NAPPSA DIGEST

The News Magazine of the Nigerian Association of Pharmacists and Pharmaceutical Scientists in the Americas

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Extending the Reach of our Voice

Celebrating the launch of NAPPSA's Official Journal American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS)

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NAPPSA Digest

NAPPSA Digest is a quarterly publication of the Nigerian Association of Pharmacists and Pharmaceutical Scientists in the Americas.

MESSAGE from THE PRESIDENT

NAPPSA News Magazine, since its inception, has been of high quality and has provided valuable information for both external and internal audiences. I would like to thank the editorial team under the leadership of Dr. Anayo M. Ukeje and Immediate Past President Dr. Anthony Ikeme for their exemplary work. Furthermore, I hereby express my profound gratitude to all the contributors without whom there will be nothing to publish and share.

Despite the uncertainty associated with the pandemic, the 15th Annual NAPPSA Scientific Conference and Exposition was held in Baltimore, in September. Overall, it was well attended and a great success with participants from North America, Europe and Nigeria. My immense gratitude goes to DC, Maryland, Virginia (DMV) Local Organizing Committee under the leadership of Pharm. Gbenga Olajide and Dr. Nina Mezu-Nwaba for hosting a successful event.

I would like to seize this opportunity to provide highlights of my recent visit to Nigeria in November, when NAPPSA delegates attended the annual conference of the Pharmaceutical Society of Nigeria (PSN) and participated in other meetings and interviews. Prior to the PSN conference, we had an opportunity of a courtesy visit with Her Excellency Hajiya Dr. Aisha Muhammad Buhari in Abuja.

We commended her on her exceptionally unique agenda known as Future Assured Initiative, that is geared towards preparing of every girl child in Nigeria via education to become a leader in science and technology.

During a presentation at the Nigeria Academy of Pharmacy about the expanding roles of pharmacists in primary healthcare, I emphasized that community pharmacists should be encouraged to assist with initiatives such as vaccinations, family planning, health education and many others. Fifteen of our colleagues including our own Dr. Nkere Ebube were inducted as fellows of the Nigerian Academy of Pharmacy and Dr. Kunle Tometi was inducted as a fellow of the Pharmaceutical Society of Nigeria.

During my tenure, I will continue to support pertinent initiatives in the ten-year strategic plan in addition to advancing the pharmacy practice model and education in Nigeria. This will involve building upon the current clinical pharmacy program initiatives in collaboration with critical stakeholders in Nigeria with an emphasis on restructuring the PharmD curriculum and post-doctoral training to align with global best practice standards with a focus on patient-centered pharmaceutical care.

With the unique diversity of our membership, I hereby encourage everyone to utilize this medium to publish best practices and novel ideas in the field of pharmacy practice and pharmaceutical science. I commend NAPPSA members for their commitment and continued support of NAPPSA in various areas of their expertise.

Warm regards,

Teresa Pounds

Teresa Pounds, PharmD

NAPPSA President

FROM the EDITOR'S DESK

NAPPSA Digest, volume 1, number 4 edition of Q4 2021 is a culmination of relentless efforts of the editorial team to grow and sustain the quarterly publication of quality "NAPPSA Digest". This masterpiece is another collector's item full of informative News and articles. It also celebrates the launch of NAPPSA Official Journal, American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS), titled "Extending the Reach of our Voice".

This edition focuses on the NAPPSA Journal intended to catalyze and accelerate the extension of NAPPSA voice globally, particularly in the areas of medical, biological, pharmaceutical and related healthcare-technology fields of research, development, regulation and commercialization of pharmaceutical products". This effort is complemented by the establishment of "NAPPSA Endowment Fund" highlighted in volume 1, number 2 edition. The proceeds from these activities including NAPPSA 5k run/walk and B-2-B will fund the well-articulated "NAPPSA 10-Year Strategy Plan" highlighted in volume 1, number 1 edition.

The edition also featured the "Insight into Regulatory Intelligence in the Pharmaceutical Industry by Charles Jagun"; The launching of the "NAPPSA CARES initiative" at 2021 annual conference and exhibition in Maryland. The initiative is part of NAPPASA's resolve to positively impact any local community where NAPPSA conference is held. Our "Race to 1 Million Dollars", the NAPPSA 5k run/walk was organized for fundraising to implement NAPPSA 10-Year Strategy Plan. Highlighted also is NAPPSA 2021 elections and leadership changes.

The therapeutic update section draws our attention to: "Heart Failure", "Hypertension" COVID-19 Vaccine", Blood Pressure-Lowering Drugs" and Blood Pressure Control etc.

Our regulatory updates section covers a wide range of new regulatory Guidance, EUA updates, approvals, and public health information including clinical trials. Also featured are the regulars; Career spotlight, Blogger's Corner and NAPPSA Events Calendar. The content brings 2021 into focus, keeps readers abreast of NAPPSA activities and what is going on in the areas of interest for NAPPSA and its readership.

My special thanks to NAPPSA President, Teresa Pounds, PharmD for the opportunity given to the Newsletter editorial team to continue the work unimpeded after the change of leadership. Big shout out to our IPP, Dr Anthony Ikeme for his continuing efforts in providing content, editing, design and production of the NAPPSA Digest News Magazine.

My deep appreciation goes to Patrick Nwakama, who reviews every article and provides regulatory updates I also thank the Editorial Team; Victoria Oshunkentan, Victoria Adu and all the contributors who provided the content to the Newsletter in the form of articles or updates, for their sustained efforts in maintaining the quality of the News Magazine, the NAPPSA Digest. I will continue to rely on you for content generation editing & delivery of quality NAPPSA News Magazine.

To NAPPSA Digest Readership, I say thank you. Take some time off, relax, rejuvenate, and enjoy the unique content of this 4th edition put together by the expert team of NAPPSA editors and contributors.

Best regards,

Anayo Michael Ukeje

Anayo M Ukeje, PhD/DIC

Editor-in-chief

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Extending the Reach of our Voice

Celebrating the Launch of NAPPSA Official Journal, AJPPS

By: Anthony Ikeme, PhD, Patrick Nwakama, PharmD, BCPS, Ashiwel Undieh, MPharm, PhD

> "AJPPS is an integral part of the milestone NAPPSA 10-Year Strategy Plan

Having an official peer-reviewed journal of NAPPSA, the American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS) is a core component of the Association's mission to *"Seek and propagate critical information in the medical, biological, pharmaceutical and related healthcare-technology fields to optimize the discovery, development, regulation and utilization of pharmaceutical products".* AJPPS is an integral part of the milestone NAPPSA 10-Year Strategy Plan approved by the general membership at the 2020 NAPPSA Annual Conference.

	Sub-Specialty Areas
1	Biochemistry and Biotechnology
2	Drug Evaluation and Clinical Trials
3	Drug Research and Development
4	Epidemiology and Public Health
5	Ethnomedicine and Phytomedicines
6	Medical Science and Practice
7	Microbiology and Immunology
8	Neuroscience and Behavioral Sciences
9	Nutrition and Nutraceuticals
10	Pharmaceutical and Medicinal Chemistry
11	Pharmaceutical Education
12	Pharmaceutical Technology and Manufacturing
13	Pharmaceutics and Drug Delivery
14	Pharmacology and Toxicology
15	Pharmacotherapy/Pharmaceutical Care
16	Pharmacy Profession and Advocacy
17	Physiology and Pathology
18	Veterinary Science and Medicine

The first official call for papers for AJPPS was announced in the June 2021 Issue of the NAPPSA News Magazine and the first peer-reviewed manuscript was formally accepted on November 23, 2021. The first journal articles of the first volume of AJPPS are expected to be published in January 2022. This is a significant milestone in NAPPSA's quest to establish itself as a respected leader among pharmacy and pharmaceutical science organizations.

As envisioned by the Journal founding team, AJPPS is set up as an open access, peer-reviewed journal committed to publishing high-quality articles in 18 sub-specialty areas spanning the entire spectrum of pharmacy practice and science.

AJPPS is envisioned to positively impact the pharmacy profession in three distinct ways.

Firstly, the journal's primary focus is to provide a platform for the publication of original articles that extend the boundaries of knowledge in the pharmacy and pharmaceutical science discipline and profession. AJPPS employs the peer review process, defined as *"a process of scrutinizing and validating scholarly work or research findings prior to dissemination"*[1] in making publication decisions. Peer review is intended to serve two primary purposes. Firstly, it acts as a filter to ensure that only high quality research is

published, by determining the validity, significance, and originality of the study.[2] Secondly, peer review is intended to improve the accuracy, clarity, and completeness of manuscripts before publication.[3] Through their reviews, peer reviewers provide suggestions to authors on how to improve the quality of their manuscripts, and also identify any errors that need correcting before publication.[2] In this way, AJPPS will make its mark as a high-quality contributor to pharmacy and pharmaceutical science research and discourse.

Anthony Ikeme, PhD
Chair

Ashiwel Undieh, MPharm, PhD
Editor-in-Chief

Patrick Nwakama, PharmD, BCPS
Editor-in-Chief

Sunny Ohia, PhD
Member

Otito Iwuchukwu, PhD
Member

Secondly, AJPPS joins the league of journals that cover the broad spectrum of the Pharmacy and Pharmaceutical Science continuum. This is intended to mirror the essence of NAPPSA's founding mission and the structure of her inclusive membership. It also allows for crosscutting and interdisciplinary research endeavors and publications that spans pharmaceutical care, practice, clinical research and beyond.

Thirdly, AJPPS is envisioned to be dynamic and bidirectional in its impact. It will not only publish articles that seek to translate pharmaceutical science into practice but will welcome publications that communicate practice needs to guide scientific inquiry. The integration of this feedback loop in the interaction between academic research and Practice is critical for continuous improvement, evolution of knowledge and development of the pharmacy and pharmaceutical science discipline.

> **AJPPS is positioned to serve as a galvanizing force for filling equity gaps in Global Health and Pharmaceutical Research**

AJPPS is positioned to be much more than described so far. By virtue of the circumstances of its founding, AJPPS is inevitably positioned to serve as a galvanizing force for filling some equity gaps in the Global Health and Pharma sector research enterprise. In addition, AJPPS is poised to have additional positive impact in the following ways:

- **Serve as a Platform for the promotion of True North-South Research Partnership:** The notion of partnership between the Global North and South in the evolution of global academic and scientific research, and the idea of equal positioning of Northern and Southern actors in the setting of scientific research agenda is a mirage. For the avoidance of doubt, Northern actors as used in this context, encompass what is also generally referred to as "Western actors", i.e., institutions and individuals representing the USA and Canada, Europe, Australia, and New Zealand, whereas Southern actors represent low- and middle-income countries. Academics from Southern countries report frustrations at not being consulted when the main conceptual issues of research projects are discussed. However, in the name of political

correctness, these frustrations are not spoken aloud.[4] Additionally, when partnerships provide aid or assistance to underfunded African research institutions, they are often tied with hypotheses about program priorities that Northern funders require from their Southern collaborators.[4] AJPPS is uniquely positioned to repair this anomaly. The fact that it is a journal founded by Northern-based professionals with Southern ancestral and intellectual roots means that research agenda setting, choice of topics and themes for special journal editions will not sideline Southern priorities. The journal editorial team are in a good position to foster true collaboration between Northern and Sothern actors in an equitable basis.

- **Earn the NAPPSA Global Community a Seat at the table:** As the saying goes *"If you are not at the table then you are probably on the menu."* AJPPS is a bold move that allows researchers and academicians within the NAPPSA global network the opportunity to project their research work products to the global stage. Select presenters at the NAPPSA conferences with seminal presentations can benefit from the publication of their work as part of the conference proceedings in special conference journal editions. This allows the community the opportunity to help shape the global research agenda.

- **Elevation of NAPPSA Profile and Brand:** As the official journal of the Nigerian Association of Pharmacists and Pharmaceutical Scientists in the Americas, AJPPS has raised NAPPSA's profile as a pre-eminent professional organization amongst her peers. Having an enhanced profile and brand means name recognition, open doors and access to more opportunities. It is incumbent on NAPPSA leadership to leverage this elevated platform to continue the propagation of the NAPPSA vision and objectives. NAPPSA has set the tone and is set to inspire other professional organizations to follow in their footsteps.

The Journal Management Board and the Editorial Team have worked diligently to create all the necessary infrastructure and journal management process to ensure a seamless take off.

As structured, the Journal Management Board has a total of five members, including two Editors-in-Chief. The Journal Management Board is accountable to NAPPSA Board and is responsible for monitoring, tracking and directing the financial, business and operational affairs of the Journal.

The Journal Editorial Team is headed by the Editors-in-Chief and includes the Associate Editors, Editorial Advisory Board members, and the Managing Editor. The Editors-in-Chief are independently responsible for the day-to-day operations and content management of the Journal.

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American Journal of Pharmacotherapy and Pharmaceutical Sciences

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About the Journal

The American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS) is an open access peer-reviewed journal committed to publishing high-quality articles in the field of Pharmacotherapy, Public Health, Ethnomedicine, Toxicology, Food Science, Nutrition, Biomedical and Pharmaceutical Sciences.

Review Process

The American Journal of Pharmacotherapy and Pharmaceutical Sciences has a highly rigorous peer-review process that makes sure that manuscripts are scientifically accurate, relevant, novel, and important. Authors disclose all conflicts, affiliations, and financial associations such that the published content is not biased.

Benefits

An article published in the journal can be viewed without a fee by readers all over the world. The author also gets to retain copyright to the article and the figures. This allows authors to extend their exposure in the world of medical research and get worldwide recognition for their work.

How to Submit A Manuscript

The American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS) accepts all manuscripts online via
https://editorialassist.com/#/login/ajpps
Please refer to instructions to authors available at
https://ajpps.org/for-authors/ for more information

Types of Articles

The American Journal of Pharmacotherapy and Pharmaceutical Sciences publishes manuscripts in the following categories

- Original research article
- Review article
- Case report
- Research method
- Short Communication
- Letter to the Editor
- Invited Editorial
- Commentaries

Insight into Regulatory Intelligence in the Pharmaceutical Industry

By Charles Jagun, MS, DBA

Introduction

Before pharmaceutical products (including medical devices) are allowed into distribution, they are expected to be approved by regulatory authorities. These could be national health authorities, medical product regulatory agencies, local or regional authorities. The purpose is to ensure that products available to the public are safe and effective. As product designs, development, and manufacturing change and get smarter, regulatory authorities have also become proactive and alert to guarantee pharmaceuticals' safety and effectiveness. Manufacturers and those involved in the pharmaceutical value chain must comply with the dynamic global regulatory landscape, increasing the burden on drug and medical device manufacturers. To effectively keep to date in product development and lifecycle management requirements, it is incumbent on pharmaceutical stakeholders to keep internal stakeholders informed with current information on various regulatory changes, competitive intelligence and provide input on submissions and comments on new guidance documents. Hence, having insight into regulatory intelligence to address the challenges of the steady flux of information in the pharmaceutical sector is critical to meet these challenges. Despite recognizing the essential role of RI in the survival of pharmaceutical companies, many of the companies find it challenging to allocate the much-needed resources to this function or even make provision for one.

Understanding Regulatory Intelligence

The increasing demand for pharmaceutical products has forced stakeholders to demand higher scrutiny of the pharmaceutical industry by regulators. The demand has resulted in constant issuance, revisions, and updates of regulations, policies, and standards. The flood of requirements by various regulatory agencies has become daunting, complex, and time-consuming to keep track of by companies who desire to be current. Failure to keep track or up to date with the requirements face regulatory enforcement, fines, regulatory authorities' inspections, warnings, and closure depending on the level of noncompliance. Companies need a structured regulatory intelligence strategy to facilitate regulatory and quality compliance consistency throughout the development, manufacturing, and lifecycle management of pharmaceutical products in today's fast-paced pharmaceutical industry.

The US Drug Information Association Regulatory Intelligence Working Group summarized regulatory intelligence as "the act of gathering and analyzing publicly available regulatory information. This includes communicating the implications of that information and monitoring the current regulatory environment for opportunities to shape future regulations, guidance, policy, and legislation." The good news is that companies that integrate regulatory intelligence (RI) as a critical component of their regulatory strategy can be rest assured of obtaining, analyzing, and acting on the latest requirement.

RI is an umbrella concept that comprises:

- Sourcing of regulatory information
- Analysis and interpretation
- input into management decisions and policies
- Information archive

Establishing a RI function or dedicated resource in the company facilitates the coordination of regulatory information from all sources. Speakers at conferences and symposia have reiterated RI's critical role in ensuring companies comply with regulatory requirements. The RI function is involved in impact assessments, stakeholder identification, prioritization, regulatory trending, follow-up, and evaluation of regulatory intelligence in collaboration with SMEs.

The RI also performs an essential role in gathering intelligence on competitors to maintain a competitive edge in new designs, approvals, product launches, and indications. This gives a company the critical time and opportunity to respond to a potential threat to market share. Insight into pending applications for approvals affords management the requisite information for a policy decision.

- The RI function, mostly domiciled within the research and development department of large organizations, is equally charged with the following responsibilities:

- Maintain a list of Subject matter experts (SMEs)
- After initial triage of updates, the function forwards such to the appropriate SMEs for further analysis and resolution
- Maintain a tracker to keep running log of the progress of any actionable intelligence received, track from when the information was received till the conclusion
- Perform regular follow-ups with SMEs based on the reported regulatory intelligence
- Provide updates and metrics to senior management on regulatory intelligence updates monthly or quarterly as made be appropriate for the company

Developing Regulatory Intelligence Function

Regulatory intelligence can be extracted from a wide range of information and applied for business advantage. Hence, the approach to RI function development and strategy involves collaboration with stakeholders, particularly with regulatory affairs SMEs, on the best way for obtaining and disseminating regulatory information. The schematic figure below shows the RI development timeline and milestones with critical deliverables. The SMEs could be regulatory experts for a country or region, quality experts, scientists, engineers, clinical and medical experts.

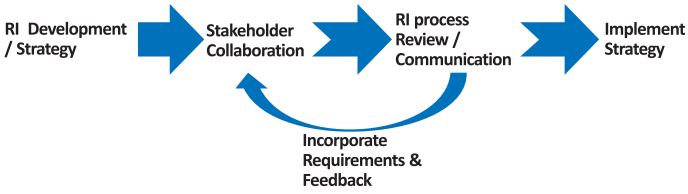

Figure 1: Establishing a RI function in a pharmaceutical company

Regulatory Intelligence Process

Generally, the RI process comprises information/data gathering from multiple sources, analysis and summarizing extracted information involving SMEs, impact assessment, dissemination, and intelligence storage. A detailed schematic representation of how regulatory information can be retrieved and converted to actionable intelligence is depicted in Figure 2.

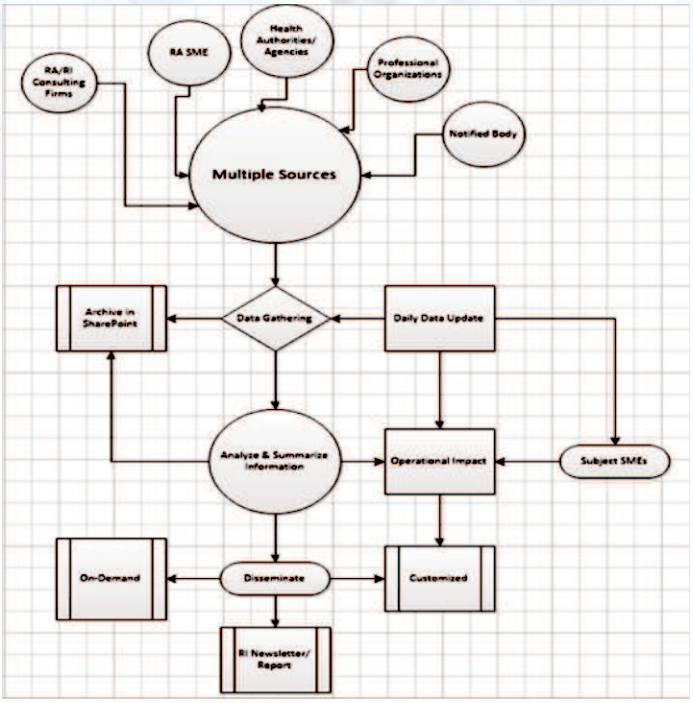

Figure 2: Sample of the typical regulatory intelligence process

Sources of Pharmaceutical Intelligence

Numerous sources and techniques (newsletters, conferences, journals, publications, press releases, etc.) may be used to obtain regulatory information globally across countries. The RI function can deploy resources within the company for gathering raw data to be processed into intelligence ready for actionable use. A third party may also provide scheduled updates globally due to the language barrier and access to critical information. Examples of sources include regulatory authorities, including Food and Drug Administration (FDA), European Medicines Agency (EMA), Health Canada, Japan Pharmaceuticals and Medical Devices Agency (PMDA), UK Medicines and Healthcare products Regulatory Agency (MHRA), Danish Medicines Agency (DMA), National Agency for Food and Drug Administration and Control (NAFDAC), Indian Central Drugs Standard Control Organization (DSCO), Brazilian Health Regulatory Agency (ANVISA), Therapeutic Goods Administration (TGA), South Africa Health Products Regulatory Authority (SAHPRA), etc. Organizations such as the World Health Organization (WHO), International Standards Organization (ISO), International Coalition of Medicines Regulatory Authorities (ICMRA), The European Association of Medical Devices Notified Bodies (TEAM-NB), Medical Device Coordination Group (MDCG), South East Asia Regulatory Network, to name a few, while examples of other resources include Techstreet, PharmaIntelligence, IQVIA, Advanced Medical Technology Association (AdvaMed), etc.

Conclusion

In conclusion, regulatory intelligence is critical to a successful regulatory strategy for pharmaceutical product development, clinical trial management, product approval, and lifecycle management in today's dynamic regulatory environment. As the global regulatory landscape continues to change, a proactive investment in information gathering and interpretation of regulatory documents ensures that companies make better decisions that lead to timely approvals, reduced delays, and staying ahead of the competition.

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2021 NAPPSA Scientific Conference Highlights

2021 Conference Summary

September 23-26, 2021

The 15th Annual Scientific Conference and Exposition of the Nigerian Association of Pharmacists and Pharmaceutical Scientists in the Americas (NAPPSA) was held in Baltimore, Maryland, USA on September 23-26, 2021. The conference theme was **"Pharmaceutical R&D and Healthcare Delivery for a Post-Pandemic World."**

The conference drew participants from North America, Europe and Africa and included pharmacists, pharmaceutical scientists, physicians, academicians from schools of pharmacy in the US and Nigeria, Regulatory experts and others. Government institutions and professional organizations represented included the Pharmacists Council of Nigeria (PCN), Pharmaceutical Society of Nigeria (PSN), National Agency for Food and Drug Administration and Control (NAFDAC), US Food and Drug Administration (FDA), Association of Nigerian Physicians in the Americas (ANPA), and International Association of Nigerian Physical Therapists ((IANPT).

The sessions included more than 20 scheduled presentations and roundtable discussions as well as three scientific poster presentations. Participants earned over 14 pharmacy continuing education (CE) credit hours. The DC, Maryland, Virginia (DMV) Local Organizing Committee (LOC) co-chaired by Gbenga Olajide and Nina Mezu-Nwaba exceeded all expectations in hospitality. The tireless efforts of the NAPPSA President, Dr Anthony Ikeme, and the LOC members were rewarded by citations from the Governor of Maryland, Larry Hogan, and the Mayor of Baltimore, Brandon Scott issued to NAPPSA, NAPPSA President, Distinguished Speakers, and key leaders of the DMV LOC.

The conference formally opened with a welcome message by NAPPSA President, Dr. Anthony Ikeme. The presentations were cutting edge and highlighted current and newer innovations to control the spread of the COVID-19 pandemic.

Day 1 opened with the Education session themed "Pharmacy Education: Greater Health Care Lessons for Pharmacy and Beyond in the COVID-19 Crisis" which took an in-depth look at the impact of the COVID-19 on Pharmacy Education and the innovations it has engendered in Pharmacy Education globally. The Education session ended with a moderated round table on "Greater Health Care Lessons for Pharmacists and Pharmaceutical Scientists in the COVID-19 Emergency and Beyond."

Day 2 featured the formal opening ceremony and the keynote session of the conference, themed "The Post-Pandemic Agenda for Pharmaceutical R&D and Healthcare Delivery". The session discussed ways to leverage the lessons of the pandemic to chart a new course for Pharmaceutical R&D to enhance its capacity to underpin healthcare delivery goals. Day 2 closed with a session on "Regulation and the Supply Chain" during which regulatory

Day 3 of the conference began with our 5K Run/Walk at the M&T bank stadium, Baltimore, Maryland. The NAPPSA Run/Walk initiated in 2020 has now become and integral part of our annual conferences as part of the efforts to raise funds towards the NAPPSA Endowment Fund. Day 3 ended with the Business-to-Business session themed "Optimizing Your Community Pharmacy Services" which included a moderated round-table that delved into ways to enhance Community Pharmacy provider status and how to achieve point of care status for your independent pharmacy.

The Final day featured a session on "Clinical Therapeutics" and covered topics in Mental Health, Convalescent Plasma, COVID-19 Vaccines and Cardiovascular Health. The Conference was also enriched with a robust Poster session which span across Days 2-3.

The conference also featured transitioning of the NAPPSA Presidency from **Dr. Anthony Ikeme** to **Dr. Teresa Pounds** as well as the election of **Mr. Emmanuel Ezirim** as President-Elect. New Board members were elected to take the positions being vacated by those board members transitioning off the NAPPSA Board.

The NAPPSA members expressed their sincere gratitude to the outgoing Board members for their service and dedication, and warmly welcomed the new members of the NAPPSA Board of Trustees.

Four scholarships of $2500 each were awarded to 4 deserving students at the gala. The Scholarships were sponsored by Auburn Pharmaceuticals, Fordoz Pharmaceuticals and the and Ukwu Family and the recipients were: Moji Awe, Ayomipo Adeyemo, Juliet Obi, and Victoria Oyanna.

The NAPPSA President, Dr. Ikeme presented the NAPPSA "Distinguished Leadership Award" to Professor Moji Adeyeye, the Director-General of NAFDAC. Other recipients of the Presidential Awards included: Dr. Patrick Nwakama, Emmanuel Ezirim, Dr. Nina Mezu-Nwaba, and Mr. Gbenga Olajide who received the "Outstanding Service Award". Similarly, Cardinal Health, Takeda Pharmaceuticals and Manny Santiago were presented with the "Friend of NAPPSA Award" for their contributions to NAPPSA progress. The incoming President, Dr Pounds also presented Distinguished Leadership Award to Dr. Anthony Ikeme the outgoing President for his extraordinary leadership.

The gala banquet ended with an Inaugural Address by the incoming President, Dr. Teresa Pounds in which she rallied NAPPSA members and pledged her support and commitment in continuing the implementation of the Ten-Year Strategic Plan and other existing NAPPSA projects such as the NAPPSA 5K Run/Walk and the B2B roadshows geared towards the Endowment Fund. She also laid out her passion and commitment to NAPPSA being in the forefront of helping to develop an advanced pharmacy practice/education model in Nigeria.

Teresa Pounds, *PharmD, BCNSP*
President, NAPPSA

Anthony Ikeme, *PhD*
Immediate Past President, NAPPSA

Aloysius C. Ibe, *DrPh*
NAPPSA Secretary

NAPPSA CARES Makes a Debut

The first order of the 2021 NAPPSA conference was the launch of the *NAPPSA CARES* initiative. As conceptualized by the Immediate Past President, Dr Anthony Ikeme, the initiative is borne out of a resolve to positively impact any local community where NAPPSA conference is held. For the inaugural edition at the 2021 NAPPSA Conference in Baltimore, Dr Ikeme, led a team of NAPPSA members to volunteer at a Baltimore Local Catholic Charity, Our Daily Bread Center.

The sum of $2000 was donated to support the great job this great charity is doing. The team also presented a copies of the NAPPSA Annual Report and the inaugural edition of the NAPPSA Digest to provide them access to more of the NAPPSA story. We also left them one of the NAPPSA Cares T-Shirts as a commemorative keep-sake to remember NAPPSA by.

Per the approval of the NAPPSA Board, *NAPPSA CARES* will become a part of the NAPPSA Tradition. The socialization of NAPPSA into the fabrics of the American society require that we make our presence felt wherever we go. This initiative also allows us to spread our value of giving and caring across America one city at a time going forward.

2021 NAPPSA 5K RUN/WALK
RACE TO $1 MILLION

Promoting a healthy habit for a good cause. Running to raise funds fo the NAPPSA Endowment Fund.

The 2021 NAPPSA 5K Walk/Run was a huge success. The NAPPSA Walk/Run was launched in 2020 to raise funds for the NAPPSA Endowment while promoting the healthy habit of exercising. It is also one of the ways we draw the attention of the local community in our host city to the NAPPSA brand, our mission, objectives, programs and projects.

The 2021 edition was special in many ways. For the first

NAPPSA ENDOWMENT FUND

time, we were able to complete the Walk/Run at our conference city in person, following the virtual format we adopted in 2020 at the peak of the pandemic. Like 2020, we successfully surpassed the six figure mark with over $100,000 (One hundred thousand dollars) raised, which took us several steps closer to the first $1M of our NAPPSA Endowment Fund.

Over 50 NAPPSA volunteers congregated at the M&T Bank stadium, Baltimore for the Walk/Run and many shared pictures and videos on the NAPPSA platforms, social media and other platforms to build awareness for NAPPSA's mission and vision. Next location for the NAPPSA Run/Walk is Tampa Florida. We can't wait.

Over $100K Raised

NAPPSA Leadership Changes Hands

Every 2 years, the leadership of NAPPSA changes guards with the assumption of office by the President-Elect and the election of a new President-Elect. The 2021 NAPPSA Scientific Conference is no different. It witnessed the transition of the NAPPSA Presidency from Dr. Anthony Ikeme to Dr. Teresa Pounds as well as the election of Mr. Emmanuel Ezirim as President-Elect. 8 Board membership slots up for election were filled by 5 newly elected Board members and 3 current members who were re-elected for another 4 year term.

New Board Member List

- Chinyere Anyanwu
- Ayotunde Fajembola
- Nonye Iwuchukwu
- Nkiru Mbionwu
- Patrick Nwakama
- Kate Okpukpara
- Chinyere Onyebuchi
- Chioma Ugwa

Alongside the remaining officials of the Executive team, these individuals serve as the NAPPSA leadership team for the next 2 years. We look forward to another phase of growth in NAPPSA under the new leadership.

Nnodum Pharmaceuticals Corporation

Product Name

- Reno Caps Softgel
- Hematogen Softgel Capsule
- Hematogen FA Softgel Capsule
- Hematogen Forte Softgel Capsule
- Iferex 150 Capsule
- Iferex 150 Forte
- Ammonium Lactate 12% Cream
- Ammonium Lactate 12% Lotion
- Vitamin D3 10,000 IU
- Prenatal Vitamin
- Ziks Arthritis Pain Relief

Reference Name

- Nephron Caps
- Chromagen
- Chromagen FA
- Chromagen Forte
- Niferex 150
- Niferex 150 Forte
- Lac-hydrin Cream
- Lac-hydrin Lotion
- Cholecalciferol 0.25mg

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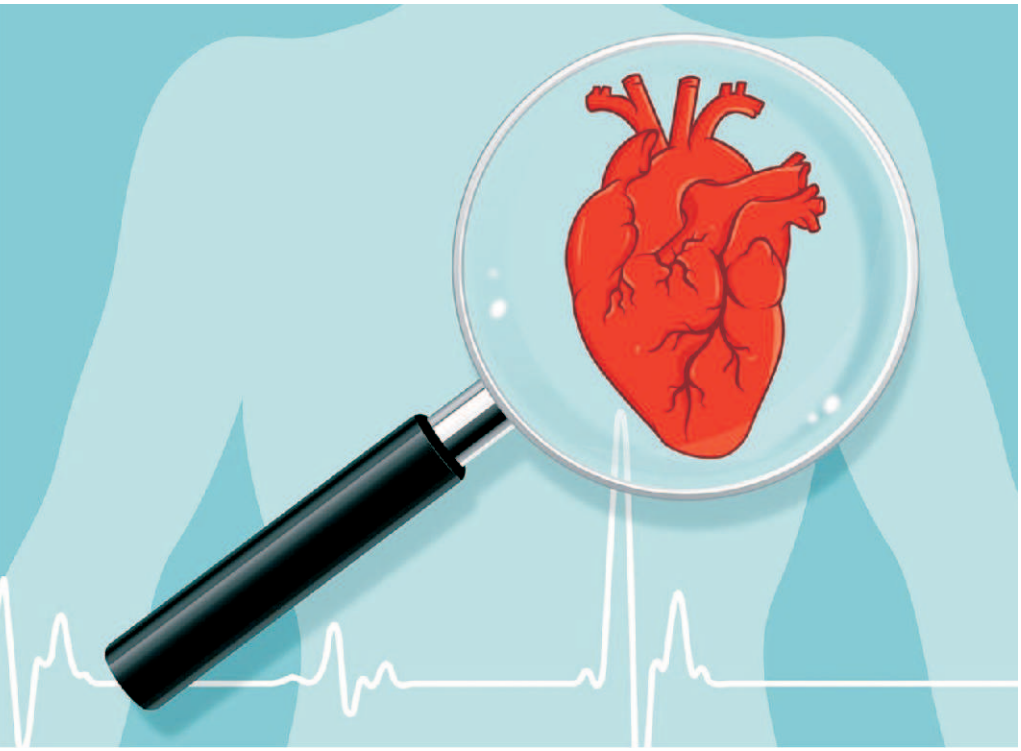

Empagliflozin in Heart Failure with Preserved Ejection Fraction (HFpEF)

One of the most important studies published in 2021 is the EMPEROR-Preserved study on empagliflozin, a sodium glucose cotransporter-2 (SGLT2) inhibitor, in patients with heart failure with preserved ejection fraction (HFpEF).[1,2] HFpEF has been highly burdensome, not only in terms of morbidity and mortality, but also in terms of lack of therapeutic options. No randomized controlled trial so far has yielded a positive result in its primary analysis. Along these lines, EMPEROR-Preserved is a true landmark study: patients with HF and an EF >40% randomized to empagliflozin, 10 mg per day (n = 2997), had a 20% reduction in the combined primary endpoint of cardiovascular death or HF hospitalization, attributable to a 30% reduction in HF hospitalizations. The difference between the two study groups emerged shortly after randomization and continued to subtly widen over the course of the study period (32 months). In terms of subgroups, the benefit of empagliflozin was most robust in those with an EF of 41% to 49%, still significant in those with an EF of 50% to 59%, but not statistically seen in those with an EF > 60%. Age $\geqslant$ 70 years, and, interestingly, BMI <30 kg/m^2 but not obesity were other noteworthy strata for empagliflozin benefit. Of note, a benefit was seen in diabetics and non-diabetics. Moreover, the benefit was on top and independent of angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, or angiotensin receptor – neprilysin inhibitor use. Mineralocorticoid antagonist use at baseline, however, had an attenuating effect on the benefit.

Based on the overall trial results, the FDA granted a breakthrough therapy designation to empagliflozin for the treatment of HFpEF.[3] At present, empagliflozin is not FDA-approved for the treatment of HFpEF, although it is for HFpEF in addition to guideline-directed therapies. This is based on the EMPEROR-Reduced trial, which showed results akin to those of EMPEROR-Preserved: mainly a reduction in HF hospitalization. This is, however, a clinically very relevant endpoint, indicating that empagliflozin decreased progression/deterioration of disease. Of note, the benefit was seen mainly in those with baseline NYHA class II, thus possibly helping not as severely symptomatic patients. This may relate, at least in part, to a less rapid decline in renal function in patients on empagliflozin, but more analyses will need to be done.

In summary, for the highly burdened population of patients with HFpEF, empagliflozin is, indeed, a breakthrough. The EMPEROR not only has new clothes, but also, he has his first useful garment. Born out of serendipity, SGLT2 inhibition emerges not only as a drug for diabetes control, but a remedy for cardiovascular integrity. EMPEROR-Preserved: one of the stories of year 2021 and one for many patients with HFpEF in years to come.

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Most Inflammatory Bowel Disease Patients Respond Well to COVID-19 Vaccine, even if Taking Immunomodulators

Only corticosteroids were associated with a slightly reduced antibody response to vaccination

Almost all patients with inflammatory bowel disease (IBD) had a good antibody response to messenger RNA (mRNA) SARS-CoV-2 vaccination, even those taking immunomodulatory medication to control their disease, according to results of the PREVENT-COVID trial, presented at the 2021 Annual Scientific Meeting & Postgraduate Course of the American College of Gastroenterology. One exception was the small number of patients taking corticosteroids in whom antibody response appeared to be slightly suppressed.

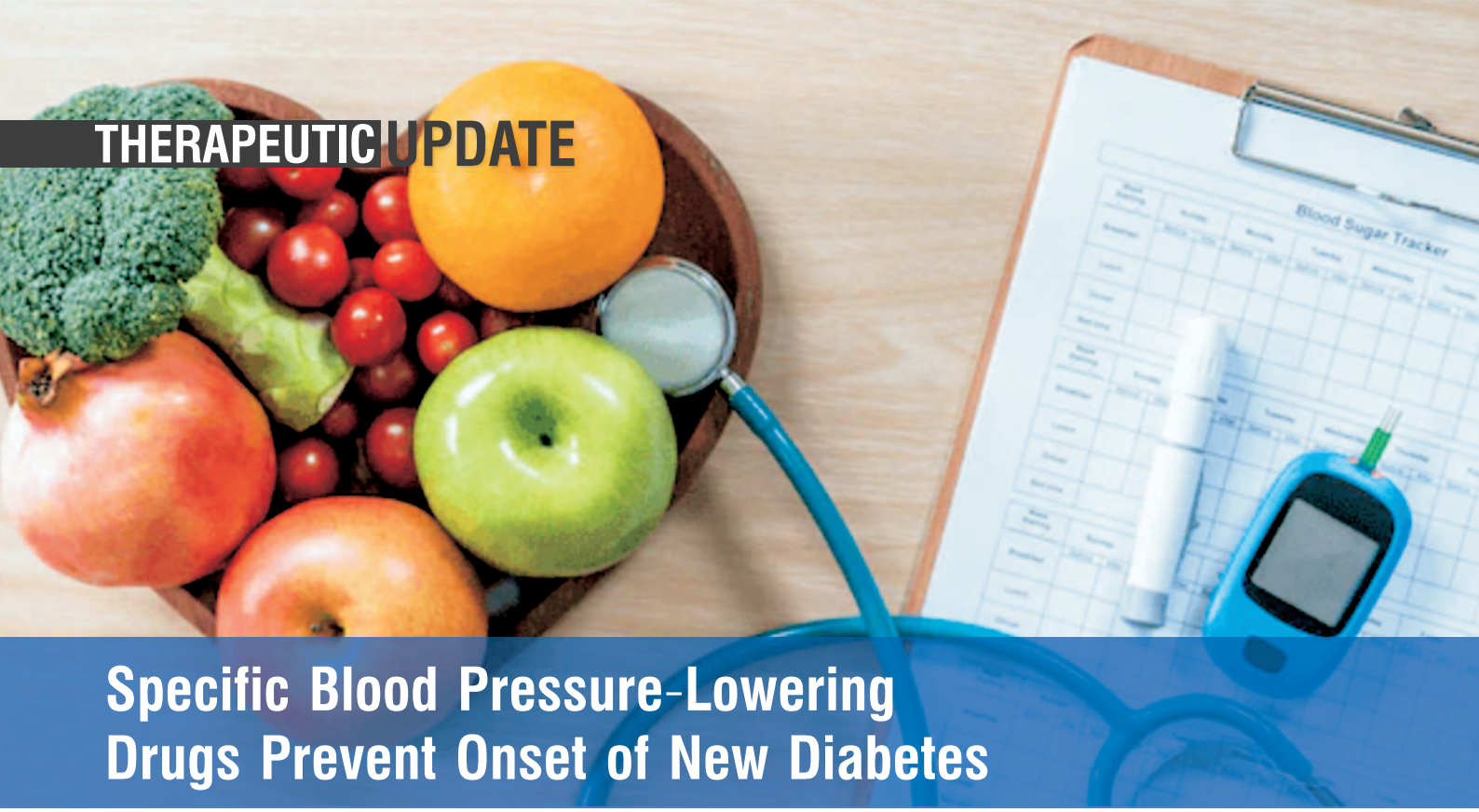
"Individuals on immunosuppression were excluded from COVID-19 vaccine clinical trials [that] led to their emergency use authorization," wrote the authors on their presentation slides. They were led by Kimberly N. Weaver, MD, of the University of North Carolina School of Medicine at Chapel Hill. "Patients with IBD on immunosuppressive medications have the potential for attenuated response to the SARS-CoV-2 vaccination."

PREVENT-COVID is an ongoing, prospective, observational cohort study examining COVID-19 vaccine effectiveness and immune response among 787 patients with IBD from all over the United States. The participants all received COVID-19 vaccines prior to June 17, 2021 and were asked to provide serum samples to evaluate antibody development 8 weeks following completion of their vaccine series. The vaccines they received could include the mRNA BNT162b2 (Pfizer-BioNTech) and 1273 (NIH-Moderna) vaccines as well as the viral vector Ad26.COV2. S (Johnson & Johnson) vaccine.

Participants are completing surveys at baseline, monthly for 2 months, and then quarterly for 2 years, which include information on specific vaccines, vaccine related adverse events, IBD medications, clinical symptoms of IBD, and development of COVID-19. The investigators are conducting quantitative analysis of anti-receptor binding domain (RBD) IgG antibodies specific to SARS-CoV-2 on serum samples. They are also conducting qualitative assessment of nucleocapsid antibodies, as an indicator of past infection. Those who report prior COVID infection and/or have positive nucleocapsid antibody tests are excluded from the study. Participants' mean age is 48 years, 73% are female, and 95% are white. Almost all (95.4%) have detectable anti-RBD antibodies. All participants received the BNT162b2 (58%) or 1273 (42%) mRNA vaccines.

Antibody response to COVID-19 vaccination was generally similar across age group, vaccine type, and IBD medication class. This included patients taking anti-TNF monotherapy, anti-TNF combination therapy, vedolizumab, ustekinumab, and combination therapy that included mesalamine, mercaptopurine, azathioprine, budesonide, and/or methotrexate. Notably, however, among the 35 patients who were taking corticosteroids, the antibody response was reduced, with 85.7% (95% confidence interval 70.6 – 93.7) having detectable anti-RBD antibodies, compared with 95.9% (95% confidence interval 94.2 – 97.1) among those who were not using corticosteroids.

"A vast majority (95%) of IBD patients had detectable anti-RBD IgG antibodies after completing mRNA SARS-CoV-2 vaccine series," concluded the authors on their presentation slides. "Most IBD medications do not prevent an initial antibody response after SARS-CoV-2 vaccination, unlike other classes of immune suppression, such as B-cell depletion therapy. Additional data forthcoming on a larger subset of participants in PREVENT-COVID study will allow for analysis of factors associated with humoral immune response, [which may help direct] potential optimization of immunization strategies."



Specific Blood Pressure-Lowering Drugs Prevent Onset of New Diabetes

Lowering blood pressure - known to prevent the vascular complications of Type 2 Diabetes - can also stop the onset of diabetes itself, although the effects vary according to antihypertensive drug class, results from a new meta-analysis show.

Angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARB) - so-called renin-angiotensin system (RAS) blockers - showed the strongest association with preventive effects, while conversely, beta-blocker and thiazide diuretic antihypertensives were linked to an increased risk of new-onset diabetes. "This study suggests that blood pressure lowering can help prevent diabetes in addition to its well-established beneficial effects in reducing cardiovascular events," write Milad Nazarzadeh and colleagues with the Blood Pressure Lowering Treatment Trialists' Collaboration in their article published in The Lancet.

"The differing effects of the drug classes support decision-making for antihypertensive drug choice according to an individual's risk profile," note Nazarzadeh, of Deep Medicine, Oxford Martin School, University of Oxford, UK, and colleagues. "In particular, [RAS inhibitors], ACE inhibitors and ARBs, should become the drugs of choice when clinical risk of diabetes is of concern, whereas beta blockers and thiazide diuretics should be avoided where possible," they add. In an accompanying editorial, Matthew A. Cavender, MD, MPH, and Robert C. Wirka, MD, of the University of North Carolina at Chapel Hill, agree that the new findings, along with the bulk of previous evidence, point to an important role of RAS-inhibiting drugs in diabetes prevention.

"Based on the accumulated evidence, including the results of these analyses, blood pressure control, particularly with RAS inhibition, should be considered as a possible strategy to reduce the risk of developing diabetes," they write. They note that, while "the absolute risk reduction found in this meta-analysis is modest, interventions with small benefits can have an outsized effect when applied to conditions as common as hypertension."

And commenting on the findings to the UK Science & Media Centre, Marc George, MBChB, PhD, blood pressure clinical lead for University College London Hospital, UK, said: "Lowering blood pressure prevents heart attacks, strokes, and kidney failure, and this new large and comprehensive study published in The Lancet also shows that it lowers the risk of developing diabetes. Until now this effect was not clear." Kevin McConway, PhD, emeritus professor of applied statistics, The Open University, UK, similarly concurs: "Though there is good evidence that lowering people's blood pressure, if it is too high, can have important health benefits in reducing the risk of heart attacks and strokes, it hasn't been clear whether lowering blood pressure can reduce the chance of developing type 2 diabetes in the future. This is an impressive study."

Reference: *Lancet*. *2021*; *398*:*1778-1779*, *1803-1810*.

Blood Pressure Control Lower for Current Smokers, Especially Men

Rates of BP control lower for current smokers; 45.5 percent of men had blood pressure >180 and/or >100 mm Hg

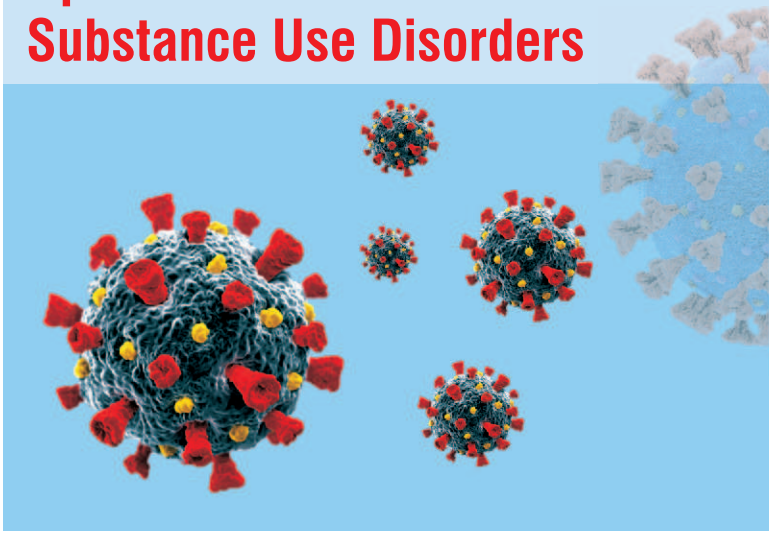
For adults with hypertension on drug therapy, especially men, smoking is associated with lower rates of blood pressure (BP) control, according to a study presented at ACC Latin America 2021, hosted by the American College of Cardiology and held virtually from Nov. 5 to 6.

Márcio Gonçalves de Sousa, M.D., Ph.D., from the Dante Pazzanese institute of Cardiology in São Paulo, Brazil, and colleagues conducted a retrospective evaluation of 710 adults with hypertension. BP was classified as controlled (C: <140/90 mm Hg), S1 (140 to 159 and/or 90 to 99 mm Hg), S2 (160 to 179 and/or 100 to 109 mm Hg), or S3 (>180 and/or >100 mm Hg). Patients were classified according to tobacco use as never smokers (NS), current smokers (CS), or former smokers.

The researchers found that BP control rates were similar for men and women (36.1 and 32.5 percent, respectively), as was the prevalence of S1 (28.6 versus 22.9 percent), S2 (18.8 versus 24 percent), and S3 (16.5 versus 20.7 percent). BP categorization did not differ by gender for NS (C: 37.1 versus 34.9 percent; S1: 25.8 versus 22.3 percent; S2: 22.6 versus 21.7 percent; and S3: 14.5 versus 21.1 percent). Lower rates of BP control were seen for men and women who were CS (C: 9.1 versus 25.0 percent; S1: 30.0 versus 43.8 percent; S2: 18.2 versus 25.0 percent; and S3: 45.5 versus 6.3 percent).

"There is synergy between these two risk factors: hypertension exponentially increases the smoker's cardiovascular risk and smoking increases the risk of hypertension, thus worsening their control," Gonçalves de Sousa said in a statement.

Breakthrough COVID-19 Risk Up for Patients with Substance Use Disorders



After controlling for lifetime comorbidities and adverse socioeconomic determinants of health, infection risk increased only for cannabis use disorder

The risk for breakthrough COVID-19 infections is increased for fully vaccinated patients with substance use disorders (SUDs), according to a study published online Oct. 6 in World Psychiatry.

Lindsey Wang, from the Case Western Reserve University in Cleveland, and colleagues examined the risk, time trends, outcomes, and disparities of COVID-19 breakthrough infection in fully vaccinated SUD patients from 14 days after vaccination completion. Data were included for 579,372 individuals (30,183 with a diagnosis of SUD and 549,189 without) who were fully vaccinated between December 2020 and August 2021.

The researchers found that the risk for breakthrough infection varied among SUD patients, from 6.8 percent for tobacco use disorder to 7.8 percent for cannabis use disorder, all significantly higher than the 3.6 percent in the non-SUD population. After adjustment for demographics and vaccine types, breakthrough infection risk remained significantly higher for all SUD subtypes, except tobacco use disorder, and was highest for cocaine and cannabis use disorder (hazard ratios, 2.06 and 1.92, respectively). After matching the groups for lifetime comorbidities and adverse socioeconomic determinants of health, the risk for breakthrough infection was increased only for cannabis use disorder (hazard ratio, 1.55). The risk for breakthrough infection was elevated for SUD patients who had received the Pfizer versus the Moderna vaccine (hazard ratio, 1.49).

"The overall risk of COVID-19 infection among vaccinated SUD patients was low, highlighting the effectiveness and the need for full vaccination in this population," the authors write. "However, our findings document that this group remains a vulnerable one even after vaccination."

COVID-19 Tied to a Wide Range of ECG Findings

It is now clear that COVID-19 infection, while largely a respiratory illness, has several cardiac manifestations that include myocardial infarction, myocarditis and various patterns of changes observed on electrocardiograms.

In a new report in Cardiac Electrophysiology Clinics, Dr. Luigi Di Biase of Montefiore-Einstein Center for Heart & Vascular Care in New York and colleagues review the electrocardiographic findings that have been described to date in patients with COVID-19, as well as possible mechanisms contributing to these findings.

Of note, they say clinicians "should be cognizant of some of the reported ECG changes, such as abnormal QRS axis in nearly 20% of patients, conduction abnormalities in approximately 20%, atrioventricular block in about 2.5%, and premature beats in nearly 10% of patients."

"ST and T wave changes in COVID-19 patients can be due to myocardial infarction or myocardial injury secondary to myocarditis, inflammatory responses, or microthrombi, and should therefore be interpreted in the correct clinical context since they can be associated with illness severity and mortality," they advise.

They note that QTc-interval changes have been "extensively" studied and they suggest baseline and follow-up ECG for QTc monitoring in hospitalized patients with COVID-19.

Clinically significant QTc prolongation can be defined as QTc of 500 ms or greater with a normal QRS interval; 550 ms or greater if QRS is 120 ms or greater; or QTc increase of 60 ms or greater from baseline.

Dr. Di Biase and colleagues also note that nearly 9.3% of patients admitted with COVID-19 infection have arrhythmias, most commonly atrial fibrillation.

"Arrhythmias can be a sign of myocardial injury and increased disease severity, and the treatment focus should be on the underlying infection and any potential triggers," the authors advise.

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"Arrhythmias can be a sign of myocardial injury and increased disease severity, and the treatment focus should be on the underlying infection and any potential triggers," the authors advise.

"Knowledge of these electrocardiographic features, paired with patients' clinical status, cardiac imaging findings, and cardiac biomarkers can assist clinicians in accurately assessing and tailoring care through an understanding of the underlying disease processes," Dr. Di Biase and colleagues conclude.

Reference: https://bit.ly/3ogYY3V Cardiac Electrophysiology Clinics, online October 30, 2021.

One or More Long-term Symptoms Present in Over One-third of COVID-19 Patients

At least one long-term COVID-19 symptom was found in 37% of patients three to six months after they were infected by the virus, a large study from Oxford University.

The most common symptoms included breathing problems, fatigue, pain and anxiety, Oxford University said, after investigating symptoms in over 270,000 people recovering from COVID-19. The symptoms were more frequent among people who had been previously hospitalized with COVID-19 and were slightly more common among women, according to the study published in PLoS Medicine.

The study did not provide any detailed causes of long-COVID symptoms, their severity, or how long they could last. It, however, said older people and men had more breathing difficulties and cognitive problems, whereas young people and women had more headaches, abdominal symptoms and anxiety or depression.

"We need to identify the mechanisms underlying the diverse symptoms that can affect survivors," Professor Paul Harrison of the Department of Psychiatry at Oxford University, who headed the study. "This information will be essential if the long-term health consequences of COVID-19 are to be prevented or treated effectively," Harrison added.

Reference: *https://bit.ly/3EYqmeF PLoS Medicine, online September 28, 2021.*

FDA authorizes sale of e-cigarettes for the first time, shifting debate and drawing fire from critics

For the first time, the US FDA authorized tobacco companies to market electronic cigarettes. Regulators authorized three products in a similar fashion as they would with pharmaceuticals, although this time it was for longtime tobacco company RJ Reynolds.

The authorizations were for a vaping device and associated tobacco-flavored pods, with FDA saying the benefits in weaning longtime smokers off traditional cigarettes outweighed the risks of getting younger people addicted. The agency emphasized it is only authorizing products that taste like tobacco, rather than flavored pods more appealing to kids and teenagers, such as candy, mint and fruit.

Nonetheless, the move will likely shift public debate about e-cigarettes and is already drawing criticism from anti-smoking advocates, the New York Times and others reported. Energy & Commerce committee chair Frank Pallone (D-NJ) said in a statement, "While I am pleased that FDA denied requests by the manufacturer to market certain flavors, I remain concerned given this product's popularity with youth." "FDA has turned its back on the public health by approving a high-nicotine e-cigarette," Rep. Raja Krishnamoorthi (D-IL) said in a statement, adding, "FDA has ignored the data and missed another opportunity to address the youth vaping epidemic."

In explaining its reasons for the authorization, the FDA appeared to approach its decision similar to how it considers experimental drugs. The agency studied how e-cigarettes have helped smokers who fully switched to the electronic products, reducing exposure to harmful carcinogens. FDA then weighed that benefit against the risk of youth becoming more addicted to vaping products. Regulators said they conducted studies saying tobacco-flavored products were among the least preferred by young e-cigarette users and noted RJ Reynolds will have to complete post-marketing requirements to ensure the authorization does not get revoked.

The Vuse products will also be forbidden from being marketed as safe or "FDA approved," the agency said. In the same announcement, FDA placed strict limitations on digital, radio and television advertising, as well as denying authorization to 10 flavored Vuse cartridges. E-cigarettes first emerged in the early-to-mid-2000s, aimed at attracting longtime smokers to switch to a less harmful product while avoiding the withdrawal symptoms typically accompanying stopping traditional cigarette use. But flavored products soon appeared on the market, notably in brands like Juul and Vuse, and use among teenagers began to skyrocket.

Vaping has long been unregulated but the FDA has been moving to crack down in recent years. This past August, regulators ordered several e-cigarette and pod manufacturers to pull more than 55,000 flavors or planned flavors from the market or risk enforcement, saying they failed to provide enough evidence the products provided a public health benefit.

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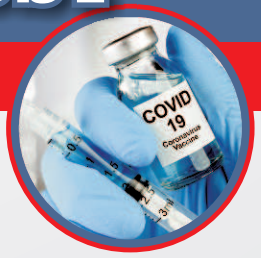

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FDA Grants First of Its Kind Indication for Chronic Sleep Disorder Treatment

The U.S. Food and Drug Administration today approved a new indication for Xywav for idiopathic hypersomnia (IH) in adults. IH is an uncommon chronic sleep disorder that causes people to be excessively sleepy during the day even after a good night's sleep. Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution is already approved for the treatment of cataplexy or excessive daytime sleepiness in patients seven years or older with narcolepsy.

"A novel indication for Xywav is significant as the FDA has never granted an approval for idiopathic hypersomnia," said Eric Bastings, M.D., deputy director of the Office of Neuroscience in the FDA's Center for Drug Evaluation and Research. "Idiopathic hypersomnia is a life-long condition, and the approval of Xywav will be instrumental in providing treatment for symptoms such as excessive sleepiness and difficulty waking, and in effectively managing this debilitating disorder."

The effectiveness of Xywav was evaluated in a double-blind placebo-controlled randomized-withdrawal study in 154 adult patients (ages 19 to 75 years) with IH. In the clinical study, patients who were randomized to switch from Xywav to placebo experienced worsening on measures of sleepiness and symptoms of IH compared to patients randomized to continue treatment with Xywav.

In the clinical trial for IH, the most common adverse events as a result of the treatment observed in the study included nausea (21.4%), headache (16.2%), dizziness (11.7%), anxiety (10.4%) and vomiting (10.4%).

Xywav has a boxed warning for central nervous system depression and abuse and misuse. The active moiety of Xywav is oxybate, also known as gamma-hydroxybutyrate (GHB), a Schedule I controlled substance. Abuse or misuse of illicit GHB has been associated with serious side effects including seizures, trouble breathing, changes in alertness, coma, and death. Clinically significant respiratory depression and reduced level of alertness has occurred in adult patients taking sodium oxybate.

Because of the potential risks associated with Xywav, it is subject to strict safety controls on prescribing and dispensing under a program called a Risk Evaluation and Mitigation Strategy (REMS).

Specifically, under the Xywav REMS, it can be prescribed only by a certified prescriber, and dispensed only to an enrolled patient by a certified pharmacy. Only a certified pharmacy that ships directly to patients can dispense Xywav. Xywav will not be available in retail pharmacies.

The FDA granted this application Fast Track and Priority Review designations. Xywav also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases. The FDA granted the approval of Xywav to Jazz Pharmaceuticals plc.

FDA, HHS Update COVID-19 Test Emergency Use Authorization Policies

In November 2021, the US FDA released revised guidance on its regulatory priorities and policies for COVID-19 tests.

In the new document, FDA stated it intends to focus its review of Emergency Use Authorization (EUA) requests on certain types of SARS-CoV-2 tests, including at-home and point-of-care (POC) diagnostic tests for use with or without a prescription that can be manufactured in high volumes, i.e., with a manufacturing capacity of at least 500,000 tests per week within three months of receiving EUA.

The agency will also focus on high-volume, lab-based molecular tests — as well as home collection kits for use with these tests — that can expand testing capacity and accessibility, whether through pooling specimens to increase throughput, testing specimens collected at home and shipped to a lab, screening asymptomatic people, or detecting multiple respiratory viruses at once. These tests should also be from experienced developers who have indicated the ability to scale up manufacturing capacity, the Agency noted.

Certain lab based and POC high-volume antibody tests that can measure the amount of antibodies or amount of neutralizing antibodies are also part of the guidance, as well as tests that are supported by a US government stakeholder, such as the Biomedical Advanced Research and Development Authority or the National Institutes of Health's Rapid Acceleration of Diagnostics initiative.

Developers of other kinds of tests not mentioned in the guidance document can pursue market authorization through other pathways, including 510(k) clearance or de novo classification, the agency said.

In addition, the US Department of Health and Human Services withdrew a policy directing FDA not to enforce premarket review requirements for laboratory-developed tests (LDTs). Under previous guidance, developers could distribute their validated tests as LDTs without objection from FDA, as long as the agency was notified.

However, FDA noted that "many of the COVID-19 tests offered prior to FDA review were determined to have poor performance" and is no longer allowing developers to use the pathway for SARS-CoV-2 tests.

For LDTs where an EUA request was submitted before the new guidance was released, developers can continue to offer the test while FDA reviews the EUA request, if the request was submitted after February 1 or the developer confirms to FDA in the next 45 days that it wants the agency to continue reviewing its request.

In response to the LDT policy revision, the American Clinical Laboratory Association (ACLA) released a statement noting that the guidance "marks another shift in federal policy regarding the regulation of LDTs."

"While we appreciate the administration's focus on the need for high-quality testing, continually shifting regulatory policies creates uncertainty and undermines patient access to lifesaving diagnostics," ACLA added. "This underscores the clear need for comprehensive diagnostic reform legislation that can provide long-term clarity and continuity for clinical labs and their work to support medical breakthroughs moving forward."

According to the new guidance, FDA is also withdrawing a policy that allowed states and territories to authorize labs to develop and use their own COVID-19 tests without submitting an EUA request. Under the original guidance, states would authorize labs under a process they established and take responsibility for those tests. The policy only applied to tests developed and used within a single high-complexity CLIA-certified lab.

Reference:

Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) https://www.fda.gov/media/135659/download*

The ACTIV COVID-19 Clinical Trials:

5 Things to Know

The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative is currently conducting clinical trials to advance COVID-19 vaccines and therapeutics to both prevent COVID-19 and treat mild to life-threatening COVID-19 infection. The mission of ACTIV is to reduce the morbidity and mortality from COVID-19 and to accelerate the end of the SARS-CoV-2 outbreak.

ACTIV is a public-private partnership led by the National Institutes of Health (NIH), which leverages scientific innovation from across US government agencies, private pharmaceutical companies, academia, and philanthropic foundations. The Foundation for the National Institutes of Health provides logistical and management support to ACTIV. In addition to the NIH, collaborating agencies include the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research and Development Authority, the Department of Defense, and the Veterans Administration.

The ACTIV therapeutic trials were designed to address treatment needs across the spectrum of patient populations (from outpatient to critical care) matrixed by different therapeutics targets (eg, viral target vs host target). The ACTIV therapeutic protocols allow for rigorous assessment of safety and efficacy of candidate therapeutics in flexible, multi-stage, multi-arm, randomized controlled trial designs. Potential therapeutic candidates remain under investigation if they show promise of clinical benefit; they are dropped if data indicate that they are unlikely to be of clinical benefit (futility). The ACTIV trials also offer a seamless transition from phase 2 to phase 3 trials, and a gain in efficiency since multiple agents are compared with a common placebo. Here are five things to know about the ACTIV trials.

1. ACTIV clinical trials are recruiting participants for outpatient and inpatient studies to identify safe and effective COVID-19 treatments.

Researchers continue to test a multitude of potential treatments that target COVID-19 pathogenesis in both outpatients with mild to moderate symptoms of COVID-19 and hospitalized patients with more severe symptoms. In the ACTIV trials researchers are investigating ways to:

- Test immune modulators for hospitalized patients to help them get better faster (ACTIV-1);
- Evaluate treatments that inhibit SARS-CoV-2 replication and/or attachment of SARS-CoV-2 to cells to decrease viral load and limit disease progression (ACTIV-2);
- Prevent patients with mild to moderate COVID-19 from progressing to the point where they need hospitalization (ACTIV-2);
- Help hospitalized patients with COVID-19 get home faster and stay home without needing readmission (ACTIV-3);
- Help patients with respiratory failure from COVID-19 reduce oxygen requirements and go home faster (ACTIV-3b);
- Test anticoagulants and antiplatelets to prevent, reduce, and treat thrombotic complications, such as heart attack, stroke, blood clots, deep vein thrombosis, and pulmonary embolism (ACTIV-4); and
- Evaluate medications previously approved by the FDA for non–COVID-19 indications to reduce the duration and severity of symptoms associated with mild to moderate COVID-19 (ACTIV-6).

2. ACTIV and ACTIV-associated trials contributed to FDA Emergency Use Authorizations (EUAs) for remdesivir and monoclonal antibodies.

COVID-19 clinical trials are contributing to the development of monoclonal antibody (mAb) treatments and multiple vaccines. Treatment with mAbs have proven to be successful in reducing hospitalization and lessening serious symptoms if administered within the first 10 days of a COVID-19 diagnosis. mAbs also help prevent COVID-19 for those who are immunocompromised or at increased risk for severe COVID-19 progression after exposure to COVID-19. Patients with newly diagnosed COVID-19 may be unaware of mAb treatment options and ongoing clinical trials for COVID-19. Healthcare providers should provide patient education about mAb treatment and an infusion location as soon as possible after a positive COVID-19 for those eligible for the treatments. Healthcare providers can learn more about mAbs as a treatment option by visiting the Combat COVID Monoclonal Antibody Resources for Clinicians page, which includes a mAb treatment locator tool and information on ordering, administering, billing, and coding.

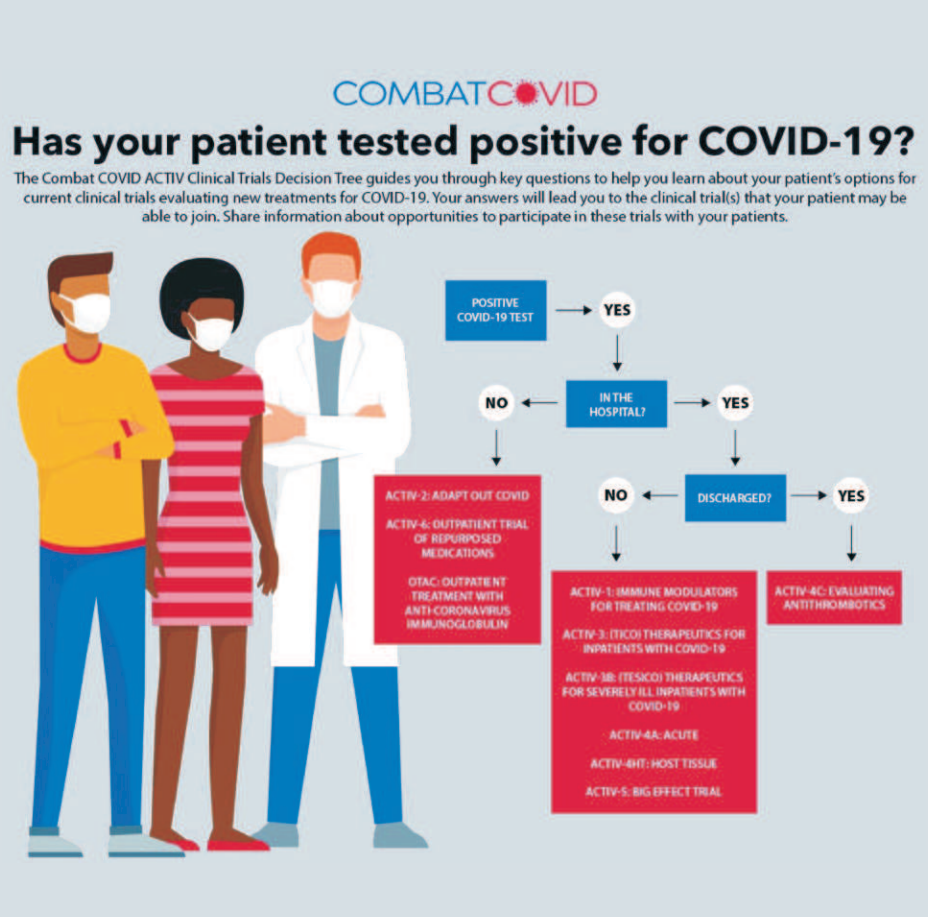
3. Strong efforts are being made to reach and engage all people in the ACTIV clinical trials.

Inclusive research is essential to ensure that new treatments are effective for persons of all races, ethnicities, sexes, and ages, and for those with preexisting conditions that can affect the course of the disease. COVID-19 has disproportionately affected minority communities with higher COVID-19 infection and hospitalization rates, making diverse participation in clinical trial testing for effective treatments more important than ever.

Healthcare providers play a pivotal role in helping to educate and facilitate the participation of minorities in clinical trials. To date, across the ACTIV clinical trials for COVID-19, participation among Black/African American and/or Hispanic/Latino patients is about 50% of the trial population, with an average of 18% Black/African American and 34% Hispanic/Latino, depending on the trial. Continued broad participation is essential to ensure that approved treatments work for everyone.

4. CombatCOVID.hhs.gov is a one-stop shop for information on the ACTIV and ACTIV-affiliated clinical trials, vaccines, and mAb treatment.

Researchers need the help of patients, their family members, and healthcare providers to enroll volunteer participants in clinical trials. Because hundreds of clinical research sites are participating in the ACTIV clinical trials, thousands of patients are needed to help evaluate proposed treatments. Patients look to their healthcare providers to help them learn about and understand the purpose of the research and to determine which clinical trial may be appropriate for them.



If your patient is not in the hospital, they may be eligible for:

- ACTIV-2: Adapt Out COVID
- ACTIV-6: Outpatient Trial of Repurposed Medications
- OTAC: Outpatient Treatment with Anti-Coronavirus Immunoglobulin

If your patient is currently in the hospital, they may be eligible for:

- ACTIV-1: Immune Modulators for Treating COVID-19
- ACTIV-3: (TICO) Therapeutics for Inpatients with COVID-19
- ACTIV-3b: (TESICO) Therapeutics for Severely Ill Inpatients with COVID-19
- ACTIV-4a: ACUTE
- ACTIV-4HT: Host Tissue
- ACTIV-5: Big Effect Trial

If your patient was in the hospital but has been discharged, they may be eligible for:

- ACTIV-4c: Evaluating Antithrombotics

5. Healthcare providers and participants are crucial partners with researchers to identify new treatments for COVID-19.

CombatCOVID.hhs.gov and CombateCOVID.hhs.gov (en espanõl) provide up-to-date information in English and Spanish for healthcare providers, patients, and the public about vaccines, mAbs, and ACTIV investigational treatments. Healthcare providers can find:

- Current, accurate information for each ACTIV trial arm as studies are launched and concluded by the NIH;
- Educational resources to download and distribute to patients.
- Treatment guidelines and EUA fact sheets for specific therapies; and
- mAb administration resources.

NAPPSA
Activities in Nigeria

NAPPSA at PSN

The NAPPSA President, Dr Teresa Pounds, led a strong team of NAPPSA leaders to the 94th Annual National Conference of the Pharmaceutical Council of Nigeria, tagged "Garden City 2021" with the theme COVID-19 Lessons: Broadening & Strengthening the Pharmaceutical and Health Sector" which ran from the 1st – 6th November, 2021 at Alfred Diete Spiff Civic Center, Moscow Road, Port Harcourt, Rivers State. Included in the delegation are Emmanuel Ezirim (President-Elect), Dr Emma Omehe (Treasurer), Dr Kunle Tometi (NAPPSA Liaison to PSN), and Dr Christian Ike.

Headline speakers at the conference include the PSN President, Mazi Sam Ohuabunwa, who expressed pride that the Pharmacy profession have been advanced to a higher spectrum in the minds of Nigerians and now attracts respect and honor; Keynote Speaker and Director-General of NAFDAC, Prof. Mojisola Adeyeye, who discussed the impact of the Pandemic on drug insecurity.

The NAPPSA President, Dr Teresa Pounds delivered the NAPPSA Goodwill Message to PSN where she promised that NAPPSA will work with the key stakeholders to ensure that we educate the relevant agencies about the multi-disciplinary team approach in providing patient-centered care.

Commissioning of PCN Lagos Zonal Office

The NAPPSA President was a special Guest at the commissioning ceremony of the newly built Lagos Zonal Office (LAZO) of the Pharmacists Council of Nigeria (PCN) which took place at the Medical Compound, Yaba, on Friday, 29th October, 2021. In her goodwill message on behalf of NAPPSA, the President touted the strong relationship NAPPSA has built over the years and expressed pride in the great progress the Pharmacy profession has made under the PCN oversight. Prof. Ahmed Mora, Chair of the PCN Governing Council, expressed his gratitude to the NAPPSA President for her acceptance of the invitation and her attendance.

NAPPSA President Delivers NAPharm Keynote

The NAPPSA President delivered the Keynote Speech at the Investiture of New Fellows and Life Fellows of the Nigeria Academy of Pharmacy (NAPharm), on Friday, October 22, 2021 during which 15 new Fellows were inducted into the Academy and Life Fellowship conferred on 10 of its founding Fellows, who have crossed 75 years old.

In her presentation titled "Expanding role of pharmacists in primary healthcare", Dr Pounds enjoined pharmacists to collaborate, not just with their fellow pharmacists but also with professionals in other disciplines in the health sector.

She also noted that pharmacists play major roles in primary healthcare, stressing that the roles of pharmacists in healthcare, in the last eight years, has expanded across all fronts.

Expatiating on role of pharmacists in the primary healthcare, Dr Pounds averred that pharmacist communicate with the public easily because they are always accessible.

The 10 Fellows of the academy who bagged the Life Fellowship are Prince Julius Adelusi-Adeluyi; Pharm.(Chief) Olu Ainkugbe; Pharm. Bruno Nwankwo; Prof. Philip Olurinola; Pharm. (Dr) Evans C. Chidomere; Prof. Fola Tayo; Pharm. (Dr) Gabriel L. Eradiri; Prof. Oleka K. Udeala; Pharm. Godfrey Obiaga and Pharm. (Sir) Ifeanyi Atueyi.

NAPPSA President Emeritus, Dr Nkere Ebube, were among the new Fellows inducted into the Academy.

Nigerian First Lady Hosts NAPPSA President

The NAPPSA President, Dr Teresa Pounds, paid a courtesy visit on the First Lady, Federal Republic of Nigeria, Dr. Aisha Muhammadu Buhari on Thursday, October 28, 2021. The main purpose of the visit was to discuss issues surrounding the plight of the Girl Child in the Nigerian society. During the visit, the First Lady charged pharmacists to build useful partnerships for national development. She specifically observed that there are many challenges facing the girl-child especially in health and education as well as that of drug and gender-based abuse and that addressing these issues require a lot of introspection and constructive partnership. She said, while aspiring to make their tomorrow better, we have to keep them safe and secure today. She expressed her delight that NAPPSA has aligned its thoughts with the aspirations of the First Lady's Future Assured initiative with regards to the issues around the girl-child and hopes to collaborate with NAPPSA in that effort. She gave an example of the Future Assured College in Maiduguri which was established to educate young girls affected by insurgency and poverty and support them to attain a brighter future. This, she said, is a project that should be multiplied. The President of NAPPSA, on her part spoke of the aim of the Association, which is to play a role in the promotion of healthy living and disease prevention in Nigeria. She said the work of Future Assured has not gone unrecognized and they promised to continue to support Future Assured in raising healthy, educated, and responsible young women. Among the targets of NAPPSA, Dr. Pounds spoke of aligning with other associations to build capacity as well as transfer knowledge and skill, especially from the diaspora Nigerians. She also spoke of NAPPSA's commitment to making a difference through their professional calling.

A Focus on Nuclear Pharmacy

Nuclear pharmacy is a specialty area of pharmacy practice involved with the preparation of radioactive materials to improve and promote health through the safe and effective use of radioactive drugs to diagnose and treat specific disease states.

Nuclear pharmacists compound radiopharmaceuticals for nuclear medicine departments and outpatient diagnostic clinics. The specialty was the first pharmacy specialty established by the Board of Pharmaceutical Specialties (BPS) in 1978.

According to Gregory Smallwood, PharmD, FCCP, a former associate professor and clinical coordinator of experiential education at PCOM School of Pharmacy, nuclear pharmacy is well suited for the people who are strong in math and science—especially physics. "The potential for employment is good," he added. "You don't have that many who go into it."

What does a nuclear pharmacist do?

A nuclear pharmacist's responsibilities include:

- Ordering, receiving, storing and controlling inventory of radioactive drugs (radiopharmaceuticals), other drugs used in nuclear medicine, and related supplies.
- Preparing radiopharmaceuticals by combining radioisotopes with reagent kits and compounding radiopharmaceuticals that are not commercially available.
- Performing functional checks of instruments, equipment, and devices and determining radiopharmaceutical quality and purity.
- Filling prescription orders.
- Packaging, labeling, and transporting radiopharmaceuticals.
- Properly handling hazardous chemicals and biological specimens.

- Communicating radiopharmaceutical-related information to others.
- Ensuring that patients receive proper preparation before radiopharmaceutical administration and trouble-shooting unanticipated outcomes.
- Laboratory testing of new radiopharmaceuticals, new compounding procedures, and quality control methods and participating in clinical trials.

How do you become a nuclear pharmacist?

In order to become a nuclear pharmacist, you must complete training in basic areas of radiation physics and instrumentation, radiation protection, radiation biology, math related to radioactivity decay and radiopharmaceutical chemistry. In addition to the didactic training, practical training in a nuclear pharmacy is required. To become a Board of Pharmacy Specialties (BPS) Board Certified Nuclear Pharmacist® (BCNP), Smallwood explained, a pharmacist must:

- Graduate from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the U.S. that qualifies that individual to practice in that jurisdiction (foreign-trained pharmacists must pass the Foreign Pharmacy Graduate Examination Committee examination).
- Maintain a current, active license to practice pharmacy in the U.S. or another jurisdiction.
- Complete up to 4,000 hours of experience in nuclear pharmacy, including a residency accredited by the American Society of Health-System Pharmacists (ASHP); an internship to satisfy the requirements of state boards of pharmacy; and experience in a nuclear practice in a licensed nuclear pharmacy or health care facility (up to 2,000 of the 4,000 required hours can be academic hours, including undergraduate or graduate courses in nuclear pharmacy, an MS or PhD program in nuclear pharmacy, and/or successful completion of a nuclear pharmacy certificate program).
- Achieve a passing score on the BPS Nuclear Pharmacy Certification Examination.

What is the average nuclear pharmacist salary?

The salary for a nuclear pharmacists can vary depending upon location, experience, certifications and other skills. Pharmacists, in general, typically earn annual salaries in the low six-figures. A nuclear pharmacist in the U.S., according to Salary.com, can expect an average salary of $142,002 (as of March 2021).

Where do nuclear pharmacists work?

There are two main types of environments where nuclear pharmacists are employed. Institutional nuclear pharmacy is usually linked to a major medical center/hospital where preparations are made on-site. This is in contrast to the commercial centralized nuclear pharmacy where radiopharmaceuticals are prepared and then delivered to the hospital and/or clinic. While the quantity of radiopharmaceuticals used is relatively small in both settings, nuclear pharmacists must complete additional training in radiation safety regarding the compounding, preparation, and delivery of radioactive materials.

"There are risks involved because you are working with radioactive isotopes," Smallwood said. "You have to wear a dosimeter to see how much radiation you are receiving and each facility has limits as to how much exposure you can have."

Most nuclear pharmacists, whether hospital-based or commercial, practice in a laboratory environment. The radiopharmaceuticals must be prepared, tested and shipped so that they are ready to administer when a patient arrives for a study. This usually translates into the pharmacy opening early in the morning and with one or more pharmacists working the "early shift" usually beginning at midnight. In addition, radiopharmaceuticals must be available 24/7 for emergencies and a nuclear pharmacist is on-call at times. The shifts and on-call are shared among the pharmacists.

"If you are not an early bird, [nuclear pharmacy] is not for you," Smallwood said.

All dosages are dispensed to the nuclear medicine physician who administers them to the patient and handles the insurance processing. There are delivery drivers who transport the doses to the physicians. The nuclear pharmacy is not open to the public due to the nature of the products used.

What is the nuclear pharmacy jobs outlook?

Little or no growth is expected in pharmacist employment over the next decade according to the Bureau of Labor Statistics. The nuclear pharmacy specialty, according to Smallwood, is a particularly competitive field.

"There are job openings but often times, the candidate has to be willing to relocate," he said.

Article culled from PCOM.EDU, 14Nov2021. Information about nuclear pharmacy written by Gregory Smallwood, PharmD, FCCP.

A Lamp to Our Feet

By Ucheoma Nwizu, PharmD, BCACP

His A1c was 13.8%. This means his blood sugar runs mostly in the 400s. I have been managing him now for three years and in this time his A1c has never been at goal. Yet he is always well groomed, somewhat articulate, and he goes to church, just like me. Sometimes he comes to the clinic with his wife. She is often interested in learning what an appropriate diet for him should be, but she ends up making pastries for him and he tells me he cannot resist her cooking. It has been a back-and-forth therapeutic relationship, and I have learnt to shoot for the more attainable goal of just keeping him out of glycemic emergencies, and not push too hard for goal or perfect blood sugar readings.

For some reason, I haven't seen him for a year. The records showed I saw him sometime in the summer of last year. He re-emerges with this A1c....the highest it has been in a long time. So, we started our conversation. I had a lot of questions. Where have you been? How were you getting your insulin? How come you didn't come see me? He had his own story to tell. Life had been rough in the past year. His wife had been diagnosed with breast cancer and just had a double mastectomy. There was a COVID outbreak in his family and he had lost two siblings to the virus. My heart went out to him.

Then I looked up at his chart, ... noted he hadn't been vaccinated against COVID. I asked him about it and he said ...' I am still thinking about it. My wife wants to get it and I told her she can get it if she likes. She is on her own on that one'. Instantly my sympathy quickly dissipated. All through the pandemic, I have exercised respect for patients who have refused the COVID vaccine. I have employed all reasonable strategies to help dissipate vaccine hesitancy. But in this moment, I lost it completely and I railed on him. What with his terribly controlled diabetes, his cardiovascular disease. In fact, at this visit he had complained of leg swelling and shortness of breath that is worsened when he lay down. A discussion that flagged me as urgent and I began trying desperately to squeeze him in for a face-to-face visit with his PCP who already had an overbooked schedule. I felt my righteous indignation was more than justified. He deserved a worse verbal cleansing except I was restrained by the limits of propriety and professionalism.

To my surprise, after I finished my lecture on the need for vaccination, he simply said ... 'Well.... I will think about what you said'. I felt deflated. Ashamed of myself. I should have given him a chance to share his concerns about the vaccine. Scolding this 70-year-old man was not any way to succeed. So, after the visit, I picked up the phone and called him back, apologized and asked him to share his concerns. He did and I listened. His reasons were a combination of distrust for the vaccine process, the speed of manufacture, of the government which he has perceived as altogether not honest, a distrust for medical science that speaks a language that does not translate appropriately to the layman. and finally, a trust in divine providence. We are all going to die someday.....he said to me. I listened and I felt that there was something about his approach to death that I found defiant. Death has indeed lost its sting for him. I recognized this outlook. It is an attitude that comes after one has lost again and again. When one feels closer to the dead than the living. I understood that. I didn't quite agree with his decision, but I had to let him be.

After the conversation, I couldn't help but wonder what I could have done differently. How should I have approached this man. How do I approach patients who disagree with medical science? I asked myself those question not to learn new communication strategies, but I really wanted to change my heart and attitude towards patients that I might feel justifiably angry with.

I recall the early days of HIV medications. A number of people believed the HIV virus was a conspiracy, the medications were poisons, and they were convinced of their own evidence for why they would not seek help. As the medications improved with continually changing guidelines, it took some skill to explain to patients that what we knew the day before is no longer true today. To us it made perfect sense that we change practice with emerging data. To the patient it was all so confusing as it appeared that the expert never seemed to make up their minds. The funny thing was that some of us were arrogant in the face of the patients, and we demanded that we be trusted because ... after all we had the training and continued education that entitled us to this trust. I had to pull from my past experience working on an earlier pandemic.

He missed two subsequent appointments with me. I didn't ask him why. When he finally returned, I didn't discuss the vaccine. We worked on his blood sugar, adjusting his insulin, and helping him get the new continuous glucose monitoring. Yesterday when he came, I brought up the issue of the vaccine. I explained to him about medical research works, what we do know about COVID vaccine and what we don't know. I explained how medical science sometimes only has a 'lamp unto their feet' and not the 'full light to their path'. And when we can only see so far, we still have to take a step.

He agreed to get vaccinated! He and his Mrs.

Waves, Variants, Vaccines: **What More to Expect From COVID-19**

Salvador Macip, MD, PhD

The COVID-19 pandemic has entered a new phase, which for many is particularly confusing. After the improvements seen at the end of summer, a new wave is surfing the planet and a potentially dangerous variant has emerged in South Africa, which has the experts worried. Weren't vaccines supposed to solve everything? Why are we still feeling like we keep going back to square one?

Vaccines work, and they work beautifully. They have reduced mortality around 10-fold and brought hospital admissions to very low levels. However, they can't do what they were not designed to: eliminate transmission. A fully vaccinated adult has around 50% less chance of getting infected or transmitting the virus. Although these numbers are great, they are not zero. This means that if we throw all caution to the wind after being immunized, cases will rise again. Which is exactly what's happening.

This is the main reason behind what Europe is calling "the sixth wave," an uncontrollable rise in new cases that started after the summer, after the vaccination rates crossed the 70% threshold, particularly in Western Europe. Although the percentage of mortality is nothing close to what we saw in pre-vaccine waves, the trend is still worrying.

A high number of infections will inevitably lead to more severe cases, which could have been avoided if the wave had been nipped in the bud. But this requires remembering that the pandemic is still very much alive, and we still must continue doing what we know works: testing, handwashing, ventilation, masks. Many people seem to have forgotten that.

In the face of this new wave, there are different strategies to follow. The most logical one is to increase vaccination efforts, particularly in places like the US, where less than 60% of the population has received a full course. Reaching those that so far have refused to get a jab is not easy. Many are unlikely to change their minds, whatever we do. But others are still on the fence, and these should become the urgent target of all campaigns.

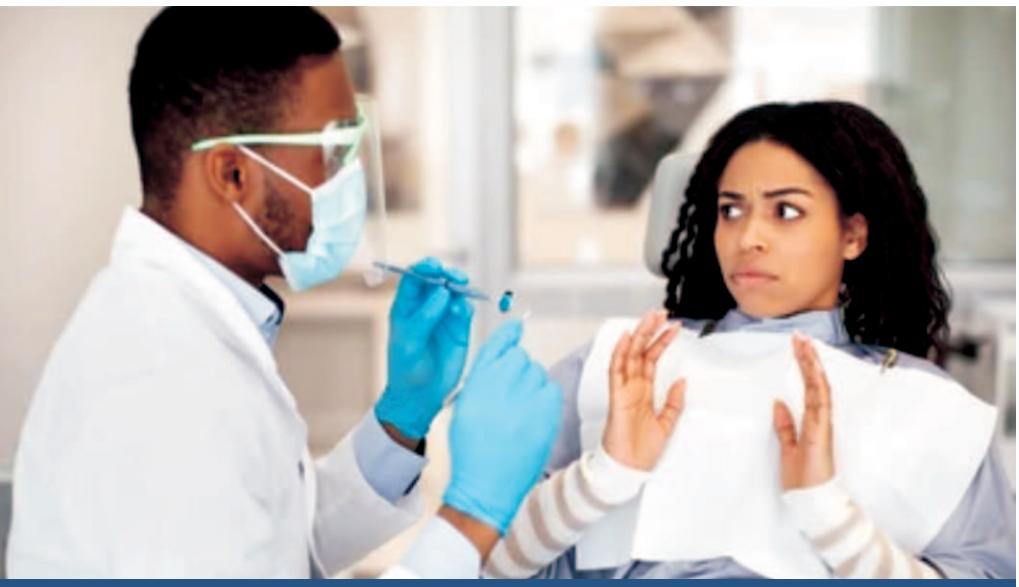
One way to promote vaccination is to limit the activities of those that are not fully immunized. This is the job of the COVID pass, aggressively implemented in some countries in Europe (even forbidding access to work or to leave your house if you don't have one), and more timidly in others (just to access recreational activities).

Meanwhile, other paths are being pursued in parallel. We are still not sure how effective boosters or child vaccinations will be, but they are likely to contribute somewhat to reducing the spread of the virus. That's why they are also at the top of the list of things to try before moving to the next level — going back to restrictions. Some countries can't afford the luxury of waiting for more people to get vaccinated and have already had to implement curfews and even lockdowns, which should always be the last resort, given the strong impact they have. We must be aware that these strategies work, and we may still have to resort to them at some point while the pandemic is still active. One step forward, one step back. That's how it goes.

Apart from this, we must start thinking once and for all about how to respond to the pandemic in a global way. As we discussed before, there is no point in vaccinating everyone in the richest countries if a full continent is still struggling to cross the 10% immunization rate. We know that this increases the chances of new, more aggressive versions of the virus appearing. The Omicron variant, spreading now across the globe, has just confirmed this. We still don't know how bad it's going to be (more infectious, certainly, but maybe not more deaths, and hopefully still sensitive to the antibodies we have); we'll have to wait and see. In any case, this will still happen in places where the virus can circulate freely, and we'd better reduce our chances of a truly aggressive variant coming up in the future by vaccinating those that need it the most first.

With cases in the States and Europe steeply rising again, even before we see whether Omicron is going to change the rulebook, the best we can do is to insist that, although we are much better than we were last year, this is far from over.

We must remain vigilant. Get a jab if you haven't received one. Get another one if it's offered to you (or to your children). And don't forget that this is not enough, and we still need the rest of tools we must protect us, common sense being chief among them. While we do this, let's remind our leaders that we are all in it together and we must help the countries that are still struggling if we want to improve everyone's chances of coming out of this alive. The pandemic is far from over, and no one will be safe from it until we all are.



Overcoming Dental Phobias

Everyone gets a little nervous when visiting the dentist—it's never fun to have tools poke at your teeth and gums. But if the fear becomes overwhelming, so much so that you're unable to keep up with regular cleanings and check-ups, we can offer some tips to help you relax and take control of your oral health.

Top 5 Dental Phobias & Ways to Overcome Them

Why you should not fear the dentist

Many people feel slightly anxious before going to the dentist, especially when scheduled for more complex procedures. But if you feel panicky when driving by a dental office or find yourself unable to sleep the night before your appointment, you may have a dental phobia. It's estimated that up to 25% of Americans are considered "dental phobic," or extremely fearful of going to the dentist.

If you share this fear, the trick is to overcome your anxiety so, at the least, you seek dental treatment when you need it.

Top 5 dental phobias

Do these sounds familiar? Read on for the most common fears about visiting the dentist's office:

1. Pain: If you experienced early childhood dental trauma, you likely share the top fear of seeing a dentist—that it might hurt!

2. Needles: No one enjoys a sharp, pointy object zeroing in on your gums or cheek.

3. Dentists: Your anxiety trigger might be that masked person, hovering over you, particularly if you know your teeth really need work.

4. Drills: Sounds of buzzing and whirring can instantly cause anxiety in phobic patients.

5. Choking: Holding your mouth open so wide for a long period of time can make you feel like you've lost control over your gag reflex.

Ways to overcome dental fear

Don't pay attention to scary stories: Remember that everyone's experience at the dentist is different. Don't let someone else's story or fear influence how you handle your oral health.

Shop for a good dentist: Visiting several dentists to get a feel for their personality and the office environment is a good way to make sure you're as comfortable as possible when it's time for a cleaning or procedure.

Ask for a sedative: Do not be embarrassed to admit you need something to calm your nerves. Your dentist can prescribe a sedative to take prior to coming into the office so you're relaxed.

Distract yourself while waiting: Read a book or plug in your headphones while you're sitting in the waiting room. Waiting can heighten anxiety, so entertaining yourself can take your mind off the situation.

See a counselor: For extreme cases of dental fear, you may need to talk with a professional counselor. This doesn't mean you're crazy! Talking with someone may help you find a solution to conquer your fears.

And the #1 way to beat your fear of the dentist. . .

Practice good oral health habits! Brush at least twice and floss once every day. If you don't have tooth decay, your dentist won't have much to do when you visit, right?

The new and improved dental visit

If you have a fear of the dentist, innovative advances in painless dentistry and improved training on how to treat patients with these fears you have enabled dentists to make visits more comfortable and less stressful than ever before. Modern dental practices offer positive distractions that can help you keep your mind off the treatment.

Most offices have cozy, well-furnished waiting rooms with soothing music. Some offer headphones so you can listen to music or a TV installed in the ceiling so you can zone out during your cleaning or treatment. You can ask for sunglasses if the glaring overhead lights bother your eyes. Dentists also recommend relaxation techniques, such as deep breathing or mental imaging. With practice, you may even be able to fall asleep—or at least enter a deep meditative state—during treatment.

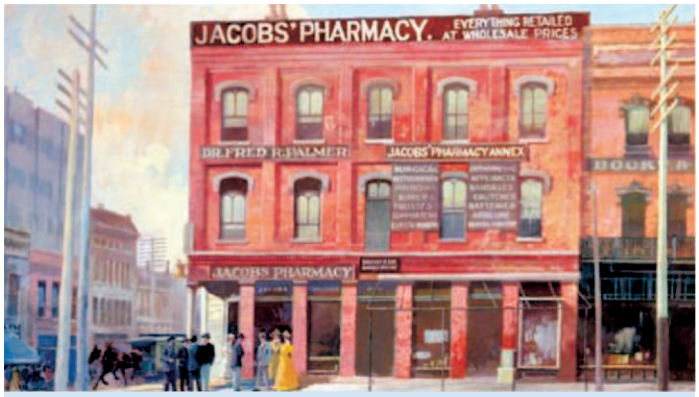
How a Pharmacist, John Pemberton, invented Coca Cola

One of the world's most famous drinks, Coca Cola, has a very interesting origin. It was invented in Atlanta, Georgia on May 8, 1886 by a local Pharmacists, Dr John Stith Pemberton. Come with us down memory lane for this interesting history

Origin of the Coca Cola drink

In April 1865, Dr. Pemberton sustained a saber wound to the chest during the Battle of Columbus. He soon became addicted to the morphine used to ease his pain. In 1866, seeking a cure for his addiction, he began to experiment with painkillers that would serve as morphine-free alternatives to morphine. His first recipe was "Dr. Tuggle's Compound Syrup of Globe Flower", in which the active ingredient was derived from the buttonbush (Cephalanthus occidentalis), a toxic plant. He next began experimenting with coca and coca wines, eventually creating a recipe that contained extracts of kola nut and damiana, which he called Pemberton's French Wine Coca.

According to Coca-Cola historian Phil Mooney, Pemberton's world-famous soda was created in Columbus, Georgia and carried to Atlanta. With public concern about drug addiction, depression, and alcoholism among war veterans, and "neurasthenia" among "highly-strung" Southern women, Pemberton's "medicine" was advertised as particularly beneficial for "ladies, and all those whose sedentary employment causes nervous prostration"



Jacob's Pharmacy was located across the street from Pemberton's Pharmacy near the corner of Broad and Peachtree Streets.

In 1886, when Atlanta and Fulton County enacted temperance

legislation, Pemberton had to produce a non-alcoholic alternative to his French Wine Coca. Pemberton relied on Atlanta drugstore owner-proprietor Willis E. Venable, owner of Jacob's Pharmacy, to test, and help him perfect, the recipe for the beverage, which he formulated by trial and error. It was sampled, pronounced "excellent" and placed on sale for five cents a glass as a soda fountain drink. With Venable's assistance, Pemberton worked out a set of directions for its preparation.

He blended the base syrup with carbonated water by accident when trying to make another glassful of the beverage. This new blend was considered Delicious and Refreshing," a theme that continues to echo today wherever Coca-Cola is enjoyed and Pemberton decided then to sell this as a fountain drink rather than a medicine. Thinking that "the two Cs would look well in advertising because of its the allite rative sound, which was popular among other wine medicines of the time," Dr. Pemberton's partner and bookkeeper, Frank M. Robinson, suggested the name and penned the now famous trademark "Coca-Cola" in his unique script. Although the name refers to the two main ingredients, because of controversy over its cocaine content, The Coca-Cola Company later said that the name was "meaningless but fanciful". Robinson's hand wrote the Spencerian script on the bottles and ads. Pemberton made many health claims for his product, touting it as a "valuable brain tonic" that would cure headaches, relieve exhaustion, and calm nerves, and marketed it as "delicious, refreshing, pure joy, exhilarating", and "invigorating.

He blended the base syrup with carbonated water by accident when trying to make another glassful of the beverage. Pemberton decided then to sell this as a fountain drink rather than a medicine. Frank Mason Robinson came up with the name "Coca-Cola" for the alliterative sound, which was popular among other wine medicines of the time. Although the name refers to the two main ingredients, because of controversy over its cocaine content, The Coca-Cola Company later said that the name was "meaningless but fanciful". Robinson's hand wrote the Spencerian script on the bottles and ads.

The first newspaper ad for Coca-Cola soon appeared in The Atlanta Journal, inviting thirsty citizens to try "the new and popular soda fountain drink." Hand-painted oilcloth signs reading "Coca-Cola" appeared on store awnings, with the suggestion "Drink" added to inform passersby that the new beverage was for soda fountain refreshment. During the first year, sales averaged a modest nine drinks per day.

Pemberton made many health claims for his product, touting it as a "valuable brain tonic" that would cure headaches, relieve exhaustion, and calm nerves, and marketed it as "delicious, refreshing, pure joy, exhilarating", and "invigorating".

Pemberton Sells the business

Soon after Coca-Cola hit the market, Dr. Pemberton fell ill and nearly bankrupt. Sick and desperate, he began selling rights to his formula to his business partners in Atlanta. Part of his motivation to sell was that he still suffered from expensive continuing morphine addiction. Pemberton had a hunch that his formula "someday will be a national drink", so he attempted to retain a share of the ownership to leave to his son. However, Pemberton's son wanted the money, so in 1888, Pemberton and his son sold the remaining portion of the patent to a fellow Atlanta pharmacist, Asa Griggs Candler, for US$1,750, which in 2020 purchasing power is equal to US$47,230.

Death

A sign in Knoxville, Georgia, commemorating John Pemberton.

Dr. Pemberton never realized the potential of the beverage he created. He gradually sold portions of his business to various partners and, just prior to his death in 1888, sold his remaining interest in Coca-Cola to Asa G. Candler. An Atlantan with great business acumen, Mr. Candler proceeded to buy additional rights and acquire complete control. Pemberton died from stomach cancer at age 57 in August 1888. At the time of his death, he also suffered from poverty and addiction to morphine. His body was returned to Columbus, Georgia, where he was buried at Linwood Cemetery. His grave marker is engraved with symbols showing his service in the Confederate Army and his membership as a Freemason. His son Charley continued to sell his father's formula, but six years later Charles Pemberton died, having succumbed to opium addiction.

Adapted from John Stith Pemberton - Wikipedia

EVENT CALENDAR 2022

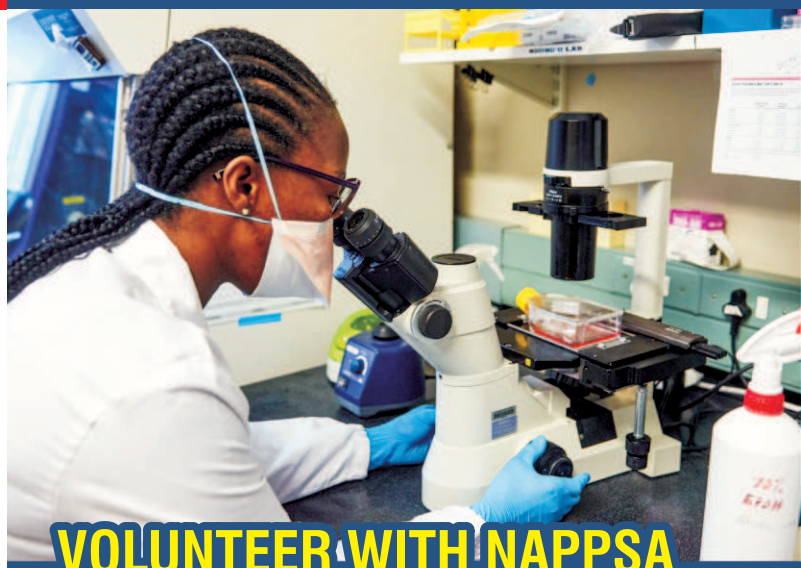
JANUARY 29, 2022
NAPPSA Business-2-Business Roadshow
Baltimore, MD

FEBRUARY 19, 2022
NAPPSA Business-2-Business Roadshow
Atlanta, GA

SEPTEMBER 18-22, 2022
80th FIP World Congress of Pharmacy and Pharmaceutical Sciences
Seville, Spain

SEPTEMBER 22-25, 2022
16th Annual NAPPSA Scientific Conference and Exposition
Renaissance Tampa International Plaza Hotel, Tampa, Florida

NOVEMBER 1-6, 2021
95th Annual Conference of PSN
Location TBD



VOLUNTEER WITH NAPPSA

Run/Walk for NAPPSA Fundraising

Your participation will help raise funds for the NAPPSA Endowment Fund. NAPPSA's Endowment Fund enhances NAPPSA's capacity to continue her wide portfolio of good works in the USA and Africa.

Be a Mentor

NAPPSA is looking for willing mentors to help groom the next generation of leaders in the fields of pharmacy and pharmaceutical science professions.

Serve in a Committee

Most of NAPPSA's work and activities are driven through the various NAPPSA committees. NAPPSA is always looking for members with ideas and passion about NAPPSA's growth to volunteer their time and knowledge at the Committee level.

Develop a Webinar

Do you have a webinar Idea? Then reach out to the program committee at program@nappsa.org. Webinars offer a great opportunity to deliver the latest information on the various aspects of NAPPSA's vision and member educational needs without the need for travel or time away from home and office.

Contact Us

Want to volunteer in any of the above? Send an email to nappsa@nappsa.org or call the NAPPSA office at (919) 230-1488

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NAPPSA Office Services

SERVICES

- Membership Dues
- Host Local Event in Your Area
- Conference Registration
- FAQs
- Committee Meeting Minutes
- Setup and Manage Zoom Calls
- Archiving
- Publish News/Eblasts
- Create NAPPSA Presentations

During Business Hours
919-230-1488

Twenty four hrs Support
888-237-8017

WEB ADDRESS
tmdmanagement1.com


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