TEXAS STATE BOARD OF PHARMACY

October 26, 2022

Justin Gordon
Division Chief
Open Records Division
Office of the Attorney General
P.O. Box 12548
Austin, Texas 78711-2548

Re: Request from Robert Montoya for specified categories of information
(TSBP Request No. M.10.14.22)

Dear Justin Gordon:

On October 14, 2022, the Texas State Board of Pharmacy ("TSBP") received two requests under the Texas Public Information Act (the "Act") from Robert Montoya for specified categories of information. A copy of both requests for information is attached as Exhibit A.

We have released some of the responsive information. A copy of the release letter is attached as Exhibit B. A representative sample of the remaining responsive information is attached as Exhibit C. TSBP asserts the information indicated is excepted from disclosure under sections 552.101 and 552.118 of the Government Code.

Section 552.101 of the Government Code

Section 552.101 excepts from disclosure "information considered to be confidential by law, either constitutional, statutory or by judicial decision." Gov't Code § 552.101.

Section 565.055 of the Occupations Code

Section 552.101 encompasses information made confidential by other statutes, such as section 565.055 of the Occupations Code. Section 565.055 provides:

> (a) The board or the board's authorized representative may investigate and gather evidence concerning any alleged violation of this subtitle or a board rule.

> (b) Information or material compiled by the board in connection with an investigation, including an investigative file of the board, is confidential and not subject to:
>
> (1) disclosure under Chapter 552, Government Code; or
>
> (2) any means of legal compulsion for release, including disclosure, discovery, or subpoena, to anyone other than the board or a board employee or board agent involved in discipline of a license holder.
>
> (c) Notwithstanding Subsection (b), information or material compiled by the board in connection with an investigation may be disclosed to:
>
> (1) a person involved with the board in a disciplinary action against the license holder;
>
> (2) an entity in another jurisdiction that licenses or disciplines pharmacists or pharmacies;
>
> (3) a pharmaceutical or pharmacy peer review committee as described under Chapter 564;
>
> (4) a law enforcement agency; or
>
> (5) a person engaged in bona fide research, if all information identifying a specific individual has been deleted.

Occ. Code § 565.055. Further, in construing the predecessor statute, Open Records Decision No. 474 previously determined that reports made by investigators to TSBP are excepted from disclosure.

> We agree that information collected and compiled by investigators as well as reports made by investigators to the board are within the scope of the exception… We think that an 'investigative file' for purposes of [this] section includes documents relating to the gathering of facts and the assessment of the validity of the complaints against the licensees.

ORD 474 at 2 (1987). The information indicated consists of compilations of evidence created in the course of investigating and gathering evidence concerning alleged violations of the Texas Pharmacy Act or a Board Rule. The documents at issue are part of TSBP's investigative files. The requestor is not entitled to this information pursuant to section 565.055(c). Accordingly, the information at issue is confidential under section 565.055(b) in conjunction with section 552.101 of the Government Code and is not subject to disclosure under the Act.

Section 555.010 of the Occupations Code

Section 552.101 encompasses section 555.010 of the Occupations Code, which provides:

> The identity of a person who reports to or assists the board under Section 552.002(c) and a document that could disclose the identity of that person are confidential and are not considered public information for the purposes of Chapter 552, Government Code.

Occ. Code § 555.010. Section 552.002 of the Occupations Code states, in relevant part:

> (c) Any person who has knowledge relating to an action or omission of a pharmacist or pharmacy licensed by the board that constitutes a ground for disciplinary action under Section 565.001 or 565.002, or a rule adopted under one of those sections, may provide relevant records, report relevant information, or provide assistance to the board.

Occ. Code § 555.002(c). The information indicated could disclose the identity of a complainant or a person who assisted the Board. This information is confidential under section 555.010 of the Occupations Code and excepted from disclosure under section 552.101 of the Government Code.

Section 481.076 of the Health and Safety Code

Section 552.101 encompasses information made confidential by other statutes, such as section 481.076 of the Health and Safety Code. Section 481.076 provides, in part:

> (i) Information submitted to the board under Section 481.074(q) or 481.075 is confidential and remains confidential regardless of whether the board permits access to the information under this section.

Health & Safety Code § 481.076(i). For reference, section 481.074(q) provides:

> (q) Each dispensing pharmacist shall send all required information, including any information required to complete the Schedule III through V prescription forms, to the board by electronic transfer or another form approved by the board not later than the seventh day after the date the prescription is completely filled.

Health & Safety Code § 481.074(q). Section 481.075 provides, in part:

> (i) Each dispensing pharmacist shall:
> . . .

> (3) send all required information, including any information required to complete an official prescription form or electronic prescription record, to the board by electronic transfer or another form approved by the board not later than the seventh day after the date the prescription is completely filled.

Health & Safety Code § 481.074(i)(3). The information indicated was submitted to TSBP under section 481.074(q) and/or section 481.075. Therefore, this information is excepted from disclosure under section 552.101 of the Government Code in conjunction with section 481.076 of the Health and Safety Code.

Section 552.118 of the Government Code

Section 552.118 provides:

> Information is excepted from the requirements of Section 552.021 if it is:
>
> (1) information on or derived from an official prescription form filed with the Texas State Board of Pharmacy under Section 481.0755, Health and Safety Code, or an electronic prescription record filed with the Texas State Board of Pharmacy under Section 481.075, Health and Safety Code; or
>
> (2) other information collected under Section 481.075 or 481.0755 of that code.

Gov't Code § 552.118. The information indicated contains information collected under sections 481.075 and/or 481.0755. This information is excepted from disclosure under section 552.118 of the Government Code.

TSBP respectfully requests a decision from the Open Records Division regarding the applicability of the argued exceptions as provided by the Act.

Should you need additional information, please feel free to contact me at (512) 305-8060.

Sincerely,

Eamon D. Briggs
Assistant General Counsel

Cc: Robert Montoya
rmontoya@texasscorecard.com
(w/o enclosures)

TEXAS STATE BOARD OF PHARMACY

October 26, 2022

Robert Montoya
Texas Scorecard
Email: rmontoya@texasscorecard.com

Re: Request from Robert Montoya for specified categories of information
(TSBP Request No. M.10.14.22)

Dear Robert Montoya:

On October 14, 2022, the Texas State Board of Pharmacy ("TSBP") received your two requests under the Texas Public Information Act (the "Act") for specified categories of information.

We have enclosed public information responsive to your request. We believe the remaining information responsive to your request is confidential. We have requested that the Open Records Division of the Office of the Attorney General issue a ruling as to whether this information may be withheld under the Act.

If you need additional information, please contact me at (512) 305-8060.

Sincerely,

Eamon D. Briggs
Assistant General Counsel

From: Apple News <newsdigest@insideapple.apple.com>
Sent: Thursday, February 24, 2022 6:27 AM
To: Javier Ledesma
Subject: What to know about Russia's attack on Ukraine, a shift in the Trump investigation, and more

Good Morning From Apple News

It's Thursday, February 24. Here's what you need to know.

TOP STORIES

Russia attacks Ukraine

Explosions were reported in multiple Ukrainian cities — including the capital, Kyiv — this morning, minutes after Vladimir Putin declared the start of Russia's "special military operation." Officials said Russian troops have entered from the north and south.

CNN >

President Biden vowed to hold Russia accountable for the attack, calling it "unprovoked and unjustified." The White House said it would announce new, severe sanctions on Moscow today.

THE WALL STREET JOURNAL >

Oil prices reached $100 a barrel for the first time since 2014, and global stock markets plunged.

REUTERS >

Two prosecutors leading the Manhattan DA's criminal probe into Trump and his businesses resigned, raising questions about the future of the investigation.

THE WASHINGTON POST >

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The Far-Right Activists Trying to Take Down the Pope

How Steve Bannon, Milo Yiannopoulos, and others are intent on transforming the Catholic Church.

MOTHER JONES ›

FIVE STORIES WE'RE TALKING ABOUT

Texas governor Greg Abbott told state health agencies to consider gender-affirming treatment for transgender teenagers as child abuse.

USA TODAY ›

Who might benefit from a fourth COVID shot — and who might not.

NPR ›

She said her husband was abusive. A judge took away her kids and ordered her arrest.

PROPUBLICA ›

A teacher spent 70 years collecting Black-history artifacts. Here's a look inside her home.

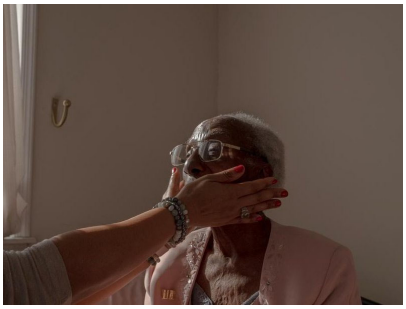
SMITHSONIAN MAGAZINE ›

News+

A guide to getting rid of almost everything.

THE NEW YORKER ›

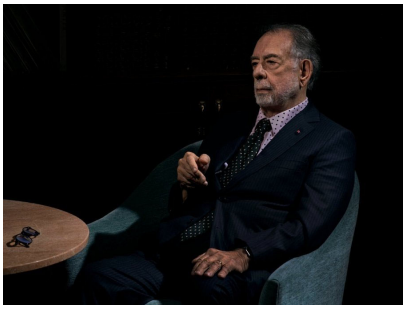
STORIES TO LISTEN TO



News+ Audio

Death doulas used to be rare. The pandemic changed that.

TIME ›



News+ Audio

Francis Ford Coppola is spending $120 million to make the film of his dreams. Will his investment pay off?

GQ ›

News+ Audio

Vito Paulekas was the ultimate influencer — born 100 years too soon.

LOS ANGELES TIMES ›

THE LAST WORD

“For the first 10 minutes my mind was blank.”

Ukrainian soldiers on the front line describe how it feels to face the Russian attack.

THE TELEGRAPH >

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From: Office of TX Attorney General <TXAttorneyGeneral@public.govdelivery.com>
Sent: Tuesday, February 22, 2022 9:41 AM
To: Eamon Briggs
Subject: Notification of Opinion: KP-0401

KEN PAXTON
ATTORNEY GENERAL of TEXAS

Request for Opinion

Re: Whether certain medical procedures performed on children constitute child abuse (RQ-0426-KP)

Opinion: KP-0401

Summary

Each of the "sex change" procedures and treatments enumerated above, when performed on children, can legally constitute child abuse under several provisions of chapter 261 of the Texas Family Code.

When considering questions of child abuse, a court would likely consider the fundamental right to procreation, issues of physical and emotional harm associated with these procedures and treatments, consent laws in Texas and throughout the country, and existing child abuse standards.

From: Office of TX Attorney General <TXAttorneyGeneral@public.govdelivery.com>
Sent: Monday, February 21, 2022 2:37 PM
To: Madeline Fojtik
Subject: AG Paxton Declares So-Called Sex-Change Procedures on Children and Prescription of Puberty Blockers to be "Child Abuse" Under Texas Law

KEN PAXTON
ATTORNEY GENERAL *of* TEXAS

FOR IMMEDIATE RELEASE
February 21, 2022
www.texasattorneygeneral.gov

PRESS OFFICE: (512) 463-2050
Communications@oag.texas.gov

AG Paxton Declares So-Called Sex-Change Procedures on Children and Prescription of Puberty Blockers to be "Child Abuse" Under Texas Law

AUSTIN – Attorney General Ken Paxton released a formal attorney general opinion concluding that performing certain “sex-change” procedures on children, and prescribing puberty-blockers to them, is “child abuse” under Texas law. The holding comes at a critical time when more and more Texans are seeing the horrors that flow from the merging of medicine and misguided ideology.

Specifically, the opinion concludes that certain procedures done on minors such as castration, fabrication of a “penis” using tissue from other body parts, fabrication of a “vagina” involving the removal of male sex organs, prescription of puberty-suppressors and infertility-inducers, and the like are all “abuse” under section 261.001 of the Texas Family Code.

“There is no doubt that these procedures are ‘abuse’ under Texas law, and thus must be halted,” said Attorney General Paxton. “The Texas Department of Family and Protective Services (DFPS) has a responsibility to act accordingly. I’ll do everything I can to protect against those who take advantage of and harm young Texans.”

This opinion comes after Attorney General Paxton opined in an October 2019 letter to DFPS, stating that the “transition” of James Younger—the biological male son of Jeff Younger—to a “female” through puberty-blocking drugs, among other things, was “abuse” under at least three definitions set out in the Family Code, and that DFPS, therefore, had an independent duty to investigate.

The opinion also follows Gov. Abbott’s August 2021 letter to DFPS requesting a determination of “whether genital mutilation of a child for purposes of gender transitioning through reassignment surgery constitutes child abuse.” The Commissioner of DFPS replied that “genital mutilation of a child through reassignment surgery is child abuse.”

Read the opinion here.

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From: Office of TX Attorney General <TXAttorneyGeneral@public.govdelivery.com>
Sent: Monday, November 22, 2021 11:16 AM
To: David Meryman
Subject: Paxton Joins Multistate Coalition to Stop Experimentation on Youth

KEN PAXTON
ATTORNEY GENERAL *of* TEXAS

FOR IMMEDIATE RELEASE
November 22, 2021
www.texasattorneygeneral.gov

PRESS OFFICE: (512) 463-2050
Communications@oag.texas.gov

Paxton Joins Multistate Coalition to Stop Experimentation on Youth

AUSTIN – Attorney General Ken Paxton joined a multistate coalition to defend against a challenge to Arkansas' law that stops experimentation on children experiencing gender dysphoria. In the scientific community, the general consensus has been that more research is needed before providing children with potentially irreversible "gender-affirming care," such as providing puberty blockers, cross-sex hormones, or surgical interventions. Multiple studies show that most childhood gender-identity issues resolve naturally with time, and that it is impossible to know ahead of time which child's symptoms may persist into adulthood, warranting further treatment.

The medical evidence also shows that nearly all children whose gender dysphoria is treated with puberty blockers to "buy time" will proceed to take cross-sex hormones and seek other medical interventions with irreversible, lifelong consequences—complications such as infertility, loss of sexual function, increased risk of heart attack and

stroke, bone-density problems, risk of altered brain development, social harms from delayed puberty, and mental health concerns.

Read the full Amicus Brief here.

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From: APhA's Pharmacy Today <PTdaily@aphanet.org>
Sent: Wednesday, January 19, 2022 12:00 PM
To: Synthia Hill
Subject: January 19, 2022: White House to distribute 400 million free N95 masks starting next week

Pharmacy Today
An official publication of the American Pharmacists Association

JANUARY 19, 2022

Top News: White House to distribute 400 million free N95 masks starting next week

Underscoring the importance of masking as a defense against coronavirus transmission, the Biden administration is digging into the Strategic National Stockpile to ensure Americans have access to high-quality face coverings. Shipments of 400 million N95 respirators, which are superior to cloth versions, will begin by the end of this week. Starting late next week, U.S. adults will be able to pick up three N95 masks for free at tens of thousands of pharmacies and other designated locations. Officials say a similar effort to provide high-quality respirators for children is likely to follow. The masks, designed to fit snugly around the face, filter out 95% of virus particles and are generally accepted as the most effective type of face covering. Experts applauded the White House's move as an important step toward controlling the spread of coronavirus, especially the highly virulent Omicron variant. (Read More) - May Require Paid Subscription

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ALSO IN TODAY'S NEWS

DRUGS & DISEASES

Drugmaker Gilead alleges counterfeiting ring sold its HIV drugs

Gilead Sciences is blaming a criminal enterprise for contaminating its drug supply chain with illegal and potentially harmful product — "counterfeit" HIV medications, specifically. The perpetrators allegedly paid homeless and/or drug-addicted patients with HIV for more than $250 million worth of valid prescription for bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy) and emtricitabine and tenofovir alafenamide (Descovy), which they then resold to pharmacies used fake documentation or altered packaging. The scheme also included fake tablets, according to Gilead, which ultimately identified more than 85,000 bottles of brand-name medicine that never should have been on the market. Some of those bottles included the wrong medicine altogether, such as OTC analgesic or an antipsychotic. Gilead said it was alerted to a potential problem in August 2020, subsequently launched an internal investigation, and eventually traced the activity back to an obscure network of secondary suppliers and distributors, including Safe Chain Solutions, Scripts Wholesale Inc., and ProPharma Distribution LLC — which are all named as defendants in a lawsuit Gilead has lodged. The lawsuit, filed in July, was unsealed on Tuesday. (Read More) - May Require Paid Subscription

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New government website for ordering COVID tests is up and running

The federal government on Tuesday unveiled a new website allowing people to order up to four free rapid COVID-19 tests, occurring a day ahead of its formal launch. At one point on Tuesday evening, more than 1 million visitors were on the home page and the ordering page of covidtests.gov, more than 40 times as many as were on the U.S. Postal Service's (USPS) tracking page for packages, according to analytics.usa.gov. White House Press Secretary Jen Psaki said the official launch would take place on Wednesday morning, but that the site had begun accepting orders during what she said was a "beta testing phase" conducted by the U.S. Digital Service, the government's technology support arm. Some people who reside in apartment complexes said they were unable to order tests if

other tenants had already put in requests from the same building. Some who receive their mail at post office boxes also reported being blocked from ordering after the site said orders would ship only to valid residential addresses. USPS recommends that customers file a service request or contact the Postal Service's help desk if they had problems ordering. (Read More) - May Require Paid Subscription

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Omicron variant encourages some to drop COVID-19 precautions, despite risks

In response to the widespread and milder nature of the Omicron variant of SARS-CoV-2, some individuals are taking fewer precautions to ward off infection, including those who may be more at-risk of having severe COVID-19, health experts say. They note that Omicron still poses risks to older adults and those who are immunocompromised or have underlying health conditions. Some physicians are also concerned about Omicron resulting in more long-COVID cases. Greg Vanichkachorn, an occupational and aerospace medicine physician at Mayo Clinic in Rochester, MN, says: "One of my greatest fears is that these patients that are now experiencing these mild cases may go on to have long-haul COVID. If that is the case with so many people getting sick, we could have this tsunami of long-haul cases in a few weeks or months." He says his clinic has seen a few patients who are still experiencing symptoms about 3 weeks after their initial Omicron infection. Vanichkachorn recommends that if patients have not recovered within 2-3 weeks after an infection, they should seek medical care. CDC continues to warn people against nonessential travel and eating inside restaurants. Karen Edwards, an epidemiologist at the University of California, Irvine, says more interactions between potentially infected people will give the virus more routes to spread and potentially mutate. Michael Lin, an infectious-disease physician at Rush University Medical Center in Chicago, also notes anyone who is infected can unknowingly transmit COVID-19 to people for whom Omicron might be more of a threat. (Read More)

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More young kids are getting sick from cannabis edibles

Marijuana-infused drinks and foods often appears the same as their drug-free counterparts, making it easy for people to accidentally ingest them. Some states have passed laws governing how these foods can be packaged and presented. Colorado requires cannabis edibles to be in child-resistant packaging and display the letters "THC," short for tetrahydrocannabinol. The state also prohibits the sale of edibles that look like fruit, animals, or people. However, unintentional marijuana exposures are on the rise in Colorado and other states where recreational cannabis is legal. In Washington state, unintentional cannabis exposures among children under age 6 years nearly tripled in the 5 years after cannabis stores opened. Nationwide, there were a total of 187 exposures to marijuana edibles among children aged 12 years and under in 2016, according to data from the American Association of Poison Control Centers. By 2020, that number rose to more than 3,100. Sharon Levy, director of the Adolescent Substance Use and Addiction Program at Boston Children's Hospital, says: "That's just the tip of the iceberg," noting that not everyone will call Poison Control to report an exposure. Of those who did call Poison Control, edibles were responsible for nearly one-half of the 4,172 marijuana exposures among children aged 9 years and under between 2017 and 2019, according to a study published in *Pediatrics* in April 2021. Other exposures were from things like extracts and dried marijuana plants. (Read More) - May Require Paid Subscription

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Effect of casirivimab and imdevimab antibody combination on development of symptomatic COVID-19 in early asymptomatic SARS-CoV-2 infection

Researchers report results from the second leg of their study investigating the effect of combined casirivimab and imdevimab on disease progression among household contacts of individuals with SARS-CoV-2. In the first part, they demonstrated that, compared with placebo, dual therapy with the monoclonal antibodies significantly prevented symptomatic infection among uninfected close contacts. For the second part, the focus was on household contacts whose tested positive for the virus on a PCR screen but who were asymptomatic. The study population included 314 individuals, one-half of whom were randomly assigned to 600 mg each of subcutaneous casirivimab and imdevimab and one-half of whom were allocated to placebo. Among 204 enrollees included in the primary analysis, just 29% of those who received the antibody cocktail developed symptomatic COVID-19 over the next 28 days compared with more than 42% of the control participants who did. The intervention also reduced the number of symptomatic weeks and the number of high viral load weeks, and it was associated with a lower rate of COVID-19 related hospitalizations or emergency department visits. Collectively, the findings suggest that easy-to-administer antibody treatments can be used to arrest COVID progression from asymptomatic infection to symptomatic disease. (Read More) - May Require Paid Subscription

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PRACTICE & TRENDS

Rick Gates wins Pharmacy Executive of the Year accolade

Chain Drug Review has bestowed its Pharmacy Executive of the Year award to Rick Gates, who serves as senior vice president of pharmacy and health care at Walgreens. The award recognizing Gates' efforts to regularly introduce new programs that broaden pharmacy's role in the health care ecosystem, including during the COVID-19 pandemic. Gates believes that pharmacists have the potential to strengthen their role as health care providers by gaining the power to test and treat patients for different conditions and illnesses or by forming shared practice agreements with physicians. He says: "A great example is our current pilot in Florida with a flu test and treat program that allows pharmacists to prescribe therapy for those that test positive for flu. This helps make patient experience and care even more accessible to the community." Gates adds that Walgreens continues to invest in technologies to improve processes so that pharmacy team members can function at the top of their license and interact more personally with their patients. He explains, "Using cutting-edge automation technology from iA, a company we recently made a majority investment in, we will leverage our existing AmerisourceBergen distribution network to efficiently fill prescriptions and quickly get them to our pharmacies through micro-fulfillment centers. We've already opened two automated micro-fulfillment facilities serving over 1,000 pharmacies in the Phoenix and Dallas areas, with plans to have an additional 22 facilities by 2024." (Read More)

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Naloxone vending machines installed across U.S. to fight opioid crisis

As drug overdose deaths escalate during the COVID-19 pandemic, a growing number of free vending machines are being installed nationwide to dispense doses of naloxone (Narcan—Emergent Biosolutions), which can reverse the effects of an opioid overdose. Preliminary federal data show that more than 87,000 Americans died of opioid overdoses over the 12-month period that ended in September. That figure is higher than any year since the opioid epidemic began in the 1990s. New York City intends to operate 10 public health vending machines that dispense free naloxone and other "harm reduction" supplies in locations that have been significantly affected by drug overdoses. The vending machines will carry sterile syringes, safe-sex kits, and toiletries, according to city health officials. The self-serve vending machines are also being installed in correctional facilities as part of government-funded pilot initiatives. Los Angeles County last year began offering naloxone to people leaving prison, distributing more than 34,000 doses via free vending machines. Naloxone vending machines were also installed in 15 communities in Michigan, primarily at drug rehab agencies and county jails statewide. Other states that have deployed such vending machines include Indiana and Kentucky. (Read More)

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LAWS, REGS & RULINGS

Illinois law allows pharmacists to dispense contraception

Under a new state law in Illinois, pharmacists can now dispense hormonal contraception to consumers without a physician's prescription. The law, HB135/Public Act 102-0103, requires a trained pharmacist to have an agreement with a physician for oversight of a patient, who must be evaluated by the pharmacist. This evaluation includes a self-screening risk assessment and "counseling and education about all methods of contraception … and their proper use and effectiveness." The law takes effect in January 2022, but implementing it will take longer because pharmacists will need to undergo additional training and as the state requests federal approval for extending the change to Medicaid recipients. Moreover, pharmacies that are already understaffed need to prepare and decide how to handle the volume. Individuals with government-backed health coverage are expected to be able to take advantage of the change within months. Private insurers have until 2023 to cover pharmacist-direct-dispensed contraceptives. Katie Thiede, co-founder and director of Illinois Contraceptive Access Now (ICAN), says: "There's this great demand and yet just 20% of the need for contraceptive services among young women and women with fewer resources is met by publicly funded providers." ICAN estimates that "800,000 Illinois women age 15-44 with fewer resources" live in counties without health centers that offer the "full range of contraceptive methods." For some individuals, seeing a physician may be financially, physically, or practically challenging, but the Illinois Pharmacists Association says most Illinois residents live within a five-mile range of a pharmacist. (Read More)

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Judge grants stay in federal case against pharmacy DIR fees until proposed rule finalized

The U.S. District Court for the District of Columbia has granted a stay in the case of "NCPA v Becerra." The case challenges the legality of retroactive pharmacy price concessions, or pharmacy direct and indirect remuneration (DIR) fees. In a statement, APhA and the National Community Pharmacists Association (NCPA) said: "We are pleased by the Court's decision to grant our request for a stay or a pause in the litigation until the recently proposed rule potentially addressing retroactive pharmacy DIR fees is finalized. We are currently analyzing the proposed rule to determine whether it addresses our longstanding concerns with retroactive pharmacy DIR fees, and we plan to submit comments reflecting our analysis." Also involved in the case are the Coalition of State Rheumatology Organizations, Fruth Pharmacy of West Virginia, Hi-School Pharmacy of Washington, Kare Pharmacy of New Mexico, and Tyson Drugs of Mississippi. (Read More)

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In Arkansas, trans teens await an uncertain future

A lawsuit in Arkansas is being followed closely, with the outcome likely to have broad implications for gender-affirming care among minors. The state is the first in the country to forbid providers from giving transgender youth hormones or puberty blockers to limit their natural development and facilitate a transition to the gender with which they identify. The optimal treatment period is age 8–14 years, but Arkansas' Save Adolescents from Experimentation (SAFE) Act would outlaw this kind of care for patients younger than age 18 years, the legal threshold for consent. Doctors would be unable to refer patients to other medical professionals, even out of state, and private insurers would be allowed to deny coverage. The American Civil Liberties Union is going after the law, which was supposed to take effect last July but has been suspended while the court case unfolds. If the challenge fails, parents of transgender children in Arkansas are considering relocating to states that permit gender-affirming health care. For many of those who cannot uproot themselves, there is a fear that their transgender child will become depressed or succumb to suicidal ideation. (Read More) - May Require Paid Subscription

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Detainees sue Arkansas jail that gave them ivermectin to treat COVID

The American Civil Liberties Union (ACLU) has filed a federal law suit on behalf of four inmates at a Washington County, AR, detention center who received ivermectin to treat their COVID-19 infections. The four men said in the lawsuit that after testing positive for COVID-19 in August, they received a "cocktail of drugs" twice daily day from Robert Karas, who oversees Karas Correctional Health. The men said Karas told them the cocktail contained vitamins, antibiotics, and steroids, according to a complaint filed this month in the U.S. District Court for the Western District of Arkansas. The men asserted they were unaware they took ivermectin, an antiparasitic drug commonly used for livestock that FDA has warned should not be used to treat COVID-19. Along with Karas, the lawsuit named Sheriff Tim Helder and the Washington County Detention Center as defendants. The ACLU said the correctional facility had been administering ivermectin to detainees as early as November 2020. The lawsuit said the men "ingested incredibly high doses" of the drug, causing some to experience gastrointestinal and vision issues. Holly Dickson, executive director of the ACLU of Arkansas, says the men learned what they were taking only after the sheriff told the Quorum Court Finance and Budget

Committee of Washington County in August that detainees were being treated for COVID-19 with ivermectin. (Read More) - May Require Paid Subscription

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2215 Constitution Avenue NW, Washington, DC 20037
Tel 202.628.4410 Fax 202.783.2351

From: APhA's Pharmacy Today <PTdaily@aphanet.org>
Sent: Wednesday, October 13, 2021 7:29 AM
To: Ben Santana
Subject: October 13, 2021: Aspirin use to prevent 1st heart attack or stroke should be curtailed, U.S. panel says

Pharmacy Today
An official publication of the American Pharmacists Association

OCTOBER 13, 2021

Top News: Aspirin use to prevent 1st heart attack or stroke should be curtailed, U.S. panel says

Experts now believe that daily use of low-dose aspirin, once viewed as an inexpensive and effective prophylaxis against heart disease, has more potential harms than benefits. The proposed new draft guidelines from the U.S. Preventive Services Task Force (USPSTF) apply to patients younger than age 60 years with elevated risk for heart disease who might have been prescribed 81–100 mg per day to avert a first heart attack or stroke. For those aged 60 years and older, previously directed to their providers for decision making on the use of low-dose aspirin for the prevention of high cardiovascular disease risk, USPSTF now is discouraging the regimen due to concerns about serious bleeding risks in this age demographic. It also is stepping back from its 2016 guidance recommending low-dose aspirin to prevent colorectal cancer, saying additional research was warranted. The expert panel is accepting public comment on the new recommendations, which could affect tens of millions of adults with high risk for cardiovascular disease, until November 8. (Read More) - May Require Paid Subscription

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DRUGS & DISEASES

FDA staff don't take position on Moderna COVID-19 booster

FDA staff members took a neutral position on Moderna's application for a booster dose of its COVID-19 vaccine. According to documents released Tuesday, FDA staff assessed Moderna's study data and said an additional dose appeared to work well and be safe but that its benefit would depend on how much the protection from the initial regimen waned. In addition, FDA said the data suggested that the first two doses of the Moderna vaccine still offer protection against severe disease and death. Moderna requested that the booster be one-half of the dose used in the primary series. Both doses were studied, and the FDA review focused on the lower dose. FDA staff also said the third dose strengthened the antibody response sufficiently, which was one of the endpoints of the study. However, the extra dose narrowly missed meeting the other study endpoint, of increasing antibody levels by a significant magnitude and in a sufficiently high portion of study subjects. Moderna had reached a different conclusion and used different figures for the second endpoint on antibody levels in a report it submitted to FDA. It is unclear why there were inconsistencies. FDA's staff assessment will now be sent to a committee of external experts who are scheduled to convene Thursday. (Read More) - May Require Paid Subscription

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Effectiveness and safety of NSAIDs and opioid treatment for knee and hip osteoarthritis

Researchers explored various preparations and doses of NSAIDs, opioids, and paracetamol in an effort to identify the optimal regimen for patients with knee and hip osteoarthritis (OA). The systematic review and network meta-analysis included 192 randomized studies, with a collective sample of nearly

103,000 participants. While the literature suggested that opioids—no matter the formulation—have potential harms that offset any potential clinical benefit, topical diclofenac at a dose of 150 mg daily and etoricoxib at a dose of 60 mg daily emerged as the best NSAID options for pain and physical function in the OA population. However, the review authors noted, these therapies might not be appropriate for long-term treatment or for patients with comorbidities. Based on the evidence, they determined that 70–81 mg/day of topical diclofenac should be the first line of care for knee osteoarthritis. The lower dose avoids the risk of treatment termination due to adverse events observed with 150 mg/day of diclofenac, and it also boasts reduced systemic exposure. (Read More) - May Require Paid Subscription

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Influenza practically vanished last year. Now doctors are bracing for potential 'twindemic' of influenza and COVID-19 spikes

This influenza season could be particularly severe and put additional strain on hospitals, health officials warn. Based on recent survey data, slightly more than one-half of American adults intended to get an influenza vaccine, which is similar to pre-pandemic surveys conducted by the National Foundation for Infectious Diseases. However, experts warn that Americans have built up less natural immunity against influenza because so few were infected last season. Hospitals reported a nationwide resurgence of common viruses such as respiratory syncytial virus in the spring and summer, with high numbers of toddlers coming in with severe cases. Nancy Foster, vice president for quality and patient safety policy at the American Hospital Association, notes that some hospitals, including in Florida and California, experienced low supplies of oxygen because of the heavy demand from COVID-19 patients. Meanwhile, some experts predict the coming season could be typical or milder than usual, noting that some schools are enforcing mask mandates and some offices are delaying reopenings until next year. The National Foundation for Infectious Diseases survey found that nearly one-half of respondents were more likely to stay home when sick because of the COVID-19 pandemic and slightly more would wear masks in some crowded situations. Physicians are urging parents to bring their children in for influenza vaccines earlier because the season has already started in much of the nation. (Read More)

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PRACTICE & TRENDS

Walgreens closing 5 San Francisco stores due to 'organized retail crime'

A Walgreens spokesperson confirmed Tuesday that the company will close five more stores in San Francisco because of persistent organized crime. Walgreens spokesperson Phil Caruso said, "Retail theft across our San Francisco stores has continued to increase in the past few months to 5 times our chain average. During this time to help combat this issue, we increased our investments in security measures in stores across the city to 46 times our chain average in an effort to provide a safe environment." Walgreens expects to relocate employees from the shuttered stores to other nearby locations. Under California law, thefts of less than $950 in goods are penalized as nonviolent misdemeanors. Since early 2019, Walgreens has closed at least 10 stores in the city. San Francisco

Board of Supervisor Ahsha Safai of District 11 said the closure of the store on Mission Street in particular will be disruptive. He wrote on Twitter: "I am completely devastated by this news — this Walgreens is less than a mile from seven schools and has been a staple for seniors, families and children for decades. This closure will significantly impact this community." (Read More)

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Cutting out even a little salt can have big health benefits

Americans consume far too much salt, but experts believe scaling back just a little on the sodium chloride can potentially yield significant health benefits. High salt intake is alarming for its contribution to kidney disease, heart disease, and high blood pressure. According to a 2010 Stanford University study, however, eliminating less than one-sixth of a teaspoon of sodium per day would prevent an estimated 1 million strokes or heart attacks. New research out of China also found that replacing regular table salt with reduced-sodium salt significantly curtailed the rate of cardiovascular events—including death—over less than 5 years of followup in people at high risk for stroke. Because the amount of dietary sodium considered healthy continues to change and remains the subject of debate in the United States, many experts suggest reducing levels in prepared and processed foods is the best approach for now. Campbells, Nabisco, General Mills, and the CVS store label Abound are among the brands that have acted to lower the sodium content in their products voluntarily. In the meantime, consumers can be proactive by rinsing beans and other canned foods before eating or by salting foods after they have been cooked rather during the preparation stage. (Read More) - May Require Paid Subscription

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WHO report: Globe falls short on mental health goals in 'worldwide failure'

A new Mental Health Atlas report from the World Health Organization (WHO) indicates a worldwide disparity in achieving mental health investment goals. The report concluded that although mental health received more attention in the past few years, the quality of services has not kept up with demand. The report analyzed data from 171 countries. WHO Director-General Tedros Adhanom Ghebreyesus said, "It is extremely concerning that, despite the evident and increasing need for mental health services, which has become even more acute during the COVID-19 pandemic, good intentions are not being met with investment." In 2019, WHO extended its mental health action plan to 2030, but countries have not reached several of the initial targets for last year. The report, issued every 3 years, found that 51% of WHO's 194 members had a mental health policy or plan aligned with international regional human rights agreements last year, far below the 80% goal. Only 52% of member nations met the goal for mental health promotion and prevention programs, also falling short of the 80% target. The report found that the only target met was that rate of suicide declined by 10%, although just 35 countries had a "stand-alone prevention strategy, policy, or plan." In addition, the report found that the median number of mental health workers per 100,000 people increased slightly from nine in 2014 to 13 last year. Just 2% of government health budgets commit funding for mental health, essentially unchanged in the past 2 years. (Read More)

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Study highlights impact of antibiotic resistance on older Americans

A study published in *Clinical Infectious Diseases* indicates that approximately 40% of the deaths caused by the six most prevalent antibiotic-resistant infections occur among older Americans. Researchers from the University of Utah School of Medicine, the Veterans Affairs (VA) Salt Lake City Health Care System, Pew Charitable Trusts, and the Infectious Diseases Society of America estimated that for the six pathogens collectively, the aggregate cost for 2017 was $1.9 billion, with 11,852 deaths, and 448,224 inpatient days. The estimates were based on a retrospective cohort analysis involving VA patients aged 65 years and over who had positive cultures for multidrug-resistant bacteria from 2007 through 2018. The analysis focused on Methicillin-resistant *Staphylococcus aureus* (MRSA), extended-spectrum beta-lactamase (ESBL)-producing *Enterobacteriaceae*, multidrug-resistant *Pseudomonas aeruginosa*, vancomycin-resistant *Enterococcus*, carbapenem-resistant *Enterobacteriaceae*, and carbapenem-resistant *Acinetobacter baumannii* (CR Acinetobacter). Study co-author David Hyun, MD, director of Pew's antibiotic resistance project, and his co-authors found that among those aged 65 years and over, the adjusted attributable 30-day mortality ranged from 14.8% for invasive MRSA infections to 26.9% of invasive CR Acinetobacter infections. Attributable costs for treating those infections ranged from $23,301 (MRSA) to $54,494 (CR Acinetobacter). Invasive hospital infections caused by ESBL-producing *Enterobacteriaceae* had a 16.2% mortality rate and cost an average of $36,077 to treat. Hyun said, "Americans 65 and older are disproportionately affected; 40% of deaths ... and 41% of the health care costs, are associated with infections in this group," while accounting for only 15% of the U.S. population. (Read More)

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LAWS, REGS & RULINGS

FDA authorizes an e-cigarette for first time, saying benefit for smokers outweighs risk to youths

FDA has authorized the sale of the Vuse device and two related nicotine cartridges, on the grounds that aerosols from some e-cigarettes are much less toxic than traditional cigarettes. The prospect of helping adults reduce or stop smoking, the agency asserted, outweighs the risks of American youths starting the practice. That being said, the agency emphasized that giving R.J. Reynolds Tobacco Co. the green light to sell some of its Vuse line is not an endorsement of the products as "FDA approved" or safe. "All tobacco products are harmful and addictive and those who do not use tobacco products should not start," FDA noted. It also turned down Reynolds' applications to sell flavored nicotine cartridges that typically appeal to young smokers, is requiring its compliance with measures "aimed at reducing youth exposure and access to the products," and has threatened to withdraw its authorization if surveillance data reflects significant use of Vuse products by new smokers. FDA's review of e-cigarettes ended on September 9, after which manufacturers were to stop vending their products or request FDA authorization to keep selling them. (Read More) - May Require Paid Subscription

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Biden-Harris administration greenlights coverage of LGBTQ+ care as an essential health benefit in Colorado

CMS has, for the first time, approved a request to provide gender-affirming care in individual and small group health insurance markets as part of Colorado's Essential Health Benefit (EHB) benchmark. The state's new EHB-benchmark plan will increase coverage for gender-affirming care that meets individual needs and discourages the use of a "one-size-fits-all" framework for transgender persons seeking medical care. Now, a wider range of services for transgender individuals will be covered under the EHB-benchmark plan in Colorado, including eye and lid modifications, face tightening, facial bone remodeling for facial feminization, breast/chest construction and reductions, and laser hair removal. In addition, the state is adding EHBs in the benchmark plan to include mental wellness exams and expanded coverage for 14 prescription drug classes. These changes go into effect on January 1, 2023. "To truly break down barriers to care, we must expand access to the full scope of health care, including gender-affirming surgery and other treatments, for people who rely on coverage through Medicare, Medicaid & CHIP and the Marketplaces," said CMS Administrator Chiquita Brooks-LaSure. "Colorado's expansion of their essential health benefits to include gender-affirming surgery and other treatments is a model for other states to follow and we invite other states to follow suit." (Read More)

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FDA withdrawing temporary guidances for alcohol-based hand sanitizers

FDA announced Tuesday that it will withdraw guidances first issued at the outset of the COVID-19 pandemic outlining temporary policies for manufacturers who were not drug manufacturers to produce certain alcohol-based hand sanitizer and alcohol for use in hand sanitizers during the public health emergency. According to the agency, effective December 31, 2021, companies making alcohol-based hand sanitizers under the temporary policy must halt production of such products. Any companies that want to continue producing hand sanitizer after that point must comply with the tentative final monograph for OTC topical antiseptics and other requirements. Companies that do not wish to continue producing these products can deregister. Sales of hand sanitizers produced under the temporary guidances and manufactured prior to or on December 31, 2021, must end by March 31, 2022. Patrizia Cavazzoni, MD, director of FDA's Center for Drug Evaluation and Research, said: "In recent months, the supply of alcohol-based hand sanitizer from traditional suppliers has increased, and now, most consumers and health care personnel are no longer having difficulty obtaining these products. Therefore, we have determined it's appropriate to withdraw the temporary guidances and are providing manufacturers time to adjust their business plans related to production of these products under these temporary policies." (Read More)

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Drugs for non-TB pulmonary disease see new FDA guidance

FDA released new draft guidance for sponsors who are developing drugs to treat nontuberculous mycobacterial pulmonary disease (NTM-PD), which is caused by *Mycobacterium avium* complex (MAC). The draft guidance notes that at present, "treatment for NTM-PD involves multidrug regimens with durations lasting months to years that often cause drug-drug interactions and adverse reactions such as hepatotoxicity, nephrotoxicity, ocular toxicity, and skin reactions." FDA said that a key consideration for drug developers is the selection of clinically meaningful endpoints for trial design and

conduct. Developers who are thinking about using a surrogate endpoint such as microbiologic outcome are advised to consult with FDA before proceeding, even if the endpoint is "reasonably likely to predict clinical benefit." FDA also noted that certain patients with sufficient monitoring may be able to participate in a brief, placebo-controlled trial of a single agent that would serve as proof of concept. However, sponsors should conduct two Phase III trials that are both randomized and double-blinded. If a single trial shows "robust evidence of efficacy with confirmatory evidence," however, that may suffice. Any new agents are likely be used in combination with other antibacterials, so the trial design should be designed to measure how a new drug would contribute to existing therapies. The guidance presents three possible Phase III trial designs, while noting that additional designs could also be acceptable to FDA. (Read More)

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State

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Rising meat prices could close small Texas barbecue joints, shifting scene to high-end restaurants

U.S. Rep. Colin Allred tests positive for COVID-19 after trip to Europe

Federal gun charges added to charges against man accused of shooting 3 Houston police officers

Josh Brodesky: With latest theory, Paxton sinks even lower

Belinda Román: Domestic workers prop up city; give them the rights they deserve

Where's the leave? McAllen school district struggles to meet COVID pay demand

DHS secretary acknowledges Border Patrol staffing shortages during visit to Texas border

By the numbers: Increases, decreases reported in migrant apprehensions

Is it a political scandal or just business as usual? It depends on which corner you are in

Erica Grieder: Republicans think their new voting law is working fine. Perhaps the confusion is the point.

Greg Jefferson: In state's Broadway U-turn, San Antonio banker Bugg said it but Abbott was at the wheel

Transgender prisoner in Texas denied gender-affirming surgery, lawyer says

County

A fight has erupted over where to put a Grand Parkway intersection. Millions of dollars are at stake.

City

Round Rock ISD trustee announces plans to resign at next board meeting

Is Panther Island really 800 acres? It depends how you measure

Four Dallas arts groups receive $450,000 in National Endowment for the Arts rescue grants

National

Rents are up 40 percent in some cities, forcing millions to find another place to live

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State

Allen West won't be charged over mask tussle at DFW Airport

Texas' 'best kept secret' endangered by 'environmentally focused' development, land owner says

Who should review school library books? Texans are split, News/UT-Tyler poll finds

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Texas Attorney General Ken Paxton: Gender-affirming care for transgender children is abuse

Abortion recedes from spotlight in Texas' primary election

Over 125,000 still without water in border town of Laredo, Texas

Texas' new teacher certification test faces opposition

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Truckers can haul in upwards of $20,000 a week. So why is there a serious driver shortage?

UT president defends tenure after Lt. Gov. Dan Patrick seeks to end it at Texas universities

Beaumont plans to sue Netflix, Hulu, and Disney, alleging the companies owe Texas cities money

Houston-area educators possible victims of domestic violence shooting in San Antonio

Rural communities struggle to retain nurses amid pandemic

Joaquin Castro: Calling on U.S. to stand up for Rusesabagina's release

Cesar Blanco: National recognition brings pride to El Paso

Rep. Tony Gonzales hopes to keep Texas Congressional District 23 red

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Clay Jenkins once again lowers Dallas County COVID-19 threat level to orange, or 'extreme caution'

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Third Ward residents decry violence, demand action against problem bars

Two longtime Spring Branch ISD trustees chose not to run for another term on the Board

Kroger's new Dallas robot-operated online grocery warehouse designed to grab market share

National

Bearish bets against markets are surging

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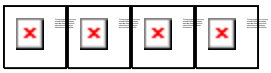

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ERCOT predicts no power conservation requests in Texas

State

Texas Gov. Greg Abbott hints at pardons for indicted Austin police officers

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Beto O'Rourke in Fort Worth on election night

The left's South Texas star isn't the progressive they warned you about

Texas Gov. Greg Abbott may criticize California, but he's happy to collect checks there

Chris Tomlinson: Dan Patrick's attacks threaten innovation that drives Texas's economy

Billionaires from around the nation pick sides in Texas governor's race

Dallas DA John Creuzot bucks Abbott, Paxton and declines to prosecute families for trans youth care

The Texas wine industry is just getting started. Grape farmers say the end is near.

Tesla's Elon Musk escalates fight with SEC and highway safety administration

Fort Worth residents get to comment on 2 redistricting maps

Texas Dems chair calls on party leader to resign after racist comment

White House: Texas stance on gender-affirming care for transgender youth is 'dangerous'

County

Betsy Price, Tim O'Hare exchange insults in Republican primary election for Tarrant County judge

City

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Petition drive under way in Denton to decriminalize marijuana

National

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Local TV station owner Tegna will sell to Standard General in a $5.4B cash deal

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