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Subject: Androgel[®] (testosterone) BPCA Drug Use Review

Drug Name(s): Androgel[®] (testosterone)

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Applicant/sponsor: Unimed Pharmaceuticals

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EXECUTIVE SUMMARY

This review examines drug utilization patterns for Androgel[®] (testosterone), a testosterone replacement agent, in the pediatric and adult population, patients aged 0-17, 18-29, 30-39, 40-49, 50-59, 60-69, 70-79 and 80+ years. Since approximately 98% of testosterone was sold in the topical formulation in year 2007 and of that, 73% was sold to U.S. retail settings and about 23% was sold to mail service settings, this review focuses on the outpatient setting. Outpatient proprietary drug use databases licensed by FDA were used to examine the patterns of use for Androgel[®] (testosterone) during the eight 12-month periods from 2000 through 2007 and year-to-date November 2008.

For the entire study period from January 1, 2000 – November 30, 2008:

- The gel form of testosterone represented approximately 65.6% of the total projected number of dispensed prescriptions since year 2002.
- Androgel[®] is the most commonly dispensed gel form of testosterone with approximately 1.4 million prescriptions dispensed in year 2007.
- The majority of Androgel[®] is dispensed in the adult age group 50-59 years with 34.8% and pediatric patients (0-17 years) account for less than 1%.
- General Practice/Family Medicine/Doctors of Osteopathy was the top prescribing specialty for Androgel[®].
- Use of Androgel[®] (testosterone) in the pediatric population has been declining over the study periods examined. However, use of testosterone in the adult population has been gradually increasing.
- A top diagnosis code associated with the use of Androgel[®] was “Testicular Hypofunc Nec” (ICD-9 257.2).

1 INTRODUCTION

Using the currently available proprietary drug use databases licensed by the Agency, this review describes outpatient drug use patterns for Androgel[®] (testosterone) in the pediatric population as well as in the adult population and includes data for eight 12-month periods starting in year 2000 through 2007 and year-to-date October 2008.

2 METHODS AND MATERIALS

IMS Health, IMS National Sales Perspectives[™] data (see Appendix 2 for full database description) were used to determine the setting in which testosterone by product form was sold. Sales of this product by number of packets, tubes, vials, and capsules (eaches) sold from the manufacturer into the various retail and non-retail channels of distribution were analyzed.¹ During year 2007, the majority of testosterone (98%) was sold in the topical dosage form, of which 73% was toward retail settings (chain stores, independent pharmacies, and food stores) and approximately 23% were sold to mail service settings. Approximately 5% was sold toward non-retail settings. Thus, the examination of testosterone utilization patterns focused on the outpatient setting, mail service not included.

Outpatient use and patient demographics (stratified by ages 0-17 years, 18-29 years, 30-39 years, 40-49, 50-59, 60-69, 70-79 and 80+ years for Androgel[®]) were measured from SDI: Vector One[®]: National (VONA) and Total Patient Tracker (TPT) (Appendix 2). Indications for use were obtained from the SDI's Physician's Drug and Diagnosis Audit (PDDA) (Appendix 2). From these data sources, estimates of the number of prescriptions dispensed, the number of patients who received a prescription for Androgel[®] (testosterone), and the number of drug mentions by office-based physicians, were obtained for years 2000 through 2007 and

¹ IMS Health, IMS National Sales Perspectives[™], Data extracted 1-9-2009, Years Jan 2003 to Oct 2008. Source file: 0901Andr.DVR

year-to-date November 2008. For comparative purposes, other testosterone product forms were also examined: including bulk products, patches, vials for IM injection, creams, and ointments.

3 RESULTS

Overall, dispensed prescriptions in the testosterone market have gradually increased since year 2001 with approximately 2.5 million prescriptions dispensed in year 2007 (Figure 1: Appendix 1)). From year 2002 through year-to-date November 2008, dispensed prescriptions for the gel form of testosterone represented approximately 65.6% of the projected number of prescriptions dispensed. Dispensed gel formulation prescriptions increased by 97.5% during this time period. Of all testosterone formulations, dispensed prescriptions for the transdermal patch had experienced the most decline with a 53.4% decrease from year 2000 to year-to-date November 2008. Androgel[®] is the most commonly dispensed gel form of testosterone with approximately 1.4 million prescriptions dispensed followed by Testim[®], another gel form of testosterone, with approximately 368,987 prescriptions in year 2007 (Appendix 1: Table 1). First-Testosterone MC (cream) and First Testosterone (ointment), agents used in compounding testosterone, account for less than 1% of dispensed prescriptions for the time period studied.

Table 2 in Appendix 1 shows the total number of prescriptions dispensed by age in the outpatient retail setting. During the time period studied, dispensed prescriptions for Androgel[®] in the pediatric population (ages 0-17 years) accounted for less than 1% of the total projected number of dispensed prescriptions for Androgel[®]. The majority of prescriptions dispensed for Androgel[®] were in adults aged 50-59 years with 34.8% followed by adults aged 40-49 years and 60-69 years with approximately 24.5% and 20.7%, respectively. Table 3 in Appendix 1 shows the total number of prescriptions dispensed by gender in the outpatient retail setting. For the testosterone products Androgel[®] and Testim[®] more prescriptions are dispensed to males (97.5% and 96.9%, respectively) compared to females from year 2003 through year-to-date November 2008. However, for the testosterone products First-Testosterone MC and First Testosterone more prescriptions are dispensed to females (92% and 95.5%, respectively) compared to males from year 2003 through year-to-date November 2008.

Trends for patient data were similar to that of prescription data. Approximately 728,359 patients received a prescription for testosterone in year 2007 (Table 4: Appendix 1). The number of patients receiving a prescription for topical testosterone was 484,048 in year 2007 (Table 5: Appendix 2). The majority of patients to receive a prescription for topical form of testosterone were in the age group 50-59 years with approximately 34% in the time period studied. In all of the age groups, Androgel was the most commonly prescribed topical form of testosterone.

During the time period studied, General Practice/Family Medicine/Doctors of Osteopathy was the top prescribing specialty for Androgel[®] with approximately 28.1% of prescriptions followed by Internal Medicine and Urology with 27.3% and 16.2% of prescriptions, respectively (Table 6: Appendix 1). In the beginning of the study period, year 2000, Internal Medicine was the top prescribing specialty for Androgel[®] however, by year-to-date November 2008 there was a switch to the top prescribing specialty being General Practice/Family Medicine/Doctors of Osteopathy. The top prescribing specialty for Testim[®] are General Practice/Family Medicine/Doctors of Osteopathy with 24.7% followed closely by Urology and Internal Medicine with 23.4% and 22.8%, respectively. From year 2003, Urology was the top prescribing specialty for Testim[®] however, by year-to-date November 2008 there was a switch to the top specialty being General Practice/Family Medicine/Doctors of Osteopathy. During the time period studied, OB/GYN was the top prescribing specialty for both First-Testosterone MC and First Testosterone with approximately 59.6% and 69.8% of prescriptions, respectively.

According to office-based physician practices in the U.S., “Testicular Hypofunc Nec” (ICD-9 257.2) and Other Disorders of Penis (ICD-9 607.8) were the top diagnosis codes associated with the use of Androgel[®] (data not shown) during the study period.

4 LIMITATIONS

Findings from this consult should be interpreted in the context of the known limitations of the databases used. We estimated that testosterone is distributed primarily in outpatient settings based on the IMS Health, IMS National Sales Perspectives™. These data do not provide a direct estimate of use but do provide a national estimate of units sold from the manufacturer into the 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 the facilities purchase drugs in quantities reflective of actual patient use.

Indications for use were obtained using SDI's PDDA, a monthly survey of 3,100 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 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

Androgel® (testosterone) is the most common form of testosterone used over the time period studied. The majority of prescriptions dispensed for Androgel® (testosterone) are among the adult population aged 50-59 years. Pediatric patients accounted for less than 1% of dispensed prescriptions over the entire review period.

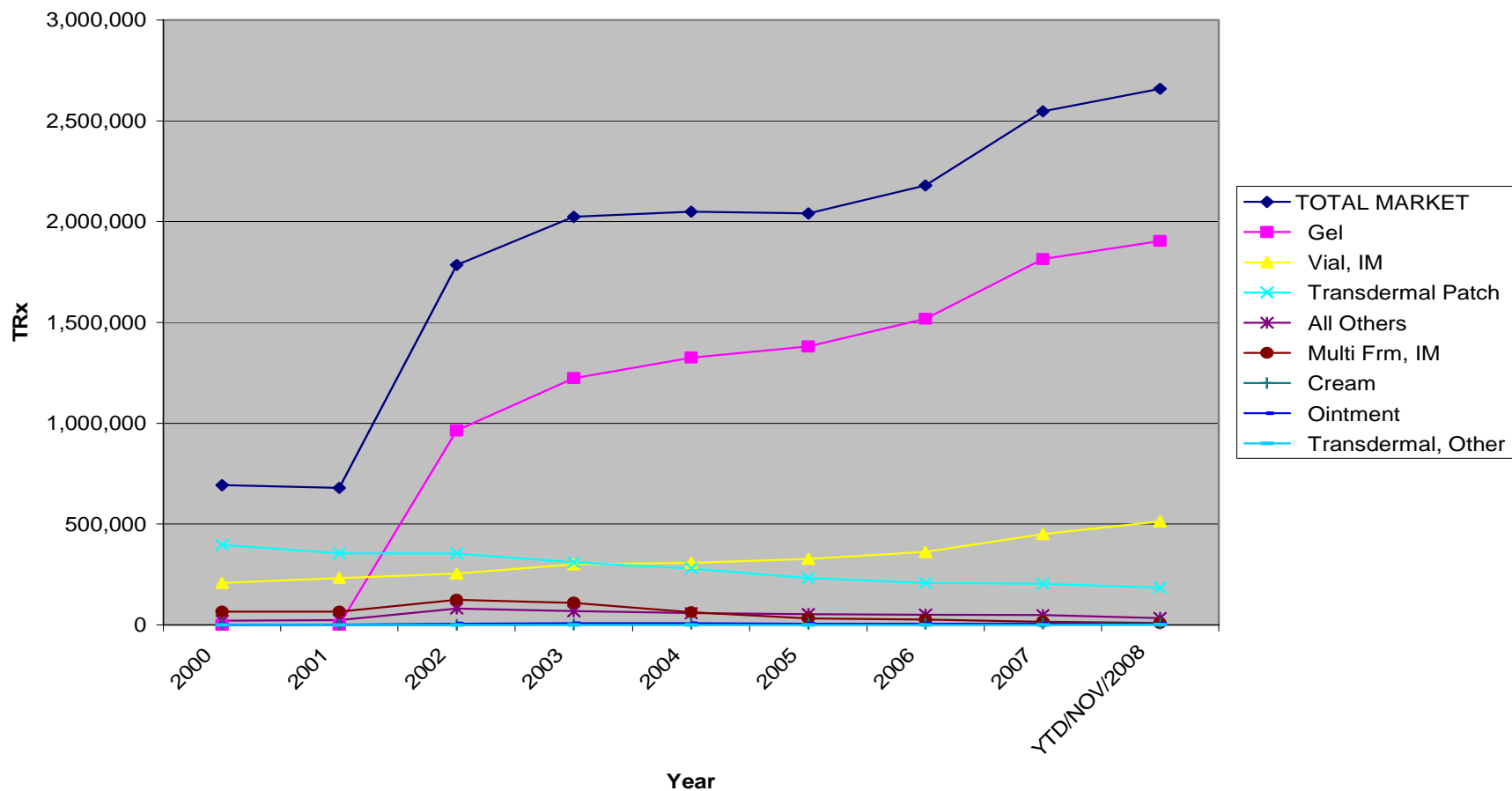
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APPENDICES

APPENDIX 1: Tables and Figures

Figure 1: Number of dispensed prescriptions of testosterone by form through U.S. outpatient retail pharmacies, 2000-2007 and YTD/Nov 2008



Source: SDI Vector One®: National. Data Extracted 1-7-09. File: VONA 2008-1704 Testosterone 1-7-09.xls

Table 1: Total number of dispensed prescriptions of testosterone by product form through U.S. outpatient retail pharmacies, Years 2000-2007 and YTD/Nov 2008

| | 2000 | | 2001 | | 2002 | | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | YTD/NOV/2008 | |
|---------------------------|-------------|--------|-------------|--------|-------------|--------|-------------|--------|-------------|--------|-------------|--------|-------------|--------|-------------|--------|--------------|--------|
| | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share |
| | N | % | N | % | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| TOTAL MARKET | 692,676 | 100.0% | 679,392 | 100.0% | 1,784,338 | 100.0% | 2,023,756 | 100.0% | 2,049,698 | 100.0% | 2,040,695 | 100.0% | 2,178,922 | 100.0% | 2,546,729 | 100.0% | 2,659,361 | 100.0% |
| Gel | -- | -- | -- | -- | 964,163 | 54.0% | 1,224,094 | 60.5% | 1,326,271 | 64.7% | 1,381,100 | 67.7% | 1,518,268 | 69.7% | 1,814,637 | 71.3% | 1,904,176 | 71.6% |
| AndroGel | -- | -- | -- | -- | 964,163 | 100.0% | 1,169,817 | 95.6% | 1,187,507 | 89.5% | 1,188,959 | 86.1% | 1,245,716 | 82.0% | 1,445,650 | 79.7% | 1,484,302 | 77.9% |
| Testim | -- | -- | -- | -- | -- | -- | 54,277 | 4.4% | 138,764 | 10.5% | 192,141 | 13.9% | 272,552 | 18.0% | 368,987 | 20.3% | 419,874 | 22.1% |
| Vial, IM | 208,086 | 30.0% | 231,955 | 34.1% | 253,947 | 14.2% | 300,299 | 14.8% | 307,551 | 15.0% | 327,832 | 16.1% | 361,492 | 16.6% | 450,640 | 17.7% | 514,000 | 19.3% |
| Testosterone Cypion | 3,312 | 1.6% | 2,091 | 0.9% | 1,189 | 0.5% | 1,062 | 0.4% | 52,367 | 17.0% | 123,817 | 37.8% | 181,682 | 50.3% | 284,630 | 63.2% | 382,028 | 74.3% |
| Testosterone Ethan | 2,972 | 1.4% | 2,119 | 0.9% | 487 | 0.2% | 169 | 0.1% | 21,409 | 7.0% | 45,919 | 14.0% | 50,284 | 13.9% | 68,102 | 15.1% | 72,445 | 14.1% |
| Depo-Testosterone | 197,695 | 95.0% | 225,667 | 97.3% | 250,384 | 98.6% | 297,754 | 99.2% | 232,835 | 75.7% | 157,575 | 48.1% | 129,128 | 35.7% | 97,634 | 21.7% | 59,251 | 11.5% |
| Testosterone Prop | 3,743 | 1.8% | 1,827 | 0.8% | 1,622 | 0.6% | 1,054 | 0.4% | 772 | 0.3% | 433 | 0.1% | 223 | 0.1% | 178 | 0.0% | 231 | 0.0% |
| Testosterone | 307 | 0.1% | 207 | 0.1% | 265 | 0.1% | 226 | 0.1% | 158 | 0.1% | 88 | 0.0% | 175 | 0.0% | 96 | 0.0% | 45 | 0.0% |
| Everone | 12 | 0.0% | 6 | 0.0% | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Testolin | -- | -- | -- | -- | -- | -- | 31 | 0.0% | 10 | 0.0% | -- | -- | -- | -- | -- | -- | -- | -- |
| Testred Cypiont 200 | 5 | 0.0% | 2 | 0.0% | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Andropository | 27 | 0.0% | 16 | 0.0% | -- | -- | 3 | 0.0% | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Andro LA 200 | 13 | 0.0% | 20 | 0.0% | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- |
| Transdermal Patch | 397,282 | 57.4% | 356,119 | 52.4% | 354,233 | 19.9% | 310,268 | 15.3% | 279,847 | 13.7% | 232,372 | 11.4% | 208,690 | 9.6% | 204,274 | 8.0% | 185,159 | 7.0% |
| Androderm | 211,450 | 53.2% | 196,667 | 55.2% | 238,787 | 67.4% | 273,958 | 88.3% | 258,989 | 92.5% | 220,097 | 94.7% | 199,652 | 95.7% | 196,099 | 96.0% | 178,480 | 96.4% |
| Striant | -- | -- | -- | -- | -- | -- | 3,359 | 1.1% | 16,711 | 6.0% | 11,989 | 5.2% | 8,881 | 4.3% | 8,113 | 4.0% | 6,655 | 3.6% |
| Testoderm TTS | 141,599 | 35.6% | 126,630 | 35.6% | 84,114 | 23.7% | 2,920 | 0.9% | 262 | 0.1% | 79 | 0.0% | 48 | 0.0% | 29 | 0.0% | 15 | 0.0% |
| Testoderm | 44,233 | 11.1% | 32,822 | 9.2% | 31,332 | 8.8% | 30,031 | 9.7% | 3,885 | 1.4% | 207 | 0.1% | 109 | 0.1% | 33 | 0.0% | 9 | 0.0% |
| All Others | 21,007 | 3.0% | 24,456 | 3.6% | 81,736 | 4.6% | 68,203 | 3.4% | 58,750 | 2.9% | 53,206 | 2.6% | 51,679 | 2.4% | 48,169 | 1.9% | 33,759 | 1.3% |
| Testosterone Bulk | 9,006 | 42.9% | 11,868 | 48.5% | 48,795 | 59.7% | 37,297 | 54.7% | 32,290 | 55.0% | 30,509 | 57.3% | 29,506 | 57.1% | 28,070 | 58.3% | 17,932 | 53.1% |
| Testosterone Prp Blk | 11,995 | 57.1% | 12,577 | 51.4% | 32,872 | 40.2% | 30,868 | 45.3% | 26,400 | 44.9% | 22,649 | 42.6% | 22,143 | 42.8% | 19,957 | 41.4% | 11,071 | 32.8% |
| Testosterone Cyp Bul | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 4,035 | 12.0% |
| Testopel | 6 | 0.0% | 11 | 0.0% | 69 | 0.1% | 38 | 0.1% | 60 | 0.1% | 48 | 0.1% | 30 | 0.1% | 142 | 0.3% | 721 | 2.1% |
| Multi Frm, IM | 66,299 | 9.6% | 65,751 | 9.7% | 123,869 | 6.9% | 109,524 | 5.4% | 62,977 | 3.1% | 33,088 | 1.6% | 26,315 | 1.2% | 15,870 | 0.6% | 9,529 | 0.4% |
| Delatestryl | 66,299 | 100.0% | 65,751 | 100.0% | 123,869 | 100.0% | 109,524 | 100.0% | 62,977 | 100.0% | 33,088 | 100.0% | 26,315 | 100.0% | 15,870 | 100.0% | 9,529 | 100.0% |
| Cream | -- | -- | -- | -- | -- | -- | 2,981 | 0.1% | 6,177 | 0.3% | 6,680 | 0.3% | 6,256 | 0.3% | 7,110 | 0.3% | 6,938 | 0.3% |
| First-Testosteron MC | -- | -- | -- | -- | -- | -- | 2,981 | 100.0% | 6,177 | 100.0% | 6,680 | 100.0% | 6,256 | 100.0% | 7,110 | 100.0% | 6,938 | 100.0% |
| Ointment | 2 | 0.0% | 1,111 | 0.2% | 6,390 | 0.4% | 8,387 | 0.4% | 8,125 | 0.4% | 6,417 | 0.3% | 6,222 | 0.3% | 6,029 | 0.2% | 5,167 | 0.2% |
| First-Testosterone | 2 | 100.0% | 1,111 | 100.0% | 6,390 | 100.0% | 8,387 | 100.0% | 8,125 | 100.0% | 6,417 | 100.0% | 6,222 | 100.0% | 6,029 | 100.0% | 5,167 | 100.0% |
| Transdermal, Other | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 633 | 0.0% |
| AndroGel | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | -- | 633 | 100.0% |

Source: SDI Vector One®: National Data Extracted 1-7-09. File: VONA 2008-1704 Testosterone 1-7-09.xls

Table 2. Total number of prescriptions dispensed for topical testosterone by age through U.S. outpatient retail pharmacies, Year 2002-2007 and YTD/Nov 2008

| | 2002 | | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | YTD/NOV/2008 | |
|-----------------------------|----------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|
| | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share |
| | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| TOTAL MARKET | 970,726 | 100.0% | 1,235,498 | 100.0% | 1,340,607 | 100.0% | 1,394,244 | 100.0% | 1,530,751 | 100.0% | 1,827,765 | 100.0% | 1,916,283 | 100.0% |
| AndroGel | 964,315 | 99.3% | 1,169,852 | 94.7% | 1,187,546 | 88.6% | 1,189,015 | 85.3% | 1,245,745 | 81.4% | 1,445,651 | 79.1% | 1,484,327 | 77.5% |
| 0-17 | 3,294 | 0.3% | 3,464 | 0.3% | 3,267 | 0.3% | 3,009 | 0.3% | 2,959 | 0.2% | 3,218 | 0.2% | 2,591 | 0.2% |
| 18-29 | 24,842 | 2.6% | 27,503 | 2.4% | 28,120 | 2.4% | 27,026 | 2.3% | 27,094 | 2.2% | 29,438 | 2.0% | 29,369 | 2.0% |
| 30-39 | 101,842 | 10.6% | 110,794 | 9.5% | 105,694 | 8.9% | 101,511 | 8.5% | 100,709 | 8.1% | 113,449 | 7.8% | 112,041 | 7.5% |
| 40-49 | 253,421 | 26.3% | 300,543 | 25.7% | 303,299 | 25.5% | 293,955 | 24.7% | 295,867 | 23.8% | 334,812 | 23.2% | 336,098 | 22.6% |
| 50-59 | 328,291 | 34.0% | 405,501 | 34.7% | 416,018 | 35.0% | 422,330 | 35.5% | 436,447 | 35.0% | 502,604 | 34.8% | 510,324 | 34.4% |
| 60-69 | 177,124 | 18.4% | 226,575 | 19.4% | 231,875 | 19.5% | 237,422 | 20.0% | 268,153 | 21.5% | 328,435 | 22.7% | 350,994 | 23.6% |
| 70-79 | 58,723 | 6.1% | 74,968 | 6.4% | 75,657 | 6.4% | 78,830 | 6.6% | 88,229 | 7.1% | 103,467 | 7.2% | 110,959 | 7.5% |
| 80+ | 15,209 | 1.6% | 18,627 | 1.6% | 20,085 | 1.7% | 21,379 | 1.8% | 24,572 | 2.0% | 28,942 | 2.0% | 30,839 | 2.1% |
| UNSPEC. | 1,569 | 0.2% | 1,877 | 0.2% | 3,531 | 0.3% | 3,553 | 0.3% | 1,715 | 0.1% | 1,286 | 0.1% | 1,112 | 0.1% |
| Testim | -- | -- | 54,254 | 4.4% | 138,760 | 10.4% | 192,141 | 13.8% | 272,532 | 17.8% | 368,983 | 20.2% | 419,872 | 21.9% |
| 0-17 | -- | -- | 126 | 0.2% | 332 | 0.2% | 346 | 0.2% | 351 | 0.1% | 338 | 0.1% | 319 | 0.1% |
| 18-29 | -- | -- | 1,410 | 2.6% | 3,099 | 2.2% | 4,113 | 2.1% | 5,297 | 1.9% | 6,583 | 1.8% | 7,334 | 1.7% |
| 30-39 | -- | -- | 6,166 | 11.4% | 13,930 | 10.0% | 17,671 | 9.2% | 23,708 | 8.7% | 30,846 | 8.4% | 35,782 | 8.5% |
| 40-49 | -- | -- | 14,768 | 27.2% | 35,872 | 25.9% | 49,190 | 25.6% | 66,444 | 24.4% | 89,928 | 24.4% | 98,693 | 23.5% |
| 50-59 | -- | -- | 17,262 | 31.8% | 47,236 | 34.0% | 65,200 | 33.9% | 92,028 | 33.8% | 123,161 | 33.4% | 141,706 | 33.7% |
| 60-69 | -- | -- | 10,148 | 18.7% | 26,830 | 19.3% | 38,583 | 20.1% | 58,363 | 21.4% | 82,565 | 22.4% | 95,998 | 22.9% |
| 70-79 | -- | -- | 3,477 | 6.4% | 9,113 | 6.6% | 13,284 | 6.9% | 20,708 | 7.6% | 27,529 | 7.5% | 31,379 | 7.5% |
| 80+ | -- | -- | 762 | 1.4% | 1,922 | 1.4% | 3,264 | 1.7% | 5,340 | 2.0% | 7,643 | 2.1% | 8,222 | 2.0% |
| UNSPEC. | -- | -- | 135 | 0.2% | 426 | 0.3% | 490 | 0.3% | 293 | 0.1% | 390 | 0.1% | 439 | 0.1% |
| First-Testosteron MC | -- | -- | 2,996 | 0.2% | 6,174 | 0.5% | 6,677 | 0.5% | 6,264 | 0.4% | 7,109 | 0.4% | 6,921 | 0.4% |
| 0-17 | -- | -- | 15 | 0.5% | 21 | 0.3% | 36 | 0.5% | 27 | 0.4% | 39 | 0.5% | 38 | 0.5% |
| 18-29 | -- | -- | 77 | 2.6% | 243 | 3.9% | 115 | 1.7% | 133 | 2.1% | 168 | 2.4% | 121 | 1.7% |
| 30-39 | -- | -- | 402 | 13.4% | 655 | 10.6% | 463 | 6.9% | 508 | 8.1% | 572 | 8.0% | 631 | 9.1% |
| 40-49 | -- | -- | 809 | 27.0% | 1,486 | 24.1% | 1,445 | 21.6% | 1,409 | 22.5% | 1,336 | 18.8% | 1,266 | 18.3% |
| 50-59 | -- | -- | 1,045 | 34.9% | 2,072 | 33.6% | 2,327 | 34.9% | 2,241 | 35.8% | 2,369 | 33.3% | 2,404 | 34.7% |
| 60-69 | -- | -- | 314 | 10.5% | 895 | 14.5% | 1,210 | 18.1% | 1,201 | 19.2% | 1,620 | 22.8% | 1,375 | 19.9% |
| 70-79 | -- | -- | 201 | 6.7% | 441 | 7.1% | 563 | 8.4% | 502 | 8.0% | 675 | 9.5% | 638 | 9.2% |
| 80+ | -- | -- | 68 | 2.3% | 312 | 5.1% | 502 | 7.5% | 234 | 3.7% | 319 | 4.5% | 377 | 5.4% |
| UNSPEC. | -- | -- | 65 | 2.2% | 49 | 0.8% | 16 | 0.2% | 9 | 0.1% | 11 | 0.2% | 71 | 1.0% |
| First-Testosterone | 6,411 | 0.7% | 8,396 | 0.7% | 8,127 | 0.6% | 6,411 | 0.5% | 6,210 | 0.4% | 6,022 | 0.3% | 5,163 | 0.3% |
| 0-17 | 17 | 0.3% | 39 | 0.5% | 17 | 0.2% | 14 | 0.2% | 14 | 0.2% | 42 | 0.7% | 37 | 0.7% |
| 18-29 | 188 | 2.9% | 227 | 2.7% | 209 | 2.6% | 112 | 1.7% | 119 | 1.9% | 76 | 1.3% | 93 | 1.8% |
| 30-39 | 658 | 10.3% | 847 | 10.1% | 656 | 8.1% | 398 | 6.2% | 357 | 5.7% | 352 | 5.8% | 285 | 5.5% |
| 40-49 | 1,425 | 22.2% | 1,832 | 21.8% | 1,594 | 19.6% | 1,003 | 15.6% | 1,020 | 16.4% | 885 | 14.7% | 720 | 13.9% |
| 50-59 | 1,836 | 28.6% | 2,352 | 28.0% | 2,564 | 31.5% | 1,948 | 30.4% | 1,897 | 30.5% | 1,823 | 30.3% | 1,655 | 32.1% |
| 60-69 | 1,055 | 16.5% | 1,525 | 18.2% | 1,643 | 20.2% | 1,326 | 20.7% | 1,339 | 21.6% | 1,346 | 22.4% | 1,077 | 20.9% |
| 70-79 | 785 | 12.2% | 930 | 11.1% | 884 | 10.9% | 875 | 13.6% | 850 | 13.7% | 847 | 14.1% | 715 | 13.8% |
| 80+ | 431 | 6.7% | 603 | 7.2% | 540 | 6.6% | 719 | 11.2% | 608 | 9.8% | 628 | 10.4% | 553 | 10.7% |
| UNSPEC. | 16 | 0.2% | 41 | 0.5% | 20 | 0.2% | 16 | 0.2% | 6 | 0.1% | 23 | 0.4% | 28 | 0.5% |

SDI Vector One®: National. Data Extracted 1-7-09. File: VONA 2008-1704 Testosterone by Age 1-7-09.xls

Table 3. Total number of dispensed prescriptions of topical testosterone by gender through U.S. outpatient retail pharmacies, Years 2002-2007 and YTD/Nov 2008

| | 2002 | | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | YTD/NOV/2008 | |
|-----------------------------|----------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|
| | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share |
| | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| TOTAL MARKET | 970,726 | 100.0% | 1,235,498 | 100.0% | 1,340,607 | 100.0% | 1,394,244 | 100.0% | 1,530,751 | 100.0% | 1,827,765 | 100.0% | 1,916,283 | 100.0% |
| AndroGel | 964,315 | 99.3% | 1,169,852 | 94.7% | 1,187,546 | 88.6% | 1,189,015 | 85.3% | 1,245,745 | 81.4% | 1,445,651 | 79.1% | 1,484,327 | 77.5% |
| Male | 934,559 | 96.9% | 1,135,912 | 97.1% | 1,149,246 | 96.8% | 1,151,624 | 96.9% | 1,218,024 | 97.8% | 1,418,695 | 98.1% | 1,459,823 | 98.3% |
| Female | 28,616 | 3.0% | 31,922 | 2.7% | 33,380 | 2.8% | 31,521 | 2.7% | 25,442 | 2.0% | 25,184 | 1.7% | 22,993 | 1.5% |
| UNSPEC. | 1,140 | 0.1% | 2,018 | 0.2% | 4,920 | 0.4% | 5,870 | 0.5% | 2,279 | 0.2% | 1,772 | 0.1% | 1,511 | 0.1% |
| Testim | -- | -- | 54,254 | 4.4% | 138,760 | 10.4% | 192,141 | 13.8% | 272,532 | 17.8% | 368,983 | 20.2% | 419,872 | 21.9% |
| Male | -- | -- | 52,128 | 96.1% | 132,585 | 95.5% | 185,295 | 96.4% | 265,591 | 97.5% | 361,246 | 97.9% | 412,016 | 98.1% |
| Female | -- | -- | 2,036 | 3.8% | 5,382 | 3.9% | 5,651 | 2.9% | 6,430 | 2.4% | 7,292 | 2.0% | 7,450 | 1.8% |
| UNSPEC. | -- | -- | 90 | 0.2% | 793 | 0.6% | 1,195 | 0.6% | 511 | 0.2% | 445 | 0.1% | 406 | 0.1% |
| First-Testosteron MC | -- | -- | 2,996 | 0.2% | 6,174 | 0.5% | 6,677 | 0.5% | 6,264 | 0.4% | 7,109 | 0.4% | 6,921 | 0.4% |
| Female | -- | -- | 2,863 | 95.6% | 5,915 | 95.8% | 6,140 | 92.0% | 5,784 | 92.3% | 6,403 | 90.1% | 5,943 | 85.9% |
| Male | -- | -- | 129 | 4.3% | 231 | 3.7% | 513 | 7.7% | 468 | 7.5% | 688 | 9.7% | 956 | 13.8% |
| UNSPEC. | -- | -- | 4 | 0.1% | 28 | 0.5% | 24 | 0.4% | 12 | 0.2% | 18 | 0.3% | 22 | 0.3% |
| First-Testosterone | 6,411 | 0.7% | 8,396 | 0.7% | 8,127 | 0.6% | 6,411 | 0.5% | 6,210 | 0.4% | 6,022 | 0.3% | 5,163 | 0.3% |
| Female | 6,247 | 97.4% | 7,994 | 95.2% | 7,842 | 96.5% | 6,160 | 96.1% | 5,957 | 95.9% | 5,719 | 95.0% | 4,862 | 94.2% |
| Male | 160 | 2.5% | 385 | 4.6% | 269 | 3.3% | 242 | 3.8% | 249 | 4.0% | 296 | 4.9% | 293 | 5.7% |
| UNSPEC. | 4 | 0.1% | 17 | 0.2% | 16 | 0.2% | 9 | 0.1% | 4 | 0.1% | 7 | 0.1% | 8 | 0.2% |

Source: SDI Vector One®: National. Data Extracted 1-7-09. File: VONA 2008-1704 Testosterone by Gender 1-7-09.xls

Table 4: Total number of unique patients receiving a prescription of testosterone by product form through U.S. outpatient retail pharmacies, Years 2002-2007 and YTD/Nov 2008

| | | 2002 | | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | YTD/NOV/2008 | |
|------------------------------|---|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| Grand Total | | 558,810 | 100.00% | 652,299 | 100.00% | 623,157 | 100.00% | 602,397 | 100.00% | 639,329 | 100.00% | 728,359 | 100.00% | 806,005 | 100.00% |
| ANDRODERM | ANDRODERM TRANSDERMAL PATCH 2.5MG | 18,956 | 21.50% | 19,345 | 19.62% | 17,708 | 19.96% | 14,197 | 19.57% | 12,957 | 20.13% | 13,247 | 21.05% | 12,727 | 20.55% |
| | ANDRODERM TRANSDERMAL PATCH 5MG | 73,392 | 83.23% | 83,670 | 84.85% | 75,002 | 84.54% | 61,324 | 84.52% | 54,309 | 84.36% | 52,796 | 83.89% | 51,913 | 83.80% |
| ANDROGEL | ANDROGEL DERM GEL 1% | | | | | 8,818 | 2.75% | 62,699 | 19.94% | 102,047 | 30.83% | 142,465 | 37.99% | 182,581 | 44.21% |
| | ANDROGEL DERM GEL 1%/25MG | 40,667 | 14.96% | 45,614 | 13.44% | 39,864 | 12.44% | 32,062 | 10.20% | 27,530 | 8.32% | 27,105 | 7.23% | 26,391 | 6.39% |
| | ANDROGEL DERM GEL 1%/50MG | 247,589 | 91.08% | 311,900 | 91.88% | 289,812 | 90.43% | 243,650 | 77.48% | 222,186 | 67.12% | 228,234 | 60.86% | 225,553 | 54.61% |
| | ANDROGEL TRANSDERMAL OTHER 1% | | | | | | | | | | | | | 331 | 0.08% |
| | ANDROGEL TRANSDERMAL OTHER 25MG/2.5GM | | | | | | | | | | | | | 78 | 0.02% |
| | ANDROGEL TRANSDERMAL OTHER 50MG/5GM | | | | | | | | | | | | | 66 | 0.02% |
| ANDROPOSITORY | ANDROPOSITORY INJ VIAL IM 200MG | | | 3 | 100.00% | | | | | | | | | | |
| DELAESTRYL | DELAESTRYL INJ MULTI FORM IM 200MG | 50,411 | 100.00% | 44,176 | 100.00% | 26,065 | 100.00% | 12,818 | 100.00% | 10,423 | 100.00% | 6,165 | 100.00% | 4,045 | 100.00% |
| DEPO-TESTOSTERONE | DEPO-TESTOSTERONE INJ VIAL IM 100MG | 16,646 | 12.57% | 16,239 | 10.65% | 14,696 | 12.74% | 12,617 | 17.65% | 12,843 | 23.36% | 8,423 | 21.51% | 5,350 | 21.47% |
| | DEPO-TESTOSTERONE INJ VIAL IM 200MG | 120,553 | 91.05% | 137,985 | 90.52% | 101,788 | 88.23% | 59,512 | 83.26% | 42,791 | 77.82% | 31,042 | 79.29% | 19,723 | 79.14% |
| FIRST-TESTOSTERON MC | FIRST-TESTOSTERON MC DERM CREAM 2% | | | 2,517 | 100.00% | 4,713 | 100.00% | 4,593 | 100.00% | 4,511 | 100.00% | 4,960 | 100.00% | 4,884 | 100.00% |
| FIRST-TESTOSTERONE | FIRST-TESTOSTERONE DERM OINTMENT 2% | 4,927 | 100.00% | 6,343 | 100.00% | 6,033 | 100.00% | 4,656 | 100.00% | 4,321 | 100.00% | 4,220 | 100.00% | 3,690 | 100.00% |
| STRIANT | STRIANT TRANSDERMAL PATCH 30MG | | | 2,845 | 100.00% | 9,669 | 100.00% | 4,873 | 100.00% | 3,324 | 100.00% | 2,964 | 100.00% | 2,419 | 100.00% |
| TESTIM | TESTIM DERM GEL 1% | | | 25,471 | 100.00% | 50,383 | 100.00% | 65,455 | 100.00% | 86,399 | 100.00% | 114,315 | 100.00% | 130,283 | 100.00% |
| TESTODERM | TESTODERM TRANSDERMAL PATCH 4MG | 3,858 | 33.39% | 3,814 | 34.14% | 732 | 27.89% | 63 | 48.38% | 33 | 53.46% | 19 | 76.70% | 4 | 50.40% |
| | TESTODERM TRANSDERMAL PATCH 6MG | 7,983 | 69.10% | 7,620 | 68.20% | 1,926 | 73.42% | 70 | 53.85% | 29 | 46.50% | 6 | 23.77% | 4 | 49.60% |
| TESTODERM TTS | TESTODERM TTS TRANSDERMAL PATCH 5MG | 31,129 | 100.00% | 2,503 | 100.00% | 230 | 100.00% | 64 | 100.00% | 48 | 100.00% | 29 | 100.00% | 15 | 100.00% |
| TESTOLIN | TESTOLIN INJ VIAL IM 100MG | 12 | 100.00% | 33 | 100.00% | 6 | 100.00% | | | | | | | | |
| TESTOPEL | TESTOPEL INSERTS/IMPLANTS OTHER 75MG | 30 | 100.00% | 28 | 100.00% | 36 | 100.00% | 31 | 100.00% | 17 | 100.00% | 104 | 100.00% | 472 | 100.00% |
| TESTOSTERONE | TESTOSTERONE INJ VIAL IM 100MG | 204 | 100.00% | 154 | 100.00% | 101 | 100.00% | 70 | 100.00% | 130 | 100.00% | 86 | 100.00% | 33 | 100.00% |
| TESTOSTERONE BULK | TESTOSTERONE BULK ALL OTHERS | 20,898 | 100.00% | 18,499 | 100.00% | 15,007 | 100.00% | 12,847 | 100.00% | 12,097 | 100.00% | 10,864 | 100.00% | 7,306 | 100.00% |
| TESTOSTERONE CYPION | TESTOSTERONE CYPION INJ VIAL IM 100MG | 158 | 17.80% | 109 | 12.70% | 54 | 0.15% | 37 | 0.05% | 221 | 0.23% | 7,546 | 5.55% | 12,132 | 6.97% |
| | TESTOSTERONE CYPION INJ VIAL IM 200MG | 728 | 81.96% | 748 | 87.06% | 35,352 | 99.86% | 68,243 | 99.96% | 96,625 | 99.82% | 129,405 | 95.15% | 163,370 | 93.86% |
| TESTOSTERONE CYP BULK | TESTOSTERONE CYP BULK ALL OTHERS | | | | | | | | | | | | | 3,348 | 100.00% |
| TESTOSTERONE ETHAN | TESTOSTERONE ETHAN INJ VIAL IM 200MG | 282 | 67.71% | 149 | 93.80% | 11,203 | 99.94% | 18,943 | 99.98% | 21,696 | 99.97% | 26,312 | 99.96% | 28,525 | 100.00% |
| | TESTOSTERONE ETHAN INJ VIAL IM, SUST. ACTION 200MG | 135 | 32.48% | 9 | 5.75% | 10 | 0.09% | 5 | 0.03% | 12 | 0.05% | 16 | 0.06% | | |
| TESTOSTERONE PROP | TESTOSTERONE PROP INJ VIAL IM 100MG | 1,219 | 100.00% | 769 | 100.00% | 558 | 100.00% | 318 | 100.00% | 178 | 100.00% | 115 | 100.00% | 161 | 100.00% |
| TESTOSTERONE PRP BLK | TESTOSTERONE PRP BLK ALL OTHERS | 18,939 | 100.00% | 18,421 | 100.00% | 14,969 | 100.00% | 12,123 | 100.00% | 11,651 | 100.00% | 10,054 | 100.00% | 5,943 | 100.00% |
| TESTRED | TESTRED OSC REGULAR 10MG | 10,478 | 100.00% | 8,807 | 100.00% | 7,815 | 100.00% | 6,298 | 100.00% | 5,215 | 100.00% | 4,780 | 100.00% | 4,028 | 100.00% |

Source: SDI Vector One®: Total Patient Tracker. Extracted 1-9-09. File: 2008-1704 Testosterone 1-9-09.xls and 2008-1704 Testosterone YTD 2008 1-9-09.xls

Table 5. Total number of patients receiving a prescription for topical testosterone by age through U.S. outpatient retail pharmacies, Year 2002-2007 and YTD/Nov 2008

| | | 2002 | | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | YTD/NOV/2008 | |
|-------------|----------------------|-------------|---------|-------------|---------|-------------|---------|-------------|---------|-------------|---------|-------------|---------|--------------|---------|
| | | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share |
| | | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| 0 - 17 | TOTAL MARKET | 276,532 | 100.00% | 364,994 | 100.00% | 370,853 | 100.00% | 376,502 | 100.00% | 413,084 | 100.00% | 484,048 | 100.00% | 537,622 | 100.00% |
| | Age Group Total | 1,270 | 0.46% | 1,499 | 0.41% | 1,296 | 0.35% | 1,248 | 0.33% | 1,153 | 0.28% | 1,297 | 0.27% | 1,266 | 0.24% |
| | ANDROGEL | 1,258 | 99.01% | 1,368 | 91.24% | 1,127 | 86.92% | 1,049 | 84.06% | 980 | 84.97% | 1,108 | 85.44% | 1,070 | 84.58% |
| | FIRST-TESTOSTERON MC | | | 12 | 0.78% | 16 | 1.25% | 26 | 2.11% | 27 | 2.31% | 37 | 2.88% | 37 | 2.92% |
| | FIRST-TESTOSTERONE | 12 | 0.93% | 30 | 1.98% | 15 | 1.15% | 15 | 1.19% | 14 | 1.23% | 37 | 2.82% | 35 | 2.79% |
| | TESTIM | | | 92 | 6.14% | 165 | 12.71% | 194 | 15.53% | 149 | 12.95% | 133 | 10.28% | 129 | 10.22% |
| 18 - 29 | Age Group Total | 7,572 | 2.74% | 9,525 | 2.61% | 9,812 | 2.65% | 9,373 | 2.49% | 9,963 | 2.41% | 11,222 | 2.32% | 11,823 | 2.20% |
| | ANDROGEL | 7,409 | 97.85% | 8,776 | 92.14% | 8,313 | 84.72% | 7,898 | 84.26% | 8,066 | 80.96% | 8,753 | 78.00% | 9,194 | 77.76% |
| | FIRST-TESTOSTERON MC | | | 76 | 0.79% | 220 | 2.24% | 111 | 1.18% | 121 | 1.22% | 155 | 1.38% | 97 | 0.82% |
| | FIRST-TESTOSTERONE | 173 | 2.28% | 212 | 2.23% | 199 | 2.03% | 105 | 1.12% | 115 | 1.16% | 75 | 0.67% | 86 | 0.73% |
| | TESTIM | | | 732 | 7.69% | 1,398 | 14.25% | 1,570 | 16.75% | 1,981 | 19.88% | 2,617 | 23.32% | 2,750 | 23.26% |
| | Age Group Total | 31,048 | 11.23% | 38,500 | 10.55% | 38,290 | 10.32% | 36,528 | 9.70% | 38,265 | 9.26% | 43,220 | 8.93% | 46,911 | 8.73% |
| 30 - 39 | ANDROGEL | 30,508 | 98.26% | 35,360 | 91.84% | 32,671 | 85.32% | 30,227 | 82.75% | 30,487 | 79.67% | 33,225 | 76.87% | 35,353 | 75.36% |
| | FIRST-TESTOSTERON MC | | | 364 | 0.94% | 589 | 1.54% | 403 | 1.10% | 435 | 1.14% | 482 | 1.12% | 531 | 1.13% |
| | FIRST-TESTOSTERONE | 566 | 1.82% | 752 | 1.95% | 612 | 1.60% | 354 | 0.97% | 323 | 0.84% | 310 | 0.72% | 255 | 0.54% |
| | TESTIM | | | 2,939 | 7.63% | 5,548 | 14.49% | 6,635 | 18.16% | 8,287 | 21.66% | 10,542 | 24.39% | 12,211 | 26.03% |
| | Age Group Total | 72,318 | 26.15% | 95,182 | 26.08% | 96,209 | 25.94% | 95,464 | 25.36% | 101,003 | 24.45% | 115,687 | 23.90% | 124,927 | 23.24% |
| | ANDROGEL | 71,214 | 98.47% | 88,568 | 93.05% | 83,307 | 86.59% | 79,976 | 83.78% | 81,038 | 80.23% | 89,642 | 77.49% | 95,624 | 76.54% |
| 40 - 49 | FIRST-TESTOSTERON MC | | | 685 | 0.72% | 1,206 | 1.25% | 1,052 | 1.10% | 1,057 | 1.05% | 1,019 | 0.88% | 1,043 | 0.83% |
| | FIRST-TESTOSTERONE | 1,161 | 1.61% | 1,488 | 1.56% | 1,285 | 1.34% | 823 | 0.86% | 811 | 0.80% | 727 | 0.63% | 589 | 0.47% |
| | TESTIM | | | 6,786 | 7.13% | 13,147 | 13.67% | 16,770 | 17.57% | 21,369 | 21.16% | 27,934 | 24.15% | 31,266 | 25.03% |
| | Age Group Total | 92,818 | 33.57% | 123,199 | 33.75% | 126,323 | 34.06% | 130,169 | 34.57% | 141,473 | 34.25% | 164,550 | 33.99% | 181,273 | 33.72% |
| | ANDROGEL | 91,433 | 98.51% | 115,199 | 93.51% | 109,926 | 87.02% | 109,363 | 84.02% | 114,082 | 80.64% | 128,481 | 78.08% | 139,713 | 77.07% |
| | FIRST-TESTOSTERON MC | | | 861 | 0.70% | 1,545 | 1.22% | 1,558 | 1.20% | 1,622 | 1.15% | 1,628 | 0.99% | 1,680 | 0.93% |
| 50 - 59 | FIRST-TESTOSTERONE | 1,463 | 1.58% | 1,821 | 1.48% | 1,945 | 1.54% | 1,480 | 1.14% | 1,326 | 0.94% | 1,255 | 0.76% | 1,180 | 0.65% |
| | TESTIM | | | 8,057 | 6.54% | 16,553 | 13.10% | 21,844 | 16.78% | 28,697 | 20.28% | 37,769 | 22.95% | 43,307 | 23.89% |
| | Age Group Total | 53,329 | 19.28% | 71,811 | 19.67% | 72,885 | 19.65% | 76,620 | 20.35% | 90,983 | 22.03% | 111,762 | 23.09% | 127,858 | 23.78% |
| | ANDROGEL | 52,593 | 98.62% | 67,293 | 93.71% | 63,313 | 86.87% | 64,209 | 83.80% | 72,913 | 80.14% | 86,613 | 77.50% | 98,938 | 77.38% |
| | FIRST-TESTOSTERON MC | | | 278 | 0.39% | 649 | 0.89% | 796 | 1.04% | 816 | 0.90% | 1,047 | 0.94% | 873 | 0.68% |
| | FIRST-TESTOSTERONE | 788 | 1.48% | 1,051 | 1.46% | 1,079 | 1.48% | 884 | 1.15% | 863 | 0.95% | 917 | 0.82% | 711 | 0.56% |
| 60 - 69 | TESTIM | | | 4,862 | 6.77% | 9,753 | 13.38% | 13,284 | 17.34% | 19,082 | 20.97% | 26,235 | 23.47% | 30,133 | 23.57% |
| | Age Group Total | 20,407 | 7.38% | 26,896 | 7.37% | 27,447 | 7.40% | 28,903 | 7.68% | 33,888 | 8.20% | 40,028 | 8.27% | 45,262 | 8.42% |
| | ANDROGEL | 19,899 | 97.51% | 24,840 | 92.35% | 23,478 | 85.54% | 23,815 | 82.40% | 26,858 | 79.25% | 30,632 | 76.53% | 34,602 | 76.45% |
| | FIRST-TESTOSTERON MC | | | 148 | 0.55% | 277 | 1.01% | 361 | 1.25% | 325 | 0.96% | 422 | 1.05% | 379 | 0.84% |
| | FIRST-TESTOSTERONE | 523 | 2.56% | 648 | 2.41% | 600 | 2.18% | 601 | 2.08% | 529 | 1.56% | 532 | 1.33% | 522 | 1.15% |
| | TESTIM | | | 1,779 | 6.61% | 3,724 | 13.57% | 4,984 | 17.24% | 7,074 | 20.87% | 9,379 | 23.43% | 10,707 | 23.66% |
| 70 - 79 | Age Group Total | 5,681 | 2.05% | 7,442 | 2.04% | 7,866 | 2.12% | 8,480 | 2.25% | 9,852 | 2.39% | 12,079 | 2.50% | 13,553 | 2.52% |
| | ANDROGEL | 5,414 | 95.29% | 6,770 | 90.97% | 6,704 | 85.23% | 6,753 | 79.63% | 7,621 | 77.35% | 9,085 | 75.21% | 10,354 | 76.39% |
| | FIRST-TESTOSTERON MC | | | 47 | 0.63% | 169 | 2.15% | 251 | 2.95% | 139 | 1.41% | 213 | 1.77% | 217 | 1.60% |
| | FIRST-TESTOSTERONE | 269 | 4.73% | 335 | 4.50% | 298 | 3.79% | 354 | 4.17% | 355 | 3.60% | 363 | 3.00% | 307 | 2.26% |
| | TESTIM | | | 397 | 5.34% | 849 | 10.79% | 1,378 | 16.25% | 2,011 | 20.41% | 2,691 | 22.28% | 2,932 | 21.63% |
| | Age Group Total | 236 | 0.09% | 1,484 | 0.41% | 2,871 | 0.77% | 2,975 | 0.79% | 1,921 | 0.47% | 1,944 | 0.40% | 1,933 | 0.36% |
| 80+ | ANDROGEL | 220 | 93.43% | 1,220 | 82.17% | 2,464 | 85.83% | 2,450 | 82.34% | 1,561 | 81.27% | 1,507 | 77.54% | 1,357 | 70.19% |
| | FIRST-TESTOSTERON MC | | | 69 | 4.68% | 62 | 2.17% | 31 | 1.03% | 15 | 0.80% | 24 | 1.22% | 66 | 3.41% |
| | FIRST-TESTOSTERONE | 15 | 6.22% | 55 | 3.74% | 33 | 1.14% | 61 | 2.04% | 27 | 1.38% | 56 | 2.91% | 52 | 2.68% |
| | TESTIM | | | 167 | 11.28% | 345 | 12.01% | 436 | 14.66% | 331 | 17.23% | 383 | 19.69% | 475 | 24.55% |
| | Age Group Total | 220 | 0.09% | 1,220 | 0.33% | 2,464 | 0.66% | 2,450 | 0.66% | 1,561 | 0.39% | 1,507 | 0.31% | 1,357 | 0.24% |
| | ANDROGEL | 220 | 93.43% | 1,220 | 82.17% | 2,464 | 85.83% | 2,450 | 82.34% | 1,561 | 81.27% | 1,507 | 77.54% | 1,357 | 70.19% |
| UNKNOWN AGE | FIRST-TESTOSTERON MC | | | 69 | 4.68% | 62 | 2.17% | 31 | 1.03% | 15 | 0.80% | 24 | 1.22% | 66 | 3.41% |
| | FIRST-TESTOSTERONE | 15 | 6.22% | 55 | 3.74% | 33 | 1.14% | 61 | 2.04% | 27 | 1.38% | 56 | 2.91% | 52 | 2.68% |
| | TESTIM | | | 167 | 11.28% | 345 | 12.01% | 436 | 14.66% | 331 | 17.23% | 383 | 19.69% | 475 | 24.55% |
| | Age Group Total | 220 | 0.09% | 1,220 | 0.33% | 2,464 | 0.66% | 2,450 | 0.66% | 1,561 | 0.39% | 1,507 | 0.31% | 1,357 | 0.24% |
| | ANDROGEL | 220 | 93.43% | 1,220 | 82.17% | 2,464 | 85.83% | 2,450 | 82.34% | 1,561 | 81.27% | 1,507 | 77.54% | 1,357 | 70.19% |
| | FIRST-TESTOSTERON MC | | | 69 | 4.68% | 62 | 2.17% | 31 | 1.03% | 15 | 0.80% | 24 | 1.22% | 66 | 3.41% |

Source: SDI Vector One®: Total Patient Tracker. Extracted 1-23-09. File: 2008-1704 Testosterone by Age 1-23-09.xls and 2008-1704 Testosterone by Age YTD 2008 1-23-09.xls

Table 6. Total number of dispensed prescriptions of topical testosterone by physician specialty through U.S. outpatient retail pharmacies, Years 2000-2007 and YTD/Nov 2008

| | 2000 | | 2001 | | 2002 | | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | YTD/NOV/2008 | |
|------------------------------|----------------|---------------|----------------|---------------|----------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------|---------------|
| | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share | Retail TRxs | Share |
| | N | % | N | % | N | % | N | % | N | % | N | % | N | % | N | % | N | % |
| TOTAL MARKET | 154,303 | 100.0% | 624,825 | 100.0% | 970,579 | 100.0% | 1,235,505 | 100.0% | 1,340,574 | 100.0% | 1,394,203 | 100.0% | 1,530,766 | 100.0% | 1,827,761 | 100.0% | 1,916,285 | 100.0% |
| AndroGel | 154,301 | 100.0% | 623,714 | 99.8% | 964,192 | 99.3% | 1,169,834 | 94.7% | 1,187,513 | 88.6% | 1,188,961 | 85.3% | 1,245,733 | 81.4% | 1,445,639 | 79.1% | 1,484,306 | 77.5% |
| GP/FM/DO | 32,047 | 20.8% | 146,684 | 23.5% | 242,570 | 25.2% | 330,830 | 28.3% | 346,262 | 29.2% | 351,000 | 29.5% | 384,035 | 30.8% | 471,553 | 32.6% | 496,214 | 33.4% |
| IM | 43,574 | 28.2% | 172,196 | 27.6% | 260,253 | 27.0% | 322,748 | 27.6% | 325,006 | 27.4% | 321,016 | 27.0% | 335,970 | 27.0% | 391,024 | 27.0% | 399,045 | 26.9% |
| UROL | 31,358 | 20.3% | 125,804 | 20.2% | 172,449 | 17.9% | 191,594 | 16.4% | 179,088 | 15.1% | 176,360 | 14.8% | 183,194 | 14.7% | 193,670 | 13.4% | 188,469 | 12.7% |
| ENDO | 21,714 | 14.1% | 82,093 | 13.2% | 109,370 | 11.3% | 121,890 | 10.4% | 118,114 | 9.9% | 120,494 | 10.1% | 130,944 | 10.5% | 147,789 | 10.2% | 148,299 | 10.0% |
| UNSPEC | 1,049 | 0.7% | 4,956 | 0.8% | 55,336 | 5.7% | 54,217 | 4.6% | 60,973 | 5.1% | 52,736 | 4.4% | 38,153 | 3.1% | 40,003 | 2.8% | 48,023 | 3.2% |
| NP | 1,235 | 0.8% | 5,220 | 0.8% | 7,722 | 0.8% | 11,005 | 0.9% | 13,267 | 1.1% | 15,825 | 1.3% | 19,702 | 1.6% | 26,277 | 1.8% | 32,198 | 2.2% |
| ID | 5,973 | 3.9% | 19,451 | 3.1% | 21,502 | 2.2% | 22,464 | 1.9% | 24,252 | 2.0% | 26,922 | 2.3% | 25,250 | 2.0% | 28,429 | 2.0% | 25,818 | 1.7% |
| HOSP | 1,632 | 1.1% | 7,013 | 1.1% | 8,399 | 0.9% | 10,431 | 0.9% | 11,336 | 1.0% | 11,594 | 1.0% | 10,971 | 0.9% | 11,414 | 0.8% | 9,111 | 0.6% |
| OB/GYN | 1,198 | 0.8% | 5,077 | 0.8% | 7,522 | 0.8% | 8,241 | 0.7% | 9,388 | 0.8% | 9,780 | 0.8% | 7,552 | 0.6% | 7,484 | 0.5% | 7,177 | 0.5% |
| DIAB | 1,484 | 1.0% | 5,781 | 0.9% | 6,110 | 0.6% | 7,392 | 0.6% | 6,691 | 0.6% | 5,952 | 0.5% | 6,114 | 0.5% | 5,758 | 0.4% | 5,559 | 0.4% |
| All Others | 13,037 | 8.4% | 49,439 | 7.9% | 72,959 | 7.6% | 89,022 | 7.6% | 93,136 | 7.8% | 97,282 | 8.2% | 103,848 | 8.3% | 122,238 | 8.5% | 124,393 | 8.4% |
| Testim | -- | -- | -- | -- | -- | -- | 54,286 | 4.4% | 138,773 | 10.4% | 192,136 | 13.8% | 272,552 | 17.8% | 368,976 | 20.2% | 419,886 | 21.9% |
| GP/FM/DO | -- | -- | -- | -- | -- | -- | 10,169 | 18.7% | 30,283 | 21.8% | 48,062 | 25.0% | 75,339 | 27.6% | 102,034 | 27.7% | 115,545 | 27.5% |
| UROL | -- | -- | -- | -- | -- | -- | 15,452 | 28.5% | 33,774 | 24.3% | 40,856 | 21.3% | 55,651 | 20.4% | 83,280 | 22.6% | 97,841 | 23.3% |
| IM | -- | -- | -- | -- | -- | -- | 11,495 | 21.2% | 29,767 | 21.5% | 45,930 | 23.9% | 67,517 | 24.8% | 85,214 | 23.1% | 93,358 | 22.2% |
| UNSPEC | -- | -- | -- | -- | -- | -- | 2,540 | 4.7% | 6,963 | 5.0% | 8,502 | 4.4% | 7,618 | 2.8% | 9,537 | 2.6% | 12,404 | 3.0% |
| NP | -- | -- | -- | -- | -- | -- | 608 | 1.1% | 1,684 | 1.2% | 2,749 | 1.4% | 4,256 | 1.6% | 6,779 | 1.8% | 9,095 | 2.2% |
| ID | -- | -- | -- | -- | -- | -- | 1,009 | 1.9% | 2,493 | 1.8% | 4,265 | 2.2% | 5,825 | 2.1% | 6,609 | 1.8% | 6,057 | 1.4% |
| EM | -- | -- | -- | -- | -- | -- | 176 | 0.3% | 541 | 0.4% | 945 | 0.5% | 1,554 | 0.6% | 2,302 | 0.6% | 2,378 | 0.6% |
| HOSP | -- | -- | -- | -- | -- | -- | 391 | 0.7% | 1,044 | 0.8% | 1,460 | 0.8% | 1,987 | 0.7% | 2,438 | 0.7% | 2,173 | 0.5% |
| DIAB | -- | -- | -- | -- | -- | -- | 413 | 0.8% | 1,067 | 0.8% | 781 | 0.4% | 984 | 0.4% | 1,411 | 0.4% | 1,570 | 0.4% |
| ALLER | -- | -- | -- | -- | -- | -- | 37 | 0.1% | 95 | 0.1% | 104 | 0.1% | 61 | 0.0% | 52 | 0.0% | 63 | 0.0% |
| All Others | -- | -- | -- | -- | -- | -- | 11,996 | 22.1% | 31,062 | 22.4% | 38,482 | 20.0% | 51,760 | 19.0% | 69,320 | 18.8% | 79,402 | 18.9% |
| First-Testosterone MC | -- | -- | -- | -- | -- | -- | 2,987 | 0.2% | 6,170 | 0.5% | 6,683 | 0.5% | 6,261 | 0.4% | 7,112 | 0.4% | 6,929 | 0.4% |
| OB/GYN | -- | -- | -- | -- | -- | -- | 1,866 | 62.5% | 3,450 | 55.9% | 4,202 | 62.9% | 3,868 | 61.8% | 4,098 | 57.6% | 3,927 | 56.7% |
| GP/FM/DO | -- | -- | -- | -- | -- | -- | 331 | 11.1% | 951 | 15.4% | 777 | 11.6% | 877 | 14.0% | 1,087 | 15.3% | 1,198 | 17.3% |
| IM | -- | -- | -- | -- | -- | -- | 140 | 4.7% | 333 | 5.4% | 349 | 5.2% | 382 | 6.1% | 603 | 8.5% | 403 | 5.8% |
| NP | -- | -- | -- | -- | -- | -- | 93 | 3.1% | 161 | 2.6% | 240 | 3.6% | 186 | 3.0% | 302 | 4.2% | 349 | 5.0% |
| UNSPEC | -- | -- | -- | -- | -- | -- | 249 | 8.3% | 557 | 9.0% | 302 | 4.5% | 252 | 4.0% | 302 | 4.2% | 286 | 4.1% |
| ONCOLOGY | -- | -- | -- | -- | -- | -- | 40 | 1.3% | 72 | 1.2% | 151 | 2.3% | 127 | 2.0% | 87 | 1.2% | 78 | 1.1% |
| ENDO | -- | -- | -- | -- | -- | -- | 13 | 0.4% | 30 | 0.5% | 128 | 1.9% | 80 | 1.3% | 70 | 1.0% | 70 | 1.0% |
| PA | -- | -- | -- | -- | -- | -- | 28 | 0.9% | 41 | 0.7% | 26 | 0.4% | 56 | 0.9% | 55 | 0.8% | 59 | 0.9% |
| HOSP | -- | -- | -- | -- | -- | -- | 28 | 0.9% | 42 | 0.7% | 28 | 0.4% | 50 | 0.8% | 55 | 0.8% | 29 | 0.4% |
| DERM | -- | -- | -- | -- | -- | -- | 11 | 0.4% | 52 | 0.8% | 59 | 0.9% | 39 | 0.6% | 26 | 0.4% | 18 | 0.3% |
| All Others | -- | -- | -- | -- | -- | -- | 188 | 6.3% | 481 | 7.8% | 421 | 6.3% | 344 | 5.5% | 427 | 6.0% | 512 | 7.4% |
| First-Testosterone | 2 | 0.0% | 1,111 | 0.2% | 6,387 | 0.7% | 8,398 | 0.7% | 8,118 | 0.6% | 6,423 | 0.5% | 6,220 | 0.4% | 6,034 | 0.3% | 5,164 | 0.3% |
| OB/GYN | 2 | 100.0% | 820 | 73.8% | 4,198 | 65.7% | 5,240 | 62.4% | 5,163 | 63.6% | 4,296 | 66.9% | 4,229 | 68.0% | 3,858 | 63.9% | 3,306 | 64.0% |
| GP/FM/DO | -- | -- | 102 | 9.2% | 873 | 13.7% | 1,166 | 13.9% | 1,179 | 14.5% | 814 | 12.7% | 797 | 12.8% | 797 | 13.2% | 805 | 15.6% |
| IM | -- | -- | 61 | 5.5% | 267 | 4.2% | 550 | 6.5% | 460 | 5.7% | 390 | 6.1% | 301 | 4.8% | 375 | 6.2% | 250 | 4.8% |
| NP | -- | -- | 25 | 2.3% | 110 | 1.7% | 155 | 1.8% | 173 | 2.1% | 127 | 2.0% | 172 | 2.8% | 164 | 2.7% | 169 | 3.3% |
| DERM | -- | -- | 11 | 1.0% | 91 | 1.4% | 75 | 0.9% | 111 | 1.4% | 73 | 1.1% | 74 | 1.2% | 83 | 1.4% | 81 | 1.6% |
| UROL | -- | -- | 15 | 1.4% | 69 | 1.1% | 58 | 0.7% | 30 | 0.4% | 22 | 0.3% | 38 | 0.6% | 67 | 1.1% | 50 | 1.0% |
| PA | -- | -- | 3 | 0.3% | 28 | 0.4% | 75 | 0.9% | 46 | 0.6% | 45 | 0.7% | 45 | 0.7% | 54 | 0.9% | 42 | 0.8% |
| HOSP | -- | -- | 18 | 1.6% | 62 | 1.0% | 85 | 1.0% | 93 | 1.1% | 51 | 0.8% | 46 | 0.7% | 80 | 1.3% | 39 | 0.8% |
| ENDO | -- | -- | 14 | 1.3% | 27 | 0.4% | 57 | 0.7% | 54 | 0.7% | 51 | 0.8% | 46 | 0.7% | 63 | 1.0% | 35 | 0.7% |
| OTHER | -- | -- | 6 | 0.5% | 12 | 0.2% | 13 | 0.2% | 45 | 0.6% | 14 | 0.2% | 32 | 0.5% | 37 | 0.6% | 11 | 0.2% |
| All Others | -- | -- | 36 | 3.2% | 650 | 10.2% | 924 | 11.0% | 764 | 9.4% | 540 | 8.4% | 440 | 7.1% | 456 | 7.6% | 376 | 7.3% |

Source: SDI Vector One®: National. Data Extracted 1-8-09. File: VONA 2008-1704 Testosterone by Physician Specialty 1-8-09.xls

APPENDIX 2: Database Descriptions

SDI Vector One®: National (VONA)

SDI'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.

The Vector One® database integrates prescription activity from a variety of sources including national retail chains, mass merchandisers, mail order pharmacies, pharmacy benefits managers and their data systems, and provider groups. Vector One® receives over 2.0 billion prescription claims per year, representing over 160 million unique patients. Since 2002 Vector One® has captured information on over 8 billion prescriptions representing 200 million unique patients.

Prescriptions are captured from a sample of approximately 59,000 pharmacies throughout the US. The pharmacies in the data base account for nearly all retail pharmacies and represent nearly half of retail prescriptions dispensed nationwide. SDI receives all prescriptions from approximately one-third of the stores and a significant sample of prescriptions from the remaining stores.

SDI Vector One®: Total Patient Tracker (TPT)

SDI'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.

TPT derives its data from the Vector One® database which integrates prescription activity from a variety of sources including national retail chains, mail order pharmacies, mass merchandisers, pharmacy benefits managers and their data systems. Vector One® receives over 2 billion prescription claims per year, which represents over 160 million patients tracked across time.

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.

SDI Physician Drug & Diagnosis Audit (PDDA)

SDI's Physician Drug & Diagnosis Audit (PDDA) 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 approximately 3,100 office-based physicians representing 29 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 data are then projected nationally by physician specialty and region to reflect national prescribing patterns.

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.

SDI uses the term "drug occurrences" to refer to the number of times a product has been reported on a patient information form during an office-based patient visit for that period. It is important to note that a "drug occurrence" does not necessarily result in a prescription being generated. A "drug occurrence" can result from a prescription written, a sample given, a recommendation for OTC products, recommendation with sample, a product dispensed or administered in the office, a hospital order, a nursing home order or a combination of these.

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