FDA Clears Avastin

The FDA approved a combination of Avastin (bevacizumab) plus the chemotherapy agents carboplatin and paclitaxel, followed by Avastin alone for the treatment of patients with advanced ovarian cancer following the initial surgery. Avastin is manufactured by Genentech, a subsidiary of Roche Holding AG.

RX RETAIL PHARMACY

Camber's New Generic

Camber Pharmaceuticals has added sildenafil tablets to its growing portfolio of products. The new sildenafil tablets come in 25 mg and 100 mg and are available in 30- and 100-count bottles. It is the generic version of Viagra from Pfizer Inc., and it is used to treat erectile dysfunction in men.

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News

CVS Expands Disposal Program

CVS Health expanded its safe medication disposal program to 32 CVS Pharmacy locations in Virginia, supplementing the 64 units CVS donated to local law enforcement departments across the state. Virginia Attorney General Mark Herring and Chesterfield deputy chief of police, Lt. Col. Dan Kelly, attended the launch of the program at a Richmond CVS Pharmacy location.

Cardinal Donates

The Cardinal Health Foundation awarded over $3 million in grants to more than 70 nonprofit organizations to support local efforts to fight the opioid epidemic across West Virginia, Ohio, Kentucky and Tennessee.

PDX inventory tool

PDX has introduced its predictive inventory management solution called Turn Rx. Turn Rx provides an intuitive Web user interface that enables a pharmacy business to manage and track inventory at a store and corporate level. Turn Rx automates the daily order process and provides the option to create store-level, regional or chain-level rules on inventory replenishment. Turn Rx is said to be fully integrated with Enterprise Pharmacy System and has the flexibility to integrate with any wholesaler.

Roche buys shares

Roche is paying $2.4 billion to acquire the remaining shares of Foundation Medicine. Foundation Medicine is a Cambridge, Mass.-based company that specializes in personalized cancer treatments.

Treating UTIs

Urinary tract infections (UTIs) are one of the most common reasons people end up in the emergency room, but this could be prevented as Canadian pharmacists are allowed to treat the condition, according to a study published in the *Canadian Pharmacists Journal*. About 88.9% of patients who received care for a UTI from a pharmacist reported that their symptoms were resolved at a two-week follow-up.

Newsmakers

GSK Names New President of Vaccines

Roger Connor was named president of GlaxoSmithKline PLC's vaccines business, replacing Luc Debruyne, who is leaving at the end of 2018. Connor, who will assume the new position on September 1, is currently GSK's president of global manufacturing and supply.

Nick Hart (Lupin)

Lupin appointed Nick Hart as president of specialty for its U.S. business. Hart will lead the specialty strategic business unit in the United States and will be responsible for Lupin's specialty brand business growth strategy, P&L and organization. Hart brings over 25 years of specialty business, strategic and commercial operations experience to Lupin.

Kelly Smith (University of Georgia)

The University of Georgia named Kelly Smith, currently the college's associate dean for academic and student affairs, as dean. The promotion is effective August 1.

David Wheeler (Maxor)

Maxor National Pharmacy Services appointed David Wheeler as chief financial officer. Wheeler brings decades of executive leadership experience to Maxor, including more than 15 years of experience as CFO and a board member of other leading pharmacy benefit managers.

Shannon Thyme Klinger (Novartis)

Novartis announced today that Felix Ehrat, group general counsel of Novartis, has decided to retire from the company. Shannon Thyme Klinger, currently chief ethics, risk and compliance officer, will be appointed group general counsel and senior vice president for global regulatory affairs, responsible for regulatory strategy and execution across the company's portfolio.

Mark Beveridge (Moberg Pharma AB)

Moberg Pharma AB appointed Mark Beveridge as vice president of finance and member of the management team. He has held various finance positions at Moberg Pharma since 2015.

Raising Vaccination Rates

Focus

By John King

It's an exciting time to be a part of the pharmacy industry. Pharmacies are evolving to become health hubs for their communities, thanks to the need for increased access to lower-cost settings of care combined with new regulations in many states which now recognize pharmacists as providers. Pharmacies that embrace this evolving role in health care delivery and form trusted, strategic relationships with their patients will emerge successful in a highly competitive market.

There is one public health initiative in particular where I believe forward-thinking pharmacies can leverage patient relationships and access to make a significant impact: adult immunization rates. Pharmacies are already becoming the preferred setting for many patients to receive immunizations. The number of influenza vaccinations administered in community pharmacies increased from 3.2 million in 2007 to a staggering 20.9 million in just six years. But despite this jump in pharmacy-administered vaccinations, the overall adult immunization rate only saw a 0.9% increase over this same time period.

So what gives? Most adults know they need an annual flu shot. But what about the two-dose pneumococcal vaccine regimen? Or the new shingles vaccination? A significant opportunity exists to educate patients about necessary immunizations, and the pharmacy is in a perfect position to take advantage of this opportunity. Studies show that patients visit their pharmacy at least five times more often than they visit other health care providers. Pharmacists are also consistently ranked among the most trusted professionals in the United States. Adult immunization rates need to improve, and pharmacies can make it happen.

At OmniSYS, over 20,000 pharmacies participate in our vaccine identification and communication program. Working together with retail pharmacy customers and pharmaceutical manufacturing partners, we have a goal to immunize 4 million adults against pneumococcal pneumonia by 2020. During the last immunization season we identified 800,000 flu shot patients who were eligible for a pneumococcal vaccine, resulting in nearly 200,000 vaccines successfully administered. To put this in perspective, one out of four flu shot patients left a participating pharmacy with the required companion vaccine. We analyzed data, collected feedback and reviewed results from our participating pharmacies, and developed the best practices outlined below for driving increased companion immunization rates.

Leverage data to determine eligibility

Determining patient eligibility for specific vaccines is a critical piece of the puzzle. Pharmacies have access to a wealth of data that can and should be leveraged to determine patient eligibility. Before making a vaccine recommendation to a patient, the pharmacist needs to know if a particular vaccine is clinically necessary for the patient and if the vaccine is eligible for reimbursement. Data sources including claim history, payer information, state immunization registries, Advisory Committee on Immunization Practices (ACIP) guidelines and Centers for Disease Control and Prevention (CDC) guidelines should be aggregated and analyzed to provide a complete picture of patient eligibility.

John King

Recommend, don't ask

An important best practice we've noticed in our research is that pharmacists who recommend a vaccine have a much higher success rate than those who ask a patient about a vaccine. While the difference in language is subtle, it's important. Patients trust a recommendation from their pharmacist, and the use of active versus passive language makes a significant impact on the number of patients who say yes to receiving a companion vaccine.

Focus on specific recommendations

Pharmacist recommendations should always be vaccine- and patient-specific. Broad recommendations based on a single criteria such as patient age have a low response rate from patients and, in many cases, may not be reimbursable by the patient's insurance. Pharmacists who are able to tell a patient that a vaccine is recommended for them based on their personal medical history and that the vaccine is covered by their insurance see a much higher response rate.

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Rx Has Boosted Immunization Numbers

NEW YORK — A new study published in the *Journal of the American Pharmacists Association* revealed that pharmacy-based immunization services have increased influenza and pneumococcal vaccinations by millions since immunizations became more accessible in pharmacies.

All the data researchers used came from 2006 through 2010, a time when changes in immunization policy led to a significant push to offer vaccination services in pharmacies. The researchers studied the data to determine whether more widespread availability of pharmacy-based immunizations had actually increased vaccination rates beyond national trends, as opposed to shifting immunization services away from other providers.

In looking at the data, the researchers found that pharmacy-based immunization services rose significantly between 2006 and 2010. In 2010, pharmacy-based immunization was available in 97% of counties, up from only 36% of counties in 2006. Adult influenza vaccination rates increased from 40% in 2006 to 49% in 2010, and adult pneumococcal vaccination rates grew from 28% in 2006 to 35% in 2010. The researchers estimate that 6 million additional influenza immunizations and more than 3 million pneumococcal immunizations are given each year because they are available at pharmacies.

These new findings are in alignment with another study that came out in 2017 — by researchers from Avalere and the National Association of Chain Drug Stores — which found that "overall, as states moved to allow pharmacists to administer influenza immunizations, the odds that an adult resident received an influenza immunization rose, with the effect increasing over time."

These studies and more are being featured by the American Disease Prevention Coalition — NACDS is a member of the coalition's steering committee. The Coalition is pursuing enhancements to state policies to improve patients' access to pharmacist-provided vaccinations.

RX/News

Technology Can Advance a 21st Century Regulatory Process

By Dean Erhardt

The NEW YORK — Driven by the 21st Century Cures Act, Food and Drug Administration Commissioner Scott Gottlieb has publicly stated a goal of moving the FDA into the new century by creating a regulatory process that is modern and efficient.

It doesn't seem all that long ago, about 1992, that the Prescription Drug User Fee Act (PDUFA) was passed, allowing the FDA to collect fees from drug manufacturers to fund the new drug approval process. PDUFA must be reauthorized every five years. Upon the latest renewal, this included the Food and Drug Administration Reauthorization Act (FDARA) which incorporates the reauthorization of PDUFA through September 2022.

According to the FDA website, PDUFA VI will provide for the continued timely review of new drug and biologic license applications. However, there is prevailing cynicism in the market regarding the FDA's commitment to a timely review process, given the long delays and date changes imposed on companies by PDUFA.

According to Commissioner Gottlieb's blog, the stated goal that should be welcomed in every corner of the industry is: "To advance this progress, it's key that the FDA adopt a regulatory approach to these technologies that's as innovative and nimble as the opportunities that we're tasked with evaluating."

Clearly, the FDA is tasked with significant responsibility, and the need for pharmaceuticals to go through a stringent review process that ensures safe and effective medications should not be underestimated. That said, the industry should be receptive to a streamlined process that leverages current technology, such as artificial intelligence and computer simulation. These technology innovations could possibly bend the cost curve if the cost of clinical trials could be — at least in some cases — materially impacted.

The FDA is not the only stakeholder interested in improving the approval process. In May, *The Wall Street Journal* asked, "Are Big Clinical Trials Relevant? Researchers Disagree." This was not a prompt to debate the merits of one pathway versus another. What is evident is that smaller, nimble trials that are tailored to a patient's genetic makeup should:

• Lower the cost of getting a product to market.

• Lower the price, and therefore, the cost, to the health care system by enabling lower cost vis-à-vis lower overall investment cost.

Dean Erhardt

Of course, as manufacturers go through the FDA approval process, the clinical trial is not the only investment requirement. As one would imagine, companies — particularly new companies — have other significant costs during their commercialization process, such as setting up their distribution program; attaining state licensing; staffing a commercial organization, which may include a substantial salesforce; developing clinical education programs; and many other activities.

A delay in the approval process impacts all of these areas and can cost many millions to a manufacturer outside of the actual FDA approval process. In addition, FDA delays can force manufacturers to make significant layoffs, only to hire again later.

The FDA and other regulatory bodies might also look beyond drugs and biologics to devices and e-health products that are approved via the 510K process. Many of these products are highly innovative and bring unique solutions in such high-profile disease states as opioid dependency and substance use disorder.

The products, while not drugs, can also address significant diseases that are underserved today, in some cases with no potential for negative impact (i.e., side effects).

One example might be gammaCore (manufactured by electroCore), which initially was approved for the acute treatment of pain associated with episodic cluster headache in adult patients, also known as the suicide headache. This product has subsequently attained approval for the acute treatment of pain associated with migraine headache in adult patients, albeit using neuromodulation, these products are therapeutic just like medicines. While discussing issues that require regulatory approval, it may also be time for the Centers for Medicare and Medicaid Services (CMS) to look at how to reimburse for some of these products.

Finally, it is encouraging to witness the development of the agency known as the Oncology Center of Excellence. This organization holds promise not only to accelerate treatment options, but also to encourage manufacturers to invest in cures for ultra-orphan diseases, such as diffuse intrinsic pontine glioma (DIPG), a type of brain cancer that primarily affects children and leaves them with almost no hope. This serves as an example of a disease where there has been no significant innovative therapy since the 1960s.

With a more innovative approach to drug development perhaps more can be done for these types of diseases without having to break the bank in order to get a product to market.

Realistically, our world is changing at a record pace, largely driven by technology. Now it is incumbent upon the FDA and others to challenge themselves to create a regulatory approach "that's as innovative and nimble as the opportunities that we're tasked with evaluating" — as Gottlieb called for.

The other option is for the industry to simply stay the course and continue to outpace the regulatory environment. This will require spending unnecessary time and money, and potentially delay life-saving options for patients everywhere.

Dean Erhardt is chief executive officer of D2 Consulting.

Opioids on the Decline

WASHINGTON — States that passed laws setting limits on opioid prescriptions experienced the steepest declines in the number of prescription opioids sold in 2017, according to Avalere Health.

The firm said its research suggests that sales of prescription opioids declined 11% in 2017 from a year earlier.

The biggest declines were in the seven states — Connecticut, Maine, Massachusetts, New York, Pennsylvania, Rhode Island and Vermont — where legislators took action in 2016 limiting opioid prescriptions to a three- to 14-day supply or limiting the morphine milligram equivalent (MME) amount of medication that could be prescribed, Avalere said.

The biggest decline was in Maine, where sales of prescription opioids were down nearly 25% from 2016 levels.

Prescription opioid supplies are declining even in states that have not imposed prescription limits, according the Avalere's data, which show declines in every state but Idaho in 2017.

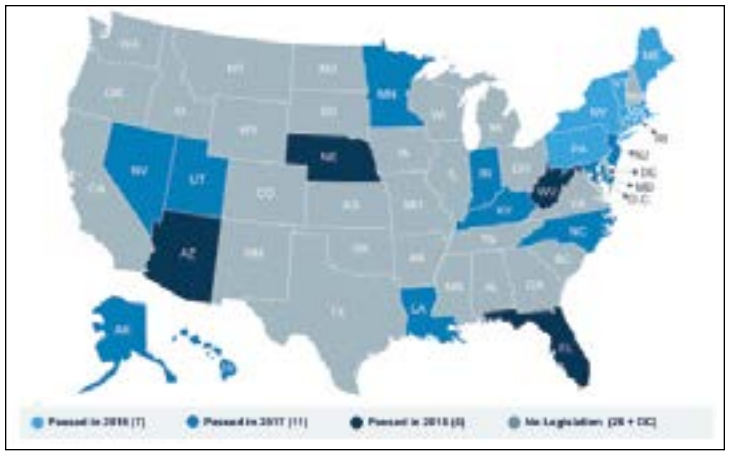
States have been wrestling with the opioid issue for years, with varying degrees of success, said Kelly Brantley, vice president at Avalere.

"Limiting the supply of opioids, such as through fill limits, is gaining traction as part of a broader set of strategies being tested by states as they continue to confront the opioid crisis," she said.

Twenty-two states have now enacted opioid fill limits that restrict the quantity of opioids a physician can prescribe to an individual patient over a specific time frame.

"As Congress considers sweeping legislative initiatives to address this epidemic, state governments are continuing to advance solutions within their own states," Clara Soh, a director at Avalere, said in a statement.

For its part, the Food and Drug Administration is committed to addressing the crisis on all fronts, with a significant focus on decreasing exposure to opioids and preventing new addiction by taking steps to encourage more appropriate prescribing; supporting treatment of those with opioid use disorder and promoting development of improved as well as lower cost forms of medication-assisted treatment; fostering the development of novel pain treatment therapies that may not be as addictive as opioids, and opioids more resistant to abuse and misuse; and taking action against those who contribute to the illegal importation and sale of opioid products. The agency will also continue to evaluate how drugs on the market are used, in both medical and illicit settings, and take regulatory action where needed.



States with laws limiting opioid prescribing amounts.

Rx Can Boost Numbers of Vaccinations

From 55

Work with your workflow

Pharmacists are busy. As pharmacies look for ways to improve immunization rates, it is important to take pharmacist workflow into account. Is it possible to determine eligibility and indication for each patient by checking the clinical guidelines for that particular vaccination, the payer's requirements for reimbursement, the patient's medical history and your local immunization registry for the patient's history? Yes. Is that something that a busy pharmacist has time to do while a patient is waiting in the store? Not likely. Pharmacies can leverage technology to streamline the identification of eligible patients, but ensuring this technology does not break the pharmacist's workflow is critical to success.

As health care in the United States continues to shift to lower-cost, higher-value settings of care, the pharmacy has the potential to play a pivotal role in addressing stagnant adult immunization rates by leveraging their access to patients who need vaccinations and are already in their store on a regular basis. By implementing proven best practices, pharmacies can make a significant impact on public health and move the needle on adult immunization rates.

John King is chief executive officer of OmniSYS, a technology company that helps pharmacies and pharmaceutical manufacturers drive growth by engaging patients, competing on value and distinguishing their brands.

Pharmacists Help Adherence Rates in the Elderly

THE HAGUE, Netherlands — Pharmacist interventions can significantly improve medication adherence in the elderly, a new report from the International Pharmaceutical Federation (FIP) has found.

Services including counseling with prescription refills, dosage administration aids and reminder systems are among interventions that improve adherence for seniors with chronic conditions, the study says.

The authors of the report, "Use of medicines by the elderly: The role of pharmacy in promoting adherence," reviewed existing knowledge of pharmacy programs and services' capability for boosting adherence in this growing patient population.

"Pharmacists have a key role in monitoring and improving patient adherence to medicines, both as a single profession as well as within a multidisciplinary, patient-centered collaborative team," commented Parisa Aslani, professor in medicines use optimization at the University of Sydney School of Pharmacy in Australia and lead author of the report.

Elderly patients are at particular risk for nonadherence because they often take several medicines for multiple conditions, and taking these medicines properly can be a challenge, especially for those with declining cognitive function or mobility and manual dexterity issues. The authors point out that mild or early cognitive decline can go unnoticed by health professionals and recommend that pharmacists be given training to prevent them from missing signs of cognitive impairment, allowing them to adjust the way in which they communicate with patients and the actions they take.

It's important for medication regimens to be convenient "and, as far as possible, undemanding," Aslani remarked.

It is imperative "to develop and implement interventions that address the individual needs of patients," she said, adding that it is vital for such interventions to have "long-term sustainability."