RECALL INDEX
2023 EDITION 1

PRODUCT SAFETY AND RECALL
UNITED STATES EDITION

DATA, TRENDS & PREDICTIONS **FOR US INDUSTRIES**

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The Sedgwick brand protection Recall Index is a 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 brings you updates pertaining to recall and regulatory activity from the first quarter of 2023, January through March, as well as an early look at April data. After last year's record-breaking number of units recalled, we are watching what 2023 will bring. In Q1, there were 863 recalls across the five industry sectors we track. This is the highest single-quarter total since Q4 2018. Every sector experienced an uplift in recall activity this quarter, except for USDA food recalls, which remained flat.

Despite the increase in events, the 205.66 million units recalled was 21.6% fewer than last quarter and significantly lower than the 913.84 million recalled in Q1 2022. The industry sector with the biggest percentage increase in recalled units compared to Q4 2022 was food and drink, with the USDA recalling 2.88 million pounds of product. That is a 1,129.0% increase compared to the previous quarter, though the number of recalls stayed the same (at 11 events). Pharmaceutical products also experienced a dramatic quarter-over-quarter increase with 49.54 million units recalled, an increase of 1,071.8% from Q4 2022. Overall medical devices were the most impacted sector by volume with nearly 83.26 million units recalled, up 34.3% from the previous quarter. These are still far below the Q1 2022 figures for medical devices and pharmaceuticals.

In addition to analyzing the data, the Sedgwick brand protection Recall Index offers counsel on what issues companies should be following and what regulators may be doing next. Some of our strategic partners at global law firms, insurance companies, and communications firms offer their exclusive analysis to help organizations plan for the future and mitigate risk.

We are watching how the increased adoption of digital health tools will change the way patient care is delivered. It will also change the way recalls are managed. New cybersecurity regulations put additional burdens on medical device companies to make sure their compliance and recall plans are keeping up with changing technology.

Another change is the FDA's proposed reorganization of its Human Foods Program, based on recommendations from a third-party investigation and an internal review. In addition, the USDA's final rule to strengthen control systems around food labeled as 'organic' took effect in March, which will impact companies throughout the supply chain from growers to grocers.

With dynamic changes happening across industries and government agencies, we are confident there is something you can learn from this report that will support your decision making and business operations. We invite you to read the entire report, or just focus on the sections that matter most to your sector.

One final note, 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 influenced by global issues, we encourage you to read our European Edition. Like this report, it shares recall data from regulatory agencies and offers expert analysis on product safety and regulatory 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:

Q4 2022 U.S. Recall Index: click here
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AUTOMOTIVE

The automotive industry is constantly evolving. The latest developments include new regulations for the national electric vehicle (EV) charging station infrastructure, trade disputes around standards in the United States-Mexico-Canada Agreement (USMCA), legal risks associated with autonomous vehicles (AVs), and new emissions standards for heavy-duty highway vehicles and engines.

The U.S. Department of Transportation's (DOT's) Federal Highway Administration (FHWA) published the National Electric Vehicle Infrastructure (NEVI) Standards and Requirements in March 2023. These rules apply to federally-funded EV charging stations under the NEVI Formula Program and other publicly-accessible EV chargers. The standards regulate installation, operation, maintenance, data requirements, and other factors. The aim is to provide a predictable charging experience for EV users across the country.

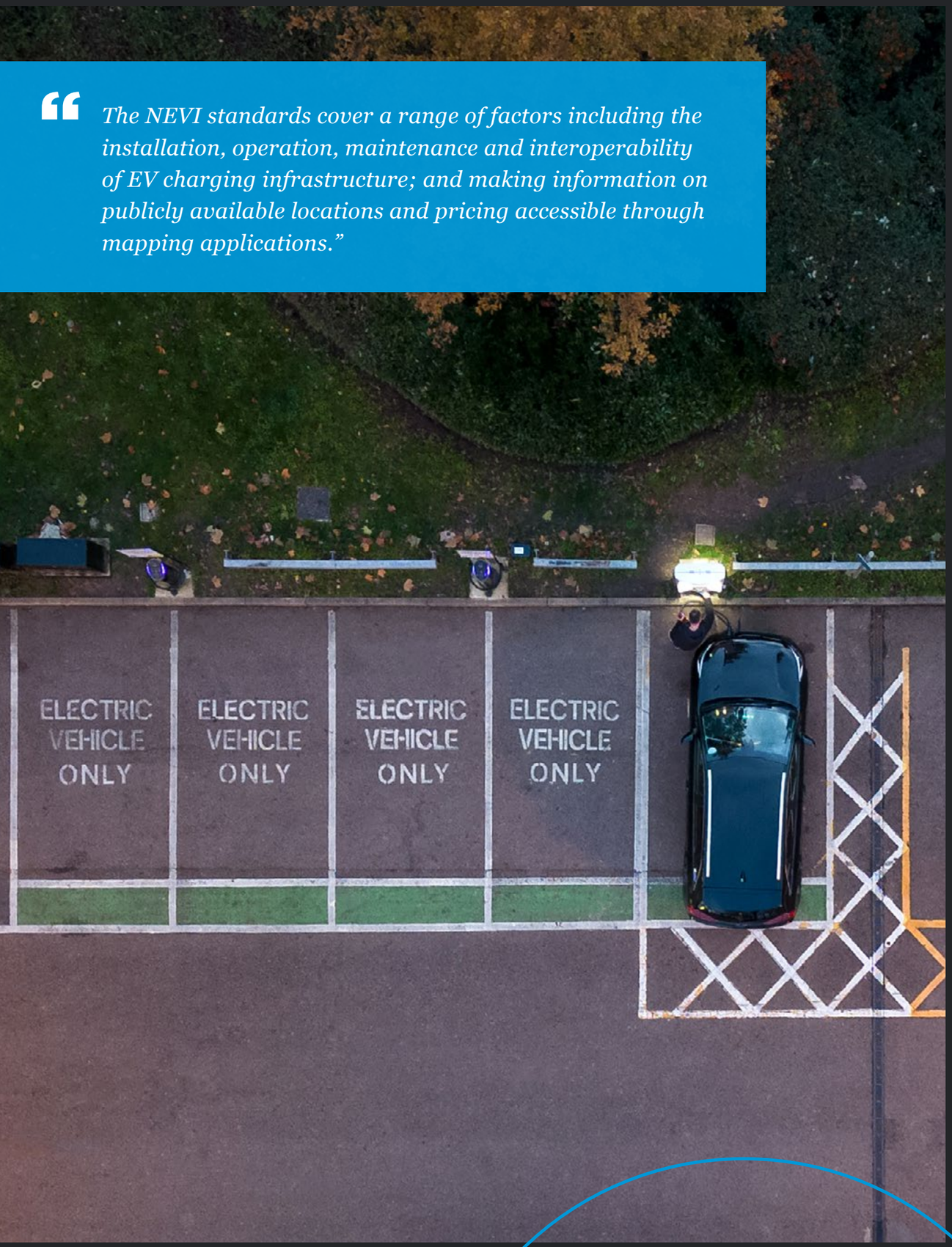
Meanwhile, under the USMCA, automakers must meet minimum standards for the percentage of materials in cars and automotive parts that originate in North America to qualify for the duty-free benefits outlined in the trade agreement. A recent dispute over the calculation of regional value content (RVC) has been resolved, with a USMCA panel ruling against the U.S. This decision could have significant implications for automakers and consumers and may impact other ongoing USMCA disputes in other sections among the U.S., Canada and Mexico.

The development of AVs is also creating new challenges for the industry not only in terms of cybersecurity and product liability, but also with increased legal risk. New AVs with advanced media and gaming technologies could create opportunities for hackers and risks for distracted driving that may make automakers and other stakeholders liable.

Finally, the Environmental Protection Agency (EPA) has finalized new emissions standards for heavy-duty trucks, which are more than 80% stronger than current standards and will apply to vehicles from model year 2027.

As automakers continue to innovate and evolve, they must navigate these new regulations to ensure compliance, maintain customer satisfaction, and uphold their reputation in the industry.

> *"As automakers continue to expand their production of EVs, they should note the regulations in the final NEVI rule and ensure their vehicles are compatible with the charging infrastructure being installed along federal highways."*



> *The NEVI standards cover a range of factors including the installation, operation, maintenance and interoperability of EV charging infrastructure; and making information on publicly available locations and pricing accessible through mapping applications."*

Standards set for federally-funded EV charging stations

On March 30, 2023, the National Electric Vehicle Infrastructure (NEVI) Standards and Requirements from the U.S. Department of Transportation's (DOT's) Federal Highway Administration (FHWA) went into effect. This final rule establishes the standards and requirements for projects under the NEVI Formula Program, which is designed to create an interconnected EV charging infrastructure along federal highways that have been designated as Alternative Fuel Corridors. The rule also applies to any EV charging infrastructure construction project funded with certain federal funds that is treated as a project on a Federal-aid highway, as well as some other publicly-accessible electric vehicle (EV) chargers.

The standards and requirements cover a range of factors including the installation, operation, or maintenance of EV charging infrastructure; the interoperability of EV charging infrastructure; the format and schedule for the submission of data along with other data policies; and making information on publicly available EV charging infrastructure locations and pricing accessible through mapping applications.

Among the key provisions outlined in the final rule are the need for transparency around the procurement process; that every charging station has a minimum of four charging ports and is able to accommodate connectors; that stations located along an Alternative Fuel Corridor are available to users 24 hours a day, seven days a week; and that charging stations provide a contactless payment method that accepts major debit and credit cards, and allows payment through text message or by an automated toll-free number.

Other rules include the need to display prices in real-time with any additional fees clearly displayed and explained, and the need for the EV charging infrastructure to be installed and maintained only by employees with the appropriate licenses, training, and certifications.

In its announcement about this national infrastructure, the Biden-Harris Administration said that these standards will help give the public a predictable EV charging experience, regardless of their vehicle or location in the country.

As automakers continue to expand their production of EVs, they should note the regulations in the final rule and ensure their vehicles are compatible with the charging infrastructure being installed along federal highways. For stakeholders seeking federal funds for charging station projects, they will want to ensure their plans meet the requirements outlined in the plan.

U.S. loses challenge in interpretation of fair trade agreement

The United States-Mexico-Canada Agreement (USMCA) sets minimum standards for the percentage of materials used in cars, trucks, and vehicle parts that must originate in North America for the finished products to qualify for the duty-free benefits of the USMCA.

There is a formula to determine the total amount of this "originating content," also known as the "regional value content" (RVC). There are also separate specific RVC thresholds for seven vehicle "core parts" that must be met. If these core parts do not meet the "originating" standard, the overall vehicle will not qualify for preferential tariff treatment under the USMCA.

In December a USMCA panel ruled against the U.S. in a dispute with Mexico and Canada over how the RVC formula should be calculated and applied for automobiles and core parts. The panel found that the U.S. interpretation was inconsistent with the trade agreement.

The issue is whether a producer can determine the RVC of a finished vehicle or truck by relying on any of several calculation methodologies, including the "roll-up" of originating core parts in the finished vehicle RVC calculation. This is the position Canada and Mexico take.

The practice of "roll-up" has long been used in free trade agreements, according to attorneys with Thompson Hine. The idea is that once a good meets the standards to be "originating," it is considered to be 100% "originating" in all subsequent production processes and calculations. x

If the minimum requirements are met, the percentage is "rolled-up" to 100% for future calculations. For example, if the RVC for a specific core part is 78% and the producer determines it has met or exceeded this requirement, then they can "roll-up" the RVC of its part to 100%. On a bill of materials (BOM) for the downstream product, a vehicle producer may attribute the content value of originating materials as 100%.

> *Experts have highlighted the rising cybersecurity risk of increasingly high-tech automobiles. The strong wireless connections needed to provide ongoing over-the-air software updates create opportunities for hackers and data corruption."*

The U.S. argued that the RVC calculation for the overall vehicle is separate than for the core parts. The panel ruled that this view is inconsistent with the agreement. The U.S. cannot appeal the decision and the parties have 45 days from receipt of the final report to reach a resolution. Otherwise, Mexico and Canada may suspend application of benefits until a resolution is reached.

This could have big implications for automakers and consumers if the price of vehicles and core parts goes up for goods imported into the U.S. Legal experts say that this dispute may also impact other ongoing USMCA disputes among Canada, Mexico, and the U.S. in other sectors ranging from dairy to energy.

There are also "originating" standards in other recent regulations including the Inflation Reduction Act (IRA) and Build America, Buy America (BABA), which the U.S. may use to get the results it wanted from the USMCA. Automakers and suppliers will need to follow any guidances carefully and may need to navigate inconsistent standards for sourcing and compliance.

Legal risks of autonomous vehicles

Experts have highlighted the rising cybersecurity risk of increasingly high-tech automobiles. A joint venture between a major automaker and a leading manufacturer of gaming stations and other electronics has developed a prototype for a new autonomous, smart car that takes high-tech to a new level.

The model presented at the Consumer Electronics Show in January 2023 had 45 cameras and sensors inside and outside the vehicle, as well as high-speed computing power for the electronic control unit (ECU), which is the main "computer" of a car that processes information from a range of inputs to regulate vehicle performance.

According to the companies, the goal is to transform "mobility space into entertainment space by seamlessly integrating real and virtual worlds." This includes a panoramic screen spanning the entire front dashboard area, a uniquely-designed steering wheel to minimize the distraction of the screen, and a "media bar" on the exterior of the car that allows passengers to display messages, colors, and more to interact with the world outside the vehicle.

As experts with WIT point out, the strong wireless connections that will be needed to provide ongoing over-the-air software updates create opportunities for hackers and data corruption. In addition, gaming systems like the ones incorporated into the vehicle have also been prone to cyberattacks.

The legal authorities also note that there may be a range of product liability issues, including the potential for distracted driving both from the vehicle operators and from people outside the vehicle who are distracted by the media bar or other flashy features.

With several other partnerships looking to roll-out their own versions of vehicles with advanced media and gaming technologies, regulators will need to keep a close eye on these developments and update regulations as needed to keep drivers and the public safe. Automakers will want to engage with experts who can provide insights from both an automotive and video gaming perspective to help minimize their legal and reputational risk.

Final emissions standards set for heavy-duty highway vehicles and engines

In December 2022, the Environmental Protection Agency (EPA) finalized national clean air standards to cut smog- and soot-forming emissions from heavy-duty trucks. The new standards will apply to vehicles beginning with model year 2027 and are more than 80% stronger than current standards. The agency said this step is part of the Clean Trucks Plan to move heavy-duty trucking fleets towards low-carbon and electric technologies.

The final rule has provisions for longer useful life and warranty periods to ensure that as vehicles age, they continue to meet the EPA's more stringent emissions standards for a longer period of time. Under the regulation, manufacturers must also better ensure that vehicle engines and emission control systems work properly on the road. This includes demonstrating that engines are designed to limit access to electronic pollution controls and prevent vehicle drivers from tampering with emission controls.

According to attorneys with Foley & Lardner, the rule also includes incentive programs for manufacturers to further reduce emissions, and creates four specific pathways to generate nitrogen oxide (NOx) emission credits for vehicles produced in model years 2023 through 2026. However, the final rule does not include provisions that allow manufacturers to generate NOx emission credits from heavy-duty zero-emission vehicles, which were included in earlier proposals.

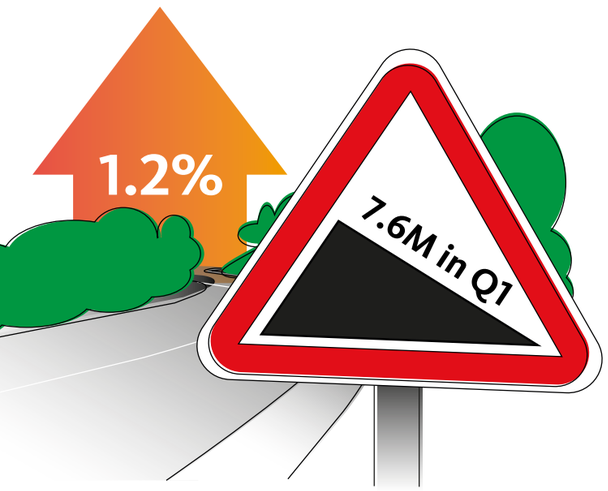
There are more regulations on the way. The EPA plans to release proposals for the "Phase 3" greenhouse gas (GHG) standards for heavy-duty vehicles and multipollutant standards for light- and medium-duty vehicles. These are the other two parts of the Clean Trucks Plan.

Experts predict that there will be changes throughout the supply chain as the heavy-duty sector continues to move toward electrification. They anticipate the stricter standards could also result in delays in the supply chain and engine availability that will impact engine inventories and new product development for vehicle manufacturers. Automakers should be preparing now for these upcoming changes.

The limited hardship exemptions for vehicle and engine manufacturers related to the implementation of new emission standards include very detailed criteria. It will be extremely difficult for automakers to take advantage of those provisions. Engine and vehicle manufacturers should be planning and preparing now for the implementation of these new standards for the model year 2027.

Automotive **recall events increased 3.4%,** from 237 in Q4, to 245 in Q1.

Despite this rise, total events remain in-line with the quarterly average of the last 5 years (246).



The number of **impacted vehicles rose 1.2%,** from 7.5M in Q4, to 7.6M in Q1.

Despite this rise, the average recall size fell 2.1% (to 31.1K), and remains almost a third (29.4%) below its 5-year quarterly average (44.0K).

Accounting for 48 events, **'Electrical systems' was the leading cause** of Q1 recalls (19.6%).

This supplanted Equipment, which held the top position for the last 2 years.

APRIL 2023 insight

There were 79 U.S. automotive recalls in April 2023, slightly lower than the Q1 2023 monthly average of 82 events. After increasing each month in the first quarter for a monthly average of 2.54 million units, the number of automotive units recalled in April 2023 fell to 1.74 million units.

Electrical systems were the leading cause of NHTSA recalls in April 2023, with 16 events. Faulty equipment was the second most commonly cited cause for recalls, with 11 events, followed by Structure with eight events.

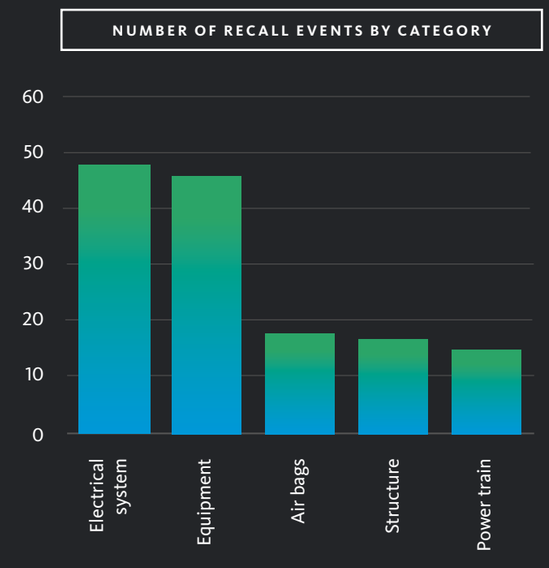
The most recalls were in the vehicle category, with 70 events that affected 1.17 million units. However, in terms of units impacted, one single event in the tire category accounted for 542,110 units, making it the largest automotive recall in April.

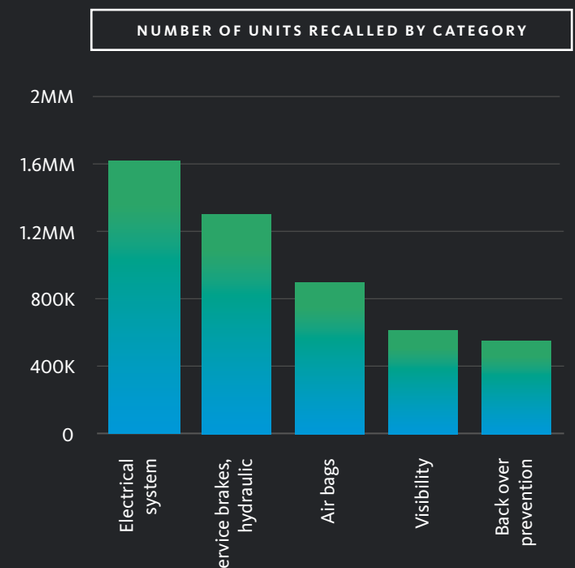
FIRST QUARTER BY THE NUMBERS

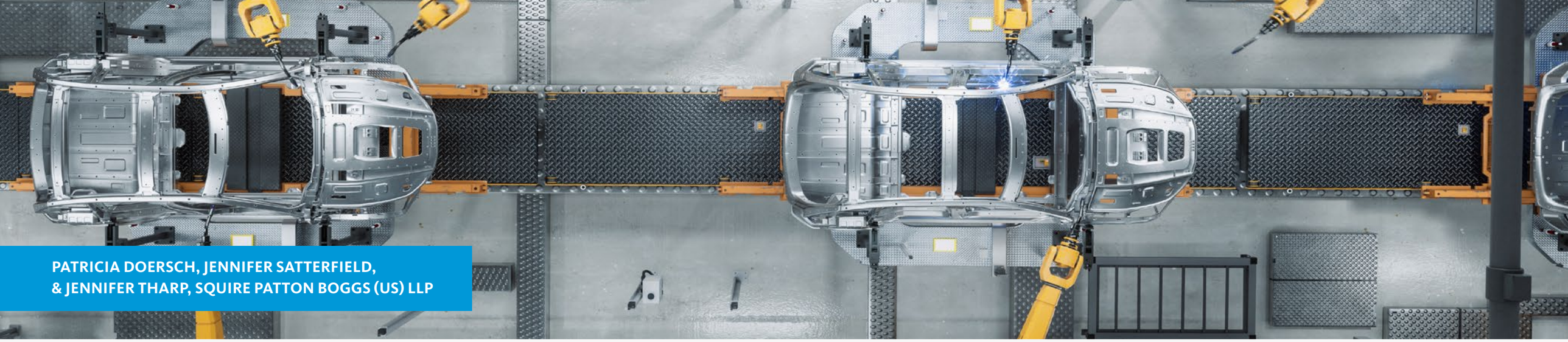
The National Highway Traffic Safety Administration (NHTSA) issued 245 automotive recalls in Q1 2023, an increase of 3.4% compared to the previous quarter. The number of impacted units also increased slightly, from 7.52 million in Q4 2022, to 7.61 million in Q1 2023.

Electrical systems were the leading cause cited for NHTSA recalls, linked to 48 events compared to 33 last quarter. This category was also linked to the most units recalled in Q1 2023 with 1.68 million units, or 22.1%. Equipment had the second-most recalls with 46 events, though only 263,464 units were impacted. Service brakes were cited in 12 recalls, but 1.34 million units were recalled in this category, fueled by a single recall involving 1.28 million units. This made service brakes the second-largest category for automotive recalls by unit.

Automobiles were the largest product category of recalls with 216 in Q1, up only one event compared to last quarter. The number of units impacted quarter-over-quarter also held steady with 7.32 million automobiles recalled in Q1 2023, and 7.30 million in Q4 2022. The number of tire recalls decreased from five last quarter to only one in Q1. The number of units impacted in these recalls dropped even more, with 34,628 units recalled in Q4 2022 versus only three in Q1 2023.







PATRICIA DOERSCH, JENNIFER SATTERFIELD,
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RECALL STRATEGY IN THE FAST-PACED WORLD OF AUTOMOTIVE TECHNOLOGY – WHEN DOES LACK OF COMMON EQUIPMENT CONSTITUTE A SAFETY DEFECT IN THE UNITED STATES?

When a motor vehicle or motor vehicle equipment has a safety defect or noncompliance, the typical procedure in the United States is for manufacturers to initiate a recall and submit applicable documentation to the National Highway Traffic Safety Administration (NHTSA). Manufacturers usually do this voluntarily, as NHTSA has established an expectation in the industry that the threat of enforcement stands ready for those who fail to act on safety-related concerns. However, what happens when the issue in question does not fit into the neat box of a defect or noncompliance? Where does the agency's role fall? These are the questions facing industry stakeholders and manufacturers in the wake of recent vehicle thefts.

Social media and public media outlets have been reporting over the past year on a disproportionate number of vehicle thefts of certain manufacturers' model year 2015-2019 vehicles. Specifically, this population of vehicles lacks electronic immobilizers, which are considered industry standard anti-theft devices. These immobilizers use a computer chip in the vehicle and another in the key to confirm the key does, in fact, belong to that vehicle. Without the correct key, the immobilizer should prevent the car from starting. Since the vehicles in question lack the electronic immobilizer, thieves have been able to utilize USB cables to turn the ignition charge, start the vehicle, and release the steering lock. After reviewing popular videos depicting how to hotwire these vehicles using something as simple as a USB charger, thieves have been stealing them for the purpose of joyriding and online clout, rather than resale.

In light of these incidents, insurance providers are reportedly declining to cover these vehicles. Further, the rising number of injuries and deaths that have been attributed to the thefts has spurred several legal battles and calls for the manufacturers to recall and remedy the vehicles. Specifically, 23 state attorneys general sent a letter on March 20, 2023 to the manufacturers demanding "swift and comprehensive action." Subsequently, the attorneys general for 17 states and the District of Columbia wrote a letter dated April 20, 2023 to NHTSA, urging the agency "to exercise its authority to order a mandatory recall or ensure [the manufacturers] institute a voluntary recall." The attorneys general believe that the vehicles' "vulnerability to theft constitutes a defect posing an unreasonable risk to safety, providing NHTSA with an independent basis to order a recall." Many major cities have also initiated lawsuits against the manufacturers for their failure to implement the immobilizers, including Baltimore, MD; Cleveland, OH; Columbus, OH; Milwaukee, WI; Rochester, NY; San Diego, CA; Seattle, WA; and St. Louis, MO.

1. Not every automotive safety concern is appropriately addressed via recall.

While NHTSA's mission is to help reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the nation's highways, remedying this anti-theft technology concern via recall may not be appropriate. State attorneys general have made considerable effort to tie the thefts to increased safety risks from aggressive driver behavior. However, a vehicle recall may not be an effective means to address such driver behavior because it is not a reasonably foreseeable safety consequence attributable to the technology shortcoming in the vehicle. In other words, there is necessarily an independent element of driver action in between the technical issue—the lack of an immobilizer—and the end consequence—the aggressive driving behavior that could ultimately lead to a crash.

Nonetheless, automakers must meet NHTSA's anti-theft standards, and failure to do so could be grounds for a recall based on noncompliance – rather than a safety-related defect. In their April 20, 2023 letter, the attorneys general assert that, because the ignition system is relatively simple to bypass, the vehicles are in violation of 49 CFR § 571.114, Federal Motor Vehicle Safety Standard No. 114, which pertains to "theft protection and rollaway protection." This standard requires vehicles to have "a starting system which, whenever the key is removed from the starting system prevents: (a) [t]he normal activation of the vehicle's engine or motor; and (b) [e]ither steering, or forward self-mobility, of the vehicle, or both." NHTSA has not called on the involved automakers to conduct a recall, which is an indication that the agency believes that the standard's required protection against "normal activation of the vehicle's engine or motor" when the key is removed is satisfied in this case.

If a lack of such anti-theft technology is not a safety-related defect or noncompliance, then what types of technology shortcomings qualify? Technology issues that directly constitute an unreasonable risk of motor vehicle safety can be safety defects, and this is always a very fact-specific assessment that focuses on the ***reasonably foreseeable safety consequences of the failure mode***. NHTSA has opined in Enforcement Bulletin 2016-02 that it has authority to regulate software and automated safety technologies, including software and after-market software updates.

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2. Automakers should keep up with their peers in terms of vehicle safety performance.

A recent example of a safety-related technological defect leading to a recall involved the performance of automatic power sliding doors. Per the submitted Part 573 report, the automatic power sliding doors in several instances closed without the customers' awareness, leading to subsequent injuries. The purpose of the recall was to increase customer awareness of the defect and provide a software solution to add warning chimes to the door's closing mechanism. In this recall, the manufacturer did not acknowledge the presence of a defect but voluntarily recalled based on both a NHTSA request and an analysis of peer vehicles.

In fact, if manufacturers do not perform such peer studies, it is likely NHTSA will do so in the event of a potential safety concern. A step NHTSA may take for new technologies during an investigation is to perform a comparison of similar performance data solicited from the peers of the investigated automaker. For example, prior to the power sliding door recall, NHTSA collected data from other manufacturers and compared different attributes such as the speed and force of the door movement.

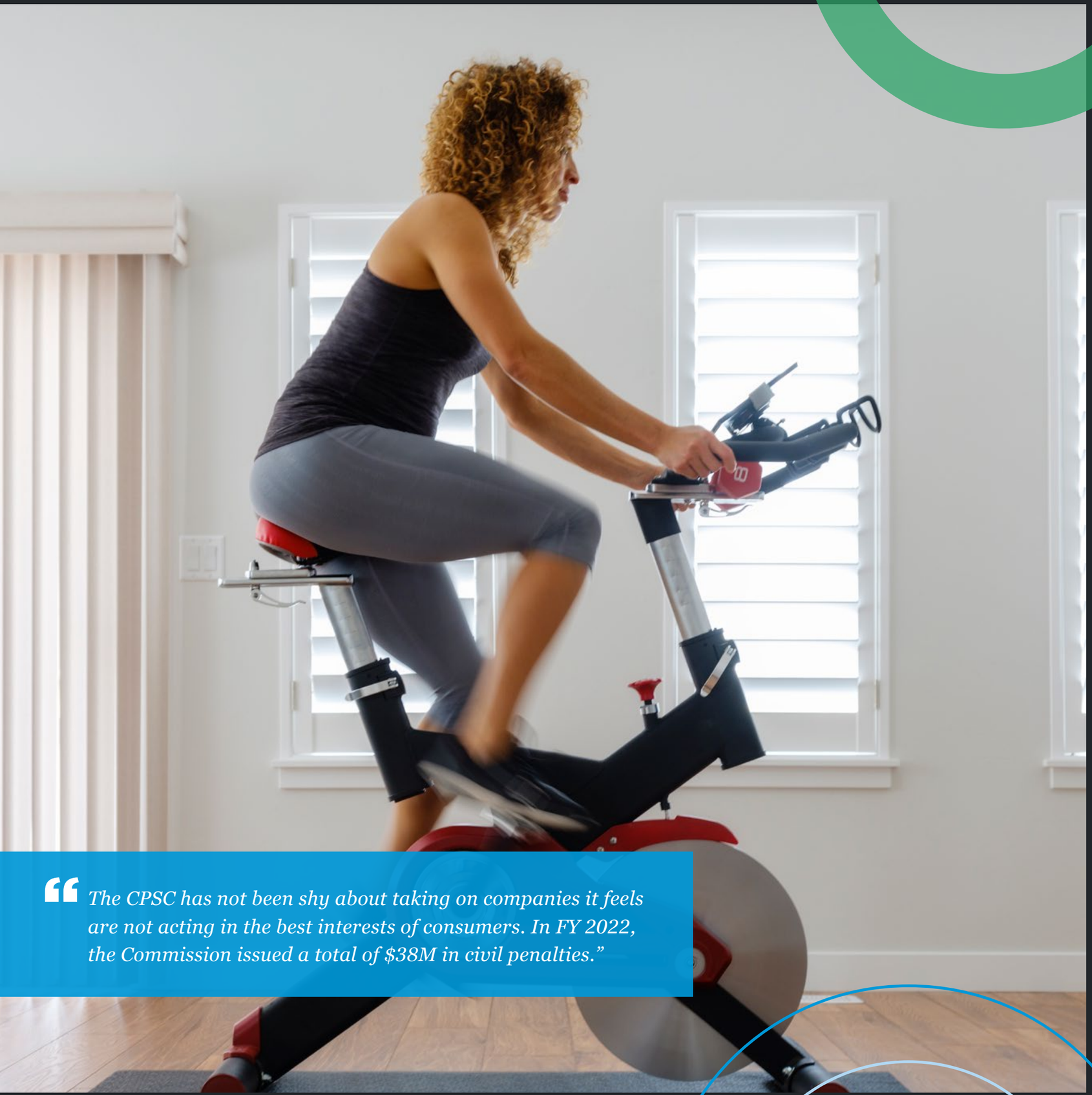
Likewise, NHTSA sent information request letters to twelve manufacturers as a part of its investigation of one manufacturer's advanced driver assistance system (ADAS). The information request solicited "production and field incident reporting data as well as information concerning the engineering and performance of their systems [with the same driving automation system designation as the system under investigation]."

3. The future landscape – or the benefits of staying with the pack.

One lesson to be learned from the immobilizer issue is that manufacturers should consider the implications of "staying with the pack" as the auto manufacturing industry adopts technologies. While not a direct analogy, the sliding door recall shows the benefit of reviewing peer technologies and industry standards in order to have a well-functioning safety compliance program and proactively identify potential safety-related defects.

As one resource, manufacturers can look to organizations like the Insurance Institute for Highway Safety ("IIHS") to keep abreast of changes in the industry. For example, earlier IIHS "studies show that vehicle theft losses plunged after immobilizers were introduced." Another recent study by the IIHS found that the two automakers "lagged behind other manufacturers in equipping their vehicles with standard passive immobilizers; for example, only 26 percent of their 2015 vehicle series were equipped with standard immobilizers compared with 96 percent of all other makes combined." The work of IIHS has the potential to drive positive change at a faster rate than slow-moving legislation and regulation by the federal government, since both insurers and consumers pay attention to IIHS safety ratings and studies.

At the end of the day, NHTSA does not evaluate the need for a recall based on the age of technology or whether it is in line with industry standard. However, monitoring industry standards can help reduce the risk of avoidable safety defects and noncompliance by learning from peer vehicles. Once NHTSA begins an investigation, it likely will assess the safety performance of a motor vehicle or related equipment against peer vehicles. Performing your own analysis can help you keep one step ahead.



> *"The CPSC has not been shy about taking on companies it feels are not acting in the best interests of consumers. In FY 2022, the Commission issued a total of $38M in civil penalties."*

CONSUMER PRODUCTS

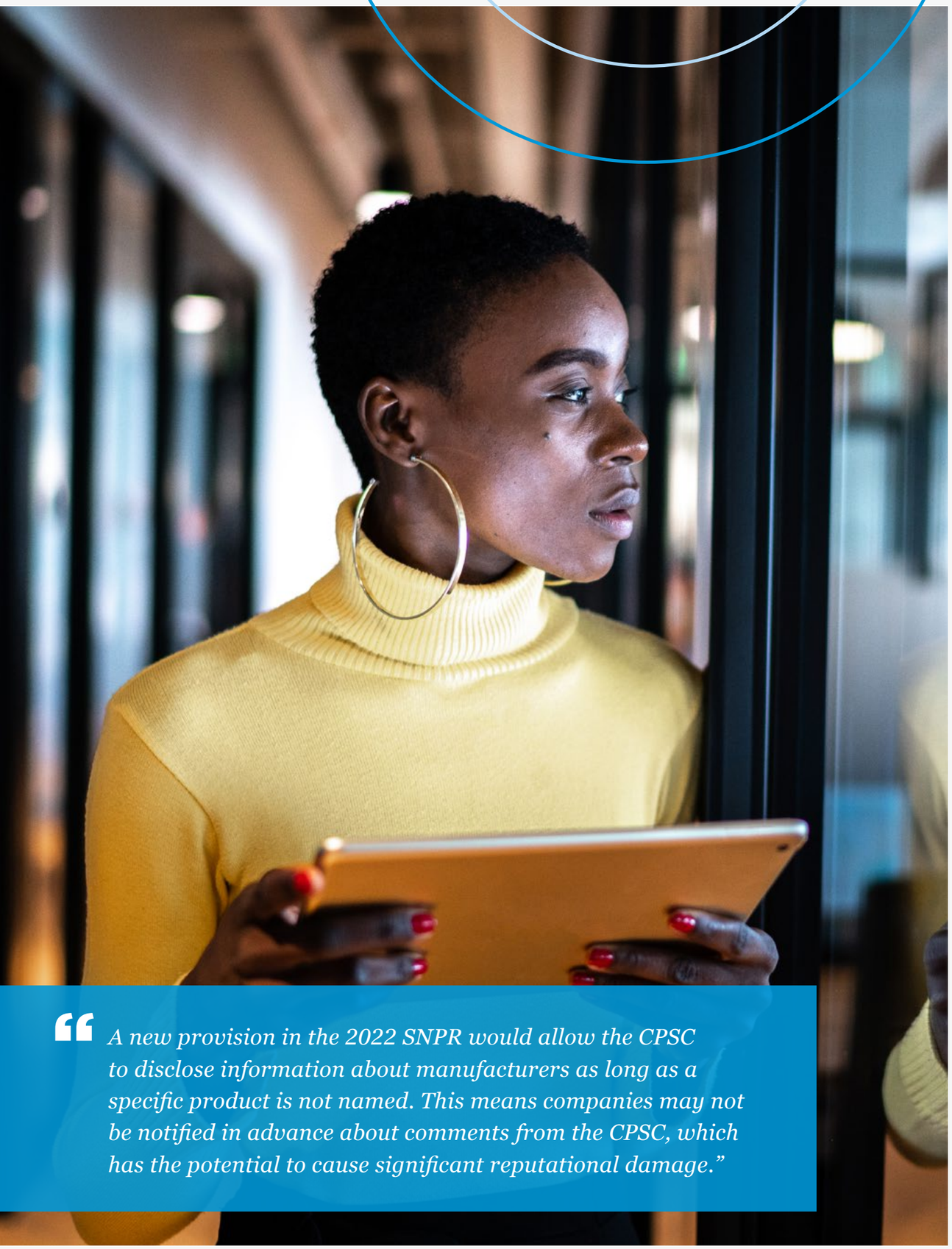
The Federal Trade Commission (FTC) has been actively enforcing several policies including those around "Made in America" labels. It also recently released guidance for privacy and data security in vehicles and expanded its oversight of health products to include more than just dietary supplements.

The Commission's forceful approach is likely to continue. In February 2023, President Biden renominated Rebecca Kelly Slaughter to serve another term as an FTC Commissioner. In March, Christine Wilson, the lone Republican, resigned, leaving the five-person Commission with only three members, all Democrats.

Like the FTC, the Consumer Product Safety Commission (CPSC) has not been shy about taking on companies it feels are not acting in the best interests of consumers. The agency laid out its agenda in February when Chairman Alexander Hoehn-Saric addressed the International Consumer Product Health and Safety Organization (ICPHSO) at its annual symposium. Chairman Hoehn-Saric highlighted the Commission's work in improving consumer awareness about product recalls and pushing for direct notice to consumers whenever possible. These statements suggest the agency will continue to aggressively pursue remedies from consumer product manufacturers.

This includes the use of unilateral press releases if the Commission cannot negotiate a voluntary recall with companies. Chairman Hoehn-Saric said that since the start of fiscal year (FY) 2022, 13 unilateral press releases have been issued, more than in the previous four years combined. The Chairman also promised to pursue civil penalties and legal remedies if companies violate the law.

In FY 2022, the Commission issued a total of $38 million in civil penalties. In January 2023, it unanimously approved a civil penalty settlement of more than $19 million with one exercise equipment company.



> *A new provision in the 2022 SNPR would allow the CPSC to disclose information about manufacturers as long as a specific product is not named. This means companies may not be notified in advance about comments from the CPSC, which has the potential to cause significant reputational damage."*

In addition, Hoehn-Saric said the Commission is prioritizing standards for portable generator safety, gas furnaces, adult portable bed rails, infant loungers, and infant support pillows this year, as well as more active enforcement of rules such as the Infant Sleep Products Rule.

Despite the promises of more stringent enforcement, the Chairman did clarify an inaccurate claim that the CPSC wanted to ban gas stoves. He stressed this was not true, though he did say that the health risks from gas stoves should be studied and addressed, as appropriate.

Other issues of concern for manufacturers include an effort from the CPSC to change its disclosure rules. In addition, a new safety standard for batteries has been proposed that aims to reduce the risk of injury from ingestion of button cell or coin batteries by young children.

The Environmental Protection Agency (EPA) has proposed a rule to restrict the use of hydrofluorocarbons (HFCs) in certain products and equipment. The agency is also ramping up its enforcement actions around HFCs, and manufacturers and importers need to take note of this.

Multiple state and federal agencies are introducing more regulations around perfluoroalkyl and polyfluoroalkyl substances (PFAS). The EPA is proposing various actions and several states have enacted or proposed regulations concerning PFAS in children's products. U.S. companies that sell globally also need to be aware of actions taken by the EU to restrict or ban most uses of PFAS, including in food-contact materials.

All of these revisions mean more risk for companies and a need to work closely with partners up and down the supply chain to ensure that manufacturers and marketers know what materials are in the products they are selling.

CPSC votes to change disclosure rules

The Consumer Product Safety Commission (CPSC) is increasingly using the media and the court of public opinion to get companies to take swift actions around product safety. This is evident in its aggressive use of unilateral press releases when it disagrees with a company on the need to recall a product.

The agency has taken another step towards making sure product safety concerns can be publicized by voting to issue a supplemental notice of proposed rulemaking (SNPR) on the CPSC's procedures for disclosing information to the public under Section 6(b) of the Consumer Product Safety Act (CPSA).

A majority of commissioners voted to repeal the rule, which requires that the CPSC give manufacturers or private labelers advance notice and an opportunity to comment on information the Commission proposes to release if the public can easily identify the company from the CPSC's statement. The only commissioner to vote against the rule change did so because he felt it was not strict enough and there would still be delays in getting important safety information to the public.

Under Section 6(b), the agency must also try to ensure that any product-specific information it shares with the public is accurate and provide companies 15 days to comment on a potential recall before the CPSC releases any information to the public.

In a statement, CPSC Chair Alexander Hoehn-Saric said the provisions of Section 6(b) mean that the CPSC "cannot adequately inform the public of unreasonable risk of injury associated with products that are often already in consumers' homes."

An earlier attempt in 2014 to revise how Section 6(b) is interpreted was criticized by companies for eroding confidentiality and fairness safeguards that encourage businesses to report potential safety issues to the CPSC, according to legal experts at Keller and Heckman.

Attorneys with Arnold & Porter note that a new provision in the 2022 SNPR would allow the CPSC to disclose information about manufacturers as long as a specific product is not named. This means companies may not be notified in advance about comments from the CPSC, which has the potential to cause significant reputational damage.

According to the CPSC's Fiscal Year 2023 Operating Plan, the agency will issue a Final Rule before October 2023. Consumer product companies should take this time to review their recall plans and ensure they have provisions for a crisis communications response if the CPSC makes statements without prior notification.

New safety standard for batteries passed

On February 9, 2023, the CPSC published its Notice for Proposed Rulemaking (NPR) for the Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (safety rule 16 CFR 1263). The proposed rule sets performance, labeling, and other related requirements mandated by Reese's Law.

Reese's Law aims to reduce or eliminate the risk of injury from ingestion of button cell or coin batteries by children six years old and younger. The broad scope of the rule could include apparel, footwear, accessories, hard goods, and more.

Under the draft NPR, consumer products containing or using button cell or coin batteries will also need to be tested and certified as compliant. Experts with UL Solutions state that these performance tests will examine use criteria and construction in addition to looking at factors such as drop, impact, crush, and compression tests to see how well the batteries or products stand up to abuse.

To help companies better prepare, the experts recommend several steps including reviewing products sold in the U.S. that would be covered by the rule, evaluating products to see if any adjustments need to be made, and finding a CPSC-accepted, third-party laboratory that can test the products and provide a Children's Product Certificate (CPC) or a General Certificate of Conformity (GCC) as required.

According to attorneys with Crowell & Moring, while the proposed rule only applies to button cell and coin batteries, Reese's Law gives the CPSC authority to extend these requirements to any battery that it determines is an ingestion hazard. Given the Commission's aggressive actions in other consumer safety areas, it would not be surprising to see more battery types and products subject to the new rule.

It is anticipated that the final rule will be enacted in August 2023. After that, companies will have 180 days to comply with the new regulations.

Is it the end of HFCs?

In December 2022, the Environmental Protection Agency (EPA) published a proposed rule under the American Innovation & Manufacturing Act (AIM Act) to restrict the use of hydrofluorocarbons (HFCs) in certain products and equipment where more climate-friendly alternatives are available. Both imported and domestically-manufactured products would be subject to the new rule.

HFCs are man-made industrial chemicals primarily used in refrigeration, air-conditioning, insulating foams, and aerosol propellants. They are considered super-pollutants by the EPA. While they are typically contained within equipment, they can leak out as greenhouse gas as the equipment wears or if there is faulty maintenance.

The AIM Act granted the EPA the authority to limit or prohibit the use of HFCs in specific sectors as well as the power to phase in these requirements over time. The proposed rule restricts the use of HFCs used in certain foams, aerosol products, refrigeration, air conditioning, and heat pump equipment beginning in 2025.

The EPA is also ramping up its enforcement actions around HFCs and announced three landmark settlements with HFC importers who violated the Clean Air Act's (CAA) Greenhouse Gas Reporting Program. For failing to report their imported quantities of HFC, the companies faced penalties between $247,601 and $382,473 each. The agency said it is aggressively pursuing similar actions against several other importers. In addition, the EPA issued the first notices of violation (NOVs) under the AIM Act against companies who allegedly imported regulated substances without required allowances.

Manufacturers and importers should take note that the EPA is strictly monitoring companies. Legal experts with Manko Gold Katcher & Fox recommend manufacturers and distributors transition to acceptable alternatives quickly. They also caution that the proposed rule implements recordkeeping, labeling, and reporting requirements to demonstrate product compliance. These changes need to be incorporated into companies' compliance programs and product planning.

An overview of PFAS regulations

Many state and federal agencies are prioritizing regulations around perfluoroalkyl and polyfluoroalkyl substances (PFAS). This class of thousands of synthetic chemicals is used in a wide range of consumer, commercial and industrial products to provide several different features. Several offices of the Environmental Protection Agency (EPA) have proposed at least ten different actions around PFAS, according to experts with Hunton Andrews Kurth LLP. These include deciding if Perfluorooctane sulfonate (PFOS) and Perfluorooctanoic acid (PFOA) should be designated as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and changing the requirements for PFAS and community right-to-know toxic chemical release reporting.

As of February 2023, seven states have enacted regulations concerning PFAS substances in Children's or Juvenile Products. Six other states have proposed regulations in 2022 or 2023 for these products which are expected to move through the legislative process later this year. The rules are a mix of notification requirements and bans on various forms of PFAS.

The Modernization of Cosmetics Regulation Act of 2022 (MOCRA) that was included in the Consolidated Appropriations Act, 2023 (H.R. 2617) signed in December 2022 also has provisions related to PFAS.

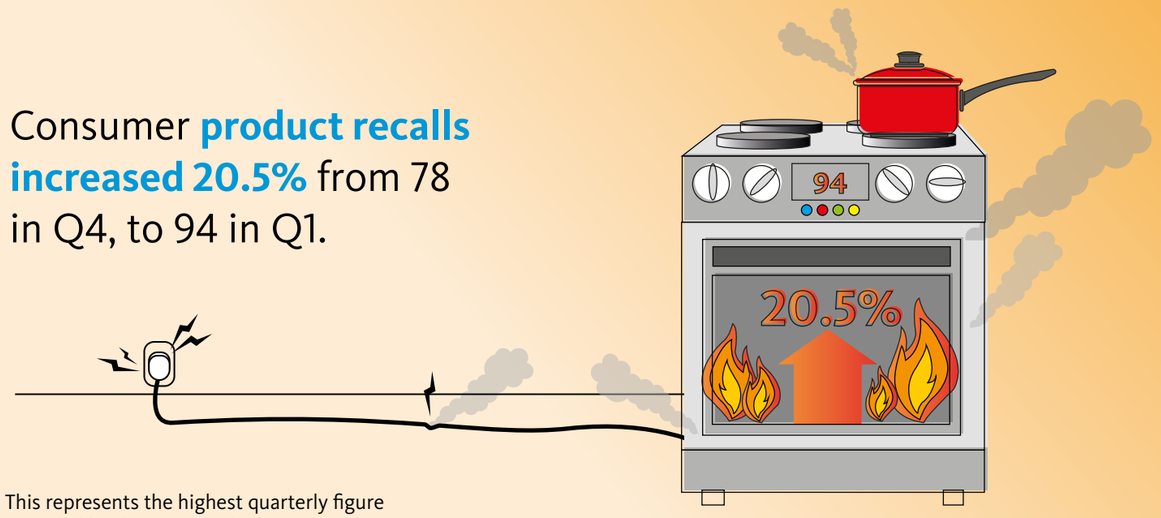
Legal experts with Patterson Belknap Webb & Tyler LLP report that MOCRA directs the U.S. Food and Drug Administration (FDA) to evaluate the use and safety of PFAS in cosmetic products and assess the scientific evidence to determine if there are any risks tied to their use in cosmetics. The FDA's report with its findings is due December 29, 2025. The results of the FDA's assessment could spur additional class action claims against any products containing PFAS if the FDA determines they are unsafe.

U.S. companies that sell globally also need to be aware of actions the EU is taking around PFAS. Five EU Member States submitted a proposal to the European Chemicals Agency (ECHA) to restrict or ban most uses of PFAS, including in food-contact materials. The draft covers fluoropolymers and approximately 10,000 different PFAS.

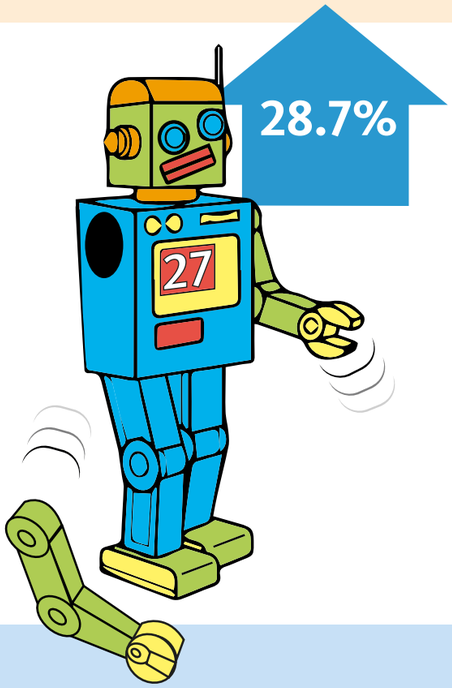
Given the increasing number of regulations for PFAS, companies will need to conduct their own risk assessment to see where they are vulnerable and determine how vital these chemicals are to their products' performance. If it is possible to produce their products without them, that would mitigate their risk from both regulators and plaintiffs' lawyers.

> *"Given the increasing number of regulations for PFAS, companies will need to conduct their own risk assessment to see where they are vulnerable and determine how vital these chemicals are to their products' performance."*

Consumer **product recalls increased 20.5%** from 78 in Q4, to 94 in Q1.



This represents the highest quarterly figure recorded by the CPSC in the last 5 years.

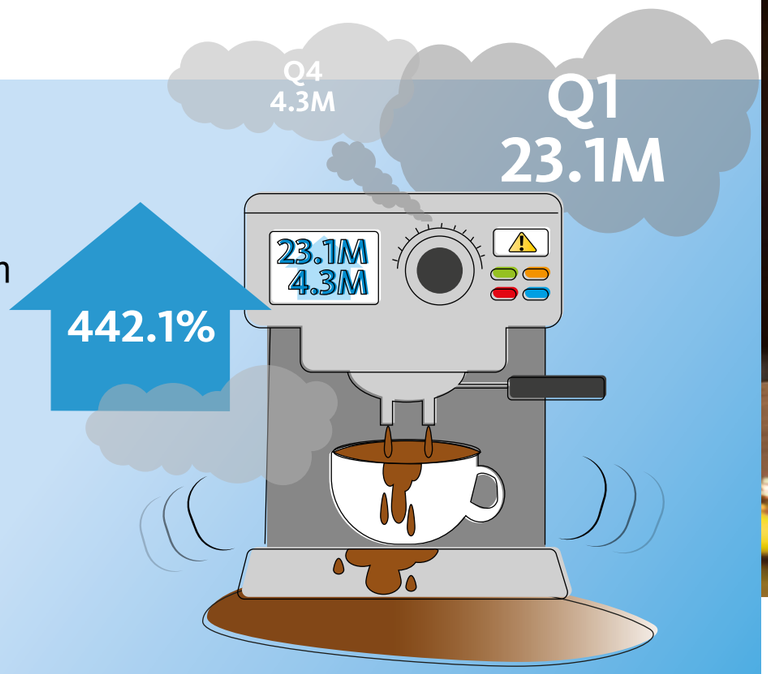


Children's products **dominated Q1 recalls** with 27 events (28.7% of all recorded activity).

This supplanted Sports & Recreation products, which held the top position for the last 2 years.

Total impacted units rocketed 442.1%, from 4.3M in Q4, to 23.1M.

This represents the highest quarterly figure recorded by the CPSC in the last 5 years.



FIRST QUARTER BY THE NUMBERS

Q1 2023 was an active month for consumer product recalls. There were 94 events, the most recalls in a single quarter since Q3 2015. This represents a 20.5% increase from the 78 events recorded last quarter. The total number of units recalled also increased by 442.1% from the previous quarter to 23.12 million, making it the highest quarter by units since Q4 2017. The average recall size was 245,976 units, which is the second-largest number recorded since Q4 2017.

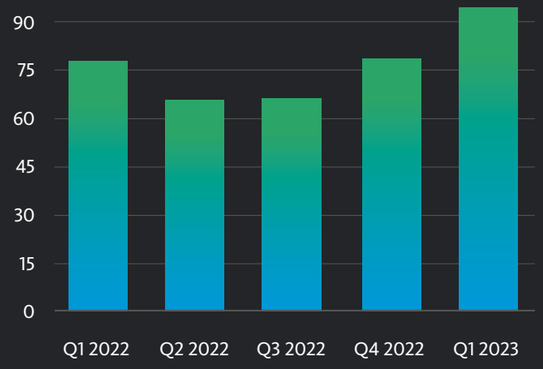
Despite the large number of recalls and units involved, the number of reported incidents decreased by 23.3% compared to Q4 2022, to 2,297. There were also 79.2% fewer injuries, with 57 recorded in Q1 2023. However, the number of deaths rose from three last quarter to 14, making Q1 2023 the highest quarter for fatalities since Q2 2019 and the fifth-highest since Q4 1997.

Burns were the top consumer product hazard by event in Q1 2023, with 23 recalls. Fire was the second-leading concern with 18 events, followed by injury with 10. Hazardous materials were the top risk by unit with 6.90 million units, mostly due to a single recall of multi-purpose cleaners that impacted 4.96 million units.

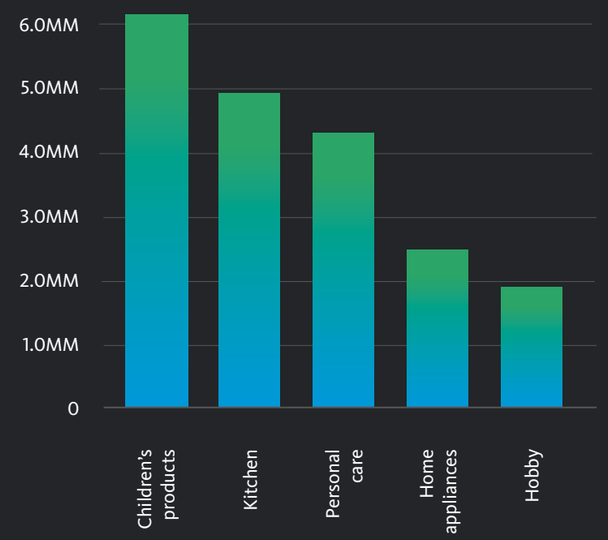
Children's Products accounted for the most recalls by product category, making up 28.7% of recalls with 27 events in Q1 2023. Sports & Recreation was second with 22 recalls, and Home Furnishings & Décor was third with 10.

In terms of units impacted, Children's Products was also the top product category with 6.29 million units recalled, or 27.2% of all units in Q1 2023. The majority of these were tied to a rocker sleeper recall. Kitchen products was second with 4.96 million units, nearly all of which were linked to the single recall of multi-purpose cleaners.

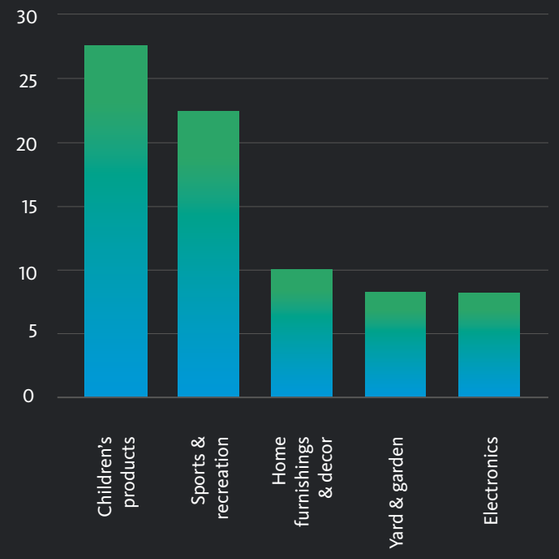
NUMBER OF RECALLS BY QUARTER



NUMBER OF UNITS RECALLED BY CATEGORY



NUMBER OF RECALLS BY RISK TYPE



APRIL 2023 insight

There were 25 U.S. consumer product recalls in April 2023, falling from the Q1 2023 monthly average of 31 events. The number of units recalled fell by 63.2% to 2.84 million in April 2023 compared to the Q1 2023 monthly average of 7.71 million.

Apparel was tied to the most April 2023 consumer product recalls with seven events. This was followed by Yard & Garden with six events and Sports & Recreation with five events. There were three deaths associated to a single recall of an A/V cart.

Yard & Garden had the most units recalled. A single event involving fiberglass sledgehammers impacted 2.25 million units, or 99.7% of all Yard & Garden units. Home Appliances had the second-highest number of units recalled, with 410,350. A recall of travel steam irons accounted for 78.5% of the units affected in this category in April 2023.

JEREMY RICHARDSON, PARTNER,
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THE FIRST RULE TO MITIGATE FALSE ADVERTISING CLASS ACTION LITIGATION RISK: DISCLOSURE, DISCLOSURE, DISCLOSURE

Consumer products manufacturers face the risk of numerous class-action lawsuits alleging failures to disclose the presence of both chemicals that are known to be harmful as well as potentially harmful chemicals. With few exceptions, these lawsuits do not allege physical harm from exposure. Rather, they rely on plaintiffs who say had they known a particular chemical was in a product, they would not have bought the product or, puzzlingly, they still would have bought it, but only if they had paid less. In this latter instance, the plaintiffs claim to have paid a premium because of the failure to disclose.

Plaintiffs seeking reimbursement of some or all of the product's retail purchase price in "premium price" cases may number in the tens of thousands. Each consumer possibly made multiple purchases, resulting in damages that can be "bet the company"-sized figures. Generally, these damages apply to purchases made as many as six years prior to the filing of a complaint, though some states have shorter look-back periods. Companies may also be liable for the plaintiffs' costs and legal fees.

To mitigate this threat, consumer products manufacturers can disclose on the product label or product packaging any ingredients that may be substances of concern. However, it is nearly impossible to predict where future claims will come from and what component or ingredient will be targeted. Often, plaintiffs' lawyers start with the idea that something is missing from or wrong on a product label, packaging, or website. From there, the lawyers draft a complaint, find a plaintiff, maybe send a demand letter, and file a lawsuit.

Physical injury and medical monitoring claims are rare, but do exist, especially for products containing ingredients deemed unsafe by regulators. Manufacturers should not intentionally add to their products unsafe levels of ingredients known to be hazardous. Manufacturers should know of and regularly monitor restricted substance lists (RSLs), as they are frequently updated. Several regulatory agencies, non-government organizations, and trade associations maintain RSLs. For example, the California Office of Environmental Health Hazard Assessment and the American Apparel and Footwear Association (AAFA) make their lists publicly available at no charge.

Even when efforts are made to avoid chemicals of concern and other restricted substances, companies should test their products often, especially if they change a supplier. But companies don't always know when a supplier makes changes in its supply chain. And companies may not learn, until it is too late, if a supplier or contract manufacturer has substituted an ingredient. This is especially true with the continued disruptions to the global supply chain exacerbated by the pandemic and global conflicts. Manufacturers should have quality assurance processes in place that include random testing of samples down to the batch level. Most companies are not equipped to do sophisticated in-house testing, so it is important to maintain good relationships with certified third-party labs.

These best practices apply to all restricted substances and known chemicals of concern. But companies often face ethical, not so black-and-white, challenges around new chemicals. Should companies use chemicals until there is a known link to cancer, birth defects, or other harm? Or should companies avoid new chemicals until they are known to be safe? And how is "safe" defined, since in general regulatory agencies will not say with absolute clarity and certainty that a substance won't cause cancer, for example. Even if there is little to no evidence that suggests it does.

Many chemicals were invented to solve urgent problems. One example is the tetraethyl lead (TEL) additive for gasoline. Chemical engineer Thomas Midgley Jr. first discovered lead's effectiveness to decrease engine knocking in automobiles in 1920. It wasn't until decades later that people considered lead as a health hazard, especially for children.

Leaded gasoline was phased out in the U.S. beginning in 1975, though this was prompted not only by concerns about lead levels in air and soil and its neurotoxicity impact, but also because of advances in automotive engineering and petroleum chemistry that made it less vital. Other countries began banning leaded gasoline, starting with Japan in 1986. In July 2021 the sale of leaded gas was completely phased out worldwide.

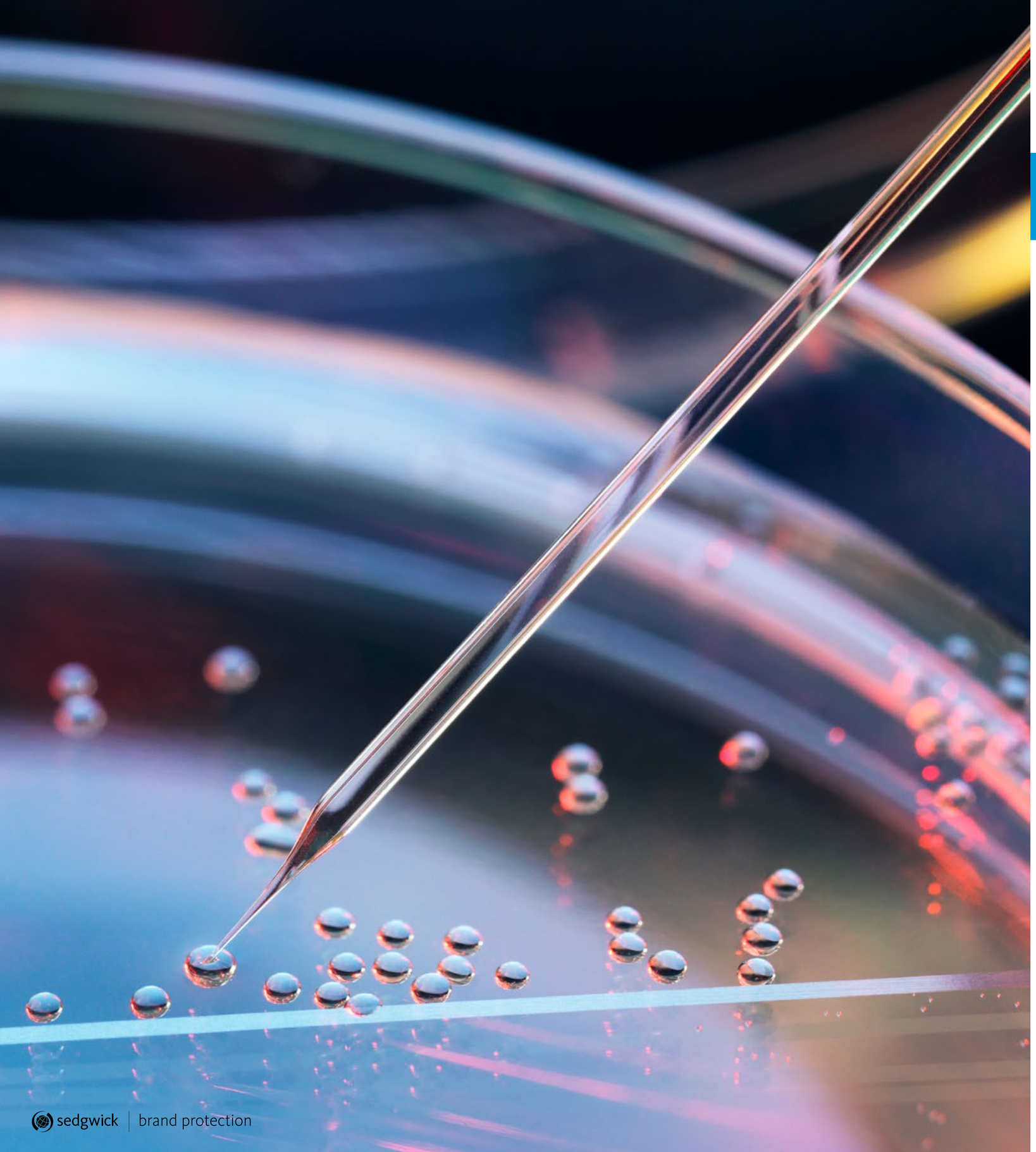
Today we see similar discussions with respect to perfluoroalkyl and polyfluoroalkyl substances, or PFAS, a class of more than 3,000 synthetic chemicals found in a wide range of consumer, commercial, and industrial products. PFAS have been used since the 1940s and can be found in everything from food packaging and high-performance outdoor clothing to household cleaners, carpeting, and corrosion-resistant pipes and wires. In recent years, state and federal regulators and advocacy groups have raised concerns about the health risks posed by PFAS. Several states have enacted laws banning or restricting the use of certain PFAS for certain applications.

Like TEL, PFAS compounds solve real consumer problems. They can be used to provide non-stick surfaces, stain resistance, water resistance, and other performance attributes. While some of the benefits are "nice-to-have," like a stain-resistant carpet, in other applications the benefits are critical. This includes their use in high-performance gear for park rangers, firefighters, military personnel, and others for whom protective gear is an essential health and safety requirement.

There is no one clear regulation on PFAS, especially since there are so many chemicals which fall into the category, each with its own risk profile. Generally, PFAS tend to be divided into two subgroups depending on their number of carbon atoms: long-chain and short-chain. Long-chain PFAS have been in use for a longer time. PFOA used in Teflon pans is arguably the most famous example. Because they have been around longer, their risks are better known. Less is known about the short-chain PFAS which many manufacturers now use in place of their long-chain cousins. Some states have instituted bans against these chemicals while others only require disclosure when they are used. In addition, distinctions are made between "essential use," as with protective gear where there is no equivalent substitute, and other applications where there are alternatives manufacturers could use. Some regulators also separate incidents when PFAS are intentionally added versus unintentional contamination.

This brings us back to whether or not companies should use a chemical until they know it is bad. Or should they not use it until they know it is good?

Inventors of the many substances in the family of PFAS solved real problems or at least improved performance of various consumer products. Presumably they did not know these chemicals could harm consumers. And this brings us back to disclosure.



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CONTINUED FROM PREVIOUS PAGE

For companies trying to be innovative and solve consumer and public problems, it may not be possible to know if a chemical will contribute to a future health hazard. But if manufacturers know what goes into their products, they can be transparent about that with consumers.

If companies disclose any use of chemicals, they may reduce the risk of false advertising claims. Even California Proposition 65, which is viewed by some to be very restrictive and burdensome, technically doesn't ban chemicals. It is a disclosure requirement. Companies must warn California consumers about significant exposure to chemicals that cause cancer, birth defects, or other reproductive harm. There are approximately 900 chemicals on the list currently and it is updated at least once a year.

For substances whose safety profile is not yet fully known, companies should consider the possible risk of exposure to consumers and assess known safety data, with the understanding that the determinations about safety may change over time. This is particularly true as testing equipment improves and measurements are not only more precise, but capable of detecting smaller and smaller quantities.

Regular quality assurance testing should alert manufacturers to substituted ingredients and contamination. As to intentional use of restricted substances and chemicals of concern, whether a company chooses to disclose the use of all, or only certain ingredients, is a decision to be carefully considered. However, some regulated products must have full or partial ingredient lists, and Cal Prop 65 requires warnings. Knowing what is in the product is the first step to deciding whether and what to disclose.

FOOD AND DRINK

On February 23, 2023, the U.S. Food and Drug Administration (FDA) Foods Program released the list of topics it expects to publish as a draft or final guidance by the end of 2023, including both revisions to existing guidance documents and new topics. The key areas are allergens, dietary supplements, food additives, topics related to the Food Safety Modernization Act (FSMA), and labeling. The guidance documents will not be binding, however companies should be monitoring the FDA's recommendations for how to interpret regulations such as the FSMA or to understand what the agency considers best practices.

The FDA and the infant formula industry continue to recover from the significant disruption, reputational damage, and consumer harm from last year's crisis. On March 8, 2023, the agency issued a constituent update and sent a letter to key stakeholders involved in the manufacturing and distribution of powdered infant formula.

In the update, the FDA referenced the multiple guidance documents it has published since last year and highlighted its enforcement discretion and the development of a cronobacter prevention strategy. Other steps the agency mentioned include enhanced inspectional activities, more engagement with the infant formula industry, and taking regulatory action when appropriate.

The agency called on all parties involved to take prompt action to improve processes and implement the programs outlined in its letter. It also reminded constituents that Congress added new requirements for manufacturers aimed at mitigating supply chain disruptions through mandatory shortage notifications and risk management plans.

Other priorities for the agency include the proposed restructuring of the FDA's Human Foods Program (HFP) in response to the evaluation by the Reagan-Udall Foundation released late last year. The new structure unifies the functions of various offices to ensure food safety and advancing nutrition.

The FDA has also issued draft recommendations on labeling plant-based milk alternatives to provide guidance to the food industry on how to label and market these products while ensuring transparency about their nutritional content.

In addition, the U.S. Department of Agriculture (USDA) is working to implement its Strengthening Organic Enforcement (SOE) final rule which went into effect in March 2023. The goal is to strengthen organic control systems and improve farm-to-market traceability to address "organic fraud."

These developments reflect the growing emphasis on food safety, transparency, and consumer confidence in the food industry. Companies in the sector will need to stay up-to-date with these changes and adjust their practices and labeling accordingly to ensure compliance and maintain consumer trust.

> *"The FDA and the infant formula industry continues to recover from last year's crisis. The agency reminded constituents that Congress added new requirements for manufacturers aimed at mitigating supply chain disruptions through mandatory shortage notifications."*

Proposed changes to the Human Foods Program

The Reagan-Udall Foundation released its highly-anticipated evaluation of the FDA's Human Foods Program (HFP) in December 2022. In January 2023, the FDA announced a proposed restructuring in response to the report. FDA Commissioner Dr. Robert Califf said that the changes would also address findings from an internal review of the agency's infant formula supply chain response that was completed last year.

As part of the restructuring, the functions of the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response (OFPR), and certain functions of the Office of Regulatory Affairs (ORA) will be unified under a new HFP. The program will focus on keeping food safe and nutritious while ensuring the agency remains on the cutting edge of the latest advancements in science, technology, and nutrition.

Other structural changes outlined by Commissioner Califf include the creation of a Center for Excellence in Nutrition, which would include the Office of Critical Foods. In addition, the FDA would establish an Office of Integrated Food Safety System Partnerships to elevate, coordinate, and integrate the agency's food safety and response activities with state and local regulatory partners for a more integrated system for food safety. This change follows provisions in the Food Safety Modernization Act of 2011. The FDA is likely to look to collaborate more with state-level inspection agencies.

Commissioner Califf also proposed a Human Foods Advisory Committee that will support the agency's decision-making activities. The committee will include external experts to advise on challenging and emerging issues in food safety, nutrition, and innovative food technologies.

The need to strengthen the agency's enterprise information technology and analytical capabilities was also stressed as part of the new structure. The focus will be on improving workflow and enabling better communications, more efficient operations, and enhanced risk assessment to shape the priorities of the program and the agency's work in the field.

Under the new structure, the ORA would support not only the HFP, but also all other FDA regulatory programs as an enterprise-wide organization focusing on critical activities. This will give the ORA a singular focus on inspections, laboratory testing, import, and investigative operations. The change is aligned with the FDA's public health and prevention-oriented goals.

The CFSAN, ORA, and OFPR will continue to operate under their current structures until the details of the proposal are finalized. In the meantime, stakeholders in the food sector who want to have their voices heard should follow announcements about how to participate in the Human Foods Advisory Committee.

Stronger enforcement of organic labeling on the way

The USDA's Strengthening Organic Enforcement (SOE) final rule went into effect on March 20, 2023. However, companies have until March 19, 2024 to comply with the new regulations. The rule applies to the National Organic Program (NOP) and relates to the production, handling, and sale of organic agricultural products.

The USDA reports dramatic growth in the organic market and an increase in "organic fraud," where non-organic products are marketed as organic since the first organic regulations went into effect in 2002. Some of the provisions in the final rule were mandated by the 2018 Farm Bill and address recommendations made by the National Organic Standards Board.

The agency said the changes were made to protect integrity in the organic supply chain and increase consumers and industry trust in the USDA organic label. Under the provisions in the final rule, there will be stronger organic control systems, improved farm-to-market traceability, and robust enforcement of the USDA organic regulations.

There are a wide range of topics covered by the new regulations including their applicability of, and exemptions from, organic certification, recordkeeping and product traceability, standardized certificates of organic operation, unannounced on-site inspections of certified operations, use of import certificates, and fraud prevention.

Under the previous regulations, any operation that produces or handles organic agricultural products must be certified organic. However, the final rule provides a new definition for "handle" that includes trading, facilitating sale on behalf of a seller, exporting for sale in the U.S., repackaging, labeling, and storing, among other activities. Entities not already certified as organic will want to review the new wording to determine if they are required to be so. Most entities in the middle of an organic supply chain will need certification.

The requirements for certified operations were also updated, including a mandate that they develop and implement improved recordkeeping and organic fraud prevention processes. Among these processes are supplier verification and verifying the organic status of agricultural products received. Other requirements include making nonretail containers used to ship or store organic products traceable for audit trail documentation.

There is one change that will ease some of the requirements for certified operators. Previously they needed to submit a full system plan each year. Under the final rule, certified operations will only need to re-submit the plan when it has been revised, and in that case only the updated sections must be submitted.

Among the other changes in the final rule are updates related to inspection of certified operations and enforcement, clarification around procedures for establishing, evaluating, and terminating equivalence determinations with foreign government organic programs, and amendments to the provisions for certifying agents and their activities. The regulations also establish an increase in on-site inspections and uniform qualification and training standards.

Attorneys with Jones Day predict that once the new rule is enacted, brands and retailers that sell products labeled as organic will likely see an increase in consumer claims alleging organic fraud. That provides even more incentive for companies to assess how the changes will impact their operations and ensure they are in compliance before March 19, 2024.

> *"The USDA's Stengthening Organic Enforcement (SOE) final rule went into effect on March 20, 2023. Brands and retailers that sell products labeled as organic will likely see an increase in consumer claims alleging organic fraud."*

Labeling guidance for plant-based milk alternatives

On February 22, 2023 the FDA issued its draft recommendations, Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry. The agency notes that the market availability and consumption of plant-based milk alternatives (PBMA) have increased and there are many more plant sources being used. Frequently all of these products are being labeled as “milk.”

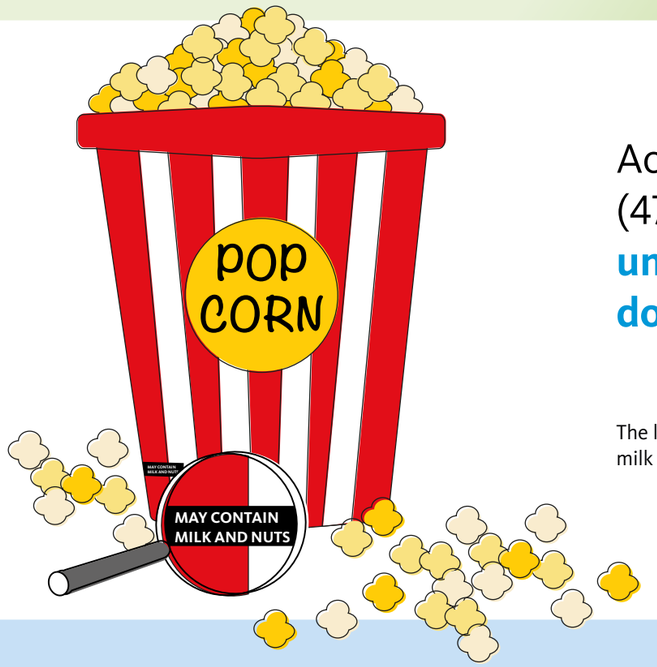
The FDA reviewed more than 13,000 comments that were received in response to its 2018 request for information on using the names of dairy foods such as “milk” when labeling PBMA. It determined that consumers generally understand that these products do not contain milk and specifically choose them because they are not milk. Companies will be able to continue to label plant-based products as “milk,” though the FDA recommends that the specific name of the plant source is used, such as “soy” or “almond.”

In its findings, the FDA concluded that consumers may not be aware of the nutritional differences between milk and PBMA products. The draft guidance recommends that PBMA using the term “milk” in their label, such as “soy milk” or “almond milk,” include a voluntary nutrient statement that conveys how the product compares with milk if the nutritional values are different.

While the guidance is not a binding regulation, it will be considered a best practice and will build goodwill with consumers by offering more transparency about nutritional content and ingredients. It is also a good prediction of how the FDA will handle labeling for other plant-based dairy alternatives, such as plant-based cheese or yogurt. A guidance for these products is expected later this year.

FDA food **recalls surged 23.2%** from 95 in Q4, to 117 events in Q1.

Despite this uplift, Class I recall designations (as a percent of events) are at their lowest for 10 years.

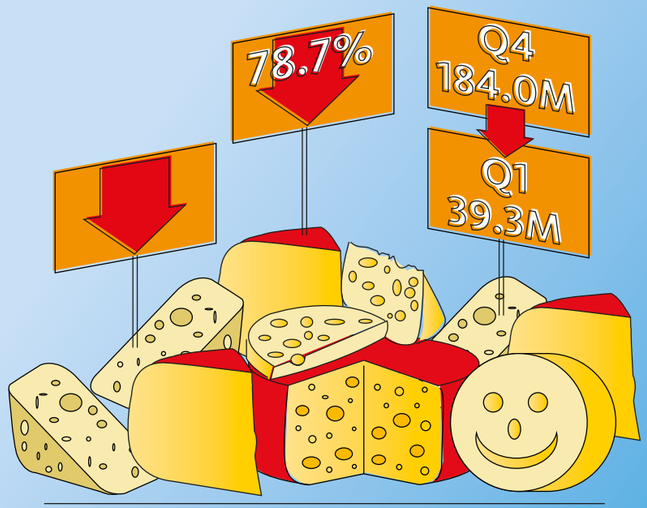


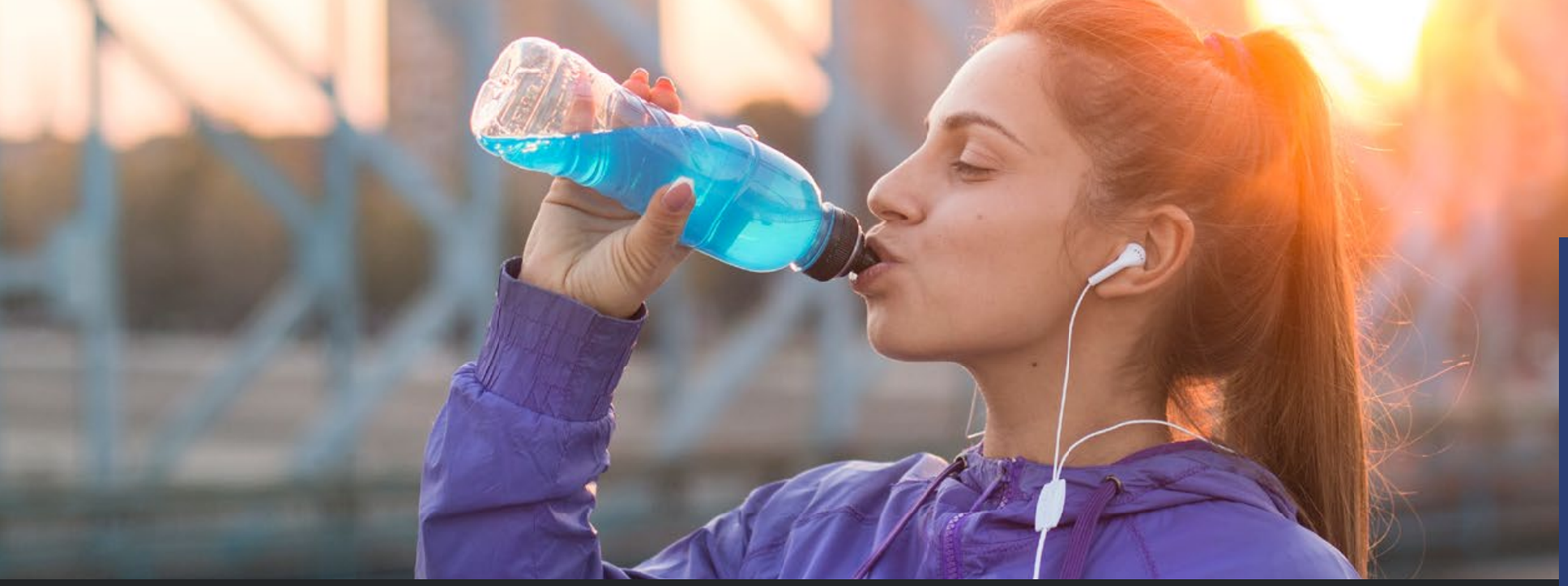
Accounting for 56 or half (47.9%) of all events, **undeclared allergens dominated Q1 recalls.**

The leading allergens comprised nuts (15 events), milk (14), soy (8), and wheat (6).

While events rocketed in Q1, **defective units plummeted 78.7%,** from 184.0M to 39.3M.

Despite this decrease, impacted units remain consistent with quarterly average of the last 5 years (43.4M).





FIRST QUARTER BY THE NUMBERS

FDA

After a decrease last quarter, the number of FDA food recalls increased by 23.2% to 117 in Q1 2023. However, the number of units impacted plummeted 78.7% compared to last quarter, from 183.99 million to 39.25 million. A major recall for a workout beverage contaminated with plastic was responsible for 21.00 million units, or 53.5% of all products recalled this quarter.

Undeclared allergens was the leading cause of U.S. food recalls for the ninth consecutive quarter, with 56 recalls in Q1 2023. This includes two recalls for undeclared sesame, which became the ninth major food allergen on January 1, 2023. Foreign materials were second with 19 events. Bacterial contamination was third with 15 events. These events included three recalls for cronobacter sakazakii contamination that was responsible for the infant formula crisis last year. Two of the food products recalled in Q1 2023 were for infant formula.

Foreign materials impacted the most units in the food and drink sector, with 29.74 million units affected, primarily related to the workout beverage recall. Undeclared allergen recalls were linked to the second largest number of units, with 5.52 million, mostly tied to recalls for possible nut products. Quality concerns were responsible for the third highest number of units, with 3.09 million units recalled.

Out of the last 25 quarters (dating back to Q1 2017), 20 have had prepared foods as the top recall category. That trend continued in Q1 2023 with 26 events, or 22.2% of all recalls. Produce was second with 22 recalls. Dairy and baked goods were tied for third with 13 recalls each.

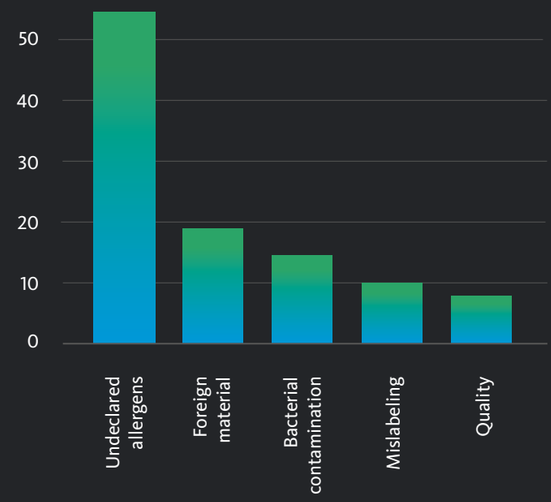
The number of Class I recall events fell from 34 to 29 in Q1, and involved 3.31 million units. Class II recalls increased from 55 last quarter to 67 in Q1 2023. Despite the rise in events, the number of units involved in Class II recalls dropped significantly from 181.89 million in Q4 2022 to 33.76 million in Q1 2023. The number of Class III recalls rose from six to 21 recalls which impacted 2.18 million units.

APRIL 2023 insight

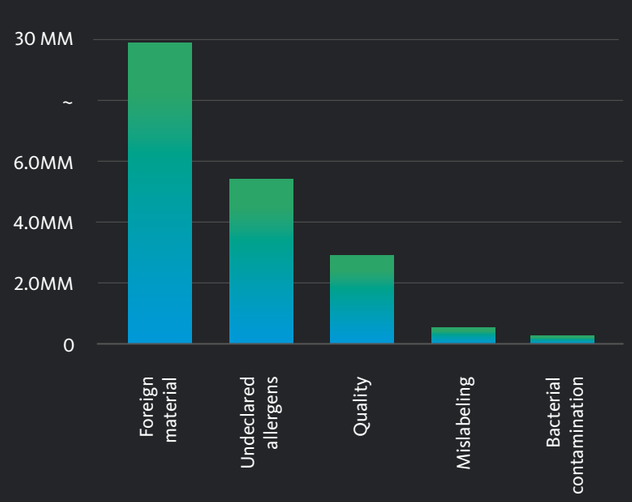
The FDA issued 41 recalls in April 2023, on par with the Q1 2023 monthly average of 39 events. The number of units recalled increased 37.0% to 17.92 million compared to the Q1 monthly average of 13.08 million. The increase in units recalled can largely be attributed to a single foreign material recall for metal contamination that impacted 15.67 million units.

Consistent with the previous quarter, undeclared allergens remained the leading cause of FDA food recalls with 18 events, including one recall for sesame, which was added as a major food allergen in January 2023. Foreign material was the second leading cause with six events, followed by bacterial contamination with five events. By unit, foreign material was the leading cause of FDA food recalls accounting for 16.58 million units or 92.5% of all food units recalled in April 2023.

NUMBER OF FDA RECALLS BY REASON



FDA UNITS IMPACTED BY REASON



USDA

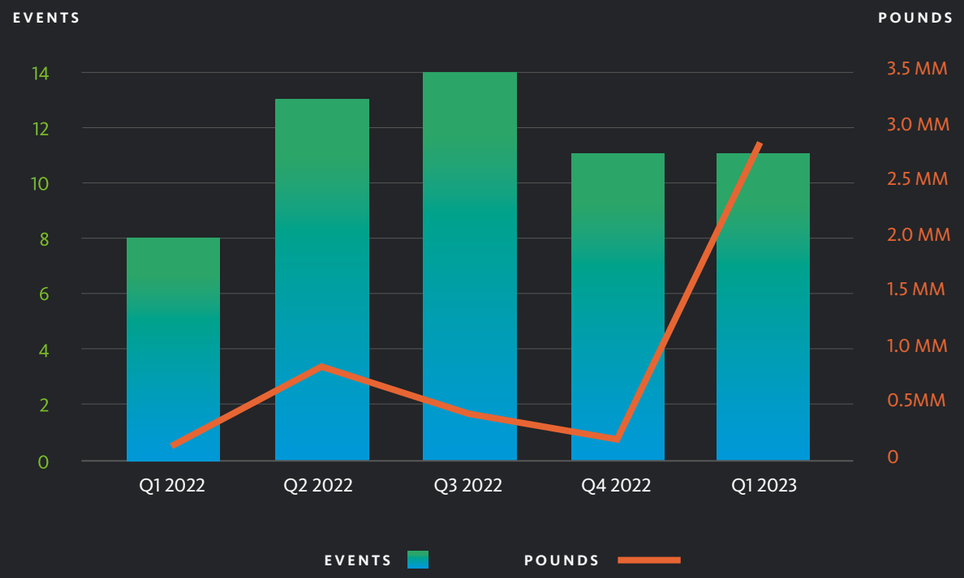
There were 11 USDA recalls in Q1 2023, holding steady from the previous quarter. However, the number of units impacted jumped by 1,129.0% to 2.88 million pounds. This is the second-highest recorded figure in a single quarter since Q1 2020.

The top reason for USDA recalls by event was no inspection with four events. Undeclared allergens were cited as the reason for three recalls, and bacterial contamination for two. Foreign material contamination and packaging defects were cited in one recall each.

By unit count, packaging defects were the leading cause of recalls, impacting 2.58 million pounds. No inspection was second, linked to 217,886 pounds of product recalled. By product category, multiple meats were responsible for the most units recalled in Q1 2023 with 2.60 million pounds. Goat was second with 196,019 pounds recalled.

By product category, multiple meats were linked to three recalls. Beef, poultry, and pork were all cited in two events each. Seafood and goat were each involved in one USDA recall in Q1 2023.

NUMBER OF USDA RECALLS AND IMPACTED UNITS BY QUARTER



APRIL

2023 insight

In April 2023, the USDA issued four recalls, tying with the Q1 2023 monthly average. However, the number of pounds recalled fell 91.4% to 82,948 pounds from the Q1 monthly average of 961,238 pounds. A single recall of ready-to-eat meat and poultry sausage products for misbranding/temperature abuse accounted for 74.2% of all units recalled in April 2023, impacting 61,574 pounds.

Misbranding/undeclared allergens was the top reason for USDA recalls in April 2023 with two events, both for undeclared soy. Foreign materials and misbranding/temperature abuse were both cited in one recall each. In terms of product category, beef had two recalls and poultry and multiple meats had one recall each.

ANITA LUDWAR, DIRECTOR OF SPECIAL PROJECTS & INNOVATION, **INDEX BIOSYSTEMS**

LEVERAGING BIOLOGICAL TAGGANTS FOR INCOMING ENHANCED TRACEABILITY RULES AND NEXT GENERATION PROCESSING CONTROLS

Poor traceability and supply chain complexity are known challenges within agriculture and food supply chains, and persist due to the inability to connect physical products to their supply chain data. A primary reason for this is that fungible goods like raw agricultural products and ingredients are too difficult to trace and differentiate through aggregation, processing and transformation. Without the ability to reliably trace a product, it is challenging to identify the origin of an outbreak, determine which products were affected by a contamination event, and secure product recall, contamination, or general liability insurance products designed to offset these associated risks.

Food product recalls are already at a 10-year high. Given the increased frequency of severe weather events, and the anticipated increase of pathogens in these altered ecosystems, a changing climate is expected to have a significant impact on food safety. In addition, new traceability rules from the U.S. Food and Drug Administration (FDA), alongside a $41 million USD increase to the FDA budget, suggest audits and recall events will continue to rise in the future. Furthermore, of the $7+ billion USD in losses that are incurred by the U.S. food and agriculture industry due to voluntary recalls each year, the majority of these losses remain largely uninsured.

All of these forces are creating a perfect storm and beg some serious questions.

How can you protect against a risk that you can't reasonably prove or disprove is your own? How can you make a claim that you are, or are not associated with a loss event when you can't definitively prove that a commingled or transformed product includes your own?

Now is the time for food industry members to evaluate their tech stack to ensure alignment with incoming FDA traceability requirements, and to consider mitigating risk where possible through tech-backed insurance products.

FDA Food Traceability Final Rule takes effect January 2026

In 2011, the Food Safety Modernization Act (FSMA) was signed into law in the United States, representing the most comprehensive update to food safety prevention and response in over 70 years. The Food Traceability Final Rule (Rule 204), published in 2022, is a key FSMA requirement that was developed to enhance the FDA's ability to quickly and accurately trace the source of contaminated product in the event of an outbreak. The Final Rule, which has a compliance date of January 2026, will ideally improve the FDA's ability to respond quickly to contamination events and take swift action to prevent further illness and protect public health.

Stakeholders that interact with high-risk products listed on the Food Traceability List (FTL) will be required to collect and maintain product data throughout their supply chain, including the maintenance of unique identifiers called Traceability Lot Codes (TLCs). All tracking events and key data elements will be associated with these TLCs, and new TLCs will be created when raw agricultural products are transformed into finished food products.

Simply put, there is a lot of data that needs to be collected, maintained, and shared along the supply chain, and this data needs to be readily accessible to the FDA in the event of an outbreak. Data custodianship is complex and systemic issues or poor coordination between participants can lead to breaks in the chain of custody. Technologies that solely rely on digital systems remain vulnerable to these breaks, especially when a product is disconnected or misplaced from its digital record.

Evaluating technologies to fulfill FSMA requirements

Taking the time to thoughtfully evaluate traceability technologies upfront is a valuable investment for companies as they comply with the Final Rule. Improved traceability through the Final Rule will allow for the quick identification and isolation of contaminated products, faster and more accurate recalls, and improved consumer trust – both of brands and the food system as a whole.

There are several considerations when evaluating traceability technologies:

- Can the software be easily used by office and factory workers alike?
- Does the traceability software integrate with existing ERP and IMS systems?
- Will it support the creation of new TLCs as products are aggregated and transformed into finished goods?

For many software-focused products, there remains a disconnect between a physical product and its supply chain data. Data is accurately tracked through the supply chain, however a product without a barcode loses its identity entirely. Molecular taggants offer a solution to this challenge and provide a link that allows for TLC identification directly from the product itself. A range of solutions exist to provide this missing link such as:

- DNA-based taggants, which are easily manufactured and may degrade within harsh environments without encapsulation.
- Synthetic taggants, which are durable and often require specialized equipment for detection.
- Biological taggants such as BioTags, which are economical, durable and detectable through standard Testing, Inspection & Certification companies.

It is important to consider how the taggant is paired with its software counterpart to evaluate its efficacy for compliance to the Final Rule, as well as its application and detection methods to determine the overall ease of use with your existing workflows.

Mitigating risk with technology-backed insurance policies

Despite $7 billion in losses due to voluntary recall incurred by the $1.2 trillion U.S. food and agriculture industry, there is only $700 million of global recall and contamination insurance market capacity. The complexity and variability of the food supply chain can make it difficult for insurers to accurately assess and price the risks associated with product contamination and recall events. Without traceability data, claims can be frequent and broad in scope, with litigation increasingly common. As a result, premiums are often prohibitively expensive depending on the level of coverage needed by the business.

ANITA LUDWAR, DIRECTOR OF SPECIAL PROJECTS & INNOVATION, **INDEX BIOSYSTEMS**

CONTINUED FROM PREVIOUS PAGE

In many underserved markets, we are seeing innovative products and technologies being deployed to underpin insurance policies that have historically been deemed 'too risky' to insure, such as product contamination and recall insurance. These technology-backed policies allow companies to adopt risk mitigation technologies that are coupled with fairly priced premiums to further mitigate supply chain risks.

Within food and agricultural supply chains there are several examples of such products.

One example includes a parametric policy backed by a novel sensor that is used in shipping containers to monitor the environment and ensure food is not spoiled during transportation. If a shipment is delayed, the sensor data can confirm whether the shipment environment was maintained at appropriate temperatures to prevent food spoilage during the delay, and prevent a shipment from needlessly going to waste.

Another includes product contamination and recall insurance for fresh food supply chains that is backed by molecular taggants, which link supply chain data directly to the product itself. In the case of a product contamination event, these taggants allow the origin of a product to be easily identified, even in batches that are aggregated, co-mingled, and transformed into finished goods. Instead of a broad recall for all products within the contaminated product's category, uninvolved products can be absolved from these events with a more targeted and timely recall resolution.

The use of biological taggants as a risk mitigation tool extends well beyond traceability in crisis response scenarios. One notable example is their co-application with antimicrobial treatments and kill steps. These taggants persist on product where the antimicrobial treatment, by design, breaks down and becomes undetectable shortly after application. In such cases, the biological taggant not only verifies a treatment was applied to a given product but also confirms the product was exposed to the proper dosage. In another case, biological taggants can be used as a proxy for microbial pathogens to assess equipment clean-in-place processes, mitigating risk and detecting sources of cross contamination at a production batch level.

Future-proofing agriculture and food supply chains

With final rule compliance mandatory by January 2026, it is important for industry to begin innovating traceability systems today. By leveraging biological taggants, industry has the opportunity to gain molecular-level insights into their processes. Although the final rule is only applicable to foods on the FTL for now, many industry members within commodity supply chains anticipate the traceability requirements will inevitably expand to include other products such as milled flours and spices. It is no longer a question of if advanced traceability technologies like biological taggants are required, but increasingly a question of when.

> *"Under the new rule, non-compliance with any medical device cybersecurity requirement is a civil offense under the FD&C Act. Companies can face penalties up to $15,000 for each such violation and $1,000,000 for all such violations adjudicated in a single proceeding."*

MEDICAL DEVICE

In September 2022, the FDA notified manufacturers that all medical device 510(k) submissions will be required to use the FDA's electronic Submission Template And Resource (eSTAR) format beginning October 1, 2023. Now, there may be some additional incentives for industry adoption of this new format.

On January 10, 2023 the FDA announced a joint pilot program with Health Canada to test the use of a single eSTAR application submitted to both agencies simultaneously. The test was limited to nine participants using the non-In Vitro Diagnostic eSTAR and all the slots were filled by January 27.

Another pilot program launched by the FDA in January was for a voluntary Total Product Life Cycle Advisory Program (TAP) Pilot. The goal is to promote earlier and more frequent communications between the FDA and medical device sponsors. The program also provides for early engagement between FDA review teams and other payors such as the Centers for Medicare & Medicaid Services (CMS). Some experts speculate this could help accelerate Medicare coverage for breakthrough medical technology.

Other issues on the FDA's agenda include advocating for an increased budget for fiscal year 2023 that would include more funds to improve the medical device supply chain and prevent shortages. The FDA and stakeholders across the medical device sector are also planning for the new cybersecurity requirements that were signed into law in December 2022 as part of the Consolidated Appropriations Act.

In addition, the agency expanded its guidance around "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection" to make it clear that these rules apply to medical devices as well as pharmaceuticals. The document puts parameters around when a drug or device can be deemed "adulterated" if a facility owner refuses or impedes an FDA inspection.

The FDA is trying to streamline some processes for medical device companies, though other new requirements are also rolling out that will add complexities for manufacturers and supply chain partners.

Medical devices are a priority in the FDA's 2024 budget

On March 9, 2023, the FDA published its budget request for fiscal year (FY) 2024 seeking $7.2 billion. This includes a $372 million increase in budget authority, 10% more than the FY 2023 Enacted Level, as well as a $150 million increase in user fees.

According to the agency, this funding would have an immediate impact on food, tobacco, and medical product safety while also preparing the agency to address rapid innovation across the food and medical products fields.

Among the high priority program areas in the draft budget is a $11.6 million increase to improve the medical device supply chain and shortage programs. The agency wants to strengthen its capabilities to ensure patients have access to medical devices at all times.

The FDA also offered several legislative proposals in its budget request that would expand its authorities to protect and promote public health. It asked to remove the current limitations on manufacturers to only notify the FDA about interruptions or discontinuances in the manufacture of certain medical devices during or in advance of a public health emergency (PHE).

The agency notes that medical device shortages, which can significantly impact patient care and jeopardize healthcare workers' safety, may occur in many situations that fall outside of PHEs. The FDA wants manufacturers to be required to issue notifications any time production may be disrupted or supplies may not meet demand. It also wants the authority to require and review risk management plans to help ensure that manufacturers are prepared for production disruptions that would impact supply.

Medical device manufacturers should review their current procedures for production shortages and evaluate what changes, if any, would need to be made if this provision is approved. They should also examine their risk management plans before the FDA asks to review them.

New cybersecurity requirements for medical devices

Under Section 3305 of the federal omnibus bill that was signed into law in December 2022, the FDA now has the authority to establish cybersecurity requirements for Internet-connected medical devices.

Attorneys with Paul, Weiss, Rifkind, Wharton & Garrison LLP note that it is rare for Congress to give an agency the authority to regulate the cybersecurity of systems and devices that are owned and operated by private companies and individuals. They speculate that the standards developed by the FDA may be the basis for security regulation for Internet of Things (IoT) devices in other sectors.

There are three key points in the FDA's new authority that the attorneys note: 1) it applies to a broad range of devices; 2) it only applies to future devices and not medical devices already on the market; and 3) it is sector-specific to medical devices. This may signal that agencies are moving away from an industry-agnostic, one-size-fits-all approach to cybersecurity regulations and instead looking for guidance from companies about considerations unique to their sector and products.

Under the new regulations, there is specific information that companies are now required to provide to the FDA as part of their premarket submission. This includes a plan to monitor, identify, and address post-market cybersecurity vulnerabilities and a Software Bill of Materials that includes any commercial, open-source, and off-the-shelf software components the device uses.

Under the new rule, non-compliance with any medical device cybersecurity requirement is a civil offense under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Companies can face penalties up to $15,000 for each such violation and $1,000,000 for all such violations adjudicated in a single proceeding.

Experts from Ankura Consulting Group recommend several steps for companies who will be applying for FDA approval under the new regulations. These include developing a plan to identify and address post-market cybersecurity vulnerabilities; designing and maintaining a process to provide reasonable assurance that the device and related systems are cybersecure; and developing and documenting a secure software development approach and process.

FDA launches Total Product Life Cycle Advisory Program Pilot

The enrollment for first phase of the FDA's voluntary Total Product Life Cycle Advisory Program (TAP) Pilot began on January 1, 2023. Run by the Center for Devices and Radiological Health (CDRH), TAP promotes early, frequent, and strategic communications between the FDA and medical device sponsors. Its primary goal is to ensure that U.S. patients have access to high-quality, safe, effective, and innovative medical devices.

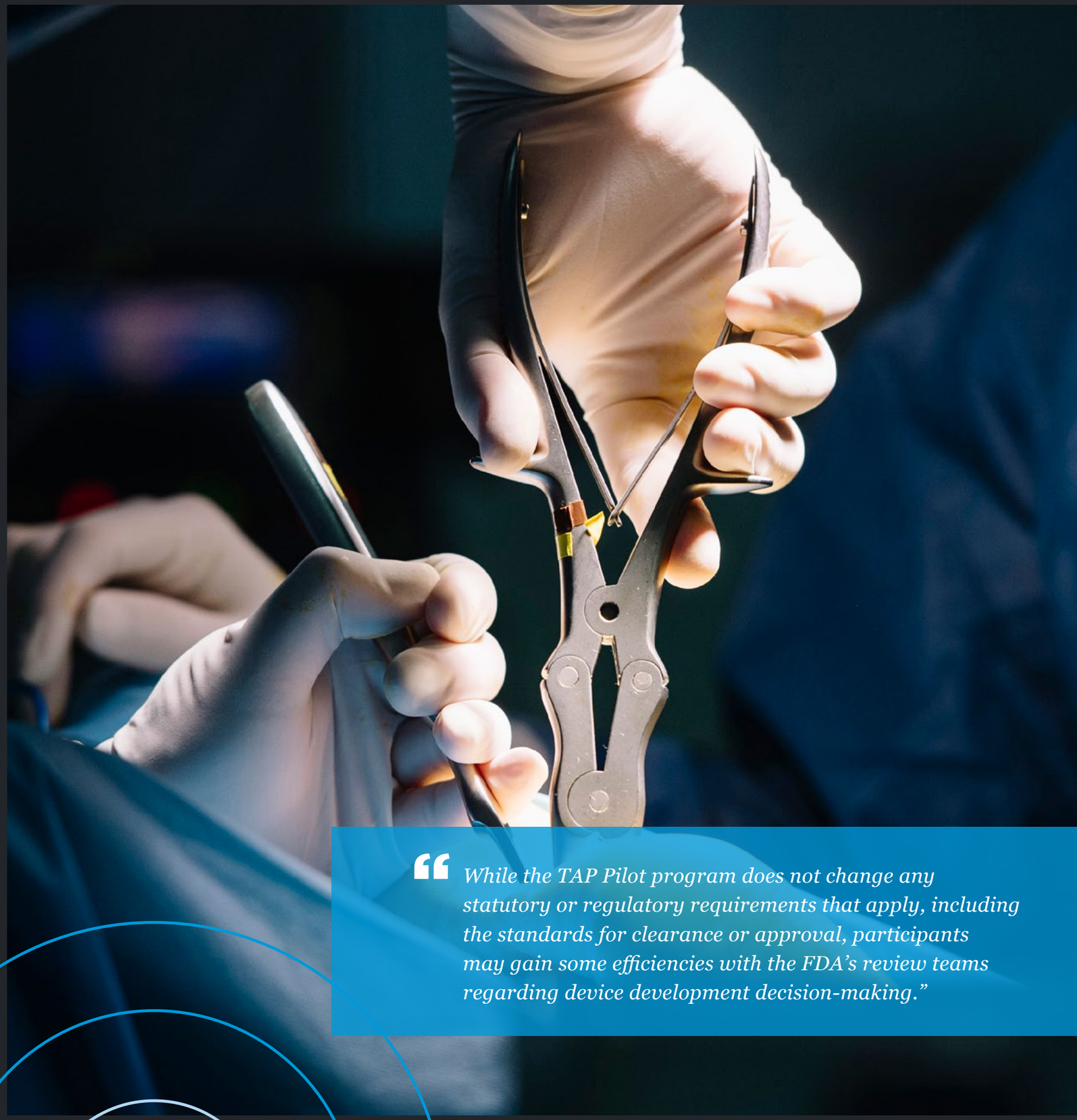
The pilot program was one of the commitments included in the Medical Device User Fee Amendments V (MDUFA V) which is in effect through fiscal years 2023 – 2027.

For its part, the FDA has promised to give to device manufacturers more timely premarket interactions, more collaboration to better align expectations regarding evidence generation, and earlier identification, assessment, and mitigation of device development risk.

In the initial TAP Pilot Soft Launch phase, the FDA will enroll up to 15 devices in the Office of Health Technology 2 (OHT2): Office of Cardiovascular Devices. To be eligible in the first phase, a device must have been granted Breakthrough Device Designation in FY2023 - FY2025. It must also still be in the early development process at the time of enrollment.

According to attorneys with Goodwin Procter, while the pilot program does not change any statutory or regulatory requirements that apply, including the standards for clearance or approval, participants may gain some efficiencies with the FDA's review teams regarding device development decision-making.

In addition, they note that the TAP Pilot includes early engagement between FDA review teams and other payors. The legal experts do not predict that the program will directly address Medicare coverage for medical technology. However, they do expect some potential evolution in Medicare coverage over the next year. A regulatory proposal by the Centers for Medicare & Medicaid Services (CMS) to provide accelerated coverage for breakthrough medical technology had originally been anticipated in October 2022. Now it is expected that the proposed rule on "Transitional Coverage for Emerging Technologies" (TCET) will be released in Q2 2023. This would shorten the length of time between approval and coverage for breakthrough devices.



> *"While the TAP Pilot program does not change any statutory or regulatory requirements that apply, including the standards for clearance or approval, participants may gain some efficiencies with the FDA's review teams regarding device development decision-making."*

Inspection guidance expanded to include medical device facilities

The FDA clarified its enforcement power for inspections with the revised draft guidance "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection." The document makes it clear that these rules apply to medical devices, not only pharmaceuticals.

Section 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) empowers the FDA to conduct inspections at reasonable times, within reasonable limits, and in a reasonable manner. The Act further states that a drug is deemed to be "adulterated" under the FDA's Safety and Innovation Act (FDASIA) if the owner, operator, or agent of a facility that manufactures, processes, packs, or holds that drug refuses to allow, delays, denies, or limits an inspection.

The updated guidance expands this rule to also cover medical devices. However, except for for-cause inspections, the FDA will be required to pre-announce inspections at medical device facilities. This is not the case for drug facilities.

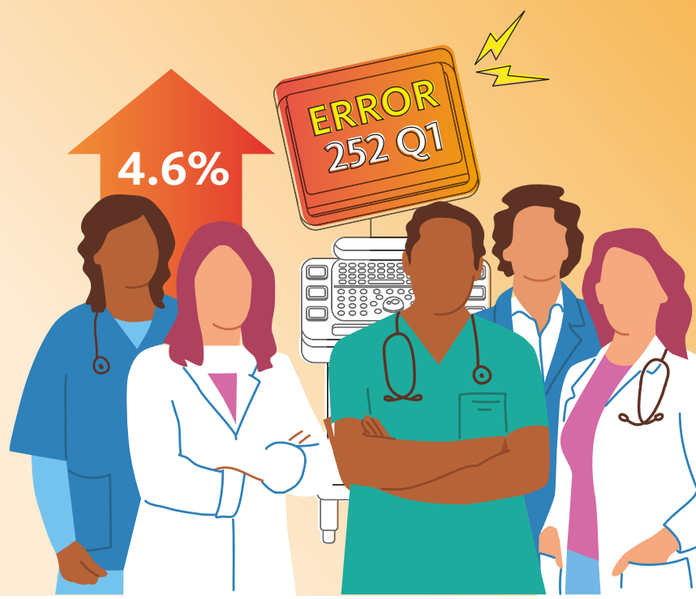
Attorneys with Hogan Lovells note one of the changes in the new draft guidance compared to earlier versions that relates to pre-announced inspections. If a facility agrees to a pre-announced inspection date, but then when the investigator enters the facility and the inspection cannot be conducted, this could be deemed an "unacceptable" action, which gives the agency the authority to designate the products manufactured at the facility as adulterated. Some of the unacceptable reasons for a delay include the necessary facility personnel are not available or the operations are shut down without reasonable explanation.

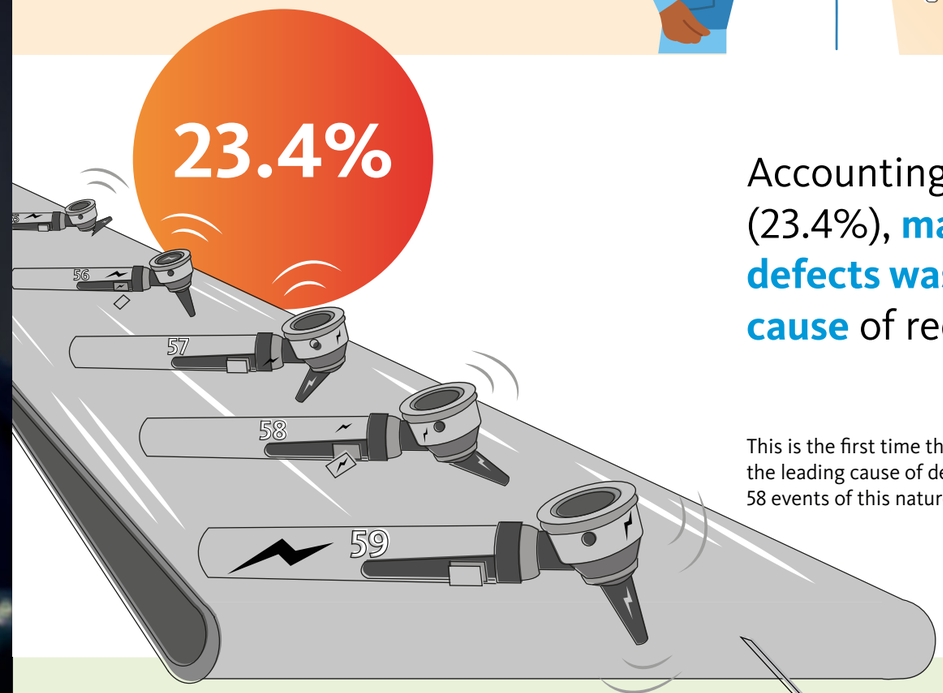
The legal experts also highlight two new examples related to company records that would be "unreasonable" for a facility to limit access for an inspection: failure to provide an electronic copy of an original record at the FDA's request and omitting or limiting the data contained in the electronic records when providing electronic copies of the records to the FDA. These apply to both drug and medical device companies.

The attorneys counsel companies to act swiftly during an inspection. If there are challenges that come up, the companies should provide the FDA inspectors with a plan to address them. They also advise that if a company can show it is doing its best to provide the requested information, it typically won't need to worry that FDA may consider their behavior a refusal.

Medical device **recall events increased** 4.6% in Q1, from 241 (in Q4) to 252.

This marks the highest quarterly total in 2.5 years.



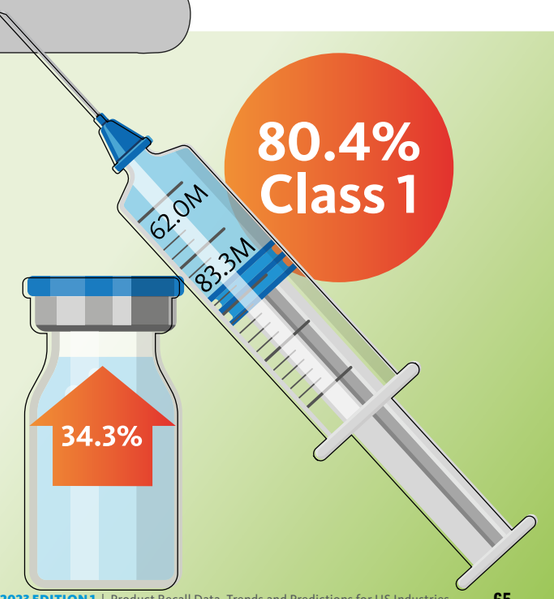


Accounting for 59 events (23.4%), **manufacturing defects was the leading cause** of recall activity in Q1.

This is the first time that Manufacturing defects has been the leading cause of device recalls. For context, there were 58 events of this nature for the whole of 2022.

Total impacted units rocketed 34.3% from 62.0M in Q4, to 83.3M.

Of this figure, 67.0M (80.4%) were assigned Class I designation. Only 2 quarters in the last 10 years have experienced a greater percentage.



FIRST QUARTER BY THE NUMBERS

The number of medical device recalls marginally increased in Q1 2023 with 252 events compared to 241 recalls in Q4 2022. There was a more dramatic uptick in the number of impacted units, which rose by 34.3% to 83.26 million this quarter. This resulted in the average recall size increasing by 28.5% to 330,388 units.

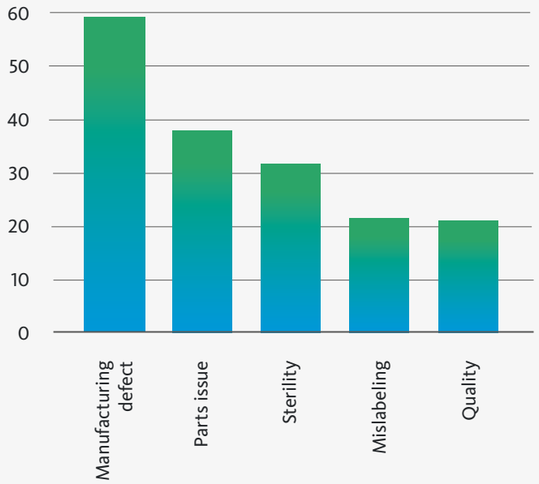
Manufacturing defects were the leading reason for recalls in the sector, accounting for 59 events, or 23.4% of all medical device recalls. Parts issues were the second-most common concern and were linked to 38 events. Sterility was third with 32 events. There were 15 recalls involving medical device software, the same number as last quarter.

In terms of units impacted, quality concerns accounted for 68.50 million units, or more than 82.3% of all medical devices recalled in Q1 2023. A single recall for 66.45 million CADD infusion sets was responsible for 79.8% of all units recalled across the sector. Sterility issues impacted the second-highest number of medical device units with 12.92 million in Q1 2023. That includes one recall of 7.42 million syringes and another recall involving 3.38 million disconnect caps.

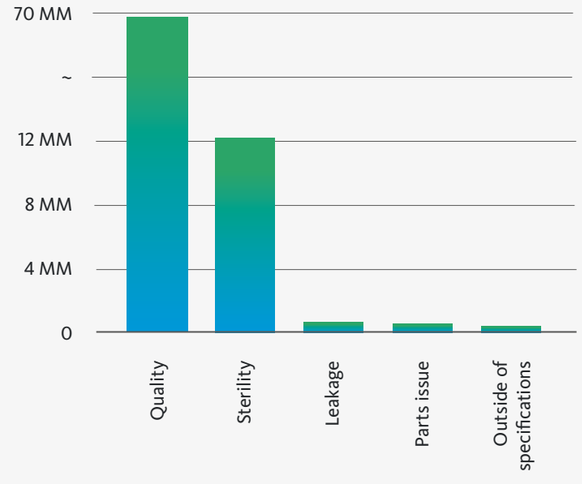
There were five recalls related to tests for COVID-19 for false results, leakage, and no Emergency Use Authorization (EUA). In total, 220,609 units were impacted.

The number of Class I recalls for medical devices decreased to 14 compared to 18 in the previous quarter. However, the number of Class I units impacted surged to 66.97 million in Q1 2023 compared to 3.02 million in Q4 2022. Class II recall events were up from 216 in Q4 2022 to 232 this quarter, though the number of units recalled fell by 72.4%. With the Class III recalls, despite a slight decrease in the number of events, which went from seven to six quarter-over-quarter, the number of units impacted increased to 46,184, 272.2% more than Q4 2022.

NUMBER OF FDA RECALLS BY REASON



NUMBER OF UNITS IMPACTED BY REASON



APRIL 2023 insight

In April 2023, there were 76 medical device recalls, which is only a slight decrease from the Q1 2023 monthly average of 84. There were 7.71 million units recalled, which was a 72.2% decrease from the Q1 monthly average of 27.75 million units.

In terms of events, parts issues were the most commonly cited cause for medical device recalls in April 2023, with 10 events. Quality was second with nine recalls. This was followed by mislabeling, device failure, failed calibrations, and false results, which had seven events each.

Fire hazard was the leading cause of recalls by unit, largely as a result of a single recall for a lithium-ion battery that impacted 3.24 million units.

The FDA classified five recalls as Class I, the most serious type. These recalls impacted a total of 4.03 million units. There was one recall with a Class III designation, and 70 assigned Class II in April 2023.

VERNESSA POLLARD, PARTNER,
MCDERMOTT WILL & EMERY

DIGITAL HEALTH STRATEGY DOESN'T STOP – OR START – AT FDA APPROVAL

Virtually every traditional medical device and drug manufacturer now has a digital health business unit or a digital health component to their product development and commercialization strategy. It makes sense that companies want to leverage the advantages that software, including generative artificial intelligence (AI) and machine learning (ML), and connected devices offer to patients and healthcare providers. However, it also creates new regulatory challenges as companies try to navigate uncharted territory from a regulatory perspective.

Defining a medical device

Sometimes the biggest challenge can be defining what qualifies as a medical device. There are products that are regulated as medical devices like toothbrushes and band-aids that most people might not think would be in that category.

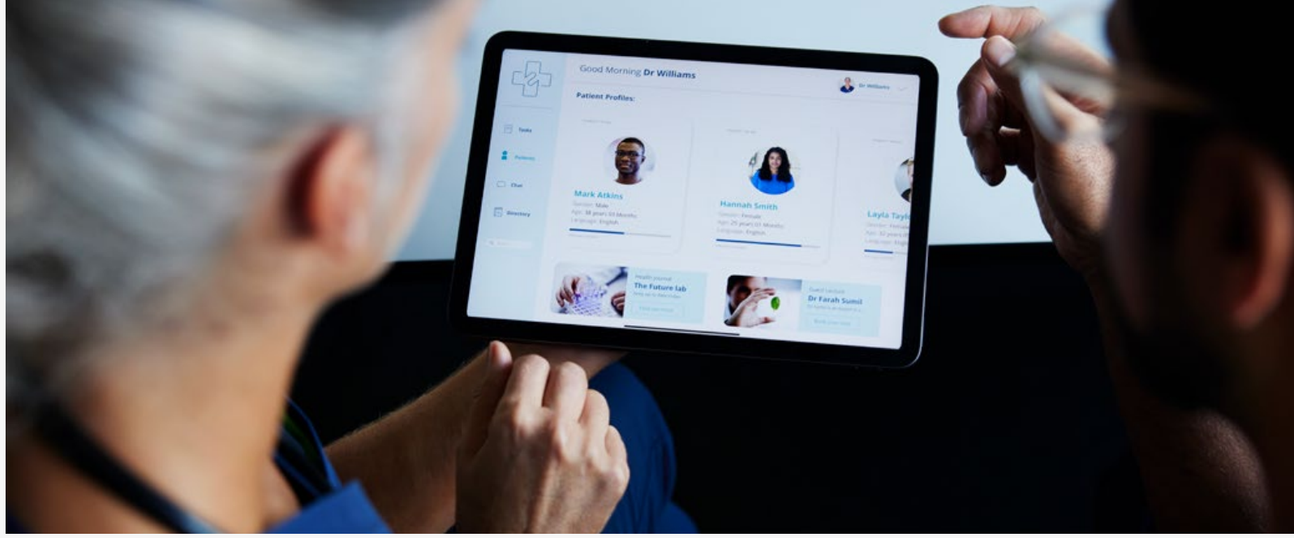
There is also a wealth of software and consumer-facing products that have a medical use that are subject to the same rules as more traditional medical devices. In September 2022, the U.S. Food and Drug Administration (FDA) issued its final guidance on Clinical Decision Support (CDS) software that could expand the types of products that are regulated Software as a Medical Device (SaMD).

Although manufacturers and developers make the initial determination of whether their product is a medical device, that decision is informed by a number of factors such as whether the FDA already regulates that category or function as a medical device. The decision is also based on both what a product claims to do and also how it actually functions. It is also worth noting that even if a product isn't subject to FDA regulations, it may be subject to other consumer product regulations. For example, it could be subject to Consumer Product Safety Commission (CPSC), Federal Trade Commission (FTC), Office of Inspector General (OIG), or other rules, especially if the manufacturer or marketer is making health claims.

New products under old rules

Companies are trying to understand and navigate FDA and other regulatory issues, not just through the initial marketing authorization, but through the entire lifecycle of these products. Innovations which are beneficial from a patient care perspective can introduce complexities in how medical devices are developed, commercialized, and introduced to the market. While regulators are trying to keep pace with technology, rule-making takes time. Many of the current regulatory requirements like good manufacturing practice (GMP) regulations were developed for traditional, physical drugs and medical devices and not for software or applications a patient or healthcare provider can download.

As part of their digital health strategy, companies need to think about the interoperability of their software-driven products with traditional medical devices or wireless communication systems in clinical or at-home settings. There are questions around interoperability with other systems for software-based devices that exist in a broader platform that may not be a physical medical device.



Companies need to plan for a quality management system that is scalable and appropriate for software as a medical device (SaMD), including when that product is designed to interact with some other wearable or electronic health record that is not a medical device.

A new approach to recalls

Medical device manufacturers entering in the development of SaMD or other digital health tools will also need to adjust their traditional device processes to align with software-based devices. Even the definition of a product malfunction needs to be examined in the context of digital health or software-based products. For example, if a patient can't access the SaMD's functions due to lack of availability of Wi-Fi or a malfunction of the platform the device links to, but not the device itself, is that a malfunction? If this occurs, does it present a risk to the patient's health? Does the software have back-ups to prevent data loss or data disruption, particularly if the software is delivering therapy or performing critical continuous health monitoring functions?

As part of the risk management process that companies go through in developing SaMD products, they need to consider what happens if software doesn't function or a patient can't access the software. If the phone or platform that the patient is relying on to use their device fails, is that a product malfunction? Who is liable?

Companies will also need to take a holistic approach to their complaint-handling and recall processes and adverse event policies to optimize them for software solutions. Recall events may be defined differently for SaMD. For example, a recallable event might occur if a software application that is approved for use outside of the U.S. is accidentally made available for download by U.S. customers. Another potentially recallable event might include a data breach and resulting upgrades to the software to prevent a risk of hacking or interference with patient access to the software functions.

There are nuances that must be considered with software products that don't apply to traditional, tangible medical devices. For example, can you lock down the app? How do you navigate that action? What if some users depend on that app and you suddenly turn it off without warning? How do you alert consumers? Can or should you modify the traditional recall notification mechanisms to provide "in-app" notifications or SMS notifications?

Other issues companies need to be prepared to navigate include how to optimize recall policies when the recalls involve turning off patient or physician access to product globally. That is very different than physically removing a product from a home or hospital or having consumers mail in or destroy a defective product.

Another challenge in the digital health sector is that patients may not consider an app a medical device. That will also affect how adverse events and complaints are reported, characterized, and handled.

In addition, many SaMD and healthcare apps collect large amounts of user- and patient- generated data because the technology is designed to do that. Often these apps get daily information about patients, sometimes in real-time. How is that data protected if there is a malfunction or recall?

VERNESSA POLLARD, PARTNER,
MCDERMOTT WILL & EMERY

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The way that companies communicate about a hardware or software problem may need to be different with a software-based medical device. Companies that leverage text and SMS messages, apps, and digital technology to communicate about product problems and issues create new concerns that go beyond FDA product safety matters. There are issues related to data privacy laws, Health Insurance Portability and Accountability Act (HIPAA) regulations, cybersecurity rules, and more.

Bring the whole team together

To help minimize these challenges and the potential enforcement risks and other liabilities, companies should expand their concept of R&D and risk management to include data risks, cybersecurity, and interoperability elements. The CIO and cybersecurity, data, and HIPAA personnel should be brought into the R&D process early and in ways they may not have been for a traditional medical device. It is best to hear their perspective on the IT infrastructure and other logistical and legal challenges on the front end. That will allow companies to better optimize these products and know how to deal with them during a recall. These other team members should also be part of discussions around quality systems, product development, commercialization, and recall strategy.

Even rules around software are changing as healthcare goes increasingly digital. Software updates and patches, which companies might tend to think of as routine servicing of the software and not FDA-related, now need to be assessed by the FDA. The FDA needs to determine if the upgrade qualifies as a recall, corrective action, or removal with any reporting or recall logistics associated with it. These include upgrades or patches done to address a cybersecurity risk or fix a bug in the software that could impact performance or safety.

Clash of cultures

One thing some established medical device and biotech companies are doing to help navigate the software side of development is to partner with early-stage or larger tech companies. This approach offers tremendous benefits in terms of speed, know-how, and other efficiencies, but it can come with its own challenges. The tech companies are often brilliant at developing and optimizing software to address life-critical needs, but they may not be as experienced at navigating and implementing quality systems, design controls, and other requirements for medical products.

This can lead to a clash of cultures that may not be apparent until after the deal is signed. Companies need to navigate how to bridge the delta between the speed and the innovation that early-stage start-ups can bring and the rigor and conservatism with which large FDA-regulated companies necessarily approach product development. There needs to be a way to marry those processes and cultures that is scalable and sensible but doesn't slow down development.

What's next

Another looming threat that is expected to be more common in the next 5-10 years is consumer class action lawsuits and product liability cases for design, negligent design, and failure to warn against SaMD products, especially with AI and ML tools.

Currently, most of the enforcement actions around SaMD products are from the FDA, FTC, or OIG. However, as these tools are more widely adopted, there will likely be more plaintiffs' lawsuits.

There are endless possibilities with digital health products. There are also a lot of challenges that companies need to be paying attention to for their overall strategy. Many companies focus on building or acquiring new technologies and gaining FDA approval.

It is also important to focus on how to manage these products and apply traditional product lifecycle management processes postmarket. Companies need to think beyond commercializing the product. They must have a strategy for optimizing quality management systems and recall processes in ways that account for differences between SaMD and traditional medical devices.

PHARMACEUTICAL

The pharmaceutical industry is facing significant change and uncertainty as 2023 progresses. With the ending of the federal COVID 19 public health emergency (PHE) on May 11, 2023, companies must decide whether they will seek full authorization for any products marketed under emergency use authorizations (EUAs). There are also considerations around changes in drug distribution, clinical trials, and oversight that were granted during the pandemic. The U.S. Department of Health and Human Services (HHS) provided a roadmap to help stakeholders plan for these changes.

Another issue impacting the pharmaceutical industry is the Modernization of Cosmetics Regulation Act of 2022 (MOCRA) which was passed at the end of 2022. The act significantly expands the FDA's rulemaking and enforcement authority over cosmetics and expands the definition of what products are considered cosmetics. The new requirements align the oversight of these products more closely with other FDA-regulated products such as dietary supplements and over-the-counter drugs. This change puts new burdens on cosmetics companies, such as the need to adhere to Good Manufacturing Practices (GMPs), additional labeling, and adverse event reporting, among others.

Cannabis and cannabidiol (CBD), an active ingredient in cannabis, are also facing big changes. While the FDA has said that there needs to be a new regulatory pathway created before CBD can be safely regulated as a dietary supplement or food additive, the agency is moving forward with researching medical uses for the ingredients.

In addition, the FDA is looking to tighten regulations around manufacturing tobacco products. The proposed rules aim to minimize or prevent contamination, ensure product consistency, and improve traceability of products in the event of a corrective action.

Manufacturers and marketers across the industry will have to prepare for new monitoring and enforcement, and ensure their compliance and recall plans are up-to-date.

> *"Despite the rise in popularity of CBD as an additive, the FDA denied three citizen petitions in January 2023 requesting rulemaking that would allow CBD products to be marketed as dietary supplements."*

The end of the COVID-19 public health emergency

After being in effect for more than three years, the U.S. federal public health emergency (PHE) for COVID-19 expired on May 11. The U.S. Department of Health and Human Services (HHS) published a roadmap in February 2023 outlining some of the things that would, and would not, be affected by the ending of the PHE.

The agency stressed that the Administration would continue to respond to COVID-19 issues once the PHE had ended and that COVID-19 vaccines and treatments would still be easily accessible. The HHS also stated that access to pathways for emergency use authorizations (EUAs) through the FDA for COVID-19 products including tests, vaccines, and treatments would continue, which should be reassuring for the pharmaceutical and medical device sectors as well as other stakeholders.

The statement from the HHS said that existing EUAs for COVID-19 products will remain in effect under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, the FDA may continue to issue new EUAs going forward when the required criteria are met.

The agency's roadmap also gave the Substance Abuse and Mental Health Services Administration (SAMHSA) continued flexibility for certain drugs that are part of Opioid Treatment Programs (OTPs). This includes allowing authorized access to these medications through a telehealth appointment or as a take-home dose.

Legal experts with Hogan Lovells summarized some of the other impacts that pharmaceutical and biological product manufacturers can expect, including continued use of "remote regulatory assessment" tools adopted during the pandemic. In addition, the FDA will retain the authority to grant waivers and exemptions to allow for continued distribution of covered products even though the guidance for Drug Supply Chain Security will expire.

The FDA is also expected to allow clinical trial sponsors to continue to use decentralized tools that were authorized during the PHE. In the interest of giving more flexibility to trial sponsors and participants, these practices include the use of wearables and other digital health platforms to collect data, as well as permitting remote assessments and more home health visits.

Pharmaceutical companies should be aware that liability immunity provided to manufacturers, distributors, and other entities under the Public Readiness and Emergency Preparedness (PREP) Act may be impacted with the end of the PHE. They should work with their legal counsel to determine where they may face risks in the post-PHE environment.

Regulations for CBD and cannabis

Despite the rise in popularity of CBD as an additive to a range of products from foods to topical products, the FDA denied three citizen petitions in January 2023 requesting rulemaking that would allow CBD products to be marketed as dietary supplements. The FDA stated it is not clear how these products could meet current safety standards for supplements or food additives and called for Congress to develop a new regulatory pathway for CBD products.

Any new channel for CBD will likely consider safeguards such as labeling requirements, content limits, quality assurance requirements, and a minimum age to purchase. Lawyers with DLA Piper suggest that taking a legislative approach to regulating CBD may be part of an attempt to develop a more inclusive federal cannabis policy that includes recreational use. The fact that cannabis use is legal is some states, even for recreational purposes, but not federally, makes regulations more complicated.

Without this pathway for regulation, the FDA continues to assert its enforcement power against companies selling products containing CBD. In November it posted warning letters to five hemp companies for illegally selling unapproved CBD products that contain an "unsafe food additive."

Several legal experts, including attorneys with Bradley Arant Boult Cummings LLP, note that while the FDA has issued multiple warning letters to companies marketing CBD products, this latest round takes a different stance. Previous warning letters reprimanded companies for making unfounded health claims. Not all of the letters in the latest round included that violation. The FDA also warned companies against selling products in forms that would be appealing to children, for including CBD in animal foods or pet treats, and other infractions. This may signal a shift in enforcement.

> *“The FDA’s proposal for new requirements for tobacco product manufacturers will impact product recalls by establishing requirements related to the identification, tracing, and corrective actions for contaminated products, including products that have already been distributed.”*

Despite the FDA’s slow approach to approving CBD for use in foods or dietary supplements, it is moving forward with exploring medical uses. In December 2022, the Medical Marijuana and Cannabidiol Research Expansion Act was passed. The FDA issued its final guidance for using cannabis and cannabis-derived compounds in clinical research shortly afterwards, in January 2023.

The guidance document is intended to provide a clearer pathway for researchers to source, test, and secure approval of cannabis and cannabis-derived drugs. It outlines the agency’s regulatory concepts and mechanisms and offers clarity around approved sources of cannabis, resources for information on quality considerations, and details on how to calculate the delta-9 THC concentration of cannabis. Cannabis with a THC concentration higher than 0.3 percent must comply with the Controlled Substances Act (CSA) and U.S. Drug Enforcement Administration (DEA) requirements.

Drug companies can expect to have to carefully thread the needle on their products, at least while cannabis is still banned federally. The fact that the FDA is monitoring this sector carefully makes it even more important that manufacturers and suppliers find the right balance.

FDA publishes dietary supplement ingredient directory

On March 6, 2023 the FDA launched its Dietary Supplement Ingredient Directory which pulls ingredient information previously found on different FDA webpages into a central location with information about what the agency has said about a specific ingredient and whether any regulatory action has been taken with regard to it.

The aim is to help manufacturers, retailers, and consumers stay informed about ingredients that may be found in products marketed as dietary supplements. Some of the 27 ingredients on the list include cannabidiol (CBD), pure and highly concentrated caffeine, and N-acetyl-L-cysteine (NAC).

While the FDA will update the directory periodically, it cautions that it is not intended to be a comprehensive list of all dietary supplement ingredients. The agency also notes that the list may not include all actions the FDA has taken with respect to a particular ingredient.

Attorneys with Baker McKenzie note that the publication of the new directory indicates that the FDA will continue to monitor the use of these ingredients and take enforcement action when appropriate. The legal experts caution that companies that market or plan to market these dietary supplements put themselves at risk for both FDA enforcement and consumer products liability lawsuits for marketing products containing listed ingredients.

New rule on tobacco product manufacturing practices

The FDA announced its proposal for new requirements for tobacco product manufacturers regarding manufacture, design, packing, and storage. In its statement released in March 2023, the agency said the proposed requirements will protect public health in several ways, including minimizing or preventing contamination and ensuring product consistency. The updated rules also ensure that tobacco products comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

According to the FDA, there are many ways the new requirements will improve public safety, including minimizing or preventing the manufacture and distribution of tobacco products contaminated with foreign substances and addressing issues related to inconsistencies between e-liquid product labeling and the actual concentrations in e-liquids.

The changes will also impact product recalls by establishing requirements related to the identification, tracing, and corrective actions for contaminated tobacco products, including products that have already been distributed.

As proposed, the requirements apply to both foreign and domestic manufacturers of finished and bulk tobacco products. The framework in the proposed rule includes establishing tobacco product design and development controls, ensuring that finished and bulk tobacco products are manufactured according to established specifications, and establishing the ability to trace all parts, ingredients, additives, materials, and batches of finished or bulk tobacco product, among other conditions.

The definition of “tobacco product manufacturer” is fairly broad and includes “any person(s), including a repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished or bulk tobacco product for sale or distribution in the United States.”

However, small tobacco product manufacturers will have four years after the effective date before they need to comply with all of the requirements of the new rule. And according to attorneys with Keller & Heckman, the manufacturers would only be required to comply with requirements applicable to its finished and bulk tobacco product manufacturing operations.

The proposed rule also clarifies that vape shops that only sell Electronic Nicotine Delivery System (ENDS) products, components, and parts would not be considered manufacturers and not be subject to the requirements in the proposed rule. However, the rule would apply if they also engage in the manufacture, preproduction design validation, packing, and storage of finished or bulk tobacco products.

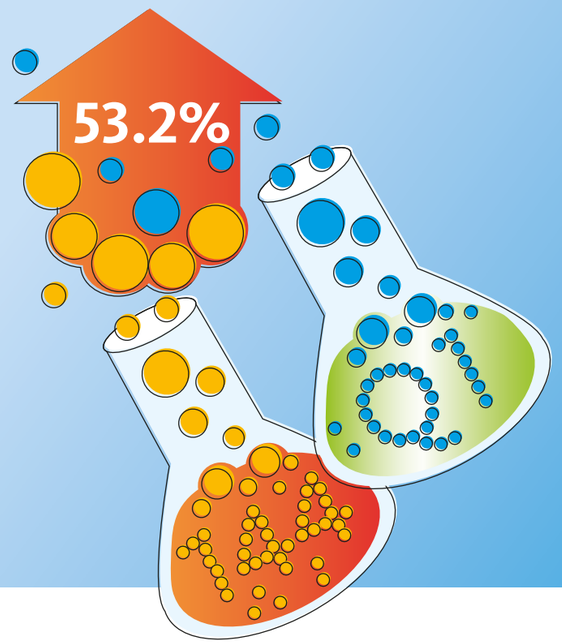
The public comment period for the proposed rule closes on September 6, 2023. Interested parties should make their voices heard to either raise concerns or show support for the draft regulation before it is finalized.

The FDA is expected to address other rulemaking priorities related to tobacco products in 2023, including a proposed standard on nicotine levels in cigarettes and proposed bans on both menthol cigarettes and characterizing flavors in cigars.

“The FDA is expected to address other rulemaking priorities related to tobacco products in 2023, including a proposed standard on nicotine levels in cigarettes and proposed bans on both menthol cigarettes and characterizing flavors in cigars.”

Pharmaceutical **recall events surged** by 53.2%, from 94 in Q4, to 144 in Q1.

This is represents the highest quarterly figure recorded in 10 years.

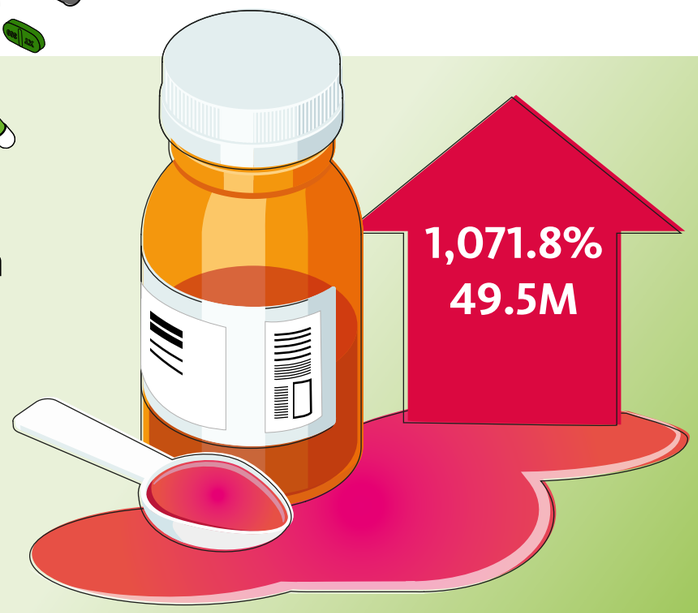


cGMP deviations dominated recall activity with 70 events and 33.2M impacted units in Q1.

In terms of units, there were three standout events: Ophthalmic solution (6.8M units), Finasteride tablets (4.5M), and Simvastatin tablets (3.3M).

Total impacted units rocketed 1,071.8% from 4.2M in Q4, to 49.5M.

Despite this surge, defective pharmaceuticals remain 32.2% below their 5 year quarterly average (73.0M units).



FIRST QUARTER BY THE NUMBERS

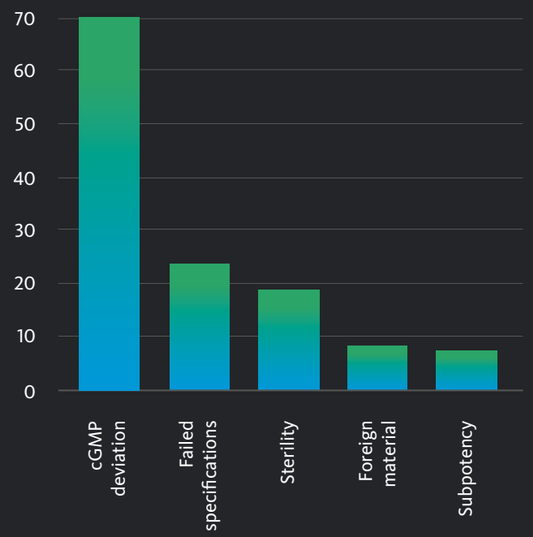
Q1 2023 recorded the highest number of pharmaceutical recalls in a single quarter in the past 18 years. There were 144 events, an increase of 53.2% compared to last quarter. The number of units recalled rose even more dramatically, from 4.23 million in Q4 2022 to 49.54 million units in Q1 2023. There were nine recalls that each involved 2 million or more units. This represents a 1,071.8% increase compared to Q4 2022; however, this escalation is more a reflection of how few units were recalled last quarter.

The average recall size was also much larger than in Q4 2022, with 344,028 on average this quarter compared to 44,975 last quarter. However, in the larger context, it is not record-breaking. In Q1 2022, the average recall size was 4.63 million.

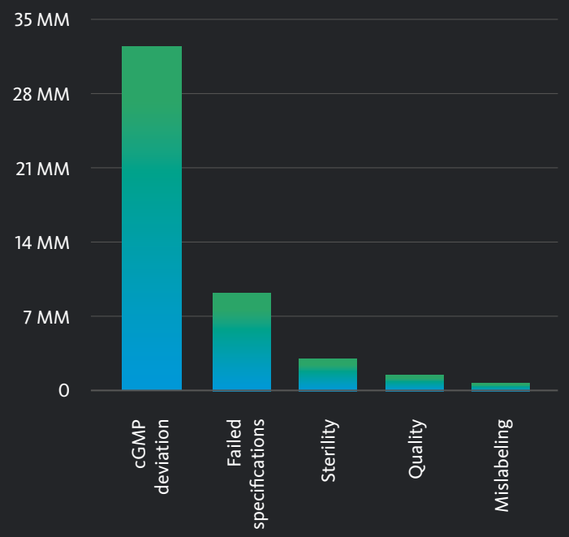
cGMP deviations were the leading cause of pharmaceutical recalls with 70 events, or 48.6% of total recalls. This is the highest number recalls for cGMP deviations in a single quarter in over 5 years. This category also had the most units recalled in Q1, with 33.15 million, or 66.9% of all recalled units this quarter. A single recall of ophthalmic solution accounted for 6.78 million units.

Failed specifications were the second most common cause for both recall events and units impacted. There were 23 events involving 9.64 million units. Sterility was the third in both categories with 19 recalls in Q1 that involved 3.73 million units.

NUMBER OF FDA RECALLS BY REASON



NUMBER OF UNITS IMPACTED BY REASON



APRIL 2023 insight

There were 37 pharmaceutical recalls in April 2023. This is 22.9% fewer than the monthly average for Q1 2023 of 48 events. In terms of units recalled, there was a 91.4% decrease to 1.41 million from the Q1 2023 monthly average of 16.51 million units.

A single recall for failed specifications of Microcrystalline Cellulose NF, which is often used as a binding agent in vitamins and supplements, impacted 901,120 units.

This made failed specifications the recall concern that impacted the most units, though there were only five events for this cause.

cGMP deviations were the most common cause by event and were tied to 16 recalls. Failed specifications and mislabeling were both cited in five events. The FDA classified nine recalls as Class III and 28 recalls as Class II.

CONCLUSION

The U.S. is entering its first quarter since January 2020 that is not under a COVID-19 public health emergency. It will be interesting to see if corporations and government agencies maintain some of the flexibility in business operations granted during the pandemic.

Regulators have already been moving ahead with stronger enforcement, especially around consumer products. Both the Consumer Product Safety Commission (CPSC) and Federal Trade Commission (FTC) promised more actions to protect consumers and hold companies accountable.

Many regulatory agencies are trying to balance innovation with oversight to ensure rules keep pace with new innovations. There are challenges in many industries from automotive to medical devices. Online marketplaces are one area creating a range of issues for companies from protecting data, to ensuring products sold online are not counterfeit, and understanding who has accountability and liability if consumers are harmed.

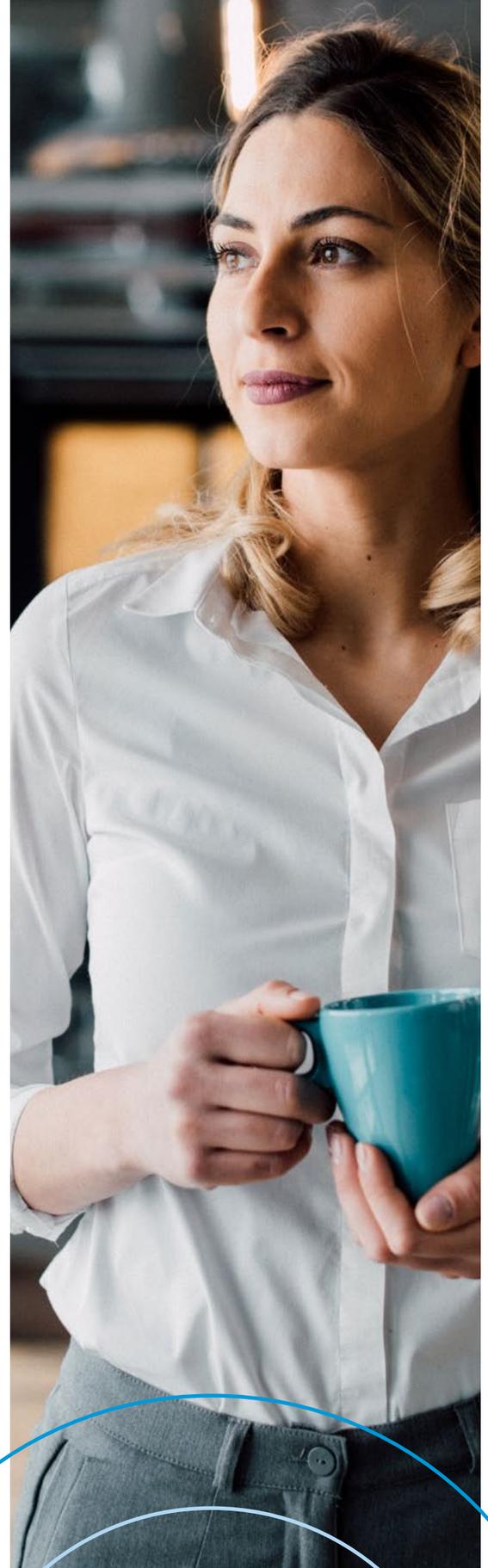
More and more rules are also being proposed or enacted that look at the entire lifecycle of a product, which means that manufacturers have to make sure their recall and product management plans reflect these added responsibilities.

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

No business likes to admit that they will eventually face a recall. 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 honour 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 product recall, remediation and customer 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 25+ years of global experience on 5,000+ 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 that these events, even those that feel devastating to companies experiencing them, that offer opportunities to demonstrate trustworthiness and to build greater customer loyalty when conducted 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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