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SUMMER 2023

QUARTERLY PUBLICATION OF THE MISSISSIPPI PHARMACISTS ASSOCIATION

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This emblem designates *Mississippi Pharmacist* is a member of the State Pharmaceutical Editorial Association, recognizing its high journalistic standards in endeavoring to keep its members well informed on all developments relative to the pharmaceutical profession.

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PRESIDENT'S MESSAGE

Members of MPhA,

I am humbled by the opportunity to serve as president of MPhA. I am also cognizant of the responsibility intrinsic with such a role. First, I would like to recognize Dr. Tripp Dixon, who did a fantastic job leading the organization during the past year. The advantage in following such a leader is the luxury of inheriting the reins of a well running organization. The challenge is to continue to provide a level of leadership to which we have become acclimated. Luckily, I am not expected to do this alone. The Executive Committee is populated with committed and talented leaders and managed by an enthusiastic Executive Director and a highly skilled Office Manager.

We recently held our Annual Convention in Oxford. It is one of our most anticipated events of the year. The Education Committee, Convention Committee and the MPhA office leadership did a tremendous job planning and executing it. Now, it is time to start planning for next year's program. We can develop a program more suited to your needs and wants if we know what those needs and wants are. Provide us with your thoughts.

As good as the program was, we seek to do more than provide education. We also want to facilitate connections. Many of us remember the challenge of 2020. We at MPhA did our best to maintain educational events. However, something was missing with virtual meetings - the chance to interact face to face. We held remote meetings to keep our members, attendees, speakers, and students safe. However, we also knew we wanted to get back to live meetings as soon as we safely could. Connection and networking is just more efficient when the parties are in the same place.

The other major purpose for our organization, besides educating and connecting, is advocacy. We have already started interacting with our legislators. One of the first issues at hand was white bagging. We knew the lawmakers needed to know the implications of white bagging from a point of view beyond that of those who could make a financial profit from it. We joined as part of a multiorganizational effort to assure appropriate education of the elected legislative officials addressing this matter.

An organization like this one is dedicated to moving the profession of pharmacy forward. That includes efforts to make it a desirable field in which to work. In order to do this, we must seek the opinions of those who do this every day. We need to know what aspects of the field are rewarding and which create the most challenge. We need input from those in the trenches.

Connection; education; advocacy. Those are the major purposes of MPhA. However, we want to focus our efforts, not on what is best for MPhA, but what is best for the pharmacy workforce of Mississippi. We strive for patient safety, but also for the well being of the pharmacy staff. Let us know how you feel about the issues, large or small. We want to be the voice of Pharmacy. To best achieve those efforts, we need to hear from you. Let us know how we can be of help.

Thanks for all you do,

Richard L. "Buddy" Ogletree, Jr., PharmD, RPh

MPhA President

President@mspharm.org

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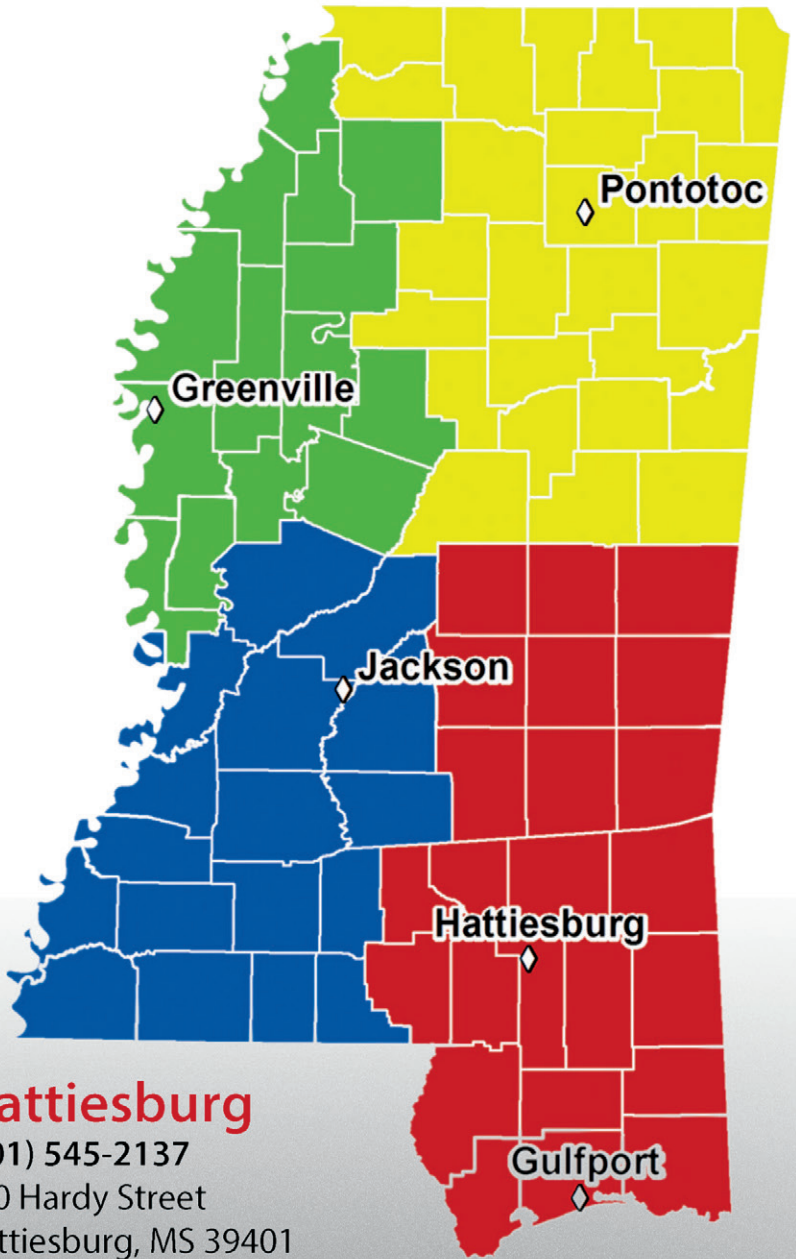

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EXECUTIVE DIRECTOR'S LETTER

Greetings,

It's always a wonderful day to be a Pharmacist in the State of Mississippi! It has brought me great joy meeting the pharmacists in a variety of practice settings across the state of Mississippi. I love hearing the wonderful ideas about pharmacy.

Congratulations to our 2023 Executive Committee and Committee Chairs. I commend each of you for your willingness to serve, dedication and commitment. Pharmacy is constantly changing and our Association must reflect the needs of the world in which we practice pharmacy. "We are stronger together" is a great motto. We are working to retool our student's membership; we want our students more involved and engaged. Our students need to be excited about advocacy.

MPhA will work tirelessly to lead our profession. Across the state, there is a common thread that pharmacists are expressing concerns over, product shortage continues to lead to frustration and upset patients. PBM reform is on the horizon and we must continue to be diligent around the issue. There is a lot of energy for PBM reform on the Hill.

As I reflect back on the past year, I am extremely proud of the work that MPhA has done on behalf of its members. MPhA's 152nd Annual Convention and Trade Show was held in Oxford on June 6-8, 2023. We challenged our pharmacists and students to be committed to excellence by sharing best practices, utilizing innovative thinking, and clinical updates. Pharmacists had the opportunities to earn up to 12 hours of live ACPE credits. The Trade Show afforded the opportunity for attendees to learn new products and services, network and win prizes. New offices were installed at the awards luncheon. Our students enjoyed playing golf and a social outing at the Growler in Oxford. It was such a fun time enjoying old friends and meeting new friends.

I want to encourage each of you to sign up for a committee for MPhA and get involved. Your voice matters. Work on building relationships with your Senator and Representative. They would love to hear from you. They are extremely concerned with the concerns and challenges pharmacist face.

I am grateful to serve each of you. I look forward to working with the Pharmacist, Pharmacy Students and Pharmacy Technicians to enhance the profession of pharmacy.

Mona Arnold-McBride

Mona Arnold-McBride, PharmD
Executive Director

MPhA
CONSULTANT SEMINAR

SAVE THE DATE
THURSDAY, SEPTEMBER 28, 2023
8:00 AM - 5:00 PM
CHECK IN BEGINS AT 7:30 AM

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JOIN A COMMITTEE

The Mississippi Pharmacists Association (MPhA) begins a new committee year each July. We invite you to join one of our committees.

You can visit our website for committee information
www.mspharm.org/committees
Each committee addresses different topics relevant to MPhA business. Examples of topics discussed at each meeting pertain to membership engagement (Membership), educational topics for conventions and journals (Education), ways to engage students and recent graduates (New Practitioner), and/or legislation (Government Affairs).

Your Voice Matters

YOU CAN MAKE A DIFFERENCE

MEET THE

Mississippi Pharmacists Association

2023-2024 Executive Committee

Buddy Ogletree - President

Dr. Buddy Ogletree graduated from the University of Mississippi. Since 2001 he has been staff pharmacist for Walmart Pharmacy. Prior to 2017, he served as a coordinator for Drug Information and Investigational Drugs at the University of Mississippi Medical Center spending over 30 years at UMMC. He was also on the faculty of the University of Mississippi School of Pharmacy for over 20 years. He has given numerous presentations and has an extensive list of publications ranging from Supplements 101 to Glucocorticoid-induced Osteoporosis.

Olivia Strain - President Elect

Olivia Strain, PharmD, is a Clinical Services Pharmacist and the PGY1 Community-based Pharmacy Residency Program Director for Walgreens in Jackson, Mississippi. She received her Doctor of Pharmacy degree from the University of Mississippi School of Pharmacy (UMSOP) in 2007. Originally from Madison, Mississippi, Olivia began working for Walgreens 15 years ago (2005) in Knoxville, Tennessee, as a pharmacy intern. Following graduation, she began her career with Walgreens in the Jackson, Mississippi area holding various roles such as a market pharmacist, pharmacy manager (for seven years), immunization and travel health lead and certified trainer, MTM lead, summer intern coordinator, and residency preceptor. Olivia is actively involved with MPhA presently serving as the Education Committee Chair (two years), an Awards and Nominations committee member (three years), and a Mississippi delegate at the annual American Pharmacists Association (APhA) House of Delegates meeting (five years).

Bob Wilbanks - Vice President

Bob Wilbanks is the Director of Pharmacy at Bolivar Medical Center in Cleveland and has vast experience as both an independent and a chain pharmacist in the retail sector. He currently serves as a MPhA Executive Committee Member-at-Large, and has also served MPhA as a member of the Education and Membership committees. He has participated in 18 medical mission trips to Mexico, Peru, and Costa Rica. A communicant of Calvary Episcopal Church, Bob is a former senior warden and is a lay reader and choir member. He is a past president of the Delta Arts Alliance and The Crosstie Arts Council, and is the longtime Foundation Chair for the Cleveland Rotary Club. Bob is a past Bowl of Hygeia and Spirit of Pharmacy award winner, and has received the Mercy Award from Lifepoint Hospitals. He is a Rotary Paul Harris Fellow, and has received the Cleveland Chamber of Commerce President's Award and the Lucy R. Janoush Citizenship Award. Bob was named the Crosstie Patron of the Year in 2019, and was honored to be the King of the Junior Auxiliary of Cleveland Children's Benefit Ball last year. He and his wife Wilma were named the Distinguished Pharmacy Alumni of the Year by the University of Mississippi School of Pharmacy in April 2022 and share three children and five grandchildren.

Emily Bond - Treasurer

Emily Melton Bond, PharmD, BCMTMS, graduated from the University of Mississippi School of Pharmacy in 2012. After graduation, Emily worked for Walgreens throughout the state as a staff pharmacist and a pharmacy manager. Currently, Emily serves as a staff pharmacist at Covenant Pharmacy in Ridgeland, a long term care pharmacy, supervising non-sterile compounding. Emily has been an active member on many committees for MPhA--including Education (four years), Awards and Nominations (four years currently), and Membership (nine years currently). She has previously served as District 1 Co-Chair and chairwoman for the Membership Committee. Her passion for the Association has been awarded with the J.D. Slater District Achievement Award (2016) and the Distinguished Young Pharmacist (2017). Emily is a member of the American Pharmacists Association, the National Community Pharmacists Association, Phi Lambda Sigma National Pharmacy Leadership Society, and Phi Delta Chi Fraternity.

MEET THE

Mississippi Pharmacists Association

2023-2024 Executive Committee

Andy Stepp - Member-at-Large

Andy Stepp graduated from the University of Mississippi School of Pharmacy in 1981. In 2023, Andy received the 2023 Bruce Citizen of the Year from the Bruce Chamber of Commerce. He was named 2020-2021 IPPE Preceptor of the Year by the UM School of Pharmacy. Andy was selected as the 2020 Chamber of Commerce Member of the Year. Andy received the Business of the Year by the Chamber of Commerce in 2015 and in 2020. Andy has served on the Bruce Chamber of Commerce Board of Directors from 2020-2024. He has been serving on the Executive Board of Directors in North Mississippi EMS since 2011. He has also been serving on the North Mississippi Full Authority since 2004. He owns Stepp-Saver Pharmacy. Andy volunteers at the Bruce Volunteer Fire Department, Emergency Medical Responder, and the First Baptist Church Security Team. Andy loves spending time with his kids and grandkids. After work and on the weekends, he enjoys playing a round of golf, riding his bike or flying. Andy is also a candidate for the Mississippi House of Representatives representing District 23.

Anna Touchstone - Member-at-Large

Anna Jane Touchstone, PharmD received her Bachelor of Science in Pharmaceutical Sciences in 2017 and her PharmD in 2020 from the University of Mississippi School of Pharmacy. She became a pharmacist at the University of Mississippi Medical Center after graduation. She is currently a member of MPhA, APhA, MSHP, and Phi Lambda Sigma. She has been involved with MPhA for over five years as both a student and pharmacist, where she has been an active member of the education, convention, and new practitioner committees. She currently serves as the Education Committee Chair, which she has done since 2021. Through the New Practitioner Committee, Anna helped start the MPhA Mentor Program in 2020 by serving as program coordinator. She was awarded MPhA Student of the Year in 2019 and MPhA Member of the Year in 2022.

Tripp Dixon - Past President

Tripp Dixon, PharmD graduated from the University of Mississippi School of Pharmacy in 2004 and completed a PGY-1 residency at Huntsville Hospital in 2006. He is currently a clinical pharmacy specialist in infectious disease and chairs the Antimicrobial Stewardship Committee at the Mississippi Baptist Medical Center in Jackson, MS. Dr. Dixon is a Clinical Assistant Professor of Adult Medicine for the University of Mississippi School of Pharmacy and was awarded Preceptor of the Year for the Introductory Pharmacy Practice Experience in 2016. He is a past-president of the Mississippi Society of Health-System Pharmacists (MSHP) and received the MSHP Service Award of Excellence for 2012 and Pharmacist of the Year in 2013. Dr. Dixon has served as the Mississippi Pharmacists Association (MPhA) Education Chairman for the past 3 years and was named MPhA Member of the Year in 2016. *The Mississippi Business Journal* selected him as a Healthcare Hero in 2014. Dr. Dixon and his wife Kelly have four children and reside in Madison, MS. They enjoy serving the community through the orphan care ministry in their local church and as a foster family in Madison County.

Mississippi Pharmacists Association

Annual Convention

The Mississippi Pharmacists Association held the 152nd Annual Convention and Trade Show at the Oxford Conference Center in Oxford, Mississippi. Our tag line is "Committed to Excellence" and the event proved to line up with that sentiment. The event started off Thursday, June 8, 2023, with a golf tournament at Kirkwood National Golf Club. In the afternoon attendees enjoyed Continuing Education classes. The University of Mississippi School of Pharmacy hosted the Opening Reception which was catered by My Michelle's. It was well attended and a great time for people to catch up with old friends and make new ones.

Attendees were impressed with the classes and the speakers were very knowledgeable on the topics covered. Oxford was such an easy destination and those that attended enjoyed seeing the Ole Miss campus, the nostalgia of being back in Oxford, and various shops and local restaurants or just walking around the Square. Others mentioned the convenience of having hotel accommodations close to the Conference Center, plenty of parking and a variety of great places to eat with easy access.

On Friday night, MPhA hosted a Trade Show reception. The Exhibitors were excited to show their products and services according to one person, "the Expo Hall was full of great energy." The Awards Luncheon was held on Saturday and Taylor Grocery in Oxford catered the event. Wilma Wilbanks, the Awards Chair wrote in our survey: "I always enjoy the awards because I love to see fellow pharmacists be recognized for their achievements. The trade show was terrific! Our Executive Director did a phenomenal job in securing vendors!" The overall take away from the event was the fact that those in attendance were able to fellowship with other pharmacists, interact with University staff and get live Continuing Education.

Next year's convention will be held in Oxford so "Save the Date." It will be held June 7–9, 2024. Be on the lookout for information to take advantage of Early Bird pricing. You will not want to miss it.

Left to Right: Dr. Dean Donna Strum, Ellen Ann Johnson, Robert Wilbanks and Leland McDivitt

The 152nd Annual Convention MPhA Awards

IN RECOGNITION OF EXCELLENCE

Hall of Fame
Lauren Bloodworth

Bowl of Hygeia
Leigh Ann Ross

Distinguished Young Pharmacist of the Year
Amanda Skal

Excellence in Innovation
Meagan Brown
Carly Brown accepted on her behalf

Spirit of Pharmacy
Anna Touchstone

Pharmacy Student of the Year
Izzabella Christian

Member of the Year
Regan McIntosh

MPhA would like to congratulate the Award Winners this year. For more information about the Awards Nomination Process and descriptions of each award, please visit our website by clicking the logo below.

Mississippi Pharmacists Association

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Angie Calhoun, Mississippi Cannabis Patients Alliance, Dean Donna Strum, Dean of Ole Miss School of Pharmacy, Mona Arnold-McBride, MPhA

Mona Arnold-McBride, MPhA, Amber Naccarato, Novo Nordisk

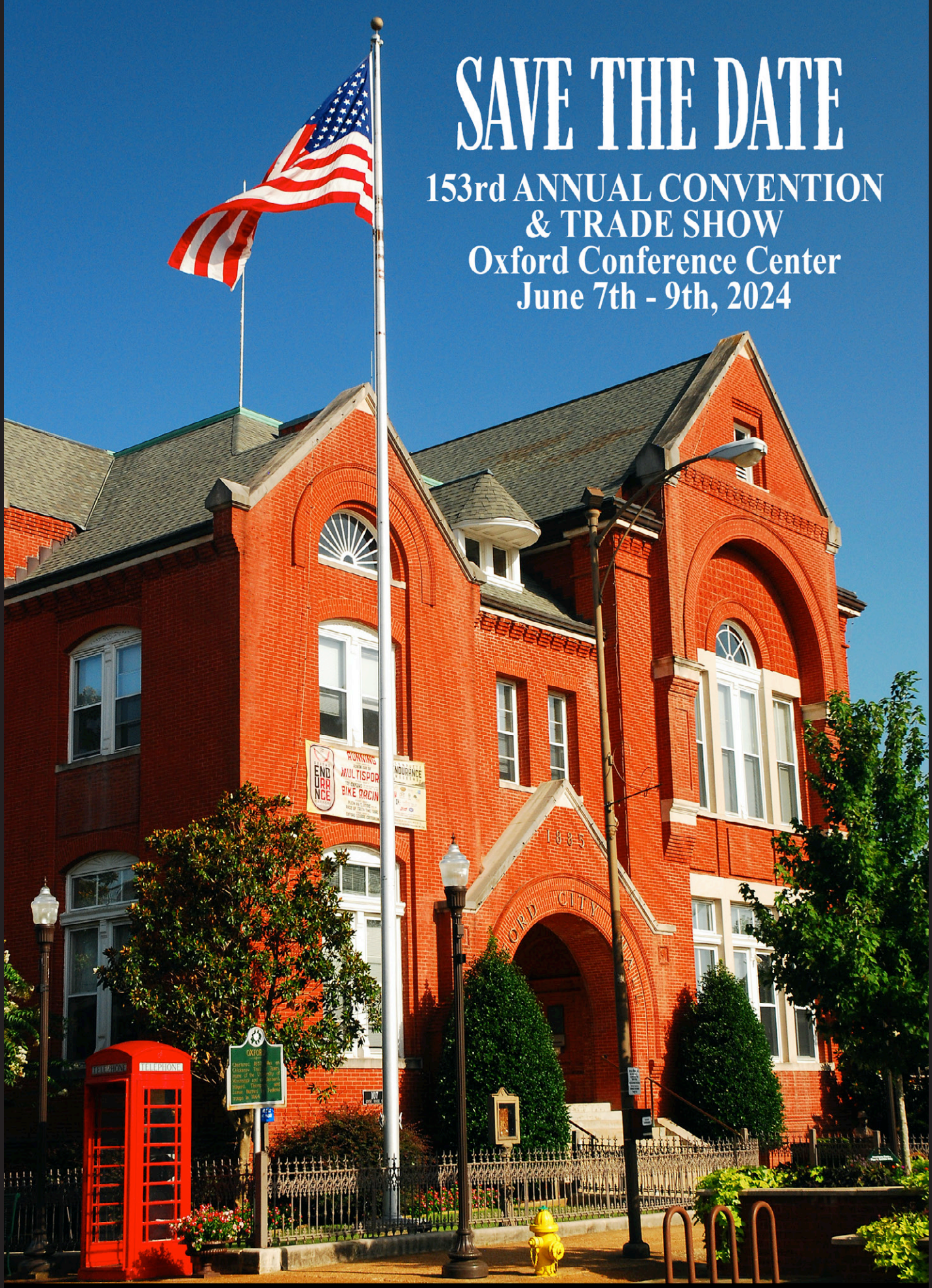
Les Lundgren and Matt Bouchard, Forte Biopharma

Rosemary Cargin and Myrtis Rankin meeting with attendees from Mosby's Drug Store.

Tripp Dixon, MPhA, Mona Arnold-McBride, MPhA, John Pattridge and Paige Blackburn, Walmart, Kelly Dixon, MPhA

Mississippi Pharmacists Association

We hope to have more sponsors and exhibitors next year, and we certainly thank everyone for their contribution in making our Annual Convention an event not to miss!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& TRADE SHOW
Oxford Conference Center
June 7th - 9th, 2024
MISSISSIPPI PHARMACISTS ASSOCIATION

STUDENT SPOTLIGHT

Eliza Cossar

I am Eliza Cossar, a 4th year pharmacy student at the University of Mississippi. I am from Senatobia, MS, where my interest in pharmacy began. I loved visiting my small-town community pharmacy as a child, and that love for the profession has been nurtured by many role models since. The relationships I have observed between pharmacists and their patients have made me confident in choosing pharmacy.

After graduation, I plan on pursuing a residency. While I am still discovering what specific career path I would like to pursue, I know that I want to use my position to be an advocate for both patients and pharmacists. I have witnessed the shortcomings that MS residents have had to endure in healthcare, and I want to help make a better and healthier life for all Mississippians. I am currently serving as co-chair of the University of Mississippi Advocacy Council, student liaison for Ole Miss's chapter of American College of Clinical Pharmacy, and am an active member of APhA/MPhA. Outside of school I enjoy going on walks with my roommates and dog, Delta, reading, and attending Ole Miss sporting events.

Tate Pepper

My name is Tate Pepper, and I'm currently in my fourth year at the University of Mississippi School of Pharmacy. I am from the beautiful Mississippi Gulf Coast and grew up in Ocean Springs. My educational journey has taken me through several different schools - from Jones County Junior College to Mississippi State, and now to Ole Miss, where I'm pursuing my passion for pharmacy.

Growing up, I always knew I wanted to pursue a career in the healthcare field. As I explored my options, I found myself drawn to pharmacy because of the relationships pharmacists build with their patients and other providers in the community. I hope to become a clinical pharmacist one day, where I can become a key part of the healthcare team using my medication expertise. I find it rewarding knowing the skills we learn can directly impact people's lives in a positive way. Additionally, I've set my sights on eventually transitioning into the pharmaceutical industry to become a medical science liaison. By combining my clinical knowledge with my communication skills and relationship-building, I believe I could continue to make a difference in improving overall health in our country.

As a student pharmacist, I challenge myself to stay involved with organizations within our school and pharmacy community. I maintain membership with The Rho Chi Pharmacy Honor Society, Kappa Psi Pharmaceutical Fraternity, Mississippi Pharmacist's Association, and the University of Mississippi Advocacy Council (UMAC). I work as a pharmacy intern at both Mississippi Baptist Medical Center in Jackson and Ocean Springs Hospital. During my free time, I enjoy playing golf, fishing, and cooking for my friends and family.

Mississippi Pharmacists Association

CONTINUING EDUCATION

When Statins Are Not Enough: Role of Non-Statin Therapies in Secondary Prevention of ASCVD

AUTHOR
Sally Earl, PharmD, BCPS

REVIEWED BY
Izzabella Christian, PharmD Candidate 2024, University of Mississippi School of Pharmacy, Robert Martin, PharmD, Buddy Ogletree, PharmD

OBJECTIVES
1. Determine appropriate treatment threshold for adding non-statin therapy in patient with history of ASCVD.
2. Differentiate non-statin therapies based on efficacy, safety and administration.
3. Formulate an appropriate non-statin regimen for secondary prevention in patients with ASCVD.

Introduction

Cardiovascular disease is responsible for a vast amount of morbidity and mortality in the United States. Heart disease was the leading cause of death in the United States in 2020.[1] According to a 2016 analysis, dyslipidemia was the 35th most expensive health condition, with an estimated cost of $26.4 billion annually. The majority of this cost was attributed to prescription medications (45.6%) and ambulatory visits (33.4%). In an effort to improve the cardiovascular health of all Americans, the American Heart Association created "Life's Simple 7". The concept is for an individual to have ideal cardiovascular health, they need to have optimal control of all seven components: diet, physical activity, smoking status, blood cholesterol, body mass index, blood pressure and blood glucose. An estimated 2 million major cardiovascular events could be prevented if all Americans could attain ideal cardiovascular health; 1.2 million with a partial improvement in these areas.[2]

Cholesterol is a well-known causal risk factor of development of atherosclerosis, leading to cardiovascular disease. Dyslipidemia decreased in prevalence among both youth (6-19) and adult Americans (>20), based on data from the early 2000's compared to that from the mid/late 2010's. However, despite this decrease, more than one third of adults continue to report having high cholesterol.[2]

Treatment Options and Recommendations

Treatment of dyslipidemia is aimed at preventing atherosclerotic cardiovascular disease (ASCVD) through the reduction of LDL-C. Reduction in LDL-C by 38.7 mg/dL (1 mmol/L) is associated with a 23% relative risk reduction in major ASCVD events.[3] Statins have been the mainstay of cholesterol treatment for many years due to the effective reduction in LDL-C, as well as the ability to reduce cardiovascular related morbidity. Statins work by inhibiting HMG-CoA reductase, the rate limiting step in endogenous cholesterol synthesis, resulting in a decrease in LDL production and an increase in LDL receptors on hepatocytes. Statins are classified based on the percent LDL-C reduction expected with high intensity statins associated with greater than 50% reduction in LDL-C, moderate intensity statins

Table 1: Statin Classification based on Intensity[4]

Low-Intensity Statin (<30% reduction)	Moderate-Intensity Statin (30-50% reduction)	High-Intensity Statin (≥50% reduction)
Simvastatin 10 mg Pravastatin 10-20 mg Lovastatin 20 mg Fluvastatin 20-40 mg	Atorvastatin 10-20 mg Rosuvastatin 5-10 mg Simvastatin 20-40 mg Pravastatin 40-80mg Lovastatin 40 mg Fluvastatin XL 80 mg Fluvastatin 40 mg BID Pitavastatin 2-4 mg	Atorvastatin 40-80 mg Rosuvastatin 20-40 mg

Table 2: 2018 ACC/AHA Guidelines for Secondary Prevention Treatment[4]

	First Line Recommendation	Second Line Recommendation
ASCVD† not at very high risk; age <75	High-intensity statin (Goal ↓ LDL-C ≥50%) (Class I)	If goal not achieved on maximal statin, consider adding ezetimibe (Class IIb)
ASCVD† not at very high risk; age >75	Moderate or high-intensity statin (Class IIa)	
Very High Risk ASCVD*	High-intensity or maximal statin (Class I)	If on maximal statin and LDL-C ≥ 70 mg/dL, adding ezetimibe is reasonable (Class IIa) If PCSK9-I is considered, add ezetimibe to maximal statin first (Class I) If on maximal statin and LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL, adding PCSK9-I is reasonable (Class IIa)

†ASCVD includes acute coronary syndrome, history of myocardial infarction, stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral artery disease, including aortic aneurysm

*Very High Risk: history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions. High-risk conditions include age ≥ 65, heterozygous familial hypercholesterolemia, history of prior CABG or PCI outside ASCVD event, DM, HTN, CKD with eGFR 15-59 mL/min/1.73m^2, current smoking, LDL-C ≥ 100mg/dL despite maximum statin and ezetimibe, history of congestive heart failure.

Table 3: Thresholds for Recommending Non-Statin Therapy for Secondary Prevention[24]

Clinical ASCVD and not very high risk	≥ 50% LDL-C reduction AND LDL-C <70 mg/dL (non-HDL <100 mg/dL)
Clinical ASCVD at very high risk*	≥ 50% LDL-C reduction AND LDL-C <55 mg/dL (non-HDL <85 mg/dL)

*Very High Risk: history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions. High-risk conditions include age ≥ 65, heterozygous familial hypercholesterolemia, history of prior CABG or PCI outside ASCVD event, DM, HTN, CKD with eGFR 15-59 mL/min/1.73m^2, current smoking, LDL-C ≥ 100mg/dL despite maximum statin and ezetimibe, history of congestive heart failure.

30-50% reduction and low intensity statins less than 30% reduction. (Table 1)

The current AHA/ACC treatment guidelines recommend statin therapy as the first-line option for secondary prevention of ASCVD.[4] In patients with clinical ASCVD, use of a high intensity statin to achieve an LDL-C reduction of at least 50% is a Class I recommendation for all patients under the age of 75. (Tables 2 and 3) Despite this recommendation, a database of 601,934 patients showed that only 22.5% of patients with history of ASCVD were on a high intensity statin, 27.6% on a low or moderate intensity statin and 49.9% on no statin therapy.[5] Patients on statins may not be able to achieve LDL goals due to genetic issues, intolerance, nonadherence or therapeutic inertia and highlights the need for non-statin treatment options and a team-based care approach to dyslipidemia treatment.[6] To date, there are six non-statin therapies that have shown improved cardiovascular outcomes when added to maximally tolerated statin therapy.

Ezetimibe

Ezetimibe (Zetia™) works by inhibiting cholesterol absorption in the small intestine. This decrease in exogenous cholesterol absorption triggers the upregulation of LDL receptors on hepatocytes. The addition of ezetimibe to a statin leads to an additional 20-25% reduction in cholesterol

compared to a 5-6% reduction with the doubling of a statin.[6] The Improved reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT) showed that ezetimibe in combination with simvastatin reduced LDL-C and ASCVD events more than simvastatin alone in patients with a recent ACS event.[7] Over 18,000 patients with ACS were randomized to simvastatin 40mg/day and ezetimibe 10mg/day versus simvastatin alone. After a median follow up of 6 years, the simvastatin plus ezetimibe cohort had a lower incidence of cardiovascular (CV) mortality, major CV events or nonfatal stroke (34.7% vs 32.7%, p= 0.015, NNT=50).

This composite outcome was driven by the reduction in MI and stroke; there was no statistically significant difference in all-cause or CV death. This was the first trial to show that a non-statin agent and statin combination reduced secondary cardiovascular events in high-risk patients and led to the inclusion of ezetimibe to the treatment guidelines.

Ezetimibe provides an attractive option for patients not achieving LDL-C goals on statins due to its ease of dosing, safety profile and cost. Ezetimibe is dosed at 10mg daily and does not require dosing adjustment for renal insufficiency. The most common adverse reactions reported in combination with statins were nasopharyngitis (3.7%), myalgias (3.2%), upper respiratory tract infection (2.9%), arthralgia (2.6%) and diarrhea (2.5%). It is available as a generic formulation.[8]

Alirocumab and Evolocumab

The first proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor was approved in 2015. PCSK9 binds to LDL receptors on hepatocytes and leads to degradation. Alirocumab (Praluent™) and evolocumab (Repatha™) are monoclonal antibodies that bind to PCSK9 and inhibit the binding of PCSK9 to LDL receptors, resulting in an increase in LDL receptors on hepatocytes. When used as monotherapy, PCSK9 inhibitors reduce LDL-C approximately 50%, similar to high-intensity statin therapy. When used in combination with statins, this LDL-C reduction increases to greater than 60% in majority of patients, with some patients achieving LDL-C less than 20 mg/dL.[9,10]

Both agents have been shown to prevent secondary events in high-risk patients when combined with statins. In the ODYSSEY Outcomes trial, alirocumab plus a high-intensity or maximally tolerated statin was compared with high-intensity or maximally tolerated statin monotherapy in patients after a recent ACS event. The combination of alirocumab plus the statin resulted in a lower incidence of the composite endpoint of death from coronary heart disease, nonfatal myocardial infarction, fatal or non-fatal ischemic stroke or unstable angina requiring hospitalization compared to statin monotherapy (9.5% vs 11.1%; p<0.001; NNT= 62). The average LDL in the alirocumab group was 48 mg/dL after 12 months; adverse events were similar between the groups.[11] In the FOURIER trial, evolocumab added to statin therapy significantly reduced the compositive of CV death, MI, stroke, hospitalization for unstable angina or coronary revascularization when compared to statin monotherapy in patients with ASCVD (9.8% vs 11.3%; p<0.001; NNT=66). Similar to ODYSSEY Outcomes trial, the combination therapy resulted in lower LDL-C than monotherapy (30 mg/dL vs 86 mg/dL at 48 months) with no significant difference related to adverse events.[12]

The 2018 ACC/AHA guidelines recommend addition of PCSK9 inhibitor after ezetimibe due to lack of long-term safety analysis and cost effectiveness. Based on 2018 pricing, PCSK9 inhibitors were estimated to have incremental cost-effectiveness ratios from $141,700 to $450,000 per quality-adjusted life-year (QALY) added. This means PCSK9 inhibitor use would be more costly than any cost saving associated with reduction in cardiovascular mortality.[4] Since their approval in 2015, the cost of PCSK9 inhibitors has dropped more than 60%. Based on this new analysis, use of PCSK9 inhibitors in patients with very high risk ASCVD with LDL-C ≥ 70 mg/dL and high risk ASCVD with LDL-C ≥ 130 mg/dL is considered reasonable (<$100,000 per QALY).[13]

PCSK9 inhibitors are self-administered as subcutaneous injections every 2-4 weeks. Both should be refrigerated; however, they may be stored at room temperature for a maximum of 30 days. The dosing varies based on indication, LDL-C response and patient preference. Drug-drug interactions are limited as most oral medications do not affect the pharmacodynamics

or pharmacokinetics of evolocumab or alirocumab. The most common adverse reactions are injection site reactions. Evolocumab should be avoided in patients with latex allergy as the needle cover does contain latex. With long term use of monoclonal antibodies, there is a concern that patients may develop neutralizing antibodies after long term use. However, both agents are fully human and few cases of this have been reported. Patients should be monitored to ensure continued LDL-C response to treatment. Given the similarities between the two agents, choice of the specific PCSK9 inhibitor used is often based on insurance coverage.[9,10]

Icosapent Ethyl

Mixed docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) containing products have been used for years to treat hypertriglyceridemia but none of these products has shown reduction in cardiovascular morbidity or mortality. Icosapent ethyl is an EPA only product indicated for use in patients with ASCVD or DM with additional risk factors and triglycerides ≥ 150mg/dL. EPA reduces hepatic VLDL production and enhances VLDL clearance without increasing LDL. In clinical trials, patients on icosapent ethyl had a 18% reduction in triglycerides and a 3% increase in LDL at 12 months.[14]

REDUCE-IT explored the effect of icosapent ethyl on cardiovascular death, myocardial infarction, stroke, coronary revascularization or hospitalization for unstable angina in patients with established cardiovascular disease or diabetes and other risk factors with controlled LDL-C (LDL-C >40mg/dL and ≤100mg/dL) and elevated TG (TG ≥ 150mg/dL and <500 mg/dL). The event-driven trial included 8,179 patients. After 5 years, icosapent ethyl resulted in a 25% relative risk reduction in the primary composite endpoint (HR 0.75, 95% CI 0.68-0.83, NNT: 21) despite no change in LDL-C.[15]

Icosapent ethyl is available as 500mg or 1000mg capsules. The recommended dose is 4 grams daily in two divided doses. Caution should be used in patients with a fish or shellfish allergy. Omega-3 fatty acids may cause prolongation of bleeding time; additional monitoring may be required for patients on anticoagulants or antiplatelets. In the clinical trials, there was an increased risk of atrial fibrillation related hospitalizations in the icosapent ethyl group compared to placebo. Patients should be monitored for any symptoms of atrial fibrillation. Other adverse events may include musculoskeletal pain, peripheral edema, constipation, and gout.[14]

Bempedoic Acid

Approved in 2020, bempedoic acid (Nexletol™) is an oral non-statin therapy that inhibits cholesterol synthesis in the same pathway as statins. Bempedoic acid inhibits ATP-citrate lyase (ACL), which is two steps upstream of HMG-CoA reductase, the therapeutic target of statins. Unlike statins, bempedoic acid is a prodrug that is activated by enzymes only available in the liver and not in muscles. The lack of active metabolite in muscle makes this an attractive option for patients who experience statin-associated muscle symptoms (SAMS). It is currently FDA approved in combination with maximally tolerated statin in patients with history of ASCVD or heterozygous familial hypercholesterolemia (HeFH). It is also commercially available as a combination product with ezetimibe (Nexlizet).[16]

The efficacy of bempedoic acid was established in multiple phase 3 trials. CLEAR Wisdom and CLEAR Harmony evaluated the addition of bempedoic acid to maximally tolerated statin in patients with ASCVD, HeFH or both. Patients in CLEAR Wisdom saw an additional 13.9-17.4% reduction in LDL-C at 12 weeks.[17] CLEAR Harmony showed similar results with bempedoic acid reducing LDL-C 18% further than placebo.[18] The CLEAR Serenity trial evaluated bempedoic acid in patients with statin intolerance. Bempedoic acid monotherapy resulted in a 21.4% reduction in LDL-C in these patients.[19] Despite these results, there is currently not an FDA approved indication for statin intolerant patients. The phase 3 cardiovascular outcomes trial, CLEAR Outcomes was published in April 2023. The trial included over 13,970 patients with cardiovascular disease or who are at high risk of cardiovascular disease and were unable or unwilling to take statins due to unacceptable adverse events. The incidence of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke or coronary revascularization was significantly lower with bempedoic acid than with placebo (11.7% vs 13.3%; p=0.004).[20]

Nexletrol™ is dosed as 180mg tablet once daily. It should be prescribed in combination with maximally

tolerated statin however, it is contraindicated with simvastatin doses greater than 20mg and pravastatin doses greater than 40mg. Due to interaction with OAT2 in the kidney, approximately one-fourth of patients may experience elevation in uric acid levels, so Nexletrol should be used with caution in patients with history of gout. Additional adverse reactions include tendon rupture, benign prostatic hyperplasia, atrial fibrillation, increased serum creatinine, and increased liver enzymes. All lab values returned to baseline after discontinuation of therapy.[16]

Inclisiran

Inclisiran (Leqvio™) is the first therapy used to reduce cholesterol that utilizes messenger RNA (mRNA) technology. mRNA is a single stranded ribonucleic acid that is responsible for coding protein synthesis. This approach has several advantages including potential higher therapeutic efficacy due to longer lasting expression compared to traditional drugs and lower toxicity because they do not need to enter the cell nucleus to function properly.[21] Inclisiran is a small interfering RNA (siRNA). Once inside the hepatocytes, inclisiran interrupts and breaks down the mRNA responsible for PCSK9 protein that promotes LDL receptor degradation. This results in an increase of LDL receptors on hepatocytes and less circulating LDL-C. Inclisiran differs from PCSK9 inhibitors by preventing formation of PCSK9 enzyme intracellularly.[22]

The clinical effects of inclisiran in patients with ASCVD or ASCVD risk factors was explored in ORION-10 and ORION-11. To be included, patients must have a history of ASCVD or have risk factors for ASCVD and fail to reach goal LDL on maximally tolerated statin. A total of 3178 patients were followed for 18 months. At 17 months, inclisiran resulted in a 52% reduction in LDL-C compared to placebo in ORION-10 cohort and 49.9% in ORION-11. Injection site reaction was the only adverse event reaching statistical significance in these trials. Both of these trials included exploratory secondary endpoints for CV related composite endpoint of CV death, signs/symptoms of cardiac arrest, nonfatal MI or stroke. There was a trend towards inclisiran lowering these events but to date, the effect of inclisiran on cardiovascular morbidity and mortality is unknown.[23] Two ongoing cardiovascular outcome trials, ORION-4 and VICTORION-2 Prevent, are underway and are expected to be completed in 2026 and 2027 respectively.

Inclisiran is supplied as a pre-filled syringe that should be administered by a healthcare professional. It is administered subcutaneously at day 0, day 90 then every 6 months thereafter. If a dose is missed by more than 3 months, a patient should restart the dosing schedule as if naïve to inclisiran. LDL-C reduction can be seen within 14 days of administration of inclisiran. Adverse reactions in clinical trials were minimal, with most related to injection site reactions. There are no contraindications, warnings or drug-drug interactions associated with inclisiran.[22]

Administration within a healthcare providers office introduces additional considerations for providers and patients. While this approach may improve adherence and add minimal burden to patients, it does require different logistical considerations than self-administered medications. There are two approaches for provider offices to utilize with inclisiran: buy and bill or white bag. The buy and bill approach involves the provider ordering inclisiran from a wholesaler, administering to patient and billing the medical insurance for medication and administration. With the white bag approach, the provider sends a prescription to specialty pharmacy. The specialty pharmacy will bill inclisiran through the patient's pharmacy benefits plan and deliver to the provider. There are many pros and cons to both approaches and a team-based approach should be used to create appropriate workflows.

Clinical Approach to Patient Care

Since the release of the 2018 ACC/AHA cholesterol guidelines, there have been new medications and new data available on using non-statin therapies. In 2022, ACC released an expert consensus decision pathway on the role of non-statin therapies in patients with ASCVD. Table 2 summarizes recommendations of the 2018 guideline, while Table 3 provides information about the 2022 update. When considering addition of a non-statin therapy, the clinician should determine the patient's ASCVD risk category, appropriate LDL-C and non-HDL goals, and percent LDL-C reduction achieved with the maximally tolerated statin. In patients with ASCVD at very high risk, if achieved

LDL-C reduction is <50% and LDL-C remains > 55 mg/dL, consider increasing statin if appropriate. If the patient is already on maximally tolerated statin therapy, the choice of non-statin therapy should include consideration of available scientific evidence for ASCVD-risk reduction benefit, safety and tolerability, potential for drug-drug interactions, efficacy, cost, adherence potential, and patient preference. (TABLE 4) Based on IMPROVE-IT, FOURIER and ODYSSEY Outcomes trial data, appropriate choices for initial additional therapy include ezetimibe, alirocumab or evolocumab. Ezetimibe may be preferred in patients who require <25% additional reduction in LDL, prefer oral medication or have cost concerns. PCSK9 monoclonal antibodies (mAb) provide greater LDL reduction and may improve adherence with every 2-4 week dosing. If additional LDL-C lowering is required, more than one non-statin agent may be used. Ezetimibe should be combined with PCSK9 mAb initially. Bempedoic acid can be considered if patient is statin intolerant or prefers to avoid injectable medications. Inclisiran can be substituted for PCSK9 mAb, however, the effect of inclisiran on cardiovascular mortality is still unknown. Inclisiran provides a viable option for patients with poor adherence or unable to self-inject PCSK9 mAb.[24]

In patients with ASCVD who do not meet criteria for very high risk, the goal LDL-C reduction with maximally tolerated statin is ≥50% and LDL <70 mg/dL. If patients are unable to reach goal, a shared decision-making approach is preferred given the gap in clinical trial evidence with this patient population. Continuation of statin monotherapy is a reasonable approach. If a decision is made to add additional non-statin therapy, ezetimibe is the recommended initial agent. PCSK9 mAb, bempedoic acid and inclisiran may be considered for similar situations as discussed above.[24]

Many patients are able to meet LDL-C goal with high-intensity statin; however, they may still benefit from additional non-statin therapy. Once patients meet LDL-C goal, providers should evaluate the patient's non-HDL and TG. If non-HDL is >100 mg/dL or TG >150 mg/dL, additional therapy should be considered. Icosapent ethyl focuses on lowering TG and non-HDL with little effect on LDL-C. Adding icosapent ethyl to statin therapy has been shown to reduce risk of additional ASCVD events.[15] Of note, prescription and OTC fish oil products are not equivalent to icosapent ethyl and should not be substituted. Fibrates and niacin are effective at reducing TG as well but have not shown the same cardiovascular benefits as icosapent ethyl. These agents should be reserved for patients with TG > 500 mg/dL.

Role of Pharmacist

With the increased utilization of non-statin therapies, pharmacists can be a valuable resource to the healthcare team treating these complex patients. Several studies have demonstrated the positive impact of pharmacists on patients achieving LDL-C goals. Bozovich and colleagues compared the percentage of patients reaching LDL-C goal as well as compliance with lipid panels and medication refills between patients managed by a pharmacist versus usual care with a cardiologist. After 6 months, the pharmacist managed-arm resulted in a significant increase in percent of patients reaching LDL-C goal (69% vs 50%) and 80% compliance with lipid panels and medication refills.[25] A similar study utilized pharmacists in community pharmacies in Canada to manage adults with uncontrolled dyslipidemia. The pharmacists had expanded scopes of practice that allowed for prescribing of medications. Patients in the pharmacist intervention group had a mean reduction in LDL-C of 43.3 mg/dL whereas the usual treatment group had only a 16.2 mg/dL reduction.[26]

Pharmacists also play a role in access and compliance with non-statin therapies. The majority, with the exception of ezetimibe, of non-statin therapies require insurance prior authorization or step therapy. Pharmacists are experts in navigating these barriers to access. During the first year PCSK9 mAb were FDA approved, more than 50% of patients were denied coverage for their insurance and if approved, 34.7% of patients did not fill the prescription.[27] Utilizing pharmacists to navigate the process, ensure appropriate prescribing, and counseling on adherence can result in increased access to these therapies for patients. The approval of inclisiran brought a new set of criteria for clinicians to navigate. Patients can access inclisiran through their either medical or pharmacy benefits. For patients who use medical benefits, the provider buys inclisiran from a wholesaler, administers the medication, and bills the insurance

directly for the medication and administration. With pharmacy benefits, the provider will send the prescription to a specialty pharmacy. The specialty pharmacy will fill the prescription, bill the insurance for inclisiran and send the medication to the patient or provider. The provider will administer the injection and bill only for administration. Both of these methods are complex. Having a dedicated clinician, such as a pharmacist, to manage this process can result in better patient outcomes and higher provider and patient satisfaction.

Conclusion

While statins remain the mainstay of secondary prevention treatment in patients with ASCVD, addition of non-statin therapies is appropriate in many patients. Pharmacists can play a vital role in ensuring appropriate therapy is prescribed, removing barriers to access and improving adherence.

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CONTINUING EDUCATION ARTICLE QUESTIONS

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When Statins Are Not Enough: Role of Non-Statin Therapies in Secondary Prevention of ASCVD

Instructions: After reading the continuing education article, quizzes can be taken at mspharm.org or detach this page. A grade of 70% or better is required to earn 2.0 hours of continuing education credit. This is a free service for MPhA members.

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Use the following patient case for Questions 1- 4

G.T. is a 68 y/o male with a PMH significant for T2DM, STEMI s/p PCI in 2019, hypothyroidism and dyslipidemia. His current medication list includes metformin 1000mg BID, levothyroxine 75 mcg daily, aspirin 81mg daily, rivaroxaban 2.5mg BID, rosuvastatin 20mg daily, lisinopril 40mg daily, and carvedilol 3.125mg BID. He was recently seen by his cardiologist for 6 month follow up. His cholesterol panel was as follows: TC- 169 mg/dL, TG- 165 mg/dL, HDL- 40 mg/dL, LDL-C 96 mg/dL (baseline LDL-C off statin: 160 mg/dL) The patient is referred to the pharmacist for further dyslipidemia management.

1. According to the 2022 ACC expert consensus decision pathway, which ASCVD risk category best describes G.T?
    a. Primary Prevention with primary severe hypercholesterolemia (LDL>190 mg/dL)
    b. Primary Prevention with diabetes
    c. Secondary prevention NOT at very high risk
    d. Secondary prevention at very high risk

2. According to the 2022 ACC expert consensus decision pathway, which of the following would be the most appropriate LDL-C treatment threshold for adding non-statin therapy for G.T?
    a. <55 mg/dL
    b. <70 mg/dL
    c. <85 mg/dL
    d. 50% reduction from baseline

3. Utilizing the 2018 ACC/AHA cholesterol guidelines, of the following would be the most appropriate next step for managing G.T.'s cholesterol?
    a. No change required; patient on high intensity statin with >50% LDL-C reduction from baseline
    b. Increase to rosuvastatin 40mg daily
    c. Add Ezetimibe 10mg daily
    d. Add icosapent ethyl 2 gm BID

4. G.T. is started on evolocumab 140mg SC every 2 weeks in addition to rosuvastatin 20mg daily. At his 3 month follow up appointment, he admits he has not been compliant with injections; administering the medication once a month instead of every 2 weeks. Which of the following recommendations would be most appropriate for G.T.?
    a. Continue evolocumab 140mg SC once monthly
    b. Increase evolocumab to 420mg SC once monthly
    c. Change evolocumab to alirocumab 150mg SC once monthly
    d. Change evolocumab to bempedoic acid 180mg po daily

5. Based on the REDUCE-IT trial, which of the following would be an accurate statement?
    a. Icosapent ethyl resulted in a significant reduction in LDL-C AND reduced cardiovascular events when added to statin therapy.
    b. Icosapent ethyl resulted in a significant reduction in LDL-C BUT did NOT reduce cardiovascular events when added to statin therapy.
    c. Icosapent ethyl resulted in a significant reduction in TG AND reduced cardiovascular events when added to statin therapy.
    d. Icosapent ethyl resulted in a significant reduction in TG BUT did NOT reduce cardiovascular events when added to statin therapy.

6. A patient presents to your pharmacy with a new prescription for alirocumab 150mg every 2 weeks. She has a PMH significant for PAD and is currently taking atorvastatin 80mg daily and ezetimibe 10mg daily for cholesterol management. She has a documented latex allergy. Which of the following would be an appropriate patient counseling point for alirocumab?
    a. Alirocumab should be administered as an IM injection.
    b. The patient should avoid use of alirocumab due to latex allergy.

c. Alirocumab can only be administered in the abdomen.
d. Alirocumab is stable at room temperature for up to 30 days.

7. A patient calls the pharmacy complaining of pain, redness and swelling in the left big toe. He asks the pharmacist to review his medications for a potential cause. You review his chart and notice he started Nexlizet 4 weeks ago. His other medications include simvastatin 20mg daily, HCTZ 25mg daily, and amlodipine 10mg daily. Based on symptoms, which of the following is the MOST LIKELY cause?
    a. Ezetimibe
    b. Bempedoic acid
    c. Simvastatin
    d. Hydrochlorothiazide
    e. Amlodipine

8. A patient is seen in clinic for follow up inclisiran injection. He is scheduled for his 3rd injection. His last appointment was 8 months ago. Which of the following is the most appropriate recommendation for the patient to maintain the correct dosing protocol?
    a. Restart dosing schedule as if patient is naïve to inclisiran.
    b. The patient missed the dose by less than 3 months; give dose today and resume every 6-month schedule.
    c. The patient missed the dose by more than 1 month; give the patient two injections today then resume normal schedule.
    d. Change inclisiran to icosapent ethyl to improve compliance.

Use the following patient case for Questions 9-11

J.P is a 55 y/o male with a history of PCI s/p STEMI in 2018. He was placed on atorvastatin 80mg, valsartan 160mg, clopidogrel 75mg, and ASA 81mg at that time. He has no significant PMH. He is at his cardiologist's office for a routine 6 month follow up. Lipid panel shows TC- 175mg/dL, TG- 190mg/dL, HDL- 35 mg/dL, LDL- 102 mg/dL. The cardiologist consults the clinical pharmacist for recommendations for J.P.'s cholesterol medication.

9. Which of the following would be the most appropriate LDL-C treatment threshold for adding non-statin therapy for J.P.?
    a. <55 mg/dL
    b. <70 mg/dL
    c. <85 mg/dL
    d. 50% reduction from baseline

10. You recommend adding ezetimibe 10mg daily to J.P.'s regimen. What would be the expected additional LDL reduction achieved with atorvastatin 80mg and ezetimibe 10mg combination?
    a. 7-10%
    b. 20-25%
    c. 30-40%
    d. 50-55%

11. J.P. returns to the clinic 6 months later. He has been compliant with atorvastatin 80mg and ezetimibe 10m daily and experienced no adverse events. His lipid panel shows TC- 154 mg/dL , TG- 175 mg/dL, HDL- 38 mg/dL, LDL- 81 mg/dL. AST and ALT are WNL. Which of the following would be the most appropriate treatment option for J.P.?
    a. No additional therapy needed; continue atorvastatin and ezetimibe
    b. Discontinue ezetimibe and begin alirocumab 300mg SQ monthly
    c. Continue ezetimibe and atorvastatin and add inclisiran
    d. Continue ezetimibe and atorvastatin and add icosapent ethyl

12. A physician read a recent news article related to the cost of PCSK9 inhibitors. Which of the following statements would be the most accurate description related to cost of treatment with a PCSK9 inhibitor?
    a. PCSK9 inhibitors have an incremental cost-effectiveness ratio of >$100,000 QALY for all patients
    b. PCSK9 inhibitors have an incremental cost-effectiveness ratio of >$100,000 QALY for patients with very high risk ASCVD
    c. PCSK9 inhibitors have an incremental cost-effectiveness ratio of <$100,000 QALY for all patients
    d. PCSK9 inhibitors have an incremental cost-effectiveness ratio of <$100,000 QALY for patients with very high risk ASCVD

Use the following patient case for Questions 13-14

P.W. is a 70 y/o female. She is referred to the pharmacist the Cardiovascular Risk Reduction Clinic. Her PMH is significant for TIA in 2021, PAD, osteoarthritis, and mild dementia. She is currently taking rosuvastatin 5mg daily. She was unable to tolerate higher doses due to myalgias. Her lipid panel shows TC- 186 mg/dL, TG- 205 mg/dL, HDL- 33 mg/dL and LDL 112 mg/dL. The cardiologist prescribed Praluent 75mg every 2-week subcutaneous injections, however, the patient did not start due to difficulty with self-injection.

13. Which of the following would be the MOST APPROPRIATE recommendation for P.W.?
    a. Discontinue Praluent; initiate Repatha
    b. Discontinue Praluent; initiate ezetimibe
    c. Discontinue Praluent; initiate inclisiran
    d. Change Praluent to every 4 week injection

14. P.W. returns to clinic for her 6 month follow up. She is now compliant with her lipid lowering therapy (rosuvastatin plus agent from Question 13). Her lipid panel shows TC- 126 mg/dL, TG- 186 mg/dL, HDL- 36 mg/dL, LDL- 53 mg/dL. What is the most appropriate recommendation at this visit?
    a. Continue current therapy
    b. Add Vascepa to current therapy
    c. Add Nexletrol to current therapy
    d. Discontinue non-statin therapy; continue rosuvastatin monotherapy

15. White bagging can best be described as:
    a. Pharmacy billing and sending a medication to physician office for administration
    b. Pharmacy billing and sending a medication to patients to bring to physician office for administration
    c. Pharmacy billing and sending a medication to a patient for self-administration
    d. Physician buying a medication from a wholesaler and directly charging patient's insurance

Abbreviation Table for Quiz

ALT	Alanine transaminase
AST	Aspartate aminotransferase
BID	Twice a day
HDL	High density lipoprotein
IM	Intramuscular
LDL	Low density lipoprotein
PAD	Peripheral arterial disease
PCI	Percutaneous coronary intervention
PMH	Past medical history
SC	subcutaneous
STEMI	ST-elevation myocardial infarction
T2DM	Type 2 diabetes mellitus
TC	Total cholesterol
TG	Triglycerides
TIA	Transient ischemic attack
WNL	Within normal limits

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Invoice Audits Are on the Rise – Are You Prepared for Success?

Most pharmacies have grown accustomed to desk audits and providing copies of prescriptions, signature logs, and even copay collection records to PBMs upon request. Additionally, many pharmacies can recount their most recent experience with an onsite auditor visiting their pharmacy and the numerous questions related to operations, policies & procedures, and credentialing. However, not as many pharmacies have experienced an invoice audit – the stakes are higher and honest mistakes can lead to very expensive lessons in the process.

PAAS National® analysts have helped our members navigate countless invoice audits. Our analyst team is here to assist you through the audit process from start to finish and that includes getting things done correctly long before the audit ever comes your way. Follow the tips below to have the most success.

PAAS Tips:

- Carefully evaluate your wholesalers/suppliers to ensure they are legitimate
  - NABP Accredited Drug Distributors can be found here[1]
  - Wholesalers licensed in your state can be found here[2]
  - Remember that OTC diabetic test strip manufacturers only sell their products to "authorized distributors".
    - Abbott https://www.diabetescare.abbott/support/distributors.html
    - Ascensia https://www.ascensiadiabetes.com/ (click on "distributors" at the bottom of the page)
    - LifeScan www.genuineonetouch.com
    - Roche https://rxvp.accu-chek.com/welcome/adr_list
    - Trividia HealthTM https://www.trividiahealth.com/where-to-buy/
- Limit purchases from other pharmacies to the minimum necessary
  - Drug Supply Chain Security Act (DSCSA) pedigree information is required unless purchase is (1) intra-company or (2) to fulfill a specific patient need
  - Full transaction details are required for audit purposes. Documentation should include:
    - Pharmacy name, address, and NCPDP number transferring from
    - Drug name, quantity, lot number, expiration date, and NDC number should all be included on the transfer invoice
    - Date of transfer and date of receipt of drug
    - Reason for transfer (e.g., complete Rx #1234)
    - Method or proof of payment (check # or credit card receipt)
- Ensure pharmacy staff are billing the correct quantity based on NCPDP billing standards – when in doubt, call PAAS for help
- Every claim billed must have NDCs that match the physical product being dispensed
  - No exceptions, all 11 digits matter
  - Includes all compound ingredients
  - PAAS recommends using barcode scanner to confirm NDC accuracy in pharmacy workflow
- Confirm the pharmacy is appropriately reversing claims that are not dispensed

PAAS National® is committed to serving community pharmacies and helping keep hard-earned money where it belongs. Contact PAAS today at (608) 873-1342 or info@paasnational.com to see why PAAS Audit Assistance membership might be right for you.

By Trenton Thiede, PharmD, MBA, President at PAAS National®, expert third party audit assistance and FWA/HIPAA compliance.

References:

1. https://nabp.pharmacy/programs/accreditations-inspections/drug-distributor/accredited-drug-distributors/
2. https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses

Mississippi Pharmacists Association

MEMBERSHIP FORM

Your membership matters to pharmacy in Mississippi

Title: ☐ Mr. ☐ Mrs. ☐ Ms. ☐ Dr.

Today's date: _____ /_____ /_____

Name:

_____
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Work Email: _____

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Dues and Contributions:

☐ Student	$0
☐ Pharmacist – first year of practice	$0/first year
☐ Pharmacist	$150/year
☐ Pharmacy Technician	$25/year
☐ Joint Pharmacist (husband/wife)	$200/year
☐ Pharmacist – retired and over 65	$75/year
☐ Non-pharmacist/Associate	$100/year

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☐ Mississippi Pharm-PAC $20 / $50 / $100

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