



Snapshot 2022

A Changing Environment for
FDA-regulated Consumer Products

SYMPOSIUM SUMMARY



About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA (FDA Foundation) is an independent 501(c)(3) created by Congress to advance regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The FDA Foundation works to improve health and safety through stakeholder engagement and public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and policies to keep pace with today's rapidly evolving science.

www.reaganudall.org

The Consumer Healthcare Products Association provided funding for this event.

Introduction

Consumer habits and expectations are changing, and the healthcare front is not immune from these changes. On April 28th, 2022, the Reagan-Udall Foundation, with the support of the Consumer Healthcare Products Association, conducted a half-day symposium, Snapshot 2022, to examine the current environment for FDA-regulated consumer products and devices, and how healthcare delivery might change in the near future. In order to get the broadest possible input, participants in the meeting included stakeholders from patient advocacy, healthcare practice, pharmacy benefits, industry, academia, and Federal agencies.

Over the past decade, advances in technology have dramatically changed how consumers access information, obtain medication, manage wellness, and even interact with healthcare professionals. The COVID-19 pandemic served to supercharge this development over the past two years, as well as to bolster consumers' comfort level with technology. The pandemic changed consumers' expectations of how, when, and where healthcare should take place.

Snapshot 2022 presented a breadth of stakeholder perspectives, from regulators to consumers, invested in improving access and responding to the changing healthcare and consumer environments. The symposium examined lessons learned during the pandemic, and how some of these experiences may result in improved consumer access to medication.

The program included an examination of two case studies to delve into what worked and didn't work with the regulatory process, and what improvements might be made. Feedback on the content presented was provided via a reactor panel.

The post-COVID-19 healthcare world will never look the same as its pre-pandemic incarnation, but adversity has resulted in creativity, and challenges have created more opportunities for consumers to access healthcare in new and different ways.

The full agenda is in the appendixes of this report. What follows are the major takeaways gleaned from the symposium.



Snapshot 2022

KEY TAKEAWAYS

COVID-19 accelerated an already changing healthcare landscape and it is unlikely to ever go back.

When the COVID-19 pandemic hit the United States in March 2020, the country's healthcare landscape had already been changing. Technology was increasingly being utilized, although largely by more affluent and better educated consumers. Consumers were seeking more convenience, but they were still largely getting much of their healthcare through traditional clinical visits.

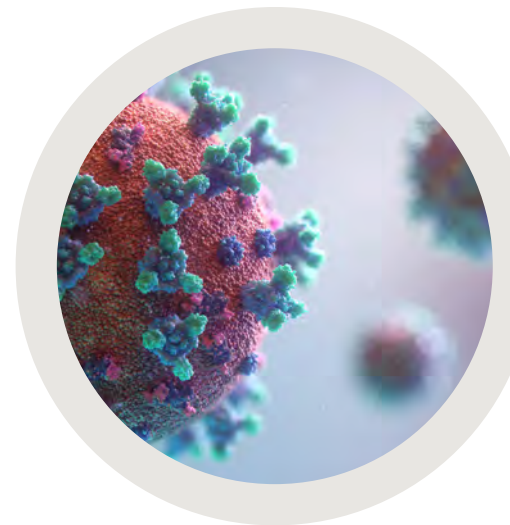
All that changed in March 2020 when the uncertainty of an unknown virus hit the country and healthcare practitioners and hospitals had to suddenly scramble to address it. Patients were now being told to avoid clinics and hospitals. This led to an uptick of technology-driven healthcare interventions, such as video appointments and tele-health, and a shift from a provider-centered marketplace to a more patient-centered one.

The virus also caused consumers to take an increased interest in their own health. Unprecedented numbers of Americans used medical devices such as blood oxygen monitoring devices, surgical face masks, and thermometers during the pandemic. And who would have ever imagined that consumers could be effectively using nasal swabs for at-home self-testing for COVID-19? Yet, at-home COVID-19 testing has been a success story for everyone involved, and a huge boon to consumers. The availability of at-home COVID-19 tests will likely drive consumer appetite for increased at-home testing and diagnostics for other conditions, such as influenza, and faster connections to treatment options.

Today's consumers want more convenience. They are accustomed to using the Internet and mobile devices for daily activities and want to use these to make healthcare more accessible—for example, to schedule appointments with their healthcare providers. Many consumers now have data from wearables, such as fitness tracking devices, and home diagnostics, such as blood glucose monitors. They increasingly desire more control of their health and their data. While consumers can benefit from the empowerment of having digital tools—particularly for diagnostics, monitoring, and preventive care—work needs to be done to figure out how to integrate the unstructured data into patients' medical records. Work also needs to be done to empower consumers to constructively connect the data they are gathering with actual reliable, evidence-based information.

Consumers increasingly want more control over where and when they get their healthcare, and convenient access is of paramount importance. They want testing at home. They want to make appointments online. They want the brick-and-mortar connection to their virtual experience to be seamless. This is why all-in-one sites that offer diagnostic tests, basic healthcare, and availability of medication will likely be increasing in popularity. “One-stop shopping” for healthcare becomes progressively more necessary as the typical American is busier than ever and is looking for ways to save time and increase ease while also improving their health and wellness.

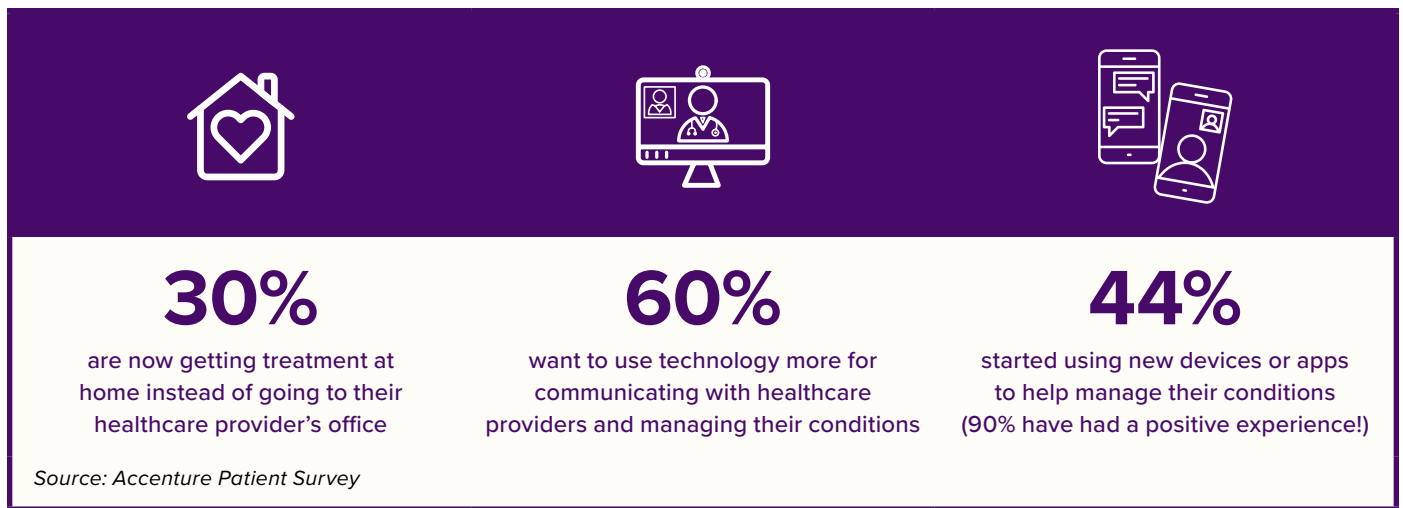
COVID-19 is not over, and the healthcare landscape is still very much in transition. Continued dialogue between consumers, industry and regulatory agencies is critical moving forward.



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Digital tools have helped expand access to healthcare drastically, but not necessarily equitably.

The number of consumers using diagnostic tools, monitoring devices and fitness wearables was on the upswing, driven both by developing technologies and by consumers' desire to have more control and understanding of their own health metrics. COVID-19 served to supercharge these trends. Results of an Accenture Patient Survey taken in May through June 2020, showed that 30 percent of patients reported getting treatment at home rather than a provider's office and 60 percent indicated a desire to use technology more for communicating with healthcare providers and managing chronic conditions. After all, they are already using email and the internet to communicate, make appointments and reservations, and get test results and other information—so why not for scheduling doctor appointments, communicating with providers, or managing chronic illness? In the Accenture Patient Survey, 44 percent of consumers reported using new devices or apps to help manage their conditions. Of those, 90 percent had a positive experience with the new technology.



Consumers are used to convenience in other aspects of their lives, and they want to manage their healthcare the same way. Digital tools and devices are allowing them to do this at a greater rate than ever before. Particularly for preventive care and chronic conditions, digital tools and apps can provide a great deal of information. For example, artificial intelligence 'chat bots' on the Internet can help answer consumer questions about common medical conditions. But this convenience comes with some concerns.

One concern is that these tools are going to benefit those people that may already be most likely to benefit—the more affluent and educated consumer, the one who already has health insurance and is connected to the internet. There is concern that consumers without access to WiFi or broadband, who don't have smart phones, may be left behind. These consumers are not able to take advantage of video physician appointments or tele-health. This creates the potential for increasing access inequality.

Then there is the concern that not every tool is appropriate for every consumer. For example, during COVID-19 there was a great deal of home use of pulse oximeters which people were using to check their oxygen levels. FDA does not review OTC oximeters sold as either general wellness or sporting products, and they should not be used for medical purposes. FDA does review prescription pulse oximeters, including those that may be prescribed for home use. One thing learned was that some pulse oximeters were less accurate when used on dark-skinned people, for example, because they had not been fully studied in that population or to detect differences in accuracy between demographic groups. Yet the devices were being relied upon for an essential decision—whether to go to the hospital for emergency treatment, or not. There is an understanding that devices and tools must be accurate and effective for all patient populations, which means understanding and eliminating bias in technologies.

There is also the need to develop new technologies and approaches to create health equity for people who have accessibility issues with home test kits – those who are blind or diminished visual acuity or those who lack the fine motor skills to handle the small components of test kits.

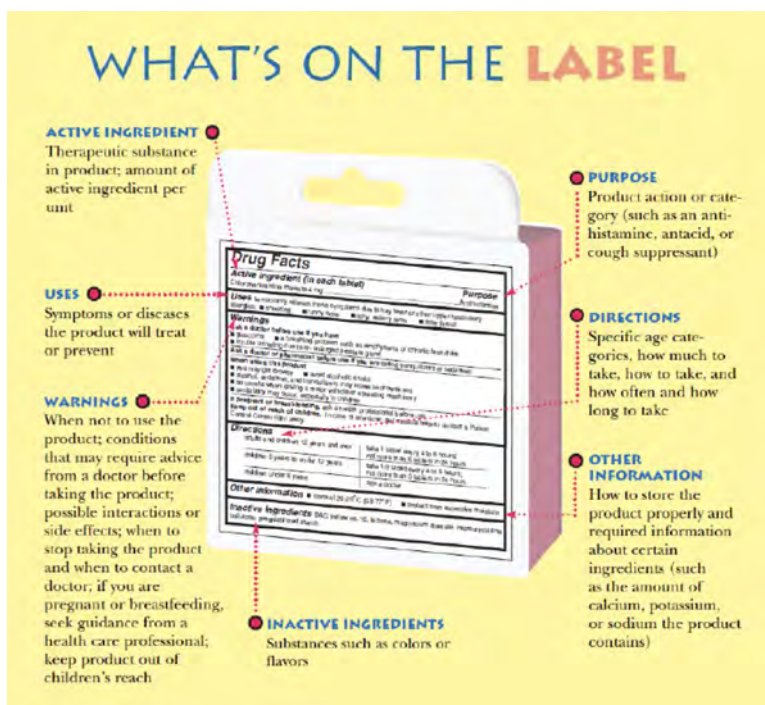
Then there is the issue of data—when data is collected by these tools and devices, how is it integrated into the patient’s medical record? While these tools can be beneficial, if the data is not being used, or used properly, is there really a benefit? And how do we ensure that consumers know what to do with the data? Moreover, in the case of contagious diseases such as COVID-19, how do we get the data to public health authorities who need to track the number, spread and location of cases?

Technology can help bridge the equity gap by bringing healthcare directly to people where they are, as we saw through telehealth, but only if the people have access to a phone. How do we avoid leaving people behind as tools are developed—in many cases it is a “digital divide” issue because 1) they can’t afford devices or 2) don’t have reliable broadband or 3) don’t have the technological ability to use these devices or 4) are physically unable to?

Labeling and Consumer Comprehension: Ensuring consumers understand how to properly use nonprescription medications tech-enabled switches.

The convenience of over-the-counter (OTC) medication is clear—most consumers can get to a drugstore, grocery store, or convenience mart to access nonprescription medications. The COVID-19 pandemic accelerated consumer desire to participate in self-care.

The development program for prescription to nonprescription switch usually relies on safety and efficacy evidence that was established for the prescription version of the product, with additional consumer studies to evaluate how well consumers understand the condition to be treated, how to use the product, and whether the product is suitable for them. Generally, this begins with looking at the prescription label, determining how to turn the information into consumer-friendly language, and focusing on areas that pose the greatest risk if a consumer gets it wrong.



Source: Center for Drug Evaluation and Research

The FDA has generally interpreted the requirement that nonprescription drugs must be labeled with adequate directions for use to mean that the Drug Facts Label alone (without any additional material or support) must be sufficient to enable consumers to appropriately self-select and properly use the drug without the intervention of a healthcare professional.

However, as anyone who has ever looked at a Drug Facts Label knows, there are many inherent challenges in making it understandable. Challenges include that the information must fit in a very small space and thus the type-size is hard to read. Additionally, key warnings may be located under flaps or in areas that consumers may not see or are afraid to open prior to purchase.

About a decade ago, the FDA began working to develop innovative approaches to nonprescription drug development with the idea that increasing availability of safe and effective nonprescription products could improve public health and increase flexibility for industry in the drug approval process. In July 2018, FDA published a draft guidance outlining two innovative approaches for demonstrating safety and efficacy for a nonprescription drug product when the Drug Facts Label alone may not be sufficient. One approach is to provide additional labeling via a wide variety of forms, including information leaflets, videos, mobile apps, websites, and others. The second innovative approach the FDA is considering is “Nonprescription Drug Product with an Additional Condition for Nonprescription Use,” or ACNU. The additional conditions must ensure appropriate self-selection of nonprescription medication by consumers, or appropriate actual use, or both.



An example of ACNU would be if, prior to purchase, a consumer was required to answer a set of questions through a mobile app, which would then determine whether the consumer was an appropriate candidate to use the drug. Another example is if, prior to purchase, consumers were required to view and then affirm that they watched a video demonstrating how to properly use the medication.

At the time of the Snapshot 2022 Symposium, rulemaking was underway to lay out the requirements for the ACNU paradigm. [On June 27, 2022, FDA issued the proposed rule.] In order to move into the ACNU approach to support a prescription to nonprescription switch, a manufacturer would first have to demonstrate that consumers couldn't use the product properly with just labeling alone—that they were failing either self-selection or comprehension of use of the product. Unlike with traditional nonprescription products, the consumer would be required to fulfill the condition of the ACNU before they could purchase the product.

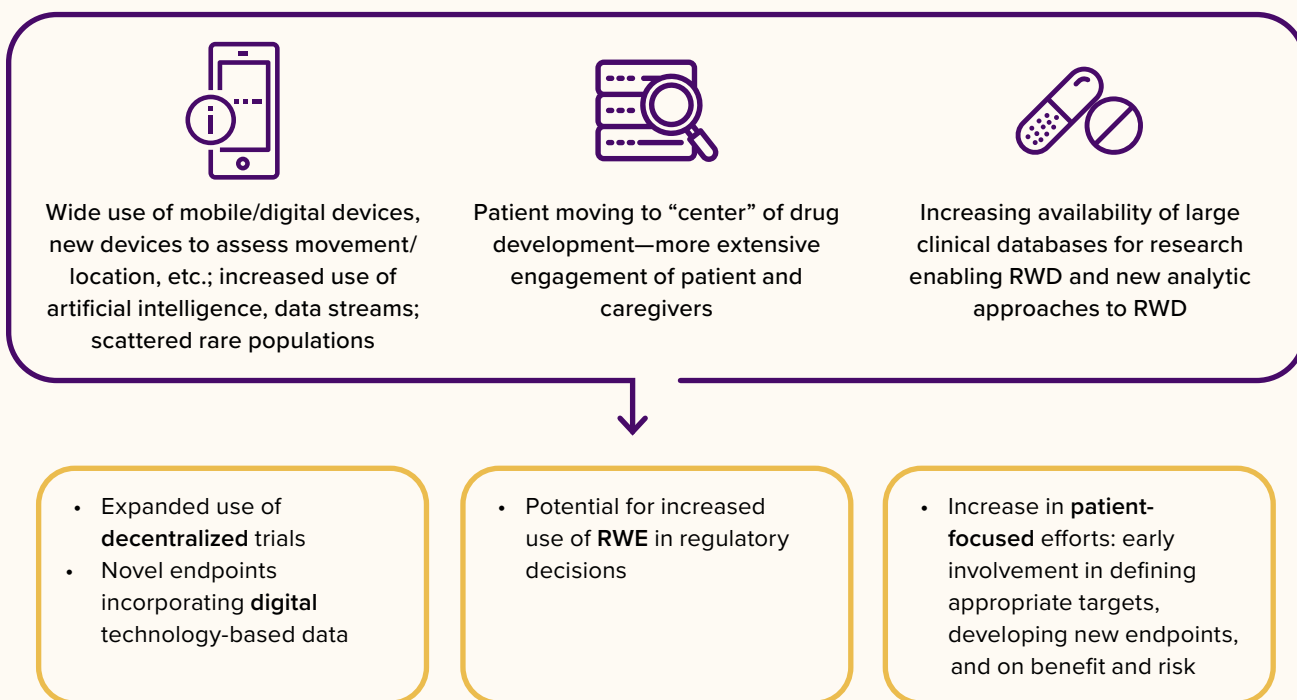
The simplest program should be used: if consumers completely understand the Drug Facts Label, they should not need to use a required mobile app or video or other condition to get the drug. The idea is not to limit access to products that consumers can appropriately select and use, but to give consumers more access to products where they might need extra help with safe selection or use.

Challenges and successes.

The drug development landscape was already evolving prior to COVID-19. Development of medications for chronic diseases has played and continues to play an important role, and despite multiple approved medications for many chronic diseases, some, such as diabetes, continue to garner a considerable investment. However, there has also been a rapidly expanding understanding of disease, genetics, and genomics, and the underlying pathophysiology or drivers of disease. New technologies and platforms have helped target previously 'un-druggable' targets. This has led to more drug development and programs targeting rare diseases. For the last several years, the majority of novel drug approvals have been for orphan and rare diseases. Additionally, there have been more programs targeting molecular subtypes of diseases or targeting patients with resistant or late-stage disease which could not be treated before. This tends to require innovative trial approaches—including greater use of mobile and digital devices to provide new data streams.

The increasing availability of large clinical databases for research has enabled real world data and new analytical approaches to how the data are handled. The patient is moving to the center of drug development, and this has translated to expanded use of decentralized trials, and adoption of novel endpoints to try to incorporate digital health tools or technology-based data. There was also a rapid proliferation of master protocols, which allowed the FDA to evaluate therapeutics more efficiently, but these can be complex and challenging to implement.

Changes in the drug development landscape



Source: Office of New Drugs, Center for Drug Evaluation and Research

When COVID-19 hit, there were immediate challenges to the drug trial process. Sites were closing, hospitals were locking down, clinical research staff were working remotely. Maintaining study integrity and protecting patients were key issues resulting in a huge shift towards virtual visits and telemedicine. There were changes in monitoring and how lab studies were conducted. There was a greater move towards the decentralized trial, and towards thinking about the burden on the patient to continue to participate in a trial during a pandemic, and how to reduce this burden. In some cases, this was done by changing the point of care or drug administration when safe and appropriate, for example by mailing medications to patients and allowing them to participate remotely in the drug administration component.

The pandemic has highlighted the need to develop community practice integration into clinical research and involve community practices in trials to increase patient enrollment and diversity and increase access for the underrepresented to clinical trials. Not only does this improve outcomes for clinical research but also patient care, as the translational gap between clinical research and clinical care decreases, so, too, could the gap in access to better care.

There have been both successes and challenges with sponsors being able to get products through the switch process to nonprescription status. A great success was the approval of home COVID-19 antigen detection tests. The need for home testing for COVID-19 became obvious early in the pandemic. Testing sites were flooded with consumers, and negative tests were being used as prerequisite for attending work and school or traveling. To reach over-the-counter status in less than a year, however, required the coordination of government and manufacturers. The government took prompt action—the Secretary of the Department of Health and Human Services (HHS) declared a public health emergency in February 2020, and a declaration that circumstances exist justifying the emergency use authorization of SARS-CoV-2 tests under section 564 of the FD&C Act, followed by Congress proclaiming a national emergency in March 2020. In April 2020, Congress provided funding to the HHS to help facilitate rapid response of development of tools with which to fight the pandemic. The FDA issued

its first policy and guidance to manufacturers in February 2020, and updated policies, guidance, and templates thereafter. FDA's Center for Devices and Radiological Health (CDRH) held weekly Virtual Townhall Meetings starting in March 2020 for 15 months, and then every other week since. Additionally, five days after Congress appropriated \$25 billion for anti-pandemic programs, the National Institutes of Health (NIH) launched the Rapid Acceleration of Diagnostics (RADx) initiative which has supported over 100 companies.

Ultimately, the quick development and deployment of the rapid COVID-19 test for in-home use is a success story highlighting the constructive communication and timely collaboration between Sponsors and the FDA. Unfortunately, the FDA's focus on the national COVID-19 crisis coupled with extraordinary work disruptions, has impeded progress on other new OTC drug products. For instance, inadequate access and communication slowed efforts to make the lifesaving opioid overdose reversal treatment, naloxone nasal spray, available as an OTC. Even with the understanding that OTC naloxone was an FDA priority to combat the expanding opioid-overdose crisis, there were several instances where feedback was delayed and/or not clear and often times relegated to written responses only. As an example, this led to confusion regarding the FDA's novel use of pictograms adjacent to the Agency's model drug facts label. Further, Drug Facts Label feedback was non-specific and confusing, and FDA comments to the Sponsor's Human Factors study protocol was not available for the Sponsor meeting, thereby impeding the Sponsor's ability to obtain clarity after months of waiting. Ultimately, the FDA's responsiveness to the switch of naloxone varied, and communication was not always clear. Increased and enhanced communication with greater opportunities for verbal dialogue would have helped, but this will require more resources for an already overtaxed agency.

Empowering consumers and improving health equity.

Moving medications to OTC status gives consumers easy access to medication which otherwise might not be available to them without the burden of pre-approval, time, and expense required to obtain it as a prescription medication. Regulatory decision-making is always going to be on the basis of benefit and risk and in particular, incremental benefit and incremental risk of OTC availability compared with prescription-only access. There are many clinical scenarios where a delay in treatment means worse outcomes. OTCs can potentially improve clinical effectiveness by giving consumers easy access to treatment, particularly those in rural areas with a deficit in healthcare availability. This is but one example of true improvements in clinical outcomes that must be considered along with any potential safety liabilities.

All stakeholders, including payors, benefit when a consumer can directly access effective treatments for illnesses. Payors benefit from not having to pay for unnecessary clinic visits or testing, and consumers gain faster access to treatment. Having OTC medication readily available in convenient retail locations, and online, serves to level the playing field by providing broader, generalized access. It needs to be mentioned, however, that OTCs may create different inequalities when it comes to paying for them as they are not commonly covered by prescription drug insurance programs, and, depending on their insurance plan, some consumers may have difficulties affording medications that were covered when prescription only but are not covered once they are OTC. Importantly, some states, however, have Medicaid and Medicare Advantage plans that cover some OTCs. What can be done to ensure that consumers will be able to afford necessary medication that had previously been paid for by insurance?

Issues still exist in terms of health equity, including lack of access to quality health care, unmet and unaddressed health conditions in diverse populations, and lack of evidence to know whether a product benefits one demographic group similarly to others. Living in a rural community can put consumers in a health 'desert,' and poverty and lack of access to technology can restrict access to diagnosis and treatment. Even clinical studies are affected by this—despite tremendous activity in the clinical research space, many patients from diverse, rural, underserved communities are not represented in trials and fail to benefit or fully benefit from emerging treatments as a result of their lack of inclusion.

How can drug development be made more inclusive? Greater community practice integration into clinical research is needed to increase patient enrollment rates and diversity of patients in trials, and to increase patient access to clinical trials. But for that to happen, community practices will need to develop new capabilities, including training in research, hiring research coordinators and staff, and investing in space to run trials and store study medications. It will require dedicated funding and updated and new standards for different types of trials to make it easier for new investigators, sites, or networks to engage in clinical research.

Another option is using real-world data (RWD) in regulatory decision making. RWD includes patient health data routinely collected from sources such as: electronic health records, claims and billing activities, product and disease registries, and other sources including home testing devices and mobile device apps. Analysis of RWD can provide clinical evidence regarding use and potential benefits and risks. Potentially, RWD and the resulting real-world evidence could be used to support marketing submissions, including data relevant to a switch from prescription to OTC use. However, RWD are of limited relevance to switches as there are no RWD of OTC use pre-approval. There may, though, be some safety data, current use data, or other data which are relevant, but not central, to the application.

Ultimately, the hope is that increasing community practice into clinical trials, utilizing real-world data to assess benefit and risk, and potentially having the option for nonprescription drugs to be approved with an ACNU, will increase access to and proper use of nonprescription drug products for a wider variety of consumers.

As Dr. Eric Brass summarized, “I think it’s quite clear that we live in a very dynamic healthcare environment and that environment provides both opportunity and the need for data driven, innovative solutions that regulators can safely implement. Those regulators need the flexibility to improve consumer access to safe and effective products through that innovation.”



Snapshot 2022

A CHANGING ENVIRONMENT FOR FDA-REGULATED CONSUMER PRODUCTS

Planned in partnership with the Consumer Healthcare Products Association

April 28, 2022, Marriott Marquis

901 Massachusetts Avenue NW, Washington, DC 20001

Virtual Attendance via Swapcard

AGENDA

12:30 pm Welcome & Opening Session

Welcome

Susan C. Winckler, RPh, Esq., CEO, Reagan-Udall Foundation for the FDA

Consumer Snapshot: The World Is Different in 2022

John Whyte, MD, MPH, Chief Medical Officer, WebMD

1:30 pm FDA in 2022: What Industry Needs to Know, Current Thinking, & Impact of Pandemic

Kevin Bugin, PhD, Deputy Director of Operations, CDER, FDA Ellen Flannery, JD, Deputy Center Director for Policy, CDRH, FDA

Reactor Panel

- Sally Greenberg, JD, Executive Director, National Consumers League
- Kirsten Moore, Director, EMAA Project
- Larider Ruffin, DNP, APN, RN, ANP-BC, AGNP-C, CRNP, CTTS, FAAN, Chair, National Black Nurses Association

2:15 pm FDA Perspective: Rx-to-OTC Switch of Drugs

Theresa Michele, MD, Director, Office of Nonprescription Drugs, CDER, FDA

Reactor Panel

- Sally Greenberg, JD, Executive Director, National Consumers League
- Kirsten Moore, Director, EMAA Project
- Larider Ruffin, DNP, APN, RN, ANP-BC, AGNP-C, CRNP, CTTS, FAAN, Chair, National Black Nurses Association

2:45 pm Break

3:15 pm **Changes in Consumer Access**

Case study: Naloxone

Bernard Simone, VP, Client Strategy and Rx-to-OTC Switch, Pinney Associates, Inc.; COO, Harm Reduction Therapeutics

Case study: COVID-19 OTC rapid antigen tests

John D. Tamerius, PhD, Special Advisor, Quidel Corporation

Reactor Panel

- Sally Greenberg, JD, Executive Director, National Consumers League
- Kirsten Moore, Director, EMAA Project
- Larider Ruffin, DNP, APN, RN, ANP-BC, AGNP-C, CRNP, CTTS, FAAN, Chair, National Black Nurses Association

4:15 pm **Expanding Consumer-Driven Health Care Interventions**

- Eric Brass, MD, PhD, Professor Emeritus of Medicine, David Geffen School of Medicine at UCLA
- Ed Hemwall, PhD, Principal, Edwin Hemwall Consulting, LLC
- Sandra Leal, PharmD, MPH, FAPhA, Vice President, Collaborative Innovation and Clinical Strategy, CVS Health
- David Spangler, Senior Vice President, Legal, Government Affairs & Policy, CHPA

5:30 pm **Reception**

Please join us for a reception at The Dignitary, located in the hotel lobby.



Snapshot 2022

A CHANGING ENVIRONMENT FOR FDA-REGULATED CONSUMER PRODUCTS

Speaker Biographies

Eric Brass, MD, PhD

Professor Emeritus of Medicine, David Geffen School of Medicine at UCLA



Dr. Eric Brass received his medical and doctoral (Pharmacology) degrees from Case Western Reserve University. He completed an internal medicine residency and clinical pharmacology fellowship at the University of Washington. After holding faculty positions at the University of Colorado and Case Western Reserve University, Dr. Brass moved to the UCLA School of Medicine where he was Chair of the Department of Medicine at the Harbor-UCLA Medical Center from 1994–2000. He is currently Professor Emeritus of Medicine, David Geffen School of Medicine at UCLA. Dr. Brass has long-standing interests in drug discovery, development, and regulation, with a particular focus on the challenges of prescription to OTC switches. He served as a member, and then as Chair, of the FDA's Nonprescription Drugs Advisory Committee. Dr. Brass has authored over 200 scientific papers, review articles and book chapters.

Kevin Bugin, PhD

Deputy Director of Operations, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)



Dr. Kevin Bugin is the acting Deputy Director of Operations in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER). Prior to his current role, Dr. Bugin served as the Chief of Staff for the Therapeutics Response Efforts as part of the U.S. Government's HHS and DOD operation formerly known as Operation Warp Speed. Dr. Bugin is adjunct faculty at the George Washington University in the Clinical Leadership Program, focusing on areas of clinical research and medicines development. Dr. Bugin joined the FDA in 2008 in the Office of Business Process Support, then joined the Division of Gastroenterology and Inborn Errors Products within OND as a Regulatory Health Project Manager in 2010. From 2017 until 2020, he served as the Director of Special Programs and the lead of CDER's New Drugs Regulatory Program Modernization. Prior to joining the FDA, Dr. Bugin held roles in multiple areas and phases of drug development, including discovery (molecular biology) at the Virginia Bioinformatics Institute, and translational research and technology transfer at the National Institute of Health's Office of Technology Transfer. He received a bachelor's degree in Biology and Chemistry from Virginia Tech in 2005, a master's degree in Biotechnology from American University in 2006, and a doctoral degree in Translational Health Science from George Washington University in 2020, with a focus on the Science of Team Science in drug development and regulatory science teams. He is certified in U.S. regulatory affairs (RAC) and participates in numerous policy and regulatory science program working groups across the FDA.

Ellen J. Flannery, JD

Deputy Center Director for Policy, Director, Office of Policy, Center for Devices and Radiological Health (CDRH), FDA



Ellen J. Flannery currently serves as Deputy Center Director for Policy in the Center for Devices and Radiological Health at the Food and Drug Administration. She also is Director of the CDRH Office of Policy. She received the FDA’s Dr. Frances O. Kelsey Award for Excellence and Courage in Protecting the Public Health in 2021. Prior to joining FDA in March 2018, she was an attorney advising and representing pharmaceutical and medical device companies and trade associations in matters arising under the Federal Food, Drug, and Cosmetic Act. Ms. Flannery was a member of three device-related committees of the Institute of Medicine (now the National Academies of Science, Engineering and Medicine), and taught food and drug law seminars at three law schools. She is a Fellow of the American Bar Foundation and past chair of the ABF Board of Directors. Ms. Flannery received a JD degree from Boston University School of Law and AB degree from Mount Holyoke College.

Sally J. Greenberg, JD

Executive Director, National Consumers League



Sally J. Greenberg joined the National Consumers League (NCL) as Executive Director on October 1, 2007. Sally has testified before Congress on consumer protection issues, including on airline passenger rights, product safety, fraud, and excessive fees on car rentals, consumer rip-offs in calling cards and in support of protections for farmworker children. Ms. Greenberg is the NCL's primary spokesperson on a variety of issues.

Ms. Greenberg came to NCL from Consumers Union, where she worked from 199–2007 on product liability and food safety issues, along with auto and product safety. Previously, Ms. Greenberg worked at the U.S. Department of Justice Foreign Claims Settlement Commission and prior to that, she spent a decade serving as the Eastern States Civil Rights Counsel for the Anti-Defamation League, based in Boston.

Ms. Greenberg currently serves on the board of directors of the Keystone Policy Center, the American National Standards Institute, and will join the Fair Labor Association board. Ms. Greenberg served as president of the Women’s Bar Association of Massachusetts and the Women’s Bar Foundation and served on several gubernatorial commissions in Massachusetts. Ms. Greenberg also served for over a decade on the board of directors of Trillium Asset Management, the oldest and largest investment management firm dedicated to socially responsible investing.

Edwin Hemwall, PhD

Principal, Edwin Hemwall Consulting, LLC



Dr. Edwin (Ed) Hemwall brings over 35 years of global pharmaceutical industry experience in providing consulting services in OTC drug product development. His focus is on Rx-to-OTC switch, medical claims, regulatory strategy, and FDA Advisory Committee preparation. Dr. Hemwall first became known as an expert in Rx-to-OTC switch in 1995 through his role in the first-in-class switch of Pepcid AC followed by other U.S. and global switches, such as the U.S. switch of Oxytrol for over-active-bladder in 2013. His clients range from well-known global corporations to private equity firms and smaller business entities. He has published and lectured as a Switch and Self-Care advocate and advised on client switch programs leading to FDA approval as recent as 2022.

His prior industry career spanned nearly 35 years in a range of clinical and regulatory leadership roles with Merck, J&J, GSK and Bayer, retiring in 2016 as a vice-president on the worldwide R&D team at Bayer Consumer Care. He has served on the U.S. FDA's Clinical Pharmacology and Pharmaceutical Sciences Advisory Committee, the Board of Directors of the U.S. Consumer Healthcare Products Association (CHPA), as Chair of CHPA's Regulatory and Scientific Affairs Committee, as co-chair of the Global Self-Care Federation Switch Working Group and as an editor for the Journal Self-Care.

Dr. Hemwall has earned bachelor's, master's and doctoral degrees in biochemistry and pharmacology and is based in Villanova, PA.

Sandra Leal, PharmD, MPH, FAPhA
Vice President, Collaborative Innovation and Clinical Strategy, CVS Health
Immediate Past President, American Pharmacists Association



Dr. Sandra Leal is Vice President of Collaborative Innovation and Clinical Strategy at CVS Health. She is the Immediate Past President of the American Pharmacists Association. Dr. Leal has had diverse experience as a pharmacist, medical director, public health clinician, and as a board member for various groups including the National Center for Farmworker Health.

Dr. Leal received her PharmD from the University of Colorado and her master's degree in Public Health Practice from the University of Massachusetts. Dr. Leal completed her residency at the Southern Arizona VA Health Care System and a Primary Health Care Policy Fellowship with the Department of Health and Human Services.

She has published and presented her work in numerous national and international publications and venues. She has been recognized as the Good Government Pharmacist of the Year by the American Pharmacists Association (APhA) for her advocacy work on pharmacist provider status. Dr. Leal is a two-time recipient of the Pinnacle Award from the APhA Foundation for her progressive practice innovations and received the ASHP Best Practice Award for her leading practice in diabetes management.

Two themes that govern Dr. Leal's professional life are a passion to eliminate barriers to care and to improve access and outcomes for patients. Dr. Leal has led efforts on both local and national levels to integrate pharmacy, public health, and advocacy to improve the healthcare system and to reduce health inequity.

Theresa Michele, MD
Director, Office of Nonprescription Drugs, CDER, FDA



Dr. Theresa Michele is currently the Director of the Office of Nonprescription Drugs (ONPD) in the Office of New Drugs, Center of Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). Prior to joining FDA in the Division of Pulmonary and Allergy Drug Products, she spent 10 years in industry, with clinical research experience across a variety of therapeutic areas in both commercial and development stage companies. She is board certified in internal medicine, pulmonary medicine, and critical care medicine, completing her training at Johns Hopkins University, where she currently serves on the faculty.

Kirsten Moore

Expanding Medication Abortion Access Project (EMAA Project)



Kirsten Moore is an advocate with twenty-five plus years of advancing policy change on hot button issues like reproductive health and gun violence prevention.

She was President and CEO of the Reproductive Health Technologies Project (RHTP) from 2002-2011. Under her leadership, RHTP led a 10-year effort that brought Plan B emergency contraception over the counter, fighting both a Republican and Democratic administration.

Ms. Moore went on to become the inaugural Director of National Partnerships for Everytown for Gun Safety Action Fund and helped move the issue of domestic violence and gun violence on to policymakers' agendas at a national and state level. She mobilized organizations like National Urban League, the National Parent Teacher Association, and the Human Rights Campaign, to focus on gun violence prevention efforts.

After the 2016 election, she moved over to Pew Charitable Trusts where she managed a portfolio of work intended to advance the public interest in a range of FDA policies, including dietary supplements, drug compounding, and laboratory test regulation, and opposing attempts to weaken FDA's review standards. This work gave her a much deeper understanding of how FDA functions and introduced her to a range of players inside and outside FDA, including professionals who were involved with the initial approval of mifepristone (2000) and the label change update (2016).

With this experience, Ms. Moore started the Expanding Medication Abortion Access Project (EMAA), with the goal of getting FDA to change the way it regulates distribution of medication abortion care pills in the U.S. In December 2021, FDA announced a change to the mifepristone REMS allowing for the retail and mail order delivery of the medication.

Larider Ruffin, DNP, APN, RN, ANP-BC, AGNP-C, CRNP, CTTS, FAAN

Chair, NBNA Substance Use Disorders Committee, National Black Nurses Association (NBNA)



Dr. Ruffin is the Chair of the NBNA Substance Use Disorders Committee. He chairs the MSN program at Stockton University and CEO at Ruffin Associates Healthy Housecalls where he maintains clinical practice as a Nurse Practitioner and Certified Tobacco Treatment Specialist. He has advocated for and treated smoking/vaping for nearly a decade.

Bernard Simone

Vice President, Client Strategy and Rx-to-OTC Switch, Pinney Associates COO, Harm Reduction Therapeutics



Bernard (Bernie) Simone engages with consumer healthcare clients to support Rx-to-OTC switch regulatory strategies and FDA engagements, commercial opportunity assessments and optimization, and new business opportunity identification, evaluation and implementation.

Bernie's 40-year career spans more than 50 therapeutic categories in OTC medicines, prescription drugs, medical devices, and dietary supplements. His experience ranges from regulatory strategy to consumer research for OTC switches to leading iconic OTC brands.

As the commercial leader for some of the top 20 U.S. OTC brands, he drove double-digit growth via identification of key target audiences and compelling consumer insights.

Bernie led the first-in-class switch of Nasacort Allergy 24HR, and the first-in-class introduction of an OTC transcutaneous electrical nerve stimulation medical device for Icy Hot. He oversaw licensing and the switch of Xyzal Allergy 24HR, led licensing of the OTC switch rights for Cialis, and led the global Cialis switch team before joining Pinney Associates in 2018.

Bernie also serves as the Chief Operations Officer and Chief Commercial Officer of Harm Reduction Therapeutics, a nonprofit devoted to saving lives from opioid overdose by making low-cost naloxone available as an OTC product.

David Spangler

Senior Vice President, Legal, Government Affairs & Policy, Consumer Healthcare Products Association (CHPA)
David Spangler leads the association's team of eight across legal, government affairs, and policy functions. He has particular expertise in regulatory matters.



Mr. Spangler joined CHPA in 1984 as a legislative analyst. He subsequently served in a number of roles for the association in the president's office, project management, international affairs, and, after completing law school in 1995, the association's legal department. Mr. Spangler was named a vice president in 1997, and a senior vice president in 2006. His responsibilities were expanded to his current role in 2019.

Mr. Spangler is a member of the District of Columbia Bar as well as the American Society of Association Executives. He authored the chapter on OTC medicines in “Modern Pharmaceutical Industry: A Prime” (Jacobsen and Wertheimer, eds., 2009) and has served on a range of committees, working groups, and the Board for the Food and Drug Law Institute and the Global Self-Care Federation. Mr. Spangler earned his Certificate in Organizational Management in 1991 from the U.S. Chamber of Commerce's Institute for Organization Management.

John D. Tamerius, PhD

Special Advisor, Quidel Corporation



Dr. John Tamerius graduated from the Univ. of Washington (Seattle, Washington) with a doctoral degree in Microbiology and Immunology. He performed graduate and postdoctoral research in tumor immunology at the Fred Hutchinson Cancer Center (Seattle) before joining the Scripps Clinic and Research Foundation (San Diego, California) as a Research Associate in the Dept. of Molecular Immunology. In 1983 he cofounded a company in San Diego (Cytotech, Inc.) where he led the development of nine FDA-cleared products, approximately 100 research products and five research-use-only (RUO) kits for studies of immune complexes, inflammation, and the complement system. Cytotech was acquired by Quidel Corporation in 1989. During his ensuing tenure at Quidel he has held several important leadership roles, including Head of Quality Assurance, VP of R&D, General Manager of Quidel's northern California division, Sr. VP of Clinical & Regulatory Affairs, and Sr. VP of Strategic & External Affairs. While head of R&D, Dr. Tamerius was in charge of the development of the QuickVue Influenza A/B lateral flow test—the first CLIA-waived rapid antigen test for diagnosis of influenza. More recently he was responsible for the clinical trials and FDA submissions that led to the FDA clearances and CLIA waivers for the immunofluorescence-based Sofia analyzer and the Sofia Influenza A+B Fluorescence Immunoassay (FIA), the Sofia RSV FIA, the Sofia Strep A+ FIA, and the Sofia hCG FIA. He also was responsible for the field studies leading to the validation of the Virena wireless communication and surveillance system. He worked with the teams that developed the Sofia SARS Antigen FIA and the QuickVue POC and QuickVue OTC tests for detection of SARS-CoV-2 antigen. Dr. Tamerius now serves as Special Advisor to the CEO of Quidel.

John Whyte, MD, MPH
Chief Medical Officer, WebMD



Dr. John Whyte is a physician and corporate executive with a unique combination of government and private sector work that provides him with an exceptional perspective on wellness, clinical trials, information technology, innovation, and health care services.

He is currently the Chief Medical Officer, WebMD. In this role, Dr. Whyte leads efforts to develop and expand strategic partnerships that create meaningful change around important and timely public health issues. He has been a leading voice in addressing the COVID pandemic, being named as one of the top 20 health influencers. He frequently speaks on evaluating digital tools and technologies, assessing their roles in the evolving health ecosystem.

Prior to WebMD, Dr. Whyte served as the Director of Professional Affairs and Stakeholder Engagement at the Center for Drugs Evaluation and Research at the U.S. Food and Drug Administration. In this role, Dr. Whyte spearheaded numerous efforts to address diversity in drug development programs especially as it relates to necessary changes in clinical trial design. Dr. Whyte led a research agenda around drug safety issues, including prescription and over-the-counter products.

Dr. Whyte worked for nearly a decade as the Chief Medical Expert and Vice President, Health and Medical Education at Discovery Channel. Dr. Whyte developed, designed, and delivered educational programming that appealed to both a medical and lay audience. This included television shows as well as online content that won over 50 awards including numerous Tellys, CINE Golden Eagle, and Freddies.

Dr. Whyte is a board-certified internist and continues to see patients. He completed an internal medicine residency at Duke University Medical Center as well as earned a master's degree in Public Health (MPH) in Health Policy and Management at Harvard University School of Public Health. He has written extensively in the medical and lay press, including two best-selling books.

Meeting Moderator

Susan C. Winckler, RPh, Esq.
Chief Executive Officer, Reagan-Udall Foundation for the FDA



Susan C. Winckler, is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Ms. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters. As Chief of Staff for the U.S. Food and Drug Administration (2007–2009), she managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.