RECALL INDEX 2021 EDITION 1

PRODUCT RECALL

UNITED STATES EDITION

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

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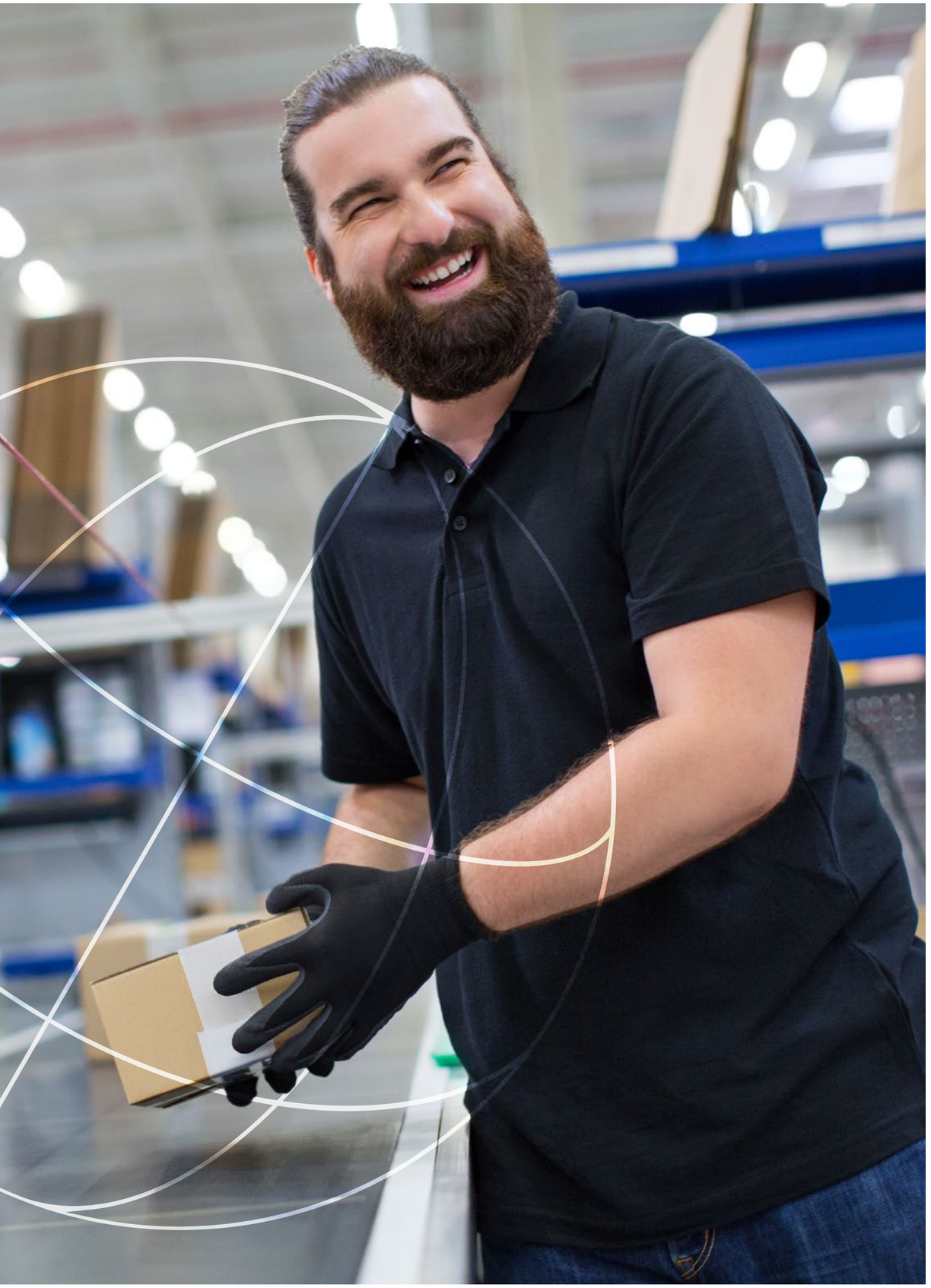

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The Sedgwick brand protection recall index is an essential reference for manufacturers and retailers seeking impartial and reliable perspective on past, present and future recall data and product safety trends.

The index collects and analyzes data from the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and the U.S. Department of Agriculture (USDA), providing businesses with insights and guidance they cannot find elsewhere.

This edition brings you data from the first four months of the year, as well as expert analysis and predictions for what to expect for the remainder of 2021 as business leaders prepare to emerge from a global pandemic that changed the regulatory landscape, political climate, market drivers and consumer behavior.

We also feature insight from some of our strategic partners at leading law firms and insurance companies to further help you prepare for the increased risks created by product innovations and evolution in the regulation of food, drugs, consumer products, medical devices and automobiles.

Under a new Democratic administration, U.S. lawmakers on both sides of the aisle and consumer advocacy organizations are maintaining their pressure on regulators to crack down on unsafe products. As a consequence, there has never been a more important time for companies to prepare for the increased scrutiny and reputational risks that come before, during and after a product recall or in-market remediation.

We trust you will find our analysis and predictions insightful. Whether you read it cover-to-cover or focus on sections of particular importance to your company or industry, you're sure to learn a great deal about what is happening today as well as gain valuable insight and perspective on future events that may impact your business.

As a reminder, this edition of the Sedgwick brand protection recall index focuses on U.S. recall data and regulatory developments. If your business also includes operations outside the U.S., 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:

European edition available here: LINK

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

Q4 2020 U.S. recall index: LINK

Q3 2020 U.S. recall index: LINK

Q2 2020 U.S. recall index: LINK

Q1 2020 U.S. recall index: LINK

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SUMMARY

As vaccines become widely available and business and travel restrictions are lifted, companies and consumers are finding their way back to normalcy. But that path will require adjustments along the way. Not every consumer, employee or business is ready or willing to make the transition to a post-COVID-19 way of life at the same pace. But regardless of the speed at which the entire country returns to business as usual, risks to brand and reputations will only increase.

Regulatory risk. First and foremost, expect oversight activities and enforcement action to accelerate. Whether inspections take the form of remote evaluations or on-site audits, inspectors will be looking broader and deeper – both in terms of reviewing documentation and environmental sampling – for evidence that companies are not only compliant now but have been so over the last 12 months or more.

To that end, a global life sciences update from the team at Sidley Austin warns companies to maintain inspection readiness, noting that companies "can be expected to be called on to address any differences in manufacturing methods implemented during COVID to ensure that any deviations are properly justified, documented, and consistent with applicable good manufacturing practice requirements." This is important advice, particularly given how frequently these types of inspections and compliance inquiries lead to recalls or other enforcement actions.

Keep in mind that the list of regulatory agencies watching is growing. An increasing number of products are finding themselves in the crosshairs of several regulatory agencies, from the traditional CPSC, FDA, USDA and NHTSA oversight to growing scrutiny by the Federal Trade Commission (FTC), the Department of Justice (DOJ) and the U.S. Environmental Protection Agency (EPA).

Legislative risk. Our prediction that regulators would embark on new rulemaking and regulations under the Biden administration appears to have been correct. We've already seen Congress act on several product safety issues – take the new Stop Tip-overs of Unstable, Risky Dressers on Youth (STURDY) Act for example. We also know NHTSA will be embarking on a formal whistleblower protection and the CPSC has publicly asked for increased funding to reinvent itself in response to safety concerns triggered by innovation, technology and the nature of ecommerce marketplaces. While these changes take time to implement, companies and industries would be wise to engage now in pre-emptive conversations on Capitol Hill with lawmakers about product safety matters.

Legal risk. Companies will also face mounting litigation risks as courts work to reduce their backlog. As we mentioned in previous index reports, the pace of new lawsuits did not stagnate amid the pandemic. In fact, the plaintiffs' bar has remained persistent in finding and filing new cases as we start to see a surge in COVID-19-related lawsuits. Those will only increase further as the plaintiffs' bar tests the liability protections and limitations of the Public Readiness and Emergency Preparedness Act (PREP Act).

Reputational risk. Negative publicity and deficient response to any of the above risks can deeply erode your brand and reputation. But a variety of other corporate product safety decisions can have the same effect. Consider companies that hold fast to a decision not to recall a product perceived as unsafe. Their reputation is arguably facing more damage in the long run because of ongoing negative publicity, regulatory scrutiny, enforcement actions, civil or criminal penalties and litigation, and which bear no burden on your decision to recall a product. On top of that, you may ultimately face the financial burden and brand damage resulting from a recall that can ultimately follow months of fighting a regulator or consumer advocacy group. All this spells reputation damage when you could have bolstered your reputation by acting out of an abundance of caution.

AUTOMOTIVE

At the outset of 2021, safety concerns related to electric vehicles and new technology remained at the forefront. As electric battery and charger recalls play out, the industry faces significant hurdles in building consumer confidence needed to meaningfully deliver on their electrification promises. But that's only the start of what promises to be a series of component-related recalls to come in 2021.

Consider concerns related to features and software rather than tires and air bags – risks associated with autonomous driving features and data privacy for example. While in some cases the remedies required for these safety issues may not require a trip to the mechanic, the shifting definition of "safety" (to include consumer privacy) and the availability of much-relied on features will create new reputational challenges for automakers. Likewise, these challeges will equally be felt by the technology companies delivering the software and programming to enable this new driving experience.

> *"As electric battery and charger recalls play out, the industry faces significant hurdles in building consumer confidence."*

If you have any doubt of the level of scrutiny placed on new technology and features, consider the challenges facing leading innovator brands in the electric vehicle space. Amid mounting skepticism from the news media, consumer advocates and automotive rivals over their safety assurances, Consumer Reports sternly warns that "early production teething problems are an all-too-common affliction with all-new or heavily redesigned models."

While these risks often fall squarely on the shoulders of automakers and original equipment manufacturers, reputational risks and regulatory scrutiny will only increase as NHTSA faces pressure from lawmakers on everything from investigation decisions to delays in rulemaking and, most recently, establishment of a whistleblower program.

Take for example Sen. Richard Blumenthal's (D-Conn.) criticism for NHTSA for not opening an investigation into an allegedly defective steering sensor and requested the agency share "all information about the defective safety feature and NHTSA's inexplicable failure to open an investigation into the matter." Decisions to investigate potential safety issues have long been a core competency for NHTSA. To the extent that competency continues to be questioned, expect the agency to default to opening investigations with the intention of finding safety risks or violations.

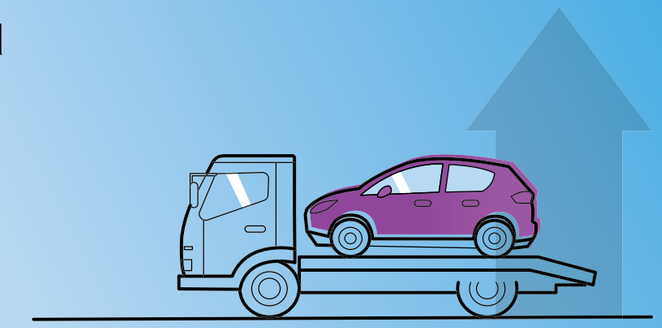
Meanwhile, an official whistleblower program is back on the priority list at NHTSA. According to a spokeswoman for NHTSA, the Biden administration is currently developing rules for the program, which is intended to emulate the whistleblower process established by the Securities and Exchange Commission (SEC) in 2011.

In fact, the SEC program offers insights into the regulatory and reputational risks that can arise from government-funded whistleblowing. A 2020 annual report to Congress on the SEC whistleblower program found that, "in FY 2020, the Commission awarded approximately $175 million to 39 individuals — both the highest dollar amount and the highest number of individuals awarded in a given fiscal year." In the roughly 10 years that the program has been in place, the SEC has received more than 40,200 whistleblower tips. Even a fraction of this activity could be devastating to the automotive industry, particularly amid a transformative movement from traditional combustion engines to electric vehicles and other technology-driven innovations.

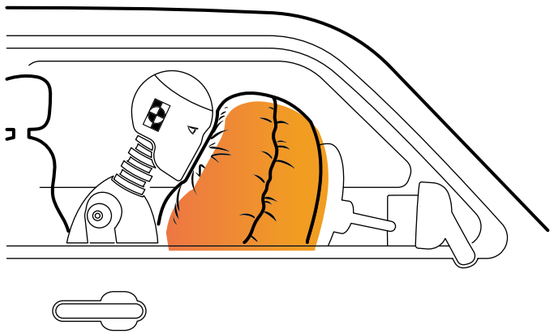
Automotive recall effectiveness is already a hot-button issue among regulators and lawmakers. Now consider how recalls are going to evolve with innovation and technology leading the way. These changes demand the same technology-led innovation in recall management. Your reputation depends on it.

> *"Automotive recall effectiveness is already a hot-button issue among regulators and lawmakers. Now consider how recalls are going to evolve with innovation and technology leading the way."*

Q1 recalls impacted 13.5M units, an **82.5% increase** on Q4 2020



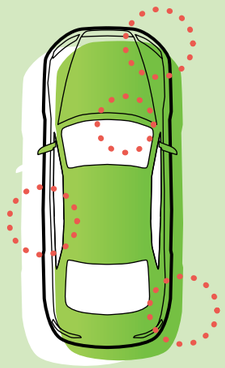
Over the past 3 years, Q1 recalls have impacted more units than any subsequent quarter.



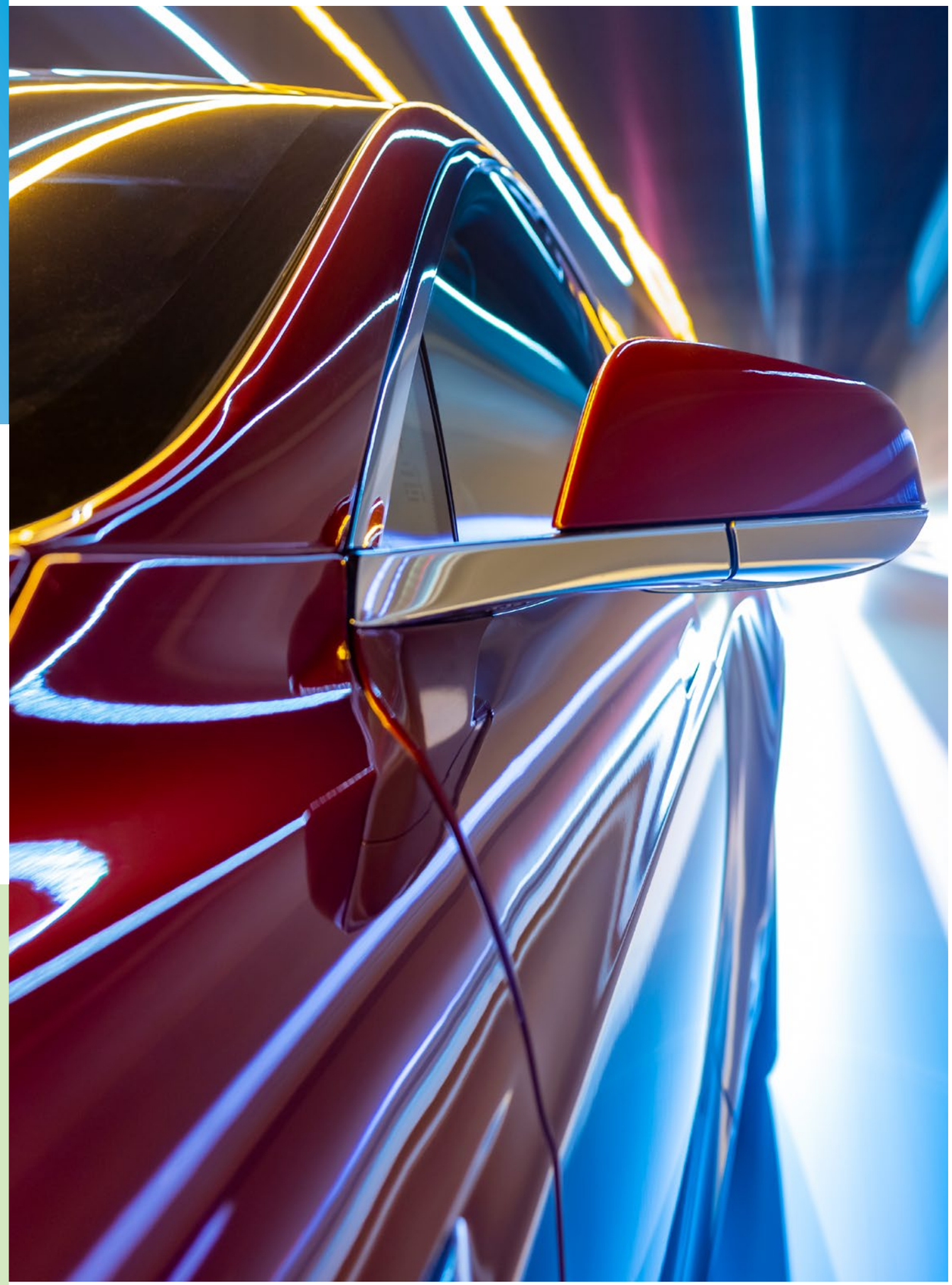
At 8.8M (65.2%), **Air bags** accounted for the greatest proportion of Q1 recalled units

Despite the original Takata defect filing date of May 2016, automakers continue to work through the regulatory scrutiny and safety concerns related to air bags and inflators.

Accounting for 26 recalls (14.2% of events), **Equipment** remained the **top cause of NHTSA recalls**



Equipment has remained the top cause of Automotive recalls for 15 of the past 16 quarters.



APRIL INSIGHT

We saw 59 automotive recalls in April, representing a marginal decline (of 3.3%) in the average monthly total experienced in quarter one (of 61 recalls). These recalls impacted just 1.4 million units compared with a monthly average 4.5 million units in the first quarter. The leading cause of April recalls was electrical systems with 12 recalls, followed by structure concerns at 10 recalls and Steering issues at 9 recalls.

FIRST QUARTER BY THE NUMBERS

First quarter 2021 recall activity remained steady compared with the average quarterly volume of recalls we saw in 2020. As noted in the 2021 state of the nation recall index, this quarterly activity remains at least 20 recalls lower than the quarterly average logged from 2014 through 2019.

First quarter recalls impacted 13.5 million units, representing an 82.5% increase compared with the fourth quarter of 2020. Over the past three years, first quarter recalls impacted the most units of any subsequent quarter. We will be watching to see whether this trend continues in 2021.

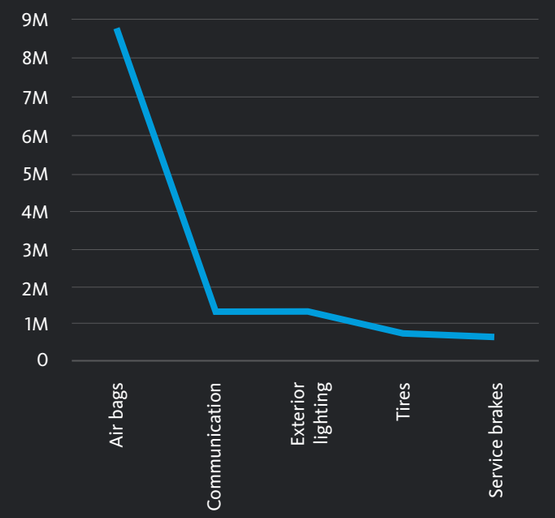
Accounting for 26 recalls, or 14.2% of events, Equipment remained the top cause for NHTSA recalls for 15 of the past 16 quarters.

Air bag recalls impacted the most units at 65.2% of all recalled units. Looking closer at this category, we saw 20 recalls accounting for 8.8 million units in the first quarter alone. In comparison, 2020 logged 46 recalls impacting 19.3 million units. Despite the original Takata defect filing date of May 2016, we are still seeing automakers work through the regulatory scrutiny and safety concerns related to air bags and inflators.

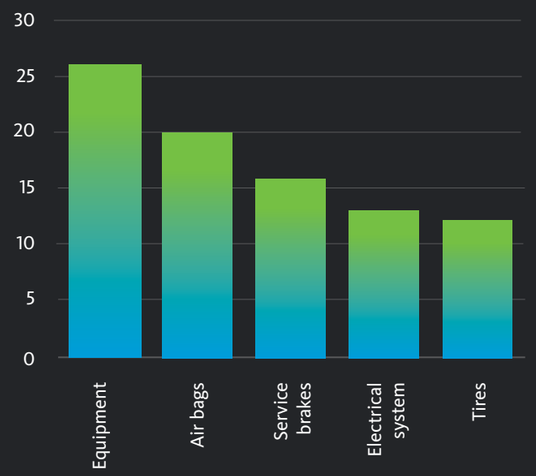
Automobiles continue to be the largest category of NHTSA recalls, accounting for 89% of first quarter recalls. Eighteen recalls impacted equipment and three impacted tires.

It is also important to keep a close eye on some of the less common, but increasingly frequent and impactful causes of automotive recalls including hybrid propulsion systems, forward collision avoidance, electronic stability control, communication systems, lane departure features and vehicle speed control. Many of these features are a reminder of the innovation and technological advances that are progressing toward electric vehicles and onward to autonomous vehicles. While we haven't seen significant activity in these areas so far in 2021, there were record numbers in 2020, followed by an ongoing stream of complaints filed with NHTSA.

NUMBER OF UNITS RECALLED BY CATEGORY



NUMBER OF RECALLS BY REASON



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NEW-AGE AUTO SAFETY RISKS HAVE ROOTS IN CYBERSECURITY AND DATA PRIVACY

Vehicle safety used to be relegated to equipment or components that created inherent safety risks. In these terms, passenger vehicles are arguably safer than they have ever been. But cars have become increasingly sophisticated in recent years, and the definition of automotive safety is expanding to include risks like cybersecurity and data privacy.

Data collection is nothing new. It is inherent in the world we live in today. Nearly every organization collects, stores and leverages information across their business - from corporate data about customers and business partners to personal information about consumers.

While vehicles are not traditionally top of mind when consumers think of data and security concerns, the automotive industry has been planning for potential risks resulting from cyberattacks ever since college students remotely hacked and took down a vehicle in 2015. Whether the potential safety or security incident stems from technology including GPS and Bluetooth or features like autonomous driving, the regulatory, legal and reputational impacts could be significant.

Preparing for and mitigating privacy and cyber threats come down to how automakers and Original Equipment Manufacturers (OEMs) handle data. Regardless of which local, state, federal or jurisdictional data and privacy regulations apply, there are three main pillars to privacy that must be considered.

Providing Notice. Companies should ensure they provide clear notice to consumers about what data can be accessed by the vehicle, what information is saved or collected, and, where appropriate or mandated, how consumers may access their data.

Determining Ownership. Automakers and OEMs are increasingly evaluating the topic of data ownership across the automotive sector – from personal vehicles and rental cars to commercial agribusiness or freight applications. To the extent possible, manufacturers and OEMs should be very intentional about the data they collect and avoid collecting data that does not align with their ultimate goals.

Securing the Data. While notice and ownership concepts are important, the ultimate challenge – and critically important aspect – is data security. The type and scope of data that can be collected is vast and constantly evolves almost daily. Companies across every industry need to ensure that the data that is collected is securely maintained. To the extent the data constitutes Personal Identifiable Information (PII), automakers and OEMs should take extra care to ensure it is collected and stored in secure manner that comports with the appropriate state regulatory scheme.

Where official data and privacy laws exist, companies should also be mindful of the unique differences across state and international regulatory schemes. In the absence of laws and regulations, automakers and OEMs can look to traditional sources of law for guidance.

The world of data security is here to stay. Companies need to take steps now to identify and prepare for and mitigate these risks, which include identifying potential security challenges based on any number of potential scenarios.

It is only a matter of time before cybersecurity and automotive risks collide in a way that could lead to global headlines, regulatory enforcement and litigation. As technology continues to evolve, constant attention must be paid to risk mitigation and crisis planning. A rapid, effective response is essential to protecting your brand and reputation.

> *"As the CPSC continues to seek relief from Section 6(b), it's clear that the agency is not going to allow itself to be handcuffed. Expect the CPSC's recent posture to be further emboldened by legislative action in Congress."*

CONSUMER PRODUCTS

The CPSC story in 2021 will be less about recall numbers and more about the agency's new-found, gloves-off approach to oversight and enforcement. Expect recalls to maintain their typical pace in the near-term, bolstered by alarming public safety announcements, fines and investigations – which could ultimately spark category-wide product investigations and recalls.

We have seen exceptional news from the CPSC over the last six months: a public penalty referral to the Department of Justice, the first civil penalty in more than a year, and public-safety warnings calling on consumers to stop using products not-yet recalled. As the CPSC continues to seek relief from Section 6(b), it's clear that the agency is not going to allow itself to be handcuffed.

Expect the CPSC's recent posture to be further emboldened by legislative action in Congress. This movement started with the $50 million stimulus for the CPSC to increase its oversight of toys and other imports in response to reported COVID-19 lapses. New legislation, including the STURDY Act, seeks to better protect consumers from furniture-related risks. Lawmakers and regulators are likely to take a similar approach that focuses on specific product-safety risks associated with products such as high-powered magnets, button batteries, phthalates, infant products and exercise equipment.

> *Manufacturers and retailers would be wise in 2021 to take a fresh look at their product safety programs. Double-check processes up and down the supply chain."*

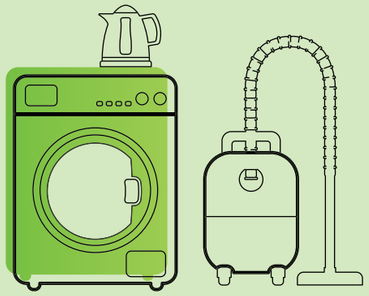
Meanwhile, the CPSC is petitioning Congress for funding that goes beyond simply increasing enforcement activities. To more than a few observers, it seems the agency is seeking to reinvent itself to better protect consumers from risks posed by evolving technology – from e-commerce platforms where the agency's oversight has been largely absent, to hazards not currently defined within the agency's portfolio. This would include everything from chronic hazards like flame retardants and playground crumb rubber to risks posed by software, including artificial intelligence (AI) and internet of things (IOT), where standards are undeveloped and products go untested.

Taken in its entirety, Foley & Lardner LLP attorneys Kristin McGaver and Erik Swanholt warn that the "ambitious budget request signals a potential avalanche of additional recalls should the CPSC get the resources it seeks for 2022." But the recall event itself is only the start of trouble for companies when it comes to regulatory, legal and reputational risk. This is especially true for big brands in 2021. Lawmakers and regulators are always seeking a poster child for non-compliance, and plaintiffs' attorneys are constantly trying to exploit safety issues for monetary damages.

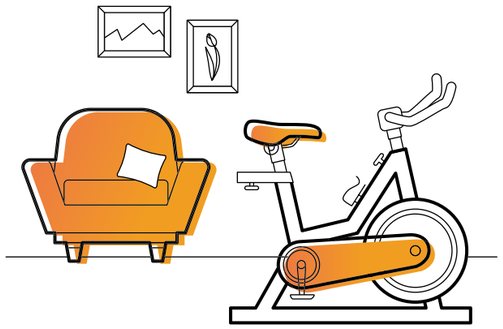
Manufacturers and retailers would be wise in 2021 to take a fresh look at their product safety programs. Double-check processes up and down the supply chain. Thoroughly understand evolving safety risks and how they could be applied to your product. Re-vet your suppliers and their quality assurance programs. Update your crisis plans, and then test them with mock recalls.

Effectively mitigating the reputational impact of a recall or other enforcement action requires a deliberate commitment to safety that starts long before the product is ever called into question.

The CPSC announced **just 47 recalls** in Q1, impacting 3.4M units



This represents the lowest number of quarterly events since Q1 2019, and a 46.0% decrease in impacted units compared to Q4 2020.



Sports & Recreation and Home Furnishings & Décor products **each faced 13 recalls** in Q1

Accounting for 55.4% of events (combined), these remain the top 2 recalled categories since 2012.

Home Furnishings & Décor recalls impacted **2.5M units** (75.3% of all units recalled in Q1)

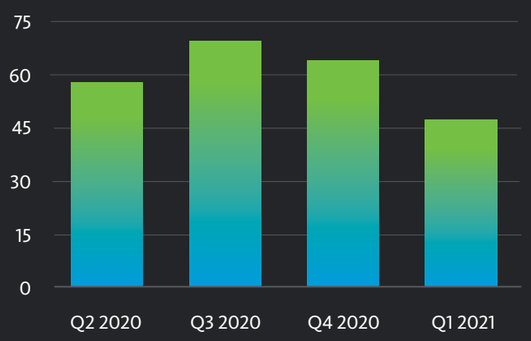
Of these, 2.3M (92.0%) were recalled due to injury risk.

FIRST QUARTER BY THE NUMBERS

The CPSC announced just 47 recalls in the first quarter of 2021, the lowest quarterly total since the first quarter of 2019. These recalls impacted 3.4 million units. The quarterly volume reflects a 28.8% decrease in events and 46.0% decrease in impacted units compared to the fourth quarter of 2020.

We also saw a 77.4% decrease in reported incidents, dropping from 1,859 incidents in the fourth quarter to 421 incidents in the first quarter. Similarly, there was a 97.7% decrease in injuries from 310 to just 7 injuries.

NUMBER OF RECALLS BY QUARTER



Sports and Recreation and Home Furnishings and Décor products continue to be the top two product categories impacted by recalls for more than nine years (since 2012). Both categories faced 13 recalls, each representing 27.7% of first quarter events. Together the categories accounted for 55.4% of all recalls.

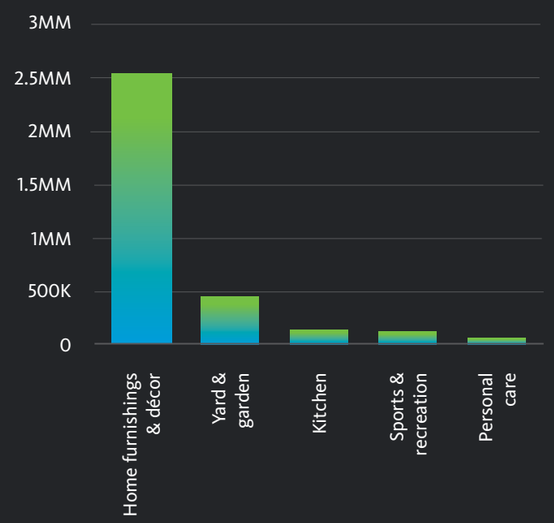
The number of impacted units, however, differed significantly. Home Furnishings & Décor recalls impacted 2.5 million units (75.3% of all recalled units). Of these units, 2.3 million were recalled due to injury risk. These recalls accounted for 204 or nearly half of all reported safety incidents.

Sports and Recreation products impacted some 110,000 units. Approximately half of those were recalled due to fire risk. Sports and Recreation products accounted for five of seven injuries reported in connection with recalled products. These recalls were also linked to 82 incidents.

Despite recent heightened publicity about concerns related to exercise equipment, there hasn't been a significant increase in recall events or units impacted. More noteworthy, we have not seen a significant increase in incidents or injuries officially linked to recall events. That said, the category is frequently at the top of recall lists, and when a recall does occur, it typically makes national headlines. That fact alone should serve as a further reminder for companies in the category to implement strong customer-satisfaction campaigns, while preparing for regulatory scrutiny, product recalls and well-publicized enforcement action.

It is worth noting that the third quarter is traditionally the quarter with the highest number of toy recalls. This held true in 2020, but after not logging any recalls in the fourth quarter amid concerns about toy safety raised by consumer advocates, media and even Congress, we saw an increase in toy recalls in the first quarter of 2021.

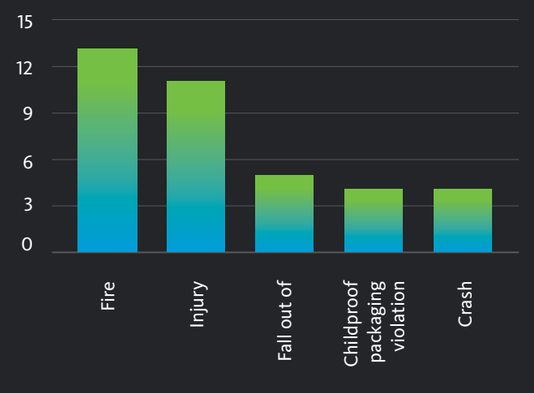
NUMBER OF UNITS RECALLED BY CATEGORY



While accounting for a small number of recalls and units, personal care products remained a focus for the agency, accounting for four recalls due to childproof packaging violations.

Fire risk was the top cause of first quarter events at 13 or 27.7% of recalls. Injury risks was the leading cause of recalled units, impacting 2.4 million units – 70.4% of all recalled units.

NUMBER OF RECALLS BY RISK TYPE



APRIL INSIGHT

April brought 23 consumer product recalls, nearly half the number of recalls documented for the entire first quarter (48.9%). This activity brings the year-to-date recall total to 70 events. April recalls impacted about 5.6 million units, compared to 3.4 million units impacted during the entire first quarter. This significant increase is the result of three events that impacted 1.3 million units or more.

The categories most impacted by April recalls were personal care and sports & recreation products, each facing 4 recalls. The leading cause of recalls was fire risk, accounting for 8 recalls.

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TODAY'S CONSUMER PRODUCT SAFETY COMMISSION—AGGRESSIVE AND VOCAL

We are on the cusp of dramatic changes at the Consumer Product Safety Commission (CPSC). From new policy and likely rulemaking to a gloves-off approach to enforcement, the CPSC has adopted a more public and aggressive approach to protecting consumers from unreasonable risks of injury from consumer products.

While some may have expected the agency to wait to ramp up enforcement until Democratic appointees were in a majority on the five-person Commission, the CPSC's latest enforcement efforts demonstrate that Acting Chairman Robert Adler intends to be a "caretaker" no more. Echoing several recommendations outlined in a Product Safety Memorandum to the Biden Transition penned by several public interest organizations, Acting Chairman Adler told International Consumer Product Health and Safety Organization (ICPHSO) annual meeting attendees in February that industry should expect more enforcement, unilateral press releases and more civil penalty cases.

The CPSC's shift appears to be backed by Congress. This March, lawmakers dramatically increased the CPSC's $135 million annual budget with an additional $50 million over 5 years for increased enforcement at the ports. Congress directed the CPSC to screen 90% or more of consumer products entering U.S. ports that are "risk-scored in the [CPSC] Risk Assessment Methodology system."

Acting Chairman Adler has long contended that the CPSC, with 15,000 different consumer product types under its jurisdiction, is woefully underfunded by Congress. In March, he asked the House Appropriations Committee to more than double the CPSC's annual budget to $280 million and an additional one-time $89 million appropriation. Adler stated that the CPSC needed to "reinvent" itself to address today's commerce with vigorous compliance, robust port surveillance, a new E-Commerce Division and an expanded Internet Surveillance Unit.

As the CPSC continues to find its new footing during the Biden administration, consumer product companies would be wise to reevaluate their product safety compliance and crisis preparedness programs to ensure they are designed and operating effectively.

CPSC is no longer afraid to get on a soapbox

The CPSC has long chafed under Section 6(b) of the Consumer Product Safety Act's (CPSA) restrictions and the agency's perceived inability to alert consumers about product safety issues in the absence of an agreement from the involved company. Recently, however, the agency found a way to go public on a product safety issue without legislative changes to Section 6(b).

In the past, the CPSC often issued unilateral press releases for categories of products like hoverboards, products with lithium-ion batteries and inclined baby sleepers. But the agency's most recent public product safety warning got specific. In April, the CPSC warned consumers about product safety risks related to Peloton's popular Tread+ treadmill, encouraging consumers to stop using the product. Peloton responded by refusing to conduct a voluntary recall of the Tread+ because, according to the company, the Tread+ was safe when consumers followed the product's safety instructions and warnings.

The resulting publicity—several networks' nightly news segments and hundreds of published reports—had exactly the intended effect. Within weeks, the increased consumer awareness, substantial adverse publicity, stock price decline and actual and threatened lawsuits led Peloton to change its position, agreeing to conduct a full recall of its Tread and Tread+ products. This result almost guarantees the CPSC will take this approach again. Motivated by its desire to protect the public from unreasonable risk of injury and to avoid being criticized by publications like ***The Wall Street Journal***, ***The Washington Post*** and ***USA Today***, the CPSC is likely to maintain its aggressive posture.

CPSC enforcement actions, including civil penalties, will increase over the coming months

Expect more enforcement actions in 2021 – from civil penalties to referrals to the U.S. Department of Justice to bring lawsuits against recalcitrant companies. Consider the $12 million and nearly $8 million civil penalty settlements agreed to early this year by fire extinguisher company Kidde and exercise equipment manufacturer Cybex, respectively. As with most civil penalty cases, the CPSC charged these companies with failing to file a timely CPSA Section 15(b) report once they had information that their products presented a "substantial product hazard." In addition, the CPSC charged that Kidde had submitted Section 15(b) reports to the CPSC that falsely underreported the scope and nature of the product defect, risk and number of products and models affected. Further, the CPSC charged Kidde with selling products bearing an unauthorized registered certification mark, because those products did not comply with that product's consensus standard.

The two publicly announced civil penalty settlements will likely be followed by additional civil penalty settlements this year. You don't have to take my word for it. Acting CPSC Chairman Adler told the ICPHSO annual meeting attendees the "unnecessary hiatus" in civil penalties has ended, adding that they would in fact become more frequent as civil penalties "are a necessary part of any properly run enforcement agency."

Take product safety risk management to the next level

Companies should learn from the two recent civil penalty cases and avoid the kind of wrongful conduct charged by the CPSC. Companies should err on the side of early reporting product safety issues to the CPSC. In addition, companies must never knowingly make a false statement to the CPSC or any other government agency.

To mitigate legal and reputational risk, companies need to be proactive and thorough in evaluating product safety concerns – especially when deciding whether and what to disclose to the CPSC. As part of that process, companies must closely monitor what is being said about its product on social media, even if no consumer has submitted a product safety complaint directly to the company.

The Consent Decrees that the CPSC required of Kidde and Cybex to resolve the civil penalty investigations provide companies a road map of what the CPSC considers to be good product safety risk management practices. Companies would be wise to review these requirements to see how your company policies match up with what the CPSC considers to be best practices.

Specifically, the recent Consent Decrees stated that internal company policies/practices must include:

- written policies that ensure CPSA compliance information reaches responsible persons, including senior management;
- procedures to review product safety reports and implement corrective actions;
- testing to determine compliance with mandatory and consensus product safety standards and full disclosure to product safety certifying bodies; and
- record retention of relevant documents for at least 5 years.

In addition, controls and procedures to ensure mandatory reporting to the CPSC must require that:

- information required by law to be disclosed to the CPSC is reported; and
- reporting to the CPSC is timely, truthful, complete, and accurate.

Companies that engage in overseas contract manufacturing must also be vigilant to prevent contract manufacturers and their subcontractors from torpedoing compliance efforts. Product testing is a must, but a passing test result on a sample that is not representative of the products your company is importing is worth little. And you are kidding yourself if your company relies on pre-production test results after a “material change” to the product’s design, manufacturing process or source of the product’s component parts.

The CPSC has made clear that the industry should expect more enforcement, unilateral press releases and civil penalty cases. As the agency becomes more aggressive and vocal, companies should evaluate their product safety compliance and crisis plans. Now is the time to make the necessary adjustments—not when the agency comes knocking.

FOOD AND BEVERAGE

Emerging from the COVID-19 pandemic, the food and beverage industry will see new food safety rules, increased oversight and enforcement, and more lawsuits. Companies should expect a continued regulatory focus on safeguarding the food supply chain, improving traceability and ultimately a return to traditional oversight activities. But if we dig a little deeper, we can see several priorities emerging.

> *“Companies should expect a continued regulatory focus on safeguarding the food supply chain, improving traceability and ultimately a return to traditional oversight activities.”*

Protecting infants and young children. In late March, U.S. Sens. Amy Klobuchar (D-Minn.) and Tammy Duckworth (D-Ill.) introduced the Baby Food Safety Act of 2021 aiming to improve the way infant and toddler foods are regulated. Soon after, the FDA in early April released its Closer to Zero plan for reducing children's exposure to toxic elements, including naturally occurring elements like arsenic, lead, cadmium and mercury. While these actions represent significant steps toward rulemaking and future enforcement, the risks to food companies do not stop there.

Numerous class-action lawsuits against food companies are underway and state attorneys general, including New York Attorney General Letitia James and D.C. Attorney General Karl Racine, have launched investigations and filed their own lawsuits on behalf of their constituents.

Expanding oversight and enforcement related to contaminants. Heavy metals are far from the only food contaminant now under scrutiny. Congress and federal regulators are also accelerating efforts to protect consumers who suffer from food allergies and other food-related sensitivities. As an example, Congress recently passed legislation requiring sesame be added to the existing list of eight major allergens subject to labeling requirements. The FDA has also issued statements and warning letters to numerous companies, demonstrating the agency's commitment to ensuring food manufacturers comply with allergen-related regulations.

Meanwhile, the USDA is holding public meetings to discuss U.S. positions at the global Codex Alimentarius Commission, which is focused on setting maximum levels of cadmium in chocolate, levels of lead in multiple food categories, radioactivity in water, methylmercury in fish and aflatoxins in spices. All may create challenges for food manufacturers.

Evaluating concerns about plant-based alternatives. One of the evolving technologies that brings the largest reputational risk is the alternative protein category. According to research published by international food and beverage flavor and nutrition solutions supplier Kerry, U.S. consumers make purchasing decisions based on how safe they perceive the food to be, whether or not the data supports their perceptions. According to an article in Powder & Bulk Solids, "49% of consumers in North America said they have concerns about the safety of plant-based meat alternatives and 51% reported concerns with plant-based dairy alternatives." The article attributes an increase in anxiety to perceived lax regulatory oversight "compared with traditional protein operations."

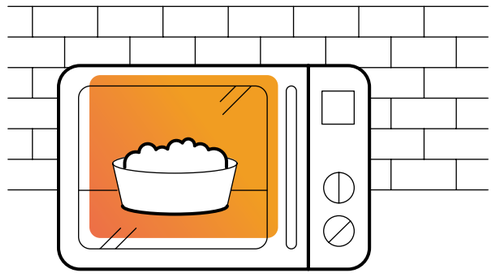
Companies operating in this space must be aware of growing concern surrounding plant-based alternatives and its potential impact on legislative and regulatory scrutiny concerns. While recall data does not currently suggest these products are any less safe for consumers to eat, one recall – especially if managed poorly – has the potential to cause the entire category to stumble.

So how do you mitigate food safety risks? Ensure a strong food safety culture. Consider this advice from one of our strategic partners, Leslie Krasny with Krasny Law Office. "Regulatory agency investigations of foodborne illness outbreaks and recalls often conclude that the root causes involved human error in implementing food safety programs," Krasny writes in a recent article published by Food Processing. "There is industry consensus that establishing a successful food safety culture requires a top-down approach, with the leadership team prioritizing the identification and maintenance of practices to influence attitudes and modify behavior, in all areas of a company," Krasny adds. "Promoting a collective mindset of greater vigilance and individual responsibility can improve performance in a supportive environment."

A strong food safety culture also prepares the company for the times when a recall or corrective action is required. Developing a plan, and then practicing how to execute it, is critical to quick effective recall management.

FDA recall activity fell from **92 recalls** in Q4 2020, to **88 recalls** in Q1 2021

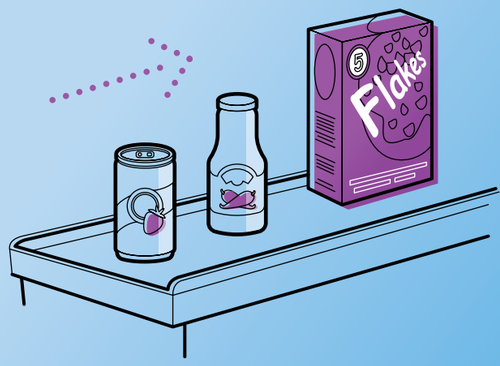
This is only the second time we have seen fewer than 90 FDA events since 2012.



Accounting for 19 recalls (21.6%), **Prepared foods was the top category** impacting Q1 recalls

Prepared foods has remained the top cause of Food and Beverage recalls for 16 of the past 17 quarters.

Q1 recalls impacted 2.4M units, a **31.9% increase** on Q4 2020 (at 1.8M units)



Whilst 28.4% of Q1 recalls were of Class I severity, they impacted just 3.6% of all units.
Foreign material accounted for 1.1M (44.8%) of units.

FIRST QUARTER BY THE NUMBERS

FDA

Overall, first quarter activity represents a 4.4% decrease in events, but a 31.9% increase in units impacted quarter-over-quarter. FDA recall activity slipped further from quarterly average recall levels from 92 events in the fourth quarter for 2020 to 88 recalls in the first quarter of 2021. This is only the second time we have seen fewer than 90 recalls since we started collecting this data in 2012. The first time was in the second quarter of 2020 at the very outset of the COVID-19 pandemic. If this level of activity continues without significant increases over the next three quarters, it is likely we'll see annual recall totals drop below 400 events for the first time in at least 10 years.

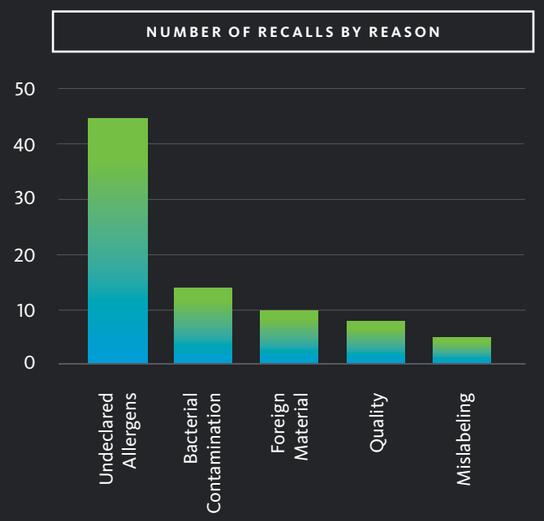
First quarter recalls impacted 2.4 million units, compared to 1.8 million units in the final quarter of 2020.

Of first-quarter recalls, 28.4% of events were Class I. This remains in line with recent quarters when approximately one-third of recalls were designated as Class I. These most severe events, however, impacted just 3.6% of all first quarter units recalled.

Undeclared allergens returned as the leading cause of recall events for the 22nd time in the last 25 quarters. Recalls due to allergen-related concerns accounted for 45 events or 51.1% of first quarter recalls. Of these recalls, 10 contained more than one undeclared allergen. Prepared foods was the category most often impacted by undeclared allergen recalls, followed by flavorings (such as dressings and sauces) and produce (such as salad kits and frozen vegetables).

Foreign material recalls impacted the most units at 1.1 million or 44.8% of all impacted units. Bacterial contamination was the cause for 14 recalls, with 7 events resulting from Salmonella contamination, 6 due to listeria, and 1 linked to botulism concerns.

Prepared foods was the top product category impacted by first quarter recalls for the 16th time in the last 17 quarters. The category accounted for 19 recalls or 21.6% of first quarter events, recalls of baked goods impacted the most units at 1.1 million units or 43.2% of all units recalled in the first quarter.



APRIL INSIGHT

The FDA announced 40 food recalls in April, while the USDA announced 5 recalls. In both cases, April logged half the number of recalls announced during the entire first quarter. The leading cause of FDA recalls was undeclared allergens with 16 recalls. The product category most impacted by FDA recalls was prepared foods with 21 recalls. Of the 5 USDA recalls in April, two impacted beef products. Two USDA recalls were the result of bacterial contamination, and two additional events were due to quality concerns.

USDA

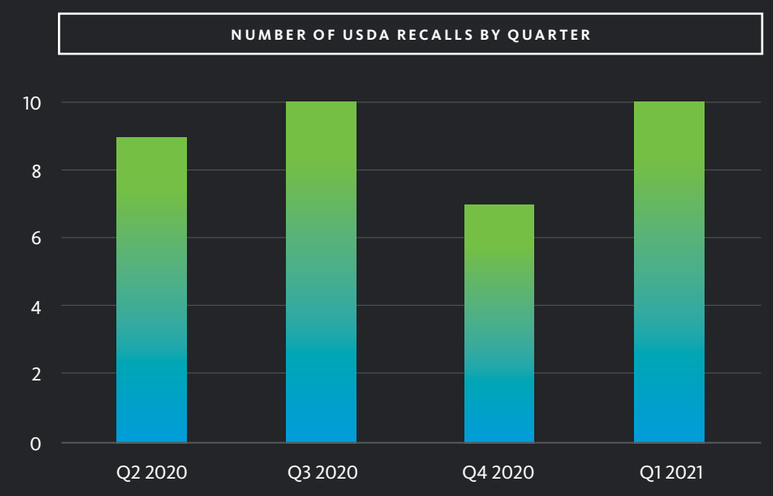
USDA recalls increased from seven events in the fourth quarter of 2020 to 10 recalls in the first quarter of 2021. This activity remains low compared to quarterly averages in 2019 and years prior. To provide additional perspective, 2020 logged an average of eight recalls each quarter compared to an average quarterly volume of more than 30 recalls over the previous five years.

For the second straight quarter, and only the second time since we started analyzing this data, the top cause of recall events was a lack of inspection. This cause accounted for 5 of the 10 recalls announced during the first quarter.

In fact, "No Inspection" was tied with undeclared allergens as the top cause of recalls for 2020, each resulting in 12 recalls, or 37.5% of recalls. As we noted in our 2021 state of the nation recall index, the lack of an inspection is not a rarity. However, we are currently seeing this cause account for a greater percentage of recalls amid the COVID-19 pandemic.

The remaining five recalls were the result of foreign matter contamination (2 recalls) quality concerns (1 recall), listeria contamination (1 recall), and undeclared allergens (1 recall).

Pork products were the most impacted category in terms of both events and units in the first quarter, with four recalls impacting nearly 800,000 pounds. Beef products accounted for 3 recalls impacting about 400,000 pounds. To provide further context, poultry products were the leading category impacted by product recalls in 2020 and 2019, only surpassed by beef products in 2018.



BRIAN GRANT, DIRECTOR OF FOOD & AGRIBUSINESS, **COTTINGHAM & BUTLER**

NEW APPROACH TO REGULATORY OVERSIGHT, SAME RISKS AND MITIGATION MEASURES

The regulatory and legal environment for the food industry is evolving – both in response to the challenges created by the COVID-19 pandemic and under the direction of the Biden administration and a Democratic-controlled Congress.

While there have been questions about what the Food and Drug Administration (FDA) and U.S. Department of Agriculture will prioritize in terms of oversight and enforcement, we are beginning to get some clarity.

For starters, the FDA is seeking to fundamentally change its approach to food safety inspections in the post-pandemic era. Favoring remote or virtual inspections, the FDA is considering asking Congress for authority to demand companies send their records to the agency. As it stands now, companies insist that FDA visit a facility and review the records in person without being able to make copies.

While any significant shift in oversight will come with changes, it is important for companies to maintain a focus on mitigating its largest risks.

Foreign supplier verification

The Foreign Supplier Verification Programs (FSVP) rule is not a new obligation for the food industry. In fact, the final rule went into effect on January 26, 2016. But it remains a major issue.

According to Food Safety News, Foreign Supplier Verification Program (FSVP) citations increased 51 percent in 2020, making it "the third year in a row that failure to develop an FSVP was the top-cited inspection violation." That may in part be because compliance can be determined based on straight-forward document review – an oversight tactic that regulators relied on heavily during the pandemic because it could happen without an on-site inspection.

In summary, the rule requires food importers to develop and maintain FSVPs that help ensure that food is produced in an FDA compliant and safe manner. While large, established companies have strong practices in place already, the smaller, middle-market companies or spinoff entities are often at risk. This is particularly true for entities like flavor houses and ingredient suppliers.

Contamination and Prop 65

The ways that Proposition 65 can impact companies are (almost) endless. Even years after the law went into effect, when companies think they have their bases covered, the California Office of Environmental Health Hazard Assessment (OEHHA) proposed amendments to the format of the warning labels required for compliance.

While companies currently using the short form warning label in question likely have until 2022 to comply, it is critical that a thorough review of all products and labels is conducted sooner rather than later. While swapping a label may sound simple to some, it can be costly. Where the regulated chemical has not been listed on the warning, companies may need to investigate what chemicals must be named on the long form label.

On a parallel track, companies would be wise to re-evaluate their entire Prop 65 compliance plan to identify risks, exposures, and appropriate mitigation measures, including putting financial backstops in the form of insurance.

This effort will be even more valuable if the Biden administration has any intention to legislate Prop 65 at a federal level. After all, there is a belief among some experts that if there was Administration willing and able to make this happen, this would be it.

Whole genome sequencing

Whole genome sequencing is a topic that comes up in nearly every food safety conversation. With this surveillance technology, the ability to detect even small foodborne illness outbreaks is greatly enhanced – and the reliability and depth of product tracing continues to get stronger.

While the availability of this technology from an insurance perspective doesn't change the risk profile, it does allow for better traceability back to a source, thereby mitigating risks and, in some cases, deferring costs in the event of a significant outbreak.

Food safety culture

Food safety has always been a priority across the industry. That said, we are seeing even more attention paid to improving food safety culture. This is evidenced by the increasing size of in-house food safety teams across the industry. Companies are not just adding people, they are seeking to grow their experience and expertise.

On top of that, food safety professionals are invested in learning and improving – both for their own professional benefit and the benefit of their employers.

That also translates to a growing number of companies closely evaluating recall insurance options to ensure proper coverage. These are all important steps to risk mitigation. With the right team in place, companies can ensure more than regulatory compliance.

> *“After more than two months of silence the FDA (in March) published 16 warning letters sent to medical device companies. Then in April, the agency released five more.”*

MEDICAL DEVICE

As the healthcare industry collectively works to guide us out of a global pandemic, there are strong indications that the medical device industry is on the brink of a regulatory crackdown.

To begin with, after more than two months of silence the FDA (in March) published 16 warning letters sent to medical device companies. Most of the letters pertained to products unapproved to mitigate or prevent COVID-19. Then in April, the agency released five more letters addressed to companies selling COVID-19 tests without appropriate authorization.

These warning letters and similar public corrective actions by the FDA should serve as a reminder of the significant regulatory challenges, legal consequences, insurance implications and reputational risk facing companies.

Based on what we’ve seen in the first quarter, here are five things you need to consider when operating in a post-pandemic environment.

Global regulators are collaborating. We noted in our 2021 state of the nation recall index that regulatory oversight and enforcement is increasingly a collaborative effort among global government agencies. Even if collaboration hasn't yet become routine practice, the FDA in March updated its electronic Medical Device Reporting system to accept the adverse event codes developed by the International Medical Device Regulators Forum. It's a sign that regulators around the world at a minimum want to be speaking the same language and have access to the same information. Manufacturers and healthcare professionals would be wise to do the same, likely through their trade associations and other business groups.

Accelerating innovation will have a regulatory impact. As the FDA noted in a Voices piece on accelerating medical device innovation, "Progress in science and technology offers extraordinary opportunities to develop innovative medical products that can save lives and lead to better treatments, better diagnostics and better care for patients." But for the FDA, the advancements don't stop there. The agency is committed to innovating its oversight process to ensure devices on the market continue to be safe and effective.

The scope of safety investigations is broadening. The FDA's Center for Devices and Radiological Health (CDRH) and Circulatory System Devices Panel (CSDP) of the Medical Devices Advisory Committee is expected to meet later this year to examine the safety of endovascular stent grafts. While the first half of the meeting will focus on a benefit-risk profile for a single system, the latter half will expand the conversation to the entire product category.

In a similar fashion, the FDA "sounded the alarm over recent adverse event reports that indicate patient infections linked to reprocessed urological endoscopes, including cystoscopes, ureteroscopes and cystourethroscopes," according to Medtech Insight. The article further notes that "the FDA said its review of adverse events related to urological endoscopes was informed by its work over the past few years with duodenoscopes that were linked to patient deaths from bacterial outbreaks because of inadequate device cleaning."

While this process is not necessarily groundbreaking, the fact that the FDA is embarking on this approach during a pandemic shows the agency is intent on applying its safety lessons across categories and industries, leaving the door open for regulatory and legal risk to extend to companies not currently under scrutiny.

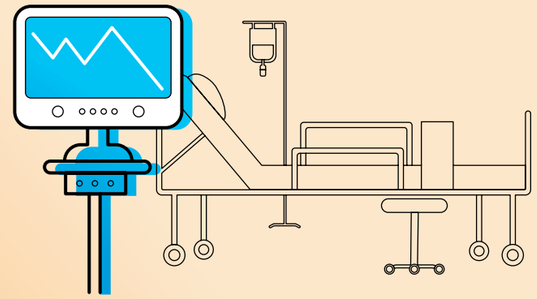
There are potential limits on liability protections. If you had any doubt about the prediction that Public Readiness and Emergency Preparedness (PREP) Act protections will be tested in the courtroom, those doubts should be long gone. And a chief reason has arguably nothing to do with COVID-19. Instead, it's a recent test of the Supreme Court's Riegel v. Medtronic, which found that federal medical device regulation laws provide lawsuit protections for devices with FDA premarket approval. But this decade-old legal precedent failed to result in a dismissal of the case. Given the plaintiffs' recent victory here, expect lawyers to aggressively test the waters on the level of immunity the PREP Act proffers to medical device manufacturers.

Recall management as a litigation risk. It is well-known that recalls are often an invitation for litigation. But the risk associated with the lawsuit shift beyond the filing of a lawsuit and its routine product liability claims. When there are questions about regulatory compliance or the effectiveness of a recall, the plaintiffs' bar takes notice. For example, in one ongoing case, a medical device company is facing charges directly related to allegations that the company failed to report adverse events linked to its product. Whether or not these allegations have merit, the mere inference can be devasting.

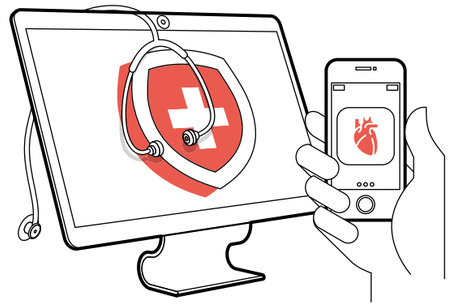
The best way to mitigate these risks is through effective crisis planning and recall management – a process that should reach beyond the walls of your organization and the words printed in your crisis plan. Keep a close eye on regulatory investigations and bellwether lawsuits, to better understand the potential safety concerns impacting products in the same or related categories. In doing so, you may be able to avoid getting swept up in a tide of regulatory enforcement and mounting litigation.

> *"Keep a close eye on regulatory investigations and bellwether lawsuits, to better understand the potential safety concerns impacting products in the same or related categories."*

Recalls **decreased 9.8%** in Q1 2021 (from 235 in Q4 2020) to 212



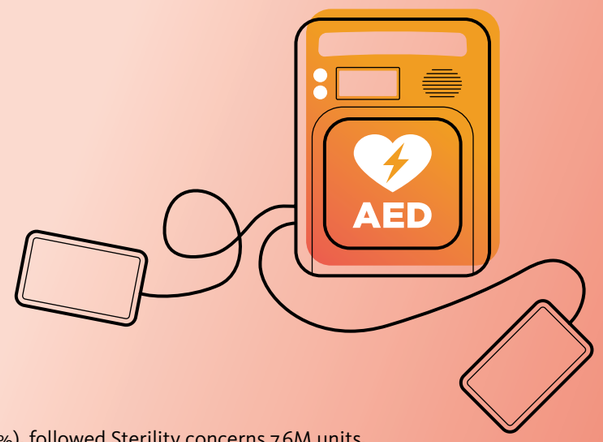
Medical device recall events have now decreased in 3 straight quarters, resulting in a 7-quarter low.



Accounting for 47 events (22.2%), **Software issues remained the top cause** of Q1 recalls

Software issues have remained the top cause of medical device recalls for 19 of the past 20 quarters.

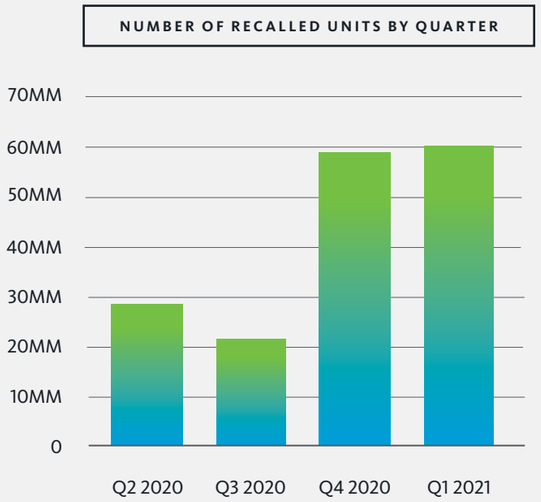
Impacted units **increased 2.5%** to 60.8M, the highest since Q1 2020



Quality concerns impacted 43.6M units (71.8%), followed Sterility concerns 7.6M units.

FIRST QUARTER BY THE NUMBERS

Recalls decreased slightly for the third straight quarter to 212 events in the first quarter, down 9.8% from 235 recalls in the fourth quarter, and resulting in a seven-quarter low. Despite the decline in events, impacted units increased 2.5% to 60.8 million units, the highest since the first quarter of 2020.

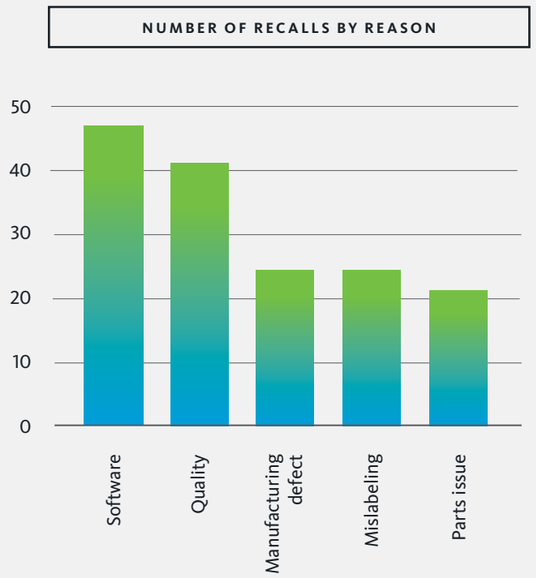


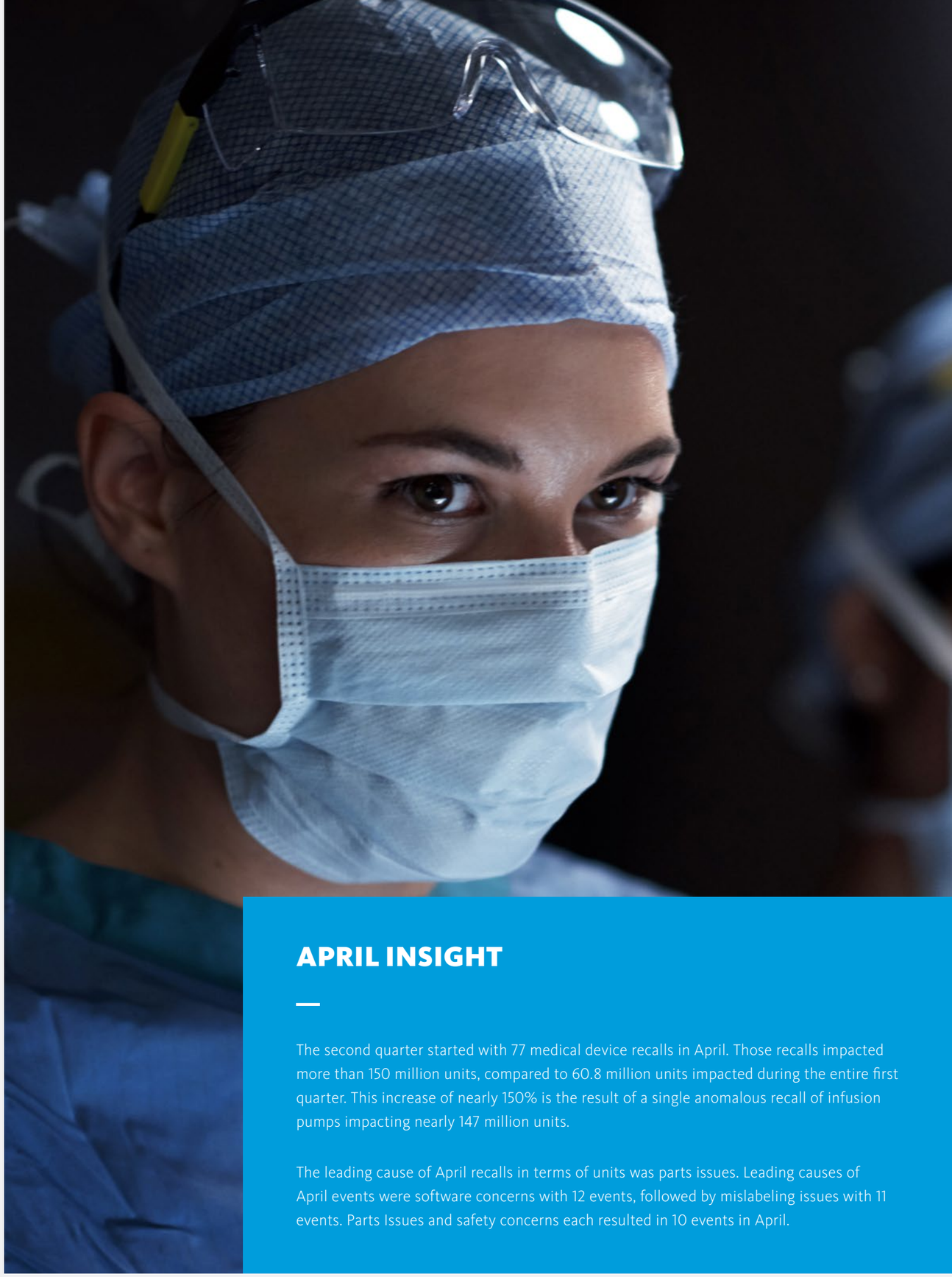
Software issues were the top reason for recalls for the 19th time in the last 20 quarters at 47 events. Quality concerns, however, impacted 43.6 million units or 71.8% of recalled units in the first quarter. The second leading cause of recalled units was sterility concerns. While just 11 recalls were announced due to sterility issues, these recalls impacted 7.6 million units. Safety concerns, were the third leading cause of recalled units, representing 6.1 million units across 19 events.

Of first-quarter recalls, one event resulting from quality concerns impacted nearly 30 million units, or almost half of all units recalled. Even when you remove this anomalous recall, quality concerns remain the leading cause of recalled units. On the other side of the coin, 38 events impacted fewer than 100 units.

Of first quarter recalls, 11 recalls (5.2%) were labelled with the FDA's most serious Class I designation. These recalls impacted roughly 180,000 units, or 0.3% of first quarter units. Class II recalls accounted for 197 recalls impacting 60.6 million units. The remaining four recalls – accounting for fewer than 300 units – received FDA's Class III designation.

More than half of first quarter recalls (54.7%) were distributed nationwide, with 31.6% impacting an international customer base.





APRIL INSIGHT

The second quarter started with 77 medical device recalls in April. Those recalls impacted more than 150 million units, compared to 60.8 million units impacted during the entire first quarter. This increase of nearly 150% is the result of a single anomalous recall of infusion pumps impacting nearly 147 million units.

The leading cause of April recalls in terms of units was parts issues. Leading causes of April events were software concerns with 12 events, followed by mislabeling issues with 11 events. Parts Issues and safety concerns each resulted in 10 events in April.

JIANLIN SONG, OF COUNSEL,
WILSON ELSER

COVID-19 SUPPLY CHAIN ISSUES INVITING POST-PANDEMIC LITIGATION

As the pandemic took hold, it became clear that the Food and Drug Administration (FDA) needed to take drastic steps to protect United States (US) citizens from the coronavirus. Part of that response was the issuance of what has become a long list of Emergency Use Authorizations (EUAs). These measures simplified the pre-market approval process for products considered essential in preventing the transmission of the coronavirus and treating patients with COVID-19. Amid supply chain shortages, companies outside the US, especially those in Asia and the Middle East, sought to take advantage of the EUAs and enter the US market.

But the business opportunities provided under the EUA process are being met by a growing number of risks for companies.

Regulatory compliance

As the number and severity of COVID-19 cases continues to decrease, companies need to prepare for the FDA to cull back the number of EUAs as a first step in returning to pre-pandemic regulations, policies and guidelines. Companies that entered the medical device industry in an opportunistic fashion – even if with the best intentions – need to prepare for this eventuality. The moment an EUA is revoked, a company could face scrutiny and enforcement actions, including a recall, if the product does not comply with medical device safety standards or current good manufacturing processes.

The risks are even more acute for companies that entered the US market for the first time during the pandemic. These companies often have little working knowledge of FDA regulations in a normal operating environment. The paperwork required for approval under an EUA was a fraction of what the FDA will expect under its long-standing safety guidelines and manufacturing requirements.

Manufacturers would be wise to start down the road to official product registration and compliance now if they intend to continue producing medical devices for the US market. If not, putting plans in place to pull the product from the market may be the best way to minimize future regulatory and legal risks.

Recalls and withdrawals

In the latter half of 2020, we started to see companies pull masks, respirators and other devices off the market in response to safety concerns. Companies should expect the frequency and scrutiny of these recalls and withdrawals to increase as EUAs are revoked. With that mind, manufacturers should conduct a full safety assessment that includes an evaluation of compliance with pre-pandemic regulatory standards. Companies should then use that assessment to develop and validate a recall plan. Collect the information you need, engage expert partners and counsel, and set up a mechanism for monitoring FDA and regulatory enforcement sites, safety notifications and industry developments that could inform your product strategy. At the same time, familiarize yourself with FDA recall and withdrawal requirements – from notification and reverse logistics to product storage and destruction.

Throughout this process, keep in mind that product recalls and withdrawals have long been invitations to litigation in the US – even when the recall is executed flawlessly.

Increased litigation

We are beginning to see lawsuits against medical device companies that participated in the COVID-19 response. Initial cases will serve to determine how liability protection under the Public Readiness and Emergency Preparedness (PREP) Act will be defined. While there are undoubtedly protections that will be afforded to companies under this Act, defense strategies are not bulletproof. We know from experience that FDA regulation has little influence or impact in jurors' minds. A defense argument that cites a lack of FDA guidance will be countered with the expectation that a product should always meet minimum safety standards – a message that will resonate with consumers.

The biggest challenge for companies in this environment is that – win or lose – financial expenses and reputational risks are high. A winning legal defense doesn't happen overnight. It plays out over prolonged litigation. Then when the plaintiffs' bar finds a weakness in the protections, expect a tsunami of cases modeling the same approach.

When it comes to the future regulatory environment for the medical device industry, dramatic changes are unlikely. Instead, the FDA is slowly, gradually returning to a "business-as-usual" approach to oversight and enforcement. For companies new to the medical device sector, that risk is enough to have a devasting financial and reputational impact on the company.

PHARMACEUTICAL

When consumers think of pharmaceutical recalls, the most highly-publicized events come to mind – from the historical Tylenol and Vioxx withdrawals to more recent recalls of metformin, ranitidine and valsartan. While all these events are “old news” in the world of recall management, the trend from brand-specific to brand-agnostic recall awareness is one the entire industry needs to watch carefully.

If this trend continues, a single recall exponentially increases the risks to entire product categories – from regulatory scrutiny and potential litigation to lost sales and eroding trust. (If you make it a practice to learn from companies outside your industry, you will know this is a risk that the infant-sleep product category knows all too well.)

There are a few fundamental risks underpinning this shift in consumer awareness.

> *“The trend from brand-specific to brand-agnostic recall awareness is one the entire pharmaceutical industry needs to watch carefully.”*

The expanding reach of contamination-related recalls. Contamination concerns are a long-standing risk for the pharmaceutical industry. But this risk, like every other, is evolving. Companies not only need to control for known contaminants, but also chemicals and substances previously unidentified. Consider NDMA – a contaminant that, until recently, companies didn't even know they should be looking for in pharmaceuticals.

But this notion of a growing list of contaminants isn't the only takeaway. Keep in mind that the impact of contamination concerns reaches far beyond the burden of a recall. We often discuss the regulatory scrutiny, litigation and reputational fallout that can follow a recall. These are certainly true in the case of metformin, ranitidine and valsartan. As the number of lawsuits and plaintiffs increase, the consumer trust in once-popular drugs decreases. As a result of this environment, one pharmaceutical company was forced to sell its manufacturing plant at a fraction of its value following the industry-wide ranitidine recalls. While not a direct recall cost, this type of financial loss can impact a company's ability to operate.

Increasing influence of independent labs and safety advocates. We have raised this risk previously, but it is no less relevant today. In the latest chapter of this story, online pharmacy Valisure recently filed a citizen's petition calling on the FDA to recall hand sanitizers contaminated with benzene. As a reminder, Valisure is the pharmacy that sounded the alarm on NDMA.

It's clear that Valisure and other activists are eager to pursue products and companies they believe are placing consumers at risk. So much so that they have moved to crowdsourcing the effort. As Valisure continues to test hand sanitizers for potential benzene contamination, MedPage Today reported that the pharmacy is inviting businesses and consumers to submit samples directly to the company for testing.

As Valisure and similar organizations see these efforts pay off, expect their scope and crowdsourcing approach to reach far beyond NDMA and hand sanitizers. One category that can expect special scrutiny is dietary supplements. The Center for Science in the Public Interest (CSPI), Consumer Federation of America, Consumer Reports and National Consumers League are already among the groups calling on Congress to reform dietary supplement regulations. Systemic concerns like those seen with NDMA and benzene contamination would bolster their campaign.

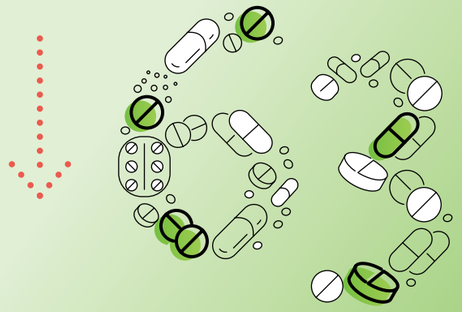
Dietary supplement manufacturers should be ready for renewed activist and media attention. Sound recall planning, combined with forward-looking public relations and social media strategies are called for.

Recalls as an indicator of compliance risks. A recent Bloomberg Quint article shared that healthcare intelligence company IQVIA referred to recalls as a "leading indicator of facility compliance risk, especially in the absence of regular U.S. FDA inspections." We certainly agree that a product recall can support the prediction that other regulatory violations will occur. But it is just as likely that a violation is identified and reported first, and the recall follows.

Regardless of which comes first, the risks of regulatory non-compliance reach far beyond a single recall or enforcement action. In an extreme case, consider the recent order of permanent injunction against dietary supplement manufacturer Confidence USA Inc. After a decade-long history of alleged non-compliance with cGMP regulations, including failure to verify that products met specifications for contamination limits, the company was forced to shutter.

We are slowly emerging from an era in which FDA oversight and enforcement activities have been restricted, particularly in terms of on-site inspections. As time passes, expect the FDA to focus more on manufacturers with a track record of recalls and violations. While we don't know exactly how this will play out through 2021, we know from experience that the companies that succeed are often the ones developing relationships and working closest with the FDA – in the good times and the bad.

Pharmaceutical
recalls dropped 25%
to just 63 events in Q1

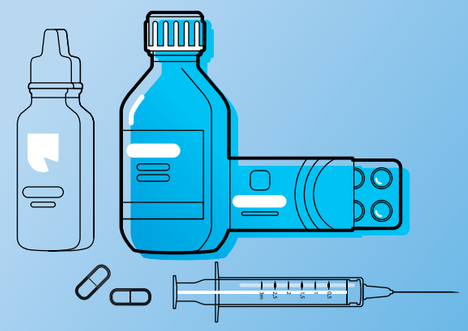


An expected decline given the COVID-19 era in which FDA oversight and enforcement activities have been restricted, particularly in terms of on-site inspections.

Failed specifications
were the leading cause of both Q1 events and units impacted

These accounted for 18 recall events (28.6%) and 4.1M affected units (33.3%).

Of Q1 recalls, **the FDA classified 7 as the most serious Class I.** These impacted 1M units (8.2%)



Class II events accounted for 37 (8.1M units), with 19 (3.3M units) being designated Class III.

FIRST QUARTER BY THE NUMBERS

Despite the FDA's work to resume inspection and regulatory enforcement activity in late 2020 and early 2021, and continued concerns related to COVD-19 products, pharmaceutical recalls dropped 25% to just 63 events in the first quarter. This decrease further represented a 58.5% drop in recalled units compared to the fourth quarter of 2020. This is the lowest number of recalled units since the third quarter of 2018.

Failed specifications were the leading cause of first quarter recalls in terms of events and units impacted. These 18 recalls accounted for 28.6% of first quarter events, and 4.1 million units, or 33.3% of recalled units.

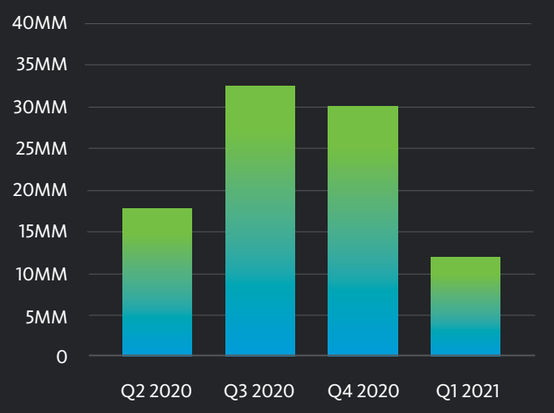
Mislabeling concerns accounted for approximately 900,000 units over 12 events. While these recalls are generally small in their nature, these are often preventable events with adequate quality assurance programs in place.

Three first-quarter recalls that were documented in the FDA enforcement reports were hand-sanitizer products, but none of these events were linked to the most recent safety concern: benzene contamination.

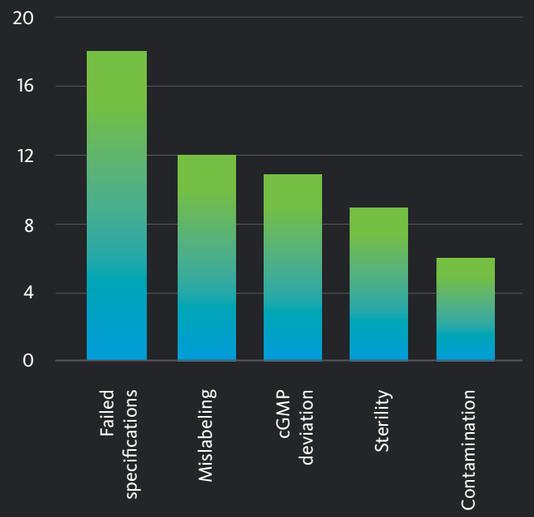
Of first-quarter recalls, the FDA classified seven as the most serious Class I. These recalls impacted 1.0 million units, or 8.2% of first quarter units. Class II recalls accounted for 37 events impacting 8.1 million units. The remaining 19 recalls and 3.3 million impacted units received FDA's Class III designation.

Fifty-five first quarter recalls impacted products distributed nationwide. These recalls accounted for 87.3% of recalls – the highest percentage since before the first quarter of 2015, just 8 affected products sent internationally.

NUMBER OF RECALLED UNITS BY QUARTER



NUMBER OF RECALLS BY REASON



APRIL INSIGHT

There were 22 pharmaceutical recalls in April, maintaining a level of activity similar to monthly averages logged through the first quarter. But while the number of recalls remained steady at the start of the second quarter, the average recall size has dropped significantly. April recalls impacted only about 380,000 units, compared to a monthly average 4.1 million units in the first quarter.

The leading cause of April events was failed specifications (8), followed by quality issues (3) and mislabeling (3).

KELLY JONES HOWELL,
PARTNER, **HARRIS BEACH LLC**

REGULATORY AND LEGAL RISKS ON THE RISE IN THE POST-PANDEMIC ERA

Expect COVID-19 to remain a driving force for regulatory and legal developments impacting the pharmaceutical industry in 2021. While vaccines provide a light at the end of the tunnel, the current and future regulatory and business environment is and will continue to be shaped by two key factors: (1) the global pandemic, and (2) a new presidential administration.

Already in 2021, we have seen increased enforcement paired with rollbacks of policies and regulatory frameworks introduced under the previous administration. Beyond those developments, it remains difficult to predict exactly what the regulatory environment will look like in 2021 and beyond. But even in that challenge there is consensus: we are entering an era of change.

And unfortunately, the industry's success to date in helping the world emerge from the pandemic is going to be met with increased regulatory scrutiny and litigation.

Increase in inspections could lead to more recalls

As COVID-19 restrictions are lifted and FDA inspectors get back on the road, manufacturers can expect an increase in inspections and oversight activities. But the uptick represents more than the agency's attempt to catch up with the inspection backlog. It signals a deliberate shift away from the previous administration's oversight posture.

Given the supply and manufacturing challenges experienced over the last 12-15 months, it is likely FDA will use the inspections to look for contamination concerns, manufacturing discrepancies, cGMP violations and quality issues. But the inspection itself is only part of the regulatory risk facing companies.

Additionally, where FDA relied heavily on informal correspondence under the prior administration, we expect the current administration will revert back to more formal handling of its communications—expect to see increasing numbers of warning letters, consent orders and enforcement proceedings. When these actions are made public, it could result in increased regulatory scrutiny, litigation, recalls and reputational damage.

Inquiries related to product labeling and promotion will increase

By virtue of this past year, pharmaceutical manufacturers changed the way they market their products, heavily relying on social media and digital resources. When conferences and trade shows went virtual, so did the pharmaceutical booths. Many of these changes were unprecedented, and companies had to adapt within existing regulations without specific regulatory guidance from FDA for communicating in this new completely virtual environment.

Without in-person dialogue, more communication occurred over email among prescribing physicians, perhaps without the realization that these writings could be interpreted as an extension of product labeling. In response, expect FDA to place an emphasis on evaluating marketing, labeling and promotion activities. COVID-19 related products will receive the most scrutiny.

It is also worth noting that the FDA has traditionally steered clear of pursuing legal challenges related to off-label use of pharmaceutical products. Frankly, the agency has not had great success in this area. That said, with the right set of clear facts, off-label promotion related to COVID-19 product could be ripe for a legal challenge.

Litigation in the wake of the pandemic

Companies should prepare for a potential uptick in litigation, particularly for products related to the prevention, testing and treatment of COVID-19. This increase will not be immediate, instead stretching its way through the statute of limitations as plaintiffs' lawyers attempt to capitalize on tragedies resulting from the pandemic.

As charges are brought forward, manufacturers are hopeful that they will benefit from protections afforded by the Public Readiness and Emergency Preparedness Act (PREP). In certain cases, the legislation is straightforward in the immunity protections that it offers. That said, there is at least one big question mark related to "willful misconduct."

This concept is less rigid in its definition, which means that the parameters in which the term can be used will likely be determined in the course of litigation. We expect most cases of this nature to start in federal district courts, ultimately traveling up through appellate courts. This process will be costly for companies – both financially and reputationally. From a litigator's perspective, the risk could be even greater in the event of a recall, enormous supply chain disruption or confirmed quality issues at the manufacturing site.

Companies would be well served to re-evaluate their safety policies, supplier and manufacturer partnerships, and quality controls considering the evolving regulatory and litigation landscape. In addition, manufacturers of COVID-19 products should consider requesting a legal analysis of the PREP Act and a pre-litigation risk assessment of their product category to better understand and reduce potential exposure.

CONCLUSION

Manufacturers are operating in one of the most turbulent and uncertain times in recent history. There appears to be a light at the end of the COVID-19 tunnel, and economists predict a business boom for the remainder of the year. But while consumers may be eager for a return to normal, the 2019 “business-as-usual” posture for regulators and legislators is a thing of the past. Activists and regulators are poised for action, with the new Biden administration signaling that it will be a willing ally.

We stand by the prediction we made in our state of the nation recall index. The only thing we can be sure of in 2021 is expanding reputational risks to companies across all sectors. From a product-safety standpoint, the risks are numerous:

- 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

Companies across all industries would be wise to closely re-evaluate all manufacturing processes and vet supply chain partners. Invest some time and resources now to prepare your recall management, crisis and communication plans. As you do that, remember to turn to expert partners for their experience and insights that can save you millions of dollars in regulatory and litigation costs.

Given how quickly our business and regulatory environments are evolving, expert partners help uphold your commitments to customers, supply chain partners, industry groups and regulators, while protecting your reputation among the stakeholders that matter most.

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.

ABOUT SEDGWICK BRAND PROTECTION

We are in-market risk experts. We are problem solvers. We are crisis managers.

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 2021 (and beyond), 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 myriad of reputational threats that you face every day.

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