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**Drug Use Review**

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**\*\*This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information in this document has been cleared for public release.\*\***

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## EXECUTIVE SUMMARY

This review analyzes the sales distribution and the outpatient retail utilization patterns for oral single-ingredient levonorgestrel products in the patient populations aged 0-17 and 18+ years for years 2002 through 2010. Proprietary drug use databases licensed by the FDA were used to conduct this analysis. The three oral single-ingredient levonorgestrel products identified from these drug use databases were Plan B<sup>®</sup>, Plan B One-Step<sup>®</sup>, and branded generic Next Choice<sup>™</sup>. Data findings are as followed:

### Sales distribution from manufacturers to various channels of distribution:

- Approximately 21 million packages were sold for oral single-ingredient levonorgestrel products over the cumulative time period from year 2002 to year 2010. The sales of oral single-ingredient levonorgestrel products, as a whole, gradually increased throughout the time period examined.
- Plan B<sup>®</sup> sales increased from 129,000 packages sold during year 2002 to 3.4 million packages sold during year 2008, but drastically decreased to 775 packages sold during year 2010 after the introduction of Plan B One-Step<sup>®</sup> and Next Choice<sup>™</sup> in year 2009.
- During year 2010, Plan B One-Step<sup>®</sup> accounted for 35% of total sales (2.5 million packages) and Next Choice<sup>™</sup> accounted for 65% of total sales (4.7 million packages).

### Prescription and patient counts from outpatient retail pharmacies:

- Approximately 2.8 million prescriptions were dispensed and 1.8 million patients received dispensed prescriptions for oral single-ingredient levonorgestrel products for the cumulative time period from year 2002 to year 2010.
- The total number of patients receiving dispensed prescriptions for oral single-ingredient levonorgestrel products, as a whole, increased by almost 7.5-fold from year 2002 (64,400 patients) to year 2006 (484,000 patients), but decreased to 190,000 patients during year 2010.
- The number of patients aged 0-17 years who received a dispensed prescription for oral single-ingredient levonorgestrel products as a whole increased from 5,600 patients in year 2002 to 36,900 patients in year 2006 but then decreased to 19,200 patients in year 2010.
- The number of patients aged 18 years and older who received a dispensed prescription for oral single-ingredient levonorgestrel products as a whole increased from 58,900 patients in year 2002 to 448,000 patients in year 2006 but then decreased to 172,000 patients in year 2010.
- During year 2010, approximately 106,000 patients received dispensed prescriptions for Next Choice<sup>™</sup>; 85,500 patients received dispensed prescriptions for Plan B One-Step<sup>®</sup>; and 3,800 patients received dispensed prescriptions for Plan B<sup>®</sup>.
- During year 2010, pediatric patients aged 17 years and younger accounted for around 11% (401 patients) of patients receiving dispensed prescriptions for Plan B<sup>®</sup>, 9% (8,000 patients) of patients receiving dispensed prescriptions for Plan B One-Step<sup>®</sup>, and 10% (10,900 patients) of patients receiving dispensed prescriptions for Next Choice<sup>™</sup>.
- The greatest proportion of dispensed prescriptions for Plan B<sup>®</sup> were prescribed by “Gynecologists” (31%) while the greatest proportion dispensed prescriptions for Plan B One-Step<sup>®</sup> (47%) and Next Choice<sup>™</sup> (22%) had a prescriber whose specialty was “Unspecified.”

- “Contracep MGMT-Counsel” (ICD-9 code V25.0) was the most common diagnosis associated with the use of Plan B<sup>®</sup> and Next Choice<sup>™</sup> among all age groups.

## 1 INTRODUCTION

In preparation for the Pediatric Advisory Committee meeting to be held on January 30-31, 2012, the Office of Pediatric Therapeutics (OPT) and Pediatric and Maternal Health Staff (PMHS) requested a review of the drug utilization patterns for oral single-ingredient levonorgestrel products. Using the currently available proprietary drug use databases licensed by the Agency, this review summarizes the sales from manufacturers to various channels of distribution and the outpatient retail utilization patterns in terms of prescription and patient counts for oral single-ingredient levonorgestrel products by age (0-17 and 18+ years) from year 2002 through year 2010, annually and cumulative. Additionally, prescribing specialty and diagnoses associated with the use of oral single-ingredient levonorgestrel products in the pediatric and adult populations were examined for the same cumulative time period from year 2002 through year 2010.

### 1.1 BACKGROUND

Oral single-ingredient levonorgestrel is a “progestin-only emergency contraceptive, indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure, but is not intended for routine use as a contraceptive.” It was initially approved on July 28, 1999 only as a prescription product under NDA 021045 and marketed as Plan B<sup>®</sup> whose packages contain two tablets of 0.75mg. On August 24, 2006, Plan B<sup>®</sup> became available as an over-the-counter product for women who are 18 years and older, but remained as a prescription product only for women who are younger than 18 years. Generic oral single-ingredient levonorgestrel (Next Choice<sup>™</sup>, packages of two tablets of 0.75mg) then became available as a prescription product only on June 24, 2009, under ANDA 078666. On July 10, 2009, the labeling was changed to allow access of over-the-counter Plan B<sup>®</sup> to women who are 17 years and older. On this same day, Plan B<sup>®</sup> One-Step whose packages contain one tablet of 1.5mg was approved under NDA 021998 as a prescription product for women aged younger than 17 years and as an over-the-counter product for women aged 17 years and older. Finally, generic oral single-ingredient levonorgestrel (Next Choice<sup>™</sup>) also became available as an over-the-counter product for women aged 17 years and older under ANDA 078665 on August 28, 2009, and as both prescription and over-the-counter product under ANDA 090740 on December 30, 2010.<sup>1,2,3,4</sup>

The regulatory history and product labeling of oral single-ingredient levonorgestrel products are also summarized in the following table.

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<sup>1</sup> U.S. Food and Drug Administration: Drugs@FDA. Plan B<sup>®</sup> Approval History. Collected in August 2011. Available at: [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label\\_ApprovalHistory#applist](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#applist)

<sup>2</sup> U.S. Food and Drug Administration: Drugs@FDA. Plan B<sup>®</sup> Package Insert. Collected in August 2011. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/021045s0151bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021045s0151bl.pdf)

<sup>3</sup> U.S. Food and Drug Administration: Drugs@FDA. Plan B<sup>®</sup> One-Step Package Insert. Collected in August 2011. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/0219981bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/0219981bl.pdf)

<sup>4</sup> Watson Pharma, Inc. Next Choice<sup>™</sup> Package Insert. Collected in August 2011. Available at: [http://pi.watson.com/data\\_stream.asp?product\\_group=1648&p=pi&language=E](http://pi.watson.com/data_stream.asp?product_group=1648&p=pi&language=E)

<b>Table 1. Summary of regulatory history and product labeling of oral single-ingredient levonorgestrel products</b>		
<b>Brand/Generic/Formulations</b>	<b>NDA/ANDA/Approval Date</b>	<b>Indications</b>
Plan B <sup>®</sup> (0.75mg oral tablets)	NDA 021045 <ul style="list-style-type: none"> <li>• Prescription only: July 28, 1999</li> <li>• Over-the-counter product only for women aged 18 years and older: August 24, 2006</li> <li>• Over-the-counter product only for women aged 17 years and older: July 10, 2009</li> </ul>	Emergency contraceptive
Plan B One-Step <sup>®</sup> (1.5mg oral tablets)	NDA 021998 <ul style="list-style-type: none"> <li>• Prescription for women aged younger than 17 years: July 10, 2009</li> <li>• Over-the-counter product for women aged 17 years and older: July 10, 2009</li> </ul>	Emergency contraceptive
Generic oral single-ingredient levonorgestrel (Next Choice <sup>™</sup> 0.75mg oral tablets)	a) ANDA 078666 <ul style="list-style-type: none"> <li>• Prescription only: June 24, 2009</li> </ul> b) ANDA 078665 <ul style="list-style-type: none"> <li>• Prescription for women aged younger than 17 years: August 28, 2009</li> <li>• Over-the-counter for women aged 17 years and older: August 28, 2009</li> </ul> c) ANDA 090740 <ul style="list-style-type: none"> <li>• Prescription for women aged younger than 17 years: December 30, 2010</li> <li>• Over-the-counter for women aged 17 years and older: December 30, 2010</li> </ul>	Emergency contraceptive

## 2 METHODS AND MATERIAL

### 2.1 DETERMINING SETTINGS OF CARE

The IMS Health, IMS National Sales Perspectives<sup>™</sup> (see Appendix 2 for full database description) was used to determine the various retail and non-retail channels of distribution for oral single-ingredient levonorgestrel products (Plan B<sup>®</sup>, Plan B One-Step<sup>®</sup>, and Next Choice<sup>™</sup>). Sales data for year 2010 indicated that 73% of packages of Plan B<sup>®</sup> were sold to outpatient retail pharmacies and 27% to non-retail settings -- of which, 41% were sold to non-federal hospitals and 32% to clinics. Approximately 98% of sales of Plan B One-Step<sup>®</sup> were sold to outpatient retail pharmacies during year 2010. Approximately 63.5% of branded generic Next Choice<sup>™</sup> was sold to outpatient retail

pharmacies and 36.5% was sold to non-retail settings -- of which, clinics accounted for 96%.<sup>5</sup> As a result, outpatient retail utilization patterns were examined for all oral single-ingredient levonorgestrel products. Mail order and non-retail data, including clinic data, were excluded from this analysis.

## 2.2 DATA SOURCES USED

Proprietary drug use databases licensed by the Agency were used to conduct this analysis (see Appendix 2 for full databases description).

The IMS Health, IMS National Sales Perspective™ was used to obtain the total sales distribution of oral single-ingredient levonorgestrel products from manufacturers to retail and non-retail channels of distribution for years 2002 through 2010, annually and cumulative. The sales data represent the amount of product being sold into the “back door” of various drug distribution outlets (e.g. retail pharmacies, hospitals, clinics, etc.) – they do not reflect what is being sold to or administered to patients directly but may be a possible surrogate for use.

The IMS, Vector One®: National (VONA) and Total Patient Tracker (TPT) were used to obtain estimates of total outpatient dispensed prescriptions and total patients receiving dispensed prescriptions, respectively, for oral single-ingredient levonorgestrel products stratified by age (0-17 and 18+ years) for years 2002 through 2010. Diagnoses associated with the use of oral single-ingredient levonorgestrel products stratified by age (0-17 and 18+ years) were obtained from SDI, Physician Drug and Diagnosis Audit (PDDA) from years 2002 through 2010, cumulative.

The Shopper Insights Advantage™ (SIA) database to which the FDA newly has access, allowing description of the use of OTC products, was explored to determine whether use of these products could be detected and described.

## 3 RESULTS

### 3.1 SALES DISTRIBUTION ANALYSIS (TABLE 2 AND FIGURE 1)

Approximately 21 million packages of oral single-ingredient levonorgestrel products (Plan B®, Plan B One-Step®, and Next Choice™) were sold from manufacturers to various channels of distribution for years 2002-2010, cumulative. The number of packages sold for oral single-ingredient levonorgestrel products, as a whole, increased by almost 56-fold from 129,000 packages sold in year 2002 to 7.2 million packages sold in year 2010. Between the years 2002 and 2008, there was a 26-fold increase in the number of packages of Plan B® sold from 129,000 packages of sold in year 2002 to 3.4 million packages sold in year 2008. Plan B One-Step® and Next Choice™ were introduced to the market mid-year in 2009; after which the number of packages sold for Plan B® decreased to 2.9 million packages in year 2009 and further decreased to 775 packages in year 2010. During year 2010, Plan B One-Step® accounted for 35% of total sales (2.5 million packages) and Next Choice™ accounted for 65% of total sales (4.7 million packages).

### 3.2 OUTPATIENT RETAIL ANALYSIS

#### 3.2.1 Prescription Count by Age (Table 3)

Over the cumulative time period from year 2002 to year 2010, approximately 2.8 million prescriptions were dispensed for oral single-ingredient levonorgestrel products through U.S. outpatient retail

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<sup>5</sup> Source: IMS Health, IMS National Sales Perspectives™. Year 2010. Extracted December 2011. File: NSPC 2011-2690 Plan B brand generic channel 12-2-11.xls

pharmacies. As a whole, the total dispensed prescriptions for oral single-ingredient levonorgestrel products increased by almost 7.5-fold from around 80,500 prescriptions dispensed in year 2002 to 608,000 prescriptions dispensed in year 2006. However, by year 2010, the number of dispensed prescriptions decreased by approximately 57% to 261,000 prescriptions. During year 2010, Next Choice<sup>TM</sup> accounted for approximately 53% (138,000 prescriptions) of dispensed prescriptions while Plan B One-Step<sup>®</sup> accounted for 45.5% (119,000 prescriptions) and Plan B<sup>®</sup> accounted for 2% (4,200 prescriptions).

Throughout the time period examined the majority of prescriptions dispensed for Plan B<sup>®</sup>, Plan B One-Step<sup>®</sup>, and Next Choice<sup>TM</sup> were to adults aged 18 years and greater. During year 2010, pediatric patients aged 17 years and younger accounted for around 11% (445 prescriptions) of dispensed prescriptions for Plan B<sup>®</sup>, 11% (12,600 prescriptions) of dispensed prescriptions for Plan B One-Step<sup>®</sup>, and 10% (14,300 prescriptions) of dispensed prescriptions for Next Choice<sup>TM</sup>.

### **3.2.2 Patient Count by Age (Table 4 and Figures 2-3)**

The patient count data followed similar trends as prescription count data. Over the cumulative time period from year 2002 to year 2010, approximately 1.8 million patients received dispensed prescriptions for oral single-ingredient levonorgestrel products through U.S. outpatient retail pharmacies. As a whole, the total number of patients receiving dispensed prescriptions for oral single-ingredient levonorgestrel products increased by almost 7.5-fold from around 64,400 patients during year 2002 to 484,000 patients during year 2006. However, by year 2010, the number of patients receiving dispensed prescriptions for oral single-ingredient levonorgestrel products decreased by around 61% to 190,000 patients. During year 2010, Plan B One-Step<sup>®</sup>, Next Choice<sup>TM</sup>, and Plan B<sup>®</sup> accounted for approximately 45% (85,500 patients), 56% (106,000 patients), and 2% (3,800 patients), respectively, of total patients receiving dispensed prescriptions for all oral single-ingredient levonorgestrel products (Table 4, Figure 2).

The number of patients aged 0-17 years who received dispensed prescriptions for oral single-ingredient levonorgestrel products as a whole increased by nearly 7-fold from 5,600 patients in year 2002 to 36,900 patients in year 2006. However, by year 2010, the number of patients aged 0-17 years decreased by around 48% to 19,200 patients. Similarly, the number of patients aged 18 years and older who received dispensed prescriptions for oral single-ingredient levonorgestrel products as a whole increased by nearly 8-fold from 58,900 patients during year 2002 to 448,000 patients during year 2006. The number of patients aged 18 years and older decreased by 62% to 172,000 patients during year 2010 (Figure 3).

Throughout the time period examined from year 2002 to year 2010, the majority of patients who received dispensed prescriptions for Plan B<sup>®</sup>, Plan B One-Step<sup>®</sup>, and Next Choice<sup>TM</sup> were adults aged 18 years and greater. During year 2010, pediatric patients aged 17 years and younger accounted for around 11% (401 patients) of patients receiving dispensed prescriptions for Plan B<sup>®</sup>, 9% (8,000 patients) of patients receiving dispensed prescriptions for Plan B One-Step<sup>®</sup>, and 10% (10,900 patients) of patients receiving dispensed prescriptions for Next Choice<sup>TM</sup> (Table 4, Figure 2).

### **3.2.3 Households Purchasing Over-the-Counter Oral Single-Ingredient Levonorgestrel**

Our exploration of Shopper Insights Advantage™ (SIA) database to examine the number of households purchasing OTC oral single-ingredient levonorgestrel products proved unsuccessful; too little use of these products was found to allow for a productive analysis.<sup>6</sup>

### **3.2.4 Top 10 Prescribing Specialties (Table 5)**

Over the cumulative time period from year 2002 to year 2010, “Obstetrics/Gynecology” was the top prescribing specialty for Plan B® with around 31% (784,000 prescriptions) of dispensed prescriptions, followed by “General Practice/Family Medicine/Doctor of Osteopathy” with around 17% (431,000 prescriptions), and “Hospitalists” with around 8% (209,000 prescriptions) of dispensed prescriptions. Approximately 20.5% (517,000 prescriptions) of dispensed prescriptions for Plan B® had an “Unspecified” specialty while “Pediatricians” accounted for approximately 2.5% (62,100 prescriptions) of dispensed prescriptions for Plan B®.

The highest proportion of dispensed prescriptions for Next Choice™ had an “Unspecified” specialty with approximately 22% (39,300 prescriptions) during years 2002-2010, cumulative.

“Obstetrics/Gynecology,” “General Practice/Family Medicine/Doctor of Osteopathy,” and “Nurse Practitioners” followed with around 20% (36,300 prescriptions), 19% (34,400 prescriptions), and 12.5% (22,800 prescriptions) of dispensed prescriptions for Next Choice™, respectively.

“Pediatricians” accounted for almost 5% (8,500 prescriptions) of dispensed prescriptions.

Cumulatively from year 2002 to year 2010, the highest proportion of dispensed prescriptions for Plan B One-Step® had an “Unspecified” specialty with approximately 47% (70,800 prescriptions).

“Obstetrics/Gynecology,” “General Practice/Family Medicine/Doctor of Osteopathy,” and “Nurse Practitioners” followed with 13% (20,200 prescriptions), with 11% (16,500 prescriptions), and with 9% (13,200 prescriptions), respectively, of dispensed prescriptions for Plan B One-Step®.

“Pediatricians” accounted for around 2% (3,300 prescriptions) of dispensed prescriptions.

### **3.2.5 Indications for Use of Oral Single-Ingredient Levonorgestrel by Age (Table 6)**

Diagnoses associated with the use of oral single-ingredient levonorgestrel products stratified by age from year 2002 to year 2010 were coded according to the International Classification of Diseases (ICD-9-CM) and 95% confidence intervals were applied. The number of mentions of oral single-ingredient levonorgestrel products among the pediatric population in office-based physician visits was below the acceptable count allowable to provide a reliable estimate of national use, and should therefore be interpreted with caution.

Among pediatric patients aged 17 years and younger, Plan B® was the only drug mentioned for use during office-based physician visits with the only diagnosis of “Contracep MGMT-Counsel” (ICD-9 code V25.0) for years 2002 through 2010, cumulative. The point estimate for the number of mentions associated with the diagnosis “Contracep MGMT-Counsel” was 68,000 uses (95% CI, 29,000 - 107,000 uses) during the time period examined.

Over the cumulative time period from year 2002 to year 2010, “Contracep MGMT-Counsel” (ICD-9 code V25.0) was the top diagnosis associated with the use of Plan B® (85% of uses) and Next Choice™ (100% of uses) among adults aged 18 years and greater. The point estimate for the number of mentions associated with the diagnosis of “Contracep MGMT-Counsel” was approximately 745,000

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<sup>6</sup> Source: Shopper Insights Advantage™ (SIA). Years 2007-2010. Data extracted November 2011. File: SIA 2011 2690 Plan B 11-10-11.xls



uses (95% CI, 616,000 – 874,000 uses) for Plan B<sup>®</sup> and approximately 32,000 uses (95% CI, 6,000 – 59,000 uses) for Next Choice<sup>™</sup>.

## 4 DISCUSSION

Although there appears to be an increase in the distribution of oral single-ingredient levonorgestrel products as a whole during the time period examined, the prescription use of these products through the outpatient retail settings appears to have decreased since the approval of the OTC labeling of Plan B<sup>®</sup> in year 2006. Moreover, the prescription use of oral single-ingredient levonorgestrel products among both pediatrics and adults through outpatient retail pharmacies appears to have decreased since year 2006. These trends suggest that patients could be switching from obtaining these products through prescriptions in the outpatient retail settings to purchasing them over-the-counter, but due to limitations in the data available to the Agency, we cannot verify that assumption. Another common setting for obtaining these products is through clinics (e.g., Planned Parenthood); however data from clinics could not be included in this analysis, again due to limitations in the data available to the Agency. Since the sales distribution data suggest that clinics represent a site for distribution of a substantial volume of these products, this could represent an important limitation of the current analysis.

Findings from this review should be interpreted in the context of the known limitations of the databases used. Based on the IMS Health, IMS National Sales Perspectives<sup>™</sup>, sales data for year 2010 showed that the majority of Plan B<sup>®</sup>, Plan B One-Step<sup>®</sup>, and Next Choice<sup>™</sup> were sold to outpatient retail pharmacies. These data do not provide a direct estimate of use but do provide a national estimate of units sold from the manufacturer to various channels of distribution. The amount of product purchased by these retail and non-retail channels of distribution may be a possible surrogate for use, if we assume that facilities purchase drugs in quantities reflective of actual patient use. Furthermore, IMS estimates that approximately 50% of all U.S. OTC sales activity is captured in this database.<sup>7</sup>

The Agency recently acquired access to a data source, Shopper Insights Advantage<sup>™</sup> (SIA), for quantifying and describing the use of OTC products. This data source, however, relies on survey information and the willingness of individuals in randomly selected households in a panel to disclose the purchase and use of OTC products. One of the limitations of this design is that the use of products considered “sensitive,” such as oral single-ingredient levonorgestrel products, are likely to be underestimated. A quick examination of the data confirmed little reported use, and due to these limitations, the data were not included in this review.

The estimates provided in this review are national estimates, but no statistical tests were performed to determine statistically significant changes over time or between products. Therefore, all changes over time or between products should be considered approximate, and may be due to random error.

SDI uses the term “drug uses” to refer to 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.

Indications for use were obtained using SDI’s PDDA, a monthly survey of 3,200 office based physicians. Although PDDA data are helpful to understand how drug products are prescribed by physicians, the small sample size and the relatively low usage of these products limits the ability to

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<sup>7</sup> IMS Health, IMS National Sales Perspectives<sup>™</sup> Retail and Non-Retail Sample Coverage of the Universe (09/15/06).

identify trends in the data. In general, PDDA data are best used to identify the typical uses for the products in clinical practice, and the VONA outpatient prescription data to evaluate trends over time.

## 5 CONCLUSIONS

Over the cumulative time period from year 2002 through year 2010, approximately 21 million packages were sold for oral single-ingredient levonorgestrel products from manufacturers to various channels of distribution. In regard to the use trend of the individual products, the sales of Plan B<sup>®</sup> appear to have decreased since with the introduction of Plan B One-Step<sup>®</sup> and Next Choice<sup>™</sup> to the market in year 2009.

Cumulatively from year 2002 to year 2010, approximately 1.8 million patients received dispensed prescriptions for oral single-ingredient levonorgestrel products through outpatient retail pharmacies. During year 2010, pediatric patients aged 17 years and younger accounted for around 11% (401 patients) of patients receiving dispensed prescriptions for Plan B<sup>®</sup>, 9% (8,000 patients) of patients receiving dispensed prescriptions for Plan B One-Step<sup>®</sup>, and 10% (10,900 patients) of patients receiving dispensed prescriptions for Next Choice<sup>™</sup>. Although the sales into the market of oral single-ingredient levonorgestrel products, as a whole, appear to have gradually increased during the time period examined, the number of patients receiving dispensed prescriptions of oral single-ingredient levonorgestrel products from outpatient retail pharmacies appears to have decreased among both pediatrics and adults after the approval of the OTC labeling in year 2006. This may suggest a shift toward OTC purchasing and/or clinic prescriptions, but the available data do not allow for confirmation of that trend.

## APPENDIX 1: TABLES AND FIGURES

**Table 2. Sales of Plan B®, Plan B® One-Step, and Next Choice™ distributed from manufacturers to retail\* and non-retail\*\* channels of distribution, years 2002-2010**

	Year 2002	Year 2003	Year 2004	Year 2005	Year 2006	Year 2007	Year 2008	Year 2009		Year 2010		Cumulative 1/2002-12/2010	
	Eaches***	Eaches	Eaches	Eaches	Eaches	Eaches	Eaches	Eaches	%	Eaches	%	Eaches	%
OTAL MARKET	128,765	254,396	502,226	762,664	1,102,270	2,503,406	3,389,678	5,115,728	100.0%	7,200,987	100.0%	20,960,120	100.0%
NEXT CHOICE™ (0.75MG)								1,235,412	24.1%	4,710,244	65.4%	5,945,656	28.4%
PLAN B® ONE-STEP (1.5MG)								962,996	18.8%	2,489,968	34.6%	3,452,964	16.5%
PLAN B® (0.75MG)	128,765	254,396	502,226	762,664	1,102,270	2,503,406	3,389,678	2,917,320	57.0%	775	0.0%	11,561,500	55.2%

Source: IMS Health, IMS National Sales Perspective™. Years 2002-2010. Extracted August 2011. Files: NSPC 2011-2690 Plan B brand generic 8-9-11.xls, 2002plan.dvf, 2003plan.dvf, 2004plan.dvf, 2005plan.dvf, 2006plan.dvf, 2007plan.dvf, 2008plan.dvf

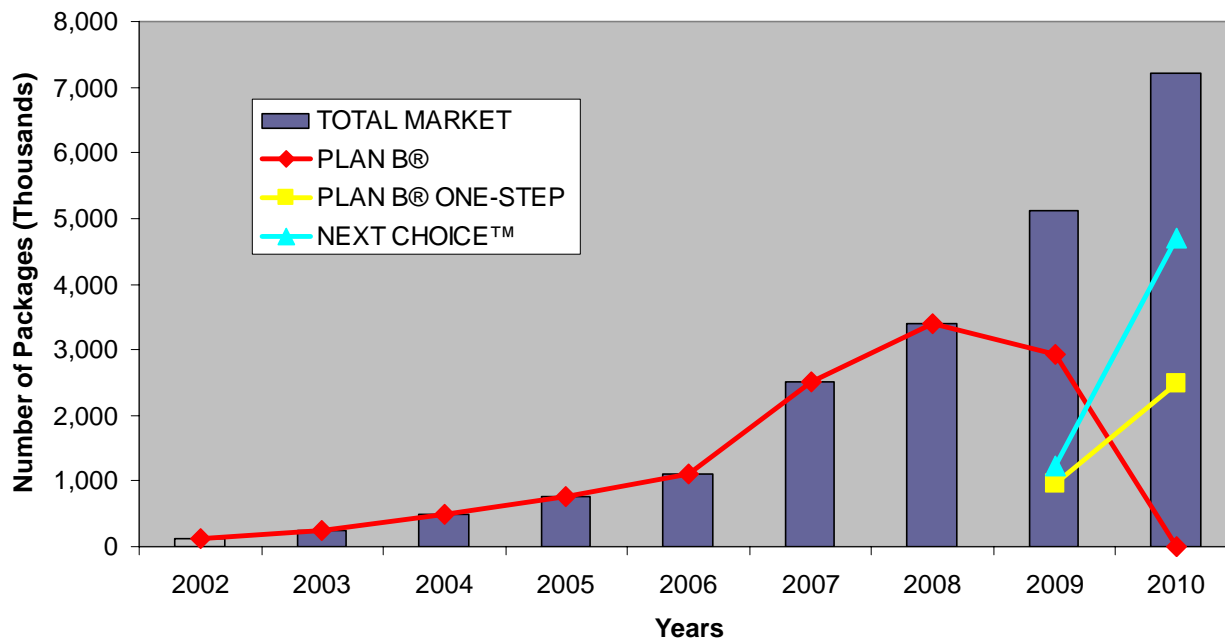
\*Retail channels include chain, independent, foodstore, mail order, and mass merchandise pharmacies in the entire United States.

\*\*Non-Retail channels include hospitals, long-term care facilities, clinics, home healthcare providers, and HMOs in the entire United States.

\*\*\*Eaches refer to the number of packages, bottles, vials, or syringes of a product shipped as a unit.

**Figure 1. Sales of Plan B®, Plan B® One-Step, and Next Choice™ distributed from manufacturers to retail and non-retail channels of distribution, years 2002-2010**

Source: IMS Health, IMS National Sales Perspective™. Years 2002-2010. Extracted August 2011.



**Table 3. Total dispensed prescriptions for Plan B®, Plan B® One-Step, and Next Choice™ by age in the U.S. outpatient retail pharmacies, years 2002-2010**

	Year 2002		Year 2003		Year 2004		Year 2005		Year 2006		Year 2007		Year 2008		Year 2009		Year 2010		Cumulative 1/2002 12/2010	
	TRxs		TRxs		TRxs		TRxs		TRxs		TRxs		TRxs		TRxs	%	TRxs	%	TRxs	%
<b>Total Prescriptions</b>	<b>80,549</b>		<b>172,565</b>		<b>380,331</b>		<b>553,506</b>		<b>607,977</b>		<b>277,090</b>		<b>252,330</b>		<b>262,362</b>	<b>100.0%</b>	<b>261,352</b>	<b>100.0%</b>	<b>2,848,062</b>	<b>100.0%</b>
<b>Next Choice™ (0.75mg)</b>	--		--		--		--		--		--		--		43,799	16.7%	138,278	52.9%	182,076	6.4%
0-17 years	--		--		--		--		--		--		--		4,807	11.0%	14,270	10.3%	19,076	10.5%
18+ years	--		--		--		--		--		--		--		38,991	89.0%	124,006	89.7%	162,997	89.5%
UNSPEC	--		--		--		--		--		--		--		1	0.0%	2	0.0%	3	0.0%
<b>Plan B® One-Step (1.5mg)</b>	--		--		--		--		--		--		--		32,486	12.4%	118,872	45.5%	151,358	5.3%
0-17 years	--		--		--		--		--		--		--		3,588	11.0%	12,572	10.6%	16,160	10.7%
18+ years	--		--		--		--		--		--		--		28,895	88.9%	106,299	89.4%	135,195	89.3%
UNSPEC	--		--		--		--		--		--		--		2	0.0%	1	0.0%	4	0.0%
<b>Plan B® (0.75mg)</b>	<b>80,549</b>		<b>172,565</b>		<b>380,331</b>		<b>553,506</b>		<b>607,977</b>		<b>277,090</b>		<b>252,330</b>		<b>186,077</b>	<b>70.9%</b>	<b>4,202</b>	<b>1.6%</b>	<b>2,514,627</b>	<b>88.3%</b>
0-17 years	5,053		10,879		22,482		30,944		46,602		36,048		33,976		24,093	12.9%	445	10.6%	210,523	8.4%
18+ years	75,448		160,564		355,421		519,281		561,271		240,804		218,140		161,896	87.0%	3,757	89.4%	2,296,583	91.3%
UNSPEC	48		1,122		2,428		3,281		104		237		214		88	0.0%	--	--	7,521	0.3%

Source: IMS, Vector One®: National (VONA). Years 2002-2010. Extracted August 2011. File: VONA 2011-2690 Plan B age product strength 11-9-11.xls

**Table 4. Total patients receiving dispensed prescriptions for Plan B®, Plan B® One-Step, and Next Choice™ by age in the U.S. outpatient retail pharmacies, years 2002-2010**

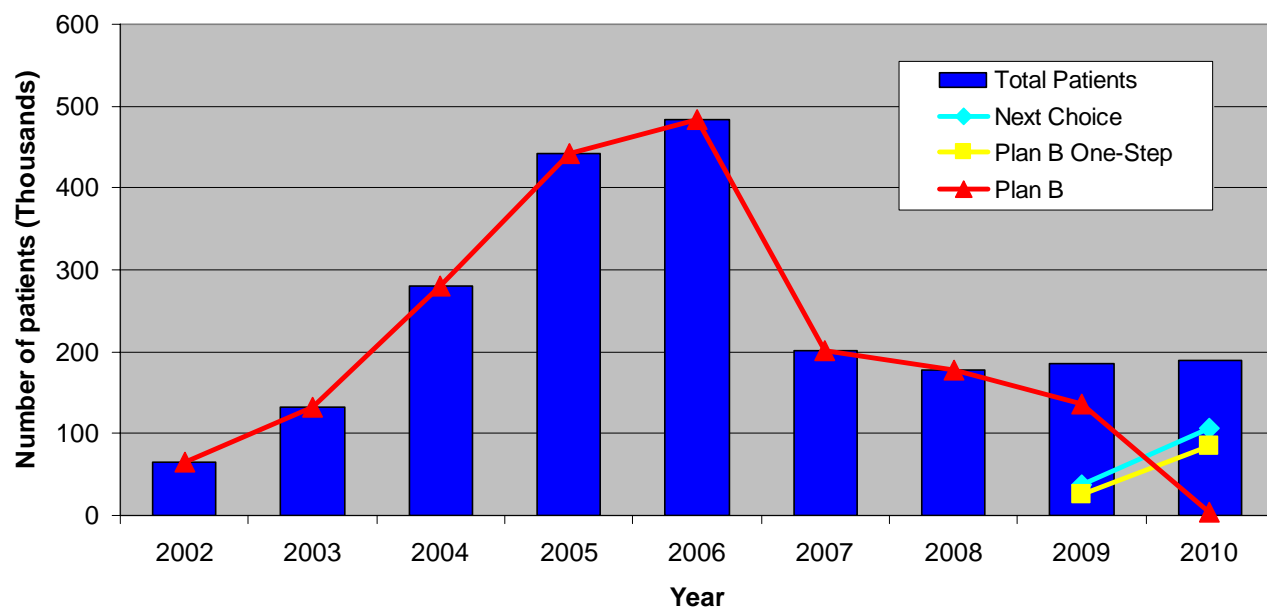
	Year 2002		Year 2003		Year 2004		Year 2005		Year 2006		Year 2007		Year 2008		Year 2009		Year 2010		Cumulative 1/2002 12/2010	
	Patients		Patients		Patients		Patients		Patients		Patients		Patients		Patients	%	Patients	%	Patients	%
<b>Total Patients</b>	<b>64,439</b>		<b>131,768</b>		<b>280,911</b>		<b>442,214</b>		<b>484,081</b>		<b>201,536</b>		<b>176,687</b>		<b>186,335</b>	<b>100.0%</b>	<b>190,408</b>	<b>100.0%</b>	<b>1,824,082</b>	<b>100.0%</b>
<b>Next Choice™ (0.75mg)</b>															37,587	20.2%	106,097	55.7%	135,942	7.5%
0-17 years															4,096	10.9%	10,885	10.3%	14,279	10.5%
18+ years															33,513	89.2%	95,527	90.0%	122,218	89.9%
Unknown Age															1	0.0%	2	0.0%	3	0.0%
<b>Plan B® One-Step (1.5mg)</b>															25,630	13.8%	85,491	44.9%	107,290	5.9%
0-17 years															2,490	9.7%	8,010	9.4%	10,175	9.5%
18+ years															23,144	90.3%	77,672	90.9%	97,370	90.8%
Unknown Age															2	0.0%	1	0.0%	4	0.0%
<b>Plan B® (0.75mg)</b>	<b>64,439</b>		<b>131,768</b>		<b>280,911</b>		<b>442,214</b>		<b>484,081</b>		<b>201,536</b>		<b>176,687</b>		<b>136,068</b>	<b>73.0%</b>	<b>3,797</b>	<b>2.0%</b>	<b>1,640,157</b>	<b>89.9%</b>
0-17 years	5,570		11,098		21,504		34,683		36,941		25,435		22,317		16,235	11.9%	401	10.6%	158,055	9.6%
18+ years	58,897		120,817		259,780		408,299		448,000		176,584		154,796		120,009	88.2%	3,399	89.5%	1,499,321	91.4%
Unknown Age	43		72		41		60		79		58		36		25	0.0%			396	0.0%

\*Due to the possibility of double counting patients who are receiving treatment over multiple periods in the study, unique patient counts may not be added across time periods. Summing across patient age bands is not advisable and will result in overestimates of patient counts.

Source: IMS, Vector One®: Total Patient Tracker (TPT). Years 2002-2010. Extracted August 2011. Files: TPT 2011-2690 Plan B age product 11-9-11.xls; TPT 2011-2690 Plan B age product aggregate 11-9-11.xls

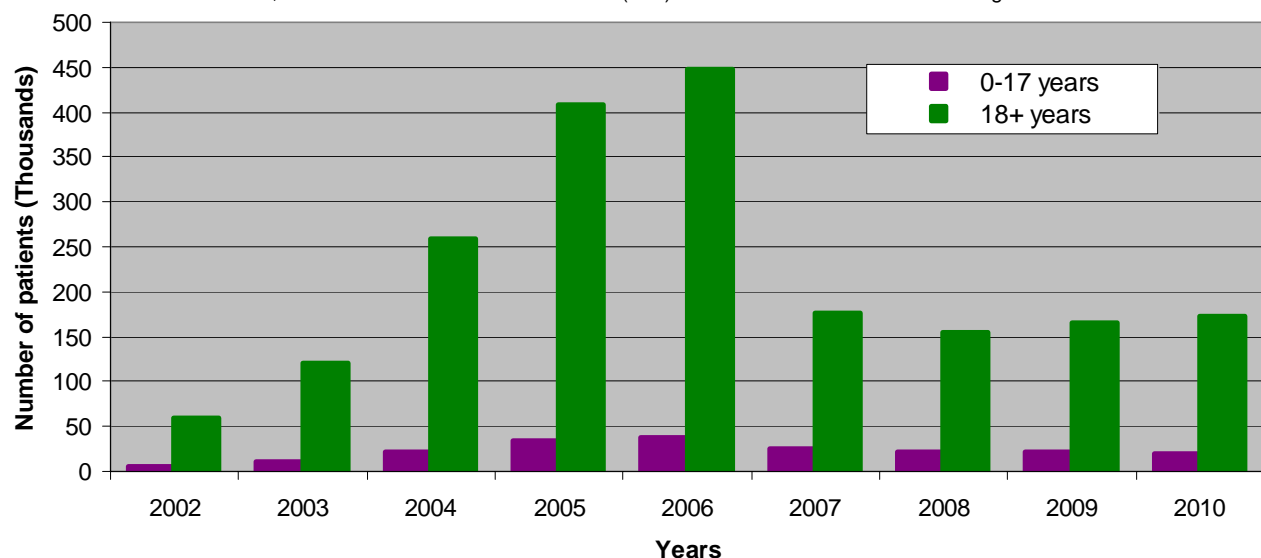
**Figure 2. Total patients receiving dispensed prescriptions for Plan B®, Plan B® One-Step, and Next Choice™ in the U.S. outpatient retail pharmacies, years 2002-2010**

Source: IMS, Vector One®: Total Patient Tracker (TPT). Years 2002-2010. Extracted August 2011.



**Figure 3. Number of patients receiving dispensed prescriptions for oral single-ingredient levonorgestrel products by age, years 2002-2010**

Source: IMS, Vector One®: Total Patient Tracker (TPT). Years 2002-2010. Extracted August 2011.



**Table 5. Total number of dispensed prescriptions for Plan B®, Plan B® One-Step, and Next Choice™ by top 10 prescribing specialties, cumulative years 2002-2010**

	Cumulative 1/2002-12/2010	
	TRxs	%
<b>Total Market</b>	<b>2,848,403</b>	<b>100.0%</b>
<b>Plan B®</b>	<b>2,514,969</b>	<b>88.3%</b>
OB/GYN	784,114	31.2%
UNSPEC	516,646	20.5%
GP/FM/DO	430,560	17.1%
HOSP	208,572	8.3%
NP	170,960	6.8%
IM	133,043	5.3%
PED	62,062	2.5%
PA	48,226	1.9%
EM	33,111	1.3%
PSYCH	7,768	0.3%
OTHERS	119,907	4.8%
<b>Next Choice™</b>	<b>182,076</b>	<b>6.4%</b>
UNSPEC	39,312	21.6%
OB/GYN	36,290	19.9%
GP/FM/DO	34,408	18.9%
NP	22,797	12.5%
PA	10,796	5.9%
HOSP	8,809	4.8%
PED	8,487	4.7%
IM	8,160	4.5%
EM	1,082	0.6%
GEN SURG	781	0.4%
OTHERS	11,154	6.1%
<b>Plan B® One-Step</b>	<b>151,358</b>	<b>5.3%</b>
UNSPEC	70,766	46.8%
OB/GYN	20,161	13.3%
GP/FM/DO	16,537	10.9%
NP	13,195	8.7%
HOSP	10,941	7.2%
IM	4,595	3.0%
PA	4,397	2.9%
PED	3,303	2.2%
EM	1,586	1.0%
DENT	192	0.1%
OTHERS	5,685	3.8%

Source: IMS, Vector One®: National (VONA). Years 2002-2010. Extracted August 2011. File: VONA 2011-2690 Plan B Products by Specialty 10-14-11.xls

**Table 6. Diagnoses associated with the use of oral single-ingredient levonorgestrel products as reported from office-based physician practices in the U.S., cumulative years 2002-2010**

	Cumulative 1/2002 12/2010	
	Uses (000)	%
<b>Total Market</b>	<b>1,031</b>	<b>100.0%</b>
<b>Plan B®</b>	<b>999</b>	<b>96.9%</b>
<b>0-17 years</b>	68	6.8%
<b>V250 CONTRACEP MGMT-COUNSEL</b>	68	100.0%
<b>18+ years</b>	876	87.6%
<b>V250 CONTRACEP MGMT-COUNSEL</b>	745	85.1%
<b>V254 CONTRACEPT SURVEILLANCE</b>	34	3.9%
<b>V617 UNWANTED PREGNANCY NEC</b>	14	1.6%
<b>V078 PROPHYLACTIC MEASURE NEC</b>	14	1.6%
<b>9958 ADVERSE EFFECT NEC</b>	13	1.4%
<b>V723 GYNECOLOGIC EXAMINATION</b>	12	1.4%
<b>All Others</b>	44	5.1%
<b>UNSPEC</b>	55	5.5%
<b>Next Choice™</b>	<b>32</b>	<b>3.1%</b>
<b>18+ years</b>	32	100.0%
<b>V250 CONTRACEP MGMT-COUNSEL</b>	32	100.0%

Source: SDI, Physician Drug and Diagnosis Audit™ (PDDA). Years 2002-2010.  
 Extracted October 2011. File: PDDA 2011-2690 Plan B Products by Age and  
 Diagnosis CI 10-17-11.xls

## **APPENDIX 2: DATABASES DESCRIPTION**

### ***IMS Health, IMS National Sales Perspectives™: Retail and Non-Retail***

The IMS Health, IMS National Sales Perspectives™ measures the volume of drug products, both prescription and over-the-counter, and selected diagnostic products moving from manufacturers into various outlets within the retail and non-retail markets. Volume is expressed in terms of sales dollars, eaches, extended units, and share of market. These data are based on national projections. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service. Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings.

### ***IMS's Vector One®: National (VONA)***

IMS's VONA measures retail dispensing of prescriptions or the frequency with which drugs move out of retail pharmacies into the hands of consumers via formal prescriptions. Information on the physician specialty, the patient's age and gender, and estimates for the numbers of patients that are continuing or new to therapy are available.

Vector One® receives over 2.1 billion prescription claims annually, representing over 150 million unique patients. Since 2002 Vector One® has captured information on over 10 billion prescriptions representing over 200 million unique patients. Vector One® receives nearly two-thirds of retail prescriptions dispensed nationwide. Through Vector One®, IMS receives all prescriptions from approximately one half of the retail stores in the United States.

### ***IMS's Vector One®: Total Patient Tracker (TPT)***

IMS's Total Patient Tracker is a national-level projected audit designed to estimate the total number of unique patients across all drugs and therapeutic classes in the retail outpatient setting over time.

TPT derives its data from the Vector One® database which integrates prescription activity from a sample received from payers, switches, and other software systems that may arbitrage prescriptions at various points in the sales cycle. Vector One® receives over 2.1 billion prescription claims annually, representing over 150 million unique patients. Since 2002 Vector One® has captured information on over 10 billion prescriptions representing over 200 million unique patients. Vector One® receives nearly two-thirds of retail prescriptions dispensed nationwide. Through Vector One®, IMS receives all prescriptions from approximately one half of the retail stores in the United States.

### ***SDI Physician Drug & Diagnosis Audit (PDDA) with Pain Panel***

SDI's Physician Drug & Diagnosis Audit (PDDA) with Pain Panel is a monthly survey designed to provide descriptive information on the patterns and treatment of diseases encountered in office-based physician practices in the U.S. The survey consists of data collected from over 3,200 office-based physicians representing 30 specialties across the United States that report on all patient activity during one typical workday per month. These data may include profiles and trends of diagnoses, patients, drug products mentioned during the office visit and treatment patterns. The Pain Panel supplement



surveys over 115 pain specialists physicians each month. With the inclusion of visits to pain specialists, this will allow additional insight into the pain market. The data are then projected nationally by physician specialty and region to reflect national prescribing patterns.

### **Shopper Insights Advantage™ (SIA)**

Shopper Insights Advantage™ (SIA) is a web-based application that provides users with immediate access to 5 years of household panel purchase data, demographics of shoppers and product buyers and prevalence of six major medical conditions for those household. The panel data draws from the Consumer Network of approximately 85,000 active households (56,000 households meeting 1-year reporting requirements) who record their CPG purchases on an ongoing basis. SIA is fueled by the weekly, transaction-level purchase records to provide projected household purchase data using pre-defined, customizable report templates and full ad-hoc reporting capabilities. Purchase data are included for health care categories down to the brand level. Purchase metrics include % of household buying, buying rate (\$/volume/units per buyer), frequency of purchase and other standard measures. Demographics cover income levels, education, age, and nearly all other major demographics attributes. The presence of six prevalent medical conditions (high cholesterol; high blood pressure; obesity; diabetes; heart attack; and stroke) are captured through an annual survey of the CN panel. Aggregate information on these conditions is in the SIA interface. All data are projected nationally, to US census regions and divisions, and markets for all retail venues reported by panelists including Food, Drug, Mass Merchandiser/Supercenter, Club stores, Dollars stores and other Specialty outlets.

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Drug use data cleared

JUDY A STAFFA

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