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OTC Monograph Woes No Surprise To FDA Commissioner Nominee Gottlieb

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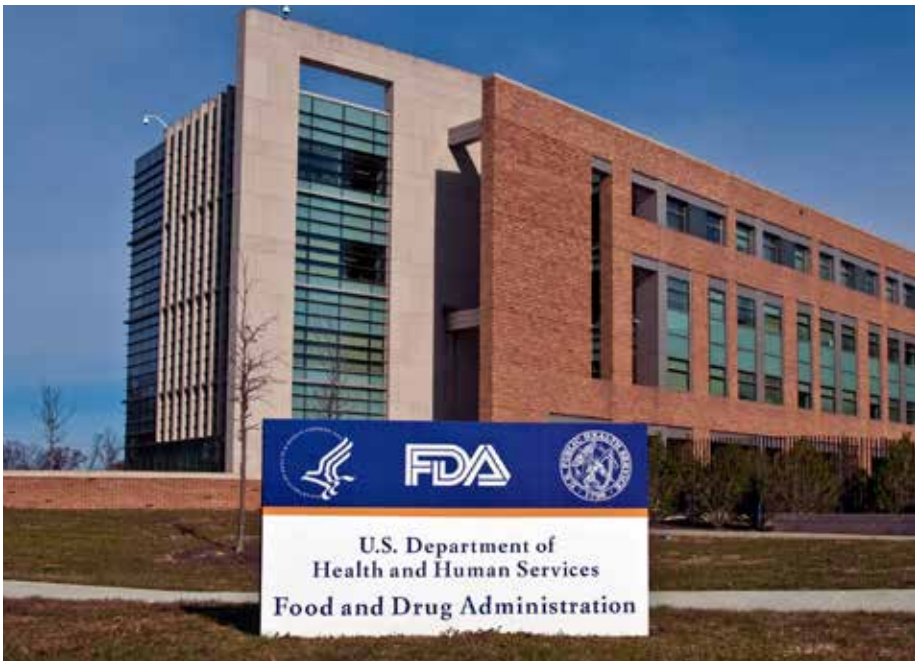

FDA Commissioner nominee Scott Gottlieb says the OTC monograph program, a system the agency is looking at modernizing, needed "immediate action" 10 years ago before he left a commissioner's office post.

Gottlieb was asked only one question about nonprescription drugs regulation during his confirmation hearing before the Senate Health, Education, Labor and Pensions Committee on April 5, but it covered a large part of FDA's current concerns about the OTC market.

The monograph system, established in the early 1970s to allow long-used ingredients to remain available and to make additional ingredients available, has stalled under a process that requires notice-and-comment rulemaking for any addition or change. The gridlocked process not only impedes adding OTC ingredients and indications, but also prevents FDA from efficiently responding to problems with monograph products on the market.

Gottlieb, responding to questions by HELP member Sen. Robert Casey, D-PA, said he knew of monograph concerns before he ended his second stint in FDA commissioner's office posts in 2007.

"Anytime a problem persists from when I was there 10 years ago to today it is an indication that I think it requires immediate action," said Gottlieb.

The monograph system, Casey said, is a program "which I think many would argue is ineffective and in need of improvement."

Pointing out that he and Sen. Johnny Isakson, R-GA, are working on monograph modernization legislation, Casey asked Gottlieb to work with Congress on improving the program with changes that would "ensure that both safety and efficacy information is communicated to consumers in a timely fashion."

Gottlieb replied that he is familiar with legislation Congress is working on and he is aware of support at FDA for lawmakers' ideas.

"I think … this is a system that is in need of modernization. So this is something I would be very committed to work with you on if I had the opportunity to be confirmed into this role," he said.

The Consumer Healthcare Products Association recently said it expects a bill soon will be introduced in Congress to allow FDA to add to or change a monograph through administrative orders rather than requiring a rulemaking will authorize a more efficient process for making monograph drug label changes. *(Also see "OTC Monograph Reform, User Fee Legislation Coming 'Any Day' – CHPA" - Pink Sheet, 30 Mar, 2017.)*

CHPA aligns with Gottlieb's prognosis for the monograph program. "We agree that the time to act is now and we are actively engaging with Capitol Hill and FDA now to reform the OTC monograph system. We appreciate FDA's work and attention to make sure the system is more responsive and that it better enables innovation," said John Gay, the trade group's senior vice president for government affairs, in an email.

FDA in 2014 launched an initiative to improve and modernize the OTC monograph system and a separate initiative in 2016 on a potential user fee program to pay for its monograph work. CHPA expects Congress will cover both topics in the pending legislation. *(Also see "'Real Challenge' To Improve*

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OTC Monograph Program Without User Fees – FDA" - Rose Sheet, 16 Jun, 2016.)

SWITCHES ALSO IN GOTTLIEB'S VIEW

Gottlieb, a physician and currently a resident fellow at the American Enterprise Institute conservative think tank, was a senior advisor to former FDA Commissioner Mark McClellan from 2003-2004 before moving with McClellan to the Centers for Medicare and Medicaid Services as senior advisor and returned to FDA in 2005 as deputy commissioner for medical and scientific affairs for a year and half.

In addition to FDA's monograph travails, Gottlieb is no stranger to the other major piece of the agency's OTC concerns. He was aware soon after his latest departure that approval of additional nonprescription drugs through the Rx-to-OTC switch process had slowed and that some adjustments in that system also could be needed.

After discussion of making drugs available nonprescription but via behind-the-counter sales only flourished with FDA's approval of the original *Plan B* (levonorgestrel/0.75mgx2) emergency contraception in 2007, Gottlieb

FDA Commissioner nominee Scott Gottlieb

suggested the agency encourage switch sponsors, in on an ad hoc basis, to submit plans for risk-management proposals, including BTC sales. *(Also see "Behind-The-Counter Guidance Stalled, But Interest Grows To Expand Access" - Pink Sheet, 30 Jun, 2008.)*

The FDA Amendments Act of 2007 gave the agency wider latitude for risk-management requirements on Rx products, meaning FDA still could not require BTC sales for nonprescription drugs and including that limit on consumer access would continue to be voluntary in switch proposals.

Gottlieb's CMS experience also influenced his thinking on making more drugs available nonprescription. Also in 2007, he suggested sponsors work with insurers in advance of nonprescription switches to develop reimbursement plans to benefit consumers, particularly when considering a potential BTC product.

At an industry conference, he said insurers and payers face growing incentives to reimburse consumers for some nonprescription drugs as more drugs become available and as more consumers look first for remedies available without prescriptions. Payers' attitudes have evolved since the OTC switch of *Claritin* (loratadine) antihistamine in 2002 forced consumers to pay more out of pocket than they had in insurance co-pays for the Rx version. *(Also see "Evolving Switch Scene Could Drive Nonprescription Reimbursement – Gottlieb" - Pink Sheet, 9 Jul, 2007.)*

During the HELP hearing, Casey also queried Gottlieb advocating against a hiring freeze and budget cuts, even if it conflicted with Trump administration views. *(Also see "Gottlieb's Confirmation: He's Willing To Disagree With Trump, Sec. Price" - Pink Sheet, 5 Apr, 2017.)*

The committee's vote on Gottlieb is at least two weeks away, according to Chairman Lamar Alexander, R-TN.

FDA Should Call Last Round For OTC Hangover Indication, Advisory Committee Suggests

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Including hangover as an indication for OTC monograph drugs could be more problem than remedy by contributing to misuse of antacid/analgesic and aspirin/caffeine nonprescription products, an FDA advisory panel concludes.

Comments from members of the Nonprescription Drug and the Drug Safety and Risk Management advisory committees during a joint meeting of April 4 could push FDA toward dropping hangover as a monograph indication.

The committee did not vote on the issue. But members raised a variety of issues including consumer's self-diagnosis of hangover, rather than more serious conditions such as alcohol withdrawal or other symptoms such as upset stomach, and potentially greater risk of bleeding for those using alcohol and taking analgesics.

Antacids for conditions such as heartburn, nausea, fullness, belching, gas, acid indigestion or sour stomach are marketed under FDA's internal analgesic and antacid monographs, which are in final status. Some products with a specific hangover indication are marketed under the internal analgesic monograph.

Monographs for overindulgence and stimulant products currently include a specific hangover indication. While products are available under those monographs, the policies remain only at the "tentative final" stage. They are caught up in FDA's long-stalled process of conducting rulemakings for finalizing proposed monographs or amending final monographs with additional ingredients or indications.

FDA scheduled the NDAC and DSRMAC meeting for advice on whether hangover is appropriate as an OTC indication based on findings by the agency's advisors, made in 1982, that antacid/analgesic combinations were generally regarded as safe and effective for minor pain and upset stomach associated with overindulgence in food, alcohol or booth, and aspirin/caffeine combinations were GRASE for hangovers. *(Also see "OTC Hangover*

Remedy Safety On Tap For FDA Advisory Committees" - Pink Sheet, 3 Mar, 2017.)

Karen Mahoney, deputy director of FDA's Division of Nonprescription Drug Products, explained to the panel that the division has not determined whether to include hangover as an indication or antacid/analgesic and aspirin/caffeine as accepted combinations in final monographs.

"There is still a need for information to help the FDA make its decision and write final monographs. The input that the committee gives us today will be very beneficial as we attempt to finalize those monographs," Mahoney said.

FDA sought the panel's comments on the hangover indication but did not seek a formal voting recommendation.

The panel made one voting recommendation, advising that antacid/analgesic combinations do not meet the OTC monograph threshold for safe and effective ingredient combinations. *(Also see "What's Next For Antacid/Analgesic OTCs After Negative US FDA Panel?" - Pink Sheet, 4 Apr, 2017.)* Concerns about a potential link between aspirin or acetaminophen use and serious internal bleeding prompted FDA's inquiry on this topic.

A spokeswoman said DNDP has not set a timetable for its next step in determining whether hangover will remain in the monograph.

HANGOVER SYMPTOMS VARY

Research presented for the Consumer Healthcare Products Association and presentations by **Bayer HealthCare LLC**, maker of *Alka-Seltzer* products for acid indigestion and minor head and body aches, and *Blowfish* aspirin/caffeine hangover remedy firm **Rally Labs LLC** attested to the safety and efficacy of OTCs marketed under monographs and to hangover as an indication that is easily self-identified by consumers.

"Hangover is well known to everyone, well known to the general public as the morning after the night before," said CHPA consultant Damaris Rohsenow, of Brown University's Center for Alcohol and Addiction Studies, during her presentation on hangover treatment studies she has conducted.

Rally Labs founder and CEO Brenna Haysom pointed out that 90,500 consumers conduct online searches for hangover each month, slightly less than searches for headache and heartburn but more than cough and congestion. "A large number of consumers are actively trying to treat these symptoms," Haysom said.

The monograph indication for treating hangover, she added, "confirms the safety and effectiveness of the product."

The overindulgence TFM defines hangover as "a condition consisting of a complex of symptoms involving the gastrointestinal, neurologic and metabolic systems that follow recent excessive alcohol ingestion," and say the symptoms may include nausea, heartburn, thirst, tremor, disturbances of equilibrium, fatigue, generalized aches and pains, headache, dullness and depression or irritability.

Rohsenow said her research limits hangover symptoms to four general areas, fatigue, thirst, nausea and head and body ache. "It's well known to the public. There's no mystery there," she said.

> "Hangover is well known to everyone, well known to the general public as the morning after the night before."
> – CHPA consultant Damaris Rohsenow of Brown University's Center for Alcohol and Addiction Studies

MARGIN FOR ERROR A CONCERN

Physicians, pharmacists and medical researchers on the panel, however, did not agree.

"If I don't understand hangover … is the average consumer going to be able to differentiate hangover from chronic alcoholism or alcohol withdrawal?" said temporary DSRMAC member Timothy Lipman, a clinical medicine professor at Georgetown University and former head of GI-hepatology-nutrition section at the Washington VA Medical Center.

A second temporary DSRMAC member, Steven Solga a gastroenterologist and a clinical medicine professor at the University of Pennsylvania Perelman School of Medicine, observed that his and others' research shows that short-term use of aspirin does not directly cause bleeding but reacts with other chemicals in the body to create conditions susceptible to hemorrhaging. However, persons who need help for a hangover could already be susceptible to internal bleeding.

"I'm not sure anybody waking up with hangover is really going to think about it that clearly," said Solga.

Others on the panel pointed out that consumers may be using antacid/analgesic combination OTCs for what they consider a hangover, but they could be experiencing only minor pain or only upset stomach. Through such misuse, consumers unnecessarily are using aspirin or other analgesics, increasing their potential risk for stomach bleeding; or antacids, which when overused can cause constipation, diarrhea, slower breathing due to a rise in blood pH or infections due to hyper-suppression of stomach acids.

Rohsenow's research, conducted with Boston University School of Medicine pro-

HANGOVER AND OTC MONOGRAPHS

These four monographs were part of the advisory committee discussion:

- Internal analgesic: status is final, hangover indication included
- Antacid: status is final, hangover indication not included.
- Overindulgence: status is tentative final, hangover indication included
- Stimulant: status is tentative final, hangover indication included

fessor Jonathan Howland, shows that treating a hangover might not require a pain reliever and stomach aide.

Their presentation slides stated, "People may not get all of these symptoms each time they have hangover," and "One person might want to treat headache but not stomachache or vice versa."

NDAC member Neil Farber, a general internist and a professor of clinical medicine at the University of California, San Diego, noted that while "medications need to be generally safe and effective," label indications and directions determine whether drug ingredients are used appropriately.

Linking drugs, in single- or combination-ingredient formulations, to an indication requires accurately defining a condition through symptoms, but FDA's initial monograph advisors might have been off the mark in the TFM for overindulgence and hangover indications, said Farber.

HANGOVER OR WORSE?

Allowing drugs to be labeled as hangover remedies also could contribute to consumers using analgesics while still drinking or with alcohol still in their systems, which increases risk of liver damage, and could obscure conditions consumers may have other than pain and upset stomach from an isolated event of drinking too much, researchers suggest.

"We are very concerned about products that are marketed for hangovers that contain acetaminophen or aspirin," said Megan Polanin, a senior fellow at the National Center for Health Research, during the open public hearing period of the meeting.

Polanin, who works on NCHR's patient advocate training project and manages its Affordable Care Act project, noted that many consumers are not aware that acetaminophen isn't indicated as a hangover remedy, and they aren't likely to learn when they need the remedy.

"A person who has been drinking enough to experience a hangover or to expect a hangover is not likely to be in condition to be able to read and understand an OTC drug label," she said.

Timothy Lipman, a temporary DSRMAC member and a clinical medicine professor at Georgetown University, also observed that informed decisions on medicine use don't follow high alcohol consumption.

"At 8 a.m. I don't care whether I'm still intoxicated or hungover, I just want get rid of my headache and my lousy feeling," said Lipman, former head of GI-hepatology-nutrition section at the Washington VA Medical Center, in describing a likely circumstance.

Polanin also suggested FDA change acetaminophen- and aspirin-containing OTC labeling from the current warning against using when consuming three or more alcoholic drinks in a day to also advise against using after any episode of heavy drinking.

"It is important to keep in mind, however, that many people do not consider drinking five or more drinks at a time to be heavy drinking or even binge drinking," she added.

"Do we know what the definition of overindulgence is?" he said. "Are we actually asking the same question as hangover?"

Mahoney pointed out that whether consumers appropriately use OTCs indicated for hangover is a critical part of FDA's evaluation of the indication. Like scientific information on drug ingredients and indications, research findings on self-selection of OTCs have changed since the monograph process began and the TFMs FDA is reconsidering were proposed.

"These recommendations were made a long time ago and science has progressed greatly. Not only clinical science, but also our understanding of how important consumer comprehension is," Mahoney said.

DATA UNIMPRESSIVE OR UNDERREPORTED?

The science about potential risks from allowing OTC drugs to use a hangover indication isn't swaying the industry, though.

From 1969 through July 2016, FDA's Adverse Event Reporting System show 20 cases of serious bleeding potentially linked to antacid/aspirin use, though 80% of those – 16 – included risk factors such as age, history of stomach ulcers or alcohol abuse and use of contraindicated drug.

FAERS data also show no reports of serious bleeding potentially linked to use of aspirin/caffeine products indicated for overindulgence or hangover, according to the Center for Drug Evaluation's meeting presentation.

Rally Labs' Haysom stated the firm has not received any serious adverse events reports from consumers, though she committed to later providing the panel with information on other AERs the New York firm has received.

The industry's non-voting representative on the panel, Roger Berlin of 1,681 Consulting LLC in Philadelphia, noted the 20 reports are spread across 44 years and "just about all of the cases are confounded."

"If you look at the data FDA has put together, it's not necessarily compelling," said Berlin, a physician, an expert in global prescription and nonprescription pharmaceutical development and a former pharma firm executive.

Like Mahoney, other CDER officials acknowledged the comparatively small number of reports of serious bleeding linked to antacid/aspirin products, but they also told the panel they expect many incidents are

not reported.

"It's not a lot of reports but we have reason to believe that under-reporting could be significant for this," said Christopher Jones, director of CDER's Office of Pharmacovigilance and Epidemiology.

Under-reporting of internal bleeding could stem from physicians and other health care professionals not considering it a condition meriting an adverse event report or consumers simply not being aware of FAERS or that they can contact product marketers.

The small number of reports "should not be interpreted as a lack of risk for serious gastrointestinal bleeding," said Ali Niak, medical officer for CDER's OPE and its Office of Surveillance and Epidemiology.

"If I see someone with GI bleeding from aspirin, I'm not going to report it to the FDA even though I should," added Niak, also a physician.

"I, as a practicing physician, also don't report these cases," said DSRMAC member Niteesh Choudry, a Harvard Medical School professor and Brigham and Women's Hospital physician.

Claritin 'Be An Outsider' Campaign Links Bayer Brand And Public Health

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Bayer AG's US OTC drug business says its advertising aims in part to help improve consumers' health, and the latest digital media campaign for its *Claritin* antihistamine line says more time outdoors is one way most people can better their lives.

Advertising consultants give credit to **Bayer HealthCare LLC**'s "Be An Outsider" and other goodwill campaigns for keeping brands in consumers' attention, but some are not sold on the programs' effectiveness for generating sales.

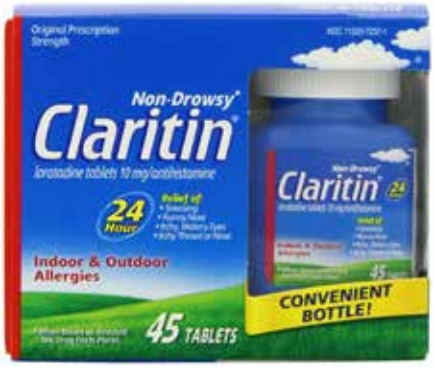
"Be An Outsider" encourages people to get outside more, something that the 40% of US consumers with seasonal allergies could look to Claritin (loratadine or loratadine/pseudoephedrine) and other OTC allergy remedies and antihistamines to help them do. The campaign notes survey data show all US consumers on average spend 95% of their time indoors, the equivalent of 346 days in a year or 33 years in a span of 35 *(see box)*.

"To us that was a startling signal that there is an inside epidemic in the United States," said Mike DiBiasi, vice president of allergy products for Bayer HealthCare, at a recent media briefing in New York city on the campaign and the survey.

"Claritin really has a role here to encourage people to be an outsider," he added.

DONATIONS PER PICTURE

Bayer is donating $5 to the Boys & Girls Clubs of America organization for every photo of people engaging in outdoor activity posted by June 30 on social media platforms using Be An Outsider or Claritin tags.



Non-Drowsy Claritin and other products in the antihistamine line are encouraging consumers to get outside more.

Up to a total of $50,000 will be donated.

Be An Outsider images and videos will post to Facebook and Instagram and on the Claritin brand website, and retail store signs developed from those materials are a possibility in the second year of the campaign.

The firm also is launching a three-year commitment of $500,000 in funding for the organization, extending the support it provided during 2016 to refurbish Boys & Girls Club outdoor facilities in Atlanta and New York. The program this year supports development of an outdoor resource and activity guide to help support staff at 4,300 Boys & Girls Clubs to get local youth outside and during the next two years Bayer will work with the organization to determine key areas its funding can support, which may include refurbishing "outdoor play areas for select clubs in need," according to the firm.

Bayer launched the campaign on April 4 with an appearance in New York by actor Josh Duhamel, who engaged in outdoor activities with children from schools in the city and spoke with them about health benefits from being outside.

Like Bayer's current "HeroSmith" ad campaign to promote carrying aspirin for use as an immediate response to a heart attack, Be An Outsider is on digital media only and is not planned to include TV commercials. HeroSmith launched in Fort Smith, Ark., earlier in 2017 and is planned for additional locations around the US in 2018. *(Also see "Bayer Plans 19 Consumer Product Launches To Revive Sluggish Sales" - Pink Sheet, 23 Feb, 2017.)*

And both campaigns aim to connect with consumers through goodwill from Bayer and its brands.

DiBiasi acknowledged that a firm the size of Bayer and a brand as established as Claritin could use numerous strategies, including reducing prices, to promote products and boost sales. Instead, Be An Outsider and HeroSmith show Bayer brands' interest in improving consumers' lives, he said.

"It's the power to good in the world that a brand can exhibit," DiBiasi said.

ALL BENEFIT, NO RISK?

DiBiasi also acknowledged that cynical responses or reviews are likely to Bayer's goodwill campaigns. "The easiest thing to do is to do nothing because you don't open yourself up to criticism. At Bayer, that's not what we're going to do."

What consumers will do in response to Be An Outsider, HeroSmith and similar campaigns linking a brand with a beneficial

cause is difficult to gauge, advertising consultants say. Improved consumer opinion of a brand could result, but higher sales might not track with it.

"That's their hope but you're dealing with a smarter, much more brand-literate consumer segment," said Robert Passikoff, founder and president of Brand Keys Inc. in New York.

Millennial generation consumers make up much of the target audience for most advertising, particularly through social medial and other digital platforms, and they are "probably the most demanding consumer segment in marketing history," Passikoff said in an interview.

He noted that pharmaceutical firms, in general, probably have ample room for improving their images with consumers. "You want to try and leverage whatever you can in terms of good faith, corporate responsibility and so forth."

George Quesnelle, senior strategic advisor at consultancy Pinney Associates in Bethesda, Md., had experience with similar campaigns when he was with **GlaxoSmithKline PLC**. "We called it doing well while doing good," he said in an email.

Other current examples of consumer product brands promoting goodwill and their products are those supporting the Susan B. Cormen Foundation to help fight breast cancer, Quesnelle said.

"I actually think that tying a brand to a cause can be a very good thing for the brand and the cause. It generates contributions to the cause and creates goodwill for the brand," he said.

"In the past, brands I have had responsibility for developed relationships with the American Cancer Society and the Asthma and Allergy Society as well as participating in the Susan B. Cormen promotions. I see nothing but benefit coming out of it for the brand and the cause."

INDOOR TIME ADDS UP

In a Bayer-sponsored study to determine how much time US consumers are outside, Columbia University researcher Matthew Neidell,analyzed data from the federal Bureau of Labor Services' 2015 American Time Use Survey, which asked 40,000 people ages 15 and up about their daily activities and the amount of time used for each.

The average for respondents across the survey was 95% of their time inside, which includes commuting and other travel in addition to working indoors and sleeping, watching TV and other activities typically done in a person's home.

The most indoor time among consumers in large US cities was 97% in Baltimore, with Dallas and Miami at 96%, while Seattle consumers were inside the least, 93%, Neidell, an associate professor in health policy and management at Columbia's Mailman School of Public Health, determined from the data.

He said the data showed little variance by consumers' age, gender, location or other demographics. The largest chunk of time each day goes to sleeping, 37.1%, while watching TV is the next largest time block, 12.3% of a consumer's day on average.

The data analysis also showed among consumers' indoor time:

- 5% is used traveling;
- 4.75% goes to relaxing and leisure;
- 4.58% is for at eating and drinking;
- 2.88% is needed for grooming.

"It's a national pattern that we're seeing everywhere," Neidell said.

Because time indoors account for so much of an average consumer's day, a small change makes a big difference in the time outdoors for most. For instance, a 1% change would mean 20% more outside for the average person.

"That is a sizable change," said Neidell.

Reckitt Reaps ROI Reward In Geo-Targeted Symptoms App Promoting *Mucinex, Delsym*

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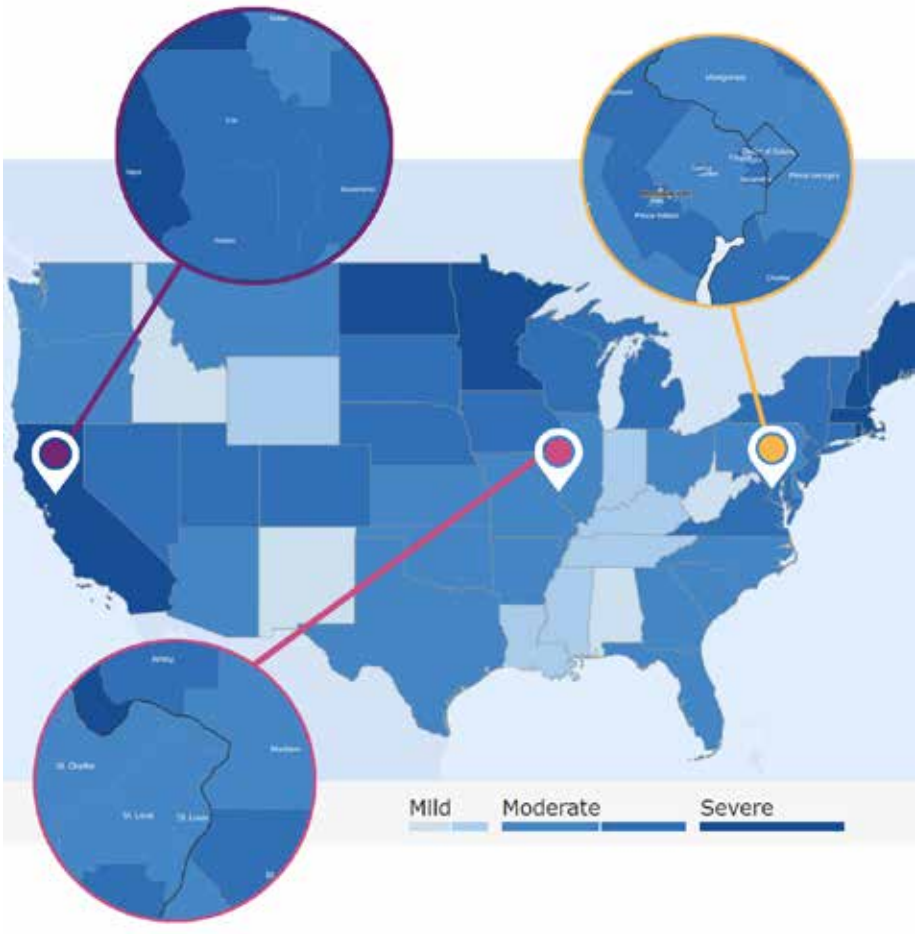
Reckitt Benckiser Group PLC says its spending for the WebMD-hosted Cold & Flu Tracker Map, a geo-targeted digital tool for consumers to track incidences of symptoms, and on related advertising have generated a return on investment three times greater than the firm's traditional digital marketing.

"On average, RB campaigns on WebMD deliver a double-digit increase in sales lift and 52% greater ROI" than what is considered the consumer packaged goods industry average for digital marketing, says RB Health Care Marketing Director Emma Howe, attributing industry data to Chicago-based market research firm IRI.

Geo-targeted, customized digital campaigns similar to the firm's tracker on WebMD launched in 2012 could help OTC marketers increase ROI, particularly in the area of cough/cold and flu, Howe suggested in a recent presentation she gave during the Consumer Healthcare Products Association Annual Executive Conference in Amelia Island, Fla.

Map Provides Route To Mucinex, Delsym



WebMD's RB-sponsored Cold & Flu Tracker Map uses state, city or zip code information to assess whether local cold and flu symptoms are "mild," "moderate" or "severe." With users' information, the map zooms in and indicates local conditions, such as in the Washington, D.C., St. Louis and Sacramento, Calif., areas.
Source: WebMD

London-based RB's OTC drugs marketed in the US include the *Mucinex* decongestant line (guaifenesin single-ingredient and with combinations of acetaminophen, dextromethorphan or phenylephrine) and *Delsym* (dextromethorphan single-ingredient and with combinations of acetaminophen, dextromethorphan, phenylephrine, doxylamine or menthol) cough/cold line.

"When measured against doing a broad, non-geo-targeted type of digital campaign, the ROI for doing these specialty, targeted campaigns with the right symptom message at the right location, is three times higher" than campaigns "broad" in scope and not personalized, Howe said during an interview following her March 21 presentation.

The campaigns also show consumers where to purchase products, unlike random advertising for cold and flu products.

SYNCHRONIZING ADVERTISING, INVENTORY

Howe said in addition to helping consumers stay on top of cough/cold symptom levels in their areas, the data from WebMD's apps let RB know where to target marketing resources and send email alerts.

"So we know which cities we're going to fund" ad spending, she said. "It's very exciting when we talk about the fact that the best time to reach that consumer is the time they are most at risk for getting sick."

Howe said providing the information in affected regions is critical from a marketing standpoint as 86% of consumers do not search for cold and cough product information until they start to feel sick. "When you are talking about out category of cold and flu, one of the biggest problems is consumers are not really wanting to engage with that category until the moment they start experiencing symptoms," she said.

The map not only helps track illness, but also "enables us to connect" with consumers on the regional level, Howe noted. While WebMD and RB do not store consumer data from entering symptoms in the cold and flu

tools, they use illness trends identified in the Cold & Flu Tracker Map to target consumers generally in certain regions with ads customized to trending conditions.

Digital ads customized for a region or state featuring the "Mr. Mucus" advertising cartoon character are sent to users, noting specific conditions. An ad shown during the presentation included a New York City area map with the cold conditions tracker showing where conditions were heaviest, along with a picture of a Mucinex product and a link to purchase the items online.

WebMD also emails alerts to consumers who opt-in to receive information on preventing or treating conditions prevalent in their areas. The emails feature "buy now" links to retailers that carry the products online. Howe noted that two out of three OTC buyers conduct research prior to purchases, and the RB campaign provides information they need "at the moment" and reduces their time looking for information.

Retailers also benefit from these campaigns as they can more timely stock-up on products, Howe said during the Pink Sheet interview. "The value is the opportunity to really allocate resources in a real-time basis," she said.

Most retailers work with low inventory levels to limit costs, but they also need to stock shelves for peak demand, such as when cold conditions are prevalent. Information from campaigns like RB's provides some advance notice on high demand period.

"This is really about having stock on shelf for when incidence is really peaking," Howe said.

RB's and other cold tracker apps is not the first. Manufacturers have for several years steered consumers at point of sale with cold/flu symptom trackers that provide zip code-based information, or with pollen trackers that help allergy suffers. *(Also see "Tracker Apps Help Steer Consumers In Cough/Cold Space" - Pink Sheet, 14 Oct, 2013.)*

GlaxoSmithKline PLC's *Theraflu* brand of cough/cold/flu symptom treatments (combinations of acetaminophen, dextromethorphan, pheniramine or phenylephrine) partnered with the Weather Channel to offer the Cold and Flu Report of zip code-based "sick scores" between 0 and 100 representing the level of activity. **Prestige Brands Holdings Inc.**'s *Chloraseptic* (combinations of phenol, menthol, benzocaine, dextromethorphan or glycerin) sore throat spray, lozenge and liquid products offers a similar feature on its website.

> "This is really about having stock on shelf for when incidence is really peaking." – RB marketing executive Emma Howe

Procter & Gamble Co.'s *Vick's* (dextromethorphan single-ingredient and with combinations of acetaminophen, chlorpheniramine, phenylephrine, doxylamine or guaifenesin), brand and **Pfizer Inc.**'s *Robitussin* (dextromethorphan single-ingredient and with combinations of acetaminophen, chlorpheniramine, phenylephrine, doxylamine, guaifenesin or pseudoephedrine) brand hosted similar tools in 2012 and 2013, but those technologies no longer are featured on their websites.

SYMPTOMS FORECAST, A MONTH AHEAD

The RB-sponsored Cold & Flu Tracker Map on WebMD's website opens with a map of the US and allows consumers to enter state, city or zip code information to assess whether cold and flu symptoms are "mild," "moderate" or "severe" in those areas. After location information is entered, the map screen narrows down to specific local areas and indicates the status of conditions there and a corresponding interactive box asks users to note whether they "feel good or are "getting sick" or "already sick."

WebMD Health Corp. Group Vice President Eric Trepanier, who also spoke about the firms' partnership at the CHPA conference, said the tracker then stores users' wellness status, their regions and information entered into WebMD's separate "Symptom Checker" feature, which allows users to enter symptoms for advice on treatment and processes 2.5m symptom checks a day.

The wellness status information, which is owned by WebMD and leveraged by RB through the deal, is processed to create a tri-colored map demonstrating where symptoms are greatest.

RB, which also markets *Lysol* disinfectant products, also sponsors a "Cold & Flu Alert" on WebMD that breaks down by region the incidence of symptoms: nasal congestion, fever, runny nose, dough, sneezing and sore throat. The webpage also features columns with insight on treating illness, with every page displaying a note "brought to you by Mucinex, Delsym, Lysol."

Howe said the tracker and checker both provide "valuable" data sets for understanding real time cold and flu trends and creating a predictive model to determine illness trends four weeks ahead.

In an interview, Trepanier said the interactive map is updated weekly and uses a combination of geo-location data and "information compiled from millions of monthly visits to WebMD's Symptom Checker to display a real-time analysis of the spread of cold and flu."

He said the technology to predict conditions four weeks in advance is proprietary but has been "highly predictive" of Centers for Disease Control and Prevention prevalence data and may even improve upon the centers' statistics.

"While the CDC only tracks illness as reported by physicians after patients seek treatment, the WebMD Cold and Flu Map tracks conditions at the symptom- and geographic-level, and captures patients who search on WebMD but do not visit the doctor," Trepanier said.

WALGREENS 'RELIEF ADVISOR' DEBUTS

In a separate interview, Trepanier also said WebMd is talking with other OTC firms about similar apps, though the Cold & Flu Tracker interactive tool that help makes the symptom data consumer friendly is an "exclusive" component in the firm's relationship with RB.

"While RB is a leading partner that leverages WebMD's proprietary data to inform their marketing programs, our data can also be used with other clients to inform media strategy should they want to. Beyond cold/flu, WebMD has several other sets of robust and unique data that manufacturers and retailers can leverage to support data-driven marketing activations," he said.

During WebMD's quarterly earnings briefing in February, CEO Steve Zatz said the 2016-2017 flu season is the firm's largest effort to date to leverage geo-prevalence

information for outreach to consumers.

The outreach includes "Relief Advisor" WebMD hosts for Walgreens Co. that consumers to enter information on their symptoms and "receive medically reviewed health information from WebMD, including treatment advice as well as the active ingredients they should look for when buying OTC products to treat their cold, cough and flu," Zatz said.

Relief Advisor, which launched later in the first quarter and is accessible through both Walgreens and WebMD's platforms, asks for users' gender and age and allows them to choose from a variety of symptoms. Choosing "sinus pain" and "sore throat," for example, prompts recommendations including "sit in a steam filled room," and "drink plenty of fluids" and suggests products – *Walgreens* brand Regular Strength Pain Reliever Acetaminophen tablets and Chloraspetic Max Sore Throat Relief Spray (benzocaine) as well as chamomile tea.

The symptom tracking apps cater to the self-care market, where consumers increasingly depend on digital tools to help guide them on purchasing OTC drugs and dietary supplements for mild health concerns as an alternative to expensive doctor's visits and Rx drugs. Market researchers have said the OTC drug industry has been slow, however, in capitalizing on using digital technology to guide consumers. *(Also see "Technology Gap Separates OTC Drug Firms From Self-Care Sales Growth" - Pink Sheet, 16 Mar, 2017.)*

Consumer Business Reliable And Right At Home At GlaxoSmithKline

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GlaxoSmithKline PLC CEO Emma Walmsley says the firm's consumer products business, which she headed until her recent appointment to Glaxo's helm, is a steady revenue source for the firm as well as being one-third of its operating structure.

Walmsley didn't reference her previous post during Glaxo's 2017 first-quarter earnings briefing on April 26, her first as CEO, but her familiarity with the business that markets OTC brands including *Flonase* allergy treatment and *Excedrin* pain relief was clear in her response to multiple questions from analysts about the firm's future as a three-part operation.

The firm's OTC drug and consumer health products business is not leaving as it, along with GSK's vaccines unit, are more reliable revenue drivers than the pharma business, she said.

"We … do see both logic and benefit in being three-business health care company, not least because of some of the uncertainty and volatility that we see in the high-return pharma business. We like to have more certainty in terms of reliable cash flows both from vaccines and consumer," she said.

The consumer unit's value isn't realized entirely separately from the pharma business, though. Walmsley noted Glaxo's pipeline for moving Rx drugs to OTC or nonprescription sales.

"We believe in some of the synergies, both from an operating point of view and a life cycle management point of view, when we look at switches," she said.

SWITCH LAUNCHED DURING Q2

Glaxo's first-quarter consumer business results included sales of its second Rx-to-OTC switch launched in the US in three years, *Flonase Sensimist Allergy Relief* (fluticasone furoate/27.5mcg spray). *(Also see "GSK Aims Flonase Sensimist To Counter Generic Nasal Allergy Competition" - Pink Sheet, 8 Feb, 2017.)* The firm also extended

CEO Emma Walmsley confirms the importance of Glaxo's consumer business in her first earnings briefing at the firm's helm.

distribution of the original OTC Flonase (fluticasone propionate/0.05mg) intranasal corticosteroid in Canada and Europe during the quarter.

However, the loss of consumer product revenues in Nigeria, where GSK exited in September; a slump in India due to cash shortages caused by the country's demonetization of its ₹500 ($7.70) and ₹1,000 ($15) bills; and a slow allergy season during the January-March period offset the gains to hold growth at 16% based on adjusted currency exchange rates to £2.04bn ($2.6bn), or 2% on constant exchange rates, the firm reported.

Excluding the impact of divesting the Nigeria business, consumer product sales grew at 17% AER, 3% CER, it said.

Oral care products were a key consumer business sales driver, helped by the US launch during the quarter of *parodontax* brand stannous fluoride toothpaste labeled to help stop bleeding gums and continued strong performance by the *Sensodyne* line as sales grew 21% AER, 6% CER, to £628m ($810.4m). *(Also see "Glaxo's Parodontax Brings Bleeding Gums Claim To US Toothpaste Battle" - Pink Sheet, 17 Mar, 2017.)*

Sales for the wellness division of the business grew 16% AER, 2% CER, to £1.07bn ($1.4bn) on strong performances by pain relief brands, notably Excedrin (acetaminophen, aspirin, caffeine) and *Fenbid* (ibuprofen). The division's OTC respiratory product sales grew 15% AER, 1% CER, on

"We ... do see both logic and benefit in being three-business health care company, not least because of some of the uncertainty and volatility that we see in the high-return pharma business." – Glaxo CEO Emma Walmsley

a stronger flu season behind double-digit growth from the *Theraflu* (acetaminophen, pheniramine, phenylephrine) oral products and *Otrivin* (xylometazoline) nasal spray.

However, gains from those brands largely were offset by a later start to the US allergy season and increased private label competition for Flonase. The brand's sales increased 11% AER, though down 3% CER, despite positive initial launch take-up of Flonase Sensimist, Glaxo said.

In the nutritional products sector, foreign exchange trimmed 8% from sales growth reported at 3% AER to £182m ($235m).

Skin care product sales grew 16% AER, 4% CER to £163m ($210.4m) as international region sales jumped 26% AER, 10% CER, on *Fenistil* (dimetindene) topicals growing 19% AER, 10% CER, with good momentum particularly in the Middle East. Strong international sales of *Lamisil Once* offset the impact of competition in the US and Europe as the line extension for the Lamisil (terbinafine) athlete's foot treatment grew 28% AER, 6% CER. However, *Physiogel* moisturizing products sales were hit by competitor activity in key markets, Glaxo said.

CAUTIOUS OUTLOOK, BUT LEADING

Chief Financial Officer Simon Dingemans said during the briefing that India's cash shortage began to wane during the latter weeks of the quarter, and sales of Glaxo's *Horlick's* nutritional beverages should pick up there during the rest of 2017.

"I think as we move through the course of the year, we are expecting improvements in the Indian position. … We should see that pick up performance," Dingemans said, but he added that, "macro conditions" in emerging markets "remain tough" and warrant "a note of caution in terms of how far much further forward" the business will move.

Costs from leaving Nigeria also will affect the unit's results through the second quarter, the CFO said. "So, we should see in the second half of the year a bit better performance than we've seen so far, but it does remain challenging," he said.

On the whole, though, Walmsley, who succeeded Andrew Witty as Glaxo's CEO on April 1, sees nothing but opportunity for Glaxo's consumer health business, which also markets **Novartis AG**'s OTCs and nutritionals in a joint venture GSK majority owns and operates. *(Also see "From Witty To Walmsley – The Priorities For GSK's New CEO" - Scrip, 4 Apr, 2017.)*

The JV, **GlaxoSmithKline Consumer Healthcare LP**, is in the catbird seat for considering adding brands from competitors, or acquiring entire businesses that may become available, she said.

"We've structured the JV to allow for potential further consolidation in the industry, which we'd like to be part of to a degree," the CEO said.

"As the leader in the consumer health care sector, we actually keep an eye on what's out there," Walmsley said, adding that Novartis would be part of any decisions for the JV, too.

In a same-day research note, Credit Suisse European Pharma Team analysts said Walmsley "gave a confident performance" during the briefing, including making clear Glaxo's commitment to a three-business structure.

Tylenol Delivers J&J Relief As Global 'Consumer Staples' Sales Slump

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Johnson & Johnson says *Tylenol* products were a bright spot for its consumer health segment in the first quarter as a "global category slowdown" makes an impact across the overall consumer products spectrum.

Global OTC drug business sales grew 1.4% on a reported basis to $1.01bn, the firm said April 18. US sales for the segment advanced 2.4% to $477m and international sales were flat at $536m, up 0.6%.

J&J's overall consumer health segment sales in the January-March period reached $3.22bn, up a reported 1%, domestic sales advanced 4.1% to $1.41bn and international sales slipped 1.3% to $1.81bn.

J&J reported overall net income of $4.4bn, or $1.61 per share, down from $4.5bn, $1.59 per share, in the year-ago quarter. Revenue totaled $17.8bn, up 1.6% but below consensus forecasts of $18bn.

Spokesman Joseph Wolk said the same "overarching theme" is influencing J&J's business and other consumer product firms, both within and outside the pharma industry: first-quarter results "negatively impacted by global category slowdown."

Wolk, recently named investor relations vice president after longtime VP Louise Mehrotra's retirement, said consumer product market analysts' research and "peer commentary" published recently are "highlighting higher gas prices, retailers reducing inventory levels and delayed tax refunds among many factors for slower growth."

For instance, a Zacks Equity Research March 29 analysts' blog acknowledged the consumer staples sector has been weak "for quite some time now," making investors skeptical. "Headwinds like unfavorable currency, food deflation, declining volumes, potential price wars, a competitive environment, slowdown in international markets and other global issues have been plaguing the companies in the sector," Zack's analysts said.

Nevertheless, J&J could count on the venerable Tylenol brand for a silver lining to the consumer segment dark cloud. Sales of adult and children's Tylenol products were ahead of other products in the categories and adult Tylenol has climbed to the No. 2 selling branded ibuprofen analgesic, Wolk said.

In January, the New Brunswick, N.J.-based firm reported its analgesics segment was back on track after the firm remediated its three manufacturing sites impacted by a consent decree with FDA following good manufacturing practice problems. The firm reported it had returned all recalled product lines to store shelves and the OTC unit sales grew 2.1% in 2016 $3.98bn. *(Also see "J&J Promotes Preventive Care, Wellness In US Health Debate" - Pink Sheet, 26 Jan, 2017.)*

J&J CONFIDENT IN RETAILER INVENTORIES ...

Still, analysts suggested J&J and other consumer product firms could be slowed by retailers spending less on inventories with consumer spending slowing.

Retailers' deceleration in product stocking, though, is "a phenomenon that we think is not long-lived," said J&J Chief Financial Officer Dominic Caruso. "Obviously, eventually as consumption either picks up or even continues at a reasonable pace, inventory will need to be restocked at the trades. So we'll see some correction to that," Caruso said.

He added that product launches, including some in the first quarter, are expected to generate around 2 points of incremental growth for J&J's consumer business in 2017. (J&J declined to comment on details about product launches.)

The products "could impact our total growth rate by an incremental two points of growth going forward. So we don't think that the first quarter results for consumer will continue at the pace that we just saw. We think they'll improve throughout the year," Caruso said.

The CFO also noted "many industry reports" suggest the consumer health care category will rebound in the near-term and J&J expects to be "well-positioned to grow above market through geographic expansion of current products."

In a same-day report, Morningstar Equity Research analyst Damien Conover also anticipates a rosier outlook for J&J's consumer group – close to 3% growth annually over the next three years.

"While the consumer group posted growth below this longer term view in the quarter, due partly to competitive pressures, we believe the brand power and entrenched products should return to a more normalized growth rate in the remainder of the year."

... SEES NO E-COMMERCE MARKET SHARE THREAT

Caruso also dismissed analysts' concern that "accelerating e-commerce" will take market share from J&J's consumer health brands to competing products. The firm has its own online sales footprint as well as its presence on store shelves, he said.

"Our brands are iconic in nature. They do still have quite an appeal to a mass audience, and you see us continuing to advertise, for example, in *Neutrogena* and *Aveeno* and Tylenol. So we think those brands still hold up well in more classic marketing, although we're very present in e-commerce," he said.

J&J made e-commerce one of its strategic 'how-to-win" priorities to strengthen its go-to-market and commercial capabilities following the FDA consent decree. *(Also see "Expanding $1 Billion Brand Club Fits In J&J Consumer Big Picture" - Pink Sheet, 4 Apr, 2016.)*

Like J&J, OTC drug and personal care product firms **Procter & Gamble Co.** and **Colgate-Palmolive Co.** have committed to e-commerce strategies but plan to keep their primary focus on traditional sales platforms.

P&G, which markets *Prilosec OTC* heartburn medication and *Vicks* cough and cold products, in 2016 said it would continue its direct-to-consumer business, which consists of P&G Shop and subscription-based businesses for men's grooming, but would keep its focus on conventional sales. *(Also see "Colgate Builds On Oral Care, Counts E-commerce As Emerging Sector" - Rose Sheet, 31 Oct, 2016.)*

Colgate also said it does not feel pressure to launch an "aggressive" online sales strategy, even though it does have an e-commerce team and manages its online finances as a standalone business. *(Also see "P&G Keeps Direct-to-Consumer In Perspective, Retail Distribution Primary" - Pink Sheet, 26 Oct, 2016.)*

'Slow-Growth' Global Trend Shakes Up P&G Product Strategy Start To Finish

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Procter & Gamble Co. counts on "irresistible superiority" in product development, packaging and marketing to spur growth as sales for all but one of its businesses, health care, slumped in its latest quarter.

Its health care unit, marketing products including the *Vick's* cough and cold line, *Prilosec OTC* heartburn medicine, *Pepto-Bismol* upset stomach formula and the *Crest* oral care line, recorded sales of $1.84bn in P&G's fiscal 2017 third quarter, up 4% from the year-ago period on a strong cough and cold season and oral care market share gains, the firm reported on April 26.

P&G's other categories did not fare as well in the January-March period *(see box next page)*.

During company's same-day earnings briefing with analysts, Chief Financial Officer Jon Moeller said sales by all businesses in the 10 categories P&G competes in "decelerated significantly in the quarter" to a global average of nearly 3% growth in the first half of the firm's fiscal year, October through March, and to below 2% in the quarter.

In the US, P&G's largest market, sales in the categories grew 2% in the first half of the firm's fiscal 2017 but were up less than 1% in its third quarter, a slump that Moeller, similar to **Johnson & Johnson** executives' recent take on consumer spending, attributed to "macro environment" factors including geopolitical disruptions, foreign exchange losses, delayed tax returns, higher gas prices, bad weather and consumers overall spending less. *(Also see "Tylenol Delivers J&J Relief As Global 'Consumer Staples' Sales Slump" - Pink Sheet, 18 Apr, 2017.)*

All those problems and others P&G sees in the "slow-growth environment" add up to changing its approach.

"With this as a reality, we're putting even more emphasis on several strategic moves on products and package superiority, executional excellence, cost and cash productivity and organization design, culture and accountability," Moeller said.

He said P&G targets establishing "an even higher standard of excellence – that of irresistible superiority for our products and packages, coupled with superior execution of communication, in-store fundamentals and consumer value."

P&G CFO Jon Moeller

> Seeing a "slow-growth environment" globally, P&G is changing its product development strategy, "putting even more emphasis on several strategic moves on products and package superiority, executional excellence, cost and cash productivity and organization design, culture and accountability."
> – CFO Jon Moeller

Irresistibly superiority, the CFO said, comes when a consumer has an experience with a P&G product that "makes it hard to go back to what they were using before."

He noted P&G's *Tide Pods* and *Downy Unstoppables* laundry products as examples of products that "change consumers' views of what's possible" in a category.

P&G will conduct behavioral tests with consumers and its products. For example, deprivation testing will ask consumers to assign a product they already use, typically a competitive item, a score up to 100, then replaces that product with a P&G product the subjects will use for several weeks before they return to their original products and are asked to score them again.

"If their score of the original product has not changed appreciably after use of the new product, we've not made a significant difference in expectation or delight and, therefore, wouldn't rate the new product as irresistibly superior," Moeller said.

"If they rate their old product significantly lower after use of the new product, we know the new product has elevated the level of performance they expect in the category."

The approach also extends to packaging, which "also creates recognizable brand blocks at shelf, aids the consumer in selecting the best product for their needs and reinforces the equity of our brands," Moeller said.

Packaging is important both in stores and for e-commerce, although some online companies are de-emphasizing packaging, Moeller noted when asked about the costs as part of e-commerce, which is 5% of P&G's business.

"There's kind of a new moment of truth, when you think about it, in an e-commerce purchase," he said.

"There's a first moment of truth, which is on the site. There's a second moment of truth when you open that brown box and

what's inside of it and how is that packaged. I don't see packaging as being an area that should receive less attention going forward. If anything, it should receive more."

$2BN MARKETING SLASH

Messaging is another element of P&G's irresistibly superior approach. Its advertising will focus on superior performance claims that communicate a brand's benefit superiority to create awareness and trial.

"Superior brand communication is advertising that makes you think, talk, laugh, cry, smile, act and, of course, buy. Advertising that drives growth for brands in the categories in which they compete, and is a voice for good by expressing points of views on issues that matter and where the brand matters," Moeller said.

An example is the "Like a Girl" campaign for P&G's *Tampax* feminine hygiene brand that sought to emphasize the importance of maintaining girls' confidence through puberty.

P&G's shift also includes cutting out ineffective advertising. Earlier in 2017, P&G – which spends about $10bn a year on advertising – announced it will no longer work with the digital publishers unless they meet standards set by the company. The firm and **Unilever PLC** also recently announced they are part of the Coalition for Better Ads to develop strategies to combat ad-blocking capabilities, which are utilized increasingly by consumers to skip or block advertising on computer screens. *(Also see "Manufacturing, Advertising Coalition Tackles Digital Ad-Block Devastation" - Pink Sheet, 6 Oct, 2016.)*

Moeller said as part of the firm's more targeted and refined advertising approach, it is planning a $2bn reduction in advertising over the next five years, and anticipates trimming another $500,000 by reducing the number of agencies it retains.

P&G also is eyeing about $1.5bn in savings from trade spending. The firm in 2016, however, announced it would increase its digital advertising in 2017 substantially. *(Also see "P&G Portfolio Rationalization Brushes Off 20% Of Oral Care SKUs" - Rose Sheet, 1 Mar, 2017.)*

P&G's organic sales growth still is slowed by its work to streamline product forms and stock-keeping units, an effort it launched in 2014 that created a 0.5% drag in the quarter, according to Moeller. *(Also see "P&G To Cut Portfolio In Half, Refocus On Core In Simplification Strategy" - Pink Sheet, 1 Aug, 2014.)*

P&G maintains its earlier forecast for organic sales growth of 2% to 3% for its full fiscal year and total sales growth to be down 1%, in line with the prior year. The firm is maintaining its core earnings per share growth of mid-single digits.

Some analysts expressed skepticism on P&G's new product development approach, but several seemed optimistic that the company's prospects are strong, given its nimbler structure.

"Following the end of its efforts to rationalize its brand set (shedding more than 100 brands from its mix over the past few years, leaving it with just 65 brands), we think its more focused investments (and hence an ability to more effectively tap into and respond to evolving consumer trends) should yield improvements across its product mix, driving accelerating sales and volume growth," said Morningstar analyst Erin Lash in a same-day research note.

OUTSIDE HEALTH CARE, FROM FLAT TO 6% DOWN

P&G's overall sales declined 1% to $15.6bn for the January-March period, with its net income for the quarter down 8.4% to $2.52bn, or 93 cents a share, versus $2.75bn, or 95 cents a share in the year-ago period.

While health care unit for the second consecutive quarter led P&G sales, the firm reported:

- grooming product sales dropped 6% to $1.52bn on lower volume and reduced pricing and competitive pressures;
- beauty care slipped 2% to $2.67bn;
- baby, feminine and family care slipped 1% to $4.47bn;
- fabric and home care finished the quarter down 1% to $4.96bn.

MORE TOOTH WHITENING PATENT LITIGATION

P&G filed a patent infringement complaint and motion for preliminary injunction alleging that store brand manufacturer **Ranir LLC** infringed its tooth-whitening technology used in *Crest Whitestrips*.

The complaint filed in US District Court for the Southern District of Ohio on March 20 alleges Grand Rapids, Mich.-based Ranir violated P&G patents with tooth whitening strips that are packaged for sale under store brands including lines marketed by Walmart and Kroger. Introduced in in 2001, Whitestrips "revolutionized the tooth whitening industry, resulting in annual sales in excess of $250 million," the complaint states.

P&G prevailed in other Whitestrips patent infringement lawsuits over the past decade, including litigation filed in the same court in 2014 against private label firms Clio USA, Team Technologies Inc. and Brushpoint Innovations Inc., which agreed to discontinue marketing the products. *(Also see "P&G Crest Whitestrips Patents Stand Up To 'Indefiniteness' Challenge" - Rose Sheet, 1 Oct, 2014.)*

'Evolving' With Health Care, CHPA Considers Device, Supplement Sectors

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The Consumer Healthcare Products Association is conducting an "inward analysis" on potentially expanding membership opportunities to firms in additional product categories where current members increasingly are extending their businesses.

"Health care, especially consumer health care, is evolving at lightning speed, and so too, must CHPA," said President and CEO Scott Melville at the trade group's Annual Executive Conference in Amelia Island, Fla., on March 21.

CHPA's 2020 project will analyze how the association can better "evolve with members," includes "taking a fresh look at membership, or at least categories of membership," and will consider ways to "more actively" engage these areas, specifically the dietary supplement industry, said Melville.

"Project 2020 will provide a road map for the future," Melville said.

He said the analysis would consider implications of expanding membership to more companies that market supplement products beyond the current 26 members that manufacture or market vitamins, supplements or nutritionals in addition to OTC drugs, including **Pfizer Inc.**, **Procter & Gamble Co.**, **Prestige Brand Holdings Inc.** and **Perrigo Co. PLC**.

CHPA says 35% of its members market products in the supplement category while 94% market products that include OTC drug ingredients.

Melville also suggested membership could expand to firms marketing consumer medical devices, those categorized by FDA as class I and II.

Class I devices present "minimal potential for harm to the user" and include products such as elastic bandages and enema kits, while class II comprise "most" medical devices such as pregnancy kits, according to FDA. CHPA notes fitness trackers and other wearable devices that aid in health maintenance can also fit this category.

Melville also observed that the supplement and consumer device categories have similarities with nonprescription drugs. "These products categories have important regulatory distinctions from OTC drugs, but also much in common. First and foremost, they are all consumer health care products, are all regulated by the FDA, are not covered by insurance and don't require medical professionals' intervention, and are purchased at retail by the consumer."

Consumer health care market researchers point to more consumers embracing self-care for minor ailments and looking for ways to treat more conditions without using health care serves, often by using OTC drugs and supplements. OTC firms, however, have been slow to offer digital technology tools to guide consumers to products that facilitate their self-care interests. *(Also see "Technology Gap Separates OTC Drug Firms From Self-Care Sales Growth" - Pink Sheet, 16 Mar, 2017.)*

CHPA spokesman Mike Tringale emphasized the 2020 project is in its infancy as an effort to consider "broadening our scope in the way our members have." He added the group's focus of remains on its existing members, businesses that manufacture, market or distribute consumer health products.

CHPA also has associate members that supply goods and services to manufacturers, including advertising agencies, television networks, contract manufacturers, internet services, law firms, market researchers and packaging companies.

The group already works with the Council for Responsible Nutrition and the Personal Care Products Council on joint research and policy statements on topics that overlap the OTC space and the industries those trade groups represent.

During his presentation, Melville also touched on the group's priorities in 2017, including anticipating the introduction of a bill to modernize FDA's OTC monograph system and establish a user fee program to pay for the agency's work, and backing legislation to again allow direct purchases of OTC drugs with pre-tax savings accounts. *(Also see "OTC Monograph Reform, User Fee Legislation Coming 'Any Day' – CHPA" - Pink Sheet, 30 Mar, 2017.)*

Another point in his presentation was on concern about state legislation introduced in Hawaii to ban the use of oxybenzone-containing sunscreens. *(Also see "Hawaii's Proposed Oxybenzone Sunscreen Ban Fails Science Test – CHPA" - Pink Sheet, 27 Mar, 2017.)*

7 MEMBERS NEW TO BOARD

During the March 19-22 conference, CHPA also elected members and officers to its board. One-third of the board is elected annually, with manufacturers elected for three years and associate members for two. In addition to 16 members re-elected to board, seven new members were elected:

- Agustin Caceres, president, North America, **Genomma Lab USA Inc.**
- Peter Caldini, regional president, North America, **Pfizer Consumer Healthcare**
- Sharon Glass, senior VP, brand development, **Catalina**
- Avani Kanubaddi, CEO, **Welmedix Consumer Healthcare**
- Mike Rosenberg, senior VP, national advertising, **Healthgrades Inc.**
- Rich Simonson, chief operating officer, **Carma Laboratories Inc.**
- Jeffrey Vernimb, general manager, **Moberg Pharma North America LLC**

Prestige Brands Stands By Nix Lice 'Kill' Claims Despite NAD Objection

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Prestige Brands Holdings Inc. declines National Advertising Division findings against using "kill" in claims for its *Nix Ultra Lice Removal System*, potentially attracting Federal Trade Commission attention instead.

In a case report published April 3, NAD said it sending its review to the FTC because Prestige Brands affirmed it would not comply with its recommendations to discontinue using "kill" in claims on packaging and on the Nix website and it is not appealing the decision through the industry self-regulation process administered by the Council of Better Business Bureaus.

In a statement included in the report, Prestige Brands said it disagrees with NAD's finding that "eliminating" a lice infestation is not tantamount to "killing"' lice and nits. The Tarrytown, N.Y.-based firm stated it is declining to comply with NAD's recommendations and elected not to appeal NAD's recommendations" to the National Advertising Review Board, a five-member panel of advertising and marketing experts that consider arguments against NAD decisions.

The firm did not respond to a request to comment on why it is not appealing to NARB. The review process was changed in 2015, limiting NAD staff's input in deliberations. *(Also see "NAD Voice Muted In Deliberations On Appeals Of Its Decisions" - Pink Sheet, 5 Oct, 2015.)*

FTC officials have said say they prioritize investigating ad claim reviews referred by NAD, the investigative arm of the CBBB's Advertising Self-Regulatory Council, but also expect that firms will reconsider and cooperate in the industry self-regulation process rather than potentially incur more costly enforcement action by the agency. In some cases, though, the agency doesn't agree with NAD's objections and takes no enforcement action if a firm ignores NADs' recommendations.

Bayer HealthCare LLC, maker of competing lice treatment product *RID*, challenged Prestige Brand's ad claims to NAD. The core of the review focused on Prestige Brands' claims its product "kills" lice, super lice and eggs. The marketing included a check-list chart comparing the Nix product to RID, showing Nix with a stronger prolfile for lice treatment.

> With consumer concern growing over "super lice" – which appear to grow resistant to drugs over time – some firms have begun offering non-drug treatments, such as Nix Ultra and other formulations containing tea tree oil, lavender oil or dimethicone.

DIMETHICONE NIX V. PEDICULICIDE RID

FDA regulates as OTC drugs lice treatments, including RID, that contain insecticide ingredients included in the final monograph for pediculicides; these include ingredients such as pyrethrum extract or permethrin, which kill the bugs on contact. Also available are Rx lice treatments containing stronger ingredients such as benzyl alcohol (5%) and malathion.

However, with concerns growing over "super lice" – which appear to grow resistant to drugs over time – some marketers have begun offering non-drug treatments, such as Nix Ultra and other formulations containing tea tree oil, lavender oil or dimethicone.

Nix Ultra contains a non-pesticide, silicone-based polymer 4% dimethicone and mineral oil gel combination, and includes a fine-toothed metal comb to remove nits and lice from hair shafts. Lice/nits die once away from the scalp, their food source, Prestige Brands claims.

Although Nix Ultra does not contain an OTC monograph ingredient, other products in the Nix line are OTC pesticide formulations, including permethrin (280mg) in Nix Lice Killing Crème Rinse.

Bayer argued that "by making stark comparisons between Nix Ultra and RID shampoo regarding 'killing' efficacy, consumers may understand Nix Ultra to be an FDA-approved drug – and one that is both 'non-toxic' and 'pesticide-free' – when that is not the case."

At the review outset, Prestige Brands said it discontinued the claim that its product "kills super lice" but stood by its other kill claims and offered as evidence two clinical trials and other scientific research.

One trial conducted by the firm's ingredient supplier found that subjects who received a product containing a formula similar to Nix Ultra were free of live lice at the final visit of a nine-day period and that 13 of 15 were nit-free.

A study Prestige Brands conducted in 2016 demonstrated subjects who received Nix Ultra had a lice infestation cure rate "equal to that" of RID's Essential Lice Elimination Kit. Separately, two in vitro studies the company submitted concluded that lice exposed to dimethicone in a lab were killed by the exposure.

'ELIMINATING' EQUALS 'KILLING'?

NAD attorneys contended that the fundamental disagreement in the review was the meaning of kill in the context of a lice treatment performance claim. Bayer argued the claim Nix Ultra kills lice, nits and super lice means the product physically kills the pests through direct action on them, which is how its product works.

Prestige Brands, however, argued the claim kill has broader meaning. "That is, by removing lice from the head and hair using Nix Ultra leads to the death of lice (and nits) because they cannot ultimately survive off of the human scalp," it said.

NAD attorneys said as neither firm provided evidence showing how consumers would understand the word kill, they had to "step into the shoes" of consumers to interpret the claim.

Companies typically can make lice treatment claims if they have supporting studies that show the industry -standard method for measuring killing efficacy, NAD noted. Yet, that was not the case with Nix' data.

"In the context of lice treatment product advertising, consumers could reasonably understand that a claim that a product 'kills' lice or their eggs means that the pests are killed as a direct result of their interaction with the product," according to the attorneys.

Similarly, they found "consumers may reasonably not consider the removal of live lice and nits from one's head to be 'killing' the pests, even if successfully removed and disposed of lice would eventually die because they were separated from their food source."

The attorneys added that lice treatment products have different mechanisms for eliminating infestations, some removing and others killing bugs. "Consumers, either because of their personal preferences or specific needs, may choose a lice treatment based on its specific mechanism of action," they said.

Due to the potential influence of mechanism of action on consumers' purchasing decisions, ad claims "should be crafted to avoid conveying the message that they treat lice infestation with a mechanism that they do not use," the attorneys explained. They emphasized message explicitness for claims paired with claims about benefits that from other products using a different mechanism of action.

NAD determined that to support the claims "kills" lice and nits, a firm would need evidence its product directly kills the pests as its mechanism to eliminate an infestation, not simply a way for removing the bugs from the scalp.

Looking at the studies Prestige Brands submitted, NAD attorneys said "much" of the clinical evidence is focused on the effectiveness of the dimethicone-based formulation and combing in "eliminating" lice infestations, "removing" lice and/or nits or "curing" lice infestations. They also noted that in vitro tests "are not sufficient evidence to support the efficacy of a lice treatment product on a human head."

NAD's position on in vitro testing tracked with is findings in a 2015 review of **TyraTech Inc.**'s ad claims for its homeopathic *Vamousse* lice treatment product. NAD disagreed with the Morrisville, N.C., firm's argument that it did not need to conduct human trials since the product worked on lice, not people. *(Also see "Lice Treatment Claims Require Tests On Humans, Not Just Bugs – NAD" - Rose Sheet, 9 Jul, 2015.)*

NAD recommended Prestige Bands discontinue claims, including in the comparison chart, that its product kills lice, super lice and eggs.

With the kill claims removed, NAD said the firm could substantiate another claim in the comparison chart, that its product is "free of pesticides," and that the remaining attributes compared in the chart did not falsely disparage the RID shampoo product.

Nix and RID are close competitors in the parasite treatment category, largely comprising lice treatment products and led by private label products with 26.4% market share and $41m in sales, according to market research firm IRI's data from US retailers including supermarkets, drugstores and mass merchandisers, military commissaries and select club and discount chains

RID leads brands in the category with 23.9% market share of all pesticide brands and sales of $37.7m; Nix is second with about 20% of the category and sales of $31.6m, according to the Chicago-based firm's data for the 52-week period through March 31.

'Do Not Flush' Labels For Acne, Hemorrhoid Wipes Won't Stop Consumers – CHPA

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The Consumer Healthcare Products Association and other opponents of "do not flush" labeling requirements for nonwoven disposable wipes hope a recent labeling rule passed in Washington, D.C., does not augur similar rules in other areas of the US.

The regulation, the "Nonwoven Disposable Products Act of 2016" (Act 21-604), passed in D.C. and scheduled to take effect in January, is similar to legislation in Maryland, Minnesota, New Jersey and New York and a pending New York City ordinance that seek restrictions or requirements for labeling the wipe products.

According to the requirements of the regulation the D.C. City Council enacted in March, disposable wipes for acne and hemorrhoids as well as other personal care wipes made of nonwoven disposable material that does not meet the act's definition of "flushable" will not be available in the city starting in January unless labeled with "do not flush" on packaging.

CHPA President and CEO Scott Melville highlighted opposition to wipes labeling legislation among the trade group's 2017 priorities at the CHPA Annual Executive Conference in Amelia Island, Fla., in March . He warned that companies marketing acne or hemorrhoid wipes could be impacted. *(Also see "OTC Monograph Reform, User Fee Legislation Coming 'Any Day' – CHPA" - Pink Sheet, 30 Mar, 2017.)*

The D.C. bill, which became law following a 30-day congressional review, is intended is to prevent clogs in the city's wastewater system. The Washington Suburban Sanitary Commission, which handles sewage in the city and large swath of the its suburbs, spent $1m on grinding machines to destroy a disrupting build-up of wipes and other paper products in the sewer system, according to media reports.

The act prohibits, starting in January, manufacturers of nonwoven disposable wipes sold in D.C. from labeling the products "as safe to flush, safe for sewer systems, or safe for septic systems, unless" they are flushable.

It states that "flushable" is a "nonwoven disposable product" that "disperses in a short period of time," "is not buoyant" and "does not contain plastic or any other material that does not readily degrade in a range of natural environments."

> Starting in 2018 in Washington, D.C., acne and hemorrhoid wipe manufacturers "must clearly and conspicuously label the nonwoven disposable product to communicate that the nonwoven disposable product should not be flushed."

The act defines "label" as to "represent by statement, word, picture, design or emblem on the packaging of a nonwoven disposable product" and defines "nonwoven disposable product" as an item "constructed from nonwoven sheets, including moist toilet tissue or cloth, that is designed, marketed, or commonly used for personal hygiene purposes."

Further, manufacturers "must clearly and conspicuously label the nonwoven disposable product to communicate that the nonwoven disposable product should not be flushed."

Manufacturers that do not comply will face civil fines and penalties or sanctions, and the city may seek injunctive relief or "other appropriate remedy in any court of competent jurisdiction to enforce compliance with this act," the law states.

Products the act targets include **Pfizer Inc.'s** *Preparation H* Medicated Hemorrhoidal Wipes, **TargetCorp.**'s store brand *Up&Up* Medicated Wipes and **Wal-Mart Stores Inc.**'s store brand *Equate* Flushable Hemorrhoidal Medicated Wipes. All the hemorrhoid products, which are regulated as cosmetic products, contain witch hazel and all packages currently bear a "flushable" and/or "septic safe" claim.

Wipes for acne contain either OTC drug monograph acne-fighting ingredients or natural extracts and most are not labeled "flushable" on packaging. The products include **Valeant Pharmaceuticals International Inc.**'s *AcneFree* wipes with salicylic acid and **Johnson & Johnson**'s *Neutrogena* cleansing wipes with grapefruit extract.

The rule also targets product categories including flushable baby wipes, adult personal hygiene wipes as well as those not advertised as flushable.

LABELING NOT THE ISSUE - CHPA

Opponents of the D.C. rule and similar legislation in other states say the problem with sewage buildup is due to consumers flushing wipes intended for the trash. They say if firms no longer distribute flushable wipes to states or other jurisdictions due to rules similar to D.C.'s, many consumers will turn to plastic-embedded, non-flushable baby wipes for purposes they currently use nonwoven flushable wipes. An absence of nonwoven wipes would compound sewer system blockage because plastic-embedded products do not disintegrate and collect with similar materials into blocks that must be removed.

Opponents also note a New York City independent study at its Wards Island wastewater treatment plant that found that products legitimately marketed as "flushable" account for 2% of plant clogs. The remainder of the clogging material is form consumer improperly flushing other items not intended to be flushed, such as paper towels and non-flushable baby wipes.

Emphasizing the New York study in a 2016 release, INDA said it partnered with the National Association of Clean Water Agencies to reduce the burden of non-flushable disposable products in the wastewater system. NACWA Director of Regulatory Affairs Cynthia Finley noted problems in sewer systems are caused by flushing products that don't disintegrate in the sewer system, including baby wipes, personal care wipes, paper towels and feminine care products.

"These products are sometimes disposed of in toilets because of how and where they are used, causing significant economic burdens on local wastewater treatment systems," Finely said.

INDA also emphasized many firms already follow industry standards, thanks to its guidelines for wipe "flushability." Most recently updated in 2013, the guidance provides INDA members with a code of practice for labeling products as flushable or not. The guidelines also define product qualities that necessitate a "do not flush" label.

INDA guidelines says "flushability" is appropriate if a product:

- "clears toilets and properly maintained drainage pipe systems when the suppliers' recommended usage instructions are correctly followed";
- "passes through wastewater conveyance systems and is compatible with wastewater treatment, reuse and disposal systems without causing system blockage, clogging or other operational problems";
- "is unrecognizable in effluent leaving onsite and municipal wastewater treatment systems and in digested sludge from wastewater treatment plans that are applied to soil."

NEW YORK CITY PROPOSAL

Similar legislation (Intro. No. 666) was introduced in New York City in 2015 and is pending review by the city's Environmental Protection Committee, according to a city legislative website.

The bill would make it unlawful to "sell or offer for sale a nonwoven disposable product whose packaging indicates that such product is flushable unless such product satisfies the definition for flushable" in the bill and "complies with testing standards established by the commissioner of environmental protection through rulemaking."

Additionally, it would prohibit the "sale or offer for sale a nonwoven disposable product that does not satisfy the definition for flushable…unless the packaging of such product indicates that such product is not flushable." Retailers violating the regulation law would face a civil penalty of up to $2,500.

New York state legislators in January introduced legislation in the state Senate (S2901) and Assembly (A3698) to amend the state's general business law to prohibit labeling or advertising a nonwoven disposable product for sale as flushable without approval from the state. The law would take effect 90 days after enactment.

The legislation, in committee review in both chambers, excludes media and wholesalers or retailers that distribute or sell but do not package or label a nonwoven disposable product advertised, packaged or labeled as flushable or safe for sewer or septic. It says each violation of the law could draw a fine of up to $5,000.

The Maryland Senate passed SB 280 in March to prohibit advertising or labeling of nonwoven disposable products as safe to flush or for disposal in sewerage systems or septic systems unless the product meets the bill's definition for flushable: "disperses in the low-force conditions of a sewage system a short period of time after flushing, is not buoyant and does not contain plastic or any other material that does not readily degrade in a range of natural environments."

A version of the bill also was introduced into the House in March and was referred to the Interim study by Economic Matters.

If enacted, the law would take effect in January, requiring manufacturers to clearly and conspicuously label such a product in a manner that alerts the purchaser that a product should not be flushed.

In Minnesota, companion bills in the Senate (SF 2040) and House (HF 2292) have been referred to committee. Similar to the other state bills, the proposals would prohibit labeling or advertising nonwoven disposal product as flushable or septic or sewer safe unless it meets a definition stated in the legislation: "meets the tests for flushability established by the [Federal Trade Commission] for non-misleading representations regarding the flushability of nonwoven disposable products, or that complies with the most recent INDA code of practice for product labeling" approved by the state Pollution Control Agency."

The bill also would levy a $100 civil penalty for each pre-packaged salable unit offered for sale, with a $5,000 maximum.

For New Jersey's 2016-2017 session, A3218 states similar prohibitions for nonwoven disposable product labeling and was introduced in February 2016 but has remained in the Environment and Solid Waste Committee. No companion bill has been introduced in the state Senate.

Additionally, FTC is pushing to persuade marketers from advertising products as flushable unless they are proven to be. In 2015, FTC approved a final consent *order* that prohibits **Nice-Pak Products Inc.** from marketing its moist toilet tissue and cloths as flushable or safe for sewers systems unless it is able to provide substantiation for the claims.