NAPPSA DIGEST

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

SEPTEMBER 2023 Vol. 3 No. 3

NAPPSA

Past, Present and the Future

In this Issue:

- First Presidential Exit Interview
- Regulatory and Therapeutic Updates
- The Young Professionals Corner
- Blogger's Corner

Contents

05 **COVER**
Presidential Exit Interview
NAPPSA for me is a proof of concept

DEPARTMENTS

03 **Message from the President**

04 **From the Editor's Desk**

15 **Therapeutic Update**
Artificial Sweetener Consumption Linked to Type 2 Diabetes

First-Line Therapy in T2D:
Has Metformin Been 'Dethroned'?

SGLT2 Inhibitor Plus GLP-1 Agonist in Diabetes with High CVD Risk

17 **Regulatory Update**
FDA Approves New Drug to Prevent RSV in Babies and Toddlers
New RSV Shot Is a Monoclonal Antibody, not a Vaccine

FDA Approves Low-Dose Colchicine for Cardiovascular Indication

2022 US FDA New Drug Approvals

20 **The Young Professional Corner**
Immigration, Emigration and Pharmacy Education:
Insights and Opportunities

NAPPSA Digest

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

22 **NAPPSA TIDBITS**

25 **Career Spotlight**
Opportunities for Pharmacists in the Pharmaceutical Industry

31 **Blogger's Corner**
R.E.S.P.E.C.T
(What does it mean in mental health?)

Summary of major challenges in drug development and how they could be resolved, an adapted excerpt from Pharmanews Diaspora Column

33 **Science History**
The history of **ANTIBIOTICS**

34 **Event Calendar**
Catalogue of upcoming events

MESSAGE from THE PRESIDENT

I feel very delighted to preface yet another edition of our world class News Magazine, the NAPPSA Digest, which is our tool for chronicling the NAPPSA story as it unfolds.

This edition is particularly special and aptly themed, "Past, Present and the Future" because it reflects the virtue of continuity which is the foundation upon which NAPPSA's success is built, as reflected in the direct line it draws across 3 NAPPSA Presidential cycles.

Firstly, the edition documents the events of today as reflected in its documentation of our efforts to build a collaborative framework between NAPPSA YP and PANS, the young professional arm of PSN; our ongoing investments in the development of the clinical sub-profession of NAPPSA; and our partnership with Shriner's hospital on a 5K FunRun to raise funds for NAPPSA Endowment and Shriners Hospital for Children.

Secondly, it hearkens to the past via its introduction of yet another idea for documenting NAPPSA history, the Presidential Exit Interview series. The Exit Interview series will ensure that our collective learnings as an organization are not lost, but are retained as reference points to be built upon for attaining even greater heights. It also allows NAPPSA members access to the thoughts and the inner workings of the mind of each President to better contextualize the vision and programs they pursued as the President. Thanks to the NAPPSA YP Chair, Dr Sherriff Benson, for doing an awesome job in this very first Presidential Exit Interview, with the Immediate Past President (IPP) of NAPPSA: Dr Anthony Ikeme.

Finally this edition speaks of the future as it is coming out at a time when we are preparing to inaugurate the President-Elect, Emmanuel Ezirim, as the next president of NAPPSA.

It is very commendable and worthy of celebration that NAPPSA is built with sustainability in mind to ensure that our path to greater future is smooth and seamless. Thanks to the founding fathers for envisioning such a well-rounded organization that encompasses all aspects of pharmacy and pharmaceutical sciences.

With the unique diversity of our membership, I remain confident that we have all the tools and skill set to continue to grow from strength to strength in all areas of pharmacy practice and pharmaceutical science.

As always, I remain grateful to the editorial team under the leadership of Dr. Anayo M. Ukeje, and entire team of editors, including Patrick Nwakama, Victoria Oshunkentan and the Immediate Past President, Dr. Anthony Ikeme for their exemplary work and continuing efforts to sustain this News Magazine.

Warm regards,

Teresa Pounds

Teresa Pounds, PharmD
NAPPSA President

FROM the EDITOR'S DESK

NAPPSA Digest, 2023 special edition is a continuation of relentless efforts of the editorial team to grow and sustain the quality of "NAPPSA Digest" Publication. This edition aptly titled "Past, Present and the Future" is a collector's item as usual full of informative News and articles, it contains a particularly novel "Presidential Exit Interview which links the past with the present and extents the present into the future to ensure continuity. It also celebrates our past achievements such as the launch of NAPPSA Official Journal, American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS), our continuing successful 5k Run with increasing collaborations such as that with Shriner's hospital.

This edition rightly focuses on our past achievements, NAPPSA Journal "NAPPSA Endowment sustained by our continuing successful 5K run and proceeds from NAPPSA B-2-B as we race towards our $1 million Endowment fund target.

This edition also featured the usuals including but not limited to message from NAPPSA President, Therapeutic Update, Young Professionals' corner dealing with "Immigration, Emigration and Pharmacy Education: Insights and opportunities", NAPPSA TitBits, drawing attention to NAPPSA partnership with Shriner's hospital on a 5K FunRun to raise funds for NAPPSA Endowment

Career Spotlight highlighted opportunities for Pharmacists in the Pharmaceutical industry, Blogger's corner revealing the meaning of R.E. S.P.E.C.T in mental health as well as the "History of Antibiotics and our calendar of events.

My special thanks go to NAPPSA President, Dr. Teresa Pounds for her continuing support to the Newsletter editorial team. Big thanks to our indomitable IPP, Dr. Anthony Ikeme for his relentless efforts in providing content, editing, design and production of the NAPPSA Digest News Magazine.

My appreciation goes to Patrick Nwakama, who not only provides content, but reviews every article and provides regulatory and therapeutic areas updates. I also thank other Editorial Team members; Victoria Oshunkentan, Victoria Adu and all the contributors who provided the content to this special edition of 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 all of you for content generation editing & delivery of quality NAPPSA News Magazine.

To NAPPSA Digest Readership, I say thank you for trusting us to provide topical articles, information, News and NAPPSA events calendar to you. Take some time to relax, rejuvenate, read and enjoy the unique content of this special 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

PRESIDENTIAL EXIT INTERVIEW

NAPPSA for me is a proof of concept

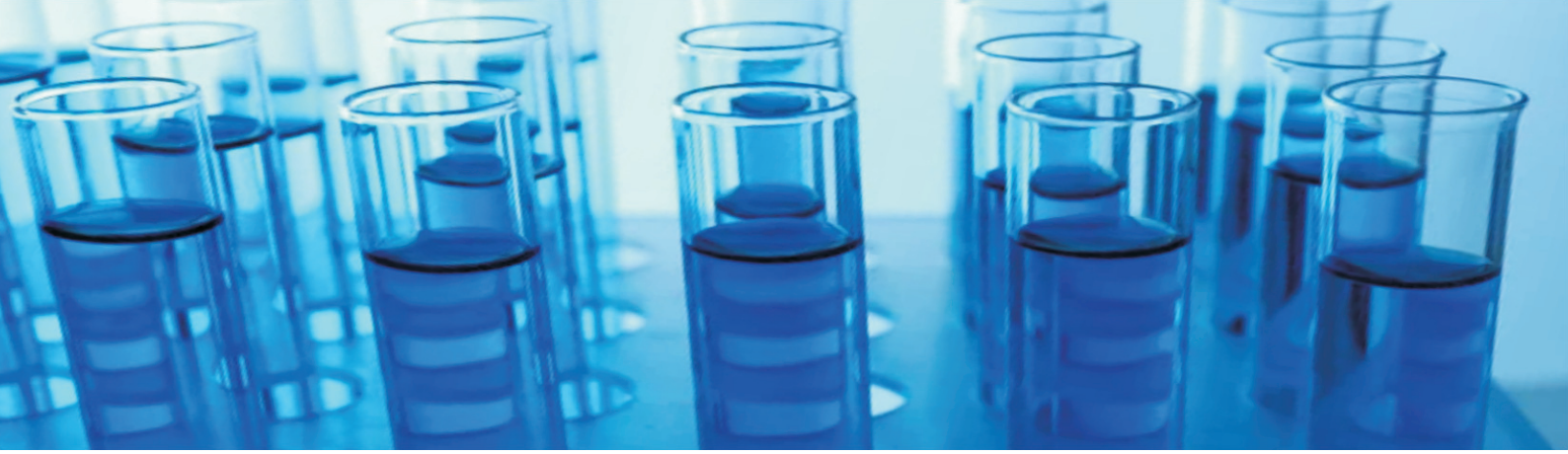
Revisiting the times and accomplishments of the 5th NAPPSA President: Dr Anthony Ikeme

The NAPPSA Digest Editorial team introduced the Presidential Exit Interview Series to serve as an epilogue at the conclusion of each NAPPSA Presidency. It allows NAPPSA members access to the thoughts and the inner workings of the mind of each President to better contextualize the vision and programs they pursued as President. In this very first Presidential Exit Interview, the NAPPSA YP Chair, Dr Sherriff Benson sat down with the Immediate Past President (IPP) of NAPPSA: Dr Anthony Ikeme. He spoke eloquently about his dreams, vision and programs he championed as NAPPSA President. See excerpts below.

Congratulations on your successful tenure as President of NAPPSA. I will start by asking you this, what made you aspire to the NAPPSA Presidency?

Thank you for that question. My interest in the Presidency of NAPPSA evolved out of my observations while in the service of the organization. I was introduced to NAPPSA by Dr Echeazu Ogu one Sunday evening at a social event in Wilmington Delaware, exactly 4 days before the 2007 Inaugural NAPPSA Conference in Houston. He spoke so glowingly of the NAPPSA vision that I knew I had to attend and see this new organization for myself, and I am very glad I did. I was so impressed with what I saw that I embraced everything NAPPSA and threw myself into the service of the organization. In the course of my service, I served as the Program Chair, Secretary of the NAPPSA Implementation Committee, Secretary of Abuja Healthcare Summit planning committee, Member of the NAPPSA Board, Member of the NAPPSA Foundation Board and others. Over the course of my involvement in these endeavors, I kept feeling that NAPPSA could be more. I saw growth and transformational opportunities in all aspects of NAPPSA activities. Where many saw a mere professional association, I saw a platform that can be deployed for transformational initiatives.

You see, NAPPSA for me is proof of concept. I have always had this concept and belief that our only limits as Nigerians (nay Africans) are the ones we impose on ourselves. NAPPSA Presidency was an opportunity to test that concept and prove that we can actually be the best among equals. So here we were, a talented and highly accomplished group of professionals, living in one of the greatest democracies in the world, where there is a reasonable expectation that rule of law will be respected, where competence and talent is rewarded. What is stopping us from being the best we can be? What is stopping us from deploying our collective energy and talent to change our world? Nothing!



I saw clearly in my head how NAPPSA could serve as the catalyst, the trigger point for the transformation of the Nigerian Pharmacy professionals in the USA, the Nigerian Pharmaceutical Sector, as well as Nigeria and Africa as a whole. But it was difficult to convey this understanding in my head and the passion in my heart to someone else who does not see what I see. That was when I made the decision that it is best to practically demonstrate what I believe by serving in the capacity of NAPPSA President.

During your campaign for the presidency and during your inauguration, you listed some objectives you intended to focus on during your tenure. What would you consider as your major achievements during your presidency?

Another great question. Because of how my decision to aspire to NAPPSA presidency evolved, I came prepared with a clear vision and purpose. If there was one singular thing that formed the organizing principle for the success of my tenure, then it was the establishment of the NAPPSA 10-Year Growth Strategy Plan. Everything else flowed from it

You see a fundamental thought that repeatedly rang in my ears throughout my years of service in NAPPSA, was the saying that "if you fail to plan, then you have planned to fail". I was determined that our collective learnings and history over the many years of NAPPSA existence should be used as a basis to re-imagine the future of the organization in a way that sharpens our focus and builds on our areas of strength. This was why I proposed a

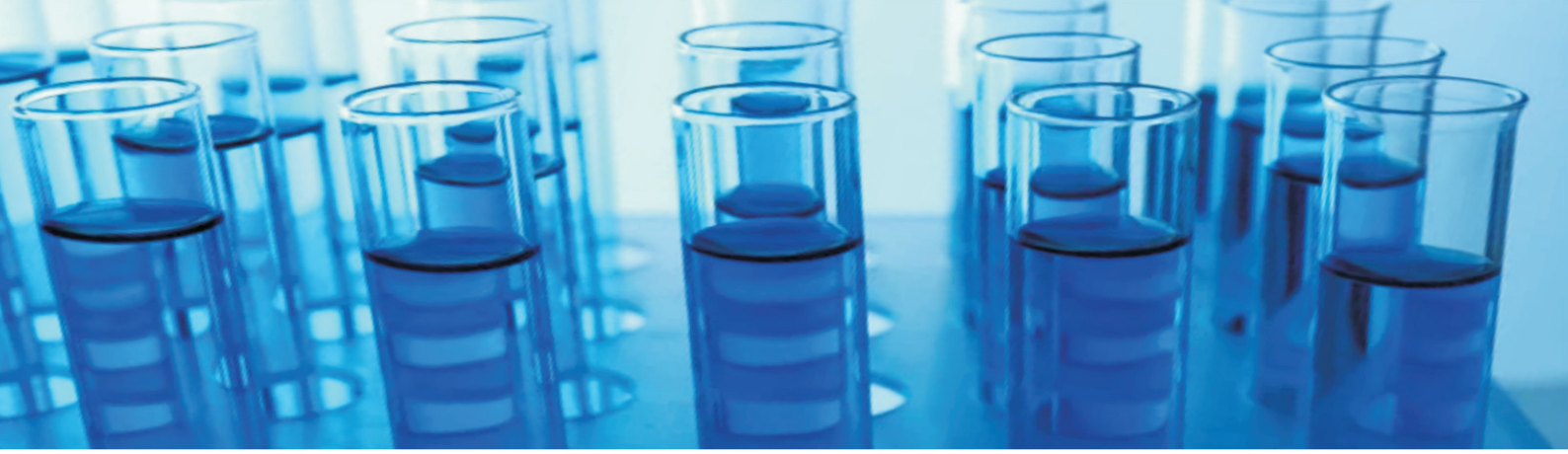
> "I was determined that our collective learnings and history over the years should be used as a basis to re-imagine the future"

strategy plan. I was very encouraged that all cadres of NAPPSA leadership at the time (including all the NAPPSA founding members, all past presidents, Executive Committee and NAPPSA Board members) as well as the entire NAPPSA membership embraced the vision. It was the successful establishment of that plan and the success in its early implementation that made many to consider my tenure as beginning of what they call **NAPPSA 2.0.**

So what is the NAPPSA 10-Year Strategy Plan? Simply put, it is a deliberate and measurable process for driving and tracking NAPPSA's growth in all facets of her business for the 10-year period: 2020-2030. As NAPPSA continue to reinvent itself and evolve into better versions of itself, I have always believed that sustained growth can only be achieved and sustained when there is a clear direction and set priorities that ensure that we have better thinking, better decisions and ultimately better results. The 10-year plan brings the future into the present, so that we can do something about it now. It helps us to simplify decisions, get everyone on the same page and ensure that our activities are aligned to our priorities. The roadmap it creates ensures that we increase our organizational footprint and maximize our impact as a professional organization here in the USA, back home in Nigeria and around the world.

It sets timelines for achieving key visionary milestones including the acceleration of the growth of the NAPPSA B2B Network, which is the engine of NAPPSA's financial sustainability, creation of a NAPPSA official Journal, setting up of the NAPPSA Endowment fund, the establishment of a NAPPSA House and a NAPPSA Research Institute.

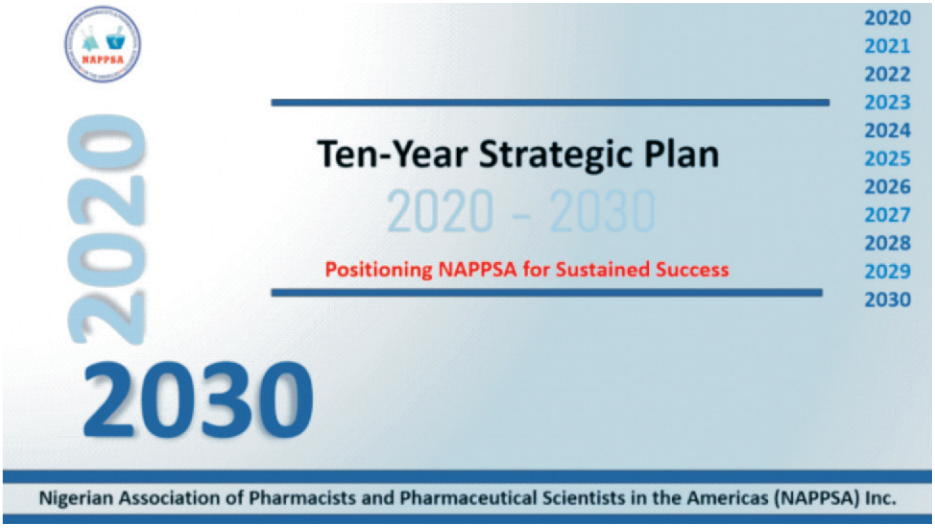
As lofty as these goals were, we knew it was not enough to just establish the plan and walk away beating our chest that we have an accomplished tenure. There are many plans in many institutions, and even nations, that languish away on the shelves unimplemented. We knew that we had to make progress on the plan during my tenure as proof of concept and to instill belief in the minds of the general membership and future administrations



that this plan is doable. So, my greatest pleasure is that we made significant progress in the implementation of the plan during my tenure.

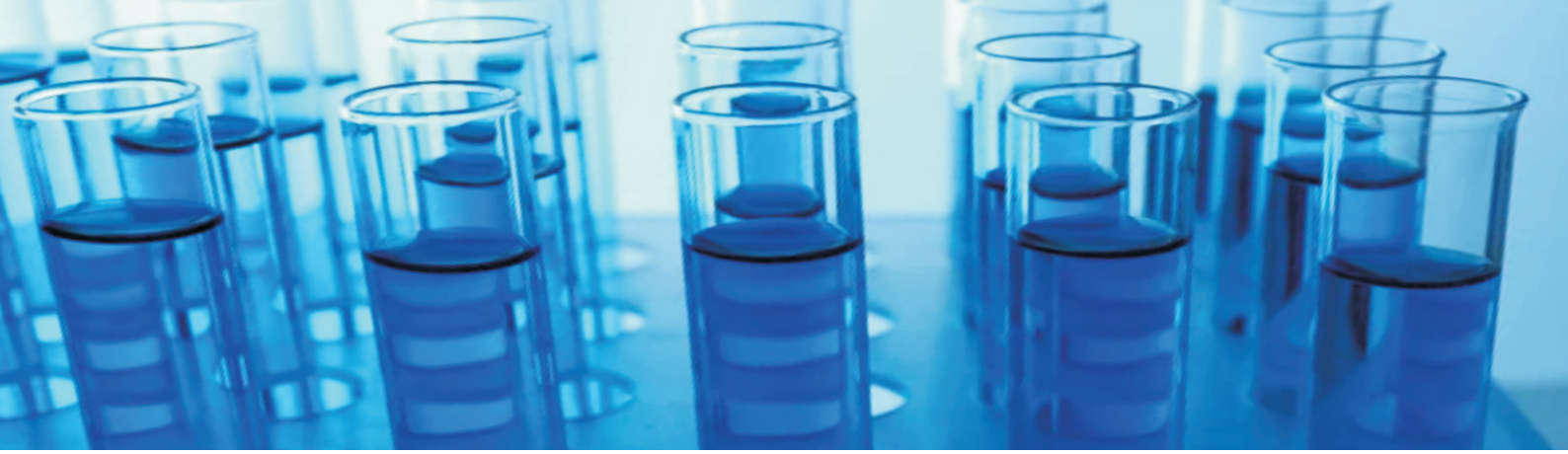
First focus in the implementation of the plan was finding the financial resources. And so, I partnered with my good friend and partner in generating ideas for NAPPSA progress, Emmanuel Ezirim who is the Chair of NAPPSA B2B and the current President-Elect. We hit the road on B-2-B Roadshows across the country, leading to the acceleration of growth in the membership of our B2B Network and a steep increase in the B2B revenues to NAPPSA. Next, we set up the NAPPSA 5K FunRun to both draw attention to healthy living and raise money for NAPPSA's financial stability. The progress we made with both the B-2-B and the 5K Run fundraiser gave us confidence to launch the NAPPSA Endowment Fund which today is well on its way to the first $1M dollar mark. We also successfully established the NAPPSA Official Journal, American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS). We are now poised to commence efforts to acquire the NAPPSA House which will host our NAPPSA Research Institute. Overall, our 10-Year Strategy Plan is Inclusive, ensures commitment to Quality, provides incentives for consistent delivery, allows for NAPPSA's sustainability, has Milestones along the way to measure the impact of our progress, and has an inbuilt Dynamism to allow for continual improvements as we make progress.

Outside of the strategy plan, other notable accomplishments that is worth mentioning include:



> **The NAPPSA 10-Year Strategy plan is a deliberate and measurable process for driving and tracking NAPPSA's growth and progress**

- We launched our **Young Professional Campus Outreach,** to reach out to Nigerian Pharmacy and pharmaceutical Science Students in the USA, to provide early career guidance to inform their curriculum and internship choices as they plan their future.
- We launched the **Young professional Hangout Series** to provide a platform for addressing real life issues and teaching those soft life skills that underpin life success and advancement to leadership positions.
- We established the **NAPPSA Pharmaceutical Science Focus Group** designed to create programs and projects that appeal to Pharmaceutical Scientists. Their newly created Pharmaceutical Science Focus Strategy Document charts a visionary cause for our Pharmaceutical Science Community.
- On the main issue that defined my tenure, **the COVID-19 pandemic**, NAPPSA took a front row seat. We participated in the discussion and dissemination of scientific clarity about COVID-19 through press statements, letters to congress, government agencies, and via collaborative inter-organizational initiatives.
- We stepped up to support the Nigerian Healthcare Community through our donation of COVID-19 Diagnostics and PPE to the National Center for Disease Control (NCDC).
- We successfully established NAPPSA 5K Walk/Run for both fundraising and to draw attention to Healthy living.



- While other organizations cancelled their Annual Conferences in 2020, we innovated. We hosted NAPPSA's first ever technology driven Virtual Scientific Conference
- We established the NAPPSA-ANPA-NANNNA Interprofessional Healthcare Webinar Series
- We established the official NAPPSA News Magazine: NAPPSA Digest

It was indeed a very productive 2 years that have opened new doors and new possibilities for our great organization. I am committed to continuing to contribute to build on all areas of our progress.

Let's delve deeper here a little bit. You mentioned the recently launched peer review Journal, AJPPS. In what ways will it enhance pharmacy practice and what are the research conducted so far?

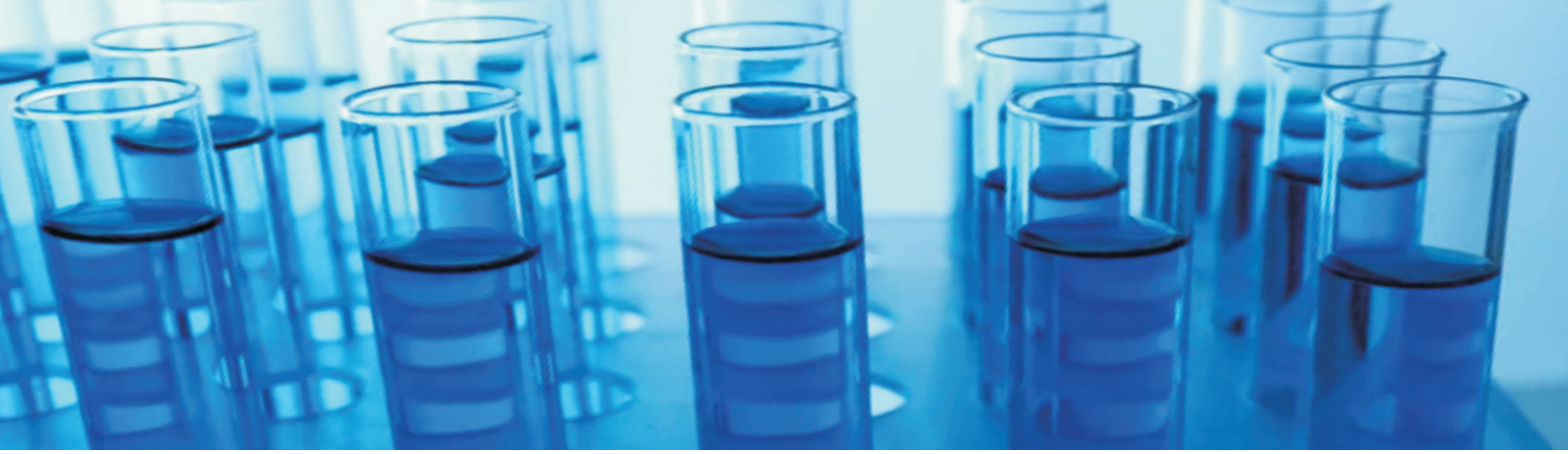
The launch of the NAPPSA official peer review Journal, American Journal of Pharmacotherapy and Pharmaceutical Sciences (AJPPS) is one of the core strategic initiatives envisioned in the 10-Year NAPPSA Strategy Plan. I dare say that we are the first Nigerian diasporan professional organization to own her own peer review journal. Why a Journal, you might ask. Our peer review journal has raised our organizational profile as expected and is now serving as an outlet for our scholarly inclined pharmacists and pharmaceutical scientists to achieve professional fulfilment. It will also serve as a destination for worthy NAPPSA conference podium presentations, proceedings of our annual conferences, as well as NAPPSA solution oriented White Papers.

> **AJPPS now serves as an outlet for our scholarly inclined pharmacists and pharmaceutical scientists to achieve professional fulfilment**

As conceptualized, AJPPS covers the broadest spectrum of the Pharmacy and Pharmaceutical Science continuum. This is purposefully intended to mirror the essence of NAPPSA's founding mission and the structure of her inclusive membership. It not only publishes articles that seek to translate pharmaceutical science into practice, but it also welcomes 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.

But AJPPS is set to be much more than all we have 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. Academics from Southern countries report frustrations at not being consulted when the main conceptual issues of research projects are discussed. 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. AJPPS is uniquely positioned to bridge this anomaly. The fact that it is a journal founded by Northern-based professionals with Southern ancestral 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 a manner that ensure that African research priorities are not neglected in scientific discourse.

Finally, 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. An enhanced profile and brand mean name recognition, open doors and access. 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. Huge thanks to the Editors-in-Chief, Prof. Ashiwel Undieh and Dr Patrick Nwakama, and the other members of the Journal Sub-Committee: Dr Sunny Ohia and Dr Otito Iwuchukwu for their great contribution to making AJPPS a reality. I encourage everyone to visit www.ajpps.org to download the wide range of research and review articles the Journal has published so far. The link to submit manuscripts and for application for editorial team membership is also available on the website.

There are other elements of your 10-Year NAPPSA Growth Strategy Plan that sounds very exciting. Elaborate more on the Endowment Fund

The NAPPSA Endowment is another first among our peers. We are very proud of the fact that we are the first Nigerian Diasporan Professional Organization in North America, or even in the world to set up an Endowment Fund. The NAPPSA Endowment Fund, is envisioned to provide stability and sustainability to finances of NAPPSA. It creates a steady source of funding for running the operations, programs and projects of NAPPSA in a manner consistent with the stated mission of the organization. NAPPSA.

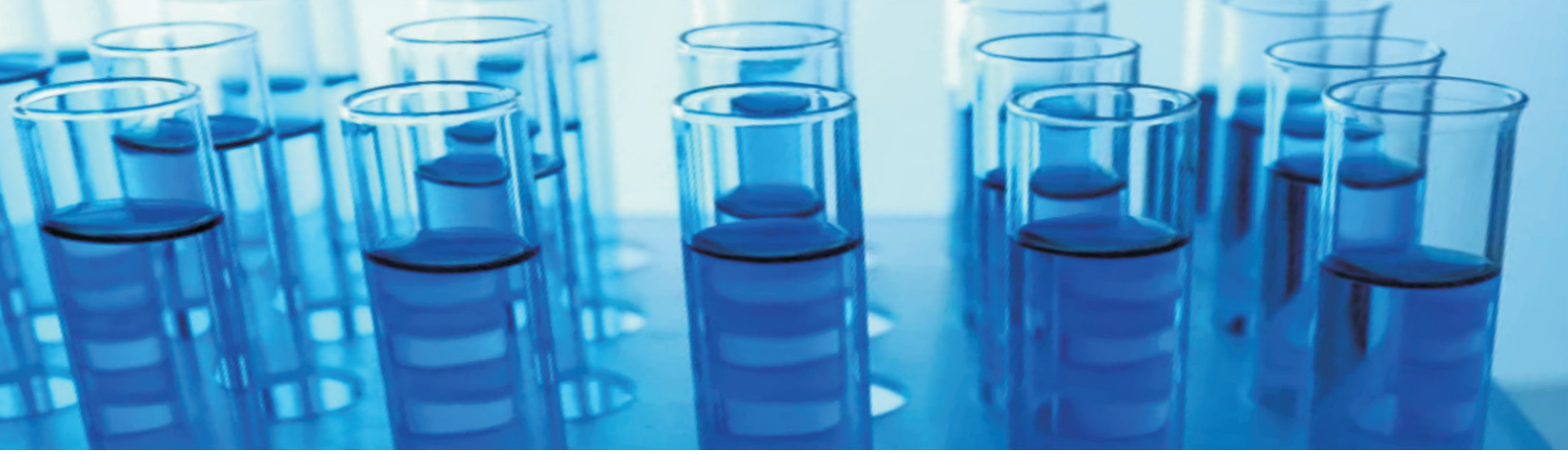
We consider this accomplishment one of the most important milestones in

> **The NAPPSA endowment fund is envisioned to provide stability and sustainability to the finances of NAPPSA**

NAPPSA's history as it creates a new chapter of possibilities in our growth strategy. It sends a strong message to our external observers, partners and collaborators that we have planned for long-term stability, fiscal responsibility, and financial viability. It enhances the NAPPSA's prestige, trustworthiness and credibility. With time and its sustained growth, it will relieve pressure on annual fundraising and streamline organizational budget and financial planning.

I encourage all NAPPSA members and the general public to visit the Endowment page of the NAPPSA website and see the details on how the NAPPSA Endowment Fund Oversight Board harnesses the three core pillars of the Endowment Matrix, namely: the fundraising strategy, the spending strat¬egy, and the investment strategy, to optimize the Fund's performance.

I must say a huge thank you to the members of the Endowment Oversight Board, Nnodum Iheme, Dr Funmi Ajayi, Dr Patrick Nwakama, Gbenga Olajide, Emmanuel Ezirim and of course the current NAPPSA President, Dr Teresa Ponds who serves in adhoc capacity, for the great work they are doing to sustain the momentum. Through their efforts and the support of the NAPPSA leadership and general membership, we have surpassed the half million-dollar mark and is now well on our way to achieve the first $1M milestone. Thanks to every member of the NAPPSA B-2-B who have contributed to the rising B-2-B returns and everyone of the 62 inaugural NAPPSA 3K FundRacers. It is



their commitment and dedication to the process that gave us the initial belief and ultimately propelled us to coming this close to a million-dollar endowed organization in just 2 years. When fully matured, proceeds from the Endowment Fund will be used to support NAPPSA Scholarships, grants to scientific researchers, fund PhD projects, improve research capacity in Nigerian Universities and other major research institutes, and to support research initiatives of the proposed NAPPSA Research Institute (NRI). Our future is bright indeed.

You also mentioned the NAPPSA House and NAPPSA Research Institute. Can you share how that advances NAPPSA's mission and Vision

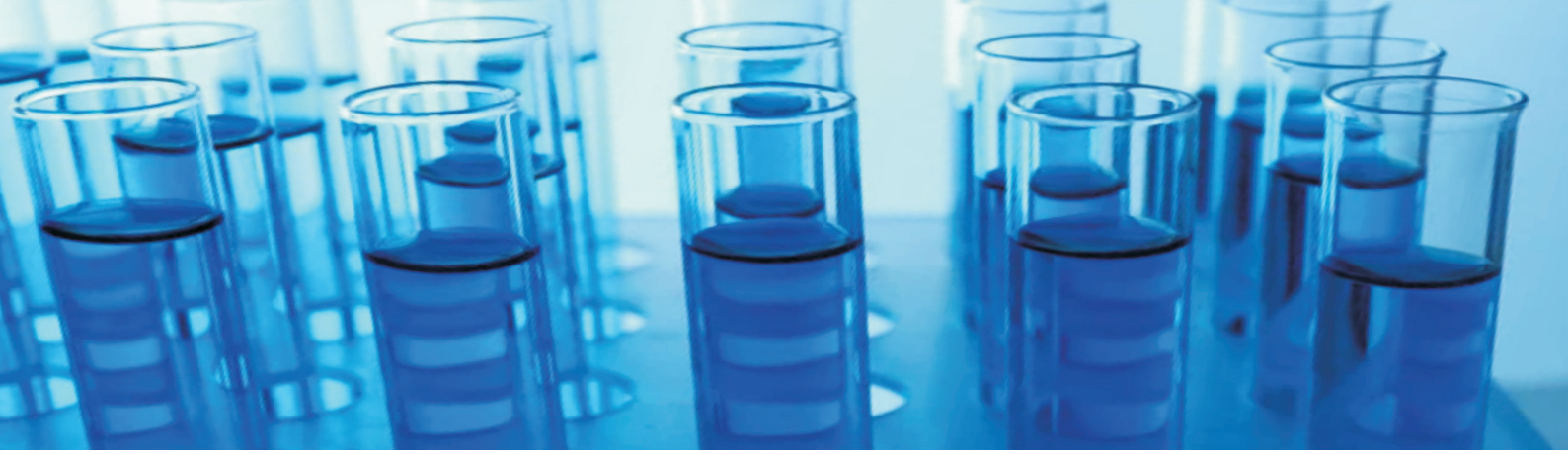
The NAPPSA House will serve as a permanent location for the NAPPSA office. After 15 years of existence, NAPPSA deserves a space that will serve as her permanent home to hold the various artefacts and historical relics that tell her story. With the great strides we are making in both the professional realm and the Nigerian pharmaceutical sector, I envisage that NAPPSA house will become an iconic edifice of pride to Nigerian pharmacy professionals and all Nigerians in general. It will be a beacon of inspiration to other professional organizations and a practical demonstration of our deep held belief that we have equal stake with every other immigrant community or group in America in shaping our world.

Perhaps the most exciting use of the NAPPSA House will be its role as host to the NAPPSA Research institute. The NAPPSA Research Institute is a strategic initiative in the strategy plan that creates a framework for collaborative research partnerships among leading NAPPSA Research Scientists, and between NAPPSA and other scholarly institutes on areas of common interest. It will ensure that African unique perspectives and interests are represented at the highest level in pharmaceutical research. It will also broker research partnerships between Diasporan research scientists and their counterparts in the homeland.

> **NAPPSA House will become an iconic edifice of pride to Nigerian pharmacy professionals in America and all Nigerians in general**

Definitely, leading an association like NAPPSA comes with some challenges. But your tenure was particularly challenging because you led the organization through the global pandemic. Looking back at your tenure, what could you identify as your toughest challenge?

You are absolutely correct, the global COVID-19 pandemic was our toughest Challenge during my tenure as NAPPSA President. You see it came at a very awkward time for NAPPSA. The pandemic by itself posed significant challenges to all Non-profits and organizations, but it was an even tougher proposition for NAPPSA, because NAPPSA was also in the midst of other organizational changes. As at March of 2020, when the pandemic tightened its grip on the world, NAPPSA had just completed a leadership transition where I took over at the helm and I was right in the middle of enthroning a new strategic plan for our organizational transformation. These changes had to continue despite the pandemic even as we grappled with the new challenges posed by the COVID-19 crisis.



But rather than cower in the face of the pandemic, we rose to the challenge. The pandemic months valorized NAPPSA's determination to make the concept of Leading from the Front an integral part of our organizational culture. Over the course of the pandemic months, our leadership in information dissemination and scientific knowledge brokerage shone brightest. At all levels and in all issues concerning COVID-19, we stood in the front line and helped advance the science, discussion of policies and advocacy for change. In the face of the multiple non-verified therapeutic claims for COVID-19, NAPPSA spoke up strongly via multiple press releases to provide general update on the science of coronavirus and to educate the public about the dangers of unsubstantiated claims about COVID-19 treatment protocols.

Our leadership was also manifest in the use of technology to maximize connectivity. We were one of the first organizations to quickly transition to full scale virtual operation using Zoom for our Board and Committee meetings. We designed new ways of using WhatsApp for not just communication but for events and social hangouts. Technology enabled us to increase participation and served as a coping mechanism for many members of our organization who needed that sense of community and camaraderie during the lonesome months of the pandemic lock down. Most importantly, we were among the few organizations who boldly experimented with a Virtual Conference when it became clear that the pandemic lock down will not allow for a live in-person conference. Rather than cancel our 2020 annual conference like many organizations did, we designed ways to utilize technology to execute all aspects of conference virtually including the annual gala and NAPPSA Walk/Run team building activity.

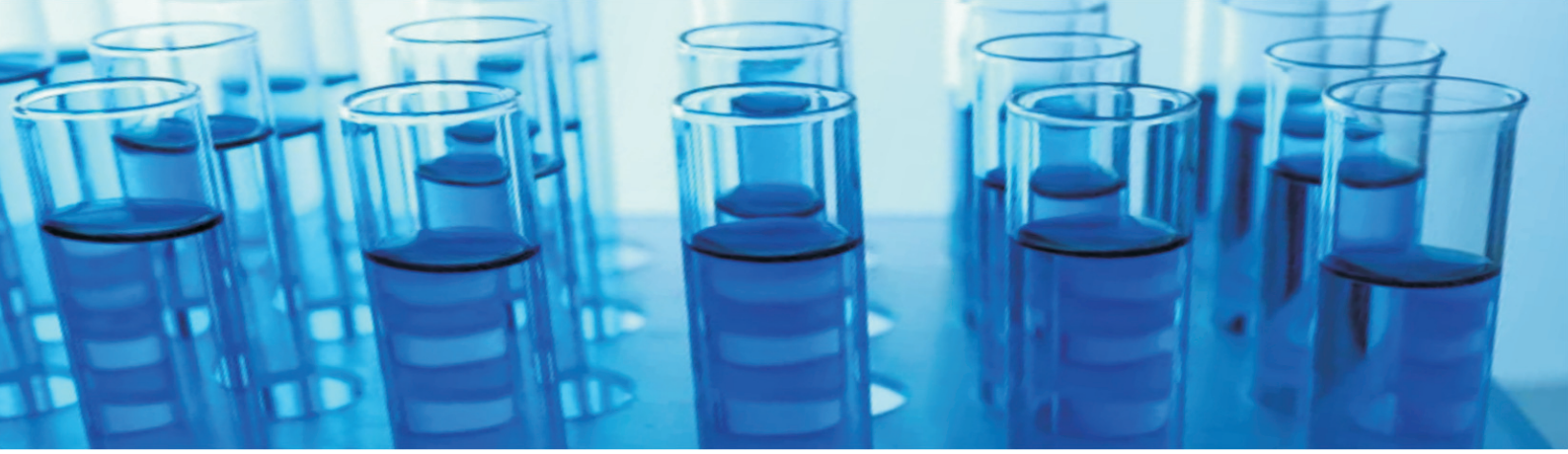
> **The pandemic months valorized NAPPSA's determination to make the concept of Leading from the Front an integral part of our organizational culture.**

The pandemic was the greatest challenge of my presidency, but we repurposed the adversity into opportunity.

As a pharmaceutical scientist and a Clinical Research Professional, would you say your knowledge and experience in the industry has improved or impacted your profession?

That is a difficult question to answer. I don't think it is my place to describe if and how my contributions have contributed to my chosen profession or area of practice. But I can share some of the things I have done to show areas of the industry and professional development that interest me.

Apart from my well documented activities at NAPPSA, I have been actively involved in building capacity for clinical research and pharmaceutical sector development in Nigeria. I founded Clintriad Nigeria Ltd, the first indigenous Contract Research Organization in Nigeria. Clintriad was one of the pioneers in capacity building for clinical trials and build-up of a database of investigational sites, investigators and other resources for clinical research in West Africa. I serve as one of the international resource persons and member of the board of the Association for Good Clinical Practices



in Nigeria (AGCPN) and has served in leadership capacities for various AGCPN transformational initiatives including Chair of AGCPN-NAFDAC clinical Trial Capacity Building Workshop Taskforce (2010), the Co-Chair of the AGCPN-NAFDAC Clinical Trial Technical Working Group (CTWG), and the Program Coordinator of the All-Africa Clinical Trial Summit. Through these channels, we made progress in creating awareness about the importance of clinical research and contributed to improving capacity for pharmaceutical science and product innovation in Africa through strategic partnerships with governments and key players within the sector.

I also served as the USA National Coordinator, African Technology Policy Studies Network. In this capacity, he is responsible for coordinating ATPS programs and projects in the USA. ATPS is a multi-disciplinary network of researchers, practitioners and policy makers that promotes science, technology and innovation (STI) policy research, dialogue and practice, for African Development. The range of my interests and activities betray where my passion is, namely, is to build capacity for progress in my profession, community, in my country, Nigeria, Africa and the world. I will let others judge if my contribution moved the needle of not.

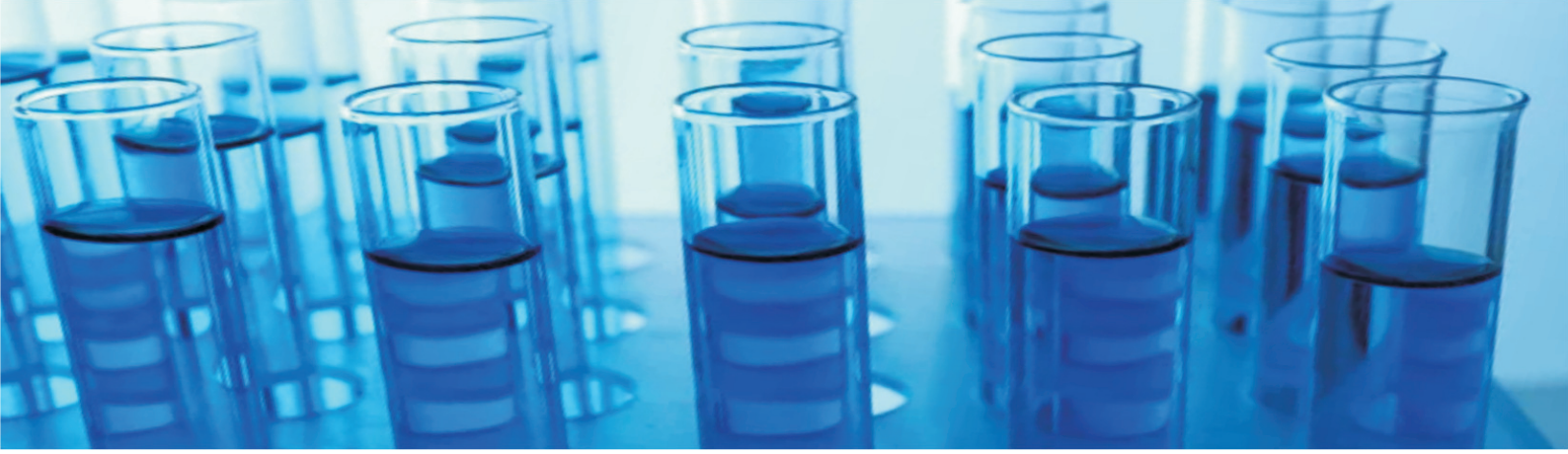
Also, during your tenure, you visited some government parastatals in Nigeria, especially in the healthcare sector. What were your take homes during this visits?

One of the greatest lessons of the

> **We are strongest when we lean on our inter-connectedness and work collaboratively with our allies and partners.**

pandemic is one thing we have always known, the fact that we are strongest when we lean on our inter-connectedness and work collaboratively with our allies and partners. Through collaborations, organizations are able to share resources, collaboratively solve problems, and work together to maintain service provision to the constituencies they mutually serve. During my tenure, we invested heavily in collaborations. Here in the USA, our collaboration with the US Department of Health and Human Services (US DHHS), Association of Nigerian Physicians in the Americas (ANPA), NANNNA, PSN and other professional institutions and non-profits gained new significance in the course of the pandemic. It was particularly pronounced in the area of mass education and awareness creation about COVID-19 within the African immigrant communities in the USA. Key examples of our successful collaborations include our collaboration with ANPA and NANNNA to address COVID-19 Vaccine Hesitancy, the George Floyd police brutality incident and the ENDSars issue in Nigeria; and our partnership with the US DHHS to increase awareness about access to Monoclonal Antibodies (mAbs) within the immigrant communities as part of the US government initiative to minimize COVID-19 deaths and hospitalizations. These collaborations enabled us to extend the reach of our influence and maximize our impact.

My visit to NAFDAC, PSN, NCDC, PCN, NAIP, NIPRD, and NiDCOM was to take this collaborative disposition a notch further by promoting the importance of collaboration between the homeland and Diaspora. History tell us that Great things happen when the homeland and Diaspora join forces for progress. And there are many examples from history to inspire us along this path. It was the collaboration between the Indian Diaspora and the Indians in the nation's IT sector that led to the replication of the American Silicon Valley in India: in the name of Bangalore. Historical data show that the Diaspora Chinese provided the lion's share of inward foreign investment that fueled the



growth of China and worked collaboratively with their partners at home to deploy these investments to power the local economy. Perhaps the most cited example of the collaborative success of diaspora and homeland is found in the Jewish story. The Jewish Diaspora has provided investments, loans, donations, technology, business contacts, and tourism, and have worked collaboratively with their counterparts in the homeland to channel these contributions to where they are needed for maximum impact.

My visit to these institutions is to extend NAPPSA's hands of partnership to serve as their diasporan partner in the development of the Nigerian pharmaceutical sector. As I shared during my talk at the PSN conference in Kaduna in 2019, I still believe that the key stakeholders in the Nigerian Pharmaceutical sector, from both diaspora and the homeland, should come together and form a Pharmaceutical Sector Focus Group to champion the development of the Nigerian Pharmaceutical sector. With such a platform, there is no limit to what we can accomplish. Just let your imagination run wild. We can create targeted Investment Groups and Venture capital consortiums to address specific gaps within the Nigerian pharmaceutical sector. We can match willing foreign investors with profitable homegrown businesses looking for expansion. We can generate the data that can demonstrate to policy makers the impact of what we are advocating for on the Nigerian economy. A show of unity between the homeland and Diasporan professionals can send a more formidable message to the government and policy makers to introduce policy incentives to catalyze progress in the pharmaceutical sector.

> **"Success is achieved when the pillars upon which visions are erected are based on a solid foundation."**

What is your advice to future NAPPSA leaders?

3 key words of advice:

The First is Lead from your area of greatest strength. Take ownership of your niche and just build from there. You see, NAPPSA is evidently on track for unprecedented growth and progress. The ten-year strategy plan is a compass that is already taking NAPPSA to where it has never been before. But as great as it is, and as successful as we have been so far with the execution of the strategy plan, we need not be limited by its current stipulations. The plan is designed to be expandable and is receptive to new ideas. Let the success we have achieved be an inspiration and proof that there is no limit to our ability and potential, once we can keep our dreams alive, and have no fetters on our imagination.

The second: Focus on competence and merit. Make sure that in all appointments to leadership position, we put round pegs in round holes and square pegs in square holes. Success is achieved when the pillars upon which visions are erected are based on a solid foundation.

Finally, never ever take your foot off the pedal! Stay focused on the goal and disregard distractions and noise that is neither value adding nor constructive.

2023 NAPPSA 5K RUN/WALK

SUPPORT NAPPSA ON THE NOBLE CAUSE

NIGERIAN ASSOCIATION OF PHARMACISTS & PHARMACEUTICAL SCIENTISTS IN THE AMERICAS
NAPPSA

Help Fund the NAPPSA Endowment Fund

5K NAPPSARUNS

JOIN US FOR THE NAPPSA FUN RUN/WALK

@ 17th Annual Conference

Location: COLUMBUS PARK OF ROSES

HIGHLIGHTS

- Run or Walk for NAPPSA
- Music & Refreshment
- Raffle Prizes and Giveaways
- Hangout with friends
- Experience the magnificient Oriole Stadium

FREE HEALTH SERVICES

- Health Screenings
- Health Education

SEPTEMBER **23** 2023

6 AM

Our Endowment Supports

SCHOLARSHIP | ACADEMIC GRANTS | MEDICAL MISSIONS | EMERGENCY RESPONSE

Artificial Sweetener Consumption Linked to Type 2 Diabetes

Carolina Gonzalez-Lopez, MD

Given the obesity and diabetes epidemic, there is a growing use of artificial sweeteners in ultra-processed foods. However, previous studies have found an association between artificial sweeteners and the risk of breast cancer, obesity-related cancers, and CVD. In the present study, the authors evaluated the associations between artificial sweeteners, more specifically aspartame, acesulfame K, and sucralose, and type 2 diabetes risk. With a robust sample of 105,588 participants, the results showed that, compared with non-consumers, consumers of higher amounts of artificial sweeteners had a higher type 2 diabetes risk, more so with aspartame and acesulfame K than with sucralose.

The results of this study provide a new piece of evidence that complements recent mounting scientific literature regarding the potential adverse effects associated with artificial sweeteners on chronic disease and can add a layer of discussion with patients.

Diabetes Care 2023;46(9):1–10 | https://doi.org/10.2337/dc23-0206

First-Line Therapy in T2D: Has Metformin Been 'Dethroned'?

Joshua J. Neumiller, PharmD, Radica Z. Alicic, MD

Initially approved by US Food and Drug Administration in 1994, metformin has been the preferred first-line glucose-lowering agent for patients with type 2 diabetes (T2D) owing to its effectiveness, low hypoglycemia risk, weight neutrality, long clinical track record of safety, and affordability. However, the advent of newer glucose-lowering agents with evidence-based cardiovascular (CV) and renal benefits calls into question whether metformin should continue to be the initial pharmacotherapy for all patients with T2D. To help determine whether metformin has been "dethroned" as first-line treatment for T2D, here is a brief review of recent evidence and current guideline recommendations.

The current ADA recommendations stress cardiorenal risk reduction while concurrently achieving and maintaining glycemic and weight management goals. Based on evolving outcome trial data, GLP-1 receptor agonists and SGLT2 inhibitors with evidence of benefit are recommended for patients with established or at high risk for ASCVD. Further, the Standards preferentially recommend SGLT2 inhibitors for patients with HF and/or CKD. Because evidence suggests no heterogeneity of benefit based on A1c for MACE outcomes with GLP-1 receptor agonists and no heterogeneity of benefit for HF or CKD benefits with SGLT2 inhibitors, these agents are recommended for cardiorenal risk reduction regardless of the need to lower glucose.

The 2023 update to the American Association of Clinical Endocrinology (AACE) Consensus Statement: Type 2 Diabetes Management Algorithm similarly recommends the use of GLP-1 receptor agonists and SGLT2 inhibitors to improve cardiorenal outcomes. To further emphasize the importance of prescribing agents with proven organ-protective benefits, the AACE consensus statement provides a complications-centric algorithm to guide therapeutic decisions for risk reduction in patients with key comorbidities (e.g., ASCVD, HF, CKD) and a separate glucocentric algorithm to guide selection and intensification of glucose-lowering agents in patients without key comorbidities to meet individualized glycemic targets. Within the complications-centric algorithm, AACE recommends GLP-1 receptor agonists and SGLT2 inhibitors as first-line treatment for cardiorenal risk reduction regardless of background metformin use or A1c level.

In addition to the emphasis on the use of GLP-1 receptor agonists and SGLT2 inhibitors for organ protection, guidelines now recommend SGLT2 inhibitors as the standard-of-care therapy in patients with T2D and CKD with an estimated glomerular filtration rate ≥ 20 mL/min/1.73 m2, and irrespective of ejection fraction or a diagnosis of diabetes in

the setting of HF. Overall, a common thread within current guidelines is the importance of individualized therapy based on patient- and medication-specific factors.

So, has metformin been "dethroned" as a first-line therapy for T2D? As is often the case in medicine, the answer depends on the individual patient and clinical situation. Metformin remains an important first-line treatment in combination with lifestyle interventions to help patients with T2D without key cardiorenal comorbidities achieve individualized glycemic targets. However, based on evidence demonstrating cardiorenal protective benefits and improved glycemia and weight loss, GLP-1 agonists and SGLT2 inhibitors may be considered as first-line treatment for patients with T2D with or at high risk for ASCVD, HF, or CKD, regardless of the need for additional glucose-lowering agents and independent of background metformin. Ultimately, the choice of first-line therapy for patients with T2D should be informed by individualized treatment goals, preferences, and cost-related access. Continued efforts to increase patient access to GLP-1 receptor agonists and SGLT2 inhibitors as first-line treatment when indicated are essential to ensure optimal treatment and outcomes.

SGLT2 Inhibitor Plus GLP-1 Agonist in Diabetes with High CVD Risk

The era of guidelines that recommended treatment with either a sodium-glucose cotransporter-2 (SGLT-2) inhibitor or a glucagon-like peptide-1 (GLP-1) receptor agonist in people with type 2 diabetes mellitus and established cardiovascular disease (CVD) ended with new recommendations from the European Society of Cardiology (ESC) that call for starting both classes simultaneously.

"A key change is that we removed the 'and-or' and the 'either-or' terms and recommend using both classes simultaneously in patients who are eligible based on their clinical indications and without contraindications or intolerance," said Darren K. McGuire, MD, at ESC Congress 2023.

ESC's new guidelines for managing CVD in patients with diabetes, released on August 25 and presented in several sessions at the Congress, also break with the past by calling for starting treatment with both an SGLT-2 inhibitor and a GLP-1 receptor agonist without regard to a person's existing level of glucose control, including their current and target hemoglobin A1c levels, and regardless of background therapy, added Dr. McGuire, a cardiologist at the UT Southwestern Medical Center in Dallas, Texas, and a member of the ESC panel that wrote the new guidelines.

Instead, the new guidance calls for starting both drug classes promptly in people diagnosed with type 2 diabetes and established atherosclerotic CVD. Both the previous 2019 ESC guidelines and the current Standards of Care for 2023 document from the American Diabetes Association call for using one class or the other, but they hedge on combined treatment as discretionary.

Different Mechanisms Mean Additive Benefits

"With increasing numbers of patients with type 2 diabetes in trials for SGLT-2 inhibitors or GLP-1 receptor agonists who were also on the other drug class, we've done large, stratified analyses that suggest no treatment-effect modification" when people received agents from both drug classes, Dr. McGuire explained in an interview. "While we don't understand the mechanisms of action of these drugs for CVD, we've become very confident that they use different mechanisms" that appear to have at least partially additive effects. "Their benefits for CVD risk reduction are completely independent of their glucose effects. They are cardiology drugs," McGuire added.

The new ESC guidelines highlight two other clinical settings where people with type 2 diabetes should receive an SGLT-2 inhibitor regardless of their existing level of glucose control and any other medical treatment: people with heart failure and people with chronic kidney disease (CKD) based on a depressed estimated glomerular filtration rate and an elevated urine albumin-to-creatinine ratio.

Nephropathy was considered by the ESC's guideline panel to confer risk that is similar to that of established atherosclerotic CVD, McGuire said.

FDA Approves New Drug to Prevent RSV in Babies and Toddlers

New RSV Shot Is a Monoclonal Antibody, not a Vaccine

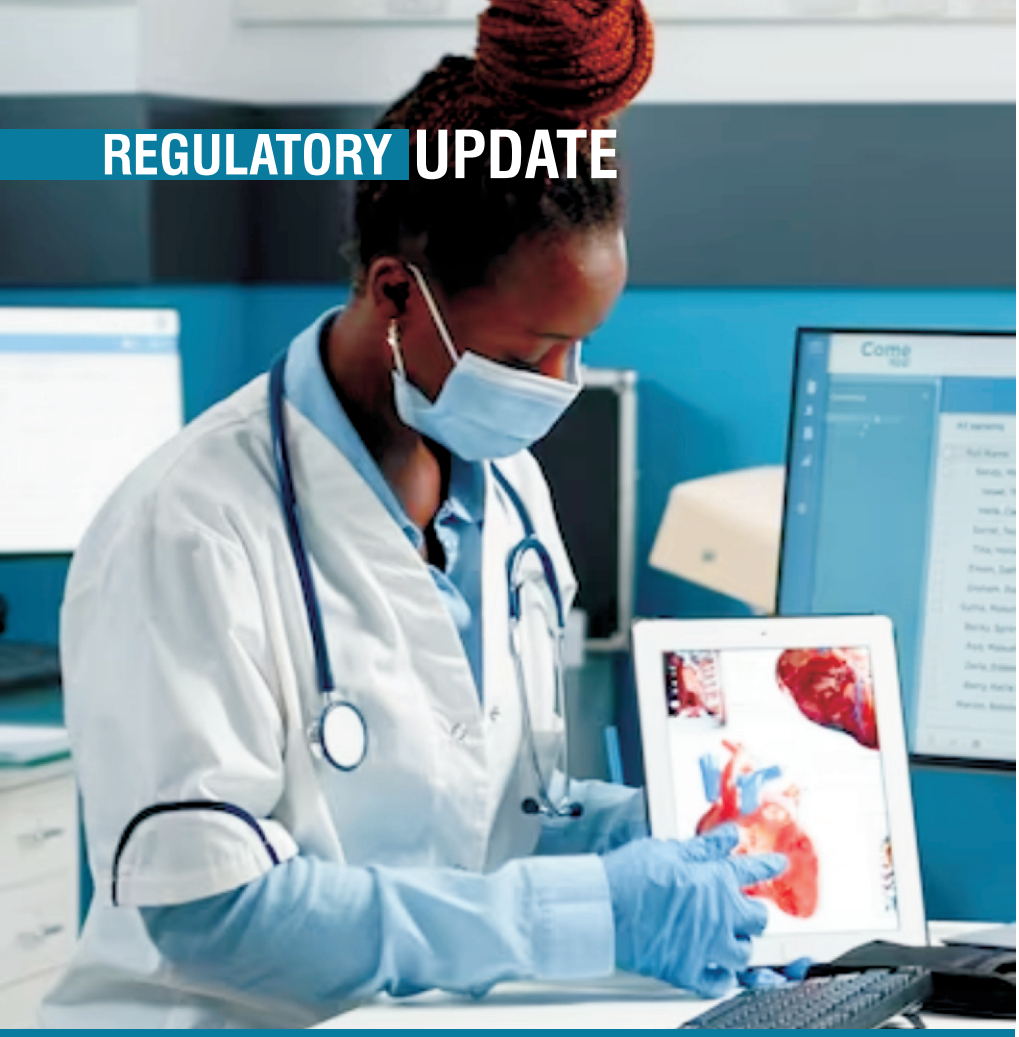
On July 17, 2023, the U.S. Food and Drug Administration approved Beyfortus (nirsevimab) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Nirsevimab is approved for infants (up to 8 months old) born during or entering their first RSV season, and in children up to 2 years of age who are still vulnerable to severe RSV through their second season.

It is not a vaccine, but a monoclonal antibody used for prevention. That may cause confusion because a vaccine for RSV was approved just 3 months ago for adults aged 60 years and older. And monoclonal antibodies are often used for treatment rather than prevention. Adding to potential confusion is the fact the Centers for Disease Control and Prevention has included nirsevimab in the Vaccines for Children program, which covers the costs for uninsured kids and makes it more accessible.

If monoclonal antibodies can be used for preventing disease in infants, could they become a viable vaccine alternative for adults? Specialists say no. That's partly because of the difference in body size. Although an injection is an option for a newborn, pediatricians suggest, it would take far too much of the treatment to work as a shot for adults. Ruth Karron, MD, an expert in pediatric infectious diseases at Johns Hopkins Medicine, said that while vaccines come in small amounts and activate immune cells, monoclonal antibodies are more like a drug, with the dose based on weight. "You'd have to give it intravenously," for larger doses she explained, which has never been studied before and would also be very expensive. "It really couldn't be an option for adults," she said.

What's the Difference Between Vaccines and Antibodies?

Monoclonal antibodies are proteins made in a lab to mimic the immune system's ability to fight pathogens such as viruses. Dr. Karron explained that a wide variety of monoclonal antibodies have long been used to treat diseases such as cancers and autoimmune disease. In recent years, the antibodies have been used to treat COVID. Monoclonal antibodies have also been used to treat RSV in children, but the effects don't last long — they confer passive immunity and "when it's gone, it's gone," Karron said. That means kids at high risk for severe RSV have had to get monthly injections. But with nirsevimab, the mutated antibodies stay in circulation longer so they can last 5 or 6 months, enough to cover the RSV season, Karron explained. "It's highly, highly effective," she said.



FDA Approves Low-Dose Colchicine for Cardiovascular Indication

The recent US approval of a new low dose of colchicine 0.5 mg (Lodoco®) with a broad indication for use in atherosclerotic cardiovascular disease (ASCVD) represents a completely new approach to treatment, specifically targeting inflammation as a driver of atherosclerosis.

The US Food and Drug Administration granted colchicine a very broad label: to reduce the risk for cardiovascular events in adult patients with established ASCVD or with multiple risk factors for cardiovascular disease. But how will the drug be used in clinical practice?

"The idea of inflammation as a driver of atherosclerosis and cardiovascular risk has been around for decades, and it is very well known that atherosclerosis is an inflammatory process. However, treating inflammation is new as we haven't had a specific agent targeting inflammation before, notes Dr. Michael Blaha, Director of Clinical Research, Ciccarone Center for the Prevention of Cardiovascular Disease at Johns Hopkins Hospital, Baltimore. Blaha is not surprised by the FDA-approved indication for colchicine, pointing out that the main large-scale trial supporting its use in ASCVD, the LoDoCo-2 trial, included a similar broad population. "The paradigm coming forward is the idea of residual risk that patients have after they been treated with the standard of care - which in most cases is a statin and blood pressure control - and what is driving that residual risk," he notes. "If we think patients are still at high risk of recurrent cardiovascular events, we have to think what we will do next. This is where this drug will come in."

Blaha points out that there are now multiple options for reducing residual risk; he believes that it will depend on the profile of the patient as to which of those options is chosen first. "If after high-dose statin treatment they still have raised LDL, then we can add another LDL lowering drug; or it might be diabetes and obesity that we want to address first; or elevated triglycerides. But now, we can also consider residual inflammatory risk if we think the patient has residual plaque inflammation," he says. "So, colchicine will be one of several choices beyond a statin that we can think about as the next step for treating residual risk."

Colchicine, which targets residual inflammation as an underlying cause of atherosclerotic cardiovascular disease can be used alone or in combination with cholesterol-lowering medications at a daily dosage of 0.5 mg. Data supporting the approval has come from two major randomized trials, LoDoCo-2 and COLCOT. In the LoDoCo-2 trial, the anti-inflammatory drug cut the risk of cardiovascular events by one third when added to standard prevention therapies in patients with chronic coronary disease. And in the COLCOT study, use of colchicine reduced cardiovascular events by 23% compared with placebo in patients with a recent MI.

Is CRP Measurement Necessary?

Though elevated levels of high-sensitivity C-reactive protein (hsCRP) is a marker of inflammation in ASCVD, the two main trials of colchicine in ASCVD, both of which showed large benefits of the drug, did not measure hsCRP, leading to questions as to whether measurement of this biomarker is necessary to select patients for colchicine treatment.

Colchicine has been available for many years and used at higher doses for the acute treatment of gout and pericarditis, but the current formulation is a much lower dose for long-term use in patients with atherosclerotic heart disease.

2022 US FDA New Drug Approvals				
No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use
37	NexoBrid	anacaulase	12/28/2022	To remove eschar in adults with deep partial thickness or full thickness thermal burns
36	Briumvi	ublituximab	12/28/2022	To treat relapsing forms of multiple sclerosis
35	Xenoview	hyperpolarized Xe	12/23/2022	To evaluate pulmonary function and imaging
34	Lunsumio	mosunetuzumab	12/22/2022	To treat adults with relapsed or refractory follicular lymphoma, a type of non-Hodgkin lymphoma
33	Sunlenca	lenacapavir	12/22/2022	To treat adults with HIV whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations
32	Krazati	adagrasib	12/12/2022	To treat KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer in adults who have received at least one prior systemic therapy
31	Rezlidhia	olutasidenib	12/1/2022	To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation
30	Tzield	teplizumab	11/18/2022	To delay the onset of stage 3 type 1 diabetes
29	Elahere	mirvetuximab soravtansine	11/14/2022	To treat patients with recurrent ovarian cancer that is resistant to platinum therapy
28	Tecvayli	teclistamab	10/25/2022	To treat relapsed or refractory multiple myeloma among adults who have received at least four specific lines of therapy
27	Imjudo	tremelimumab	10/21/2022	To treat unresectable hepatocellular carcinoma
26	Lytgobi	futibatinib	9/30/2022	To treat intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements
25	Relyvrio	sodium phenylbutyrate/taursodio	9/29/2022	To treat amyotrophic lateral sclerosis (ALS)
24	Omlonti	oomidenepag isopropyl ophthalmic solution	9/22/2022	To reduce elevated intraocular pressure in patients with open **-angle glaucoma or ocular hypertension**
23	Elucirem	gadopiclenol	9/21/2022	To detect and visualize lesions, together with MRI, with abnormal vascularity in the central nervous system and the body
22	Terlivaz	terlipressin	9/14/2022	To improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function
21	Rolvedon	eflapegrastim	9/9/2022	To decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia
20	Sotyktu	deucravacitinib	9/9/2022	To treat moderate-to-severe plaque psoriasis
19	Daxxify	daxibotulinumtoxinA	9/7/2022	To treat moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity
18	Spevigo	spesolimab	9/1/2022	To treat generalized pustular psoriasis flares
17	Xenpozyme	Olipudase alfa	8/31/2022	To treat Acid Sphingomyelinase Deficiency
16	Amvuttra	vutrisiran	6/13/2022	To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis
15	Vtama	tapinarof	5/23/2022	To treat plaque psoriasis
14	Mounjaro	tirzepatide	5/13/2022	To improve blood sugar control in diabetes, in addition to diet and exercise
13	Voquezna	vonoprazan, amoxicillin, and clarithromycin	5/3/2022	To treat Helicobacter pylori infection
12	Camzyos	mavacamten	4/28/2022	To treat certain classes of obstructive hypertrophic cardiomyopathy
11	Vivjoa	oteseconazole	4/26/2022	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential
10	Pluvicto	lutetium (177Lu) vipivotide tetraxetan	3/23/2022	To treat prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer following other therapies
9	Opdualag	nivolumab and relatlimab	3/18/2022	To treat unresectable or metastatic melanoma
8	Ztalmy	ganaxolone	3/18/2022	To treat seizures in cyclin-dependent kinase-like 5 deficiency disorder
7	Vonjo	pacritinib	2/28/2022	To treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets
6	Pyrukynd	mitapivat	2/17/2022	To treat hemolytic anemia in pyruvate kinase deficiency
5	Enjaymo	sutimlimab	2/4/2022	To decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease
4	Vabysmo	faricimab	1/28/2022	To treat neovascular (wet) aged-related macular degeneration and diabetic macular edema
3	Kimmtrak	tebentafusp	1/25/2022	To treat unresectable or metastatic uveal melanoma
2	Cibinqo	abrocitinib	1/14/2022	To treat refractory, moderate-to-severe atopic dermatitis
1	Quviviq	daridorexant	1/7/2022	To treat insomnia

Immigration, Emigration and Pharmacy Education: Insights and Opportunities

Elvis Duru
Pharmacotherapy PhD Student
The University of Utah

Olajumoke Olateju
Pharmaceutical Science
PhD Student
University of Houston, Texas

Emmanuale Ayanjoke
Clinical Pharmacist
Ziks Family Pharmacy

The August NAPPSA YP hangout focused on the nexus between Immigration, Emigration and Pharmacy Education as it delves into the educational journey of young Nigerian pharmacy students who successfully made the transition from Nigerian educational system to the educational landscape of the United States.

Key resource persons for this insightful hangout include Elvis Duru (pharmacotherapy PhD Student from University of Utah), Olajumoke Olateju (Pharmscience PhD Student at University of Houston) and Emmanuel Ayanjoke (Clinical Pharmacists, Ziks Family Pharmacy).

The hangout explored the pathways to pursuing advanced degrees like PhD, PharmD, and Masters in the USA, while also discovering the abundant job opportunities that await at the back end.

Key Takeaways from the Hangout include:

- Recognition that the educational differences between Nigeria and US are not so great and that one does not have to start their education over and that a Masters is not necessary to start a PhD program
- Knowledge of the funding options available for PhD candidates and PharmD candidates at US universities and scholarship opportunities through NAPPSA.
- Understanding that licensed Pharmacists in Nigeria have a Pathway to receive license here in America by utilizing Licensure of Foreign Pharmacy Graduates pathways
- Recognition that there is a need for more of this kind of programming as a resource for professionals seeking to make the transition between the two nations

CALL FOR PAPERS

Submit your manuscript to a flagship journal in Pharmaceutical Science

As an authoritative outlet for new research in pharmacotherapy and pharmaceutical sciences, AJPPS invites you to submit your work and have it read by leaders in pharmacy, medicine and science.

Submit your next paper to AJPPS
Types of feature articles published

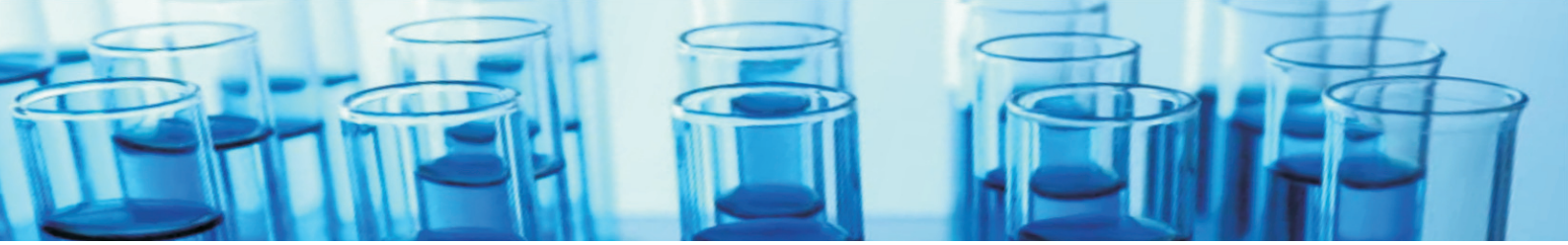
- Original research
- Reviews & Minireviews
- White papers
- Perspectives
- Case report
- Updates
- Editorials

Benefits

- Expert peer review
- Rapid review/quick decision
- Disseminated to a very wide audience/readers
- Available worldwide online

Instruction for Authors:

Visit https://ajpps.org/for/-authors/



NAPPSA TIDBITS

NAPPSA Partners with Shriners Hospital for a FunRun FundRaiser

NAPPSA ENDOWMENT FUND

GIVE HOPE WITH EACH STRIDE
BAYSIDE HUSTLE

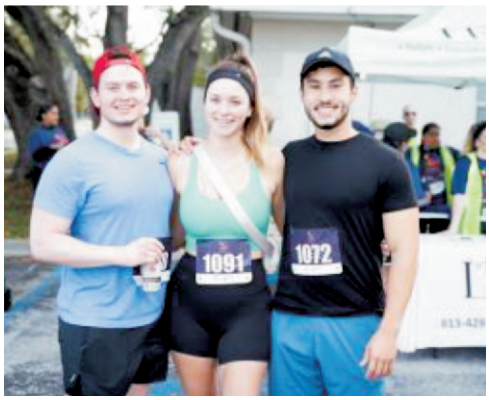
Shriners Hospitals for Children®

On Saturday, August 19, 2023, the BAYSIDE HUSTLE for NAPPSA Endowment Fund was launched. The Bayside Hustle is a 5K RUN/ Walk event is a collaborative initiative of the Tampa Bay NAPPSA members in collaboration with the Shriners Hospital for Children to raise money for both institutions. An initiative conceived by Victor Obi, the Bayside Hustle is set up as pilot effort to demonstrate a new way to expand the footprint of the annual NAPPSA 5k Run/Walk in the Tampa Bay Area and beyond by forming critical partnerships with reputable local institutions.

The success of this pilot and partnership with Shriners Hospital for Children, will enable NAPPSA to expand this concept and support other NAPPSA members to replicate variants of the BAYSIDE HUSTLE in 100 cities across the USA and beyond including Nigeria. The set up will be the same in all communities and will involve partnering with well-known reputable organizations in our various communities to organize yearly 5K Runs/Walks for the benefit of the NAPPSA Endowment and the partner local organization in the local community.

160 volunteers participated in the inaugural version of the Hustle which took place at the Tampa Bayshore Blvd on August 19, 2023.

BAYSIDE HUSTLE FOR NAPPSA AND SHRINERS IN PICTURES



Moving with Science

OPPORTUNITIES FOR PHARMACISTS IN THE PHARMACEUTICAL INDUSTRY

By Ellen Berkley

Pharmacists are equipped with unique skills that are highly desirable in the pharmaceutical industry — among them conducting research and developing new therapeutics, designing and managing clinical trials, establishing safety regulations, providing medical information and education, and engaging with key opinion leaders. No matter where you are in your career as a pharmacist, if you have an interest in the pharmaceutical industry but are unsure of the opportunities available or how to get there, read on.

Today, more pharmacy students and seasoned practitioners alike are drawn to careers that allow them to use their PharmD training in nontraditional settings, landing distinct roles from a diversity of backgrounds. Fellowships, for example, are a great way to gain early entry into the industry. A fellowship is a 1- to 2-year comprehensive training program designed for PharmDs to develop robust cross-functional experience in the sector. That said, many pharmacists are able to break into the business through networking and bringing complementary skills and experiences to the table.

The pharmaceutical industry aims to discover and produce safe and effective new drugs. Hence there are many different departments that benefit from the expertise of a PharmD. The diversity of roles in pharmaceuticals accommodates a broad range of interests, from clinical research and medical writing to more traditional business functions such as legal affairs, marketing, and sales.

Here are nine specific roles that you can play in the pharmaceutical industry:

1. Medical information and communication
2. Medical science liaison
3. Regulatory affairs
4. Pharmacovigilance
5. Research and development
6. Clinical development
7. Marketing
8. Market Access
9. Sales

Let's get into the details of each.

Medical information and communication

Professionals in this role serve as the in-house scientific and

clinical experts for both internal and external stakeholders within the Medical Affairs department. They review all information for medical accuracy, from early-phase clinical trials to post-approval marketing materials, before there's dissemination to the company's target audience.

Responsibilities

- Synthesize and produce evidence-based scientific and clinical drug information responses to on- and off-label inquiries from those interested in company products.
- Review marketing materials to ensure accuracy of product's benefits and risks and adherence to regulatory guidelines.
- Evaluate comparable products to support strategic planning.
- Assist in training field colleagues.

PharmD Skills involved:

- Ability to understand, synthesize, and disseminate scientific and clinical data to the medical community.
- Scientific and clinical expertise in certain therapeutic areas
- Strong verbal and written communication
- Cross-functional teamwork and multitasking
- Attention to detail.

Medical science liaison

Professionals in this role serve as the field-based scientific and clinical experts on a given product within the Medical Affairs department, commonly focusing on a certain therapeutic area, and traveling to converse with key opinion leaders, known as KOLs, over 60% of the time. They link the research and development division with the commercial side of the pharmaceutical business by communicating medical information to internal and external stakeholders.

Responsibilities:

- Provide in-depth scientific and medical information on the company's products to KOLs such as physicians, scientists, and other healthcare professionals who hold knowledge in their relevant therapeutic area.
- Coordinate between the company and KOLs, cultivating strong two-way relationships to ensure the safe and effective use of a specific agent and relay key insights learned to contribute to product development.
- Develop drug information presentations and deliver them to target audiences.
- Offer evidence-based education on a given product.

PharmD skills involved:

- Strong verbal and written communication and interpersonal skills
- Scientific and clinical expertise in certain therapeutic areas
- Ability to understand, synthesize, and disseminate scientific and clinical data to the medical community.
- Flexibility and adaptability.
- Critical and strategic thinking.

Regulatory affairs

Professionals in this role manage rules and regulations that exist to protect public health by directing product quality in the pharmaceutical industry. They link the company to relevant health authorities such as the FDA in the United States to comply with drug development regulatory standards, from discovery and preclinical to clinical and post-marketing oversight. Other facets of the job include the following:

- Specializing in one or a few products within a certain therapeutic area, and strategically planning the FDA regulatory approval process.
- Serving one of many regulatory functions such as chemistry, manufacturing, and controls (CMC), publishing and operational support, regulatory international, product development, and regulatory intelligence, as well as advertising, labeling, and promotion.

Responsibilities

- Gather evidence from clinical trial data and submit it to regulatory bodies to prove product safety and efficacy, ensuring that drugs under development meet state and federal product regulations.
- Assist with the preparation and filing of investigational new drug applications, new drug applications, or biologics license applications.
- Collaborate with cross-functional colleagues to help companies develop strategies to enhance FDA approval, ensuring that studies are developed in agreement with health authority regulations and post-approval claims are consistent with clinical trial data.

PharmD skills involved:

- Strong scientific background
- Understanding of regulatory compliance, benefits versus risks, and product quality
- Ability to analyze clinical data and translate results into balanced and accurate claims.
- Cross-functional collaboration
- Critical and strategic thinking
- Attention to detail.

Pharmacovigilance

Professionals in this role serve as the drug safety officers to prevent, discover, and evaluate drug-related problems. They continuously monitor a drug's safety profile throughout its lifecycle pre- and post-marketing, ensuring its benefits outweigh its risks, reporting adverse effects to regulatory bodies, and providing patient education to the medical community.

Responsibilities

- Assess product safety reports, review safety events from clinical trial data, analyze trends, and compile product safety profile.
- Continue to monitor drug adverse effects in the real-world population and strategize appropriate mitigating actions.
- Promote medication safety and prevent the misuse of medications by communicating safety information to the company's R&D department.
- Collaborate with regulatory authorities and external stakeholders to provide insight and improve product quality.

PharmD skills involved:

- Strong verbal and written communication.
- In-depth understanding of pharmacology and patient safety.
- Expertise in adverse event documentation, monitoring, and reporting.
- Ability to organize and prioritize tasks.
- Attention to detail.
- Cross-functional collaboration.

Research and development

Professionals in this role primarily serve in a laboratory setting to help develop new drug products, evaluate existing products, and create new product formulations. They function as the backbone of the company, with extra attention from the general public especially during the pandemic.

Responsibility

- Explore disease mechanisms and guide the discovery and development of new therapeutic agents.
- Identify and test drug candidates by conducting rigorous experiments and performing data analysis to determine therapeutic viability.
- Generate and manage a company's drug "pipeline" so that, pending favorable clinical trial results and regulatory approval, medications can enter the market.

PharmD skills involved:

- Scientific knowledge and understanding of drug mechanisms.

- Attention to detail.
- Analytical and critical problem-solving
- Ability to organize and prioritize tasks.
- Ability to analyze large data sets.

Clinical development

Professionals in this role support drug candidates through all four phases of clinical trials, from early-stage safety and late-stage efficacy to post-approval examination. They serve one of many different functions such as clinical scientist, clinical director/medical manager, trial manager, operations lead, or clinical supply lead.

Responsibilities

- Develop clinical trial protocols and assist in design and execution.
- Help plan and perform clinical trials, assist in patient recruitment, and form relationships with relevant institutions.
- Evaluate product data on safety and efficacy, produce study summaries, and work with regulatory bodies.

PharmD skills involved.

- Critical thinking and problem-solving
- Strong clinical background
- Cross-functional collaboration
- Ability to organize and prioritize tasks.
- Flexibility and adaptability
- Project management

Marketing

Professionals in this role serve as a commercial crux of the pharmaceutical industry, creating and delivering accurate promotional materials on company products, especially close to and post-product launch. They follow industry guidelines and navigate laws, regulations, and standards to ensure the promotion of their company's product is consistent with up-to-date medical information.

Responsibilities

- Collaborate with medical and legal partners to ensure accurate product information.
- Develop and lead marketing strategies and engagement plans with KOLs.
- Perform competitive analyses, research marketplace trends, and evaluate patient needs to uniquely position the company's product within the market to add value in comparison to standard of care.
- Build branding and promotional materials, and disseminate product value through medium such as advertisements, speaker programs, and conference exhibits.

PharmD skills involved:

- Entrepreneurial spirit and strategic business-level thinking
- Strong verbal and written communication and interpersonal skills
- Attention to detail.
- Creativity and problem-solving
- Flexibility and adaptability

Market access

Professionals in this role expand patient and healthcare provider access to company products through communications with stakeholders such as payers, pharmacy benefit managers, health systems, and pharmacies.

Responsibilities

- Develop payer reimbursement, drug distribution, and product adherence strategies.
- Evaluate and optimize product allocation within the indicated patient population.
- Support medication adherence strategies and disease state outreach

PharmD skills involved:

- Clinical expertise and patient care experience.
- Understanding of potential challenges that patients face receiving a prescription.
- Strong verbal and written communication and interpersonal skills.
- Creativity and strategic thinking.
- Flexibility and adaptability.

CAREER SPOTLIGHT

Sales

Professionals in this role connect the company with target customers, providing on-label medical information and product samples at institutions such as medical offices, pharmacies, and hospitals. They also provide education to healthcare providers on clinical data through visual aids.

Responsibilities

- Call and visit target audience, providing drug information and product samples.
- Pitch the company's products based on in-depth and accurate information from the clinical trial data.
- Establish relationships with entire HCP team including physicians, pharmacists, nurses, medical assistants, and other staff.
- Collaborate with and deliver feedback to marketing colleagues on sales messages.

PharmD skills involved:

- Strong verbal and written communication and interpersonal skills.
- Strategic business-level thinking.
- Cross-functional collaboration.
- Ability to organize and prioritize tasks.
- Flexibility and adaptability.

The bottom line

Pharmacy is a highly regulated profession, and as pharmacists, we are trained as medication experts. Additionally, pharmacists thrive in managing many tasks simultaneously and quickly prioritizing requests. So, pharmacists bring tremendous value to the many cross-functional teams they work on throughout the pharmaceutical industry.

Whether you are a student, fellow, or pharmacist looking to land a job in the exciting and rapidly evolving pharmaceutical industry, check out the Industry Pharmacists Organization for more information on how to guide your path to becoming an industry pharmacist.

Article culled from GoodRx.com, 14Aug2022. Authored by Ellen Berkely.

ENDOWMENT

NAPPSA
ENDOWMENT FUND

Fulfill your charitable goals and create a legacy for good

Visit or call to learn how you can support
www.nappsa.org or 888-237-8017


Scholarships

Facilitate Volunteers


Grants for Pharmaceutical Research


Access to Medicines

BEYOND TODAY, INVESTING IN OUR FUTURE

R.E.S.P.E.C.T
(What does it mean in mental health?)

By: Ucheoma Nwizu, PharmD, BCPA

MSB is a 70-year-old lady with schizophrenia. I manage her for diabetes. She came to our clinic from the endocrinology clinic. She left them because she desired a closer follow-up for her diabetes management. One of the advantages of having a pharmacist manage diabetes is the closer follow-up.

During my first visit we her, we focused on organizing her medications. She was on multiple medications for her mental health. There were concerns about adherence. But we started. The first thing was to simplify her regimen. We both agreed that it was unnecessary to take medication three times a day when there are once or twice-daily alternatives. We also agreed to transition weekly medications to daily medication. I discovered that she was a creature of habit and establishing the same rhythm for her medications would be beneficial.

Knowing that she desired more frequent follow-ups, we scheduled weekly visits for the first six weeks to adjust her insulin doses. My initial goal was to get to know her better and build trust. Additionally, I wanted to get her accustomed to reading her blood sugar off her glucometer. She came to see me every week for the first four weeks. Her blood sugar had slowly come down to the 200s. At week four, she came to see me, and as soon as I sat down the following conversation ensued.

MSB: "You know, I don't think I like seeing you every week'

Me: 'Hmmmm. I understand. We could alternate phone appointments with clinic visits but the only reason you have to come here is that you are not able to tell me your glucometer readings '

MSB: But I can!

Me: You told me you couldn't

MSB: But you showed me how already

Me: I actually didn't think you were paying attention.

Indeed, I did show her how to read from her glucometer but she had such a pan face I didn't think she grasped anything I said. She proceeded to demonstrate how to read off her glucometer. She was precise and accurate. I was surprised.

Me: "I actually didn't know you heard anything I said"

MSB: I did

And she added with a smile and a twinkle in her eye "I am not stupid"

I laughed. But in my heart, I was repentant. How I misjudged her!

As I got up to leave the room, I reached out and shook her hand. It occurred to me that this was the first time since I met her that I shook her hand. This was the first time too I acknowledged that I respected her.

Oh, How I misjudged her!

I left the room with a new desire to show more respect to all patients regardless of their psychiatric diagnosis.

Summary of major challenges in drug development and how they could be resolved, an adapted excerpt from Pharmanews Diaspora Column

By: Anayo M Ukeje, PhD/DIC

What's "Drug Development"

Drug development involves the entire process of bringing a new drug or device to market. It is an integrated, multidisciplinary endeavor that includes drug discovery, chemistry and pharmacology, nonclinical safety testing, manufacturing, clinical trials, and regulatory submissions. In other words, there are four main phases of drug development: discovery, preclinical studies, clinical development and marketing approval.

Major challenges in drug development are development timescale (length/duration), which depends on type of drug (small/large molecules), aseptic processing/terminally sterilized dosage form, complexity and uncertainty of success including manufacturing difficulties. Also, limited market potential and regulatory requirements (USA, EU & ROW) costs contribute to major challenges. On the technical side, Safety & toxicity issues pose the greatest challenges.

The resolution of some of these challenges must start by reducing the timescale and costs of development through innovative right first-time approach, quality by design, removal of barriers in knowledge transfer and increase in regulatory harmonization amongst major regulatory authorities like the use of European Medicinal Agency (EMA) to granting of medicine license that is valid across all EU member states (centralized procedure); common EU-FDA "Mutual Recognition Agreements" Article 8.3 provides FDA and European Union the option to rely on inspection reports issued by a recognized authority for manufacturing facilities, thus strengthening the use of each other's drug inspection expertise and resources which results in greater efficiencies for both regulatory authorities. This provides a more practical means to oversee the large number of drug manufacturing facilities outside of the United States and European Union.

Deployment of "African medicines regulatory Harmonization Initiative" to facilitate and coordinate the harmonization of medicines regulation and improve access to quality, safe, efficacious and affordable medicines in Africa as part of the broader African Union Framework on Pharmaceutical Manufacturing Plan for Africa (PMPA) seeks to adopt a similar model to reduce cost of development and approval process.

The history of ANTIBIOTICS

Antibiotics have been used for millennia to treat infections, although until the last century or so people did not know the infections were caused by bacteria. Various moulds and plant extracts were used to treat infections by some of the earliest civilisations – the ancient Egyptians, for example, applied mouldy bread to infected wounds. Nevertheless, until the 20th century, infections that we now consider straightforward to treat – such as pneumonia and diarrhoea – that are caused by bacteria, were the number one cause of human death in the developed world.

It wasn't until the late 19th century that scientists began to observe antibacterial chemicals in action. Paul Ehrlich, a German physician, noted that certain chemical dyes coloured some bacterial cells but not others. He concluded that, according to this principle, it must be possible to create substances that can kill certain bacteria selectively without harming other cells. In 1909, he discovered that a chemical called arsphenamine was an effective treatment for syphilis. This became the first modern antibiotic, although Ehrlich himself referred to his discovery as 'chemotherapy' – the use of a chemical to treat a disease. The word 'antibiotics' was first used over 30 years later by the Ukrainian-American inventor and microbiologist Selman Waksman, who in his lifetime discovered over 20 antibiotics.

Alexander Fleming was, it seems, a bit disorderly in his work and accidentally discovered penicillin. Upon returning from a holiday in Suffolk in 1928, he noticed that a fungus, Penicillium notatum, had contaminated a culture plate of Staphylococcus bacteria he had accidentally left uncovered. The fungus had created bacteria-free zones wherever it grew on the plate. Fleming isolated and grew the mould in pure culture. He found that P. notatum proved extremely effective even at very low concentrations, preventing Staphylococcus growth even when diluted 800 times, and was less toxic than the disinfectants used at the time.

After early trials in treating human wounds, collaborations with British pharmaceutical companies ensured that the mass production of penicillin (the antibiotic chemical produced by P. notatum) was possible. Following a fire in Boston, Massachusetts, USA, in which nearly 500 people died, many survivors received skin grafts which are liable to infection by Staphylococcus. Treatment with penicillin was hugely successful, and the US government began supporting the mass production of the drug. By D-Day in 1944, penicillin was being widely used to treat troops for infections both in the field and in hospitals throughout Europe. By the end of World War II, penicillin was nicknamed 'the wonder drug' and had saved many lives.

Scientists in Oxford were instrumental in developing the mass production process, and Howard Florey and Ernst Chain shared the 1945 Nobel Prize in Medicine with Alexander Fleming for their role in creating the first mass-produced antibiotic.

Adapted from microbiologysociety.org

EVENT CALENDAR 2022

SEPTEMBER 21-24, 2023
17th Annual NAPPSA Scientific Conference and Exposition
Hilton Columbus Polaris
Columbus, OH

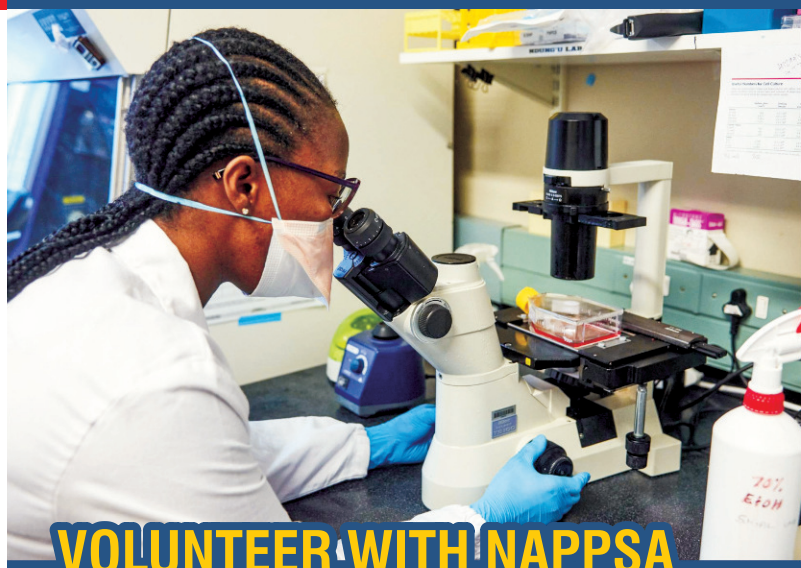
SEPTEMBER 24-28, 2023
Brisbane 2023
81st FIP World Congress of Pharmacists and Pharmaceutical Scientists
Brisbane, Australia

October 14-17, 2023
NCPA 2023 Annual Convention and Expo
Orange County Convention Center
Orlando Florida

October 22-25, 2023
AAPS 2023 PHARMSCI 360
October 22-25, 2023
Orange County Convention Center
Orlando, FL

OCTOBER 30-NOVEMBER 4, 2023
Jewel City 2023 Conference
96th Annual Conference of PSN
Gombe International Conference Center
Gombe, Nigeria

March 22-25, 2024
APhA 2024
APhA Annual Meeting and Exposition
Orlando, FL



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

PharmaMedics is a multi-dimensional business consulting, advisory and facilitating service provider with great capacity for building mutually beneficial co-petitive inter-business linkages and relationships. With a strong background and core expertise in the Pharmaceutical and Medical Sectors, PharmaMedics has successfully expanded into business strategy, development and management. The 4 cardinal areas of our operations include:

- SOURCING & PROCUREMENT RISK MANAGEMENT
- PHARMACEUTICAL AND MEDICAL PRODUCT DISTRIBUTIONS
- IMPORT AND EXPORT FACILITATION SERVICES
- IN-COUNTRY B-2-B PARTNERSHIPS

PharmaMedics
.....The Business-2-Business Link


NIGERIAN ASSOCIATION OF PHARMACISTS & PHARMACEUTICAL SCIENTISTS
NAPPSA
IN THE AMERICAS

NAPPSA, INC.