AAiPS

Newsletter

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AMERICANASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS
P.O. Box 189 Mount Freedom, NJ 07970

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INSIDE THIS ISSUE

Newsletter Editor & Co-Editor: Raghu Kasu, Dinesh Nyavanandi
Editorial Board: Mike Yelvigi, Sampat Singhvi

PRESIDENT'S MESSAGE

Dear Members,

I ended my message in 2020 with a wish for a return to normalcy in 2021. Well, 2021 is here and we are experiencing a gradual return to normalcy thanks to the efforts of the Pharmaceutical Industry, and the creativity, innovation, and diligence of their scientists. We all should be product of this moonshot event in history.

Last year, we stayed in touch virtually via Zoom and AAIPS organized the first ever AAiPS Virtual Student Research Awards Showcase on Dec 10 where six awardees presented their research projects in short 8-10 min presentations via a Zoom meeting. This event was well planned out by the awards and program committee chairs and was greatly appreciated by those who attended the virtual showcase. There were requests to make it a permanent annual event.

COVID-19 virus and its variants will continue to dominate our lives and conversations around if and when we will be completely back to normal. The AAiPS Executive Committee has yet to decide about a face to face meeting in 2021 but we will continue to plan virtual meetings, arrange interesting talks, organize the graduate student's research awards and stay connected. I welcome your ideas and suggestions for 2021 and beyond.

In the interim stay well, stay safe!

Sincerely,

Rupa Doshi, Ph.D. President, AAiPS

QUOTE OF THE QUARTER

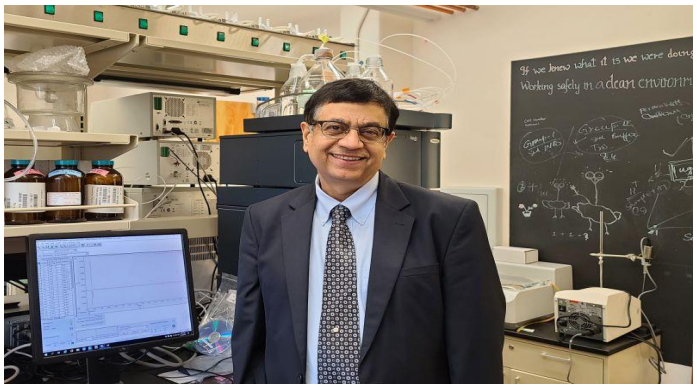
"Love challenges, be intrigued by mistakes, enjoy effort and keep on learning."

-Carol Dweck

AAiPS QUATERLEY WEBINAR UPDATE

On April 29th evening, AAiPS hosted a webinar on the topic "***Advances in Transdermal Delivery Systems: Basics".*** The speaker was, ***Dr. Ajay K. Banga, Chair, Dept of Pharmaceutical Sciences, College of Pharmacy, Mercer University, Atlanta, GA.***

Dr. Banga discussed various aspects of transdermal dosage forms development and its current status. He highlighted the advances made in developing "Microneedle dosage forms" for transdermal applications. The meeting was well attended and had lots of discussion on the topic.



AAiPS Executive Committee would like to thank their Students Awards Chair (Dr. Hardeep Saluja) & other Graduate Awards Committee 2020 members for their efforts in making this happen during this COVID times.

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Pharmaceutical News:

More expansion for Piramal as Indian CDMO gobbles up local peptide manufacturer for $105 M

Piramal Pharma, with ambitions to grow as a CDMO force, is spending (PDF) $105 million in a straight-cash buyout of Hemmo Pharmaceuticals.

This is a local deal for Piramal—which is based in Mumbai—but one that carries global implications. Hemmo, in business for 38 years, develops and manufactures synthetic peptide ingredients from its two main sites nearby. The company has a manufacturing site in suburban Turbhe that's certified by the U.S. Food and Drug Administration and several other international regulatory agencies.

Hemmo brings 250 employees and allows Piramal to gain access to the growing peptide active pharmaceutical ingredient market.

Up to 15M Johnson & Johnson coronavirus vaccine doses ruined due to human error: NYT

Johnson & Johnson's COVID-19 vaccine rollout has been slower than expected in the U.S., with just 6.8 million doses delivered to states in the first month. Now, The New York Times has revealed behind-the-scenes details into an unfortunate mix-up in the production process**.**

Workers at an Emergent BioSolutions plant in Baltimore mixed up vaccine ingredients weeks ago and ruined a large batch of the vaccine containing up to 15 million doses, the NYT reports. The FDA is investigating the mistake, but the episode has led to a temporary halt of future J&J shot deliveries from the site, according to the newspaper. In a statement, J&J said it is working with federal authorities to deliver 24 million doses of the vaccine in April.

The mistake happened early in the production process, so none of the doses made it out to distribution.

Federal investigators have ruled that the episode was the result of "human error," NYT reports.

Moving forward, J&J is moving to implement tighter controls at its manufacturing partner, the company's statement said. J&J and AstraZeneca, another leading COVID-19 vaccine player, tapped the contract manufacturer in their production ramp-up efforts last year. J&J has met its goal to ship 20 million doses to the U.S. government by the end of March, the company said in its statement. Centers for Disease Control and Prevention (CDC) data show that just 6.8 million doses have been delivered to states, and 3.3 million doses have been administered.

Moderna CEO Bancel snags close to $13M in 2020 pay, thanks to COVID-19 vaccine work

Moderna entered 2020 a clinical-stage biotech with messenger RNA on the brain. Now, the company is among the few with an authorized COVID-19 vaccine, and that swift ascent could land it among the top vaccine players by revenue this year, CEO Stéphane Bancel said in January.

And all that action helped bulk up Bancel's pocketbook. Bancel snared a pay package worth $12.85 million for 2020, up from $8.9 million in 2019, according to a proxy filing this month. The chief executive collected a salary of $950,000, a $1.9 million bonus, and stock options worth $9 million.

The total is far below what Bancel totted up for 2018, after the company's $604 million public offering. That year, the CEO's pay package amounted to $58.6 million, putting him at the top of Fierce Pharma's list of highest-paid biopharma CEOs that year.

Moderna's big success story last year was the development of its COVID-19 vaccine, now among a handful of shots rolling out in the U.S., Europe and beyond. The biotech was also the second vaccine player—after Pfizer and BioNTech—to bag U.S. authorization for an mRNA shot.

Before the pandemic, the technology had never been used in an approved product. Now, companies like Pfizer and Moderna are looking at the gene-based tech to advance vaccines against other diseases. And that's just one prominent example.

Pfizer launches COVID-19 vaccine test in children as new data support mRNA shots in pregnant women.

While COVID-19 shots have proven effective in clinical trials—and now in the real world, too—relatively little is known about how they work in children and pregnant women. Moderna, Pfizer and Johnson & Johnson aim to change that.

Just as data are showing mRNA shots work in pregnant women, Pfizer has started testing its shot in children aged 6 months to 11 years. That pediatric trial follows a similar move by Moderna earlier this month.

Pfizer and its partner BioNTech are running a Phase 1/2/3 dose-escalation study in three age groups—5 to 11, 2 to 5 and 6 months to 2 years. The companies may run a study in infants under 6 months "once an acceptable safety profile has been established."

Moderna, for its part, started a phase 2/3 study in children under 12 years of age earlier this month. That study will start first in older children, and once investigators determine the shot to be safe, they'll move to test the shot in younger children, Forbes reports.

Johnson & Johnson has said it's planning various studies in children and pregnant women, The New York Times reports.

Even as vaccines reach millions of Americans daily, vaccinating children is seen as a key step in reaching herd immunity to beat back the pandemic. During a recent Senate hearing, the Biden administration's chief medical adviser, Anthony Fauci, said the United States will need to vaccinate children to reach herd immunity.

Pfizer's vaccine is authorized for people 16 and older, while Moderna and Johnson & Johnson are authorized for people 18 and older.

Lawmakers are once again eyeing drug prices—and this time, the threat to pharma is real: analysts

With the $1.9 trillion American Rescue Plan in the books, congressional lawmakers and White House officials are turning their attention elsewhere. And that could be bad news for drug makers.

In fact, as the Biden team works through a new, $3 trillion package, lawmakers are looking at targeting drug prices as one component, The Washington Post reports. Under a potential proposal, drug makers would have to lower certain prices or pay penalties, according to the newspaper.

Lawmakers are looking at drug price savings as one way to pay for other measures included in the package, The New York Times says. Meanwhile, reports suggest Democrats plan to score savings on pharmaceuticals to help offset newly passed expansions to the Affordable Care Act.

“For the first time in many years the threat of material changes in drug pricing are likely,” Cowen analysts Rick Weissenstein and Eric Assaraf wrote to clients this week. “The drug lobby is in the unfamiliar position of playing defense.”

In a commentary on the drug pricing landscape, the Cowen analysts said they expected an “aggressive” bill to develop in the House of Representatives but that a “less onerous” bill would come out of the Senate. The process is complex, and there are numerous political considerations at play, they cautioned, noting the process would take months.

Under the reconciliation process, which Democrats will likely use for their bill, a key rule calls for spending to be offset by savings, the analysts wrote.

“It is this rule that makes it likely drug makers will be targeted for savings,” they added.

Novartis is shutting down Colorado plant, laying off 400 employees after overestimating gene therapy demand.

Just 14 months after opening an ambitious gene therapy manufacturing facility in Longmont, Colorado, Novartis is closing up shop there.

Novartis will close the plant, 35 miles north of Denver, by July 9 and lay off about 400 employees. The six-building, 692,000 square foot complex employed scientists, engineers, analysts and manufacturing and operations personnel.

The facility opened primarily to produce Zolgensma, Novartis’ gene therapy to treat newborns with spinal muscular atrophy. But the company's abrupt move to close the site is evidence that Novartis might have overestimated the demand.

Further, a spokesman said the company has made "process improvements" that will enable it to operate fewer gene therapy sites in the long run.

“At the time we acquired the Longmont facility, we anticipated that we would require all three sites to meet the needs of our business,” a company spokesman wrote in an email. “Based on the evolving dynamics of

the gene therapy landscape and progress we've made with process improvements, we now know that we can fulfill our long-term demand, including patients who may benefit from our next wave of gene therapies, with two commercial sites."

JPM: Viatris CEO trumpets 'disciplined' deal-making for post-merger road map

Now that Mylan and Pfizer's Upjohn established medicine business have officially combined to become Viatris, CEO Michael Goettler has laid out a growth road map for the new company which involves "disciplined" deal-making.

Viatris management will keep a close eye on "the discipline around capital investment opportunities" as the two companies integrate, Goettler said at the annual J.P. Morgan Healthcare event**.**

Goettler touted Viatris' commercial presence, manufacturing strength and global supply network, as well as its medical, regulatory and development capabilities, which are now offered to potential partners as a platform.

But right now, Viatris' near-term plan—which covers the next three to four years—is focused on stabilizing the business and investing in its own pipeline, he said.

That means cutting costs—an effort that'll involve chopping 20% of the combined businesses' 45,000-strong workforce. The aim is to save $1 billion annually by laying off workers and closing, downsizing, or selling up to 15 manufacturing facilities.

Meanwhile, Viatris plans to use its cash to pay down debt, pay out dividends and cover the roughly $1 billion to $1.3 billion in costs associated with layoffs.

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