Friday, April 24, 2020

Louisiana Independent Pharmacies Association

LIPA Newsletter:

Bringing you the latest news and information concerning independent pharmacies and the profession at-large….

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Members,

We know we have at least one more week with the statewide shelter in place order in the fight against coronavirus. The Governor has stated his intent to announce details on Monday for Phase 1 of the reopening of the economy. He stressed that there will still be the need for social distancing and that masks should be worn by everyone when in public. Also, the opening of restaurants and entertainment facilities will definitely not happen as part of Phase 1.

The Governor listed on Wednesday his top priorities as being--

1) continuation of the shelter in place order through at least April 30th,
2)to expand testing, and
3) to implement vigorous "contact tracing" and identify people who have been in close proximity with a person who tests positive for COVID-19.

House and Senate leadership indicated during a Thursday morning meeting of the Louisiana Economic Recovery Taskforce that they are approaching economic recovery in three phases. They anticipate the Legislature will reconvene "sometime in May" at which point their primary focus will be immediate relief needed to restart the economy (Phase 1). They stated there's a "strong likelihood" of a Special Session which will not have the constraints that apply to the Regular Session and what legislation can be considered (this is an even year and therefore limited to fiscal bills only) (Phase 2). However, any matters to be considered in a special session are limited to those items specifically listed, mentioned or otherwise enumerated in "the call" which is the proclamation calling for the legislature to meet. Long term economic recovery will need to address broader reforms such as tax reform and liability reform. (Phase 3).

The legislature may be convened for a special session which the Constitution calls an Extraordinary Session by the governor and shall be convened by the presiding officers of both houses upon written petition of a majority of the elected members of each house. At least seven calendar days prior to convening the legislature in extraordinary session, the governor or the presiding officers, as the case may be, shall issue a proclamation stating the objects of the extraordinary session, the date on which it shall convene, and the number of days for which it is convened. The power to legislate shall be limited, under penalty of nullity, to the objects specifically enumerated in the proclamation. The session shall be limited to the number of days stated therein, which shall not exceed thirty calendar days.

There also exists the power of the Governor to call an Emergency Session without prior notice or proclamation in the event of public emergency caused by epidemic, enemy attack, or public catastrophe.

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Will HCQ block the spread of COVID-19? As pharmacies and pharmacists, our members are in a unique position to help identify treatments for COVID-19 by collecting and providing data on Hydroxychloroquine (HCQ) use. You can do so by talking to your patients who are currently taking HCQ for any reason other than COVID-19 and respond to this survey being disseminated by Ricky Mannino and Sadie Mannino Bennett that can be found at this link: **Hydroxychloroquine Case Study**

For this project, they are requesting that you talk to your patients who are currently taking Hydroxychloroquine for any reason other than COVID-19 and gather the information in the brief survey which will inform research being conducted to assess whether there is potential for HCQ as prophylaxis for COVID.

More HCQ clinical research news Tulane University announced this week that their researchers are investigating whether HCQ can prevent COVID-19. They are recruiting anyone who has been in close contact with someone with confirmed COVID-19 to participate in the study to determine whether hydroxychloroquine can prevent transmission in people exposed to the virus and hope to enroll 500 participants locally. The **study** can be conducted in its entirety from home is being funded by the Bill and Melinda Gates Foundation. As to the importance of the study, "if this trial is successful, it will provide people with another prevention measure in addition to staying at home and practicing physical distancing to slow the pandemic and continue to flatten the curve."

Testing, testing, testing *"We need more testing"* is an often-repeated phrase when people talk about the prerequisites for reopening businesses and jump-starting economic recovery. President Trump has said that doubling tests is the key to lifting lockdowns. Testing means different things to different people. Are they talking about the "gold standard" COVID-19 nasal test that has been so graphically described? Blood tests to detect antibodies/serology?

The state announced this week that it is moving away from high demand drive-thru testing centers and will move to a "spoke and hub" system that will move testing back to local hospitals, clinics and FQHC's which will **send tests to local labs** that can provide results within 24 to 48 hours. **The Advocate** posted a story late yesterday quoting the Governor as saying that the state needs a "slight boost" to be able to administer at least 140,000 tests per month to begin the slow and phased reopening of Louisiana's economy and state officials say they hope to ramp up to 200,000.

Meanwhile, Politico reported on a number of thorny issues complicating the ability of private labs to double their current level of testing (from 1 million to 2 million per day) including the need for more high-speed lab-machines and addressing supply chain shortages. "*Testing supply shortages can feel like a game of whack-a-mole. As labs have expanded their testing capacity, shortages of the swabs and tubes used to collect and transport patient samples have become more pronounced."* The government is using the Defense Production Act—or at least the threat of it—to get Puritan, a small Guilford, Maine company to increase "flocked" medical swab production from 3 million to more than 20 million within 30 days. Reagents (chemicals used to prepare samples for testing) are also in short supply.

Here are a few more Louisiana numbers on COVID (diagnostic) testing:

At least **93** test sites are now up and running,
At least **80** labs, most of them in-state (but their capacity varies considerably), and
9% of new tests come back positive (10% is considered threshold (with lower better) for getting a decent picture of the rate of infection.

The FDA—which has authorized more than 50 tests to date—announced on Wednesday that they have authorized the first diagnostic test for COVID-19 with a **home collection option** –a LabCorp kit containing nasal swabs (**not** just any Q-tip) and saline. The sample is mailed back to LabCorp in an insulated envelope for testing. The test will require a doctor's order.

More on that Emergency Order allowing pharmacists to order and perform COVID testing As we reported in last week's newsletter, on April 15th, LDH published an emergency order that allows

pharmacists to both order and perform FDA-authorized COVID-19 tests. The Questions Already Answered (QAA) on the Board of Pharmacy's COVID-19 webpage were updated on Sunday to include their response to the question *"We saw the April 15 emergency order authorizing pharmacists to order and perform COVID-19 testing. Does that order also include the rapid serology testing for COVID-19 antibodies?"* The response was *"The intent of the emergency order from the State Health Officer is for diagnostic testing for COVID-19. Since serology testing assesses for the presence of antibodies and are not diagnostic for active infections, serology testing is not covered by this emergency order."*

We are concerned that this determination, the federal guidance advises:

Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), ***OASH issues this guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized.*** *See 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); see also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.1* ***By doing so, such pharmacists will qualify as "covered persons" under the PREP Act. And they may receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests.*** *42 U.S.C. § 247d-6d(a)(1).*

The federal guidance is important in both the tests being considered and authorized to be performed by pharmacists and the coverage of the PREP Act. Most significant in the consideration is the necessity of FDA-authorized as a valid test and one which leads toward your licensure to perform and the ability to be reimbursed.

LIPA has followed up with the Board of Pharmacy, the State Health Officer, the legal division of the LDH and others for further clarification as in our reading of the emergency order, it makes no mention of "diagnostic" testing but rather **FDA-authorized** tests for COVID-19. with that being said, four serology (antibody) tests have now been given FDA Emergency Use Authorization, lots of questions remain about their accuracy and if the test does indicate immunity, how long immunity to COVID will last.

In comments made Thursday to the Louisiana Economic Recovery Task Force, Dr. Catherine O'Neal who is an Infectious Disease Specialist at OLOL Hospital in Baton Rouge cautioned that the antibody/serology tests are "fraught with lack of knowledge" and said we don't know **at this point** if they will help or not.

At what percent will Louisiana's unemployment rate peak? This week, the **economic** damage from the COVID-19 pandemic continued to mount in Louisiana. Some of the numbers coming to light are shocking: WDSU News reported on Sunday that immediately prior to the pandemic, Louisiana already had the highest unemployment in the nation at 6.9. Also, the state saw the biggest jump of any state in unemployment from March 2019 to March 2020.

Dr. Loren Scott the respected economist estimates that Louisiana's "implied" unemployment rate is now22%. Some areas of the state—those most dependent on **tourism** and **oil & gas**—have been especially hard hit. Oil and gas—along with **construction**—will take much longer to rebound than other sectors of the economy, according to remarks Dr. Scott made yesterday to a meeting of the Louisiana Economic Recovery Taskforce that was recently created to advise the Legislature. He indicated that four different Liquified National Gas (LNG) construction projects that were expected to commence in the state at a total cost of $39.6B will be deferred until at least next year at the earliest because of the low oil prices and difficulty in obtaining financing.

The total amount paid to 300,000 unemployed workers in the state is now $556 million dollars;

Louisiana state government has already spent $616 million fighting the coronavirus.

With the current state unemployment rate at 22%, we are just 3 percentage points shy of the 25% national unemployment rate reached in 1933 at the peak of the Great Depression.

Making the case to LDH for temporary Medicaid pharmacy reimbursement increase LIPA

formally submitted a request to LDH [the package is attached] for a temporary increase in Medicaid pharmacy reimbursement in response to the COVID-19 public health emergency. CMS has created a streamlined and "fast track" process for approval of Disaster State Plan Amendment (SPA) requests by states that waives the usual requirements for public notice and tribal consultation timelines. Randal was able to discuss the request at length with Louisiana Medicaid leadership this week who –after reviewing the request and documentation—agreed that some adjustments are needed in Medicaid pharmacy reimbursement. The Department is currently working to determine the fiscal impact and state budget implications of temporary rate increases and their intent is to submit a Disaster SPA that will include temporary reimbursement

As we explained to LDH, multiple factors have converged (*e.g.* increased pharmacy costs of doing business, decreased overall volume of prescriptions dispensed, closed store departments resulting in reducing allocation of shared costs) to significantly **increase** the cost of dispensing prescription drugs. In addition to requesting a temporary increase in the Professional Dispensing Fee, LIPA proposed that NADAC be temporarily "bypassed" in the current Medicaid State Plan reimbursement hierarchy for both brand-name and generic drugs."

The data and comments we received from you in response to the **COVID-19 Cost of Dispensing Survey** were vitally important in providing justification to LDH for the requested increase in reimbursement. Historical information on the cost of dispensing in no way reflect the current unprecedented circumstances What you are seeing in real time with drug price volatility, shortages, and quantity limits and the time lag in NADAC makes it clear that it is not a good indicator of average costs for Louisiana's pharmacies during COVID crisis.

"Skyrocketing" number of mail-order prescriptions On Tuesday, the influential news website Axios confirmed what you already know: that "people are filling more prescriptions by mail amid the coronavirus crisis." At the same time that mail order prescriptions have increased by 5.7%, retail prescriptions are **down** by 9.6%. The Axios story's "big picture"**:** *Total prescription volumes still have declined heavily as people have traveled to their pharmacies less frequently. People also stocked up on medications, many of which came in 90-day supplies, once the coronavirus outbreak started to worsen in mid -March and consequently haven't had to refill their prescriptions as often.* In the explanation we provided to LDH for the increase in dispensing costs due to COVID-19, we included the overall decrease in volume of prescriptions (which further **increases** the **average** cost of dispensing).

One of the big "unknowns" is the degree to which patients will continue to use mail-order after the current crisis ends and the ongoing ratio of 90-day rather than 30-day prescriptions. Are the increases in cost of dispensing temporary or something that will be seen in the much longer term?

Some surgical, medical and dental procedures can resume on Monday This week, the state issued a revised order that loosens the restrictions for medical, surgical, and dental procedures that goes into effect Monday, April 27. In addition to treatment of an emergency, these procedures will also be allowed to 1) to avoid further harms from an underlying condition or disease and 2) for time sensitive dental conditions. The order includes a lot of caveats before resuming procedures: have a plan in place to monitor for COVID-19 symptoms or test if possible; ensure adequate physical distance between patients at all times; have at least a five-day minimum supply of PPE on hand [and they cannot rely on state or federal government for PPE], and a number of others.

"Fear of virus" and "covid phobia" consequences Between the restrictions on health care providers, COVID-19 containment measures taken by health care providers, stay-at home orders, and "fear of virus" Louisiana is seeing a marked **decrease** in health care utilization including the number of people seeking care in hospital emergency rooms. On Thursday, the Louisiana Emergency Response Network (LERN is the state agency tasked with coordinating care for individuals suddenly stricken with heart attacks and strokes) issued a press release indicating their data shows a mark decrease in patients seeking care for these conditions that coincides with the onset of the pandemic in Louisiana. STAT News reporting on

Thursday echoed this concern, publishing a story with the headline 'Where are all our patients?' Covid phobia is keeping patients with serious heart symptoms away from hospitals

Rutledge v. Pharmaceutical Care Management Association

Before COVID-19 spread throughout the United States, the United States Supreme Court ("USSC") granted Arkansas' writ of certiorari from the U.S. Court of Appeals for the 8th Circuit, which ruled in favor of the Pharmaceutical Care Management Association ("PCMA"), holding the Employee Retirement Income Security Act ("ERISA") preempted an Arkansas statute regulating pharmacy benefit managers. The case was originally scheduled for Monday, April 27, 2020.

In early April, the USSC postponed oral arguments until the 2020 October Term due to COVID-19. We do not have a new date at this time, but LIPA will update you as soon as the schedule is available. Shortly thereafter, the United States Solicitor General, Noel Francisco, was granted permission to participate in oral arguments on behalf of Attorney General Rutledge and Arkansas. The Solicitor General is the top litigator for the United States and will be allotted ten (10) minutes of Arkansas' thirty (30) minutes during the oral argument. PCMA will have thirty (30) minutes to argue its case.

Dozens of parties filed amicus curiae ("friend of the court") briefs in favor of AG Rutledge and Arkansas. They include the: States of California, et. al [44 states in total, including Louisiana]; Community Oncology Alliance, Inc., et al.; National Association of Chain Drug Stores, Inc.; National Council of Insurance Legislators; Arkansas Pharmacists Association, et al**. [including LIPA];** the United States; FMI and Twenty-Three Retail Trade Associations; National Association of Specialty Pharmacy; Alliance for Transparent and Affordable Prescriptions; AIDS Healthcare Foundation; AARP and AARP Foundation [supporting neither party]; and the American Medical Association, et al.

Six parties filed amicus curiae briefs in favor of PCMA.

LIPA will fully brief its members on the petitions of General Rutledge and Arkansas, Arkansas' supporters, PCMA, and PCMA's supporters in a future newsletter once the USSC reschedules oral arguments. Until then, you can find every motion filed to the USSC at the following link: Rutledge v. PCMA, No. 18-540.

Pharmacy readiness to order and perform COVID-19 tests New, less- invasive testing--including antibody/serology tests to determine if someone has already had the virus—are being developed and pending determination of test accuracy and actual FDA-authorization, the FDA has given the OK for more than 70 companies to sell their tests. While the Louisiana Emergency Order permits licensed pharmacists to order and administer tests in their stores, we want to call to your attention some **additional requirements that must be met:**

- Pharmacies will need to obtain a **CLIA Certificate of Waiver** from Louisiana LDH/Health Standards. The fee is $180 for two years (paid later, not with application submitted to Health Standards) and requests are initiated by completing the Form CMS 416 . More information can be found here, including how/where to route the form.
- The test being ordered/performed must have Emergency Use Authorization (EUA) from FDA
- The EAU must state test is authorized for settings with a CLIA Certificate of Waiver.

LDH/Health Standards information on CLIA Certificates of Waiver Randal spoke with Louisiana Health Standards Deputy Assistant Secretary Cecile Castello on Thursday about the CLIA implications of the Louisiana Emergency Order for community pharmacies. Ms. Castello conferred with her CLIA staff and provided an update this morning that included the following information:

- Confirmation that a CLIA Certificate of Waiver is s required for each physical location where testing is to be performed.
- Health Standards has processed 5 Certificate of Waivers for COVID-19 testing in pharmacies. This certificate allows **waived** testing only to be performed.

- Of the many platforms that have obtained EUA status from the FDA, only three can be tested in a patient care setting/point of care and under a CLIA Certificate of Waiver at this point in time.
- If any other testing is to be performed that has an EUA or serology testing under FDA Pathway D, a CLIA Certificate of Compliance or a Accreditation is required and the laboratory must meet the requirements of moderate or high complexity as outlined from FDA.
- Health Standards has not received any requests for certificates to cover moderate or high complexity testing in patient care settings outside of a central laboratory.

IN THE NEWS

Anti-malarial drug Trump touted is linked to higher rates of death in VA coronavirus patients, study says

The Washington Post

An anti-malarial drug President Trump has aggressively promoted to treat covid-19 had no benefit and was linked to higher rates of death for Veterans Affairs patients hospitalized with the novel coronavirus, according to a study, raising further questions about the safety and efficacy of a treatment that has seen widespread use in the pandemic.

The study by VA and academic researchers analyzed outcomes of 368 male patients nationwide, with 97 receiving hydroxychloroquine, 113 receiving hydroxychloroquine in combination with the antibiotic azithromycin, and 158 not receiving any hydroxychloroquine.

Rates of death in the groups treated with the drugs were worse than those who did not receive the drugs, the study found. Rates of patients on ventilators were roughly equal, with no benefit demonstrated by the drugs.

More than 27 percent of patients treated with hydroxychloroquine died, and 22 percent of those treated with the combination therapy died, compared with an 11.4 percent death rate in those not treated with the drugs, the study said. The results were from an observational study of outcomes and were not part of a randomized, placebo-controlled clinical trial, which is the gold standard for testing drugs.

The study was published on the site medrxiv.org, which is a clearinghouse for academic studies on the coronavirus that have not yet been peer-reviewed or published in academic journals.

"An association of increased overall mortality was identified in patients treated with hydroxychloroquine alone," wrote the authors, who are affiliated with the University of Virginia, the University of South Carolina, and the VA system in Columbia, S.C. "These findings highlight the importance of awaiting the results of ongoing prospective, randomized, controlled studies before widespread adoption of these drugs."

The coronavirus pandemic has overtaken the globe faster than science can respond. There are no vaccines or treatments approved to combat its spread or ease severe respiratory symptoms that have claimed over 175,000 lives worldwide.

In some cases, hope has trumped evidence in the worldwide rush to find countermeasures. Hospitals and doctors around the world have been prescribing chloroquine and hydroxychloroquine, often in combination with azithromycin, based on a belief it can help, despite a lack of sound evidence that the drugs make patients better or eliminate virus from the body.

Interest in the drugs peaked after Trump began repeatedly boosting their use in White House news conferences.
He tweeted a reference to a French study in March that has since come under scrutiny for its skimpy trial size and questionable methods. In a decision that did not cite any evidence of benefit, the Food and Drug Administration issued an emergency use authorization allowing the drug to be administered in hospitals.

But the dangers of these drugs to treat certain coronavirus patients is becoming apparent, especially when hydroxychloroquine is used in combination with azithromycin. The small risk of cardiac death for patients on these drugs stems from a well-known side effect: They extend the split-second time required for the heart to recharge between beats, a condition called QT prolongation.

Citing the phenomenon, a panel of the Infectious Diseases Society of America, citing the risks, strongly advised its physician members that the combination of the drugs should be given only in a clinical trial. It cited the lack of clear evidence of any benefit. Its treatment guidelines stated the "overall certainty of evidence was very low."

The stock market is hungry for a coronavirus treatment. Don't expect a magic bullet.

The French national agency in charge of drug safety reported that 43 patients taking hydroxychloroquine or a combination of the drug and azithromycin suffered cardiac-related side effects and between one and four deaths. The agency said the drugs should be given only to patients who are hospitalized with covid-19, the disease the coronavirus causes. Researchers in Brazil ended a portion of a clinical trial testing high doses of chloroquine in covid-19 patients after they developed heart problems and suffered higher mortality.

A team of researchers at New York University's Langone Medical Center found that, out of 84 patients treated with the combination of hydroxychloroquine and azithromycin, 11 percent had QT prolongation beyond 500 milliseconds — the proven danger zone for sudden cardiac death. Thirty percent of the patients overall had significant increases in their hearts' QT intervals.

Lior Jankelson, a lead researcher on the Langone study, said the danger makes it highly inadvisable for people to take the drug as a prevention or without a positive coronavirus test, which has reportedly been happening around the world.

"If the patient is not proven to be sick, then I think there is no question that the risk associated with this therapy is not reasonable," he said in an interview.

"This is a really extreme situation … where you have hundreds of thousands, if not more, of people taking a known combination that prolongs the QT interval in a generally high-risk situation," he said.

In hospitals, the way to manage the risk of fatal side effects is with electrocardiogram monitoring, according to specialists. But even advanced ECG screening may not reduce the risk.

The NYU Langone study showed that existing QT prolongation did not predict a subsequent QT increase from use of the drugs.

IN THE NEWS

Renal failure was a greater risk factor — indicating the sickest patients are at the greatest risk of dangerous side effects from the drugs.

OVID-19 Reveals Fissures in the Nation's Prescription Drug Supply Chain

Arnold Ventures

With the virus ravaging New York, my 87-year-old father — fly-fishing author and former book publisher Nick Lyons — called his pharmacy and told them he was down to his last few pills of his statin, a cholesterol-lowering drug and one of five medications he takes every day. Much to his chagrin, the pharmacist said they were out of that drug and had no idea when they'd get more. When my father complained to the pharmacist that he'd been a good customer for more than 40 years and really needed his statin, the pharmacist suggested he go to an urgent care facility to see whether they had some to spare. But my father has been self-quarantined in upstate New York and was unable to get to such a facility.

There are countless stories more frustrating and scary than my father's, but in the richest country in the world, his illustrates how fiercely Americans rely on their daily meds and have come to expect that they will be available whenever they need them; how quickly people become frustrated, even panicked, when they face the prospect that they can't get the drug they need; and how wide-ranging the impacts of COVID-19 have been on the availability of prescription drugs at neighborhood pharmacies and hospitals.

As the pandemic's death toll continues to climb — nearly 170,000 deaths globally by April 20, roughly 40,000 of which were in the U.S. — one under-explored consequence of the crisis is how the virus's rapid spread is straining the demand, supply, and pricing of medications on which we depend. In short, the pandemic has laid bare fundamental flaws that have long existed — but have never been fully exposed — in the way the United States sources, manufactures, and distributes drugs.

"We are the wealthiest country in the world, we have very deep pockets... So how is it possible that we could have shortages?" asked Rena Conti, Associate Research Director of Biopharma and Public Policy at Boston University.

Drug shortages have suddenly appeared among medicines that were never in short supply before. Drugs touted as potential treatments for COVID-19 have been snatched up quickly by doctors and hospitals, even though there's no medical evidence yet to suggest they work. Drugs needed to sedate patients for ventilators are increasingly difficult to come by. And consumers are stockpiling 90-day refills of their regular drugs, instead of placing usual 30-day orders, adding pressure to a system not designed to carry the extra load.

Health policy experts say the pandemic has opened a window through which they and the public can better view systemic flaws that have long been present in the U.S. but hidden from public view. Examining these flaws, they say, may lead to necessary change in the future once the pandemic eases.

"We've become very concerned about the fragility and the fragmentation of our supply chain," said Kristi Martin, Arnold Ventures Vice President for Drug Pricing. She added that the crisis had underscored how easily the U.S. drug supply can experience "stock out" — a scenario when there are not enough products in the system to fulfill an order — and the crisis shined a light on the cracks in the system that merit closer examination once the crisis subsides.

"Hopefully, it will lead to a better system," she said. "People will take it apart and will say, 'There are probably policy changes that we can contemplate, or industry changes, so that this doesn't happen again.'"

Signs of Trouble

The first indications that the pandemic was hitting the U.S. drug supply came as early as Feb. 27, when the FDA issued a notice warning of a drug shortage due to an "issue with manufacturing an active pharmaceutical ingredient." U.S. pharmaceutical companies often source such ingredients — the building blocks of drugs — from China and India, where the pandemic has severely constrained and — in some cases — completely shuttered manufacturing and distribution.

Even as the pandemic has eased in China and factories are once again firing up, the Congressional Research Service has predicted that U.S. drug companies will continue to have trouble accessing the active pharmaceutical ingredients (APIs) needed to make generic drugs — which could in turn lead to price hikes, according to a recent report in Inside Health Policy. The United States sources many of its generic drugs from India, which imports most of its APIs from China, according to the Inside Health Policy article.

Among the drugs that experienced shortages are those needed by patients with lung function and cardiac issues, as well as drugs that assist in pain management. Demand has also increased for drugs to sedate patients while they're on ventilators, such as fentanyl, midazolam, and propofol; and for albuterol inhalers, often used to help open airways in asthma patients.

One emergency room doctor, Dr. Tom Forsberg, who serves as the Medical Director for Emergency Medicine Education and the Trauma Co-Director for Centra Health in Lynchburg, Virginia, said he was notified of shortages for medications used for intubation, a medical procedure to insert a tube into the windpipe to help with breathing and prepare patients for ventilation, in addition to pain management and albuterol inhalers. Most notably, demand has dramatically increased for hydroxychloroquine, the anti-malaria drug touted by President Trump as a possible treatment for COVID-19 even though it has not received FDA approval, with hospitals and pharmacies in New York and other metro areas reporting shortages and competing for supply despite no clinical evidence yet to suggest that it's effective.

Conti, of Boston University, said she, along with Erin Fox, Director of Drug Information at the University of Utah, have been warning for more than a decade about the vulnerabilities of the supply chain that have now been exposed by the pandemic.

"I had been concerned about the hospital-based products where there is really one manufacturer and that manufacturer supplies the U.S. and many other allied countries," Conti said.

In other words, if, for whatever reason, one manufacturer is disrupted, how does that impact the chain of supply and the availability of alternatives?

Supply of Generics is Concerning

Among the drugs most at risk of shortages are the generics that most Americans take. Nearly 90 percent of all prescriptions in the U.S. are generic drugs, heightening the urgency to ensure that the supply chain is adequate. Conti said that branded drugs likely are protected by supply and demand disruptions, since pharmaceutical companies have a vested interest in ensuring supply in order to generate revenue and meet shareholders' forecasts in a given quarter. However, she noted that generic drugs operate on lower profit margins and do not provide as much incentive for pharmaceutical companies to invest in robust production mechanisms.

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