

STATE OF THE NATION 2021

PRODUCT RECALL
UNITED STATES EDITION





The Sedgwick Brand Protection Recall Index remains 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 2021 State of the Nation Recall Index goes beyond our traditional quarterly reviews, bringing you not only information about the latest quarter, but also offering a year-in-review look at recall data and trends from 2020. In addition, we provide a glimpse into January recall numbers.

Our analysis and predictions let you know what to expect in 2021 as regulators and business leaders alike look ahead to a post-pandemic world and a continuation of what has been one of the most turbulent eras in U.S. government history.

Insights from some of our strategic partners at leading law firms, insurance companies, and communications firms offer further expert analysis to help you prepare for the changes and trends in the regulation of food, drugs, consumer products, medical devices, and automobiles.

As U.S. lawmakers increasingly question whether regulators are effectively protecting consumers and the number of new products grows every day, there has never been a more important time for companies at every level in the supply chain to be primed and ready for recalls and related threats to their livelihood.

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 and what is likely to happen next that will impact your business.

One final note: this 2021 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.

European edition available here: [LINK](#)

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: [LINK](#)



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SUMMARY

2020 was full of risk and great uncertainty for companies across all industries. While a year for the history books is now behind us, don't expect much to change in 2021. In fact, expect COVID-19 to continue impacting regulatory oversight and enforcement activities for at least the first half of the year.

We may see regulators shift their priorities or approach to rulemaking and regulation under the Biden administration, but these changes take time. In the meantime, there are five regulatory and business considerations that companies across industries, and up and down the supply chain, need to plan for if they are to emerge as leaders in 2021 and long into the future.

The regulatory agencies watching you are numerous.

An increasing number of companies are finding the products they manufacture subject to oversight by more than one regulatory agency. Not to mention their business operations are under constant scrutiny by the Federal Trade Commission (FTC) and the Department of Justice (DOJ). Consider these examples:

- CPSC, FDA, and FTC may all have a hand in regulating face masks used to protect against the transmission of coronavirus.
- NHTSA and FDA both regulate automakers that shifted resources to produce medical devices.
- U.S. Department of Transportation, NHTSA, and CPSC have regulatory enforcement authority on products such as lithium-ion batteries and micro mobility products.
- U.S. Environmental Protection Agency (EPA) is putting its own stake in the ground on products traditionally regulated by FDA, including hand-sanitizer wipes and cosmetic products containing talc.
- Customs and Border Patrol supports FDA and CPSC on regulatory enforcement, investigating, holding, or denying imported products at the ports.

Arguably more important than regulatory collaboration, however, is the fact that regulatory actions are increasingly public, particularly for products regulated by the CPSC and the FDA. We discuss this further within our industry commentary in the pages that follow.

National regulators have a global impact. While the degree of regulatory scrutiny and resources devoted to product safety vary around the world, actions by the FDA, Health Canada, and regulators throughout the European Union and United Kingdom have a global impact. Expect this trend to continue as regulators around the world make agreements to share more records and detailed reports from on-site audits and investigations. With this approach, violations may ultimately impact your business beyond the borders of the primary regulatory jurisdiction.

In fact, even if an enforcement action is based on one country's investigation, it now often has an effect in multiple countries. We saw this with the discovery of ineffective and contaminated hand sanitizer products. In this particular case, the FDA was a leading force with their efforts to protect consumers from dangerous sanitizer products, recalling or placing them under import alert. Public warnings were even placed on products that the agency had no record of ever reaching U.S. consumers. While Health Canada and regulators across the EU took a similar approach, these products remained available on store shelves throughout Mexico.

FDA then took the precautionary step of issuing a country-wide import alert on all hand sanitizers from Mexico – the first time such a drastic step was taken. Companies should be aware that this action is likely to happen again, and next time, the CPSC could flex its regulatory muscle as well.

Litigation risks are increasing and evolving. The courts may have moved more deliberately during the pandemic, but new lawsuits haven't slowed as the plaintiffs' bar has remained persistent in finding and filing new cases. We're seeing a high volume of typical civil claims, but we're starting to see a surge in lawsuits related to COVID-19. The Products Liability Litigation team at Faegre Drinker offered this list of claims companies are already facing:

- Failing to warn about the presence of COVID-19 in a manufacturing or distribution facility.
- Sanitizers, protective gear, and disinfectants that misrepresent the protection against viruses, germs, and bacteria.
- Products falsely claiming to protect against COVID-19.
- Dietary supplements and other foods that allegedly cure, treat, or mitigate COVID-19 and its symptoms.
- Drugs and vaccines claiming to treat COVID-19 or lessen its impact.
- Testing claiming to detect COVID-19 or related antibodies.
- Products claiming to boost immune systems.
- Exposure to COVID-19 from contaminated devices or packaging.
- Failing to warn about potential side effects or impacts caused by drugs or devices.

Drugs, medical devices, and food products are named explicitly in this list, but similar claims may apply to automotive and consumer product companies. While the Public Readiness and Emergency Preparedness Act (PREP Act) aims to provide immunity from liability to, among others, "entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures," expect those protections to be tested by the plaintiffs' bar.

Regulatory inspections and enforcement will be fast and furious in the immediate post-COVID-19 future. The pandemic will continue to limit regulatory inspections, especially those that would typically include on-site audits, product sampling, and environmental swabbing. But by mid-year, expect to see FDA inspectors back on the road.

Companies allegedly making counterfeit or fraudulent products will be a priority, as will any manufacturers with spotty recordkeeping or past violations. With those inspections we expect an increase in warning letters, pressure for recalls, regulatory sanctions, and negative publicity.

Product safety is the responsibility of the entire supply chain. It is well understood that manufacturers bear the brunt of product liability claims and regulatory enforcement. But retailers and supply chain partners are increasingly implicated in product safety matters. As a result, these organizations are starting to take matters into their own hands.

Take Amazon for example. After scrutiny from the CPSC and FDA, Amazon began imposing quality-control requirements on firms selling supplements on its site. If a seller cannot demonstrate the product it sells complies with FDA regulations for labeling and cGMPs, the product will be removed. The mammoth e-commerce site is seeking similar documentation for products regulated by the CPSC.

With these broad observations in mind, let's take a look at our predictions and recall data specific to each industry.

CONSUMER PRODUCTS

As we look at what 2021 has in store for CPSC and the consumer product industry, much will rest on the fact that the Biden administration has an opportunity to secure a Democratic majority within the agency. With that is likely to come an increase in enforcement efforts, stricter safety standards, and a shift from voluntary guidance to mandatory standards.

The following pages outline what we see as the top issues on the CPSC's priority list.



“CPSC estimates an annual average of 25,500 emergency department-treated injuries (2017–2019) and 571 fatalities that occurred between 2000 and 2019.”

Home Furnishings and Décor in the Spotlight

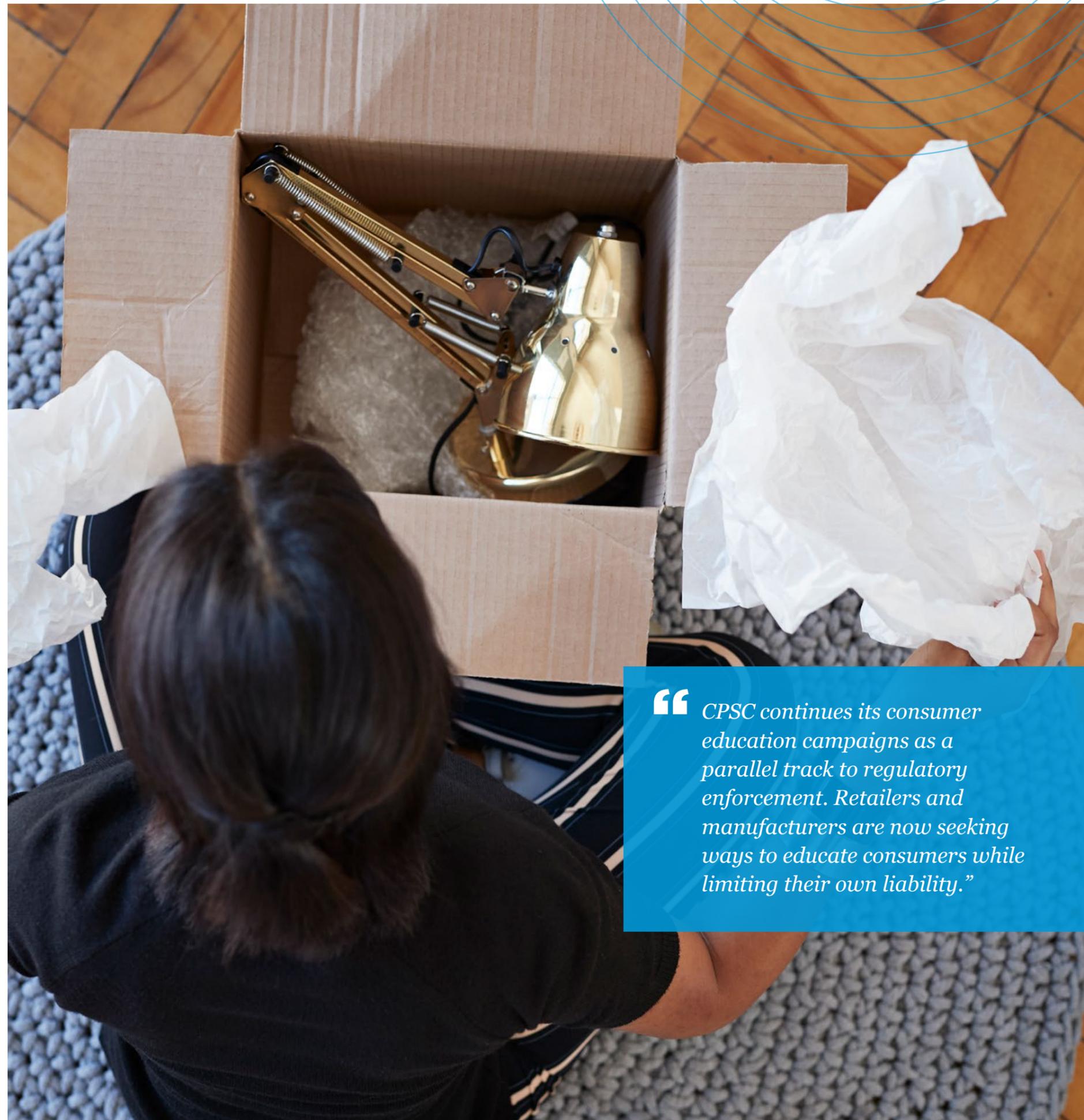
The Home Furnishings Association recently warned members that the CPSC would be seeking to address issues related to upholstered furniture flammability, furniture stability (including tip-over risks), and formaldehyde emissions from composite wood products in 2021. It would be no surprise to us since this category is almost always the most impacted by recalls on a quarterly basis.

It would also be a logical follow on from the CPSC's recently published "[Product Instability or Tip-Over Injuries and Fatalities Associated with Televisions, Furniture, and Appliances: 2020 Report](#)." In the report, CPSC estimates an "annual average of 25,500 emergency department (ED)-treated injuries (2017–2019)" and 571 fatalities that occurred between 2000 and 2019. Those are staggering numbers. In response, CPSC continues its consumer education campaigns as a parallel track to regulatory enforcement. Now it looks like retailers and manufacturers are seeking ways to educate consumers while limiting their own liability.

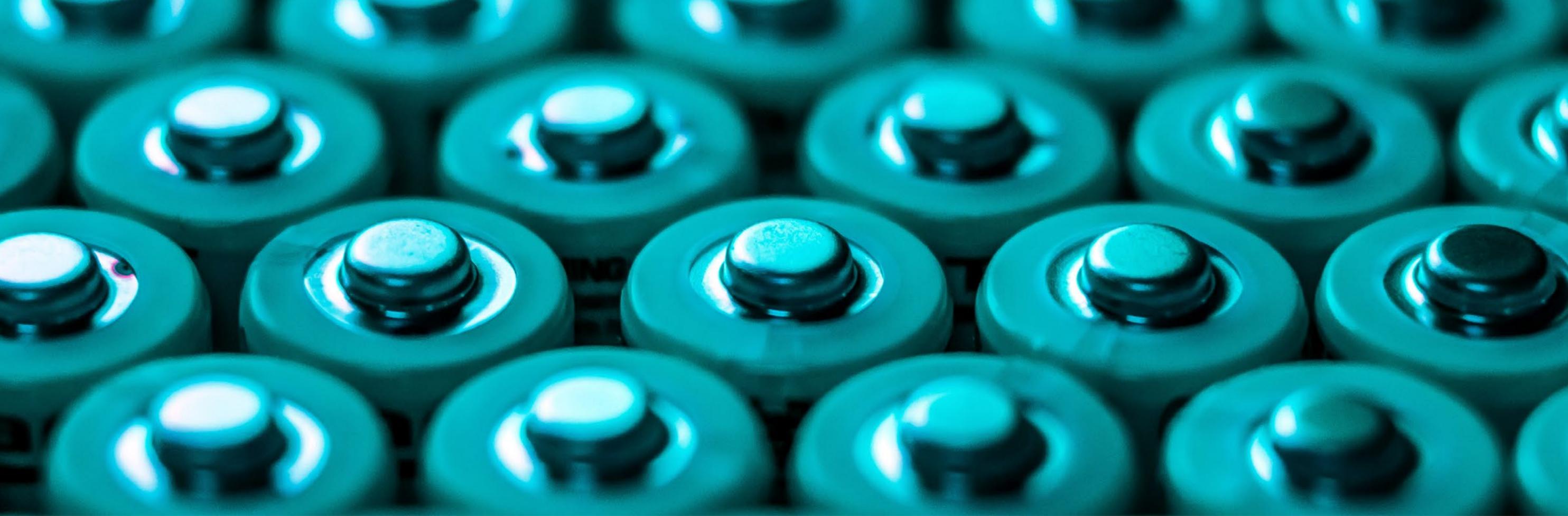
In late January 2021, a leading home furnishing brand announced it would require U.S. shoppers to acknowledge and accept tip-over risks associated with certain furniture and the recommendation they attach the furniture to the wall. In doing so, consumers would provide their name and email address as personal identifiers.

Nancy Cowles, executive director for Kids in Danger, said the move was "a good step" because ensuring consumers are made aware of the safety risks is important. But she also warned that her organization, Kids in Danger, is really focused on making furniture more stable.

As it pertains to recalls, could the solution actually spur a new generation of product registration cards?



“CPSC continues its consumer education campaigns as a parallel track to regulatory enforcement. Retailers and manufacturers are now seeking ways to educate consumers while limiting their own liability.”



Battery-Related Risks, Oversight, and Enforcement Continue to Evolve

Lithium-ion batteries have become ubiquitous to household devices, automobiles, toys, and gadgets of all kinds. Companies around the world turn to lithium-based solutions to power products despite significant risks. We know the CPSC has long been concerned about safety issues associated with these products, but its latest warning was meant for consumers rather than manufacturers.

The CPSC recently urged consumers “not to buy or use loose 18650 lithium-ion battery cells” typically manufactured as part of larger battery packs. The cells, which are intended for individual sale, are being separated, rewrapped, and sold individually on e-commerce websites. The battery cells may have exposed metal positive and negative terminals that can overheat, short-circuit, and ultimately result in “fires, explosions, serious injuries and even death.”

This warning is the latest phase in a product component at the heart of safety issues for many product categories. From smartphones and laptops to hoverboards and electric cars, lithium-ion batteries are notorious for fire risk. They have caused household devices, cars, and even homes to catch fire, resulting in numerous life-threatening injuries. Recalls nearly always follow. One Q4 2020 example was LG Chem Ltd.’s recall of home energy storage batteries that could overheat and start fires.

New Phase of Oversight is Coming for Internet of Things (“IoT”) Products

Before leaving office, former President Donald Trump signed the Internet of Things (IoT) Cybersecurity Improvement Act into law. The ultimate result will be the first federal regulations for IoT devices, which will include security requirements, as well as guidelines for managing disclosures about those devices’ security vulnerabilities. It’s a signal that traditional product safety regulations and the world of data and privacy have finally collided. Companies should expect the regulatory environment to continue evolving under a Biden administration, with more IoT product-related regulations on their way over the next four years.

Ecommerce in the Crosshairs

Over the course of 2020 we examined how Amazon ended up in the crosshairs of consumer product safety issues and product liability claims, and what it would mean for the industry. While we don’t yet have clarity on when or how the legal and regulatory landscape will change for ecommerce companies like Amazon, Alibaba, and others, we do expect it to happen.

In fact, it’s clear that Amazon is feeling the heat. Third-party Amazon sellers are reportedly receiving a flurry of requests for regulatory compliance documents for the products they sell. It could be due to court decisions or in an attempt to pre-empt an imminent regulatory crackdown. Either way, third-party seller and ecommerce businesses would be wise to catch up with any regulatory record-keeping and ensuring the products they sell are authentic, legal, compliant with regulations, and safe for consumers.



Increased Publicity of Enforcement Actions

Product safety advocate groups have long criticized the CPSC for a perceived lack of regulatory oversight and enforcement. Whether or not those criticisms were fair, it was clear by late 2020 that CPSC leadership became more aggressive and vocal in its enforcement actions.

For example, Acting Chairman Robert Adler announced in mid-November that the CPSC was referring to the U.S. Justice Department a case for prosecution of a civil penalty. The Department of Justice later disclosed that a federal judge had ordered Walter Kidde Portable Equipment Inc. to pay a \$12 million civil penalty in connection with allegations that the company failed to timely inform the CPSC about problems with fire extinguishers it manufactured. While the process followed its normal course, the CPSC's announcement was an unusual publicity ploy perceived by some as the regulator trying to take credit for the case.

Consider a second example. The CPSC, along with U.S. Customs and Border Protection, announced in January the seizure of nearly 600 imported girl's bicycles that violated lead paint standards. Again, while the seizure is not unusual, a public announcement for some 600 units seems to be, particularly when you compare it with other government releases issued around the same time for seizures of liquid meth, cocaine, and counterfeit masks for use in protecting against COVID-19.

Regardless of your position in the supply chain and the type of products you manufacture, distribute, or sell, it's likely that under a Democratic majority CPSC will become even more aggressive in publicizing its efforts to protect consumers. Now is the time to double-check your records, and enhance your product safety processes and procedures, before the agency is granted more power – and greater leeway in using that power – to protect consumers.

2020 BY THE NUMBERS

The CPSC announced 66 recalls in the fourth quarter of 2020, bringing the annual total to 257 recalls. While this represents a 7% decrease in recalls quarter-over-quarter, the real story is in the annual numbers. Despite the far-reaching and long-lasting impact of the global pandemic, we saw a 7% year-over-year increase in recalls from 2019 to 2020. This level of recall activity maintained an average five consumer-product recalls every week in 2020.

Recalls in 2020 impacted just over 20 million units. Only one event impacted more than 1 million units: a recall of 5.7 million children's water bottles. Setting that singular recall aside, six recalls impacted more than 500,000 units and an additional 27 recalls impacted between 100,000 and 500,000 units.

Looking more closely at the number of units impacted by recalls, we saw a 116% increase in the fourth quarter, with an average recall impacting about 94,000 units. That's more than twice as large as the average third-quarter 2020 recall. Overall, the average recall in 2020 impacted 78,000 units compared to 90,000 units in 2019.

The product category most often impacted by recalls in 2020 was Home Furnishings and Décor with 57 recalls. Close behind was Sports and Recreation products with 54 recalls and Personal Care products with 41 recalls. Sports and Recreation and Home Furnishings and Décor products have been the top two product categories impacted by recalls for at least the last nine years (since 2012).

Personal Care products, on the other hand, are typically responsible for a small number of recall events each year. In 2019, there were just 12 recalls of Personal Care products. This anomalous activity in 2020 was largely due to a significant number of essential oil recalls and other personal products – all the result of childproof

packaging violations. It is worth noting, however, that despite this 241.7% increase in the number of Personal Care product recalls from 2019 to 2020, the number of impacted units increased by only 21.1% from about 1.1 million units to 1.3 million units.

Injury risk was the top cause of 2020 recalls at 50 events, with fire and childproof packaging violations close behind at 47 and 42 events respectively. Injury and fire risks have been the top two causes for recalls for the past three years. Not surprisingly, the vast majority of injury and fire-related recalls impacted Sports and Recreation and Home Furnishings and Décor products.

JANUARY 2021 INSIGHT

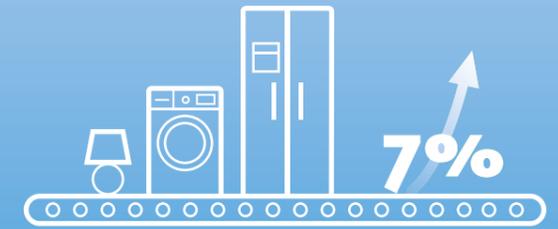
The CPSC announced 10 consumer product recalls in January 2021, compared to a monthly average of 21 recalls in 2020. If recalls maintain this pace for the remainder of the first quarter of 2021, we will see less than half of the quarterly average number of recalls logged since at least 1998.

January 2021 recalls impacted just shy of 200,000 units, compared to a monthly average of 1.7 million units impacted in 2020.

Sports and Recreation products led with three recalls, followed by Home Furnishings and Décor with 2 recalls. Fall and fire risks were the leading causes of recalls, each accounting for three recalls.

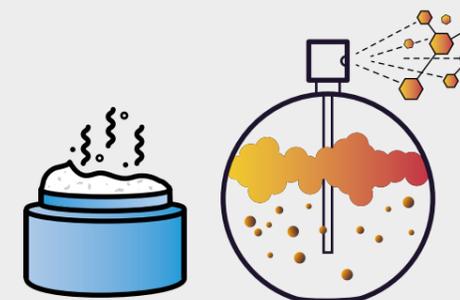
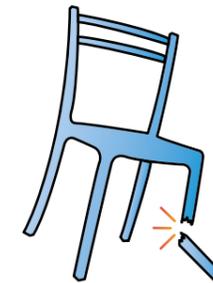


Despite the impact of the global pandemic, **2020 saw a 7% year-on-year increase** in recalls from 2019.



Home Furnishings and Décor

was the most recalled product category in 2020 (57 events), up 36% from 2019.



Personal Care product recalls spiked at **41 events in 2020**, compared to **12 events in 2019**.

WELCOME TO A NEW ERA OF REGULATORY ENFORCEMENT

Expect 2021 to be the start of a new era for the Consumer Product Safety Commission (CPSC). With the opportunity to nominate a Chair and at least two additional Commissioners over the next four years, the Biden administration has the power to influence the direction of the CPSC beyond a single presidential term.

To begin, it is very likely that the Biden administration's first nominee to fill the vacancy for CPSC Chair will be someone with consumer advocacy experience. With such an appointment, an era of more active enforcement and rulemaking can be expected.

Where will increased scrutiny and enforcement come from?

Risks Created by a Strained Supply Chain

Consumer preferences and demand have evolved significantly in 2020, driven in large part by the COVID-19 pandemic. As manufacturers work to respond to these changes, sourcing high-quality raw materials and components in the quantity needed is challenging.

Complicating matters, detecting quality and safety issues stemming from suppliers is not happening in the traditional fashion, in the form of in-person audits, inspections, and product reviews. With suppliers facing only a fraction of the scrutiny experienced previously, there is more incentive for them to cut corners to meet new demands and accelerated delivery expectations.

It is critical that companies take additional proactive and precautionary steps to mitigate the risks created by their stressed supply chains.

While some of the traditional proactive methods for mitigating product safety and quality issues may be less effective during the pandemic, other options abound.

When other safeguards fail, remember customers can serve as an important warning system. By listening and being responsive to the concerns raised, deciding when to take action to prevent possible future incidents and mitigate the risk of enforcement action becomes easier.

Be **more** proactive when monitoring and responding to consumer concerns.

If you are not in the practice of monitoring social media, product reviews, third-party seller sites, and conversations with retail partners, now is the time to start. Lower your threshold for launching an investigation based on the number or seriousness of complaints. Ensure your teams are proactively identifying potential risks and issues, and escalating quickly. These steps will allow you to identify and then address potential issues earlier. Taking these steps also demonstrates a commitment to safety which could help avoid the perception of a delay in CPSC reporting and the related enforcement risks.

While these steps are focused on consumer interaction, there are also ways to limit potential exposure on the manufacturing side by improving traceability. Consider, for example, how batching is handled. The definition of a "batch" varies greatly across the manufacturing industry.



But when oversight of a supply chain is limited, there is significant benefit to a discreet batching system.

For example, instead of one week of production, pare the batch down to one day. When sourcing a component from multiple partners, change batch numbers when switching suppliers or lots. Change SKUs following changes in components or product redesign. This type of carefully designed protocol ultimately has the power to minimize recall exposure when a quality or safety issue is identified.

Increased Presence at the Ports

Even before we see makeup of the CPSC change, the agency is pushing for increased resources and expanded authority. That includes a stronger presence at the ports, a concept already endorsed by Congress.

Importers must be aware of these impending changes. A stopped shipment at the port translates directly to delays, but the impact doesn't stop there. There are legal and regulatory enforcement risks.

When CPSC's increased enforcement at ports first begins, the agency may show some flexibility, allowing companies to correct technical violations such as a missing tracking label or Certificate of Conformity. But after that first violation, it is safe (and wise) to assume the agency will take a harsher future stance. Soon, companies should be prepared for shipments to be held, and even destroyed, at higher rates when compared to what was experienced 2019 and 2020.

We should also expect CPSC to exercise its muscle in areas where it has gained new authority. Lawmakers also tucked

CPSC-related items into broader bills. For example, tucked into the "COVID-19 Regulatory Relief and Work from Home Safety Act" was a provision that instructs the CPSC to adopt the California upholstered furniture flammability standard TB 117-2013. As part of this mandate, the Act requires manufacturers to apply a label to furniture that asserts compliance with this new standard. This label requirement makes enforcement not just attractive for the CPSC, but easy. Once the law takes effect, expect the CPSC to launch an enforcement program utilizing both port and retailer inspections to identify non-compliant products, and either stop them at the ports or pressure companies to announce recalls.

Now is the time to get the house in order, before facing double trouble: complete destruction of product shipments at the ports combined with regulatory enforcement actions by the CPSC, Customs and Border Protection, and possibly others.

Intellectual Property and Product Safety Will Collide

Manufacturers and traditional brick-and-mortar retailers alike are growing increasingly concerned about Intellectual Property (IP) issues, particularly when it comes to the potential for fraudulent products to find a way into consumers' hands. These industries are joining forces to pressure legislators and regulators to address concerns over IP violations, especially as they relate to e-commerce and platform sellers. Legislators and regulators have taken notice. At the CPSC, Commissioner Dana Baiocco, for one, is very interested in curtailing the online sale of counterfeit and fraudulent products by leveraging an increased presence at the ports.

IP is traditionally outside the scope of the CPSC's jurisdiction. When it comes to the import of fraudulent, counterfeit products, regulation falls more squarely under the purview of U.S. Customs and Border Protection.

But regulators understand that, when a product is fraudulent or counterfeit, the violations often go beyond IP laws. For example, counterfeit products likely do not meet relevant safety standards, and were probably not tested by third-party laboratories. As the agencies collaborate more frequently at the ports, increased enforcement is a likely result. If Customs and Border Protection stops a shipment of product for IP concerns, inspectors may also call CPSC to evaluate the product for safety issues.

Surgical Approach to Legislation, Enforcement will Broaden

Expect the CPSC's approach to rulemaking and enforcement to be far more impactful in the months and years to come.

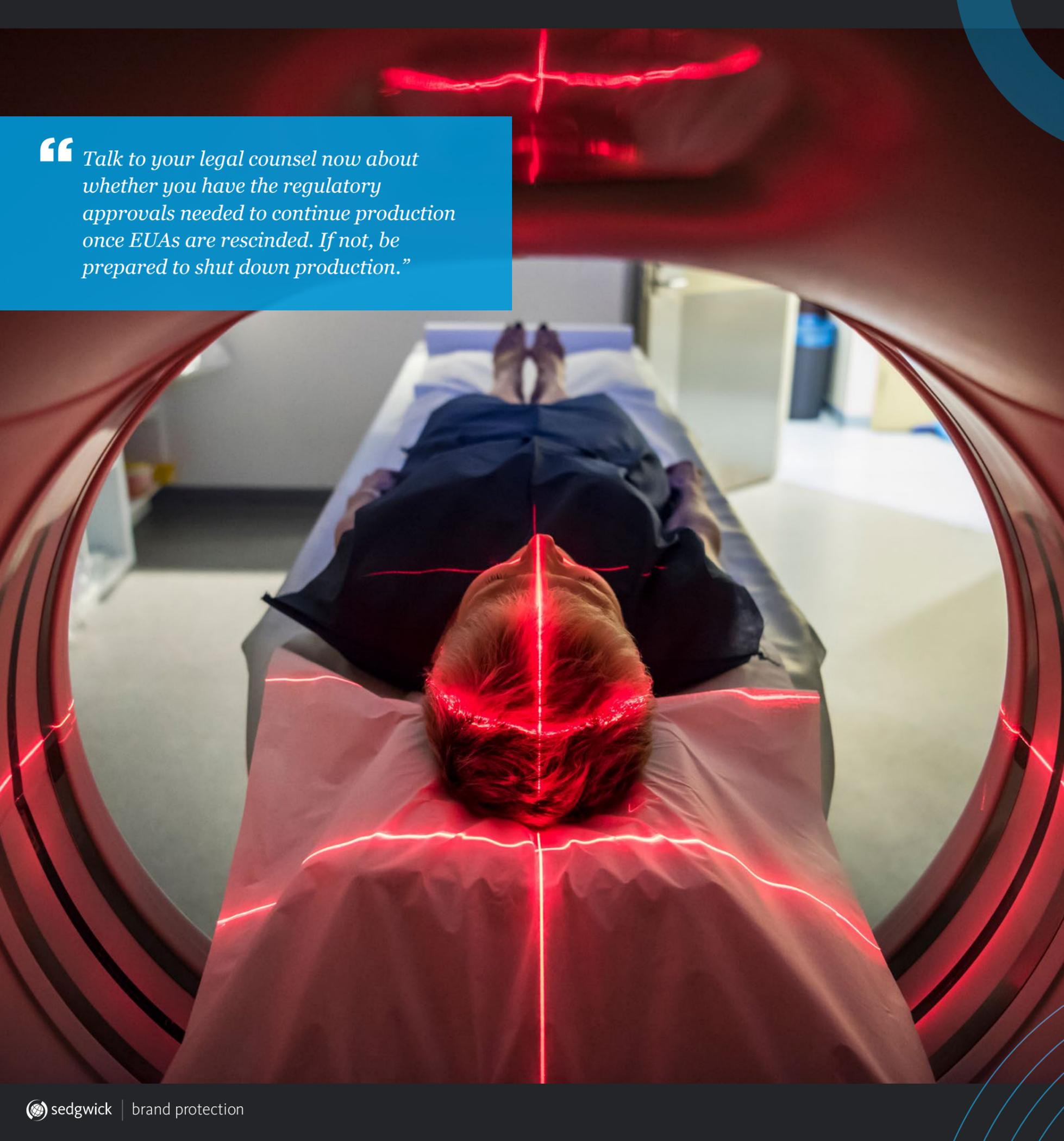
Under the Trump administration, attempts at legislation were narrowly focused. Most legislation was focused on specific hazards or products, like furniture stability or portable fuel containers.

With both houses under Democratic control, there is greater appetite for a comprehensive review of the CPSC and its statute (the Consumer Product Safety Improvement Act). Key changes would likely include an increase on the CPSC's penalty authority, removing the controversial Section 6(b) requirements limiting the CPSC's ability to disclose product safety information, and removing barriers to CPSC's ability to pass new mandatory safety standards.

Until then, recent announcements by the CPSC should serve as a reminder that the agency will likely want to show that we are in a new era. In the Commission's mind, the bigger the announcement, the better. Think enforcement activities like major recalls, sweeping port inspections, and financial penalties. These are the types of activities that will ultimately help the agency counter the perception that it isn't doing enough to protect consumers, and especially vulnerable populations like children.



“ Now is the time to get the house in order, before facing double trouble: complete destruction of product shipments at the ports combined with regulatory enforcement actions by the CPSC, Customs and Border Protection, and possibly others.”



“Talk to your legal counsel now about whether you have the regulatory approvals needed to continue production once EUAs are rescinded. If not, be prepared to shut down production.”

MEDICAL DEVICE

As we look ahead, here's what medical device companies need to think about in 2021 and beyond.

Emergency Use Authorizations (EUAs) Will Come to an End

The time will come, possibly as early as mid to late 2021, that the FDA will begin revoking EUAs, reverting to unapproved status medical devices that were not approved by traditional means. From that moment forward, legal protections currently offered to the companies manufacturing or distributing these products will likely be non-existent.

What that means for future product liability cases, class action litigation, and regulatory enforcement may very well depend on your ability to demonstrate a strong safety record and a history of appropriate marketing activity (in other words, you did not commit COVID-19 fraud). You should also be talking to your legal counsel now about whether you have the regulatory approvals needed to continue production once EUAs are rescinded. If not, be prepared to shut down production of those unapproved medical devices and withdraw devices from the market the moment the EUA is revoked.

COVID-19 Fraud will Draw Scrutiny From the FDA and DOJ

Suspected COVID-19 fraud will be a hot-button issue across industries, and the medical device sector is no exception. In a “[COVID-19 Product Regulation Enforcement Roadmap](#)” recently authored by the team at Morrison Foerster, legal experts warn that companies can expect enforcement activities such as warning letters or product recalls for products claiming to:

- Provide any type of COVID-19 testing.
- “Treat” or “fight” COVID-19 or “inhibit” the virus.
- “Prevent” or “reduce the risk” of contracting COVID-19; or
- Treat or reverse bodily symptoms caused by COVID-19.

But these risks go beyond allegations of product efficacy and patient safety.

If you need a specific example for just how damaging an accusation like this could be, consider the recent indictment of Decision Diagnostics Corp. (DECN) CEO Keith Berman. According to a Justice Department announcement, Berman was “indicted by a federal grand jury in connection with an alleged scheme to defraud investors by making false and misleading statements about the purported development of a new COVID-19 test, leading to millions of dollars in investor losses.”

FDA Action on Artificial Intelligence-Enabled Software

The FDA’s Focus Areas of Regulatory Science (FARS) highlighted several priorities related to medical device safety, including the agency’s focus on improving the way it conducts product safety surveillance.

As the FDA went deeper, the agency released a plan for how it will develop and evolve the regulatory framework by which it will oversee artificial intelligence/machine learning (AI/ML)-based software as a medical device (SaMD). While the framework offers helpful insight and direction from the FDA, it will be constantly evolving as the agency learns more and the technology behind the software and devices progresses.

It is critical that companies in this space work closely with FDA to the extent they are able. After all, software is, and will continue to be, a primary reason for medical device recalls.

Virtual Inspections will Inform Future Inspections and Regulatory Enforcement

It is well-known that the number of on-site inspections of medical device facilities plummeted in 2020 as a result of the COVID-19 pandemic. In response, FDA has been seeking ways to remotely evaluate regulatory compliance. That process is no doubt going to involve requests for various records and video meetings aiming to evaluate a company’s due diligence and quality management systems.

When speaking about the progress being made, FDA Assistant Commissioner for Medical Products Elizabeth Miller explained that company records can be “used as an indicator of a firm’s compliance and may allow us to focus and limit time needed on an on-site inspection, or in advance of an inspection to later occur.” In other words, proving you are running a tight ship could delay future scrutiny. Otherwise, be prepared to be among the first companies receiving an unannounced visit when FDA inspectors get back on the road. If this approach proves to be beneficial to the agency, expect these more detailed virtual inspections to be a long-standing part of the regulatory oversight process.

Regulatory Enforcement will be a Collaborative Effort

International collaboration will also be critical to ensuring the safety of the global drug supply. We know that many regulatory bodies are working out processes for sharing findings of remote and in-person inspections to better protect consumers worldwide. Companies should plan for the inevitable fact that any inspectors, regardless of the regulatory body they officially represent, will be sharing the information they collect with their counterparts around the world. Whether it is findings from an on-site inspection or results of remote sampling, expect regulators to freely share the information to protect consumers across their borders.



“Company records can be used as an indicator of a firm’s compliance and may allow us [FDA] to focus and limit time needed on an on-site inspection, or in advance of an inspection to later occur.”

2020 BY THE NUMBERS

Recalls decreased slightly to 235 incidents in the fourth quarter, down just 2.9% from 242 recalls in the third quarter and resulting in a seven-quarter low. Despite this decline, we saw a total of 1,078 recalls in 2020, just short of our predicted 1,100 recalls for the year. By comparison, 2019 saw a total of 884 recalls.

In a similar fashion, we saw a year-over-year increase in impacted units. 2020 recalls impacted a total of about 467 million units, the most units impacted by recalls since at least 2012. In 2019, recalls impacted just over 430 million units. This record was in part due to a quarterly record-high number of units impacted in the first quarter of 2020, resulting from a single anomalous event impacting more than 314 million units.

At 169 recalls, software issues were the top reason for recalls for the 18th time in the last 19 quarters, and the leading cause of recalls for 2020. But this does not carry over as the leading cause of recalls in terms of impacted units. While 43 fourth quarter recalls, or 18% of fourth quarter events, were the result of software issues, these 43 recalls impacted a mere 640,000 units, or just 1% of recalled units.

Other leading causes of recalls in 2020 were quality concerns and mislabeling issues, accounting for 148 and 124 recalls respectively. By comparison, software led 2019 recalls with 184 events, with quality and mislabeling issues also among leading causes, triggering 117 and 105 events respectively.

The leading cause of fourth quarter recalls in terms of impacted units was mislabeling, accounting for 22 million units. Mislabeling was followed by quality issues impacting about 18 million units.

When we look at activity over the duration of 2020, 67.4% of recalled units were the result of a product being manufactured outside of specifications. Nearly all of these were involved in the anomalous recall referenced above. In 2019, the leading cause of recalls by units was quality concerns, impacting 273 million units. In 2018, manufacturing defects were the leading cause, impacting 196 million units.

Of fourth-quarter recalls, 84.3% impacted products distributed nationwide. In terms of the global impact of recalls, 46.5% of U.S. FDA recalls impacted products distributed to international customers.

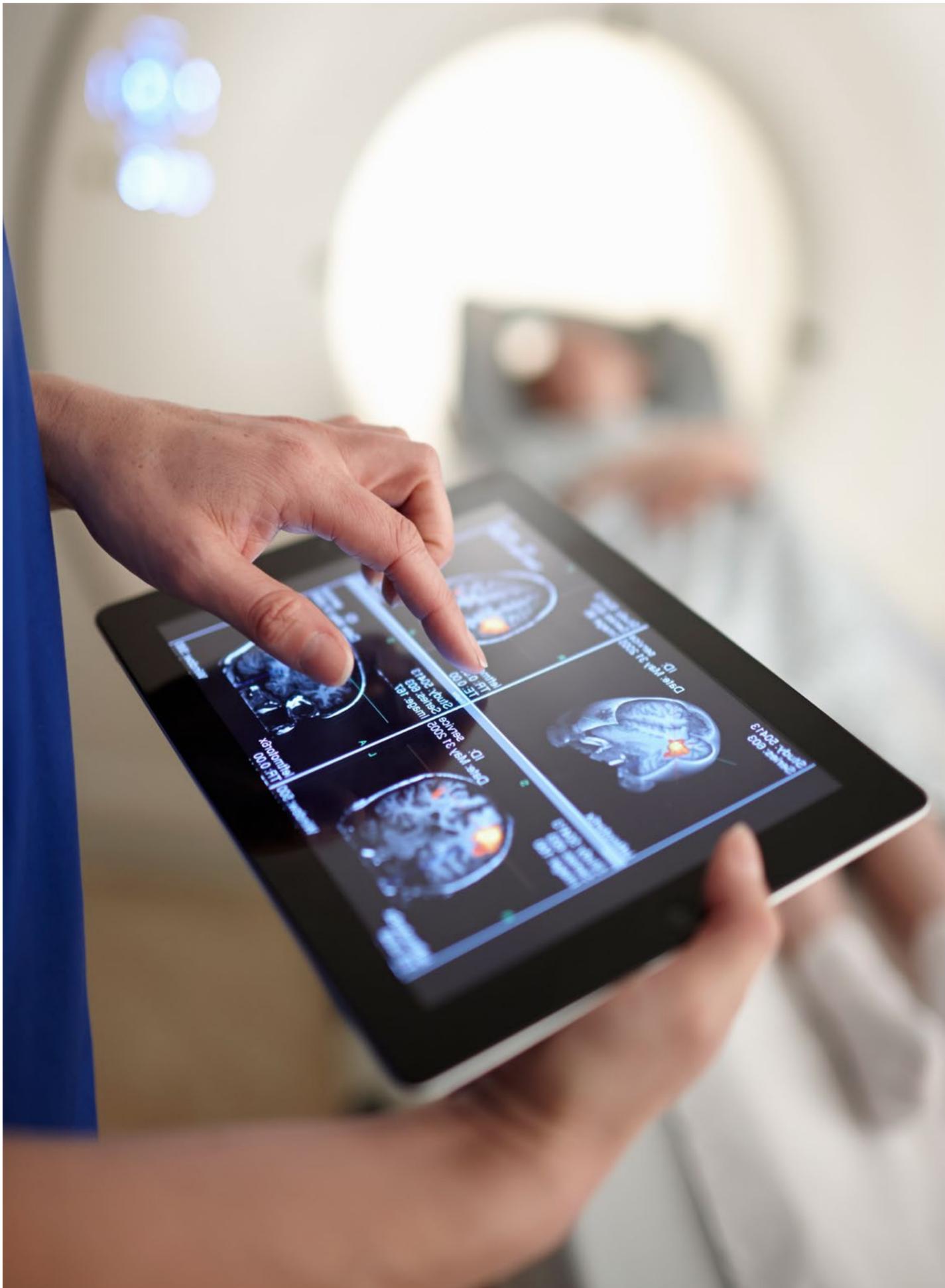


JANUARY 2021 INSIGHT

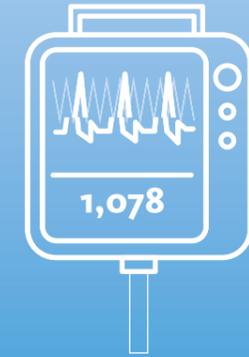
The FDA disclosed 63 medical device recalls in January 2021, compared to a monthly average of 90 recalls in 2020.

January recalls impacted about 6.8 million units, with one event accounting for 63.7% of all affected units. Adjusting for that anomalous recall, the average January 2021 recall impacted just under 40,000 units. By comparison, the average recall size for a 2020 recall was 433,000 units. In further evidence of the smaller size of January medical device recalls, 58 recalls in January 2021 impacted fewer than 10,000 units.

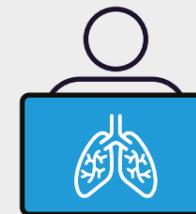
Software issues were the leading cause of January 2021 recalls at 15 events, followed by Quality concerns with 12 recalls.



2020 saw 1,078 medical device recalls, compared to 884 in 2019, **a 22% increase.**



467M units were impacted in 2020, **a record high since 2012.**



Software issues remained the top reason of recalls for 18 of the past 19 quarters, and the leading cause of recalls for 2020. **In Q4 2020, there were 169 recalls in total.**

CONSEQUENCES OF A PANDEMIC-DRIVEN DEVICE INDUSTRY

As companies and regulators around the world navigate a global pandemic, nearly everything known about supply and demand or regulatory oversight activities has been turned upside down.

The medical device industry is experiencing new market entrants sparked purely by an increase in demand for COVID-19 devices such as diagnostic tests, ventilators, and personal protective equipment (PPE). Simultaneously the Food and Drug Administration (FDA) needed to find new ways to conduct oversight and enforcement activities in a remote or virtual fashion – all while prioritizing its support of the nation’s coronavirus response.

Through this process, there have been a few COVID-19 inspired consequences that the medical device industry should expect to remain even when the pandemic is over.

Creative Approaches to Regulatory Oversight

With inspections at record low levels over the last year, the FDA is becoming more creative in how it approaches regulatory oversight. For one, it is widely known that the agency is utilizing virtual inspections where it can. Less discussed is that the FDA, in lieu of in-person inspections and traditional record reviews, is taking to Google for insight on potential enforcement actions.

FDA staff are reviewing publicly available information on the Internet for discrepancies or violations in the marketing or positioning of a product. When something runs afoul, instead of issuing warning letters, for less egregious issues or concerns regulators are picking up the phone or sending emails and telling companies to

make corrections. Much of this on the COVID-19 side of things, but it is not limited to pandemic response products. This online research could also serve as an indicator of where the FDA should focus its efforts even when on-site inspections and other traditional oversight activities resume.

Opportunistic Marketing that Turns into Fraud

When it comes to manufacturing-related risks, the supply chain continues to be a concern for medical device companies. In some cases, component manufacturers are making false or exaggerated claims, often related to COVID-19. There have been many missteps here, particularly among companies that have the mindset that claims may be made since only a component of a product is provided and the claims provide ideas or suggestions for end use. This is absolutely not the case, however, opening these component manufacturers up to scrutiny that could have been avoided.

These matters have the potential to worsen if a manufacturer of a finished product adopts a claim, putting both companies at risk of regulatory enforcement actions. Violations to this end, however, have been rare and will likely stay that way. Manufacturers of end-use devices generally have a greater understanding of the regulatory environment, specifically the guidance for making product-related claims.



The biggest challenges will be for companies that, often unknowingly, go too far in trying to capitalize on pandemic-inspired consumer demand. These are companies that, for whatever reason, want to get into the COVID-19 market, and start making claims about the efficacy of products in preventing transmission of the coronavirus, testing for infections (or antibodies), or treating someone who has contracted the virus. There are several companies that realized too late that the moment a medical-related claim was made, they entered the world of medical devices. At that moment, FDA regulatory oversight and enforcement actions became a reality.

Evolution of Emergency Use Authorizations

As long as the country is in a state of declared pandemic, Emergency Use Authorizations (EUAs) will remain a critical component of regulatory guidance, oversight, and enforcement. Further, the process and protections will likely continue to evolve.

In fact, changes in the EUA process have been one of the biggest challenges facing medical device manufacturers. Consider the case of face masks and PPE – some of the

first products addressed through the EUA process, only for the recommendations to change a few months later as agency thinking and understanding of potential risks also evolved. Those types of changes are a challenge for businesses to follow and adapt in the normal course of business, let alone during a time of supply chain disruptions, increased demand, and product shortages.

The impact of EUAs is also likely to last far longer than the pandemic. The longer EUAs stick around, the more long-term the effects on the composition of the medical device industry. Many companies that benefited from EUAs are currently evaluating whether to take the next step of filing a 510(k) before the EUAs expire in order to be a medical device company for the long-haul. The reasons could vary – from viewing the move as a survival tactic that will help the company emerge from the pandemic to a strong desire to be a medical device company long-term.

Either way, the medical device industry is more likely to maintain something more similar to its current competitive composition than revert to its pre-COVID-19 business landscape.

Recalls are Driving Litigation

Separate and apart from the pandemic response, but still very much relevant to COVID-19 products, medical device companies must understand the legal ramifications of enforcement actions – and specifically product recalls.

Increasingly, plaintiff consumer litigation law firms are monitoring the FDA website for recall activity as inspiration for lawsuits. In fact, it is almost inevitable that a recalling firm will face at least one lawsuit as a direct result of the recall announcement. A lawsuit could come in several shapes and forms (or even a combination of the following):

- Class action product liability,
- Unfair trade practices,
- State law violations (e.g., Prop 65 in California), and
- Securities class action, to name a few.

Companies need to be careful about what is said about the recall and underlying issues, and how it is communicated. While there will be specific information the FDA requires as part of the recall, be very careful how the issue and actions are characterized beyond the FDA process. Just one wrong word has the potential to increase legal exposure.

As companies consider potential legal risk, keep in mind COVID-19 products may benefit from some of the indemnity provisions within the Public Readiness and Emergency Preparedness (PREP) Act, these protections are not likely to be the blanket indemnification some may think. There is always the risk that a plaintiff's attorney tries to apply state law theories, pursue medical negligence or malpractice claims, or even test the PREP Act indemnity directly. Companies must prepare for this eventuality, because even if the lawsuit ultimately goes away, it will have a lasting impact in the form of a costly legal expense, an operational distraction, and, the longer it plays out, potentially, a damaged reputation.

To sum these consequences up with one overarching piece of advice: be sure to think big and broad about risk and exposure within the medical device industry. While regulatory safety issues should be a top priority, public and private companies need to think holistically about the risks faced in terms of state and international laws, rules, statutes, and litigation. Too narrow of a focus on any one of these will likely serve to increase your risk exposure somewhere else.



PHARMACEUTICAL

As we look ahead, here's what pharmaceutical companies need to think about in 2021 and beyond.

Drug Quality and Current Good Manufacturing Practices (cGMP) are Top Recall Enforcement Priorities

Whether we look at prescription drugs or over-the-counter medications, the leading causes of recalls and enforcement actions are typically the same. From a recall perspective, we know that violations in Current Good Manufacturing Practice (cGMP) regulations and quality issues are routinely the top reasons for recalls.

Expect the FDA to have a continued focus on cGMP, especially when it comes to foreign Active Pharmaceutical Ingredient (API) manufacturers. It is critical for manufacturers, especially during a global pandemic, to be even more diligent with ensuring suppliers are meeting standards and quality requirements. Regardless of when it happens, companies need to be prepared if the agency takes enforcement action or requires a recall that reaches as far back as the last inspection or start of the pandemic.



“It is critical for manufacturers, especially during a global pandemic, to be even more diligent with ensuring suppliers are meeting standards and quality requirements.”

NDMA Continues to Trigger Recalls, Litigation

Valisure's 2019 discovery of likely carcinogen N-Nitrosodimethylamine (NDMA) in heartburn and diabetes medications is having long-lasting ramifications.

We continue to see a regular stream of NDMA-related recalls through 2020 and into 2021. We saw nine recalls due to NDMA in the fourth quarter of 2020 alone, bringing the total to 36 for the year. By comparison, just 12 recalls were announced for NDMA contamination in 2019. We suspect this story is far from over. Recalls are likely to continue as regulators and pharmaceutical companies grapple with understanding how and when the contamination occurs.

In fact, it is very likely about to get worse. U.S. District Judge Robert Kugler in New Jersey allowed fraud allegations to proceed against several generic valsartan

blood pressure drug manufacturers that allegedly sold the products they knew were contaminated with NDMA.

On top of that, Valisure recently published a study in the *Journal of the American Medical Association (JAMA) Network Open* which suggests ranitidine drugs can cause NDMA to form under a range of conditions, including in the human body, thus increasing cancer risk. In fact, if you do an Internet search for 'ranitidine,' you may see ads from plaintiff law firms atop the results, along with links to multiple studies citing the drug's link to cancer. We expect an increase in litigation in light of these findings.

Regulatory Enforcement is Now a Collaborative Effort among Global Agencies and Independent Organizations

The impact of Valisure's 2019 discovery of NDMA contamination sparked a string of product recalls, influential consumer protection efforts, and stricter regulatory enforcement. As a result, independent organizations have seen how they, like Valisure, can have a public role in protecting patients, and they are jumping on board to proactively monitor drug quality and safety.

From pharmacies to academic institutions, these organizations are conducting their own investigations, testing, and publicizing any findings that call the safety of products into question. These efforts increased as COVID-19 kept the FDA from conducting on-site inspections. One example we shared in the Third Edition of the Recall Index was the petition from University of Kentucky researchers to FDA, requesting a recall of Mylan and Hikma versions of an injectable diuretic after finding high impurity levels.

In addition, collaboration among regulators worldwide is proving even more critical to ensuring the safety of the global drug supply. We know that many regulatory bodies are working out processes for sharing findings of remote and in-person inspections to better protect consumers worldwide.

Companies should plan for the inevitable fact that any inspectors, regardless of the regulatory body they officially represent, will be sharing the information they collect with their counterparts around the world. Whether it is findings from an on-site inspection or results of remote sampling, expect regulators to freely share the information to protect consumers across their borders.

COVID-19 Products Remain in the Spotlight

Remember that the definition of COVID-19 products is broad. It includes products recommended by health officials to prevent the transmission of the coronavirus, as well as treatments and vaccines. Hand sanitizers is one product category scrutinized by the FDA. Dietary supplements making COVID-19 claims is another. Safety of these products is a primary concern, but suspected fraud is another hot-button issue.

As of mid-November 2020, more than 1,200 fraudulent products were identified by FDA. As at-home COVID-19 testing kits become more available, and consumers continue to look for ways to protect themselves or recover from the coronavirus, fraud will remain a top priority. As long as COVID-19 remains a concern, these products will stay in the spotlight.

The team at law firm Morrison Foerster recently published a "[COVID-19 Product Regulation Enforcement Roadmap](#)" in which the authors offer the below list of product claims most likely to spark FDA scrutiny. Expect enforcement activities such as warning letters or product recalls for products claiming to:

- Provide any type of COVID-19 testing.
- "Treat" or "fight" COVID-19 or "inhibit" the virus.
- "Prevent" or "reduce the risk" of contracting COVID-19; or
- Treat or reverse bodily symptoms caused by COVID-19.

But it is not just the FDA that's worried about the dangers these products may pose to people and the environment. The U.S. Environmental Protection Agency (EPA) has taken action indicating that it sees certain products, like hand sanitizer wipes, falling under its regulatory purview. The EPA has called on at least one hand-wipe manufacturer to submit a recall plan, saying the product is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act. This is not surprising given the all-hands-on-deck approach to product regulation and safety during the pandemic, and companies should only expect to see more of this type of regulatory overlap and even collaboration.



“Regardless of the type of pharmaceutical product you manufacture or its intended use, now is the time to prepare for increased regulatory oversight and enforcement in 2021 and beyond.”

Return Focus on Longstanding Priorities

The FDA’s Focus Areas of Regulatory Science (FARS) highlights several issues that are directly related to product safety, including a focus on the quality of compounded drugs, technologies to reduce pathogen contamination, and leveraging data to improve product safety surveillance.

Likewise, we know product safety risks impacting hot-button issues such as API safety, opioids, cannabis, and vaping products haven’t fallen entirely off FDA’s radar, but they have taken a back seat to pandemic response. Don’t expect that to last forever. In fact, the tide may already be changing at the federal and state level.

On September 10, 2020, the FDA announced the issuance of warning letters to 17 website operators in China, Iceland, India, New Zealand, Pakistan, and the United States involved in the illegal importation and sale of unapproved and misbranded opioids. These letters are a reminder that the FDA will pursue companies throughout the supply chain, making it even more important the companies understand their risks up and downstream.

Meanwhile, Oregon cannabis regulators recently banned several additives that potentially could harm marijuana vape users. Depending on the path the FDA ultimately takes with cannabis and Cannabidiol products, growers, producers, manufacturers, and retailers must all be prepared for increased regulatory scrutiny, warning letters, and ultimately enforcement action at the state and federal level.

Regardless of the type of pharmaceutical product you manufacture or its intended use, now is the time to prepare for increased regulatory oversight and enforcement in 2021 and beyond.



2020 BY THE NUMBERS

About halfway through 2020, we predicted that it would still be feasible for the drug industry to experience a similar level of recall activity to 2019 – before COVID-19 response changed the way businesses and regulators operate. Our prediction became reality.

Even with minimal inspection and regulatory enforcement activity, we saw 344 pharmaceutical recalls in 2020, representing a 2.4% increase compared to 2019. While this is a small increase in the number of events, 2020 recalls impacted nearly 133 million units, or 50.6% more units than were impacted by 2019 recalls.

Fourth-quarter recalls impacted 84 recalls compared with 100 recalls announced in the third quarter. This is a 16% decrease in recall events quarter-over-quarter. These recalls impacted 30 million units, representing a 11.1% decrease compared to the third quarter.

cGMP deviations and failed specifications were tied as the leading cause of fourth-quarter recalls, each leading to 24 events. It marks the sixth time in the last seven quarters that cGMP deviations were a leading cause of recalls. Not surprisingly, it secured cGMP deviations as the top cause of recalls in 2020.

For perspective, cGMP deviations were the leading cause of recalls in 2019, and the second-leading cause in 2018 followed by failed specifications.

cGMP deviations were the top cause in terms of units in the fourth quarter, impacting more than 24 million units or 81% of all recalled units. Similarly, cGMP deviations were the leading cause of units recalled for the entirety of 2020, accounting for 63 million or 47% of recalled units.

Among fourth-quarter recalls, 64 impacted products distributed nationwide, while just 5 affected products sent internationally. When we look at activity over the course of the year, 273 recalls impacted products nationwide, and 18 impacted products sent internationally.



JANUARY 2021 INSIGHT

The FDA logged 23 pharmaceutical recalls in January 2021, with just one of these events receiving the FDA's Class I designation. By comparison, the FDA announced 33 recalls in January 2020 and a monthly average 29 recalls for the year.

January 2021 recalls impacted about 4.9 million units. That equates to an average recall size of about 214,000 units. By comparison, an average 11 million units were recalled each month in 2020. The average size of a pharmaceutical recall in 2020 was about 386,000 units.

Failed specifications, cGMP deviations, and sterility issues were the leading causes of recalls at five events each.

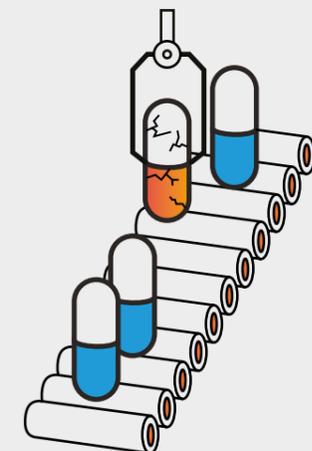


NDMA-related recalls have **increased threefold** from **12 (2019)** to **36 (2020)**.

More than **1,200 fraudulent** COVID-19 products were identified by FDA in 2020. The clamp down on counterfeiting will remain a key priority in 2021.



Current Good Manufacturing Practice (cGMP) deviations were the leading cause of recalls in 2020, accounting for **63 million or 47% of recalled units**.



POST-PANDEMIC RISKS ARE HIGH FOR THE PHARMACEUTICAL INDUSTRY

A year into the pandemic, the FDA is still squarely focused on COVID-19 response. As a result, routine inspections and enforcement actions remain less frequent and the approval process for traditional pharmaceutical and medical device products has slowed.

While it may appear the risks and scrutiny for the pharmaceutical industry that existed pre-pandemic have lessened for the time being, the bounce back to an era of more intense scrutiny and enforcement may be closer than conventional wisdom predicts. The impact of COVID-19 regulatory actions, evolving scientific understanding, and a new Administration are three developments that must be considered and followed closely.

COVID-19, Emergency Use Authorizations, and Future Liability

One way the FDA has been able to support the pharmaceutical industry during the pandemic is through Emergency Use Authorizations (EUAs) enabling companies and organizations to expedite to market products like drugs, vaccines, and devices used in the prevention, detection, and treatment of COVID-19.

Given the urgent need to contain COVID-19, the FDA and other health officials did not want companies to discourage innovation that could lead to prevention, detection, or treatment solutions out of fear of future legal liability. In response, the United States Department of Health & Human Services (HHS) issued new amendments to its Declaration under the Public Readiness and Emergency Preparedness (PREP) Act that enhanced protections for companies involved in addressing emergency products needed for COVID-19.

While this is an important protective measure for companies, the liability immunity provided under the PREP Act is yet to be tested. In other words, there is no precedent yet as to how courts will interpret and apply the statutory protections.

In the meantime, companies with any product in the drug and device space should consider, and prepare for, the risk that someone having an adverse experience with a product will likely pursue legal action.

Evolving Science Introduces New Risks

A critical component of the FDA's mission is ensuring products on the market are safe. This is an endless, complicated job that will never be finished – not because the FDA is not working tirelessly but because science teaches us something new every day. Consider the issues related to the potential contaminant nitrosamine, or specifically N-nitrosodimethylamine (NDMA).

Varying levels of NDMA have been found in some pharmaceuticals, including certain blood pressure medications and heartburn medications. While those medications have been withdrawn from the market, the FDA has continued to engage in a root cause analysis. In responding to the recent uptick in reports of nitrosamines in pharmaceuticals, the FDA noted that

improved technology has enabled the detection of even trace amounts of impurities in drug product, which may be the reason why more products have been found to have low levels of nitrosamines. While health experts and FDA officials are thinking about how to address this issue, the FDA has moved forward with guidance and rulemaking. For example, in September of 2020, the FDA issued a guidance on the recommended steps manufacturers of Active Pharmaceutical Ingredients (APIs) and finished drug products should take to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products.

At the same time, the companies that make these products are named in a growing number of lawsuits. More clarity is expected in 2021– both because of the regulatory and the litigation processes.

In the meantime, expect certain pharmacies and academic institutions to continue disclosing results

of their investigations. Consumers believe these organizations are working in the best interest of the public, even though, in some cases, the answers to many questions like who's conducting the research, why they are studying the issue, what their methodology is, and whether results have been verified is incomplete.

Companies should plan now for how to respond if and when another impurity is identified. It is not unreasonable to think that other potential impurities may be discovered as science evolves.

In that planning, consider the fundamental question at the heart of the toughest issues facing the pharmaceutical industry. What obligations does a company have to advance science to determine any and every potential risk? There's no single, easy answer to this question. But it's one that companies should consider. Regulatory compliance is not always considered enough in the Court of Public Opinion.





**ANDREW KAPLAN, PARTNER,
CROWELL & MORING**

CONTINUED FROM PREVIOUS PAGE

Future of the FDA Under the Biden Administration

Under the Biden administration, there will be changes at the FDA, both in terms of leadership and the direction of the agency. Over the last four years, there was a substantial decline in formal enforcement mechanisms used by the FDA – a trend that was exacerbated by the pandemic. Expect that trend to reverse. From an increase in official warning letters and consent decrees to utilizing the Courts, companies may face more regulatory and legal risk in the years to come than they did during the prior administration.

A segment of these actions will be related to products granted approval under EUAs. The FDA will be focused on ensuring that the products that have been approved through this process are complying with the regulatory requirements.

As FDA staff get back to doing more in-person audits and inspections, the ease at which the agency can monitor and evaluate regulatory compliance and product safety will greatly increase.

Companies must maintain a focus not just on the obvious risks of quality control, cGMP, and maintaining regulatory compliance, but also ensuring a safe and reliable global supply chain. One organization's misstep can have a lasting regulatory, legal, financial, and reputational impact up and down the supply chain.



“ 91% of shoppers trust their grocery store to sell safe food. That is ultimately reflective of consumer confidence in the food industry.”

Source: 2020 U.S. Grocery Shopper Trends Report

FOOD AND BEVERAGE

2020 was a tumultuous year for the food industry. Companies maintained their operations, but faced supply chain disruptions, product shortages, labor issues, continued threats of litigation, and shifts in consumer shopping habits and buying preferences.

The good news is that the Food Marketing Institute's [2020 U.S. Grocery Shopper Trends Report](#) found that 91% of shoppers trust their grocery store to sell safe food. That confidence is ultimately reflective of consumer confidence in the food industry. Still, the industry will see new food safety rules, increased oversight and enforcement, and more lawsuits in the future.

Food Safety Litigation Risks Remain

While the claims evolve and shift over time, food safety class-action lawsuits remain a top risk for food companies the federal government ordered to remain in operation during the pandemic. Where slack-fill lawsuits were once hot, we now see labeling-related cases increasing in popularity. Chief among them at the moment are “all-natural” claims or allegations related to the origin of a product. In the same spirit of seeking clarity on the terms used to market a product, plant-based protein products should prepare for their day in court. Before we see a drop in these types of cases, we will need regulators to clearly define terms like “all-natural” or what products can be called “milk.” Otherwise, we leave it up to consumer interpretation, which could be ripe for legal action, particularly false-advertising claims.

But there will be another wave that is more focused on workers than consumers. Food companies, and specifically meat packers, are facing lawsuits alleging that plant employees were placed at an increased risk of contracting COVID-19. The claims are new ground for food companies, and frankly manufacturers or producers across industries. A potential defense also remains untested. As Law.com reports, “Tyson Foods Inc. is turning to federal preemption to wipe out negligence lawsuits brought by dozens of employees and their families who got sick from the coronavirus.” This could be a watershed moment for this type of litigation, at least in the food space, and should be closely watched.

Shifting Recall Mindset May Backfire

As food companies struggled to meet shifting consumer demand, bounce back from product shortages, and frankly survive to see another day, the recall mindset shifted. While companies continued to recall products that posed a health or safety risk to consumers, non-health or safety related recalls dropped off significantly. It’s what regulatory attorneys and food safety experts call a “only-recall-if-absolutely-necessary” mindset.

Under that concept, rather than risk a recall of a product that fails to meet a full-line requirement, a manufacturer may elect to risk a false-advertising lawsuit to meet the recent shift in retail food demand.

But this isn’t the only risk. Companies that made these bets may also ultimately need to answer to FDA if the agency determines that a company’s records aren’t sufficient to support a decision not to recall a product.

A Crackdown on Undeclared Allergens

We know that regulators see no excuse when it comes to certain food safety and labeling risks. Chief among them is a failure to appropriately warn consumers about the potential presence of allergens in a product. Yet undeclared allergens remain the leading cause of food recalls.

These factors combined are likely the impetus for FDA’s January 2021 public update on food allergen-related consumer protection efforts that suggests a regulatory crackdown has started.

FDA notes in the public update that, “Since March 2020, FDA sent warning letters to eight registered food facilities that have manufactured and distributed foods with undeclared major food allergens that resulted in Class I recalls. Those registered food facilities are required by statute to implement food safety preventive controls that significantly minimize or prevent the hazard of undeclared major food allergens before the food is distributed.”

The FDA often determines whether food facilities have appropriate controls in place through on-site inspections, which we know have been limited. For now, expect regulators to ask for evidence that you have the proper preventative controls in place in the form of paper or electronic records. Then, when they get back on site, be prepared to show them those controls in action.

But the crackdown might not be limited to the big eight allergens.

In November 2020, FDA issued a draft guidance “encouraging food manufacturers to voluntarily declare sesame in the ingredient list on food labels.” In the release of that guidance, FDA noted that, “while the exact frequency of sesame allergies in the U.S. is unknown, it is estimated in some recent studies to be more than 0.1%, which is similar to allergies to soy and fish.”

Recalls Likely to Increase in Post-Pandemic Era

The companies we work with in the food industry are undoubtedly committed to following food-safety regulations and implementing best practices to protect consumers from food-related risks. But when you add supply chain disruptions, changing consumer preferences, and the need to implement enhanced safety protocols to protect employees from COVID-19, there’s a chance for compliance or product quality to slip.

In his personal outlook for food safety in 2021, David Acheson, founder and CEO of The Acheson Group and former FDA Associate Commissioner for Foods, notes that “the gravest food safety concern may be some businesses ‘cutting corners’ which could cause a greater risk of food adulteration of food, misrepresentation of ingredients, and recalls – for which we may see an overall rise in food recalls in 2021.”

While that is certainly the case, we may also see an increase in recalls as a result of simple lapses in record-keeping that create enough concern among FDA and USDA inspectors that a recall is required.

Regardless, food companies should be focused not only on continuing to evolve in response to consumer and market forces, but also the regulatory and legal environments that are presenting new risks – especially for companies trying to innovate.



2020 BY THE NUMBERS

FDA

FDA recall activity slipped from 106 recalls in the third quarter to just 92 in the fourth quarter. This brings 2020 recalls to 418 events, down from 498 recalls in 2019. This continues the downward trend in FDA recalls we have seen since 2016's high of 719 recalls.

Fourth quarter activity represents a 13.2% decrease quarter-over-quarter. Recall activity decreased 16.1% year-over-year.

Recalls in the fourth quarter impacted a mere 1.8 million units. This represents a 79.9% decrease compared to the third quarter and the lowest volume of units we have seen since the second quarter of 2013. Over the course of 2020, 27.4 million units were recalled. Again, this represented the fewest number of units recalled annually since 2012. For comparison, recalled units decreased 252.3% compared to 2019 when more than 96.5 million units were impacted by recalls, and 907.3% compared to 2018 when more than 276 million units were recalled.

Of fourth-quarter recalls, 35.8% of events were Class I. This is in line with recent years when about one-third of recalls were designated as Class I. These most severe

events impacted 22.7% of all units in the fourth quarter. Class I recalls impacted 38.5% of all recalled units in 2020.

Bacterial contamination was the leading cause of FDA food recalls in terms of events and units in the fourth quarter, taking over undeclared allergens as the top cause of events for the first time since the first quarter of 2017. Bacterial contamination was the reason for 27 fourth quarter recalls impacting 1.6 million units. Eighteen of these events were the result of Salmonella contamination.

Listeria was the top cause of recalls resulting from bacterial contamination in 2020, leading to 43 recalls. Salmonella was a close second with 42 recalls. Listeria and Salmonella have routinely been the top bacterial contaminants impacting FDA recalls since at least 2015.

Undeclared allergens remained the top cause of FDA food recalls for at least the sixth straight year, accounting for 41.1% of 2020 recalls. Bacterial contamination, however, impacted the most units on an annual basis, impacting about 12.4 million units or 45.2% of recalled units.

Of the 170 recalls in 2020 due to undeclared allergens, 43 contained only undeclared milk, 18 contained only undeclared nuts, and 17 contained only undeclared soy. Another 27 recalls contained more than one undeclared allergen.

Prepared foods were the top product category impacted by fourth quarter recalls for the 15th time in the last 16 quarters. The category accounted for 22 recalls or 23.9% of fourth quarter events, and 1.2 million units or 66.5% of all units recalled in the fourth quarter.

When we examine activity over the course of 2020, prepared foods were the subject of 114 recalls, or 27.3% of recalls. This type of volume has become typical for prepared foods in recent years as millennial and Gen Z consumers – who tend to value convenience – grew as a consumer segment. It is also worth noting that prepared foods are most often recalled due to undeclared allergens and bacterial contamination – the usual leading causes of recalls across all categories.

JANUARY 2021 INSIGHT

The FDA announced 23 food recalls in January 2021. By comparison, the FDA on average announced 35 recalls each month in 2020. The leading cause of January 2021 recalls was undeclared allergens, accounting for 12 events. Baked Goods and Produce tied for the leading cause of FDA food recalls at six events.

**UNDECLARED ALLERGENS
REMAINED THE TOP CAUSE OF
FDA FOOD RECALLS FOR AT
LEAST THE SIXTH STRAIGHT
YEAR, ACCOUNTING FOR**

41%

OF 2020 RECALLS.

USDA

USDA recalls remained extremely low through the close of 2020 compared with recent years. With just seven recalls in the fourth quarter, USDA announced only 32 recalls in 2020 compared to 123 recalls announced in 2019 and 125 recalls in 2018.

For the first time since we started analyzing this data, the top cause of recall events and units for the quarter was a lack of inspection. 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. While that is notable, it is prudent to note that the lack of an inspection is not a rarity, having led to 26 recalls in 2019, or 21.1% of the year’s recalls. What is arguably more unusual is that we saw zero recalls due to bacterial contamination in the fourth quarter, and just a single event for the entire year.

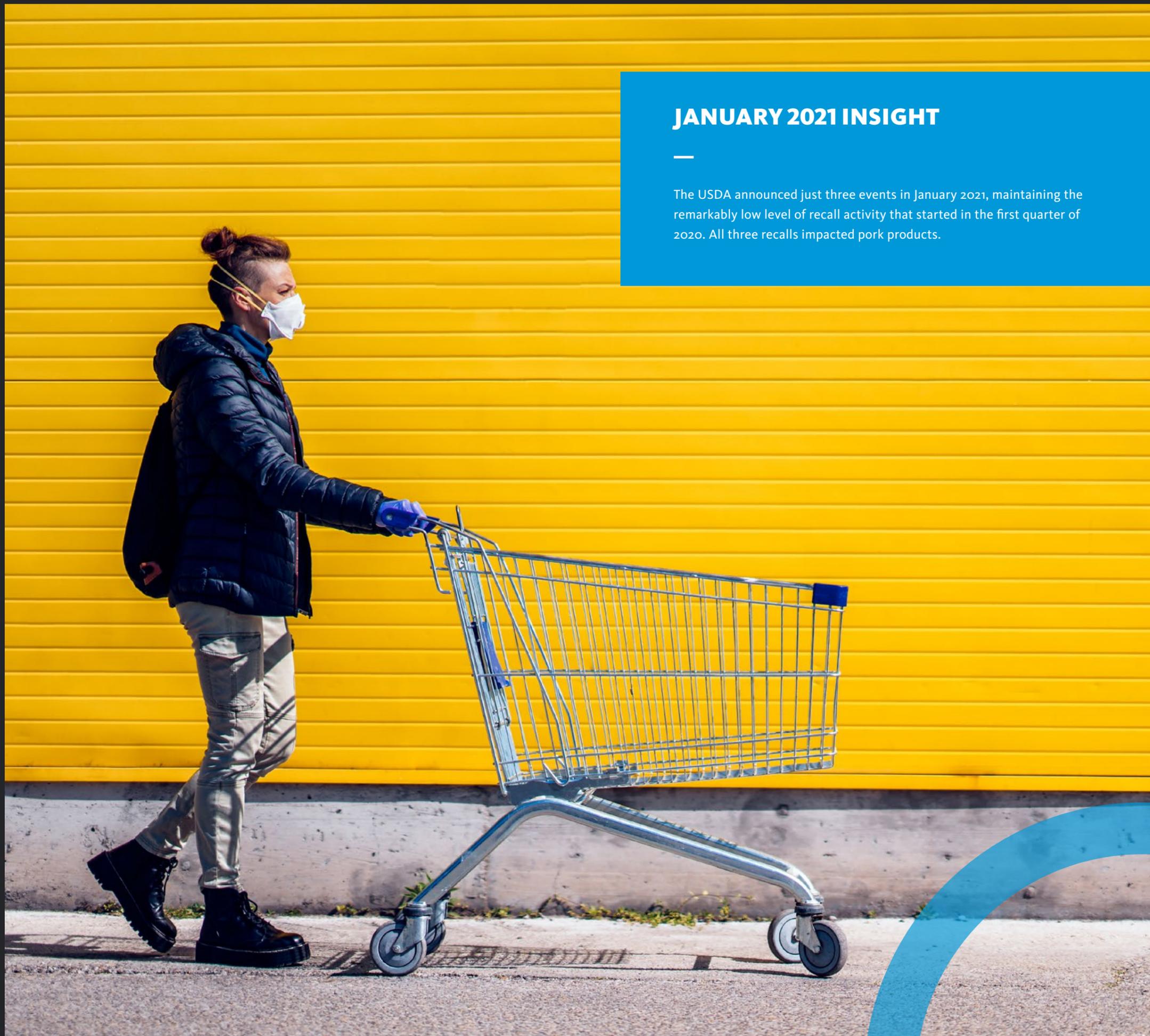
There are also other disparities in the data when we draw further comparisons between 2020 and previous years. The leading cause of USDA food recalls in 2019 was foreign material with 34 events, followed by undeclared allergens with 31 recalls. These causes resulted in 5 and 12 events respectively.

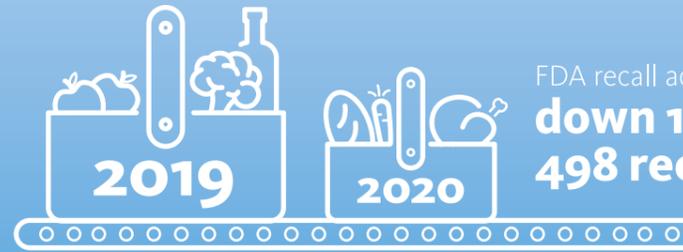
Quarterly recall activity remained low at an average eight recalls each quarter in 2020 compared with an average quarterly volume of more than 30 recalls over the last three years.

Poultry products were the most impacted category in terms of both events and units in 2020. Eleven recalls impacting more than 600,000 pounds. Products containing multiple meat ingredients were a close second with 10 recalls impacting about 536,000 pounds. To provide further context, poultry products were the leading category impacted by product recalls in 4 of the last five years, only surpassed by beef products in 2018.

JANUARY 2021 INSIGHT

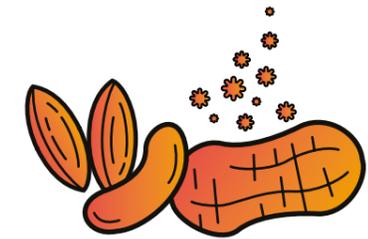
The USDA announced just three events in January 2021, maintaining the remarkably low level of recall activity that started in the first quarter of 2020. All three recalls impacted pork products.



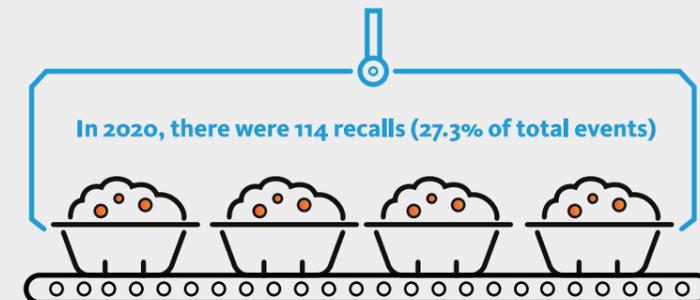


FDA recall activity fell to 418 events in 2020, **down 16% from 498 recalls in 2019.**

Undeclared allergens remained the top cause of FDA food recalls for six consecutive years, accounting for **41% of 2020 recalls.**



Prepared foods remained the most recalled category for 15 of the past 16 quarters.





**BRIAN EYINK, PARTNER,
HOGAN LOVELLS**

FOR FOOD INDUSTRY, ENFORCEMENT ERA IS COMING

A global pandemic and presidential election cycle made 2020 a peculiar year for regulatory enforcement. These circumstances, and the challenges of adjusting to an ever-changing “new normal,” make it difficult to pinpoint longer-term Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) enforcement trends among all the noise.

Some short-term trends are clear. A careful look at USDA recalls reveals that, while recall activity dropped to low levels in 2020, it was trending in that direction before the pandemic set in. Exactly why that happened is unclear. It could be safety improvements, a change in regulatory posture, or, more likely, a combination of both. These reductions occurred even as the USDA maintained inspections throughout the COVID-19 pandemic.

The FDA, on the other hand, drastically scaled back its food enforcement portfolio, suspending for a time nearly all facility inspections except for serious for-cause inspections that were pre-announced per COVID-19 protocol. With low inspection activity, a drop in FDA enforcement activity followed.

While it's difficult to imagine 2020 representing any sort of long-term status quo, we can still make several predictions for post-pandemic FDA and USDA enforcement under the Biden administration.

Regulators will Adopt an Enforcement-Oriented Posture

Food companies are entering a world where regulatory oversight will become more focused on enforcement, a pivot from “educate then regulate” to just “regulate.” Some of this change will reflect a Democratic predisposition toward more aggressive regulation, although FDA and USDA remained vigorous enforcers even under the Trump administration. But this pivot will be about more than just a change in political leadership.

FDA is entering a new, more enforcement-oriented phase in FDA Food Safety Modernization Act (FSMA) implementation. As FDA rolled out a series of game-changing regulations, the agency adopted an “educate while you regulate” approach, recognizing that it would take several years for companies to truly adapt to the new regulations. With the major FSMA regulations now firmly in place, and with FDA having already conducted one or more rounds of FSMA inspections, FDA is already beginning to view the “education” phase as having

concluded, and food companies will see that manifest as inspections become increasingly focused on driving enforcement actions rather than educational efforts. This can already be seen in the recent uptick in FDA Warning Letters citing violations of Foreign Supplier Verification Program (FSVP) requirements.

This trend will be amplified as the country emerges from the worst of the COVID-19 pandemic and FDA resumes more regular inspections. Chances are, as FDA investigators start making their rounds, they will find food safety issues that may have previously slipped under the radar, triggering 483s, warning letters, and recalls.

Recordkeeping Violations will Trigger Enforcement Actions, Recalls

Companies regulated by the FDA will face increased risks related to recordkeeping obligations. Recordkeeping will become increasingly important in two ways. First, now that FSMA recordkeeping requirements have been in full effect for several inspection cycles, FDA will likely shift its enforcement approach and review records with increasing rigor. Recordkeeping lapses that went unnoticed in the past will increasingly be targeted. Second, because FDA all but suspended inspections during the worst of the COVID-19 pandemic, a company's food safety records will provide the best opportunity for FDA to look back in time. That means companies can still face enforcement risks for things that happened during the height of the pandemic.

This shift may ultimately start before FDA inspections fully return to business as usual. The FDA has expressed interest in remote records access in some situations, although that authority was considered but ultimately omitted when Congress passed FSMA. Nonetheless, if FDA finds itself in a position where it is difficult or high-risk to conduct in-person inspections, yet has the ability to obtain records remotely, enforcement will become highly dependent on recordkeeping.

Slips in recordkeeping could have costly impacts. Completing every form accurately is important regardless of the staffing challenges, supply chain disruptions, product shortages and shifting demand caused by the pandemic. And if FDA or USDA reviews those records, it could be months or years after the fact, when the immediate memory of the myriad challenges posed by COVID-19 crisis has begun to fade.

Undeclared Allergens Will Be an Enforcement Priority

FDA and USDA have long been concerned about undeclared allergens, the leading cause of all food recalls. Both agencies have consistently expressed frustration with undeclared allergen recalls, especially when the result of human error.

In response, FDA in particular has signaled over the last several months that protecting consumers from undeclared allergen risks is a top priority. From publicized warning letters to new guidance on sesame, the publicity the FDA is generating around undeclared allergens is the agency's way of saying “shame on you” to the food industry. Companies should expect ramped up enforcement to reinforce to this point.

On-site Inspections will be More Searching

Once on-site inspections resume, be prepared for the FDA and USDA to demonstrate a more searching approach beyond just record reviews. Inspectors will look closely for environmental pathogens. Increased swabbing and product sampling can be expected. And, as has been the case for several years now, any positive results will undergo whole genome sequencing (WGS), and those patterns will be run through databases to see if they match sequences from prior inspections or foodborne illness.

Inspections will also continue to emphasize the basics, including adherence to Good Manufacturing Practices (GMPs) and sanitation. In an economically challenging year, decisions to cut costs and reduced maintenance budgets could affect facility repair, and high employee turnover could result in poorer adherence to training. Expect inspectors and investigators to take notice.

The bottom line for 2021 and the post-pandemic future is that federal access to production, manufacturing, and storage facilities—coupled with overarching trends in FSMA implementation and a change in administration—will mean more recalls and more enforcement. Now is an important time to be vigilant. It is the time to increase and support food safety programs to minimize risk, protect consumers, and protect your company.

AUTOMOTIVE

Electric vehicles are soon to have their moment in history thanks in part to the new Biden administration, which is promulgating regulations highly favorable to that automotive category. But beyond this news, 2021 is likely to be another challenging year for the auto industry, marked by decreased consumer demand for new cars, an aging fleet, near-constant recalls, regulatory oversight and enforcement actions, and a U.S. regulatory agency seeking to improve its reputation. Here is what we see as top priorities in 2021:

Recalls will be Scrutinized

Recall effectiveness has been a long-standing challenge for automakers. In response, throughout 2020 we saw NHTSA and automakers launch programs and innovations in response to data showing that consumers ignore recall fixes 40 percent of the time. But with no single industrywide solution to this challenge, companies should expect continued scrutiny and sanctions until effectiveness rates increase.

“With consumers ignoring recall fixes 40% of the time, automakers should expect continued scrutiny and sanctions until effectiveness rates increase.”



But effectiveness rates are not the only aspect of recalls that we expect to be increasingly scrutinized. Kaitlin Wowak, assistant professor of IT, analytics, and operations at Notre Dame's Mendoza College of Business, recently published a study titled, "[Hiding in the Herd: The Product Recall Clustering Phenomenon](#)." Among the chief findings, automakers delay recall announcements to minimize the financial impact, often resulting in clusters of similar recalls by other companies.

Wowak further notes that NHTSA does not ask manufacturers to provide the date they became aware of the potential or confirmed defect, adding that doing so "may discourage them from hiding in the herd and prompt them to make more timely and transparent recall decisions, reducing the prevalence of clustering, which creates unnecessary delays in removing harmful products from the market."

A Potential Turning Point for Electric Vehicles

In January 2021, we started hearing more about the Biden administration's goals for the transportation industry, most notably the promise of an Electric Vehicle (EV) era. He aims to deliver on the promise through tax credits for EV purchases, tax credits to automakers, establishing the necessary EV charging infrastructure, as well as investments into batteries and other technological advancements.

These policies are certain to increase the adoption rate for electric and hybrid vehicles. But there will be growing pains. Electric vehicles are still too expensive for most consumers – an issue possibly exacerbated by the financial impact of the COVID-19 pandemic and the lower auto purchasing rates of younger, urban consumers. To the extent that consumers are looking to buy a car, many are opting to shop for a used or certified pre-owned vehicle. Very few EVs currently fit this description. Even when cost isn't a factor, concerns about charging times, range, and lifespan rank high among consumer concerns.

Then there are the perceived safety issues recently associated with certain EVs. There have been several reports of the Lithium-ion batteries used to power EVs, impacting a number of automakers who have since initiated product recalls. In response, NHTSA launched a new [Battery Safety Initiative](#) that will prioritize collecting safety data, researching issues like battery diagnostics and cybersecurity, investigating incidents, and making the agency a global leader in battery safety regulations. On top of industry-wide issues, one leading global EV OEM has faced some quality issues and manufacturing errors, which are increasingly the focus of NHTSA scrutiny, service bulletins, and recalls. Chief among them in recent weeks is safety issues related to infotainment systems, bringing us to our next prediction.

“ Even when cost isn't a factor, concerns about Electric Vehicle charging times, range, and lifespan rank high among consumer concerns. Then there are the perceived safety issues. ”



Smart Auto Technology Will Face Increased Scrutiny, Regulation, and Litigation

The team at Morrison Foerster pointed out in a [recent article for Law360](#) that “in 2020 plaintiffs filed more putative class action complaints against vehicle manufacturers related to infotainment systems in vehicles” that either did not operate as expected or they caused safety issues.

In another case (that was later dismissed by the court), we saw the first product liability suit against an automaker alleging that a pedestrian fatality involved a vehicle with an Automated Driving Systems (ADS). These

cases, and others like them, are expected to be more active in 2021.

But consumers aren't the only ones responding to the growth in smart auto technology. For example, NHTSA is working on a new safety framework specifically on ADS. The agency recently submitted advance notice of proposed rulemaking, and accepted comments on that framework through February 1. The notice left the door open for NHTSA to develop specific Federal Motor Vehicle Safety Standards (FMVSS) for ADS.

Pressure on NHTSA will Transfer to Automakers

Criticism of NHTSA is nothing new, but we have certainly seen a wave of complaints in recent months as we prepared for the Biden administration to drive the regulatory agenda at the Department of Transportation and NHTSA. Among the criticisms levied by Fair Warning and others:

- NHTSA has failed to meet Congressional deadlines to put in place enforceable rules and safety measures.
- Civil settlements with automakers, dealers, and component manufacturers for such offenses as hiding safety defects and delaying recalls declined sharply.
- NHTSA has been without an official Administrator for an entire presidential term.
- The agency has not set rules for autonomous driving features.

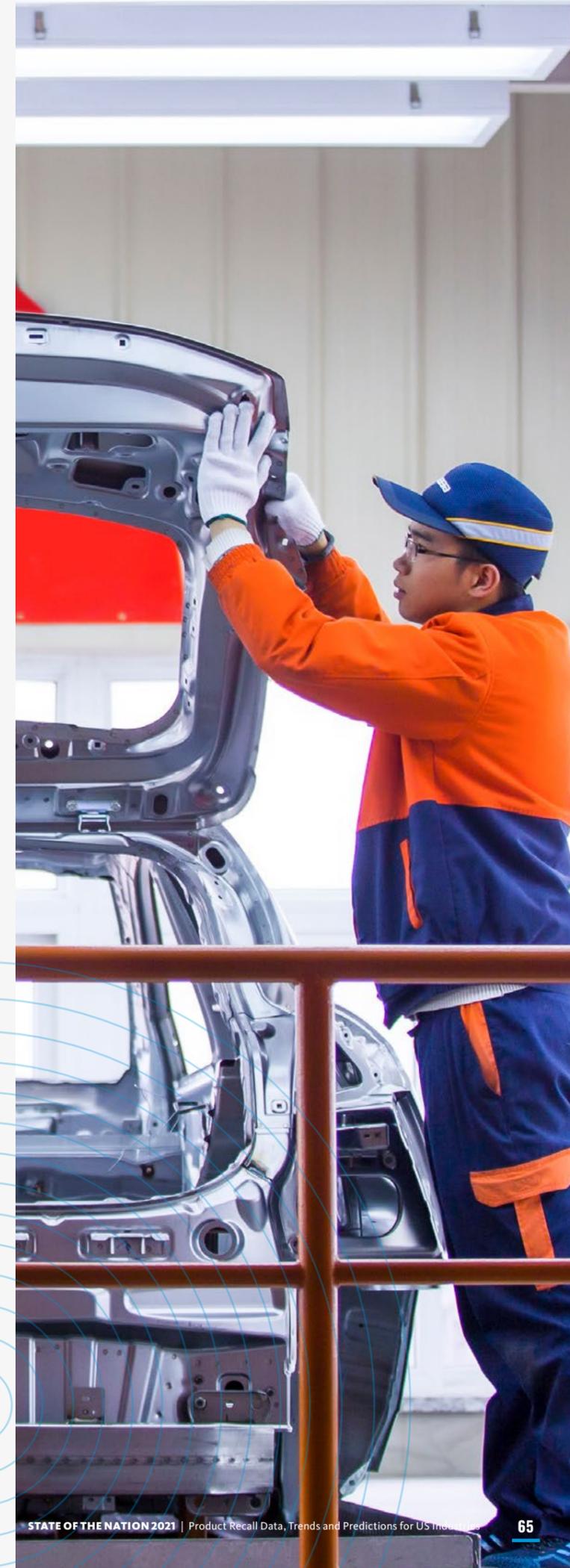
In early 2020, the National Transportation Safety Board (NTSB) also took a swing at NHTSA. Following NHTSA's investigation into a fatal crash involving an autopilot system, NTSB criticized the agency for failing to thoroughly evaluate how well driver monitoring systems worked, and whether passengers could be put at risk as a result of system limitations. On top of that, the NTSB said NHTSA did not have a strong system in place for investigating potential defects related to autopilot technology.

Stability in NHTSA Leadership on its Way

With the installation of a new Administrator, we can expect stability and direction that the agency purportedly lacked during the Trump administration.

That is not to say that the agency and the companies and products it regulates are any less safe than they were previously. In fact, recall and enforcement activities were fairly steady over the duration of the last four years, with only a slight dip in 2020, likely a result of the COVID-19 pandemic.

Given the public scrutiny and criticism the agency has seen from consumer advocacy organizations, a clear leader and direction will likely be a welcome change, at least for agency staff. But what remains to be seen is who will take the helm and what their agenda will be for the agency. To that end, there are more questions than answers about the direction of regulatory enforcement. Companies would be wise to prepare for worst-case scenarios because one thing is for sure: the new Administrator will be looking to repair the agency's poor reputation among consumer advocates, likely at the cost of automakers and OEMs.





2020 BY THE NUMBERS

As we predicted in our Third Edition of the 2020 Recall Index, automotive recall activity increased 16% in the fourth quarter to 181 recalls. But the quarterly activity was not enough to surpass 800 recalls for the year, a threshold the industry passed every year since 2013. Fourth quarter events impacted 7.4 million units, representing a 39.6% increase compared with the third quarter.

Despite the decrease in recall events, automotive recalls still impacted more than 50.3 million units in 2020, just shy of the 50.7 million recalled units in 2019 and significantly higher than the 30 million recalled units in 2018.

We continue to expect steady recall activity in both events and units impacted in 2021, particularly in response to ongoing investigations into seat belts and lithium-ion batteries used in electric vehicles.

Equipment remained the top cause for NHTSA recalls at 35 recalls impacting the category. Representing 19.3% of fourth quarter recalls, equipment remained the top cause of recalls for 14 of the past 15 quarters. Recalls of fuel systems, however, impacted the most units, accounting for 3.3 million units, 44.1% of all units recalled.

Auto vehicles continue to be the largest category of NHTSA recalls, accounting for 165 fourth-quarter recalls. Fifteen fourth quarter recalls impacted equipment, while one impacted tires.

When we look at 2020 activity, 666 events impacted automobiles, while the equipment category experienced 67 recalls. Going deeper, when we look at affected units, the leading cause of recalls was air bags – as it has been since at least 2017. This component was the cause of 44 automobile recalls impacting eight million vehicles, and an additional two equipment recalls affecting 11 million units.

AUTOMOTIVE RECALL
ACTIVITY INCREASED

16%

IN THE FOURTH QUARTER
TO 181 RECALLS.

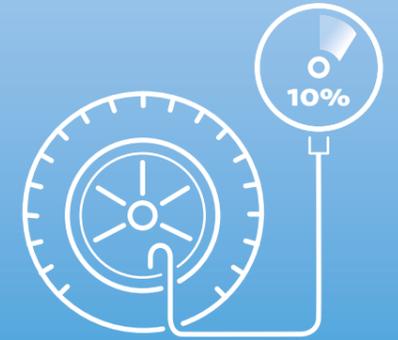
JANUARY 2021 INSIGHT

NHTSA announced 24 recalls in January 2021 compared to a monthly average of 61 recalls in 2020. Five recalls impacted equipment with the remainder impacting automobiles. January 2021 recalls impacted about 522,000 total units, or an average 22,000 units per recall. By comparison, the average size of a recall in 2020 was about 68,000 units.

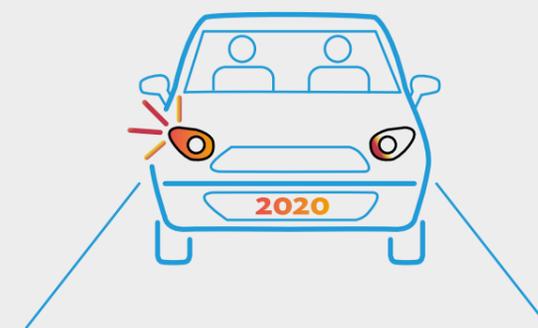
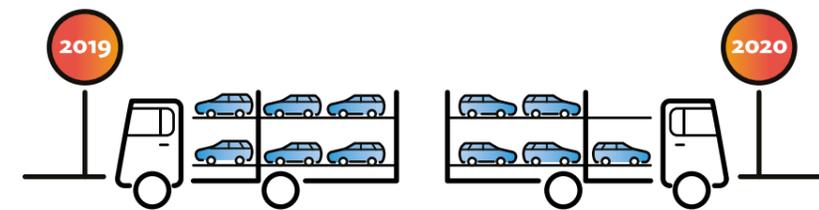




Auto recalls declined 10% from 2019 (823) to 2020 (739), the **lowest events** recorded since 2013.



Despite the drop in recall events, total units impacted reached **50.3M in 2020, just shy of the 50.7M in 2019**, and far exceeded 30.0M in 2018.



Equipment remained the **top cause of recalls** for 14 of the past 15 quarters. In Q4 2020, there were 35 recalls (**19.3% of the category**).



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A “WHOLE COMPANY” RESPONSE TO THE BIDEN ADMINISTRATION’S “WHOLE GOVERNMENT” FOCUS ON AUTO SAFETY AND CLIMATE INITIATIVES

Safety is a core part of Transportation Secretary Pete Buttigieg’s vision for the transportation and automotive industries. He envisions a whole-government approach to regulation, oversight, enforcement, and risk mitigation.

At the same time, he also plans to prioritize combatting climate change. That’s a noble goal, but when the rubber meets the road, what does Secretary Buttigieg’s vision mean for automakers, equipment suppliers, and software providers when it comes to automotive safety?

Under the Trump Administration, while investigations, recalls, and enforcement actions generally declined. The Trump Administration similarly sought to reduce the agency’s fuel-economy goals and associated penalty amounts. In 2021 and beyond, the National Highway Traffic Safety Administration (NHTSA) is expected to shift into reverse, renewing the agency’s focus on both safety and fuel economy imperatives. The agency’s actions are likely to take various forms, including new investigations, consent orders, and civil penalties, as well as criminal investigations in cooperation with the Department of Justice Criminal Division and U.S. Attorneys Offices.

While the whole-government approach promises significant advancement of the twin goals of safety and climate protection, it also underscores the complexities and challenges both the automotive industry and NHTSA are likely to face in ensuring coordination and harmonization amongst an array of federal and state regulators. Indeed, in recent years NHTSA’s automotive oversight has collided with the Environmental Protection Agency’s (EPA) environmental protection priorities, conflicting state-by-state regulations, and litigation at the federal, state, and consumer levels.

One illustration of this complex regulatory and legal environment is reflected in the proceedings related to the Takata air bag recall. In addition to the costly recall demands, stakeholders faced a number of other challenges, including product liability and class action lawsuits, criminal and state Attorneys General investigations, bankruptcy proceedings, and federal

and state environmental and hazardous materials transportation agency action.

Due to the NHTSA recall, as well as product liability lawsuits, Takata was required to preserve and store a percentage of recalled air bags and inflators, so that the inflators would be available for defect analysis.

The storage of a large number of recalled air bag inflators spurred concerns of other agencies that enforced federal and state environmental and hazardous transport laws. When the EPA learned about the millions of inflators being stored, the agency expressed concerns that they might be considered hazardous waste. State regulators expressed similar concerns, and other constituents of the Department of Transportation also raised questions relating to the requirements for shipping these inflators. Simply put, the interests and objections of these parties and others did not always align. Given the competing priorities of multiple overlapping regulators and private parties, it was critical to negotiate a coordinated approach acceptable to multiple stakeholders. Ultimately, the regulators and private parties were able to reconcile these competing concerns by drawing on NHTSA, EPA, and other regulatory expertise to craft a preservation and disposal plan workable for all stakeholders. Takata’s preservation obligations were lifted in phases to accommodate both NHTSA and private plaintiffs’ desire to store inflators for inspection, while also ensuring the ability to comply with EPA and state disposal requirements, and court-imposed protective orders.

While noteworthy in its own right, the Takata experience underscores the growing complexity of the legal and regulatory risks facing companies today.

The next frontier for intense and coordinated regulatory oversight and enforcement is likely to be lithium-ion and other batteries used in automobiles. Like air bag inflators, issues concerning the preservation, transportation, and disposal of recalled batteries may result in diverging viewpoints among various regulatory agencies and private parties. Moreover, Secretary Buttigieg’s goal of encouraging a shift from traditional combustion engines to electric vehicles is likely to result in safety-related growing pains. Safety-related risks related to lithium-ion batteries are already the cause of several ongoing investigations and auto recalls worldwide.

Lithium-ion challenges are just one of the speed bumps on the road to transforming the automotive industry into Secretary Buttigieg’s and President Joe Biden’s vision of a transportation industry dominated by clean technology.

Another area likely to be the subject of growing regulatory scrutiny relates to software, which has both safety and environmental implications. We can expect the Biden Administration’s NHTSA to increase its focus on software safety enforcement.



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CONTINUED FROM PREVIOUS PAGE

In a 2016 NHTSA Enforcement Bulletin, the agency asserted that it has regulatory jurisdiction over software embedded in automated cars, as well as software that is not embedded within the vehicle, but is critical to vehicle operation. The number of automotive recalls involving software has increased substantially in recent years. Types of software recalls include issues related to brake ECU, powertrain control modules, backup cameras, engine control modules, and fuel injection ECU.

As much as software can present unique safety risks, it may also offer the industry—and NHTSA—an opportunity to enhance recall effectiveness rates. While NHTSA currently requires first-class mail as the primary means of recall notification, the reality is that automakers are increasingly able to reach consumers while in a vehicle. In some cases, the automaker may be able to push new software fixes to remedy certain recall issues and minimize safety risks remotely. We can expect NHTSA to explore whether to require companies to use software as a tool to facilitate recalls and roll out software-related safety improvements. Software may also have environmental and fuel-economy ramifications, and result in EPA-related recalls, as exemplified by recent EPA enforcement activity relating to software-related “defeat devices.”

At the same time that NHTSA endeavors to update its policies and priorities to encourage innovation and embrace new technology, we can also expect NHTSA to shift into high gear on enforcement actions and civil penalties to return to Obama-era levels. Taken together, these shifts suggests that a new era of automotive safety regulation is emerging.

Under the Biden Administration, it will be more important than ever for companies in the automotive industry to take a holistic approach to automotive issues, focusing both on NHTSA-related safety issues as well as cross-cutting concerns that may be raised by EPA, State Attorneys General, the Department of Justice, the plaintiffs’ bar, and automotive safety advocates, among others. Managing these risks is not going to get easier. In fact, the stakes will only get higher as more regulators and lawmakers have skin in the game. At the same time, innovative technologies will offer the industry new opportunities to monitor safety issues, enhance recalls, and provide environmental benefits. Companies should focus on having the right teams in place to address this evolving suite of issues, rather than narrowly focusing on safety, recall, environmental, or other compartmentalized issues. In short, they should focus on a “whole company” response to the Biden Administration’s “whole government” focus on automotive safety, efficiency, and equity.

CONCLUSION

Companies are arguably operating in the most turbulent and uncertain time in recent history. For starters, there are the ongoing challenges created by a global pandemic. Then there are the expectations and demands of an ever-changing consumer market using social media as a forceful and effective weapon.

Add to that a paradigm shift from an U.S. administration focused on reducing regulation to one committed to not only restoring regulations but enhancing them to better protect consumers and the environment. Then consider the impact a Democratic majority could have in the U.S. House of Representatives and Senate. And while the judicial process has slowed in response to COVID-19, the plaintiffs' bar remains active in its pursuit for new class-action lawsuits among an increasingly litigious society.

As the regulatory landscape becomes more robust, supply chains grow more complex and customers' expectations grow, companies need to better manage these risks before, during, and after business and product crises to minimize impacts and protect ongoing value.

Given how quickly our business and regulatory environments are evolving, expert partners are even more critical to upholding 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 [HERE](#).



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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.

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