February 15, 2026

Dear Regina,

Welcome to the 2026 BioMarketing Insight's monthly newsletter.

The New Year started off fine, then I was hit by the Bitlocker Recovery Key Disaster for Microsoft Windows 11. For those who've already encountered this problem, you are probably rolling your eyes. For those who have never heard about it, buyer **BEWARE**. This is why my newsletter is a little late this month.

Bitlocker is an an encryption program on your hard drive that Microsoft automatically installed and enabled on your Windows 11 computer that is suppose to prevent anyone from stealing your information should your computer get stolen or someone has access to your computer. What they **DON'T** tell you is that it's installed on your computer and that you **MUST** create a Bitlocker Recovery Key should that happen.

keyboard that will trigger the lock down of your computer. I could be anything. You'll get that dreaded Blue screen asking for your Recovery Key, but it is very confusing as to what they want.

Your Recover Key contains thirty three (33) numbers to gain access to your computer. If you don't have the key which I didn't since I didn't even know about it, the Microsoft (MS) tech support will tell you that you have to reinstall Windows 11 which wipes out all of your files, photos, programs, settings etc. It is basically a factory reset. You have to start from scratch. You do not have the option of reinstalling Windows and keeping your files because Bitlocker thinks your computer is stolen. MS will tell you to go to a local computer tech to get your files off of the hard drive, reinstall windows 11 and transfer your files back to your computer. I found out that you can't get your files off the hard drive because it is encrypted and you still need the key. Similar to it being stolen. The only way you can get your files is if you backed it up in the cloud. If you didn't you are out of luck. But you still have to reinstall all of your programs, apps and input your settings again. MIcrosoft ratting: zero (0).

I nearly had a heart attack when I heard this. I also called HP and they were no help. They said the same thing as the MS tech. Luckily, I went back to the tech shop that helped set up my new computer and transfer my data from old hard drive on to my new computer and they had the recovery key since they set up my computer.

To prevent all this aggravation, you can either create a recovery key or turn off the Device Encryption under Privacy and Security. The computer tech suggested that if I am not traveling with a laptop, such as for a business, then I really don't need BitLocker to be enabled.

This month I will be covering "New Theories in Understanding Alzheimer's Disease". To read this article, just go to the Table of Content and click on the link.

If you missed the newsletter on "Why it Took Decades to Develop the First Hormone-Free Male Birth Control Pill", click on this link.

The next newsletter will be March 15, 2026.

2025 was a year of uncertainty and chaos. Here is to 2026 being a year of calm and positive certainty. But if you need a little inspiration or something to make us laugh to get us through this time of uncertainty, 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," and ending with Celine Dion and Josh Groban with "The Prayer".

Should you or your colleagues want to join my mailing list, click on "join my email list" link below.

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

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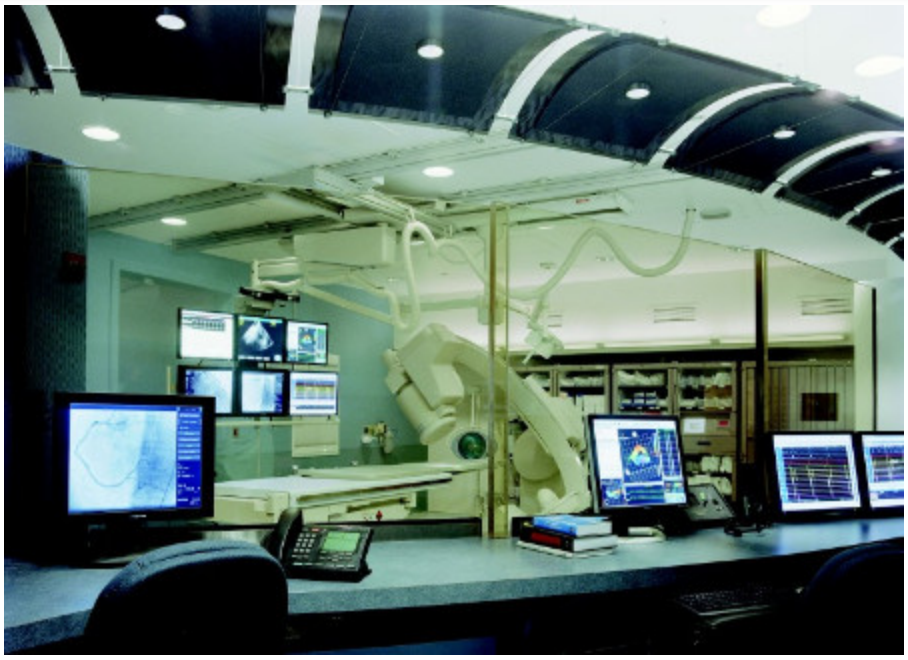
Join my mailing list



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 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.

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Recap: September 15-18, 2025
BioProcess International, Boston

I am pleased to announce that I spoke at the BioProcess International Conference on September 17th, 2025. The title of my presentation is "Creating a Winning Target Product Profile: A Roadmap for Successful Biopharmaceutical Development". For more information on my presentation, click here. For more information on the agenda and other speakers, click here.

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I am pleased to announce that I was be a Key Note Speaker and a Scientific Committee Member at the IVC 2025 Conference in Orlando, FL, October 23 - 25, 2025. The title of my presentation is "The importance of post-marketing surveillance and real-world data: For a product to be successful". Information on Scientific Committee members, click here. For more information on the conference, 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.

Even with the current uncertainty of our country, we will get through it. Keep voicing your opinion on what is right, what is wrong and the needs of the people. This is the only way things will change.

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

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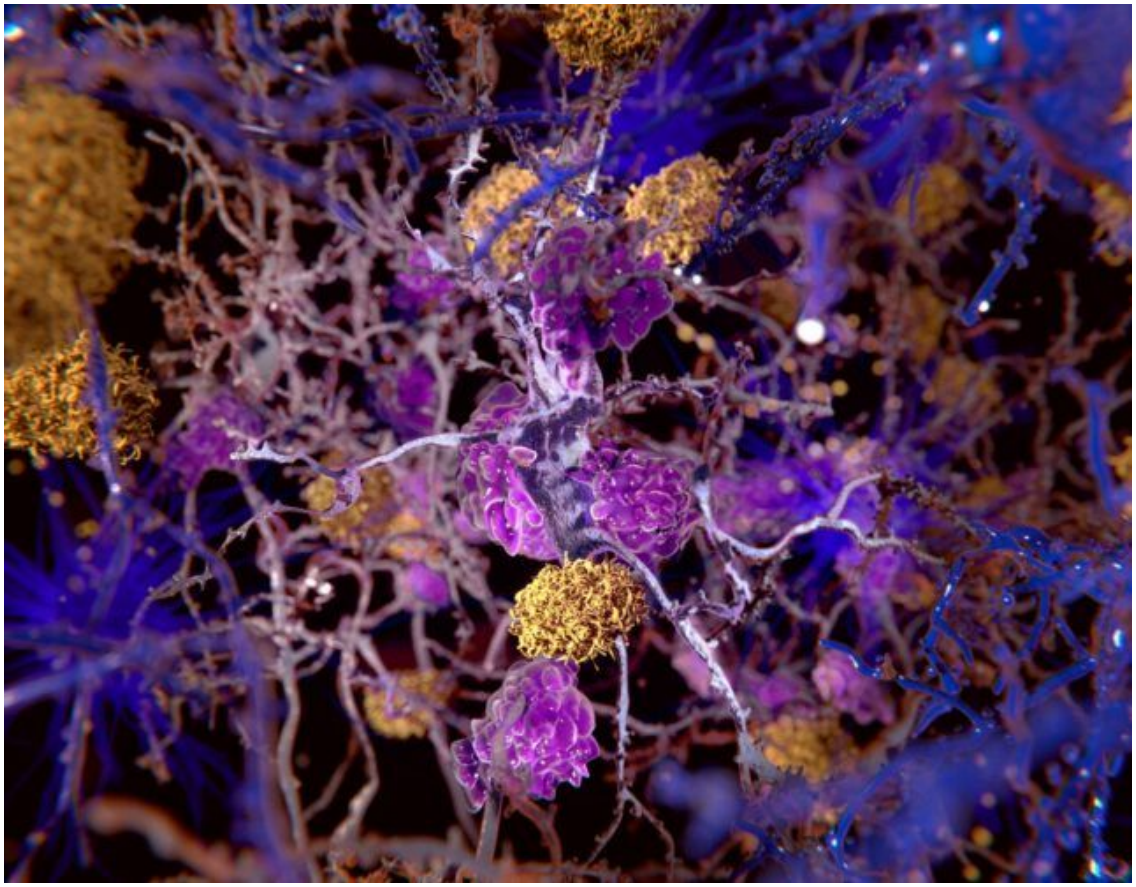

New Theories in Understanding Alzheimer's Disease

Someone in the world develops dementia every 3 seconds. There are over 55 million people worldwide living with dementia in 2020. This number will almost double every 20 years, reaching 78 million in 2030 and 139 million in 2050. Much of the increase will be in developing countries, low and middle income and will increase from 60% to 71% by 2050.

Research shows that most people currently living with dementia were not formally diagnosed. In high income countries, only 20-50% of dementia cases are recognized and documented in primary care. This 'treatment gap' is certainly greater in low and middle income countries, with one study in India suggesting 90% remain undiagnosed.

The total estimated worldwide cost of dementia was US$ 818 billion in 2015, which represented 1.09% of global GDP at that time. The annual global cost of dementia is now above **US$ 1.3 trillion** and is expected to rise to **US$ 2.8 trillion** by 2030.

An estimated 6.7 million older adults have Alzheimer's disease (AD), a form of dementia and the most common type, 60%-80% of dementia cases in the United States. That number is expected to double by 2060.

Though dementia mostly affects older adults, it is not a part of normal aging according to the CDC. This makes it difficult to identify who will develop AD, yet more and more people are developing dementia as noted above

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AD is such a complex disease that scientists have spent decades trying to understand the etiology of AD and they still don't fully understand it. Most of the research has been focused on preventing beta amyloid plaque in slowing or haltering the progression of AD. Unfortunately, till today, it has not proven to be true as some people have gone on to have AD even with the prevention or reduction of beta amyloid and those that have beta amyloid do not progress on to develop AD.

1) Alzheimer's as an Autoimmune Disease

AD has always been considered a disease that specifically affects the brain, the control center of your body. However, researchers at the the Krembil Brain Institute, part of the University Health Network in Toronto, believe that Alzheimer's is principally a disorder of the immune system within the brain

The immune system, found in every organ in the body, is a collection of cells and molecules that work in harmony to help repair injuries and protect from foreign invaders.

When a person trips and falls, the immune system helps to mend the damaged tissues.

immune system is there to fight back.

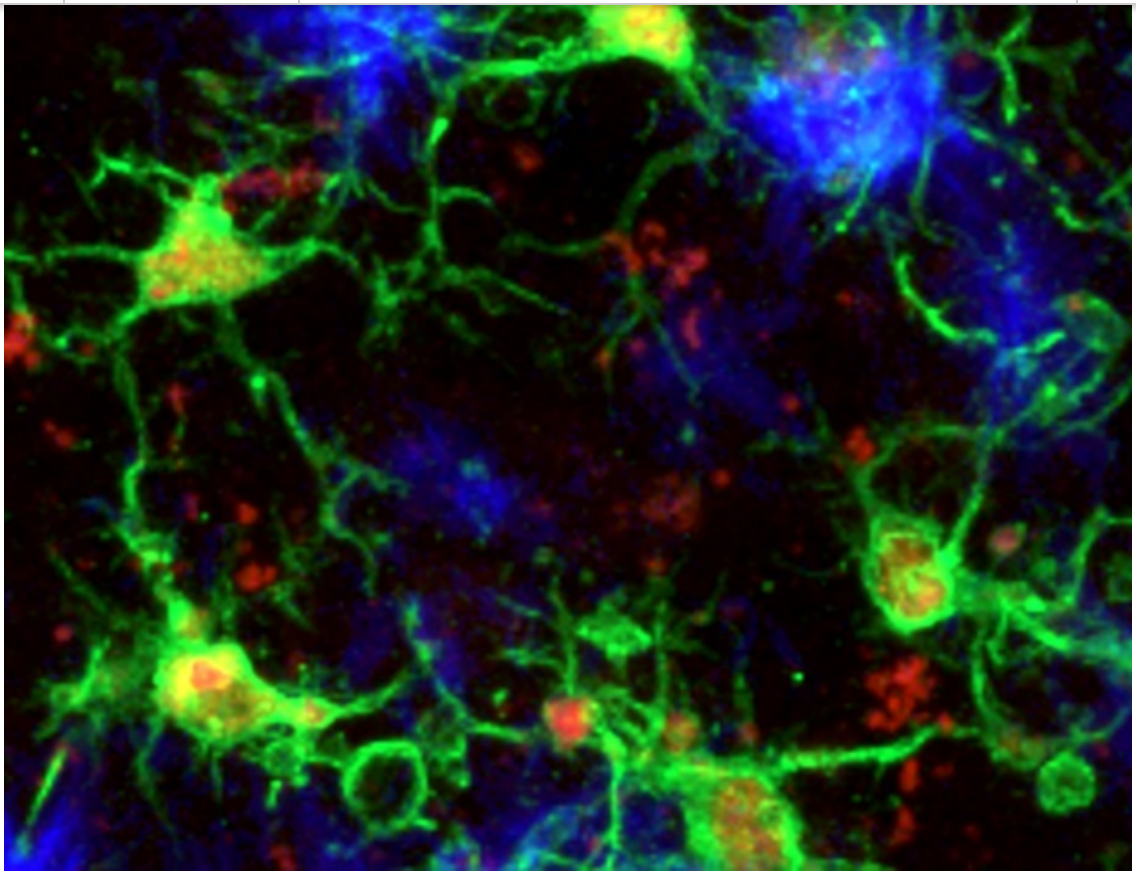
Donald Weaver, Professor of Chemistry and Director of Krembil Research Institute, believes that beta-amyloid is not an abnormal protein that is produced but rather a molecule that is produced and part of the brain's immune system. It is supposed to be there.
When brain trauma occurs or when bacteria is present in the brain, beta-amyloid is a key contributor to the brain's comprehensive immune response. And this is where the problem begins.

Because of striking similarities between the fat molecules that make up both the membranes of bacteria and the membranes of brain cells, beta-amyloid cannot tell the difference between invading bacteria and host brain cells and mistakenly attacks the very brain cells it is supposed to be protect.

This leads to a chronic, progressive loss of brain cell function, which ultimately culminates in dementia – all because the body's immune system cannot differentiate between bacteria and brain cells.

In their model of Alzheimer's, beta-amyloid helps to protect and bolster our immune system, but unfortunately, it also plays a central role in the autoimmune process that, they believe, may lead to the development of Alzheimer's.

Although conventional drugs used to treat other autoimmune diseases may not work against Alzheimer's, they strongly believe that targeting other immune-regulating pathways in the brain will lead to new and effective treatment approaches for the disease.



Microglia (green) responding to amyloid-beta plaques (blue) in the mouse brain. (Ayata et al., *Nature*, 2025)

2) Immune Cells, Microglia

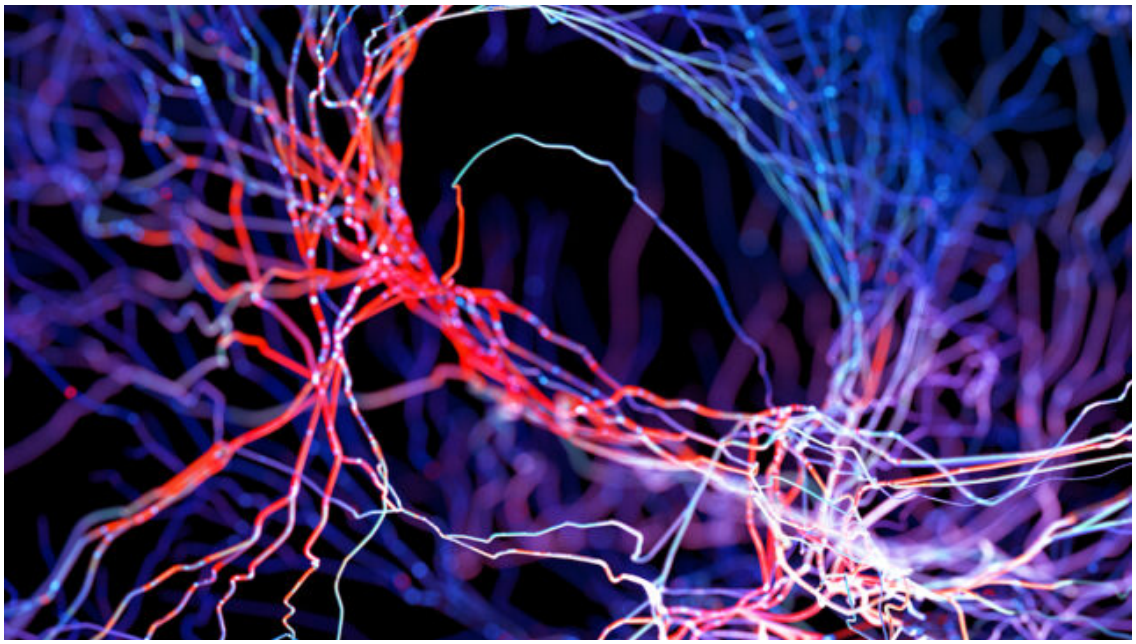
Microglia, immune cells in the brain may play a crucial role in preventing the onset of Alzheimer's disease, according to a new study – a discovery that coax cells into this protective state. They can effectively tackle the symptoms of Alzheimer's, but also make them worse through inflammation.

Pinar Ayata, neuroscientist at Icahn School of Medicine and her team found that when microglia get close to the amyloid-beta protein clumps, a tell-tale sign of the disease, they enter a special state of neuroprotection.

"Microglia are not simply destructive responders in Alzheimer's disease – they can become the brain's protectors," says neuroscientist Anne Schaefer, from the Icahn School of Medicine in New York.

"This finding extends our earlier observations on the remarkable plasticity of microglia states and their important roles in diverse brain functions."

of a protein called CD28, a crucial participant in the wider immune system.
Microglia with this combination were better able to slow down the build-up of amyloid-beta protein clumps in mouse brains, while also limiting aggregations of tau – another potentially toxic protein associated with Alzheimer's.



Sticky protein clumps damage neurons in diseases such as Alzheimer's. (Andriy Onufriyenko/Getty Images)

3) Looking at Spermine

Researchers at the Paul Scherrer Institute (PSI) in Switzerland found that extra spermine given to worms with Alzheimer's and Parkinson's-like symptoms showed improved health in old age, with cells less likely to lose power and wear out.

We all know that Spermine is involved with the body's metabolism, converting food into energy, and keeping all the key biological functions running. Spermine has the potential to stop the toxic build-up of proteins in the brain that characterizes diseases like Alzheimer's and Parkinson's.

A close analysis of cells in test tubes showed that spermine encourages tau and alpha-synuclein proteins, typically misbehaving in Alzheimer's and Parkinson's, to condense together into liquid-like droplets making it easier for the body's waste recycling system, known as autophagy, to clear it out, maintaining normal cell function.

When Tau and alpha-synuclein proteins malfunction, they can form hard, sticky aggregates that go on to damage brain cells in neurodegenerative diseases

Parkinson's, but they're definitely involved.
The researchers showed that spermine only interferes with tau and alpha-synuclein when they're at too high a concentration, and are more likely to misfold under stress, leading to toxic clumps.

4) What Does Cancer Have to Do With it?

For decades, researchers have noted that cancer and Alzheimer's disease are rarely found in the same person, fueling speculation that one condition might offer some degree of protection from the other.

Now, a mice study provides a possible molecular solution to the medical mystery: cystatin C, a protein produced by cancer cells seems to infiltrate the brain, where it helps to break apart clumps of misfolded proteins that are often associated with Alzheimer's disease. A mystery that took 15 years to identify.

These new theories are in their infancy and require more research to validate the theory and then move from animal studies to human studies.

5) What can we do?

But in the meantime, there are things that can be done to help prevent dementia. The Lancet Commission on Dementia Prevention, Intervention and Care noted that reducing age-related incidence of dementia could prevent up to 35% of dementia cases. Based on results from large cohort studies in high-income countries and using population attributable risk, the commission identified modifying nine risk factors: low education, midlife hearing loss, obesity, hypertension, late-life depression, smoking, physical inactivity, diabetes, and social isolation. In this life-style conceptual framework, modifications of risk factors can influence dementia decades before clinical disease onset.

However, large randomized controlled trials (RCT, > 250 participants per arm, minimum of 6 months follow-up), primarily set to prevent dementia using lifestyle interventions have shown modest or negative results. The 2017 National Academy of Medicine report concluded that the current evidence is limited and there are no specific interventions to warrant a public health recommendation for dementia prevention. More studies are needed to validate this theory.

While these nine risk factors are sound in science, it's not easy for the general public to monitor and manage all these risk factors, especially when prevention efforts need to start decades before symptoms appear.

model that is simple and memorable – something the public can easily embrace, understand, and follow.

The acronym **SHIELD** (Sleep, Head Injury prevention, Exercise, Learning, and Diet) may fill that role. SHIELD brings together the most significant, overlapping dementia risk factors into five core pillars, offering a clear and effective strategy for prevention. For more information on SHIELD, click on link.

Sleep

Sleep is a foundational element of SHIELD. Maintaining healthy sleep habits is a key protective factor against dementia. Adequate sleep supports brain function, memory, mood, and learning.

Insufficient (less than five hours per night) or poor-quality sleep (frequent awakenings), especially in midlife, increases the risk of cognitive decline and dementia. Chronic poor sleep leads to a build-up in the brain of amyloid-beta protein, which is implicated in the development of AD.

Head injury

Head injury prevention is, rather surprisingly, often overlooked in conversations about dementia. There are strong links between traumatic brain injuries, including concussions, and higher AD risk.

Such head injuries can occur in a wide variety of settings, not just professional sports. Intimate partner violence, for example, is unfortunately common in our society and is a frequent, but neglected, cause of head trauma.

Exercise

Regular movement, even in small amounts, enables better brain aging. Exercise is perhaps the most powerful lifestyle habit for reducing the risk of AD. Exercise directly addresses multiple major risk factors, including obesity, high blood pressure, high cholesterol, and depression. It also supports the growth of brain cells, memory and emotional health.

Learning

Learning, both in and out of school, remains one of the strongest protective factors against dementia. Lower educational levels, such as not finishing secondary school, are linked to a significantly increased risk for dementia.

Learning contributes to the brain's "cognitive reserve," which is the brain's ability to function

Diet

No single food prevents dementia. Rather, a combination of nutrient-rich foods supports overall brain health. A healthy diet can lower dementia risk by emphasizing whole foods like fruits, vegetables, whole grains, nuts, and fish, like a Mediterranean diet while restricting processed foods, red meat, and sweets. The Mediterranean diet has been linked with a decrease in Alzheimer's disease.

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Closing Thoughts

Of all the diseases that scientists have extensively studied, dementia or AD is the least understood. It's the most complicated organ of all organs as it is the control center of the body. So why would we think it would be simple to find a treatment? All past studies have focused on one thing, reducing or preventing beta amyloid which did not proved to be successful. Others have focused only on tau and that also proved to be unsuccessful. Why not beta amyloid and tau together? This is not a disease of aging nor a single mutation that can be corrected. So why aren't we looking at it with a wider lense?

I like the theory that dementia is not a brain disease but an immune response when it becomes unbalanced or injured similar to when dysbiosis occurs with our microbiome. Everything in a healthy body has a purpose. Before, junk DNA was thought to be useless until someone discovered that they regulate gene expression (turning genes on/off), control 3D genome architecture, assisting in chromosome structuring (satellite DNA), and facilitating cellular responses to the environment.

Beta amyloid protects the body from injury except when something happens which

The analogy that comes to mind is a full orchestra. One can make music with a single instrument or a five-piece orchestra. But to make great music, one needs a full orchestra and any elimination of any section or instrument makes the music less rich. A healthy body is like a full orchestra where all sections and instruments are needed to have great and rich music.

So, eliminating any section or instrument, affects the music from being rich and great. Perhaps tweaking the music by correcting a player that is off key or out of sync help to make the music great again. Similar to spermine which only interferes with tau and alpha-synuclein when they're at too high a concentration, and are more likely to misfold under stress, leading to toxic clumps.

But in the meantime, we can practice SHIELD which might prevent dementia. Worse case scenario, one is in better health.

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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 economic value of your product for reimbursement, feel free to contact me at 617-404-8826 or regina@biomarketinginsight.com.
