

STATE OF THE NATION 2024

PRODUCT SAFETY AND RECALL
UNITED STATES EDITION



The Sedgwick brand protection Recall Index is the leading resource for manufacturers, suppliers, and retailers seeking an unbiased, informed perspective on past and present trends and predictions for what's next in product safety and product recalls. It reviews five product categories: Automotive, Consumer Products, Food and Drink, Pharmaceutical, and Medical Devices.

The report collects and analyzes data from the U.S. Consumer Product Safety Commission (CPSC), the U.S. Food and Drug Administration (FDA), the U.S. National Highway Traffic Safety Administration (NHTSA), and the U.S. Department of Agriculture (USDA) to provide businesses valuable insights to help protect their brands against operational risk and reputational damage.

This edition provides a year-in-review of 2023 to showcase the state of the nation. It also includes a more detailed breakdown of recall data from the fourth quarter of 2023, October 1 – December 31, along with an early look at January 2024 figures as we start the new year.

In 2023, there were 3,301 recall events across the five industries we track, representing a five-year high. Both the pharmaceutical and consumer products sectors experienced their highest recall rates in the past ten years, with 517 and 322 events respectively.

Overall, the total volume of units recalled in the U.S. was much lower than 2022's record-breaking 1.48 billion. Across all five industries there were 759.36 million units recalled. However, the consumer products industry set a seven-year annual high with 135.23 million units impacted. In contrast, medical devices saw a six-year low, followed by pharmaceuticals which experienced a four-year low, in terms of impacted units. Pharmaceuticals dropped from a record-high of 567.35 million units in 2022 to 98.51 million in all of 2023.

Not only does the Sedgwick brand protection Recall Index provide the latest recall data, but it also offers essential insight

and perspective on what issues companies across industries should be watching out for, including changes to the regulatory environment. We include exclusive analysis from some of our strategic partners at global law firms, insurance companies, and communications firms to help organizations plan for the future and mitigate product safety risk.

One of the topics that dominated discussions across all industries in 2023 was the increasing use of artificial intelligence and machine learning (AI/ML). Regulators looked at potential consumer risk from AI technologies in products ranging from toys to medical devices and struggled with drafting new rules or updating old ones to reflect the power and potential dangers of this evolving innovation.

The Biden Administration secured a voluntary commitment from several leading AI companies that they would focus on safety, security, and trust when developing AI technology. In October, the Administration published a comprehensive executive order with standards, guidelines, and best practices in eight different areas that government agencies should follow when developing and implementing AI technology.

In a series of guidances and discussion papers in 2023, the FDA addressed the use of AI/ML in drug and biological product development as well as the marketing approval process for AI/ML-enabled medical devices. The agency is looking for stakeholder input as it begins to develop new regulations.

Another prominent topic in 2023 that is closely associated with AI is cybersecurity. This was an issue for automakers as more and more vehicles use software and apps to provide features for consumers, such as in-vehicle entertainment. It is also an important issue for consumer products to ensure bad actors cannot hack and compromise the safety of toys or other in-home devices.

In July, the Federal Communications Commission (FCC) and [the Biden Administration introduced](#) the U.S. Cyber Trust Mark program. The initiative is designed to help consumers select electronics and appliances that

meet certain voluntary cybersecurity certification and labeling criteria.

Another area vulnerable to cyber attacks is medical devices. [The Consolidated Appropriations Act](#) gave the FDA enforcement power for cybersecurity risks for the first time. The agency introduced new cybersecurity requirements including provisions for a plan to monitor, identify, and address post-market cybersecurity vulnerabilities as part of a product's pre-market submission as well as extended post-market responsibilities.

In the food sector, the FDA attempted to repair damage to its own reputation suffered during 2022's infant formula crisis, which is still having implications. One of the impacts was the decision to completely restructure the Human Foods Program.

The agency also continued its normal business of food safety and had several updates to definitions and processes in areas such as organics and the "Generally Recognized As Safe" list of food additives.

Before we move into our more comprehensive summary of the year, we want to point out that this edition of the Recall Index focuses on U.S. recall data and regulatory developments. If your business also operates outside the U.S. or your supply chain is affected by global issues – and we know virtually all of them are – we recommend that you also download our European edition. Like this report, it shares recall data from regulatory agencies and offers exclusive analysis around product safety and policy changes – but from the perspective of companies and regulators operating in the UK and the European Union.

European edition available here: [click here](#)

If you would like more information about what we have observed in recent quarters, you can find previous editions of the Recall Index below:

Q3 2023 U.S. Recall Index: [click here](#)

Q2 2023 U.S. Recall Index: [click here](#)

Q1 2023 U.S. Recall Index: [click here](#)

Q4 2022 U.S. Recall Index: [click here](#)



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SUMMARY

In addition to cybersecurity and the use of AI, another trend we observed in 2023 that we expect to continue through 2024 is more regulation for online sellers and secondary markets. Online retailers and platforms are being held accountable for protecting consumers from fraudulent claims and dangerous products.

The U.S. Consumer Product Safety Commission (CPSC) Chairman Alex Hoehn-Saric has made it clear that regulating these marketplaces will be a top priority for the agency, including taking steps to hold third-party sellers accountable. The Federal Trade Commission (FTC) has also put new regulations in place with the passage of its Integrity, Notification, and Fairness in Online Retail Marketplaces for Consumers Act ([INFORM Consumers Act](#)). The rule adds more transparency to online transactions and works to keep stolen, counterfeit, or unsafe items from being sold on these platforms. It also gives consumers a way to report suspicious conduct.

After calls at both the state and national levels for mandatory safety standards for lithium-ion batteries, the CPSC has said it is working on making this happen. However, any new regulations will unlikely take effect before 2025. Until then, manufacturers of micromobility devices such as e-scooters, hoverboards, e-bicycles, and e-unicycles are encouraged to follow the voluntary standards.

Collaboration was another big theme in 2023. This was seen as attorneys general (AGs) came together if they thought federal regulators were not moving fast enough. In April, a group of [AGs wrote a letter to the National Highway Traffic Safety Administration](#) (NHTSA) trying to prompt a recall of certain vehicles that lacked a specific anti-theft device. The AGs wanted NHTSA to intervene because they felt the automakers were not doing enough.

In November, 25 state AGs [asked](#) the FDA to take urgent action to address pulse oximeter inaccuracies for people with dark skin pigmentation. The original issue was raised almost two years earlier and the AGs said that the delay was creating unnecessary health risks.

Even if these actions do not produce the government response the AGs were hoping for, they raised the issue with the public and increased brand risk for the companies involved if changes are not made.

Another type of collaboration observed is agencies working together. There were several issues that the FTC and FDA worked on jointly in 2023, including sending cease-and-desist letters to six companies marketing edible products containing a cannabis-derived ingredient and trying to correct improper or inaccurate listings for drug patents in the FDA's Orange Book reference guide. Having agencies with different enforcement powers working together is good for consumers and risky for companies who are not in compliance.

Here are some of the highlights for the year:

Automotive

Much of the attention across the automotive industry in 2023 was on the evolution of electric vehicles (EVs) and autonomous vehicles (AVs). Research from [J.D. Power](#) revealed that consumers are concerned about having reliable access to charging stations if they are away from home. The U.S. Department of Transportation's (DOT's) Federal Highway Administration (FHWA) is trying to address those concerns by creating a network of charging stations through its National Electric Vehicle Infrastructure (NEVI) Formula Program.



The Federal Trade Commission (FTC) is reviewing the Labeling Requirements for Alternative Fuels and Alternative Fueled Vehicles (AFVs). The agency asked the public for input on labeling for EV charging stations as part of its assessment to ensure consumers can make informed choices when fueling or charging their vehicles.

Other ways regulators are trying to encourage consumers to choose EVs is through tax incentives. The U.S. Department of the Treasury and Internal Revenue Service (IRS) published proposed rules that could grant buyers of new clean vehicles up to \$7,500 in tax credits.

In addition, the U.S. Environmental Protection Agency (EPA) proposed new federal vehicle emissions standards for light- and medium-duty vehicles, heavy-duty

vocational vehicles, and heavy-duty trucks. Some of these regulations would begin to apply to 2027 model year vehicles, which will push manufacturers into making changes or risk non-compliance.

While the move to EVs appears inevitable, according to [a Cox Automotive survey](#), dealers do not feel ready to support an influx of EV customers in sales or service. Automakers will also need to revamp their production processes and find new suppliers for parts unique to EVs. Hopefully, the risk will pay off with consumers embracing the more environmentally friendly vehicles.

For a more in-depth analysis of the automotive industry in 2023, and our predictions for the remainder of 2024, [click here](#).



Consumer products

While the U.S. Consumer Product Safety Commission (CPSC) is the only agency that can issue recalls for consumer products, the Federal Trade Commission (FTC) has an important role in protecting consumers. It aggressively enforced policies on a range of issues in 2023 including challenging the use of “Made in America” labels, cracking down on companies that use deceptive advertising practices and false claims, working to finalize its revised “Green Guides” for promoting eco-friendly products, and taking action on junk fees.

The CPSC also had a busy year. The Commission was focused on improving consumer awareness about product recalls and seeking penalties for companies that fail to report suspected safety issues promptly.

In November, the [Department of Justice \(DOJ\) convicted](#) two corporate executives in the first criminal prosecution of the Consumer Product Safety Act’s duty to report provision. In addition, the CPSC [announced](#) in August that a major appliance manufacturer had agreed to pay an \$11.5 million [civil penalty](#) for knowingly failing to immediately report a defect with its cooktops that posed an unreasonable risk to consumers. The agency issued a total of \$55.30 million in fines in 2023 compared to \$38.00 million in 2022 and \$7.95 million in 2021.

The CPSC also continues to issue unilateral press releases if it feels potentially harmful products are on the market and which companies will not agree to a voluntary recall. In a speech in July, [CPSC Chairman Alex Hoehn-Saric said](#) unilateral press releases were rarely used in the past, but now the Commission considers them a regular tool to keep consumers informed.

Companies should be on notice for more oversight from both agencies as they work to protect consumers.

For a more in-depth analysis of the consumer product industry in 2023, and our predictions for the remainder of 2024, [click here](#).

Food and drink

Throughout 2023, the U.S. Food and Drug Administration (FDA) continued to recover from the 2022 infant formula recall, both in terms of product safety and its own reputation. The agency offered multiple updates, recommendations, and warning letters to industry stakeholders throughout the year including a tip sheet for critical foods companies, such as infant formula manufacturers, on how to plan for supply chain disruptions.

The FDA also took the first steps in restructuring its Human Foods Program (HFP) in response to the critical evaluation released by the Reagan-Udall Foundation in late 2022. In December 2023, new HFP Deputy Commissioner James Jones said the priorities of the updated program would be to prevent foodborne illness, decrease diet-related chronic disease, and safeguard the food supply.

Other issues the agency addressed in 2023 include labeling recommendations for plant-based milk alternatives, new guidance on the use of Dietary Guidance Statements in food labeling, and its Compliance Policy Guide (CPG) regarding major food allergen labeling and cross-contact.

Like other sectors, food industry regulators are concerned about online marketplaces. The FDA is working to improve consumer access to consistent and accurate food labeling information provided through online grocery platforms.

For a more in-depth analysis of the food and drink industry in 2023, and our predictions for the remainder of 2024, [click here](#).

Pharmaceuticals

The [Consolidated Appropriations Act, 2023](#) (H.R. 2617), that was signed into law on December 29, 2022, led to a lot of changes across the pharmaceutical industry in 2023. Stakeholders worked to implement provisions in both the Food and Drug Omnibus Reform Act of 2022 (FDORA) and the [Modernization of Cosmetics Regulation Act of 2022](#) (MoCRA) that were part of the larger legislation.

The U.S. Food and Drug Administration (FDA) published several guidances to help cosmetics manufacturers prepare to comply with MoCRA. The rule imposes stricter oversight so that cosmetics are regulated in a similar way to other products under the FDA’s purview such as pharmaceuticals and medical devices.

Companies were also working to transition back to normal operations after the [federal COVID-19 public health emergency \(PHE\) ended on May 11, 2023](#). Companies that had gained marketing approvals under emergency use authorizations during the pandemic needed to decide if they would seek full authorizations for those products.

Some tools the agency allowed during the pandemic are being adopted on a permanent basis. These include the use of decentralized clinical trials (DCTs) and remote regulatory assessments (RRAs). The FDA issued several guidances around allowing the continuation of these practices.

The FDA also continued its strong enforcement against products containing cannabis and cannabidiol (CBD), an active ingredient in cannabis, as well as tobacco products, vapes, e-cigarettes, and other electronic nicotine delivery systems (ENDS).

For a more in-depth analysis of the pharmaceutical industry in 2023, and our predictions for the remainder of 2024, [click here](#).

Medical devices

The U.S. Food and Drug Administration (FDA) launched a pilot program in January for a [voluntary Total Product Life Cycle Advisory Program \(TAP\) Pilot](#). The initiative was designed to promote earlier and more frequent communications between the FDA and medical device sponsors. It also highlights the fact that the agency wants manufacturers to be responsible for the full product life, which creates more risk for companies.

In March, the FDA granted marketing authorization to an infant sleep system as a medical device instead of a consumer product. Experts speculate that this could impact the basic definition of a medical device and have implications for other sleep products that might need to comply with FDA rules.

Also on the FDA’s agenda is how to increase health equity and access to care for everyone. The COVID-19 pandemic changed how and when telehealth platforms and at-home-use medical technologies are deployed. The agency published guidances around continuing and even expanding the use of these technologies while also keeping patients safe.

In October, the FDA announced it will provide guidance on issues relating to digital health technologies, including artificial intelligence, wearables, virtual reality, and remote patient monitoring through the creation of a Digital Health Advisory Committee. The agency was accepting nominations for committee members but did not have a firm date for when the final committee would be decided.

For a more in-depth analysis of the medical device industry in 2023, and our predictions for the remainder of 2024, [click here](#).

AUTOMOTIVE

To help promote the purchase of zero-emission “clean vehicles,” [the Department of the Treasury and the Internal Revenue Service clarified parts](#) of the section 30D clean vehicle credit in December. The guidance helps define “foreign entities of concern” (FEOC) and the due diligence required for FEOC compliance. Vehicles placed in service starting in 2024 are not eligible for the credit if their batteries contain any components that were manufactured or assembled by a FEOC.

Another move that will support the growth of electric vehicles (EVs) in the U.S. was made by the Federal Trade Commission (FTC). In October, the agency issued a request for public comment as it begins a new review of the Labeling Requirements for Alternative Fuels and Alternative Fueled Vehicles (AFVs), or the Alternative Fuels Rule. The FTC is looking for input on labeling for electric vehicle charging stations as part of its assessment.

In December, the FTC finalized a law that prohibits auto dealers from using bait-and-switch tactics or adding hidden junk fees when selling cars to consumers. The agency estimates the new rule will save consumers nationwide more than \$3.4 billion and an estimated 72 million hours each year spent shopping for vehicles.

The U.S. Tire Manufacturers Association (USTMA) and the U.S. Geological Survey (USGS) [announced a research partnership](#) in November into tire components. The project focuses on finding an alternative for the organic chemical 6PPD. Despite being widely used in motor vehicle tires for decades, recent studies have found the chemical kills several species of fish.

Regulators’ focus on environmental protections through both growing the number of EVs and charging stations and ensuring safer products is something the automotive industry should heed. It is a good strategy not only from a regulatory perspective but also in terms of consumer preferences.

“Regulators’ focus on environmental protections through both growing the number of EVs and charging stations and ensuring safer products is something the automotive industry should heed.”

“The CARS Rule imposes extensive recordkeeping obligations, necessitating an overhaul of existing practices for many dealers. Failure to adhere exposes them to potential monetary penalties.”

The FTC considers labeling changes for EV charging stations

The Federal Trade Commission (FTC) has begun [a new review of the Alternative Fuels Rule](#), also known as the Labeling Requirements for Alternative Fuels and Alternative Fueled Vehicles (AFVs). The regulation requires informative labels on fuel dispensers for non-liquid alternative fuels, such as electricity, compressed natural gas, and hydrogen so that consumers can make informed buying decisions.

[Attorneys with Greensfelder, Hemker & Gale report](#) that it is the first time the rule has been reviewed in 10 years. After the last assessment, the agency changed the regulation and replaced the separate FTC labeling requirements for AFVs such as electric cars with the Environmental Protection Agency's (EPA's) fuel economy labeling requirements.

In the latest evaluation, which was announced in October, the FTC is looking for input from the public regarding the costs, benefits, necessity, and regulatory and economic impact of the rule. It is also asking for comments on issues specific to labeling for EV charging stations operated by retailers for consumers, including what types of information the labels should disclose and where they should appear.

The comment period closed on December 26, 2023, but stakeholders should review the comments and watch for updates from the FTC regarding its findings and any changes that may be on the way. [The legal experts note](#) that it often takes at least a year for the FTC to issue updated rules from the time comments close, but companies should anticipate changes.

Law passed to protect car-buying consumers

In December, the Federal Trade Commission (FTC) [finalized the Combating Auto Retail Scams \(CARS\) Rule](#). The law is designed to protect consumers from two common types of illegal tactics when buying a car: bait-and-switch and hidden junk fees. It also includes special protections for members of the military and their families. The agency says this group is often targeted with false or misleading information about auto dealers' affiliation with the military and other specific issues that affect servicemembers.

The CARS Rule regulates auto dealers in four key areas. **First**, it prohibits misrepresentations by the dealers about key information such as price and cost. **Second**, dealers must provide the actual price any consumer will pay for the vehicle (the offering price); tell consumers that optional add-ons (like extended warranties) are not required; and give information about the total payment when discussing monthly payments.

Third, under the rule, dealers may not charge for any add-ons that do not provide a benefit to consumers. Examples of these “bogus” fees include warranty programs that duplicate a manufacturer's warranty and software or audio subscription services on a vehicle that cannot support the software or subscription.

Finally, dealers must get the consumer's “express, informed consent” for any charges that they pay as part of a vehicle purchase. Under the CARS Rule, the FTC will be able to seek consumer redress, civil penalties, and other monetary relief for rule violations.

Attorneys with [Kelley Drye & Warren LLP](#) highlighted some of the rule's key takeaways, including the fact that the final version is narrower in scope than the June 2022 draft. Certain disclosure and consumer consent requirements have been excluded. [The FTC said it received](#) tens of thousands of comments from consumers, servicemembers, veterans, auto dealers, and others about the proposed rule. After careful review of the comments, the agency made “substantial changes” to create the final rule.

[The attorneys also note that the final rule](#) imposes extensive recordkeeping obligations, necessitating an overhaul of existing practices for many dealers. Failure to adhere to these updated requirements exposes them to potential monetary penalties. These requirements include the need to retain copies of records such as sales scripts, training and marketing materials, financing and lease documents, consumer complaints and inquiries related to sales or add-ons, and more. These documents must be kept for two years from the date of creation to comply with the rule.

The FTC created [guidance on the CARS Rule for auto dealers](#), including a website with frequently asked questions and other advice as dealerships prepare for the rule to take effect on July 30, 2024.



“ Under the law, domestic and foreign manufacturers of motor vehicle tires containing 6PPD must take certain steps for any products sold in California.”

Industry and regulators exploring alternatives to toxic tire components

While perfluoroalkyl and polyfluoroalkyl substances, or PFAS, have received a lot of attention and increasing regulation, they are far from the only chemical raising concerns. 6PPD is an organic chemical that has been used for decades to help prevent degradation, particularly in rubber products. [According to the California Department of Toxic Substances Control \(DTSC\)](#), 6PPD is found in most, if not all, motor vehicle tires and protects rubber from reactions with ozone and oxygen, which can lead to cracks.

As tires wear down through use, particles of rubber containing 6PPD are released into the environment. [The Environmental Protection Agency \(EPA\) reports](#) that when [6PPD reacts with ozone](#) in the air, it forms [6PPD-quinone](#), which research indicates is toxic enough to quickly kill some species of fish. [A 2021 publication in the journal Science](#) linked coho salmon death to 6PPD-quinone in stormwater. Since that study, other fish species have been identified as vulnerable to 6PPD-quinone including brook trout, steelhead/rainbow trout, and Chinook salmon.

In October 2023, a [DTSC California Safer Consumer Products regulation](#) went to effect making motor vehicle tires containing 6PPD a “priority product.” Under the law, domestic and foreign manufacturers of motor vehicle tires containing 6PPD must take certain steps for any products sold in California.

In an effort to find an alternative to 6PPD, the U.S. Tire Manufacturers Association (USTMA) and the U.S. Geological Survey (USGS) [announced a partnership](#) in November to research, assess, and refine methods to evaluate potential alternatives to 6PPD for use in tires.

The USTMA and the USGS Western Fisheries Research Center [have established a Collaborative Research and Development Agreement](#) to develop a new method for in vitro toxicity testing of alternatives to 6PPD. The USTMA states that while this initial research is not expected to immediately identify a 6PPD alternative, it will inform future research. The hope is that the findings will enable scientists to be more focused as they look for alternatives.

The partnership between USTMA and USGS is set to run through September 2024. It will likely serve as a template for other organizations facing similar challenges for components that have been in their supply chain for years and have more recently been shown to pose safety risks.

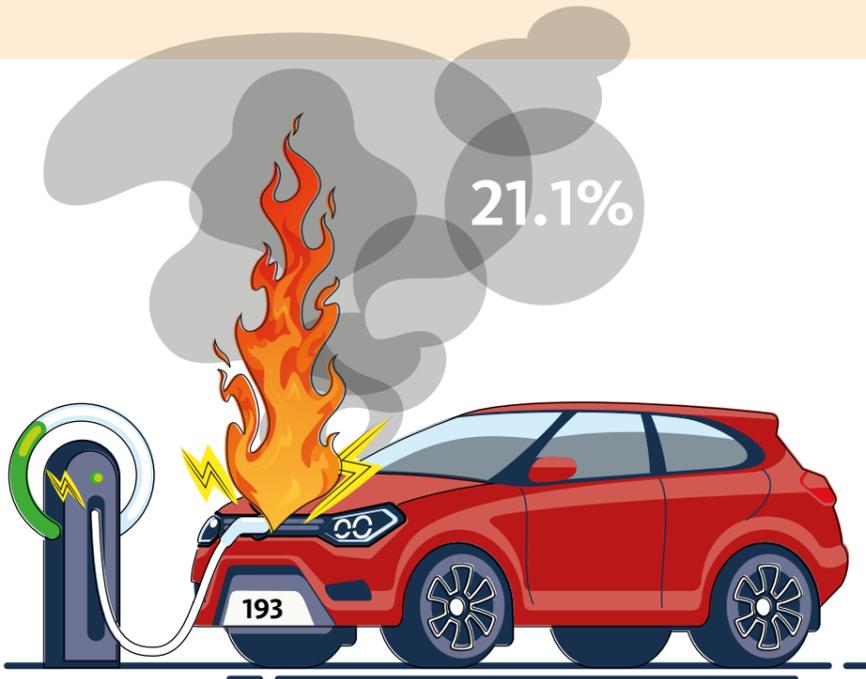
Annual automotive recall events fell

4.1%, from 955 in 2022, to 916 in 2023.

This decline is largely attributed to Q3 2023 which saw 197 recalls. Only 2 quarters in the last 10 years have recorded fewer events (Q1 2016 and Q1 2014).



21.1%



Electrical system was the **leading cause of recall events** in 2023, accounting for 193 (or 21.1%).

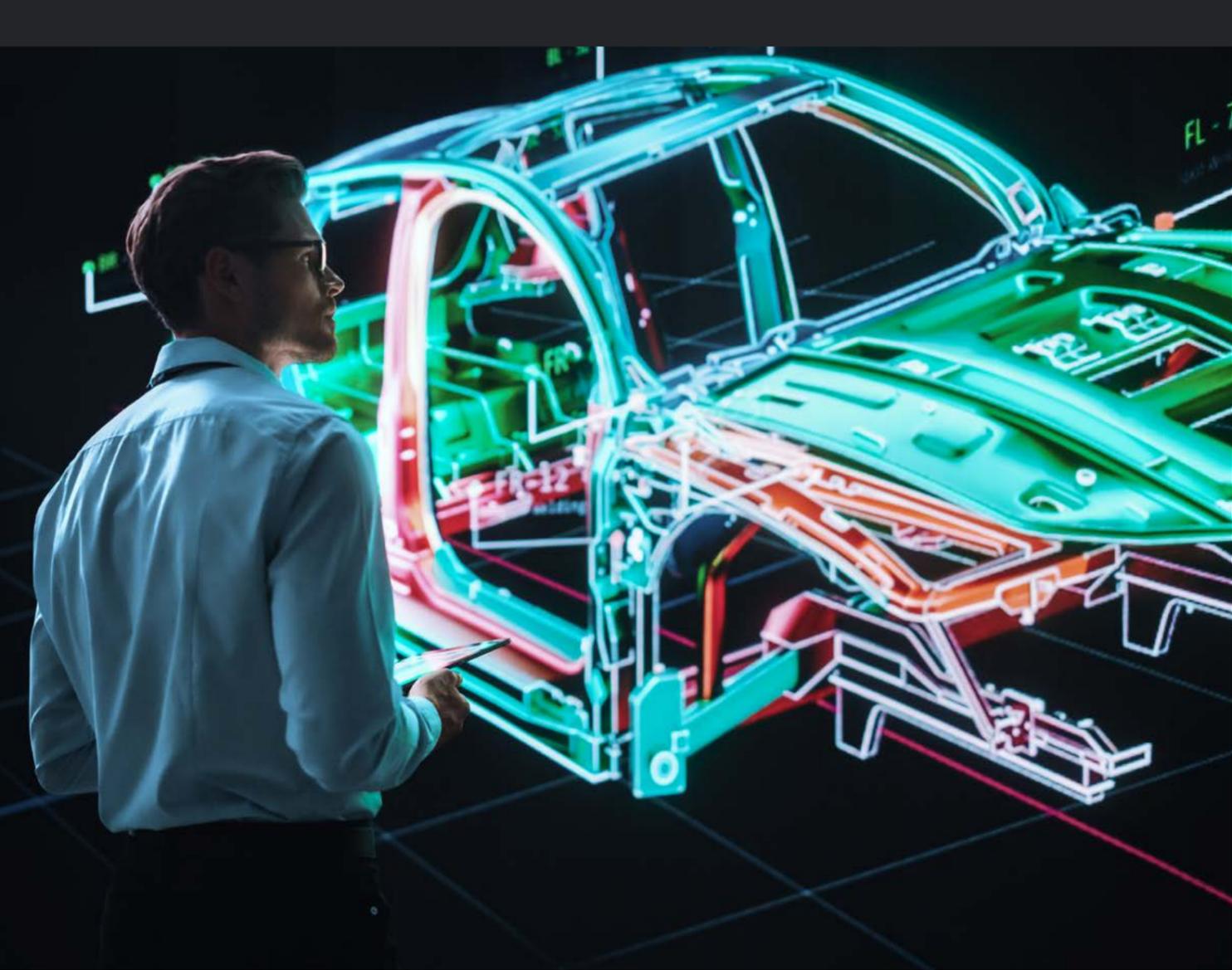
This marks the highest figure attributed to Electrical systems for over 5 years. As the sector accelerates towards its electrified future, we expect this trend to continue.

Despite events falling, **total impacted units increased** from 31.2M in 2022, to 38.4M.

With this increase, 2023 marks a 3-year high for impacted vehicles in the U.S.

GARAGE REPAIRS





2023 BY THE NUMBERS

Year-over-year, the number of automotive recalls issued by the National Highway Traffic Safety Administration (NHTSA) decreased for a second consecutive year. There were 916 in all of 2023 compared to 955 in 2022. However, the number of units recalled was 23.1% higher in 2023, with 38.43 million for the year compared to 31.21 million units impacted in all of 2022.

Looking at Q4 2023, NHTSA issued 240 automotive recalls, a 21.8% increase compared to the previous quarter. The number of units impacted was also higher, increasing from 7.92 million in Q3 to 14.69 million in Q4. This is the highest quarterly total since Q1 2020 and the third-highest since Q3 2016. With the increase in units (and decline of events), the average recall size was higher, growing from 40,179 units in Q3 to 61,195 in Q4.

Electrical systems was the leading cause of U.S. automotive recalls in every quarter of 2023. It was linked to 53 events in the final quarter, compared to 41 in Q3, 51 in Q2, and 48 in Q1. Structure was the second-most common concern in Q4, cited in 28 recalls, and equipment was third with 26 events.

Electrical systems was also the most common reason for automotive recalls by volume in Q4 2023. There were 4.92 million units impacted. Hydraulic service brakes was second with 3.38 million units affected, and gasoline-powered fuel systems was third with 2.65 million units involved in recalls this quarter.

Automobiles were the largest product category of recalls with 212 events in Q4 2023, up from 176 last quarter. The equipment category had 24 recalls that impacted 3.57 million units. There were three recalls for tires and one for child seats in Q4 2023.

JANUARY

2024 insight

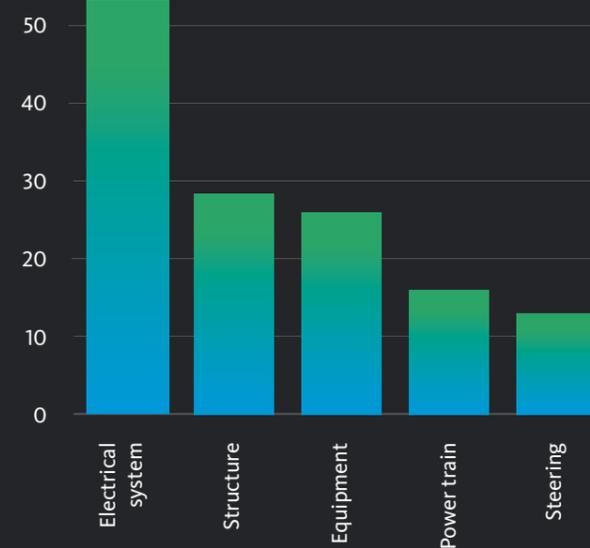
There were 63 U.S. automotive recalls in January 2024, down more than 21% compared to the Q4 2023 monthly average of 80 events. The number of units fell slightly less. NHTSA recalled 4.6 million units in January, compared to the Q4 2023 monthly average of 4.9 million units.

Electrical systems was the leading cause of recalls for the automotive sector in January 2024, tied to 18 events. Faulty equipment was the second-most commonly-cited reason with

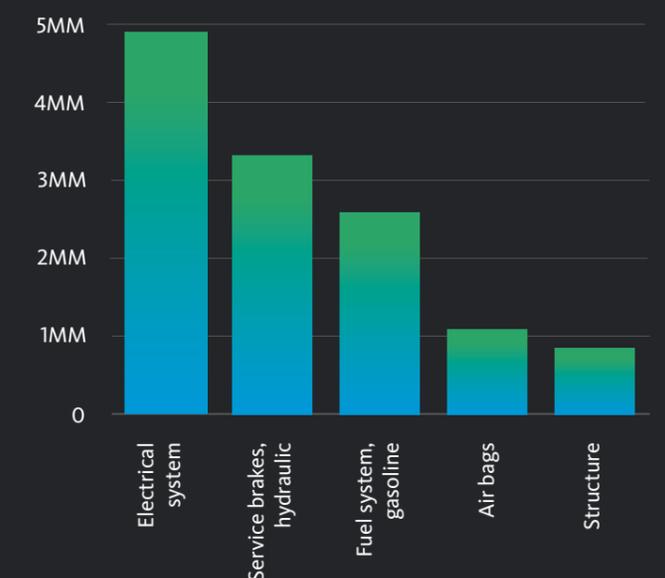
11 events. Electrical systems were also the top concern in terms of volume, impacting 2.22 million units. Structure was the second-highest category by volume with 1.99 million units impacted across three recalls.

In terms of product category, vehicles had the most recalls with 57 events which impacted 4.58 million units, more than any other segment. There were six recalls in January tied to electric or hybrid vehicles.

NUMBER OF RECALL EVENTS BY CATEGORY IN Q4



NUMBER OF UNITS RECALLED BY CATEGORY IN Q4





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CHALLENGES & RISKS FOR ELECTRIC VEHICLE SAFETY

The global push toward a carbon-free future has sparked an electric vehicle (EV) revolution and a subsequent rapid increase in lithium-ion (Li-ion) battery production to power the millions of EVs on the road. For the automotive industry, the demand for Li-ion-powered EVs has reached an inflection point. More than [100 countries](#) have pledged to achieve net-zero emissions in the coming decades, and some are planning to ban the sales of new internal combustion engines at the same time.

In the U.S., [billions of dollars](#) have been allocated to facilitate the nationwide transition to EVs, including infrastructure to support a national network of vehicle charging stations. Annual global EV sales are also growing steadily as underlying technologies mature, EV costs decrease, and new regulatory obligations loom.

As consumers continue to adopt EVs in greater numbers, manufacturers have an opportunity to proactively mitigate the unique potential safety risks. By harnessing emerging technologies to improve EV battery safety, stakeholders can not only advance consumer protection goals but also help ensure compliance with critical, quickly evolving regulatory requirements.

Product safety challenges for the EV industry

As EV technologies and regulations develop, the automotive industry is faced with numerous product safety challenges ranging from advanced driver assistance systems (ADAS) to crash safety for large-format battery systems. EVs present new challenges with respect to their weight and the interaction with the U.S. transportation infrastructure. Many EV batteries weigh more than the internal combustion engines they replace. [Recent findings](#) by road safety officials have shown that automotive guardrail barriers may be insufficient for heavier EVs at certain speeds.

More broadly, many automakers are focused on how to manage the technical challenges related to large-format battery systems as more and more of these batteries are incorporated into vehicles. These concerns include implementing sophisticated improvements such as early warning detection systems that alert passengers to potential battery failures, ways to protect passengers from hazardous scenarios, and measures to mitigate thermal runaway propagation within the battery pack that can lead to battery fires.

Meeting these core objectives without substantially increasing the vehicle's cost or throttling its performance has put the EV industry at a critical juncture.

The role of data in the future of EVs

Anticipating regulatory trends and consumer expectations can help manufacturers drive commercial success in an increasingly competitive business environment while simultaneously supporting consumer safety. As EVs evolve, the use of data to drive the battery pack design, develop robust testing and validation programs, and implement sophisticated battery management programs will be critical to shaping the future of EVs.

While today's EV battery management systems often provide warnings for abnormal readings of key parameters (e.g., temperature, cell voltage, and isolation resistance), opportunities exist for manufacturers to develop advanced, data-driven approaches to maximize the safety and performance of battery packs. For instance, [numerous sensors are under development](#) that can detect changes in gas composition and pressure to potentially identify and contain thermal runaway events by isolating the battery and warning passengers or others nearby of a potential hazard.

Furthermore, the collection of continuous state-of-health measurements for batteries is also leading to novel applications where battery usage changes based on its condition. These adjustments lead to improvements in battery performance and longevity. Ongoing measurements of the battery, such as voltage and impedance, can be used to tune the maximum allowable charging rate of the battery as it ages. These settings could be unique to each vehicle to provide individual consumers with an optimal balance of performance, user experience, and safety. The adjusted control parameters can either

be administered through on-board programs or through periodic software updates and may not even require action from the EV owner.

The changing recall landscape

Government agencies around the world have indicated that new regulations to advance EV safety are on the horizon. The U.S. and EU have announced their intent to require early battery failure detection systems in all future EVs and will also engage standards that extend beyond EV battery safety and functionality. For instance, the EU recently unveiled a "cradle-to-grave" blueprint regulating the entire battery lifecycle with a circular supply chain that spans production to disposal and recycling. These and other evolving standards are certain to impact a range of stakeholders from battery manufacturers and original equipment manufacturers (OEMs) to consumers.

Even EVs that are compliant with current standards can have unexpected issues arise which may require a recall or other reactive technical solution. Increasingly, data can help manufacturers respond more quickly and effectively to these issues.

Continuous monitoring

With the growing adoption of EVs, the data collected through the number of miles on the road can provide critical insights into charging and discharging behavior and trends over the lifetime of a vehicle. Continuous real-time monitoring and analysis of battery pack data such as charge and discharge characteristics, cell-balancing activity, thermal management operations, and fault diagnosis can identify predictive maintenance strategies, indicate the need to adjust operational conditions, or reveal opportunities to potentially lower the risk of an issue.

Defining recall size

Manufacturers who achieve data visibility across the battery and powertrain can also identify potential issues and/or scope recalls on a more granular level. This includes the ability to isolate the potentially affected production lot and trace the origin of defective components.

Deploying a software information architecture that fully leverages the data streams of EVs can enable vehicle-by-vehicle analysis during a warranty or recall investigation



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versus having to cast a wider net over a vehicle's lot or model. By assessing an individual vehicle's performance for degradation or failure markers, the number of affected vehicles in a recall can be minimized to only those exhibiting the relevant characteristics or behavior. In turn, this could substantially reduce the potential cost of a recall for EV manufacturers and improve customer outcomes.

What's next for EV manufacturers?

Despite the growing number of automotive players and EV models on the market, it is important to remember that the technology is still evolving. As with any other consumer product, there will be a constant push for progress propelled by market forces and increasing global safety regulations.

EV manufacturers will continue to evaluate new battery cell chemistries and technologies to reduce potential safety risks and improve the mileage range of EVs. Similarly, advanced data analytics can help better utilize information collected from the battery pack to flag potential operational concerns and address them earlier in the battery's life, thus helping prevent safety issues from arising in the first place.

Likewise, EV manufacturers may develop techniques to better harness information generated throughout a fleet of vehicles to proactively identify potential issues and solutions that wouldn't have been easily identifiable by analyzing a small subset of the vehicle population.

Beyond safety-related issues and recalls, EV manufacturers should also be prepared to address gaps between users' expectations and real-world performance. The U.S. Environmental Protection Agency (EPA) range and the Worldwide Harmonized Light Vehicles Test

Procedure (WLTP) range used in the EU represent test results for an EV's driving range under specific test conditions. It is not uncommon for real-world driving results to differ from test conditions, resulting in [different ranges](#) between estimated and actual performance. An EV's true range depends on many variables such as throttle and/or braking tendencies, temperature, road conditions, etc.

The potential gap between the battery range or battery life advertised during purchase compared to what consumers actually achieve will undoubtedly lead to disputes, similar to what has occurred with consumer electronics. In the same vein, if battery pack performance is changed remotely by an automaker to preserve its lifespan, safety, or other reasons, the resulting reduction in mileage may also be perceived negatively by consumers. Striking the balance between optimizing performance, reliability, and safety—and attempting to match the marketed range estimates—will be crucial for automakers.

Manufacturers must also navigate the challenge that while some solutions such as improved sensors may be easy to integrate with current EV battery pack designs, new innovations such as solid-state batteries are fundamentally different than current technologies and may require a redesign of the entire battery system. These advances could someday lead to EVs that are safer, more reliable, and more desirable for consumers, but they will demand different solutions for manufacturers in terms of reliability, mass production, and other design factors.

Vehicle manufacturers will have to adapt to many changing regulations and expectations in a heavily-regulated environment. The ultimate goal of protecting the environment and consumers is admirable, but the path there will be challenging.

CONSUMER PRODUCTS

In November, the Department of Justice (DOJ) announced a conviction for two corporate executives in the first-ever criminal prosecution for failure to report under the Consumer Product Safety Act. The case involved defective residential dehumidifiers that had been linked to multiple fires and resulted in numerous product recalls between September 2013 and August 2023.

[Experts with Michael Best & Friedrich LLP](#) said that the executives delayed the recalls of the defective products by misrepresenting information to the Consumer Product Safety Commission (CPSC). The lag resulted in numerous additional incidents and injuries. According to the company's own internal communications, it knew the products were flawed but continued to sell them to avoid business losses. In addition, it was shown that the company falsified safety certifications and allowed consumers to believe the products were safe when they were not. The convicted executives actively hid this information from the CPSC. While this was the first criminal conviction, [the lawyers predict](#) more are on the way and these types of actions will increase.

Also in November, CPSC Chair Alex Hoehn-Saric addressed the International Consumer Product Health and Safety Organization (ICPHSO) at its international symposium. [His comments](#) focused on online marketplaces, saying that these platforms need to have product safety built into all aspects of the operation, an idea he called "Product Safety by Design." He described the three core principles of this concept: promoting a corporate culture of safety, holding third-party sellers accountable, and empowering consumers with safety tools and information. It is likely the CPSC's actions under Chair Hoehn-Saric will place a high priority on these tenets as it increases oversight for online sellers.

“The CPSC will place a high priority on three tenets (1. promoting a corporate culture of safety, 2. holding third-party sellers accountable, and 3. empowering consumers with safety tools and information) as it increases oversight for online sellers.”



“The FTC published a proposed rule to prohibit hidden and bogus fees for goods or services. Businesses will need to assess the consumer-facing aspects of their sales processes to ensure they meet the new disclosure requirements.”

The Federal Trade Commission is also looking at consumer protections with its proposed rule to ban junk fees, which it claims cost consumers tens of billions of dollars a year. While there are already rules against unfair or deceptive fee practices, the proposed rule would give the agency more enforcement power.

Artificial intelligence (AI) is another topic that continues to be important to regulators. In October, the Biden Administration published a comprehensive executive order for government agencies on developing and implementing AI technology. The order lays out recommended standards, guidelines, and best practices in eight different areas. While the document is not an enforceable regulation, it is likely that any future mandatory rules will align with the suggestions. Agencies are already sharing their plans on how to comply with the directive.

More regulation is also coming for micromobility devices such as e-scooters, hoverboards, e-bicycles, and e-unicycles, particularly around meeting safety standards for the lithium-ion batteries that power these devices. Currently there are only voluntary standards. In October, CPSC Commissioner Mary T. Boyle said the agency is starting work to make these guidelines mandatory.

As we have seen throughout 2023, there is a balance between promoting new innovations and working to ensure these technologies are safe for consumers. There is also an increasing focus on enforcement around advertising language. Manufacturers and retailers should be following the actions of regulators carefully to minimize their risks.

FTC works to protect consumers from misleading fees

In October, the Federal Trade Commission (FTC) published a [proposed rule](#) to prohibit hidden and bogus fees for goods or services, also known as “junk fees.” In [its announcement](#), the agency estimated that these fees can cost consumers tens of billions of dollars per year and harm both honest businesses and consumers.

The FTC received more than 12,000 comments last year on an earlier inquiry about on how junk fees affect businesses

and personal purchases. The input covered a wide range of spending categories including using internet apps and internet service providers, booking hotels and resort fees, purchasing concert tickets online, renting an apartment, and paying utility bills.

The draft regulation focuses on two types of junk fees. The first is hidden fees that are disclosed later in the buying process, and which significantly increase the total consumer price. The second type is bogus fees, which businesses will often misrepresent or not adequately explain, leaving consumers unsure about what they are paying for.

The rule would also require companies to clearly and conspicuously display the “total price,” [defined as](#) “the maximum total of all fees or charges a consumer must pay,” with the allowable exclusion of shipping charges and government charges. Having the true total cost inclusive of all mandatory fees will make it easier for buyers to compare prices for the best value.

As [lawyers with Greenberg Traurig, LLP](#) point out, unfair or deceptive fee practices are already unlawful under Section 5 of the FTC Act. However, if the new law moves forward as drafted, the FTC will have the authority to secure refunds for harmed consumers and seek civil penalties and monetary redress against companies that do not comply.

The FTC has [passed similar restrictions](#) specifically for the automotive industry, and other federal agencies and organizations are also working to prohibit junk fees including the Consumer Financial Protection Bureau (CFPB), the Federal Communications Commission (FCC), the Department of Housing and Urban Development (HUD), and the Department of Transportation (DOT).

[Attorneys with Holland & Knight](#) observed that many industries and business sectors will need to make significant changes to their advertising practices. They will also need to assess the consumer-facing aspects of their sales processes to ensure they meet the new disclosure requirements. In addition, the legal experts advise that certain industries such as concert ticket sellers and mobile app-based delivery services might need to make major changes to their sales platforms.



“ In light of the new FTC resolution, it is recommended that companies developing AI create comprehensive policies and procedures to guide that development.”

New AI executive order for government agencies and executive branch offices

On October 30, the Biden Administration published [a wide-ranging executive order](#) (EO) on the safe, secure, and trustworthy development and use of artificial intelligence (AI). The EO noted AI’s “extraordinary potential for both promise and peril,” recognizing the problems it can solve when used responsibly and also warning of the dangers it can do to society and national security if care is not taken.

The order is part of the Administration’s broader focus on AI, which included a [Blueprint for an AI Bill of Rights](#) and work to secure [voluntary commitments from leading AI system developers](#) earlier in the year.

An analysis by [attorneys with Covington & Burling LLP](#) shows that the EO directs government agencies to develop rules or other forms of disclosures from companies that develop or provide infrastructure for AI models in certain scenarios. The Administration has said that some of those regulations should be proposed within three months of the order’s publication.

The EO offers a plan for managing the development and use of AI in eight areas: 1) ensuring the safety and security of AI technology, 2) promoting innovation and competition, 3) protecting consumers, patients, passengers, and students, 4) supporting workers, 5) advancing equity and civil rights, 6) protecting privacy, 7) advancing federal government use of AI, and 8) strengthening American leadership abroad.

In another AI regulatory measure, the Federal Trade Commission (FTC) [announced](#) on November 21, 2023, that it had approved an omnibus resolution authorizing the use of “compulsory process” for nonpublic investigations concerning products or services that use AI. Under the resolution, companies would be required to comply with information or document requests, such as subpoenas or civil investigative demands (CIDs), which are both forms of compulsory process. Entities that do not comply may face contempt charges from the courts.

[In its announcement](#), the FTC said the measure will streamline its ability to issue CIDs in AI-related consumer protection and competition investigations. This will make it easier to obtain documents, information, and testimony needed in their review.

[Legal experts with Sheppard Mullin Richter & Hampton LLP](#) recommend that companies developing AI create comprehensive policies and procedures to guide that development, especially in light of the new FTC resolution. The Biden Administration’s EO also makes it clear that companies need to plan for and document their AI standards, guidelines, and best practices.

CPSC takes action on lithium-ion batteries

In October, the U.S. Consumer Product Safety Commission (CPSC) issued a report [on deaths, injuries, and hazard patterns related to micromobility products](#) such as e-scooters, self-balancing scooters (also known as hoverboards), e-bicycles, and e-unicycles. The study showed a nearly 21% increase in injuries associated with all micromobility devices from 2021 to 2022. According to the CPSC's findings, injuries associated with these products have trended upward since 2017, increasing an estimated 23% each year.

The report also urged consumers to only use micromobility products that have been designed, manufactured, and certified for compliance with the applicable consensus safety standards.

Until now, manufacturers' compliance with recommended UL safety standards for batteries used in these types of products has been voluntary, though industry experts have recommended stronger regulations. In December 2022, the CPSC [urged micromobility product manufacturers](#) to review their product lines to ensure they comply with established voluntary safety standards to help reduce the risk of fire and serious injury or death for consumers.

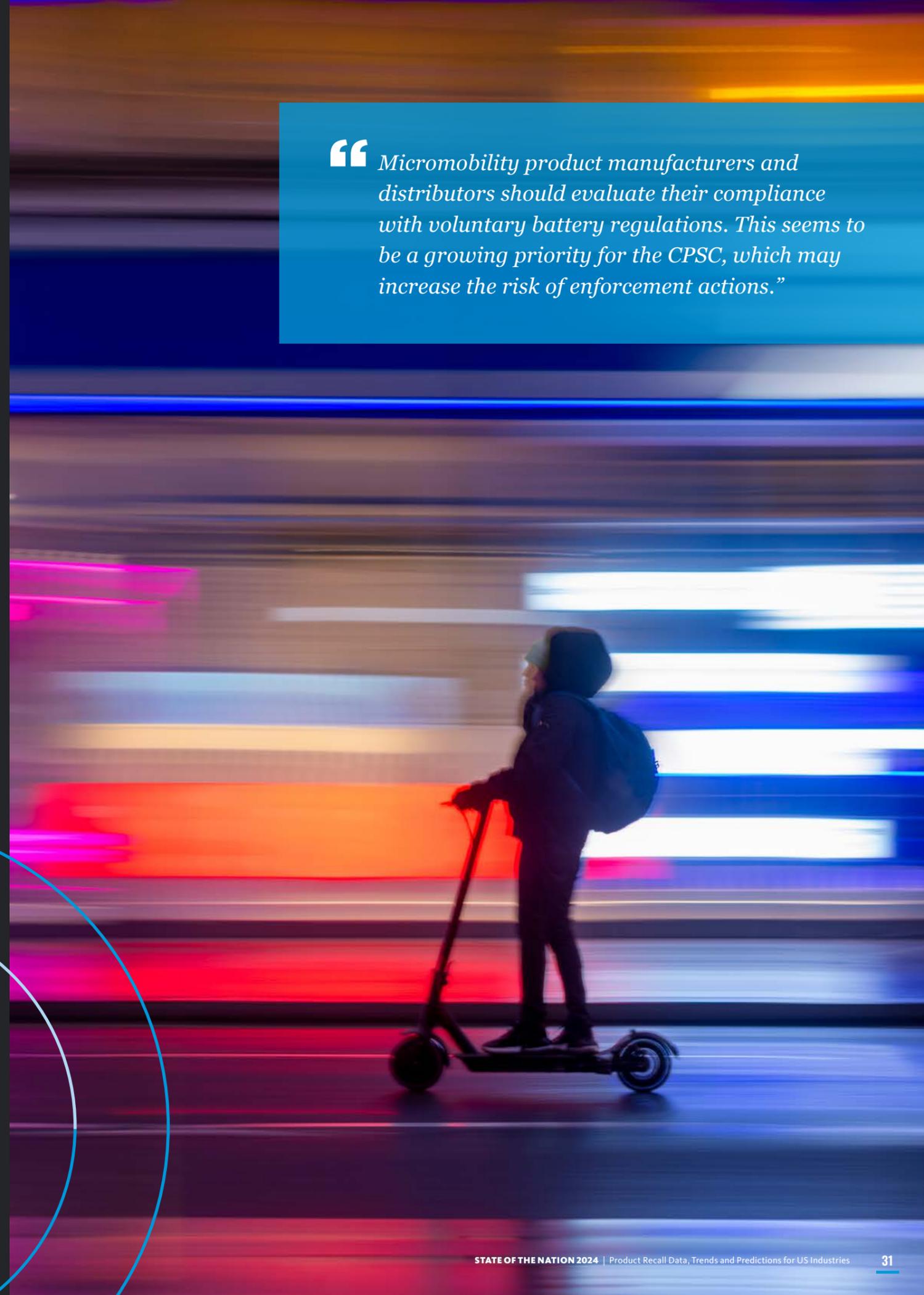
Now the agency may be taking stronger action. According to a [report from Bicycle Retailer](#), in October, CPSC Commissioner Mary T. Boyle said the Commission will consider mandatory battery regulations for micromobility devices. Boyle said that the CPSC will research possible lithium-ion battery requirements and the current voluntary standards may expand. [According to the media report](#), mandatory regulations are unlikely before 2025.

[Legal experts with Covington & Burling LLP](#) outlined some of the steps the CPSC would have to take before it could adopt a mandatory rule, including conducting a cost-benefit analysis to determine if the rule is necessary and would provide benefits without being overly costly or burdensome.

[The attorneys also observed](#) that the Commission has other tools at its disposal including unilateral press releases. In October, [the CPSC issued a press release](#) warning consumers to stop using a certain brand of electric scooter because of a fire hazard, noting that the device was linked to two deaths in an apartment fire in New York City.

Micromobility product manufacturers and distributors should evaluate their compliance with the voluntary regulations and track the new rules as they advance to determine if there are changes they will need to make. They should also be aware that this seems to be a growing priority for the CPSC, which may increase the risk of enforcement actions.

“*Micromobility product manufacturers and distributors should evaluate their compliance with voluntary battery regulations. This seems to be a growing priority for the CPSC, which may increase the risk of enforcement actions.*”



CPSC recall events increased 12.6% in 2023, from 286 in 2022, to 322.

With this increase, 2023 marks the highest number of consumer product recalls in over 5 years.



Fire risk was the leading cause of recalls in 2023 (with 67 events or 20.8%).

This marks the highest annual figure attributed to Fire risks in over 5 years. The leading product categories affected were Sports & Recreation, Home Appliances, and Yard & Garden.



There were a total of 135.2M defective consumer product units in the U.S. in 2023.

Only 1 year in the past 10 has recorded a greater number (245.4M units in 2016).



2023 BY THE NUMBERS

The Consumer Products Safety Commission (CPSC) issued a total of 322 recalls in 2023, marking a 10 year high for the sector. In addition, there were 135.23 million units recalled for the year - for context, only one year in the last ten has recorded more (2016 with 245.40M).

These high annual totals were partially driven by heavy activity in Q4 2023, which saw an increase in recalls and impacted units compared to Q3. There were 87 CPSC recalls this quarter compared to 65 events last quarter, a 33.8% increase. The change in units impacted was more significant, rising by 855.5% from 8.67 million last quarter to 82.79 million in Q4. Only two years in the last ten have recorded more impacted units (Q4 2017 with 107.36M, and Q1 2016 with 140.93M).

The average recall size was also higher, increasing from 133,308 units in Q3 to 951,654 in Q4. There were four recalls in Q4 2023 that involved more than 2 million units, compared to only one in Q3 2023.

Fire was the top consumer product hazard by event in Q4 2023, tied to 16 recalls. Injury was the second-leading concern with 14 events, followed by falls with 10 recalls. Choking was the top risk by unit with 70.64 million units impacted, followed by fire with 7.08 million units affected.

Children's Products accounted for the most recalls by product category, linked to 21 events in Q4 2023. Sports & Recreation was second with 19 recalls, and Yard and Garden was third with 11 events.

In terms of units impacted, Children's Products was the top product category with 70.88 million units recalled, or 85.6% of all units in Q4 2023. Most of these were from a single choking hazard recall of rolling candy. The Kitchen category had 5.25 million units recalled, making it the second-highest by volume. Home Appliances had the third-highest number of units impacted with 3.01 million.

Despite a higher recall total, the number of incidents fell by 20.4% quarter-over-quarter, dropping from 8,971 in Q3 to 7,141 in Q4. The number of injuries increased to 178 (from 170 in Q3) and the number of deaths was lower, with four in Q3 compared to two in Q4.

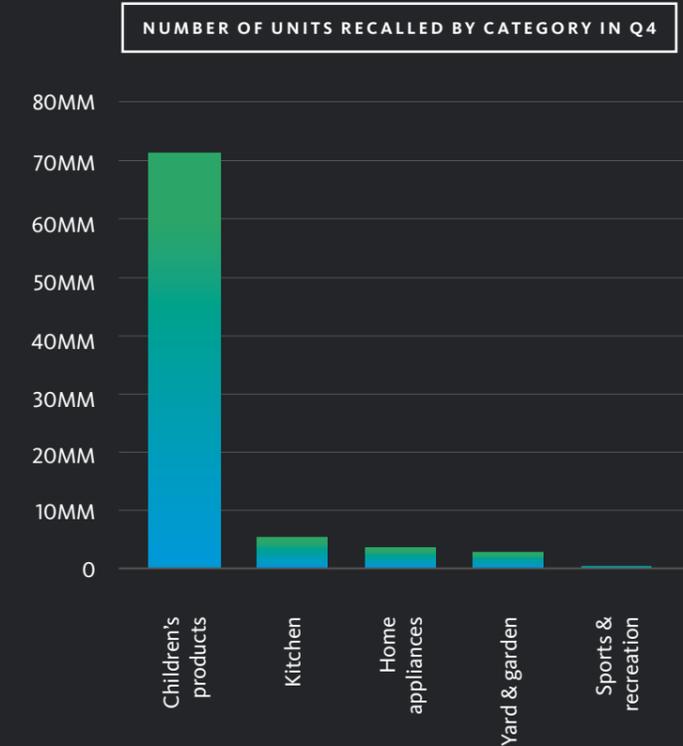
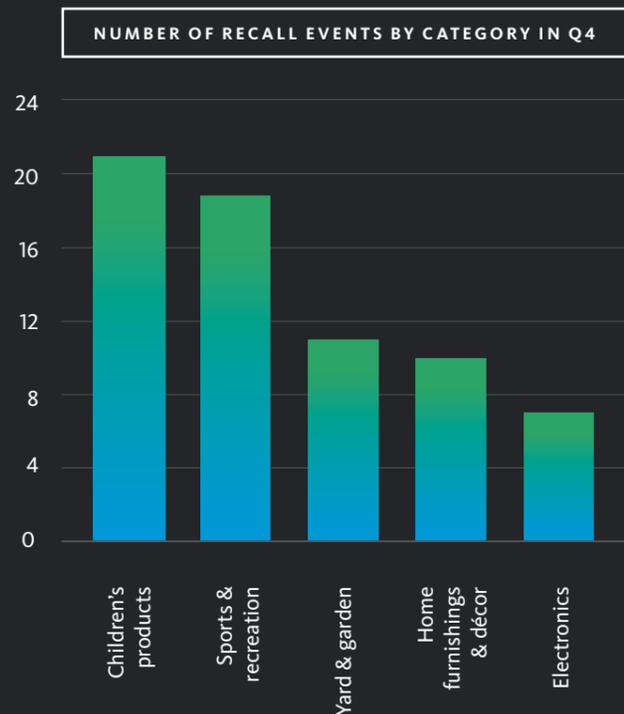
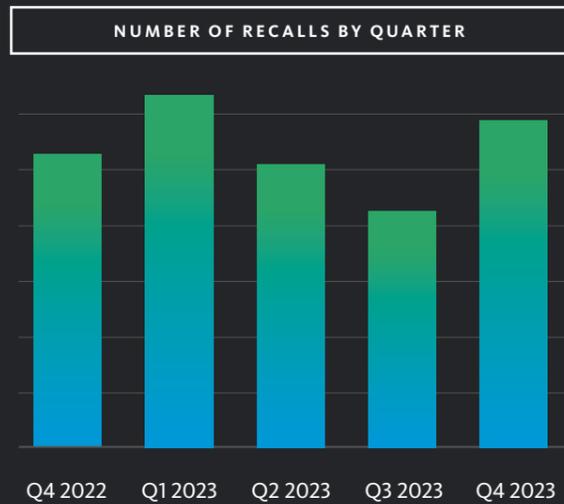


JANUARY 2024 insight

There were 17 U.S. consumer product recalls in January 2024, more than 41% fewer than the Q4 2023 monthly average of 29 events. The number of units fell by nearly 97% to 647,618 in January 2024 compared to the Q4 2023 monthly average of 27.6 million units. However, the total items for a recall of furniture tip-over restraints was still pending, so this figure is subject to increase. The number of units in the restraint recall was estimated to be in the millions.

Home Furnishings & Décor was the top category for January 2024 consumer product recalls with four events. Yard & Garden, Sports & Recreation, and Electronics each had three.

Home Furnishings & Décor also had the most units recalled with 639,134, even without the total for the tip-over restraints. Electronics had the second-highest number of impacted units with 91,000. Most of these were due to a single personal massager recall. Sports & Recreation was close behind with 83,315 units recalled in January.



CPSC TRENDS IN 2023 AND WHAT TO EXPECT IN 2024

In 2023, we saw enforcement trends at the Consumer Product Safety Commission (CPSC) continue on the same path as recent years. We have no reason to expect 2024 to be any different, given the current Democratic majority at the Commission, and in light of the CPSC's continued pressure on consumer product companies and steady pace for issuing new rules.

In 2024, we expect to see final rules for several product categories including table saws and portable generators. Based on the CPSC's 2024 operating plan, the CPSC will also likely continue to develop a plan for improving safety standards for lithium-ion batteries, especially in micromobility products.

Activity in 2023

Continued Regulation of Infant and Children's Products

A review of the CPSC's regulatory actions in the last three years on [Regulations.gov](#) showed the agency issued 11 new final rules or direct final rules in calendar year 2023. This is comparable to the 15 rules issued in 2022 and 11 rules issued in 2021.

Several of the new rules in 2023 focused on infant and child safety, including the following:

Dressers and Clothing Storage Units – On September 1, 2023, the CPSC's direct final rule adopting [ASTM F2057-23](#) as a mandatory safety standard went into effect. As part of the federal [Stop Tip-overs of Unstable, Risky Dressers on Youth \(STURDY\) law](#), the measure aims to protect children from deaths and injuries associated with tip-overs of dressers and other clothing storage units. [CPSC Chairman Alexander Hoehn-Saric](#) said he expects the industry to work quickly to meet the new criteria.

Infant Sleep Products – Two final rules related to the Safe Sleep for Babies Act of 2021 also went into effect in September 2023: a ban on crib bumpers (16 C.F.R. Part 1309) and a ban on inclined sleepers for infants (16 C.F.R. Part 1310). Both categories of products are now labeled as banned hazardous products under the Consumer Product Safety Act (CPSA).

Button and Coin Cell Batteries – Pursuant to its authority under Reese's Law, which is designed to protect children six years and younger from button cell and coin battery ingestion hazards, the CPSC published two rules imposing additional requirements for these types of batteries and consumer products that contain them. The first is a direct final rule ([88 FR 65274](#)) adopting ANSI/UL 4200A as a mandatory safety standard, which includes construction, performance, and labeling requirements. The second is a final rule ([88 FR 65296](#)) to establish warning label requirements for the packaging of button cell and coin batteries, including those packaged separately with a consumer product.

The CPSC's focus on infant and children's products is expected to continue in 2024, as it is an area of easy agreement with significant support from other stakeholders. We already see this in several proposed rules that are listed as "priority activities" in the FY 2024 operating plan, including mandatory safety standards for infant nursing pillows, bassinets and cradles, infant and toddler rockers, and infant support cushions.



Recalls

The CPSC's increased enforcement activity has again led to a record high of product recalls in FY 2023. CPSC announced 312 recalls in FY 2023, representing a 20% increase over FY 2022. Much of this increase can be contributed to "Regulatory Recalls" and "Defect Recalls." CPSC announced 83 Regulatory Recalls, citing that the recalled product violated a mandatory standard, and 62 Defect Recalls, asserting the recalled product may contain a defect that poses a substantial product hazard to consumers.

Commissioner Peter A. Feldman [announced](#) in November that this significant increase was "no accident" but rather reflects the Commission's continued push to re-prioritize its core goals of enforcement and compliance. Commissioner Feldman attributed the higher numbers to recent increases in funding, which had been frozen between 2014 and 2020. The CPSC used these resources to hire more staff, provide new case management tools, and reinstate the Children's Product Defect Team.

In addition to the overall increase in product recalls, 2023 saw several major recalls encompassing millions of consumer products.

Most recently, a consumer appliance company announced a recall in December 2023 of 4.8 million portable blenders for posing fire and laceration hazards to consumers. The firm received more than 300 reports of the blades

breaking while in use and one report of a laceration injury. Additionally, the firm received 17 reports of overheating or fires, which caused about \$150,000 in property damage, and 49 reports of minor burns.

Predictions for 2024

Product liability attorneys should be on the lookout for several proposed and final rules coming down the pipeline in 2024. In a November 2023 [statement](#) regarding the passage of CPSC's FY 2024 Operating Plan, Chairman Hoehn-Saric stated that the agency is focused on finalizing mandatory standards for table saws, portable generators, and several infant products, as well as improving standards for lithium-ion battery safety.

Here is what manufacturers and distributors of those products should know:

Table Saws – An average of 30,000 table saw blade-contact injuries—including lacerations, fractures, and amputations—are treated in U.S. emergency departments each year. Currently, UL 62841-3-1, the voluntary standard that took effect in January of 2010, requires all table saws sold in the U.S. to include a modular blade guard and an anti-kickback device attached to a riving knife. But in 2017, CPSC staff studied National Electronic Injury Surveillance System (NEISS) data on table saw incidents and confirmed that many users remove the blade guard to make certain types of cuts, negating its purpose.

To address this hazard, on November 1, 2023, [the CPSC proposed a rule under the CPSA](#) that would set limits for the depth of cut a table saw can make in certain operating conditions. The proposed rule would be codified at 16 C.F.R. Part 1264.

In an October 2023 [press release](#), Commissioner Trumka said that he expects this rule to “provide the greatest net benefit to society of any rule in the agency’s history. . .” estimating it will provide up to a \$2.32 billion net benefit every year by reducing injuries and trips to the emergency room.

Portable Generators – CPSC data shows an average of 74 generator-related deaths linked to carbon monoxide (CO) poisoning per year, as well as thousands of non-fatal poisonings. On April 20, 2023, the CPSC proposed a rule under the CPSA to address the hazard of acute CO poisoning linked to portable generators.

The proposed 16 C.F.R. Part 1281 would adopt key requirements from the current voluntary standards that regulate portable generators: UL 2201 and PGMA G300. It would also add more requirements to achieve real-world effectiveness such as setting a maximum rate for CO emissions and a mandatory automatic shutoff when high CO concentrations are detected. In addition, the proposed rule would require portable generators to be tested in accordance with various sections of PGMA G300, with changes to the concentrations to align with the requirements in UL 2201. Other requirements include the inclusion of a CO shutoff notification system and various labeling requirements, which would alert consumers to the reason for the shutoff and notify them to point the exhaust away from occupied structures.

Lithium-Ion Batteries – Due to the growing market for consumer products containing lithium-ion batteries and the potential fire risks that they pose, the CPSC held a meeting on July 27, 2023 regarding lithium-ion battery

safety. There was a specific focus on micromobility products, such as e-bikes, e-scooter, and hoverboards during the discussion.

In a [statement](#) recapping the forum, Commissioner Trumka said, “One takeaway was clear: all of the experts asked CPSC to set the rules of the road by implementing a strong mandatory safety standard governing lithium-ion batteries in e-bikes.” Along with implementing safety concepts found in the UL’s voluntary standards, including UL 2849 and UL 2272, experts also urged the CPSC to consider additional measures such as “check battery” indicators to warn consumers when a battery is unstable and at risk of failure (analogous to “check engine” lights in cars), automatic shutoffs for batteries and chargers when a fire risk is present, tamper-proof battery containers to prevent consumer access to battery cells, and a system that tracks a battery’s health, including degradation and damage.

[Chairman Alexander Hoehn-Saric](#) recognized the importance of improving the safety of lithium-ion batteries but warned that “developing mandatory standards under CPSC’s statute is a burdensome and slow process.”

In the meantime, Hoehn-Saric urged manufacturers, importers, retailers, and online marketplaces to comply with current voluntary standards to protect consumers.

What’s Next

Ultimately, the CPSC has ambitious goals in 2024, as outlined in its FY 2024 Operating Plan, which was approved by a three-to-one vote. The agency has stated its commitment to reducing the hazards associated with infant and toddler products and to take initiative to improve safety standards for batteries and micromobility products as these devices become more prevalent in today’s society.



FOOD AND DRINK

In the fourth quarter of 2023, the U.S. Food and Drug Administration's (FDA's) restructuring plan for the Human Foods Program (HFP) advanced. The new Deputy Commissioner for Human Foods, James Jones, [released a statement](#) supporting FDA Commissioner Robert Califf's vision for the HFP and emphasized that the priorities of the program would be preventing foodborne illness, decreasing diet-related chronic disease, and safeguarding the food supply.

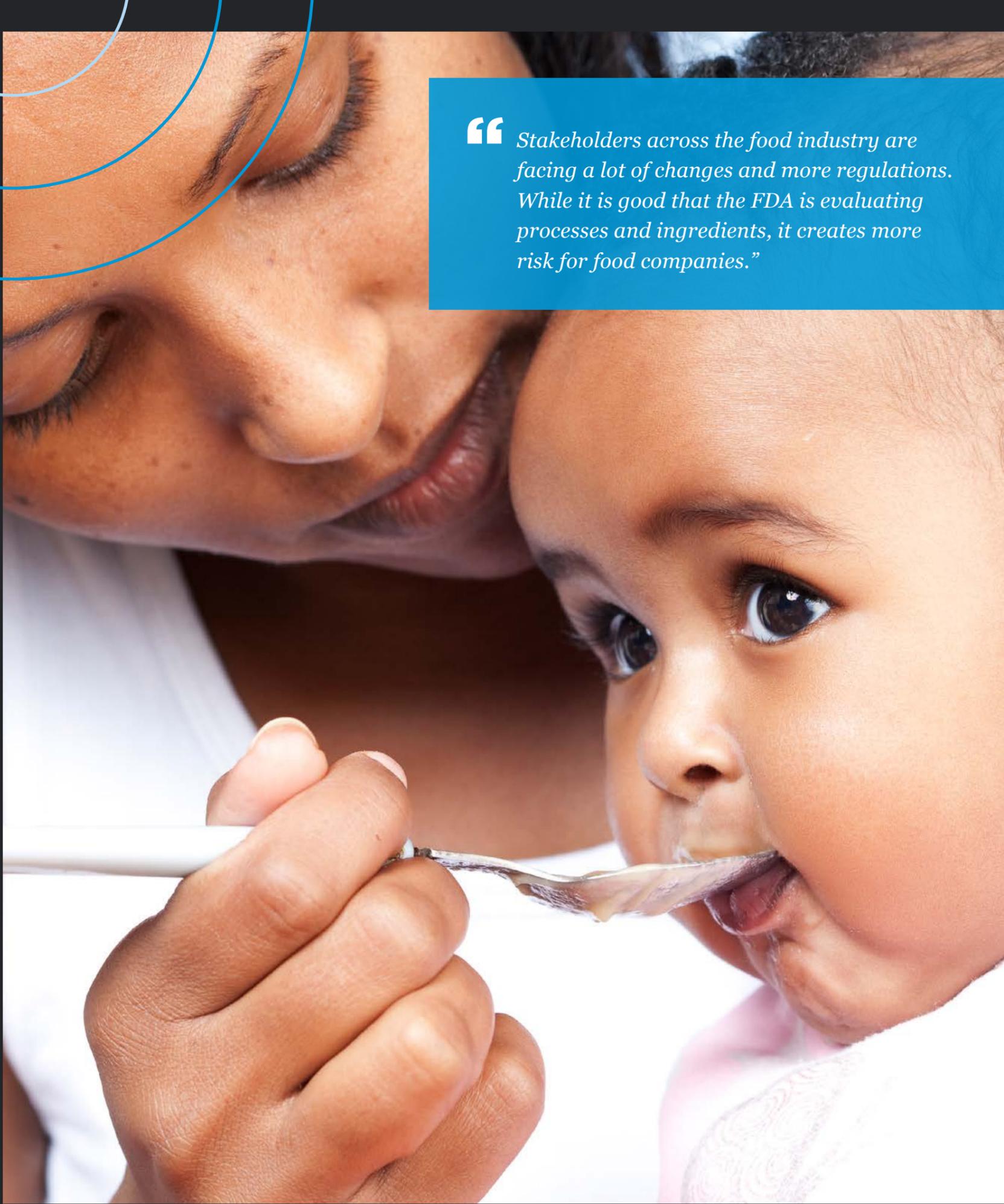
One of the actions Deputy Commissioner Jones mentioned was the creation of an Office of Critical Foods, which will regulate infant formula and medical foods. The FDA also published a tip sheet in December for critical foods companies on how to plan for supply chain disruptions.

The HFP considers reducing exposure to contaminants and other harmful chemicals in foods an important step to safeguard the food supply. To support this concept, the FDA proposed a rule in November to ban the use of brominated vegetable oil (BVO) in foods because the safety of this ingredient has been questioned.

The agency is also [investigating lead contamination in applesauce](#) after initial reports in October 2023. The FDA has recalled three brands of cinnamon apple puree and applesauce products and warned consumers not to eat, sell, or serve the impacted products and to throw out any packages they may have. As of December 26, 2023, the FDA had received 82 confirmed complaints or reports of adverse events potentially linked to the recalled products.

Another way the FDA is working to keep foods safe is through the [Food Traceability Rule](#). In November, the agency offered additional updates and tools to help companies prepare to meet the new requirements for maintaining specific data about certain food products as they move along the supply chain. While the recalled applesauce would not have been impacted by the rule, the hope is that having more data about products and where they are in the supply chain will make recalls more efficient and effective once the rule is implemented in 2026.

Stakeholders across the food industry are facing a lot of changes and more regulations. While it is good that the FDA is evaluating processes and ingredients, it creates more risk and responsibilities for food companies.



“ Stakeholders across the food industry are facing a lot of changes and more regulations. While it is good that the FDA is evaluating processes and ingredients, it creates more risk for food companies.”



More guidance for infant risk management

The [FDA shared its updated infant formula compliance program](#) in October as part of the agency's work to strengthen the safety, resiliency, and oversight of the infant formula industry.

The compliance program lays out the FDA's approach to inspections, sample collection and analysis, and compliance activities to help ensure that infant formula products in the U.S. food supply are safe and nutritious. The updated strategy reflects recommendations that were made after the September 2022 internal [evaluation of the agency's response](#) to the 2022 infant formula crisis.

Some of the changes include instructions for annual environmental sampling to test for Cronobacter and Salmonella bacteria at powdered infant formula facilities and guidance on how to notify the FDA if a sample tests positive for these bacteria, or if a sample is found to not meet the FDA's nutrition regulations.

In addition, there is expanded information on the new infant formula-related requirements that were included in the Food and Drug Omnibus Reform Act of 2022 (FDORA), which was signed into law in December 2022. Under the FDORA, manufacturers of critical foods, which include infant formula and medical foods, must develop plans for responding to supply disruptions.

The FDA published a [tip sheet](#) in December 2023 that helps critical foods manufacturers plan for supply disruptions and comply with the new regulations. It also advises manufacturers to assess their risk management plans' redundancies and identify and evaluate actions that would reduce the impact of a supply disruption. Some of the mitigation measures the tip sheet suggests are having alternative production sites and alternative suppliers or stockpiling of inventory.

Legal experts with [Foley & Lardner](#) recommend that companies develop systems to ensure their products meet the appropriate quality standards and customer expectations. They also suggest that companies evaluate their manufacturing risks and develop contingency plans to address issues before they arise during the manufacturing process.

While no one wants a supply crisis, early planning and testing can help mitigate risks in the worst outcomes, should one occur.

FDA proposes banning food additive

In November, the U.S. Food and Drug Administration (FDA) published a [proposal to revoke the authorization](#) for brominated vegetable oil use in food. [Brominated vegetable oil \(BVO\)](#) is a vegetable oil that is modified with the chemical element bromine. Typically, it is used to keep the citrus flavoring from floating to the top in some beverages.

BVO has been used as a food ingredient since the 1920s. In the late 1950s and early 1960s, the FDA considered the use of BVO to be [generally recognized as safe \(GRAS\)](#) and placed BVO on its original “GRAS list.” Safety questions arose in the late 1960s, and while the ingredient remained on the GRAS list, the FDA began regulating BVO as a food additive.

It took until early 1970 for the FDA to [conclude that the use of BVO in food was not GRAS](#) because of toxicity concerns. In the intervening years, the FDA has continued to study BVO, and recent data demonstrate adverse health effects in animals at levels similar to real-world human exposure. This research and other unresolved safety questions led the FDA to conclude that the use of BVO in food is not safe and that bioaccumulation of bromine can have toxic effects on the [thyroid](#). The ingredient is already banned in beverages in Australia, the European Union, Japan, and New Zealand.

Many beverage makers have reformulated their products to replace BVO with an alternative ingredient, [according to the FDA](#). However, some products containing BVO can still be found on the market.

Not waiting for the FDA to take action, California enacted Assembly Bill 418 (the [California Food Safety Act](#)) in November 2023, which prohibits the manufacturing, selling, delivering, distributing, or holding food that contains BVO, as well as several other food additives. The rule takes effect on January 1, 2027 and comes with a \$5,000 civil penalty for first violations. New York introduced a [similar bill](#) prohibiting certain food additives, including BVO.

The FDA has stressed the importance of reassessing the safety of food ingredients as new, relevant data becomes available. In May, [the agency announced](#) it was starting “a more modernized, systematic reassessment of chemicals with a focus on post-market review.” It said it would evaluate ingredients through both data and information submitted through [petitions or notifications](#) as well as through its own initiatives.

The comment period for the proposed BVO rule closed on January 17, 2024. Companies across the food industry should continue to watch the FDA’s progress. They also need to be aware of state activities, such as those in California and New York, which can often be testing grounds for federal regulations that come later.



“California enacted Assembly Bill 418, which prohibits the manufacturing, selling, delivering, distributing, or holding food that contains BVO. The rule comes with a \$5,000 civil penalty for first violations.”



New tools for complying with the Food Traceability Rule

The U.S. Food and Drug Administration (FDA) shared new tools and FAQs in November to assist companies in complying with the [Food Traceability Rule](#). The rule goes into effect on January 20, 2026, though the agency [announced](#) in September that it would not conduct routine inspections under the regulation until 2027.

The rule requires companies that manufacture, process, pack, or hold specific foods to maintain specific data about their products as they move along the supply chain and provide that product information to partners. The goal is to improve the availability of information needed for effective and efficient tracing of foods and food products.

The rule applies to foods identified on the FDA's [Food Traceability List](#) and includes all fresh-cut fruits and vegetables, shell eggs, and nut butters, as well as certain fresh produce including leafy greens, cucumbers, melons, sprouts, and tomatoes, and ready-to-eat deli salads, some cheeses, and certain fresh, frozen, and smoked seafood products.

Some of the resources include a new webpage about traceability lot codes, examples of how Key Data Elements (KDEs) could appear on invoices and bills of lading, examples of a traceability plan, new Frequently Asked Questions (FAQs), and information on how to apply for a waiver or exemption.

The FDA's [traceability webpage](#) also has new tools such as supply chain examples for different commodities, a "Getting Started with the Food Traceability Rule" guide, and an interactive tool that explains Critical Tracking Events and Key Data Elements.

Despite the fact that enforcement will not begin until 2027, impacted companies should be planning now to ensure their food traceability systems are in place and well-tested. The number of updates from the FDA illustrates how comprehensive and complex the new regulation is.



At 232 events, **Undeclared allergens** was the leading cause of recall in 2023 (45.8%).

The leading undeclared allergens were Nuts and Milk which both recorded 55 events each, followed by Soy (29) and Sesame (21).



FDA recall events increased 19.6% in 2023, from 423 in 2022, to 506.

With this increase, 2023 marks the highest number of food and drink recalls in over 5 years.

Total **impacted units plummeted** by more than half, from 416.9M in 2022, to 199.7M in 2023.

Despite this overall decline, 'Prepared food' items experienced a 432.2% increase in recalled units, rising from 13.1M in 2022, to 69.9M in 2023.





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2024 insight

2023 BY THE NUMBERS

FDA

As a full year, 2023 saw the highest number of FDA food recalls in the past five years with 506 events. However, by volume the total dropped from 416.93 million units impacted in 2022 to 199.72 million in 2023. It is worth noting that 2022 had the most annual units recalled in over 10 years, driven by two strong quarters and major recalls of infant formula and supplements.

Compared to Q3 2023, Q4 had fewer total recalls and fewer units impacted. There were 105 FDA food recalls in Q4, down 19.8% from Q3. There were 6.20 million units recalled, a 84.6% decrease from the previous quarter. There was only one recall that impacted more than 1 million units in Q4, compared to five recalls exceeding that size in Q3.

There were 42 recalls for undeclared allergens, making it the leading cause of U.S. food recalls for all but one quarter over the last 6 years. There were seven recalls involving undeclared sesame, which affected 79,550 units. Bacterial contamination was second in terms of events with 25 recalls in Q4. It also had the second-highest number of units recalled with 1.34 million. Foreign materials was third in both volume and events with 11 recalls which affected 674,599 units.

Non-bacterial contamination drove the highest volume of FDA food recalls in Q4, accounting for 3.07 million units. Almost all of these were tied to a single recall of applesauce for excessive levels of lead.

Produce was the top recall product category in Q4 2023 in terms of events with 27 recalls. Prepared Foods was the second-highest category with 19 recalls, and Baked Goods was third with 15.

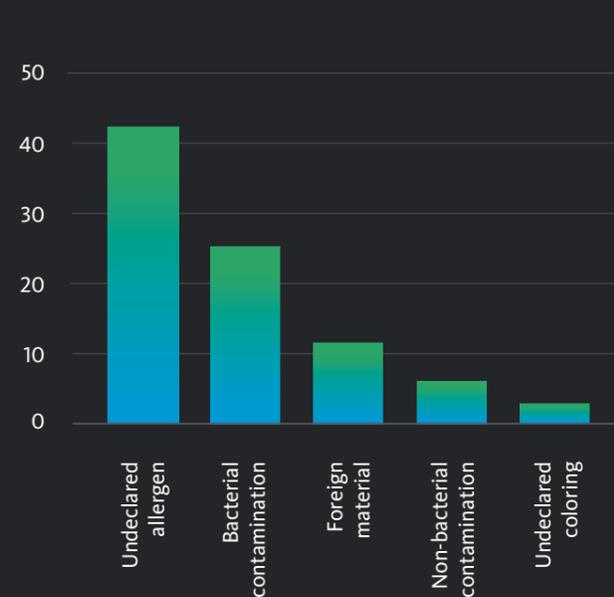
In terms of units impacted, Flavorings had the most with 3.12 million units, largely fueled by the applesauce recall. Produce was second with 1.07 million units affected, and Prepared Foods was third with 734,669 units involved in recalls.

The number of Class I recalls in Q4 2023 rose to 47 compared to 38 in Q3. With this increase, Class I recalls for the whole of 2023 reached a 5-year high. In terms of recalled units, the number of Class I designations fell from 12.73 million to 4.51 million quarter-over-quarter. In contrast, the number of Class II and III recalls decreased to 49 and nine respectively, compared to 74 and 19 in the previous quarter. Not surprisingly, the number of units recalled also decreased in both categories. The Class II units dropped from 5.20 million to 1.59 million. Even more dramatic was the decrease in Class III recall volume from 22.27 million units in Q3 to 106,491 units in Q4. To give some context, the Q3 figure was the highest number of units recalled in this class in the past 13 years, so it is unsurprising that the Q4 number was lower.

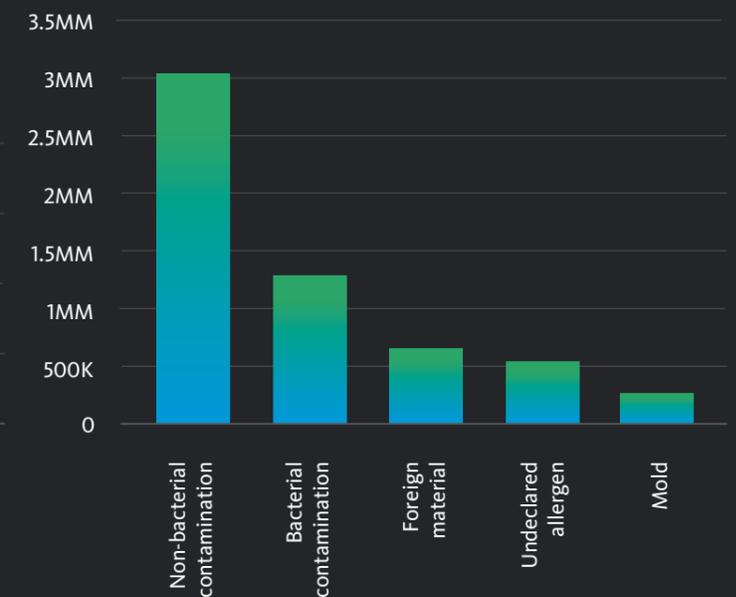
The FDA issued 46 food and drink recalls in January 2024, up 31.4% from the Q4 2023 monthly average of 35 events. The number of units recalled in January increased to 3.6 million units compared to the Q4 monthly average of 2.07 million.

Undeclared allergens remained the leading cause of FDA food recalls with 17 events in January 2024. Bacterial contamination was the second-leading cause with 13 events, including one for powdered infant formula contaminated with *Cronobacter sakazakii*. Bacterial contamination was also the leading cause of FDA food recalls by volume, accounting for 1.54 million units in January 2024. It was followed closely by foreign materials which impacted 1.51 million units.

NUMBER OF FDA RECALLS BY REASON IN Q4



FDA UNITS IMPACTED BY REASON IN Q4



USDA

By recall event, 2023 had the most annual incidents in the past four years. There were 65 USDA recalls for the year, compared to 46 in 2022. There were also more units recalled in 2023 with 4.03 million pounds, compared to 1.73 million pounds in 2022, though this year is far from the five-year high of 13.35 million pounds set in 2021.

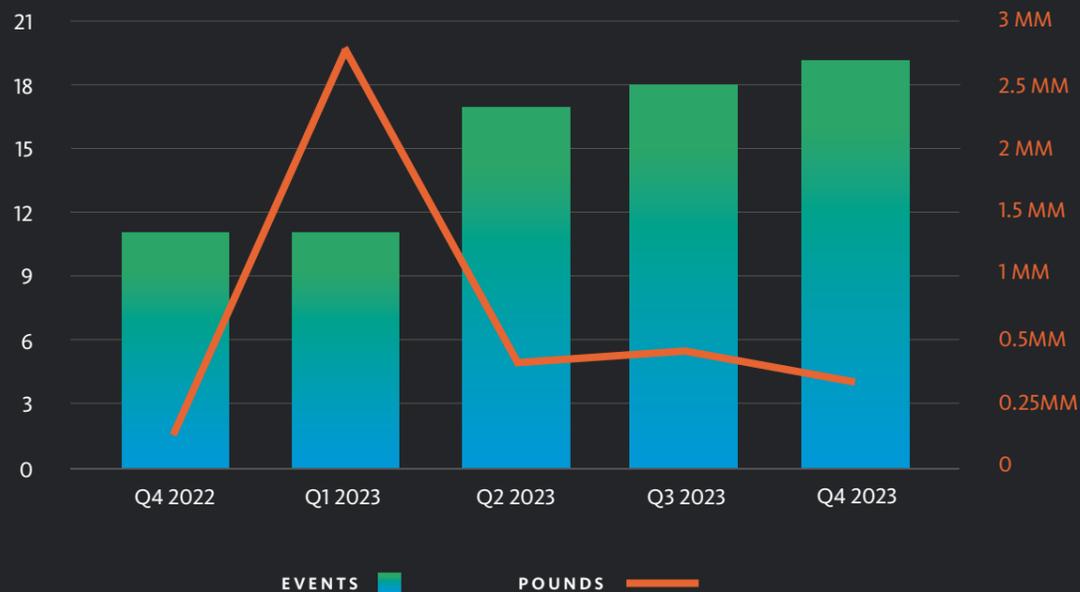
In Q4, the number of USDA food recalls increased slightly from Q3, going from 18 to 19 events. However, the number of units decreased by 33.8% from 467,811 pounds last quarter to 309,722 pounds this quarter.

The top reason for USDA recalls by event was bacterial contamination with six events. No inspection, foreign materials, and misbranding/undeclared allergens were tied for second with three events each. Ineligible to export was linked to two recalls, and no import inspection and quality issues were linked to one recall apiece.

By unit count, misbranding/undeclared allergens was the leading cause of recalls, impacting 163,481 pounds. Foreign materials was second, linked to 61,989 pounds of product recalled. Beef was responsible for the most units recalled by product category in Q4 2023 with 170,725 pounds. Poultry was second with 87,937 pounds recalled, and pork was third with 44,567 pounds impacted.

Poultry had six recalls, the most of any product category. Beef was second with five events, and multiple meats and pork were each involved in four USDA recalls in Q4 2023.

NUMBER OF USDA RECALLS AND IMPACTED POUNDS BY QUARTER



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In January 2024, the USDA issued two recalls, down from the Q4 2023 monthly average of 6.33 events. However, the number of pounds recalled increased to 144,136 compared to the Q4 monthly average of 103,241 pounds, up nearly 28%.

Of the two USDA recalls, one was for foreign materials and affected 133,039 pounds of poultry products. The second was for bacterial contamination, specifically Salmonella, which impacted 11,097 pounds of pork products.





SONIA NATH, PARTNER,
COOLEY LLP

THE TOP FDA CONCERNS IN 2023

The infant formula crisis of 2022 still dominated FDA activity in the food sector throughout 2023. The agency issued numerous letters and guidances, both to help manufacturers protect the supply of infant formula and to show that it was proactively working to prevent another serious incident. There were three more infant formula recalls in 2023, which shows there are still issues in the industry that need to be addressed.

However, the FDA's activity wasn't isolated to one product. The agency dealt with a range of other foodborne illness recalls including a large outbreak of salmonella in cantaloupe and a growing concern for applesauce tainted with lead.

The FDA is not only looking to help manufacturers and distributors make their processes better, but it is also focused on improving its own systems. The agency is working to implement a major restructuring with the aim of adding more efficiency and accountability throughout the organization.

Infant Formula Update

Since the 2022 recall of infant formula due to **Cronobacter sakazakii** (**C. sakazakii**) contamination, ensuring the safety and availability of infant formula has been a top priority. In 2023, the FDA took additional actions to address safety challenges in the wake of the 2022 recall and the resulting infant formula shortage. These actions included 47 routine

inspections of infant formula manufacturing facilities in accordance with the [Food and Drug Omnibus Reform Act of 2022](#), as well as issuing [warning letters to three infant formula manufacturers](#).

In March 2023, the FDA [published a letter to the industry](#) noting areas of concern identified during inspections, calling on companies to ensure they are in compliance with all regulatory requirements, and requesting voluntary notification to the FDA of any positive testing for **Cronobacter** or **Salmonella** in infant formula. The agency said that it should be notified even if the contamination is discovered before the affected product is distributed.

Internally, the FDA has initiated hiring to support a "dedicated investigator cadre" to inspect infant formula manufacturing sites. It also added staffing resources for the proposed new Office of Critical Food and [updated its infant formula compliance program](#) for investigators, analysts, and compliance officers.

Despite efforts by the agency and the industry to combat infant formula contamination, there were three additional formula recalls due to potential **C. sakazakii** contamination in 2023. One company [announced a recall](#) of one of its brands of formula on March 17, 2023. The recall was limited to 13 lots of the product and was issued out of caution rather than any positive tests from distributed products.

The two other recalls were initiated by a second company that had two prior incidents of its finished products testing positive for **C. sakazakii** in 2022. Following inspection of the company's Michigan and Minnesota facilities in late 2022 and early 2023, the FDA [issued a warning letter](#) to the company in August 2023. This letter discussed concerns with the manufacturer's root cause analysis and its failure to conduct whole genome sequencing.

While the second company's root cause analysis pointed to an ingredient manufactured by a third party, the [FDA indicated](#) that whole genome sequencing would have provided more information about the strain of **C. sakazakii**. The agency said this information, in turn, could have better informed the root cause analysis and the necessary corrective actions.

In February 2023, following additional FDA review of sanitation records from the Michigan facility and discussions with the agency, [the company announced a recall](#) of two batches of one brand of infant formula due to a risk of contamination. The product was manufactured in the same continuous production campaign as one of the samples that tested positive for **C. sakazakii**. This recall impacted approximately 145,000 cans of formula. It was followed by another recall of six batches for a different brand of powdered infant formula in late December after the Israeli Ministry of Health identified a positive finding during product sampling upon import. Upon notification from the Israeli Ministry of Health, the FDA initiated a for-cause inspection of the facility.

Subsequent testing by both the FDA and company has been negative for **Cronobacter**, although the manufacturer has [expanded the recall to 19 countries](#). Given prior **Cronobacter** issues at the company's manufacturing facilities, as well as the FDA's August 2023 warning letter, it remains to be seen what, if any, further enforcement the agency may pursue following these recalls.

When the 2023 recalls are considered, three of the four largest U.S. infant formula manufacturers have issued a recall in the past two years.

Other Foodborne Illness Under Scrutiny

Outside of the FDA's ongoing efforts to combat infant formula contamination, the agency also published [nine public health advisories arising from investigation of foodborne illnesses](#) in 2023. While **Salmonella** and **Listeria** were the primary reasons for these advisories and the corresponding recalls, potentially toxic morel mushrooms, elevated levels of lead in applesauce pouches, and Hepatitis A contamination in strawberries were also concerns.

An outbreak of **Salmonella** infection in cantaloupes first reported in November 2023 resulted in [one of the year's most widespread series of recalls](#). Growers initiated [several recalls](#) in late 2023. Later, nine more companies that further processed or repackaged the contaminated products were added to the recall. The contaminated products were distributed nationwide and were [associated with 407 cases of illness and six deaths](#).

CFSAN Reorganization

In addition to its steady pace of enforcement actions, the FDA began efforts to restructure oversight of food under a new unified Human Foods Program (HFP) in 2023. The proposed changes arose from a report by the independent [Reagan-Udall Foundation](#) conducted in the wake of the infant formula crisis. The evaluation identified a number of areas for improvement including siloed operations, a lack of a single individual as a leader, and the need for internal agency reviews, clearly defined roles and responsibilities, and feedback from stakeholders and contributors.

Since the initial publication of the report in December 2022, the [FDA has taken steps toward restructuring](#) the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Food Policy and Response (OFPR), and functions of the Office of Regulatory Affairs (ORA) under the new HFP. In August 2023, James Jones was named Deputy Commissioner for Human Foods and in December, the agency released its proposal for reorganization.

[Among the proposed changes](#), the ORA will be renamed the Office of Inspections and Investigations. In addition, an Office of Critical Foods will be established within the Nutrition Center of Excellence and be tasked with ensuring the safety of infant formula. Also included in the plan is making the Office of Coordinated Outbreak Response and Evaluation (CORE) & Emergency Preparedness responsible for preparing the agency for food-related outbreaks, including recalls.

[The reorganization also establishes](#) an Office of Integrated Food Safety System Partnerships, which would coordinate with state and local regulatory agencies to strengthen food safety and response activities. The proposed reorganization is currently undergoing the required external review process. The FDA hopes that it will be able to implement the plan during 2024.

What's Ahead for 2024

Based on its activities in 2023, it is clear that even as the major internal changes move forward, the FDA will continue its enforcement actions, especially around critical foods such as infant formula. However, it will need to clearly communicate to stakeholders which offices have oversight over which processes and how any mandatory reporting processes may change. There may be a transition period while food companies and regulators get aligned.





MEDICAL DEVICE

As we have seen in other industries, there is a growing trend of attorneys general (AGs) applying pressure to government agencies if the AGs don't think change is happening fast enough. In November, 25 state AGs [sent a letter](#) to the U.S. Food and Drug Administration (FDA) demanding urgent action to address pulse oximeter inaccuracies for people of color.

The letter came exactly one year after a public meeting held by the Anesthesiology and Respiratory Therapy Devices Panel of the FDA's Medical Devices Advisory Committee and almost two years after the agency issued a safety communication about device inaccuracies when used on people with dark skin pigmentation.

The letter urged immediate action by the agency, alleging that people with darker skin tones are facing unnecessary health risks. Even if the FDA delays action, device manufacturers should review the AG's demands and see if there are changes they should make ahead of any mandatory regulations.

In another move that could impact a range of medical devices, the FDA announced in October that it is creating a new Digital Health Advisory Committee to provide guidance on issues relating to digital health technologies, including artificial intelligence, wearables, virtual reality, and remote patient monitoring.

The committee will consist of nine voting members including the chair, with temporary members added for a specific meeting depending on the topic. The agency encouraged parties interested in serving or nominating a representative to visit the [FDA Advisory Committee Membership Nomination Portal](#).

A topic that will likely be under the Digital Health Advisory Committee's purview is medical device cybersecurity. The FDA issued its final guidance in September on steps manufacturers need to take in their premarket submissions to ensure cyber devices are secure.

“*The FDA issued its final guidance in September on steps manufacturers need to take in their premarket submissions to ensure cyber devices are secure.*”

The agency is also working to transition into normal operations for device manufacturers and other stakeholders now that the COVID-19 public health emergency has ended. To help with that adjustment, it published a draft guidance on its enforcement policy for non-invasive remote monitoring devices. The document gives manufacturers more leeway in making minor adjustments to devices without filing new authorizations with the FDA.

The FDA also made progress in allowing device manufacturers to share scientific information on unapproved uses of approved/cleared medical devices. While there are still certain restrictions, a draft guidance issued in September authorizes manufacturers and distributors to share scientific information with healthcare providers about uses for their devices that were not authorized in the product's FDA approval. This does not mean that the agency will overlook all instances of scope creep.

While the FDA is rolling out new requirements for medical devices including the broad cybersecurity rules, the agency does seem to be trying to give manufacturers some ability to make minor adjustments or use cases without going through the onerous approval process. However, one thing is clear. The agency will always put patient safety first.

Final guidance issued for medical device cybersecurity

The U.S. Food and Drug Administration (FDA) issued its final guidance [Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions](#) at the end of September, updating an April 2022 draft.

After the Food and Drug Omnibus Reform Act (FDORA) was signed in December 2022, the FDA gained new statutory authority to require cybersecurity information in medical device submissions for “cyber devices” and to mandate that medical device manufacturers demonstrate “reasonable assurance” that such devices and related systems are cybersecure. In addition, under FDORA, companies who do not comply can face possible government criminal prosecution and other injunctive relief.

The mandatory cybersecurity information includes the need to submit a plan to monitor, identify, and address postmarket cybersecurity vulnerabilities and exploits; to make postmarket updates and patches available to devices and related systems to address certain cybersecurity vulnerabilities; and to provide a software bill of materials, including commercial, open-source, and off-the-shelf software components.

The FDA delayed the enforcement date of the new requirements from March 29, 2023 to October 1, 2023, saying in a [guidance](#) that it would not issue “refuse to accept” notices if premarket submissions lacked the mandated cybersecurity information until the later date and would work with device manufacturers in the interim.

[An analysis by attorneys with Ropes & Gray LLP](#) notes several changes in the final guidance compared to the earlier draft. These include the addition of a new subsection encouraging companies to conduct a cybersecurity risk assessment to help determine vulnerabilities present within a device, system, or the use environment.

The FDA also recommends that device manufacturers assess interoperability considerations if the device interfaces with other medical devices and accessories, the functions identified in the FDA's [Multiple Function Device Products: Policies and Considerations](#) guidance, relevant healthcare infrastructure, and general purpose computing platforms that may impact cybersecurity.

To help manufacturers comply with the new requirements, the final guidance includes a checklist of documents that the FDA recommends companies include in their premarket submissions.

[The legal experts stress](#) that new guidelines are another reminder that the FDA expects device manufacturers to protect against cybersecurity risks throughout the full product lifecycle. This will require companies to devote more resources to monitor for novel risks and develop ways to mitigate emerging vulnerabilities. They caution companies that while updating devices to respond to new vulnerabilities can be risky and expensive, there is more risk in doing nothing, especially with the FDA's new enforcement authority.

“Manufacturers are cautioned that while updating devices to respond to new vulnerabilities can be risky and expensive, there is more risk in doing nothing, especially with the FDA's new enforcement authority.”

FDA outlines enforcement policy for remote monitoring devices

In October, the FDA published its [Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring](#) guidance. This follows the June [publication of a request for public comment](#) around increasing patient access to at-home use medical technologies.

[Legal experts with Foley & Lardner](#) call the new guidance a win for manufacturers of remote patient monitoring and remote therapeutic monitoring devices. In an analysis of the draft guidelines, [the attorneys note](#) that the FDA will allow limited modifications to the indications, functionality, and hardware or software architecture of certain cleared medical devices without requiring agency approval for the changes.

In the document, the FDA gave an example to illustrate that a modification to the indications to allow a device to be used in a patient's home, as opposed to in a hospital setting, does not create undue risk and does not affect the physiological parameter measurement algorithm. Physiological parameter measurement algorithms are used to monitor functions such as heart rate, blood pressure, body temperature, oxygen saturation, respiratory rate, muscle strength, metabolic rate, and hormonal levels.

The FDA does note that modifications to devices that could create undue risk or affect the physiological parameter measurement algorithm would generally still require the submission of a 510(k) for the alteration. These would include changes to allow for remote programming or control of the device, measurement of new physiological parameters, or a change from prescription to over-the-counter use.

Manufacturers of devices that measure or detect common physiological parameters should review the draft proposal carefully. It may save them from having to undertake the 510(k) clearance process for small changes covered under the guidance and allow for broader use of their products in ways that may promote health equity.



Guidelines for off-label and unapproved uses for medical devices published

Medical device manufacturers need to be cautious not to promote uses that were not part of the FDA's clearance for a product. In September 2023, the agency released three new guidances around its 510(k) program, which is used to reasonably assure the safety and effectiveness of new products for a specific approved intended use. It also issued warning letters to two companies for claims outside their approved uses.

In December, the [U.S. Court of Appeals for the First Circuit affirmed the convictions](#) of two medical device company executives on multiple misdemeanor violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act). They were found guilty of commercially distributing an adulterated and misbranded medical device for an intended use different from the one the FDA had approved.

To help avoid these types of violations, the FDA issued a revised draft guidance, [Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products – Questions and Answers](#) (SIUU Draft Guidance), in October.

Under the FD&C Act, manufacturers may not sell or market medical products for an intended use that has not been approved or cleared by the FDA. The agency acknowledges that there are situations when healthcare providers may want scientific information about unapproved uses of FDA-approved/cleared medical products to guide the treatment and care of an individual patient.

Documents that can be shared under the SIUU Draft Guidance include published scientific or medical journal articles, published clinical reference resources such as medical reference tests and materials from independent clinical practice resources, or company-generated presentations of scientific information from an accompanying published reprint.

The FDA publication clarifies that these guidelines are only for FDA-approved/cleared medical products, including specific types of medical devices and drugs.

[Attorneys with Ropes & Gray LLP](#) call the proposed guidelines “a significant departure” from a 2014 draft, in part because the latest document explicitly says that firms can share their own presentations about off-label reprints. The publication also acknowledges social media as an acceptable channel to share scientific information about unapproved uses of approved/cleared medical products.

[The legal experts point out](#) that the current draft introduces a new substantiation standard that requires that any studies or analyses referenced be “scientifically sound” and “clinically relevant.”

The document makes several other recommendations for SIUU communications including that the materials should not use “persuasive marketing techniques;” they focus on the scientific content of the communication; they are separate and distinct from promotional communications about approved uses of the products; and companies use “dedicated vehicles, channels, and venues” for these types of materials.

[Lawyers with Sidley Austin LLP](#) warn companies that even if they are in full compliance with the new guidance, they could be liable for “off-label” promotion violation. The legal experts recommend that device manufacturers and pharmaceutical companies assess the potential risk of SIUU communications as they relate to a particular off-label use and balance that with possible benefits before moving ahead with any communications.

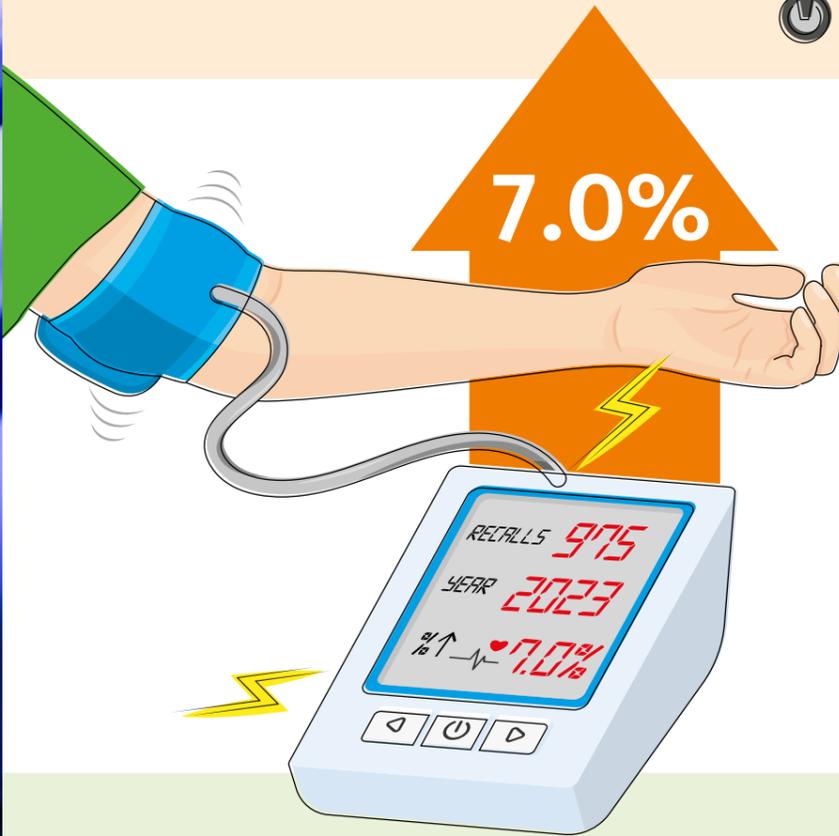


“ *In December, two company executives were convicted on multiple misdemeanor violations of the FD&C Act for commercially distributing an adulterated and misbranded device for an intended use different from the one approved by the FDA.”*



Accounting for 152 events (15.6%), **quality concerns were the leading cause of recall activity in 2023.**

Quality was the leading cause for 3 out of 4 quarters in 2023. The last time Quality was the leading cause in a given quarter was in Q1 2016.

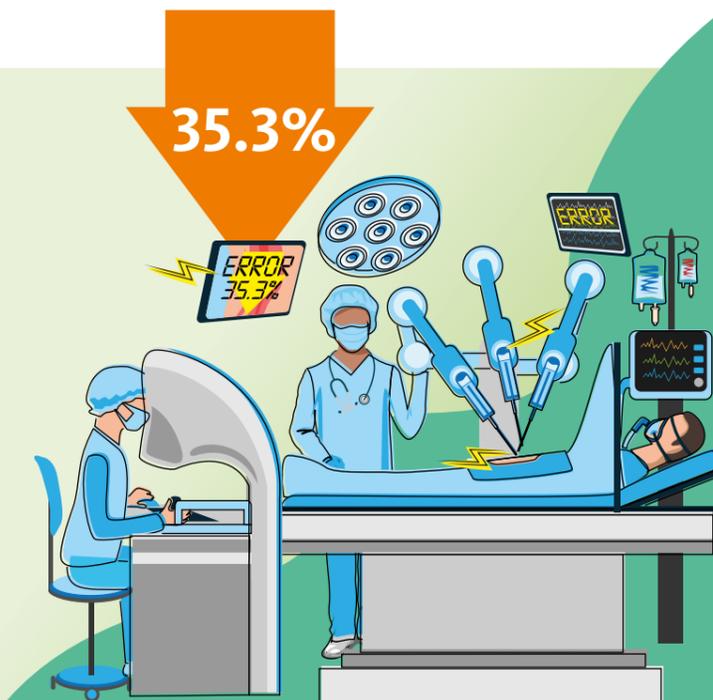


Medical device recall events increased 7.0% in 2023, from 911 (in 2022) to 975.

There were 85 Class I designated events, representing a 15-year high. For context, the last 5 years have recorded an average of 54 Class I designations annually.

While recall events increased, the **number of defective devices plummeted 35.3%**, from 438.4M in 2022, to 283.4M.

With annual events increasing 7.0%, and defective units declining 35.3%, the average recall size contracted to 290.7K units in 2023. For context, the average recall size of the last 5 years has been 508.5K.



2023 BY THE NUMBERS

There was a total of 975 medical device recalls in 2023, representing a three-year high. This is a 7.0% increase from the 911 events in 2022. However, from the perspective of units impacted, 2023 had the lowest total in six years with 283.44 million units recalled. This is a 35.3% drop compared to the 438.37 million units recalled in 2022.

Comparing quarter-to-quarter, the number of medical device recalls and units affected were both higher in Q4 than in Q3 2023. There were 260 recalls, a 17.1% increase from the 222 events in Q3. The number of impacted units rose by 346.6% to 109.35 million in Q4.

Quality issues was the leading reason for recalls in the sector, accounting for 44 events in Q4 2023. Mislabeling concerns was the second-most common cause and was linked to 31 events this quarter. Parts issues was third with 25 recalls.

In terms of volume, products out-of-specifications was the top reason for recalls in Q4 2023 affecting 50.78 million units, including a recall for infusion sets that impacted

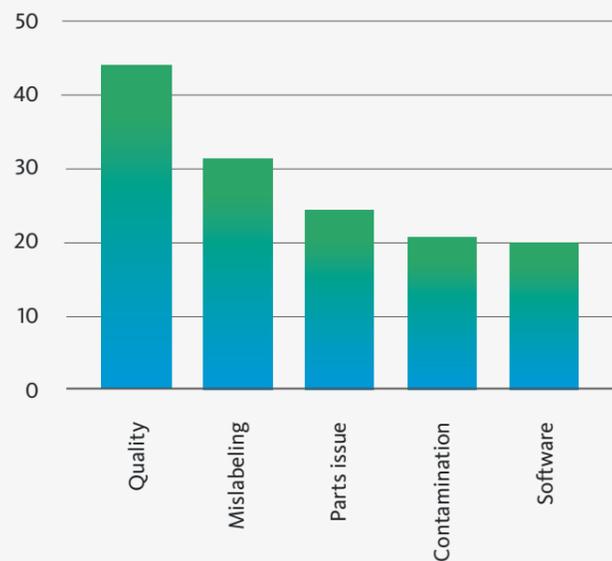
33.82 million units. Quality issues affected the second-highest number of medical device units with 30.08 million recalled in Q4, primarily due to a single recall of masks. Mislabeling affected 20.40 million units, making it the third most-common reason for recalls in this industry.

Across the 260 recalls, 150 unique companies were involved. Of this figure, 43 companies cited multiple events – 38 of these reported between two and five recalls, two reported between 6 and 10 event, and three reported in excess of 10 events each. One company had 18 events, mostly for contamination concerns.

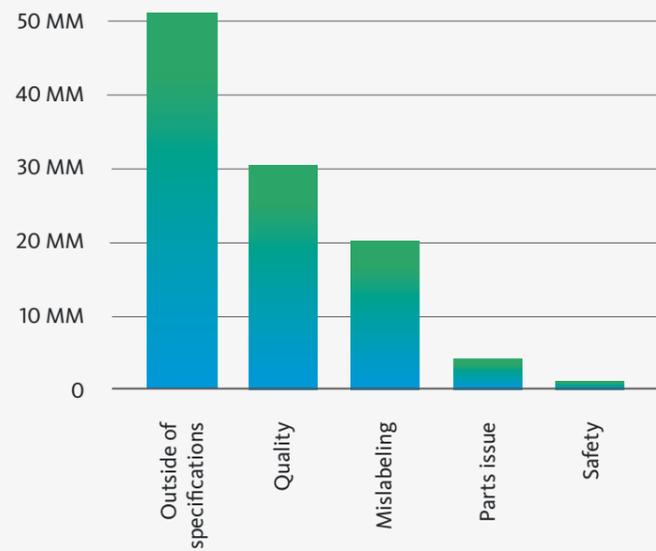
The number of recalls and units impacted rose for Class I and II medical devices between Q3 and Q4 2023. The number of units involved in Class I recalls rose from 649,124 across 19 events in Q3 to 81.31 million units across 28 recalls in Q4. In contrast, the number of Class III recalls dipped from four to three, and the number of units impacted fell to 151, the lowest number in a single quarter since Q2 2006.



NUMBER OF RECALLS BY REASON IN Q4



NUMBER OF UNITS IMPACTED BY REASON



JANUARY 2024 insight

There were 44 pharmaceutical recalls in January 2024. This is on par with the Q4 2023 monthly average of 43.67 events. The number of units recalled decreased by nearly 85% to 881,431 compared to the Q4 2023 monthly average of 5.77 million units.

By volume, contamination impacted the most units with 412,542. Foreign materials was second with 181,642 units affected, followed by superpotency issues which impacted 93,163 units in January 2024.

Contamination was also the most common recall cause by event with 16 recalls in January 2024, including two involving benzene. Failed specifications and foreign materials tied for second with seven events each, followed by superpotency with six recalls.

The FDA classified 12 pharmaceutical recalls in January 2024 as Class I and two as Class III. The remaining 30 recalls were designated as Class II and impacted 671,066 units.

MITIGATING SOFTWARE RISKS FOR MEDICAL DEVICES

There are numerous risks for medical device manufacturers and distributors. One example is design and component materials issues including product sterility and contamination. There were nearly 39.4 million units recalled over sterility concerns in 2023 across the medical device industry. Mislabeling is another notable source of potential safety risks and resulted in 102 recalls last year.

Changes in upstream suppliers, and in a company's supply chain generally, can also contribute to concerns relating to materials and overall manufacturing. Some of these sources of risk may be shared by more than one device within a company's offerings. For example, there may be systemic vulnerability in a suite of devices that would create a separate, additional dangers for companies.

One area that has seen a significant increase in risk is software and cybersecurity issues. The 2022 Food and Drug Omnibus Reform Act (FDORA) gave the FDA statutory authority to regulate cybersecurity in medical devices. Previously the agency could offer guidance but had no real enforcement power. Now there are a number of regulations in place or proposed, along with potential penalties.

Threats to medical device software

For software, risk mitigation begins with rigorous and ongoing validation of software development and software changes. It also requires careful validation of third-party software. Proactive software changes can often prevent potential risks before they occur.

Relatedly, cybersecurity is an ever-growing concern. The FDORA mandates that submissions for software as a medical device (SaMD), and for most connected devices containing

software—also known as software in a medical device, or SiMD—include a plan for addressing postmarket cybersecurity vulnerabilities. The sponsor must also have a software bill of materials (SBOM) to identify third-party components and procedures for addressing risks to the device.

Devices cleared or approved before this requirement took effect do not have to comply. However, it would be advisable for companies to voluntarily adopt these steps for any software devices that are already cleared or approved. Doing so will help insulate these devices from cyber vulnerabilities and put the company in a strong position to engage with the FDA in the event that an issue occurs.

Companies should also evaluate their materials qualifications and design validation practices. Supply chain disruptions can leave a company scrambling to find a new supplier for a component, part, or service. Using a new supplier can introduce its own unforeseen risks due to new materials or a new risk of malfunction. Strong "gatekeeping" at the front end of the procurement and sourcing process should be paired with rigorous surveillance at the back end in the testing and validation stages. Vigilant signal detection from the manufacturing process, release testing, or field reports can potentially identify early signs of a manufacturing-related issue.



Another recent change in law authorizes the FDA to grant predetermined change control plans (PCCPs) for a cleared or approved device. PCCPs allow a company to make specified modifications to their device that would otherwise require premarket review by the FDA. Particularly for devices for which changes can be readily anticipated and characterized, such as a software patch or a materials change, companies should consider approaching the FDA about obtaining approval for a PCCP.

A PCCP cannot be used for a change needed to address a violation, such as a device that is being recalled for a safety issue. However, it can empower a company to make certain proactive changes before there is a safety or effectiveness issue with the device.

Changes to the recall landscape

In September of 2023, the FDA held a public meeting on modernizing recalls of FDA-regulated commodities. FDA officials have indicated interest in revisiting the agency's [broadly applicable regulations on recalls](#) to provide greater clarity. The agency has also indicated a desire to improve its own recall response and engagement with companies in terms of timeliness and efficiency of communications. The FDA's recently announced restructuring, which is pending approval, is designed in part to improve recall coordination between product centers and the "field."

The vast majority of device recalls are voluntarily initiated, and in most cases must be reported to the FDA. Companies are to report a correction or removal within 10 days of initiation. The agency would prefer notification about a correction or removal of a device, or even the potential for

a correction or removal, even earlier when possible. The FDA is likely to continue seeking more substantive and earlier engagement from medical device companies.

Companies may also be encouraged to identify issues sooner and to be proactive about addressing such issues. The agency's interest in earlier communication is driven by a desire to mitigate and prevent both public health impact and shortages and supply chain disruptions. Moreover, once a recall notification has been made, there will be greater scrutiny as to whether the recall is appropriately scoped, and whether the company has considered all the potential effects deriving from the root cause of the recall—in particular, effects on other devices.

Another important trend relates to how recalls are communicated to providers and patients, and by whom. In recent years, the FDA has studied whether patient-focused recall communications are sufficiently clear and effective. The agency has also assessed communication channels for sharing recall information with hospitals and other providers and become more assertive about sharing information on its own about device safety issues.

These trends are occurring against a backdrop of the FDA seeking to place more responsibility for patient education on device companies throughout the product lifecycle. In the context of recalls, there is growing scrutiny of the nature and breadth of information that companies share about recalled devices, as well as greater focus on assessing the effectiveness of these communications. These changes will pose challenges for companies and may require an assessment of existing practices relating to communications with patients and providers.

**NATHAN A. BROWN, PARTNER,
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CONTINUED FROM PREVIOUS PAGE

Looking forward

The way medical devices are used and the technology that powers them are advancing rapidly. Many device types are becoming more sophisticated, partly through harnessing software and artificial intelligence (AI). At the same time, there is an inexorable movement towards more at-home and near-patient care. This includes at-home testing and sample collection for diagnostics and more monitoring devices being authorized for at-home use. Connected devices are paving the way towards diversified sites of care.

These disparate advances in health care nevertheless pose challenges for companies to monitor device performance and communicate with a wider array of intended users about devices—and when necessary, about recalls. Moving forward, there will be increasing regulatory attention to device-related communications, particularly as patients play a more direct role engaging with medical technologies.

The other significant area for change relates to the opportunities for more sophisticated surveillance of device performance and signals, either through the use of AI or other technological advances. Currently, there is a stark regulatory divide between a proactive change made to prevent a quality or safety issue (such as a device enhancement) and a correction or removal made to address a quality or safety issue that has already occurred.

Both the regulators and device manufacturers share an interest in facilitating a more proactive product lifecycle management approach to quality. Such an approach would place greater emphasis on device adaptation and would mitigate the impact of device recalls.





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COMPANIES BEWARE: MORE FDA ENFORCEMENT ACTIONS AHEAD

Medical device recalls have already received considerable attention in 2024. In January, the U.S. [Government Accountability Office \(GAO\)](#) accepted a [request from Senators Richard Durbin \(D-Illinois\) and Richard Blumenthal \(D-Connecticut\)](#) to review the U.S. Food and Drug Administration’s (FDA)’s oversight of medical device recalls. The senators’ request was made following multiple high-profile medical device recalls in the past several years involving ventilators, bilevel positive airway pressure machines, and continuous positive airway pressure (CPAP) machines. Hundreds of deaths have been linked to these products.

[In their December 2023 letter to the GAO](#), Senators Durbin and Blumenthal suggested that “FDA missed several opportunities to mitigate the harm done to the millions of patients who have used these recalled medical devices.”

In September 2023, [a CPAP machine manufacturer agreed to pay at least \\$479 million](#) in a settlement over alleged health risks. On January 29, 2024, the [manufacturer announced that it had entered a consent decree](#) with the government and would cease selling products used to treat sleep apnea in the U.S. While the terms of the decree were not disclosed because it had not yet been granted by the court, the company’s full compliance with the decree will likely take significant time and resources. Recalls can be costly, both financially and in terms of a company’s reputation.

FDA’s medical device recall authority

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines “device” broadly to include any product intended

to diagnose, cure, mitigate, prevent, or treat a disease or condition. It also applies to any product intended to affect the structure or any function of the body. To be considered a medical device, the product should not rely on chemical action within or on the body to achieve its primary intended purposes. [Certain software functions](#) are excluded from the device definition under the FD&C Act.

The FD&C Act authorizes the FDA to regulate medical devices in both premarket and postmarket settings to prevent adulterated and misbranded devices from being distributed in interstate commerce. If a medical device violates FDA regulations or poses a health risk to patients or users, under the FD&C Act the manufacturer may propose to correct or remove the device. [Corrections may include](#) repair, modification, adjustment, relabeling, destruction, or inspection, including patient monitoring. The FDA considers both corrections and removals to be recalls, which may involve not only the manufacturers, but also distributors, health care providers, and/or patients.

Most medical device recalls are conducted voluntarily by the manufacturer after it discovers a problem or the FDA raises a concern. In rare instances, if the manufacturer seems unwilling to initiate a voluntary recall and the FDA determines there is a “reasonable probability” that a device would cause “serious, adverse health consequences or death,” the agency may order the manufacturer to recall the violative device and notify health professionals and device user facilities. The FDA may also initiate a seizure action to remove the device from market.

Trends in medical device recalls

Class I recalls have increased over the last few years. This classification is the most serious and reserved for situations in which use of the product presents a reasonable probability of serious adverse health consequences or death. There was a 59.5% increase in the number of Class I recalls between 2020 and 2021, rising from 42 to 67. The number then increased steadily from 67 in 2021 to 70 in 2022 and 85 in 2023. Class I recalls in 2024 are projected to continue to increase at the rate of eight Class I recalls per month [based on FDA data for January 2024](#).

However, Class I recalls only make up approximately seven percent of medical device incidents. Class II recalls are responsible for roughly 90% of all medical device recalls in the U.S. and are used for violative devices that may cause temporary medically-reversible adverse health consequences or that have a remote probability of causing serious adverse health consequences. Class III recalls, the least serious type of event, constitute an average of three percent of all medical device recalls.

Recall data from January 2023 through January 2024

Class I recalls

In January 2024, [FDA issued](#) eight Class I recalls that impacted more than 20 million units and were linked to more than 100 injuries. All of the eight events were voluntary recalls by the manufacturer.

A [notable Class I recall in January 2024](#) involved patient return electrodes, which are used in medical procedures involving electro-surgical instruments. The devices are

designed to safely remove electrical currents from patients during surgery. There were reports of patient injuries associated with use of these electrodes, including third-degree burns that require intervention and may lead to extended hospital stays, scarring, and additional surgeries in both pediatric and adult patients. Moreover, severe burns could lead to long-term effects on patients, especially those under 12. These recalls have impacted 9,428 units, with 99 reported injuries linked to the recalls. The device’s instructions for use and labeling are being updated to restrict use of the device to patients 12 years and older.

Another notable Class I recall in January 2024 was for possible magnetic interference between certain medical devices and CPAP masks containing magnets. Under certain circumstances, when a magnet is less than two inches from certain medical devices, the magnet might disrupt the devices’ function or position, possibly causing serious harm or death. While the existing label for the CPAP masks advises keeping magnets two inches away from affected medical devices, it does not list all the specific devices that could be affected by the magnets in the device. The manufacturer is recalling the masks to update the labels and add more warnings and information to guide patients and health care professionals on safe usage. This recall impacted more than 20 million units, and six reported injuries have been linked to the device.

In 2023, there were 85 device recall events designated as Class I, which impacted more than 164.67 million units. All of these were voluntary recalls.

One notable Class I recall in 2023 began with a voluntary recall in December 2022 for a continuous ambulatory delivery device (CADD). The event continued into 2023 due to reports of at least two deaths, 14 injuries, and 1,571 incidents. Although this CADD system is intended to deliver controlled amounts of medication to a patient through a vein or other cleared rounds of administration, defects in the system caused under-delivery or non-delivery of medication while falsely displaying that the medication had been administered. In response, the manufacturer sent an [Urgent Medical Device Correction Letter](#) to customers warning of the issues and proposing safety measures to mitigate the problems.

One of the most significant recalls in recent years was first issued in 2021 for sleep apnea and respiratory care products (i.e., ventilators, bilevel positive airway pressure machines, and CPAP machines). Hundreds of deaths have been linked to those events, and as mentioned, one manufacturer has agreed to pay \$479 million and cease selling products used to treat sleep apnea in the U.S.

Class II recalls

In January 2024, 91% of all [reported medical device recall events](#) were designated as Class II. These 160 recalls included issues such as intraocular lens containing an angle out of specification, the potential for a light system to fail in the operating room, a loss of vacuum in the inner-most vacuum bag of the tibial inserts, and suction canister liners possibly experiencing loss of suction on low settings due to a misalignment of the liner with the outer hard canister.

In 2023, 869 events, or nearly 90% of all reported medical device recalls, were designated as Class II. These included issues such as sterile product pouches that were not sealed and labeling containing incorrect information in the maintenance schedule.

Class III recalls

In January 2024, there was only one event classified as Class III. It was a voluntary recall due to decreased reactivity of a reagent in an in vitro diagnostic product.

Similarly, in 2023, less than three percent of medical device recalls were designated as Class III. [These 21 reported events](#) were voluntary and included recalls for issues such as boxes of face masks incorrectly labeled as having ties rather than ear loops and some incorrect expiration dates.

Consent decrees associated with recalls and best practices

A consent decree is a court-approved order for permanent injunction that reflects a negotiated agreement between the FDA and an FDA-regulated company. Although

litigation is always an option, companies typically resolve complaints brought by the government under the FD&C Act through consent decrees rather than litigating such cases due to the uncertainty and costs associated with actions in federal court. Although such cases are generally tried before judges in “[bench trials](#)” rather than jury trials, judges tend to be swayed by the agency’s interest in protecting the public health. Additionally, the agency usually brings such cases after using other tools to encourage voluntary compliance such as requesting recalls or [issuing warning letters](#).

In most cases the FDA’s observations of product quality and safety issues associated with the recalled products and the agency’s subsequent warnings to the manufacturer precede any consent decrees. Based on data reported by Sedgwick, 152 medical device recalls (or approximately 15% of recalls) from January 1, 2023 through December 31, 2023 were due to issues with the quality of the devices, such as flawed designs and sterility concerns. The second-most-likely cause for a medical device recall was parts issues which was linked to 111 recalls.

By being alert to recent recall trends, companies can be ahead of the curve and [implement prudent practices to minimize the possibility of recalls and ensure that if recalls do occur they are conducted effectively](#). Possible steps include adhering to the quality management system (QMS) controls for design and development of devices; ensuring that there is an adequate process for sourcing conforming materials and components; developing recall procedures that include “downstream” recalls; having adequate product coding; and maintaining distribution records to facilitate faster, more accurate recall actions.

It is likely that at some point every medical device company may face a recall. Being well-prepared helps minimize the negative impact of an event.



PHARMACEUTICAL

In November, the U.S. Food and Drug Administration (FDA) issued its final rule on [Direct-to-Consumer Prescription Drug Advertisements](#) more than 13 years after the proposed rule was originally introduced. The regulation requires that radio or television advertisements presented directly to consumers for prescription drugs include a major statement relating to side effects and contraindications that is presented in “a clear, conspicuous, and neutral manner.” This follows the proposed rule in late June 2023 about presenting quantitative efficacy and risk information to consumers as well as enforcement actions by the Federal Trade Commission (FTC) against false claims.

The FTC is also working with the FDA to crack down on what it alleges are improper or inaccurate listings for drug patents in the FDA’s reference guide, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as [the Orange Book](#)). The FTC claims that inaccurate listings by patent holders delay the development of generic drugs and keep drug prices high for consumers.

As predicted early in the COVID-19 pandemic, some of the measures that regulators adopted during the crisis are here to stay. At the end of 2023, the FDA announced that remote regulatory assessments (RRAs), which it had relied on as a temporary measure during the pandemic when travel and on-site meetings were restricted, will now be permanent tools in the agency’s arsenal. The FDA issued two guidances around when and how it would use remote interactive evaluations (RIEs) and certain alternative tools.

The agency also continued to prepare manufacturers for the implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), parts of which went into effect on December 29, 2023. It issued [a final guidance](#) on how to report serious adverse events associated with the use of cosmetic products. Even with the guidance, the FDA was criticized by the Government Accountability Office (GAO) which issued a [report](#) that cited shortcomings in the FDA’s implementation plan for MoCRA and offered recommendations to strengthen the roll-out.

We can expect to see continued collaboration between the FDA and FTC in the agencies’ efforts to protect consumers. There may also be some bumps in the road for both the FDA and the cosmetic industry as MoCRA is rolled out and imposes much stricter regulations on the industry.

“There may be some bumps in the road for both the FDA and the cosmetic industry as MoCRA is rolled out and imposes much stricter regulations on the industry.”



FTC alleges improper listing of product patents

The FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as [the Orange Book](#)) identifies drug products approved by the agency and provides related patent and exclusivity information. The correlating [Orange Book Database](#) lists active ingredients, proprietary names, applicants, application numbers, dosage forms, routes of administration for included drugs, as well as patent information, which is updated daily in the Orange Book's electronic form.

In November, the Federal Trade Commission (FTC) challenged drug product and medical device manufacturers over more than 100 patents, alleging that they were "improperly or inaccurately listed" in the Orange Book. The agency also [sent notice letters](#) to 10 major pharmaceutical and medical device companies, which along with the patent listing disputes, identify specific patents that the agency claims are improperly listed.

These enforcement actions follow a [policy statement](#) the FTC issued in October warning that it would be examining the improper submission of Orange Book patents. The statement noted that any delays in generic competition can lessen access to cheaper alternatives for patients and lead to higher costs across the entire healthcare system.

[According to the FTC](#), when a brand-name pharmaceutical company lists a patent in the Orange Book, the introduction of competing drug products, including lower-cost generic alternatives, may be blocked for up to 30 months.

In addition to its own actions, the FTC also informed the FDA about its questions over the "accuracy or relevance" of the listed patent information. The FDA may require manufacturers to remove the disputed listings or certify that the listings are in compliance with the regulations, [according to an FTC statement](#).

The New Drug Application (NDA) holders of the disputed listings have 30 days to withdraw or amend their listings or "certify under penalty of perjury that the listings comply with applicable statutory and regulatory requirements" once the entities have received a statement of dispute from the FDA.

[Legal experts with Morrison & Foerster LLP](#) note that these Orange Book actions are aligned with a [FTC policy announcement from November 2022](#) where the Commission stated a broader view of its enforcement authority under Section 5 of the FTC Act and said it would seek more "rigorous enforcement" to prevent unfair competition across a range of conduct.

Pharmaceutical companies should review the FTC letters and evaluate their own Orange Book listings to ensure they are not in violation or making false claims.

Permanent adoption of remote facility inspections proposed

Congress granted the U.S. Food and Drug Administration (FDA) the authority to conduct records-based inspections even before the COVID-19 pandemic. However, they became an increasingly important tool when in-person inspections were not an option, and the FDA needed a way to conduct remote inspections. [According to a January 2022 Government Accountability Office \(GAO\) Report](#), between April 2021 and November 2021, the FDA conducted more than 600 domestic remote regulatory assessments (RRAs).

At the end of 2023, the FDA issued two guidances related to facility inspections. The first guidance, [Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications](#), was published in September and outlines alternative regulatory tools such as remote document assessments, remote interactive evaluations, and the use of foreign regulatory agency inspection reports that were widely used during the COVID-19 pandemic. The agency now wants to adopt these approaches as regular practices to assess good manufacturing practice (GMP) compliance at drug manufacturing facilities identified in new drug and biologic applications.

The publication lists some of the factors the FDA will consider in deciding if alternative tools may be appropriate. The agency also clarified that New Drug Application (NDA) and Biologics License Application (BLA) sponsors or facilities are not eligible for an alternative assessment and must submit for a regular pre-approval inspection.

Those guidelines were followed by the [Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities](#) guidance (RIE Draft Guidance) in October. A remote interactive evaluation (RIE) is a RRA that usually uses remote visual observation of a product, facility, manufacturing operations, and records via livestreaming or screen sharing.

The second publication, which was released in October, offers information about how the FDA will request and conduct RIEs, what an RIE virtual planning meeting will look like, and the agency's expectations during and following an RIE. It also provides specific considerations for when an RIE would be appropriate: pre-approval/pre-license inspections, post-approval inspections, surveillance inspections, follow-up and compliance inspections, and Bioresearch Monitoring (BIMO) inspections. However, the agency does specify scenarios for which an RIE cannot be used.

[Legal experts with Arnold & Porter](#) highlighted several differences between the [Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency](#) guidance issued in April 2021 and the latest RIE Guidance.

For example, the latest guidance explicitly states that the FDA may use RIEs to inspect drug compounding facilities. However, it does not state that the FDA will always provide the facility with a copy of the final RIE report, which was a provision in the COVID-19 RIE guidance.

According to the [attorneys with Arnold & Porter](#), the key thing for companies to take note of is that RIEs and other forms of RRAs will be permanent parts of the FDA's inspection and oversight program. They recommend that organizations make sure their standard operating procedures (SOPs) have considerations not just for on-site inspections but also for RIEs and other forms of RRAs. Delays in agreeing to a RIE could delay the approval of a drug or biologic, so companies should be prepared.





New serious adverse event requirements for cosmetic companies

While the U.S. Food and Drug Administration (FDA) [announced in November that it would delay enforcement](#) of the cosmetic product facility registration and cosmetic product listing requirements under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), other parts of the law went into effect on December 29, 2023.

On December 18, the agency published [a final guidance](#) on the comprehensive act, including guidelines for reporting serious adverse events associated with the use of cosmetic products. The FDA defines a “serious adverse event” as one that results in one of several scenarios including death, hospitalization, a significant disability, or a birth defect, as well as any event that requires a medical or surgical intervention to prevent one of the listed outcomes.

As the FDA was working to finalize guidance around MoCRA, the Government Accountability Office (GAO) issued a report, [“COSMETIC SAFETY: Better Planning Would Enhance FDA Efforts to Implement New Law,”](#) with seven recommendations to strengthen FDA efforts to implement its new cosmetic oversight responsibilities.

The GAO’s suggestions include creating an implementation plan for MoCRA that provides interim steps with specific interim deadlines; developing a method of collecting data and evidence to measure the agency’s implementation efforts against the MoCRA requirements; and devising a plan to strengthen diversity, equity, inclusion, and accessibility (DEIA) when recruiting and hiring staff to implement MoCRA.

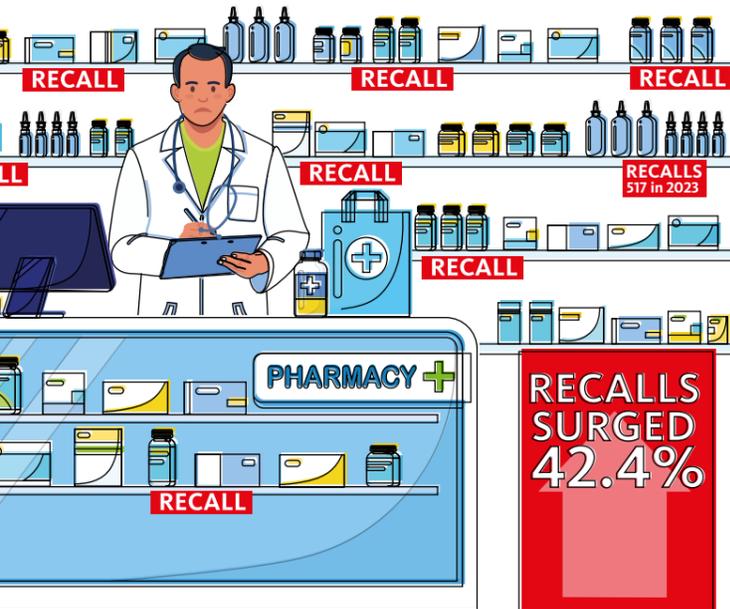
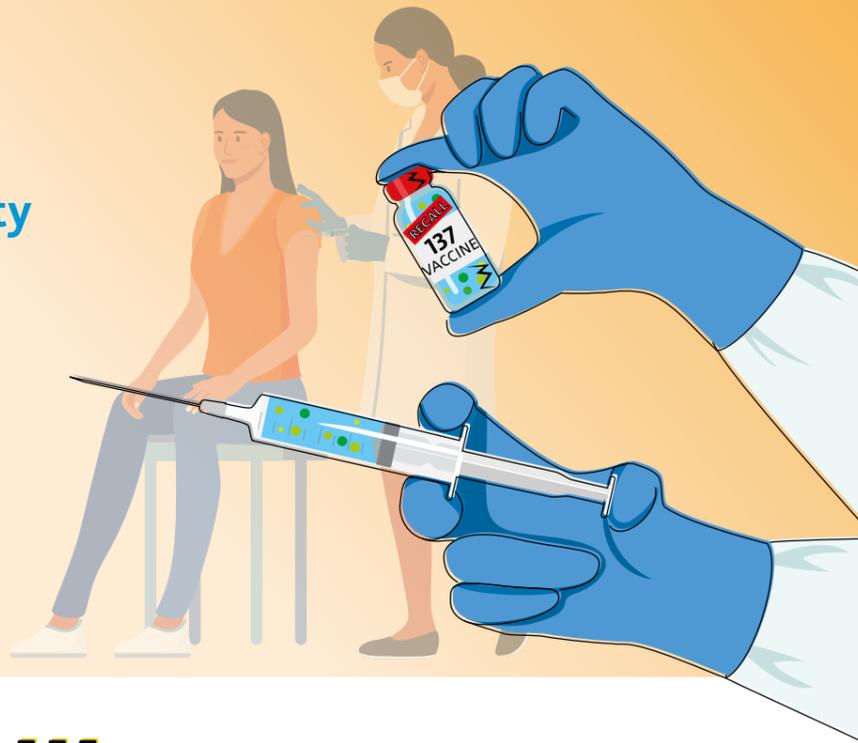
[According to attorneys with Crowell & Moring LLP](#), the GAO determined that the FDA had not fully addressed certain components of implementing the various MoCRA reforms and managing the workforce. In its comments on the GAO’s report, the FDA generally agreed with the findings and has already taken some steps that would address them such as requesting additional funding to hire new staff to assist in implementing the act.

Cosmetics companies will want to be sure their recall and risk planning includes the steps outlined in the serious adverse event reporting guidance. Even if the FDA does not fully embrace the GAO’s recommendations for MoCRA implementation, the public and other stakeholders will take note if an event is managed poorly.

“*Even if the FDA does not fully embrace the GAO’s recommendations for MoCRA implementation, the public and other stakeholders will take note if an event is managed poorly.*”

Accounting for 137 events (26.5%), **sterility** was the leading cause of recalls in 2023.

This marks the highest number of events attributed to Sterility in the last 5 years, and the first time it has been the leading cause in over 10 years.

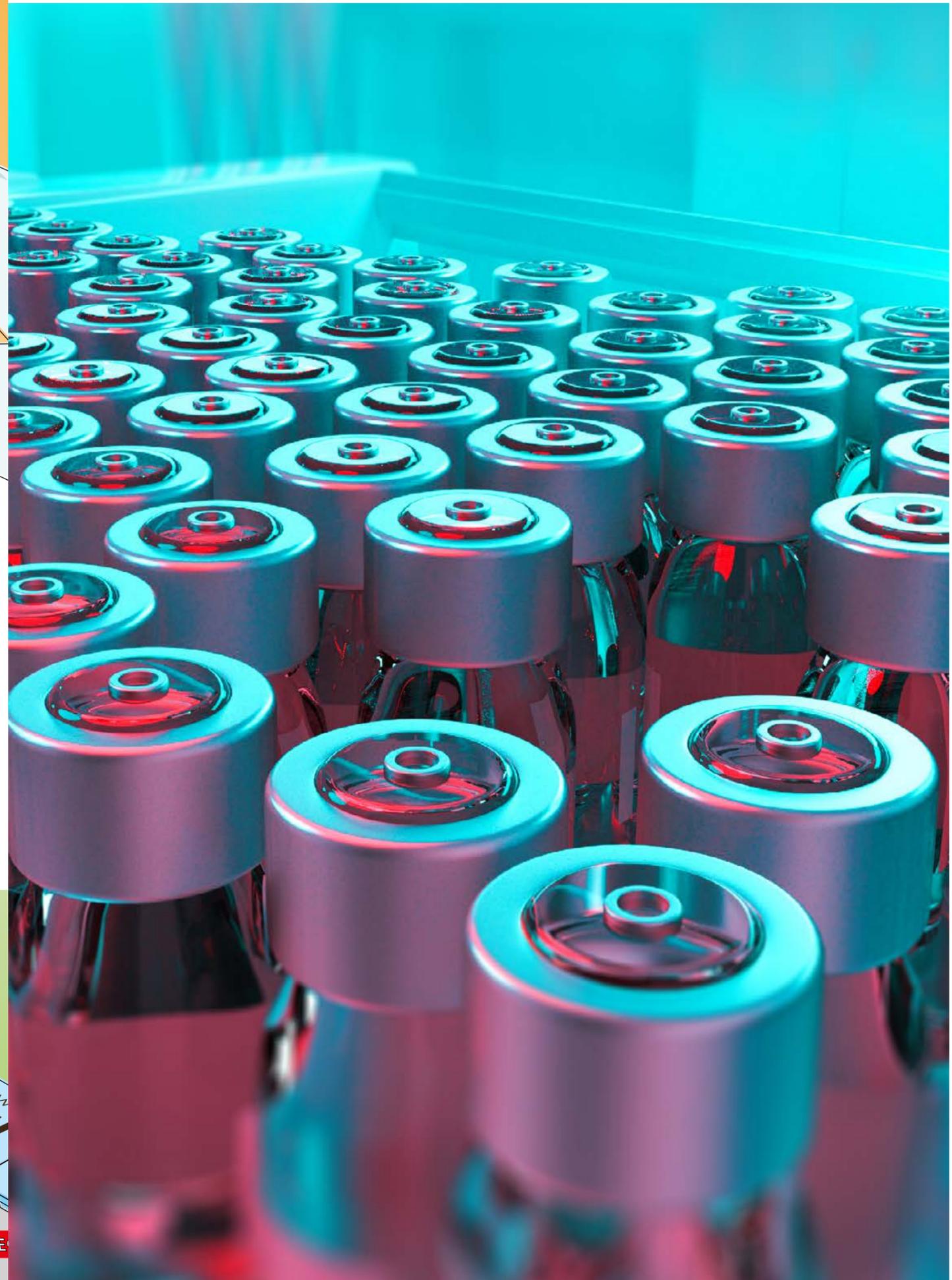
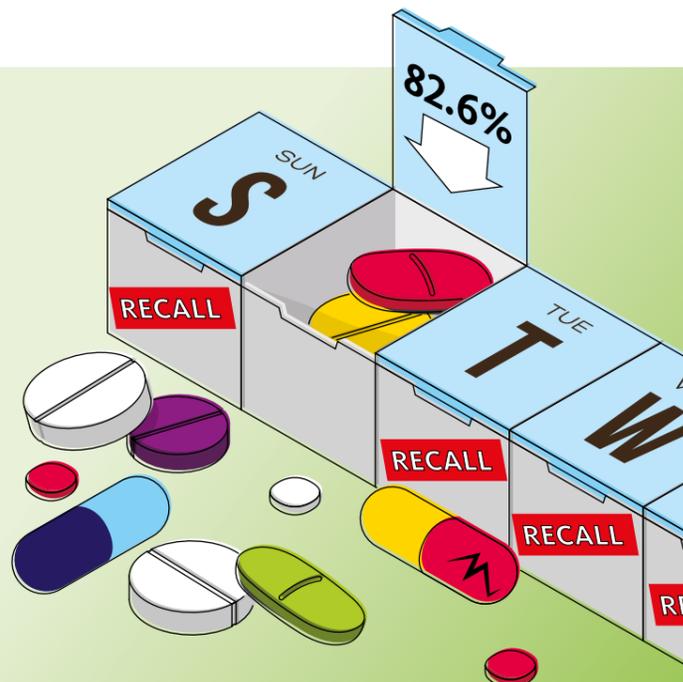


Pharmaceutical recall events surged 42.4%, from 363 in 2022, to 517 in 2023.

With this increase, 2023 marks the highest number of pharmaceutical recalls in over 10 years.

While recall events increased, the number of **defective pharmaceutical units plummeted** 82.6%, from 567.3M in 2022, to 98.5M.

With annual events increasing 42.4%, and defective units declining 82.6%, the average recall size contracted to 181.3K units in 2023. For context, the average recall size of the last 5 years has been 842.1K.



2023 BY THE NUMBERS

In total, 2023 recorded the highest number of FDA pharmaceutical recalls in over 10 years, with 517 events. For context, the previous record was set in 2018 with 376 recalls. In contrast, the number of units recalled in 2023 was the fourth-lowest across the last decade with 98.51 million units recalled in 2023. This compares to 567.35 million units in 2022, which is the highest figure recorded since 2007.

On a quarter-over-quarter basis, Q4 saw a 22.4% increase in pharmaceutical recalls, growing from 107 events last quarter to 131 this quarter. The number of units also increased, rising 133.3% from 7.42 million in Q3 to 17.31 million in Q4. There were four recalls in Q4 that impacted more than 1 million units compared to only one last quarter.

Poor temperature control was the leading cause of pharmaceutical recalls with 40 events. This is the first time in over eight years that this has been the top concern. It was also linked to the second-highest number of units impacted, at 4.26 million. Most of these were linked to a recall of over-the-counter medications stored at improper temperatures.

Failed specifications was the second-most common cause for pharmaceutical recalls by event in Q4 2023. It was linked to 27 events compared to 16 last quarter. It was also

the top issue by volume, tied to 7.39 million impacted units, primarily due to a recall of a medication to prevent nausea from chemotherapy that involved 6.02 million units.

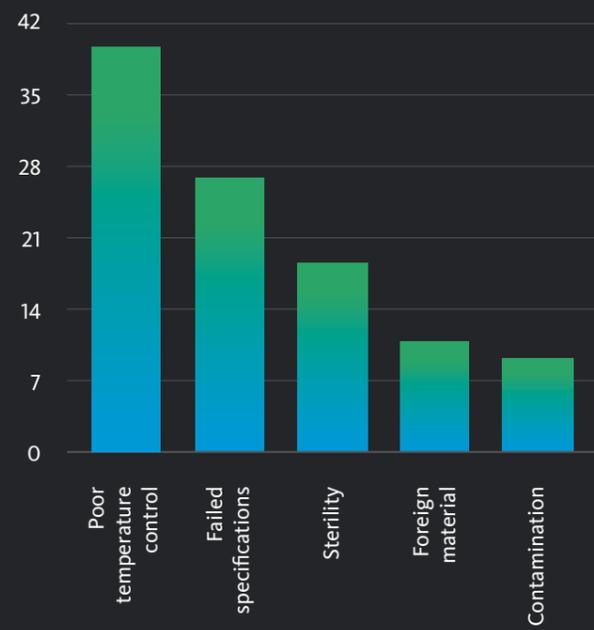
In terms of events, sterility concerns were third, with 19 recalls, including eight for eye drops. By volume, contamination impacted the third-highest number of units with 2.96 million, most of which were connected to four recalls for spray products containing benzene.

The number of events rose for all classes of recall severity in Q4 compared to Q3. The biggest change was for Class I recalls which increased from eight events last quarter to 26 this quarter. The volume of units recalled increased for Class I and II designations, with Class I units rising from 692,869 in Q3 to 5.02 million in Q4. Only the number of Class III units dropped, decreasing to 219,349 from Q3's total of 448,779.

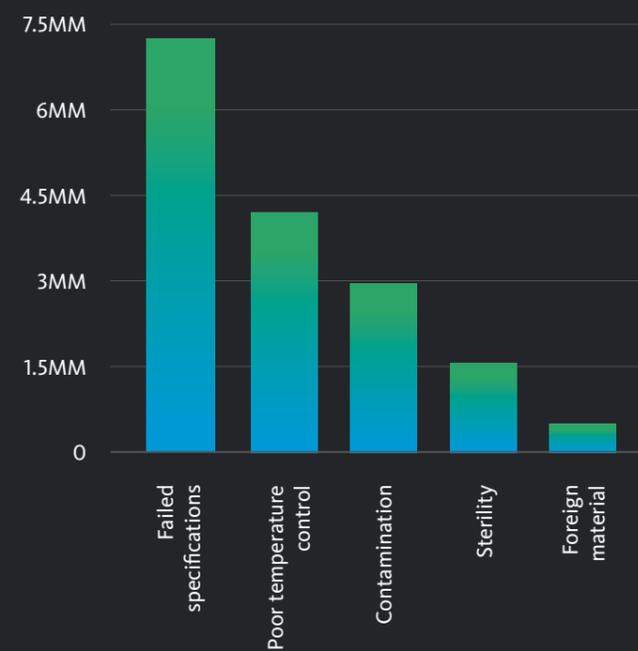
The 131 recalls in Q4 were linked to 62 unique companies. Of those, 11 companies had between two and four recalls and three had five or more, including one with 38 recalls. All 38 of the recalls with this single business were tied to poor temperature control.



NUMBER OF RECALLS BY REASON IN Q4



NUMBER OF UNITS IMPACTED BY REASON IN Q4



JANUARY 2024 insight

In January 2024, there were 107 medical device recalls, which is an increase from the Q4 2023 monthly average of 86.7. In contrast, there were 19.80 million units recalled in January 2024. This is a decrease of nearly 46% compared to the Q4 monthly average of 36.45 million units.

In terms of events, quality concerns were the most commonly-cited cause for medical device recalls in January 2024, with 20 events. Parts issues was second with 15 recalls, followed by software which was cited in 11 events.

Parts issues was the leading cause of recalls by volume and impacted 6.35 million units, largely due to one large recall of syringes. Sterility concerns led to the second-highest number of units recalled with 4.98 million. This was followed by quality issues which affected 4.4 million units.

The FDA classified nine medical device recalls in January 2024 as Class I. These recalls impacted a total of 80,200 units. Two recalls were designated as Class III. The remaining 96 recalls were categorized as Class II.



LOWELL M. ZETA, PARTNER AND SALLY GU,
SENIOR ASSOCIATE, HOGAN LOVELLS

FDA FOCUSES ON QUALITY MANAGEMENT MATURITY AS PHARMACEUTICAL RECALLS AND SHORTAGES SPIKE

It is FDA's mission to ensure medicines meet high standards for safety, effectiveness, and quality at every link in the global supply chain. This means oversight of suppliers, manufacturers, hospitals, and providers until the drug reaches patients. Supply chains have become more diverse at the same time as medicines have become more complex. This means regulatory environments must keep pace and become more exacting. This trend has contributed to an increase in U.S. pharmaceutical recalls, as seen in 2023 which had the most recall events in more than ten years.

Recall Trends in 2023

Recalls are an important mechanism for removing potentially hazardous products from the market. Most recalls are voluntarily initiated by the manufacturer, who should be able to identify and investigate emerging quality issues and, when appropriate, initiate and manage recall events. Effective recall strategies can help companies minimize the risk of subsequent FDA enforcement action.

The primary drivers of pharmaceutical recalls in the U.S. are deviations from current good manufacturing practices (CGMPs), followed by lack of sterility assurance and failed impurities/degradation specifications. For example, a series of high-profile eye drop recalls in 2023 were initiated after an FDA inspection of an Indian manufacturing facility found unsanitary conditions and contamination risks for products supplied to several U.S. retailers and distributors.

The agency has also intensified its push for more stringent supplier oversight and quality management of excipients, the inactive ingredients in drugs. For instance, FDA has issued alerts about serious adverse events associated with a specific emulsion used in cough syrups and other products. The agency discovered that the excipient contained diethylene glycol (DEG), a toxin formed during the manufacturing process. After recent reports from several other countries of DEG and ethylene glycol (EG) contamination outbreaks linked to children's cough syrups, FDA has heightened its focus on DEG/EG testing and excipient controls more generally. Specifically, FDA has issued guidance for industry on DEG/EG testing, alerts about serious adverse events associated with DEG and EG contamination, and multiple Warning Letters to drug manufacturers making products containing high risk excipients.

Benzene contamination is another ongoing concern. There has been an increase in recalls and warning letters associated with products containing benzene, a known human carcinogen that is linked to leukemia and other blood disorders. The enforcement actions have largely been for spray-on personal care products such as deodorant and sunscreen.

Recall Readiness

Preparation is critical for effective recall management and risk mitigation. In 2022, the [FDA issued a final guidance](#) that lays out the agency's expectations and recommendations to help companies ensure recall readiness at all stages in a product's distribution chain. The recommendations include establishing and maintaining written procedures to identify potential events from quality investigations, product quality compliance, and other sources; assigning recall responsibilities to appropriate personnel; conducting mock recalls; complying with FDA reporting requirements, including field alert and biological product deviation reports; communicating with customers and/or the public if a recall is appropriate; and maintaining distribution records.

In addition, companies should conduct a health hazard evaluation (HHE) of the potential health risks of the product being considered for recall as part of an underlying quality investigation during a recall. While a recall decision does not depend solely on the health risk associated with the recalled product, the evaluation helps guide the manufacturer's recall strategy. In addition, HHE findings help inform the FDA of potential risks to the public and guide appropriate actions for the company and the agency.

As part of the HHE, manufacturers should engage qualified personnel, including medical professionals or a multi-disciplinary team with subject-matter expertise, who can assess a range of factors such as whether any disease or injuries have already occurred from the use of the product. The conclusion must be supported by scientific documentation and/or state that it is the opinion of the individual(s) making the health hazard determination.

Further, HHEs should evaluate the hazard to various segments of the population who are expected to be exposed to the product with particular attention paid to

individuals who may be at greatest risk, such as children. Manufacturers should also assess the seriousness of the health hazard to which populations would be exposed, the likelihood of occurrence of the hazard, and both the immediate and long-term consequences of the potential health hazard.

Persistent Drug Shortage Crises

When determining if a drug needs to be recalled, the FDA considers whether a recall could result in a shortage of a critical medicine. Manufacturers of medically-necessary drugs who believe they may have a product that needs to be recalled should immediately notify the FDA's Drug Shortage Staff (DSS) so the Agency and manufacturer can work to avoid a shortage.

Drug shortages not only introduce significant risks to the health of patients and consumers but also disrupt hospitals, health systems, and pharmacies, and have potential national security implications. Supply disruptions persist despite the FDA's reform and prioritization to ensure the availability of drugs, as evidenced by the growing number of drug shortages and instances that require the FDA to exercise regulatory flexibilities to prevent supply disruptions. In February 2024, the FDA listed more than 120 drugs currently in shortage on the agency's Drug Shortage List, and trends from the past year indicate that ongoing and active shortages have risen to their highest levels since 2014. Recent and current shortages include critical drugs used to provide parenteral nutrition, address serious medical conditions, and treat cancer, infections, respiratory illnesses, heart failures, and psychiatric conditions. Children's acetaminophen and ibuprofen are among the medications in scarce supply due in part to an increase in respiratory illnesses.

Although the FDA's critical drug supply challenges pre-date the COVID-19 pandemic, many Americans became acutely aware of national drug shortages during the pandemic. Drug supply challenges are multi-factorial, including manufacturing quality issues, increasing complexity for manufacturing advanced medicines, over-reliance on foreign manufacturing capacities, rigidity of the global supply chain ecosystem, and surging demand. There are also U.S. and global production capacity shortfalls for some critical medical products, particularly sterile injectable drugs.



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SENIOR ASSOCIATE, HOGAN LOVELLS

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The FDA's authority has expanded in response to recent shortages. The agency has more visibility into global supply chains through increased manufacturer reporting requirements and an enhanced ability to expedite the review of selected products or procedures. For example, FDA temporarily authorized the importation of drugs produced by non-FDA-approved Chinese manufacturers to alleviate a national shortage of a critical cancer drug after the manufacturer of the critical cancer drug was temporarily shut down after an FDA inspection found quality issues. However, there are limitations to FDA's role in addressing drug shortages. It cannot require a manufacturer to produce certain drugs and is not involved in pricing or coverage decisions.

The regulatory discretion to allow products from non-approved facilities is similar to another increasingly used tool within the FDA's toolbox—allowing drug manufacturing facilities with serious compliance problems to continue manufacturing medically-necessary products while they address the issues noted by the FDA. The agency has also tried to improve access by allowing a manufacturer to implement additional safety controls such as increased testing and third-party oversight to provide greater quality assurance.

According to FDA officials within the Center for Drug Evaluation and Research (CDER) presenting at an industry conference, the percentage of FDA drug inspections classified as Official Action Indicated (OAI) for which the agency exercises regulatory discretion is unusually high. The OAI classification is used for facilities deemed to be in an unacceptable state of compliance. To prevent or mitigate shortages for critically-needed drugs, the FDA may decide not to issue a warning letter, request a

regulatory meeting, impose an import alert, or to initiate more serious enforcement even if the facility is designated as OAI if the action would disrupt supplies. In FY 2023, October 1, 2022 – September 30, 2023, there were more than 285 FDA CGMP inspections of drug manufacturing facilities with OAI classifications. Of that total, approximately 66 sites received warning letters; 62 sites resulted in regulatory meetings; 75 sites were placed on import alert; and 80 sites benefited from FDA's regulatory discretion, which means no enforcement action was taken.

According to the data, many of these OAI facilities were producing critical medicines, including COVID-related medical products. The drug supply chain has not fully recovered from shutdowns and delays during the pandemic, so the FDA granted some leniency. As the industry moves back into pre-pandemic operational and drug supply levels, the FDA is likely to use regulatory discretion less frequently. In addition, the agency may be looking to tighten the reigns because it is under increased public attention for its perceived role in drug shortages and supply chain challenges. Committees and members of Congress are looking more closely at the agency following the lack of access to several high-profile drugs, including mental health medications, medicines for diabetes and weight loss, and Respiratory Syncytial Virus (RSV) vaccine supplies for infants.

Addressing the Root Cause of Drug Shortages: Quality Maturity

As the number of pharmaceutical recalls and shortages continue to rise to record levels, the FDA is stepping up its efforts to address quality management maturity (QMM), widely considered to be one of the primary root causes of the issues.

QMM is achieved by implementing quality management practices that go beyond minimum CGMP requirements to manage continuous improvement. QMM improvements result in sustainable compliance, reliable supply chains, and confidence in the quality and accessibility of critical medicines. Investments by drug manufacturers in QMM practices mitigate the likelihood of issues associated with poor drug quality. They can also lead to greater operational performance, improved relationships with regulators and customers, and higher revenues.

The FDA proposed a QMM program in 2019 that created a rating system to inform purchasing and contracting decisions. However, the pharmaceutical industry was not convinced the program would alleviate shortages, especially when there were no clear regulatory incentives.

More recently, the agency has renewed its efforts to develop a QMM program and has run pilot programs, published multiple white papers, convened an advisory committee workshop, and solicited comments from the industry. While the exact timing and components of a formal QMM program remain unclear, the FDA appears to be applying QMM principles to its existing compliance programs. For instance, a 2022 annual report released by CDER's Office of Pharmaceutical Quality (OPQ) showed that the data for site inspection scores suggest a correlation between low scores and potential drug recalls. The FDA also revised its drug compliance programs for pre-approval inspections and drug manufacturing inspections to make key changes aligned with underlying QMM principles for a holistic approach to quality and compliance.

Additionally, FDA added a new primary objective, "Commitment to Quality in Pharmaceutical Development,"

to the agency's pre-approval inspection compliance program. The data companies provide to show they meet this primary objective will be used by the FDA for data analysis or internal trending, not as the basis for a potential enforcement action. The information may also assist in the identification of risk factors for future pre-approval inspection decisions.

According to the agency, mature quality practices that exceed CGMP requirements are indicative of a modern, risk-based pharmaceutical quality system (PQS). In turn, this approach leads to sustainable compliance and reliable production of high-quality drug products without extensive regulatory oversight. The FDA will assess pharmaceutical manufacturers' ability to develop and manufacture drugs of consistent quality.

Advice for Manufacturers

The agency's revised compliance policies suggest a higher threshold for quality systems for drug manufacturers. During inspections, the FDA has increasingly cited companies for ineffective quality systems. Specifically, it has mandated a comprehensive assessment of a company's global manufacturing operations and support from executive leadership to proactively address emerging issues and to assure a continuing state of control.

An increasing focus on proactive and continuous improvement and an effective quality risk management approach are critical to ensure the quality of the drug on the market. It also demonstrates to the FDA that the manufacturer is able to address potential risks and avert problems. In turn, this assurance could lead to more flexible approaches to oversight to support regulatory decisions.



CONCLUSION

New regulations that went into effect at the end of 2022 and early 2023 will bring a lot of changes for companies across multiple sectors, including the pharmaceutical industry as FDORA and MoCRA provisions continue to take effect. We can expect AI and cybersecurity concerns to remain a top priority in 2024 for everything from manufacturing to monitoring products in-market.

Government agencies appear to be trying to ease some burdens on manufacturers by offering transition periods or giving medical device companies some leeway in making minor changes to products without going through another approval. However, there are still burdensome new regulations that will continue to evolve as new innovations spread in the market.

The automotive sector will need to try to make the transition to EVs as seamless as possible both for its production as well as for consumers and dealers. As new emissions requirements go into effect, automakers will be forced to move to producing low emission or zero emission vehicles.

There may be some confusion for food companies with the reorganization of the FDA's Human Foods Program as manufacturers and government officials learn which office is responsible for what. However, that is unlikely to stop enforcement activities.

Consumer product companies can expect aggressive enforcement from both the FTC and CPSC, with a greater focus on seller responsibilities and the duty to report product defects. The number of fines and regulatory actions will likely continue to rise.

With all the unknowns, companies will need to plan for risks across a variety of areas, including the following:

- Business interruptions
- Supply chain challenges
- Regulatory and legislative changes
- Financial impacts
- Product updates, upgrades, and warranty work
- Product recalls and market withdrawals
- Data privacy and cybersecurity issues
- Innovation and advancements in technology
- Dynamic consumer demand
- Customer and partner apprehension

Unfortunately, recalls in today's business environment are inevitable. But many regulatory agencies recommend, even mandate, that companies have recall, remediation, and/or risk management plans in place as part of their standard business processes. Thus, when the inevitable does occur, you can better protect your consumers, brand, and bottom-line.

Working with an expert partner to leverage their experience and insights can save millions of dollars in regulatory and litigation costs, as well as time and stress on other internal resources. In addition, their expertise will help you honor your commitments to customers, supply chain partners, industry groups, and regulators, while protecting your reputation among the stakeholders that matter most.

ABOUT SEDGWICK BRAND PROTECTION

We are in-market risk experts. We are problem solvers. We protect businesses, their customers, and our environment through best practice recall, remediation, and retention solutions.

Trusted by the world's leading brands and businesses, we work in partnership to manage the risks and minimize the impacts of in-market business and product crises. When your reputation is on the line, we put our three decades of global experience on 7,000+ recalls affecting 500MM+ units to work for YOU. No one knows more about the recall and regulatory process than we do.

Through that lens, we've seen industries evolve based on changing legislation, advancements in technology, shifts in consumer preferences and behaviors, and the growing complexities brought about by the transformation of supply chains. We haven't just watched this evolution. We've been part of it. We've helped companies around the world prepare for and adapt during some of the most challenging events in their history.

While this Index report provides a roadmap for expected changes ahead, our experience means that there is nothing we haven't seen or dealt with before. In fact, it's often these events, even those that feel devastating to companies experiencing them, that offer opportunities to demonstrate trustworthiness and to build greater customer loyalty when managed well.

Sedgwick's extensive brand protection resources, combined with our unmatched experience handling thousands of recall events, give us a unique perspective on the risks, challenges, and often overlooked opportunities associated with the reputational threats you face every day.

In an increasingly-complex and regulated world, being prepared for risks is essential. Having the capabilities to act quickly and effectively is critical. Let us leverage our capabilities for you.

To find out more about our product recall capabilities, [contact us today](#).



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