appears to be in the pediatric population, and use has been increasing in both pediatric and adult populations over the past three years. We estimate that approximately 6 million prescriptions for Concerta were dispensed to 0-16 year olds in 2004, primarily to treat attention deficit disorder.

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