STATE OF THE NATION 2022

PRODUCT RECALL
UNITED STATES EDITION

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

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The Sedgwick brand protection Recall Index is the essential reference for manufacturers and retailers seeking 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), providing businesses with exclusive insights and guidance valuable to their operations.

This 2022 State of the Nation Recall Index goes beyond our traditional quarterly reviews. It provides not only information about the most recent quarter, but also offers a year-in-review look at recall data and trends from all of 2021. It also offers a look ahead into January recall numbers.

Our analysis and predictions let you know what to expect in 2022 as regulators and business leaders alike look ahead to the third calendar year of the pandemic and hope for a light at the end of the tunnel. There are also insights on how the chaotic and confrontational U.S. political arena may impact business operations.

Insights from some of our strategic partners at leading law firms, insurance companies, and communications firms offer expert analysis to help you plan for new regulations across the five market sectors.

The Biden administration continues to push for more consumer protections and safeguards – both in terms of safety and in terms of fair and equitable pricing and access for goods and services. That makes this a crucial time for companies at every level in the supply chain to be aware of changes and ready for recalls and related threats to their businesses and reputations.

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.

One final note: this 2022 State of the Nation 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 review our European Edition. Like this report, our European Edition shares recall data from global regulatory agencies, and offers expert analysis on product safety and regulatory changes impacting global companies.

The European edition is available here: click here

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

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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State of the Nation 2022

SUMMARY

Many businesses began 2021 with optimism that the COVID-19 pandemic would be over by the end of the first quarter. Unfortunately, the global health crisis continues, and with it comes continued supply chain disruptions and uncertainty. The hope that life would be back to normal during 2021 did not come to pass.

There were a total of 1 billion affected units recalled in 2021 across the 5 key U.S. industries. This makes it one of only two years to surpass the 1 billion mark in the past 10 years. However, in 2018, when we saw 1.2 billion units recalled, there were 3,414 total recall events. In 2021, there were 25% fewer recalls (2,560) and several industries saw the lowest number of recalls in the past five years. The difference is in the size of the recalls. We saw three recalls that involved more than 100 million units.

In the second quarter of 2021, there was a medical device recall for infusion pumps and a pharmaceutical recall for skin prep products that each impacted more than 108 million units. In the third quarter, a single recall of syringes involved more than 267 million units. And in the fourth quarter, three separate pharmaceutical recalls accounted for more than 97.8 million units, and a single recall of onions concerning salmonella added another 36.0 million units to the annual totals.

In terms of recall and regulatory activity there were also changes – some expected and some not – that resulted from having a new balance of power in Congress and a new Administration with President Biden. With some politicians seeming to be more concerned about embarrassing their political rivals or sticking with the status quo than in enacting bold legislative changes, some regulatory changes that were expected have not played out yet.

However, in areas where new leaders were put in place of various agencies – including the CPSC and NHTSA – enforcement was more aggressive. We saw legal actions that broke old patterns and signaled changes in regulatory attitudes.

Here are some of the highlights for the year:

Automotive

As expected, safety concerns related to electric vehicles, autonomous vehicles (AVs), and new technology remained at the forefront, with some saying that NHTSA is moving too fast in deploying AVs.

An official whistleblower program gained momentum at NHTSA resulting in the first ever award to a whistleblower in connection with information provided to the agency about two car companies and their reported violations of the Safety Act. The $24 million granted to the whistleblower is the maximum percentage allowed by law of the $81 million in cash collected by the United State.

In another first, prosecutors in California filed the first felony charges against the driver of an AV after the car, which was equipped with a partially automated driver-assist system, was involved in a fatal car crash.

A divided Congress kept other consumer safety measures from moving forward, including a collection of bills introduced by Senators Edward J. Markey (D-Mass.) and Richard Blumenthal (D-Conn.) related to several safety priorities including advanced driver-assistance systems, recall effectiveness and vehicle seat safety. These bills have not yet been voted on.

Overall, the automotive sector saw the lowest number of total units recalled and the second fewest recalls in the past five years in 2021. **For more in-depth analysis of the automotive industry in 2021, and our predictions for 2022, click here.**

Consumer products

At the start of the year, some experts warned that the CPSC's request for a significant budget increase would signal a tsunami of recalls. In fact, while we did see the second highest number of units in the past five years, we also saw the lowest number of recalls overall with 218, an 18% decrease compared to 2020.

However, that doesn't mean that the CPSC is taking things easy. The appointment of Chair Alexander Hoehn-Saric and Commissioner Richard Trumka means there is an even 2-2 split of Republicans and Democrats on the already aggressive Commission. Mary Boyle, a third Democrat, has been nominated and is awaiting Senate approval for the other Commissioner's seat.

One focus of the CPSC is in trying to force e-commerce companies and other retailers to play an active role in executing recalls. The Commission took action against a major online retailer to force it to cooperate with recalls of third-party products and not only refund consumers, which it did, but also make sure the defective products are taken out of circulation. While disposition of recalled products is in the best interest of companies in terms of both reputation and liability, it can be costly and complicated. It seems that the CPSC may increase its demands for proof this step was taken.

The CPSC is not only using its regulatory power. It is also using the power of public opinion to get companies to take action. After filing its administrative action against a residential elevator company, the CPSC went straight to the media. Frustrated with a years-long battle related to in-home elevator accidents, the CPSC took an additional step to publicly call on vacation rental platforms to require "hosts" to disable residential elevators or provide proof that the elevators are safe in the form of an inspection or certification. The agency also asked rental platforms to notify renters of the potential hazards of residential elevators.

The agency's new budget for fiscal year 2022, which began on October 1, 2021, provides a nearly 25% increase for the Office of Communication, which may be a sign that CPSC is planning more frequent outreach to businesses and consumers, including tactics like it used with the elevator makers. **For more in-depth analysis of the consumer products industry in 2021, and our predictions for 2022, click here.**

Pharmaceutical

Like the consumer products industry, the pharmaceutical industry saw a five-year low for the number of recall events, but hit the second-highest number of units involved in recalls, largely driven by two unusually large events.

As the COVID-19 pandemic entered its second year, supply chain issues remained a challenge across the pharmaceutical industry. In June 2021, the White House released a report on its 100-day review of U.S. critical supply chains, which provided the new Administration's view of the industry. The Biden-Harris administration also announced steps to safeguard the pharmaceutical supply chain, including the launch of a public-private consortium to support the onshoring of 50-100 essential medicines. Additionally, $60 million was appropriated in Defense Production Act funds to build domestic manufacturing capacity for active pharmaceutical ingredients (APIs).

Impurities and contaminants were another focus of the FDA in 2021, particularly efforts to protect consumers from potential carcinogen contamination. We saw this with nitrosamine concerns for more than three years and again with drugs and treatments impacted by NDMA contamination and, most recently, with products in which excessive levels of benzene were detected. The FDA issued five recalls in 2021 for unsafe levels of benzene. Four of these recalls came in the fourth quarter, impacting more than three manufacturers, 11 brands and more than 47 million units and counting.

One of the biggest changes for the FDA that was brought about by the pandemic is the dramatic rise in the use of Emergency Use Authorizations (EUAs). They have allowed the FDA access to a wealth of knowledge about why medication errors happen (because medication error reporting is mandatory with drugs under EUAs, not voluntary as it is with approved drugs). There has been some criticism, however, over how many products – both pharmaceutical and medical devices – were granted EUA status. **For more in-depth analysis of the pharmaceutical industry in 2021, and our predictions for 2022, click here.**

Medical devices

Like the pharmaceutical industry, EUAs were also at the forefront of the medical device industry, with an eye towards transitioning products off of them. On December 22, 2021, the FDA released two draft guidance documents regarding transitioning medical devices brought to market under special pandemic circumstances to how they can be lawfully marketed once the public health emergency (PHE) is over: Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency and Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

It is expected the guidance will most likely apply to personal protective equipment including masks, face shields, gowns and surgical gloves, as well as diagnostic tests, ventilators, disinfectant devices and respirators.

In 2021, the limits on liability protections related to the Public Readiness and Emergency Preparedness (PREP) Act were tested by the Supreme Court's Riegel v. Medtronic, which found that federal medical device regulation laws provide protections for devices with FDA premarket approval. The case itself was not dismissed by the Court, however. It is expected that lawyers will aggressively test the waters on the level of immunity the PREP Act grants to medical device manufacturers.

The growing number of cyberattacks on hospitals and healthcare systems has put a spotlight on the vulnerabilities of medical devices. Not only are they at risk of being the source of a data or security breach, but there is an added risk to patient care and health if a hacker gains control of the device. The FDA is responding to cybersecurity concerns in a variety of ways, including creating a new leadership position focused on medical device security within the Center for Devices and Radiological Health (CDRH).

The trend in the number of recalls versus number of affected units continues with medical devices. In 2021 we saw the highest number of units in the past five years with 602.5 million units impacted, but also the lowest number of recall events with 837, a 22.4% drop compared to 2020. **For more in-depth analysis of the medical device industry in 2021, and our predictions for 2022, click here.**

Food and drink

While the total number of FDA and USDA recall events in 2021 were not out of line with 2020's figures, the number of units impacted was considerably more. There were 52.1 million units impacted by FDA recalls in 2021, almost double the 27.4 million we saw in 2020. The difference is even more dramatic with USDA unit numbers. The number of units jumped from 1.4 million pounds for all of 2020 to 13.4 million pounds in 2021. This was largely the result of a single recall of ready-to-eat poultry products that impacted nearly 9 million pounds in the third quarter.

The major food allergen list was expanded for the first time in 17 years with the addition of sesame. That brings the list of major allergens subject to labeling requirements up to nine. In the fourth quarter, there were two FDA recalls and one USDA recall for sesame as an undeclared allergen.

Two plans were announced in early 2021 aimed at protecting infants and young children. U.S. Sens. Amy Klobuchar (D-Minn.) and Tammy Duckworth (D-Ill.) introduced the Baby Food Safety Act of 2021 in an effort to improve the way infant and toddler food are regulated. The FDA also released its Closer to Zero plan for reducing children's exposure to toxic elements, including naturally occurring elements like arsenic, lead, cadmium and mercury.

The FDA's New Era of Smarter Food Safety Blueprint remains a driving force for the industry. The agency announced another part of this initiative in December 2021, its Foodborne Outbreak Response Improvement Plan (FORIP), which it described as "an important step that the FDA is taking to enhance the speed, effectiveness, coordination and communication of outbreak investigations."

Tech-enabled product traceback is one of the four key components of the new program, including smarter ways to digitize and make the traceback process routine, such as improving utilization of consumer purchase data to better specify critical traceback information from the industry. This is just one example of how technology is being leveraged across the food and drink industry for recalls and notifications about hazardous products. **For more in-depth analysis of the food and drink industry in 2021, and our predictions for 2022, click here.**

Based on what we have seen in the fourth quarter of 2021, we can expect that 2022 will bring even more aggressive enforcement action across all the key agencies. While we remain hopeful that the global health crisis will finally be contained, we know that many of the challenges it brought will remain.

AUTOMOTIVE

As has been the trend for the past several quarters, advancements in vehicle technology continue to create more safety and regulatory challenges that automakers must monitor and adapt to. Data privacy concerns around “connected” vehicles, the safety of new technology and the newest crash-safety features rolling out on autonomous and electric vehicles, and even larger vehicles like buses, must all be considered.

> *“Automotive companies are well-advised to look at current FTC regulations and put their own safeguards in place to mitigate risk for consumers and for their own liabilities should there be a vehicle-related data breach.”*

> *“There are no assurances that if these types of accidents become more common, that the legal and regulatory burden won’t be spread across drivers, auto manufacturers, and parts suppliers.”*

Data and privacy concerns grow for connected vehicles

As it becomes easier to be connected anywhere and to virtually anything, the National Highway Traffic Safety Administration (NHTSA) is keenly aware of growing consumer concerns about the privacy of personal data with connected vehicles. The agency is collaborating with the Federal Trade Commission (FTC), which is the primary federal agency responsible for protecting consumer privacy, to examine data security issues related to connected vehicles.

According to an IBM report, a connected car may generate up to 25 gigabytes of data per hour from the hundreds of sensors within the vehicle, depending on the make and model. While consumers many not realize how much of their data may be exposed, the study showed that 62 percent of consumers would make a buying decision on a vehicle’s brand if one had better security and privacy than another.

Automakers understand this, but also understand the challenges. When Foley & Lardner surveyed leading automakers, suppliers, startups, investors and technology companies, the respondents identified cybersecurity and privacy concerns as the biggest obstacles to marketplace growth for connected cars.

The risks that companies and consumers face made headlights in January 2022 when a 19-year-old cybersecurity researcher remotely accessed dozens of vehicles from one manufacturer through a third-party flaw. And the hacker took it one step further by accessing the car owners’ email addresses and notifying them about the risk.

Fortunately, the research didn’t have bad intentions and he shared the vulnerability with the manufacturer, whose engineers have fixed the issue to prevent such a breach from happening in the future.

However, this example shows there are many areas of vulnerability. And the responsibility for consumer privacy can’t solely be on automakers. Connected cars are made up of components and systems from part makers, software developers, and integrators. They all can collect car data.

And consumers’ own data privacy habits and device usage can play a role. The National Automotive Dealers Association published a guide to help explain the types of information that may be collected by or through a vehicle, how it is collected and used and the options consumers have. Though a lot of people would push back on the idea that this is a consumers’ responsibility.

While California’s Consumer Privacy Act of 2018 gives California residents the right to opt-out of the sale of their data, there is no national regulation that protects consumers, or even forces transparency from the automobile manufacturers on what data is being collected and possibly sold to third parties.

Automotive companies are well-advised to look at current FTC regulations and put their own safeguards in place to mitigate risk for consumers and for their own liabilities, should there be a vehicle-related data breach.

States once again can set emissions standards

In December 2021, the U.S. Department of Transportation (DOT) finalized a rule to withdraw its portions of the Safer Affordable Fuel-Efficient Vehicles Rule Part One (SAFE I). This action by DOT allows states to issue their own greenhouse gas emissions standards and zero-emissions vehicle mandates.

After this change was announced, Transportation Secretary Pete Buttigieg noted “This final rule removes a roadblock to important state actions tackling climate change. States can now actively pursue solutions to address the climate crisis and environmental challenges in their communities.”

While the new regulation may be good news for states and the environment, it may create more challenges for automobile manufacturers who will soon have to review their compliance plans and ensure any changes made state-by-state are reflected in their manufacturing processes and product specifications.

Tougher regulation for autonomous vehicles

In January 2022, prosecutors in California filed the first felony charges against the driver of an AV. The car, which was equipped with a partially automated driver-assist system, was involved in a fatal car crash. While in this case, only the driver was charged, there are no assurances that if these types of accidents become more common, that the legal and regulatory burden won't be spread across drivers, auto manufacturers, and parts suppliers.

Both NHTSA and the National Transportation Safety Board (NTSB) have previously launched investigations into the misuse of partially automated driver-assist systems. Now that two federal agencies and the courts are monitoring the use of these systems, companies can expect increased regulation and recalls of vehicles equipped with the technology.

One step automobile manufacturers can take is to review their systems for stakeholder outreach to ensure they can quickly and precisely target the right vehicle owners and improve engagement if there is a recall or remedy.

Safety questions still abound with automated driver systems

Some experts, including Jason Levine, Executive Director of the Center for Auto Safety, worry that NHTSA is moving too fast in authorizing the use of Automated Driving System (ADS)-equipped vehicles. In a recent article, he expressed concern that NHTSA was not keeping consumer safety top-of-mind in its efforts to rapidly deploy self-driving vehicles.

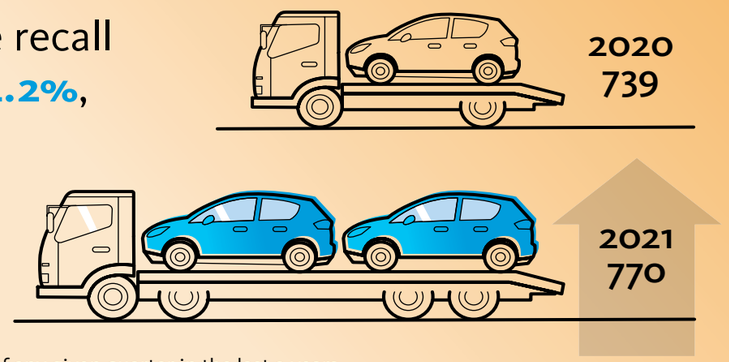
Is it enough to determine which existing requirements of Federal Motor Vehicle Safety Standards (FMVSS) are relevant to the safety needs of ADS-equipped cars and then adapt them, along with the associated test procedures? Or should regulators treat these new novel vehicles as products completely distinct from the cars that are on the road now and build new regulations purposefully for the capabilities – and liabilities – of this type of driving?

It remains unclear if features like adaptive cruise control that tracks the car in front at speeds of up to 130 mph, brakes with "extended speed thresholds" for detecting cars and pedestrians, or a smartphone app that pulls the car out of a garage or parking space while the driver is outside the vehicle can be safety tested and regulated the same way traditional vehicles have been.

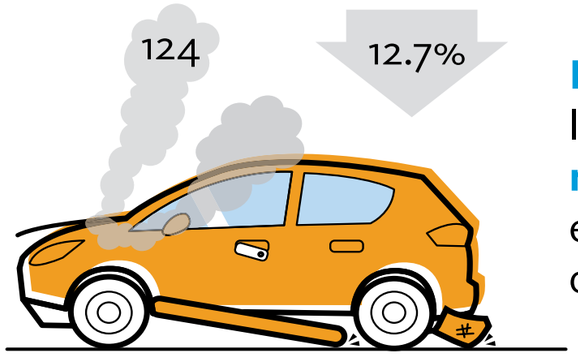
There is also a lot to be examined around what happens when an ADS car and a human driver car are in an accident. Will blame be assigned equally? NHTSA will likely provide plenty of opportunities for manufacturers and consumers to comment as regulations around this category move forward, but there is still a lot of uncertainty.

> *"With an increase in recall activity for the second-straight quarter, 2021 ended up surpassing 2020 for the total number of automotive recalls."*

Annual automotive recall events **increased 4.2%**, from 739 in 2020, to 770 in 2021.



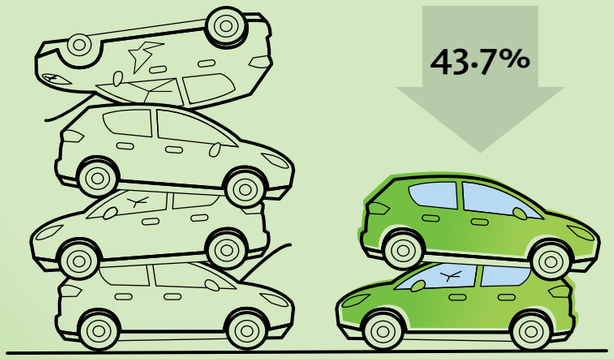
Q4 recorded 209 events, the highest of any given quarter in the last 2 years.



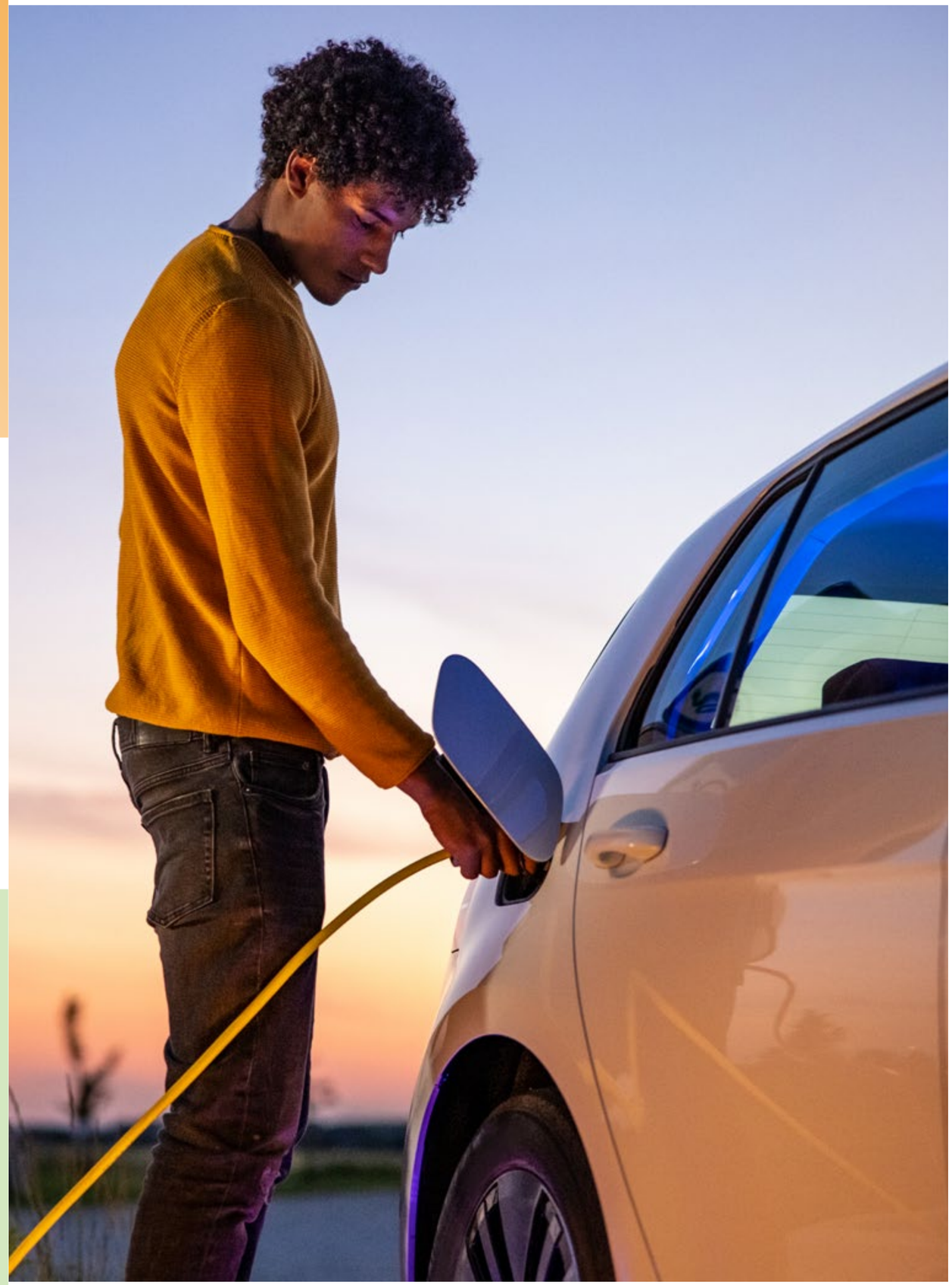
Equipment remained the leading cause of **annual recalls** in 2021. At 124 events, this is down 12.7% on a 5-year average (142).

Fuel systems were second with 91 events. Unlike Equipment, this cause experienced a dramatic uplift of 85.7% in 2021, compared to a 5-year average of 49 events.

Despite an increase in annual events, **impacted units nearly halved** (43.7%) from 2020.



2021 recorded the lowest number of impacted units (28.4M) of the last 5 years. This figure sits 30.5% below the annual average for this period.



JANUARY

2022 insight

January 2022 saw a big uptick in automotive recalls with 49 compared to only 24 events in January 2021. However, that is still below the monthly average for 2021, which was 64. There were 1.76 million units involved in the January 2022 recalls. That is also lower than the monthly average for 2021, which was 2.36 million units.

Electrical systems were the most common reason NHTSA cited in January 2022, accounting for eight recalls. Equipment and tires were linked to seven recall events each and there was one recall for air bags.

2021 BY THE NUMBERS

With an increase in recall activity for the second-straight quarter, 2021 ended up surpassing 2020 for the total number of automotive recalls. There were 209 recall events in the fourth quarter of 2021, representing an eight-quarter high and reflecting a slight increase compared to the 207 recalls in the third quarter of 2021. The total number for 2021 was 770, compared to 739 for all of 2020.

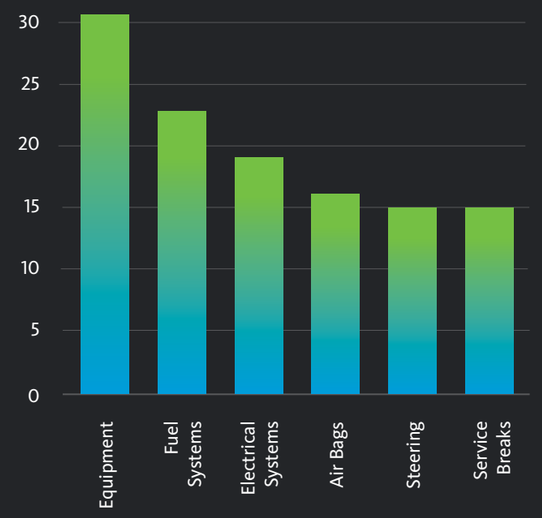
While the number of recalls was slightly up, the number of units affected was down 22.7% to approximately 3.6 million in the fourth quarter. The industry finished the year with more recall events, but fewer units recalled. In 2021, there were 28.4 million units involved in recalls, 43.7% less than in 2020, which saw 50.3 million units impacted.

As it has been for the last 10 out of 11 consecutive quarters, equipment was the leading category of recall events in the fourth quarter. However, the 31 equipment recalls of this quarter reflected a 14.8% drop compared to last quarter. Fuel systems had the second-highest number of recall events at 23, representing a 28.1% drop (from 32) in the third quarter.

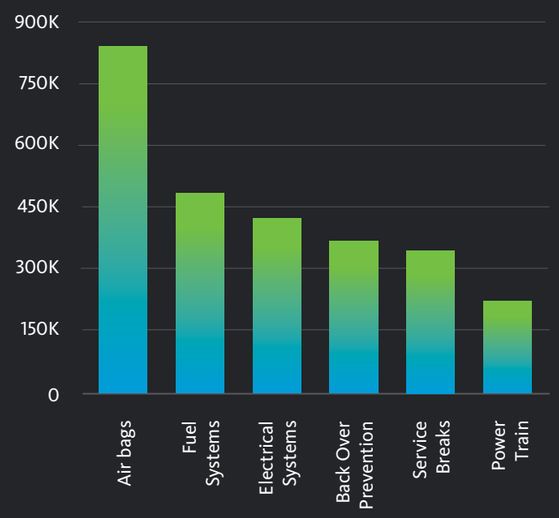
In terms of impacted units, air bags once again led the categories. There were 16 air bag recalls involving a total of 827,198 units in the fourth quarter. While that is not an insignificant number, it is one recall event less and nearly half of the 1.6 million air bags impacted last quarter.

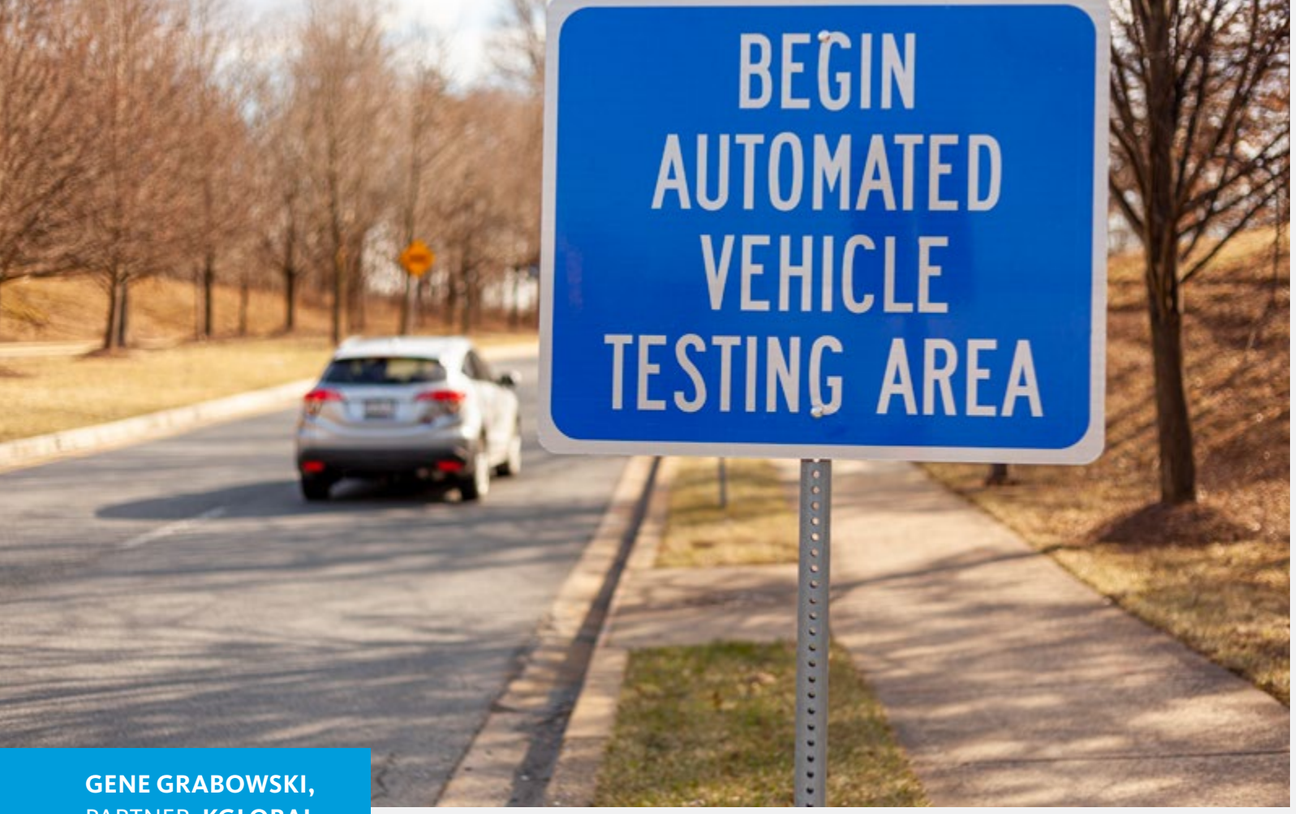
Automobiles continue to be the largest category of NHTSA recalls, with fourth-quarter events rising slightly to 191 (91.4%), compared to 184 last quarter. Compared to the third quarter, the number of child seat recalls rose slightly from one to three, and there were no recalls related to tires.

NUMBER OF RECALL EVENTS BY CATEGORY IN Q4



NUMBER OF UNITS RECALLED BY CATEGORY IN Q4





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DIGITAL TECHNOLOGY BRINGS ADDED RISKS AND LIABILITIES FOR AUTOMAKERS

Today's new cars and trucks pack as much digital computing power as they do horsepower. In fact, many auto experts now refer to them as computers on wheels.

Even an inexpensive gasoline-powered car can require more than 100 microchips, powering everything from climate controls to braking, shift timing and power steering. Luxury cars, with their more advanced entertainment and comfort features, can use more than 200 microchips. And it's estimated that the newest electric vehicles now use up to 2,000 microchips.

Consulting firm Deloitte approximates that roughly 40% of the cost of a new car – whether electric or gas-powered – can be attributed to semiconductor-based electronic systems, a figure double the evaluations in 2007. It estimates this total will approach 50% by 2030. The company further predicts that each new car will soon have more than $2,000 worth of semiconductors packed into it, consisting of up to 3,000 chips of all types.

But along with added convenience, comfort and performance, digital technology brings with it new accountability for automakers and parts manufacturers who are now responsible for the inevitable glitches and system failures occurring with increasing frequency in today's vehicles.

For example, the National Highway Traffic Safety Administration (NHTSA) has been managing hundreds of driver complaints about so-called "phantom braking" in EVs even after one leading EV manufacturer recalled nearly 12,000 vehicles for that problem in late 2021.

The problem? In this manufacturer's case the hazard was triggered by false-positives in its automatic emergency-braking system that the company said are the result of a software update. Complaints soared after the recall and they remain high, spurring continued owner concerns and increased interest among regulators, lawmakers and plaintiffs' law firms.

Alarming stories are mounting. In a report to NHTSA, one EV driver Luis Fernandez, said he was at Taylor Street and Pine Street in San Francisco when his car spotted a plastic bag several feet in front of him. The bag didn't pose a hazard and was soon out of his view, Fernandez wrote. But his car, produced by the manufacturer who issued the 12,000 vehicle recall, jolted him from 25 mph to 15 mph before he could intervene.

"Suddenly the car kind of locked, but it immediately released because the plastic bag moved away. The car just completely took precaution," Fernandez told NHTSA. "Automatically, it braked."

I personally experienced a potentially dangerous high-tech problem earlier this year just two weeks after buying a one-year-old used SUV hybrid vehicle. As my wife and I were driving on a neighborhood street in suburban Washington, DC, the car's power steering suddenly stopped working and I was forced to carefully – and forcefully – steer the car slowly into our driveway a half-mile away to await a tow to the dealership later that evening.

As it turned out, the SUV's power-steering system required a digital software update that neither we, nor the dealer, had been notified about. Had my wife been driving the car alone, she might not have been able to safely drive the car back to our home and may have had to park it alongside the road. Had we been on a highway, the malfunction could have caused a serious accident.

Smartphone and computer users are accustomed to our devices alerting us when a software update is available, asking whether they want to install the update now or later, or automatically downloading updates as they become available. But most drivers aren't yet in the habit of thinking of a software update for their vehicle. We are trained to think about a 10,000-mile oil change or scheduled tire-rotation. Nor have automakers yet prompted us to think about maintaining the technology, not just the hardware, of our vehicles.

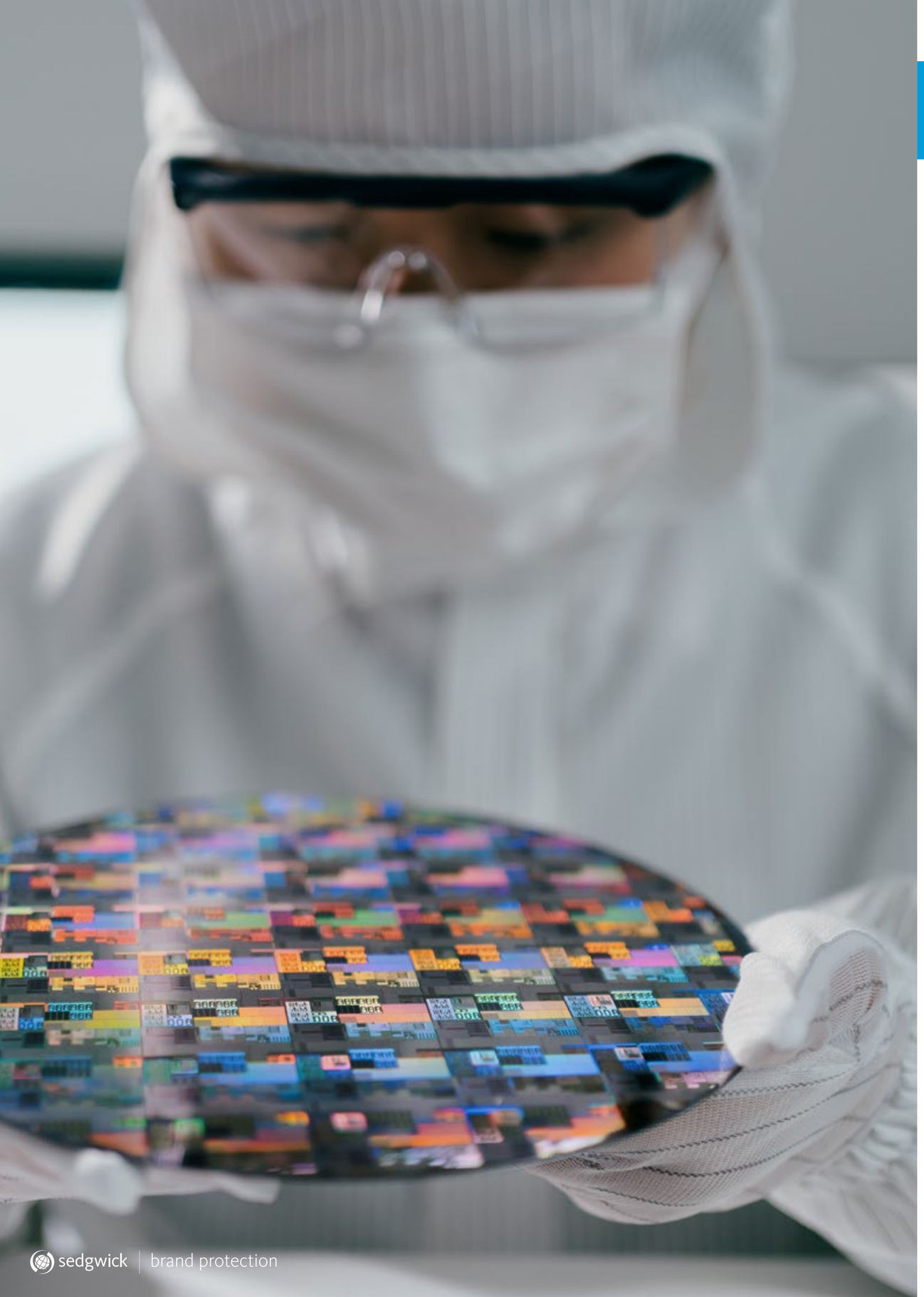
Still, it's imperative that vehicle software remains 100 percent reliable because a software malfunction behind the wheel is likely to have far graver consequences than one that occurs when someone is sitting behind a desk. Ultimately, automakers are certain to be held responsible for accidents that may be traced to faulty software or failure to adequately alert drivers about the need for regular digital maintenance.

Vehicle software updates are increasingly downloaded wirelessly into vehicles, with little or no action required from owners. In fact, by the end of the year, it's estimated that more than 200 million vehicles worldwide will be able to receive over-the-air software updates.

But that technology presumes the autos are outside, not in operation during what can be lengthy downloads, and within easy reach of wireless delivery systems. Drivers are unlikely to hold themselves responsible for download failures or accidents occurring due to malfunctioning digital systems in their cars – especially if they haven't been notified whether their autos need updates or the updates have been done silently.

Of course, one of the greatest risks involving digital auto technology arises from the fact that it can be anonymously hacked. That's because it's connected to the Internet and can be accessed by a reasonably knowledgeable person with a computer. And just as consumer product companies and retailers that maintain personal data are held responsible for cyber-security, automakers need to brace themselves for the increasing frequency in which hackers are targeting their vehicle-installed software.

Upstream Security's Global Automotive Cybersecurity Report notes a 94 percent year-over year increase in automotive cybersecurity incidents since 2016, with more than 200 in the past year alone. These included a hacker gaining control over one automaker's "entire connected vehicle fleet by exploiting a vulnerability in the OEM's server-side mechanism" and hackers taking "full control of an OEM's corporate network by reverse-engineering a vehicle's [telematics control unit] and using the telematics connection to infiltrate the network."



GENE GRABOWSKI, PARTNER, **KGLOBAL**

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Automobile owners themselves are already offering glaring examples on YouTube of hacking their own cars, unlocking and starting them, and even bypassing digital safety systems.

EVs aren't the only cars that can be hacked, but they are more prone to digital attacks, primarily because they have more computer systems onboard and because they present tempting targets for mischief-makers and cyber criminals seeking to prove they can disrupt advanced technology.

The dangers – and the liability – are obvious. One of the first examples of the digital vulnerabilities of autos occurred in 2016, when a Chinese security company hacked a specific model of one automaker and remotely controlled the car, both when it was parked and in motion.

The company quickly fixed that problem with software updates, but the cat-and-mouse game between hackers and manufacturers continues, with potentially grave consequences for drivers and automakers. Trucking companies looking forward to operating fleets of driverless vehicles are especially concerned about potential cybersecurity hazards and attendant liabilities. As Trucks.com notes: "The doors to a host of new dangers have been flung open as autonomous technologies grow in the age of Industry 4.0."

Undoubtedly the most publicized vulnerability of EVs is their reliance on lithium-ion batteries, which can burst into flames if they have been damaged, improperly manufactured, or its driving software has been improperly installed.

Because an EV's battery temperature operation range (-5 degrees to 113 degrees Fahrenheit) is narrower than an internal combustion vehicle's battery (-22 degrees to 122 degrees Fahrenheit), it can much more easily ignite, even under ordinary circumstances.

Massive recalls, regulatory sanctions and costly class-action lawsuits have already arisen over lithium-ion batteries and those promise to continue. As the technology behind the batteries evolves and their use in automobiles grows, liability issues related to them are bound to increase.

New "Autopilot" and "Full Self Driving" (FSD) features in cars may also give rise to safety concerns. Autonomous driving systems have proven to be unreliable or suspect in several nationally publicized accidents that have resulted in serious injuries and interest from consumer advocates, members of Congress, regulators and attorneys seeking redress.

Several U.S. law firms have already published articles and placed advertisements about the dangers of EVs and digitally driven cars and are seeking plaintiffs who have been harmed by the new auto technology. Even some of the world's largest elite law firms see promise in the concern and confusion arising from "connected" motor vehicles. Global elite law firm DLA Piper, for example, has established an Automated, Connected and Electric Car Group to advise parties involved on all sides of the issue.

As drivers become more dependent on digital technology to power their cars and trucks, they will come to rely more and more on the promise of service, safety, security and accountability from manufacturers and parts suppliers who put those smart machines on the road.

Those companies must take ever greater care in protecting their customers and keeping them informed fully and transparently about everything they need to know to safely operate their modern computers on wheels.

CONSUMER PRODUCTS

As 2021 closed, consumer product manufacturers were looking ahead at the myriad of regulations set to take effect in January 2022. While the Consumer Product Safety Commission (CPSC) seems to be looking for ways to make reporting easier for businesses, there is no sign that they are pulling back on the aggressive stance they have taken on compliance and enforcement. The agency is also clearly committed to ensuring that businesses take a holistic approach to notifying consumers about recalls.

> *"The CPSC's focus on more import and internet surveillance means a closer look at imported and online sales to ensure consumer products comply with all mandatory federal safety standards."*

> *“The CPSC may want more assurances that recalled products are taken out of use and, in some cases, that requirements to prove this has been done will be part of a company’s corrective action plan.”*

Commission charging ahead

While the CPSC is still waiting for the nomination of a fifth commissioner, Mary Boyle, to be approved, Chair Alexander Hoehn-Saric is using the power of his office to continue to protect consumers and hold companies accountable. Even though the current make up is two Republicans and two Democrats, the Commissioners, including Chairman Hoehn-Saric, all seem to be committed to aggressive enforcement. If Ms. Boyle, a Democrat, is confirmed, there would be less uncertainty about the voting, but given the Commission’s recent actions, it is unlikely things will change significantly in terms of actions and targets.

New fiscal year, new operating plan

The federal government’s 2022 fiscal year began on October 1, 2021. That set in place a new budget and new priorities for the CPSC, including expanding its enforcement. Thanks in part to $50 million granted to the agency over the next five years as part of the stimulus plan passed by Congress in March 2021, the CPSC is increasing its presence at the nation’s ports by adding 27 new inspectors, allocating more resources to the Field Operations team within its Office of Compliance, and expanding the agency’s laboratory facilities.

This focus on more import and internet surveillance means a closer look at imported and online sales to ensure consumer products comply with all mandatory federal safety standards. Violations could result in a cessation of sales and/or an increase of recalls.

The new plan also increases the budget of the Office of Communication by nearly 25 percent, which may signal that Chairman Hoehn-Saric is planning more frequent outreach to businesses and consumers.

Fast track gets an upgrade

The CPSC launched its upgraded Fast Track Recall Program online portal in January 2022. The program is designed to help business quickly remove potentially unsafe consumer products from the marketplace. Businesses that choose to use this program can see benefits from the CPSC in terms of the preliminary determination about the product in question, assistance in working through the recall process, and a faster resolution. The upgraded portal should be another enticement to use this program.

There are some changes that businesses should be prepared for, though, says Michelle Gillice, a partner at Arnold & Porter. The template that companies complete to report their product has character limits for certain information fields, such as the “Hazard Description” and “Nature/Extent of Injury.” Companies should look at the information required on the new online form and compare it to the current language and reporting requirements in their recall plans. Adjustments should then be applied such that, if the form is needed, they have all the relevant (and correctly formatted) information to hand.

Infant and child safety is still a top priority

It should come as no surprise that the CPSC is placing infant and child safety as a top priority. Historically, regulations have been focused on these most vulnerable of groups. The new operating plan calls for the reinstatement of the Children's Products Defect Team under the Office of Compliance.

The recent unilateral safety warning on infant pillows issued in January 2022 is another sign that the CPSC is taking a strong position to protect these vulnerable populations. Infant swings, another product category with a long history of product safety concerns, are subject to new regulations which started in January 2022 when a direct final rule came into effect and updated the mandatory standard for the product category. These changes are the result of amendments the American Society for Testing and Materials (ASTM) made to its voluntary standards around the age and developmental information for infant and cradle swings, and to harmonize the age and developmental information with the ASTM F2194 Bassinets and Cradles standard.

Residential elevators still a focus

Another category still under intense scrutiny by the Commission is residential elevators due to the risk for young children to be trapped in the space between the exterior landing door and the interior elevator car door or gate. In early January, the CPSC announced voluntary recalls for three separate elevator manufacturers, totaling approximately 69,000 units. The agency also issued warnings for a fourth company that refused to conduct a voluntary recall.

These steps come on the heels of a December 2021 recall for a fifth manufacturer and a July 2021 lawsuit against a company that refused to issue a recall. Expect that the agency will continue to surveil and enforce this sector.

Reverse logistics and remediation increasingly important

Businesses need to be thinking about their recall and corrective action plans from end-to-end, including the disposition of recalled products. This was made clear when the CPSC filed an administrative complaint in July 2021 against a major online retailer. The goal of the complaint was to force the company to accept responsibility for recalling potentially hazardous products sold on its site.

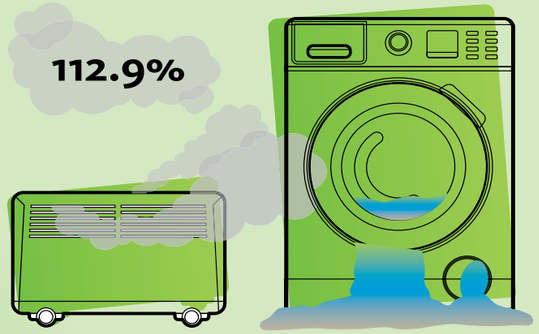
It is not enough for retailers to refund customers for defective products, though the CPSC does want customers to be made whole. However, it is also important to make sure the products are taken out of service. The CPSC may want more assurances that recalled products are taken out of use and, in some cases, that requirements to prove this has been done will be part of a company's corrective action plan, according to Ms. Gillice, Partner at Arnold & Porter.

More than ever, companies need to have a vested interest in ensuring unsafe products are removed from the market. These products present a risk of massive product-liability claims and could also damage their reputation if people are hurt by them, or believe the poor quality is typical for the brand.

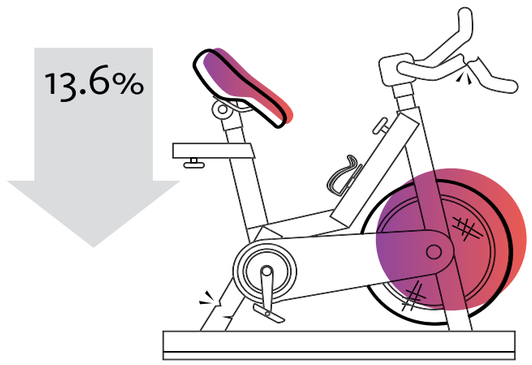
Start the year with a fresh eye on processes

As companies look back on 2021 and move into 2022, it's the perfect time to review their current plans and procedures, especially given the aggressive actions the CPSC has taken and the changes in federal regulations. And changes are not limited to regulations. If there have been internal changes at the company in terms of processes or products or vendors, those should be examined as well to make sure that recall and remediation plans take these new circumstances into account. Any delay in corrective actions are almost certain to hurt companies' reputation and their bottom-lines.

Annual **impacted units** of consumer products **surged 112.9%**, from 20.1M in 2020, to 42.8M in 2021.



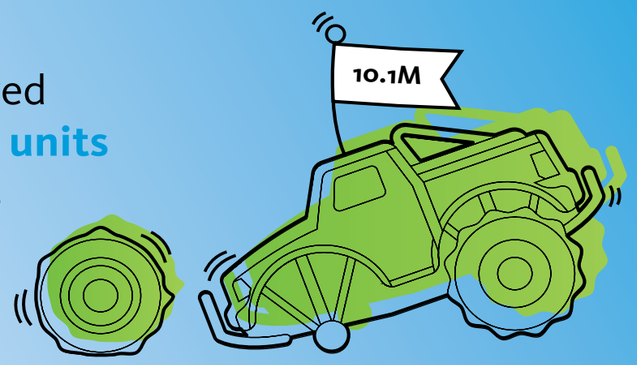
Despite this uplift, the volume of affected units in 2021 sits 31.2% down on the annual average of the past 15 years.



Sports & Recreation was the most recalled category in 2021. At **57 events**, this is down 13.6% on a 10-year average (66).

Accounting for 26% of annual events, Sports & Recreation has been the top recalled category for 7 of the last 10 years.

Only 2 categories registered more than **10M impacted units** in 2021: Home furnishings and Toys (10.5M and 10.1M respectively).



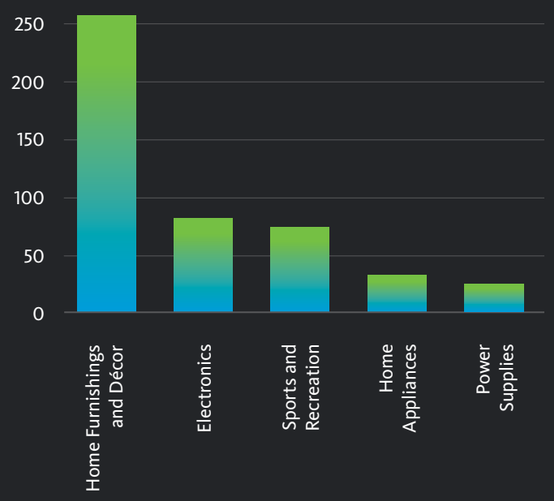
Accounting for only 7 events in 2021, the average Toy recall registered 1.4M units. This is 547.8% greater than the average Toy recall over the last 10 years.

2021 BY THE NUMBERS

The CPSC announced 47 recalls in the fourth quarter of 2021, which is significantly lower than the volume of quarterly averages observed in 2019 and 2020, and a drop from Q3 2021 as well. Fourth quarter recalls impacted about 2.7 million units, representing an 87.5% drop compared to the previous quarter. This is unsurprising given that Q3 saw an atypical recall of toy magnet products that alone accounted for 10 million units. However, in contrast, when looking at total annual units impacted, 2021 experienced a significant uplift on the year previous, more than doubling from 20.1M units, to 42.8 million units.

After seeing the highest number of reported incidents in several years in Q3 (6,332 events), this number fell by 91.4% to 544 in the fourth quarter. Injuries also dropped from 150 to 49, though the number of deaths allegedly linked to recalled products rose slightly, from 9 to 10.

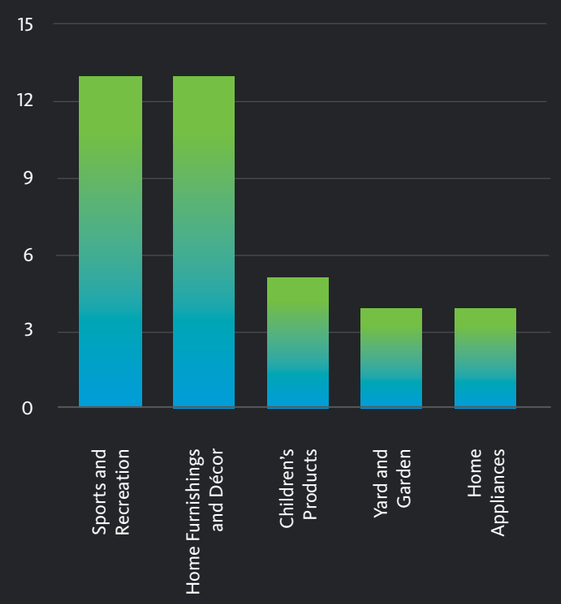
NUMBER OF INCIDENTS BY CATEGORY IN Q4



The recall of 873,000 bed rails in three separate events led to a bad quarter for Home Furnishings and Décor products. That category had the most incidents, (255), injuries (22) and reported deaths (7). Electronics and Sports and Recreation were second and third for number of incidents with 78 and 75 respectively. In terms of injuries, Sports and Recreation were second with 12 injuries reported.

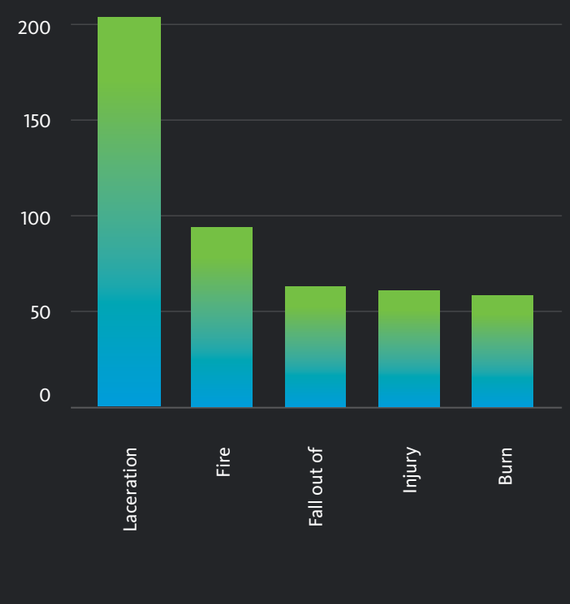
Sports and Recreation and Home Furnishings and Décor products tied for the most impacted product category with 13 recall events, or 28% of the total, each. Home Furnishings and Décor products were also the leading category of recalled units at 1.393 million (54.7%). The next closest category in terms of units was Home Appliances with 464,038 units recalled.

NUMBER OF RECALL EVENTS BY CATEGORY IN Q4



Lacerations were the top cause of fourth quarter incidents at 203 or 40%. Entrapment/strangulation risks for bed rails were the leading cause of recalled units, impacting 912,900 units, or 35.9% of all recalled units.

NUMBER OF INCIDENTS BY RISK TYPE IN Q4



JANUARY insight

The CPSC announced 19 consumer product recalls in January 2022, compared to a monthly average of 18 recalls in 2021.

Those January recalls impacted slightly more than 500,820 units. The majority of those units came from a single recall of 333,725 pacifiers. While the total for the month is 150% more units compared to January 2021, it is still well below the monthly average for 2021, which was 3.57 million units.

In terms of number of recall events, Sports and Recreation products led with six recalls, followed by Apparel with four events, and Home Furnishings and Décor with three. The children's product category experienced two recalls, involving the pacifier, as well as wooden wagons.

MICHELLE GILLICE, PARTNER,
ARNOLD & PORTER

CPSC REPORTING AND RECALLS: WHAT'S NEW, WHAT TO EXPECT AND HOW TO PREPARE

With recent leadership changes at the Consumer Product Safety Commission (CPSC), including the confirmation of Alexander Hoehn-Saric as Chair, the Commission is evenly split 2-2 between Democratic and Republican Commissioners. Assuming the Senate confirms the nomination of a fifth Commissioner, the Commission will shift to a 3-2 Democratic majority. However, even before this occurs, it appears likely that CPSC will continue its trend of aggressive enforcement, which in 2021, notably included the filing of two administrative complaints to compel product recalls.

CPSC ushered in 2022 with the announcement of three residential elevator voluntary recalls and one safety warning regarding a fourth company's product because, according to CPSC, the company refused to recall the product. Shortly thereafter, CPSC exercised its muscle and issued a safety warning urging consumers to stop using certain infant loungers because the company involved is refusing to conduct a voluntary recall of the product. After CPSC issues a unilateral safety warning, typically within several weeks or months, either the company voluntarily recalls the product at issue or CPSC staff files an administrative complaint to compel the recall.

CPSC staff has made recent changes for purposes of streamlining the voluntary recall process for Fast Track recalls. CPSC has upgraded the online Section 15 reporting system. As of January 31, 2022, any company that wishes to conduct a voluntary recall through the Fast Track program must report using the online reporting system. CPSC touts the user-friendly interface, automated case updates, deadline reminders and other features to help expedite the recall process.

Companies using the online reporting system for the first time will likely find it different from how they previously reported to CPSC. For instance, the initial report template is brief, with no option for uploading attachments, and contains character limits for certain information fields, such as the "Hazard Description" and "Nature/Extent of Injury." Following submission of the initial report, a company will receive notice to complete the online "Additional Information" template which serves as the "Full Report". Like the initial report template, the Additional Information template has a number of required information fields that must be completed in order to advance to the next screen and complete the report. For example, the template requires the company to identify the exact date upon which the "hazard" was "discovered" and provide a narrative description of how the hazard was discovered. Given these and other changes, companies should take some time to be become familiar with the new initial report template before a potential issue arises for which the company may wish to conduct a recall under the Fast Track program.

CPSC staff has also made changes to the implementation non-Fast Track voluntary recalls in an effort to increase recall awareness and reach affected consumers. Previously, staff typically took a "one and done" approach with respect to requiring companies to post a recall notice on social media. As a result, recalling companies typically posted notice one time on Facebook and Twitter on the date CPSC announced the recall, assuming the company had accounts on those sites. More recently, in non-Fast Track recalls, staff has been requiring that a company's corrective action plan (CAP) agreement include posting recall notice on social media more than once following the recall announcement and on additional social media platforms where the company has an account.

In addition, staff requests that recalling companies post notice of the recall at the top of their website homepage for at least 120 days, before moving the recall link elsewhere on the homepage. Whether such notification terms will be required for Fast Track recalls remains to be seen.

The disposition of recalled products remains a key priority in CAP agreements, which companies negotiate with CPSC. For recalls in which the remedy is either a replacement or refund, CPSC expects that the recalled product will be taken out of use or otherwise removed from consumers. Removal does not necessarily mean that the product must be returned to the company. It can and has involved requiring consumers to provide proof of destruction or disposal of the recalled item in order to receive the recall remedy. For example, consumers may be required to submit proof in the form of photo showing that they have rendered the recalled unit non-functional (e.g., cutting the power cord of an electrical item).

In fact, in a recall lawsuit filed against an online distributor last year, CPSC took issue with the distributor's practice of providing consumers with refunds for alleged noncompliant or hazardous products without facilitating the return or destruction of such products. Putting CAP agreement requirements aside, recalling companies have a strong interest in getting recalled products out of the hands of consumers to help protect customers, reduce product liability risk and protect brand reputation.

Given the risk of substantial civil and even criminal penalties for late reporting, and CPSC's ongoing trend of aggressive enforcement, it is more important than ever for companies to ensure that they have internal controls in place to capture, track and analyze complaints and other information that may trigger reporting to CPSC under Section 15. New positions, technology and changes to organizational structure and business processes can impact how a company gathers and assesses potential product safety information for reporting purposes and whether it believes a recall is warranted.

Companies should look closely at their processes and procedures for complying with Section 15 reporting requirements and as well as those for recall implementation and make any necessary changes.

FOOD AND DRINK

A massive salmonella outbreak in whole onions dominated food safety news for a portion of the fourth quarter and led to a 1,547% increase in units recalled compared to the third quarter. This event notwithstanding, total recall events in 2021 fell to their lowest number in 11 years. That doesn't mean that the regulators slowed down, though. Several new proposals, including the FDA's robust plan to improve the response to foodborne illnesses were rolled out.

In addition, the FDA has proposed changes to water requirements under the Food Safety and Modernization Act (FSMA) that would address concerns farmers raised about the reported impracticality and complexity of current regulations.

> *"The number of FDA food recalls has been dropping steadily for the past five years. The 414 recalls in all of 2021 mark the fewest in the past 11 years."*

The number of food recalls continues to fall

The number of FDA food recalls has been dropping steadily for the past five years. The 414 recalls in all of 2021 mark the fewest in the past 11 years. Some people claim that the pandemic is the reason the number of recalls has fallen – fewer inspectors, reduced production from the fields to the factories, more people eating at home. However, the truth is, the number of recalls had been declining year-over-year since 2017 when the FSMA was fully implemented.

Of course, given the complexity of the supply chain, it is impossible to credit one specific reason for this change. Likely it is a combination of a number of factors, though it does seem that fewer foodborne pathogens are getting into our food systems.

According to data from the Centers for Disease Control and Prevention (CDC), which tracks cases of foodborne illnesses linked to pathogens, 2020 saw a decrease for the pathogens typically transmitted through foods. Infections caused by the nine pathogens currently tracked by the CDC dropped by 29% between 2019 and 2020 in the study area. The agency does give the caveat that the numbers tend to lag by several years, but the drop in recall activity suggests this trend is continuing. And the FDA's new initiative around foodborne outbreaks will provide even more resources to prevent or mitigate these types of events.

FDA launches foodborne outbreak response improvement plan

In December 2021, the FDA announced its Foodborne Outbreak Response Improvement Plan (FORIP), which it described as "an important step that the FDA is taking to enhance the speed, effectiveness, coordination, and communication of outbreak investigations."

This new plan focuses on four areas:

- **Tech-enabled product traceback** – Smarter ways to digitize and make the traceback process routine, including improving utilization of consumer purchase data to better specify critical traceback information from the industry.
- **Root cause investigations (RCIs)** – Adapting and strengthening protocols and procedures for conducting timely RCIs, standardizing criteria and formats for producing reports on RCIs of outbreaks, and expediting the release of information to the public.
- **Analysis and dissemination of outbreak data** – Ways to strengthen analysis and dissemination of outbreak data including working with CDC, USDA-FSIS and other health partners to identify reoccurring, emerging, and persistent strains of pathogens.
- **Operational improvements** – Continuous operational improvements that will enhance product tracing, root cause analysis and the use and dissemination of outbreak data.

While the FDA presented this plan as, "a series of actions we intend to take to respond more quickly and more efficiently to foodborne outbreaks and reduce the number of foodborne outbreaks that go unsolved in the future," it is clear that the actions will not be only for the agency. How reporting and tracing regulations will change for companies is not clear yet, but businesses should review the plan and start planning for how their operations and reporting structures may need to adapt.

Changes to FSMA water rules

In December 2021, the FDA proposed a revision to Subpart E of the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule that would change the pre-harvest agricultural water requirements for covered produce (other than sprouts).

The agency said the proposed changes are intended to address stakeholder concerns about the "complexity and practical implementation of certain pre-harvest agricultural water requirements," while still protecting public health and adapt to future advancements in agricultural water quality science.

The revisions require that covered farms (other than sprouts farms) conduct an annual systems-based pre-harvest agricultural water assessment to identify possible conditions likely to introduce hazards into, or onto, covered produce or food contact surfaces. That assessment would include an evaluation of the farm's water system, agricultural water practices, environmental conditions, crop characteristics, and other relevant factors. If any risks are identified in the assessment, farms would be required to consider corrective or mitigation measures.

While the new rule is not yet final, and the FDA is taking comments until April 5, 2022, farmers should be planning for the changes to go through and determine what adjustments they may need to make in their operations so that they will be in compliance.

Sesame gaining attention

Under the Food Allergy Safety, Treatment, Education and Research Act of 2021 (FASTER Act), sesame was added to the list of major food allergens for which labeling disclosures are mandatory in April 2021. While companies are not required to declare the presence of sesame on food packaging labels until January 1, 2023, when the new rule goes into effect, there have already been three recalls involving the ingredient. In the fourth quarter, there were two FDA recalls and one USDA recall for sesame as an undeclared allergen.

It is too early to tell if these recalls were a speed bump as the new requirements roll out, or if sesame will continue to be a concern for labeling and recalls.

> *"Businesses should review the foodborne outbreak response improvement plan, and start planning for how their operations and reporting structures may need to adapt."*

Food Safety Inspections on the Rise at State and Federal Level

We've seen fewer food facility inspections over the past two years as the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) shifted resources to immediate public health needs related to the COVID-19 pandemic.

That shift in activities may also be a factor in the decrease in foodborne illness outbreaks and recalls over that same time period. In addition, people who were sickened by foodborne pathogens like Salmonella and STEC E.coli may have avoided going to the doctor or a hospital because of the pandemic. So, more than a few cases may have gone undetected or not reported.

But there is reason to believe things are changing, according to Rachael Spiegel, a partner with Faegre Drinker Biddle and Reath, LLP. We are seeing an increase in FDA and CDC monitoring and also more activity from state departments of health and departments of agriculture. Agencies are shifting their focus away from COVID and back to monitoring traditional public health issues such as foodborne illness.

For example, FDA and state departments of agriculture are starting to increase random sampling and testing of food products from retail settings. We saw multiple recalls of leafy greens due to Listeria monocytogenes in December 2020 and January 2021. Many of these recalls were the result of random retail sampling.

After a reduction in in-person facility inspections due to COVID-19 restrictions, FDA is also resuming in-person facility inspections for compliance with the Food Safety Modernization Act (FSMA). For the first few years after FSMA's final rules were implemented, FDA understood that some companies were going to need time to bring their facilities into compliance with FSMA regulations. This was especially true for those companies that were not heavily regulated pre-FSMA, such as animal feed and pet food companies, said Ms. Spiegel. During this time, FDA signaled that it would work with manufacturers and processors to make sure facilities were coming into FSMA compliance.

In recent years, FDA has signaled that is shifting from education to enforcement of FSMA regulations. We've been seeing an increase in 483s and Warning Letters from the agency noting that companies have had ample time to come into compliance with Current Good Manufacturing Practices (CGMP) and Preventive Controls requirements, among other obligations.

The agency now wants to see written programs and policies in place. And if companies don't have them, the FDA will take action. There has been an increase in monitoring for these compliance areas, as well as an increase in Food Defense Inspections.

FDA has announced that it will be inspecting companies and evaluating their "culture of food safety." A food safety culture is a subjective concept to evaluate and varies from inspector, the type of food manufacturing, as well as the type of facility. An animal feed facility's food safety culture will be very different than that of an aseptic packaged food facility, explained Ms. Spiegel.

Feedback from the industry is that inspectors need proper training to understand that companies' "food safety culture" will vary, depending on the food product and type of facility. While the FDA has been educating the public regarding this "food safety culture" through a series of webinars, food producers and manufacturers are still wary that inspectors will fairly apply this subjective standard during inspections.

While the definition of "culture of food safety" may be vague. There are some concrete steps companies can make, according to Ms. Spiegel. First, companies can define their culture of food safety by incorporating a written definition in their food safety plan. A qualified Food Safety Quality Assurance (FSQA) manager will have an understanding of what an effective culture of food safety looks like.

Once the company has defined its food safety culture, it needs to put written policies and procedures in place that align with their definition and food safety plan. Next, they need to make sure they are actually following those written policies and procedures. In addition, the company should be conducting regular documented employee trainings regarding food safety.

Another step companies can take if they do have an issue, such as a recall or a preventive control failure, is to conduct a written "root cause analysis" to document that they investigated the problem and implemented corrective actions to prevent the issue from occurring again.

In addition, food companies must establish a culture for reporting concerns. Employees should not be afraid to report potential food safety issues, and any reports should be thoroughly documented and investigated. There must be open communication around food safety at the facility.

One of the reasons companies should be aware of this increase in inspections is because information about inspections is now more public than ever before. In January 2022, the FDA added ten years of historical data from the Reportable Food Registry (RFR) to the already robust FDA Data Dashboard.

This means detailed granular information about recalls, import issues, inspections, compliance actions and other events are accessible to anyone. Prior to this database, besides Warning Letters and Import Alerts, both of which are published by FDA, much of the information in the Data Dashboard, especially Form 483 observations, were not made publicly available by FDA.

FDA will issue a Form 483 during inspections detailing observations of regulatory non-conformance, such as inadequate sanitation, failure to have documented food safety procedures, or other FSMA violations. If a company is issued a 483, it should respond in writing to FDA, outlining what steps the company has taken to correct the observations identified by FDA. If FDA is not satisfied with the company's response, it can issue a Warning Letter.

FDA publishes all Warning Letters on its website. However, prior to the Data Dashboard, unless someone submitted a request to FDA under the Freedom of Information Act (FOIA) for a specific 483, the contents of most 483s were kept confidential between the company and FDA.

However, with the changes to the Data Dashboard, the FDA is now publishing certain observations of things it finds during inspections – the type of information contained in a 483. Anyone can type in the name of a company or the Facility Establishment Identifier (FEI) and all inspections and recalls affiliated with the company or FEI for the last 10 years will show up.

> *“It is a fact of life in the food industry that recalls will happen. With supply chain issues, cost issues and worker issues, there are so many pressures to produce products and keep production lines running. But food safety should not be sacrificed.”*

The Data Dashboard will state if no action was taken or if a voluntary action was taken. This means that while not explicitly stating a 483 was issued, the information in the database makes it easier to assume that one was. Companies no longer have the ability to keep this information private.

This is a huge risk for companies, especially if they are processing or manufacturing high risk products that are subject to frequent recalls because those products don’t undergo a “kill step.” It is very easy to see if a company has had reoccurring recalls, reoccurring inspections or unaddressed issues that the FDA has written them up over.

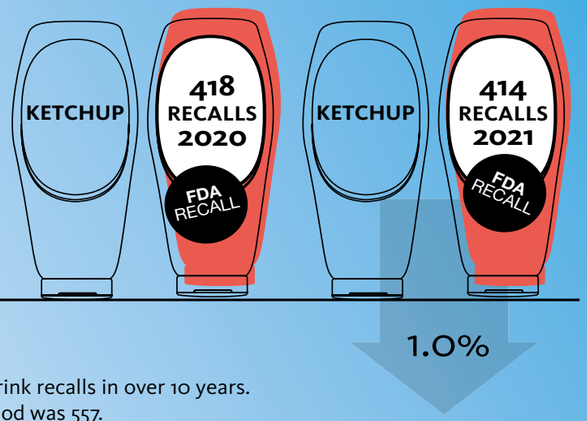
However, this information can also be a really good tool for smart FQSA managers to look at internal risk. They can evaluate their own company’s record and compare it to their competitors’ actions.

It is a fact of life in the food industry that recalls will happen, said Ms. Spiegel. The best companies can do is mitigate risk. Produce manufacturers have undergone a significant shift in production over the last 10-20 years. And they are still seeing substantial changes with water testing requirements, produce safety rules and more.

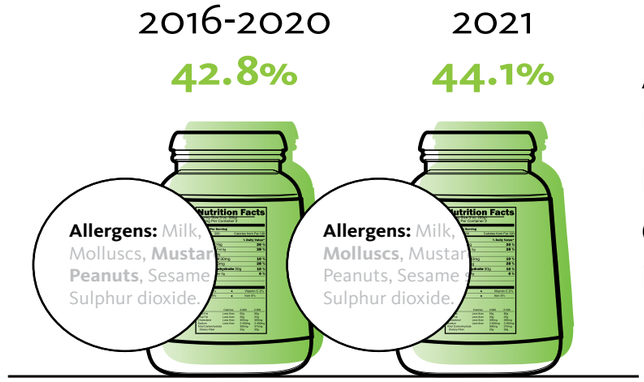
At the end of the day, with supply chain issues, cost issues and worker issues, there are so many pressures to produce products and keep production lines running. But food safety should not be sacrificed.

And with more inspections and more exposure for violations and safety issues, there are more incentives than ever to emphasis food safety and a robust recall plan.

FDA recall activity fell just 1.0% from **418 recalls** in 2020, to **414 recalls** in 2021.



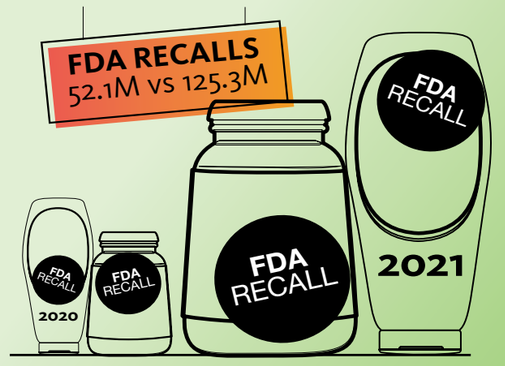
2021 experienced the lowest number of food and drink recalls in over 10 years. The average number of annual recalls over this period was 557.



At 183 events, **Undeclared allergens** remained the top cause of recall events in 2021 (44.1%).

Undeclared allergens has been the leading annual cause of recalls for 5 consecutive years, accounting for 42.8% of all events.

Impacted units in **2021 doubled** from the previous year, but remained significantly below their 10-year annual average (52.1M vs 125.3M).



The average recall size in 2021 was 125.8K units, which is 40.1% lower than the annual average of the past 10 years (209.9K).

JANUARY insight

The FDA published 25 food recalls in January 2022, the same number that we saw in January 2021. That is lower than the monthly average of 35 recalls for all of 2021. The number of units recalled for January 2022 was 176,944. That is considerably less than the average of 4.33 million units per month that we saw in 2021.

Undeclared allergens was the leading cause of FDA food recalls for the month, linked to 14 recall events. Bacterial contamination was linked to four recalls, all for listeria. Prepared Foods led in terms of product categories, with eight recalls. Produce was second with seven recall events in January 2022.

2021 BY THE NUMBERS

FDA

A massive outbreak of salmonella in whole onions led to a 1,547% increase in units recalled compared to the third quarter. Of the 126 recalls in the fourth quarter, 14 of them were related to salmonella in onions. Among the 39.4 million units recalled this quarter, 91.9% of them were connected to onions.

In addition to a huge rise in the number of units recalled, the number of recall events by the FDA also rose in the fourth quarter to 126, representing a 34% increase from Q3. Even with this increase, overall 2021 saw four fewer recalls for the year compared to 2020, with 414 and 418 respectively. It marks the fewest recalls for the past 11 years.

However, largely due to the onion scare, the number of recalled units for the year nearly doubled compared to 2020 with 52.1 million units in 2021 compared to 27.4 million for all of 2020.

Consistent with previous quarters, the 46 Class I recalls in the fourth quarter made up 37% of events. This remains in line with the expectation that around one-third of recalls are designated as Class I. However, because the onion recall was classified as Class I, the number of units in this category was disproportionately large at 36.3 million units recalled.

Undeclared allergens remained the leading cause of recall events for the 25th time in the last 28 quarters (equating to 7 years) with 42 events. Despite being the cause for 33.3% of the events, recalls due to allergen-related concerns accounted for only 0.4% of all related units because of the surge with onions.

Across undeclared allergen related product categories, prepared foods (15), baked goods (9), and flavorings (7) had the most events. Dairy saw four recalls, beverages, supplements and produce each saw two undeclared allergen events and seafood saw one.

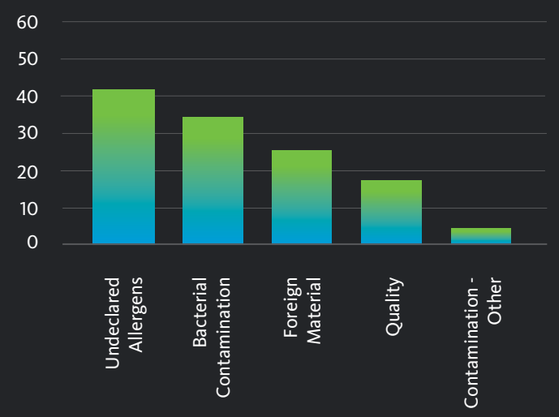
Milk and eggs tied as the primary cause of allergen-related recalls, with six recall events each as a single component and three more recalls where both were cited. While sesame will not officially be a major allergen under the FDA regulations until January 2023, there were two sesame-related recalls in the fourth quarter impacting a total of 1,137 units.

Bacterial contamination concerns were the second most common cause of recalls at 34 events, but by far the leader in number of units due to the onion recalls. In terms of units, foreign materials was a distant second with 2.6 million units impacted across 26 recall events.

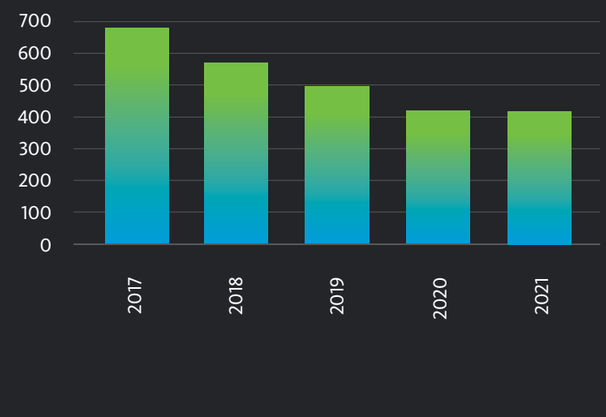
Produce was the top category impacted by fourth quarter recalls, both in terms of events and units. It was linked to 31 recalls (24.6%) and 36.3 million units (92.0%) for the quarter. Prepared Foods were the second-most common category with 24 recalls impacting 293,087 units.

The number of unique companies involved in recalls was also up this quarter to 114 compared to 94 in the third quarter. This is highest number since the first quarter of 2020.

NUMBER OF FDA Q4 RECALLS BY REASON



NUMBER OF FDA RECALLS BY YEAR



USDA

The number of USDA recalls fell slightly in the fourth quarter to 12, a 7.7% drop. While this is low compared to fourth quarter results from 2016 to 2019, compared to 2020 it is 71.4% higher for the respective quarter. Overall, 2021 saw 47 USDA recalls, or 46.9% more than in 2020 for the full year.

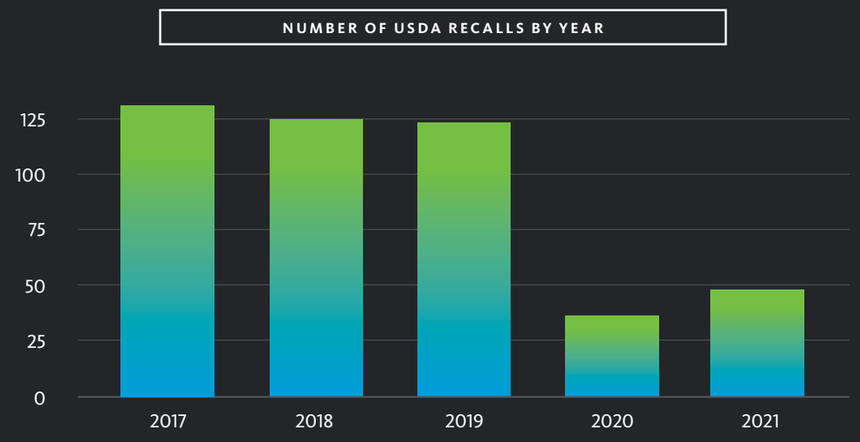
After a spike in the number of pounds recalled in the third quarter, figures dropped by 88.5% in the fourth quarter to 1.2 million pounds. While lower than the third quarter, this figure is nearly 300% higher compared to the fourth quarter of 2020.

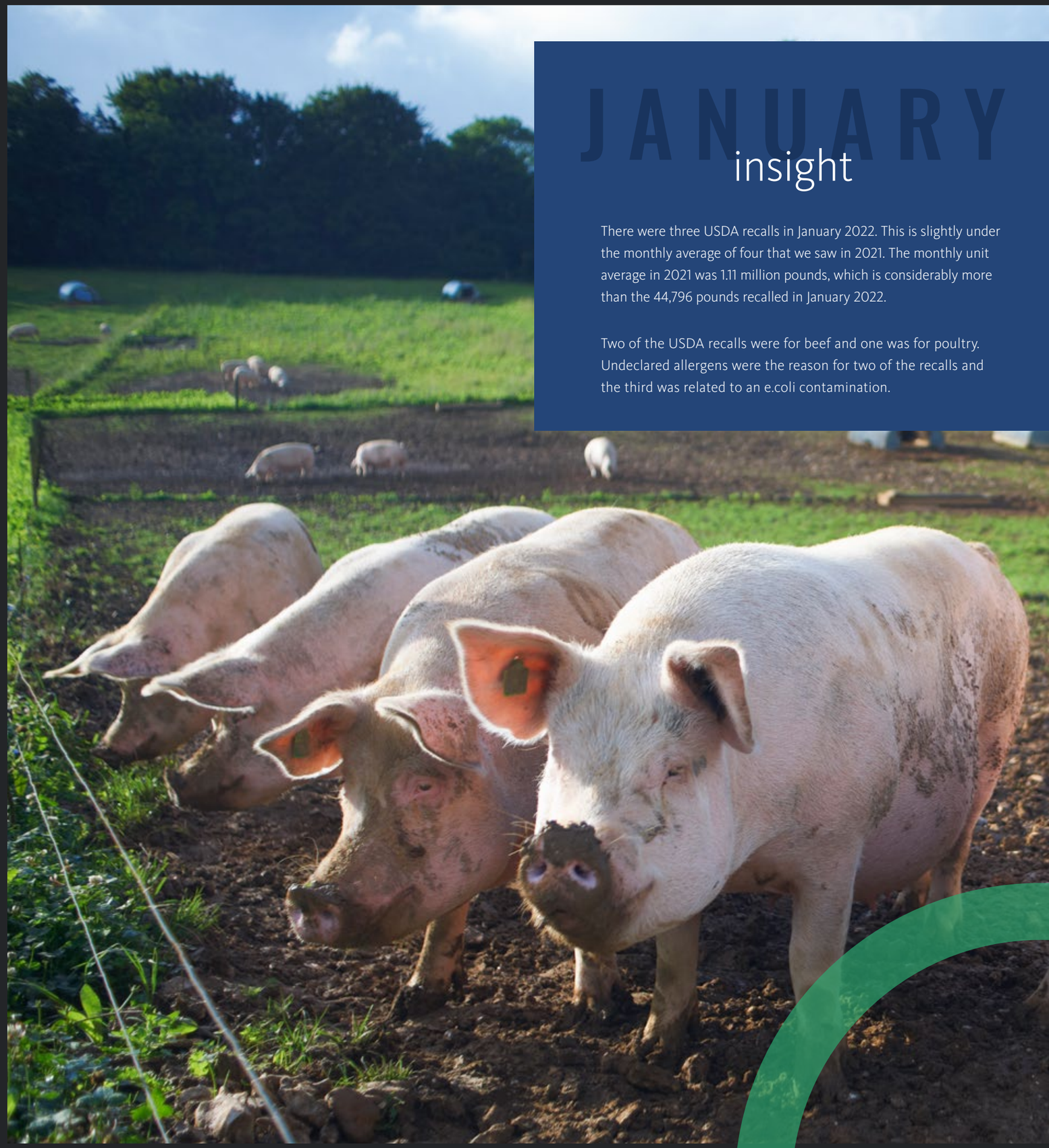
Bacterial contamination concerns remained the leading cause of recalls in the fourth quarter in terms of events with four incidents. Two of these were for listeria, one for salmonella and one for bacillus cereus. In terms of pounds, a single recall for lead contamination in beef, reported as "other contamination," was the reason for the largest number of pounds of food recalled, with 684,774 pounds in the recall, accounting for 55.8% of all volume.

The remaining eight recalls were the result of foreign material contamination (3), lack of inspection (3), undeclared allergen (1), and other contamination (1). Notably, the allergen was sesame, showing that companies are taking note even before sesame is officially included as a major allergen in 2023.

Pork products were the most impacted category in the fourth quarter of 2021 with five recall events, or 41.7% of all recalls. In terms of pounds, beef was the most impacted with two recalls affecting 691,650 pounds. Five pork recalls impacted about 377,974 pounds. Three poultry recalls impacted about 113,218 pounds. One lamb recall affecting 24,462 pounds and one multiple meat source recall that impacted 20,759 pounds were the other events in the fourth quarter.

The USDA classified 10 of the fourth quarter food recalls as Class I and the other two as Class II.





JANUARY

insight

There were three USDA recalls in January 2022. This is slightly under the monthly average of four that we saw in 2021. The monthly unit average in 2021 was 1.11 million pounds, which is considerably more than the 44,796 pounds recalled in January 2022.

Two of the USDA recalls were for beef and one was for poultry. Undeclared allergens were the reason for two of the recalls and the third was related to an e.coli contamination.

> *“Mislabeling was the top cause of recalls in the fourth quarter, a change from software, which has been the leading cause for 21 of the last 23 quarters.”*

MEDICAL DEVICE

While we can’t declare victory yet over the COVID-19 pandemic, the FDA is starting to think about what happens next for all of the medical devices that were granted Emergency Use Authorizations (EUAs) or fell within special public health emergency enforcement.

Another change that the pandemic brought to medical devices was 3D printing at the point-of-care (PoC). The FDA is gathering input on how to regulate this and where the responsibility and liability resides for production conducted outside a manufacturing facility.

New technology is also under review with guidance on Software as a Medical Device (SaMD) to update FDA policies from 2005.

But not everything is happening on the federal level. State Attorneys General are pushing back on the FDA over a proposal to approve and regulate a new class of over-the-counter (OTC) hearing aids and what that step might mean for consumer safety.

> *"The FDA has been urging medical device companies for well over a year to begin transitioning to "normal" by submitting marketing applications. Hopefully companies heeded this advice."*

Transitioning medical devices in a post-pandemic market

On December 22, 2021, the FDA released two draft guidance documents regarding transitioning medical devices brought to market during the public health emergency (PHE): Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency and Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

The FDA explicitly states that both documents are intended "to help facilitate continued patient, consumer, and healthcare provider access to devices needed in the prevention, treatment, and diagnosis of COVID-19." The proposals are designed to assist transiting devices brought to market during the pandemic so that they can be lawfully marketed once the authorities declare the public health emergency is over.

It is expected the FDA's guidance will most likely apply to personal protective equipment including masks, face shields, gowns, and surgical gloves, as well as diagnostic tests, ventilators, disinfectant devices, and respirators.

The FDA has been urging medical device companies for well over a year to begin transitioning to "normal" by submitting marketing applications. Hopefully companies heeded this advice and it won't prove too onerous to gain the required approvals. Both proposals provide companies with 180 days to comply with the new changes once they are finalized and the PHE is declared to be over. The FDA has not said if it will shift internal resources to help process the new marketing applications coming from these two classes.

The FDA states that it "does not intend to object to the continued distribution of devices within the scope of this guidance" while applications are under review with the FDA, assuming certain conditions have been met.

New guidance for software as a medical device

Software has become an important part of many healthcare products and is integrated widely into digital platforms that serve both medical and non-medical purposes. It can even be viewed as a medical device on its own, which would qualify as "Software as a Medical Device (SaMD)." An example of this would be software that allows a smartphone to view images obtained from an MRI for diagnostic purposes.

In November 2021, the FDA released its Content of Premarket Submissions for Device Software Functions draft guidance. This outlined the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions, including software in a medical device (SiMD) and software as a medical device (SaMD). It describes information that would be typically generated and documented during software development, verification, and design validation.

Once finalized, the document will replace FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005. Stakeholders had until February 2, 2022 to submit comments, and software manufacturers should start reviewing the proposed regulations now to help with their next FDA submission, even if the final guidance is still under review.

Big changes for hearing aids

In October 2021, the U.S. FDA proposed a rule to establish a new category of over-the-counter (OTC) hearing aids that would be sold directly to consumers in stores or online without a medical exam or a fitting by an audiologist. The FDA says the proposed rule is designed to help "increase competition in the market while also ensuring the safety and effectiveness of OTC and prescription hearing aids."

However, not everyone is supportive of this new proposal. In January 2022, the National Association of Attorneys General sent a comment letter to the FDA, signed by a bipartisan group of 42 Attorney Generals, asking the FDA to ensure that Attorney Generals continue to be "the primary enforcers of our respective states' consumer protection laws" and that states "maintain a role as regulators" in the emerging OTC hearing aid market.

The Attorney Generals requested that the FDA consider three changes to its current proposal:

- The FDA should define preemption terms so that things like state warranty requirements, mandatory disclosures, returns, and written notice of money-back guarantees set out by the states are not preempted by the FDA regulations.
- The FDA should state explicitly the type of state requirements that the final rule would not preempt, expanding the general regulations under 21 C.F.R. § 808 to be specific to hearing aids.
- The FDA should explicitly state that the existing processes in place in 21 C.F.R. §808.20 regarding how to petition the FDA for a preemption determination will still apply and that the FDA will "find against preemption when consistent with the statutory language" or it is in the public interest.

The FDA's comment period ended on January 18, 2022. Hearing aid manufacturers, audiologists, consumers, and retailers will be watching to see what the FDA and the state Attorney Generals do next.

What 3D printing of medical devices could mean to manufacturers

In December 2021, the FDA published a discussion paper regarding 3D printing medical devices at the POC in hospitals and doctor's offices. While the paper is not considered a draft or guidance, it does provide insights into what questions the FDA will be looking at as this technology moves forward, and what medical device manufacturers should be thinking about if their products can be produced in this way.

Product shortages and supply chain disruptions brought on by manufacturing and shipping challenges during the COVID-19 pandemic made the option of 3D printing certain medical devices desirable. In addition, as the paper states, 3D printing can help a healthcare facility (HCF) "quickly respond to patient needs, bring personalized care to patients in a timely manner, and lead to new innovations in patient care and treatment."

The FDA's initial outline for a regulatory approach for devices manufactured using 3D printing at the PoC focuses on four challenges:

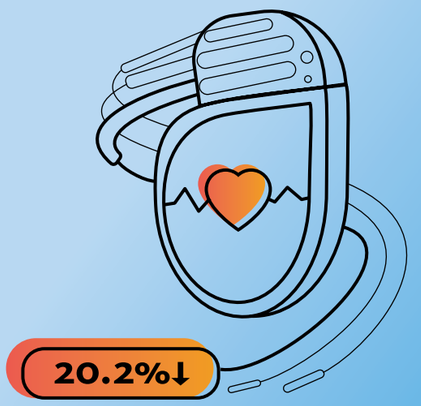
- **Assuring devices 3D printed at the PoC are safe and effective** – FDA regulation is designed to provide a reasonable assurance that devices are safe and effective; this assurance applies regardless of where and how a product is manufactured.
- **Assuring appropriate control of devices 3D printed at the POC** – Appropriate controls during product design and manufacturing help assure that product specifications are met; these approaches are well-defined for traditional manufacturing but are less defined for 3D printing at the PoC.
- **Clarifying the responsible entity** – Under the Federal Food, Drug, and Cosmetic (FD&C) Act, specific requirements apply depending on the activities an entity conducts across a device's life cycle. There may be uncertainty regarding responsibilities for activities related to 3D printing at the PoC, including device design, testing, FDA premarket submissions, manufacturing, quality control, complaint handling, adverse event reporting, and corrective actions. The entities responsible for 3D printing at the PoC should understand the requirements related to these activities.
- **POC training and capabilities** – Under many circumstances, the PoC facility could be responsible for complex processes, such as patient-matching or post-processing activities, to generate a final finished device. Additionally, devices can vary in risk depending on their intended use and technological characteristics. Therefore, the entities responsible for 3D printing at the PoC should have the requisite knowledge and expertise to conduct these activities.

Early discussions suggest that the FDA believes the manufacturer's ability and obligation to ensure that a device meets its predetermined specifications will not change regardless of where the device is produced – in a traditional manufacturing facility or 3D printed at the point of care. This could place a tremendous burden on device manufacturers. It is one thing to control the manufacturing and testing at your own facility. It is very different if production is being carried out across multiple healthcare facilities that are out of your control.

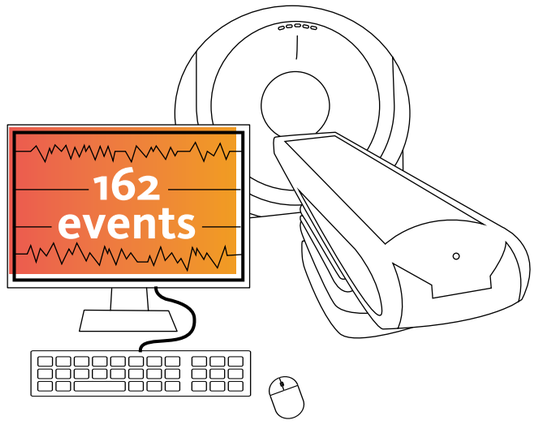
Medical device companies will have to think carefully about whether or not the value of having its product produced quickly and theoretically in larger quantities at the PoC outweighs the legal liabilities.

"Medical device companies will have to think carefully about whether or not the value of having its product produced quickly and theoretically in larger quantities at the point of care outweighs the legal liabilities."

At 837 events, 2021 medical device recalls were **20.2% lower** than their 10-year annual average (1,049).



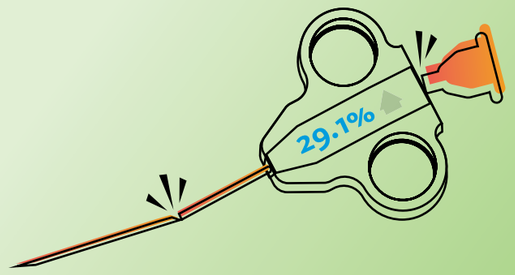
In total, 8.0% of all recalls in 2021 were of Class I designation.
This compares to an annual average of 4.6% over the last 10 years.



Accounting for **162 events (19.4%)**, Software issues remained the top cause of recalls in 2021.

Software issues have remained the leading annual cause of Medical device recalls for over 6 years.

Impacted units increased **29.1% (from 2020) to 602.5M**, nearly doubling the average annual figure of 307.3M for the past 10 years.

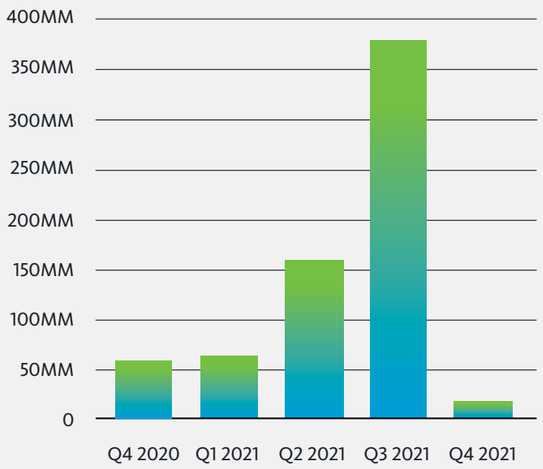


This rise was predominantly driven by Parts issues which totalled 469.0M units (or 77.8%).

2021 BY THE NUMBERS

The number of medical device recalls fell 7.7% in the fourth quarter compared to the previous quarter. The 217 recalls mark the lowest fourth quarter figure since 2017. The number of units fell dramatically, down 96.9% to 11.6 million units compared to more than 372 million in the third quarter.

NUMBER OF RECALLED UNITS BY QUARTER



Mislabeling was the top cause of recalls in the fourth quarter, a change from software, which has been the leading cause for 21 of the last 23 quarters. The 43 events attributed to mislabeling accounted for 19.8% of fourth quarter recalls. Software was the second most common reason for recalls at 39 events, followed by quality concerns (31), and parts issues (25).

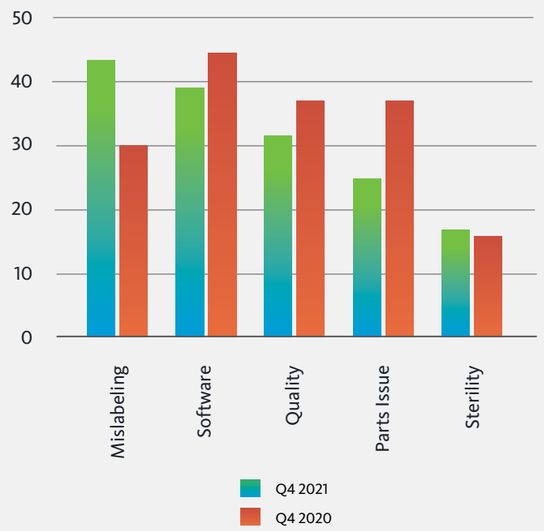
Sterility was the leading cause of recalls in terms of units impacted, accounting for over 4.1 million units, or 35.7% of recalled units. Parts issues were the second most common reason for recalls, with approximately 2.6 million units in the fourth quarter. Leakage concerns were responsible for more than 2 million units being recalled in the fourth quarter, the third highest category.

Twenty one events (9.7%) in the fourth quarter were labeled with the FDA's most serious Class I designation. These recalls impacted 582,383 units, or 5.0% of units recalled in the fourth quarter.

As is typically the case, Class II recalls accounted for the largest percentage of recalls at 192 events and the largest number of units at 11.0 million in the fourth quarter. The remaining four recalls, which involved only 232 units, received FDA's Class III designation.

Of fourth quarter recalls, 77.4% were distributed nationwide, and 52.5% impacted an international customer base.

NUMBER OF RECALLS BY REASON IN Q4 YOY



JANUARY insight

The FDA announced 59 medical device recalls in January 2022, compared to a monthly average of 70 recalls in 2021. January recalls impacted 17.2 million units, driven largely by one infant heel warmer recall that involved 15.5 million units. Overall, the number of units for January 2022 was 153% higher than January 2021.

There were two recalls in the FDA's Class I designation and two designated as Class III. The remaining 55 events were Class II. Software issues were the leading cause of January 2022 recalls, cited in 16 events. Mislabeling was the reason for 11 recall events, followed by Quality (8), Parts Issues (7), and Safety (6).

JOHN FUSON, PARTNER, **AND ANDREW KAPLAN,** CHAIR OF MASS TORT, PRODUCT, & CONSUMER LITIGATION GROUP, **CROWELL & MORING LLP**

TRANSITIONING FROM THE PUBLIC HEALTH EMERGENCY INTO A POST-PANDEMIC WORLD

As we begin our third year of the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) continues to apply lessons learned to improve regulatory processes and keep consumers safe during a crisis as well as look ahead to a post-pandemic world.

Continued focus on the pandemic

FDA continues to keep a close eye on the safety and efficacy of COVID-related products in the market. These include relatively basic items such as masks, hand sanitizers, and temperature monitors, as well as more complex items like diagnostic tests, especially as demand for fast and easy at-home COVID tests rises.

As it has from the beginning of the pandemic, FDA will balance the need to address shortages and get medically essential, high demand products to market quickly with its responsibility to ensure the safety and efficacy of those products.

Masks offer a great real-time example of FDA's struggle with this balancing act. In the early months of the pandemic, we saw multiple changes to FDA's guidance for masks as it became clear that some masks failed to meet performance standards and as market demands changed. As shortages became less acute and as some masks proved woefully inadequate, FDA tightened its regulatory restrictions.

We see a similar pattern emerging with COVID-19 diagnostic tests, especially at-home rapid tests. Initially FDA allowed companies to self-validate their own tests and bring them to market without agency review. Now the Agency has tightened requirements and requires all manufacturers to come forth with data showing their products meet appropriate detection standards before going to market.

Preparing for a post-pandemic world

The greater scrutiny of products and tightening of regulations signals the beginnings of FDA's transition to a post-pandemic world. We expect the Agency will continue to increase oversight as it withdraws Emergency Use Authorizations (EUAs) and allowances under COVID-19 enforcement policies as the public health emergency (PHE) subsides. But as the Agency returns to its normal premarket review process and reasserts other regulatory requirements, will companies be ready?

A lot of EUAs waived certain regulatory obligations including Good Manufacturing Practice (GMP) compliance and registration requirements. As those requirements come back into force, companies will face more regulatory risks.

Another bit of relief companies enjoyed during the PHE is immunity from tort liability under the Public Readiness and Emergency Preparedness Act (PREP Act). Once the public health emergency is declared over, however, not only will FDA withdraw EUAs and require all products to fully comply with requirements under the Federal Food, Drug, and Cosmetic Act (FDCA), but PREP Act immunity will also disappear. That will be a significant development for many manufacturers and we expect it will influence their decisions about whether to continue making pandemic-related supplies, especially if there is an increase in litigation targeting devices that were previously protected.

To begin preparing for the move from emergency policies and procedures, last December FDA issued draft Transition Plans for medical devices with EUAs or that fell within enforcement policies issued during the PHE. Both plans contemplate phased approaches to give manufacturers, healthcare providers, patients and consumers time to adjust to normal regulatory conditions.

Manufacturers must take steps to secure marketing approval and comply with other traditional regulatory requirements if they want to keep products covered by EUAs or PHE enforcement policies on the market once the PHE ends and the EUAs and enforcement policies are withdrawn. The draft Transition Plans contemplate that manufacturers will have 180 days' notice prior to the withdrawal of EUAs and that FDA will allow products with pending, agency-accepted marketing applications to remain on the market until a marketing decision is made.

Some have raised concerns about how FDA will manage processing of all the medical devices transitioning from EUAs. There are, however, reasons to be hopeful that this transition will go smoothly. First, it is expected that FDA will shift resources back to the regular flow of 510(k) reviews since they will not be processing EUAs. In addition, there are third-party reviewer programs for medical devices that many products may be eligible for.

Companies that were marketing products under an EUA and decide to seek 510(k) approval will have a head start for the approval timeline because they likely possess more data and the FDA has experience with those companies and their products. The companies will also have already gone through some form of pre-submission meeting as part of EUA process.

Finally, the agency is encouraging manufacturers to notify FDA of their plans and to start the 510(k) process now, which should help spread applications out over time. FDA has specifically stated that it wants to maintain supply chain health and does not want products in limbo or off the market as the products transition to full regulatory approval.

Changes to postmarket surveillance requirements

Looking to the year ahead, another area we expect FDA to focus on, and that will reflect lessons learned during the pandemic, is postmarket surveillance. FDA has gained a lot of knowledge about products that were rushed to market by watching how they have performed. Draft guidance documents that FDA says it will finalize this year will clarify the agency's expectation on postmarket surveillance for medical devices.

JOHN FUSON, PARTNER, **AND ANDREW KAPLAN,** CHAIR OF MASS TORT, PRODUCT, & CONSUMER LITIGATION GROUP, **CROWELL & MORING LLP**

CONTINUED FROM PREVIOUS PAGE

FDA is closely examining adverse event (AE) reporting. There are expected to be changes in AE reporting for certain device categories, though not for specific devices. FDA focuses on trends across device categories in postmarket surveillance and any changes to reporting requirements will reflect that.

Manufacturers will have to shoulder the burden of monitoring adverse events and reporting on them in a timely and effective matter to the FDA. During its inspections, FDA looks closely at how companies are monitoring, investigating and reporting AEs. AEs are key to driving decisions about postmarket surveillance and any issuance of orders for new product studies.

This focus on surveillance is another potential area of tort vulnerability for medical device companies. Product litigation is often event-focused, such as a regulatory action or a product recall. Postmarket surveillance during the transition period from EUA may make companies more vulnerable to litigation if there are an unusual number of AEs or FDA does not feel that AEs were addressed adequately. In addition, if a company decides not to market after its EUA expires, that may raise red flags and cause a closer look at the product – either by regulators or by plaintiff's attorneys.

Final thoughts

There are several things that companies can do as they look to mitigate risk and continue to thrive in a post-pandemic environment.

First, if they are planning to market devices covered by EUAs or PHE enforcement policies after the PHE ends, they should start the 510(k) process now. Consider engaging with the FDA early through a pre-submission meeting.

Companies should also review their manufacturing processes. A lot of GMP requirements were waived under EUAs. Companies that were already producing approved medical devices before the pandemic should be familiar with GMP compliance and their obligations. For companies new to medical-device manufacturing or the FDA, achieving compliance with GMP requirements will create a challenge. They will need to have systems, quality control, standard operating procedures and other processes in place to meet the GMP standards. And it is almost certain that any new medical device manufacturer – especially one producing COVID-19 diagnostic tests – will be subject to an FDA inspection.

Some companies new to medical device manufacturing may not have the facilities and infrastructure in place to continue their manufacturing efforts. As a result, we may see a wave of larger companies acquiring smaller ones and adding products to their portfolios.

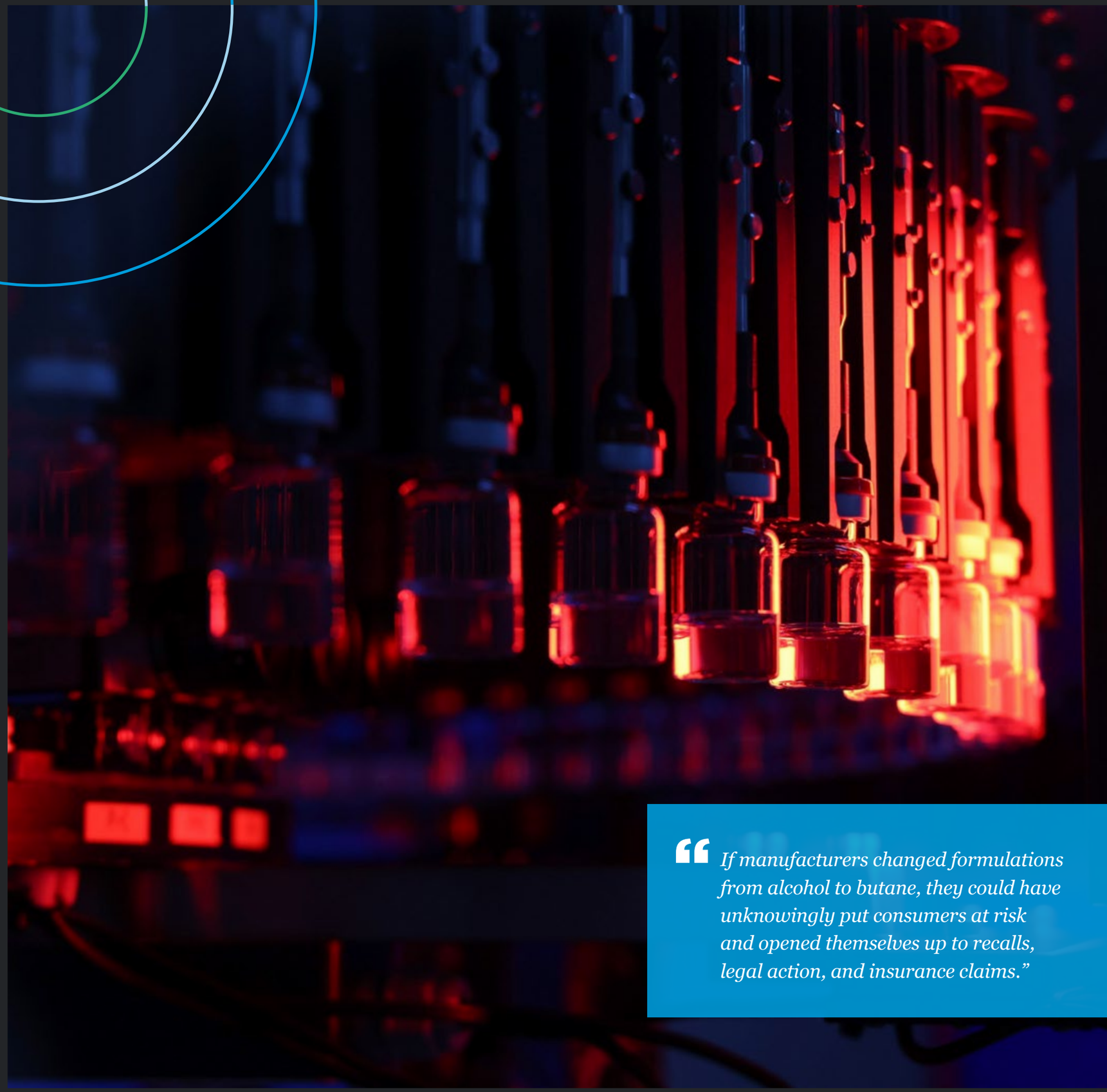
In those cases, due diligence will be especially important. This applies to both regulatory due diligence to ensure products will meet the necessary requirements and also due diligence to mitigate risk of litigation.

Reducing the risk of litigation starts with having your regulatory house in order. Now is the time for companies to take stock of processes as they transition products from the EUA environment to a post-pandemic way of doing business.

PHARMACEUTICAL

COVID-19 treatments and vaccines continue to dominate the immediate concerns of the pharmaceutical industry. As companies with approved vaccines seek authorization to use these on larger populations, it's now much easier for consumers to find places to get vaccinated. The supply shortage that existed earlier in 2021 has been resolved.

Beyond the production and administering of vaccines, the pandemic continues to force some manufacturers to look for new suppliers or change formulas, which may have contributed to the growing number of benzene recalls. It is expected that benzene will continue to be a concern in 2022.



> *"If manufacturers changed formulations from alcohol to butane, they could have unknowingly put consumers at risk and opened themselves up to recalls, legal action, and insurance claims."*

Emergency use authorizations (EUAs) continue to play a critical role

The COVID-19 pandemic has opened the door to an unprecedented number of products to which the FDA has granted Emergency Use Authorization (EUA). A study published in December 2021 by the Journal of the American Medical Association reports that between January 1, 2020 and January 22, 2021, 393 products were granted EUAs for COVID-19–related purposes. By June 2021, that number had risen to 600, though some EUAs have been revoked.

It is expected that the FDA will continue to grant EUAs in an effort to try to end, or at least contain, the pandemic. In December 2021 alone, two new drugs to treat COVID-19 and one drug for pre-exposure prophylaxis for prevention of COVID-19 were granted EUAs. As pharmaceutical companies seek these special authorizations, they should make sure that they are not rushing anything on compliance and recall preparedness.

Even though the requirements for EUAs are different than for normal FDA approvals, there are still safeguards and testing that must be submitted as part of the application. However, some factors like interactions with other drugs or side effects may become evident as the drug is used in the larger population. Companies need to be ready to act quickly if there is a recall because they will be under greater scrutiny for EUA drugs than for a drug that went through the more traditional approval process.

New guidance on real-world data and evidence

In December 2021, the FDA responded to the mandate under the 21st Century Cures Act to issue guidance on the use of real-world evidence (RWE) in regulatory decision-making by releasing a draft guidance document entitled, *Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products*.

Supporters of RWE believe it can, and should, play a role in informing the FDA, patients, healthcare providers, and other stakeholders about treatment effects among underrepresented populations across therapeutic areas. Some groups feel that clinical trial study populations are typically not fully representative patient populations and RWE and real-world data (RWD) can give a more complete picture of efficacy and safety.

The focus of this guidance is primarily on observational, or non-interventional studies. It looks at how 21 CFR (Code of Federal Regulations) Part 312 could be applicable to studies that use RWD and clearly defines certain terms. It also addresses the FDA's expectations related to studies using RWD in support of a regulatory decision for the safety and effectiveness of a drug.

Companies with new drugs in the pipeline, or plans to launch new drugs and have an interest in incorporating RWE, would do well to review the proposed guidelines and provide input to the FDA. Interested stakeholders have until March 8, 2022, to submit comments on the draft guidance.

Beware of benzene

Supply chain issues and manufacturing shortages due to the pandemic caused many businesses to look for new suppliers to keep their operations running smoothly. However, the need to bring on new vendors to meet output demands has also put manufacturers at risk of receiving products that do not meet their normal standards, and have not been thoroughly vetted through their typical safety and compliance processes.

This may be why we have seen a rise in benzene and benzene-related recalls in products in 2021. The FDA issued five recalls in 2021 for unsafe levels of benzene, an ingredient linked to cancer in humans. The affected products ranged from hand sanitizer and sunscreen, to deodorant and shampoo. Four of these recalls came in the fourth quarter, impacting more than three manufacturers, 11 brands, and more than 47 million units and counting. Typically, benzene is classified as a cGMP deviation in the recent recall activity, though it has also been involved in contamination recalls in 2021.

It is suspected that the high levels of benzene reported are linked to the use of butane as an aerosol spray propellent. Aerosols that used alcohol as a propellant instead were likely to have much lower levels of benzene present. If manufacturers changed formulations from alcohol to butane, they could have unknowingly put consumers at risk and opened themselves up to recalls, legal action, and insurance claims.

Companies need to prioritize quality control now more than ever if they produce, distribute, or sell aerosols. Their products must meet or exceed FDA guidelines for the presence of harmful contaminants. It would also be wise to review and, if necessary, update crisis, recall, and remediation plans to avoid benzene contamination and minimize risk, to consumers and to the company's reputation and operations, if there is a recall.

Pharma industry policing itself over ethics

On January 1, 2022, the Pharmaceutical Research and Manufacturers of America's (PhRMA's) updated Code on Interactions with Health Care Professionals went into effect. The voluntary code is designed to help pharmaceutical companies maintain high legal and ethical standards in their relationships with healthcare professionals. Some of those relationships were called into question by the Department of Health and Human Services' (HHS') Office of Inspector General (OIG). In its November 2020 Special Fraud Alert the HHS looked at potential abuse and fraud, especially around healthcare professionals being paid large sums for speaking at or participating in pharmaceutical company events.

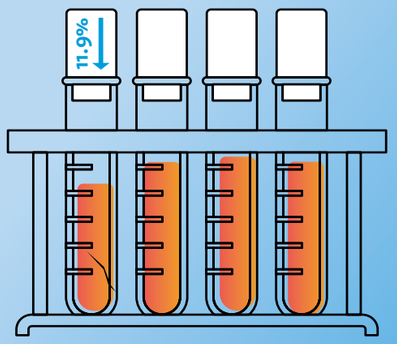
While PhRMA's new code is not legally binding, companies that adopt its rules are less likely to run afoul of federal fraud and abuse laws like the Anti-Kickback Statute. Several states have incorporated the new guidelines into their own laws, including California, Connecticut, Massachusetts, and Nevada, as well as the District of Columbia. This makes the code enforceable in those jurisdictions.

The updates in PhRMA's revised code address the same five areas covered in the OIG Special Fraud Alert: Speaker, Event, Venue, Food, and Attendees. However, it goes beyond just company-sponsored speaking events, which were the primary focus of the OIG document. The PhRMA version also includes situations such as healthcare professional consulting or presentations at internal company events. In addition, It emphasizes that its rules apply to both virtual and in-person events.

For pharmaceutical companies operating in jurisdictions where these guidelines have become law, it will be important to make any changes to events to comply with the new code. Even if companies aren't legally bound to follow these rules, from a reputation and risk management standpoint, it would be a good practice.

> *"While PhRMA's new code is not legally binding, companies that adopt its rules are less likely to run afoul of federal fraud and abuse laws like the Anti-Kickback Statute."*

Pharmaceutical recall events in 2021 were **11.9% below** their 10-year annual average (274 vs 311).

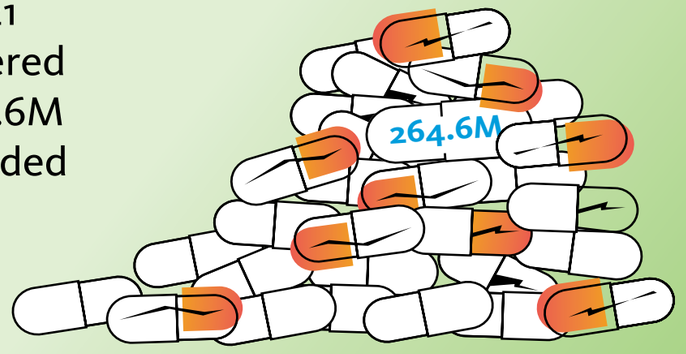


Only two other years have recorded a lower number over this period: 243 (in 2012) and 239 (in 2015).

Accounting for 63 events, **Failed specifications was the leading cause** of recalls in 2021 (23.0%).

Prior to 2020 and 2019 (when cGMP deviations dominated), Failed specifications had been the leading cause of recalls for 3 consecutive years.

Impacted units in 2021 doubled those registered in the year prior (264.6M vs 132.8M), and exceeded the 10-year annual **average of 144.1M**.



In the last 5 years, only 2 quarters have seen a single cause exceed 100M units. No quarter on record has seen a single cause account for such a high percentage of overall units recalled.

2021 BY THE NUMBERS

Pharmaceutical recalls dropped by 23.3% in the fourth quarter of 2021 to 66 events, marking the lowest number of fourth quarter recalls in the past five years. While the number of events went down, the number of units rose sharply to 102.6 million, a 169.1% increase compared to the third quarter. A single recall for failed stability specification for acetaminophen accounted for 51.5 million units - more than half of all total units impacted in the quarter. Compared to 2020, the year finished with 20.3% fewer events (344 vs 274), but double (99.2%) the units impacted (132.8M vs 264.6M).

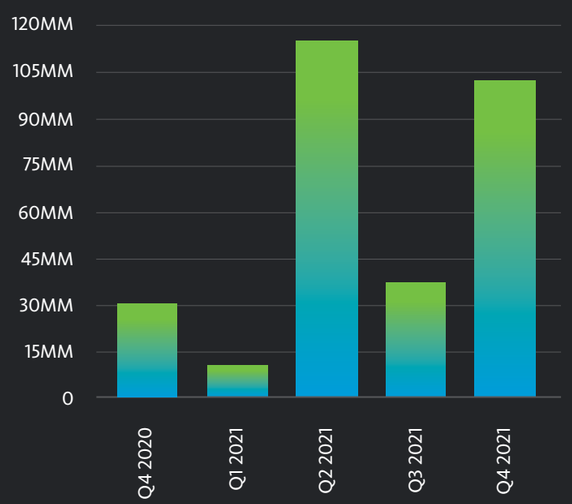
Failed specifications was the top cause of fourth quarter recalls both in terms of events and units, largely driven by the acetaminophen recall. There were 17 total recalls (25.8%) and 52.5 million units (51.0%) related to failed specifications. Sterility concerns accounted for 11 recalls and cGMP deviations saw nine in the fourth quarter, a drop of 50% compared to the previous quarter.

In terms of units, cGMP deviations had the second most units impacted with 47.9 million. Most of these were from two separate benzene-related events – a recall of 23.5 million units of sunscreen and another recall involving 22.8 million units of deodorant powder spray. There were only three recalls documented as hand-sanitizer products in the fourth quarter, compared to 11 in the third quarter.

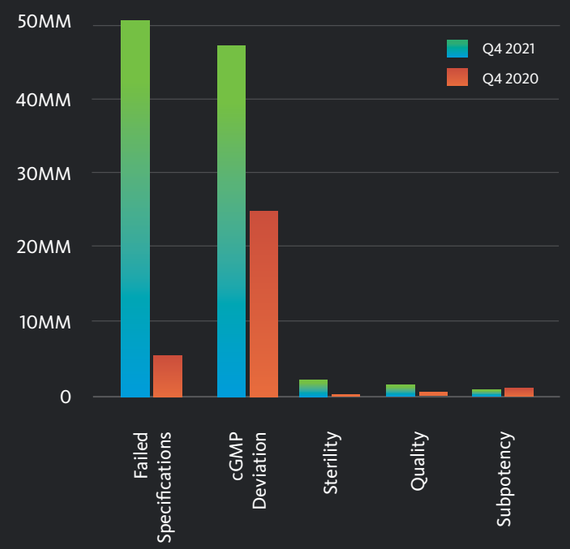
The FDA classified 8 (12.1%) of fourth quarter 2021 recalls as Class I, which are the most serious. These recalls impacted approximately 299,000 units. Class II recalls accounted for 45 recalls (68.2%) impacting 49.8 million units. The remaining 13 recalls (19.7%), which impacted 52.5 million units, were designated as Class III. This was the only class to see an increase in the number of recalls in the fourth quarter, though all three categories saw an increase in the number of units recalled.

Of the pharmaceutical recalls in the fourth quarter, 54 (81.8%) impacted products nationwide. Four recalls (6.1%) impacted products distributed internationally.

NUMBER OF RECALLED UNITS BY QUARTER



NUMBER OF RECALLED UNITS BY REASON IN Q4 YOY



JANUARY insight

There were 32 pharmaceutical recalls by the FDA in January 2022, up 39% from January 2021. This figure is also higher than the monthly average of 23 recalls for all of 2021. Five of the January 2022 recall events received the FDA's Class I designation.

Recalls in January 2022 impacted approximately 29 million units. This is significantly higher than the 4.9 million units recalled in January 2021. It is also an increase compared to the 22 million units recalled on average each month in 2021. The jump in the number of units was primarily triggered by one recall for pain reliever that impacted 26.5 million units.

CONCLUSION

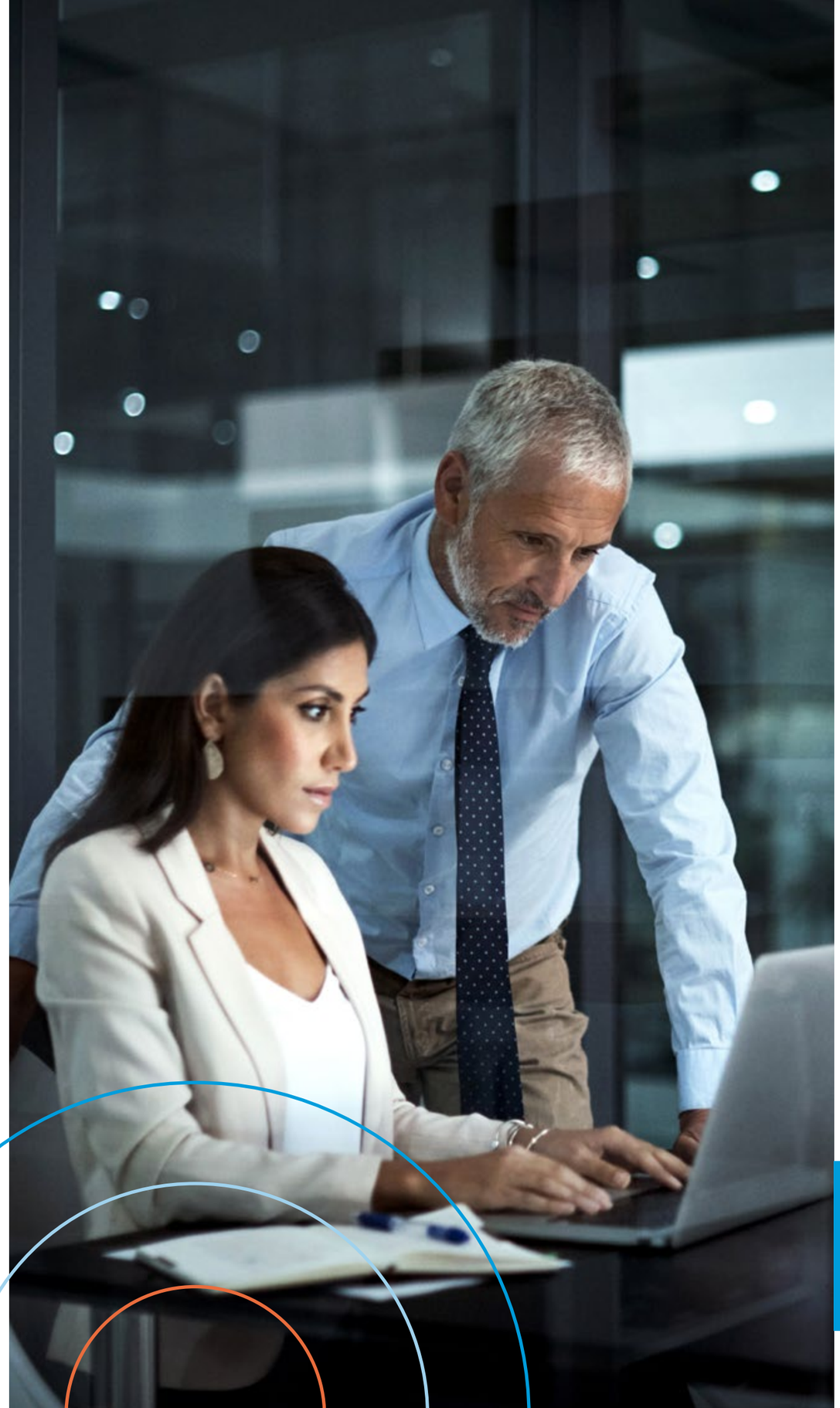
The ongoing global health crisis means continued uncertainty in terms of supply chains, normal business operations, and regulatory oversight. It does seem that the Biden administration will continue to push for regulations and regulators who put consumer safety and fair pricing first. However, any changes that require Congressional approval may be stalled.

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

While no one wants to admit that they will face a product recall, if plans to mitigate such instances are tested and updated – and become as routine as other business processes – then when the inevitable occurs, both your brand and bottom-line will remain protected.

Working with an expert partner to leverage their experience and insights can help deliver significant saving in regulatory and litigation costs, as well as time and 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.

But we haven't just watched it, 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.

So, while we predict continued change in 2022, it's nothing we haven't seen or dealt with before. In fact, it's often that these events, even what feels like a devastating product 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.

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