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August 15th, 2023

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

In this month's newsletter I will cover "The Battle of the Oral Obesity Drug and Who Will be First". You can find my article under the Table of Content and click on the link.

If you missed the last months newsletter on "FDA Approves Alzheimer's Drug Leqembi, Will Physicians Rush to Prescribe it?" click [here](#) to read the article.

If you missed the photos of our 2nd Annual AAPI Heritage Festival held on Saturday, May 20th, 2023, click on this [link](#) to see highlights of the festival. Our Festival made the front page of the local Daily Times Chronicle.

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enjoy the music from the Berklee School of Music in their song "What the World Needs Now," and ending with Celine Dion and Josh Groban with "The Prayer".

Please read on for other current news in the Table of Content below. The next newsletter will be September 15, 2023.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.

Please email [me](#), Regina Au, if you have any questions, comments, or suggestions.



Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
[BioMarketing Insight](#)



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Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact [me](#) for an appointment. For successful commercial adoption of your product or looking to grow your business, contact [me](#) for an appointment.

For more information on our services, click on the links below:

[Product Development](#)

[Market Development](#)

[Marketing Strategies](#)

[Scenario Planning](#) - for more information, email [me](#).



Recap of the AAPI Heritage Festival - Saturday, May 20th, 2023

The Asian American Pacific Islander (AAPI) Heritage Festival was a success in celebrating AAPI Heritage Month with both the Asian and nonAsian communities. This celebration was to build awareness and educate our community on the various cultures and contributions the different Asian and Pacific Islanders ethnic groups have brought to enrich our American History.

Our Festival made the front page of the Daily Times Chronicle. See the article and pictures of our speakers, musicians and performers. In addition, we had our "Contributions AAPI Have Made to American History" Exhibit on display in the lobby and continued on into the program room. More pictures will be revealed next month.

Guest Speakers: Massachusetts State Representative Vanna Howard
Mayor Scott Galvin of Woburn

Special Guest Musician: Kevin So

Guest Musician: Entian Lee, Chinese Zither

Guest Performers: Swasti Bhargava & Aanvi Bhargava, Ekam Boston
Anvee Gudipati, Sreshta Mahavadi, Ekam Boston

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City Council seeks more info on fill

By PATRICK BLAIS

WOBURN - The City Council wants to consult with the city engineer's office and other department head managers before allowing a Lowell Street landowner to spread out fill in a low-lying depression. During the elected officials' latest gathering in City

Hall, Boxford resident Valentino Tocci Jr. explained that he is looking to bring in more than 100 cubic yards of fill to the back yard of a two-family property at 2 Lowell St., which sits in the city's Central Square area by Main Street.

The council, looking for additional details about the total volume of soil and rocks being brought in and

Lowell St

how the work will impact the site, ultimately at a 6 meeting.

According to Town Engineer Tom Cummings, the nearby professional engineer's office is reviewing a proximate .61-acre site towards that corner of Cummings' property, which reportedly does not match the topography of the area. Cummings said a significant storm event could cause an issue. Since that area is mostly unsightly, Cummings said he would like to see that area explained.

"This is mostly an issue. Since that area is mostly unsightly, Cummings said he would like to see that area explained.

"We would then still accept rainwater runoff," he continued. Cummings said he would like to see that area explained.

Since the special meeting, both Cummings and Planning Director Regina Au said the council cited the water storage volume situation on about 100 feet of the street.

In order to be safe, Cummings said he would like to see that area explained.

"There is no other shape, other than a square, that would remain in this lot," Cummings said. Cummings noted that



THE ASIAN AMERICAN PACIFIC ISLANDERS HERITAGE FESTIVAL was held at the Woburn Public Library with many posters describing the contributions made to American history. Volunteers and participants in the AAPI Heritage Festival included (l-r) Katherine Jiao, Vicky Wu, AAPIEC Inc. President Regina Au, and Ekam USA-Boston Chapter Director Nagasree Chakka. Some of the entertainment were dancers and musicians inside the library along with food vendors set up outside in the library's parking lot. (KAPAndrewsPhotos)

Board adopts - Burlington middle school ...

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General Guidelines to Launch and Build a Clinical Trial Using Microbiome Products in an Era of Personalized Medicine.

I am pleased to announce that I was a speaker at the Westchester Biotech Project for Consortium on Translational Research in the Microbiome on November 11th, 2021. The Topic: General Guidelines to launch and build a clinical trial using microbiome products in an era of personalized medicine. My presentation was on "How to Launch and Market a Successful Microbiome Product: Five Major Considerations". For more information on this event, click [here](#). This webinar it will be available next month, so check back here.

For more information on Westchester Biotech Project and future webinars, click [here](#).

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Inspirations

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.

The Pandemic is NOT Over, But We Will Get Through It Together By Taking COVID Precautions: Masking, Regular Testing, Updated Vaccinations and Practice Good Hygiene Every Day.



Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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One Biotech Executive's View on the COVID-19 Vaccine

I am pleased to announce that my article on the COVID-19 Vaccine was published in Lioness Magazine. To read my article click on the link [here](#).

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The Battle of the Oral Obesity Drug and Who Will be First

Source: liveinfitness.com

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- All-causes of death (mortality).
- High blood pressure (hypertension).
- High LDL cholesterol, low HDL cholesterol, or high levels of triglycerides (dyslipidemia).
- Type 2 diabetes.
- Coronary heart disease.
- Stroke.
- Gallbladder disease.
- Osteoarthritis (a breakdown of cartilage and bone within a joint).
- Sleep apnea and breathing problems.
- [Many types of cancer.](#)
- Low quality of life.
- Mental illness such as clinical depression, anxiety, and other mental disorders
- Body pain and difficulty with physical functioning

Obesity

EFFECTS ON THE BODY

Metabolic Syndrome Risk Factors



Type 2 diabetes.



Cardiovascular diseases.



Fatty liver disease.



Kidney disease.



Gallstones.

Direct Effects



Asthma.



Sleep apnea.



Obesity hypoventilation syndrome.



Osteoarthritis.



Back pain.



Gout.

Source: clevelandclinic.org

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Control and Prevention ([CDC](#)). The effects of obesity are numerous increasing metabolic risk for diseases and direct effects on the body. See diagram above.

There are a number of Big pharmaceutical companies that are in race to bring out the first oral obesity drug with better efficacy. It's "The battle of the oral obesity drugs" as to which company will get FDA approval for an oral drug that is better than what is currently on or will be on the market. There are five companies that we know of in the competition: Pfizer, Eli Lilly, Novartis, Boehringer Ingelheim and Novo Nordisk and here are the highlights.

1. [Boehringer's](#)/Zealand phase 2 data showed nearly 19% weight loss for survodutide, aka known as BI 456906. 6/26/23.
2. [Eli Lilly](#) data showed their once daily GLP-1 receptor agonist orforglipron achieved a 14.7% weight loss at 36 weeks. 6/26/23
3. [Pfizer](#) drops oral obesity drug after seeing liver safety concern, focuses on less-convenient, dosed twice as often candidate. 6/26/23
4. [Eli Lilly](#) is bolstering its obesity pipeline with the acquisition of Versanis and lead asset bimagrumab for a \$1.92 billion deal. 7/14/23
5. [Novartis](#) axes secretive obesity program after MBL949 high-risk, high-reward bet with a "unique mechanism of action" fails in phase 2 due to lackluster efficacy. 7/18/23
6. [Novo Nordisk, Eli Lilly and Boehringer Ingelheim](#) back bill to bring obesity drug coverage to Medicare. Under current laws, Medicare who creates a reimbursement code for all other insurances to use is barred from covering obesity drugs. 7/20/23
 - Sens. Bill Cassidy, M.D., R-Louisiana, and Tom Carper, D-Delaware, plus Reps. Brad Wenstrup, R-Ohio, and Raul Ruiz, D-California, have proposed the Treat and Reduce Obesity Act, which would step up the government's fight against the obesity epidemic.
 - As the lawmakers note, many common conditions such as heart disease and diabetes are associated with obesity. They say the bill would "work to directly prevent these comorbidities through expanded coverage of new health care specialists and chronic weight management medications for Medicare recipients."
 - "There is a clear need to address obesity," Cassidy said in a Thursday statement. "Expanding Medicare coverage to the treatments patients need enables them to improve their health and benefits us all."
1. [Novo Nordisk](#) is strengthening its position in the exploding obesity market, by agreeing to buy Canadian biotech Inversago Pharma, who is focusing on drugs that block the cannabinoid CB1 receptor for \$1.1 billion. 8/10/23
2. [Novo Nordisk](#), Denmark, show that a weekly dose of Wegovy (semaglutide) slashed the risk of severe cardiovascular events by 20% in adults with heart disease and either overweight or obesity. The results are the first to suggest that semaglutide

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3. [Phenomix Sciences](#), an obesity phenotyping startup is taking a personalized approach to identifying obesity. "...85% of patients have fundamentally four different subtypes or phenotypes of obesity." said CEO Mark Bagnall.

There will be a lot more information to come regarding the progress of the FDA approval process for these pharma companies as well as getting coverage for the drug. Without insurance coverage, majority of patients would not be able to afford the drug and therefore, no market access.

The Product Development process in developing a drug/biologic and getting it approved by the FDA can be very challenging and laborious. Getting the drug/biologic reimbursed by Medicare and the rest of the insurance companies can also be very challenging as mentioned here where Medicare is barred from covering obesity drugs.

Even if Medicare isn't barred from covering obesity drugs, whether Medicare will cover the drug can still be challenging. Once Medicare creates a code for reimbursement, the rest of the insurance companies will also use that code for reimbursement. What can be done? Read on in my closing thoughts to see how you can de-risk the product development process and beyond.



Closing Thoughts

[De-risking the product development process and beyond](#)

To de-risk this process, it's important to incorporate the business/marketing aspects of selling your drug/biologic early in product development. This starts with the Target Product Profile (TPP):

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life that contributes to how often a patient has to take the drug to work and the list goes on.

Marketing sets the metrics to these parameters to be able to compete in the market and be better. Why would a physician use a product that is not better than what is currently on the market? For example in the obesity market, the better product is an oral medication since people don't like receiving shots or getting IV infusion. This all has to do with compliance, what is easy for the patient. If it is not easy for the patient, the likelihood of the patient taking the medication is significantly lower. Even with a once/day drug, compliance goes down about 50% after the first year. But it is not as simple as how often one has to take it, it's the whole treatment regimen.

A drug can have the best efficacy, but if the patient is not taking it correctly, then the drug won't work or won't work as well. All the physician is going to remember is that the drug didn't work. This is why the marketing TPP is so important and needs to be incorporated early in product development. It's a lot harder to change the TPP the further you are progressing down the product development process since a company has to file with the FDA to prove that the new molecule formulation works even if you proved it with the previous formulation. Even a simple thing as changing vendors has to be filed with the FDA.

The second things that companies need to consider is the reimbursement piece as the first thing the insurance company will ask is why should I pay for your drug? And show me the data to support it. This means a company has to collect data during their clinical trials and incorporate their corresponding end points in the clinical trial design. If a drug company doesn't do this, the insurance company will tell them to come back when they have this data.

There are a number of other important aspects that need to consider during the product development process but is beyond the length of this newsletter. If you would like to discuss it further, you can email me at regina@biomarketinginsight.com to set up a time to chat.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and

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