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Authored by Melissa D. Berry, a principal attorney editor on the Publisher's Staff and a member of the Ohio bar.

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I. INTRODUCTION

Powerful Senate Committee Invites Pharma Executives to Testify

(Reuters) - A powerful U.S. Senate committee on Monday invited seven pharmaceutical companies to testify at a hearing later this month examining rising prescription drug prices. [FN1]

Republican Senator Chuck Grassley, chairman of the Senate Finance Committee, and Democratic Senator Ron Wyden, ranking member of the committee, invited executives from AbbVie Inc, AstraZeneca PLC, Bristol-Myers Squibb Co, Johnson & Johnson, Merck & Co Inc, Pfizer Inc and Sanofi SA.

The U.S. Congress has been intensifying scrutiny of the pharmaceutical industry as rising prescription drug prices consistently poll as a top voter concern. It is also a priority for the administration of President Donald Trump, who made it a central issue of the 2016 presidential campaign.

The Senate Finance Committee held its first hearing on drug prices in January, when Grassley and Wyden noted that several drug companies declined an invitation to testify. Some of the companies were re-invited on Monday, though the senators did not specify which ones.

The Senate is controlled by Republicans and the House of Representatives is controlled by Democrats.

The invitation follows a slew of actions by lawmakers to heighten scrutiny of the pharmaceutical industry. The House Oversight Committee also held a drug pricing hearing in January, and a handful of House Democrats have sent letters to drug companies asking for information on their pricing practices.

CMS Office of the Actuary Releases 2018-2027 Projections of National Health Expenditures

National health expenditure growth is expected to average 5.5 percent annually from 2018-2027, reaching nearly $6.0 trillion by 2027, according to a report published today by the independent Office of the Actuary at the Centers for Medicare & Medicaid Services (CMS).

Growth in national health spending is projected to be faster than projected growth in Gross Domestic Product (GDP) by 0.8 percentage points over the same period. As a result, the report projects the health share of GDP to rise from 17.9 percent in 2017 to 19.4 percent by 2027.

The outlook for national health spending and enrollment over the next decade is expected to be driven primarily by:

• Key economic factors, such as growth in income and employment, and demographic factors, such as the baby-boom generation continuing to age from private insurance into Medicare; and

• Increases in prices for medical goods and services (projected to grow 2.5 percent over 2018-2027 compared to 1.1 percent during the period of 2014-2017).

Similar to the findings in last year's report, the report found that by 2027, federal, state and local governments are projected to finance 47 percent of national health spending, an increase of 2 percentage points from 45 percent in 2017. As a result of comparatively higher projected enrollment growth in Medicare, average annual spending growth in Medicare (7.4 percent) is expected to exceed that of Medicaid (5.5 percent) and private health insurance (4.8 percent).

Selected highlights in projected health insurance enrollment and national health expenditures by sector and payer include:

Health Insurance Enrollment: Net enrollment gains across all sources are generally expected to keep pace with population growth with the insured share of the population going from 90.9 percent in 2017 to 89.7 percent in 2027.

Medicare: Medicare spending growth is projected to average 7.4 percent over 2018-2027, the fastest rate among the major payers. Underlying the strong average annual Medicare spending growth are projected sustained strong enrollment growth as the baby-boomers continue to age into the program and growth in the use and intensity of covered services that is consistent with the rates observed during Medicare's long-term history.

Medicaid: Average annual growth of 5.5 percent is projected for Medicaid spending for 2018-2027. Medicaid expansions during 2019 in Idaho, Maine, Nebraska, Utah, and Virginia are expected to result in the first acceleration in growth in spending for the program since 2014 (from 2.2 percent in 2018 to 4.8 percent in 2019). Medicaid spending growth is then projected to average 6.0 percent for 2020 through 2027 as the program's spending patterns reflect an enrollment mix more heavily influenced by comparatively more expensive aged and disabled enrollees.

Private Health Insurance and Out-of-Pocket: For 2018-2027, private health insurance spending growth is projected to average 4.8 percent, slowest among the major payers, which is partly due to slow enrollment growth related to the baby-boomers transitioning from private coverage into Medicare. Out-of-pocket expenditures are also projected to grow at an average rate of 4.8 percent over 2018-2027 and to represent 9.8 percent of total spending by 2027 (down from 10.5 percent in 2017).

Prescription Drugs: Spending growth for prescription drugs is projected to generally accelerate over 2018-2027 (and average 5.6 percent) mostly as a result of faster utilization growth. Underlying faster growth in the utilization of prescription drugs, particularly over 2020-2027, are a number of factors including efforts on the part of employers and insurers to encourage better medication adherence among those with chronic conditions, changing pharmacotherapy guidelines, faster projected private health insurance spending growth in lagged response to higher income growth, and an expected influx of new and expensive innovative drugs into the market towards the latter stage of the period.

Hospital: Hospital spending growth is projected to average 5.6 percent for 2018-2027. This includes a projected acceleration in 2019, to 5.1 percent from 4.4 percent in 2018, reflecting the net result of faster expected growth in both Medicare (higher payment updates) and Medicaid (as a result of expansion in five states), but slower projected growth in private health insurance as enrollment declines slightly due to the repeal of the individual mandate.

Physician and Clinical Services: Physician and clinical services spending is projected to grow an average of 5.4 percent per year over 2018-2027. This includes faster growth in prices over 2020-2027 for physician and clinical services due to anticipated rising wage growth related to increased demand from the aging population.

The full report is available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.

Female and Minority Health Professionals Face Discrimination from Rural Colleagues

(Reuters) - Even as rural America struggles to attract enough healthcare providers, women and minority health professionals are sometimes driven out of rural communities by the discrimination and harassment from colleagues, a new study finds. [FN2]

In interviews for the study, many of the healthcare professionals who were female, nonwhite, and of certain sexual orientation and gender identity minority groups described burnout from bias, harassment and hostility from their colleagues, researchers report in JAMA Network Open.

“We're trying very hard to bring healthcare providers to underserved rural communities,” said study leader Dr. Michelle Ko from the University of California, Davis. “But we have to be very cognizant of how bias, harassment and institutional discrimination can be barriers to that. These issues affect not only the wellbeing of the health professionals but also patients' access to care.”

Ko said she was surprised by the findings. The study started out “with broad open-ended questions about practice challenges, strategies for dealing with those challenges and about personal journeys,” Ko explained. “Very quickly these issues came up.”

Ko and colleague Armin Dorri interviewed 26 physicians, nurse practitioners and clinic directors practicing in primary care settings in California's San Joaquin Valley, which is predominantly agricultural and rural.

Of the 26, 16 identified as female, 12 as non-Latinx white (a gender neutral term for those of Latin-American decent) and three as SGM. Those who identified as female, nonwhite and SGM talked about feelings of isolation caused by the way they were treated by colleagues.

Most of those interviewed stressed that the vast majority of the problems were with fellow healthcare providers and not patients.

Twelve of the 16 female healthcare professionals said they were frustrated by negative comments about women's family obligations, lack of scheduling flexibility, and general disrespect, the researchers report. Three women reported harassment from male colleagues including inappropriate sexual jokes, degrading comments about women, and use of medical practice and hospital computers to view pornographic materials.

Three study participants talked about feelings of fatigue from dealing with colleagues' racial biases. The African American participant reported persistent racial microaggressions from other physicians, staff and patients; this physician had also been told, you don't look like a real doctor.

Two of those who identified as sexual or gender minorities talked about overt hostility, including receiving expletive laden notes and vandalism of their cars. They said hospitals in the area were known to deny doctors admitting privileges once someone's SGM status was known. One was asked to step down from leadership of hospital boards and medical organizations after their SGM status became known.

While a third who identified as sexual or gender minority reported no issues, this person wasn't sure if colleagues or other staff knew of their status.

“The results are disheartening but perhaps not surprising given the persistent climate of intolerance, particularly in pockets across the United States,” said Dr. Albert Wu, an internist and a professor of health policy and management at the Johns Hopkins Bloomberg School of Public Health. “Too frequently physicians who start out in rural practices find that they are unable to fit in.”

Confronted with both indirect and overt discrimination, women and sexual and gender minorities may “realize there is no hope,” Wu said. “Many have resorted to relocating to more accepting practices and communities.”

Wu would like to see national and state agencies work to identify and reduce the kind of mistreatment described in the new study. “Although this is difficult, education and other interventions can help,” he said.

Hospital Groups File Lawsuit to Block Trump's Price Transparency Rule

(Reuters) - U.S. hospital groups have challenged the Trump administration's rule that requires them to be more transparent about prices they charge patients for healthcare services, according to a lawsuit filed on Wednesday. [FN3]

The plaintiffs, including the nonprofit American Hospital Association (AHA), are looking to block the rule issued last month that mandates hospitals to publish pricing information of their services on the internet.

“The rule ... does not provide the information patients need. Mandating the public disclosure of negotiated charges would create confusion about patients' out-of-pocket costs, not prevent it,” the plaintiffs said.

The rule, seen as a violation of the First Amendment by the hospital groups, also demands confidential information on individually negotiated contract terms with all third-party payers, including private commercial health insurers.

Such disclosures would eliminate hospitals' ability to negotiate pricing with insurers that would undermine competition and blunt incentives for health insurers to sign arrangements that could potentially lower costs, the plaintiffs said.

This is not the first time that the industry has challenged President Donald Trump's efforts to lower drug prices.

In July, a federal judge sided with drugmakers by striking down a rule that would have forced pharmaceutical companies to include the wholesale prices of their drugs in television advertisements.

“Hospitals should be ashamed that they aren't willing to provide American patients the cost of a service before they purchase it,” said Caitlin Oakley, a spokeswoman for the Department of Health and Human Services, adding that the administration would continue to fight for price transparency.

The AHA, along with the Association Of American Medical Colleges and Federation Of American Hospitals, among others, said it would press for speeding up the decision on the rule, so hospitals do not spend time and resources preparing for what may be invalidated.

The rule is expected to come into effect on January 1, 2021.

II. MERGERS AND ACQUISITIONS

Bristol-Myers to Buy Celgene for $74 billion in Largest Biopharma Deal

(Reuters) - Bristol-Myers Squibb Co. said on Thursday it would buy Celgene Corp. for about $74 billion, combining two of the world's largest cancer drug businesses in the biggest pharmaceutical deal ever. [FN4]

Both Bristol-Myers and Celgene face separate challenges, and some Wall Street analysts questioned whether the combination - which the companies said would create $2.5 billion in cost savings and significantly raise earnings - would solve them. Amid clinical setbacks and other missteps, Bristol-Myers shares fell 15.2 percent in 2018 while Celgene plunged nearly 40 percent last year.

Bristol's most important cancer immunotherapy and growth driver, Opdivo, has lost much of its luster as Merck & Co.'s rival drug Keytruda seized dominance in advanced lung cancer, the most lucrative oncology market. Meanwhile, Celgene has endured high-profile clinical failures and U.S. exclusivity on its flagship multiple myeloma drug, Revlimid, will start being phased out in 2022.

On Thursday, Bristol's stock ended another 13.3 percent lower at $45.12. “Doing this transaction clearly indicates that risk to Opdivo in lung cancer is obviously a concern,” SunTrust Robinson Humphrey analyst John Boris said in an interview.

There is also shareholder concern that drugs in development would not have enough sales to offset major products losing exclusivity between 2022 and 2026.

But cash flow from Revlimid buys Bristol-Myers time to pay down debt and position for another transaction, Boris said. Revlimid is expected to record nearly $10 billion in 2018 sales.

Celgene shares were up 20.7 percent at $89.43.

Bristol-Myers Says Shareholders Vote to Approve Celgene Takeover

(Reuters) - Bristol-Myers Squibb Co.'s shareholders voted to approve the drugmaker's $74 billion acquisition of biotech Celgene Corp on Friday despite a campaign by activist hedge fund Starboard Value LP to scuttle the deal. [FN5]

The company said investors holding 75.7 percent of the shares voted were in favor of the deal in a preliminary count.

“We, from a management perspective, from a board perspective, truly believe this is the right transaction for us,” Bristol-Myers Chief Executive Giovanni Caforio told reporters after the vote.

“The focus is on us right now to execute on the integration and then deliver the value of the combined portfolio, to confirm that the new company will deliver significant value for shareholders,” he said.

Celgene said separately in a statement that its shareholders representing more than 70 percent of its shares outstanding who were entitled to vote, voted in favor of the transaction.

The companies expect the deal to close in the third quarter.

Bristol-Myers announced in early January that it planned to buy Celgene in a cash and stock transaction to bring together companies that specialize in oncology and cardiovascular drugs in what would be the largest pharmaceutical industry merger ever.

The New York-based drugmaker has said the combined company will have six drugs with expected near-term launches - five from the Celgene pipeline - representing over $15 billion in annual revenue potential - as well as strong early-stage experimental assets.

But Starboard and the company's second largest shareholder, Wellington Management, opposed the deal.

Starboard called it “poorly conceived and ill-advised,” and criticized Bristol-Myers' management and board, suggesting they would not be able to successfully execute a risky deal.

Starboard abandoned the campaign against the deal late last month after proxy advisory firms recommended investors support it.

Bristol-Myers said during a shareholders meeting that it does not expect changes to its dividend policy after the acquisition.

Bristol-Myers shares fell 50 cents, or 1.1 percent, to $45.59 in Friday afternoon trading on the New York Stock Exchange. Celgene shares fell 9 cents to $94.14 on the Nasdaq.

III. HEALTHCARE SPENDING AND COST ISSUES

J&J Raises U.S. Prices on Around Two Dozen Drugs

(Reuters) - Johnson & Johnson raised U.S. prices on around two dozen prescription drugs on Thursday, including the psoriasis treatment Stelara, prostate cancer drug Zytiga and blood thinner Xarelto, all among its top-selling products. [FN6]

J&J joined many other companies that raised U.S. prices on hundreds of prescription medicines earlier this month.

Most of the J&J increases were between 6 percent and 7 percent, according to data from Rx Savings Solutions, which helps health plans and employers seek lower cost prescription medicines.

The increases came on the same day that Democratic members of Congress introduced proposed legislation aimed at lowering the cost of prescription drugs for American consumers.

J&J said the average list price increase on its drugs will be 4.2 percent this year. However, it expects the net price it actually receives for its medicines to drop. That is because drugmakers negotiate rebates and discounts off the list price with payers in order to ensure patient access to their products.

The company does not plan to raise prices on any more drugs this year, J&J spokesman Ernie Knewitz said.

Drugmakers kicked off 2019 with U.S. price increases on more than 250 prescription medicines by Jan. 2. That total has almost doubled, with pharmaceutical companies hiking prices on nearly 490 drugs by Jan. 10, according to Rx Savings.

This includes insulin price hikes of between 4.4 percent and 5.2 percent by Sanofi and 4.9 percent by Novo Nordisk.

Sanofi said its increases were below the Centers for Medicare & Medicaid Services projections for medical inflation, and that it expects net prices to drop in 2019. Novo Nordisk said its raised list prices help offset increases in rebates to insurers and pharmacy benefit managers.

With pressure from lawmakers and the administration of President Donald Trump intensifying, the pace of drug increases has been slower than last year, when drugmakers raised prices on around 650 drugs over the first 10 days of 2018.

The United States, which leaves drug pricing to market competition, has higher prices than in other countries, where governments directly or indirectly control costs. That makes it by far the world's most lucrative market for manufacturers.

The U.S. Department of Health and Human Services has proposed policy changes aimed at lowering drug prices and passing on more of the discounts negotiated by health insurers to patients. Those measures are not expected to provide relief to consumers in the short-term, however, and fall short of giving government health agencies direct authority to negotiate or regulate drug prices.

U.S. Senators Launch Bipartisan Probe into Rising Insulin Prices

(Reuters) - Two top U.S. senators launched an investigation into rising insulin prices on Friday, sending letters to the three leading manufacturers seeking answers as to why the nearly 100-year-old drug's cost has rapidly risen, causing taxpayers to spend millions of dollars a year. [FN7]

Republican Senator Chuck Grassley, chairman of the Senate Finance Committee, and Senator Ron Wyden, the committee's top Democrat, sent letters to the heads of Eli Lilly and Co, Novo Nordisk A/S and Sanofi SA, the long-time leading manufacturers of insulin.

The senators pointed to similar, large insulin price increases at all three companies. Eli Lilly's Humalog, for instance, rose from $35 to $234 per dose between 2001 and 2015, a 585 percent increase, they wrote. Insulin has been available since the early 20th century.

The senators asked for information on the process used to determine list prices and the process used to determine net prices after negotiations with pharmacy benefits managers (PBMs) and health insurance plans. Their letters also asked for information about the cost of research and development, production, revenues and gross margins from insulin sales.

“These hardships can lead to serious medical complications that are entirely preventable and completely unacceptable for the world's wealthiest country,” the senators wrote in their letters.

“We are concerned that the substantial increases in the price of insulin over the past several years will continue their upward drive and pose increasingly severe hardships not only on patients that require access to the drug in order to stay alive but also on the taxpayer,” they wrote.

Medicare Offers to Partially Raise Payment for Cancer CAR-Ts

(Reuters) - The U.S. Centers for Medicare and Medicaid Services will slightly increase coverage for expensive CAR-T cell therapies administered at certain large hospitals, and is considering other ways to pay more for the cancer treatments, the agency said on Tuesday. [FN8]

CMS, which runs the federal government's healthcare plan for seniors, issued a proposed rule raising its maximum “new technology add-on payment” (NTAP) from 50% of estimated costs to 65%, which would increase reimbursement to $242,450 from the current $186,500.

But that is still far short of actual costs.

Both Gilead Sciences Inc's Yescarta therapy and Novartis AG's Kymriah have U.S. prices for advanced lymphoma patients of $373,000. Kymriah is also approved for a type of pediatric leukemia at a price of $475,000. Cancer centers have to be certified to administer the CAR-Ts.

Gilead said it was still reviewing the CMS proposal, but was encouraged by comments regarding payment. Novartis did not immediately respond to a request for comment.

Chimeric antigen receptor T-cell therapy, known as CAR-T, involves drawing white blood cells from a patient, processing them in the lab to target cancer, and infusing the cells back into the patient.

Medicare last year said it would pay close to its standard mark-up rate for CAR-Ts given on an outpatient basis, but patients are almost always admitted to a hospital for CAR-T treatment because of the risk of life-threatening side effects. Hospital costs can bring the total cost of CAR-T treatment to more than $1 million.

In addition to the NTAP, Medicare reimburses hospitals for CAR-T therapy under an existing coverage code for bone marrow transplants, which also falls short of actual costs.

CMS said on Tuesday it was seeking public comment on the potential creation of a new billing code for CAR-T cell therapy procedures, including ways to standardize payments across different geographies.

The earliest such a code could take effect would be October.

CMS Administrator Seema Verma said on a conference call that the agency is acting due to concerns that its current CAR-T payment structure could be “inadequate and might be impacting access to care.”

U.S. Drugmakers File Lawsuit Against Requiring Drug Prices in TV Ads

(Reuters) - U.S. drugmakers filed a lawsuit on Friday challenging a new government regulation that would require them to disclose the list price of prescription drugs in direct-to-consumer television advertisements. [FN9]

The lawsuit was jointly filed by Amgen Inc, Merck & Co, Eli Lilly and Co and the Association of National Advertisers in the U.S. district court for the district of Columbia.

The new regulation, which was finalized on May 8 by the U.S. Department of Health and Human Services (HHS) and set to take effect in July, is part of the government's efforts to bring down the cost of prescription medicines for U.S. consumers.

Drugmakers have argued against the regulation, saying list prices do not reflect the final price paid by patients as it excludes rebates and discounts drugmakers may offer, as well as patient assistance programs to make drugs more affordable for some.

“Not only does the rule raise serious freedom of speech concerns, it mandates an approach that fails to account for differences among insurance, treatments and patients themselves, by requiring disclosure of list price,” Amgen said in a statement.

“Most importantly, it does not answer the fundamental question patients are asking: ‘What will I have to pay for my medicine?”’ Amgen said.

It remains to be seen whether the advertising regulation would have any actual impact on lowering costs if the requirement goes into effect.

“If the drug companies are embarrassed by their prices or afraid that the prices will scare patients away, they should lower them,” HHS spokeswoman Caitlin Oakley said in an emailed statement.

“President Trump and Secretary Azar are committed to providing patients the information they need to make their own informed healthcare decisions.”

Trump to Issue Executive Order Seeking Transparency on Healthcare Costs: Wall Street Journal

(Reuters) - U.S. President Donald Trump plans to issue an executive order on Monday asking health insurers and doctors to disclose new details about healthcare costs, in an attempt to improve price transparency, the Wall Street Journal reported on Thursday, citing people familiar with the matter. [FN10]

The order will direct federal agencies to initiate regulations and guidance that could require insurers, doctors, hospitals and others in the industry to provide information about the negotiated cost of care, according to the report.

Insurers could be compelled to disclose prices under the Health Insurance Portability and Accountability Act and Employee Retirement Income Security Act, the report said, but added that it was unclear how aggressive the order will be because of pushback from the industry and some White House advisers.

Trump to Order Hospitals to be Transparent About Healthcare Costs

(Reuters) - President Donald Trump will sign an executive order aimed at requiring hospitals to be more transparent about prices before charging patients for healthcare services, Secretary of Health and Human Services Alex Azar said on Monday. [FN11]

The executive order will direct HHS to issue a rule that will mandate hospitals to disclose in an “easy-to-read, patient-friendly format” what prices patients and insurers will actually end up paying, Azar said.

The order will ultimately require healthcare providers and insurers to provide patients with information about the out-of-pocket costs they'll face before they receive healthcare services, he said.

Senior administration officials said on Monday that the specifics regarding the level of detail that hospitals will be required to provide are to be determined during a forthcoming rule-making process.

Judge Strikes Down Trump Administration Rule Requiring Drug Prices in TV Ads

(Reuters) - A federal judge on Monday dealt a blow to the Trump administration by striking down a new rule that would have forced pharmaceutical companies to include the wholesale prices of their drugs in television advertising. [FN12]

U.S. District Judge Amit Mehta in Washington sided with drugmakers Merck & Co Inc, Eli Lilly and Co and Amgen Inc by halting the U.S. Department of Health and Human Services (HHS) rule from taking effect on Tuesday as planned.

Mehta in his ruling set aside the entire rule as invalid, saying HHS lacked authority from the U.S. Congress to compel drug manufacturers to disclose list prices.

“It is outrageous that an Obama appointed judge sided with big PhRMA to keep high drug prices secret from the American people, leaving patients and families as the real victims,” White House spokesman Judd Deere said in a statement, referring to President Donald Trump's Democratic predecessor, Barack Obama.

PhRMA, the Pharmaceutical Research and Manufacturers of America, is the largest industry lobbying group.

HHS Secretary Alex Azar had announced the rule on May 8, saying that forcing drugmakers to disclose their prices in direct-to-consumer TV advertising could help drive down skyrocketing prescription drug costs if the companies were embarrassed by them or afraid they would scare away customers.

HHS in a statement on Tuesday said it was disappointed in the court's decision, adding that it would work with the Department of Justice on next steps in the litigation.

“President Trump and Secretary Azar remain focused on lowering drug prices and empowering patients through more transparency in healthcare costs,” the agency said.

The rule was originally suggested in May 2018 as part of Trump's “blueprint” to lower prescription drug costs for U.S. consumers.

The judge said such disclosures could well be an effective tool in halting the rising cost of prescription drugs. “But no matter how vexing the problem of spiraling drug costs may be, HHS cannot do more than what Congress has authorized,” Mehta concluded.

Under the rule, the wholesale, or list, price would be included if it was $35 or more for a month's supply or the usual course of therapy. HHS said the 10 most commonly advertised drugs had list prices of $488 to $16,938 per month or for a usual course of therapy.

PhRMA said the list prices could be confusing for patients and discourage them from seeking medical care.

Merck, Eli Lilly and Amgen filed their lawsuit alongside the Association of National Advertisers trade group on June 14, arguing the rule would confuse consumers by forcing them to disclose a price irrelevant to patients with health insurance.

Drugmakers have long argued that list prices do not reflect out-of-pocket costs for most U.S. consumers or take into account the actual prices paid after discounts and rebates negotiated with health insurers and pharmacy benefit managers to ensure patient access to the medicines.

The lawsuit alleged that HHS lacked authority to issue the rule and that it violated drugmakers' free-speech rights under the First Amendment of the U.S. Constitution.

The U.S. Justice Department defended the rule in court, saying it met a standard the U.S. Supreme Court set in 1985, when it held the government could force advertisers to disclose factual, non-controversial information.

IV. OTHER BUSINESS REPORTS

Walgreens and Microsoft Partner to Develop Digital Healthcare Services

(Reuters) - Drugstore chain Walgreens Boots Alliance Inc and Microsoft Corp said on Tuesday they have entered a seven-year agreement to research and develop new methods of delivering healthcare services through digital devices. [FN13]

As a part of the deal, the companies will focus on virtually connecting people with Walgreens stores and provide services on therapeutic areas ranging from preventative self-care to chronic disease management.

Early last year, Amazon.com Inc, Berkshire Hathaway Inc and JPMorgan Chase & Co had said they will form a company that could eventually negotiate directly with drugmakers and healthcare providers and use their vast databases to get a better handle on costs.

Walgreens and Microsoft will also develop healthcare solutions to reduce emergency room visits and decrease hospital readmissions while lowering the cost of care, the companies said.

The drugstore chain said it will pilot up to 12 stores, which will sell select healthcare-related devices, in 2019.

Microsoft will become Walgreens' cloud provider through the agreement and the Microsoft 365 software will be rolled out to more than 380,000 Walgreens employees and stores globally.

CVS, Walmart Resolve Pharmacy Contract Impasse

(Reuters) - Walmart Inc., the world's largest retailer, will remain part of CVS Health Corp.'s network for commercial and Medicaid pharmacy customers, the companies said on Friday, breaking a contract impasse disclosed earlier this week. [FN14]

The companies did not provide financial terms of the new contract.

On Tuesday, CVS said the companies had failed to agree on pricing and that Walmart was leaving the pharmacy network for prescription drug plans that CVS manages for companies and health insurers and for the government-run Medicaid program for low-income people.

Walmart and CVS also said on Tuesday they were still in discussions.

CVS shares gained 1.6 percent to $64.76 in premarket trading, recouping some of the stock's losses on Tuesday.

“We view the agreement positively for CVS,” Cantor Fitzgerald analyst Steven Halper said in a research note, explaining that the loss of Walmart pharmacies could have negatively impacted CVS' ability to sign up customers for its 2020 prescription drug plans.

Evercore ISI analyst Ross Muken said the speed at which the dispute was resolved likely points to the negotiating strength of pharmacy benefit managers in contract discussions. Consumers historically move to where their insurance is accepted, and Walmart likely would have lost out on the estimated 15 million to 20 million prescriptions it receives from CVS customers, Muken said.

In 2012, Walgreens Boots Alliance and pharmacy benefit manager Express Scripts, now part of Cigna Corp., failed to come to contract terms. Walgreens sales fell as it stopped filling prescriptions for Express Scripts customers, and the two companies reached a new agreement in the middle of the year that put Walgreens back in its network.

In addition to its retail pharmacies and stores, CVS is one of the country's biggest pharmacy benefit managers and, after buying Aetna, one of its top health insurance companies. Its prescription plans for those on the government-run Medicare program were unaffected by the contract dispute as was its Sam's Club agreements.

Sean Slovenski, a Walmart senior vice president, described the terms as “fair and equitable” in a press release.

Indivior Braces for Market Share Slide after U.S. Court Defeat

(Reuters) - Drugmaker Indivior Plc warned on Tuesday that it faces rapid losses in market share “in the immediate future” to generic versions of its blockbuster drug Suboxone, after losing the latest leg of its battle to delay the launch of competitors in a U.S. court. [FN15]

Shares in the company sank 25 percent at opening in London.

Indivior has been engaged in a long-running fight against the launch of cheaper equivalents of its opioid addiction treatment by competitors including India's Dr.Reddy's Laboratories and Teva Pharmaceuticals.

The company said it would file an emergency motion to prevent a mandate under the decision by the U.S. Court of Appeals for the Federal Circuit taking effect on Feb. 11.

Failing that, it said it expected both Dr. Reddy's and another competitor, Alvogen Pine Brook LLC, to relaunch their treatments, resulting in potentially huge losses in market share for Subloxone.

“We acknowledge that the Company faces major disruption in the immediate future from a potential material and rapid loss of market share,” Chief Executive Officer Shaun Thaxter said.

He said the company had implemented the initial stages of a contingency plan outlined in December, leaving it with $920 million in cash and equivalents at the end of the 2018 financial year.

Costs Cuts Help Indivior Post 2018 Profit Jump

(Reuters) - Drugmaker Indivior Plc said on Thursday its full-year operating profit rose largely due to cost cuts even as it braces for the launch of cheaper copies of its blockbuster drug Suboxone after a long patent battle in U.S. courts. [FN16]

The company this week lost the latest leg of its battle to delay the launch of generic versions of the film-based opioid addiction drug. It said operating profit jumped 51 percent to $292 million in 2018, while net revenue fell 8 percent to $1.01 billion.

Indivior said it expects net revenue of between $50 million and $70 million in 2019 from its long-lasting Sublocade injection. Jefferies analysts said the guidance was ahead of their estimates.

Indivior said it would not be able to forecast revenue and net income for 2019, given uncertainties around how the U.S. market for both Suboxone and generic alternatives will ultimately develop.

The United States, which accounts for 80 percent of Indivior's revenue, faces an opioid abuse epidemic that President Donald Trump has declared a public health emergency, signaling a big opportunity for Indivior's newer opioid addiction treatments and Suboxone, which generates the bulk of its revenue.

Indivior, however, has spent over two years fighting several legal battles and patent disputes to fend off generic rivals to Suboxone and has also faced some regulatory hiccups.

The company has said it faces potentially severe losses in market share in the immediate future to copycat products from India's Dr. Reddy's Laboratories and Alvogen Pine Brook, which would also open doors for other copycats to follow suit.

Indivior has put in place a multi-phase contingency plan to fight generic competitors to Suboxone, which includes launching its own generic version to undercut losses and hold a minimum cash balance of $250 million to comply with its debt covenants.

The company is also looking to its schizophrenia treatment Perseris to move away from the Suboxone film. Commercial launch of the treatment will take place in the week of Feb.18, it said.

Pharma Stocks Could See Turbulence from U.S. Senate Drug-price Hearing

(Reuters) - U.S. healthcare stocks could face more turbulence on Tuesday, after a bumpy early 2019, as top executives from some of the largest pharmaceutical companies are expected to get grilled in the U.S. Senate on the high cost of prescription drugs. [FN17]

The Senate Finance Committee hearing on drug pricing is likely to turn up the volume on the debate over healthcare costs, an issue looming as a potential negative for the sector's performance in the coming months.

As the 2020 U.S. presidential race heats up, drug companies could become political targets, causing unease for investors who hold the stocks, as was the case ahead of the last presidential election in 2016.

“I think the rhetoric is still going to be pretty harsh,” said Jeff Jonas, a healthcare portfolio manager with Gabelli Funds. “I don't think any actual policy is going to be implemented, but I think the rhetoric is going to be an overhang.”

Chief executives and other top officials are expected at Tuesday's hearing from AbbVie Inc, AstraZeneca Plc, Bristol-Myers Squibb Co, Johnson & Johnson, Merck & Co Inc, Pfizer Inc and Sanofi SA.

“We expect the hearing to be negative for the group, and continue to believe investors are under-pricing the risks,” Wells Fargo analyst David Maris said in a research note.

Kevin Gade, a portfolio manager at Bahl & Gaynor focusing on pharmaceutical and biotech stocks, said he expects the executives to point the finger for high drug prices elsewhere in the drug-supply chain, such as at pharmacy benefit managers or insurance companies.

“I don't think pharma is going to be able to win them over,” Gade said, adding that “you can only hope...that anything disastrous is avoided.”

So far this year, the S&P 500 healthcare sector has climbed 7 percent against a nearly 12 percent gain for the overall S&P 500, which is the benchmark index for large U.S. companies. S&P 500 pharmaceutical companies are up only 4 percent with S&P 500 biotech companies overall up 4.8 percent.

Investors said healthcare has underwhelmed this year largely because it was the best-performing major S&P 500 sector last year, as investors sought healthcare as a relative safe-haven when the market became more volatile at the end of 2018.

But they added that the political concerns also could be weighing on the group.

Although Republicans control the Senate committee running Tuesday's hearing, drug pricing and the cost to U.S. consumers is expected to get a fresh spotlight with Democrats having taken control of the House of Representatives in January.

Nicholas Colas, co-founder of DataTrek Research, last week recommended that investors underweight healthcare stocks in part because the companies “are in the sights of both Democrat and Republican lawmakers, an important point as the 2020 presidential campaign cycle gets under way.”

“They are an easy target because the electorate really dislikes the American healthcare system,” Colas said in a note.

OxyContin Maker Purdue Pharma Exploring Bankruptcy - Sources

(Reuters) - OxyContin maker Purdue Pharma LP is exploring filing for bankruptcy to address potentially significant liabilities from roughly 2,000 lawsuits alleging the drugmaker contributed to the deadly opioid crisis sweeping the United States, people familiar with the matter said on Monday. [FN18]

The potential move shows how Purdue and its wealthy owners, the Sackler family, are under pressure to respond to mounting litigation accusing the company of misleading doctors and patients about risks associated with prolonged use of its prescription opioids.

Purdue denies the allegations, arguing that the U.S. Food and Drug Administration-approved labels for its opioids carried warnings about the risk of abuse and misuse associated with the pain treatments.

Filing for Chapter 11 protection would halt the lawsuits and allow Purdue to negotiate legal claims with plaintiffs under the supervision of a U.S. bankruptcy judge, the sources said.

Shares of Endo International Plc and Insys Therapeutics Inc, two companies that like Purdue have been named in lawsuits related to the U.S. opioid epidemic, closed down 17 percent and more than 2 percent, respectively, on Monday.

More than 1,600 lawsuits accusing Purdue and other opioid manufacturers of using deceptive practices to push addictive drugs that led to fatal overdoses are consolidated in an Ohio federal court. Purdue has held discussions to resolve the litigation with plaintiffs' lawyers, who have often compared the cases to widespread lawsuits against the tobacco industry that resulted in a $246 billion settlement in 1998.

“We will oppose any attempt to avoid our claims, and will continue to vigorously and aggressively pursue our claims against Purdue and the Sackler family,” Connecticut Attorney General William Tong said. Connecticut has a case against Purdue and the Sacklers.

BANKRUPTCY FILING NOT CERTAIN

A Purdue bankruptcy filing is not certain, the sources said. The Stamford, Connecticut-based company has not made any final decisions and could instead continue fighting the lawsuits, they said.

“As a privately-held company, it has been Purdue Pharma's longstanding policy not to comment on our financial or legal strategy,” Purdue said in a statement.

“We are, however, committed to ensuring that our business remains strong and sustainable. We have ample liquidity and remain committed to meeting our obligations to the patients who benefit from our medicines, our suppliers and other business partners.”

Purdue faces a May trial in a case brought by Oklahoma's attorney general that, like others, accuses the company of contributing to a wave of fatal overdoses by flooding the market with highly addictive opioids while falsely claiming the drugs were safe.

Last year, U.S. President Donald Trump also said he would like to sue drug companies over the nation's opioid crisis.

Opioids, including prescription painkillers, heroin and fentanyl, were involved in 47,600 overdose deaths in 2017, a sixfold increase from 1999, according to the latest data from the U.S. Centers for Disease Control and Prevention.

Purdue hired law firm Davis Polk & Wardwell LLP for restructuring advice, Reuters reported in August, fueling concerns among litigants, including Oklahoma Attorney General Mike Hunter, that the company might seek bankruptcy protection before the trial.

Companies facing widespread lawsuits sometimes seek bankruptcy protection to address liabilities in one court even when their financial condition is not dire. California utility PG&E Corp filed for bankruptcy earlier this year after deadly wildfires raised the prospect of large legal bills even though its stock remained worth billions of dollars.

DECEPTIVE MARKETING

Massachusetts Attorney General Maura Healey in June became the first attorney general to sue not just Purdue but Sackler family members. Records in her case, which Purdue has asked a judge to dismiss, accused Sackler family members of directing deceptive marketing of opioids for years while enriching themselves to the tune of $4.2 billion.

Some other states have since also sued the Sacklers. The Sacklers are currently discussing creating a nonprofit backed by family financial contributions to combat addiction and drug abuse, a person familiar with their deliberations said.

The drugmaker downplayed the possibility of a bankruptcy filing in a Feb. 22 court filing in the Oklahoma case. “Purdue is still here - ready, willing and eager to prove in this Court that the State's claims are baseless,” the company said in court papers.

Sales of OxyContin and other opioids have fallen amid public concern about their addictive nature, and as restrictions on opioid prescribing have been enacted. OxyContin generated $1.74 billion in sales in 2017, down from $2.6 billion five years earlier, according to the most recent data compiled by Symphony Health Solutions.

Purdue Chief Executive Officer Craig Landau has cut hundreds of jobs, stopped marketing opioids to physicians and moved the company toward developing medications for sleep disorders and cancer since taking the helm in 2017.

In July, Purdue appointed a new board chairman, Steve Miller, a restructuring veteran who previously held leadership positions at troubled companies including auto-parts giant Delphi and the once-teetering insurer American International Group Inc.

Mortimer D.A. Sackler no longer sits on Purdue's board, according to a filing the company made with the Connecticut secretary of state late Monday.

The Oklahoma case and other lawsuits seek damages from Purdue and other pharmaceutical companies accused of fueling the opioid crisis. In addition to lawsuits consolidated in an Ohio federal court, more than 300 cases are pending in state courts, and dozens of state attorneys general have sued manufacturers, including Purdue.

Settlement discussions have not yet resulted in a deal.

Purdue and three executives in 2007 pleaded guilty to federal charges related to the misbranding of OxyContin and agreed to pay a total of $634.5 million in penalties, according to court records.

Amazon, Berkshire, JPMorgan Healthcare Company to Be Called Haven

(Reuters) - Amazon.com Inc, Berkshire Hathaway Inc and JPMorgan Chase & Co on Wednesday said their joint healthcare company would be called Haven and will focus on better primary care access, simpler insurance benefits and more affordable prescription drugs for their employees. [FN19]

Haven will be tasked with improving healthcare for the three companies' 1.2 million employees and family members in the United States, but will also share its findings with outsiders, according to its website, launched on Wednesday.

Haven did not say when the changes would be in place for employees.

The three companies announced plans for a new venture in January of 2018, shaking the shares of health insurance companies like UnitedHealth Group Inc and Cigna Corp that manage large corporate benefits on worries that Amazon would disrupt the traditional insurance and drug benefit businesses.

Haven Chief Executive Atul Gawande, who has been running the company since July, said in a news release that the company plans to start small and expand.

Haven said it is “interested in working with clinicians and insurance companies to improve the overall health care system,” according to the website.

Haven is based in Boston and has offices in New York.

McKesson Meets Full-year Profit Estimates, Renews Partnership with CVS

(Reuters) - U.S. drug distributor McKesson Corp forecast a full-year profit on Wednesday that matched analysts' estimates, easing some fears over drug pricing pressures and costs of opioid-related litigations. [FN20]

The company also said it had renewed a distribution agreement with its largest client, CVS Health Inc., through 2023.

“McKesson reported mixed end to its FY19, but in this environment that is likely to be enough especially as guidance met expectations,” an Evercore ISI note said.

The mid-point of the company's 2020 adjusted profit outlook of between $13.85 and $14.45 per share was a cent above the average analyst estimate, according to IBES data from Refinitiv.

The profit forecast assumes an estimated $150 million in costs tied to opioid-related litigations, the company said on conference call.

McKesson expects sales across most of its business units to grow in 2020, including its international drug distribution business, which has been hit by lower reimbursement rates paid by the UK government.

Analysts in the past have said the company's U.S. distribution business could be hurt as growing government scrutiny over rising healthcare costs in the U.S. is expected to slow the pace of rise in branded drug prices.

However, McKesson said it expected the prices of branded drugs in the United States to rise in the mid-single digit percentage range in 2020, unchanged from its expectations for last year.

The company last week agreed to pay $37 million to resolve a lawsuit by the state of West Virginia alleging it helped fuel a U.S. opioid epidemic by failing to stop suspicious orders of painkillers by pharmacies in the state.

Revenue rose 1.6 percent to $52.43 billion, but fell short of analysts' estimates of $53.15 billion. On an adjusted basis, McKesson earned $3.69 per share, while analysts had expected $3.36 per share, according to IBES data from Refinitiv.

Net loss attributable to the company narrowed to $796 million, or $4.17 per share, in the fourth quarter ended March 31, compared with a loss of $1.15 billion, or $5.58 per share, a year earlier.

Revenue rose 1.6 percent to $52.43 billion, falling short of analysts' estimates of $53.15 billion.

McKesson's shares were up 2.3 percent at $128.63 in morning trade on the New York Stock Exchange.

Mylan Gives No Clear View on Strategic Options, Shares Plunge 17 Percent

(Reuters) - Drugmaker Mylan NV on Tuesday reported lower-than-expected quarterly revenue and failed to provide greater clarity on a potential revamp of the company's strategy, sending its shares down 17 percent to a more than six-and-a-half-year low. [FN21]

The company in August announced that its board had launched a strategic review, citing tough pricing environment for generics and said last quarter that the review was nearing completion.

But on a conference call with analysts on Tuesday Chief Executive Officer Heather Bresch declined to say when Mylan would announce its review results, saying it would be in the “near-term.”

SVB Leerink analyst Ami Fadia said the delay raises questions about what the board may be considering as part of the review. “Visibility into any strategic changes could be critical in how investors view the stock.”

Mylan has been grappling with lower drug prices as well as problems at its Morgantown facility in West Virginia after the U.S. health agency issued a warning letter last year.

Mylan, which also reaffirmed its 2019 forecasts, said its quarterly revenue was hit by lower volumes and a stronger dollar.

“We believe investors had braced themselves for a bottom line miss, but not the revenue weakness,” Mizuho Securities analyst Irina Koffler said in a note titled ‘bottom line beat irrelevant’.

Drugmakers such as Mylan and Teva Pharmaceutical Industries Ltd have suffered over the past few years as a steep fall in generic prices ate into their profits, but they have lately seen prices stabilizing.

Mylan said it does not expect price erosion in the generics market in the United States to accelerate in 2019.

Revenue from its North America business, its biggest, fell 6 percent to $922.9 million and missed estimates of $952.43 million, while sales at its Europe business dropped 14 percent to $895.3 million, below $1.06 billion that analysts expected.

Total revenue fell 7 percent to $2.50 billion and missed estimates of $2.69 billion, according to IBES data from Refinitiv.

The company reported a net loss of $25 million, or 5 cents per share, in the first quarter ended March 31, compared with profit of $87.1 million, or 17 cents per share, a year earlier.

Excluding items, the company earned 82 cents per share and beat expectations of 79 cents per share.

Shares of the company fell to $23.84 in afternoon trade on Tuesday. Since Bresch took the helm in 2012, Mylan shares have risen nearly 8 percent.

JPMorgan Cuts Ties with OxyContin Maker Purdue Pharma

(Reuters) - JPMorgan Chase & Co has cut ties with Purdue Pharma LP over the OxyContin maker's alleged role in the U.S. opioid crisis, forcing it to find a new bank to manage cash and bill payments, people familiar with the matter said on Thursday. [FN22]

The move makes JPMorgan, the largest U.S. bank by assets, the most high-profile corporation known to have distanced itself from Purdue and its wealthy owners, the Sackler family, amid thousands of lawsuits alleging the company pushed addictive painkillers while downplaying their abuse and overdose risks.

JPMorgan's decision also underscores a drive among U.S. banks to reassess their relationships with clients and industries in response to controversy and political debates over matters such as immigration detention and mass shootings.

After JPMorgan informed Purdue in March that it had six months to find another bank, Purdue tapped Dallas-based regional bank Comerica Inc to handle its financial transactions and accounts, the sources said.

JPMorgan told Purdue that reputational risks associated with the public backlash against the drugmaker informed its decision to cut business ties, the sources added.

While not a lender to Purdue, JPMorgan's commercial bank managed the company's cash and bill payments, according to the sources. It is not clear how long JPMorgan served as Purdue's bank.

“Purdue is a streamlined organization with an exciting pipeline of new medicines and significant cash reserves,” the company said in a statement. “The company has multiple banking relationships and will not have any interruption to its banking and financial service needs.”

JPMorgan and Comerica declined to comment.

Purdue faces roughly 2,000 lawsuits accusing the Stamford, Connecticut-based company, and increasingly the Sacklers, of aggressively marketing prescription opioids while misleading prescribers and consumers about risks from their prolonged use.

U.S. states, counties and cities are seeking billions of dollars in damages to address harm from opioids. Nearly 400,000 people have died after overdosing on opioids between 1999 and 2017, according to the latest data from the U.S. Centers for Disease Control and Prevention. More than half the deaths resulted from prescription painkillers.

Purdue denies it contributed to the U.S. opioid crisis, pointing to U.S. Food and Drug Administration approvals of labels for the company's drugs that carried warnings about risk and abuse associated with treating pain. Purdue and its family owners argue that heroin and fentanyl are currently more significant culprits in the opioid epidemic.

However, health experts have said many people turn to those drugs after first getting hooked on prescription painkillers.

In March, Purdue and the Sackler family reached a $270 million settlement with the state of Oklahoma, which on Tuesday is set to take two other drugmakers to trial over claims they also helped fuel the opioid epidemic. Dozens of other states have lawsuits pending against Purdue, and in some instances the Sacklers, who made a financial contribution to the Oklahoma settlement even though they were not defendants in the case.

A North Dakota judge earlier this month dismissed that state's case against Purdue.

Purdue Chief Executive Officer Craig Landau in March said a bankruptcy filing remained an option for the company to address potential liabilities from widespread litigation.

LATEST TO SHUN

Various museums, universities and other nonprofits are now shunning donations or reassessing their relationships with the Sackler family, which has a long history of philanthropy.

In New York, The Metropolitan Museum of Art, which has a wing named for the Sacklers, and the American Museum of Natural History, said earlier this month they had ceased accepting donations from the family.

For JPMorgan, dropping Purdue is the latest in a series of moves aimed at steering clear of political lightning rods. In January, the bank said it would stop financing operators of private prisons, which have become the target of protests over their role detaining undocumented immigrants.

Its peers have made similar moves. In March, Wells Fargo & Co's CEO at the time, Tim Sloan, told a congressional panel the bank was exiting relationships with private prison operators.

Citigroup Inc, meanwhile, last year placed restrictions on firearms sales for retailers doing business with the bank following the deadly school shooting in Parkland, Florida. A Bank of America Corp executive said last year that the bank intended to avoid financing military-style firearms for civilians moving forward.

CVS to Expand Health Hubs to 1,500 Stores by End of 2021

(Reuters) - CVS Health Corp said it will offer expanded health services such as nutrition counseling and blood pressure screenings in 1,500 stores by the end of 2021, following through on plans announced during the pharmacy chain's 2018 acquisition of health insurer Aetna. [FN23]

It plans to convert a total of 50 stores this year in Houston, Atlanta, Philadelphia, and Tampa, representing about 15% of the stores in each of the markets, the company said ahead of a meeting on Tuesday with Wall Street analysts and investors in New York. The bulk of the expansion will be split between 2020 and 2021.

CVS first launched a handful of these stores with expanded health services it is calling health hubs in Houston earlier this year. The new format includes an employee with the title of “care concierge” who will direct customers to health services such as a nutritionist or nurse practitioner. It also will offer screenings for sleep apnea and opthalmology issues related to diabetes, among other services.

These CVS stores have experienced increases in foot traffic, front-of-store sales and MinuteClinic visits per day, as well as prescriptions dispensed, CVS pharmacy executive Kevin Hourican said in a phone interview. He declined to provide specific figures. MinuteClinics are walk-in health clinics located in CVS pharmacies.

When CVS bought Aetna for $69 billion, it said the companies would work to bring more health services into its stores beyond the MinuteClinic offerings to tackle chronic conditions like obesity, high blood pressure and diabetes.

Separately, CVS this week is in federal court in Washington D.C., where a judge is reviewing the Aetna deal. The U.S. Department of Justice and the companies agreed on an anti-trust settlement that included the sale of Medicare prescription drug plans to WellCare Health Plans Inc, but the court has not yet signed off on it.

In addition to its retail stores with pharmacies, CVS is one of the nation's largest pharmacy benefit managers.

CVS Enters Home Dialysis Care with Clinical Trial of New System

(Reuters) - CVS Health said on Wednesday it will start a clinical trial of its new home dialysis system this week, setting it up to compete directly with the two largest operators of U.S. dialysis centers, Fresenius Medical Care AG and DaVita Inc. [FN24]

CVS is one of the largest U.S. pharmacy operators and pharmacy benefits managers and also owns Aetna, a top health insurer. It had announced last year that it was working on a home hemodialysis system, which would enable patients with end stage renal disease to have more frequent dialysis and potentially better health outcomes compared with clinic-based care.

Without a transplant, patients with end-stage kidney disease require dialysis to clear their blood of waste and excess fluid, which involves spending three-to-five hours hooked up to a machine three times a week.

The U.S. government, which covers most patients with end stage renal disease in its Medicare health program, last week announced plans for several pilot programs aimed at overhauling kidney care. It would provide doctors and kidney care centers with incentives for earlier treatment for the chronic conditions that lead to kidney failure, home dialysis and kidney transplants.

Fresenius earlier this year bought NxStage, a U.S. maker of home-use dialysis machines, for $2 billion and said it would convert some of its clinics into transitional care sites to train patients to do dialysis at home. DaVita has said that it is accelerating home dialysis growth by investing in home remote monitoring and a telehealth platform that make the process easier.

CVS Executive Vice President Alan Lotvin said in an interview that by using its home dialysis equipment, patients are expected to undergo dialysis every other day for around 6 hours per day, potentially doubling the amount of dialysis they receive in a one-week period. More dialysis has been shown to lead to better patient health, he said.

CVS is enrolling up to 70 patients at up to 10 medical centers in the United States and expects the study to be completed in 16 to 18 months. If successful, it plans to begin offering kidney care dialysis services in 2021.

The company will also sell the systems, which were designed with DEKA Research & Development Corp, a New Hampshire-based company owned by Segway scooter inventor Dean Kamen, according to sources familiar with the arrangement. Reuters previously reported on the partnership.

Patients can launch and operate the system, which is contained in two cabinets that are each about the size of a small countertop refrigerator, through a software program on a tablet computer. In the trial, patients are trained for about six weeks with a nurse either at a clinic or at home and then operate the system themselves for six weeks.

Nurses and medical workers are one of the factors that drive the costs of dialysis in centers and can be a factor in home care costs. Doctors are also typically reimbursed when patients receive dialysis, a factor government officials have said undercuts earlier treatment of kidney disease.

DaVita shares have gained 12 percent this year since closing 2018 at $51.42. Fresenius shares closed 2018 at 56.64 euros and are up 25 percent. CVS shares have fallen 12 percent from $65.19 at the end of 2018.

Walgreens to Close About 200 Stores in United States

(Reuters) - Walgreens Boots Alliance Inc. said on Tuesday it plans to close about 200 U.S. stores and expects to record related pre-tax charges of between $1.9 billion and $2.4 billion. [FN25]

The Deerfield, Illinois-based company in June said it would close about 200 stores in the United Kingdom as performance in its UK Boots business continued to lag in the latest reported quarter.

The store closures are part of the company's cost management program that is aimed at mitigating the pressure related to generic drug prices, the company had said in June.

The program is expected to deliver annual cost savings in excess of $1.5 billion by 2022, the company said in a regulatory filing on Tuesday.

Cardinal Health Warns Ongoing Opioid-related Lawsuits to Hit Business

(Reuters) - Drug distributor Cardinal Health Inc warned on Tuesday that its business could be hurt as it defends itself against several opioid-related lawsuits. [FN26]

Several pharmaceutical wholesale distributors, including Cardinal, have been named as defendants in about 2,500 lawsuits for the distribution of prescription opioid pain medications. These lawsuits have been filed in various federal, state, and other courts by a variety of plaintiffs.

Cardinal said in a filing it expects to be named as a defendant in additional lawsuits.

Pharmaceutical manufacturers and distributors have been in part blamed for the U.S. opioid crisis, accused of deceptively marketing opioids in ways that downplayed their risks.

AmerisourceBergen Corp and McKesson Corp are also facing similar lawsuits.

Cardinal said it was vigorously defending itself in all opioid-related matters, but is unable to predict their outcome or estimate a range of reasonably possible losses.

Cardinal said that ongoing negative publicity could hurt the its reputation or results of operations.

Opioids were involved in 400,000 overdose deaths from 1999 to 2017, according to the U.S. Centers for Disease Control and Prevention.

On Tuesday, drugmakers Endo International Plc and Allergan Plc agreed to pay $15 million to avoid going to trial in October in a landmark opioid-related case by two Ohio counties.

Earlier this month, Bloomberg News reported that McKesson, Cardinal Health and AmerisourceBergen had proposed paying a $10 billion settlement for claims that they played a part in the U.S. opioid epidemic.

Ohio Hospital Where Doctor Accused of Opioid Murders Worked Settles Lawsuits

(Reuters) - The Ohio hospital that employed a doctor charged with 25 counts of murder for giving often fatal doses of opioid painkillers to dozens of sick patients said on Tuesday it has settled two wrongful death lawsuits for a total of $9 million. [FN27]

Columbus-area Mount Carmel Health System settled lawsuits that claim Dr. William Husel authorized drugs that led to the deaths of Donald McClung, 58, in September and Rebecca Walls, 75, in November.

“It is our hope that all of these settlements will bring some measure of closure and comfort to the families,” hospital spokeswoman Cindy Kalis said in a statement emailed to Reuters.

Husel turned himself in to Columbus police in June after a six-month investigation into what Mount Carmel called his ordering of “inappropriate” doses of fentanyl for patients, prosecutors said.

Fentanyl, often given for intense pain associated with cancer, is 100 times more powerful than morphine.

Altogether, Husel is suspected in 35 patient deaths, prosecutors said. If convicted, he faces 15 years to life in prison for each count.

He is among a wave of U.S. doctors charged for their role in a public health crisis that the Centers for Disease Control and Prevention said led to a record 47,600 opioid-related overdose deaths in 2017.

The settlements were reached at the time when court rulings in the opioid epidemic are grabbing headlines, including an Oklahoma judge's decision on Monday that Johnson & Johnson must pay $572.1 million to the state for flooding the market with painkillers.

Pfizer Invests $500 million in Expanding Gene Therapy Facility

(Reuters) - Pfizer Inc is investing $500 million to expand a manufacturing facility in Sanford, North Carolina, that plays a central role in its efforts to become a major player in gene therapy, the company said on Wednesday. [FN28]

The investment will add additional capacity and capabilities to a facility that makes some of Pfizer's most closely watched experimental treatments.

The Sanford plant manufactures therapies used for the company's late-stage experimental treatments for Duchenne Muscular Dystrophy (DMD) and hemophilia B therapies, among other gene therapies.

It is also responsible for making components for some of Pfizer's vaccines, such as Prevenar 13, which had nearly $6 billion in sales in 2018.

“The expansion of the Sanford site is expected to create hundreds of highly skilled jobs, which would increase Sanford's high-tech manufacturing environment and is part of our overall plan to invest approximately $5 billion in U.S.-based capital projects over the next several years,” Mike McDermott, president of Pfizer Global Supply, said in a statement announcing the investment.

Pfizer has been looking to move into innovative and fast- growing therapeutic areas such as oncology and gene therapy in recent years as it prepares for a looming patent cliff on some of its biggest drugs in the mid-2020's.

In March, Pfizer agreed to buy gene therapies under development at French biotech Vivet Therapeutics for as much as $636 million. It has gene therapies under development for diseases including DMD, hemophilia, and Amyotrophic lateral sclerosis (ALS).

Pfizer is in a race with rivals such as Sarepta Therapeutics Inc to be the first to bring a curative, late-stage treatment to DMD market.

Sarepta recently faced a setback when the U.S. Food and Drug Administration, citing safety risks, rejected its application to market a DMD treatment called Vyondys 53, which is not a gene therapy.

Pfizer has been making big moves toward becoming a more streamlined business focused exclusively on innovative drugs.

Late last year, it agreed to combine its consumer health business with that of GlaxoSmithKline Plc.

In July, it spun off its established pharmaceutical business, which contains its off-patent drugs, and combined it with generic drugmaker Mylan NV.

OxyContin Maker Prepares ‘Free-fall’ Bankruptcy as Settlement Talks Stall

(Reuters) - OxyContin maker Purdue Pharma LP is preparing to seek bankruptcy protection before the end of the month if it does not reach a settlement with U.S. communities over widespread opioid litigation, three people familiar with the matter said, after some states balked at the company's $10 billion to $12 billion offer in August to end their lawsuits as part of a negotiated Chapter 11 case. [FN29]

On Friday, Purdue lawyers had documents prepared for a Chapter 11 filing at a moment's notice, Reuters has learned. A federal judge, who expects plaintiffs to update him on settlement progress this week, wants 35 state attorneys general on board with a deal, a threshold that has not yet been reached, the people familiar with the matter said.

Purdue lawyers have told lead attorneys for local governments and some state attorneys general for weeks, and again in recent days, that the company will have to file for bankruptcy without a settlement if one is not reached soon, one of the people said. This approach is known as a “free-fall” bankruptcy filing because it lacks consensus on a reorganization beforehand.

Strong opposition from some attorneys general such as those in Massachusetts and New York emerged last week after confidential discussions on Purdue's settlement talks became public in media reports, with Connecticut's calling for Purdue to be “broken up and shut down,” and sold in parts. Their main sticking point is how much Purdue's controlling Sackler family will pay, the people said.

Purdue faces more than 2,000 lawsuits from cities, counties and states alleging it helped fuel the U.S. opioid epidemic, and Reuters reported in March that the company and family began exploring bankruptcy options for Purdue to halt lawsuits and attempt to resolve litigation with plaintiffs rather than fight every single case.

Purdue and the Sacklers, who also face lawsuits, have denied the allegations.

One reason the Stamford, Connecticut company is determined to file for bankruptcy this month is an October 21 trial Purdue wants to avoid, the people said. The trial, stemming from widespread lawsuits largely brought by local governments that are consolidated in an Ohio federal court, risks a verdict with outsize damages that Purdue, currently carrying $500 million in cash, cannot withstand, one of the people said.

The bankruptcy timing could slip if Purdue reaches a settlement or the October trial is delayed, the people said. Ohio's attorney general last week asked a federal appeals court to halt the trial.

Sackler representatives had no immediate comment regarding Purdue's bankruptcy planning or the details of settlement talks.

In a statement, Purdue said it “has made clear that it prefers a constructive global resolution” as opposed to “years of wasteful litigation and appeals.” Purdue is “actively working with state attorneys general and other plaintiffs on solutions that have the potential to save tens of thousands of lives and deliver billions of dollars to the communities affected by the opioid crisis,” the company said.

A representative for a plaintiffs' executive committee in the opioid litigation did not respond to a request for comment.

NEGOTIATED BANKRUPTCY VS. “FREE-FALL”

With a stable balance sheet and no significant debt, Purdue Pharma's woes are legal, rather than financial. Purdue believes that it could put itself on firmer footing, and potentially restructure and resolve lawsuits in less time, if it were able to file for bankruptcy with a settlement in hand, the people said.

In recent negotiations to resolve the litigation, documents exchanged among the parties outlining possible settlement terms included Purdue's plan to file for bankruptcy and become a public benefit corporation with a board selected by court-appointed trustees, the people said. The public trust would donate millions of doses of drugs the company developed to combat overdoses and addiction to U.S. communities, which Purdue values at $4.45 billion over 10 years.

The Sacklers, who amassed a multibillion-dollar fortune from OxyContin sales, would cede control of Purdue, they said.

On the other hand, a Chapter 11 filing without a deal could bring prolonged, more expensive bankruptcy proceedings and trigger even more litigation, the people said. Some states have said they will resist Purdue's attempt to use bankruptcy proceedings to halt litigation.

The company is preparing for states to argue their lawsuits cannot be halted by a Chapter 11 filing because their legal actions were brought to enforce public health and safety laws—exempting them from the usual bankruptcy rules that would stop their complaints.

A free-fall bankruptcy could result in recoveries closer to $1 billion for U.S. communities suing the company as opposed to the up to $12 billion in value Purdue attaches to its current proposal, according to calculations the company's lawyers have shared with plaintiffs.

Several state attorneys general contend the Sacklers' proposed settlement contribution is too low, the people said. The family offered to pay $3 billion over seven years and to add $1.5 billion or more by eventually selling another business the family owns called Mundipharma, they said.

But these state officials do not want the additional $1.5 billion to be contingent on the Mundipharma sale, and prefer the Sacklers guarantee $4.5 billion, the people said. Another contentious point is the family's proposal to pay small amounts of the $3 billion of cash initially and more later, other people familiar with the negotiations said.

Some state officials also want to know more about the family's finances before agreeing to a deal, concerned more money could be available for a settlement, these other people said.

The Sacklers as of last week had not moved from their offer, according to the three people familiar with the talks.

Mallinckrodt Sells Unit for up to $250 million, Sees Path Forward to Settle Opioid Lawsuits

(Reuters) - Mallinckrodt Plc shares surged more than 50% on Tuesday after it agreed to sell its contract manufacturing unit to reduce debt and its chief executive officer raised hopes that the company could reach a global settlement to resolve all opioid litigation. [FN30]

The drugmaker is among opioid manufacturers that are facing thousands of lawsuits seeking to hold them responsible for fueling an addiction crisis in the United States.

Investors have worried about Mallinckrodt's large debt pile and potential payouts needed to resolve the litigation.

Last week, the company agreed to pay cash of $24 million to two Ohio counties, to fully resolve certain opioid-related lawsuits and to avoid going to trial in October.

“We actually think we now may have a pathway to settle this, and that's what we're going to be working on for the next several months,” Chief Executive Officer Mark Trudeau said at a conference on Tuesday.

“The settlement (of last week) really enables us to have the appropriate time to get into discussions on what we believe is likely or potentially a pathway to settle this globally and with finality.”

Mallinckrodt said it intends to use proceeds from the sale of its unit BioVectra Inc to private equity firm H.I.G. Capital for up to $250 million in a manner consistent with its “previously disclosed capital allocation priorities.”

That primarily means paying off debt, which stood at over $5 billion, as of June 28.

Analysts view the sale, which would bring in an upfront payment of $135 million for Mallinckrodt, as a positive as it helps support near-term financial obligations.

“This is partly reactionary given the (opioid) litigation that's heated up and the fact that they have $700 million of debt that's coming due in April of next year,” Gary Nachman of BMO Capital Markets said.

The company has downplayed bankruptcy concerns and unveiled a strategy to separate its generics unit, which sells opioid drugs, from its specialty business, which sells branded drugs.

However, in August it suspended these plans, citing uncertainties tied to opioid litigation and market conditions.

Tuesday's deal advances Mallinckrodt's focus on branded, high-growth biopharmaceuticals by monetizing a non-core business, Trudeau said.

However, SVB Leerink analyst Ami Fadia said one could question the amount of value management was able to get for the asset, considering its investment.

“This has clearly taken a back seat to near-term cash needs.”

Up to Monday's close, Mallinckrodt shares have plunged nearly 87% this year.

OxyContin Maker Purdue Pharma Files for Bankruptcy Protection

(Reuters) - OxyContin maker Purdue Pharma LP filed for bankruptcy protection Sunday night, succumbing to pressure from more than 2,600 lawsuits alleging the company helped fuel the deadly U.S. opioid epidemic. [FN31]

Purdue's board met Sunday evening to approve the long-expected bankruptcy filing, which the company is pursuing to restructure under terms of a proposal to settle the widespread litigation.

Purdue, which filed for Chapter 11 protection in a federal bankruptcy court in White Plains, New York, reached a tentative deal to resolve lawsuits with 24 states and five U.S. territories, as well as lead lawyers for more than 2,000 cities, counties and other plaintiffs, the company said.

Two dozen states remain opposed or uncommitted to the proposed settlement, setting the stage for contentious legal battles over who bears responsibility for a public health crisis that has claimed the lives of nearly 400,000 people between 1999 and 2017, according to the latest U.S. data.

Thousands of cities and counties, along with nearly every state, have sued Purdue and, in some cases, its controlling Sackler family. The lawsuits, seeking billions of dollars in damages, claim the company and family aggressively marketed prescription painkillers while misleading doctors and patients about their addiction and overdose risks.

Purdue and the Sacklers have denied the allegations.

Opposing states, including Massachusetts, New York and Connecticut, want the Sacklers to guarantee more of their own money will go toward a settlement, and have questioned Purdue's calculations valuing the overall deal at more than $10 billion.

The Sacklers, who would cede control of Purdue in the proposed settlement, have offered $3 billion in cash and an additional $1.5 billion or more through the eventual sale of another company they own, called Mundipharma, according to the company and people familiar with the terms. The Sacklers have declined to revise their offer.

“This is the fork in the road. There are only two ways to go from here,” said Purdue Chairman Steve Miller in an interview with Reuters.

Miller said Purdue plans to argue to opposing states that fighting the proposed settlement will likely result in protracted litigation, increasing legal fees and depleting value that could be steered to U.S. communities reeling from opioid abuse. He described bankruptcy proceedings as the “best hope for finalizing and implementing a global resolution to this litigation.”

In a statement, members of the Sackler family controlling Purdue said they hoped those opposing the current settlement offer would eventually change their minds.

“It is our hope the bankruptcy reorganization process that is now underway will end our ownership of Purdue and ensure its assets are dedicated for the public benefit,” the family said.

The outcome of Purdue's attempted bankruptcy reorganization and settlement negotiations will help determine how much money U.S. communities receive from the company and the Sacklers to address harm from opioids. A reorganization and settlement would ultimately need to be approved by a U.S. bankruptcy judge.

States suing the Sacklers, including several over the past week, allege the family improperly reaped billions of dollars from opioid sales despite knowledge of their harmful effects. The Sacklers, some of whom previously served on the Purdue's board and are well-known wealthy philanthropists, have denied the allegations.

Purdue's proposed settlement envisions it becoming a trust that would contribute to U.S. communities, at little or no cost, tens of millions of doses of drugs the company developed to combat opioid overdoses and addiction, the company said.

Purdue values the drugs at $4.45 billion over a decade, the people familiar with the matter said. Under the proposal's terms, the restructured Purdue would be permanently bound by so-called injunctive relief, which includes restrictions on the promotion and sale of opioids.

States opposing the settlement offer have vowed to fight attempts by Purdue and the Sacklers to use bankruptcy proceedings to contain the litigation.

On Friday, New York Attorney General Letitia James said she uncovered roughly $1 billion in wire transfers “between the Sacklers, entities they control and different financial institutions, including those that have funneled funds into Swiss bank accounts.”

The information, in records an unnamed financial institution produced in response to a subpoena from James's office, detailed financial transfers involving former Purdue board member Mortimer D.A. Sackler, according to court documents her office filed.

He allegedly used shell companies “to shift Purdue money through accounts around the world and then conceal it in at least two separate multimillion-dollar real estate investments back here in New York, sanitized (until now) of any readily-detectable connections to the Sackler family,” a lawyer in James' office said in one of the court filings.

“There is nothing newsworthy about these decade-old transfers, which were perfectly legal and appropriate in every respect,” a spokesman for Mortimer D.A. Sackler said in a statement.

“This is a cynical attempt by a hostile AG's office to generate defamatory headlines to try to torpedo a mutually beneficial settlement that is supported by so many other states and would result in billions of dollars going to communities and individuals across the country that need help,” the statement added.

Purdue, meanwhile, plans to ask a bankruptcy judge to halt active litigation so it can negotiate a final settlement, the people said. But the company is preparing for states to argue their lawsuits cannot be halted by a Chapter 11 filing because their legal actions were brought to enforce public health and safety laws - exempting them from the usual bankruptcy rules that would stop their complaints.

Another thorny legal question involves the Sacklers and under what circumstances Purdue could use bankruptcy law in an attempt to also halt lawsuits against them.

Those legal skirmishes could take some time to develop, as Purdue initially must seek court approval to continue paying employees and address routine operating expenses.

Mylan to Pay $30 million U.S. SEC Fine Related to EpiPen Overcharge Probe

(Reuters) - Mylan NV has agreed to pay a $30 million fine to settle U.S. Securities and Exchange Commission charges it hid from investors the impact of a federal probe into the drugmaker's overbilling the government for its EpiPen allergy treatment. [FN32]

The SEC on Friday said Mylan kept investors in the dark when it failed to disclose or set aside money for the two-year probe by the U.S. Department of Justice, prior to announcing a $465 million settlement in October 2016.

That accord resolved claims that Mylan overbilled the government by hundreds of millions of dollars by misclassifying its EpiPen Auto-Injector as a generic drug rather than a brand-name drug.

Authorities said that enabled the company, which has offices in Canonsburg, Pennsylvania, and near London, England, to avoid paying higher rebates to state Medicaid programs.

In a statement, Mylan called the SEC civil settlement “the right course of action,” and said it was committed to the “highest levels of integrity” when communicating with investors and making disclosures in public filings.

The company did not admit or deny wrongdoing in agreeing to settle.

Mylan's share price fell more than 12% in the roughly five-week period before it announced the Justice Department accord, following reports that members of Congress were accusing the company of misclassifying EpiPen and cheating the government.

The drugmaker had raised EpiPen prices by about 400% from 2010 to 2016, yet paid a fixed rebate to Medicaid during that time. Mylan's case provided fuel to the still-continuing nationwide debate over soaring drug prices.

“It is critical that public companies accurately disclose material business risks and timely disclose and account for loss contingencies that can materially affect their bottom line,” Antonia Chion, associate director in the SEC enforcement division, said in a statement.

Mylan had in July announced an agreement in principle to settle with the SEC. Its shares were up 9 cents at $19.85 in late morning trading.

Jury Says J&J Must Pay $8 billion in Case Over Male Breast Growth Linked to Risperdal

(Reuters) - Johnson & Johnson must pay $8 billion in punitive damages to a man who previously won $680,000 over his claims that it failed to warn that young men using its antipsychotic drug Risperdal could grow breasts, a Philadelphia jury said on Tuesday. [FN33]

The Philadelphia Court of Common Pleas jury's verdict in favor of Nicholas Murray came in the first case in which a Pennsylvania jury had been able to consider awarding punitive damages in one of thousands of Risperdal cases pending in the state.

“This jury, as have other juries in other litigations, once again imposed punitive damages on a corporation that valued profits over safety and profits over patients,” Murray's lawyers, Tom Kline and Jason Itkin, said in a joint statement. “Johnson & Johnson and (subsidiary) Janssen chose billions over children.”

J&J said the award was “grossly disproportionate with the initial compensatory award in this case, and the company is confident it will be overturned.” It added that the jury in the case had not been allowed to hear evidence of Risperdal's benefits.

Professor Carl Tobias of the University of Richmond School of Law said he expects the punitive damages to be lowered on appeal, citing a U.S. Supreme Court decision which found that “few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process.”

Tobias said the verdict was about sending a message.

“A jury, if it's outrageous enough conduct, will award a big number and let the lawyers and judges work it out,” he said.

Tobias added that the verdict could be a sign that J&J will face more large damages awards in other Risperdal cases.

“The kind of evidence in this trial may persuade another jury or judge to do something similar,” he said.

Murray, like other male plaintiffs in the mass tort litigation over Risperdal, alleges that he developed breasts after being prescribed the medicine when he was a minor. The U.S. Food and Drug Administration approved the drug in late 1993 for treating schizophrenia and episodes of bipolar mania in adults.

Plaintiffs claim that J&J failed to warn of the risk of gynecomastia, the development of enlarged breasts in males, associated with Risperdal, which they say the company marketed for unapproved uses with children.

In his lawsuit, Murray, now 26, alleged that he developed breasts after his doctors began prescribing him Risperdal off-label in 2003 after a psychologist diagnosed him with autism spectrum disorder. Doctors are allowed to prescribe medicines as they see fit, while companies are only allowed to promote their drugs for approved uses.

A jury in 2015 awarded Murray $1.75 million after finding J&J was negligent in failing to warn of the risk of gynecomastia. A state appeals court upheld the verdict in February 2018 but reduced it to $680,000.

Plaintiffs in the mass tort litigation had been barred from seeking punitive damages since 2014, when a state court judge ruled that the law of New Jersey, which prohibits punitive damages and is J&J's home state, should be applied globally to the cases.

But a Pennsylvania Superior Court ruling in 2018 cleared the way for punitive damages awards, holding that the law of each plaintiff's state should instead apply.

Embattled Drugmaker Indivior Raises Forecasts on Suboxone Strength

(Reuters) - Indivior Plc on Tuesday raised its full-year forecasts as the embattled British drugmaker's best-selling opioid addiction drug Suboxone fared better than expected in the face of competition from copycats. [FN34]

Shares in the company have more than halved in value this year as the London-listed firm grapples with the arrival of cheaper alternatives for Suboxone after having lost out on multiple legal appeals.

That prompted Indivior to forecast a rapid loss in market share for the blockbuster treatment, which saw a slower-than expected market share loss. The company also faces a $3 billion fine in the United States for illegally marketing Suboxone.

On Tuesday, Indivior said it intends to cease production of its authorized Suboxone generic to cut losses from a change in rebating policy in the United States and instead focus on its newer injectable treatment, Sublocade.

The drugmaker reported revenue of over $1 billion last year - generated largely from the United States and from sales of Suboxone.

Indivior now expects full-year net revenue to be in the range of $750 million to $790 million, compared with the prior forecast of $670 million to $720 million. It also expects to report higher profit than the prior expectation.

The company tightened its forecast for Sublocade revenue to be between $60 million and $70 million.

Shares in Indivior were up 12.4% at 55.5 pence as of 0723 GMT.

Indivior now expects full-year net revenue to be in the range of $750 million to $790 million, compared with the prior forecast of $670 million to $720 million. It also expects to report higher profit than the prior expectation.

Missouri Appeals Court Overturns $110 million Johnson & Johnson Talc Verdict

(Reuters) - A Missouri appeals court overturned a $110 million verdict against Johnson & Johnson in a lawsuit by a Virginia woman who says she developed ovarian cancer after decades of using of its talc-based products for feminine hygiene. [FN35]

The ruling, which reverses a 2017 judgment in favor of the plaintiff, said that the Missouri court lacked the authority to judge the case.

Johnson and Johnson faces around 15,500 lawsuits related to body powders containing talc. It is also facing lawsuits tied to anti-psychotic drug Risperdal, pelvic meshes, and opioid drugs.

Johnson & Johnson Agrees to Pay about $117 million to Settle U.S. States' Mesh Probe

(Reuters) - Johnson & Johnson has agreed to pay nearly $117 million to resolve allegations that it deceptively marketed transvaginal surgical mesh devices, U.S. state attorneys general said on Thursday. [FN36]

The settlement resolves a multistate investigation that found J&J violated consumer protection laws by misrepresenting the safety and effectiveness of its devices and failing to sufficiently disclose risks associated with their use, the attorneys general said.

Thousands of women have sued the company and its Ethicon unit alleging that they were injured by its pelvic mesh devices, which are used to treat bladder issues and pelvic organ prolapse, in which organs shift from their normal positions.

The settlement resolves claims with 41 states and the District of Columbia.

The deal does not cover lawsuits over J&J's mesh marketing by four states, California, West Virginia, Kentucky and Mississippi, which remain pending.

A trial in California's case concluded in September, though a decision has not yet been issued. The state of Washington settled a similar case in April for $9.9 million.

J&J in a statement on Thursday said the settlement contains no admission of liability or misconduct on the part of Ethicon.

Earlier this year, the U.S. Food and Drug Administration ordered makers of all implants to immediately stop their sale and distribution amid claims that they caused pain, perforations, urinary problems, bleeding and other serious injuries.

J&J in 2012 stopped selling mesh implants for pelvic organ prolapse, though it continues to market devices for use in treating incontinence.

J&J shares have been under pressure this year, widely underperforming the S&P healthcare sector, as the company faces tens of thousands of lawsuits alleging deceptive marketing and harm from side effects caused by its products, including baby powder, opioid drugs and medical devices.

On Wednesday, two people familiar with the matter told Reuters the company would pay $4 billion in cash to resolve lawsuits seeking to hold it responsible for partly fueling the U.S. opioid crisis.

Last week, a jury hit J&J with $8 billion in punitive damages for a case involving its anti-psychotic drug Risperdal, highlighting the risks an all-or-nothing legal strategy could have.

Drug Companies Avert Landmark Opioids Trial as Talks on $48 billion Settlement Set to Resume

(Reuters) - Four large drug companies could resume talks on Tuesday to try to reach a $48 billion settlement of all opioid litigation against them, after agreeing with two Ohio counties to a $260 million deal to avert the first federal trial over their role in the U.S. opioid epidemic. [FN37]

Drug distributors AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp and drugmaker Teva Pharmaceutical Industries Ltd agreed to the deal that removed the immediate threat of a trial that was to begin on Monday in Cleveland.

The parties could resume talks as soon as Tuesday aimed at a broader settlement of thousands of opioid lawsuits brought by states and local governments, according to Paul Hanly, an attorney for the towns and counties.

Under Monday's local settlement, the distributors, which handle around 90% of U.S. prescription drugs, will pay a combined $215 million immediately to Ohio's Cuyahoga and Summit counties that were plaintiffs in Monday's trial.

Israel-based Teva said it was paying $20 million in cash and will contribute $25 million worth of Suboxone, an opioid addiction treatment.

Teva, the world's largest maker of generic drugs, said it will make its contribution over three years.

The companies have been accused of fueling a nationwide opioid crisis. Some 400,000 U.S. overdose deaths between 1997 and 2017 were linked to opioids, according to government data.

“While the companies strongly dispute the allegations made by the two counties, they believe settling the bellwether trial is an important stepping stone to achieving a global resolution,” the distributors said in a joint statement.

Hanly said his team rejected a proposed $18 billion settlement last week from the three distributors because the payments were due to be made over 18 years.

“One billion dollars for the entire year is a ham sandwich,” said Hanly. “It's way too small an amount.”

Teva and attorneys general for four states pushed to salvage a deal they had reached last week, which was rejected by the team representing local governments.

North Carolina Attorney General Josh Stein told reporters on a conference call that he and his counterparts in Pennsylvania, Texas and Tennessee had an agreement in principle with the distributors as well.

He said the deal was comprised of $22 billion in cash and $26 billion in treatment drugs.

Teva said it had agreed with the four attorneys general to contribute opioid treatment drugs worth $23 billion, as well as $250 million in cash over 10 years.

The other contributions to the broader settlement were to come from the distributors.

'POSITIVE MOMENTUM'

It was not yet clear if the settlement framework the four states announced would receive support from other states or the local governments, who had previously contended it was inadequate.

Pennsylvania Attorney General Josh Shapiro said he believed “there's a lot of positive momentum” after Friday's settlement talks, which he said also included Johnson & Johnson.

Hanly said the attorneys general deal was spread over too many years to be acceptable. He said he did not expect the attorneys general to participate when talks resumed this week.

The so-called bellwether, or test trial, that had been set for Monday could have helped shape a broader settlement of some 2,600 lawsuits pending over the toll opioids have taken on local communities and the nation.

Shares in the companies had risen last week in anticipation of a broader deal. On Monday, shares of the big three drug distributors were down as much as 5% but recovered after Teva's statement and closed down around 2% to 3%.

“We are not surprised to see distributor shares giving back some of last week's gains as uncertainty persists in this extremely complex litigation,” Baird analyst Eric Coldwell wrote in a note.

The settlement, if extrapolated to a nationwide deal resolving all litigation for the four defendants, suggests a settlement value of around $48 billion, based on a court-approved allocation formula. Hanly said he had not done the same calculation, but thought it was likely worth more.

The lawsuits accuse drugmakers of overstating the benefits of opioids while downplaying the risks and allege distributors failed to flag and halt a rising tide of suspicious orders.

The companies have denied wrongdoing. Drugmakers argued their products carried government-approved labels that warned of the addictive risks of opioids, while distributors had argued that their role was to make sure medicines prescribed by licensed doctors were available for patients.

Monday's settlement adds to deals worth $66.4 million that the two Ohio counties earlier struck with drug companies Mallinckrodt Plc, Endo International Plc, J&J and Allergan Plc.

Cuyahoga County has said it will use the funds to expand residential treatment beds, increase emergency care follow-up and to create alternatives to jailing low-level drug offenders, among other initiatives.

Former PixarBio CEO Convicted of Defrauding Biotech Investors

(Reuters) - The former chief executive of a biotech company that once claimed that it wanted to “Make US Pharma GREAT Again” through the takeover of another company was convicted on Monday of securities fraud. [FN38]

Former PixarBio Corp CEO Frank Reynolds was found guilty by a federal jury in Boston of charges that he carried out a scheme to mislead investors into believing he was a successful inventor with a drug that would end opioid addiction.

But prosecutors said those claims about himself and the drug were overhyped and untrue. They said Reynolds' goal was to defraud investors out of their money, pump up the value of his company and get rich in the process.

He also directed two accomplices to manipulate PixarBio's stock to drive up the price of its shares, which are now worth “next to nothing,” Assistant U.S. Attorney Leslie Wright told jurors in her Oct. 9 opening statement.

“Billionaire with a B. That's what the defendant, Frank Reynolds, said he wanted to be,” Wright said. “So he tried to become one by tricking investors into believing that he was the Steve Jobs of biotech.”

Jurors also found Reynolds guilty of charges that he obstructed an agency proceeding during a related U.S. Securities and Exchange Commission investigation. U.S. District Judge Douglas Woodlock scheduled his sentencing for Feb. 6.

Reynolds declined to comment. In his own opening statement, Reynolds' attorney, David Axelrod of Ballard Spahr, said his client had truly believed all of his claims, including that his product “would help put an end to the growing opioid crisis.”

He said PixarBio was a real company that employed more than 40 people, including scientists studying the potential use of his company's product, NeuroRelease, as a non-opiate pain treatment. Reynolds himself invested large sums into it, he said.

“You're going to hear that if PixarBio was a fraud and Frank Reynolds was a con man, then he was the biggest victim of this scheme,” Axelrod said.

Reynolds founded PixarBio after resigning as chief executive of Cambridge, Massachusetts-based biotechnology company InVivo Therapeutics Holdings Corp in 2013.

Prosecutors alleged that Reynolds in the years the followed sought to defraud PixarBio investors with a series of false and misleading statements about the company's prospects, financing and his own track record.

Reynolds told investors that PixarBio had a $1 billion valuation, that it was developing a drug to end “thousands of years of morphine and opiate addiction,” and that he had even cured his own paralysis, prosecutors said.

In reality, PixarBio was never worth $1 billion; the opioid addiction cure was in fact a repackaged method of delivering another drug that was already on the market; and he had never been paralyzed, prosecutors alleged.

In January 2017, at Reynolds' direction, PixarBio issued a press release entitled “It's Time to Make US Pharma GREAT Again,” announcing a $77 million takeover bid for InVivo, prosecutors alleged.

PixarBio in fact lacked the ability to make the bid, prosecutors said, yet a day later announced it had upped its offer to $100 million.

The case is U.S. v. Reynolds, U.S. District Court for the District of Massachusetts, No. 18-cr-10154.

Walgreens Has Explored Taking Drug Store Chain Private

(Reuters) - Walgreens Boots Alliance Inc has been exploring whether to go private following private equity interest in the U.S. drug store chain, which has a market value of more than $55 billion, according to people familiar with the matter. [FN39]

In recent months, Walgreens has held preliminary discussions with some of the world's largest private equity firms about putting together what would be the biggest ever leveraged buyout, the sources said.

Walgreens has tasked investment bank Evercore Partners Inc with exploring whether a transaction can be put together, the sources said, cautioning that a deal is far from certain.

Many private equity firms have pushed back on the idea, concerned about Walgreens' business prospects and the challenges of financing the deal, the sources added.

A leveraged buyout of Walgreens would likely require participation of several private equity firms, each writing large checks, at a time when many of them have lost their appetite for teaming together on so-called club deals. Many of those takeovers were completed during a boom preceding the 2008 financial crisis and subsequently struggled or collapsed.

Walgreens Chief Executive Stefano Pessina, who is the company's largest shareholder with a 16% stake, could roll his equity into the deal to help finance the transaction, one of the sources said.

Walgreens has also contemplated divesting some of its assets, such as its 27% stake in drug wholesaler AmerisourceBergen Corp, to provide more funding, one of the sources added.

The sources asked not to be identified because the matter is confidential. Walgreens and Evercore declined to comment.

Walgreens shares rose 8% to $64.12 in New York after Reuters was first to report the news on Tuesday. It later gave back some of those gains and was up about 3%. The stock had lost 28% of its value in the last 12 months, compared to a 13% rise in the S&P 500 Index.

Walgreens' deliberations over going private reflect the challenges its business faces.

Last week, it warned it did not expect its adjusted earnings to grow in fiscal 2020 because of the low reimbursement rates for prescription drugs, especially generics, and competition from online retailers such as Amazon.com Inc.

The Deerfield, Illinois-based company, which operates Walgreens and Duane Reade pharmacies in the United States and Boots in Britain, has been closing stores and launching cross-selling partnerships with companies such as grocer Kroger Co and weight loss clinic operator Jenny Craig, as it seeks to cut costs and boost its growth prospects.

Some analysts said that going private could allow Walgreens to avoid the prying eyes of Wall Street, and invest in its business and offerings without having to worry about quarterly earnings. But many questioned whether such a large leveraged buyout was possible.

“Given poor industry fundamentals, seemingly never-ending margin pressures faced in the healthcare supply chain, and, let's face it, ongoing uncertainty about unpredictable items such as opioids exposure, we would struggle to see a monster premium beyond this current run-up (in the stock),” Baird analyst Eric Coldwell wrote in a note.

DEALMAKING

Walgreens' approach toward alliances and joint ventures stands in stark contrast to the strategy of rival CVS health Corp, which acquired U.S. health insurer Aetna Inc for $70 billion last year. CVS shares have performed better than Walgreens in the last 12 months, down about 7%.

In 2017, Walgreens dropped a $17.2 billion deal to buy smaller peer Rite Aid Corp after failing to win U.S. antitrust approval. Instead, it agreed to acquire 1,932 Rite Aid stores, about 42% of its total. The retail footprint proved too big for Walgreens, which has been gradually closing some locations.

Last year, Walgreens explored other deals, including buying out the rest of AmerisourceBergen and buying a stake in U.S. health insurer Humana Inc, as well as selling a stake to it. It did not pursue those transactions, although it has been expanding its partnership with Humana by providing primary care services and support for seniors inside Walgreens stores.

Pessina, 78, would not be the first company boss to be involved in talks to take his firm private. Dell Technologies Inc CEO Michael Dell, for example, took the computer maker private in 2013 in a $24.9 billion deal backed by private equity firm Silver Lake. After a string of acquisitions, Dell returned to the stock market as a public company last year and now has a market value of $39 billion.

But Dell owned about three-quarters of his company at the time of the leveraged buyout, making its funding easier.

Last year, former Qualcomm Inc executive chairman Paul Jacobs briefly explored a long-shot bid to take the U.S. semiconductor company, which has a market capitalization of $103 billion, private.

Bankrupt Insys Reaches Deal to Divvy Cash Among Opioid Victims

(Reuters) - Drugmaker Insys Therapeutics Inc outlined a deal on Thursday to divide its dwindling cash among governments, insurers, hospitals and individuals who accused the company of fueling the U.S. opioid crisis. [FN40]

The company was largely adopting a plan it had filed in September, which now had the support of numerous groups that initially opposed it, said Brenda Funk, who represents the company, at Thursday's hearing before a U.S. bankruptcy judge Kevin Gross in Delaware.

The agreement addresses a problem that looms over the thousands of U.S. opioid lawsuits against some of the biggest drug companies - how to carve up the tens of billions of dollars from legal settlements among the plaintiffs.

The Insys agreement established the company owed various parties a combined $1 billion, well below the billions of dollars that could have been claimed. In addition, the Department of Justice would have a claim of $243 million, along with undetermined claims for forfeiture and restitution.

“I think this compromise is sufficiently bad for everyone, but everyone should go along with it,” said Andrew Troop, who represents New York.

Most will get pennies on the dollar. Chandler, Arizona-based Insys has only $39 million in cash, according to filings.

Insys also has estimated it could receive $60 million from an agreement to sell its fentanyl spray Subsys, $56 million from insurance and funds from lawsuits.

John Kapoor, the founder and former billionaire, would seem a likely legal target. He was found guilty of conspiracy to bribe doctors to prescribe Subsys and misleading insurers.

However, federal prosecutors have said they plan to seek $242 million in restitution from Kapoor. His lawyers say that demand exceeds his personal wealth. Kapoor also faces up to 20 years in prison.

Insys filed for bankruptcy in June just days after the company struck a $225 million settlement with the Justice Department that included an agreement by a subsidiary to plead guilty to fraud.

Insys, like numerous makers or distributors of opioids, also faced lawsuits by state attorneys general, local governments, health insurers, hospitals, guardians for children harmed by exposure to opioids in the womb and classes of individuals.

The opioid crisis has contributed to more than 400,000 U.S. deaths since 1997.

In September, OxyContin maker Purdue Pharma LP also filed for bankruptcy and has proposed to settle its lawsuits for what it says is $10 billion. The judge overseeing that bankruptcy has warned the parties about fighting over the proceeds.

V. HEALTHCARE FRAUD

Walgreens Pays $269.2 Million to Settle U.S. Civil Fraud Lawsuits

(Reuters) - Walgreens Boots Alliance Inc will pay $269.2 million to settle two whistleblower lawsuits accusing it of civil fraud for overbilling federal healthcare programs over a decade, the U.S. Department of Justice said on Tuesday. [FN41]

The pharmacy chain will pay $209.2 million to resolve claims it improperly billed Medicare, Medicaid and other federal programs from 2006 to 2017 for hundreds of thousands of insulin pens it dispensed to patients it knew did not need them.

Walgreens will also pay $60 million to resolve claims it overcharged Medicaid from 2008 to 2017 by failing to disclose and charge the discount drug prices it offered the public through its Prescription Savings Club program.

The Deerfield, Illinois-based company said it “admits, acknowledges, and accepts responsibility” for conduct alleged by the federal government, according to the settlement agreements.

In a separate statement, Walgreens said it “has admitted no wrongdoing,” and that the settlements were in the best interests of customers, patients and other stakeholders.

It also said it set aside enough money for both settlements as of Nov. 30, 2018.

The company recently had more than 9,400 drugstores in the United States.

Walgreens' settlements resolve claims under the federal False Claims Act, which lets private whistleblowers sue on the federal government's behalf and share in recoveries.

The accords were respectively approved last week by U.S. District Judges Paul Crotty and Paul Oetken, who both sit in Manhattan.

About $200 million of the payout will go to the federal government, and the rest to state governments.

Walgreens also entered a corporate integrity agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services to ensure future compliance with federal healthcare programs.

Two pharmacists filed the original complaint concerning the insulin pens in July 2015. A copy of that complaint could not immediately be obtained on Tuesday.

Marc Baker, who worked for Walgreens for a decade as a pharmacy manager in Florida, filed the original complaint concerning the drug price discounts in January 2012.

Both lawsuits had been filed under seal.

The cases are U.S. ex rel Rahimi v Walgreens Boots Alliance Inc, U.S. District Court, Southern District of New York, No. 15-05686; and U.S. ex rel Baker v Walgreens Inc in the same court, No. 12-00300.

Fresenius Medical Care to Pay $231 million to Resolve Criminal, Civil Foreign Bribery Charges

(Reuters) - Germany-based dialysis clinic operator Fresenius Medical Care AG will pay about $231 million to resolve criminal and civil allegations that the company paid bribes to public health and government officials in several countries to win or retain business, the U.S. Justice Department said on Friday. [FN42]

As part of the settlement, the company admitted that it doled out bribes to officials in Angola and Saudi Arabia from 2007 through 2016, and also failed to maintain proper internal accounting controls, the department said.

The Justice Department agreed not to prosecute the company criminally in exchange for Fresenius paying a penalty of $84,715,273.

The Securities and Exchange Commission, meanwhile, ordered the company to pay $147 million in disgorgement and prejudgment interest to settle the civil charges.

“We are pleased to have concluded these investigations and to have resolved the issues that we identified and voluntarily disclosed to the U.S. authorities,” Fresenius Medical Care Chief Executive Officer Rice Powell said in a statement.

For the past few years, the Justice Department has been trying to encourage companies with potential Foreign Corrupt Practices Act violations to come forward and self-report them in exchange for prosecutorial declinations and lower penalties.

The Justice Department said on Friday that while Fresenius did self-report the issues in this case, it got a higher penalty because it did not provide “timely” responses to requests for information and some of its responses were not “fulsome.”

In addition, the misconduct allegedly occurred in 13 countries and allowed the company to profit illegally by more than $140 million, the Justice Department said.

In Morocco, for instance, the department said the company paid bribes through a “sham” commission to a Moroccan state official in order to win contracts to develop dialysis centers at state-owned military hospitals.

The scheme worked by having the commission pay 10 percent of the value of the contract to the official, and the payment would be disguised as a bonus payment to a Fresenius company employee.

In addition to Morocco, Angola and Saudi Arabia, the company also paid bribes in Spain, the Justice Department said.

“Fresenius doled out millions of dollars in bribes across the globe to gain an advantage in the medical services industry,” said Brian Benczkowski, the head of the Justice Department's criminal division.

As part of the settlement, the company has also agreed to retain an independent monitor for at least two years, he said.

Drugmakers Jazz, Alexion, Lundbeck to Pay $123 million to Resolve Charity Kickback Probe

(Reuters) - Three drugmakers will pay $122.6 million to resolve claims they used charities that help cover Medicare patients' out-of-pocket drug costs as a way to pay kickbacks aimed at encouraging use of their medications, including some expensive ones. [FN43]

The U.S. Justice Department on Thursday said Jazz Pharmaceuticals Plc, Lundbeck and Alexion Pharmaceuticals Inc were the latest companies to settle claims stemming from an industry-wide probe of drugmakers' financial support of patient assistance charities.

The government in an earlier settlement said drugmakers used such charities as a means to improperly pay the copay obligations of Medicare patients using their drugs, in violation of the Anti-Kickback Statute.

The investigation came amid growing attention to soaring U.S. drug prices. Copays are partly meant to serve as a check on healthcare expenses by exposing patients to some of a drug's cost.

Jazz will pay $57 million, Lundbeck will pay $52.6 million and Alexion will pay $13 million.

None of the companies admitted wrongdoing, a fact Lundbeck and Jazz noted in separate statements. Alexion said the settlement recognized “significant” positive changes at the company.

Drug companies are prohibited from subsidizing copayments for patients enrolled in the government's Medicare healthcare program for those aged 65 and older. Companies may donate to non-profits providing copay assistance as long as they are independent.

But according to the settlement agreements, the drugmakers used certain charities as “conduits” to pay patients' copays.

The government alleged Alexion in 2010 asked a foundation to set up a fund to support patients using Soliris, a treatment for two rare blood disorders that costs over $500,000 annually.

While such funds are typically set up to help patients afford treatments for a given disease or condition, the government said Alexion discussed wanting the fund to support only patients using Soliris.

The department said Jazz asked a foundation to set up funds to cover copays for patients using its narcolepsy treatment Xyrem and its Prialt pain medication.

The foundation's funds almost exclusively assisted patients using those two drugs through 2014 and referred pain patients seeking help paying for drugs other than Prialt elsewhere, the government said.

The department said Lundbeck, beginning in 2011, donated to a charity's fund that ostensibly covered only copays for patients with Huntington's Disease.

The fund actually helped patients who used its Xenazine drug for any condition, including unapproved ones, the government said. Medicare and a health care program for veterans subsequently paid claims for Xenazine.

Indivior Shares Tank After U.S. Indictment for Illegal Marketing

(Reuters) - Shares of Indivior Plc sank 44 percent on Wednesday after the U.S. Justice Department accused the British drugmaker of illegally boosting prescriptions for the film version of its blockbuster opioid addiction treatment Suboxone. [FN44]

An indictment filed in federal court in Abingdon, Virginia, alleged Indivior made billions of dollars by deceiving doctors and healthcare benefit programs into believing the film version of Suboxone was safer and less susceptible to abuse than similar drugs.

Shares in the company, already facing a slump in Suboxone sales due to the arrival of generic competition after a long legal fight, traded as low as 57.7 pence in early trading in London, their lowest since listing in 2014.

The U.S. market, buoyed by attempts to combat an opioid epidemic that President Donald Trump has declared a public health emergency, accounts for 80 percent of Indivior's revenue.

The indictment charged Indivior and its subsidiary Indivior Inc with conspiracy, health care fraud, mail fraud and wire fraud. If Indivior is convicted, the government will seek to have it forfeit at least $3 billion, the indictment said.

Drug Company Founder, Execs Convicted of Bribe Scheme that Fueled U.S. Opioid Crisis

(Reuters) - The founder of Insys Therapeutics Inc and four colleagues were found guilty on Thursday of bribing doctors to prescribe the drugmaker's addictive painkiller, helping to drive the U.S. opioid drug abuse crisis. [FN45]

A federal jury in Boston found John Kapoor, who served as the Chandler, Arizona-based drugmaker's chairman, and his co-defendants guilty of racketeering conspiracy for a scheme that also misled insurers into paying for the drug.

Kapoor, 75, is the highest-ranking pharmaceutical executive convicted in a case tied to a drug crisis that has led to tens of thousands of overdose deaths annually. His 2017 arrest came the same day U.S. President Donald Trump declared the epidemic a public health emergency.

Prosecutors charged that Kapoor oversaw a wide-ranging scheme to bribe doctors nationwide by retaining them to act as speakers at sham events at restaurants ostensibly meant to educate clinicians about its fentanyl spray, Subsys.

The U.S. Food and Drug Administration approved Subsys in 2012 only for use in treating severe pain in cancer patients. Yet prosecutors claimed doctors who took bribes often prescribed Subsys to patients without cancer, helping boost sales for Insys.

Prosecutors said Kapoor also directed efforts to defraud insurers into paying for the drug. His co-defendants include former Insys executives and managers Michael Gurry, Richard Simon, Sunrise Lee and Joseph Rowan.

All five pleaded not guilty and denied wrongdoing. Lawyers for Kapoor at trial acknowledged that Insys paid doctors but contended that Kapoor believed they really were being paid to talk up the product's benefits.

Drug Companies Have Duty to Halt Suspicious Opioid Orders - MDL Judge

(Reuters) - A federal judge overseeing thousands of lawsuits accusing drug manufacturers and distributors of fueling the opioid epidemic rejected their arguments that they did not have a duty under the Controlled Substances Act to halt suspicious drug orders. [FN46]

The ruling by U.S. District Judge Dan Polster in Cleveland, Ohio, was a victory for lawyers for cities and counties suing the drug companies who argued the companies' legal duties went beyond just identifying and reporting suspicious orders.

Paul Hanly, a lawyer for the plaintiffs at Simmons Hanly Conroy, called the decision “an excellent result that spares the parties time and resources at trial.” The companies did not respond to requests for comment.

Drug companies including OxyContin maker Purdue Pharma LP and distributors including McKesson Corp, AmerisourceBergen and Cardinal Health argued the plaintiffs misread the CSA and its regulations to create legal duties under it that did not exist.

But Polster held that a duty to not ship suspicious orders arises from the legal obligations under the CSA of companies registered with the DEA to maintain effective controls against the diversion of controlled substances for improper purposes.

Polster said given those obligations, he was “hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels.”

“How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot,” he wrote. “It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.”

While the judge agreed the companies were required to halt suspicious orders, he declined at this time to find the companies failed to comply with the CSA's duties to halt suspicious opioid orders shipped to two counties in Ohio.

Those counties, Summit and Cuyahoga, will be the first plaintiffs to take their cases to trial in the multidistrict litigation on Oct. 21. Polster said factual disputes will require a jury to decide the question.

The decision comes amid ongoing settlement talks pushed by Polster. The plaintiffs' lawyers in a July 19 motion asked Polster to rule on what duties the companies had under the CSA, saying a decision could “substantially advance resolution of the claims asserted by litigants from across the country.”

Opioids were involved in 400,000 overdose deaths from 1999 to 2017, according to the U.S. Centers for Disease Control and Prevention.

More than 2,300 lawsuits are pending nationally by state and local governments accusing drug manufacturers of deceptively marketing opioids in ways that downplayed their risks and drug distributors of failing to detect suspicious orders.

More than 2,000 of those lawsuits - largely by cities and counties - are pending before Polster, who since 2017 has overseen the federal multidistrict litigation over the opioid epidemic.

He has since then been pushing for a settlement that could “do something meaningful to abate this crisis.”

The companies deny wrongdoing, saying they marketed their drugs appropriately and sought to comply with their legal obligations. They also argue they did not cause the epidemic, citing other factors.

The case is In re National Prescription Opiate Litigation, U.S. District Court for the Northern District of Ohio, No. 17-md-02804.

Oklahoma Judge Finds J&J Liable in Opioid Epidemic, Orders $572 million in Damages

(Reuters) - An Oklahoma judge on Monday found Johnson & Johnson liable for fueling an opioid epidemic in the state by deceptively marketing painkillers, and ordered the drugmaker to pay damages of $572 million. [FN47]

The damages awarded by Judge Thad Balkman of Cleveland County District Court in Norman, Oklahoma, following a seven-week, non-jury trial came in what had been a $17 billion lawsuit alleging that J&J's marketing practices helped fuel the opioid epidemic by flooding the market with painkillers.

J&J said it would appeal the verdict.

J&J shares rose 5% in extended trading following the decision. Shares of other drugmakers, including Teva Pharmaceutical Industries Ltd and Endo International Plc also rose after-hours.

The case brought by Oklahoma Attorney General Mike Hunter was the first to go to trial out of thousands of lawsuits filed by state and local governments against opioid manufacturers and distributors.

Oklahoma sued J&J to help it address the epidemic for the next 30 years through addiction treatment and prevention programs.

“The opioid crisis is an imminent danger and menace to Oklahomans,” Balkman said as he delivered his decision from the bench.

The trial came after Oklahoma resolved claims against OxyContin maker Purdue Pharma LP in March for $270 million and against Teva in May for $85 million, leaving J&J as the lone defendant.

The litigation has been closely watched by plaintiffs in about 2,000 opioid lawsuits pending before a federal judge in Ohio who has been pushing for a settlement ahead of an October trial.

Some plaintiffs' lawyers have compared the opioid cases to litigation by states against the tobacco industry that led to a $246 billion settlement in 1998.

Opioids were involved in almost 400,000 overdose deaths from 1999 to 2017, according to the U.S. Centers for Disease Control and Prevention. Since 2000, some 6,000 Oklahomans have died from opioid overdoses, according to the state's lawyers.

During the trial, lawyers for Oklahoma argued that J&J carried out a years-long marketing campaign that minimized the painkillers' addiction risks and promoted their benefits.

The state's lawyers called J&J an opioid “kingpin” and argued that its marketing efforts created a public nuisance as doctors over-prescribed the drugs, leading to a surge in overdose deaths in Oklahoma.

J&J has denied wrongdoing, saying its marketing claims had scientific support and that its painkillers, Duragesic and Nucynta, accounted for a tiny fraction of opioids prescribed in Oklahoma.

The company also said in a statement that since 2008, its painkillers accounted for less than 1 percent of the U.S. market, including generics.

Lawyers for New Jersey-based J&J have said the case rested on a “radical” interpretation of the state's public nuisance law.

J&J on Monday, prior to the decision, called the state's attempt to use public nuisance law to resolve a complex social problem “misguided and legally unsustainable.”

“Not once did the state identify a single Oklahoma doctor who was misled by a single Janssen statement, nor did it prove that Janssen misleadingly marketed opioids or caused any harm in Oklahoma,” John Sparks, Oklahoma counsel for Johnson & Johnson, said in a statement.

Janssen Pharmaceuticals is the healthcare conglomerate's primary prescription drugs unit.

J&J said it has not set aside a litigation reserve to pay potential damages, and that its policy is to do so once a loss is “probable and can be reasonably estimated.”

Two Charities to Pay $6 million to Resolve U.S. Pharma Kickback Probe

(Reuters) - Two charities will pay $6 million to resolve claims they operated as pass-throughs for seven pharmaceutical companies to pay kickbacks to Medicare patients using their high-priced medications, the U.S. Justice Department said on Friday. [FN48]

The settlements with the patient assistance charities Good Days and Patient Access Network Foundation were the first with foundations linked to an industry-wide probe that has resulted in $840 million in settlements with drugmakers.

Both foundations provide assistance to patients seeking to pay out-of-pocket costs for medications. Good Days agreed to pay $2 million while PAN Foundation agreed to pay $4 million. Neither admitted wrongdoing.

Good Days in a statement said the settlement will allow it to concentrate on providing help to people in need of life-saving medications. PAN said the settlement involved “legacy matters” rather than its current operations.

Drug companies are prohibited from subsidizing co-payments for patients enrolled in the government's Medicare healthcare program for those aged 65 and older. Companies may donate to non-profits providing co-pay assistance as long as they are independent.

But the government has alleged that various drugmakers have used charities like Good Days and PAN as means to improperly pay the co-pay obligations of Medicare patients using their drugs, in violation of the Anti-Kickback Statute.

The department said Good Days, previously known as the Chronic Disease Fund, from 2010 to 2014 conspired with companies including Novartis AG, Astellas and Questcor, now owned by Mallinckrodt Plc, to pay kickbacks to Medicare patients using their drugs.

Those drugs included H.P. Acthar Gel, an expensive treatment for a rare infant seizure disorder and multiple sclerosis that is subject of a related lawsuit by the government against Mallinckrodt over Questcor's donations to the charity.

The Justice Department said Questcor from 2010 to 2014 used the charity as a conduit to improperly subsidize patients' copays, allowing it to keep raising prices for Acthar, whose price increased from $50 per vial in 2001 to $32,200 in 2014.

Mallinckrodt declined to comment. It has said it believed its actions were lawful.

PAN similarly permitted Bayer AG, Astellas, Dendreon Pharmaceuticals and Amgen Inc to use it as a conduit to pay patients kickbacks, according to the government's allegations.

Astellas and Amgen in April agreed to pay $100 million and $24.75 million, respectively, to resolve related claims.

Dendreon said it takes compliance seriously. Novartis declined to comment. The other companies' representatives did not respond to requests for comment.

VI. DATA BREACHES

OCR Has Record Year for HIPAA Enforcement in 2018

The Office for Civil Rights (OCR) at the U.S Department of Health and Human Services concluded an all-time record year in Health Insurance Portability and Accountability Act (HIPAA) enforcement activity. In 2018, OCR settled 10 cases and was granted summary judgment in a case before an Administrative Law Judge, together totaling $28.7 million from enforcement actions. This total surpassed the previous record of $23.5 million from 2016 by 22 percent. In addition, OCR also achieved the single largest individual HIPAA settlement in history of $16 million with Anthem, Inc., representing a nearly three-fold increase over the previous record settlement of $5.5 million in 2016.

OCR's final settlement of the year occurred in December 2018, when Cottage Health agreed to pay $3 million to OCR and to adopt a substantial corrective action plan to settle potential violations of the HIPAA Rules. Cottage Health operates Santa Barbara Cottage Hospital, Santa Ynez Cottage Hospital, Goleta Valley Cottage Hospital and Cottage Rehabilitation Hospital, in California. OCR received two notifications from Cottage Health regarding breaches of unsecured electronic protected health information (ePHI) affecting over 62,500 individuals, one in December 2013 and another in December 2015.

The first breach arose when ePHI on a Cottage Health server was accessible from the internet. OCR's investigation determined that security configuration settings of the Windows operating system permitted access to files containing ePHI without requiring a username and password. As a result, patient names, addresses, dates of birth, diagnoses, conditions, lab results and other treatment information were available to anyone with access to Cottage Health's server. The second breach occurred when a server was misconfigured following an IT response to a troubleshooting ticket, exposing unsecured ePHI over the internet. This ePHI included patient names, addresses, dates of birth, social security numbers, diagnoses, conditions, and other treatment information.

OCR's investigation revealed that Cottage Health failed to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of the ePHI; failed to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level; failed to perform periodic technical and non-technical evaluations in response to environmental or operational changes affecting the security of ePHI; and failed to obtain a written business associate agreement with a contractor that maintained ePHI on its behalf.

“Our record year underscores the need for covered entities to be proactive about data security if they want to avoid being on the wrong end of an enforcement action,” said OCR Director Roger Severino. “The Cottage settlement reminds us that information security is a dynamic process and the risks to ePHI may arise before, during, and after implementation covered entity makes system changes.”

More information is available at: https://www.hhs.gov/about/news/2019/02/07/ocr-concludes-all-time-record-year-for-hipaa-enforcement-with-3-million-cottage-health-settlement.html.

Quest Diagnostics Says Data Breach Could Have Hit 11.9 million Patients

(Reuters) - Quest Diagnostics Inc said on Monday it was notified by a billing collections vendor that an unauthorized user gained access to information on nearly 11.9 million patients, including credit card numbers and bank account information. [FN49]

The company has not received all the information about the incident from American Medical Collection Agency (AMCA) and has not been able to verify the accuracy of the information received from AMCA, the diagnostic information services provider said.

Optum360 LLC, a unit of UnitedHealth Group Inc, was also notified of the breach, according to Quest's regulatory filing. Optum360 provides customer billing services to Quest Diagnostics.

AMCA said the user had access between Aug. 1, 2018 and March 30, 2019 to its system that contained information that AMCA had received from various entities, including Quest Diagnostics, and information that AMCA collected itself.

The information also includes medical data and other personal details like social security numbers, AMCA told the company. Patient laboratory test results were not impacted by this incident, Quest Diagnostics said.

The company said it suspended AMCA collection requests. Quests said it was working with AMCA and Optum360, as well as outside security experts to investigate the incident and its potential impact on its patients.

Opko Health Says Over 400,000 Customers Likely Affected by Data Breach

(Reuters) - Opko Health Inc said on Thursday it was notified by its former billing collections vendor about unauthorized access to information on about 422,600 customers, making it the third healthcare company to be affected by the incident. [FN50]

American Medical Collection Agency (AMCA) informed Opko Health that the compromised data may include credit card and bank account information, email addresses and other data such as address, phone number and balance information.

However, the company said no social security numbers, bank account passwords or security questions were compromised in the unauthorized activity that occurred between August 1, 2018 and March 30, 2019.

Earlier this week, rivals Quest Diagnostics Inc and Laboratory Corporation of America Holdings also announced that they were apprised of unauthorized access to their customer data stored on AMCA system.

The data breach is estimated to have affected about 11.9 million customers of Quest Diagnostics and about 7.7 million of LabCorp.

AMCA said in an emailed statement it is investigating the incident and has also hired an external forensics firm. Meanwhile, the company has migrated its web payments services to a third-party vendor.

The company told Opko Health it was notifying state attorneys general and other state agencies and nearly 6,600 customers that availed Opko's testing services and whose credit card or bank account details were stored in AMCA's affected system.

Shares of Opko were down 1.5% at $1.92 in afternoon trading.

Opko Health said it has not yet received the list of affected customers and had not been able to verify the accuracy of the information received from AMCA.

Opko Health said its affected unit, BioReference Laboratories Inc, suspended collection requests to AMCA since October last year, and has asked the vendor to stop working on any pending collection requests involving the company's customers.

Healthcare Data Hacking Could Lead to Identity Thefts

(Reuters) - More than 70% of healthcare data breaches in the U.S. have involved sensitive demographic or financial information that could fuel identity theft, a new study suggests. [FN51]

When a healthcare company is hacked, criminals gain access not only to health information, but also to demographic and financial data that could compromise patients' privacy and financial security, researchers from the Michigan State and Johns Hopkins report.

Media reports often focus on the numbers of patients affected by these breaches, but what may be more important is the kind of data that has been stolen, they write in Annals of Internal Medicine.

Theft of medical data may not affect patients much because there isn't a big market for it, said the study's lead author, Xuefeng Jiang, a professor of accounting and information systems at the Eli Broad College of Business at Michigan State University.

“But social security numbers, credit card numbers and demographic data (such as names, birth dates, and other personal identifiers) can be sold on the dark web,” Jiang said. “The main message for hospitals and health care providers is, if you have limited resources to safeguard information, you should put more emphasis on the sensitive kinds of information that can be sold on the dark web.”

For patients, the advice is to look past the numbers in media reports and focus on what types of information have been compromised, Jiang said.

To take a closer look at the kinds of data that get stolen in healthcare data hacks, Jiang and his coauthor pored over U.S. Department of Health and Human Services records on breaches that occurred between 2009 and 2019.

The HHS requires all health plans, health care clearing houses and health care providers to notify the agency after a hack and it publishes information online whenever a breach affects 500 or more people.

After examining the hacks of 1,461 healthcare organizations, the researchers found that all involved at least one piece of demographic data. In 964 breaches, which affected 150 million patients, sensitive information, including social security numbers, drivers' license numbers, and dates of birth, was compromised. Those breaches accounted for 66% of the hacks examined by the researchers.

A total of 513 breaches, or 35%, left service or financial information vulnerable. In 186 of the 513, which affected 49 million patients, compromised sensitive financial information, including credit card and bank account numbers.

Overall, 71% of the hacks that occurred over the 10-year study period, affecting 159 million patients, compromised sensitive demographic or financial information that could be used in identity theft and financial fraud, the researchers concluded.

The new study is “important,” said Michael Pencina, a professor of biostatistics and bioinformatics and vice dean for data science and information technology at the Duke University School of Medicine in Durham, North Carolina.

“They make a good point that we need to care as much about the type of information that is hacked as the number of individuals affected,” Pencina said. “Still, whether it's medical, demographic or financial information, that's the stuff I don't want in somebody else's hands.”

As hacks become increasingly common, IT specialists debate the best way to keep data safe, Pencina said. “Is it safer to have data stored on a server locally or does it make more sense to store everything using the cloud,” he said.

While the companies offering cloud storage might be bigger targets, they also have more tools to protect against hacking, Pencina said.

OCR Imposes a $2.15 Million Civil Money Penalty against Jackson Health System for HIPAA Violations

On October 23, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services announced it imposed a civil money penalty of $2,154,000 against Jackson Health System (JHS) for violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security and Breach Notification Rules between 2013 and 2016. JHS is a nonprofit academic medical system based in Miami, Florida, which operates six major hospitals, a network of urgent care centers, multiple primary care and specialty care centers, long-term care nursing facilities, and corrections health services clinics. JHS provides health services to approximately 650,000 patients annually, and employs about 12,000 individuals.

On August 22, 2013, JHS submitted a breach report to OCR stating that its Health Information Management Department had lost paper records containing the protected health information (PHI) of 756 patients in January 2013. JHS's internal investigation determined that an additional three boxes of patient records were also lost in December 2012; however, JHS did not report the additional loss or the increased number of individuals affected to 1,436, until June 7, 2016.

In July 2015, OCR initiated an investigation following a media report that disclosed the PHI of a JHS patient. A reporter had shared a photograph of a JHS operating room screen containing the patient's medical information on social media. JHS subsequently determined that two employees had accessed this patient's electronic medical record without a job-related purpose.

On February 19, 2016, JHS submitted a breach report to OCR reporting that an employee had been selling patient PHI. The employee had inappropriately accessed over 24,000 patients' records since 2011.

OCR's investigation revealed that JHS failed to provide timely and accurate breach notification to the Secretary of HHS, conduct enterprise-wide risk analyses, manage identified risks to a reasonable and appropriate level, regularly review information system activity records, and restrict authorization of its workforce members' access to patient ePHI to the minimum necessary to accomplish their job duties.

JHS waived its right to a hearing and did not contest the findings in OCR's Notice of Proposed Determination. Accordingly, OCR issued a Notice of Final Determination and JHS has paid the full civil money penalty.

“OCR's investigation revealed a HIPAA compliance program that had been in disarray for a number of years,” said OCR Director Roger Severino. “This hospital system's compliance program failed to detect and stop an employee who stole and sold thousands of patient records; lost patient files without notifying OCR as required by law; and failed to properly secure PHI that was leaked to the media.”

VII. TRUMP ADMINISTRATION

U.S. Attorney General Nominee Open to Reconsidering Healthcare Position

(Reuters) - President Donald Trump's pick to be the next U.S. Attorney General, William Barr, told a Senate panel on Tuesday he is willing to reconsider the Justice Department's current position of not defending the country's healthcare law, commonly called Obamacare, in court. [FN52]

When asked by Senator Mazie Hirono, a Democrat, if he was open to reconsidering the position, Barr said “yes.”

He also said that the Justice Department's decision to not defend the law, the Affordable Care Act, “is a case that, if I'm confirmed, I would like to review.”

White House Scraps Key Plan to Lower U.S. Drug Prices; May Target Drugmakers

(Reuters) - The Trump administration on Thursday scrapped one of its most ambitious proposals for lowering prescription medicine prices, backing down from a policy aimed at health insurers and raising the possibility of new measures focused on drugmakers. [FN53]

The abandoned proposal would have required health insurers to pass billions of dollars in rebates they receive from drugmakers to Medicare patients.

The decision represents a new setback to U.S. President Donald Trump's efforts to deliver on a pledge to lower drug prices for consumers before the November 2020 election, when Republicans want to capitalize on voter concern over high healthcare costs.

It allows companies like Cigna Corp and CVS Health Corp, which negotiate rebates with drugmakers on behalf of the government's Medicare program, to continue to benefit from those discounts.

Shares of Cigna rose 9%, CVS gained 5% and UnitedHealth Group Inc was up 6%.

Pharmaceutical company shares fell, with Merck & Co off 4%, Bristol-Myers Squibb Co down 3% and Pfizer Inc off 2%.

Baird analyst Eric Coldwell said Trump was likely refocusing his reform efforts on the pharmaceutical companies themselves.

“There are still many headwinds for the supply chain, but... pharma and biotech seem to have drawn the ire of the administration more recently,” said Coldwell, noting the industry's successful legal challenge of a rule that would have required drugmakers to include list prices in TV ads for their medicines.

“Shelving the rebate reform initiative, which pharma strongly supported, feels like payback,” Coldwell added.

The White House first floated the idea of ending the rebates last year as part of a drug pricing “blueprint” aimed at bringing down costs.

Several Democratic presidential hopefuls have also seized on drug pricing as a key issue for the 2020 elections. Legislators, including House Speaker Nancy Pelosi, are pushing for new laws to allow the government to negotiate drug prices directly with manufacturers.

A senior administration official, speaking on the condition of anonymity, said the rule was too costly and could have hurt chances for bipartisan legislation.

“The decision was made that... it was not prudent to go forward with the rule right now, that it would be too disruptive, that the risk was probably too high, and that it might upset a legislative deal, which is our primary focus,” he said.

The rebate rule would have forced companies like Cigna and CVS either to forgo the discounts or pass them onto Medicare patients enrolled in their health insurance plans and drug plans.

They argued that such a change would force them to raise monthly premiums and had been pressing the administration to consider its impact on Medicare, which includes people aged 65 and older and the disabled, and instead focus on drugmakers.

“Only drug manufacturers have the power to set drug prices. We believe that the key to lowering drug costs is to enact policies that encourage greater competition,” JC Scott, chief executive of industry lobbyist Pharmaceutical Care Management Association, said in a statement.

PhRMA, the main pharmaceutical industry lobby group, disagreed, saying in a statement that the move ended the only government proposal that would have provided immediate savings at the pharmacy counter for patients.

'UNINTENDED WINDFALL PROFITS' FOR DRUGMAKERS

The Trump administration is considering a proposed rule that aims to bring some U.S. drug prices in the Medicare program in line with lower prices paid by other countries.

U.S. Department of Health and Human Services Secretary Alex Azar said on Thursday that Americans overpay for medicines, subsidizing socialist European systems. Most European countries pay for citizens' healthcare and directly negotiate drug prices.

Azar also said that he and Trump are working on allowing the importation of cheaper drugs from other countries, a move Trump has endorsed but which drugmakers have long opposed.

The rebate rule was estimated by the nonpartisan Congressional Budget Office to cost the government $177 billion over the next 10 years. The CBO also said it was likely drugmakers would not cut their prices because of the rule.

The government had hoped that by eliminating rebates of 15 percent to 30 percent, or more, of a drug's listed price, the prices would fall.

JP Morgan analyst Gary Taylor said in a note that political momentum had been building against the rebate rule “due to the perceived unintended windfall profits that might have accrued to pharmaceutical manufacturers.”

Politico first reported the planned scrapping of the rebate rule on Thursday and the White House confirmed the decision to Reuters.

“Based on careful analysis and thorough consideration, the President has decided to withdraw the rebate rule,” White House spokesman Judd Deere said in an emailed statement.

In recent weeks, Politico and other publications reported that the White House and Azar had disagreed over the rule. Azar said on Thursday that he planned to stay in his job as long as Trump wanted him there.

White House Preparing Order that Would Cut Drug Prices for Medicare: Sources

(Reuters) - U.S. President Donald Trump is considering a sweeping executive order that would cut prices on virtually all branded prescription drugs sold to Medicare and other government programs, according to two industry sources who had discussions with the White House. [FN54]

The order under discussion would be much broader than the Administration's previously disclosed proposal to lower prices on physician administered, or Part B, drugs by tying prices to lower costs in other countries.

The administration is now looking at ways to use this or a similar method to lower prices in Medicare's much larger Part D, which is for widely used prescription drugs patients take at home, such as for cholesterol and blood pressure, the sources said.

The White House declined to comment, and it was unclear how far along the any such plan was from being undertaken. The U.S. Department of Health and Human Services also declined to comment.

Americans pay the highest prices for prescription drugs in the world as most other developed nations have single-payer systems in which the government negotiates drug prices for its people.

The U.S. government in 2016 spent around $29 billion on prescription drugs in Medicare's Part B, which includes most injectable drugs, and nearly $100 billion in Part D, which covers as pills and other drugs usually dispensed in pharmacies.

Trump is also considering extending the pricing controls to the U.S. Department of Defense, which runs the Tricare health plan for military personnel and their families, as well as the Department of Veterans Affairs, the sources said.

Executive orders often go through various drafts and incarnations, and sometimes competing versions of the same order are floated within the Trump White House. In addition, some executive orders do not end up being signed.

The drug pricing executive order could come as soon as the next few weeks, the sources said.

U.S. Senators Chuck Grassley and Ron Wyden - the top Republican and Democrat on the U.S. Senate Finance Committee - earlier this week announced a proposal to lower prescription drug prices that could save $100 billion in costs to government healthcare programs.

The White House could delay the executive order if the Senate bill looks likely to garner bipartisan support, the sources said.

If implemented, the executive order could significantly increase the number of drugmakers whose sales could take a hit. AbbVie, Eli Lilly and Co and Pfizer Inc all have substantial exposure to Medicare Part D. Companies with major exposure to Part B include Merck & Co, Bristol-Myers Squibb Co and Roche

In early July, Trump said his administration was working on a drug pricing executive order with a “favored-nation clause, where we pay whatever the lowest nation's price is.” Trump has called the lower prices paid by other nations “global freeloading.”

Trump, a Republican, has struggled to deliver on a pledge to lower drug prices before the November 2020 election. Healthcare costs are expected to be a major focus of the campaign by Trump and Democratic rivals vying to run against him.

The Trump administration earlier this month scrapped an ambitious policy that would have required health insurers to pass billions of dollars in rebates they receive from drugmakers to Medicare patients.

Also, in July, a federal judge struck down a Trump administration rule that would have forced pharmaceutical companies to include the wholesale prices of their drugs in television advertising.

Trump Suspends Entry of Immigrants Who Cannot Pay for Healthcare

(Reuters) - U.S. President Donald Trump on Friday signed a proclamation suspending entry of immigrants who will not be covered by health insurance within 30 days of entering the United States or do not have the means to pay for their healthcare costs themselves. [FN55]

The proclamation, issued by the White House, said it would not affect any individual's eligibility for asylum or refugee status. The measure will take effect on Nov. 3, it said.

Trump has made cutting legal and illegal immigration a centerpiece of his presidency. The Trump administration said last month that it planned to allow only 18,000 refugees to resettle in the United States in the 2020 fiscal year, the lowest number in the history of the modern refugee program.

“While our healthcare system grapples with the challenges caused by uncompensated care, the United States Government is making the problem worse by admitting thousands of aliens who have not demonstrated any ability to pay for their healthcare costs,” Trump said in the proclamation.

He said the suspension applied only to people seeking to enter the United States with an immigrant visa.

The document listed the types of insurance considered approved, such as employer-sponsored plans and the Medicare program for the elderly.

But it said for people over the age of 18, coverage under the Medicaid program for the poor is not approved.

Trump's ‘Conscience’ Rule for Healthcare Workers Struck Down by U.S. Judge

(Reuters) - A federal judge on Wednesday voided a White House-backed rule making it easier for doctors, nurses and other healthcare providers to avoid performing abortions and other medical services on religious or moral grounds. [FN56]

U.S. District Judge Paul Engelmayer in Manhattan said the “conscience” rule was unconstitutionally coercive because it would let the U.S. Department of Health and Human Services (HHS) withhold billions of dollars of funding from hospitals, clinics, universities and other healthcare providers that did not comply.

“Wherever the outermost line where persuasion gives way to coercion lies, the threat to pull all HHS funding here crosses it,” Engelmayer wrote in a 147-page decision.

The judge also said the rule was “arbitrary and capricious,” and conflicted with federal laws governing the obligations of employers to accommodate workers' religious views, and hospitals to provide emergency treatment to poor patients.

Engelmayer's decision covered a lawsuit by New York state, New York City and 21 other states and municipalities that are led by Democrats or often lean Democratic, as well as two lawsuits by Planned Parenthood and other healthcare providers. California has filed its own lawsuit challenging the rule.

A spokeswoman for HHS said that agency and the U.S. Department of Justice were reviewing Engelmayer's decision.

U.S. President Donald Trump, a Republican running for reelection, has made expanding religious liberty a priority, and the conscience rule has drawn support from abortion opponents. The rule was scheduled to take effect on Nov. 22.

New York Attorney General Letitia James in a statement said the rule would have encouraged healthcare providers to “openly discriminate” against some patients.

“Health care is a basic right that should never be subject to political games,” James said.

Planned Parenthood also welcomed the decision. “Everyone deserves to access the health care they need,” Acting President Alexis McGill Johnson said. “This rule put patients' needs last.”

The states and municipalities have said the rule could undermine their ability to provide effective healthcare, and upend their efforts to accommodate workers' beliefs.

Critics have also said the rule could deprive gay, transgender and other patients of needed healthcare because some providers might deem them less worthy of treatment.

HHS countered that the rule would help enforce conscience protection laws that have been on the books for decades.

Engelmayer, an appointee of former Democratic President Barack Obama, said these protections “recognize and protect undeniably important rights,” but the government's rulemaking “was sufficiently shot through with glaring legal defects.”

He also chastised HHS for making a “factually untrue” and “demonstrably false” claim that there had been a “significant increase” in complaints about conscience protection violations.

Plaintiffs challenging the rule included Chicago and Washington, D.C., as well as Michigan, Pennsylvania and Wisconsin, states where Trump prevailed in the 2016 presidential election.

The states' case is New York et al v. U.S. Department of Health and Human Services et al, U.S. District Court, Southern District of New York, No. 19-04676.

Trump Says U.S. States Will Be Able to Buy Prescription Drugs Abroad

(Reuters) - President Donald Trump said on Friday he would be giving U.S. states the right to buy prescription drugs from other countries, as part of a bid to boost consumer access to cheaper medicines. [FN57]

“I'm going to be giving governors the right very shortly to buy ... their prescription drugs from other countries,” Trump said at a White House event accompanied by Health and Human Services (HHS) Secretary Alex Azar, among other officials.

Trump said he was working with governors including Florida Republican Ron DeSantis on the plan. “They're going to buy from other countries and skip all of the nonsense.”

Trump campaigned on a platform to reduce drug prices for U.S. consumers and has slammed the pharmaceutical industry for high prices.

Most other developed nations directly or indirectly negotiate drug pricing with companies, and in some cases may deny access to medicines they deem too expensive, while pricing in the United States is left to the free market and set by drugmakers.

Trump has floated the idea before, but it was not immediately clear how such imports would work. The idea has been mulled for years but never implemented, given U.S. regulations to ensure safety and staunch industry opposition.

Trump's comments came after HHS announced two rules to increase price transparency among hospitals, group health plans and health insurers.

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