Past Issues

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Novembber 15th, 2022

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month I talked about the industry's determination to find a treatment for NASH, a nonalcoholic fatty liver disease in which fat builds up in the liver of people who drink little or no alcohol. It can affect young, healthy people with no other comorbidities, leaving scientists and doctors bewildered as to why some livers gradually fail.

In this month's newsletter I will cover "How Our Gut Microbiome Is Link to Liver Conditions in People Who Don't Drink Excessive Amounts of Alcohol?". You can find my article under the Table of Content and click on the link.

If you missed last month newsletter on "Another Crack at NASH and How is the Liver

Past Issues

Translate ▼

If you need a little inspiration or something to make us laugh to get us through this difficult time, click on the "Inspiration" link to give yourself a few minutes to relax and enjoy the music from the Berklee School of Music in their song "What the World Needs Now," other inspirations 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 December 15, 2022

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.

Wishing everyone a Happy Thanksgiving! Have an extra helping of turkey/ham, stuffing and pumpkin pie for me.

Please email me, Regina Au, if you have any questions, comments, or suggestions.



Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
BioMarketing Insight





11/15/22, 3:00 PM

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Past Issues

Translate ▼

Table of Contents

Developing a Product? Commercializing a Product?

See Photos of the AAPI Heritage Festival - May 7th, 2022

General Guidelines to Launch and Build a Clinical Trial Using Microbiome

Products in an Era of Personalized Medicine

Fresh Thinking in the Next Normal

<u>Inspirations</u>

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

How is Our Gut Microbiome Link to Liver Conditions in People Who Don't Drink

Excessive Amounts of Alcohol?

Closing Thoughts

Previous Newsletters

Join my mailing list



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 <u>me</u> for an appointment. For successful commercial adoption of your product or looking to grow your business, contact <u>me</u> for an appointment.

Past Issues

Translate *

Product Development

Market Development

Marketing Strategies

Scenario Planning - for more information, email me.

<u>Top</u>



See Photos of the AAPI Heritage Festival - Saturday, May 7th, 2022

Asian American Pacific Islander (AAPI) Heritage month is a celebration of a diverse group of ethnic heritage within the Asian community who bring a wealth of enriched culture to our society. This celebration will endeavor to build awareness and educate our community on the various cultures and contributions these different Asian ethnic groups have brought to enrich our American Story.

History you may not know:

- 20,000 Chinese men served in the military during WWII where 40% of the men served without American citizenship due to the "Chinese Exclusion Act". They were later honored in September 2021 with the Congressional Gold Medal for their acts of patriotism, loyalty, and courage for the US.
- 110,000 Japanese American and Japanese were relocated to prison camps during the bombing of Pearl Harbor in 1941. In 1943, Japanese Americans were finally

Past Issues

Translate ▼

2010.

Theme: Contributions Asian American Pacific Islands Have Made to American History

A walk-through exhibit highlighting the contributions AAPI have made to American History was on display.

The Festival was a huge success with a full agenda of speakers, including State Senator Cindy Friedman and fireside chats with <u>Shirley Leung</u> from The Boston Globe. We also had a full agenda of performers throughout the festival. We had <u>Tibetan dancers</u>, <u>Cambodian dancer</u>, <u>Japanese dancers</u>, <u>Lion dance</u>, Kung Fu demonstration and many <u>solo performers</u> playing traditional ethnic instruments. Click <u>here</u> for the full agenda.

In addition, we had exhibitors from the various ethnic groups displaying items representing their history and culture that complemented the contributions that AAPI have made to American History.

This is AAPI Heritage month, be sure to enjoy all the activities in your area celebrating the diverse group of ethnic heritage within the AAPI community who bring a wealth of enriched culture to our society and American History. It may surprise you the tremendous amount of people who have contributed to our society and American History.

I would like to leave you with this **one thought** "while everyone is unique in their own way, it is important to celebrate our differences and our commonalities. Every person has a vital contribution to make to society - all races, all ethnicities, all religions and all genders together form one human race.

<u>Top</u>



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

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For more information on Westchester Biotech Project and future webinars, click here.

<u>Top</u>





Fresh Thinking in the Next Normal

I am pleased to announce that I was a speaker at the Institute of Management Consultants event on "What Will the "Next Normal" Be for Productivity, Motivation and Retention of Employees? Four Things Employers Need to Consider." on July 20th, 2021 at 2 pm. For more information and to register click here.

<u>Top</u>

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Inspirations

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



We Will Get Through It Together

Past Issues

Translate ▼



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

<u>Top</u>



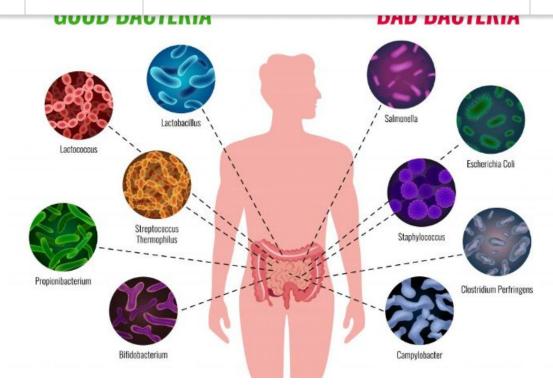
One Biotech Executive's View on the COVID-19 Vaccine

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.

<u>Top</u>

Past Issues

Translate ▼



How is Our Gut Microbiome Link to Liver Conditions in People Who Don't Drink Excessive Amounts of Alcohol?

Source:SupplementfactoryUK.com

Nonalcoholic fatty liver disease (NAFLD) describes a liver condition in which fat builds up in the liver of people who drink little or no alcohol. It can affect young, healthy people with no other comorbidities, leaving scientists and doctors stumped as to why some livers gradually fail. So how is our gut microbiome link to liver conditions in people who don't drink excessive amounts of alcohol?

Microbes can act as producers or catalysts for the production of food ingredients, enzymes, proteins, vitamins, organic acids, antibiotics and nutraceuticals. At the same time, as microbes digest food, they also secrete byproducts that can be helpful and others aren't. But some bacteria produce ethanol as they break down sugars, and a previous study in humans and mice linked ethanol-producing bacteria—namely *Klebsiella pneumoniae*—and fatty liver disease. It appears in some patients, the commensal relationship between bacteria and host become disrupted, also known as dysbiosis. The study goes further, providing a potential mechanism for how ethanol-producing bacteria in the gut can evade diagnostic testing, stealthily dumping ethanol into the gut and wreaking havoc on the liver.

A recent <u>study</u> published in Nature Medicine provides clues as to a potential cause: the bacteria dwelling in our guts.

Past Issues

Translate ▼

who was not involved in the study.

Abraham Stijn Meijnikman, a gastroenterologist at the University of Amsterdam, and a team of researchers were studying how to improve outcomes and recovery for people undergoing bariatric surgery. Meijnikman became interested in the association between nonalcoholic fatty liver disease and gut flora.

Meijnikman said one of the first people to tie the gut to ethanol production in the gut was <u>Hans Krebs</u>, the Nobel Prize—winning physician of Krebs cycle fame. Back in 1970, Krebs established that the portal vein typically has a higher ethanol concentration than the peripheral veins, the association between ethanol-producing microbes and liver disease didn't come until later.

Meijnikman and his team compared the ethanol concentration of the blood entering and leaving the liver in patients with nonalcoholic fatty liver disease (NAFLD) who were undergoing bariatric surgery. The researchers measured the amount of ethanol in the peripheral blood of 146 patients with NAFLD fasting and after a meal and compared their findings with a cohort of 51 age-matched healthy patients. In a subset of 37 patients with NAFLD, the team also measured ethanol in blood sampled from the portal vein during surgery.

In some patients, it appears, the commensal relationship between bacteria and host goes awry. In this smaller patient subset, the amount of ethanol in the portal vein was 187 millimoles higher on average compared to the peripheral blood in the group overall. This ethanol had then been cleaned out by the liver, leaving little trace of it for researchers to find in the peripheral blood.

The researchers also found a correlation between higher blood ethanol concentration in the peripheral blood and disease severity.

Meijnikman discovered causal evidence of the bacteria's role in a subsequent experiment. The researchers infused 10 individuals with NAFLD and 10 overweight but otherwise healthy controls with selective alcohol dehydrogenase (ADH) inhibitors, an enzyme that the liver uses to break down alcohol before a meal. As the researchers expected, this intervention increased patients' blood ethanol concentration 15-fold compared to patients that had not received ADH. "There was one patient who even appeared to be a little bit intoxicated," says Meijnikman. This told the researchers that normally, the liver cleans ethanol-rich blood coming from the gut before it reaches the peripheral blood.

To confirm the bacteria was responsible they disrupted the ethanol production in the gut. When the patients received a broad-spectrum antibiotic before they received an ADH

Past Issues

Translate ▼

The researchers then sequenced the gut flora of the individuals from the first experiment and their healthy counterparts, searching for ethanol-producing bacteria. They found one likely candidate, *Lactobacillaceae*, a bacteria that produces lactic acid as well as ethanol, which was associated with NAFLD. Its presence correlated with high peripheral blood ethanol after a meal, indicating that it might be at least partly responsible for ethanol production.

Meijnikman said *Lactobacillacea is probably not the* only bacterium associated with NAFLD —other bacteria may be the predominant ethanol producers in other individuals or populations. He explains that the previous study that associated *Klebsiella* with NAFLD was performed on a Chinese cohort, while the new study enrolled mostly white European participants, which may account for the disparate results.

Meijnikman said it's still unknown whether the gut microbiota is the initial cause of NAFLD and further studies are needed. He also stressed that not all patients in the study had higher-than-average concentrations of ethanol in their portal veins after a meal, suggesting that microbes may only be to blame for disease progression in some patients. "We should not go with a 'one-size-fits-all' treatment," he said.

Top



Closing Thoughts

Our microbiome seems to play an important role in our health and developing diseases.

Past Issues

Translate ▼

with identical twins, their microbiome are different, so why should it be any different for diseases? This is confirmed by the two studies covered here that linked gut microbes to *Klebsiella pneumoniae* for Chinese cohorts and *Lactobacillacea* for European coherts. As the industry have realized and what Dr. Meijnikman was quoted in saying "We should not go with a 'one-size-fits-all'".

<u>Top</u>

Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.

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