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December 15th, 2025

Dear Regina,

Welcome to 2025 BioMarketing Insight's monthly newsletter.

The December holidays (Pearl Harbor Remembrance Day, Hanukkah, Christmas Day, Kwanzaa and New Year's Eve) are here or just around the corner and I'm sure everyone is scrambling to get everything done so they can relax and be with family, friends and colleagues in celebrating their holiday. But no matter which holiday you are celebrating, the holidays is all about being present with the people you are connecting with and enjoying each others company.

Wishing you, your family and friends a wonderful Holiday! May the New Year usher in new beginnings, new opportunities, new friends, good fortune.

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Holidays are about creating
cherished memories with
loved ones and finding magic
in the simplest moments.

—
JEREMIAH SAY

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**“THE BEST AND
MOST BEAUTIFUL
THINGS IN THE
WORLD CANNOT BE
SEEN OR EVEN
TOUCHED. THEY
MUST BE FELT WITH
THE HEART.”
— HELEN KELLER**



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The best gift you can give
during the holidays is your
presence, love, and genuine
care for others. That is
priceless.

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If you missed the newsletter on "Making Sense of it All: DOGE, Government Shut Down, 100% Pharmaceutical Tariff, and the Impact it has on Everyone", click on this [link](#).

The next newsletter will be January 15, 2026. Happy New Year!

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".

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.

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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](#).

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BioProcess International

September 15 -18, 2025
Hynes Convention Center,
Boston, USA

Creating a Winning Target Product Profile: A Roadmap for Successful Biopharmaceutical Development

Use Code SPEAKER10 and Save 10%

Part of: **Biotech Week Boston**

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

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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HYBRID EVENT: You can participate in person at Orlando, Florida, USA or Virtually from your home or work.

IVC 2025 Home Scientific Committee Speakers Program Information About Contact Submit Abstract Register

5th Edition of International Vaccines Congress

October 23-25, 2025 | Orlando, Florida, USA

🔔 Tentative Program

🔔 First Round of Abstract Submissions Closes on May 29, 2025

🔔 Early Bird Registrations Closes on May 30, 2025

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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.

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

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Making Sense of it All: DOGE, Government Shut Down, 100% Pharmaceutical Tariff, and the Impact it has on Everyone

Republicans and Democrats are at an impasse over government funding and healthcare issues, launching the federal government into a partial shutdown. (Getty Images/Douglas Rissing)

In my [June 2025 newsletter](#), I wrote about Robert F. Kennedy, Jr. implementing the

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Now we are in a government shutdown, [day 13](#) as of this writing due to the Republican refusing to agree on a bipartisan continuation of government funding with the Trump Administration – the expiration of critical Affordable Care Act ([ACA](#)) tax credits that affect [24 million Americans](#) is set to lapse at the end of 2025. Democrats also want cuts to the [Medicaid program](#) for poor and disabled Americans reversed, funding to public media outlets such as PBS and NPR restored and Donald Trump's use of "pocket rescissions" to slash spending \$4.9bn in foreign aid. [Pocket rescission](#) when a president submits a request to Congress to not spend approved funds toward the end of the fiscal year, so that the legislature cannot act on the request in the 45-day timeframe and the money goes unspent as a result.

In addition, Trump announces "Starting October 1st, 2025, we will be imposing a 100% Tariff on any branded or patented Pharmaceutical Product, unless a Company IS BUILDING their Pharmaceutical Manufacturing Plant in America. 'IS BUILDING' will be defined as, breaking ground' and/or 'under construction'", posted on [Truth Social](#)

To understand the impact of all this, we need to understand the organization structure of Health Human Services ([HHS](#)).

- **Office of the Secretary:** The highest level of leadership - Robert F. Kennedy, Jr.
- Jim O'Neill Deputy Secretary
- Matt Buckham - Chief of Staff
- **Operating Divisions:** These are the major agencies that carry out HHS's core functions.
 - Centers for Disease Control and Prevention (CDC) - Jim O'Neill, Acting Director
 - National Institutes of Health (NIH) - Jay Bhattacharya, MD, PhD, Director
 - Centers for Medicare & Medicaid Services (CMS) - Mehmet Oz, MD, MBA, Administrator
 - Food and Drug Administration (FDA) - Martin A Makary, MD, MPH, Commissioner
 - Administration for Children and Families (ACF) - Andrew Gradison, Acting Assistant Secretary
 - Administration for Community Living (ACL) - Mary Lazare, Administrator

Department of Government Efficiency (DOGE)

When [DOGE](#) was implemented by Robert Kennedy Jr. these were the results:

1. The current 82,000 full-time employees will be reduced to 62,000 or 1 in 4 employees

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- NIH will decrease its workforce by approximately 1,200 employees
 - CMS will decrease its workforce by approximately 300 employees
2. 28 divisions will be consolidated to 15
 3. 10 regional offices will become 5.

This [initiative](#), which was supposed to create more efficiency, how I'm not sure because the number of personnel had decreased, but the workload stayed the same. This led to following:

1. Reduce funding by 44% for the Centers for Disease Control and Prevention (CDC),
2. Reduce funding by 40% for the National Institutes of Health (NIH), and
3. Reduce funding by 19% for the Food and Drug Administration (FDA).

In addition, Trump threatened to cut off or freeze NIH funding to universities that had either/or/and DEI programs, allegations of antisemitism and inclusion of transgender athlete. These are the [colleges and universities](#) (including the best universities), the list is too long and had funding either cancelled or frozen leading to hiring freezes, layoffs and rescinding letters to graduate students. This list does not include the medical research institutions which I'm sure will lead to layoffs as well.



The Government Shutdown

In the initial shutdown, approximately [4,200 federal workers were laid off](#) across seven federal departments: 315 workers in the Commerce Department; 466 in the Education Department; 187 in the Energy Department; between 1,100 and 1,200 in the Department of Health and Human Services; 442 in the Department of Housing and Urban Development; 176 in the Department Homeland Security; and 1,446 in the Treasury Department.

About [750,000 federal workers have been furloughed](#) during the shutdown. Trump has also threatened to block back pay of federal workers and to cut "Democrat programs" from the government if democrats don't agree to the budget.

As of [Oct. 11th](#), as the shutdown continues, layoff notices are being sent out to undisclosed

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[HHS](#) – 32,460 employees, or 41% furloughed and undisclosed number of layoff notices

[Treasury Department](#) – 35,880 employee or 46% were furloughed and 1,300 layoff notices

Began layoffs at the following: Department of Housing and Urban Development, Education Department, Commerce Department, Environmental Protection Agency, the Department of Energy and the Department of Interior, and Department of Homeland Security.

The Department of Transportation and the Federal Aviation Administration was not affected.

Trump has also ordered the [freezing of at least \\$28 billion in infrastructure funds](#) for New York, California and Illinois - all home to sizable populations of Democratic voters and critics of the administration.



Historically the world's largest funder of biomedical research, the National Institutes of Health's ability to support science has been significantly hampered since President Donald Trump started his second term. (NIH)

1) The [NIH](#) will retain 4,477, or 24.5%, of its staff during the shutdown, primarily to maintain operations at the NIH Clinical Center, which is a hospital run by the agency, according to the contingency plan. Other employees will stick around to care for lab animals or perform upkeep for infrastructure and facilities.

All basic research at the NIH will cease, as will all grant-making activities, including payments for ongoing external grants. No new clinical trials will be launched at the Clinical Center.

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NIH plan.

2) CDC - 4,891 (35.88%) of CDC and Agency for Toxic Substances and Disease Registry (ATSDR) staff will be retained, including 2,063 (15.13%) who are exempt (their activities or position are already funded or otherwise exempt) and 2,828 (20.74%) who are excepted (their activities are deemed necessary by implication, or for the safety of human life or protection of property). Of the 8,742 staff to be furloughed, approximately 1,563 are in reductions in force (RIF) status, effective dates of December 8, 2025.

According to the American Federation of Government Employees (AFGE), more than [1,300 CDC workers had received RIF notices](#), about 700 received another email rescinding that termination within 24 hours due to a coding error.

Only responses to urgent disease outbreaks and continuing efforts to support the President's Emergency Plan for AIDS Relief (PEPFAR), World Trade Center (WTC) Health Program, the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), and the Vaccines for Children (VFC) program will continue. All other activities will not continue.

3) FDA – On Oct. 6th, 2025, Foley Hoag held an event on Life Science Companies in a New Era where Atty Bryant Godfrey highlighted the following:

In 2025, the FDA employed approximately 20,000 people

1. Around 3,500 employees received reduction-in-force (RIF) notices around April 2025
2. Roughly 25% of the employees that received RIF notices rejoined the agency
3. Late July 2025, FDA Commissioner Makary indicated no further cuts are planned.

Food and drug facility inspection vacancies were deemed high in 2024 with plans to hire more inspectors in 2025. Foreign and Domestic Inspection trends are down from prior years.

Novel biologic approvals are down from February-September compared to trends in the last 5 years.

Direct to Consumer Advertising Scrutiny and Enforcement- 9/9/25: HHS and FDA announced an effort to “crack down” on deceptive advertising.

4) CMS - [CMS](#) retains 3,311 (53%) of its staff to continue essential operations, while 47% of agency staff are being furloughed (i.e., temporarily on unpaid leave). Medicare Program will continue. CMS has sufficient funding for Medicaid to fund the first quarter of FY 2026

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[CMS](#) is maintaining the staff necessary to make payments to eligible states for the Children's Health Insurance Program (CHIP). CMS is also continuing federal Marketplace activities, such as eligibility verification, using federal Marketplace user fee carryover. Other non-discretionary activities including Health Care Fraud and Abuse Control (HCFA) and Center for Medicare & Medicaid Innovation (CMMI) activities are also continuing. Everything else will slow down or be suspended.

To find out what other services are affected, click [here](#). F&Q for affected federal employees during shut down, click [here](#).



100% Pharmaceutical Tariffs

Brand-name drugs that millions of Americans rely on stand at the center of President Trump's plan.

Shutterstock / PeopleImages

When Trump announced, "a 100% Tariff on any branded or patented Pharmaceutical Product, unless a Company IS BUILDING their Pharmaceutical Manufacturing Plant in America.", he obviously didn't think about the consequences of this mandate similar to a dictatorship.

[John F. Crowley](#), President and CEO of the Biotechnology Innovation Organization (BIO) released the following statement that the immediate tariffs "would devastate our nation's small and mid-sized biotechnology companies. These 3,000+ companies are the heart and soul of America's vitally important biotechnology industry. Most of these companies do not

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majority of these small- to mid-size biotech innovators rely on contract manufacturers to produce their medicines.”

These tariffs would ultimately raise the cost of developing and manufacturing drugs which ultimately gets passed on to the consumer. In addition, smaller companies may not be able to raise more funding to offset the tariffs resulting in delaying or abandoning drugs programs. It is the small companies that are developing most of the innovative products and then get purchased by Big pharma/biotech.

Even if companies can afford to build manufacturing plants in the US, this means more FDA inspections. FDA has already been downsized significantly and there is already a high vacancy rate of inspectors and inspections are on a downward trend. How is the FDA going to handle the extra workload?

Read on for Making Sense of it All: Closing Thoughts.

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Making Sense of it All: Closing Thoughts

Congress was formed to represent and serve the People. This standoff between the Republicans and Democrats is not about representing the People, although the Democrats are in this case thinking about the people in wanting to extend the ACA that is expiring soon. The Republicans only care about retaining power and are imposing more threats so the Democrats will give in. But the only people who are hurt by all this are the People, not the Republicans.

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who can't afford healthcare under the ACA will end soon as well as funding for Medicare and Medicaid. This affects our economy.

Government funding to colleges and universities have been cancelled or frozen which has a ripple effect resulting in hiring freezes, layoffs, and graduate programs. This affects our economy.

Cancellation of foreign aid by Trump ultimately affects our economy due to our economy being a global economy.

The 100% pharmaceutical tariffs will raise drug prices, not decrease prices for the consumer. The industry is already going through a rough patch with downsizing, bankruptcy or closing their doors. The small to midsize companies cannot afford to take on more cost. In addition, the cuts in NIH funding have research institutions already laying off scientific researchers. This affects our economy.

Trump also wants pharma companies to offer lower price drugs and have it available on the [TrumpRx website](#), coming January 2026. It says "TrumpRx doesn't sell medications. Instead, it connects patients directly with the best prices, increasing transparency and cutting out costly third-party markups", implying the elimination of PBMs or Pharmacy Benefit Managers in the [executive order](#).

This website does not state how this program will work except to state that Secretary, Kennedy Jr. will be in charge and the other agencies under him. What does the Secretary of HHA know about pricing and negotiations in business when dealing with manufactures and insurance companies except for dictating what he wants? How are they going to increase transparency when there is no transparency, only dictatorship?

How we fix a broken healthcare system, no one know yet, but what we do know is that we are currently going down the wrong direction with this current administration.

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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.

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