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PHARMASCRIPT

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Controversies Surrounding High Dose Caffeine Therapy in Premature Neonates

Gina Chen, PharmD Candidate
University of Maryland School of Pharmacy

Atsue Sawai, PharmD Candidate
University of Maryland School of Pharmacy

Apnea is a developmental disorder commonly diagnosed in preterm neonates in the NICU. It can be caused by weakness in airway muscles and immaturity of the brain, resulting in the failure of physiological response to carbon dioxide and hypoxia.[1] Apneic events have been associated with retinopathy of prematurity, increased risk of infant mortality, and long-term morbidity like poor neurodevelopmental outcomes.[2] For decades, caffeine has been used to treat apnea of prematurity (AOP) and has been shown to be safe and effective while reducing the need for mechanical ventilation.[1] Caffeine, an adenosine receptor antagonist, enhances sensitivity to carbon dioxide and results in a rapid and sustained increase in diaphragmatic activity in preterm infants.[3] While the efficacy of caffeine for AOP has been demonstrated in several studies, there has been controversy surrounding the use of high-dose caffeine in these patients.

High-dose caffeine is thought to be associated with positive clinical outcomes without significant side effects. In a randomized controlled trial comparing high doses (loading 40 mg/kg and maintenance of 20 mg/kg) to low doses (loading 20 mg/kg and maintenance of 10 mg/kg) of caffeine, there was a significant reduction in apnea frequency, days of documented apnea, and the chance of extubation failure in mechanically ventilated infants. In addition, there were no significant differences in neonatal mortality, morbidity, or length of hospital stay.[4] When comparing a higher loading dose of 80 mg/kg to a lower loading dose of 20 mg/kg, there was no difference in the incidence of neonatal morbidities. There were fewer cases of extubation failure, apnea, and a shorter duration of mechanical ventilation, despite higher rates of tachycardia.[5]

Conversely, there have been studies that demonstrated concerning results for high-dose caffeine therapy in preterm neonates. In a pilot study with infants less than 32 weeks gestation, the use of a higher loading dose of 80 mg/kg compared to the FDA approved loading dose of 20 mg/kg was associated with increased risk of cerebellar hemorrhage, hypertonicity, abnormal neurological signs, and alterations in early motor performance.[6] The results from this trial ultimately discouraged larger randomized control trials. In another study using EEG, high-dose caffeine therapy (80 mg/kg) was associated with a trend in greater seizure incidence and burden, with nearly a threefold increase.[7] However, it is important to note that this association did not achieve statistical significance due to its small sample size.

Caffeine therapy for the treatment of apnea of prematurity has been well established in terms of safety and efficacy for the standard dosing. The FDA approved the regimen of a loading dose of 20 mg/kg followed by a maintenance dose of 5 mg/kg. However, the optimal dosing regimen of caffeine in preterm infants is not well-studied for higher doses. Studies suggest that higher doses of caffeine resulted in a greater response, whereas other studies propose a higher incidence of infant abnormalities. Therefore, infants who lack clinical response to standard dosing may be of interest for therapeutic drug monitoring to ensure desired outcomes. Lastly, long-term follow-up of neonatal outcomes is warranted.

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Long-Acting Intramuscular Injections of Cabotegravir/Rilpivirine vs Conventional Oral Antiretroviral Therapy In HIV-1 Maintenance Therapy

Yijie Cheng, PharmD Candidate 2023
University of Maryland School of Pharmacy

Leigh Cervino Ahern, PharmD, BCPS
The Johns Hopkins Hospital

Daily oral administration of conventional antiretroviral (ART) regimens can present numerous challenges to HIV-infected patients. Cabenuva®, a co-packaged long-acting (LA) injectable product of cabotegravir (CAB) and rilpivirine (RPV), is now approved by U.S. Food and Drug Administration (FDA) as the first and only complete non-oral treatment of HIV-1 infection for virologically suppressed adults and adolescents 12 years or older weighing at least 35 kg.[1] The regimen was subsequently incorporated into the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.[2]

Before initiating LA-CAB/RPV, HIV-1 infected patients need to achieve an undetectable viral load (defined as HIV-1 RNA serum viral load (VL) < 50 copies/mL) on conventional oral (PO) ART with no history of treatment failure and with no known or suspected resistance to either CAB or RPV. LA-CAB/RPV can be initiated as either monthly or bimonthly intramuscular (IM) injections. With monthly dosing, a high dose of IM CAB 600mg/RPV 900mg is administered at month 1, followed by a monthly low dose of IM CAB 400mg/RPV 600mg starting at month 2 for maintenance. With bimonthly dosing, a high dose of IM CAB 600mg/RPV 900mg is administered at months 1 and 2, followed by bimonthly maintenance therapy starting at month 4 with the same dose (Figure 1). The subsequent doses have a window of administration ± 7 days from the next scheduled dose.[1]

Initially, Cabenuva® was approved for adult patients as a monthly IM CAB 400mg/ RPV 600mg injectable regimen after a 28-day PO CAB/RPV lead-in therapy. The most recent FDA-label has three major updates including age expansion to adolescents, removal of oral lead-in requirements, and approval of an additional high-dose regimen with bimonthly administrations. The age expansion was based on a 16-week interim safety analysis of 23 adolescents aged 12 to 17 of an ongoing trial "More Options for Children and Adolescents (MOCHA)," where the safety profile in adolescents of using either PO/IM CAB or RPV was consistent with the safety profile established with CAB/RPV in adults.[1,3] The tolerability of direct switch to Cabenuva® from conventional ART without a PO CAB/RPV lead-in therapy was supported by the week 124 results from the "First Long-Acting Injectable Regimen (FLAIR)" trial, where the incidence of grade 3-4 adverse events were comparable between the direct-to-injection group and oral lead-in group after 24 weeks of CAB/RPV.[4]

To date, four randomized clinical trials have compared the efficacy and safety of LA-CAB/RPV to various oral ART regimens in adults (Table 1).[5-8] Additionally, the "Antiretroviral Therapy as Long Acting Suppression every 2 Months (ATLAS-2M)" trial compared the bimonthly versus monthly dosing strategies (Table 1),[9] and supported the approval of the bimonthly dosing strategy. Efficacy and safety outcomes included virologic non-response (HIV-1 VL RNA ≥ 50 copies/mL blood) and confirmed virologic failure (two consecutive HIV VL RNA ≥ 200 copies/mL blood), grade three or higher adverse events or death, and discontinuation of therapy due to adverse events (Table 2).[9]

Overall, the efficacy outcomes were similar between oral daily, IM monthly, and IM bimonthly injectable regimens in adults. However, long-acting injectables were associated with significantly higher severe adverse events primarily due to injection-site reactions (ISR). The incidence of reported ISR was most common after initial dosing and decreased over time.[6-8] Notably, the primary efficacy endpoint for the

majority of studies was reported at 12 months of treatment, not accounting for the potential development of later onset CAB/RPV resistance.

In summary, existing evidence suggests that LA-CAB/RPV has a comparable efficacy and safety profile to oral ART. However, further clinical trials will be needed to evaluate long term resistance outcomes as well as safety outcomes in adolescents and children.

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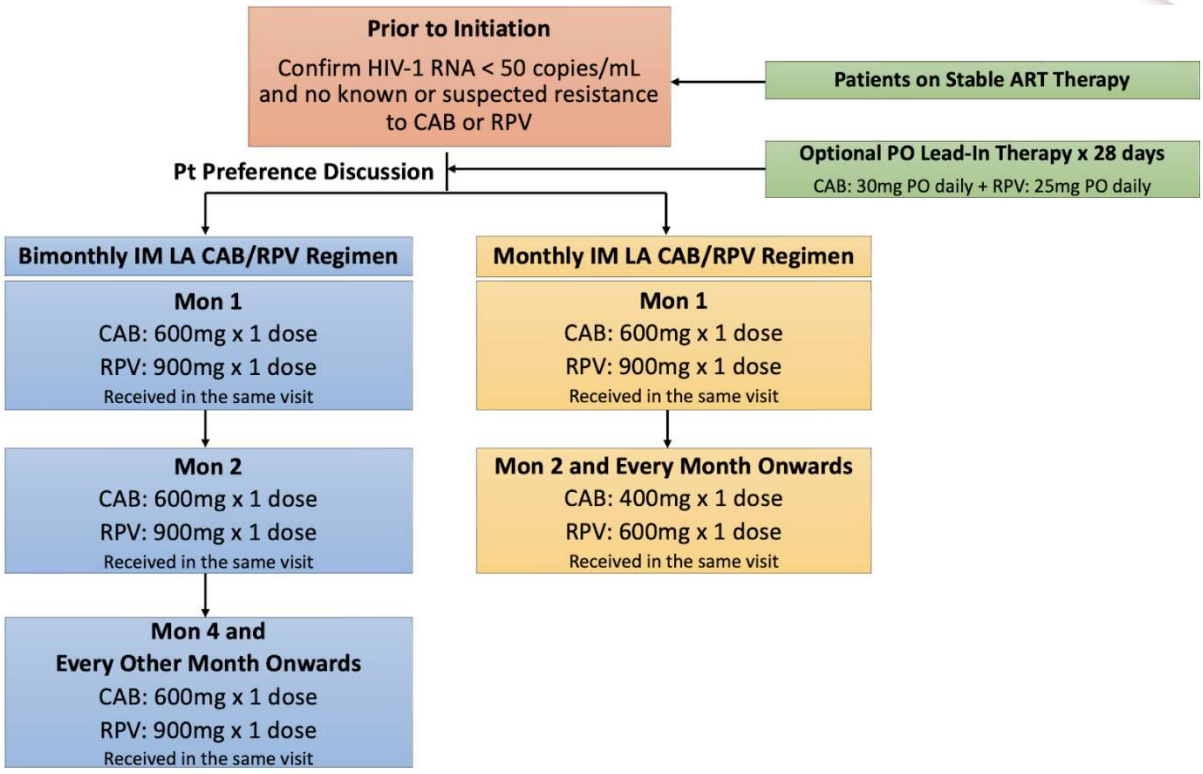

Figure 1. FDA-approved initiation schedule of gluteal intramuscular (IM) long-acting (LA) injectable of cabotegravir (CAB) and rilpivirine (RPV).
ART: antiretroviral therapy, PO: oral

Trials	LATTE-2 (2017)[5]	FLAIR (2020)[6]	ATLAS (2020)[7]	ATLAS-2M (2021)[9]	POLAR (2022)[8]
Primary Efficacy Endpoint	32 weeks	48 weeks	48 weeks	48 weeks	12 months
Comparator	IM CAB/RPV 400/600mg Q4W or 600/900 Q8W	IM CAB/RPV 400/600mg Q4W	IM CAB/RPV 400/600mg Q4W	IM CAB/RPV 600/900mg Q8W	IM CAB/RPV 600/900mg Q8W
Control	PO CAB + ABC/3TC daily (INSTI + 2 NRTI)	PO DTG/ABC/3TC daily (INSTI + 2NRTIs)	PO Standard of Care*	IM CAB/RPV 400/600mg Q4W	PO DTG/RPV daily (INSTI/NNRTI)
Purpose	Compare IM CAB/RPV with the PO CAB arm; Optimize the dosing regimen strategies for IM CAB/RPV	Compare IM CAB/RPV with PO INSTI based regimen	Compare IM CAB/RPV with PO ART Therapy (PI, NNRTI, or INSTI based)	Optimize the dosing regimen strategies for IM CAB/RPV	Compare IM CAB/RPV with PO INSTI based regimen

Table 1. Summary of current trials comparing oral ART and long-acting CAB/RPV injectables
ABC: abacavir, ART: antiretroviral, CAB: cabotegravir, DTG: dolutegravir, IM: intramuscular, INSTI: integrase strand transfer inhibitor, NNRTI: non-nucleoside reverse transcriptase inhibitors, NRTI: nucleoside reverse transcriptase inhibitor, PI: protease inhibitor, PO: oral, Q4W: every 4 weeks, Q8W: every 8 weeks, RPV: rilpivirine, 3TC: lamivudine; *Excluded DTG/ABC/3TC regimen

Trials	LATTE-2 (2017)[5]	FLAIR (2020)[6]	ATLAS (2020)[7]	ATLAS-2M (2021)[9]	POLAR (2022)[8]
Population, N (%)	LA Q4W: 115 LA Q8W: 115 PO: 56	LA Q4W: 283 PO: 283	LA Q4W: 308 PO: 308	LA Q8W: 522 LA Q4W: 523	LA Q8W: 90 PO: 7
VNR, N (%)	LA Q4W: 0 (0) LA Q8W: 5 (4) PO: 1 (2)	LA Q4W: 6 (2) PO: 7 (3)	LA Q4W: 5 (2) PO: 3 (1)	LA Q8W: 9 (2) LA Q4W: 5 (1)	LA Q8W: 0 (0) PO: 0 (0)
CVF, N (%)	LA Q4W: 0 LA Q8W: 2 (2) PO: 1 (2)	LA Q4W: 4 (1) PO: 3 (1)	LA Q4W: 3 (1) PO: 4 (1)	LA Q8W: 8 (2) LA Q4W: 2 (0.4)	LA Q8W: 0 (0) PO: 0 (0)
AE (Grade ≥ 3) or death, N (%)	LA Q4W: 21 (18) LA Q8W: 24 (21) PO: 7 (13)	LA Q4W: 31 (11) PO: 11 (4)	LA Q4W: 35 (11) PO: 23 (7)	LA Q8W: 41 (8) LA Q4W: 49 (9)	LA Q8W: 9 (10) PO: 0 (0)
AE (Grade ≥ 3, non-ISR), N (%)	LA Q4W: 14 (12) LA Q8W: 11 (10) PO: 7 (13)	LA Q4W: 22 (8) PO: 11 (4)	LA Q4W: 25 (8) PO: 23 (7)	Not reported	Not reported
DCAE, N (%)	LA Q4W: 8 (7) LA Q8W: 2 (2) PO: 1 (2)	LA Q4W: 9 (3) PO: 4 (1)	LA Q4W: 14 (5) PO: 5 (2)	LA Q8W: 12 (2) LA Q4W: 13 (2)	LA Q8W: 1 (1) PO: 0 (0)

Table 2. Summary of study outcomes evaluating LA CAB/RPV vs PO ART efficacy and safety in HIV maintenance therapy.

AE: adverse events, CFV: confirmed virological failure (2 consecutive HIV VL RNA ≥ 200 copies/mL blood), DCAE: discontinue of therapy due to adverse events, LA: long-acting antiretroviral therapy, Non-ISR: non-injection site reaction, PO: oral antiretroviral therapy, Q4W: every 4 week (CAB 400/RPV 600mg), Q8W: every 8 week (CAB 600/RPV 900mg), VNR: virological non-response (HIV-1 VL RNA ≥ 50 copies/mL blood)

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Medication Management and the Increasing Impact of the Pharmacy Technician

Molly Moore
Pharmacy Technician Supervisor, Carroll Hospital

Hospital pharmacy technicians play a crucial role in reducing the post-discharge medication access barriers that lead to preventable medication related hospital admissions and readmissions. The Medication Management Clinic at Carroll Hospital has developed a pharmacy technician driven program to proactively address this. In July of 2022, a technician access barrier resolution program was officially launched. These skilled professionals are responsible for conducting coverage determination for brand medications and subsequent long-term plans for access prior to discharge. Patients are provided with free manufacturer coupons at time of discharge to secure initiation and continuation of therapy for the first 30 days after discharge. Then, patients are assisted with applying for Patient Assistance Programs (PAP), Medicare Low Income Subsidy, and/or given a manufacturer coupon if eligible. In the first month of implementation, the clinic saved $131,446 through successful patient enrollment in PAP programs; a 97.3% saving to patients.

This innovative approach to technician integration in the discharge process, and collaboration with pharmacists and case management, has resulted in several improvements in the clinic's quality and outcome metrics. Prior to implementation (January to June 2022), it took the pharmacist a median of 7.33 days (IQR 5.75,9.5) to reach patients for post-discharge education and to review access barriers. Following implementation, the clinic's number of days to first follow up phone call has decreased to 1 day. The technicians ensure that the patient's discharge medications are available and that a long-term plan is in motion. Technician integration in patient discharge planning significantly improves the pharmacist's success rate with connecting with the patients following discharge. The program's success is a direct result of empowering technicians to engage in direct patient care and having the tools necessary to conduct prior authorizations, copay determinations, locating community resources, and leveraging manufacturer assistance programs.

Examples Success Stories

A 70-year-old male was referred to the Medication Management Clinic for assistance with determining long-term access to Jardiance®. The pharmacy technician called a community pharmacy to obtain insurance coverage. The technician learned that the patient is uninsured and uses self-pay to obtain their medications. A PAP application was mailed to the patient that would ensure the patient receives the Jardiance® from the manufacturer at zero out-of-pocket cost. The technician followed up and confirmed that the application was submitted and approved for the rest of the year. This resulted in a monthly savings of $581 and a total savings of $3,486 (July to December).

A technician was contacted about a 79-year-old female that is currently taking Eliquis® and has the potential for an expensive copay. The technician contacted the patient's community pharmacy to determine previous copays and learned that the copay for July was $85, for August $137.11, and for September it was $137.11. The technician contacted the patient's Medicare Part D plan and confirmed that the patient was in their coverage gap. The technician delivered the PAP information for Eliquis® prior to discharge. The PAP was approved, and the patient received Eliquis® from the manufacturer at zero out-of-pocket cost, saving them $137.11 a month and $411.33 for the rest of the year (October to December).

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Emerging Practitioners Committee
MSHP Residency Showcase

This past fall the Emerging Practitioners Committee hosted the MSHP Residency Showcase! This was the first time the showcase had been back in person since 2019 and it was exciting to be back! In total, there were 25 programs present for the students to interact with. Programs were from all over Maryland and surrounding states. Each program had their own table which allowed students to move freely around the room and stop to interact with their programs of interest. The free-flowing nature of the showcase allowed for students to have more personal face-to-face conversations with programs in order to get their questions answered and to start building relationships with specific programs. Students were encouraged to explore the various programs present and utilize the full 2 hours to their advantage.

During the last half hour of the Residency Showcase, there was a panel session hosted by a group of emerging practitioners that went to the last in-person ASHP Midyear Meeting in 2019 to share their perspectives of what attending an in-person Midyear is like. The panel consisted of Dr. Caitlin Soto, PharmD from Johns Hopkins Medicine, Dr. Olivia Berger, PharmD, BCPS from Johns Hopkins Bayview Medical Center, and Dr. Ricky Rovelli, PharmD from the University of Maryland Medical Center. Students were able to ask questions during the event as well as actively engage with the emerging practitioners panel. Our panel of new practitioners shared tips about how to navigate ASHP Midyear and Residency Showcase, advice for finding the right “fit” for residency, and overall words of wisdom. Each panelist shared their unique pathway that led them into their current position and what a typical day in residency looked like for them. The students ultimately found the session to be informative and inspiring as they take their next steps in their pursuit of post-graduate education and training.

The Emerging Practitioners Committee would like to thank everyone that was involved in the planning for this event as well as to those who participated in the Residency Showcase. Thank you for making this another successful year!

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Legislative Affairs Committee
MSHP Members Champion Pharmacy Scope of Practice & Reimbursement Bills in Annapolis

On February 9, 2023, MSHP members advocated for pharmacy practice bills while participating in the Maryland Pharmacy Coalition's (MPC) Legislative Day that included over 350 pharmacists, pharmacy technicians and students. Attendees met with their senators and house delegates to discuss the heath care needs of Marylanders and how growth in the provision of clinical pharmacy services, technician scope, and reimbursement for services is key to improving access to care.

Now it's your turn!

- Write your legislator in support of these MPC & MSHP backed bills. Find your legislator and click "*Contact checked legislators*": https://mgaleg.maryland.gov/mgawebsite/Members/District
- Submit a personal or organizational letter of testimony: https://mgaleg.maryland.gov/mgawebsite/Account/Register/Tracking

Thanks in advance for your advocacy. Make your voice heard!

MSHP Legislative Affairs Committee

Template Letter:

Subject: SUPPORT Pharmacy Scope of Practice & Reimbursement Bills

Dear _____, (i.e.: Senator/Delegate xxx)

I am writing to you today as a resident in your district and as a pharmacy professional member of the Maryland Society for Health-System Pharmacists. The Maryland Pharmacy Coalition members visited Annapolis on February 10, 2023, for Pharmacy Legislative Day to discuss several important bills. I urge you to support the following bills to increase access to care and improve the health of Marylanders.

- **SB678/HB1151: Reimbursement by private carriers and Maryland Medicaid for pharmacist-provided patient care services, regardless of practice setting.** Sponsors: Senator Beidle & Delegate Bhandari
    - Position: Maryland Pharmacy SUPPORTS reimbursement by private carriers and Maryland Medicaid for pharmacist-provided patient care services, regardless of practice setting.
    - Description: If a policy provides for reimbursement of a service within the lawful scope of practice of a pharmacist, that the insured or any other person covered by the policy is entitled to reimbursement, and that it may not be a condition for payment that the pharmacist be employed by a physician, pharmacy, or facility, or under a physician's orders.
    - Background: Recommended by the Maryland Insurance Administration Work Group, authorized during HB 1219- Pharmacists Status as Healthcare Providers and Study on Reimbursement passed in 2022 legislative session. States with current pharmacist payment parity legislation: Illinois, Colorado, Kentucky, New Mexico, Ohio, Oklahoma, Oregon, Tennessee, Texas, Virginia, Washington, West Virginia.
    - Impact: Payment for services by pharmacists sustainably increases access to qualified clinical professionals and improves patient outcomes.
- **HB693/SB647: State Board of Pharmacy - Board Membership and Delegated Pharmacy Acts.** Sponsors: Delegate Kipke and Senators Carozza, Lam, Mautz, and Lewis Young.
    - Position: Maryland Pharmacy SUPPORTS the ability for technicians to administer vaccinations, complete remote non-drug handling task under "supervision" and be included as a represented member of the Board of Pharmacy.
    - Description: For the purpose of authorizing technicians who meet the requirements of certain regulations to administer immunizations to a patient under certain circumstances. Purpose of amending the term "directly supervised" to "supervision" for technicians to work remote. Purpose of proper representation on the Board of Pharmacy.
    - Background: Currently pharmacists provide "direct supervision" to pharmacy technicians and this requirement precludes the capacity for remote administrative work. Pharmacy technicians are currently performing the mechanical administration of COVID-19 vaccinations.
    - Impact: Adds representation of Technicians on the Board of Pharmacy. Provides flexibility in the workplace, increases available staff, decreases commute time, and helps maintain emergency preparedness.
- **HB1156: Pharmacists - Therapy Management Contract – Form.** Sponsor: Delegate R. Lewis.
    - Position: Maryland Pharmacy SUPPORTS updating the definition of a Drug Therapy Management Contract to improve patient access to medication management services.
    - Description: For the purpose of updating the definition of a drug therapy management contract to include written, electronic, and verbal contracts. Contracts are required for all

patients being cared for by a pharmacist and physician, nurse practitioner, or podiatrist in a Drug Therapy Management Agreement.
    - Background: Current contracts must be written, therefore, when providing services via telemedicine, it creates undue burden to mail, collect, track, and store physical documents.
    - Impact: Reducing time spent on paperwork allows time for more direct patient care responsibilities, like vaccinating and educating patients. Achieves the goal of improving patient access to care while also reducing logistic requirements that contribute to healthcare worker burnout.
- **SB64: HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements.** Sponsors: Senator Lam.
    - Position: Maryland Pharmacy SUPPORTS WITH AMENDMENTS the ability for pharmacists to prescribe post exposure HIV prevention medication.
    - Description: Authorizes pharmacists to prescribe postexposure prophylaxis (PEP)for HIV prevention and educate patients on pre-exposure prophylaxis (PrEP)– includes education and training requirements; and the ability for pharmacists to conduct HIV point-of-care testing.
    - Suggested amendments: Require payment for pharmacist clinical services, modify testing language to require HIV test and delete the education and training requirements of pharmacists on financial reimbursement programs.
    - Background: With 95% of patients living within 5 miles of a pharmacy, with pharmacies open at night and on weekends, pharmacists are easily accessible health care providers. The pharmacy-setting is considered largely free of HIV-related stigma. COVID-19 has increased the experience and operational efficiencies in pharmacies related to point-of-care testing and treatment. States with direct prescribing authority: California, Colorado, Idaho, Illinois, Maine, Nevada, New Mexico, Oregon, Utah, and Virginia.
    - Impact: Reducing the time from exposure to postexposure prophylaxis improves outcomes and reduces rates of HIV infection.
- **SB372: Health Occupations - Pharmacists - Administration of Vaccines.** Sponsor: Senator Augustine.
    - Position: The Maryland Pharmacy Coalition SUPPORTS the ability for pharmacists to administer vaccinations to children ages 3-17 without a physician's prescription.
    - Description: Codifies the 2021 federal PREP Act into Maryland law. Authorizes pharmacists to administer vaccinations to children aged three and older according to the ACIP immunization schedule without a physician's prescription in response to decreasing vaccination rates among children during the COVID-19 pandemic.
    - Background: 90% of Americans live within five miles of a pharmacy and patients visit pharmacies 10 times more frequently than other healthcare providers. It would encourage administration and inclusivity as 40% of children in Maryland do not have a primary care provider. Throughout the pandemic pharmacist played a vital role in accessibility to healthcare, and provided millions of vaccinations. Pharmacists have well established protocols in place to ensure a patient is a good candidate for vaccinations, as well as access to ImmuNet to prevent the risk of "double doses"
    - Impact: Prevent decrease in healthcare access for Marylanders when the PREP Act expires.

Please vote favorably for the aforementioned bills.

Sincerely yours,

Your name here