THE 2021 RESULTS ARE IN
PHARMACY SURVEY

Formulary Development
Q&A with Dan Ollendorf, Ph.D., M.P.H.

Chronic Disease
Psychedelics for mental health disorders

Population Health
STDs

Pharmacy Survey

Drugs in the Pipeline
Muscular dystrophy

Industry Analysis
Amazon and healthcare

Managed Healthcare Executive

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ManagedHealthcareExecutive.com
INOMAX® DSIR® PLUS DELIVERY SYSTEMS

Devoted to Delivering Ongoing Innovations in Critical Care

The INOMAX® DSIR Plus Delivery Systems provide innovative design and user experience to support the ever-changing demands of the critical care space and keep patient safety a top priority.1,2

- Delivering specialized, redundant, and customizable alarm features designed to help mitigate the risk of device-related rebound pulmonary hypertension
- Advanced features enable delivery of therapy specifically for the MRI suite
- Integration with neonatal transport systems to support seamless delivery of therapy

Applications
The INOMAX® DSIR Plus Delivery Systems deliver INOMAX® (nitric oxide) gas, for inhalation. The INOMAX® DSIR Plus Delivery Systems must only be used in accordance with the indications, usage, contraindications, and warnings and precautions described in the INOMAX® package inserts and labeling. The approved patient population is limited to neonates. Refer to the INOMAX Full Prescribing Information prior to use.

Device Warnings
- Abrupt discontinuation of INOMAX® can lead to worsening oxygenation and increasing pulmonary artery pressure (rebound pulmonary hypertension syndrome). To avoid abrupt discontinuation, use the INOblender® or backup mode immediately to reinstate INOMAX® therapy and refer to the INOMAX® package insert.
- If the high NO2 alarm activates, the delivery system should be assessed for proper setup while maintaining INOMAX® delivery.
- Do not connect items that are not specified as part of the system.
- If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.
- Use only INOMAX®, pharmaceutical grade NO/N2.

Use in an MR Environment
- Only use a size “88” (1,963 liters) cylinder that is marked “MR Conditional. Keep cylinder at 100 gauss or less.” with the DSIR Plus MRI while in the scanner room. Use of any other cylinder may create a projectile hazard.

- The INOMAX® DSIR Plus MRI is classified as MR Conditional with MR scanners of 1.5 or 3.0 Tesla strength ONLY in areas where the field strength is less than 100 gauss.
- This device contains ferromagnetic components and hence will experience strong attraction close to the magnet. It should be operated at a fringe field of less than 100 gauss.
- A strong magnetic field such as that from an MRI system can affect the ability of the INOMAX® to detect if the cylinder valve is open. This can cause a “Cylinder Valve Closed” alarm to occur when the cylinder valve is actually open. If this alarm occurs, reposition/rotate the INOMAX® DSIR Plus MRI cart outside the 100 gauss area to reduce the magnetic interference in the area of the INOMAX® until the cylinder handle graphic on the display turns green. This will resolve the “Cylinder Valve Closed” alarm. Typically the required INOMAX® DSIR Plus MRI cart location adjustment is less than 6 inches (15 cm)/90 degrees. Note that interruption of INOMAX® therapy will occur one hour from point when the “Cylinder Valve Closed” alarm is activated if the alarm is not resolved.

Rx Only
Consult the Operation and Maintenance Manual, which may be found at www.inomax.com/training-and-education/device-support-resources, for complete information. For technical assistance, call (877) 566-9466.

For additional information, technical assistance, or a complete list of warnings regarding use of validated ventilators, please refer to the INOMAX® DSIR Plus Operation Manual at inomax.com/dsirplusmanual

While you take care of patients, we remain dedicated to helping advance critical care.
Learn how at inomax.com/inomax-delivery-systems/device-innovation


*No longer in use for commercial application. †This may relate to a medical device and software in development that have not yet been cleared by the FDA.
‡INOmax Total Care is included at no extra cost to contracted INOMAX® customers.

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INOMAX® Total Care®
INOMAX® (nitric oxide gas)
Brief Summary of Prescribing Information

INDICATIONS AND USAGE

Treatment of Hypoxic Respiratory Failure
INOmax® is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

CONTRAINDICATIONS
INOmax is contraindicated in neonates dependent on right-to-left shunting of blood.

WARNINGS AND PRECAUTIONS

Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation
Wean from INOMAX. Abrupt discontinuation of INOMAX may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOMAX therapy immediately.

Hypoxemia from Methemoglobinemia
Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOMAX; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOMAX to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOMAX, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide
Nitrogen dioxide (NO₂) forms in gas mixtures containing NO and O₂. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO₂ concentration, or if the NO₂ concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO₂ analyzer should be recalibrated. The dose of INOMAX and/or FiO₂ should be adjusted as appropriate.

Worsening Heart Failure
Patients with left ventricular dysfunction treated with INOMAX may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOMAX while providing symptomatic care.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOMAX doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOMAX, a result adequate to exclude INOMAX mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOMAX and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOMAX and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOMAX than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

DRUG INTERACTIONS

Nitric Oxide Donor Agents
Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

OVERDOSAGE

Overdosage with INOMAX is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO₂. Elevated NO₂ may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO₂ levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOMAX.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

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Chairman’s Letter

Results of our 2021 pharmacy survey

Last year the results from our annual pharmacy survey were published a month later, in the July issue. Midsummer 2020 was a difficult period in the history of the pandemic in the U.S. as hospitalizations and deaths started to rise again. If you looked in the rearview mirror, COVID-19 wasn’t there. Our pharmacy survey results had notes of optimism — about vaccines becoming available, for example — amid some undertones of pessimism. About 2 out of 3 of the respondents last year saw an economic downturn from the pandemic as likely.

The mood is quite different now. Masks are coming off; important numbers are coming down; and, as we went to press, almost 40% of the U.S. population was fully vaccinated. Still, there’s overlap between this year’s results and last year’s. Once again, the COVID-19 vaccines seem to engender optimism. Almost 2 out of 3 of this year’s respondents believe herd immunity will be reached by the end of October by some combination of vaccination and individuals having had the disease. Last year, a solid majority (57%) thought telehealth would be the most lasting, important effect of the pandemic. This year, telehealth got 25% of the lasting-effect votes; at-home care of all kinds, 35% — so together, that is roughly the same proportion as telehealth’s 2020 share. Interestingly, many (37%) of last year’s respondents thought increased use of mail-order pharmacy would have post-pandemic staying power. This year only 10% saw it that way.

Our survey doesn’t send a strong signal about the most favored way to deal with drugs costs, a reflection of the complexity of the issue. Enhancing point-of-prescribing tools, more aggressive utilization management, benefit design to encourage patients to pick low-cost options, narrow formularies, expanded digital tools, improved price transparency — they were all endorsed by roughly the same number of respondents as ways to deal with traditional pharmaceutical costs. For specialty drugs, 42% of the respondents favored performance-based contracts that would promote compliance with clinical pathways, but not far behind were Medicare price negotiation (36%) and formulary adoption and prescribing of biosimilars (35%).

The debate about drug prices and costs is far from over. The same is true of the pandemic. But look in the rearview mirror now and perhaps you’ll see the worst of it getting smaller and smaller, receding into our past.
Editorial Advisory Board

Francois de Brantes, M.S., MBA, is senior vice president of commercial business development at Signify Health.

Otis Brawley, M.D., is the Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University and former chief medical and scientific officer of the American Cancer Society.

Lili Brillstein is a nationally recognized thought leader in the advancement of Episodes of Care as a value-based approach for specialty care. She is the CEO of BC Collaborative, which works with stakeholders across the healthcare continuum to successfully make the move from fee for service to value-based healthcare.

Joel V. Brill, M.D., is the chief medical officer for Predictive Health, LLC, which partners with stakeholders to improve coverage of value-driven care that optimizes health for people.

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Perry Cohen, Pharm.D., is CEO of The Pharmacy Group and the TPG family of companies, which provides services to associations, healthcare and information technology organizations, payers and pharmaceutical companies.

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Cynthia Hundorfean is president and CEO of Allegheny Health Network (AHN), an integrated healthcare delivery system that serves Western Pennsylvania. AHN is part of the Highmark Health family of companies.

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John Mathewson is chief operating officer for America’s Health Insurance Plans (AHIP), the national trade association that advocates for the health insurance community and the consumers they serve across the nation.

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Kevin Ronneberg, M.D., is vice president and associate medical director for health initiatives at HealthPartners, an integrated, nonprofit provider and health insurance company located in Bloomington, Minnesota.

Marc Samuels, J.D., M.P.H., is the CEO of ADVI, a strategic advisory services life sciences firm in Washington, D.C.

William Shrank, M.D., is Humana’s senior vice president and chief medical officer. In this role, he is responsible for leading and implementing the company’s integrated care delivery strategy. This strategy emphasizes a consumer-friendly, evidence-based, technology-enabled approach to personalized health improvement for the company’s more than 16 million Humana health plan members.

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Navigate Your Practice
Through Uncharted Waters

As we enter the next stage of the pandemic, ISMIE continues to support and encourage healthcare professionals in their fight against COVID-19. With vaccinations more readily available, our Risk Management team has released COVID-19 vaccines: Guidance for healthcare professionals to aid medical practices steering through these extraordinary times.

Read more at visit ismie.com/vaccines.
In a review of its claims data for 16 million commercial members over the past year, Prime Therapeutics found a 13% decline in the number of members with an opioid claim and a similar reduction (12%) in members with a prescription for a high dose of opioids (90 morphine milligram equivalents or above).

“Obviously it is a good thing, we think, if there are fewer people getting opioids prescribed to them, because there are just a few instances when you actually need an opioid for pain control,” Cathy Starner, Pharm.D., health outcomes consultant senior principal, said in a recent interview.

Starner said the decline in opioid prescriptions might be partly explained by the pandemic-related decrease in healthcare utilization last year. But she also noted that the decline in opioid prescriptions among Prime’s claims goes back several years, so the recent decline is part of a longer-term trend.

Specialty drugs used to be the boutique part of the drug spend: expensive, yes, but unusual. Ten years ago, specialty accounted for 15% to 20% of the money spent on drugs, according to Prem Shah, executive vice president of specialty pharmacy and product innovation at CVS Health.

But the CVS Caremark 2020 Drug Trend Report shows that specialty drugs accounted for more than half (52%) of the pharmacy spend last year. The 2020 drug trend report from Evernorth (the new Cigna entity that Express Scripts is now part of) also showed that the spend on specialty drugs edged ahead of the spending on traditional medications (50.8% versus 49.2%).

Five therapeutic categories are driving 90% of the specialty trend for CVS Caremark. “Autoimmune is the largest drive because of supplemental indications, which is driving more utilization,” says Shah. The other four were oncology, cystic fibrosis, atopic dermatitis and HIV. Shah says new oncology products continue to be a large driver of spending and that in cystic fibrosis “you are starting to see patients take more drugs per patient.”

Evernorth’s report says 17 of the top 25 drugs ranked by total pharmacy spend were specialty medications in 2020.

For Evernorth

17

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Prime Therapeutics sees a drop in opioid claims

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In Brief

**Listen to our podcasts!**

*Managed Healthcare Executive*® featured Doug L. Chaet, FACHE, in the latest episode of the “Meet the Board” podcast series shared on the “Tuning In to the C-Suite” podcast. Chaet is president of Value Evolutions and chairman of the American Association of Integrated Healthcare Delivery Systems. Chaet, a longtime member of the MHE editorial advisory board, talked about the publication and how it has evolved. Chaet also shared his thoughts on the recent history of managed care and its relationship to value-based care and ACOs.

“Tuning In to the C-Suite,” MHE’s home podcast, features healthcare professionals, leaders and executives who talk about the most important, current healthcare issues. Featured on the podcast are podcast subseries “Meet the Board” and “MHE Talks: Improving Patient Access.” To listen to episodes of “Tuning In to the C-Suite” or other subseries, you can tune in to Apple, Spotify and iHeart Radio podcasts or access them on the MHE website.

Listen in. Learn a lot.

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**Is competition the way to bring down drug prices?**

Harvard researchers say, well, maybe.

List prices for brand-name drugs have risen sharply in recent years, but it is more complicated with net prices — the prices paid after rebates and other discounts have factored in. The rise isn’t nearly as steep, and it’s not uniform. Many in the drug and PBM industry say it is the net prices that matter because those actually get paid, not the list price. And there’s an argument that the answer to rising drug prices could be more competition within drug classes because that would drive down net prices as manufacturers compete.

A team of Harvard researchers conducted a study of three classes of diabetes drugs to examine that argument. Their results, published in the May 2021 issue of *Health Affairs*, produced a mixed verdict — and more evidence that drug pricing in the United States is nothing if not complex.

The study compared list and net prices for glucagon-like peptide 1 (GLP-1) receptor agonists, dipeptidyl peptidase 4 (DPP4) inhibitors and sodium-glucose cotransporter 2 (SGLT2) inhibitors. The researchers looked at the prices from when the first drug in the class was introduced through 2017; for the GLP-1 receptor agonists, for example, that means from starting in 2005, when Byetta (exenatide) was approved, through 2017. What they found was that monthly list prices for the three classes of drugs increased, on average, about 10%, once inflation is factored in. But the trends diverged when it came to net prices. The monthly net price of the GLP-1 receptor agonists increased by 10% during the study period but decreased by 2% for the DPP4 inhibitors and by 9% for the SGLT2 inhibitors.

Competition might deserve some credit for the lower net prices for the DPP4 inhibitors and SGLT inhibitors: Thirteen DPP4 inhibitors and nine SGLT2 inhibitors entered the market during the study period. But that doesn’t explain why the eight GLP-1 receptor agonists didn’t have a similar effect or why the crowded DPP4 inhibitor marketplace didn’t put more downward pressure on net prices. The research team, led by Ameet Sarpatwari, Ph.D., J.D., noted that there was a five-year gap between when Byetta entered the market and when the next GLP-1 receptor agonist, Victoza (liraglutide), was introduced. That gap may have influenced competition and therefore net prices.

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*Medical World News*

MJJ Life Sciences™ has officially launched Medical World News®, a first-of-its-kind 24-hour online program for healthcare professionals, by healthcare professionals.
You’ve called your book “The Right Price.” So let’s start with kind of a stupid question but maybe one that will reveal something in the answer: Are the drug prices right in the United States?

It is the case that at times the price is right because the price is matching up relatively well to the benefit that a drug is bringing to the patient. It is more often the case, however, in the U.S. that because the price is not set necessarily with any inclination toward the benefit that’s brought to the patient, it’s not right. Prices are very high in the U.S. We’ve seen lots of studies and publications showing that they’re very high here — much higher than they are in other countries. And it seems as though when the price is well aligned with the value to the patient, it’s almost as if it’s an accident.

There are, of course, discussions now — a proposal by Democrats, primarily — that Medicare begin to negotiate prices directly with drug companies. And that is held out as a way to bring

Continued on page 12
INDICATIONS AND USAGE
SUNOSI is indicated to improve wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).

Limitations of Use:
SUNOSI is not indicated to treat the underlying obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating SUNOSI. SUNOSI is not a substitute for these modalities, and the treatment of the underlying airway obstruction should be continued.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
SUNOSI is contraindicated in patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of an MAOI, because of the risk of hypertensive reaction.

WARNINGS AND PRECAUTIONS
Blood Pressure and Heart Rate Increases
SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion. Epidemiological data show that chronic elevations in blood pressure increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular death. The magnitude of the increase in absolute risk is dependent on the increase in blood pressure and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension, diabetes, hyperlipidemia, and high body mass index (BMI).

Assess blood pressure and control hypertension before initiating treatment with SUNOSI. Monitor blood pressure regularly during treatment and treat new-onset hypertension and exacerbations of pre-existing hypertension. Exercise caution when treating patients at higher risk of MACE, particularly patients with known cardiovascular and cerebrovascular disease, pre-existing hypertension, and patients with advanced age. Use caution with other drugs that increase blood pressure and heart rate.

Periodically reassess the need for continued treatment with SUNOSI. If a patient experiences increases in blood pressure or heart rate that cannot be managed with dose reduction of SUNOSI or other appropriate medical intervention, consider discontinuation of SUNOSI.

Patients with moderate or severe renal impairment could be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

Psychiatric Symptoms
Psychiatric adverse reactions have been observed in clinical trials with SUNOSI, including anxiety, insomnia, and irritability. Exercise caution when treating patients with SUNOSI who have a history of psychosis or bipolar disorders, as SUNOSI has not been evaluated in these patients.

Patients with moderate or severe renal impairment may be at a higher risk of psychiatric symptoms because of the prolonged half-life of SUNOSI. Observe SUNOSI patients for the possible emergence or exacerbation of psychiatric symptoms. Consider dose reduction or discontinuation of SUNOSI if psychiatric symptoms develop.

MOST COMMON ADVERSE REACTIONS
The most common adverse reactions (incidence ≥5%) reported more frequently with the use of SUNOSI than placebo in either narcolepsy or OSA were headache, nausea, decreased appetite, anxiety, and insomnia.
SUNOSI® (solvamfetamine) tablets, for oral use, CIV
BRIEF SUMMARY OF PRESCRIBING INFORMATION: Consult the Full Prescribing Information for complete product information.
Initial U.S. Approval 2018
INDICATIONS AND USAGE
SUNOSI is indicated for the treatment of excessive daytime sleepiness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

Limitations of Use
SUNOSI is not indicated to treat the underlying airway obstruction in OSA. Ensure that the use of SUNOSI is supported by the existence of an adequate airway (obstructive sleep apnea or episodes of upper airway occlusion), normal lung function, and absence of pathology associated with sleep-disordered breathing, such as obstructive sleep apnea, central sleep apnea, or hypopnea.

DOSE AND ADMINISTRATION
Important Considerations Prior to Initiating Treatment
Prior to initiating treatment with SUNOSI, ensure blood pressure is adequately controlled. General Administration Instructions
Administer SUNOSI orally upon awakening with or without food. Avoid taking SUNOSI within 9 hours of planned bedtime because of the potential to interfere with sleep if taken too late in the day.

SUNOSI 75 mg tablets are functionally scored tablets that can be split in half (37.5 mg) at the score line.

CONTRAINDICATIONS
SUNOSI is contraindicated in patients receiving concomitant treatment with monoamine oxidase (MAO) inhibitors, or within 14 days following discontinuation of monoamine oxidase inhibitor because of the risk of hypertensive reaction.

Blood Pressure and Heart Rate Increases
SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion.

Epidemiological data show that chronic elevations in blood pressure increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular death. The magnitude of the increase in absolute risk is dependent on the chronicity of the blood pressure increase and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension, diabetes, hyperlipidemia, and high body mass index (BMI). Assess blood pressure and control hypertension before initiating treatment with SUNOSI. Monitor blood pressure regularly during treatment and treat new-onset hypertension and exacerbations of pre-existing hypertension. Exercise caution when treating patients at higher risk of MACE, particularly patients with known cardiovascular and cerebrovascular disease, pre-existing hypertension, and patients with advanced age. Use caution with other drugs that increase blood pressure and heart rate. Periodically reassess the need for continued treatment with SUNOSI. If a patient experiences increases in blood pressure or heart rate that cannot be managed with dose reduction or other appropriate changes in medical intervention, consider discontinuation of SUNOSI.

Patients with moderate or severe renal impairment may be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

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Patients with moderate or severe renal impairment may be at a higher risk of psychiatric symptoms because of the prolonged half-life of SUNOSI.

ADVERSE REACTIONS
The following adverse reactions are discussed in greater detail in other sections of the label:
- Blood Pressure and Heart Rate Increases
- Psychiatric Symptoms

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of another drug may not be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of SUNOSI has been evaluated in 1300 patients (ages 18 to 75 years) with narcolepsy or OSA. Among these patients, 396 were treated with SUNOSI in the 12-week placebo-controlled trials at doses of 37.5 mg (OSA) only, 75 mg and 150 mg orally daily. Information provided below is based on the pooled 12-week placebo-controlled studies in patients with narcolepsy or OSA.

Most Common Adverse Reactions
The most common adverse reactions (incidence ≥ 5% and greater than placebo) reported more frequently with the use of SUNOSI than placebo in either the narcolepsy or OSA populations were headache, nausea, decreased appetite, anxiety, and insomnia.

Table 1 presents the adverse reactions that occurred at a rate of ≥ 2% and more frequently in SUNOSI-treated patients than in placebo-treated patients in the narcolepsy population.

Table 1: Adverse Reactions ≥ 2% in Patients Treated with SUNOSI and Greater than Placebo in Pooled 12-Week Placebo-Controlled Clinical Trials in Narcolepsy (75 mg and 150 mg)

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Placebo (%)</th>
<th>SUNOSI N = 651 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolism and Nutrition Disorders Decreased appetite</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insomnia*</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Anxiety†</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache†</td>
<td>16</td>
<td>7</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palpitations</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea*</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Constipation</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palpitations</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea*</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Constipation</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

* "Insomnia" includes insomnia, initial insomnia, middle insomnia, and terminal insomnia. “Anxiety” includes anxiety, nervousness, and panic attack. “Headache” includes headache, tension headache, and migraine headache.

Table 2 presents the adverse reactions that occurred at a rate of ≥ 2% and more frequently in SUNOSI-treated patients than in placebo-treated patients in the OSA population.

Table 2: Adverse Reactions ≥ 2% in Patients Treated with SUNOSI and Greater than Placebo in Pooled 12-Week Placebo-Controlled Clinical Trials in OSA (37.5 mg, 75 mg, and 150 mg)

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Placebo N = 118 (%)</th>
<th>SUNOSI N = 253 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolism and Nutrition Disorders Decreased appetite</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety†</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palpitations</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea*</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Abdominal pain*</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Cheek discomfort</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders Hyperpigmentation</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* "Anxiety" includes anxiety, nervousness, and panic attack. “Nausea” includes nausea and vomiting. “Abdominal pain” includes abdominal pain, abdominal pain upper, and abdominal discomfort.

Other Adverse Reactions Observed During the Premarketing Evaluation of SUNOSI
Other adverse reactions of clinical significance but greater than placebo are shown below. The following list does not include adverse reactions: 1) already listed in previous tables or elsewhere in the labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, or 4) which were not considered to have clinically significant implications.

Narcolepsy population:
- Psychiatric disorders: agitation, bruxism, irritability
- Respiratory, thoracic and mediastinal disorders: cough
- Skin and subcutaneous tissue disorders: hyperpigmentation

Other general disorders and administration site conditions: feeling jittery, chest discomfort, chest pain

Investigations: weight decreased

OSA population:
- Psychiatric disorders: bruxism, restlessness
- Nervous system disorders: disturbances in attention, tremor
- Respiratory, thoracic and mediastinal disorders: cough, dyspnea
- Gastrointestinal disorders: constipation, vomiting

Investigations: weight decreased

Drug-Dependent Adverse Reactions
In the 12-week placebo-controlled clinical trials compared that showed doses of 37.5 mg, 75 mg, and 150 mg daily of SUNOSI to placebo, the following adverse reactions were dose-related: headache, nausea, decreased appetite, anxiety, diarrhea, and dry mouth (Table 3).

Table 3: Dose-Dependent Adverse Reactions ≥ 2% in Patients Treated with SUNOSI and Greater than Placebo in Pooled 12-Week Placebo-Controlled Clinical Trials in Narcolepsy and OSA

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Placebo (%)</th>
<th>SUNOSI (37.5 mg) N = 168 (%)</th>
<th>SUNOSI (75 mg) N = 120 (%)</th>
<th>SUNOSI (150 mg) N = 218 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache**</td>
<td>8</td>
<td>15</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>Nausea**</td>
<td>5</td>
<td>9</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1</td>
<td>3</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

* "Headache" includes headache, tension headache, and head discomfort.

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Jazz Pharmaceuticals, Inc. Palo Alto, CA 94304

DRUG ABUSE AND DEPENDENCE

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Additional information provided by European regulatory agencies.

SUNOSI increases blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion. Epileptic-like adverse reactions that are not related to seizure activity have been reported with the use of dopamine agonists. SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion. Epileptic-like adverse reactions that are not related to seizure activity have been reported with the use of dopamine agonists.
The most common adverse reactions (incidence ≥5% and greater than placebo) were:

**Most Common Adverse Reactions**

<table>
<thead>
<tr>
<th>Placebo</th>
<th>SUNOSI 37.5 mg</th>
<th>SUNOSI 51 mg</th>
<th>SUNOSI 75 mg</th>
<th>SUNOSI 150 mg</th>
<th>SUNOSI 300 mg*</th>
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</thead>
<tbody>
<tr>
<td>n</td>
<td>52</td>
<td>54</td>
<td>51</td>
<td>51</td>
<td>53</td>
</tr>
<tr>
<td>SBP</td>
<td>(0.7, 6.4)</td>
<td>(0.7, 6.0)</td>
<td>(1.7, 8.2)</td>
<td>(3.2, 10.3)</td>
<td></td>
</tr>
<tr>
<td>HR</td>
<td>(1.9, 3.7)</td>
<td>(2.2, 4.2)</td>
<td>(2.4, 4.2)</td>
<td>(1.5, 6.9)</td>
<td></td>
</tr>
</tbody>
</table>

**Narcolepsy Study 1**

<table>
<thead>
<tr>
<th>N</th>
<th>48</th>
<th>35</th>
<th>41</th>
<th>35</th>
<th>39</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>(0.1, -4.7)</td>
<td>(1.4, -4.9)</td>
<td>(1.7, 4.9)</td>
<td>(1.5, 6.9)</td>
<td></td>
</tr>
<tr>
<td>HR</td>
<td>(2.1, 3.8)</td>
<td>(1.8, 3.3)</td>
<td>(1.8, 3.3)</td>
<td>(1.5, 3.3)</td>
<td></td>
</tr>
</tbody>
</table>

**OSA Study 2**

<table>
<thead>
<tr>
<th>n</th>
<th>107</th>
<th>106</th>
<th>105</th>
<th>104</th>
<th>103</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>(0.1, 3.3)</td>
<td>(0.1, -9.5)</td>
<td>(0.6, 6.0)</td>
<td>(1.4, 4.4)</td>
<td>(3.0, 6.0)</td>
</tr>
<tr>
<td>HR</td>
<td>2.3</td>
<td>2.9</td>
<td>2.9</td>
<td>2.4</td>
<td>2.4</td>
</tr>
</tbody>
</table>

SBP = systolic blood pressure, DBP = diastolic blood pressure, HR = heart rate

**Drug Interactions**

Monoamine Oxidase (MAO) Inhibitors

Do not administer SUNOSI concomitantly with MAOIs or within 14 days after discontinuing MAOI therapy. Concomitant use of MAOIs and stimulergic drugs may increase the risk of a hypertensive reaction. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

**Drugs that Increase Blood Pressure and/or Heart Rate**

Concomitant use of SUNOSI with other drugs that increase blood pressure and/or heart rate has not been evaluated, and such combinations should be used with caution.

**Dopaminergic Drugs**

Dopaminergic drugs that increase levels of dopamine or that bind directly to dopamine receptors might result in pharmacodynamic interactions with SUNOSI. Interactions with dopaminergic drugs have not been evaluated with SUNOSI. Use caution when concomitantly administering dopaminergic drugs with SUNOSI.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to SUNOSI during pregnancy. Healthcare providers are encouraged to register pregnant patients, or pregnant women may enroll themselves in the registry by calling 1-877-283-6220 or contacting the company at www.SUNOSIPregnancyRegistry.com.

**Ablation Studies**

Although data from case reports are not sufficient to determine drug-associated risks of maternal death, malformation, miscarriage, or adverse maternal or fetal outcomes, and animal reproductive studies, oral administration of solriamfetol during organogenesis caused maternal and fetal toxicity at doses ranging from x 4 to 5 times and rats and rabbits at doses ≥7 times the MRHD based on mg/m2 body surface area. Oral administration of solriamfetol to pregnant rats during pregnancy and lactation at doses ≥7 times the MRHD based on mg/m2 body surface area resulted in maternal toxicity and adverse effects on fertility, growth, and development in offspring (see Data). The estimated background risk of major birth defects and miscarriage for the indicated populations can be compared to the estimated risk of adverse events. In the U.S. general population, the estimated background risk of major birth defects is 2% to 4% and 15% to 20%, respectively.

**Data**

**Animal Data**

Solriamfetol was administered orally to pregnant rats during the period of organogenesis at 15, 67, and 295 mg/kg/day, which are approximately 1, 4, and 19 times the MRHD based on mg/m2 body surface area. Solriamfetol at 4 times the MRHD caused maternal toxicity that included hypertensive, significant decreases in body weight, weight gain, and food consumption. Fetal toxicity at these maternal toxicity doses included increased incidence of abortion and neonatal deaths, fetal malformation, increased incidence of malformations, and decreased fetal weight.

**Human Data**

Solriamfetol was teratogenic at 19 times the MRHD; it increased the incidence of fetal malformations that included severe cerebrosal mal-alignment, hindlimb rotation, bent limb presentations, and situs inversus. There was also an effect of increased malformation, the effect level for malformation is 4 times and for maternal and embryofetal toxicity is approximately 1 times the MRHD based on mg/m2 body surface area. Solriamfetol caused maternal toxicity of body weight loss and decreased food consumption. Solriamfetol was tested at 9 times the MRHD, it caused fetal skeletal malformation (slight-to-moderate stereomere mal-alignment) and decreased fetal weight. The no-adverse-effect level for malformation was approximately 2 times and for maternal toxicity is approximately 5 times the MRHD based on mg/m2 body surface area.

Solriamfetol was administered orally to pregnant rats during the period of organogenesis at gestation days 7 through lactation day 20 postpartum at doses of 35, 110, and 350 mg/kg/day, which are approximately 2, 7, and 22 times the MRHD based on mg/m2 body surface area. At 7 times the MRHD, solriamfetol caused maternal toxicity that included decreased body weight gain, decreased food consumption, and hypermetria. At these maternally toxic doses, fetal toxicity included increased incidence of malformations, postnatal pup mortality, and increased maternal depressive behavior. Fetal malformative toxicity in offspring after lactation day 20 included decreased body weight, decreased weight gain, and delayed sexual maturity. Fetal malformations were decreased at maternally toxic doses 7 times the MRHD from Maternal use of SUNOSI without affecting learning and memory. The no-adverse-effect level for maternal and developmental toxicity is approximately 2 times the MRHD based on mg/m2 body surface area.

**Lactation**

There are no data available on the presence of solriamfetol or its metabolites in human milk, the effects on the breastfeeding infant of SUNOSI, and any potential adverse effects to the breastfed child from SUNOSI or the underlying maternal condition.

**Drug Interactions**

Monitor breastfed infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.

**Pregnancy**

Safety and effectiveness in pediatric patients have not been established. Clinical studies of SUNOSI in pediatric patients have not been conducted.

**Geriatric Use**

Increased adverse reactions, including cardiovascular and psychiatric events, were seen in elderly and younger patients in clinical trials of SUNOSI. Therefore, these adverse reactions should be considered when the treatment of elderly patients is considered.

**Drug Interactions**

Monitor breastfed infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.

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**Drug Interactions**

Monitor breastfed infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.
prices down and maybe bring them closer to this value that you’re talking about. Do you see that as a way of getting there?

I think one of the challenges with the current bills that are in discussion is that one of the ways in which they are proposing to empower Medicare to negotiate prices is to allow Medicare to fall back on an average — or some sort of arithmetic calculation — of the prices paid in other countries with healthcare systems that have similarities to ours, similar economic indicators, et cetera.

The challenge with that is that prices are generally too high across the board. What that equates to is a general price cut for medications that Medicare is paying for without regard to whether or not those medications are bringing significant benefit to their patient populations. You’re essentially cutting the price paid for a product that may cure a rare cancer in a child at the same level as you’re cutting the price for a new medication for toenail fungus. It’s essentially an across-the-board cut without relationship to the benefit being brought to the patient.

In addition, this allows policy makers and politicians to sidestep the thorny issue of whether to use cost-effectiveness analysis — the use of a formal analysis to understand how the costs relate to the benefits. They don’t have to do that if they’re simply referencing the price paid in other countries.

But most of the other countries that are being proposed as reference countries do use cost-effectiveness analysis to set their prices. So we’re essentially importing their approach to value assessment here. That’s not something, obviously, that’s part of public debate, but it’s a key nuance in what’s being discussed.

Let’s pivot and discuss value. The metric that’s used most often in the discussion of drug value is the QALY — the quality-adjusted life year. But you basically come down as saying — and I think you invoke Winston Churchill here, who I guess was invoked by Peter Singer — that QALYs are a terrible thing, but it’s the best of the available alternatives. QALYs take into account both the length of life and morbidity. Are you pro QALY?

Yes, we are. And we recognize that it has its limitations, (but) it is going to provide some measure of the average experience for a patient with the disease and the potential effects of treatment on that disease. We recognize that most diseases are quite heterogeneous, and patients will have very different experiences. It is a summary measure and won’t necessarily take into account all aspects of value that a patient may consider important. But it is an approach to, as you say, estimate the effect of disease and treatment on the length of life and quality of life while alive.

There are critics out there who say that the quality (aspect of the QALY) discriminates on its face against those with severe disease or disabilities by valuing their lives at a lower level. But really, its use in practice is to compare the effects of two different treatments.

Now, another thing that we often say is that while the QALY and cost-effectiveness analysis is an input into decision-making, but it’s only one. There are other important aspects of new treatments that should be considered. Is this the first new treatment that’s become available for very severe disease in a very long time, for example? Is there a significant burden of disease?

If we’re paying a lot of money, for example, for new treatments for hepatitis C, given the public health
The price is often not right

Managed Healthcare Executive.com

I believe there’s also a discussion in the book, and it relates to COVID-19, about whether the QALY is too narrowly focused on health issues and doesn’t factor in the societal knock-on effects of some treatments.

We do talk about this, and the gut feeling is generally that the societal perspective is important to estimate (whether) information and data are available, which is not always the case. It’s often-times difficult to estimate societal impacts with a lot of precision. But it’s important to understand what the results are looking like from a societal perspective and compare that to the health system perspective, in part, just to see if there’s a difference. It may make a significant difference. In other cases, it may not.

It’s also important to reflect on what the decision problem is and who the decision maker is. You might think that there is significant benefit to, let’s say, a therapy that improves the ability to return fully to work and be more productive. That seems like a no-brainer. But if you think about the way the health system works in our country, that’s much more important to the self-insured employer, who’s going to be fully at risk for the costs and benefits of the health plan to their employees, than it would be to an employer whose contracting with the health plan is not necessarily all that focused on productivity benefits; they’re more focused on where the savings might be to the health system in direct medical costs.

We’ve been discussing distortions in price and coming up with something that’s a little bit more rational, systematic — a QALY-based system with all the qualifications and other things that must be factored in. But this doesn’t really address the question of who or what should do this work. I’m curious: What are your ideas about who should do this work and with what sort of authority? Should there be a federal board or some entity? Or might ICER be deputized in and take on a sort of governmental agency?

Readers of the book, if they didn’t already know, will learn that we had a technology assessment agency in this country — an official government agency that focused not only on health but also cost-effectiveness questions in other sectors as well. It was a quasi-governmental agency (and) did receive government appropriations but had a very balanced board in terms of stakeholders and special interests. It was an interesting model, and it did a lot of important methodologic work. But in its independent role, it questioned the scientific credibility of Ronald Reagan’s “Star Wars” program and then started to die a slow death afterward.

So the idea of an official government entity that would use cost-effectiveness and the QALY to inform public policy seems very far-fetched at this point, given not only the history the Office of Technology Assessment but also the discussions around cost-effectiveness and the QALY that have happened politically since then.

I think our feeling is that this is another example of American exceptionalism — the idea that we should not have our choices dictated to us. And so whether or not the majority of the populace feels that way, we know that people will take political advantage of that idea.

The country’s ready for some drug pricing relief. There’s no question about that. We argue in the book that this is another example of American exceptionalism — the idea that we should not have our choices dictated to us. And so whether or not the majority of the populace feels that way, we know that people will take political advantage of that idea.

The notion that there could be some group of bean counters, making some determination about what the right price looks like, is anathema to many in this country.

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MANAGED HEALTHCARE EXECUTIVE® | JUNE 2021
Our annual pharmacy survey provides insights into pharmaceutical utilization and costs trends. This year we had over 225 respondents answer questions about everything from the COVID-19 and herd immunity to the best strategies for coping with specialty drug costs to the most promising drug in the 2021 pipeline. The respondents were divided among the healthcare sectors we cover: providers, health plans, PBMs, and consultants. We hope the results increase your awareness and give you insight into what your peers are thinking about medications and their use and cost. Many thanks to all of you who helped us by filling out a survey. — Managed Healthcare Executive® editors
COVID-19 vaccinations

By what month will herd immunity against COVID-19 be achieved in the U.S. through vaccination and individuals having had the infection?

- August: 30%
- September: 14%
- October: 19%
- November: 13%
- December: 9%
- Not by the end of 2021: 15%

Lasting COVID-19 effects

What will be the most important, lasting effect of the COVID-19 pandemic on the U.S. healthcare system?

- 35% Increase in at-home care of all kinds
- 25% Increase in telehealth
- 18% Increase in provider/hospital consolidation
- 18% Increased attention on addressing inequities in healthcare
- 4% Increase in value-based payment and a decrease in fee for service

What will be the most important, lasting effect of the COVID-19 pandemic on the pharmaceutical sector?

- 27% Increase in research and development focused on infectious disease
- 23% Increase in the adoption of more restrictive and limited formulary/drug benefit offerings
- 13% Delays in the introduction of new drugs because of disruptions in clinical trials
- 12% Increase in use of pharma-funded patient assistance programs
- 11% Increase in the transition from hospital- and clinic-administered infusion to home infusion
- 10% Increased use of mail-order pharmacy
- 5% Decrease in uptake of new therapies traditional marketing and disruption of detailing activities

*Because of rounding, percentages for the answers to this and several other questions do not add up to 100.
COVID-19 vaccinations

Rate your level of concern about the current vaccines being insufficiently protective against the coronavirus variants.

![Graph showing concern levels for COVID-19 vaccines]

Drug expenditures

Which conditions will account for the strongest upward pressure on drug expenditures in 2021? (Pick up to three.)

- 55% COVID-19
- 29% Autoimmune disease other than multiple sclerosis and rheumatoid arthritis
- 28% Hematological cancers
- 21% Diabetes
- 20% Heart disease
- 18% Solid tumors
- 15% HIV/AIDS
- 15% Rheumatoid arthritis
- 12% Depression
- 9% Multiple sclerosis
- 8% Migraine
- 5% Anticoagulation
- 5% Rare/orphan diseases (collectively)
What are the most effective ways to reduce specialty pharmaceutical costs?  
(PICK UP TO THREE.)

- 42% Performance-based contracting between payer and prescribers to promote compliance with clinical pathways
- 36% Medicare price negotiation
- 35% Formulary adoption and prescribing of biosimilars
- 30% Formulary structures and limits based on cost-effectiveness assessments by groups such as ICER
- 25% Performance-based (outcomes-based) contracting between payer and drug manufacturers
- 23% Mandated use of specialty pharmacy white-bagging to limit buy-and-bill incentives
- 14% Expanded tools/resources to manage infused specialty products under the medical and/or pharmacy benefit
- 12% Exclusive contracting with a single specialty pharmacy

What are the most effective ways to reduce traditional pharmaceutical costs?  
(PICK UP TO THREE.)

- 30% Expanded digital tools to promote lower-cost alternatives directly to patients
- 30% Improved price transparency
- 29% Revised benefit design to create incentives for patients to choose low-cost options
- 29% Narrower, simpler formulary design with more exclusions
- 28% More aggressive and expansive utilization management strategies
- 25% Enhanced point-of-prescribing tools to encourage use of most cost-effective medications
- 17% Lower out-of-pocket costs for high-value medications
- 17% Performance-based contracts to promote formulary compliance and generic drug prescribing

COVID-19 vaccinations

How many vaccines do you expect to be available in the U.S. by the end of the year?

- 18% 3
- 45% 4
- 19% 5
- 18% More than 5

2021 Pharmacy survey

Pharmaceutical costs

2021 Pharmacy survey continued on page 20
Why your network needs LTACH partnerships to meet complex pulmonary needs

By Sean R. Muldoon, MD, MPH, FCCP, CMO and Audra Early, SVP of Strategy and Network Development, Kindred Hospitals

As respiratory conditions increasingly affect Americans, providers and payors are seeking new strategies to address respiratory complications and failure. Specialized acute care after an initial hospital stay is playing a critical role in improving patient outcomes, reducing readmissions, and decreasing long-term effects of critical illness.

The Increasing Demand for Pulmonary Care

A new study found that rates of acute respiratory distress syndrome (ARDS) have persisted in the US and that acute respiratory failure mortality rates have been increasing over the past 5 years.¹

Furthermore, patients with a viral infection such as COVID-19 often experience significant pulmonary complications as a result of the infection and its side effects, including secondary bacterial pneumonia and acute respiratory distress syndrome (ARDS). These patients frequently require, in addition to weaning from prolonged mechanical ventilation, continued considerable medical interventions due to the numerous long-term effects of the virus and acute-on-chronic diseases.²

Studies also suggest that the increased need for pulmonary care expertise requires support from other care settings as traditional ICUs face bed and staffing shortages.³

LTACH Expertise in Pulmonary Care and Recovery

A patient’s long-term lung health is directly dependent on the type and intensity of the care they receive. Long-Term Acute Care Hospitals (LTACH) are uniquely equipped to complement the acute care initiated in the hospital, including the care of patients on mechanical ventilation. Patients with COVID-19 can experience strokes and sepsis, which can lead to multi-system failure and leave a critically ill patient with long-term damage to the lungs. LTACHs specialize in treating these patients. Ongoing research also demonstrates the unique value that LTACHs offer to ventilator-dependent patients.³

How Kindred Can Help Your Respiratory Patients

Acute care providers and payors need partners who can continue to provide physician-directed care that critical respiratory patients require, particularly those on prolonged mechanical ventilation.

Kindred Hospitals specialize in the treatment of medically complex patients with daily specialty physician oversight, interdisciplinary teams of ICU- and CCU-level caregivers, and 24/7 respiratory coverage. They are also in the process of achieving disease-specific certification for sepsis and respiratory failure from The Joint Commission for Respiratory Failure in all hospital locations.

Kindred Hospitals have proven to be a key partner in decompressing ICUs as traditional hospitals have faced patient surges and are they committed to pursuing an innovative approach to managed care. Health plan partnerships are customized by product and can be built on DRG rates, on negotiated per diem rates, or within value-based arrangements.

In today’s growing value-based care environment, partnerships between payors and LTACHs will continue to be critical for improving outcomes and reducing rehospitalization for pulmonary patients.

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What will be the biggest driver of specialty drug expenditures in 2021?

- **26%** Shift from traditional to specialty medications for treatment of common diseases
- **23%** Growing demand because of an aging population with multiple chronic conditions
- **17%** COVID-19 dynamics affecting specialty drug prescribing and patient utilization
- **15%** Orphan drug approvals by the FDA
- **15%** Price increases by manufacturers
- **5%** Limited number of biosimilars on the market

Contract pressures

Which of the following is likely to be the most significant change in contracts between plan sponsors and PBMs in the near future?

- **29%** Decreased emphasis on rebate guarantees and a shift toward lowest net-cost formularies
- **20%** Greater emphasis on transparency
- **19%** Greater emphasis on financial penalties for operational execution
- **18%** Increased demand for pass-through rebates and network pharmacy pricing
- **13%** Greater emphasis on trend and cost-based guarantees and shared-savings contracts
- **2%** Full-risk capitation

COVID-19 vaccinations

How likely is it that COVID-19 vaccination will become an annual immunization?

- **6%** Unlikely
- **17%** Somewhat unlikely
- **44%** Neutral
- **11%** Likely
- **22%** Very likely
COVID-19 vaccinations
Rate the Biden administration’s response to pandemic.

Clinical impact
Which drug that has come on the market in the past 12 months holds the most promise for reducing morbidity and mortality?

- **26%** Imcivree (setmelanotide) for rare forms of obesity
- **22%** Oxlumo (lumasiran) for primary hyperoxaluria type 1
- **22%** Zokinvy (lonafarnib) for rare conditions related to premature aging
- **21%** Orgovyx (relugolix) for prostate cancer
- **10%** Evrysdi (risdiplam) for spinal muscular atrophy

Which drug in the pipeline holds the most promise?

- **35%** Farxiga (dapagliflozin) for chronic kidney disease in adults with or without type 2 diabetes (a new indication)
- **31%** Roxadustat for anemia associated with chronic kidney disease
- **24%** Teplizumab for prevention of type 1 diabetes
- **10%** Valoctocogene roxaparvovec for severe hemophilia A
Federal policies

Which of these federal policies do you favor as a way to curb drug prices?

- **23%** Requiring PBMs to reimburse pharmacies at or above pharmacies’ drug acquisition costs
- **20%** Restricting the use of copay accumulator programs
- **20%** Putting limits on drug price increases
- **12%** Negotiating Medicare drug prices
- **11%** Putting limits on out-of-pocket costs for Medicare beneficiaries
- **8%** Mandating transparency in coverage rules
- **7%** Linking Medicare Part B drug prices to prices paid in other countries (the Most Favored Nation model)

Which of these federal policies do you think is most likely to occur in 2021?

- **29%** Limits on out-of-pocket costs for Medicare beneficiaries
- **23%** Most Favored Nation model for Medicare Part B drugs
- **21%** Federal limits on drug price increase
- **10%** None of the above
- **9%** CMS negotiating Medicare drug prices
- **9%** No substantial federal policy change will occur
Psychedelics take a long, strange trip to respectability

Research and investment are increasing into psilocybin and MDMA as treatments for several mental health disorders. by LARRY HANOVER

Whether marijuana is a gateway drug is debatable. But it has certainly opened the doors for a projected multibillion-dollar market for psychedelic drugs as treatments for a variety of mental health disorders.

Pushback against psilocybin (the active ingredient in magic mushrooms) and MDMA (3,4-methylenedioxymethamphetamine, known as ecstasy or molly) in the '70s and '80s culminated in their criminalization. But with the legalization of marijuana for medical use in many states in the '90s and now a wave of legalization for recreational use, research into psychedelics for medical purposes is booming.

Author Michael Pollan wrote a book, "How to Change Your Mind," that kick-started interest in psychedelics. Kevin O'Leary of "Shark Tank" is a big investor. The psychedelics market is projected to grow by 16.3% over the next eight years to nearly $7 billion by 2027, according to Data Bridge Market Research.

Now two recent studies published in prestigious journals are lending credence to psychedelics as a possible and entirely research-worthy way of treating mental health disorders.

In early May, Nature published the results of a phase 3 study that showed MDMA is effective in treating post-traumatic stress disorder. A few weeks earlier, British researchers reported results from a phase 2 study in The New England Journal of Medicine that showed psilocybin was considerably more effective than Lexapro (escitalopram), a selective serotonin reuptake inhibitor, in treating depression. Some of the researchers involved in that study receive support from companies developing psychedelics for medical use.

Matthew Johnson, Ph.D., associate director of the Johns Hopkins Center for Psychedelic & Consciousness Research, says to be prepared for explosive growth. "When I started 20 years ago, you knew (pursuing psychedelics) might be career suicide," Johnson says. "Since then, it’s been a bit of a risk, but the data keep speaking for themselves."

Researchers need to be careful. In a pilot study on smoking cessation with psilocybin that Johnson was involved in, there were four to eight hours of therapy as preparation, and two people had to be in the room monitoring the patient during treatment. "A person, even though it’s physiologically very safe compared to many compounds, can feel like they’re going to die," Johnson says. "There has to be a trusted person to say, ‘We’re here with you; just keep breathing, trust, let go and be open.’"

Jason Luoma, Ph.D., CEO of Portland Psychotherapy, has focused his research on people struggling with shame and found MDMA effective. "MDMA tends to create the experience of feeling a sense of love, a sense of connection with other people, and that is pretty profound," he says.

Luoma adds that despite the myths, psilocybin has no addictive potential, and MDMA’s potential is low. Approvals of psychedelics probably will need to be associated with FDA risk evaluation and mitigation strategies (REMS) to ensure no off-label uses, in Luoma’s opinion: "The big fear is people who are really, really anti-drug will pick up the one adverse reaction that happened out of 10,000 patients and ... blow it up and essentially harm the whole research agenda."

Larry Hanover is a freelance writer in southern New Jersey.
Because of concerns over community spread of COVID-19, the pandemic has greatly accelerated patient interest in home hemodialysis treatments. There’s also a need to find solutions that will improve the quality of life of people living with kidney failure.

For these reasons, Fresenius Medical Care North America, based in Waltham, Massachusetts, encourages many to consider home dialysis for greater scheduling flexibility, fewer food restrictions and improved clinical outcomes.

“These aspirations are shared by CMS, which has launched payment initiatives to support a greater uptake of home dialysis in the U.S.,” says Joe Turk, president, home and critical care therapies, Fresenius Medical Care North America. “While our company was aligned toward home dialysis well before this federal effort, the entire industry is now clearly focused on advancing technology, education and support for home dialysis.”

Theresa Mottes, M.S.N., RN, president of the Nephrology Nursing Certification Commission, has more than 25 years of pediatric renal replacement therapy experience in the critical care and outpatient dialysis settings and spent 15 years with the pediatric dialysis program at C.S. Mott Children’s Hospital in Ann Arbor, Michigan. She says she has witnessed a big shift from predominantly in-center to home dialysis, either hemodialysis or peritoneal dialysis.

“Technological advancements will be necessary for the success of home dialysis,” she says. “For a paradigm shift to home dialysis, the industry will need technology to develop a machine that is fully integrated and improves the ease of use.”

Although some are out there already, in development are several smaller, potentially wearable devices that reduce the burden of chronic kidney disease treatments, Mottes says.

Home dialysis also makes it much easier for physicians to prescribe individualized therapy without the constraints of an in-center schedule, which is typically three days per week for all patients.

“We’ve seen significant improvement in cardiovascular-related hospitalizations for patients dialyzing at home five or six days a week, and many patients report having more energy with a more frequent schedule,” Turk says. “We also have studies showing that the use of connected health can also help reduce hospitalizations, allowing for more timely interventions.”

Transitional care units (TCUs) continue to be important to in-home dialysis. Industry experts reveal half of patients experiencing kidney failure who start dialysis do so without any ability to prepare for this life change. This means they do not have the chance to be fully educated on all treatment options and make informed decisions aligning with their life needs and values.

According to Turk, TCUs give patients a better chance to stabilize, offering the ability to start dialysis in a simpler, more focused fashion. “It also tends to lead to more patients pursuing home dialysis because patients are better prepared and empowered to make this choice,” he says. “In fact, FMCNA (Fresenius) has seen over 40% of patients who go through a TCU ultimately choose a home modality: hemodialysis or peritoneal dialysis.”

Connectivity is another important development. Dialysis machines traditionally have been very analog, but today’s systems can instantly, securely transmit data to the cloud for providers to access remotely. This makes kidney disease treatment more convenient for patients and providers. In the home setting, utilizing smart sensors and wireless data transfer frees patients from manual data entry and ensures that providers get the information they need.

**Tools to use**

Leslie Trigg, CEO of Outset Medical in San Jose, California, notes that the company has always believed dialyzing at home was vital to
restoring identity, autonomy and a sense of self-worth for those managing kidney disease. “Due to reported patient satisfaction, compounded with the government’s initiative to shift towards home dialysis, we’re expecting to see this segment expand significantly over the next few years,” she says.

To deliver on its promise, Outset embarked on a clinical trial in 2016 to generate data showing the safety and efficacy of dialyzing at home with Tablo. The clinical and regulatory journey took four years and culminated in FDA clearance of the device in 2020 for the home setting.

Tablo combines the technology of multiple machines into one compact, 36-inch-tall unit that is approved for use from the hospital to the home.

“Our vision is to create a seamless and supported transition to the home,” Trigg says.

Recently, Onset Medical heard from clinicians that the pandemic introduced a critical need to reduce patient proximity during dialysis treatments to reduce COVID-19 transmission rates. In response to this, it incorporated their feedback to update the design of Tablo’s data analytics platform, TabloHub.

“TabloHub uses data transmitted securely and wirelessly from Tablo systems to the cloud to enable physicians to remotely support and monitor this vulnerable patient population with live and historical data,” Trigg says. “Clinicians have the ability to view real-time patient data without needing to be in the same room as their patients.”

Fresenius’ The NxStage home hemodialysis machine is the first and only portable hemodialysis system cleared for home use in the U.S., according to the company, and the only machine small enough to take on the road or even on a plane.

“While the machine itself has been transformative, the 37% growth in home hemodialysis treatments among our patients in 2020 is also attributed to the depth of patient and staff training and real-time support that surrounds the device,” says Turk of Fresenius. “We also recently expanded our long-standing collaboration with DaVita (another dialysis company) to help bring NxStage home hemodialysis to more patients than ever before.”

Fresenius’ connected health solutions also include TheHub that comprises three integrated applications allowing patients, care teams and physicians to better collaborate and monitor patient treatments.

“Importantly, we incorporate these algorithms and data into our clinical care models across our 2,600 dialysis clinics to ensure these insights are converted into actionable intelligence,” Turk says.

Looking ahead

Many people involved in kidney disease care expect the use of home hemodialysis to continue to increase over the next five years. “This past year has shown health professionals and patients that remote dialysis treatment works due to the benefits home dialysis provides — independence and convenience for patients and the reduction of resources and staffing needs for providers,” Trigg says. “Dialysis clinics are already reporting higher home dialysis growth rates as a result of the COVID-19 pandemic and telehealth utilization.”

CMS’ new kidney care payment model, which began this year in January, increases the incentive for the home dialysis care with increased payments. This federal push for more at-home kidney disease treatment is expected to seed more innovation in kidney care.

Value-based care in collaboration with private insurers and the federal government will continue to play an important role as the industry advocates for more timely referrals to a nephrologist and early, upstream efforts to slow the progression of kidney disease. As a result, clinicians will have more time to educate patients about the advantage of home therapies.

“We believe every patient should be considered for home dialysis” comments Turk. “The best way to help grow adoption of home dialysis is to have more patients prepared to make this choice earlier in the process.”

Keith Loria is a freelance writer in the Washington, D.C., area
For years, sexually transmitted disease (STD) rates in the United States were rising, despite all the advice and messaging about safe sex practices. By many measures, 2019 was the worst year on record. Then COVID-19 hit and the trend reversed. The giant pause on traditional social life apparently extended to sexual activity and its attendant disease risks.

The downturn "probably reflect-ed not only a lack of sexual activity in the community but also a lack of access to STD testing," notes Gabriel Wagner, M.D., an infectious disease specialist and clinical associate professor at University of California, San Diego. Chlamydia cases reported to the CDC in early April 2020 were 53% below 2019 levels, gonorrhea cases were 33% lower, and syphilis cases, 33% lower, said Hillard Weinstock, M.D., M.P.H., chief of the surveillance and data management branch in the CDC’s Division of STD Prevention during the agency’s STD Prevention Conference in September 2020. He noted that the data were as of August 2020 and could change slightly.

The reversal, though, was likely a COVID-19 aberration. Toward the end of last year, STD rates began to climb again. "As more pandemic restrictions are lifted, it is probable that STD rates will rise and surpass those of prior years, consistent with historic trends," says Wagner.

Reported cases of syphilis returned to 2019 levels by mid-June 2020. Similarly, reported cases of gonorrhea returned to 2019 levels in mid-June 2020. However, cases of chlamydia, as of late June 2020, had not yet returned to their 2019 levels, according to CDC statistics.

Shifting to COVID-19
Tracking and treating STDs have long been the responsibility of public health departments. Before the pandemic, reductions in funding for STD screening and treatment programs throughout the country had likely contributed to the risk of STDs. Since the start of the pandemic, many of the remaining staff members for STD programs have been shifted to the COVID-19 response, diminishing the numbers even further. According to one survey, as of January 2021, about one-third of state and local STD program staff were still working on COVID-19 response efforts. Staff also reported burnout as they pivoted from COVID-19 back to STD interventon and partner work. A recent report on sexually transmitted infections (STIs) by the National Academy of Sciences, Engineering, and Medicine concluded that the "pandemic has exposed weaknesses in public health preparedness due to weak infrastructure, an under-capacitated and under-resourced workforce, and limited surge capacity."

Similar interruption occurred in services for HIV prevention. The same clinics and staff previously providing testing for STIs and treatment also offered preexposure prophylaxis (PrEP), a pill containing antiviral medications that people at risk for contracting HIV take to prevent infections. "PrEP services fared far better than other STI prevention efforts," says Michelle Collins-Ogle, M.D., FAAP, a pediatric infectious disease specialist at The Children’s Hospital at Montefiore in the Bronx, New York. But PrEP services and uptake have not escaped the effects of the pandemic, and researchers have documented a drop off that parallels declines in sexual activity and
HPV decline
One major exception to the pre-pandemic uptick in STDs has been a sharp decline in the number of infections with the human papillomavirus (HPV) because of the introduction of the Gardasil vaccine in 2006. Findings reported in Morbidity and Mortality Weekly Report (MMWR) in March showed a drop in the prevalence of infections with the four types of HPV the original Gardasil vaccine protected against since the vaccine was introduced. The decrease was 88% among women ages 14 to 19 and 81% among women ages 20 to 24.

Compared with the pre-vaccine era, from 2015 to 2018 HPV infections decreased among sexually experienced girls and women who were vaccinated (97% among 14- to 19-year-olds; 86% among 20- to 24-year-olds), as well as those who were not vaccinated (87% among 14- to 19-year-olds; 65% among 20- to 24-year-olds), according to the data reported in MMWR.

The Gardasil vaccine was later modified to protect against five more types of HPV. The FDA approved that version of the vaccine, called Gardasil 9, in 2014.

HPV infections cause most cervical cancer cases, and research shows that the vaccine and the reduced number of infections have led to a decrease in cervical cancer cases. CDC researchers reported in Cancer Epidemiology, Biomarkers & Prevention last year that the rates of the most common type of cervical cancer (the type that affects the squamous cells) decreased 12.7% per year from 1999 to 2017 among women ages 15 to 20, 5.5% among women ages 21 to 24, and 2.3% among women ages 25 to 29.

Researchers have grappled with how to calculate cost burden from STDs, partly because doing so puts prevention budgets in perspective. In the April 2021 issue of the journal Sexually Transmitted Diseases, researchers estimated that 27 million STIs were transmitted in 2018 and that those resulted in lifetime direct healthcare costs for those infected of about $16 billion. HIV cases account for most of those costs ($13.7 billion), with HPV a distant second at about $800 million. The costs associated with HIV are high because an infection may mean a lifetime of treatment. HPV infections are expensive because of the cost of treating HPV-related cancers, which include cervical, anal, penile and oropharynx cancers.

Weinstock says the pandemic has highlighted the need to figure out how to deliver high-quality STD services in new ways. The CDC has identified several possibilities:

- STD express clinics that would provide walk-in testing and treatment without a full clinical examination.
- Partnerships with pharmacies and retail health clinics that can provide new access points for on-site testing and treatment.
- Telehealth that can close gaps in testing and treatment, ensure access to healthcare providers and support self-testing or patient-collected specimens.

Weinstock notes that many of these services are part of the strategies highlighted in the recently released HHS Sexually Transmitted Infections National Strategic Plan, which provides a road map for how to control infections over the next five years.

Karen Appold is a medical writer in the Lehigh Valley region of Pennsylvania.
Thanks to decades of research, new treatments for muscular dystrophy that address the disease at the generic level may soon change the course of the disease and help more people.

Muscular dystrophy is a rare group of genetic disorders that cause muscles to waste away over time, creating an inability to move and making everyday tasks difficult, depleting quality of life, and causing early death. The disorders are caused by a defective gene located on the X chromosome that controls production of dystrophin, a protein complex found in muscle fibers.

The most common form of muscular dystrophy is Duchenne muscular dystrophy (DMD), typically seen in boys. Other forms include Becker muscular dystrophy, which is similar to DMD but milder, and limb-girdle muscular dystrophy, which affects the shoulder and pelvic muscles.

Until recently, managing symptoms was the only approach to muscular dystrophy; for example, using corticosteroids that can help strengthen muscle and slow the disease. But there are risks to long-term use of corticosteroids, including weakening of bone tissue that increases the risk of fractures.

Now several pharmaceutical companies are developing gene therapy for muscular dystrophy. Results have been mixed. Earlier this year, Sarepta Therapeutics, a biotech company headquartered in Cambridge, Massachusetts, that focuses on genetic medicine for disorders like DMD, saw its stock price drop in half after it revealed that its investigational gene therapy for DMD, SRP-9001, fell short of its primary end point in a midstage trial. Sarepta attributed these results to differences in fitness among the patients included in the study, and the company released results in May that were more promising.

Sarepta has three products marketed for the treatment of DMD: Exondys 51 (eteplirsen), Vyondys 53 (golodirsen) and Amondys 45 (casimersen). These exon-skipping therapies are indicated for treatment if certain mutations are present and are designed to increase the production of dystrophin. Sarepta also hopes to regain its muscular dystrophy pipeline momentum with a gene therapy for limb-girdle muscular dystrophy, which has no approved treatments.

Pfizer is also looking to make headway in DMD with its gene therapy, fordadistrogene movaparvovec. The company has a phase 3 trial underway and plans to enroll patients across 15 countries. The FDA is addressing outstanding questions regarding the investigational new drug application, says Nicole Kjesbo, Pharm.D., leader of the pipeline team at Prime Therapeutics, a PBM headquartered in Eagan, Minnesota.

Another gene therapy for DMD is under development by Genethon, a French gene therapy company, says Kjesbo. In April, the first patient was dosed with Genethon’s investigational treatment, GNT 0004. Solid Biosciences, a Cambridge, Massachusetts, biotech company, also has a gene therapy candidate for DMD in early-stage trials.

Several companies have therapies for muscular dystrophy in the pipeline that are not gene therapies:

- Taiho Pharmaceutical, a Japanese company, has started a phase 3 trial of its oral treatment, pizuglanstat, which is designed to dampen the inflammatory response in the muscles of DMD patients.

- Italfarmaco, an Italian company, is testing how well givinostat, an oral treatment, promotes muscle repair in DMD.

- FibroGen, headquartered in San Francisco, is testing pamrevlumab, a monoclonal antibody that inhibits connective tissue growth factor in patients with several different illnesses, including DMD.

Jaime Rosenberg is a freelance medical writer based in Jersey City, New Jersey.
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It’s hard to think back to Amazon’s origin story, a website launched in the summer of 1995 that only sold books. Now that bookseller has 200 million Prime members globally buying not just books but food, clothing, appliances and most anything else that can fit in a warehouse. The company rakes in $50 billion a year from Amazon Web Services (AWS), quietly storing data, including medical records. Its 2021 first-quarter earnings were $8.1 billion. And if Amazon’s latest venture works, companies will soon be contracting with the retailer for telehealth and primary care services as well.

From books to in-home check-up: Why?

If Amazon wants to continue growing at 25% to 30% per year, as it has done the past few years, it needs to generate large revenues, says Robin Gaster, a visiting public policy scholar at George Washington University and the author of “Behemoth, Amazon Rising: Power and Seduction in the Age of Amazon.”

“Some can see Amazon casting around for a business that will get really big really quick for them. I’m sure this is the reason they’re in groceries,” Gaster says, adding that groceries are a low-margin, high-capital business and there’s no evidence Amazon will do better than others in this space. “That brings us to healthcare, which of course is much bigger than groceries. One can imagine them looking at healthcare and seeing a far bigger opportunity to be disruptive. Amazon thinks on an entirely different scale. Healthcare is their biggest opportunity.”

Amazon Care launched as a pilot project in September 2019, a virtual health program for some of the company’s Seattle-area employees. Along with its ownership of PillPack, Alexa’s use in healthcare, and its Haven collaboration, Amazon seemed to be connecting the healthcare dots last summer, says Bryan Niehaus, a vice president with the healthcare consulting firm Advis in suburban Chicago.

“We thought Haven may be a large piece of that puzzle. But with Haven not moving forward, and then finally folding, we’re seeing the new directions Amazon is taking,” Niehaus says. “Amazon is pushing into direct-care delivery more aggressively and combining some of those disparate elements.”

Predictions that the company would make a major move to dominate American healthcare have not come to pass. So far.

by DEBORAH ABRAMS KAPLAN

“Amazon thinks on an entirely different scale. Healthcare is their biggest opportunity.”

— ROBIN GASTER, A VISITING PUBLIC POLICY SCHOLAR AT GEORGE WASHINGTON UNIVERSITY AND AUTHOR OF “BEHEMOTH, AMAZON RISING: POWER AND SEDUCTION IN THE AGE OF AMAZON.”
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Amazon vs. traditional healthcare: Who will win?

The push for increased telehealth acceptance because of the COVID-19 pandemic may have accelerated this move, and Amazon Care is a natural extension of the current in-house pilot. The company plans to offer it to its 1.2 million employees nationwide and to other companies as well.

**A different model of healthcare**

Although there have been a few announcements about Amazon Care, details are scant. The app-based care platform is designed to provide primary care through telehealth and pharmacy, with some in-home visits. Although Amazon’s legions of warehouse workers may have access to on-site clinics, “Amazon is preparing for this voice-driven health future by creating a primary care system that is not bricks and mortar,” says Gaster, who also has a consulting business called Incumetrics that measures and assesses innovation. “Our phone is our gateway into healthcare in the future, and it doesn’t mean going to the doctor.”

Established healthcare institutions might be worried about Amazon targeting them; however, Gaster thinks Amazon won’t be coming at them directly but rather from below: “There’s a huge subprimary area of healthcare where we don’t actually go to a primary care physician.” The subprimary area is wellness and chronic disease management, as well as minor or preliminary healthcare initial diagnostics, he says, and these increasingly can be done at home. For example, some cellphones can do electrocardiogram testing and diabetes monitoring. In late 2020, Amazon piloted its health-tracking Halo Band that can monitor physical activity, sleep, temperature and even body fat composition.

“We’ll see this pretty drastic change in which people are not tied to the healthcare their job provides, and it’s a radical opportunity for a disruptive entrant,” Gaster says. AWS is already used for healthcare; PillPack’s at-home prescription delivery relies on Amazon’s established logistics network; and Alexa can order supplies, refill prescriptions and answer insurance-related questions.

“I believe Amazon will eat healthcare from below, not above,” he says. Niehaus envisions Amazon targeting companies that are contracting directly with healthcare systems to provide comprehensive coverage. It may focus on core services to increase access to appointments. He doesn’t anticipate all healthcare organizations feeling an immediate Amazon presence, especially if their core services are inpatient and outpatient services, along with specialty care.

Amazon is coming into the home-based health scene at a time when President Joe Biden’s American Jobs Plan is proposing $400 billion for home or community-based care over eight years. Amazon, like other companies, will need additional workforce to execute a national presence, says Niehaus. Although there’s an opportunity, there’s competition as well. Existing telehealth companies built up a telehealth presence during the pandemic. There are legacy home-health companies too. Amazon could build on its own or buy up existing companies, but rapid scaling can be difficult. The country has a shortage of providers, including physicians, nurses and advanced care practitioners, observes Niehaus. Amazon would be facing stiff competition for qualified providers who are in an entirely different segment of the labor market than the people it hires to pack and deliver boxes.

Amazon’s business and labor practices have plenty of critics, but it has won over American consumers with a buying/delivery experience that is fast, easy and reliable. Would that reputation — and its scale — help in the delivery of healthcare?

“There’s a big opportunity to continue to use omnichannel to curate in a way that’s customized, but I don’t think you’re going to see Amazon disrupt the health system as much as people may think,” says Bird Blitch, co-founder and CEO of Patientco, a payment technology company in Atlanta. One reason is that many people still trust the existing healthcare system as a way to get much of their care.

**Alexa, check on my mother**

Alexa is connected to more than 100 million smart home devices, according to CEO Jeff Bezos’ 2020 letter to shareholders. Providers can already build HIPAA-compliant tools to schedule appointments, find nearby providers, answer health questions and refill prescriptions. Gaster envisions a future where people ask Alexa what to do for a sprained knee, and Alexa will ask a few questions and give advice like wrapping and elevating it. “There’s a huge subcritical area that is just wide open,” he says. Healthcare systems are traditionally set up to focus on what happens after the patient enters the office, because that’s where they get paid. “Before that is where most healthcare concerns exist,” Gaster says. “I think Amazon is incredibly well positioned, and it will acquire enormous amounts of data through
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(Alexa) and its Amazon Care projects, through PillPack and through AWS.

Digital health company Sharecare partnered with Amazon to add 80,000 health and wellness questions to its Alexa database, along with medical-vetted content. Given its HIPAA compliance, “Amazon has the potential to change how patients navigate their care,” says Blitch. A 2019 survey showed that 52% of people were interested in using voice assistants for healthcare. “I think we’ll see more providers rolling out voice assistant experiences,” something that Blitch says his company’s customers use with their payment system.

Alexa Care Hub allows the device to monitor the activity of older relatives. It can be set up so the caregiver knows whether the relative asked a question about the weather, watched a movie or went outside. “Because it can be connected to Ring, you can get a lot of information,” says Gaster. “This is obviously with consent at both ends, and this is far beyond traditional healthcare, but it’s clearly about health.”

Amazon already has a presence in the majority of U.S. homes. Around 62% of U.S. households hold a Prime membership, according to 2019 data. “They have a massive loyal customer base,” says Blitch. “They have a lot of data they can identify and respond to, including the consumers’ latest preferences and demands.”

These factors may allow Amazon to leverage their technology and their ability to remove customer obstacles to give people more control over their healthcare.

Insurance and regulation
After Amazon Care rolls out and presuming it is successful, Niehaus anticipates that the next step would be to layer on services. That could be expanding a physical healthcare footprint or developing or acquiring insurance products. Consider CVS Health, which is a drugstore chain, an insurer, a PBM and a provider (the MinuteClinics and the HealthHUBs). From what’s known publicly, Niehaus says, Amazon Care isn’t set up to bill insurers. It’s possible that employers will directly contract with them or they’ll offer a self-pay consumer option.

But Amazon may also need to step gingerly. If the company’s healthcare profile grows, there will be pushback against the “Amazonification” of healthcare from current stakeholders. It may invite scrutiny and oversight about whether additional regulations are needed and what those might look like, though. That includes the home health space, which the Biden administration has highlighted for additional funding through the infrastructure bill, even if details are not yet available. “Regulations are our checks and balances working as intended,” observes Niehaus.

Another way Amazon insinuates itself into healthcare could occur behind the scenes. Amazon has launched HealthLake, which aggregates healthcare data and standardizes it into required interoperability formats, with “HIPAA-eligible service that enables healthcare providers, health insurance companies, and pharmaceutical companies to store, transform, query, and analyze health data at scale,” says the website. Given the CMS mandate for interoperability and patient access, this will likely be a growth area.

Gaster spins an extended metaphor to explain Amazon’s perspective and possible role in health: “The existing healthcare systems are formidable castles with enormous moats and cannons pointing in all directions. There are lots of lawyers at the battlements ready to take on the company, but Amazon is spreading out over the countryside, taking areas the castle can’t protect. In the end, castles will surrender when they don’t have supplies.

The search for areas of opportunity may allow Amazon to expand into other areas of healthcare, with almost no recognition or interest in the collateral damage the company sometimes causes, says Gaster. “That’s true in warehouses. It’s true on the Marketplace platform. It’s true in AWS,” he says. “Being obsessive is dangerous. They don’t care about the impact of what they do. They just focus on the customers.”