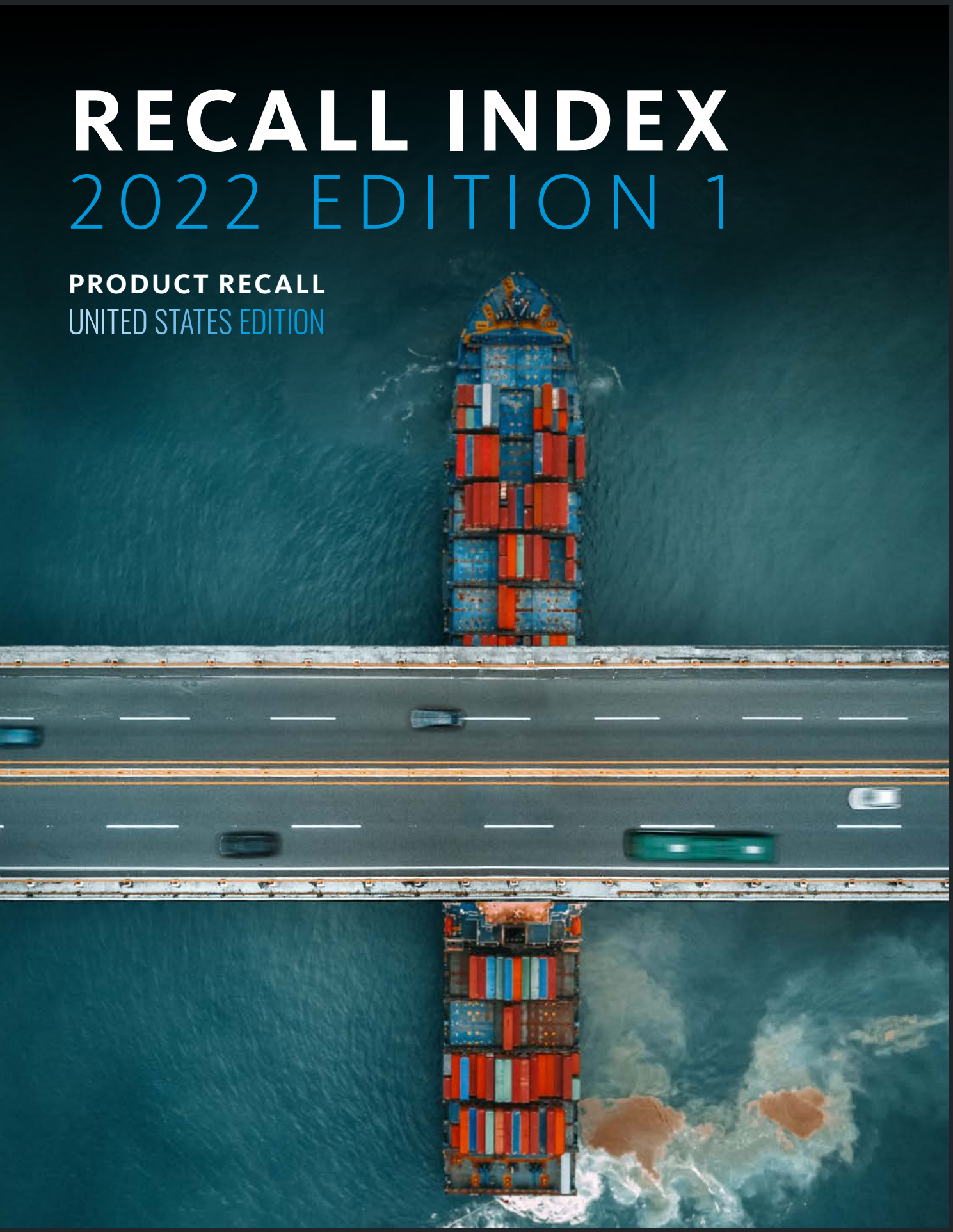
RECALL INDEX
2022 EDITION 1

PRODUCT RECALL
UNITED STATES EDITION



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

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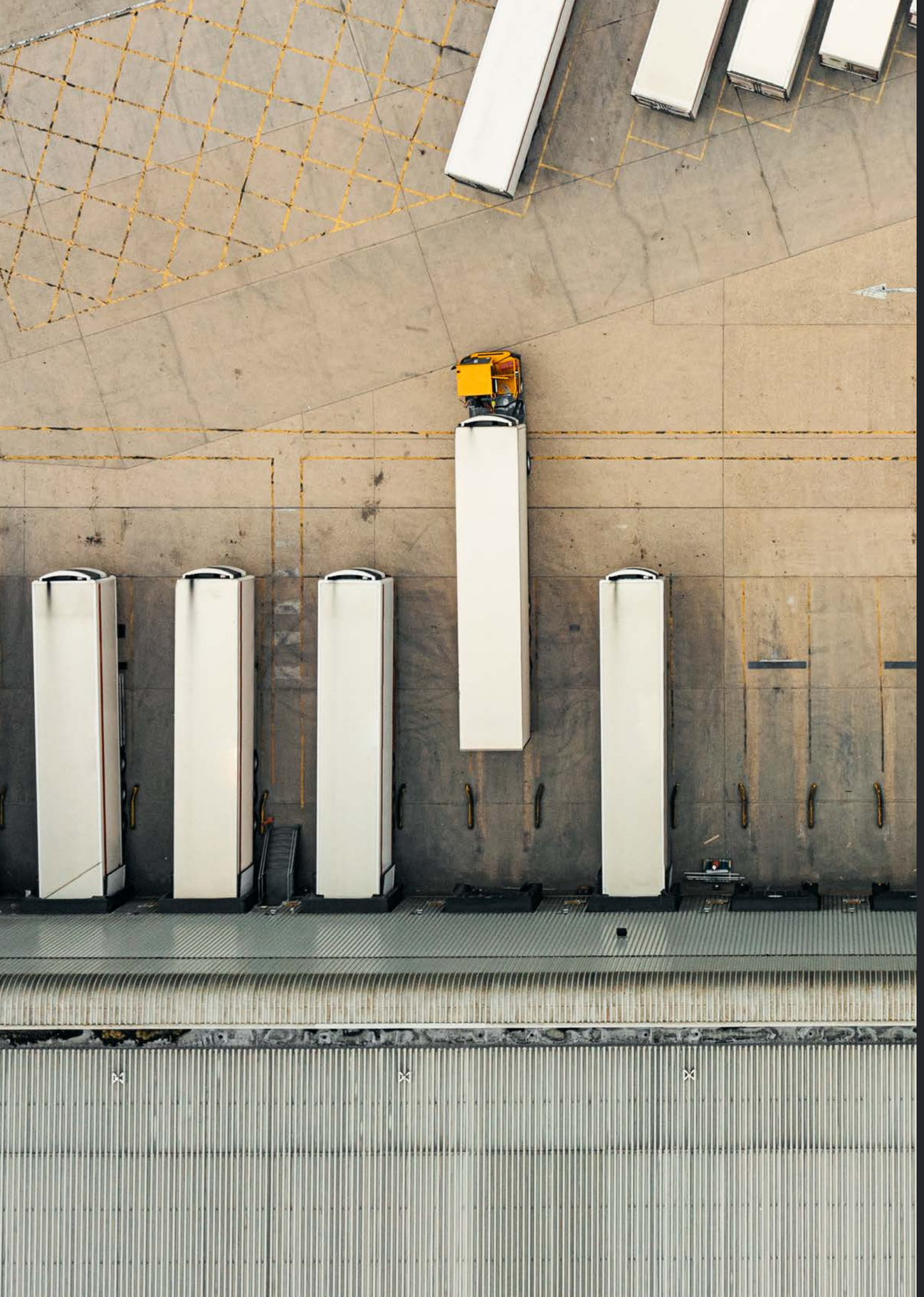

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The Sedgwick brand protection Recall Index is the essential reference for manufacturers and retailers seeking an impartial and reliable perspective on past, present, and future recall data and product safety trends. It reviews five product categories: 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 with exclusive insights and guidance valuable to their operations.

This edition brings you recall data from the first three months of 2022, as well as expert analysis and predictions for what to expect in the year ahead as business leaders and regulators continue to grapple with challenges from the ongoing pandemic, chaotic geopolitical events, global inflation, and ongoing supply chain challenges.

Analysis from some of our strategic partners at leading law firms, insurance companies, and communications firms offers expert insights to help organizations plan for new regulations across the five market sectors.

We are seeing many agencies take an aggressive position on consumer protection. The FDA is also taking measures to try to lower healthcare costs. In addition, there are signs that agencies are going to be less forgiving of companies who are slow to update their operations to comply with regulations such as the Food Safety Modernization Act (FSMA). Companies should be carefully reviewing their recall processes and safety protocols to ensure they are in alignment with all relevant laws. This will be crucial as business picks up and operations seek to regain some of the productivity lost during COVID-19 imposed shut-downs.

Whether you read the Recall Index cover-to-cover or focus on sections of particular importance to your company or industry, you're sure to learn something new about what is happening today and what is on the horizon that could impact your business or your industry.

One final note, this edition of the Recall Index focuses on U.S. recall data and regulatory developments. If your business also includes operations outside the United States, we encourage you to read our European edition. Like this report, that version shares recall data from regulatory agencies and offers expert analysis on product safety and regulatory changes from a UK and EU perspective.

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 below:

State of the Nation 2022 U.S. Recall Index: click here
Q3 2021 U.S. Recall Index: click here
Q2 2021 U.S. Recall Index: click here
Q1 2021 U.S. Recall Index: click here

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2022 edition 1

SUMMARY

In 2021, the total number of units recalled across all five market sectors – Automotive, Pharmaceutical, Food and Beverage, Medical Devices and Consumer Products – totaled 1 billion. We are certain to pass that benchmark in 2022 since the first quarter alone saw 913.8 million units recalled. That is the highest number of units in a single quarter in the past 10 years. This quarter alone saw more units recalled by the FDA in the food sector than we saw for the entire year in the previous four years. For the pharmaceutical sector, Q1 2022 outpaced the full-year totals for the past six years in terms of units.

This surge in impacted units involved 710 recalls, which is a modest 4.8% increase from the fourth quarter of 2021. But the number of units is up 464.8% from the previous quarter. The pharmaceutical industry saw the highest per-quarter number of units in nearly 15 years and every other sector was up compared to Q4 2021, with the exception of USDA. USDA recalled units were at their second-lowest number in the past 10 years, falling 94.7% from last quarter to 65,272 pounds in the first quarter of this year.

One of the recalls that received the most attention was for 14.9 million units of three brands of powder infant formula. While not the biggest FDA recall of the quarter, the fact that two infants died and the facility where the formula was produced had a long history of safety violations led to harsh criticism for both the company and for the FDA for not acting more quickly to protect the public.

We continued to see more aggressive enforcement from other agencies, including CPSC, which took a stand against two companies it felt were not acting quickly enough. In one case it filed a lawsuit against a manufacturer of infant loungers who refused to issue a voluntary recall even after two deaths were linked to its products. It also levied a $6.5 million civil penalty against a workout equipment manufacturer for not immediately reporting safety issues with two of its products.

However, agencies are also trying to provide clear direction to companies about their responsibilities when there is a problem. The FDA issued a guidance on how companies can be "recall ready." The document addresses recall communication plans and training for voluntary recalls of drugs, devices, biological products, food, cosmetics, and tobacco. It also instructs companies about how to maintain distribution records and establish procedures for initiating a recall.

We predict agencies will continue to hold companies accountable, especially as the U.S. Congress continues to be largely stalled due to political infighting and gridlock.

HERE ARE SOME OF THE HIGHLIGHTS FOR THE FIRST QUARTER OF 2022:

Automotive

Regulators worked to close loopholes for autonomous vehicles (AVs) and electric vehicles (EVs), while also updating guidelines to ensure their applicability to both internal combustion engine (ICE) and newer categories of vehicles.

On March 10, 2022, the National Highway Traffic Safety Administration (NHTSA) issued a Final Rule amending certain Federal Motor Vehicle Safety Standards (FMVSS) regarding occupant protection in vehicles equipped with Automated Driving Systems (ADS). In the Fall 2021 Unified Agenda, NHTSA indicated that it wanted to look at a framework for automated driving systems safety, as well as ways to facilitate new automated driving system vehicle designs for crash avoidance testing.

NHTSA is also planning to update the FMVSS that applies to high-voltage batteries such that it also includes heavy- and medium-duty vehicles.

Makers of AVs and EVs should anticipate more regulation in multiple areas. While new regulations can make things more burdensome for manufacturers, the added safety will increase consumer confidence in these newer types of vehicles and undoubtedly help drive the market forward.

There were 221 automotive recalls in Q1 of 2022, which is lower than the quarterly average for 2021. However, the number of units recalled significantly rose (by 114.2%) to 9.3 million units.

For more in-depth analysis of the automotive industry in Q1, click here.

Consumer products

A study from a consumer protection nonprofit organization reported an alarming increase in deaths from children's products, with 14 in 2021 compared to zero in 2020. The number of injuries and incidents year-over-year also increased dramatically with 136 injures and 6,058 incidents reported in 2021 compared to nine injuries and 704 incidents in 2020. The organization called on the Consumer Product and Safety Commission (CPSC) to do more to protect children.

Regulators at a national and state level are monitoring the fashion industry and its claims around sustainability and eco-friendly practices. Companies must be prepared to back up these statements or risk enforcement actions.

After only 47 recalls for consumer products in Q4 2021, the number of events jumped nearly 64% to 77 recalls in Q1 2022 and the number of units impacted rose 161.8%. A single recall for gummy vitamins that led to more than 3.7 million units being recalled and 18 reported injuries was largely responsible for the gains in Q1.

For more in-depth analysis of the consumer products industry in Q1, click here.

Pharmaceutical

The appointment of a permanent commissioner to the Food and Drug Administration (FDA) has led to speculation that the agency will focus heavily on regulating electronic nicotine delivery systems (ENDS) devices, or vaping devices.

The FDA has also taken several steps to try and make drugs less expensive and make the supply chain more reliable. This includes a proposal for national standards to license wholesale drug distributors (WDDs) and third-party logistics providers (3PLs) instead of the current state-by-state network.

Another way the FDA is trying to get less expensive drugs on the market more quickly is by clarifying the processes around application submissions, labeling and review for generic drugs. It published a new guidance around this topic in February 2022.

There were more than 435 million units recalled across the pharmaceutical industry in Q1 2022. That is the largest number of units recorded in nearly 15 years. Most of that volume was from four recalls attributed to cGMP deviations involving acetaminophen products, with one recall alone impacting 326.9 million units. The other three recalls added a further 95.8 million units to the quarter.

For more in-depth analysis of the pharmaceutical industry in Q1, click here.

Medical devices

The big regulatory shift in the medical device industry in Q1 2022 was the FDA's move to harmonize U.S. medical device manufacturing standards with those of other nations. While most experts agree that this will make things easier for device manufacturers, concerns remain about the burdens on smaller companies and on the timeframe that the FDA has laid out.

Our prediction last quarter that COVID-19 tests would be under scrutiny is bearing out. A consumer class action suit was filed in February 2022 against the maker of a COVID-19 rapid antigen test for marketing a product that had not received FDA approval.

We also saw eight different recalls for rapid antigen COVID-19 tests which impacted more than 2.3 million units. Most of the recalls were attributed to safety concerns because the tests had not been approved by the FDA. Other causes were mislabeling, outside specifications and device failure.

As with other industries, the number of medical devices recalled skyrocketed in the first quarter. The number of recalled units increased by 2,624.9% to 314.8 million units. A single recall for a device used as a connector for a catheter port involved more than 288 million units.

For more in-depth analysis of the medical device industry in Q1, click here.

Food and drink

The FDA made it clear that food safety and enforcement of the Food Safety Modernization Act (FSMA) were top priorities when it published its list of guidance to issue in the next 12 months. As we noted last quarter, the FDA seems to believe companies have had enough time to adapt to the new regulations under the FSMA and are going to start enforcement.

As a result of a large recall of powder infant formula that was tied to two death, the FDA has stated that once the immediate public health risk from the tainted formula is minimized, it will conduct a programmatic review related to agency programs and policies for infant formula and special medical food complaints, illnesses and recalls.

There were four sizable FDA recalls in Q1 2022 that helped push the total number of units up 274% to 1.3 million. A recall of caffeine supplements over quality issues accounted for more than 86.5 million units. We also saw 31.2 million units of lettuce recalled in one of three incidents over concerns for listeria. Bacterial contamination led to the recall of 14.9 million units of infant formula, and 11.8 million units of soy beverage were recalled due to quality issues.

The United States Department for Agriculture (USDA) is the only agency that saw a decrease in the number units recalled. There were only 65,272 pounds recalled, a 94.7% drop compared to the previous quarter.

As regulator return to more normal operations and break free from the restrictions that the pandemic put on inspection, we can expect to see the trend of more recalls and impacted units continue. Companies who were operating with smaller staffs or who had to change their production lines or supplies during the pandemic will be wise to audit their internal processes before inspectors come calling.

We are also likely to see some unpredictability in the market as political situations around the world remain volatile and government actions such as sanctions against certain countries impact normal trade and supply chain movements.

AUTOMOTIVE

Autonomous vehicles (AVs) and electric vehicles (EVs) continue to dominate conversations across the automotive industry and among its many stakeholders. Among the latest and most important developments, regulators are seeking to identify and close any regulatory loopholes to ensure that safety measures written for internal combustion engine (ICE) vehicles equally apply to these new categories.

> *"Federal agencies are preparing for more Automated Vehicles. In March, NHTSA issued a Final Rule amendingcertain Federal Motor Vehicle Safety Standards regarding occupant protection in vehicles equipped with Automated Driving Systems."*

Autonomous vehicles gaining traction – and regulations

The autonomous vehicle (AV) industry received a big boost in February 2022 when the California Public Utilities Commission (CPUC) issued its first "Drivered Deployment" permits to two self-driving car companies. These permits allow the companies to provide passenger service in AVs with a safety driver present on selected public roads and designated areas in San Francisco and San Mateo.

Federal agencies are also preparing for more AVs. On March 10, 2022, the National Highway Traffic Safety Administration (NHTSA) issued a Final Rule amending certain Federal Motor Vehicle Safety Standards (FMVSS) regarding occupant protection in vehicles equipped with Automated Driving Systems (ADS). The Rule will go into effect on September 8, 2022.

This follows the June 2021 standing general order from NHTSA that required 108 vehicle and equipment manufacturers, and operators of Automated Driving Systems (ADS) and Advanced Driver Assistance Systems (ADAS) to submit regular reports of safety-related incidents. This marks a shift in the Agency's previous "hands off" approach to innovation around driverless vehicles.

And more regulation is on the way. In the Fall 2021 Unified Agenda, NHTSA indicated that it wanted to look at a framework for automated driving systems safety, as well as ways to facilitate new automated driving system vehicle designs for crash avoidance testing.

While new regulations make things more burdensome for manufacturers, the added safety will increase consumer confidence in this new technology and undoubtedly help drive the market forward.

NHTSA website adds new safety alert

On March 17, 2022, NHTSA added a new feature on its website to help motorists quickly identify if their vehicle has an urgent safety recall. An "urgent" recall means that the vehicle should not be driven or parked inside until repairs are undertaken.

A red box will display at the top of the page at NHTSA.gov/Recalls if the vehicle that has been searched for has an open "do not drive" or a fire risk recall. This comes on the heels of several fire-related automotive recalls across multiple brands. NHTSA hopes this new feature will impress upon vehicle owners how urgent these recalls are and convince them to take preventative actions until the recall repair is completed.

While this tool is helpful for consumers, some may argue that it creates greater reputational risk for automakers. The more their vehicles are associated with urgent repairs, the less confidence consumers, retail partners, and regulators may have in their company. Hopefully this website feature will encourage vehicle owners to act quickly, enabling automakers to execute any recall and repair plans quickly and efficiently.

> *"Automakers with EV models need to be aware of regulatory changes not only from current vehicle safety standards, but also evolving risks and liabilities around new technology and services such as charging stations."*

Updates to the electric vehicle market

Automotive research company Kelley Blue Book estimates 1.5 million electric vehicles (EVs) were sold in the U.S. in 2021. This means battery-electric, hybrids and plug-in hybrids combined made up 9.7% of U.S. light-vehicle sales last year. And there is no sign that the demand for EVs is slowing down.

With more EVs on the road, NHTSA is planning to update the Federal Motor Vehicle Safety Standard (FMVSS) that applies to high-voltage batteries so that it also includes heavy- and medium-duty vehicles.

Another area seeing rapid expansion for EVs is the progress towards a stronger, more robust EV-charging infrastructure across the U.S. Federal, state, and private organizations are working to put more resources into developing a network of charging stations.

The most ambitious initiatives are included in the Biden Administration's August 2021 Executive Order on Strengthening American Leadership in Clean Cars and Trucks, the Infrastructure Investment and Jobs Act (IIJA) which passed in November 2021, and the EPA's new emissions rules published at the end of December 2021. These initiatives outline a mix of benefits and penalties to help promote more EVs on the road. These actions include the EPA looking at new rules around emission standards and $7.5 billion in funds to develop a national EV-charging infrastructure.

On the state level, the Michigan Department of Transportation awarded a contract in February 2022 to develop the nation's first wireless charging infrastructure on a public road in the U.S. Completion of the project is expected in 2023.

The public-private sector is also interested in EVs. The National Electric Highway Coalition (NEHC), a group of more than 60 investor-owned and municipal electric companies and electric cooperatives is working to expand the EV infrastructure. According to a memorandum signed in March 2022, the members of the NEHC are required to "commit in good faith to establish a foundational EV fast charging network across their service territories using any approach they see fit by no later than the end of 2023."

In addition, a major truck manufacturer has announced a partnership with an energy company and investment management firm to design, develop, install, and operate a nationwide charging network for medium- and heavy-duty battery electric vehicles and hydrogen fuel cell vehicles. According to a joint statement from the companies, the move was prompted by the lack of publicly available EV charging infrastructure for commercial fleets. This is one of the biggest hurdles to the electrification of trucking, according to the statement.

Automakers with EV models need to be aware of regulatory changes not only from current vehicle safety standards, but also evolving risks and liabilities around new technology and services such as charging stations. If there is a malfunction at a charging station that impacts a vehicle's safety – is that the responsibility of the automaker or the charging station manufacturer, or do they share liability? That is one of the many issues that will need to be explored and planned for as the industry grows.

> *"The introduction of the REPAIR Act could result in a loss of revenue for auto dealers if access to data is granted and consumers decide to take their vehicles to independent repair shops."*

National Right to Repair Act proposed

In February 2022, the Right to Equitable and Professional Auto Industry Repair (REPAIR) Act (H.R. 6570 or "the Act") was introduced in the U.S. Congress. The proposed legislation would require original equipment manufacturers (OEMs) to make it easier for vehicle owners to access data generated by their cars.

If passed, the Act would also lay the foundation for the Federal Trade Commission (FTC) and NHTSA to regulate security standards for access to vehicle-generated data. The vehicle systems involved can include GPS systems, onboard vehicle diagnostics, wireless telematics devices, and black box technologies. These devices record and transmit a wide range of vehicle data including speed, location, maintenance requirements, and servicing.

The State of Massachusetts passed similar amendments to its right to repair law in November 2020, though implementation of the rule is being challenged in Massachusetts federal court by automotive OEMs who opposed the measure.

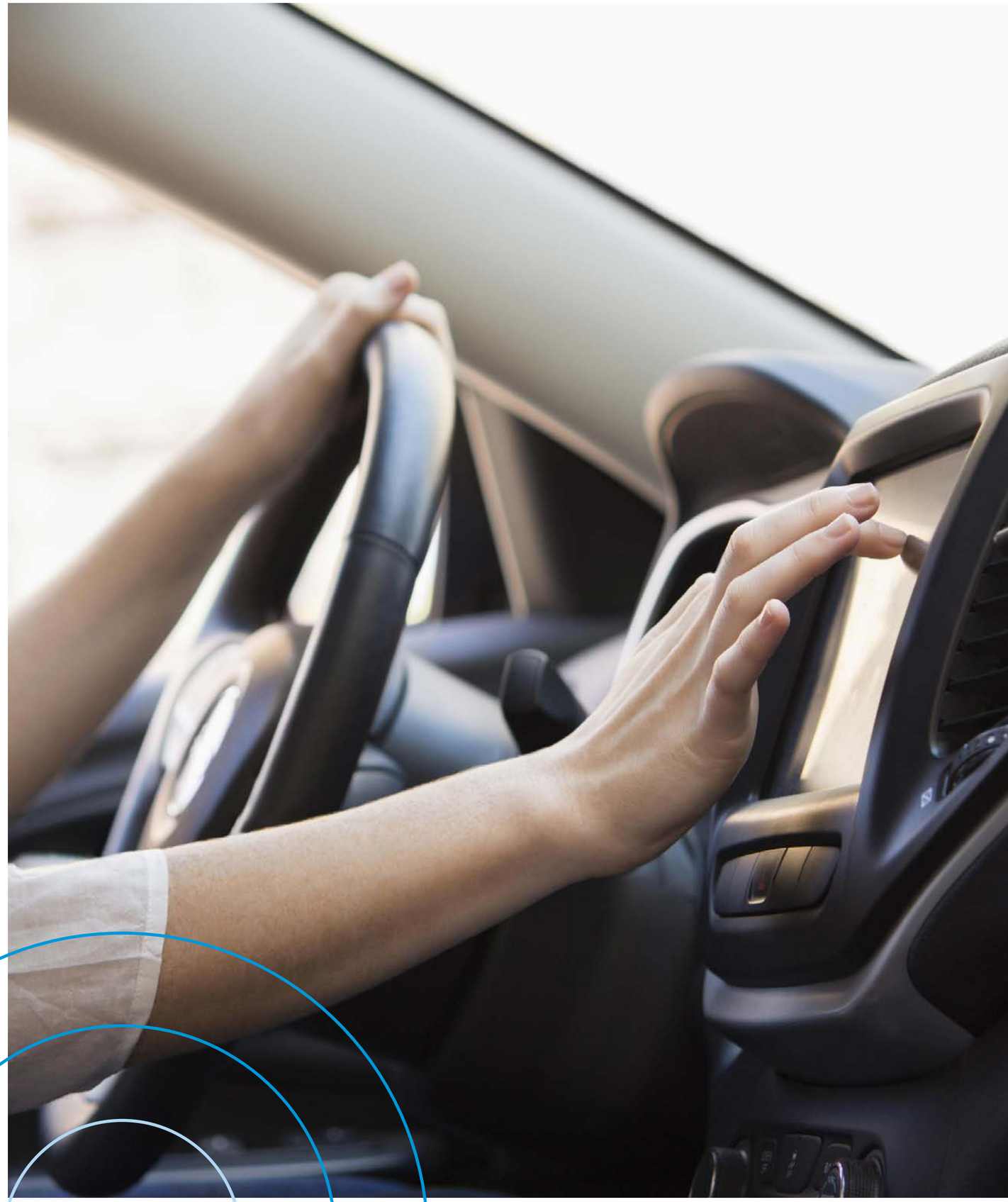
According to the Act, vehicle owners must have access to data "...related to diagnostics, repair, service, wear, and calibration or recalibration of parts and systems required to return a vehicle to operational specifications in compliance with Federal motor vehicle safety and emissions laws, regulations, and standards."

OEMs that deploy wireless technology, or "telematics" to transmit vehicle-generated data would have to create a platform by which vehicle owners could access this data, according to the proposed law. In addition, the FTC would need to designate an independent entity to establish and administer access to the platform within two years. Part of the push-back from OEMs are claims that the technology to create such a cybersecure standard access platform does not exist today.

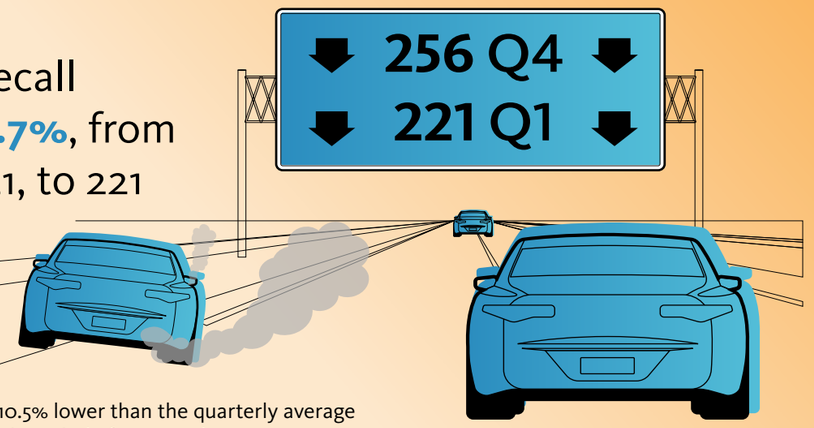
Standards and enforcement for this Act are complicated because multiple agencies would be involved. The FTC would be responsible for enforcing the Act's provisions. NHTSA would be required to establish federal standards for access to this data through the access platform and develop guidance to ensure the security of such data and vehicles generally.

It is not surprising that OEMs are concerned about this type of legislation. There is already pressure on them to protect data as more and more vehicles become connected. This legislation could also result in a loss of revenue for auto dealers if consumers decide to take their vehicles to independent repair shops or undertake their own maintenance if access to relevant vehicle data is granted. Additionally, it could complicate the recall landscape if there is any uncertainty about who is now liable for ensuring any repairs or updates that result from a recall are carried out.

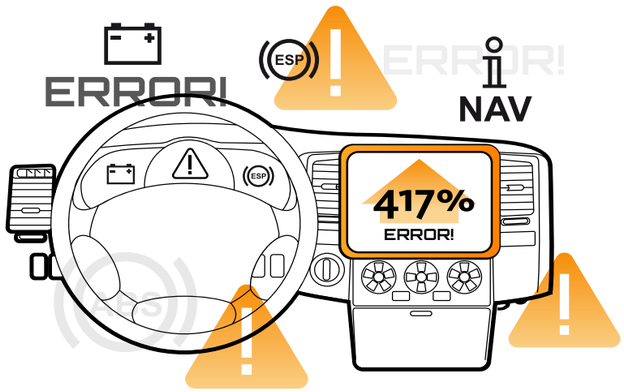
Both consumers and automakers will be following the progress of this legislation closely.



Automotive recall **events fell 13.7%**, from 256 in Q4 2021, to 221 in Q1 2022.



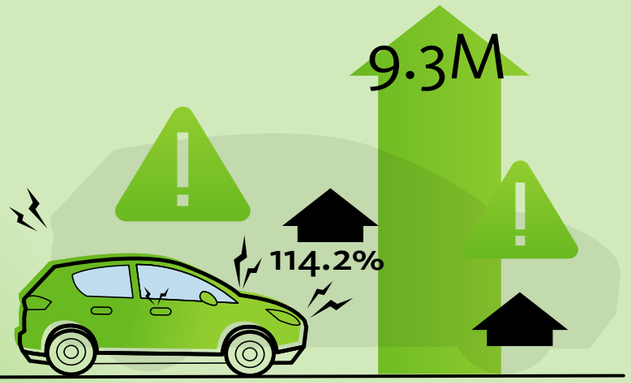
For context, this figure sits 10.5% lower than the quarterly average recorded during the pandemic period of 2020 and 2021.



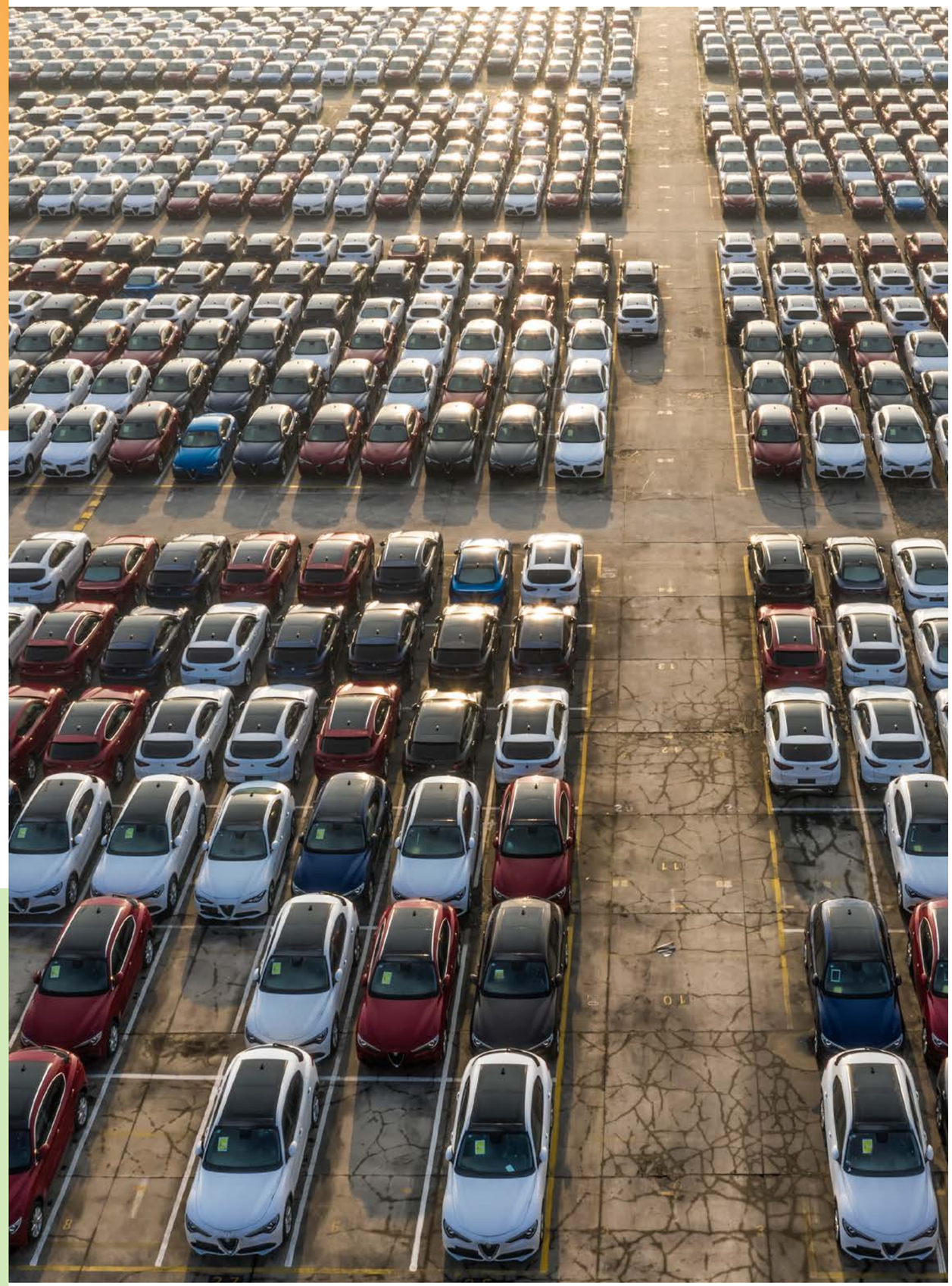
The number of **Electrical system** units **recalled** in Q1 surged 417% (to 2.7M).

Electrical systems accounted for the greatest volume of units recalled at 28.8%.

Despite a decrease in overall events, **impacted units more than doubled** (114.2%) to 9.3M.



Encouragingly, this figure remains comfortably below the 5-year quarterly average of 11.1M.



APRIL insight

There were 73 U.S. automotive recalls in April 2022. This is in line with the monthly average for Q1 2022 of 73.7. The number of units were down 11.7 percent. There were approximately 2.6 million units recalled in April, compared to a Q1 2022 monthly average of 3 million.

Electrical systems were the most common reason referenced in automotive recalls in April 2022, with 13. Equipment was the second most common cause and was linked to nine events.

Visibility was linked to the most units recalled with 714,906. This included two separate recalls related to inoperative windshield wipers.

FIRST QUARTER BY THE NUMBERS

There were 221 automotive recalls in Q1 of 2022, which is 19.1% lower than the quarterly average for 2021. However, while there were fewer recalls compared to Q4 2021, the number of units and the size of the recalls were significantly higher. There were 9.3 million units involved in the Q1 2022 recalls, 114.2% higher than Q4 2021. The average size of the recalls jumped more than 148% to 41,874 units.

Equipment remained the top cause for NHTSA recalls, as it has been for 16 of the last 20 quarters. There were 46 recalls that cited this cause in Q1 2022. Electrical system concerns were cited in 35 recalls, and fuel systems in 16.

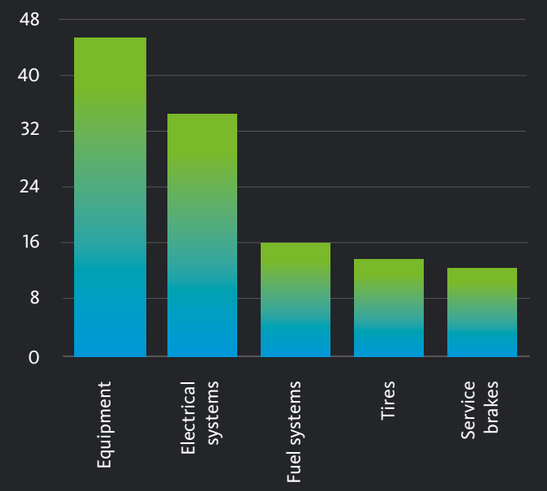
Forward collision avoidance systems and hybrid propulsion systems accounted for only one and two recalls respectively. However, there were no recalls for hybrid propulsion systems in all of 2021, and only two for forward collision avoidance concerns. As more hybrid and electric cars get on the road, these numbers will likely rise.

While air bag recalls were responsible for the most recalled units in Q1 2021, they fell to sixth position in Q1 2022. The most units (2.7 million) were tied to electrical systems. Engine and engine cooling concerns were second with 1.3 million units recalled and issues related to visibility were third, impacting approximately 1.1 million units.

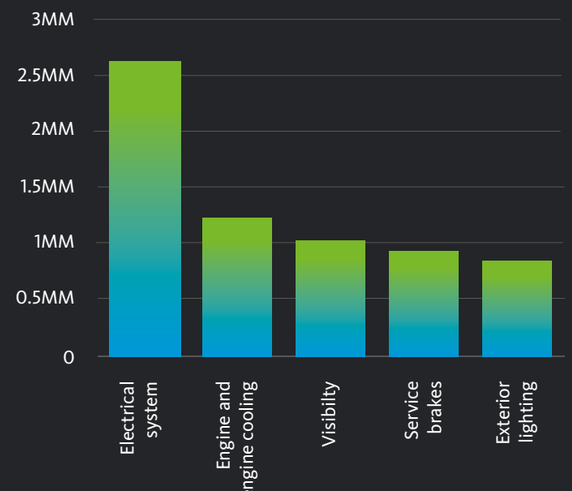
These are all substantial increases per category compared to this quarter last year. Twenty of the 221 recalls in Q1 2022 involved more than 125,000 units.

Once again, automobiles were the largest category of NHTSA recalls, accounting for 192 events in the first quarter of 2022. Equipment was cited in 26 recalls and tires were impacted in three. After seeing three recalls for child seats in Q4 2021, there were none this quarter.

NUMBER OF RECALL EVENTS BY CATEGORY



NUMBER OF UNITS RECALLED BY CATEGORY



WAYNE MITCHELL, GLOBAL DIRECTOR SALES AND MARKETING, **SEDGWICK BRAND PROTECTION**

EMERGING TRENDS FOR THE U.S. AUTOMOTIVE INDUSTRY IN 2022

While the automotive sector is slowly returning to pre-pandemic levels of operation, it – like other industries – continues to be plagued by ongoing challenges. Some of these, such as continued supply chain disruptions and associated price hikes for key components and raw materials, can be attributed to the impact of COVID-19. Other issues are tied to stricter regulation or geopolitical events.

Since it is unlikely that the U.S. automotive industry will be able to carry out every aspect of producing a vehicle – from sourcing raw materials to manufacturing the component parts – without relying on global partners, the challenges are likely to persist.

In addition to the economic and production-related challenges, the automotive industry is also under increased regulatory pressure. The National Highway Traffic Safety Administration (NHTSA) and lawmakers are focused on making newer in-vehicle technologies safer for drivers, passengers and pedestrians. There are also efforts to make sure older regulations are updated to include enforcement for new vehicle technology.

Another facet that the automotive industry shares with other sectors, is its emphasis on sustainable operations. Specifically for automakers, this means taking steps to make electric vehicles (EVs) more appealing and convenient to consumers in an effort to reduce emissions. One way to support this transition is to build a nationwide infrastructure for EV charging stations and provide manufacturers with the tools to continue increasing production.

Ongoing materials shortages

The semiconductor chip shortage continues to be a significant issue for the automotive industry. Many analysts are now predicting that the shortage will extend into 2023 or possibly even 2024. Most of the semiconductor market is concentrated in Asia, which will continue to pose a challenge if the emergence of new COVID-19 variants prompt countries to lock-down, halting production and further exacerbating shortages.

Both the European Commission and the U.S. Congress have passed legislation to increase production of semiconductor chips and to reduce reliance on foreign markets. A few chip companies have also announced plans to build manufacturing facilities in the U.S., but these are long-term efforts. Notwithstanding the signing of production and supply agreements, it can take up to three years to get a facility built and fully operational if everything goes smoothly.

Another critical shortage may also result from the conflict in Ukraine. Roughly 45% to 54% of neon, a key ingredient for making semiconductor chips, comes from two companies located here. These companies halted production in early March, removing a significant portion of the supply of neon. Many chipmakers have said they have sufficient stockpiles of neon to ensure the decreased supply doesn't affect their production, but if this source remains out of reach, companies who have not diversified their supply chains and found suppliers in other regions may be forced to cut their own production, further contributing to the semiconductor shortage.

Rising fuel prices may also spur more interest in and demand for fully electric or hybrid vehicles, as consumers try to find less expensive ways to remain mobile. Increased demand for EVs could place further strain on the semiconductor supply chain, since EVs can use thousands of more chips per vehicle than their internal combustion counterparts. EV manufacturers have also raised concerns about component shortages and higher raw materials prices, especially for the lithium used in EV batteries.

Regulators prioritize safety of new technologies

New data concerning traffic fatalities made headlines in mid-May 2022, after NHTSA's preliminary estimates found that 42,915 people died in motor vehicle traffic crashes in the U.S. in 2021. This number represents a 10.5% increase over 2020 and is the highest number of traffic fatalities since 2005.

Following the recent release of this data, it's unclear what action regulators and lawmakers will take to address safety concerns and what burden will fall to automakers. But it's nearly certain that regulatory activity will stir as a result of this significant increase.

Both NHTSA and the Department of Transportation (DOT) announced efforts in Q1 2022 to improve road safety. These plans are supported by funding from the Bipartisan Infrastructure Law and initiatives under the National Roadway Safety Strategy (NRSS). The NRSS also includes several provisions that would focus on new technology, whether it is regulating features like advanced driver assistance systems (ADAS) or requiring other technology that would improve a vehicle's ability to detect pedestrians and obstacles.

Under the NRSS, the DOT has also stated that it will work to investigate emerging safety issues related to the deployment of new technologies in a timely manner. While not explicitly stated, these technologies likely include ADAS, which are becoming increasingly popular in new vehicles and (when operated correctly) have the potential to make them safer.

A study from the American Automobile Association (AAA) Foundation for Traffic Safety found that 'self-taught' drivers using ADAS technology had less understanding of how the technology worked than a separate group who underwent a brief training. The gaps in understanding were related to false beliefs that ADAS technology, in this case adaptive cruise control, would provide steering input to stay in its lane, respond to objects in the road or work in all weather conditions.

WAYNE MITCHELL, GLOBAL DIRECTOR SALES AND MARKETING, **SEDGWICK BRAND PROTECTION**

CONTINUED FROM PREVIOUS PAGE

Vehicles with "autopilot"-type capabilities have also recently come under scrutiny by NHTSA, which is looking at whether autopilot can encourage driver misuse, among other things. A rising concern is the tendency of people using automated driving systems to "zone out," leading them to take up to 40 seconds to regain control of the vehicle if the system fails or cannot respond to an obstacle. Regulators may decide that manufacturers must be responsible for compensating for driver errors when they are designing ADAS and automated driving systems (ADS).

With new vehicles now increasingly equipped with ADAS or ADS, regulators will be paying closer attention to how they're created and deployed. For manufacturers, increased federal scrutiny of ADS will necessitate an exacting quality control process and a proactive recall strategy to ensure compliance in this evolving regulatory space.

Sustainability and electric vehicles

Nearly half of respondents to a recent McKinsey survey said that battery or charging issues are their top concerns keeping them from buying an EV.

To help alleviate these concerns, President Biden announced in late December that the Bipartisan Infrastructure Law included $5 billion to fund a nationwide infrastructure of 500,000 charging stations. The charging infrastructure would also serve to help achieve the Biden Administration's goal to have EVs make up 50% of total new vehicle sales by 2030. With EV sales currently at only 3% of the U.S. market, other incentives will be needed to reach this ambitious goal in eight years.

While many support a nationwide charging infrastructure, there remains concern that these stations may be vulnerable to hackers. The increased connectivity of every aspect of the automotive industry means that automakers and consumers should expect to hear more about the risks of a cyberattack.

If public charging stations are targeted by hackers, it would be difficult for drivers to know whether they were about to use a compromised station, leaving them vulnerable to hacking. If this were to occur, it is difficult to know whether the government, the manufacturer of the charging station, the manufacturer of the vehicle, or the driver would be responsible for the resulting damage.

Looking ahead

The automotive industry will continue to face serious supply chain disruptions throughout the rest of 2022 and likely into early 2023. While this and other factors are out of manufacturers' control, there are steps that companies can take to ensure continued operations and maintain brand value, including diversifying their supply chains, communicating transparently with consumers, and applying special measures to protect their technology from hackers.

> *“Companies should not hesitate to report incidents to the CPSC as required by law. Delaying may not only result in hefty fines, but might also do serious damage to its customers’ and partners’ trust.”*

CONSUMER PRODUCTS

The Consumer Product Safety Commission (CPSC) is making it clear that companies need to report any safety issues promptly or risk legal actions and steep fines. However, some people think the Commission isn’t acting aggressively enough to protect children.

Regulators at a national and state level are monitoring the fashion industry and its claims around sustainability and eco-friendly practices. Companies must be prepared to back up these statements.

> *“Review recall processes at least annually and be sure social media is included in the recall plan. The only thing worse than a recall is a badly executed recall.”*

CPSC continues aggressive enforcement over delays to report

The CPSC has taken an aggressive stance on ensuring that companies report suspected safety issues promptly. In 2021, the Commission filed an administrative complaint against a residential elevator company that refused to issue a voluntary recall over safety concerns. The CPSC filed a subsequent administrative complaint in February 2022, but this time the action was taken against a manufacturer of infant loungers whose products were determined to pose a suffocation hazard.

While the CPSC Chair Alexander Hoehn-Saric called such complaints a “last resort,” the manufacturer had refused to conduct a voluntary recall even after reports of two infant deaths. The Commission issued a public health and safety warning in January 2022, but the manufacturer still failed to act.

The CPSC also levied a $6.5 million civil penalty against a workout equipment manufacturer that did not immediately report safety issues with two of its products. The machines were subject to a recall in 2017, but only after the company received reports of 55 incidents which were not immediately reported to the CPSC, including 11 head injuries.

In addition to the fine, the company has also agreed to improve its compliance program to align with the Consumer Product Safety Act (CPSA). The company is required to maintain a system of internal controls and procedures to ensure that information required to be disclosed to the Commission is recorded, processed, and reported in accordance with applicable law.

Companies should not hesitate to report incidents to the CPSC as required by law. Delaying may not only result in hefty fines, but might also do serious damage to its customers’ and partners’ trust.

Deaths, injuries and incidents around children’s products increase sharply

Consumer protection nonprofit Kids in Danger (KID) released its annual report in March 2022 tracking recalls for children’s products last year. The study found an alarming increase in deaths with 14 in 2021 compared to zero in 2020. Twelve of the deaths were from two brands of infant loungers, both of which were recalled due to a suffocation hazard. Of the other two deaths, one was linked to a bunk bed and one to a high-powered magnet set. The magnets were part of a 10 million unit recall.

The number of incidents year-over-year also increased dramatically with 136 injures and 6,058 incidents reported in 2021, compared to nine injuries and 704 incidents in 2020.

Despite the CPSC taking a more aggressive enforcement stance, KID believes more needs to be done to protect children. Its recommendations include completely banning small high-powered magnets and taking steps to prioritize recall effectiveness, which KID says “currently appears to be an afterthought.” According to the nonprofit organization, one way to make recalls more effective is to post all recalls on multiple social media platforms. According to KID’s report, the CPSC only posted 50% of children’s product recalls on Facebook, 40% on Twitter, and 5% on Instagram. Recalling companies also used social media sparingly, posting just 44% of recalls on Facebook, 32% on Twitter, and 22% on Instagram.

KID also criticized the CPSC for what it called “a lack of transparency” in the recall process. It claimed it is hard to measure how effectively the CPSC and companies are undertaking recalls. This serves as a reminder for all companies, but especially those in the children’s product space. Review recall processes at least annually and be sure social media is included in the recall plan. The only thing worse than a recall is a badly executed recall.

Fashion industry facing regulation over sustainability claims

More and more companies are looking to promote their environmental and sustainability efforts and the fashion industry is no exception. According to a 2019 report from the UN, this sector produces 20 percent of all wastewater, is responsible for up to 10 percent of global greenhouse gas emissions, and loses $500 billion of value every year due to clothing underutilization and lack of recycling.

It is understandable that companies would want to position themselves as working to make their businesses more eco-friendly. Now more and more regulators at all levels are monitoring those claims and insisting companies substantiate their assertions.

In the U.S., the Federal Trade Commission (FTC) announced that it will review its Green Guides this year to update what is considered a "road map" for businesses to ensure eco-claims made in their marketing and advertising are lawful.

National Advertising Division (NAD) of the Council of Better Business Bureaus investigated one fashion retailer's sustainability claims to ensure that there was a reasonable basis for its claim that there were "no new plastics" in a specific apparel collection. Overall, the retailer's claims were found to be true, though NAD did have some recommendations.

At a state level, both California and New York are looking at environmental advertising. California recently expanded its Truth in Environmental Advertising law to specifically address claims about recyclable materials. New York legislators introduced the Vanguard Fashion Sustainability and Accountability Act which would require fashion companies with more than $100 million in revenue doing business in the state to disclose their social and environmental impact including energy, greenhouse gas emissions, water, plastic, and chemical management.

Regulators in the UK and EU have also announced a focus on ensuring any advertisements highlighting a company's sustainability or "good for the environment" record can be backed up with facts.

Many companies are looking for ways to reduce their carbon footprint and help the environment and their workers. But it will be important that they have clear documentation and metrics around these efforts so they aren't dismissed as "greenwashing" or false advertising.

Regulators working to simplify terms of service language

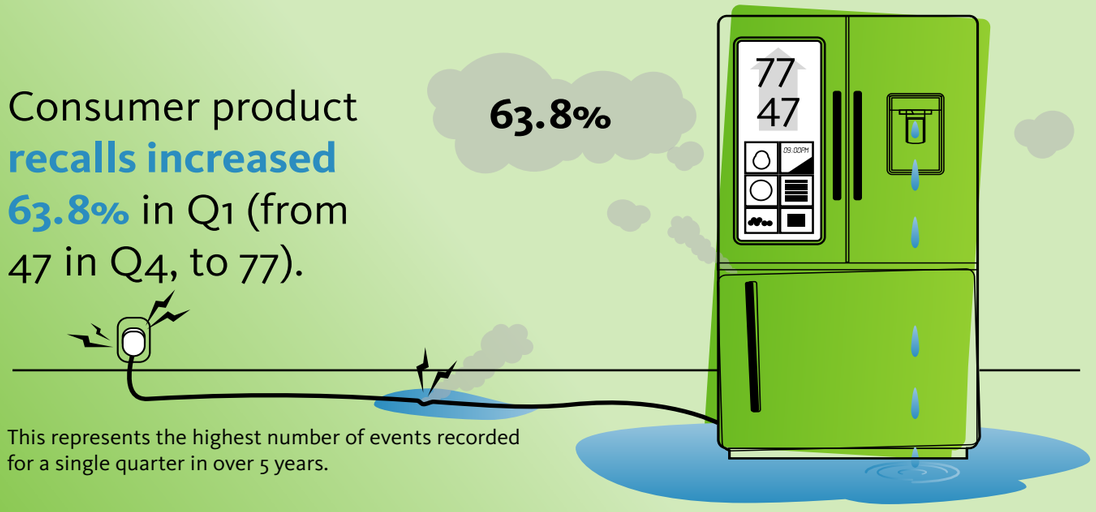
Website operators rely on their site's terms of service to protect their intellectual property, set terms for warranties, and limit their liability. However, for most consumers, website Terms and Conditions are confusing, if they are even read at all.

In January 2022, the Terms-of-service Labeling, Design and Readability Act (TLDR Act) was introduced in the U.S. Congress with the goal of informing consumers about the data collected from them and ensuring the terms are easily understandable.

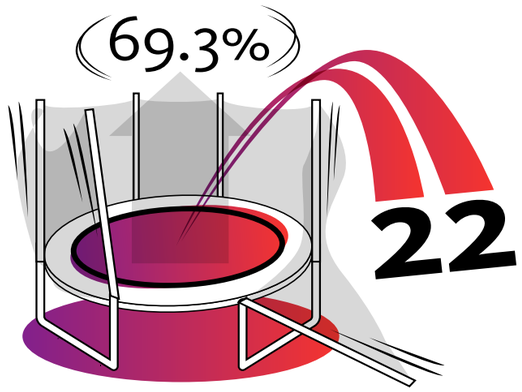
The Act, if passed, would also require that a website's terms of service include the categories of sensitive consumer information collected, why such information is needed, with whom it is shared, and the rights consumers have around their content. Companies would also be required to list any reported data breaches over the past three years.

Under the Act, companies would be subject to penalties from the FTC for violations, and State Attorneys General could also bring civil actions in some cases. Though the bill is in its early stages, it would be prudent for companies to compare the proposed regulations to their current terms of service to see what they would need to change to comply.

Consumer product **recalls increased 63.8%** in Q1 (from 47 in Q4, to 77).



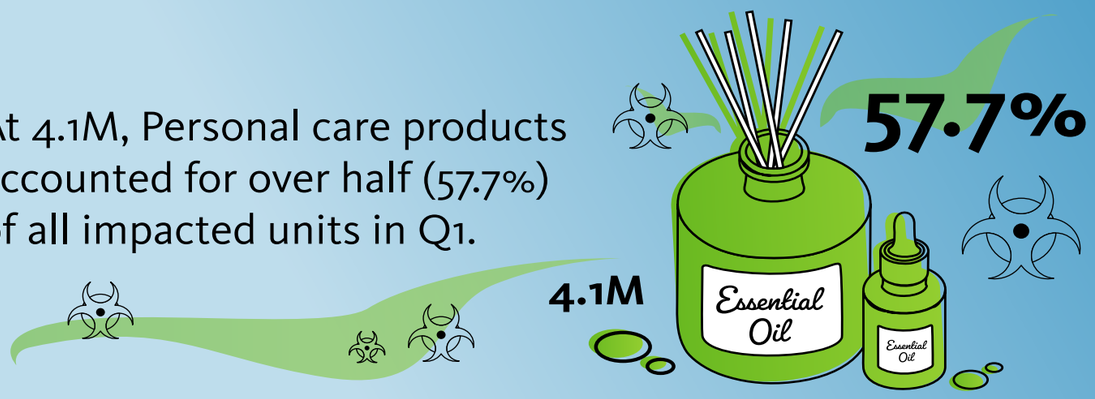
This represents the highest number of events recorded for a single quarter in over 5 years.



Sports & Recreation products experienced **22 recalls** in Q1, a 69.3% increase on last quarter.

Accounting for 28.6% of total events, Sports & Recreation products have remained the top recalled category for 19 of the last 24 quarters.

At 4.1M, Personal care products accounted for over half (57.7%) of all impacted units in Q1.



This is only the second time in 10 years that Personal care products have been the leading cause of recalled units (2.3M units in Q1 2013).

FIRST QUARTER BY THE NUMBERS

After only 47 recalls for consumer products in Q4 2021, the number of events jumped nearly 64% to 77 events in Q1 2022. Even more dramatic was the increase in units impacted. More than 6.96 million units were affected, a 161.0% rise from the previous quarter.

There was also a 116.5% increase in reported incidents: rising from 544 incidents in the fourth quarter of 2021 to 1,178 incidents in the first quarter of 2022. In addition, the number of injuries grew by 198% to 146. On a more positive note, there were no deaths reported in Q1 2022, a significant drop from the 10 reported in the previous quarter.

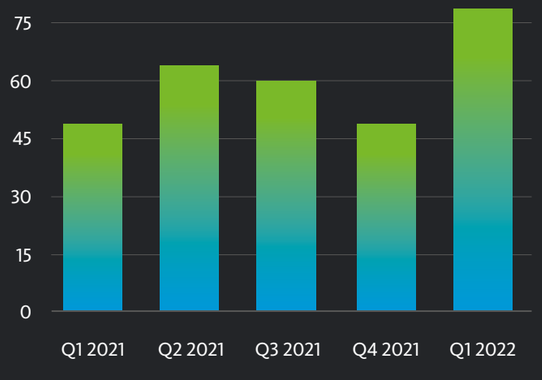
The jump in the number of units is largely attributed to a single recall for gummy vitamins that led to 3.7 million units being recalled and 18 reported injuries. There was also a recall for smart watches that were reported to overheat. This event involved 1 million units and was tied to 78 injuries.

Sports and Recreation remained the top product category impacted by recalls. It has been the leading category for 21 of the past 28 quarters. There were 22 recalls tied to Sports and Recreation, or 28.6% of all consumer product recalls this quarter. Apparel was second with 11 recalls and Home Furnishings and Electronics both experienced eight events in the first quarter.

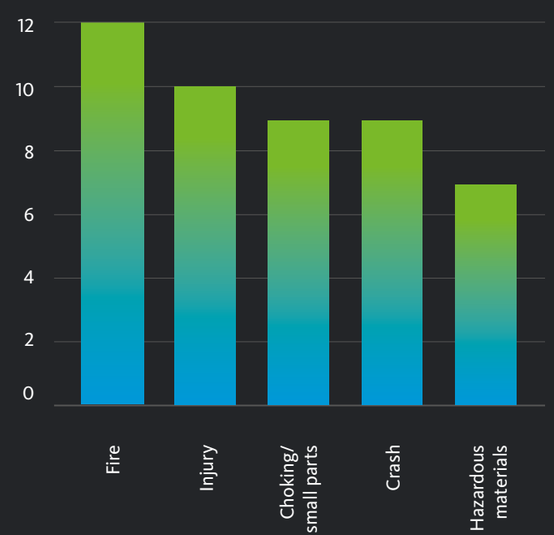
While the Personal Care category only had five recalls, it led the number of units at 4.0 million, or 57.7% of all units recalled. In terms of incidents, Sports and Recreation had the most with 292, followd by Electronics with 249.

Fire risk was the most common cause for recall events in the first quarter at 12 (15.6%). Injury risks was the leading cause of recalled units, impacting 4.1 million units, or 58.3% of all recalled products.

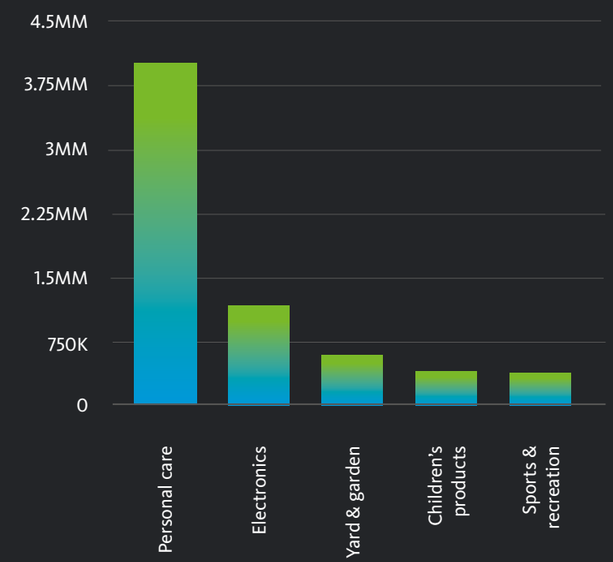
NUMBER OF RECALLS BY QUARTER



NUMBER OF RECALLS BY RISK TYPE



NUMBER OF UNITS RECALLED BY CATEGORY



APRIL insight

Consumer product recall numbers for April 2022 closely followed the monthly averages from Q1 2022. There were 23 recalls in April, compared to a monthly average of 25.7. The Q1 2022 monthly average for units recalled was 2.32 million, compared to 2.4 million in April 2022.

As a category, Home Furnishing & Décor had the most recalls, with five events. Home Appliances, Yard & Garden and Sports & Recreation each had three recalls in April. The risks from consumer products was also split fairly evenly. Four recalls each were linked to Childproof packaging violations and Fire. Choking/small parts, Fall onto, and Injury were cited as risks in three recalls each.

WILLIAM TROUTMAN, PARTNER,
NORTON ROSE FULBRIGHT

CPSC UNILATERAL ACTIONS CAUSE CHALLENGES FOR COMPANIES

After being without an official chairman for four years, the Consumer Product Safety Commission (CPSC) confirmed Chair Alexander Hoehn-Saric in October 2021. The Commission is still awaiting the confirmation of its fifth commissioner. As the agency continues to evolve, there are questions about what the next few years of CPSC activity will look like and what its priorities will be.

However, there is one enforcement trend that seems to be one the rise – the use of unilateral actions. The increased use of these actions is causing confusion for companies and some unintended consequences up and down the supply chain.

Unilateral actions are used when the CPSC makes an assessment about a product risk and the product manufacturer or importer doesn't agree with the Commission. More and more the CPSC is taking unilateral action against the company, or sometimes several companies in that category. This may take the form of press releases, social media campaigns and other tactics. The CPSC presents this as informing the public about a hazard, but ultimately, it puts immense pressure on a company to conduct a voluntary recall or take whatever step the CPSC has determined is necessary.

No one would argue against protecting consumers and the importance of consumer safety. But when the CPSC acts unilaterally, it is usually because there is no standard in place that relates to the product or risk at issue.

Conducting enforcement actions without a clear standard creates a gray area. It by-passes the traditional rule-making process and the administrative law process. When a regulatory agency's behavior is unpredictable, companies don't know how to comply.

If the CPSC issues a unilateral press release about an individual company and a specific product, it creates a lot of uncertainty. Other companies with similar products try to determine if they have a problem as well, but with no clear process or criteria, that is a difficult assessment to make.

An example of this situation is currently going on with infant loungers. In June of 2021, the CPSC approved a new federal rule to ensure that products marketed or intended for infant sleep are safe for babies under five months old. There are also standards for bassinets and cradles.

Manufacturers of infant sleep products have a regulation they can refer to as they design, manufacture and market their products. They have information about how to comply with the standard.

Infant loungers are not sleep products. Many of the manufacturers have warning labels on the products themselves. There are also warnings on the packaging. The instructions state these products are not for sleep. They are not marketed as infant sleep products.

However, even though the CPSC publicly admits that the infant loungers are not marketed for or intended to be used for sleep by infants, the Commission has deemed these products unsafe. The CPSC has stated that despite all the warnings and instructions, it is foreseeable that parents or caregivers will use them incorrectly, putting infants at risk.

A very popular brand cooperated with the CPSC and issued a very large recall of several infant loungers—even though the products were not intended for sleep.

The CPSC requested that another brand also recall its infant loungers, but the manufacturer has resisted. The CPSC first issued a unilateral press release warning consumers not to use the products. It then sued the company in Administrative Court to force a recall. This action puts the company at risk—and potentially all of its employees.

In its complaint, the CPSC admits the products are not intended for infant sleep. The Commission acknowledges that the warnings say they should not be used for sleep. However, it states that it is foreseeable that a parent might not wake a child who has fallen asleep in the lounger or might leave the child unattended. Therefore, the CPSC argues the products create a suffocation risk and need to be recalled, despite there being comprehensive instructions and warnings.

The impact of the CPSC's unilateral action is not confined to these two manufacturers. Any company that manufactures, imports or sells an infant product not intended for sleep—but that might foreseeably be used for sleep if a parent or caregiver disregards instructions and warnings—is potentially on the CPSC's radar. Which means that company is at risk of being called out by the CPSC, and potentially subject to an administrative lawsuit.

Everyone in the supply chain also has an obligation to report to the CPSC if they obtain information that reasonably supports the conclusion that there is a "substantial product hazard." If the CPSC issues a unilateral press release stating that a product is unsafe, does everyone now have an obligation to report to the CPSC? If a company doesn't report, that company may be open to "failure to report" claims from the CPSC. That can be a big risk. Over the past 15 years, penalties for "failure to report" claims have gone from several hundred thousand dollars to tens of millions of dollars.

If the CPSC has said that two brands of infant loungers, or really any product, create a substantial product hazard, what should a retailer selling a third brand of infant lounger do? If that third product looks like the other two identified brands, is that retailer subject to reporting requirements for someone else's product when there is no clear standard? If a retailer asks an upstream supplier about the need to report, and the supplier says nothing needs to be reported, the retailer is depending on the supplier to be right. The infant lounger company that is currently being sued by the CPSC supplies its products to many different types of retailers. Those retailers don't know what to do.

The CPSC generally tells companies "when in doubt, report." But if they do report, the company is entering a regulatory process that it doesn't control. That process could go on for months or even years and has an uncertain outcome. And if a retailer reports for fear of a "failure to report" claim despite the upstream supplier saying no report is warranted, the retailer has now pulled the supplier into the conversation with the CPSC.

Beyond the CPSC, do they want to risk being called out by NGOs that might go further than the CPSC, risking brand damage and angry consumers? Do they want to risk shareholders viewing them as a company that doesn't keeping its consumers safe?

And if they do decide to stop selling or recall a product, that creates another vulnerability. There may be disputes with upstream suppliers who have a different risk calculus and may not agree with the decision to pull product without an official determination. More and more companies are investing in recall insurance—but it may not be clear if the protections those policies offered are triggered by CPSC press releases and tweets, or if there has to be an actual recall. The infant lounger company that has been sued by the CPSC knows that damage can be done without an official recall.

CPSC officials say that they intend to take more unilateral actions. If they are challenged about this approach or asked about the lack of a rule-making process, the implicit response is that the Commission's mandate is to protect consumers. Companies want to provide safe products to consumers, too. There is no upside to having one's brand connected to a consumer safety incident.

But companies also want clear guidance and rules they can follow. They want a way to protect consumer safety and also protect their own employees and all the people in the supply chain who depend on the sale of their products to support their families and livelihoods. Unilateral actions fail to provide that clarity.

FOOD AND DRINK

A recall of infant formula that resulted in two deaths raised alarm bells, for both the recalled product and the FDA's reaction. The manufacturer had a history of safety violations and repeated offenses at the facility that produced the tainted formula, including several detections for the same bacteria that was named in the outbreak.

The FDA published a list of its 30 priorities for issuing guidance over the next 12 months. While the list covers a range of topics, food safety and enforcement of the Food Safety Modernization Act (FSMA) were the most prominent.

Regulators and consumer advocates are focused on residual agricultural chemicals in the food supply. New EPA regulations are now in effect for chlorpyrifos and the FDA has outlined its approach to enforcement if growers don't comply.

> *"A recent case in Louisiana served as a reminder that even if manufacturers are following state regulations, if those are not aligned with federal law, there can still be problems."*

Infant formula recall raises concerns

A recall of powder baby formula has raised concerns among parents and policy makers. The manufacturer issued a voluntary recall on February 17, 2022 affecting three of the company's powder infant formula brands manufactured at a specific facility in Michigan. As of April 1, 2022, Cronobacter sakazakii bacteria in the formula had been linked to four illnesses and two deaths.

Both the company and the FDA are under heavy criticism for not taking action sooner. Findings from FDA Form 483 documents for inspections in 2019, 2021 and 2022 noted that there was not a system of process controls that was "designed to ensure that infant formula does not become adulterated." The Agency also found eight instances of Cronobacter bacteria between 2019-2022 in the facility.

Federal documents from the 2022 FDA inspection also showed numerous problems with equipment and the environment in the production facility. The fact that the FDA publicly shared 483 information, which is typically kept confidential, should serve as a warning to other companies.

Personal injury lawyers are already alerting parents that they may be entitled to financial compensation from the manufacturer, even if the company took measures to prevent contamination and outbreaks.

The FDA has stated that once the immediate public health risk is minimized, it will conduct a programmatic review related to agency programs and policies for infant formula and special medical food complaints, illnesses, and recalls.

It will be interesting to see what changes the FDA makes in the wake of this outbreak. However, it should also serve as a warning to any company that has had repeated 483s for the same issue. With more FDA data being made public through dashboards and other channels, it is likely that enforcement – and reputational risk – will be much higher when it is clear that warnings were ignored.

FDA posts priorities for 2022

On January 31, 2022, the FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Office of Food Policy and Response (OFPR) published an updated list of priority guidance documents related to foods and dietary supplements. The Agency stated that most of these documents would be issued by January 2023.

The 30 documents cover topics including allergens, cosmetics, dietary supplements, food additives, labeling, and nutrition, with most of them centered on food safety and the Food Safety Modernization Act (FSMA).

In March 2022, the FDA published one of these guidance documents related to the FSMA focused on Good Manufacturing Practice (GMP), foreign supplier verification programs and other controls. Another guidance issued in March announced the FDA's intent not to enforce certain requirements established under the FSMA. Instead, the Agency will extend current enforcement discretion policies and implement new policies. Specifically affected are supply-chain program requirements applicable for co-manufacturers, requirements related to FDA's Mitigation Strategies to Protect Food Against Intentional Adulteration rule (IA Rule), and certain supplier verification and approval requirements.

With all these changes ahead, food producers, distributors, and retailers should work with their regulatory counsel to ensure they are prepared to comply with the changes and stay ahead of new regulations.

Food manufacturers need to guard against false claims

Labeling requirements and definitions can be tricky for food manufacturers. Whether it is knowing what qualifies as French dressing or yogurt or how many strawberries belong in a strawberry toaster pastry, it is challenging. And more and more consumers are filing lawsuits demanding that manufacturers substantiate claims around everything from "health" and "lightly sweetened," to what qualifies as a "smoked" almond or a "twist of lemon." While these may seem like nonsense suits, sometimes the plaintiffs are winning. And even when the manufacturers win, or get the cases dismissed, there are still legal fees and reputational risks.

A recent case in Louisiana also served as a reminder that even if manufacturers are following state regulations, if those are not aligned with federal law, there can still be problems.

Regulators may be trying to help. The FDA is planning to conduct consumer research on voluntary symbols that could be used to claim a food is "healthy," based on the nutrient content. However, the Agency is careful to note that the research is around only the symbol. Deciding what the criteria are to call a food "healthy" will be a separate process.

When in doubt, manufacturers should err on the side of caution when making labeling claims. This will help mitigate the risk for both regulatory enforcement and costly consumer lawsuits.

FDA monitoring chemicals in the food supply

Two agrichemicals are being closely watched by environmentalists and regulators – chlorpyrifos and glyphosate.

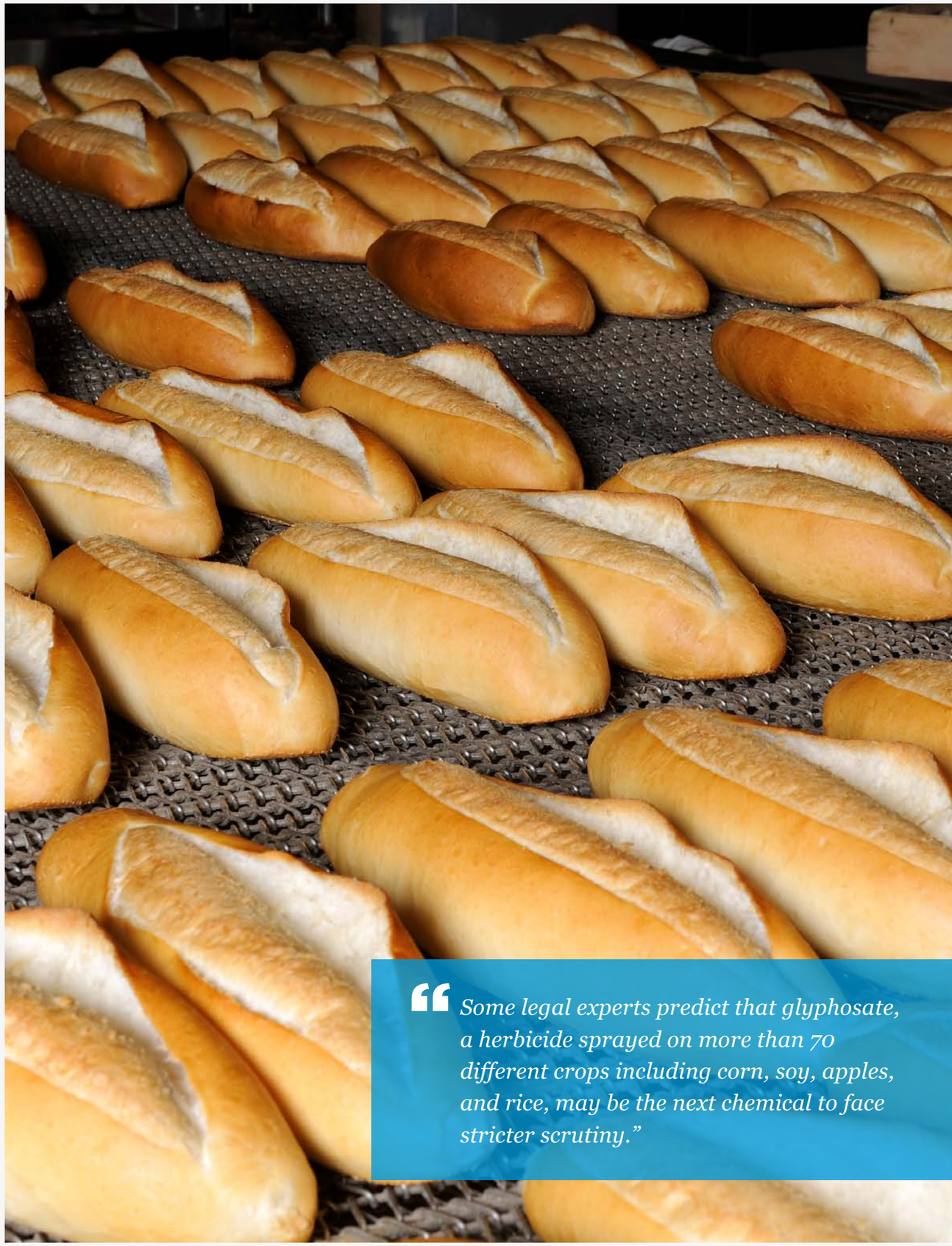
On February 9, 2022 the FDA published a guidance document to assist food producers and processors that handle foods which may contain residues of the pesticide chemical chlorpyrifos. A final rule from the Environmental Protection Agency (EPA) established February 28, 2022 as the last date that any tolerances, or maximum residue limits, for chlorpyrifos were acceptable on raw agricultural commodities and processed foods.

Per the new guidelines, the FDA will implement a two-phase enforcement approach that includes the Agency exercising enforcement discretion for up to 24 months depending on the food commodity and some discretion to show that any chlorpyrifos residue detected is from a lawful application made before the February 2022 expiration date.

Some legal experts predict that glyphosate, a herbicide sprayed on more than 70 different crops including corn, soy, apples, and rice, may be the next chemical to face stricter scrutiny. To-date, lawsuits against pesticide manufactures and growers over glyphosate residue on food crops have all been dismissed on the grounds that "reasonable consumers" would not be surprised to find trace levels of pesticides in their food.

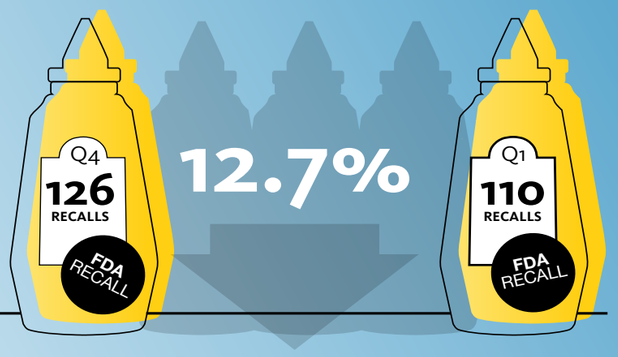
According to Food Navigator, some major Consumer Packaged Goods companies are already talking about phasing out glyphosate as a pre-harvest drying agent and there are more than 100 brands and more than 5,000 products certified as glyphosate residue free.

With voluntary action already being taken by companies, it is hard to know if the FDA or the EPA will put stricter controls around glyphosate. However, growers and processors should make sure they have updated their testing and processing regarding chlorpyrifos and have discussed any use of glyphosate from a reputational, if not regulatory, standpoint.

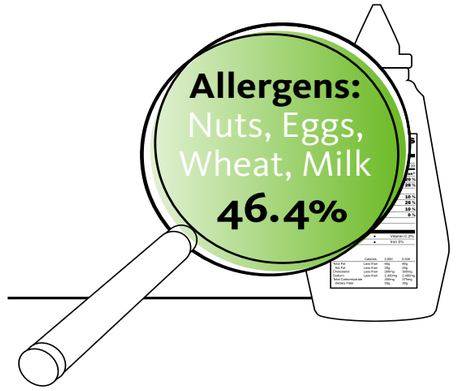


> *"Some legal experts predict that glyphosate, a herbicide sprayed on more than 70 different crops including corn, soy, apples, and rice, may be the next chemical to face stricter scrutiny."*

FDA recall **activity fell 12.7%** in Q1, from 126 events (in Q4), to 110.



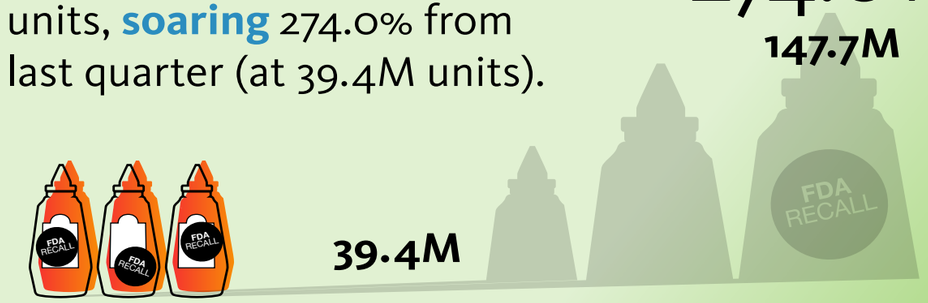
Despite this decline, Q1 events remain on par with the quarterly average of the past 3 years (111).



While **Undeclared allergens** remain the leading cause of events (51 or 46.4%), Quality concerns dominated in terms of impacted units (at 98.3M).

For context, the total number of units recalled due to Quality concerns over the last 5 years (2017 – 2021) stands at 87.3M.

Q1 **recalls impacted** 147.7M units, **soaring** 274.0% from last quarter (at 39.4M units).



This rise, combined with a decline in events, inflated the average recall size to 1.3M units. This eclipses the 10-year average of 207K units.

FIRST QUARTER BY THE NUMBERS

FDA

The trend across multiple sectors of seeing fewer recalls but more units recalled held true for the food industry in the first quarter of 2022. The number of recalls was down 12.7% compared to Q4 2021, with 110 events. But there was a 274% increase in the number of units, which grew to 147.4 million. This combination resulted in the average size of the recalls jumping from 312,823 in Q4 2021 to 1.3 million in Q1 2022.

There were four sizable recalls that helped push the total for the quarter up. Firstly, a recall of caffeine supplements over quality issues accounted for 86.5 million units. Secondly, there was more trouble for produce companies which saw 31.2 million units of lettuce recalled over concerns for listeria. Thirdly, bacterial contamination led to the recall of 14.9 million units of infant formula, and fourthly, 11.8 million units of soy beverage were recalled due to quality issues.

Q1 2022 saw 33 recalls that were designated as Class I. These events accounted for 48.5 million units. There were 71 Class II recalls involving 98.9 million units, and only six recalls were designated as Class III.

Undeclared allergens were the leading cause of recall events in the first quarter with 51 recalls. It has been the top cause for all but three quarters since 2015. Based on the number of units, quality concerns had the biggest impact in the food sector this quarter. Quality was linked to 98.3 million units, including the large supplement recall and the soy beverage event. This represents the highest volume of quality concerns for over 5 years.

Produce was the category with the most recall events, at 29 or 26.4% of all recalls for Q1 2022. However, by volume, supplements recorded the most units with 101.5 million including the aforementioned caffeine supplement and infant formula recalls.

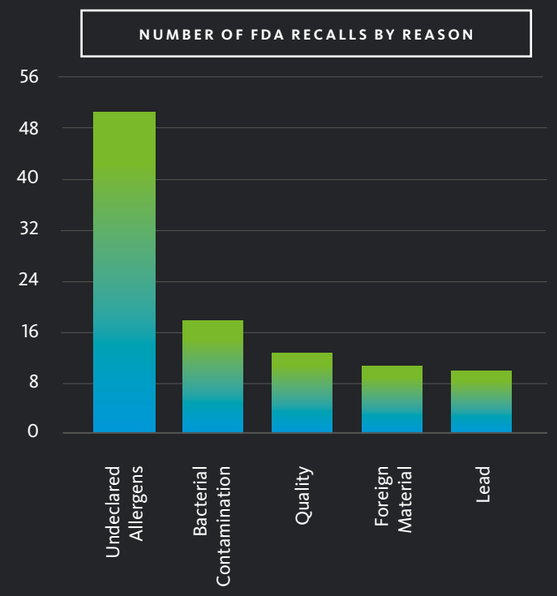
The 110 recalls in Q1 2022 impacted 108 unique companies, which suggests a fairly even distribution of recall events.

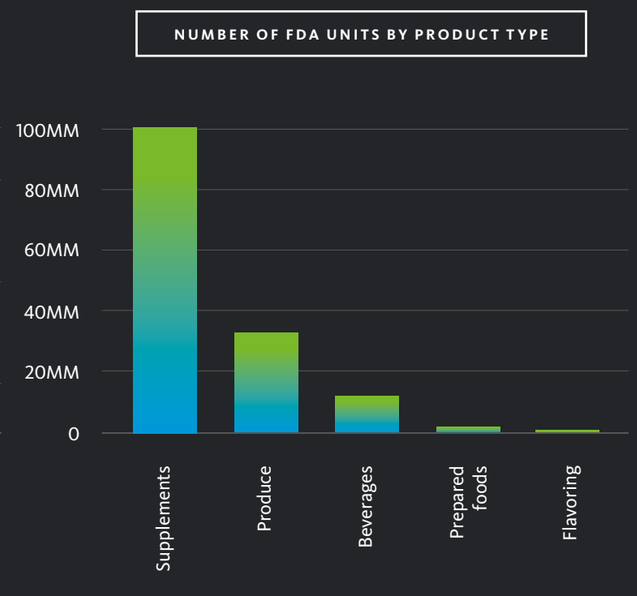
APRIL insight

In April 2022, the FDA issued 33 food recalls. That is a 10.0 percent decline compared to the monthly average in Q1 2022. The number of units dropped significantly, from an average of 49.1 million in Q1 to 567,355 units in April. Of those units, 65.3% were from a single recall.

Undeclared allergens were responsible for 43.8 percent of the April 2022 recalls, linked to 14 events. Foreign materials were the second leading cause of recalls, with eight and bacterial contamination was third with seven events.

In terms of product category, produce took the top spot with 13 recalls. Prepared foods had five and baked goods had four.





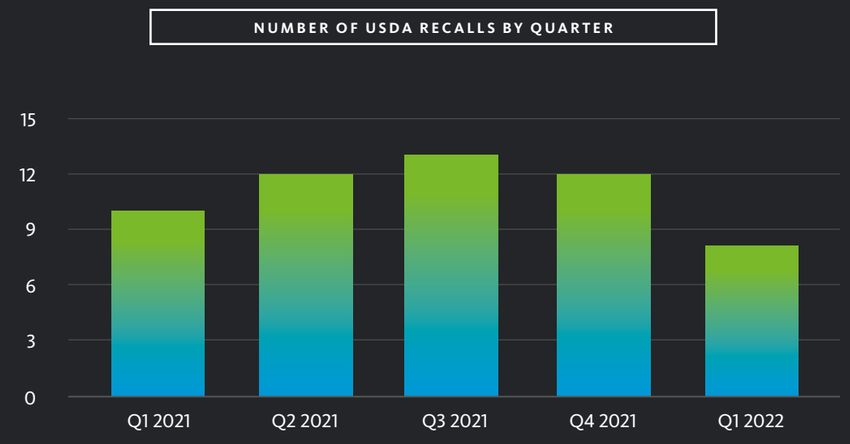
USDA

USDA recalls decreased by 33.3% to only eight in Q1 2022. This is the fewest number of recalls since Q4 2020. There was also a 94.7% drop in units compared to the previous quarter, with 65,272 pounds recalled.

Undeclared allergens were the leading cause of recalls, accounting for four of the eight events. Bacterial contamination was linked to two recalls, and misbranding and lack of inspection were cited in one recall each.

Bacterial contamination, while linked to only 25% of the recalls, had the most volume with those two recalls accounting for 29,990 pounds. Most of that was from a single recall of E.coli in beef.

Beef products were the most impacted category in terms of both events and units in the first quarters, with five recalls impacting 52,966 pounds. Poultry was linked to two recalls, and fish to one.



APRIL insight

The USDA published four recalls in April 2022. This is an increase compared to the monthly average of 2.6. The 159,566 pounds that were recalled in April represent an increase of more than 144.5 percent compared to all of the first quarter. Of that, 75.8% was tied to a single recall for beef contaminated with E.coli.

Beef was the top category recalled in April 2022 by volume and number of events. There were two beef recalls compared to one each for poultry and for pork. Half of the USDA recalls cited no inspection. Undercooking and bacterial contamination each were named in one recall.

CYNTHIA MEYER, PARTNER,
KLEINFELD, KAPLAN & BECKER

SOCIAL MEDIA GIVES CONSUMERS A LOUDER VOICE IN THE FOOD INDUSTRY

Ten years ago, it would have been relatively unusual to hear people talk about the U.S. Food and Drug Administration (FDA) if they weren't in an FDA-regulated industry or somehow otherwise involved in the regulatory process. The FDA seemed to gain a lot more public visibility after Scott Gottlieb became FDA Commissioner in 2017. Under Commissioner Gottlieb, the FDA became more proactive in communicating with the public, issuing many public statements on its website and through Twitter.

Now, it is common to hear the agency mentioned in the media and in everyday conversation. Of course, the FDA's regulation of drugs and medical devices gained a lot of attention during the pandemic, but food issues are being discussed more as well.

There were lots of headlines about spinach recalls, tainted romaine, and arsenic in apple juice. Most recently, stories about FDA's recent recall of infant formula and the resulting market shortages have featured prominently in the news. With the increased attention has also come increased scrutiny. In April, a scathing report in Politico outlined many criticisms against the agency for its allegedly poor record of protecting the public health from food safety and nutrition issues, due in part to its slow, bureaucratic processes.

While regulators may not be acting quickly, some consumers – and plaintiffs' attorneys – certainly are. More and more, we are seeing consumers take action to raise concerns in the public sphere about food issues. They are also asking food companies more questions directly and looking for transparency from manufacturers.

In our modern times where the Internet provides an infinite number of potential information sources, each catered to an individual's preferences and perspective, social media plays an outsized role in shaping people's opinions and giving them a voice. Sometimes, the results can be beneficial and empowering for individuals. For example, people who have the same rare illness can find each other on Facebook groups that can provide a forum for sharing personal experiences and finding comfort. Or parents whose children have certain food allergies can share recipes and resources. Consumers are becoming more educated about their food and are asking food manufacturers more questions about and expecting more from their food products.

But social media can be a double-edged sword for food companies. On the one hand, companies can engage directly with their consumers and prospective consumers, helping to establish goodwill and brand connection. On the other hand, a vocal critic can create a viral post or call for action that negatively affects the company's reputation, consumers' perception of its products and ultimately, the company's bottom line. Because of the threat of a negative post going viral and having a near immediate impact on the reputation and/or sales of the company, the consumer or class action risk is often the more salient one compared to the risk of FDA enforcement.

Some of these calls for action come from consumer advocacy groups who take a very vocal stand on certain ingredients. Others appear to come from individuals sharing their views on social media which happen to strike a chord with others who spread the word. Sometimes the positions asserted conflict with the FDA's thinking on the topic. For example, a consumer may read something on a website that espouses the dangers of monosodium glutamate (MSG), but the FDA maintains that the addition of MSG to food is "generally recognized as safe" (GRAS) and thus is lawfully used in food products. The agency also notes that although many people identify themselves as sensitive to MSG, studies with such individuals have not consistently been able to trigger reactions.

Regardless of regulators' or companies' views on the safety or benefits of certain ingredients in food products, consumer demand is a driving force that can significantly shift the landscape. We have seen this with the demand for organic foods, non-GMO ingredients and plant-based foods and in the demonization of processed foods and gluten. Social media is the engine that can pour gasoline on the small spark of individual consumers' thoughts.

What can companies do if they find themselves on the receiving end of reports of alleged harm or pointed criticisms about an ingredient?

The first step is to assess the report or criticism and determine whether it qualifies as a product incident that triggers the company's standard operating procedure (SOP) for receiving and investigating complaints. If it does, the relevant SOP should be followed, which commonly involves convening a multi-disciplinary response team to coordinate the investigation and response. The scientific/medical and legal/regulatory teams should be included.

Next, the company needs to gather the facts. What is the alleged issue? What products are affected? Is there a potential health hazard? What is the root cause of the problem and has it been corrected? If the criticism is about inclusion of an ingredient, what is the basis of the criticism?

If harm is alleged, undertake and document a health hazard evaluation, taking into account any reported complaints of adverse events, risks to special populations and the seriousness and likelihood of any health hazards.

Based on this evaluation, determine the next steps. Should the product be recalled or withdrawn from the market? If so, what will the scope of the recall or withdrawal be? Is reporting mandatory, or if not, should it be reported voluntarily?

Even if the complaints don't qualify as product incidents, it could be prudent to follow similar steps. If there is no product incident but there are repeated criticisms about an ingredient, the commercial side of the business can add valuable insights into what is being said on social media, how it may be impacting the markets, whether competitors are making changes, the feasibility of making any changes and the commercial impact of making a change or keeping things status quo. The legal/regulatory team can advise on any changes in legal and regulatory risks. The scientific/medical team can assess what the literature, health agencies and scientific bodies say about the ingredient.

Food manufacturers need to be aware of the growing influence of consumers. This trend will only accelerate. Social media gives consumers an unfettered voice and a platform capable of reaching millions, even billions, around the world on any given day. Successful companies will be the ones that can keep a close eye and ear on what consumers want while still making sound decisions rooted in food science, nutrition and their legal and regulatory responsibilities.

By ensuring their legal/regulatory, scientific/medical, and commercial teams are working closely together, food companies can give themselves the best odds for successfully navigating this consumer-driven landscape.

MEDICAL DEVICE

After years of discussion, the FDA is finally moving forward with a plan to harmonize U.S. medical device manufacturing standards with those of other nations. The change should make it easier for international medical device companies, though there are concerns that the transition timeline is too short, especially for smaller companies.

Experts have been predicting a spate of lawsuits for medical devices marketed during the pandemic once the liability protection under the Public Readiness and Emergency Preparedness Act (PREP Act) ends. It turns out we don't have to wait that long. There has already been a consumer class action suit against the maker of a COVID-19 rapid antigen test for marketing a product that had not received FDA approval.

> *"Since October 2020, the FDA has issued recalls for 32 COVID tests and testing agents, including eight in the first quarter of 2022."*

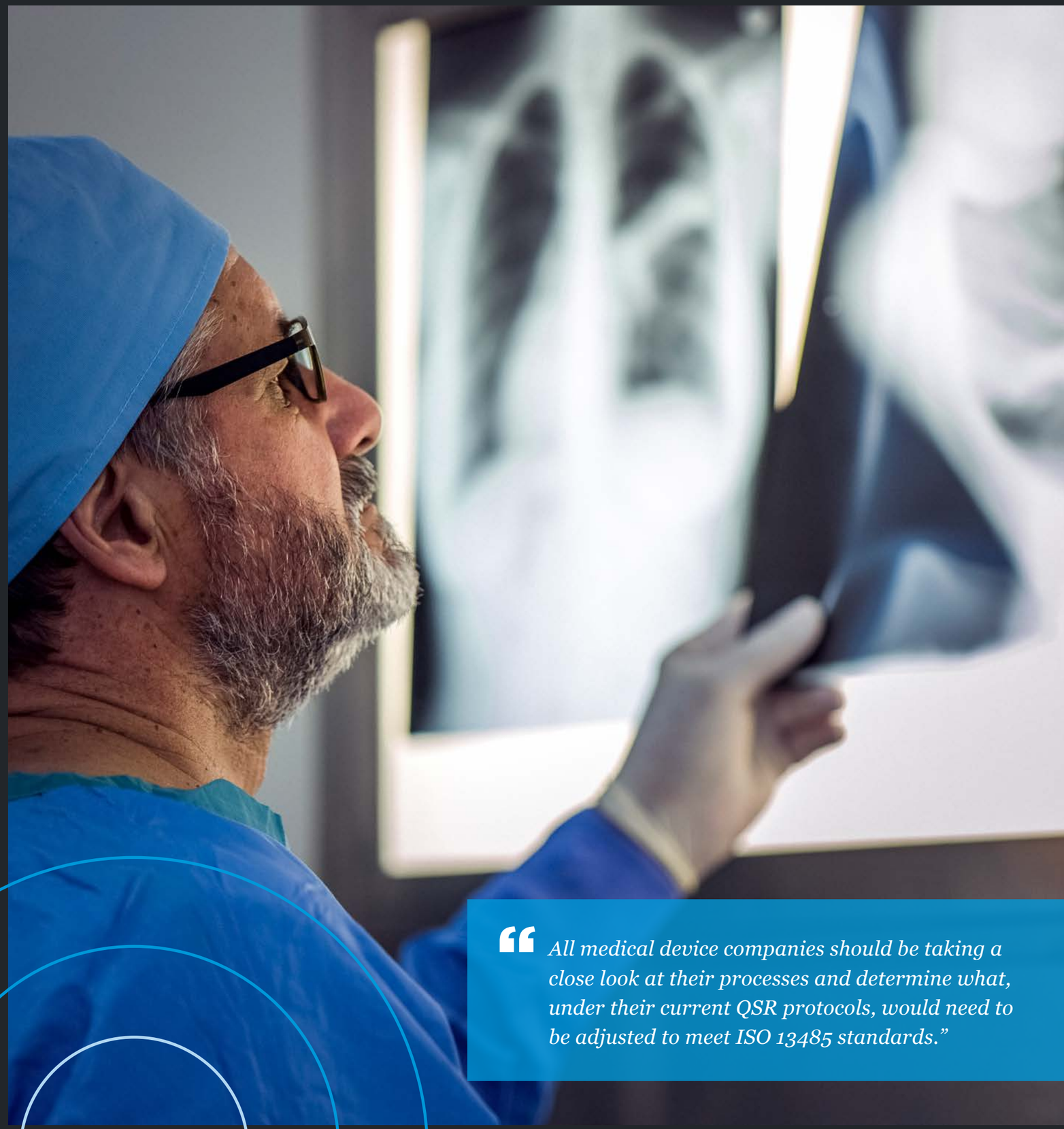
FDA works to align U.S. quality system requirements with international standards

Perhaps it was the COVID-19 pandemic that erased any doubt that the medical device industry is indeed global, but after more than four years of research and discussion, the FDA published a proposed rule on February 23, 2022 that would harmonize its Quality System Regulation (QSR) around current good manufacturing practices (cGMP) for medical devices with ISO 13485, the standard for device quality management systems (QMS) used by many other regulatory authorities worldwide.

The FDA stated that one of its main goals in taking this step is to reduce the regulatory burden for device manufacturers who currently need to comply with current FDA rules and ISO 13485 regulations if they are selling internationally. The FDA estimates that by streamlining the process to align the U.S. with other international standards, medical device companies could save up to $533 million over the next ten years simply because they are not working to comply with two different standards. The hope is that this new approach will also enable more efficient and timely access to medical devices for patients.

Overall, the medical device industry seems to be welcoming these changes, however there are concerns that the one-year transition period is not long enough for companies to adapt. Small companies who don't have experience with ISO 13485 standards will also face challenges in implementing the necessary risk management processes. There are also questions around inspections and whether or not ISO 13485 certification will be required under the new rule.

All medical device companies should be taking a close look at their processes and determine what, under their current QSR protocols, would need to be adjusted to meet ISO 13485 standards. If the one-year transition remains part of the final rule, there will be little time to make extensive manufacturing changes.



> *"All medical device companies should be taking a close look at their processes and determine what, under their current QSR protocols, would need to be adjusted to meet ISO 13485 standards."*

COVID-19 OTC tests under scrutiny

The Biden Administration announced in January 2022 that one billion at-home rapid COVID-19 tests would be distributed to Americans for free. Consumers could order tests beginning on January 19th and have the tests mailed directly to their homes. In addition, insurers were mandated to cover the cost of an over-the-counter (OTC) COVID test if consumers chose to buy them directly.

With this expanded focus on at-home tests, it could be expected that more companies would want to bring tests to market. It has also led to companies making false claims about their COVID-19 products, including tests. Since October 2020, the FDA has issued recalls for 32 COVID tests and testing agents, including eight in the first quarter of 2022.

Now there is another risk for test makers – consumer class action lawsuits. In February 2022, the FDA announced a Class I recall for one brand of at-home COVID-19 rapid antigen tests. The FDA said that the tests had been marketed and distributed to customers throughout the U.S. without FDA authorization, clearance or approval from the FDA, and without enough data to demonstrate they worked.

Two weeks after the FDA announcement, the company was sued in a consumer class action lawsuit claiming that the recalled tests were not distributed legally and were not FDA-approved, among other allegations. The suit alleges that the company falsely labeled its tests, made false claims in its advertising, and that there were negative consequences to consumers for both a false negative and false positive test.

COVID-19 test kit manufacturers should take this as a warning and ensure, firstly that their product has successfully cleared all FDA approvals, and secondly, that there are no false claims in its advertising and any claims about efficacy can be supported.

Safety of health data, a concern for FTC

In February 2022, the Federal Trade Commission (FTC) extended the definition of a "breach" in its Health Breach Notification Rule (Rule). The Commission clarified that "breach" also applies to makers of health and wellness apps that hold consumers' health information – generated from consumers and their connected devices. Under this broader definition, "breach" includes cybersecurity incidents as well as an app developer's disclosure of an individual's health information without the individual's consent.

Now foreign and domestic vendors of personal health records (PHRs), entities related to PHRs, and third-party service providers for PHRs all must comply with rules around breach notifications. This is true even if they are not covered under the Health Insurance Portability and Accountability Act (HIPAA).

Under the revised rule, the FTC also stated that under HIPAA and the and Health Information Technology for Economic and Clinical Health (HITECH) Act, these vendors are considered a "health care provider" because they furnish "health care services or supplies." Previously only doctors, clinics, psychologists, dentists, pharmacies, and other similar providers of medical and health care services were included under the "health care provider" term.

In addition, the FTC's expanded definition of PHR means that fitness trackers, continuous glucose monitors, and other devices that collect data directly from a consumer will be regulated under the Rule. Previously, the term "PHR" was meant to apply to an app that stores medical information from multiple sources (e.g., multiple health care providers' electronic health records), not just one source.

Another change to the rule that will create risk for some companies is that disclosing unsecured, individually identifiable health information without an individual's consent is also considered a breach. The term no longer applies to just cybersecurity hacks.

The FTC has promised stiff fines – a maximum penalty of $46,517 per violation per day. App makers should review their processes to make sure they align with the new definitions for "health care provider" and "PHRs" to ensure they can comply in the event of a breach and are taking the right steps to mitigate risk.

FDA focuses on women's health in medical device research and regulation

In January 2022, the FDA's Center for Devices and Radiological Health (CDRH) released its Health of Women Program Strategic Plan, which looks to protect and promote the health of women, strengthen regulatory science, and identify and address current and emerging issues in medical device research and regulation for the health of all women.

According to the CDRH, historically, biomedical research has been primarily focused on male subjects. In fact, in surgical literature, 88 percent of research studies for diseases that are more prevalent in females had more men enrolled than women. The agency claims that in many cases, current data may be incomplete because of the lack of female representation in the studies.

Terri Cornelison, M.D., Ph.D., Chief Medical Officer and Director, Health of Women Program at CDRH said in a statement "Representation in research is crucial to understand how medical products, including medical devices, interact with individuals of different sexes and genders. A lack of representation can have serious consequences for health outcomes for women. An example of this is cardiovascular devices like pacemakers that may have different outcomes and complication rates in men and women. This is just one instance of when sex and gender make a difference in designing a clinical study that will provide optimal results for safety and effectiveness for all patients."

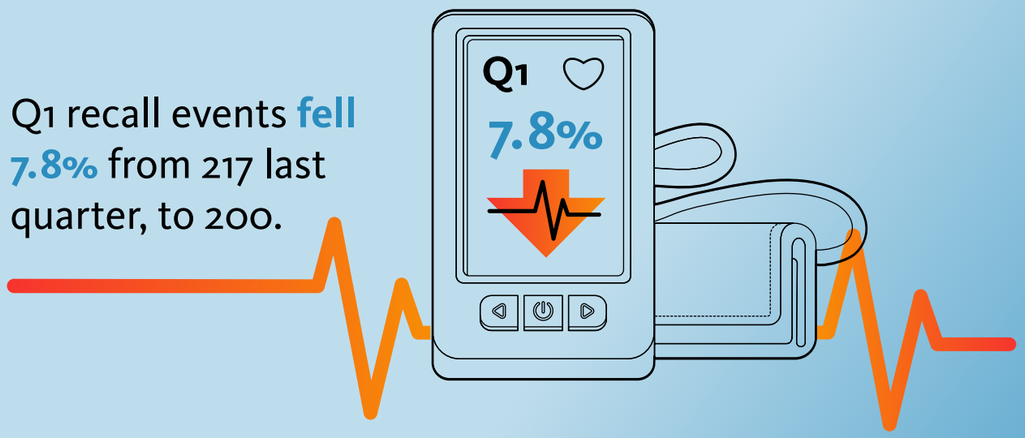
This new strategic plan is designed to help address that. It has three key priorities:

- Sex- and Gender-Specific Analysis & Reporting
- Integrated Approach for Current & Emerging Issues Related to the Health of Women
- Research Roadmap

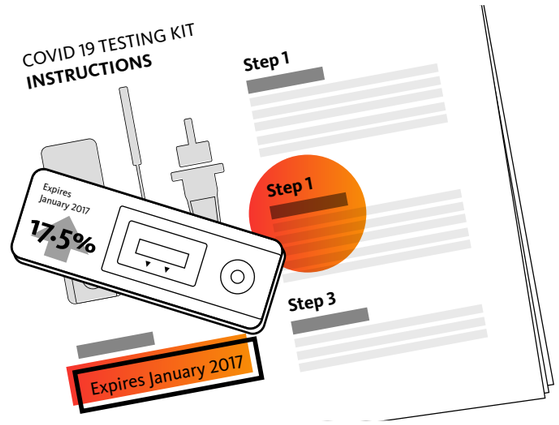
While there are no regulations or guidance yet around this new initiative, medical device manufacturers should look at the mix of males and females in their testing, and ensure that sex and gender data are part of their analysis and reporting.

> *"Medical device manufacturers should look at the mix of males and females in their testing, and ensure that sex and gender data are part of their analysis and reporting."*

Q1 recall events **fell** **7.8%** from 217 last quarter, to 200.



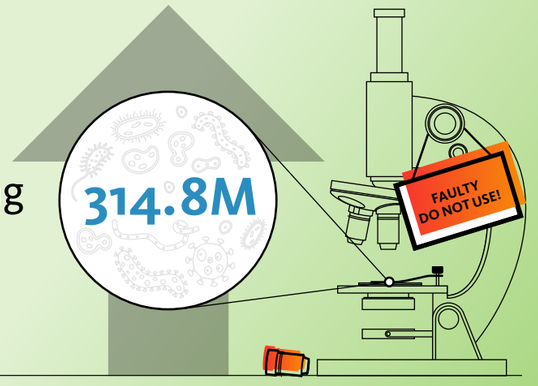
Only 5 quarters in the last 10 years have recorded fewer than 200 recall events.



Mislabeling has surpassed Software as the leading cause of recalls for the second consecutive quarter, with 35 **recalls (17.5%)**.

This is a notable shift given the dominance of Software over the last 5 years. Bar a single quarter (Q2 2020), Software has been the leading cause of recalls in the sector.

Total units recalled in Q1 surged from **11.6M (in Q4) to 314.8M**, taking the average recall size to 1.6M units.



Only one other quarter in the last 15 years has recorded an average recall size of more than 1.5M.

FIRST QUARTER BY THE NUMBERS

The medical device industry saw 200 recalls in Q1 2022. This is down slightly (7.8%) from the 217 events in Q4 2021. However, the number of units impacted skyrocketed due to a single recall for a device used as a connector for a catheter port than involved more than 288 million units. The total number of units recalled in Q1 was 314.8 million, a 2,624.9% increase from last quarter (which recorded 11.6 million).

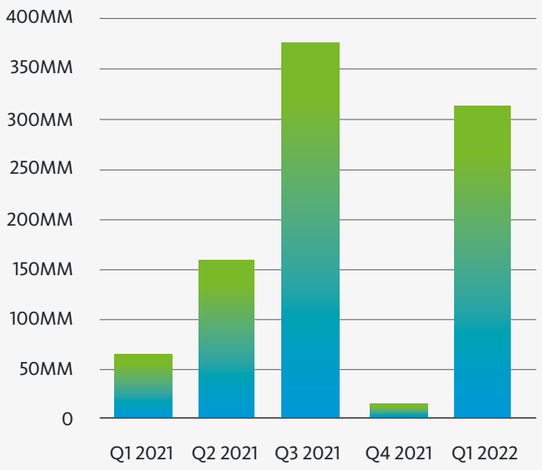
In terms of number of events, mislabeling was the top reason for recalls for the second quarter in a row with 35 recalls. Quality issues contributed 30 recalls, and software concerns accounted for 29. However, in terms of the number of units, contamination was the top cause. The single recall for the catheter port connector accounted for 91.5% of all units for the quarter. There were five additional recalls linked to contamination that combined impacted 4,635 additional units.

As expected, the FDA is closely monitoring sales and marketing for COVID-19 tests. There were eight different recalls for rapid antigen tests, impacting more than 2.3 million units. Most of the recalls were attributed to safety concerns because the tests had not been approved by the FDA. Other causes were mislabeling, outside of specifications, and device failure.

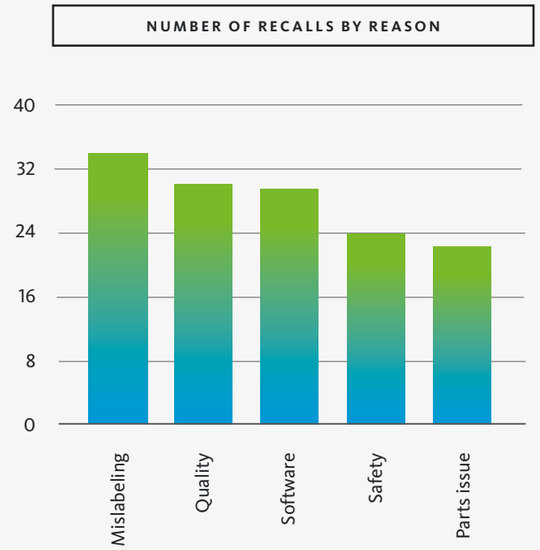
Of first quarter recalls, 17 events were designated as Class I, the FDA's most serious classification. These recalls impacted roughly 2 million units. Class II recalls accounted for 170 recalls impacting 24.5 million units. While there were only 13 Class III recalls, this category impacted more than 288 million units due to the large catheter port incident.

More than three quarters of recalls (77.5%) were distributed nationwide in Q1 2022. International consumers were impacted by 44.5% of U.S. recalls with 89 events.

NUMBER OF RECALLED UNITS BY QUARTER



NUMBER OF RECALLS BY REASON



APRIL insight

There were 147 FDA recalls for medical devices in April 2022. This is an increase of more than 120% compared to the first quarter monthly average of 67. However, despite there being more recall events, the number of units involved dropped dramatically from a per-month average of 104.9 million units in Q1 to 7.9 million units in April. Nearly half of those units came from just two large recalls. One was an event that involved approximately 2.2 million oral DNA collection kits and another was for 1.8 million defibrillator pads.

Safety was the most common reason cited by the FDA for medical device recalls in April 2022. It was linked to 31 recalls. Software was second with 29 recalls and mislabeling was tied to 21 recalls.

There were six recalls for rapid COVID-19 tests. Most of these were for safety relating to the tests being sold without FDA authorization. It is expected the number of recalls around COVID-19 tests will continue to rise.

MAYA FLORENCE,
PARTNER, **SKADDEN**

MEDICAL DEVICE COMPANIES NEED TO PREPARE FOR RETURN OF ON-SITE FDA INSPECTIONS

It is no secret that U.S. Food and Drug Administration (FDA) inspection activity was down dramatically during the pandemic. In 2018, the FDA conducted roughly 14,500 domestic inspections and 3,200 foreign inspections. In 2021, those numbers plunged to only 6,168 domestic inspections and 167 foreign inspections. That is a 60% drop in domestic inspections and a 94% decline for international inspections compared to the average activity in the four years prior to the pandemic.

These numbers are even more staggering when one realizes that these are inspections not only for medical devices but also for everything else under the FDA's purview – human food, animal food, human drugs, animal drugs, medical devices, biologics and tobacco products.

And the drop is not only in inspections. It is also in all the administrative and enforcement actions that flow from inspections. In 2021 there were 56% fewer warning letters, 60% fewer injunctions and 27% fewer recalls compared to the year before.

For the medical device industry, the number of warning letters had already been falling before the pandemic hit. Between 2015-2019, there was a 90% reduction. The FDA's Center for Devices and Radiological Health (CDRH) had planned to address the decline, but then the pandemic happened.

As businesses begin returning to pre-pandemic levels of operations, the FDA is also aspiring to move toward a regular cadence for inspections. Domestic inspections restarted in February 2022 after a few delays for pandemic resurgences. Foreign inspections restarted in April of this year.

In a November 2021 update to its May 2021 Resiliency Roadmap for FDA Inspectional Oversight, the FDA said that the number of domestic surveillance inspections it carried out in the second half of fiscal year 2021 (April 1, 2020 – September 30, 2021) was more than double the number it initially projected in the roadmap last spring. However, it will certainly take some time for the agency to get back to pre-pandemic numbers.

Despite these slow-downs, companies should avoid complacency. The FDA isn't the only organization that was forced to change its operations during the pandemic. Virtually every company was impacted in some way. They may have been forced to reduce hours, change product lines, lay off staff, switch suppliers, lengthen production times or take a range of other steps as a result of the way the public health emergency impacted the global supply chain and businesses worldwide. Going forward, the FDA will be assessing if companies kept up their focus on quality and compliance while inspection activity was paused, or if they cut corners because they had fewer employees, had limits to what could be done on-site or knew that the FDA was not aggressively inspecting facilities.

As FDA inspections ramp up, we may see a big uptick in warning letters and other enforcement activity in 2022 and early 2023. Companies who actively maintained their quality programs should be able to return to normal easily and likely do not have a huge cause for concern. Those who let controls slide during the pandemic, on the other hand, are likely to face significant scrutiny.

The companies in the medical device space that may face the greatest challenge are those that began manufacturing FDA-regulated products during COVID. Many of these companies will not have been through an FDA inspection before. They might not have a long track record of operating in compliance with the Quality System Regulation (QSR), which are the FDA's Good Manufacturing Practices requirements for medical devices. They may also lack an understanding of all the processes that complying with the QSR entails.

Even as the FDA gets back to on-site inspections, we may continue to see the use of records-based remote reviews of medical products. The FDA relied on this type of review to varying degrees during the pandemic. The agency's authority to conduct such reviews varies by product category. Congress granted the FDA the authority to request records from drug manufacturers in advance of or in lieu of an inspection prior to the pandemic. We have now started to see warning letters based solely on records-based reviews of drug manufacturers, without a facility visit. So far, these have primarily involved over-the-counter (OTC) drug manufacturers.

In contrast, Congress has not granted similar authority with respect to medical device manufacturers. Instead, during the pandemic, the FDA implemented a program of Remote Regulatory Assessments (RRAs) of medical device facilities. Participation was voluntary and a refusal to participate was not equivalent to the refusal of an FDA inspection. Nevertheless, the FDA made clear that findings from RRAs could give rise to enforcement actions. As we emerge from the pandemic, it will be interesting to see whether the FDA continues to utilize the RRA program or if it reverts to solely on-site inspections of medical device facilities.

There are several things companies can do to be prepared for either an on-site FDA inspection or an RRA. First and foremost, companies can take stock of the current state of their quality systems. Were there any changes in vendors, personnel, materials, resources, production protocol, products, etc. during the pandemic? If there were, have those changes been validated and has quality system documentation been updated accordingly?

Companies would be well-served to make efforts to identify potential issues before the FDA gets in. If it turns out that they inadvertently took their attention off of any aspects of their quality system during the pandemic, now is the time to ensure compliance. Companies should also focus their energy and attention on inspection preparedness, and may wish to consider mock audits or other efforts to ensure teams know how to react if the FDA arrives on site. This is particularly true for companies that started manufacturing new medical devices related to COVID treatments or testing, as this is an area that the FDA is particularly focused on. We've seen eight recalls of COVID-19 tests in the first quarter of 2022 already.

While it will take some time for the FDA to get back to a robust inspection schedule, medical device companies should prepare as though they may be inspected tomorrow.

PHARMACEUTICAL

After more than a year without a permanent commissioner, the U.S. Food and Drug Administration (FDA) has a new leader in Dr. Robert Califf. Like many appointments under the Biden Administration, Califf is expected to take an aggressive approach to enforcement and consumer protection.

The FDA is also taking steps to get more consistency and reliability in the prescription drug supply chain, as well as the approvals of generic drugs and over-the-counter medications.

> *"Once the (DSCSA) rule is passed, there will be a two-year grace period for WDDs and a one-year grace period for 3PLs before the new regulations preempt existing state and local licensure requirements."*

New FDA commissioner likely to tighten nicotine regulations

On February 17, 2022, the U.S. Senate confirmed cardiologist Robert M. Califf, M.D., to lead the FDA. Califf was FDA Commissioner for the last year of the Obama Administration and previously served as deputy commissioner for medical products and tobacco. After his nomination, Califf pledged to make enforcing accelerated approval requirements a "high priority," including ensuring drug makers follow through and provide confirmatory evidence once their products are approved.

Given his previous FDA experience with medical products and tobacco, many experts predict Califf will focus on vaping products, or electronic nicotine delivery systems (ENDS) devices. Even before Califf's confirmation, the FDA began reviewing premarket authorization applications for ENDS devices to see whether such products can continue to be sold.

It is expected the FDA will continue its forceful stance to prevent youth access to ENDS devices. This may include regulations to compel manufacturers to take adequate measures to prevent underage access to these products.

On March 15, 2022, the FDA was granted regulatory authority over synthetic nicotine products thanks to a provision in the $1.5 trillion omnibus spending bill that amended the definition of "tobacco product" to extend to synthetic nicotine. The new law took effect on April 14, 2022. It is expected that Califf will make enforcement of this new regulation a priority.

FDA moves to national standards for prescription drug supply chain

Requirements for wholesale drug distributors (WDDs) and third-party logistics providers (3PLs) vary greatly from state-to-state. This patchwork system creates weaknesses in the prescription drug supply chain. On February 3, 2022, the FDA published its proposal to address this issue which includes a set of national standards for the licensure of WDDs and 3PLs.

The proposed rule is designed to provide clarity and consistency for these entities when seeking licensure. The FDA also believes that national standards will reduce opportunities for dangerous and criminal conduct that would affect the prescription drug supply, including theft, diversion, and counterfeiting.

The application of national standards has been discussed for nearly a decade. The Drug Supply Chain Security Act (DSCSA), which was enacted in 2013, established a federal system to identify and trace certain prescription drug products through the pharmaceutical distribution supply chain. One of the requirements in the DSCSA was for the FDA to update and create national standards for the licensure of WDDs and 3PLs. The original deadline for this to happen was 2015, but it has taken until this year to see a proposal from the FDA.

The proposal outlines a number of provisions including clearly defining terms, setting requirements for the new federal licensure review, storage practices and recordkeeping, as well as procedures for how licensure may be denied, suspended, or reinstated.

The deadline to submit comments to the FDA on the proposed rule is June 6, 2022. Once the rule is passed, there will be a two-year grace period for WDDs and a one-year grace period for 3PLs before the new regulations preempt existing state and local licensure requirements. But the FDA has already said it doesn't intend to enforce licensing requirements for 3PLs for two years.

Any company in the prescription drug supply chain – from manufacturers to retail locations – would do well to review the proposal and determine if the new requirements for WDDs and 3PLs will impact any of their reporting and recordkeeping processes.

New guidance for over-the-counter drug manufacturers

On February 1, 2022, the FDA issued draft guidance regarding formal meetings between the FDA and sponsors or requestors of over-the-counter (OTC) monograph drugs. OTC monograph drugs are non-prescription medications manufactured using an approved list of acceptable ingredients, doses, formulations, and labeling, also known as a "monograph."

The benefit of using a drug monograph is that it allows companies to make and market an OTC product without the need for FDA pre-approval. According to the FDA, these monographs define the safety, effectiveness, and labeling for all marketing of OTC active ingredients.

The regulatory system for most OTC drugs was overhauled in March 2020 as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. This update replaced the traditional regulatory framework for this type of drug with a new process to issue, revise, and amend OTC monographs.

To accommodate this change, the FDA was required to establish procedures for meetings with interested parties to discuss submissions and matters relevant to the development and regulation of these drugs. This includes how to obtain the FDA's guidance on the studies and other information necessary to support submissions under section 505G of the Federal Food, Drug, and Cosmetic Act (FDCA) and other matters relevant to OTC monograph drugs.

The open comment period for the guidance ended on April 8, 2022. But under the FDA's Over-the-Counter Monograph User Fee Program Performance Goals and Procedures document, the agency has until July 1, 2023 to finalize the rule.

FDA acts to get generic drugs to market sooner

The FDA published new guidance documents on generic drug application submissions, labeling, and review in January 2022 as part of the Drug Competition Action Plan (DCAP). With these three new proposals, the FDA has issued 24 DCAP guidance documents since 2017.

The agency said these guidelines are part of its continued focus on making the generic drug review process more efficient and transparent, which in turn will help encourage more competition. The ultimate goal is to bring down the high cost of medicines in the U.S.

Currently, manufacturers of generic drugs submit an abbreviated new drug application (ANDA) to the FDA for the review and potential approval of their product. Generic drugs typically do not have to include data about animal or human clinical trial to establish safety and efficacy. Instead, they must provide scientific data to show their product performs in the same manner as the original, or "innovator" drug. These original products are also called reference listed drugs (RLDs).

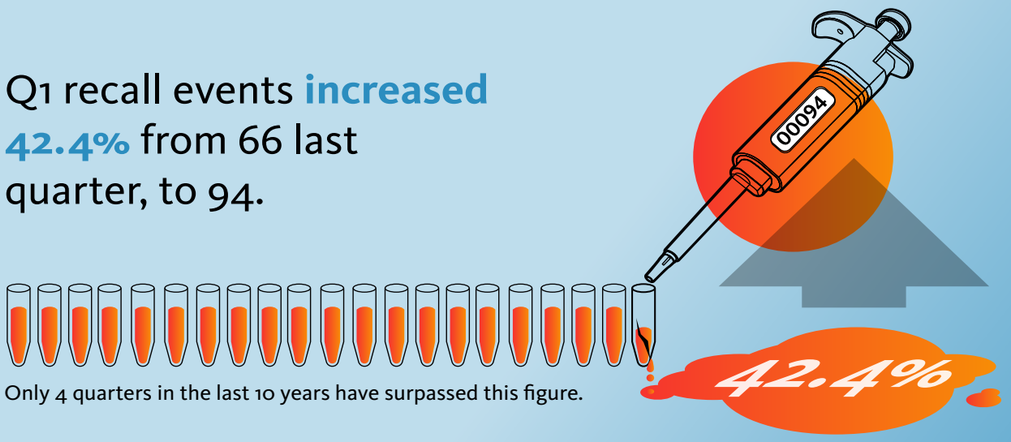
The new guidance documents cover three separate concerns related to ANDAs:

1. Information Requests and Discipline Review Letters Under Generic Drug User Fee Amendments
2. Good ANDA Submission Practices
3. Revising ANDA Labeling Following Revision of the RLD Labeling

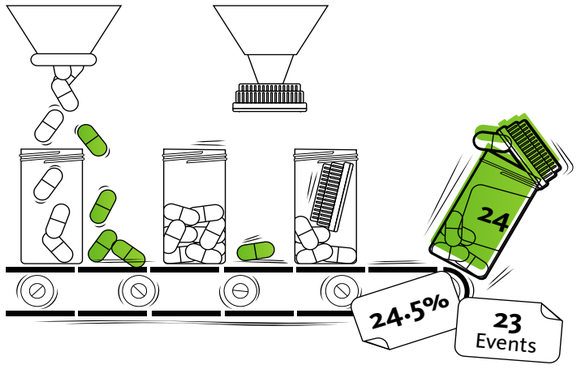
For drug manufacturers planning on submitting a product under an ANDA, or who have products currently in the ANDA pipeline, these new documents from the FDA should help reduce revisions to the application and streamline the approvals. These documents, particularly the labeling requirement, can also help mitigate the risk of recalls.

> *"The agency said these guidelines are part of its continued focus on making the generic drug review process more efficient and transparent, which in turn will help encourage more competition."*

Q1 recall events **increased 42.4%** from 66 last quarter, to 94.



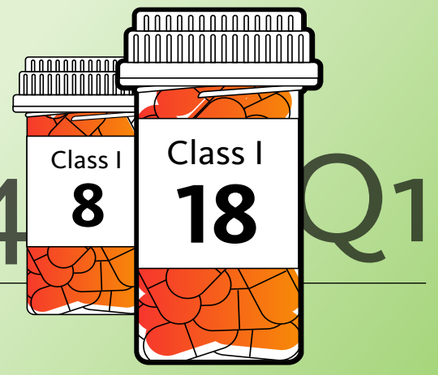
Only 4 quarters in the last 10 years have surpassed this figure.



With 23 events, **Failed specifications was the leading cause** of Q1 recalls (24.5%).

cGMP deviations impacted 428M units across a total of 22 events. This figure represents 98.3% of all units impacted in the quarter, making it the leading cause.

Class I designations in the first quarter more than doubled from Q4 (**jumping 125% from 8 to 18**).



Only 2 quarters in the past 17 years have recorded a higher number of Class I designations (Q3 2020 with 19, and Q2 2014 with 29).

FIRST QUARTER BY THE NUMBERS

The FDA's shift back to more normal operations was apparent in the increase in pharmaceutical recalls in Q1 2022. There were 94 recalls, up 42.4% compared to Q4 2021. There was a 324.3% increase in the number of units impacted as well, with more than 435 million units recalled. That is the largest number of units recorded in nearly 15 years.

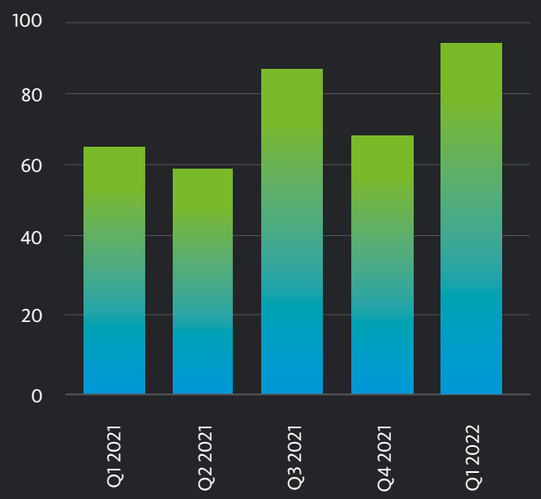
The majority of the increase in impacted units was from four recalls attributed to cGMP deviations involving acetaminophen products, with one recall alone impacting 326.9 million units. The other three recalls added a further 95.8 million units to the quarter.

Failed specifications were the leading cause of first quarter recalls, with 23 events. cGMP deviations followed with 22 but dominated in terms of units impacted at 428 million, or 98.3% of all units.

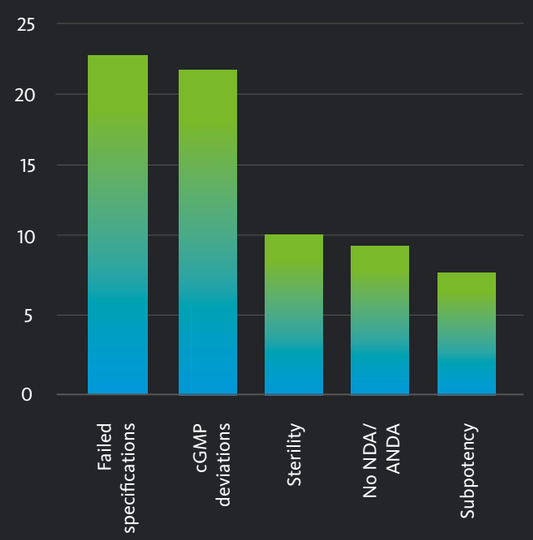
Of first-quarter recalls, the FDA classified 18 as the most serious Class I. This is a six-quarter high for Class I events and the second-highest number of this class in almost eight years. Class II recalls accounted for 63 events and 434.3 million units. It is typical for most recalls to fall under Class II. There were 10 Class III recalls and three recalls that were not designated a specific class.

Seventy-two of the first quarter recalls impacted products distributed nationwide. These events accounted for 76.6% of all pharmaceutical recalls. Only two recalls, or 2.1%, affected products shipped internationally. This is the lowest percentage in three years.

NUMBER OF RECALL EVENTS BY QUARTER



NUMBER OF RECALLS BY REASON



APRIL insight

The FDA issued 30 pharmaceutical recalls in April 2022. That is slightly below the 31.3 monthly average for Q1 2022. There were approximately 1.5 million units recalled, which is a dramatic drop from the 145 million units per month that were averaged in the first quarter. A total of 43.8% of April's impacted units were from a single recall of hand sanitizer that was contaminated with benzene.

The were six recall events cited for both cGMP deviations and failed specifications. Subpotency was noted in five recalls and mislabeling was tied to four recalls in April.

KATE HARDEY, PARTNER,
MCGUIREWOODS

FDA LIKELY TO INCREASE TRANSPARENCY AND ENFORCEMENT

FDA works to clarify regulations

One big trend we are seeing with the U.S. Food and Drug Administration (FDA) is a dramatic increase in the number of guidance documents it is publishing compared to a few years ago. These documents reflect the agency's interpretation of its policy on a regulatory issue. They are meant to help companies comply with the regulations.

Going back 10 years or so, it could feel as though some regulations lacked details and could be interpreted in several ways. That vagueness made it difficult for companies to know what the FDA wanted and how to structure their compliance and reporting processes. Companies could gain more insight into these issues though various types of meetings with the FDA, but those meetings can be intimidating.

Guidances provide a good starting point for companies to evaluate and assess internal compliance activities and processes. The FDA still welcomes conversations with companies but having more clarity around the regulations may make some of those meetings less necessary, or at least a little less scary.

In 2020, the FDA published 206 guidances documents. As of April 21, 2022, there have already been 61 issued, with up to five per day some days. In just the first four months of this year, the agency has released more documents than we saw in all of 2013, 2012 or 2011.

The FDA hasn't publicly stated why it has increased the number of publications, though it can be assumed that one reason is to support the FDA's ongoing effort to be more transparent. The documents may also reflect questions the FDA was frequently getting from companies. The fact that the pandemic caused the agency to dramatically cut the number of inspections it was doing may have contributed as well.

While all companies can benefit from the information, this wealth of FDA guidance documents is particularly helpful for early-stage companies that are new to the market. They are also relevant to companies who are developing new products. Having more information to understand FDA's thinking and interpretations will help companies make fewer missteps as they learn the process. That will hopefully get products to market faster and at a lower cost to both companies and consumers.

Various aspects of clinical trials are an example of one area where the agency is giving more details. The FDA has issued a host of guidance documents around clinical trials, such as diversity of trial participants, HIPAA and human subject protection, safety reporting and the role of real-world evidence. These and other recent guidance documents answer many questions that companies have had as they tried to comply with regulatory requirements. Now there is a better sense of what the FDA will accept and companies have a clearer path to design their trials or have discussions with the agency during the drug development process.

Another guidance the FDA recently published is designed to help companies be recall ready. This document offers insights on how companies from any industry sector should investigate issues and the processes to notify accounts. It also reinforces what should be in a company's recall plan – personnel must be trained, communications plans must be in place, there are reporting requirements that must be met and other processes that need to happen. As FDA inspections, and likely recalls, begin to ramp up again, the recall readiness publication serves as a good framework for what companies need to have in their recall playbook and what they should focus on internally.

While the FDA's inability to conduct on-site inspections may have played a part in the increase in guidances, even when the pandemic is finally declared to be over, these types of documents will still be needed. No matter how well a new regulation is written, the mechanics of how people operate are always evolving. The regulations themselves do not evolve as quickly. Having more information on how to interpret the regulations when the regulations aren't changing but business processes are will help companies maintain robust compliance.

Expect more enforcement around product claims

Lately the FDA has taken a much harder look at company websites and examining product claims. The agency is particularly focused on products that are going directly to consumers and have not gone through an FDA approval process. This category includes over-the-counter (OTC) drugs, wellness and herbal products and supplements. All of these types of products have the potential to cause serious injury to consumers particularly for supplements and wellness and herbal products that fall under a looser regulatory scheme.

Non-regulated products can be produced and marketed very quickly, and everyone is trying to be innovative. A lot of manufactures in the wellness and herbal categories don't think they need to consult with the FDA because they are not a "drug." However, if they are making health claims or even have consumer testimonials making any type of health claim, they do fall under FDA's purview.

CBD products are another category where many companies operate in a legal gray area. The FDA does not permit CBD-infused foods and dietary supplements to be lawfully sold or marketed in the U.S. While some state laws may allow certain CBD products, the FDA does not have the manpower to aggressively enforce all of these products.

KATE HARDEY, PARTNER, **MCGUIREWOODS**

CONTINUED FROM PREVIOUS PAGE

However, because it is unlawful to make health claims about CBD products, the agency will take enforcement action against companies for this violation. The FDA and the Federal Trade Commission (FTC) made this point very clear in March of 2022 when they issued seven warning letters to companies marketing CBD products with claims to cure, mitigate, treat or prevent COVID-19.

Companies in the wellness, herbal and supplements spaces are more prone to make assumptions that are not accurate about what is and is not under FDA purview. In general, this happens less often with companies manufacturing pharmaceuticals that are widely known to be regulated, such as drugs that are marketed to treat cancer. Those manufacturers expect their products to be scrutinized and have a much better understanding of the drug development and FDA approval process.

For more consumer-focused products, companies often assume that if a competitor's product is making claims that its product isn't regulated by the FDA, the company's claims are accurate and by extension, their own similar product isn't regulated either. That is typically not the case. Companies don't have the authority to decide whether or not their product is FDA regulated. It is always best to consult with regulatory counsel to be sure a products ingredients, labeling and/or marketing don't bring it within the purview of FDA.

If the FDA receives complaints about a product, there are suddenly a lot of new products in a certain category or brands are marketing aggressively, FDA may decide to do a random sampling and test the products. If it finds the company is not in compliance with safety and labeling regulations, it will likely send a warning letter.

From consumer side, it isn't surprising people buy these products. Consumers may want cheaper alternatives to expensive prescription drugs. It is important to remember that drugs that are FDA-approved are thoroughly reviewed for both safety and efficacy as part of the drug approval process.

That level of safety testing and analysis is probably not happening with direct-to-consumer products. Consumers need to decide if it is worth that risk. And companies need to make sure they are not making false claims about health benefits unless they want to face an enforcement action.

CONCLUSION

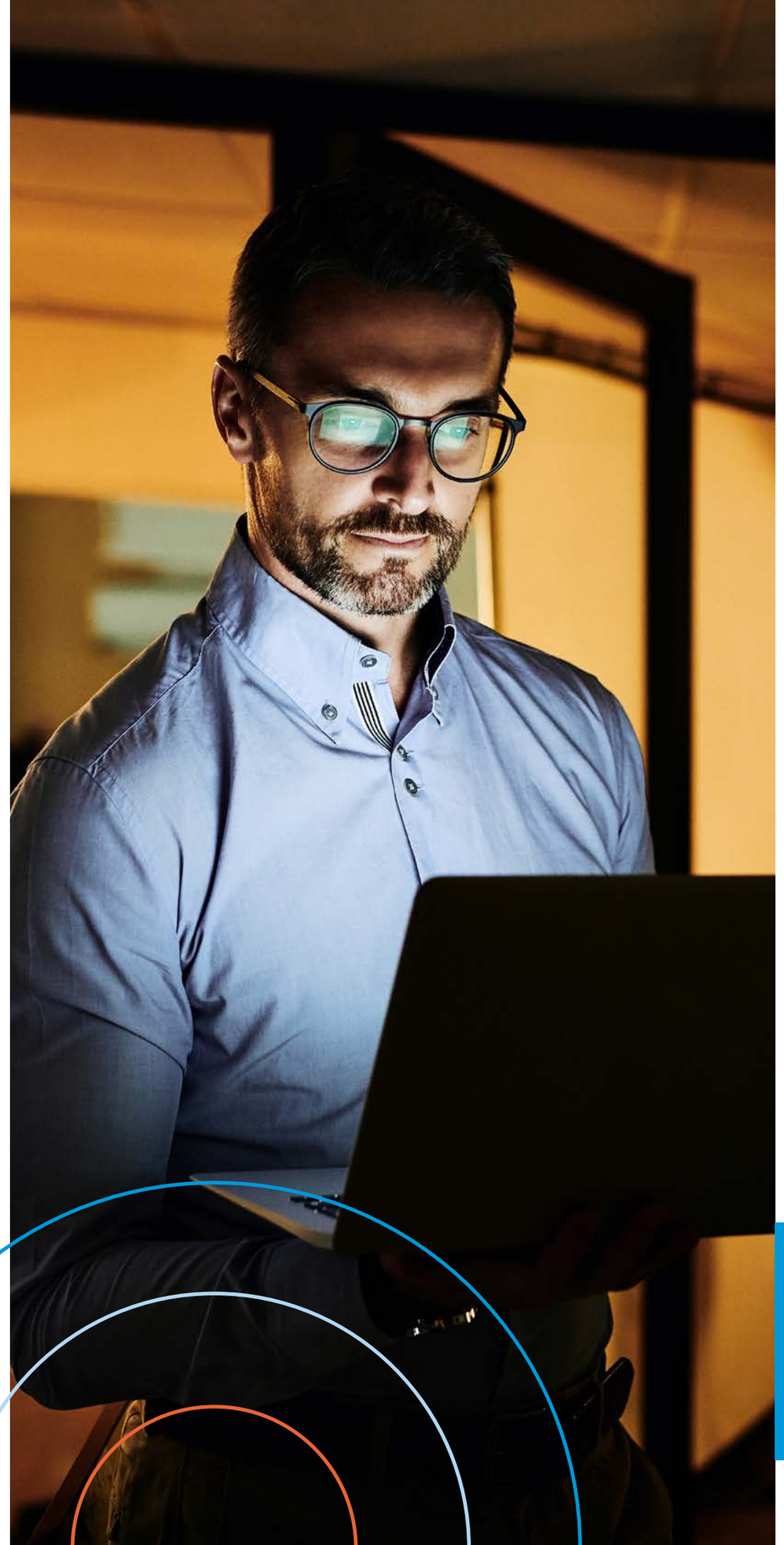
While we may hope that the pandemic is ending, it remains a stubborn factor in global business. And even if numbers of people afflicted fall, businesses will not immediately go back to pre-pandemic operations overnight. In the U.S., mid-term elections this fall will lead to unpredictable political moves as each party tries to appeal to its voters ahead of the elections. That may also mean more presidential actions if Congress is dealing with internal conflict.

The one certainty is that companies 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
- Constantly shifting consumer demand
- Customer and partner apprehension

Unfortunately, recalls in today's business environment are inevitable. But if recall and remediation plans are tested and updated – and become as routine as other business processes – then when the inevitable occurs, your brand and bottom-line will remain protected.

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



ABOUT SEDGWICK BRAND PROTECTION

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

Trusted by the world's leading brands and businesses, we work in partnership to manage the risks and minimize the impacts of in-market business and product crises.

When your reputation is on the line, we put our 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 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 what feels like a devastating prduct recall, offer opportunities to demonstrate trustworthiness and to build greater customer loyalty.

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.

To find out more about our product recall capabilities, contact us today.

Website: sedgwick.com/brandprotection

Telephone: 1.888.732.3901

Email: brand.protection@sedgwick.com

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RECALL INDEX: EDITION 1, 2022

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Website: sedgwick.com/brandprotection
Telephone: 1.888.732.3901
Email: brand.protection@sedgwick.com