U.S. FOOD & DRUG ADMINISTRATION

2023 Annual Report

OFFICE OF COMMUNICATIONS

Center for Drug Evaluation and Research

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Director's Message

"Follow the science, protect public health, and serve the American people." Since joining the U.S. Food and Drug Administration (FDA) in 2020, I've been impressed with how accurately this statement encapsulates the extraordinary commitment of my colleagues in the Center for Drug Evaluation and Research (CDER). As the executive director for CDER's Office of Communications (OCOMM), I am honored to lead the assembled experts who convey that commitment to FDA's many audiences worldwide. With our inaugural annual report, I'm excited to share some of the many ways that their work made an impact in 2023.

James-Denton (JD) Wyllie Executive Director, Office of Communications

In 2023, OCOMM's many accomplishments demonstrated our commitment to achieving the three main goals of our 2021–2025 CDER Communications Strategic Plan:

1. Strengthen public trust in the FDA and CDER;
2. Improve CDER's visibility and reputation with its primary stakeholders; and
3. Increase awareness of drug safety, effectiveness, and quality.

Why these goals? CDER's success depends, in large part, on the **public's trust** in FDA. Clear, accurate communication about CDER's role in **drugs' safety and efficacy** is essential to building that trust. By effectively communicating our efforts to protect public health, we help to gain and sustain the confidence of the people we serve every day.

Raising awareness of the center's work is even more urgent at a time when our audiences are frequently exposed to false assumptions and misinformation about science, CDER, and FDA. OCOMM's communications and initiatives are helping CDER cut through the static and counter inaccuracies and falsehoods.

2023 was marked by great innovations, challenges, and opportunities in public health, with many topics garnering national attention. Together, we at CDER have launched new campaigns and expanded existing ones on topics such as rare diseases, clinical trial innovations, sunscreen regulation, biosimilar medications, safe disposal of opioids, generic and prescription drug safety, and drug-facts labels, among others. We've used a variety of methods to convey important information to the media, health care professionals, industry, and the public.

On behalf of OCOMM, I want to thank our fellow FDA employees for their continued support of our many endeavors. Communications is a collaborative field, and we can truly only ever be as strong as our teammates help us to be. I'd also like to thank OCOMM's Program Management Analysis Staff for their instrumental expertise in budget oversight, contracts management, training, and human services—without it, many of the accomplishments listed would not have been possible.

While the accomplishments within this report capture moments in time, it's important to recognize that the ability to successfully communicate and build trust with stakeholders is a never-ending effort. I look forward to OCOMM continuing its work as a member of the "One CDER" team to inform and educate about the significant work of the FDA and its invaluable contribution to public health.

James-Denton (JD) Wyllie, Executive Director
Office of Communications

Informing CDER's Initiatives

This report describes CDER's strategic communications goals and is intended for a diverse audience. OCOMM hopes that the report fosters a deeper understanding of CDER's crucial role in safeguarding public health, advancing science, and regulating human drugs—in short, how CDER impacts millions of Americans every day.

In order to effectively achieve our communications goals, we had to first identify CDER's key stakeholders and partners. These partners ranged from the FDA commissioner to patients and caregivers (Exhibit 1). We organized the stakeholders according to the three overarching goals of CDER's 2021–2025 Communications Strategic Plan.

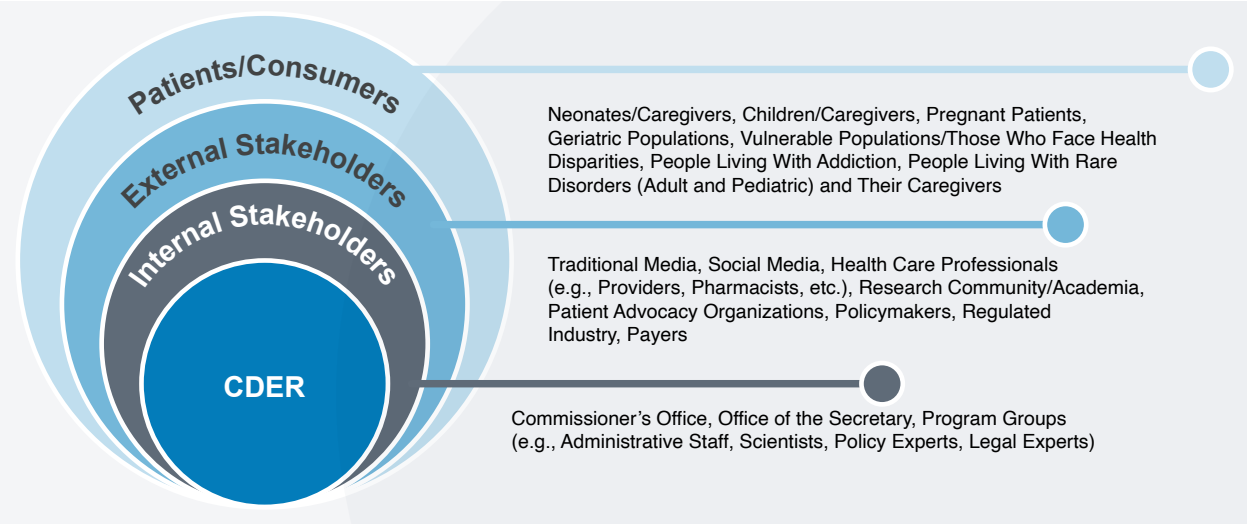

Exhibit 1. An overview of CDER's stakeholders.

In preparing communications strategies for CDER, OCOMM relies on social science's insights into human behavior, attitudes, and social dynamics. Social scientists at OCOMM gain these insights by conducting research (e.g., in-depth/long-term research studies, online/social media research, and communications testing) and sharing the findings with groups working on messages and materials related to drug safety and effectiveness. OCOMM tailors each communication for a specific target audience, including health care professionals (HCPs), industry, academia, patients, and the general public.

In 2023, OCOMM began to conduct the following **long-term studies** on priority topics:

- *Addressing Consumer Misinformation:* We began collecting data from consumers about misinformation during public health emergencies. We included traditionally marginalized groups such as racial and ethnic minorities, and those in low socioeconomic groups. OCOMM will use the findings from this research to inform FDA guidance for external messaging strategies that counter misinformation.
- *Benzodiazepine Prescribing:* This study investigates HCPs' practices and experiences prescribing and tapering benzodiazepines, both alone and in conjunction with opioids; this includes products that contain buprenorphine to treat opioid use disorder. We're conducting focus groups and interviews with physicians, physician assistants, and nurse practitioners working in diverse medical fields. The results will inform CDER's regulatory activities related to these products, which are involved in the nation's addiction and overdose crisis. We'll share the findings internally with CDER staff and leadership; to expand the takeaways with external audiences, we'll prepare a manuscript and possibly a conference presentation.

- *Understanding HCP Misinformation:* This study aims to identify the best ways FDA can support HCPs to address the growing threat of health misinformation. Misleading information has been shown to negatively affect patients' health decisions, such as rejecting vaccines and other public health measures, and using unproven and potentially dangerous treatments. The research will explore HCPs' experiences with misinformation during a public health emergency, how they evaluate misinformation, and how they address it with their patients.
- *Kratom Policy Research:* Kratom is an herbal substance with psychoactive properties, and it affects the same brain receptors as many opioid substances. Kratom is federally unregulated and nonscheduled, but it's legal in many areas of the country, despite the fact that little is understood about it. This study is part of a CDER-wide research initiative to aid regulatory decision-making around these substances. It will gather insights directly from HCPs and people who use kratom, who typically use multiple substances nonmedically. The goal is to learn attitudes, behaviors, and experiences related to kratom use across different states and policies, including its short- and long-term impacts on health and safety.

To inform CDER's regulatory activities, OCOMM researchers also collected and analyzed **online/social media** data, exploring the social context for the use and misuse of various potentially harmful substances. Online/social media data allow OCOMM to collect feedback that users of these substances provide in real time and in their own words. This form of research also avoids the usual constraints of traditional research methods, including fear of honestly discussing recreational drug use with federal government researchers. These studies included:

- *Opioids:* Throughout the year, OCOMM social scientists monitored and analyzed online and social media data as part of CDER's proactive pharmacovigilance research activities. The purpose of those activities is to discover not only which drugs and substances are being used but also how and why they're being used, as well as adverse events. We prepared monthly reports on the nonmedical use of FDA-approved opioids; two of the reports reviewed trends over the previous 6 months. They described the social context for nonmedical use of these opioids and other substances, including novel and reemergent substances of interest to CDER. Our 2023 reports described 81 unique substances.
- *Marijuana:* Based on an administration directive to explore whether marijuana should remain listed as Schedule I under the Controlled Substances Act, OCOMM researchers conducted a detailed qualitative analysis of conversations about marijuana online and on social media. The findings from these CDER-wide studies informed the Eight Factor Analysis (8FA) review of the substance required by the Controlled Substances Act for rescheduling or descheduling a controlled substance. CDER's final 8FA report to the Drug Enforcement Administration recommended down-scheduling marijuana to Schedule III.

The communications testing program collects feedback from consumers and HCPs on a variety of CDER materials or messages to be posted on FDA's website and social media accounts as well as on medicine packages and patient instructions. Researchers examine participants' thoughts and reactions, including whether the materials are understandable, relevant, and useful in helping readers make informed health decisions. OCOMM scientists also want to learn if the communications have potential unintended effects. If a message is confusing or misses the mark, we ask for participants' suggestions on how to improve the words, explanations, formats, and graphics without compromising accuracy.

In 2023, message testing was conducted on the following materials:

- An educational fact sheet about **biosimilars and interchangeable biosimilars**
- Social media messages about the dangers of diversion and nonmedical use of **prescription stimulants**
- An infographic about **drug shortages**

Strengthening Public Trust in FDA and CDER

The rapid advancement of communication technologies and social media have made it easier than ever to share information. Unfortunately, these advancements also have led to an environment where both deliberate and unintentional misinformation has flourished.

At FDA CDER, we have noticed significant increases in misinformation related to FDA goals and responsibilities, as well as drug development and safety. We must focus our immediate attention on this increase because of the vital role that belief in CDER expertise and belief in the rigorous standards of FDA plays in maintaining the strength of our nation's public health system. To that end, OCOMM took several steps in 2023 to combat misinformation externally and internally.

External Communications

OCOMM committed to messaging CDER information in plain language to effectively educate and inform stakeholders about our science-led decisions and actions. Additionally, we focused on proactive communications to ensure that stakeholders heard about the important public health issues of the day from FDA first, rather than allow the issues to be inaccurately represented via second or third parties. Examples include:

- We were closely involved in FDA's public response for Mpox (monkeypox), a rare disease caused by infection with Mpox virus. The virus can spread to anyone through close, personal, often skin-to-skin contact. OCOMM proactively informed CDER's audiences about the shelf-life extension of the TPOXX (tecovirimat) injection, which can be used to treat and prevent Mpox, and about the warning letters to companies that illegally sell products claiming to cure, treat, or prevent Mpox infection.
- We provided messaging on potentially cancer-causing substances called nitrosamines. Nitrosamines have been found in some drugs, including those used to treat elevated blood pressure, heartburn, acid reflux, and diabetes. Many of these drugs from certain manufacturers have been recalled. In August 2023, FDA released its guidance on Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRI). The guidance provides industry with a recommended framework for predicting the mutagenic and carcinogenic potential of NDSRIs that could be in drug products.
- We continuously track drug shortages, which impact patients and providers across the country. Drug manufacturers also inform the agency about their ability to supply the market. In July 2023, a tornado in North Carolina damaged a sterile injectable plant, impacting supply for dozens of drugs, including those for attention deficit/hyperactivity disorder (ADHD). OCOMM conducted both proactive and reactive communications.
- We contributed to the outreach process that produced content for FDA, including a refresh of the Treating and Dealing With ADHD page.
- We provided invaluable strategic communications support to CDER's Rare Diseases Team to engage the rare disease patient community, strengthen internal and external partnerships, and foster collaboration with outside experts to help find solutions for the challenges in rare disease drug development. OCOMM managed the CDER Rare Disease News email list (now with approximately 25,000 subscribers), communication and editorial activities for CDER's Accelerating Rare disease Cures (ARC) Program, roll out activities for the new Genetic Metabolic Diseases Advisory Committee, and the Support for clinical Trials Advancing Rare disease Therapeutics Pilot Program.

Education and Outreach Campaigns

In 2023, OCOMM addressed the spread of misinformation head-on by developing, executing, and sustaining several internal and external public health outreach/education campaigns. Each campaign targeted a particular segment of CDER's audiences. We reached each audience through a carefully selected mix of traditional, digital, and social media (Facebook; X (formerly Twitter); Instagram; LinkedIn; and starting in September, Threads), as shown in Exhibit 2.

OCOMM designed the campaigns to convey important truths and increase transparency and trust. For each one, we developed outreach materials that educate audiences about FDA's role in public health and in the regulatory process as well as the agency's robust regulatory framework.

Don't Get Burned

Don't Get Burned educates consumers about the risks of spending time in the sun. It encourages them to use broad-spectrum sunscreen products with an SPF of 15 or higher to protect against skin cancer and early skin aging. OCOMM placed public service announcements (PSAs) on a variety of broadcast channels to reach a wide audience about one of CDER's most consumer-friendly initiatives.

Total impressions[1] in 2023:
301,897,764

1,995,520 waiting-room placements

29,071 airings on local TV stations

3,433 airings on network TV programs

3,215 airings on Nielsen radio stations[2]

BeSafeRx

The *BeSafeRx* campaign raises awareness about the dangers of purchasing medications from fraudulent and unsafe web-based pharmacies. This messaging is critical now that consumers have multiple options for filling prescriptions online. The campaign describes how to identify false pharmacies and how to find a legitimate web-based pharmacy.

Total impressions in 2023:
30,950,907

3,174 airings on local TV stations

511 airings on network TV programs

2,119 airings on Nielsen radio stations

17 airings on non-Nielsen radio stations

Biosimilars Education and Outreach

This campaign, which targets patients and HCPs, raises awareness of biosimilars. It encourages better understanding and broader adoption of these medication options. OCOMM developed, produced, and promoted an animated patient video and a three-video series for HCPs. We optimized the campaign webpages to improve the user experience, and developed a suite of new materials, including a fact sheet in nine languages.

Total impressions in 2023:
165,401,391

4,158,712 Google Search and Display ad impressions

911 MAT release placements[3]

5,131,542 patient waiting-room PSA impressions

41,100 views on Reddit r/pharmacy "Ask Me Anything"

2,214,438 YouTube ad impressions

Safe Use of Acetaminophen

Acetaminophen has long been a go-to over-the-counter (OTC) pain reliever for everyone from infants to the elderly. This campaign educates consumers about how to use acetaminophen safely and warns that taking too much of it can seriously damage the liver.

Total impression in 2023:
19,893,566

7,442 airings on local TV stations

1,249 airings on Nielsen radio stations

[1] An impression is a comprehensive calculation of the number of people who received a message in a given time period. In this graphic, the reported number of impressions includes all campaign promotion efforts, some of which may not be reflected in this report.

[2] Nielsen radio stations are those subscribing to the Nielsen ratings survey.

[3] A MAT release is a branded, consumer-facing article that we write and distribute to a network of print and online news outlets. It guarantees that the topic of the MAT release gets media coverage.

Remove the Risk

The *Remove the Risk* campaign is an evergreen campaign aligned with National Prescription Drug Take Back Day. It educates consumers about the potential dangers of keeping unused opioids at home and the importance of safely disposing of opioids when they're no longer needed.

Total impressions in 2023:
775,492,391

2,097,606
in-store placements

75,659 airings on local TV stations

1,338 airings on network TV programs

5,105 airings on Nielsen radio stations

24,850 airings on non-Nielsen radio stations

FDA Video Series

We produced a three-part video series to directly address the public's misconceptions about FDA. The series describes FDA's regulatory services, its commitment to science, and the constraints it operates under. The videos are in the 2- to 3-minute range and are presented in plain language. OCOMM also created 30-second versions of the videos to increase the reach of the series' messaging.

Total impressions in 2023:
1,458,246

942,540
YouTube video views

64.53 percent
Video Completion Rate[4]

5,000+
website views

232,004
social media impressions

Generic Drugs

Nine out of 10 prescriptions are for generic drugs, so the public needs to know that these drugs are available and safe. The Generic Drugs initiative raises public awareness of generic drugs as a safe and effective treatment choice.

Total impressions in 2023:
27,355,635

1,406 airings on local TV stations

382 airings on network TV programs

2,010 airings on Nielsen radio stations

Exhibit 2 (pages 7 and 8). Education and Outreach campaigns.

[4] Video Completion Rate is defined as the percentage of viewers that watched a video from start to finish.

Maintaining and Optimizing CDER Databases

Online databases are an easy-to-use tool for consumers who want information about CDER-regulated products (e.g., labeling changes, health risks, or approval status of a given drug). In 2023, OCOMM began migrating our public-facing databases out of the Adobe ColdFusion development environment into Acquia. This new platform allows us to build, operate, and optimize front-end web applications without rebuilding each instance of a database. It allows us to develop content more quickly in the Drupal content management system, which is used for publishing content on FDA.gov. We also began working with FDA's Office of Business Informatics to automate database uploads; this will save many internal labor hours and communicate information to the public more efficiently.

OCOMM coordinates, manages, and/or maintains 19 of the 21 CDER databases. These include the Over-The-Counter Monograph Drug User Fee Program, Drug Safety-related Labeling Changes, Approved Risk Evaluation and Mitigation Strategies, and the President's Emergency Plan for AIDS Relief Database.

Over-The-Counter Monograph Drug User Fee Program (OMUFA)

OMUFA is a "rulebook" for drugs in every therapeutic category. It details drugs' approved uses, ingredients, and safety profiles, among many other characteristics. FDA's OTC monographs are a resource for the public to view administrative orders (i.e., proposed, final, and interim final orders) for nonprescription and OTC drugs that may be marketed without an approved drug application. The public can submit, search, and view comments and data.

In 2023, OCOMM made the OMUFA administrative module more efficient; it allows reviewers in the Office of Nonprescription Drugs (ONPD) to tag and search publicly submitted comments. We added five direct final orders, five monographs, and eight news items to the OTC Monographs@FDA website. OCOMM configured the internal Amazon Simple Storage Service solution that allows site visitors to access public and FDA documents more easily.

Drug Safety-related Labeling Changes (SrLC) Database

If new safety concerns emerge after a medication is on the market, FDA may require a labeling change about the drug's safety. The SrLC database includes certain labeling changes that product sponsors voluntarily submit to FDA, as well as safety-labeling changes that FDA requires or orders. Third-party vendors use these time-sensitive updates to inform their downstream applications, which are used by HCPs across the globe. OCOMM published 3,964 labeling changes across seven different labeling section types, as displayed in Exhibit 3.

Type of Labeling Change	Number of Changes
Adverse Reactions	741
Boxed Warnings	210
Contraindications	348
Drug Interactions	459
Patient Counseling Information and/or Medication Guides	744
Use in Specific Populations	665
Warnings and Precautions	797
TOTAL	**3,964**

Exhibit 3. Drug safety-related labeling changes published by OCOMM in 2023.

Approved Risk Evaluation and Mitigation Strategies (REMS) Database

A REMS is a drug safety program that FDA can require for medications with serious safety concerns to help ensure the medication's benefits outweigh its risks. Launched in 2015, the REMS website is a centralized, standardized, reliable, and user-friendly repository of information about REMS programs, including the roles of participants (e.g., patients, pharmacies, and HCPs) and requirements under each approved REMS.

OCOMM manages the comprehensive database for the REMS drug safety program, REMS@FDA. In 2023, OCOMM received 76 requests for updates, modifications, or revisions to the database. These requests included removing the approved REMS for Lotronex (alosetron hydrochloride) and the approved generics, since FDA determined the REMS was no longer necessary for safe use. As a part of managing the database, we sent monthly summaries and three important updates to more than **78,000 email subscribers**. For example, in March 2023, we notified pharmacists that under the REMS program known as Buprenorphine-containing Transmucosal products for Opioid Dependence, they can dispense buprenorphine for opioid use disorder to patients without the previously required prescriber verification under provisions of the Drug Addiction Treatment Act of 2000.

President's Emergency Plan for AIDS Relief (PEPFAR) Database

PEPFAR is led by the Department of State's Office of the U.S. Global AIDS Coordinator and Health Diplomacy. The purpose of the PEPFAR program is to address the HIV/AIDS epidemic in PEPFAR supported countries and regions in Asia and West Africa, and help save the lives of people who have the disease. FDA's role is to ensure that safe, effective, and quality-assured antiretrovirals are available for distribution to PEPFAR focus countries in areas of Asia, West Africa, and elsewhere in the Western Hemisphere. Antiretrovirals (ARVs) are the medicines used to treat and prevent HIV.

Responsibility for the PEPFAR program is distributed across FDA. The Office of Global Policy and Strategy is the agency's point of contact with all outside entities in coordinating FDA activities associated with PEPFAR. This includes drug firms wanting to participate in the expedited review process for ARVs. The Office of New Drugs (OND), Office of Generic Drugs (OGD), and Office of Pharmaceutical Quality (OPQ) approve and tentatively approve ARVs that are then available for procurement under PEPFAR.

To support PEPFAR's mission, OCOMM provides a comprehensive and interactive database containing all FDA-approved and tentatively approved ARVs reviewed in association with PEPFAR. In 2023, 11 such ARV drugs were added to the PEPFAR database, and the **webpage was visited 21,492 times**. The information in this database is critically important because PEPFAR stakeholders such as the U.S. Agency for International Development and the ARV Procurement Working Group procure only ARVs that CDER has approved or tentatively approved to be distributed outside the United States. Stakeholders also use the PEPFAR database to generate reports and access FDA-reviewed product labeling, proper storage conditions, and more.

Internal Communications

Clear communication among CDER staff is just as valuable as the center's communication with our external audiences. Everyone at CDER is an ambassador for its work, so CDER staff must understand how integrated, consistent communications support our priorities and initiatives. Internal communications keep over 6,000 CDER staff members connected and collaborative by informing them about the center's priorities, activities, and accomplishments.

In 2023, OCOMM coordinated internal communications on several fronts. Most notably, we launched our first hybrid, all-employee CDER Town Hall in April 2023 and have maintained the hybrid environment for these meetings since the launch. All CDER employees are invited to attend these meetings in person or virtually, to hear updates from multiple levels of CDER leadership and to ask questions. OCOMM supported internal communications for many large CDER initiatives and priorities, including "CDER Civility" and CDER's transition to a hybrid workplace. OCOMM also continues to help employees connect with each other personally and professionally through the #CDERCommunity initiative, *CDER Connection News*, and the *Happenings at CDER*, which issue communications monthly.

We also manage and support CDER speaker requests. Organizations regularly ask CDER employees to give a speech; make a presentation; or participate on a panel, meeting, or webinar related to CDER regulations, policies, and initiatives. By participating in these events, CDER provides stakeholders with important information and updates. In 2023, OCOMM handled over 2,600 CDER speaker requests.

Communications Resource Hub

If every CDER office shares the same center messaging about what we do and why it makes a difference, stakeholders are more likely to see us as reliable—and are more likely to trust us. In response to feedback from CDER leadership and staff, OCOMM created and launched the Communications Resource Hub, a centralized, online tool with cleared, timely materials that are ready to use (Exhibit 4). The hub makes it easy for CDER staff to give consistent messaging to our stakeholders.

Exhibit 4. Dashboard for the CDER Communications Resource Hub.

In its first year, the Communications Resource Hub was visited over 15,000 times. Six months after we launched the hub, OCOMM surveyed CDER staff on how often they use the site and how easily they can find the resources they need. Based on the feedback, we refreshed the homepage to make it easier to access and use. We also developed training materials for the hub to support employee onboarding and help new hires navigate the communications resources related to their work. We continue to update the Communications Resource Hub in 2024, adding features and resources and updating the messaging as needed.

Improving Visibility and Reputation With Primary Stakeholders

When it comes to stakeholder communications, strengthening the public's trust in CDER goes hand in hand with elevating the center's visibility and reputation. OCOMM disseminates clear, concise, easily shareable content about CDER's science-driven regulatory processes. We carefully select the most effective channels to communicate center news and announcements to different groups of stakeholders.

CDER's digital communications must meet audiences where they are, not where we think they should be. In 2023, we developed a digital strategy plan to guide CDER's communications with stakeholders on digital platforms. The plan focuses on the CDER website, fda.gov/drugs, and digital accounts (e.g., social media and GovDelivery subscriber lists) that drive traffic to related CDER resources.

The CDER website continued to perform well with audiences in 2023:

The site was viewed **54 million times,** or 20 percent of the total views of fda.gov.

Almost **one of every four** visitors to fda.gov (24 percent) viewed a CDER webpage or app screen.

The 2023 consumer warning about the risks in using certain eye drops was the **fourth most-viewed** webpage on fda.gov for the year.

The CDER homepage was the **sixth most-viewed** webpage on fda.gov.

CDER's Digital Strategy

In 2023, the CDER website was viewed more than 54 million times. OCOMM helped a variety of center stakeholders develop web content about several CDER initiatives. This resulted in publishing more than **600 pages**—and maintaining **nearly 9,000 more**—on the CDER site.

OCOMM's digital strategy team tracked the web, email, and social media performance of more than 800 communications about initiatives including the FDA video series, the CDER ARC Program, and many others. The communications included announcements, evergreen content, and guidances.

We prepared more than 50 reports analyzing the results of these communications. OCOMM identified which digital promotions were most effective by combining data on the traffic to each initiative's landing page with performance metrics for the email and social media promotion we used to promote each page. The digital strategy team applied this data and best practices in digital marketing to help stakeholders such as OGD with campaign planning and content marketing. We're also using this data to inform future campaigns and how to promote them.

OCOMM used these metrics and best practices to develop CDER's Digital Strategy Plan. The plan is a blueprint for CDER stakeholders who develop either web content or email and social media content that promotes web content. The Digital Strategy Plan also ensures that the center's digital content aligns with our audiences' awareness of FDA and CDER—and ultimately can move them beyond awareness to being a champion for the agency and the center.

CDERLearn

The CDERLearn portal features free online training courses and educational materials for HCPs, academia, students, and consumers. It is a trustworthy source that helps these audiences stay up to date on advances in medicine, technology, health care practices, and FDA regulations. For example, CDERLearn materials include a podcast on "FDA Updating Warnings to Improve Safe Use of Prescription Stimulants Used to Treat ADHD and Other Conditions" and the series "Conversations on Cancer."

Many of the courses for HCPs (e.g., physicians, physician assistants, nurses, pharmacists, and pharmacy technicians) offer continuing education (CE) credits. In 2023, we added **136 new items** and **116.25 new CE credit opportunities** for HCPs to CDERLearn. The webpage was viewed over **68,000 times**, and approximately 60 percent of visitors were new to the portal. Learners from over 23 countries accessed CDERLearn courses, including those from the United States, India, and China.

Popular courses in 2023 included:

- FDA's Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond
- Regulatory Framework for Human Drug Compounding
- The FDA Bad Ad Program and Prescription Drug Promotion
- Curriculum Materials for Health Care Degree Programs | Biosimilars

Small Business & Industry Assistance (SBIA)

SBIA connects CDER to stakeholders in the regulated pharmaceutical industry. By providing direct access to education and training through in-person and web-based events, as well as an on-demand learning repository, SBIA raises awareness of regulatory requirements and center priorities. It also creates an opportunity for a two-way dialogue that can help industry navigate FDA's processes for developing and approving drugs.

- In 2023, SBIA hosted eight virtual conferences and 22 webinars, which offered a total of 172.5 hours of training with 99.25 CE credits to physicians, nurses, and pharmacists. The conferences garnered **65,784 live attendees representing 141 countries (Exhibit 5)**.
- SBIA collaborated with 377 FDA employees from various agency centers to present at conferences and webinars. These included the Generic Drug Forum 2023, Advancing Generic Drugs: Translating Science to Approval 2023, Use of Biomarkers for Diagnosing and Assessing Treatment Response in Noncirrhotic NASH Trials workshop, Clinical Investigator Training Course 2023, and the Regulatory Education for Industry (REdI) Annual Conference 2023.
- FDA Commissioner, Robert M. Califf, M.D., gave the keynote address at the REdI Annual Conference to **21,092 attendees**. Three of CDER's directors, including CDER Director Patrizia Cavazzoni, M.D., held a plenary session titled, "User Fee Impact on FDA Programs."
- SBIA added 74 webcast recordings and 246 Section 508-compliant slide presentations to the SBIA Learn training repository.
- The 2023 NanoDay Symposium: Continuous Manufacturing of Nanomaterials was an SBIA-hosted opportunity for CDER to participate in an X thread. At the symposium, OCOMM forged new relationships for CDER with the **White House Office of Science and Technology Policy (OSTP), the National Science Foundation, the Air Force Research Laboratory, the Naval Research Laboratory, the National Institute of Food and Agriculture, the State Department, the Department of Energy, the Environmental Protection Agency,** and **the National Institute of Standards and Technology**.
- SBIA published **four issues of the SBIA Chronicles newsletter** with accompanying podcasts to highlight regulatory topics.
- SBIA responded to **5,760 inquiries** from the regulated pharmaceutical industry and disseminated **379 curated communications** to an audience of **150,940 stakeholders**, along with **363 posts** to **34,484 LinkedIn followers**.

Conferences and Exhibits

Exhibiting at professional conferences allows CDER and OCOMM to improve open dialogue with the scientific community. After a 3-year hiatus due to the COVID-19 pandemic, OCOMM exhibited at **27 professional conferences** in 2023 and reached an estimated **225,000 attendees**. At these exhibits, we promote educational content from across the center. In many cases, exhibits complement FDA staff members' participation on panels and giving presentations.

Exhibit 5. Attendees from 141 countries attended SBIA-hosted conferences in 2023.

CDER benefits in many ways from being "on the ground" at relevant conferences throughout the year: distributing information on drug safety, quality, and effectiveness to key audiences; supporting the center's hiring of scientists and HCPs; and simply being visible to important stakeholders in science and medicine. As a result of attending conferences in 2023, OCOMM initiated a CDER collaboration with Sermo, a worldwide physician community-based knowledge platform; that will serve to amplify FDA public health and drug-related information, initiatives, and educational programs.

Podcasts

Podcasts have grown dramatically in recent years—in terms of both audience and topics covered, which help to establish a relationship with the public, answer their questions, correct misinformation, build trust, and increase transparency. They're an ideal way to connect with a busy audience that is inundated with reading materials or may not have the time to read.

OCOMM produces four podcast series featuring FDA staff presenting brief, digestible information for HCPs, industry, and the public. We produced a total of 34 podcast episodes in 2023 (Exhibit 6). The podcasts cover topics for a variety of audiences, such as regulations and drug development initiatives, drug safety and significant oncology drug approvals, and frequently asked questions (FAQs) on drug-related topics.

The FAQ podcast series ("Q&A with FDA"), in particular, allows FDA subject matter experts (SMEs) to speak directly to the audience in a casual, storytelling way. It answers the top questions FDA receives from the public, while highlighting agency priorities and the expertise of SMEs and senior leaders. CDER began to offer no-cost CE credits for these podcasts in the third quarter of 2023.

"Q&A with FDA" won the 2023 Government Social Media Golden Post Award for Best Podcast.

The podcast episodes are embedded on FDA's website, where listeners can access them via RSS feed or listen directly via a podcast app. OCOMM used CDER's social media accounts to extend the podcasts' reach and engaged **117,770 listeners** in 2023.

Podcast Series	Number of Episodes
FDA Drug Safety Podcasts	3
Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.)	18
CDER SBIA Chronicles	4
Q&A with FDA	9

Exhibit 6. CDER podcast series produced in 2023.

Editorial Tools

OCOMM editorial vehicles allow CDER to discuss important and timely issues in drug development and research. These are long-form vehicles that let us describe an issue in depth and provide context. In the past year, we produced, maintained, and updated several online drug-safety resources, including official databases for Drug Safety Communications and long-form articles.

Long-form Articles

OCOMM's long-form editorial articles explore significant and timely issues in drug development and research. They take a detailed look at CDER's programs, initiatives, and priorities for the research and academic community, HCPs, regulatory industry, and consumers. Long-form articles can provide context for trending news topics, such as issues related to drug shortages of ibuprofen and acetaminophen oral suspension.

As detailed in Exhibit 7, OCOMM developed 61 articles for CDER's three recurring features, two of FDA's editorial vehicles, Consumer Updates and FDA Voices, and Healio, which presents medical news and education for physicians and other HCPs.

Editorial Vehicle	Number of Articles
CDER Conversations	10
Spotlight on CDER Science	7
From Our Perspective	10
Consumer Updates	25
FDA Voices	8
Healio	1

Exhibit 7. Editorial features on CDER, FDA, and external vehicles in 2023.

Drug Safety Communications (DSC)

DSCs are CDER's primary tool for sharing important information for patients, HCPs, and the public about new and emerging safety issues with the medicines they're taking or prescribing. These communications, which aim to help these audiences make better-informed decisions about treatment, are posted in English, Spanish, and Chinese on the DSC page and are amplified through podcasts, social media, targeted outreach to professional HCP and patient advocacy organizations, and several large email subscriber lists.

This includes the DSC-specific list; patients and HCPs can subscribe to that list to receive email alerts about medications or medical specialties that specifically interest them. The DSC email list has more than **77,000 subscribers**. The DSC information is also picked up and used by third-party health information aggregators and by trade press and mainstream media outlets.

In 2023, OCOMM issued **three** DSCs related to regulatory actions on high-profile medications:

- As part of FDA's ongoing efforts to address the nation's overdose crisis, CDER made labeling changes in spring 2023 for prescription opioids and stimulants to address misuse, abuse, addiction, overdose, and diversion. Although the number of prescriptions for opioids substantially decreased, overdose deaths involving those drugs remained steady. In turn, FDA updated prescribing information with additional guidance on using them safely.
- Prescription stimulants, including those commonly used to treat ADHD, can also be misused. Sharing prescription stimulants with people they aren't prescribed for is a major contributor to nonmedical use and addiction, which can result in overdose and death. One of the updates to the DSC on these drugs is that patients should never share their prescription stimulants with anyone. Together, these two DSCs generated more than **63,000 unique views**[5] on FDA's website.
- The third DSC (November 2023) warns about a rare but serious drug reaction, called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), with the antiseizure medications levetiracetam and clobazam. The DSC explained that DRESS can progress quickly from a rash, resulting in internal organ injury, hospitalization, and even death. It included a list of symptoms requiring immediate medical treatment. This DSC generated more than 16,677 views.

Trade Press

"Trade press" refers to magazines and newspapers that are written and published for a particular industry. Coverage by trade media tells CDER's story from an outside perspective. This can give the center validation through a source we don't directly control, but we can help guide the coverage by providing timely and accurate responses to press inquiries.

The CDER Trade Press team responds to inquiries about CDER policies, programs, and initiatives; coordinates trade interviews with CDER officials; and proactively disseminates FDA/CDER press releases and other important announcements to the trade press, resulting in **thousands of news articles**. Every day, CDER Trade Press distributes news coverage from the trade press to more than 600 FDA employees. In 2023, CDER Trade Press trained over 200 CDER staff in interview and media relations skills.

In 2023, the Trade Press team facilitated more than 20 interviews with SMEs and responded to approximately ***600 inquiries from trade-press reporters****.*

[5] "Unique views" refers to the number of unique users who click on a link for a campaign. If a single user views a link five times, the server will record five total views and one unique view.

Public Inquiries

OCOMM is the front line for public inquiries about drug safety, regulation, and many other CDER actions. Our team of pharmacists engages with the public through phone, email, social media, and postal mail to share timely and accurate information about human drug products. In 2023, OCOMM responded to more than **42,000 public inquiries**.

Drug Information Inquiries

Total Public Inquiries: 42,858 **Total MedWatch: 11,812**

Top Demographics:

- Consumer: **29,406**
- Industry: **4,937**
- Physician: **1,094**

Top Sources:

- Phone: **24,538**
- Email: **11,584**
- Facebook: **299**

Top Topics:

- Recalls: **4,690**
- Personal Import: **1,855**
- Clinical Trials/Investigational New Drugs: **299**

Graphic Design

CDER's internal creative team, CDERDesignz, helps OCOMM generate informative, digestible content. The team develops compelling visuals that reflect the scientific expertise in the center's web copy. CDERDesignz pairs FDA's visual identity guidelines with best practices in graphic design while complying with Section 508 of the Rehabilitation Act.

In 2023, CDERDesignz developed more than 1,000 graphics, annual report templates, and evergreen pieces. These materials drove traffic to CDER webpages from email and social media promotion and improved the user experience on those pages. Exhibit 8 summarizes the visual assets we produced in 2023. We completed an average of more than 17 requests for visual products each week.

In August 2023, FDA updated its visual identity and began using it to unify and update CDER's new and preexisting visual assets. To ensure consistency across CDER webpage design, OCOMM updated multiple assets with the new graphics, including guidance snapshots, infographics, and annual reports. We also helped various CDER offices use the new visual identity on online applications and forms. We recreated more than 23 default graphics for fda.gov and social media. We completed an average of more than 17 requests for visual products each week.

Visual Asset	Number of Assets Produced
Stock Images	53
Photography	183
Postcards	16
Posters	90
Publications/Reports	48
Web Graphics	314
Visual Identity Reviews	37
Infographics	29
Flyers/Fact Sheets	76
Digital Display Flyers	17
Charts/Graphs/Illustrations	33
Brochures/Pamphlets/Booklets	10
Videos/Animation	8

Exhibit 8. The number of visual assets produced by CDER in 2023.

Social Media

In 2023, 4.95 billion people—more than 61 percent of the global population[6]—were active on social media. Social platforms are a direct line of communication to several stakeholder groups CDER needs to reach. OCOMM uses social media to expand the center's outreach, build trust, and counter misinformation. The FDA social media team manages accounts on Facebook, Threads, X, Instagram, and LinkedIn.

OCOMM collaborates with other agencies to improve consumers' health and media literacy. This work is part of our long-term strategy to empower consumers to recognize misleading information on their own. Partnering with other agencies to dispel misinformation and disinformation expands OCOMM's reach and visibility to new audiences that are not familiar with FDA resources for answers to their common and not-so-common health queries. Exposure to FDA's reliable, fact-based information via cross-cutting collaborations results in a better-informed consumer. These collaborations also open channels of communication between the consumer and the agency, establishig our credibility as a health authority.

OCOMM's participation in X Chats (formerly Twitter Chats) exposes new and untapped audiences to CDER's targeted messaging on important issues—especially when it comes to misinformation. These unique engagements with partner organizations allow us to lead public conversations on timely topics to tell the CDER story. X Chats are consumer-friendly online discussions that open the door for the public to engage directly with FDA SMEs to get real-time answers to their questions, resulting in a more educated consumer and helping to protect public health.

For example, in 2023, FDA's "Drug Information" X account participated in a chat during National Consumer Protection Week in partnership with other FDA centers, government agencies, and other organizations. This chat educated consumers about common health fraud scams and pointed to FDA resources that help identify and report fraudulent medical products or services. The Acetaminophen Awareness Coalition's *Know Your Dose* campaign chat educated consumers on the importance of knowing ingredients in their medicines and following FDA-labeled directions to prevent unintentional acetaminophen overdoses, especially in children.

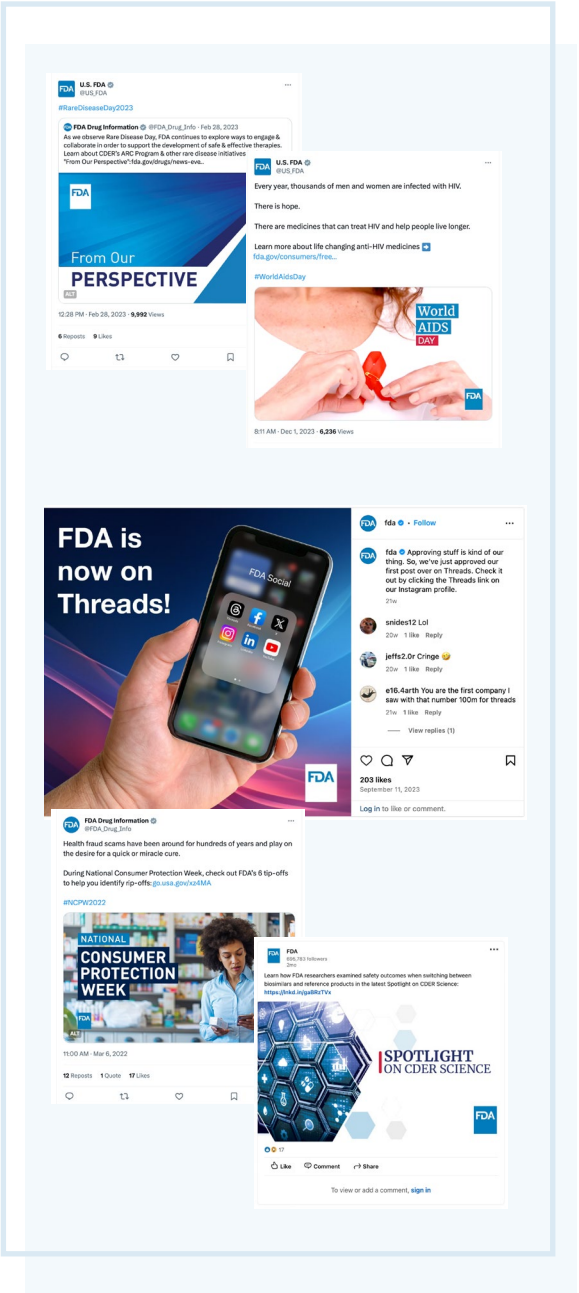

Exhibit 9. Several of FDA's posts on various social media platforms in 2023.

[6] Data Reportal (October 2023). Global Social Media Statistics.

Highlights of OCOMM's social media activity, with a few accompanying visuals in Exhibit 9, in 2023 include:

- Increased engagement on all social platforms and expanding the use of platform features such as LinkedIn carousels and polls.
- Held an X Chat during National Consumer Protection Week (#NCPW) to raise awareness about FDA's efforts to combat misinformation, promote the *BeSafeRx* campaign, and inform patients about FDA Consumer Updates on health fraud.
- Participated in the National Center for Advancing Translational Sciences' X Chat on Rare Disease Day (#RareDiseaseDay) to discuss FDA's work on rare diseases and raise awareness about CDER's ARC program.
- Implemented an evergreen content strategy to use FDA Consumer Updates to address topics based on FAQs.
- Posted about national observance days such as World AIDS Day, National Epilepsy Awareness Month, and many more.
- Promoted FDA initiatives and messages about rare diseases, generics, biosimilars, the FDA "Regulating and Approving Drugs" video series, clinical trial innovation, and more.
- Frequently disseminated updates on drug approvals, safety alerts, drug shortages, warnings, and more.
- Developed Instagram and Facebook stories—and used the Instagram Highlights[7] feature—to increase reach and engagement with CDER's stakeholders. One story described the dangers of unapproved bodybuilding supplements promoted by some social media influencers.

Professional Affairs and Stakeholder Engagement (PASE)

PASE promotes a culture of engagement at CDER by facilitating exchanges between the center's offices and review divisions and external stakeholder groups. We've found that direct communication with stakeholders is a more effective method than public inquiries to communicate with certain stakeholder groups. PASE's mission is to make these exchanges more rewarding for patients, advocacy groups, HCPs, and agencies, and to help them all learn about drug regulation.

In 2023, PASE conducted 18 listening sessions to facilitate two-way communication with professional medical associations, research organizations, and patient advocacy groups. Meeting topics included:

- Stimulant shortages (with the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association, and CDER's Drug Shortages staff)
- Whether there is a legal pathway for regulating homeopathic products (with the Americans for Homeopathy Choice Action Team and CDER's OPQ, Office of Regulatory Policy, and Office of the Center Director)
- The Neurology Drug Program (with the American Brain Coalition, CDER's Office of Neuroscience, and CDER Director, Dr. Cavazzoni, M.D.)
- Off-label use of Bactrim for acne (with the American Academy of Dermatology, CDER's Office of Surveillance and Epidemiology, and the Division of Anti-Infectives in OND)
- The importance of sunscreen access, as well as the content and messaging around the Administrative Order (with the Public Access to SunScreens Coalition and the ONPD)
- A stakeholder call on the Drug Supply Chain Security Act (with CDER's Office of Compliance to provide guidance and updates on the act)

[7] Instagram Stories Highlights live permanently on CDER's profile and can be reshared with the center's followers.

PASE manages the CDER Network of Experts (NoE) program. The NoE gives the center access to a vetted external network of organizations of clinicians, scientists, pharmacists, engineers, and other professionals to facilitate the exchange of information on new and emerging fields of science, pioneering technologies, and the increasing complexity of medical devices and pharmaceuticals. If an FDA employee has questions during the course of their work, they can turn to the NoE program to request external expertise, such as when CDER's Office of Surveillance and Epidemiology used the NoE program for expertise on topical corticosteroid withdrawal reaction/syndrome. In 2023, the CDER NoE program managed three requests, two of which were completed:

- Anesthetics and Paresthesia: The Benefits and Risks of Articaine in Dental Practice (with CDER's Division of Pharmacovigilance and SMEs from the American Dental Association)
- OTC Development of Analgesics and/or Antipyretics for Use in Less Than 12 Years Age Group (with OND's Division of Pediatric and Maternal Health, the Division of Nonprescription Drugs, and SMEs from the American College of Emergency Physicians, American Academy of Pediatrics, and the American Academy of Family Physicians)

PASE also manages FDA's Safe Use Initiative, which creates and facilitates public and private collaborations with the health care community. The initiative aims to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use. In 2023, Safe Use led 12 projects, seven of which were completed, such as:

- A scalable, patient-centered approach for "right-sizing" opioid prescribing (University of Pennsylvania)
- Assessment of a pharmacy-led interprofessional transitions-of-care program targeting patients with multiple recent hospital admissions: the ICARE Program (Auburn University)

Increase Awareness of Drug Safety, Effectiveness, and Quality

Clear communication about how and why individual drugs are reviewed and approved maintains FDA's reputation, strengthens the public's trust, and raises awareness about FDA CDER's role in protecting public health. In 2023, the center conducted this work through stakeholder groups, reports, and initiatives.

DSCs (page 15) are CDER's primary tool for sharing important information for patients, HCPs, and the public about new and emerging safety issues with medicines. Additionally, every year OCOMM issues the New Drug Therapy Approvals and the Drug Safety Priorities reports (Exhibits 10 and 11). They communicate CDER's accomplishments in maintaining the safety of the nation's prescription and OTC medications, both when reviewing them for possible approval and through continued monitoring, once they're on the market.

New Drug Therapy Approvals and Drug Safety Priorities Reports

The Advancing Health Through Innovation: New Drug Therapy Approvals 2023 report showcases CDER's role in bringing safe, effective drug therapies to patients. This 13th annual report highlights:

- How CDER continued to approve therapies to prevent, diagnose, and treat a wide range of diseases and conditions despite the ongoing global health concern of COVID-19

Exhibit 10. Cover of the New Drug Therapy Approvals 2023 report.

- CDER's "novel" drug approval actions, including efforts to widen the reach of previously approved drugs in new settings, such as for a different disease, a new patient population (e.g., children), or in a new dosage form or formulation
- The efforts and accomplishments in the area of opioid overdose, including approval of three nonprescription opioid overdose reversal drugs
- The gold standard of drug safety and efficacy evaluation FDA uses to review and approve drug applications
- CDER's efforts and accomplishments in approving more biosimilars and interchangeable biosimilars
- FDA's communications about its ongoing commitment to improving patient care by approving safe and effective treatments

The Drug Safety Priorities Fiscal Year 2023 report details CDER's work to manage drug-safety issues by using modern safety surveillance methods and responding to safety concerns in innovative ways. This ninth report highlights:

- Continuing focus on the programs and initiatives at the core of CDER's drug safety operations, including the FDA Adverse Event Reporting System and Sentinel System
- Ongoing activities to support the development and evaluation of treatments to effectively manage pain, while concentrating on strategies to address the illicit nonmedical use of prescription opioids
- Changes to the prescribing information for two highly misused drug classes, opioids and stimulants, to increase safe use and address concerns of nonmedical use, addiction, and overdose
- Approval of the first OTC naloxone nasal sprays
- Release of the "FDA and Kratom" webpage to better inform the public about safety issues with this herbal substance that is not FDA-approved for any use

Exhibit 11. Cover of the Drug Safety Priorities Fiscal Year 2023 report.

FDA Drug Topic Webinars

OCOMM presents a series of educational webinars for HCPs and students on FDA drug regulation and medication safety. CE credit is available for both live and home-study webinars for physicians, physician assistants, nurse practitioners, nurses, pharmacists, and pharmacy technicians. Our live webinars have reached audiences in over 15 countries.

In 2023, OCOMM conducted nine live webinars with over 11,500 total live attendees. To help HCPs meet their CE requirements for renewing certain state licenses, we presented webinars on pain management and opioids, medication errors, and compounding. We converted seven live CE webinars to home-study courses.

Regulatory Pharmaceutical Fellowship and FDA Pharmacy Student Experiential Program

OCOMM supports training of future pharmacists and other HCPs through the Regulatory Pharmaceutical Fellowship Program and the FDA Pharmacy Student Experiential Program.

Regulatory Pharmaceutical Fellowship Program

FDA partners with universities and colleges of pharmacy to offer FDA-affiliated fellowship programs to Doctor of Pharmacy graduates in several specialties. The purpose of the program is to train selected candidates in one of six tracks:

- Drug Information
- Drug Advertising and Promotion
- Medication Safety
- Regulatory Policy
- Biopharmaceutical Manufacturing
- Regulatory Science

In 2023, FDA added new specialty tracks in tracks in Biopharmaceutical Manufacturing and Regulatory Science in partnership with the OPQ and the OND, respectively.

As of 2023, the program has graduated **more than 50 pharmacists**. Fellows in the Regulatory Pharmaceutical Fellowship Program are making important contributions to their respective program areas. They deliver CE seminars at national meetings, publish peer-reviewed research papers, and support FDA's mission.

Pharmacy Student Experiential Program (PSEP)

PSEP offers Advanced Pharmacy Practice Experience rotations with FDA to pharmacy students in their final year of school. Using in-person and virtual experiences, the program provides hands-on experience and education from agency experts, and focuses on multidisciplinary approaches to public health issues related to drugs, biologics, and medical devices. Future pharmacists in PSEP benefit from mentorship, professional development, exposure to federal employment options, and firsthand experience with regulatory pharmacy practice.

As of 2023, under the leadership of OCOMM, the program has facilitated FDA rotations for over 10,000 pharmacy students. For the 2023-2024 academic year, PSEP received 676 applications and placed 268 students on rotation at FDA, a higher-than-average placement rate of 40 percent.

Looking Ahead

The past year offered plenty of opportunities to use proactive communications to increase CDER's transparency. We have seen wins through outreach and education, our digital presence, social science research, and public engagement.

In 2024, OCOMM will continue to tell CDER's story of safeguarding public health. We will increase awareness of CDER's public health and safety efforts and will build confidence in the quality and efficacy of approved human drugs. Working together across teams, offices, and centers, we'll continue to innovate, communicate, and evaluate CDER's efforts to ensure that safe and effective drugs are available to improve the health of people in the United States.

We'll focus on the following priorities related to our strategic communications goals:

- Maintain accuracy and transparency in all communications—especially on the safety, effectiveness, and quality of drug approvals—to all audiences.
- Reach a wider audience by developing CDER communications materials in many languages.
- Continue to develop materials in a variety of formats to increase the reach of messages about CDER's work to protect the public.

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