Recent OTC Innovation
Observations and Implications for Future Growth

Introduction

Innovation is the lifeblood of the OTC industry. From a business perspective, it drives growth, and from a public health perspective, it better satisfies consumers’ health needs. Because innovation is so important, Kline and IRI have collaborated to examine recent OTC launches and identified their success factors including:

- A point of difference, big or small, real or imagined, to better address patient needs
- Expert awareness-generating, heavy advertising and promotion investment
- Brand equity plays

The nine brands included in this assessment and shown on the timeline graphic in Table 1, have the following characteristics and were chosen for inclusion jointly by Kline and IRI:

- Launched between 2010 to 2014
- A mix of Rx-to-OTC switches, new and line extensions of monograph items, and supplements

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- Part of IRI’s New Products Pacesetters tracking and annual review
- Significant media support
- Experienced double-digit growth the year after launch
- Still growing in Year 2
Brief profiles follow of the products featured in this paper and are grouped either as Rx-to-OTC switches or monograph/supplement items.

### Winning Characteristics

**Table 1: Sales, Market Share, Ad Spending, and SOV for Profiled Brands**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Company</th>
<th>Category</th>
<th>Launch date</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Growth, %</th>
<th>Market share, % 2014-b</th>
<th>Ad spending, $ million 1-c</th>
<th>Share of Voice % year 1-c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schiff Mega Red</td>
<td>RB</td>
<td>Omega 3 supplements</td>
<td>9/10</td>
<td>49.7</td>
<td>77.3</td>
<td>55.5</td>
<td>12.3</td>
<td>10.6</td>
<td>3.2</td>
</tr>
<tr>
<td>Trubiotics One-A-Day</td>
<td>Bayer</td>
<td>Probiotics</td>
<td>8/12</td>
<td>19.4</td>
<td>25.7</td>
<td>32.5</td>
<td>25.7</td>
<td>27.1</td>
<td>29.9</td>
</tr>
<tr>
<td>Allegra</td>
<td>Sanofi</td>
<td>Allergy relief</td>
<td>3/11</td>
<td>272.8</td>
<td>311.0</td>
<td>14.0</td>
<td>17.1</td>
<td>140.7</td>
<td>45.7</td>
</tr>
<tr>
<td>Mucinex Fast Max</td>
<td>RB</td>
<td>Cold and sinus</td>
<td>10/11</td>
<td>129.3</td>
<td>199.0</td>
<td>53.9</td>
<td>6.6</td>
<td>23.1</td>
<td>6.2</td>
</tr>
<tr>
<td>DayQuil/NyQuil Severe</td>
<td>P&amp;G</td>
<td>Cold and sinus</td>
<td>7/13</td>
<td>28.7</td>
<td>90.9</td>
<td>216.7</td>
<td>4.0</td>
<td>20.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Nasacort 24HR</td>
<td>Sanofi</td>
<td>Allergy relief</td>
<td>2/14</td>
<td>130.0</td>
<td>136.5</td>
<td>5.0</td>
<td>5.4</td>
<td>69.9</td>
<td>22.7</td>
</tr>
<tr>
<td>ZzzQuil</td>
<td>P&amp;G</td>
<td>Sleeping aids</td>
<td>8/12</td>
<td>63.8</td>
<td>123.2</td>
<td>93.1</td>
<td>35.7</td>
<td>38.8</td>
<td>44.0</td>
</tr>
<tr>
<td>Nexium 24HR</td>
<td>Pfizer</td>
<td>Antacids</td>
<td>6/14</td>
<td>158.2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Flonase Allergy Relief</td>
<td>GSK</td>
<td>Allergy relief</td>
<td>2/15</td>
<td>268.1-e</td>
<td>294.4-f</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

a- IRI MULO retail sales.
b- Based on Kline’s Nonprescription Drugs USA study.c- Based on ad spending data from Kantar Media.d- Full year 2015; sales since launch in June 2014 through w/e February 7, 2016 are $500.5 million.e- Reflects IRI MULO retail sales from February 4, 2015 to November 22, 2015.f- Through December 2015.
Rx-to-OTC switches

Allegra, Flonase Allergy Relief, and Nexium 24HR have all realized significant OTC sales and market share by building on existing brand equity with both consumers and healthcare professionals from their heritage as prescription drugs. In most of these cases, the prescription drug had been supported heavily by significant direct to consumer (DTC) ad spending, making the OTC brands extremely familiar to consumers. In all cases, each brand successfully communicated a point of difference and unique positioning that resounded with consumers. Despite brand equity built from the prescription heritage, new OTC brands require large-scale advertising and promotional campaigns to have a meaningful impact on the OTC market and make launches successful. While such ad spending can be significant, it helps drive consumer awareness and trial, and there is a particular payoff for marketers of truly innovative OTCs.

Allegra

- The Rx-to-OTC switch of Allegra launched in March 2011 and was the third major low- and non-sedating oral antihistamine to switch after Claritin (Bayer) and Zyrtec (Johnson & Johnson).

- Sanofi/Chattem knew a major marketing push would be necessary to gain traction as the third comer to this category, although its Rx heritage was already significant with the allergy-suffering community.

- Launched in sync with the start of the allergy season, the aggressive 360 marketing program hit hard on points of difference versus the competition:
  - Faster than Claritin
  - Non-drowsy vs. Zyrtec and Benadryl

  In 2011, Allegra was the most heavily advertised OTC allergy brand, with expenditures totaling $140.8 million, driving a commanding 45.7% share of voice.
  - Sales hit $273 million in year 1 and continued to grow to exceed $300 million in year 2.

- Launch sales of Allegra benefited from Johnson & Johnson’s supply disruptions of Zyrtec in 2011 and 2012.

Nasacort Allergy 24HR

- The relatively dissatisfied allergy sufferer helped drive the successful launch of the Rx-to-OTC switch of Nasacort Allergy 24HR in 2014.

- Nasacort Allergy 24HR intranasal spray is different in dose form and function, delivering relief from additional allergic reactions in the body and thus improved symptom control versus existing allergy OTCs.

  Nasacort Allergy 24HR had low brand awareness as an Rx as it made the switch.
Clear communication of the strong functional point of difference helped drive trial.

An aggressive multimedia campaign totaling nearly $70 million in 2014, including television and radio advertising and interactive in-store displays, is rumored to cost an additional $2.1 million.¹

Surprisingly, with Nasacort, product efficacy trumped form for many allergy sufferers.

Flonase Allergy Relief

The second inhaled nasal steroid, Flonase Allergy Relief launched by GlaxoSmithKline in February 2015, was approved to treat both nasal and eye symptoms (such as itchy and watery eyes), which is an advantage over Nasacort Allergy 24HR.

Unlike Nasacort, the Flonase brand had strong brand awareness and equity from its prescription heritage as it entered the OTC market.

“Consumerizing” its proposition and building on the Rx heritage, advertising touted Flonase treats six causes of allergy symptoms, compared to just one, using the tagline “Six is greater than one.”

The timely (start of allergy season) and substantially supported launch drove Flonase to top the inhaled nasal steroid segment, with retail sales in its first eleven months accounting for an astounding $294 million.²

Nexium 24HR

Pfizer launched the Rx-to-OTC switch of Nexium 24HR in June 2014 and the brand joined a crowded antacid market cluttered with numerous brands in the PPI, H2 antagonists, and traditional antacid segments.

Given the intense competitive landscape of antacids and relatively high consumer satisfaction with such medicines, Pfizer brilliantly built on the “purple pill” equity from the product’s Rx heritage by investing heavily, nearly $60 million in media spend in the first six months out.

Support for Nexium at $60 million dwarfed market leader Prilosec (Procter & Gamble), which invested $56 million for the entire year in 2014. Copy touts “Time for a new routine. Try Nexium 24HR, the latest choice in frequent heartburn protection, and get Nexium Level Protection.”

Backed by a 360-degree surround sound promotional campaign, sales reached $158.2 million in the first seven months of OTC availability and $302.1 million in full year 2015.
Supplements and monograph innovations

MegaRed: A brand amidst a commodity marketplace

- Reckitt Benckiser, post acquiring Schiff in 2012, took MegaRed, originally launched in 2010, to leadership in the commodity omega 3 market nearly overnight.

- By 2014, sales reached $88 million with a share in excess of 12%, a far cry from the $10 million performance in its first year on the market in 2010.

- Reckitt Benckiser took the product’s original point of difference in 2010 and morphed it into a more consumer-friendly positioning.
  - In 2010, the product carried the Marine Stewardship Council eco-label, an exclusive label given to sustainable, well-managed fisheries.
  - The label assured that Schiff MegaRed Omega-3 Krill Oil supplement was the first mass market product to be certifiably sustainable, have minimal impact on the environment, and have 100% traceability from sea to shelf.3

- Currently, Reckitt Benckiser claims that it produces the most powerful softgel containing oil from 100% pure Antarctic krill, in an optimized combination of omega-3 fatty acids, phospholipids, and the powerful antioxidant, astaxanthin, to support healthy heart and joint health.1

ZzzQuil

- Procter & Gamble’s ZzzQuil is an example of innovation and marketing genius. The brand responds to the intersection of:
  - Consumer frustration with sleep deprivation and poor quality sleep
  - Tremendous equity and heritage of Nyquil = sleep
  - Dose form associated with home/night time use
  - Availability of a safe, time-tested monograph ingredient.

- ZzzQuil became the first OTC sleeping aid in liquid form and recorded $121.1 million in retail sales during the product’s 12 months post-launch in 2012-2013, disrupting the 54% private-label sleep aids category.

- Despite the flip side of monograph ingredient-based products being susceptible to private-label competition, ZzzQuil continued to grow share in year 2, reaching 35.7% market share in 2014 and posting $118.8 million in retail sales at the end of 2014.2
Mucinex Fast-Max

- Mucinex’s mega-brand success is founded on its patented novel products, endorsements by physicians and pharmacists, and its ground-breaking and aggressive promotional campaign that features Mr. Mucus and his family.

- In time for the 2011-2012 cough and cold season, Reckitt Benckiser launched the new Mucinex Fast-Max line of items.

- In 2012, Reckitt Benckiser spent $492.4 million in traceable media expenditures (TME) for Mucinex, the most advertising spent on any brand in the cold and sinus medication category that year (and many recent years running).¹

DayQuil/NyQuil Severe

- Mucinex’s mega-brand success is founded on its The combo-pack DayQuil/NyQuil Severe, launched in mid-2013, helped add nearly a full share point to Vicks’ share in the cold and sinus market, which reached 19.9% by 2014.

- In 2014, Procter & Gamble invested just over $80 million behind inspired copy for DayQuil/NyQuil Severe, portraying parents who apologize to their kids because they might need to take a sick day. For NyQuil, the spot added the “Best Sleep with a Cold” copy to its well-known “Nighttime, Sniffling, Sneezing, Coughing, Aching, Fever” tagline.

One-A-Day TruBiotics

- Bayer has done a great job of establishing a brand in the relatively new probiotics segment of the supplement category.
  - Knowing that the idea of probiotics for health is new to U.S. consumers, Bayer uses the

- With the product’s new claims and clever advertising, the DayQuil/NyQuil Severe brand extension experienced $91.9 million in retail sales in its first 12 months on the market.²

- Constant advertising of the new brand line, along with the company’s new speed claims about the products, resulted in an 18.4% share of the cough, cold, and sinus market.

- Additionally, Mucinex Fast-Max continues to grow, and retail sales of the brand reached $199.0 million at the end of 2014.²

¹ See note 1 for details.

² See note 2 for details.
Absent existing product innovation and entirely new launches, the OTC market inherently grows at a slow and steady pace year over year. These actions coupled with clear and concise marketing messages which reach the consumer at their moment of truth, help drive market growth. With this in mind, factors influencing our forecast, either positively or negatively for the near-term are as follows:

- Consumer adoption of new dose form and delivery technologies and devices (↑)
- Increased prevention mindset versus just treatment (↑)
- More demand for natural treatment and health/wellness products (↑)
- Stronger claims backed by science (↑)
- Rx-to-OTC switches: more expected in a variety of categories as noted in the table below (↑)
- Pricing: some uptick if strong rationale or innovation present (↑)
- Widespread messaging across broader media venue choices to boost awareness (↑)

The brand is still growing through 2014, posting the largest market share of the probiotic supplement category at 25.7%¹ and $25.7 million in retail sales.²

### Outlook for 2015 to 2018

Absent existing product innovation and entirely new launches, the OTC market inherently grows at a slow and steady pace year over year. These actions coupled with clear and concise marketing messages which reach the consumer at their moment of truth, help drive market growth. With this in mind, factors influencing our forecast, either positively or negatively for the near-term are as follows:

- Trade-offs for lower cost generic prescription drugs (↓)
- Continued openness to private-label alternatives (↓)
- Channel shifting toward online: for total OTC still relatively low, hovering near 2% of sales, but for select regimen-based categories, the growth will be double digit, driving MULO dollar gains downward (↓)

### One-A-Day TruBiotics

- Since this is a still developing category, posted sales are modest.
  - TruBiotics accounted for just over a 9% share in year one and doubled that to 18.2% by the end of year 2 in 2013.
  - True to the Bayer heritage of expert and pervasive marketing and advertising, TruBiotics was advertised in conjunction with One-A-Day vitamins.
  - Advertising was comprehensive and included widespread media coverage across television, magazines, and print.

The brand is still growing through 2014, posting the largest market share of the probiotic supplement category at 25.7%¹ and $25.7 million in retail sales.²
The prospects for the U.S. OTC market look healthy moving forward. We forecast growth for the OTC industry at nearly 4% annually through 2018, as shown below:

### Table 2: Categories of Expected Rx-to-OTC Switches

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
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<tbody>
<tr>
<td>Allergy</td>
<td>Erectile dysfunction</td>
<td>Allergy</td>
<td></td>
</tr>
<tr>
<td>Migrane</td>
<td>Sleep</td>
<td>Erectile dysfunction</td>
<td></td>
</tr>
<tr>
<td>Acne</td>
<td>Overactive bladder</td>
<td>Acne</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acne</td>
<td>Eczema</td>
<td>Migrane</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Overactive bladder</td>
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The chart below illustrates the forecasted growth:

<table>
<thead>
<tr>
<th>Year</th>
<th>$ Billion</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>34.0</td>
<td>+4.7%</td>
</tr>
<tr>
<td>2015</td>
<td>35.6</td>
<td>+2.5%</td>
</tr>
<tr>
<td>2016</td>
<td>36.5</td>
<td>+4.0%</td>
</tr>
<tr>
<td>2017</td>
<td>38.0</td>
<td>+5.0%</td>
</tr>
<tr>
<td>2018</td>
<td>39.9</td>
<td></td>
</tr>
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</table>
Base growth will hover near 2% annually, while switches and other innovations will spur the industry to a forecast of nearly two times that or CAGR of 3.9%, as shown in Table 3.

<table>
<thead>
<tr>
<th>Line item</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>CAGR, %</th>
</tr>
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<tr>
<td>Base OTC market</td>
<td>34.7</td>
<td>35.6</td>
<td>36.5</td>
<td>38.0</td>
<td>3.1</td>
</tr>
<tr>
<td>New Rx-to-OTC switches</td>
<td>0.3</td>
<td>0.5</td>
<td>0.8</td>
<td>1.0</td>
<td>49.4</td>
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<tr>
<td>OTC innovations</td>
<td>0.6</td>
<td>0.4</td>
<td>0.7</td>
<td>0.9</td>
<td>14.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35.6</strong></td>
<td><strong>36.5</strong></td>
<td><strong>38.0</strong></td>
<td><strong>39.9</strong></td>
<td><strong>3.9</strong></td>
</tr>
</tbody>
</table>

Source: IRI MULO sales data

References

1 Kline & Company: *Nonprescription Drugs USA*, 2010-2014.
4 IRI MULO sales data
About the IRI/Kline Alliance

Information Resources, Inc. (IRI) the global leader in innovative solutions and services for consumer, retail and over-the-counter healthcare companies, and Kline, a global market research and management consulting firm, have established an exclusive alliance to serve the worldwide, over-the-counter (OTC) drug and overall consumer healthcare industries. This powerful alliance will provide a higher level of data accuracy and an unparalleled, global range of thought leadership on stimulating topics in the consumer healthcare space.

As part of this collaborative relationship, IRI will contribute its granular, widely recognized, point-of-sale (POS) market data, related insights, and thought leadership. Meanwhile, Kline will provide its unmatched historical database, global network, and 360-degree view of the complex OTC drug market, including its comprehensive channel coverage and vast expertise in the area of Rx-to-OTC switches.

The collaborative thought leadership will manifest through white papers like this one on such topics as Rx-to-OTC switch, merger and acquisition activity, new product innovation, as well as trends and issues in international and emerging markets within the OTC drugs industry.

About Kline:

Kline is a worldwide consulting and research firm dedicated to providing the kind of insight and knowledge that helps companies find a clear path to success. The firm has served the management consulting and market research needs of organizations in the agrochemicals, chemicals, materials, energy, life sciences, and consumer products industries for over 50 years. For more information, visit www.KlineGroup.com.

About IRI:

IRI is a leader in delivering powerful market, consumer and media exposure information, predictive analytics and the foresight that leads to action. We go beyond the data to ignite extraordinary growth for our clients in the CPG, retail and over-the-counter health care industries by pinpointing what matters and illuminating how it can impact their businesses. Move your business forward at www.iriworldwide.com.

About the IRI Partner Ecosystem:

IRI fundamentally believes that delivering differentiated growth for clients requires deep, highly integrated partnering with a variety of best-of-breed companies. As such, IRI works closely with a broad range of industry leaders to create innovative joint solutions, services and access to capabilities to help its clients more effectively compete in their various markets and exceed their growth objectives. IRI is committed to its partnership philosophy and continues to actively enhance its ecosystem of partners through alliances, joint ventures, acquisitions and affiliations. The IRI Partner Ecosystem includes such companies as BlueKai (an Oracle Co.), The Boston Consulting Group, comScore, Datalogix (an Oracle Co.), Experian, GfK, Ipsos, Kantar, Kline, MaxPoint, Millward Brown Digital, RentRak, SPINS, Univision, MasterCard Advisors and others.

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