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Consumer Health Focus

WAITING FOR CONGRESS: Reforming, Paying For FDA OTC Monograph Program

MALCOLM SPICER malcolm.spicer@informa.com

FDA's performance goals for potential OTC monograph user fees make four references to Congress. But an Aug. 23 webinar on the program's details made it abundantly clear that Congress calls the shots on establishing the program.

The Center for Drug Evaluation and Research also was explicit during the 90-minute webinar that the program will not produce results absent user fees to support expanding its staff available.

"It would really not be possible," said Karen Mahoney, deputy director of CDER's Division of Nonprescription Drug Products.

Mahoney qualified many comments during both her presentation and a question-and-answer session by pointing out that anything FDA does to change the monograph process, including establishing a user fee program, depends on Congress. She noted in response to one question, "That's entirely up to Congress." And in the "next steps" conclusion to her presentation, she said, "Congress will consider whether to enact monograph reform with accompanying user fees."

FDA had released a performance goals document that would be used to help implement user fees and monograph reform, should those be enacted via legislation. Mahoney fielded questions on provisions in the document and legislation, including which businesses might be subject to potential annual OTC manufacturing facility fees, how the facility fee amounts would be determined, what is the starting date for timeliness and procedures in the performance goals document, and even when Congress might take up legislation to establish monograph reform and user fees.

FDA says that the proposed changes should align with the Trump administration's promotion of improving regulatory agencies' efficiency while decreasing industries' regulatory burdens.

Still, Mahoney made clear she was not speaking for the White House. "We have heard that those proposals are in keeping with some of the goals of the administration," she said.

TOO MANY SMALL BUSINESSES FOR A WAIVER

Among items FDA provide new details on, Mahoney said its proposed program does not include a waiver from user fees for small businesses. That's because 80% of monograph drug manufacturers are small businesses under the agency's existing user fee program rules.

"It would greatly increase the fees for the payers who don't qualify as small businesses," Mahoney said.

The agency encourages businesses and other entities planning to submit proposals for monograph changes under the proposed reformed process to have pre-proposal meetings with CDER staff so their proposals will have "the highest chances of success."

As with its existing use fee programs, FDA will not attach a fee to those meetings. "An important component of all user fee programs is fees are not attached to one, individual activity," Mahoney said.

Additionally, FDA would identify firms subject to the proposed facility fee from its database from annual registrations already required from drug manufacturers. Production of monograph drugs is among firms' identifications in the data.

The start date and timelines on adding staff to the agency's monograph review team and on beginning and completing its first reviews under a changed process would be adjusted based on when legislation authorizing changes might be passed.

In addition to timelines and submission standards, FDA included in the goals document a schedule for developing and launching an information technology platform accessible to the industry and the public that will track progress on proposals and on the agency's reviews. *(Also see "OTC Monograph User Fee Goals Document Beats Authorization To Finish Line" - Pink Sheet, 27 Jul, 2017.)*

President Trump, who has asked for industries to pay higher user fees, recently signed the FDA Reauthorization Act renewing existing pharmaceutical and medical device user fee programs for five years, starting in FY 2018. *(Also see "FDARA Takes Effect With Under-The-Radar Presidential Signature" - Pink Sheet, 19 Aug, 2017.)*

OTC monograph reform and user fee legislation, however, was not included in FDARA and has not been introduced in an independent bill.

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52 Vanderbilt Avenue, 11th Floor
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CONTINUED FROM COVER

Sens. Johnny Isakson, R-GA, and Bob Casey, D-PA, had circulated discussion drafts of legislation that tracked with FDA's proposed guidelines for submitting monograph change proposals. The senators also proposed raising $22m to $34m through the user fees, primarily from facility registrations, and a two-tier review system recommended by FDA and the industry. *(Also see "OTC Monograph User Fees Still On The Table, But Not In Legislation" - Pink Sheet, 11 Aug, 2017.)*

FDA and the Consumer Healthcare Products Association trade group remain optimistic that Congress will pass the legislation. Nonetheless, there's not enough time to carry out the agency's original plan to launch a monograph reform/user fees program on Oct. 1, the start of the federal fiscal year 2018.

Correction: No Market Exclusivity In Goals Document

An Aug. 11 Pink Sheet article mistakenly stated that FDA's procedures and performance goals document for a potential OTC monograph user fee program included a provision that would make manufacturers eligible for market exclusivity with certain successful proposals.

Market exclusivity based on the agency requesting human clinical trials for monograph proposals was part of an earlier discussion draft that the FDA and industry provided to members of Congress. *(Also see "Two-Tier OTC Monograph Approach Could Come With User Fee Revamp" - Pink Sheet, 19 May, 2017.)*

That component was not included in the eventual FDA/industry proposal on which FDA based its performance goals document. However, Congress could choose to add exclusivity incentives into any legislation considered in the future.

OTC Monograph User Fees Still On The Table, But Not In Legislation

MALCOLM SPICER malcolm.spicer@informa.com

FDA will not be able to implement its proposed OTC monograph reform and user fee rules on Oct. 1, the start of US federal fiscal year 2018, because those changes were contingent on Congress passing enabling legislation.

So far, such legislation has not made it beyond the discussion stage, either as an independent bill or as part of the FDA Reauthorization Act, which renewed existing pharmaceutical and medical device user fee programs for five years, starting in FY 2018. FDARA is awaiting presidential action. *(Also see "Implementing User Fees Should Be Lighter Lift For FDA This Time Around; Bill Heads To White House" - Pink Sheet, 3 Aug, 2017.)*

On Aug. 23, FDA officials will conduct a webinar to update industry stakeholders on progress in its initiative, launched a year ago, to improve and modernize its OTC monograph program. The update will include an explanation that, without the authoring legislation, proposed new performance goals and monograph procedures remain on hold.

FDA and the industry hold out hope, though, that Congress will pass a bill to change the monograph system from its currently gridlocked and under-funded program to one that allows FDA to make changes and additions to monographs through orders rather than public rulemakings; allows exclusivity periods for firms that conduct research to support those proposals; sets timelines for proposal reviews and decisions; and imposes a user fee schedule to support the agency's work.

"We continue to support OTC monograph reform and remain actively engaged with Congress, industry, and public health stakeholders on OTC monograph reform efforts," said an FDA spokeswoman in an email. "Congress will determine the timing of potential passage of monograph reform and monograph user fee legislation."

The hope of stakeholders is that passage will gain momentum during this year or the second year of the current session of Congress. Sens. Johnny Isakson, R-GA, and Bob Casey, D-PA, have championed the OTC changes, circulating discussion drafts for legislation that tracks the changes FDA proposed in its performance goals and procedures document. *(Also see "OTC Monograph User Fees Totaling $22m To $34m Floated In Senate Discussion Draft" - Pink Sheet, 19 May, 2017.)*

Supporters were unable to tie the OTC measure in time for Congress' passage of FDARA; the Senate sent the legislation to the White House on Aug. 3 and President Trump is expected to sign it into law after returning from a vacation.

"We're still very heartened and optimistic about the movement of monograph legislation," said Marc Schloss, the Consumer Healthcare Products Association trade group's head of federal affairs, in an interview.

FDA's proposed goals document also includes a schedule for developing and launching an information technology platform accessible to the industry and the public that will track progress on proposals and on the agency's reviews.

A monograph essentially offers a menu of ingredients and formulations that can be used in nonprescription drugs for certain indications. The agency launched the program in 1972 as a system for allowing OTC ingredients generally regarded as safe and effective for their intended uses to remain available and as a process for proposing additions of more ingredients or indications.

WEBINAR MUST GO ON

The webinar was planned to provide an update on FDA's progress to improve the program as well as the, FDA says. *(Also see "OTC*

Monograph User Fee Goals Document Beats Authorization To Finish Line" - Pink Sheet, 27 Jul, 2017.) "The timing of the webinar is not related to the timing of the passage of FDARA," the spokeswoman said.

"FDA commonly updates stakeholders and the public on the elements of the performance goals and procedures for potential user fee programs, prior to passage of user fee legislation," she added.

However, not only does the document state the timelines and performance goals that depend on authorizing legislation, FDA officials on multiple occasions have said the monograph program is irreparable without user fees to support the agency's work.

OTC drug manufacturers, too, acknowledge that monograph changes aren't tenable absent new legislated provisions. That view is underscored by the absence of requested monograph changes. No proposals for adding ingredients (aside from sunscreen ingredients) to a monograph or for allowing additional indications for those ingredients currently are pending with FDA.

"Does [continuing with the existing system] forestall introducing new ingredients in a meaningful way, does it forestall new combinations in a meaningful way, does it forestall really novel dosage forms? Yes, it does," said David Spangler, CHPA's senior vice president for policy and general counsel.

The proposed goals include exclusivity periods for monograph proposal sponsors as drug firms have argued that they are not incentivized to invest in the research because any firm authorized to make and market drugs can incorporate monograph changes into their portfolio immediately.

Setting timelines and eliminating lengthy rulemaking processes from monograph changes likely are more important to the industry, though.

"The bigger impediment is the fact that it takes forever," Spangler said.

Meanwhile, consumers miss out on potential savings for health care costs because the monograph system is not generating additional self-care products.

"OTC monograph reform would spur innovation, providing consumers with a wider range of choices and adding greater competition to the existing marketplace," Spangler added in an email.

Perrigo's Outgoing CEO Advocates OTC Switches, Starting With Statins

MALCOLM SPICER malcolm.spicer@informa.com

Perrigo Co. PLC CEO John Hendrickson used the pulpit of what was likely his final earnings briefing at the helm of the OTC private label leader to urge FDA and manufacturers to make more Rx drug ingredients available nonprescription.

During Perrigo's second-quarter earnings briefing on Aug. 10, Hendrickson, who will resign from his post when a successor is appointed, recommended specifically that statins "belong over the counter" through Rx-to-OTC switches, potentially through behind-the-counter sales.

Three new drug applications to FDA for a statin OTC switch failed and a fourth proposal stalled before an NDA was submitted *(see box next page)*. Hendrickson recommended that drug firms look at incorporating a requirement for pharmacists' intervention into an application to make a statin available nonprescription.

"I think some kind of pharmacy intervention could make them out over the counter, almost like a third class. Not quite there yet, but I think even those will evolve that way if you look over the next three or four years," he told analysts.

Erectile dysfunction ingredients also might have more chance for a switch with a behind-the-counter caveat in applications

Perrigo CEO John Hendrickson says "some kind of pharmacy intervention could make" available nonprescription.

to FDA, the CEO added. "Will those come over by themselves? Will there have to be a pharmacist saying, 'hey, do you have a heart condition?' … Who knows what intervention there will be, but I believe that those kinds of categories that are pretty expensive categories on the RX side will continue to switch."

Perrigo has not been involved in proposing the types of switches Hendrickson discussed though it often follows up on switched products with private label brands. But the exec took the earnings call as an opportunity to talk expansively about current issues, touching on drug pricing as well.

Savings in health care from making drug ingredients available OTC are an incentive for working with FDA on switches, he said. Drug pricing "created this stir" for Congress, state governments and payoes, and "also creates an emphasis to say, 'how do we manage that cost?' You bring products over the counter."

"It really gets the FDA starting to think not just about getting products approved for an Rx market, but also which categories make sense to switch. How we put these in a consumer choice versus government or private pay? What do we need to do? So, I think that sentiment does play into, if there are products that are safe and effective, we should help drive those."

While FDA has recently issued a drug competition plan, much of the focus has been on a decision to prioritize review of Rx generic applications for reference products with two or fewer approved ANDAs. *(Also see "Drug Pricing: Could Expedited Review Of Competing Brands Create The Desired Pressure?" - Pink Sheet, 19 Jul, 2017.)*

In addition to recommending statins, Hen-

drickson said some currently Rx dermatology treatments "are natural products to switch." Though "not billion dollar categories," the products "are safe, effective, could be self-prescribed, could be over the counter." Additional migraine treatments "are also kind of key ones" that could be switched, he said.

PRIVATE LABEL NEXIUM NEXT

In the short-term, Perrigo plans a second-half launch of private label and store brand versions ofthe *Nexium 24HR* (esomeprazole/20 mg) proton pump inhibitor, which in 2014 became the last of the Rx PPI brands to become available OTC and launched with three-year market exclusivity due to clinical data required in its NDA. *(Also see "OTC Nexium 24HR Rides Blockbuster History Into Full Field Of Competitors" - Pink Sheet, 9 May, 2014.)*

However, while private label esomeprazole for frequent heartburn is a factor in Perrigo's forecast for $225m in new product sales for 2017, it will not be the only generic of OTC Nexium available, unlike most of the firm's launches. Perrigo's product will face competition from other private label providers at launch.

The forecast is "risk-adjusted," Hendrickson said. "We are not planning on being alone in that Nexium market."

Providing retailers and other businesses with private label or store brand versions of OTC switch brands accounts for the sharpest increases in Perrigo's revenues, but the firm also has a steady growth driver from general consumer interest in spending less for generic equivalents of most every nonprescription brand.

"I believe our US consumer health care business can grow through a number of avenues. One is we have the acceptance of store brands. You may have thought we hit a cliff [but] it continues to grow," Hendrickson said.

TRIMMING INTERNATIONAL SAILS EFFECTIVE

Rather than expansion, contraction drove some of Perrigo's encouraging consumer health business results. The firm said it sold the Russian division of its international OTC drug and nutritional products business, but did not disclose the buyer or financial terms.

The sale is the latest step in trimming the segment's footprint and cutting distribution and manufacturing costs since expanding its consumer health operations

SWITCH HITS, MISSES AND MAYBES

One of the most recent OTC switches FDA approved, and the first nonprescription acne treatment approved since FDA finalized its OTC monograph for the indication, was **Galderma Laboratories L.P.**'s *Differin Gel* 0.1% (adapalene). The first-in-class product got FDA's nod in June 2016 as a once-daily topical for treating acne in consumers 12 and up. *(Also see "Nestle's Prospects To Lead OTC Acne Market Gel With Differin Approval" - Pink Sheet, 14 Jul, 2016.)*

GlaxoSmithKline PLC in late 2016 received FDA approval for Flonase SensimistAllergy Relief, the first OTC fluticasone furoate product, in a 27.5mcg spray, with plans to build upon the success of the original Flonase OTC line and help counter private label competitive activity in the intranasal corticosteroid category. *(Also see "GSK Aims Flonase Sensimist To Counter Generic Nasal Allergy Competition" - Pink Sheet, 8 Feb, 2017.)*

Merck & Co. Inc.'s three NDAs to switch *Mevacor* (lovastatin), including one done in a partnership with **Johnson & Johnson**, were not approved by FDA and Pfizer pulled the plug on a potential NDA for an OTC dose of Lipitor (atorvastatin/10 mg) after an actual-use trial showed concerns about whether consumers could accurately self-select and safely use a statin, the same reasons the agency rejecting the three Mevacor switch NDAs . *(Also see "Light Still On For Switches After Pfizer Pulls Plug On OTC Lipitor" - Pink Sheet, 3 Aug, 2015.)*

Sanofi is developing a switch application for ED drug *Cialis* (tadalafil), on license from **Eli Lilly & Co.**, and **Pfizer Inc.** has acknowledged considering an NDA for an OTC version of *Viagra* (sildenafil). *(Also see "Cialis Or Viagra Switch? Sanofi Survey, Pfizer Help Wanted Ad Could Be Signs" - Pink Sheet, 18 Nov, 2016.)*

Hendrickson's suggestion of behind-the-counter caveats for some nonprescription switches isn't an approach that FDA or others in the OTC industry have supported. The agency acknowledges firms see barriers to switch and are skeptical of options to ensure safe use of their products can be ensured through innovations such as extra-label information, instructions or questions accessed online. However, since FDA began its Nonprescription Drug Safe Use Regulatory Expansion initiative in 2012 on potential changes in the application process so sponsors could propose novel switches, including ways to expand safe use communications beyond the drug facts label, agency officials have made clear they are not suggesting behind-the-counter distribution for some switches. *(Also see "FDA's OTC Naloxone Study Is A Starting Point For Other Switches, Not A Roadmap" - Pink Sheet, 16 May, 2017.)*

Still, the first nonprescription emergency contraceptive was approved after the sponsor voluntarily amended its NDA to require pharmacy-only distribution. That requirement as well as age restrictions later were lifted, but the sponsor's initiative to limit sales of the product, which was a highly controversial topic for FDA, to pharmacy-only provided the agency with an option for approving the switch while assuaging concerns about distribution of the levonorgestrel drug. *(Also see "FDA Drops Access Restrictions On Generic OTC Emergency Contraceptives" - Pink Sheet, 5 Mar, 2014.)*

into Europe with its 2015 acquisition of German firm **Omega Pharma NV** *(Also see "Perrigo Starts Branded Consumer Product Rescue Mission In Belgium" - Pink Sheet, 8 Dec, 2016.)*

Hendrickson cautioned, though, that net income growth from Perrigo's international consumer business remains a long-term goal.

"We're still on what I consider to be a broader strategy of enhancing that business. … This isn't a next-three-months thing. This will continue to evolve over the next couple years as we continue to enhance the margin," he said.

The Dublin-based firm reported net sales for its international consumer health business were $377m, a total around 4% higher than the year-ago quarter when excluding $39m in sales from European distribution businesses the firm has exited and $16m lost to currency exchange. Sales growth in Europe, where Perrigo markets branded and private label OTCs and nutritionals, was led by $19m in new product sales and higher net sales in the allergy, analgesic and cough/cold categories.

Net sales for Perrigo's consumer products Americas division, including Canada, Mexico and Central and South America as well as the US, grew 3% to $605m during the April-June period on higher sales in the smoking cessation and dermatologic categories and stronger performance in Mexico.

Perrigo, which maintains its primary operations in Allergan, Mich., said new product sales in the Americas were $13m, primarily on US sales of its generics of Flonase Allergy Relief (fluticasone/0.05mg/metered spray) and new nicotine replacement gum products.

The Rx business reported net sales in the April-June period were down 13% from the year-ago quarter to $240m. However, even though an activist investor-led bloc of board members is pushing to divest the Rx business, analysts are encouraged that the segment is stabilizing despite the price erosion hammering the prescription generics sector and the firm says it is considering adding ingredients or businesses to its generic topicals lineup with bolt-on acquisitions.

Hendrickson, whose June announcement of leaving Perrigo came after the investors joined the board, said he is not reconsidering his decision to leave even though his argument to retain the Rx business was supported by the segment's 4% volume sales growth and $6m in new product sales in the second quarter.

Perrigo's overall results for the quarter were a $70m loss, down from a $534m loss a year ago, on an 8% dip in net sales to $1.2bn.

The firm raised its full-year adjusted diluted earnings per share guidance to a range of $4.45 to $4.70, up from $4.15 to $4.50 it forecast with its first-quarter results, reflecting its expectations for the second half and the loss of around 5 cents per share in the sale of its Rx active pharmaceutical ingredient business in Israel.

Investors showed the same buoyancy as analysts for Perrigo as the firm's share price increased 15.9% the same day to $76.84 in high volume trading, more than 10m shares. Still, the price is a long way from between $200 and $180 with **Mylan NV**'s tender pending in the second half of 2015. *(Also see "Perrigo's Return To OTC Roots Restoring Investor Confidence" - Pink Sheet, 1 May, 2017.)*

Switches, Pediatric Products Highlight OTC Outlook In Independent Pharmacies

EILEEN FRANCIS eileen.francis@informa.com

Sales of OTC cold and allergy products lead other consumer health and wellness and beauty categories in US independent pharmacies and are expected to grow on OTC allergy switch and children's items, says Hamacher Research Group.

Hamacher analyst Kyle Lentz noted in a recent blog post that cold and allergy OTC sales for the 12 months through June 2017 accounted for 17.9% share of health, wellness and beauty product spending in independent pharmacies, down slightly from the previous period.

Sanofi*Xyzal 24HR* (levocetirizine dihydrochloride) OTC allergy switch launched in February and significant launches of children's products, including the return of **Johnson & Johnson**'s *Children's Tylenol* cold products and innovative items such as **Mondelez International Inc.**'s *Halls Kids Cough & Sore Throat* suckers, should boost the segment for the next period, Lentz stated in his post.

"Adding these new products to your assortment will help drive consumers to the department and boost sales," he wrote.

Hamacher, a Waukesha, Wis., a consultancy in category management and business strategy for consumer health businesses at the retail level, gleaned the figures from market research firm Information Resources Inc. and from 12 wholesale firms that serve roughly 16,000 of the 20,000 independent pharmacies in the US.

Lentz provided the figures and suggestions for pharmacists in his "category tips" post Hamacher published online Aug. 12 and expanded on his findings during an Aug. 24 interview.

Xyzal Allergy is the first Rx-to-OTC switch of the ingredient levocetirizine dihydrochloride, available in 5mg tablets indicated for children 6 and up and adults and in a 2.5mg per 5mL oral solution for children 2 and up as well as older children. *(Also see "Xyzal Switch Extends Sanofi Into OTC 24-Hour Children's Antihistamine" - Pink Sheet, 2 Feb, 2017.)*

In January, New Brunswick, N.J.-based J&J reported its OTC analgesics segment was back on track after the company remediated three manufacturing sites subject to a consent decree with FDA following good manufacturing practice problems; J&J has returned to store shelves all product lines that were recalled as problems at the three plants became known. *(Also see "J&J Promotes Preventive Care, Wellness In US Health Debate" - Pink Sheet, 26 Jan, 2017.)*

In April, J&J announced that sales of its adult and children's Tylenol products were ahead of other products in the category. *(Also see "Tylenol Delivers J&J Relief As Glob-*

al 'Consumer Staples' Sales Slump" - Pink Sheet, 18 Apr, 2017.)

Lentz said Halls Cough & Sore Throat Pops, in a lollipop delivery format containing cough and sore throat ingredients, likely will be purchased for children between 6 to 11 as parents of younger children fear choking risks.

Each pop contains 5mg menthol, the same active ingredient in traditional Halls lozenges. Throat Pops debuted in July along with another Halls pediatric product, Kids Vitamin C Pops.

The OTC cold and allergy product category ranking demonstrates the different selling opportunity for the drugs in the independent pharmacy channel compared to major drug chains, where they trail the vitamins and dietary supplement category, Lentz said.

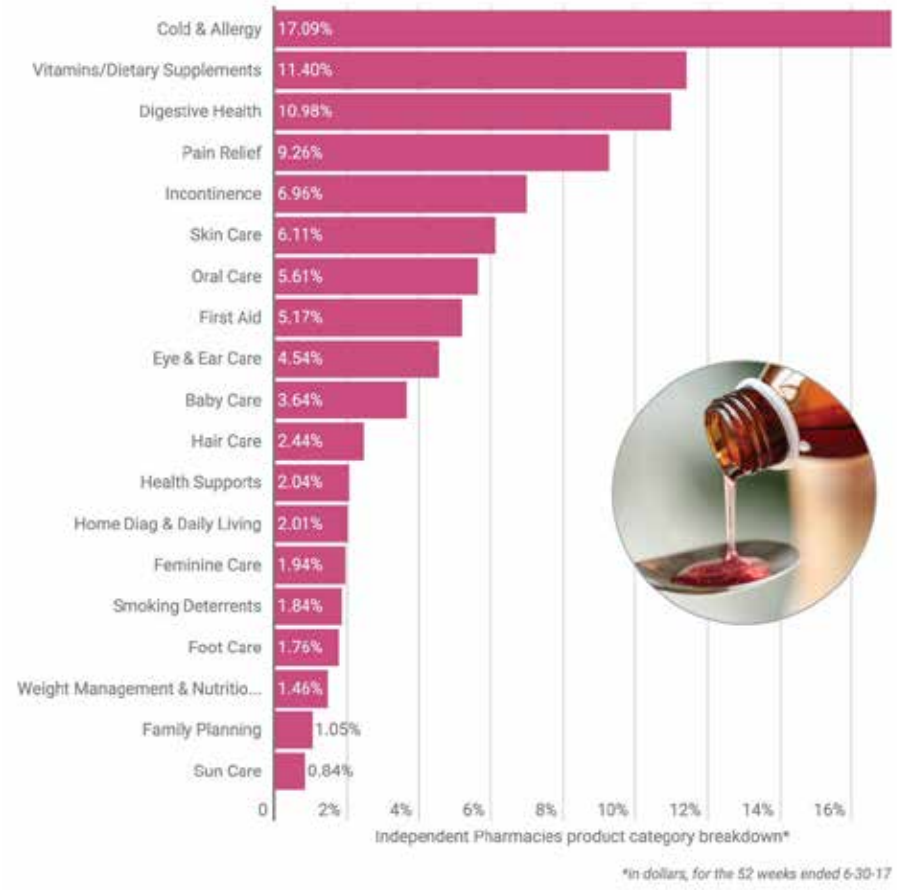
"If you go to a chain or mass outlet, you will see a good 20 to 24 feet of vitamins and dietary supplements [shelving] but in small independent chains, you're talking about small footprints, with the largest about 8 to 12 feet," he said.

Vitamins and dietary supplements are the No. 2 category in independent pharmacies, accounting for about 11.40% of the total health, wellness and beauty pie for the 12-month period.

Digestive health is third at 10.89% and pain relief is fourth with 9.26% of the total market of health, wellness and beauty items in independent pharmacies (*see chart*).

Health, Wellness And Beauty Category Sales Rankings In Independent Pharmacies

Cold/allergy OTCs lead health, wellness and beauty product category sales in independent pharmacies, but are No. 2 behind vitamins, minerals and supplements in mass-merchandise and chain drug stores, according to Hamacher.



Hamacher Resource Group Proprietary Wholesaler Withdrawal data.

TIPS FOR CONNECTING WITH INDEPENDENTS

- understand independents' customer base and whether an OTC product is geared toward them;
- pace of getting new products in-store is slower than in retail chains, and marketers working with wholesale distributors have more success;
- customer requests and recommendations are a key driver of moving products in store and keeping them there;
- independents like facts – tell them why they need your product and back it up with clinical research;
- offer samples;
- remain consistent, and build trust and your reputation through visibility and repetition;
- identify thought leaders and pharmacist influencers as pharmacists trust their peers;
- provide in-store tools and support including displays, education materials, coupons or rebates for products;
- include independent pharmacies in store locator sections of manufacturer and brand websites.

OTC DRUG OPPORTUNITY UNTAPPED

Lentz noted drug manufacturers rarely connect with independent pharmacists to sell more of their products. "Ten to 15 years ago, retailers received their information from their sales rep, who would drop by their store once a month. They would have deals, work with the independent pharmacist. Those days are pretty much gone," he said.

The move away from the personalized approach is somewhat a given, considering tighter budgets for many OTC marketers, staffing concerns and difficulty in targeting independents spread across the country, he noted.

Further, drug wholesalers aim to provide some services OTC marketers previously did in promoting products to independents, educating them on the drugs and supporting them with sales collateral. Third-party resource firms such as Hamacher also fill that role, working with retailers in helping drive front-of-store sales by identifying fast-selling products and finding the right product placement, pricing and promotions for selling products.

OTC marketers can work with Hamacher and other resource partners to navigate the channel and get their message and products in front of independent pharmacies, about 40% of all US pharmacies.

Those drug firms that stay the course alone should still consider reaching out to independents, not only to move products into store but to encourage pharmacists to recommend their products, suggested Lentz.

For example, when patients receive antibiotic prescriptions, pharmacists can recommend a probiotic to help counter some of the digestive side-effects of the medication, or for patients taking medications that induce photo-sensitivity, pointing out sunscreen products they should purchase along with the drug, Lentz noted.

Some marketers, including **Procter & Gamble Co.** and J&J are using digital apps or are partnering with health care professionals and pharmacists to drive sales of their products in drug stores. P&G invests in continuing education programs with pharmacists and dentists. *(Also see "Technology Gap Separates OTC Drug Firms From Self-Care Sales Growth" - Pink Sheet, 16 Mar, 2017.)*

OTC, Supplement Co-Packaging Potential Could Be Clipped By FDA Proposed Rule

MALCOLM SPICER malcolm.spicer@informa.com

An FDA proposed rule that deems dietary supplements unapproved drugs when co-packaged with pharmaceutical products could put firms like **Innovus Pharmaceuticals Inc.** in an enforcement bullseye if made final in its current form.

Innovus in July launched tandem sales of its *Apeaz* OTC pain relief topical and its *ArthriVarx* joint health supplement, with both products sold together though physically packaged together.

Innovus CEO Bassam Damaj said the San Diego firm, which commercializes OTC drugs and other consumer products for men's and women's health, vitality and respiratory diseases, is testing the market for supplements and OTCs sold together. "We're looking to see how it's going to perform," Damaj said in an interview.

FDA's Center for Drug Evaluation and Research says that under the currently proposed rule, the agency would determine on a case-by-case basis whether co-packaged nonprescription drugs and vitamin, mineral or supplement products already available in the US are in violation of agency policy. The agency published the proposed rule in December 2015, and in its latest regulatory agenda update, which is non-binding, sets an October 2018 target date for publishing a final rule.

Innovus Pharmaceuticals offers its Apeaz topical analgesic OTC only in tandem sales with its ArthriVarx joint health supplement.

"It is difficult to respond to questions about hypothetical scenarios, particularly where the outcome is rather fact-dependent/fact specific. Depending on the specific facts and circumstances, a dietary supplement co-packaged with an OTC drug could suggest or imply that the di-

etary supplement is intended for a drug use and would, therefore, be considered a drug under" FDA regulations, said Tralisa Colby, a public affairs specialist in CDER's Office of Communications.

However, the proposed rule – "Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph" – doesn't allow exemptions for supplements that are sold as part of a single package with a drug.

"When used as part of a fixed-combination or co-packaged drug, dietary supplements are considered to be an active ingredient in that product and subject to the requirements of this proposed rule," CDER said in the proposed rule.

In a footnote clarifying its thinking in the proposal rule, CDER said it considers "dietary supplements that are combined into a single dosage form with, or co-packaged with, a drug to meet the definition of 'drug' under" FDA regulations. The center also stated in the footnote that the "proposed rule does not otherwise address nor affect FDA policy on dietary supplements."

However, the overall language of the proposal rule – docket FDA-2015-N-1260 – indicates it would affect the supplement industry. Moreover, the industry perceives the definition of dietary supplements as drugs when co-packagesas short-sighted and unfair.

Drug manufacturers also are concerned that the proposed rule would curtailing their marketing strategy of offering multiple OTC products with similar or different indications in a single package.

A DRUG REGULATION FOR SUPPLEMENT MARKETING?

The Council for Responsible Nutrition let FDA know about its concerns in May 2016 comments on the proposed rule.

"FDA was ostensibly putting out a proposed rule around drugs and we saw them referencing supplements. We dropped [comments] into the agency just to remind them that that, 'Hey this is not supposed to be a conversation about supplements. If you want to have that, you should have that separately, but not in the context of this drug rule,'" said Steven Mister, president and CEO of the supplements trade group..

FDA previously has compelled firms that were combining drug and dietary supplements in a single formulation to cease making and marketing the products, enforcement that met little pushback. *(Also see "Bayer Warning Letters Reinforce FDA Ban On Supplement/Drug Combinations" - Pink Shee, 3 Nov, 2008.)*

> CRN believes any proposals on co-packaging supplements and OTC drugs should be a separate conversation.

But offering separate supplement and drug products in a single package differs from combining supplement and drug ingredients in a single formulation, industry says.

Mister suggests FDA seems to be on thin regulatory ice to include vitamins, minerals and supplements in the proposed drug co-packaging rule. "It says that a dietary supplement becomes a drug by virtue of being packaged with a drug."

"Now we are moving from just not putting the ingredients in the same pill to where FDA seems to be saying, 'Well, you can't even co-package them together.' We don't see anything in [FDA regulations] that prohibits that," he said in an interview.

"We're saying, 'This is not the place to have that conversation, FDA. If you want to have it then you should have a conversation separately about the co-packaging of supplements with a drug.'"

DISTINGUISHING SUPPLEMENT FROM MEDICINE?

Part of FDA's concerns about co-packaging a supplement and a drug is that consumers could confuse the products' doses and directions, perhaps using the drug product indefinitely as most supplements are used, or using a supplement at the dosage indicated for the co-packaged drug.

That isn't a potential problem with Innovus' Apeaz OTC and ArthriVarx supplement, Damaj said. "The topical product is completely different and it is not in the same box as Apeaz," he said.

Although dissimilar in delivery format, the topical drug and the oral supplement provide complementary benefits, which is why Innovus is offering them together only. "When somebody orders Apeaz, they get it with the supplement," Damaj said.

Apeaz is an OTC topical analgesic monograph compliant drug for arthritis pain relief containing– camphor 4%, menthol 10% and methyl salicylate 30% – that also contains excipient ingredients that are common as active ingredients in joint health supplements, methyl-sulfonyl methane (MSM) and glucosamine sulfate.

"There are no other products that contain those five ingredients at those concentrations and tested in the collagen arthritis model showing efficacy," Damaj said.

According to its label, Apeaz is indicated for temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

Innovus says ArthriVarx's "two main ingredients" are the herb andrographolide paniculate and hyaluronic acid in a formulation "designed to maximize joint health."

SALES DRIVER FOR FIRMS ...

Including a vitamin, mineral or supplement product that complements the indicated effect of a nonprescription drug available in a single package, as Innovus is doing with Apeaz and ArthriVarx, could have appeal as a sales driver.

That is an option CRN wants FDA to allow the industry. "We could foresee that somebody might want to have supplements and an OTC medicine that are shrink-wrapped together," Mister said.

While a tandem offering with a topical drug and an oral supplement might appear as easier for users to distinguish between the two products, CRN expects it is not asking too much of consumers to correctly follow dose and usage directions for co-packaged oral delivery drugs and supplements.

"What I think consumers are smart enough to know is that if it has a Supplement Facts box on it, it's a supplement, and if it has a Drug Facts box on it, it's a drug," Mister said.

"If you have two products that are co-packaged and they each have their own labeling consumer can figure out that one is a supplement and one is a drug."

... CONVENIENCE FOR CONSUMERS

In addition to consumers correctly distinguishing packages of nutritionals from drugs, trends in nonprescription drug use support allowing co-packaging the products.

"What's happening at the same time is you're seeing more and more OTC medicines that are meant for either a chronic condition or you're taking them every single day," Mister said.

For instance, consumers using daily OTC allergy remedies and omega-3s or herbals daily would appreciate the convenience of the drug and supplements being available together.

"Why couldn't the manufacturer whose making both of those products co-package them for consumer convenience?" Mister said, adding, "Even if it's not on the condition [indicated for the OTC], it's just convenient to have them all packaged together."

Innovus' Apeaz and ArthriVarx offering is gauging consumer regard for the convenience of supplements and drugs sold together. "So far the response has been great. We've been shipping a lot of orders," Damaj said.

Innovus markets a total of 25 consumer health products, including OTC topicals for premature ejaculation prevention and hemorrhoid treatment and supplements for prostate health, bladder control and sexual health. It also expects FDA approval this year for its abbreviated new drug application filed in 2015 for a fluticasone proportionate spray intranasal corticosteroid, a generic of **GlaxoSmithKline Consumer Healthcare LP**'s *Flonase Allergy Relief*. *(Also see "Fluticasone Spray Competition Grows With Perrigo Launch Of West-Ward Product" - Pink Shee, 6 Jun, 2016.)*

In 2016, Innovus closed its $630,000 acquisition of brands from **Beyond Human LLC**, a firm known for its testosterone booster supplement *Beyond T Human* and its natural human growth agent *HGA*. *(Also see "Industry Roundup: Supplement Labeling Guide Corrected, Nu Skin Settles" - Pink Sheet, 7 Mar, 2016.)*

More recently, Innovus in June gained a license for exclusive rights to the University of Iowa Research Foundation's US patent application on use of thymol and carvacrol (monoterpene phenols) for induction of increased skeletal muscle endurance, lean muscle mass and reduced adiposity. The monoterpene phenols are considered generally recognized as safe by FDA for use in dietary supplements and conventional foods and beverages. *(Also see "Tech Transfer Roundup: Janssen, Eisai, Apexian, Innovus And More" - Pink Sheet, 11 Jul, 2017.)*

Drug Co-Packaging Proposed Rule Could Hamper Some OTC Marketing

MALCOLM SPICER malcolm.spicer@informa.com

FDA should narrow its proposed definition of "co-packaged" drugs to avoid curtailing OTC firms' marketing strategy of offering multiple products with similar or different indications in a single package, say industry stakeholders.

A proposed rule published in December 2015 – "Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph," docket FDA-2015-N-1260 – would extend FDA regulations on Rx fixed-combination drugs to products with prescription and nonprescription ingredients, co-packaged drugs and combinations of active ingredients under consideration for inclusion in an OTC monograph.

The proposal also states that dietary supplements co-packaged with OTC drugs would be considered unapproved new drugs because they are sold with a drug product. While the proposed rule has been pending for quite some time, the issue is getting renewed attention as the OTC/supplement co-packaging strategy is an emerging sales driver for firms in both industries and is raising questions on how FDA might enforce the proposal if made final.

For OTC drugs, packages with containers of both daytime and nighttime formulations of the same ingredient could be deemed mislabeled under the proposed rule, as well as co-packaged products with little similarity in use, such as an oral analgesic sold in tandem with a topical pain relief product.

The Consumer Healthcare Products Association says the proposal could render common offerings of two or more separate OTCs in a single package as mislabeled if the products are not intended to be used together, according to the trade group's March 2016 comments to FDA's Center for Drug Evaluation and Research.

"We disagree that shrink wrapping absent labeling such as 'convenience' or 'value pack' is an implied claim that the products are intended to use used together," wrote Barbara Kochanowski, the trade group's regulatory and scientific affairs vice president.

Kochanowski explained that because "'co-packaged' has multiple meanings outside of the regulatory environment," CHPA is "concerned that this proposed rule, unless much more clearly clarified regarding exemptions, may have unintended consequences and cause regulatory uncertainty for manufacturers and retailers."

Kochanowski pointed out that other marketing terms used for self-care products sold together include "family pack, bonus pack, convenience pack, free sample, first aid," and "there could be many other terms used in the future that are also acceptable but not clearly" defined as compliant and not subject to the proposed rule.

CHPA suggests CDER define a co-packaged drug as "a product that contains two or more separate drugs in their final dosage forms that are intended to be used together at the same time for a common or related therapeutic purpose, labeled as such, and that are contained in a single package or unit."

Bayer AG, manufacturer of OTC products including the *Alka-Seltzer* lines and the *As-*

pirin brand, also suggested in March 2016 comments that CDER refine its definition for co-package. The proposed definition "is overly broad and could lead to consumer confusion," wrote Todd Paporello, vice president and head North American regulatory affairs pharmaceuticals and consumer health at Bayer's Whippany, N.J., office.

CDER should modify the definition by adding to "intended to be used together" the phrase "as evidenced by their labeling for use for the same indication in the same population," Paporello said. The qualifying phrase would exclude from FDA's "co-packaged drug" definition products with labeling that "does not treat the same symptoms in the same population."

"Consumers see and are familiar with a variety of product packaging that is currently on the market that has samples or other unrelated items attached. Regardless of whether labeled with 'value', 'convenience' or other similar words, it is clear from their labeling that the products are not intended or implied to be used together," he added.

Additionally, Paporella noted co-packaging for daytime and nighttime formulations of the same product should be considered compliant with FDA labeling regulations. "There is nothing in the labeling of day and night products that suggests or states that the products are to be used together simply because they are co-packaged together. Regardless of whether a product is intended for use during the day or night, the product has to have labeling for the safe and efficacious use of the product," he stated.

In its most recent but non- binding update to its regulatory agenda, FDA estimated it would issue a final rule in October 2018. Response to the proposal promoted FDA to extend the comment period in early 2016. *(Also see "Industry Roundup: DXM Bill Moves, CHPA Biz Dev VP, Neurobrands Injunction" - Pink Sheet, 25 Apr, 2016.)*

Bayer 'All Hands On Deck' For US Consumer Business Turnaround

MALCOLM SPICER malcolm.spicer@informa.com

Bayer AG is learning that bringing former **Merck & Co. Inc.** brands under its roof could have been the easiest part of its bid to reach the top of the consumer health market, a process that might be causing some buyer's remorse.

"Obviously, there is a ton of work still for us to do," says Erica Mann, Bayer's global consumer business chief.

Some of Bayer's consumer business work during the firm's fiscal 2017 second quarter was for a recall of more than 1m packages of *Alka-Seltzer* aspirin-antacids *(see box next page)*.

As CEO Werner Baumann similarly did during the firm's second-quarter earnings briefing on July 27, Mann assured analysts Bayer is sparing no effort to turn around its consumer product sales and that it remains committed to growing the business.

"Clearly, this requires our full attention because the environment in this highly dynamic market is changing very rapidly," Mann said, adding, "with that said, the long-term outlook remains positive.'"

Baumann noted online sales are a big piece of the change happening in the OTC drug and dietary supplement market and that Bayer, like other consumer health product manufacturers, is investing more in e-commerce for its consumer brands. And like its competitors, the US is a big reason for slumping sales.

The CEO said Bayer is adjusting its consumer health expectations for the remainder of 2017. "Very importantly, we are focusing also with our investments on the turnaround in the US," which "requires all hands on deck by Erica and her management," he said.

Bayer lowered its consumer business full-year sales forecast to around €6bn ($7.08bn) down from more than €6bn and in line with the segment's 2016 revenues, and adjusted its guidance on earnings before interest, tax, depreciation and amortization to declining by a high single-digit percentage after earlier guidance of increasing by a low- to mid-single-digit percentage.

Bayer's overall sales for the quarter increased 3% $14.4bn, adjusted for exchange rate changes, despite the consumer business slump and a nearly 3% dip in crop sciences sales to $10.3bn. Its net income fell 11.3% to $1.4bn and core earnings per share was down 16.2% to $1.65.

ACQUISITION BROUGHT SOME SURPRISES

Analysts on the call pressed for details supporting the firm's consumer business plans, and pointed out that while market conditions are unpredictable, Bayer should have known more about what it was getting with Merck & Co.'s brands, including OTC products *Claritin* (loratadine) antihistamines and *Coppertone* sunscreens. *(Also see "Bayer Consumer Health Journey Still Short Of Destination" - Pink Sheet, 26 Oct, 2016.)*

Luisa Hector, a pharma research analyst with Exane BNP Paribas, observed that Bayer's consumer business is "suffering" not only from market conditions and from consumers' use of e-commerce, "but also perhaps a bit of lack of due diligence on the Merck acquisition."

Baumann acknowledged Bayer did not anticipate increased competition for former Merck & Co. brands including Dr. Scholl's foot care products and the Coppertone line among other developments that have affected the firm's consumer business sales. *(Also see "Bayer Plans 19 Consumer Product Launches To Revive Sluggish Sales" - Pink Sheet, 23 Feb, 2017.)*

"Some of it could have potentially been seen," he said.

For instance, former Merck & Co. brand sales were "already eroding compared to our assumption" when the firms closed their transaction in 2015 after announcing the deal in May 2014, Baumann said. The revenues were "already substantially discounted to the case that was presented by Merck and that has continued."

Bayer became the second-largest OTC drug firm and expected a springboard to reach No. 1 by paying $14.2bn for Merck & Co.'s consumer business. *(Also see "Bayer Lands Merck*

ALKA-SELTZER ANTACID RECALL

A recall of Bayer's *Alka-Seltzer* Original, Extra-Strength and Gold products it began at the end of the first quarter, on March 30, after confirming a customer complaint of small holes or cracks in the foil or blister-pack packaging for the aspirin-antacid combinations.

According to FDA's recalls database, 1.07m 12-count packages of Alka-Seltzer Original, 24,672 packages of Extra Strength and 56,064 36-count packages of Gold are being recalled from nationwide US distribution by **Bayer HealthCare Pharmaceuticals Inc.**, based in Morristown, N.J. FDA on Aug. 1 categorized the voluntary and ongoing recall as class II, products that may cause temporary or medically reversible adverse health consequences but with remote probability of serious consequences.

The products contain combinations of different dosages of aspirin, sodium bicarbonate and anhydrous citric acid. However, Bayer is reformulating its Alka-Seltzer antacid line without aspirin partly due to a risk of serious bleeding potentially linked to the analgesic and because consumers are moving to single-indication products to remedy common conditions. *(Also see "Alka-Seltzer Antacid Will 'Plop, Plop Fizz, Fizz' Without Aspirin" - Pink Sheet, 26 Mar, 2017.)*

Reformulating and producing distribution inventory of an OTC monograph product should require one to two years, the firm says. Products in the brand's *Alka-Seltzer Plus* line of effervescent tablets and capsules for cough/cold, congestion and sinus relief do not contain aspirin and are not being reformulated

US CONSUMER SALES OFF 8%

Bayer reported its consumer health products sales during the April-June period slowed 2.2%, as US revenues dropped 8%, to EUR 1.5bn, adjusted for currency exchange rate changes. Outside of North America, sales grew around 2%.

US *Claritin* brand sales were down 12.3% on a weaker allergy season, though the year-ago revenues were increased by Bayer's launch of *ClariSpray* (fluticasone) allergy treatment. Coppertone sales fell 16.7% during the quarter partly from increased competition pressure.

Sales of *Bepanthen* and *Bepanthol* wound and skin care products marketed outside the US grew 4.9% on upticks in Asia/Pacific and Latin America and Bayer's *Aspirin* brand sales were flat from the year-ago quarter.

Consumer As Springboard to Lead Global OTC Industry" - Pink Sheet, 6 May, 2014.)

Bayer's US consumer business plans, Mann said, include increasing promotional support for the Claritin and Coppertone lines, launching a direct-to-consumer ad campaign for Aleve products and expanding Dr. Scholl's distribution as well as increasing "direct-to-consumer activations" for the line. Marketing will continue behind the *One A Day* vitamin line and the *Alka-Seltzer Plus* (combinations of acetaminophen, chlorpheniramine, dextromethorphan and phenylephrine) cough/cold products.

Bayer is "continually upgrading our capabilities such as those that can deal with channel shifts like e-commerce" and is "supporting the US team in this very difficult time, to make sure that they could face these challenges head on," Mann said.

LONG TERM, STAY THE COURSE

Market analysts note Bayer is not under-estimating the extent of its consumer business challenge, saying its results track with its competitors as spending across consumer product categories, including outside heath care, is slowing in the US. But, they also expect Bayer's turnaround plans to work.

Societe Generale Cross Asset Research analysts' July 28 note said Bayer's long-term "consumer trend business remains attractive in our view, and performance outside the US remains strong."

At Morningstar, Sector Director Damien Conover agreed with Bayer that consumer health market indications aren't promising for the rest of 2017. Conover said in a July 27 note that "poor market conditions are weighing on the consumer group, similar to reports from several peers," and the segment, along with Bayer's crop science business is "likely to weigh on total growth in 2017."

Also on July 27, Deutsch Bank Market Research analyst Tim Race said "Bayer appears to be suffering from the general US spending slowdown" but the consumer segment performance "has no meaningful impact" on his overall forecasts for the firm.

"We don't expect a quick fix, but [management] at last seems to understand the multifactorial issues and appear to be addressing them," Race said.

P&G Open To M&A Moves, Closed To Board Seat For Activist Investor

EILEEN FRANCIS eileen.francis@informa.com

Procter & Gamble Co. is pointing to its latest results to show its brand streamlining is working, but the firm is speaking directly to shareholders to appeal for votes against activist investor Nelson Peltz joining its board.

A week after reporting its fiscal 2017 fourth-quarter results and outlining plans for sustaining growth through focused advertising spending and returning to merger and acquisition activity, P&G in an Aug. 1 letter to shareholders made its case against Peltz, head of hedge fund Trian Fund Management LP, being elected to the board during the firm's annual meeting on Oct. 10.

Signed by President and CEO and Chairman David Taylor, the letter asked shareholders not to vote in favor of a proxy to add Peltz to the board and instead vote on P&G's 11 director nominees. The outcome of the votes will be announced during the annual meeting.

"During numerous direct interactions with P&G board members and management, and in its proxy materials, no new actionable ideas have been offered by Mr. Peltz, in our opinion, to drive additional value for P&G shareholders beyond the continued successful execution of the company's ongoing strategies and plan," Taylor stated.

The Cincinnati-based firm also argues that Peltz's views are based on "outdated information" from Trian's retention of Clayton Daley, a former P&G chief financial officer, as an advisor. Daley stepped down from his post in 2009 after 15 years with the firm and was replaced by Jon Moeller. *(Also see "P&G Focuses On Consumer Health, "Deemphasizes" Pharma" - Pink Sheet, 15 Dec, 2008.)*

"This decision appears to be compounding Trian's fundamental misunderstanding of P&G today and the operating environment the company faces."

Trian Management, with a stake of around 1.5% on its purchase of roughly $3.5bn in shares in February, isn't satisfied with PG's progress from multiple initiatives over more than five years toward gaining market share for its health, personal and household care products and increasing margins. In a July 17 Securities and Exchange Commission filing, Trian stated that Peltz will stand for election to the board. *(Also see "Activist Investor Forces P&G's Hand: Shareholder Vote On Joining Board" - Pink Sheet, 17 Jul, 2017.)*

> "Where products are consumed daily or even more than one time per day, those are categories we really like ... We want to be in categories where product superiority matters, where purchase motivation is driven by the ability of a product to meet a need in a demonstrable way."
> – CFO Moeller on M&A strategy

P&G – whose OTC drugs include *Vick's* cough/cold products (combinations of acetaminophen, dextromethorphan, phenylephrine, doxylamine and chlorpheniramine), *Pepto Bismol* upset stomach remedy (bismuth subsalicylate) and *Prilosec OTC* treatment for frequent heartburn (omeprazole) – contends its "plan is working," as shown by meeting or exceeding its 2017 commitments.

P&G'S M&A 'POWER ALLEY'

The firm's results also steer it toward considering mergers and acquisitions after several years out of M&A as it focused on trimming its portfolio. "We see the opportunity to acquire potentially new technologies, capabilities or potentially companies in spaces that are in our existing 10 core categories or adjacent or ones that leverage our capabilities," Taylor said during the company's earnings briefing on July 27.

Moeller said P&G is open to moving beyond the 10 categories in which it currently competes and offered some sign of where it would look.

"Where products are consumed daily or even more than one time per day, those are categories we really like. Categories where a product that is used or consumed once or twice or three times a year are not as attractive, by definition. We want to be in categories where product superiority matters, where purchase motivation is driven by the ability of a product to meet a need in a demonstrable way," Moeller said.

He noted many of the businesses P&G divested during its brand streamlining sold products intended for uses other than meeting a need, such as "fashion, flavors, fragrance, self-image." Those "are all good things, but not up our power alley," Moeller said.

The streamlining plan is paying off with P&G's 10 key categories growing after it shed 100 brands, moving from about 200 to 65 since 2014, including reducing its overall oral care SKUs by 20%. *(Also see "P&G Portfolio Rationalization Brushes Off 20% Of Oral Care SKUs" - Pink Sheet, 1 Mar, 2017.)*

CEO Taylor said P&G has added more "mastery and depth" to its existing product categories with external hires. "The objective is simple: improve business results by getting and keeping the right people in the right places to develop and apply deep category mastery to win," he said.

P&G is "fortunate" in retaining staff, but the company still must recruit from outside and its external hiring has roughly quadrupled across five levels of managing, including senior leadership, Taylor said.

STREAMLINED COSTS BOOST RESULTS

P&G reported organic sales growth for the April-June period grew 2% to $16.1bn,

though net sales were flat. Additionally, for the quarter the firm reported adjusted earnings per share of 85 cents, up 8% from the year-ago quarter; analysts' consensus EPS was 78 cents.

It expects organic sales for its fiscal 2018, which began July 1, to grow 2%-3%, up from its previous forecast of 2%, and forecasts operating profit growth at 5%-6%.

The firm said its performance largely reflects its focus on cost reduction, which includes a cut in digital marketing spending as well a reduced SKU-count.

"What it reflected was a choice to cut spending from a digital standpoint where it was ineffective, where either we were serving bots as opposed to human beings or where the placement of ads was not facilitating the quality of our brands," Taylor said.

P&G announced in April that 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. *(Also see "'Slow-Growth' Global Trend Shakes Up P&G Product Strategy Start To Finish" - Pink Sheet, 28 Apr, 2017.)* The firm saved $10bn through a cost-cutting strategy over the past five years and has planned another $10bn in cuts for the next five years. *(Also see "P&G Keeps Direct-to-Consumer In Perspective, Retail Distribution Primary" - Pink Sheet, 26 Oct, 2016.)*

"As we made those decisions and put our money where our mouth has been in terms of the need to increase the efficiency of that supply chain, ensure solid and strong placement of individual ads, we didn't see a reduction in the growth rate," Moeller said.

"What we'd love to do and what we're working with our media partners to do is create a very efficient supply chain that helps us build our brands, and we'd love to invest more in doing just that," he said.

HEALTH CARE SALES SLIP, BEAUTY CLIMBS

Sales for P&G health care lines slipped 4% to $1.74bn in the quarter. For its full fiscal 2017, the segment grew 2% to $7.51bn, but for the quarter it was negatively impacted by an early cough/cold season that generated sales in the first quarter, the firm said in its earnings release.

Organic sales of oral care products, including the *Crest* line and *Scope* mouthwash, slipped low single digits due to competitive activity and reduced pricing on toothpaste.

Beauty division sales grew 2% (5% organically) in the April-June period to $2.81bn, and the firm noted organic sales were up high single digits in skin and personal care product sales on the growth of the *SK-II* skin care brand and increased pricing and hair care organic sales rose low single digits. For its fiscal 2017, beauty sales were flat at $11.4bn.

Baby, feminine and family care net sales slipped 2% to $4.54bn for the quarter and for the year dipped 1% to $18.3bn, P&G said.

Its overall net sales for the fiscal year were flat at $65.01bn. Core earnings per share, which exclude the impact of diluted net earnings from discontinued operations, increased 7% to $3.92 per share.

TRUE RESULTS OR 'FALSE POSITIVE'?

Analysts largely were optimistic though cautious about P&G's results and its plans for growth.

"P&G's fourth quarter results suggest it is now poised to realize accelerating sales and volume growth, facilitated by more focused brand spend and hence an ability to more effectively tap into and response to evolving consumer trends," said Morningstar's Erin Lash in a July 27 report.

"Rather than exclusively focusing on sales gains, we believe P&G is looking to drive sustainable and profitable growth, which we view as prudent," she said.

Deutsche Bank Research Analyst Faiza Alwy said P&G's results beat its own operating profits estimate by 11% due to productivity savings and lower advertising and marketing spend. Still, Alwy said he remains cautious as "we have seen several false positives before" and added that the company is less likely to miss targets during a proxy fight.

Jeffries Equity is "supportive" of P&G's strategy, though analyst Kevin Grundy says Trian's presence "should continue to raise the execution bar."