Innovative OTC Remedies for the Seasonal Flu Epidemic

March 28, 2019

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ILLNESS Tracking:

Innovative OTC Remedies for Seasonal Flu Epidemic

March 2019
Michael Kinishi
Principal, Product Management
IRI
Headlines

• Most recent flu seasons starting earlier, lasting longer.

• Total U.S. flu incidence down 56.7 percent in 2018-19; but Massachusetts (11.6 percent) and New Hampshire (8.3 percent) are experiencing significant increase in flu incidence.

• Sales of cold/allergy/sinus and cough remedies are down.

• Sales for other health-related products, including personal thermometers, humidifiers and spray disinfectants are also down.

• 2016 flu peaked in March; season isn’t over.
IRI Illness Tracking Service, delivered on IRI’s Liquid Data platform is the most robust and comprehensive service for seasonal categories

- **Key Symptoms for Respiratory and Seasonal Allergies**
  - Total Affected Population
  - Influenza, Cough, Sore Throat, Nasal Congestion, Fever, Ear Ache, Seasonal Allergy

- **Most Granular Illness Tracking**
  - Total US, US Regions, States, IRI Markets, Retailer Trading Areas
  - Client Custom Regions

- **Age Breaks**
  - Adult/Pediatric
  - Multiple Age Breaks: (0-4 years, 5-14 years, 15-19 years, 20-49 years, 50-64 years, 65+)

- **Integrated Insights with IRI Liquid Data Platform**
  - 5 Year history of Illness and POS data
  - Weekly updates with IRI delivery cycle
  - Integrated IRI Causal Data

- **Pre-built Reports and Templates**
  - Market Maps, Priority Markets, % Change Vs. Year Ago Season, % Change vs. Prior Week etc.

**Symptoms**
Which symptoms are driving overall trends in specific markets.

**Location**
In which markets are households in your target most likely to live

**Retailer Fit**
Which retailers or stores have shoppers who are most similar to your target

**Opportunity**
Where is your product over or under performing relative to potential
**Business Situation/Opportunity**

- Without facts, many simply assume the flu season runs from December to March.
- We know our sales correlate with illness, however don’t know to what extent.
- What other product categories correlate with illness so we can consider co-promotions or merchandising?
- Sales trends vary geographically due to many factors. When sales spikes occur without supporting merchandising, promotions, etc. we're caught off-guard often resulting in out-of-stocks.
- We have products targeted to help children vs adults. Illness and sales insights by age would help us meet consumer demand.
- During the cough/cold/flu season, are there specific product forms that are growing in share?
Past 35 years season sales peak most often occurs in February. For the Health Remedies Aisle, this single peak week is over $500M

Source: Centers for Disease Control and Prevention
Most Recent Flu Seasons Starting Sooner and Lasting Longer

Total US weekly Flu Incidence

Flu Incidence 2018-19 Season
Flu Incidence Year Ago
Flu Incidence 2 Years Ago
Flu Incidence 3 Years Ago

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Business Situation/Opportunity

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Weekly sales spikes can mirror Illness Incidence. Critical to understand correlation when planning.
Business Situation/Opportunity

• Without facts, many simply assume the flu season runs from December to March.
• We know our sales correlate with illness, however don’t know to what extent.
• **What other product categories correlate with illness so we can consider co-promotions or merchandising?**
• Sales trends vary geographically due to many factors. When sales spikes occur without supporting merchandising, promotions, etc. we're caught off-guard often resulting in out-of-stocks.
• We have products targeted to help children vs adults. Illness and sales insights by age would help us meet consumer demand.
• During the cough/cold/flu season, are there specific product forms that are growing in share?
Sales of Flu Remedies and Other Associated Products are Down Versus Prior Year

Flu Impact on Sales
Total US - Multi Outlet Time: Latest 12 Weeks Ending Feb 24, 2019 and Feb 25, 2018 vs Year Ago

Sales of Flu Remedies and Other Associated Products are Down Versus Prior Year

Source: IRI Market Advantage™ Illness Tracking, 2019
Business Situation/Opportunity

• Without facts, many simply assume the flu season runs from December to March.
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Total U.S. Flu Incidence 2.7%
Time: Latest 8 Weeks Ending 01-27-19

U.S. Flu Map Shows Varying Levels of Severity

Source: IRI Market Advantage™ Illness Tracking, 2019
The Flu can Take Dramatic Leaps in Just One Month’s Time

Flu Prevalence by Market

Percent of Population with Flu

<table>
<thead>
<tr>
<th>City</th>
<th>4 Weeks Ending 01-27-19</th>
<th>4 Weeks Ending 02-24-19</th>
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<tbody>
<tr>
<td>Total US</td>
<td>2.52%</td>
<td>4.45%</td>
</tr>
<tr>
<td>Roanoke, VA</td>
<td>2.50%</td>
<td>4.45%</td>
</tr>
<tr>
<td>Charlotte, NC</td>
<td>2.22%</td>
<td>4.41%</td>
</tr>
<tr>
<td>Dallas/Ft. Worth, TX</td>
<td>3.19%</td>
<td>5.68%</td>
</tr>
<tr>
<td>Nashville, TN</td>
<td>3.55%</td>
<td>5.49%</td>
</tr>
<tr>
<td>Providence, RI</td>
<td>0.98%</td>
<td>4.24%</td>
</tr>
<tr>
<td>Des Moines, IA</td>
<td>3.30%</td>
<td>4.00%</td>
</tr>
<tr>
<td>New York, NY</td>
<td>3.09%</td>
<td>3.59%</td>
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<tr>
<td>Los Angeles, CA</td>
<td>3.48%</td>
<td>3.21%</td>
</tr>
<tr>
<td>Miami/Ft. Lauderdale, FL</td>
<td>1.43%</td>
<td>3.21%</td>
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<tr>
<td>Chicago, IL</td>
<td>0.75%</td>
<td>1.64%</td>
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<tr>
<td>Milwaukee, WI</td>
<td>0.99%</td>
<td>0.99%</td>
</tr>
</tbody>
</table>

Source: IRI Market Advantage™ Illness Tracking, 2019
Keep Those Northeast Shelves Well Stocked

Health-Aisle Dollar Sales and Flu by Region vs Year Ago – Multi Outlet, Four Weeks Ending Jan. 27, 2019

Northeast Flu relatively mild

Northeast $ Up

Flu by Region vs YA

Dollar Sales % Change vs YA

Flu Incidence % Change vs YA

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**Business Situation/Opportunity**

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Millennials Among the Hardest Hit With Flu

Total US Flu by Age

- Latest 8 Weeks Ending 01-27-19
- % of Age Group w/Flu

Source: IRI Market Advantage™ Illness Tracking, 2019
Business Situation/Opportunity

- Without facts, many simply assume the flu season runs from December to March.
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### Top Selling Cough/Cold Brands have a Broad Product Portfolio

<table>
<thead>
<tr>
<th>Top Cough/Cold Brands</th>
<th>Tablet/Capsule</th>
<th>Liquid/Powder/Pods</th>
<th>Softgel</th>
<th>Dissolvable</th>
<th>Chewable</th>
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<tbody>
<tr>
<td>Private Label</td>
<td>✓</td>
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<tr>
<td>Mucinex®</td>
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<tr>
<td>Alka Seltzer® Plus</td>
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<tr>
<td>Vicks Nyquil®/Dayquil®</td>
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<td>✓</td>
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<tr>
<td>Theraflu®</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tylenol®</td>
<td>✓</td>
<td>✓</td>
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</tbody>
</table>
Tablets, Capsules, Softgel make up 85% of the $4B+ Category

2018 Share by Form $4B+ Cough/Cold/Allergy Tablet Category

- Tablet & Capsule: 70%
- Softgel: 15%
- Dissolvable: 12%
- Chewable: 2%
- Drop: 2%
- Gummy: 2%
- Swab: 2%
Softgels represent 15% of the category yet are driving 41% Cold/Allergy/Sinus Tablet 2 year growth.

$318M Cough/Cold/Allergy Tablet Category growth for 2 years ending 12/30/18

Softgels contributing more than their share towards category growth.
Winning Shelf Space in the Seasonal Flu Epidemic

Sue Zheng
Manager, Product office

Dan Peizer
Director, Consumer Health

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RP SCHERER SOFTGEL TECHNOLOGIES
ROBUST PRODUCT LIBRARY, FASTER TO MARKET
Standard OTC Development Timeline

PRE-FORMULATION* 4-6 MONTHS
PROOF OF CONCEPT & INFORMAL STABILITY 4-7 MONTHS
ICH BATCHES & FORMAL STABILITY 5-6 MONTHS
BIO-EQUIVALENCE 2-3 MONTHS
TECHNICAL DOSSIER 1-3 MONTHS

*INCLUDES FEASIBILITY & ACCELERATED STABILITY
Lab Scale Compatibility, Pilot/Feasibility Batches
Non-GMP Batches Analytical Method Development & Validation Packaging Development
3 ICH Batches—Characterization & Confirmation Stability Programs

In Vitro Dissolution Trial In Man ($200-400K)
MOD 1 Regional administrative information
MOD 2* Quality; non-clinical/clinical overview and summary
MOD 3* Quality
MOD 4 Non-clinical study reports
MOD 5 Clinical study reports
*Mods 2 & 3 included in typical library dossier

PRODUCT SELECTED FROM CATALENT’S OTC LIBRARY
DEVELOPMENT TIMELINE REDUCED BY 12-14 MONTHS
REDUCED RISK Proof of concept has already been achieved
REDUCED TIME For “as is” products, time to filing/commercialization can be as short as 9-12 months**
REDUCED COST Saves up to $100-300K in development costs

BIO-EQUIVALENCE 2-3 MONTHS
TECHNICAL DOSSIER 1-3 MONTHS
AVERAGE 9-12 MONTHS

**WHEN COMMERCIALIZING A LIBRARY PRODUCT IN “AS IS” CONDITION TIMING TO FILE FOR APPROVAL CAN OCCUR IN 9 - 12 MONTHS. CUSTOMER PRODUCT SPECIFICATIONS AND LOCAL REGULATORY REQUIREMENTS CAN ADD TIME TO THE DEVELOPMENT PLAN.
Selected Market-Ready Softgel Products for the Flu Season

more products. better treatments. reliably supplied.
Nighttime and Daytime Cold & Flu Softgel Products

**Product Overview**
Provides relief from cough, sore throat, headache, fever, runny nose and sneezing

**Product Overview**
Provides relief from nasal congestion, cough, sore throat, headache and fever

**Active Ingredient(s)**
- Acetaminophen 325 mg
- Dextromethorphan HBr 10 mg
- Doxylamine Succinate 6.25 mg

**Active Ingredient(s)**
- Acetaminophen 325 mg
- Dextromethorphan HBr 10 mg
- Phenylephrine HCl 5 mg

**Softgel Description**
- 16 oblong softgel
- Clear green gelatin capsules
- One-sided printing in white ink

**Softgel Description**
- 16 oblong softgel
- Clear orange gelatin capsules
- One-sided printing in white ink

**Packaging**
Blister

**Shelf life**
24 months

**Packaging**
Blister

**Shelf life**
30 months
Nighttime and Daytime Sinus Softgel Products

Nighttime Product Overview
Provides relief from sinus and nasal congestion, headache, fever, runny nose and sneezing

Active Ingredient(s)
- Acetaminophen 325 mg
- Doxylamine Succinate 6.25 mg
- Phenylephrine HCl 5 mg

Softgel Description
- 16 oblong softgel
- Clear blue gelatin capsules
- One-sided printing in white ink

Packaging
- Blister
- Shelf life: 36 months

Daytime Product Overview
Provides relief from nasal congestion, sinus congestion and pressure, headache and fever

Active Ingredient(s)
- Acetaminophen 325 mg
- Phenylephrine HCl 5 mg

Softgel Description
- 16 oblong softgel
- Clear light orange gelatin capsules
- One-sided printing in white ink

Packaging
- Blister
- Shelf life: 36 months
### Nighttime and Daytime Cold & Sinus Softgel Products

#### Nighttime

**Product Overview**
Provides relief from sinus and nasal congestion, headache, fever, runny nose, sneezing, sore throat and dry cough

**Active Ingredient(s)**
- Acetaminophen: 325 mg
- Pseudoephedrine HCl: 30 mg
- Dextromethorphan HBr: 15 mg
- Doxylamine Succinate: 6.25 mg

**Softgel Description**
- 14 oblong softgel
- Clear green gelatin capsules
- One-sided printing in white ink

**Packaging**
- Blister
- 36 months

#### Daytime

**Product Overview**
Provides relief from sinus and nasal congestion, headache, fever, sore throat and cough

**Active Ingredient(s)**
- Acetaminophen: 325 mg
- Pseudoephedrine HCl: 30 mg
- Dextromethorphan HBr: 15 mg

**Softgel Description**
- 16 oblong softgel
- Clear orange gelatin capsules
- One-sided printing in white ink

**Packaging**
- Blister
- 36 months
Daytime Four Active Formula

**Product Overview**
Provides relief from fever, headache and pain, stuffy nose, cough and chest congestion

**Active Ingredient(s)**
- Acetaminophen: 325 mg
- Dextromethorphan HBr: 10 mg
- Guaifenesin: 200 mg
- Phenylephrine HCl: 5 mg

**Softgel Description**
- 16 oblong softgel
- Clear orange gelatin capsules
- One-sided printing in white ink

**Packaging**
- Blister

**Shelf life**
- 24 months
RP SCHERER SOFTGEL TECHNOLOGIES
A GLOBAL NETWORK OF 10 SOFTGEL SITES

1. ST. PETERSBURG, FL
2. BEINHEIM, FRANCE
3. APRILIA, ITALY
4. EBERBACH, GERMANY
5. BUENOS AIRES, ARGENTINA
6. SOROCABA, BRAZIL
7. INDAIATUBA, BRAZIL
8. KAKEGAWA, JAPAN
9. WINDSOR, CANADA
10. STRATHROY, CANADA
11. CHAM, SWITZERLAND
12. MONTEVIDEO, URUGUAY

MANUFACTURING FACILITY
TRADE OFFICE
Proven and Consumer Preferred

- Perceived to provide **SPEED OF ACTION**
- Help analgesics to work **FASTER**
- Make supplements **TASTE BETTER**
- Deliver more actives into smaller pills for **EASY SWALLOWING**
- Drive incremental **BRAND GROWTH**

**CHALLENGE US**
Softgel capsules are the dosage form most associated with the following attributes:

- Effective: 82%
- Fast Acting: 82%
- Easy to Digest: 89%
- Easy to Swallow: 87%
- Great for On-the-Go: 79%

% Agreement, Total (N=414)
Marketing Analysts LLC; OTC/VMS Delivery Forms Study 2009
OPTIGEL® MINI CAPSULES
Enable a higher API load into a smaller capsule (on average 30% smaller than standard fill).

OPTIGEL® MICRO CAPSULES
Our smallest capsules available (1-7mm), packaged in a sachet. Perfect for consumers who may experience difficulty swallowing.

SOFTDROP™ LOZENGES
A soft, pleasant lozenge dose. Dual-action, provides immediate and longer-lasting benefits.

EASYBURST® CHEWABLES
A range of chewable shell textures and flavored fills.

COSMOPOD® BEAUTY TWIST-OFF CAPSULES
Topical application of skin and hair care serums. Capsules are plant based, biodegradable and preservative free.

VEGICAPS® CAPSULES
Plant based shell, to support brands targeting consumers who maintain animal-free diets.
OPTIGEL™ MINI TECHNOLOGY

Consumer Benefits & Applications

An Optimal Solution for Multiple Categories

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>INGREDIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANALGESICS</td>
<td>INCLUDING IBUPROFEN, NAPROXEN, ACETAMINOPHEN</td>
</tr>
<tr>
<td>COUGH</td>
<td>INCLUDING DEXTROMETHORPHAN, PHOLCODEINE</td>
</tr>
<tr>
<td>COLD</td>
<td>INCLUDING PSEUDOEPHEDRINE, GUAIFENESIN, PHENYLEPHRINE, MENTHOL</td>
</tr>
<tr>
<td>ALLERGY</td>
<td>INCLUDING LORATADINE, CETIRIZINE, DIPHENHYDRAMINE, CHLORPHENYRAMINE, DOXYLAMINE</td>
</tr>
<tr>
<td>DIGESTIVE HEALTH</td>
<td>INCLUDING LOPERAMIDE</td>
</tr>
</tbody>
</table>

**PRODUCT FEATURES & BENEFITS**

- Full strength dosage with smaller capsule size
- 30% - 50% smaller than traditional softgels
- Perceived consumer benefit of fast and effective relief
- Improves compliance, especially for pediatric and geriatric
- Available in variety of colors, shapes, sizes, and clarity
**SOFTDROP™ LOZENGE TECHNOLOGY**

**Consumer Benefits & Applications**

- Soft, dissolvable shell provides lasting relief
- Liquid center delivers great tasting, immediate relief
- Easy to take, convenient, great for on-the-go
- Combination of flavors and sensations for unique consumer experience

---

**An Optimal Solution for Multiple Categories**

- IMMUNE SUPPORT
- COUGH & COLD TREATMENTS
- SORE THROAT RELIEF
- NATURAL COLD REMEDIES
EASYBURST® CHEWABLE TECHNOLOGY
CONSUMER BENEFITS & APPLICATIONS

An Optimal Solution for Multiple Categories

- OMEGA-3s
- MULTIVITAMINS
- LETTERS & MINERALS
- COMBINATION SUPPLEMENTS
- HERBAL EXTRACTS

PRODUCT FEATURES & BENEFITS
- Easy to take, convenient, great for on-the-go
- Improves compliance, especially for pediatric and geriatric
- Taste masking expertise with difficult ingredients
- Range of fill textures to customize consumer experience
- Custom shapes, sizes, colors and in-line printing
EasyBurst® Chewables Consumer Research: Among Gummy Users

OBJECTIVES:
Understand consumer acceptance of EasyBurst® chewables
- Purchase Interest
- Uniqueness
- Key Benefits

TARGET:
- Adults
- Gummy Users

AMONG CONSUMERS
- Total of 311 US Adult Supplement Users
- Mix of Male/Female Consumers (150/160)
- Adults - Gummy Users (181)

KEY BENEFITS
- Less sugar than typical gummy vitamin
- Great tasting chewable with strong burst of flavor
- Delivers higher level of nutrients each dose
- Convenient
- Easy to chew

91% OVERALL PURCHASE INTEREST
87% MORE UNIQUE vs. GUMMIES
89% MORE UNIQUE vs. TABLETS
64% SWITCH CURRENT FORM

% Agreement, Total (N=311) Market View Research, Catalent Vitamin Dosage Form Study 2017
EasyBurst® Chewables Consumer Research: Among Parents of Children

**OBJECTIVES:**
Understand consumer acceptance of EasyBurst® chewables
- Purchase Interest
- Uniqueness
- Key Benefits

**TARGET:**
- Children (asked Parents)

**AMONG CONSUMERS**
- Total of 311 US Adult Supplement Users
- Mix of Male/Female Consumers (150/160)
- Parents with Kids - Gummy Users (120)

**KEY BENEFITS**
- Great tasting chewable with strong burst of flavor
- Less sugar than typical gummy vitamin
- Delivers higher level of nutrients each dose
- Convenient
- Easy to chew

<table>
<thead>
<tr>
<th>Objective</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Overall Purchase Interest</td>
<td>92%</td>
</tr>
<tr>
<td>More Unique vs. Tablets</td>
<td>92%</td>
</tr>
<tr>
<td>More Unique vs. Gummies</td>
<td>90%</td>
</tr>
<tr>
<td>Switch Current Form</td>
<td>65%</td>
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</tbody>
</table>

% Agreement, Total (N=311) Market View Research, Catalent Vitamin Dosage Form Study 2017
‘TWIST OFF’ ORAL & TOPICAL TECHNOLOGY
CONSUMER BENEFITS & APPLICATIONS

An Optimal Solution for Multiple Categories

<table>
<thead>
<tr>
<th>ANALGESICS</th>
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</thead>
<tbody>
<tr>
<td>COUGH &amp; COLD</td>
</tr>
<tr>
<td>ALLERGY</td>
</tr>
<tr>
<td>DIGESTIVE</td>
</tr>
<tr>
<td>NUTRITIONAL SUPPLEMENTS</td>
</tr>
</tbody>
</table>

PRODUCT FEATURES & BENEFITS

- Easy to take and administer, especially pediatric and geriatric
- Convenient, great for on-the-go
- Flexible Dosing – take directly or as food additive
- Can also be used for topical applications like menthol rubs
- Custom shapes, sizes, colors and printing options
A MODEL THAT SUPPORTS A RANGE OF INNOVATION STRATEGIES

We can help you drive incremental revenue and grow market share with:

- Product features and claims to **DIFFERENTIATE YOUR BRAND AND DRIVE GROWTH**
- Breakthrough technology to reach **NEW CONSUMERS**
- New benefits to support **MORE USAGE OCCASIONS**
- Enjoyable forms to **INCREASE COMPLIANCE**
- Formulations for **BETTER EFFICACY** claims
- Expansive API capabilities to **EXTEND INTO ADJACENT CATEGORIES**
discover more.

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more products. better treatments. reliably supplied.™