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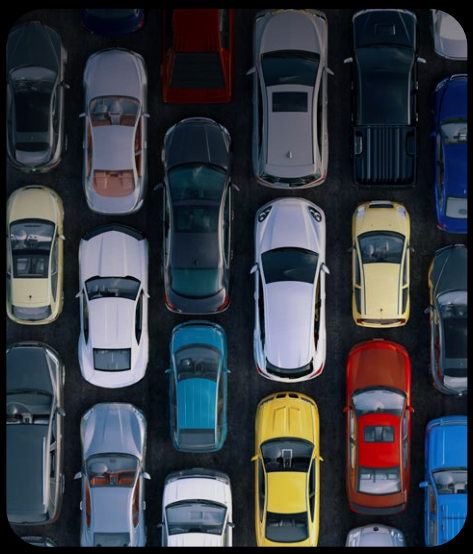
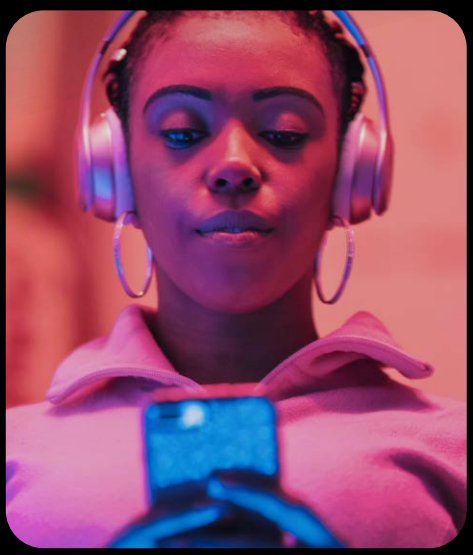
Recall Index

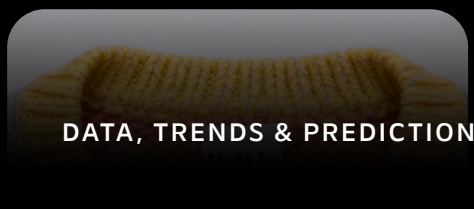
2026 edition 1

Product safety and recall

United States edition







DATA, TRENDS & PREDICTIONS FOR U.S. INDUSTRIES

Introduction

Sedgwick's Product Safety and Recall Index report is the leading resource for manufacturers, suppliers, and retailers who want an unbiased, expert view of past and present trends, as well as predictions about what's next in product safety, product recalls, and the regulatory landscape. It reviews five product categories: automotive, consumer products, food and drink, pharmaceutical, and medical device.

The report collects and analyzes recall data from the U.S. National Highway Traffic Safety Administration (NHTSA), the U.S. Consumer Product Safety Commission (CPSC), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) to provide exclusive insights to help businesses protect their brands against operational risk and reputational damage.

This edition reviews recall data from Q1 2026, covering January through March, and provides an early look at April data. In Q1 2026, the overall number of recalls decreased to 785 events compared to 877 events in Q4 2025. Almost every sector had fewer recalls this quarter than last. The exception was consumer goods, which increased from 124 events in Q4 to 142 recalls in Q1.

The total number of units recalled across all five industries increased 27.0% from 387.70 million in Q4 to 492.31 million this quarter. This is the highest quarterly total in the past four years and the third-highest in over 14 years. Every sector saw more units recalled compared to last quarter with the exception of medical devices.

The automotive sector had its highest quarterly total in two years with 12.19 million units recalled. The pharmaceutical sector reached a four year high with 218.83 million units impacted.

Sedgwick's Product Safety and Recall Index report also provides critical analysis of what lies ahead for businesses, including new regulations and evolving priorities from lawmakers. It includes perspectives from some of our strategic partners at global law firms, insurance companies, and regulatory and safety organizations to help businesses guard their brands and mitigate risk.

In the first quarter of 2026, the conflict with Iran drove oil prices up, which had a ripple effect on the cost and availability of certain goods. Restrictions on shipping routes also impacted supply chains, including fertilizer for growing crops, which could have a long-term impact on food prices.

The U.S. Supreme Court invalidated President Trump's reciprocal tariffs imposed under the International Emergency Economic Powers Act (IEEPA), but the Administration quickly implemented tariffs under a different mechanism, adding to the economic uncertainty.

Both the USDA and Federal Trade Commission (FTC) tightened enforcement around country-of-origin claims for U.S.-made products. Meanwhile, the FDA amended inspection procedures for medical devices and pharmaceutical products.

The FTC is carefully monitoring auto dealerships to ensure transparency in advertised prices and prevent hidden fees for consumers. The agency sent a new round of warning letters to dealers in the first quarter and has several lawsuits pending.

Businesses must work to protect their brands and optimize their operations amidst these evolving obligations and regulatory changes. That is why the information in this report is so valuable. We invite you to read the entire report cover to cover or just focus on the sections that matter most to your organization.

One final note: This edition of the Product Safety and Recall Index focuses on U.S. recall data and regulatory developments. If your business also operates outside the U.S. or your supply chain is affected by global issues, we recommend that you also read our other publications.

Our European edition shares recall data from regulatory agencies and offers exclusive analysis around product safety and policy changes—but from the perspective of companies and regulators operating in the UK and the European Union.

In addition, our biannual Australian Product Safety and Recall Index report provides insights on regulations and recall data for that market.

Q1 2026 European Recall Index: click here

H2 2026 Australian Recall Index: click here

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

Q4 2025 U.S. Recall Index: click here

Q3 2025 U.S. Recall Index: click here

Q2 2025 U.S. Recall Index: click here

Q1 2025 U.S. Recall Index: click here

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Automotive

Several factors created uncertainty for the automotive sector in the first quarter of 2026. In February, the Environmental Protection Agency repealed long-standing findings that greenhouse gas emissions endanger the public. This came after the Trump Administration rescinded previous policies that promoted zero-emission vehicle targets in 2025.

Also in February, the U.S. Supreme Court invalidated President Trump's reciprocal tariffs imposed on all trading partners under the International Emergency Economic Powers Act (IEEPA). The ruling gives importers the substantive basis to claim refunds on the duties they have paid. It was estimated in March 2026 that these tariffs have cost automakers at least $35.4 billion since 2025.

The day after the Supreme Court ruling, President Trump imposed a new temporary worldwide tariff of at least 10% to replace the IEEPA tariffs. The automotive sector is exempt from these new tariffs, but it is still subject to Section 232 tariffs that were not part of the court ruling.

The industry is also trying to navigate higher prices and supply chain disruptions from the conflict in the Middle East, which began on February 28, 2026. Oil shipments through the Strait of Hormuz were blocked or limited and Iran and its allies threatened to close or restrict other shipping channels.

Within the first week of the war, some auto dealers reported a surge in consumer interest in buying electric vehicles as gas prices climbed and availability seemed less predictable.

Against this backdrop, regulators continued to advance new rules. The U.S. Congress is considering a bill to implement federal requirements for vehicles equipped with automated driving systems (ADS). Lawmakers hope consistent rules will boost adoption and innovation for self-driving vehicles.

ADS is one reason automotive software and electronics are expected to see rapid growth. New research from McKinsey & Company provides insights on how the automotive industry is changing as new technology is incorporated into vehicles.

Tariff volatility, ADS regulation and software-driven vehicle complexity are forcing automakers to treat quality and compliance as company-wide disciplines.

Ninety-seven dealerships received warning letters from the Federal Trade Commission (FTC) in March over illegal advertising practices. The agency warned sellers that the price they promote must be the same price the consumer pays, and they cannot hide fees and other charges. This is a top enforcement priority for the FTC this year.

Manufacturers, dealers, and suppliers have challenges ahead across the industry. From fluctuating tariffs and oil prices to new regulations and evolving technology, stakeholders will need to ensure they remain flexible while still meeting their regulatory requirements.

Autonomous vehicle rules advance

In February, the Safely Ensuring Lives Future Deployment and Research In Vehicle Evolution Act of 2026 (the SELF DRIVE Act) was introduced to the House of Representatives to promote adoption of vehicles equipped with automated driving systems (ADS).

The measure is designed to amend Title 49 of the U.S. Code, which regulates transportation, and to strengthen the National Highway Traffic Safety Administration's (NHTSA's) authority over vehicles equipped with ADS.

The primary goals are to improve road safety, accessibility, and mobility; encourage testing and deployment of automated driving technologies; create jobs in the automotive and autonomous driving sectors; and provide clear federal rules relevant to ADS-equipped and ADS-dedicated vehicles.

The bill would add definitions for terms such as "automated driving system," "ADS-equipped vehicle," and "ADS-dedicated vehicle." It would also direct NHTSA to update or introduce motor vehicle safety requirements that apply to vehicles with automated driving systems to govern design, construction, and performance unique to ADS technologies.

In addition, the proposal adds provisions for motor vehicle testing or evaluation, rules for making systems inoperative, and measures for protecting the security of connected vehicles. These updates would establish a broader framework for regulated ADS deployment.

Furthermore, the draft bill codifies safety standards and definitions relevant to ADS technologies. However, ACT News notes that other details, such as regulatory timelines, specific safety case content requirements, and enforcement mechanisms, are still under discussion.

Some lawmakers have raised concerns about the lack of clear federal autonomous vehicle (AV) standards. They argue that the adoption of AVs has been slowed as companies try to navigate the current patchwork of state laws, which results in inconsistent and often conflicting regulations. AV industry executives have also asked for concrete rules to help drive innovation and competition.

Stakeholders across the AV sector should monitor the bill's movement through Congress, as well as any concerns that are raised, to help them plan for the final legislation.

Study predicts trends in automotive software and AI

In January, McKinsey & Company released new research on the automotive software and electronics market through 2035. The company predicts that these components will increasingly become the primary driver of value and differentiation for vehicles.

The data suggest that the global automotive software and electronics market could grow by a 4.5 percent compound annual growth rate (CAGR) and reach $519 billion by 2035. This includes control units, sensors, semiconductors, wiring, and the software stacks that run on them. The estimate is in contrast to a growth rate of only about 1% per year for the overall vehicle market. That gap underscores a shift from hardware-only competition to software-defined vehicles, connectivity, and advanced driver-assistance and safety.

The findings focus on three key areas. First, vehicle electrical/electronic (E/E) architecture is moving toward zonal and high-performance centralized computing, which enables over-the-air (OTA) updates, richer features, and faster iteration. This transition will require companies to integrate hardware, software, and suppliers more effectively if they want to stay competitive.

Second, near-term spending is tilting toward advanced driver-assistance systems (ADAS), connectivity, infotainment, and EV-related power electronics. However, this shift has been affected by slower commercialization and regulatory uncertainty. Rules for ADAS vehicles vary from state to state, which may increase buyer hesitation. In addition, the recent easing of federal emissions policies may delay EV adoption.

The third area is the continuing increase of semiconductor and sensor content per vehicle. This growth, combined with recent shortages, impacts supply security, increases cost, and makes technical roadmaps more complex for automakers and suppliers.

To prepare for these changes, manufacturers and supply chain partners should define clear ownership of architecture, middleware, and safety-critical domains. It will also be important to stress-test semiconductor sources so production isn't delayed due to potential shortages.

In addition, automakers should treat OTA updates, cybersecurity, validation, and release cadence as core manufacturing disciplines. This means investing in talent, tooling, and supplier governance to ensure features ship reliably and recalls or compliance gaps do not erode trust.

As OTA updates become increasingly common to address vehicle defects, companies may need to revise their recall processes. Manufacturers and dealers need to ensure they have the systems in place to reach current vehicle owners and conduct remote fixes.

FTC cracks down on illegal dealer advertising

In March, the Federal Trade Commission (FTC) sent letters to 97 auto groups nationwide, warning them that all advertised prices must be the total price consumers will be required to pay—including any and all mandatory fees. The Commission stated that one of its enforcement priorities is ensuring that advertised pricing is transparent and truthful.

The letters urged dealers to review their advertising and pricing practices, including ensuring that advertised prices match actual prices charged to consumers. Regulators promised to continue monitoring the marketplace and are committed to taking further action if dealers were not complying with the FTC Act and other applicable rules.

Some of the illegal pricing practices cited in the letters include advertising a price that does not reflect all required fees, advertising a price that reflects rebates or discounts not available to all consumers, and advertising a price that fails to take into account the amount of an additional required down payment.

In addition, some dealers conditioned the advertised price on consumers using dealer financing, required consumers to buy additional items not reflected in the advertised price, and advertised unavailable or non-existent vehicles.

The FTC has several pending actions regarding deceptive pricing practices in the auto industry, including cases in Illinois and Texas. A case in Maryland was settled in April. The dealership and its executives will pay a $3.1 million civil penalty and consumers may be eligible for more than $75 million in refunds from overpayment.

Attorneys with Troutman Pepper Locke recommend that auto dealers and groups closely evaluate their pricing and advertising practices across all channels, including websites, third-party listing platforms, social media, and traditional media. They should determine whether any advertised prices rely on conditional rebates, special discounts, required dealer financing, or mandatory add-ons and, if so, whether those terms are clearly disclosed and included in the headline price.

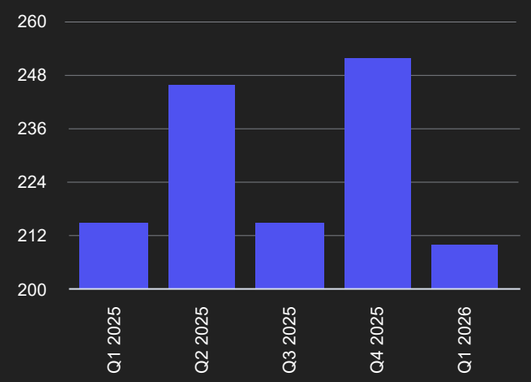
By the numbers

In Q1 2026, NHTSA issued 210 automotive recalls, down 16.7% compared to 252 in Q4 2025. This marks the lowest quarterly figure recorded in over two years, and the second-lowest figure in almost six years. In contrast, the number of affected units increased by 71.7% from 7.10 million in Q4 2025 to 12.19 million in Q1 2026, marking their highest quarterly level in the past two years.

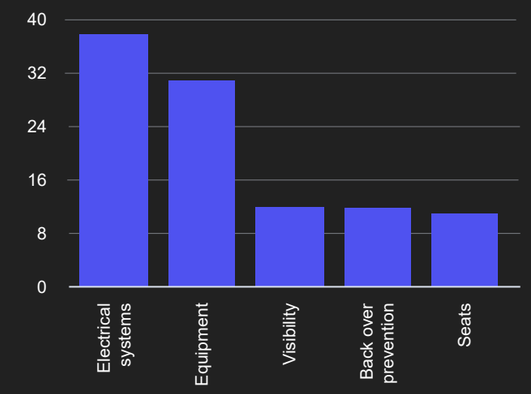
Electrical systems were the leading cause of U.S. automotive recalls by event in Q1 2026. They were linked to 38 recalls, down from 41 last quarter. Equipment was second with 31 events, which is down from 43 events in the previous quarter. Back-over prevention systems and visibility were tied for third with 12 recalls each. Back-over prevention dropped from 13 recalls, while visibility increased significantly from seven events in Q4 2025.

Electrical systems were also the top hazard by volume with 5.32 million units affected. This was fueled by a single recall of 4.38 million units, which was the only automotive recall involving more than 1.00 million units this quarter. Back-over prevention systems ranked second with 2.45 million units impacted, which is down slightly from the 2.64 million units recalled in Q4. Visibility was the third-highest category by volume with 1.04 million units affected, up considerably from 280,414 units in the previous quarter.

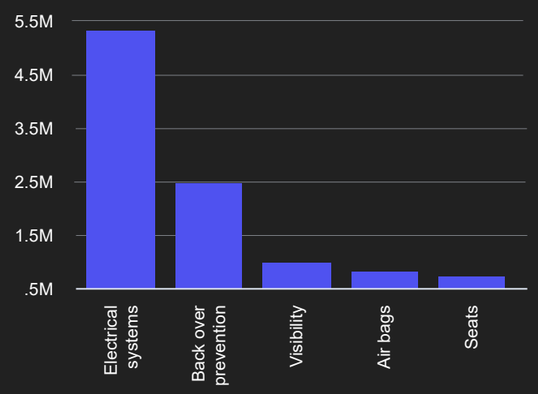
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recalled units by category (top 5)



Year-over-year analysis:

The 210 recalls in Q1 2026 are a slight decrease from the 215 recorded in Q1 2025. This marks the lowest Q1 figure in the past 6 years. The number of units surged 226.7% between Q1 2025 and Q1 2026, from 3.73 million units to 12.19 million. This marks the second-highest figure in the past 5 years.

While Electrical systems were the leading cause of automotive recalls, this is the lowest Q1 figure recorded for this category in the past 3 years. Equipment, which was second, recorded a slight drop from 33 recalls in Q1 2025, to 31. Visibility issues rose from 4 events (in Q1 2025) to 12 recalls, marking their highest-level in 10 years.

In terms of units, electrical systems surged to their highest quarterly level in 10-years with 5.32 million units, up significantly from the 1.01 million impacted vehicles in Q1 2025. Only 2 other quarters in the past 10 years have exceeded 3 million units (Q4 2023 with 4.92 million units, and Q2 2018 with 5.22 million units).

Back-over prevention recorded a 393.0% surge in impacted vehicles, from 497,588 units in Q1 2025 to 2.45 million. Visibility issues hit their highest Q1 figure in the past 3 years with 1.04 million units.

Automotive product safety risk in 2026: safety signals, market forces, and execution

GEORGE WRAY, *BORDEN LADNER GERVAIS LLP*

The North American automotive industry entered 2026 with product safety activity running at historically elevated levels and broader commercial and policy forces reshaping risk exposure. In 2025, NHTSA issued nearly one thousand vehicle safety recalls, affecting more than 29 million vehicles during the year. By the end of the first quarter of 2026 alone, more than 12 million vehicles had already been recalled, signaling that recall activity is not moderating as the year begins and that high-volume events remain a defining feature for the industry. Notably, while the total number of NHTSA vehicle recall campaigns in 2025 approached one thousand, the number of affected automotive units fell to near a multi-year low before Q1 2026's surge sharply reversed that trend—underscoring the volatility that now defines the recall landscape.

As a result, in 2026 a safety issue's legal, regulatory, and reputational outcomes will often depend as much on governance and execution as on the underlying technical defect. At the same time, recalls represent only one manifestation of a broader shift. Vehicles are becoming more software-defined—including the use of artificial intelligence—and supply chains are growing more sensitive to trade policy and geopolitical risk.

Consumers remain price-sensitive and value-driven, but they are increasingly attentive to safety, trust, and transparency—particularly in connected features and service experiences. Consumer adoption of electric vehicles (EVs) remains uneven, with battery-related safety risks emerging as a distinct exposure. Meanwhile, manufacturers face continued uncertainty around tariffs and the upcoming review of the U.S.–Mexico–Canada Agreement (USMCA).

Together, these forces are reshaping how product safety risk develops, how it escalates, and how losses ultimately present across operational, financial, and reputational dimensions.

Scale, system complexity, and execution risk are reshaping U.S. automotive product safety

Elevated recall volumes continue to signal persistent safety challenges, but the more consequential trend is concentration combined with complexity. Early 2026 recall activity has been driven by fewer, larger campaigns, with a disproportionate share tied to a small number of manufacturers and a meaningful share of affected vehicles concentrated in a single large event. That level of concentration matters because it simultaneously compresses dealer capacity, parts availability, and owner outreach and extends the exposure window between defect identification and verified remedy completion.

Modern vehicle design amplifies this effect. Advanced driver-assistance systems, battery management software, and connected features interact in ways that make defects harder to isolate and remedies harder to validate at scale.

This shift is consistent with broader industry analysis showing that vehicles are increasingly designed as software-defined platforms built on centralized or zonal electronic architectures which are intended to support continuous functionality through over-the-air (OTA) updates and advanced driver-assistance features. Recent research from McKinsey & Company highlights that software and electronics are growing significantly faster than vehicle volumes themselves. This trend reinforces the fact that many modern safety issues arise from integration, validation, and execution challenges rather than isolated component failures.

As recalls become larger, more software-driven, and more operationally complex, manufacturers' preparation for these risks increasingly determines both the safety outcome and the severity of downstream loss.

Electrification is creating a distinct battery risk stack that deserves standalone attention

The uneven growth of EVs and hybrid vehicles continues to have implications not only for commercial strategy, but also for safety and claims strategy. Battery systems introduce failure modes that differ from traditional mechanical risks, including thermal events, charging-related incidents, and software-driven battery management anomalies. These risks have an outsized reputational impact because mitigation steps can require urgent behavioral instructions such as advising owners where to park or whether a vehicle should be driven pending remedy.

Consumer data show battery-related concerns materially affect adoption and trust. In the U.S., most consumers still prefer internal combustion engines or hybrids, while EV adoption remains constrained by concerns around range, charging, cost, and battery replacement. Notably, battery safety concerns remain a key trigger for rapid escalation from technical issue to trust event.

Charging behavior adds a second layer of risk. Most U.S. consumers considering an EV expect to charge primarily at home, yet more than half report they do not currently have access to a dedicated home charger. As electrification scales, battery end-of-life handling and recycling also remain unsettled in the public mind. Consumer views vary widely on who should be responsible for collecting, storing, and recycling EV batteries, indicating continuing ambiguity across the ecosystem and an emerging governance and liability frontier.

Battery risk tends to produce higher-severity loss scenarios because the safety response can require changes in owner behavior, including how and where a vehicle is parked or charged, how it is stored after an incident, and how quickly it must be inspected. These factors expand potential exposure beyond the vehicle itself to homes, garages, and adjacent property.

The implication for manufacturers and insurers is straightforward: battery risk in 2026 is not confined to the cell. It is an integrated exposure spanning design and validation, software governance, charging behavior, service readiness, and end-of-life management. From a product-safety perspective, that sensitivity means battery-related incidents are more likely to escalate quickly from technical issues into trust events, intensifying pressure on recall communications, interim safety guidance, and remedy verification.

As battery-related risks become a more prominent contributor to recall severity rather than volume, manufacturers' preparation for detection, communication, and execution will determine loss outcomes more and more frequently.

Consumer expectations and connectivity are reshaping safety and service credibility

Product safety risk in 2026 cannot be evaluated independently of consumer expectations. Consumers place the greatest value on connected features that enhance safety and security—such as emergency assistance and anti-theft tracking. They also expressing high concern about data sharing—including location data and synced device data.

This combination heightens the stakes for both product performance and communications. Failures in safety-linked connected systems can have immediate trust consequences, and perceived opacity around data practices can deepen reputational loss even where physical safety is not implicated.

Service experience remains a meaningful determinant of trust. Consumers often evaluate service providers based on quality of work, trust, and transparency of pricing and work performed. This means that recall execution quality at the dealer level is not merely operational. It is directly tied to brand retention and future purchase behavior.

In large-scale campaigns, inconsistent dealer execution directly affects recall completion rates, customer complaints, and the durability of regulatory narratives about whether a remedy was effectively implemented.

Consumer research from Deloitte reinforces the extent to which product safety risk is now tightly linked to trust and execution. Global automotive surveys show that consumers place the greatest value on connected features that enhance safety and security, even as concerns about data sharing and transparency remain high. At the same time, electrification decisions—particularly in the U.S.—continue to be driven by practical considerations such as cost, range, charging time, and perceived battery risk.

As vehicles become more connected and consumers more attuned to safety and transparency, manufacturers' ability to manage recalls consistently across digital systems and dealer networks increasingly determines both trust and loss severity.

Manufacturers must broaden risk preparation beyond recalls alone to address these risks and challenges

In 2026, effective product safety management requires manufacturers to move beyond a recall-centric mindset and adopt a holistic risk posture that accounts for regulatory change, trade volatility, electrification complexity, and shifting consumer expectations.

Recent industry analysis from KPMG underscores how trade and tariff volatility is becoming an operational risk with direct safety implications. Automotive executives report the rise of material costs across key sourcing regions and acknowledge that a meaningful share of their product portfolios is already affected by tariffs, even as relatively few view their current response strategies as highly effective.

Importantly, many organizations estimate that it would take most of a year to pivot meaningfully if tariff conditions worsen. This admission highlights a gap between the pace of trade-driven change and the speed at which validation, sourcing, and execution processes can adapt. In this environment, disciplined change management, documentation, and scenario planning are increasingly central to product safety governance.

Operationally, recall governance should be embedded into core processes, with standing escalation pathways, clear decision rights, and documentation that supports timely defect assessment and regulatory reporting. Digital remedies require recall-grade governance, including defined criteria for safety-critical software updates, robust testing, and post-deployment monitoring.

Early 2026 patterns show that a large share of recalled vehicles may be eligible for OTA remedies. For manufacturers and dealers, the ability to verify deployment and effectiveness at scale is becoming a core control, not a technical nice-to-have.

In addition, supply-chain oversight remains critical, particularly for electronics, batteries, and software components sourced across borders. This is especially important as manufacturers adjust sourcing strategies in response to tariffs, localization incentives, and uncertainty around USMCA renegotiation.

The safety and warranty consequences of supplier and design substitutions must be treated as first-order risks requiring disciplined validation and documentation, particularly where substitutions are made under cost or timing pressure and later become the subject of defect investigations or recall scope expansions.

Canada's new automotive strategy

Canada's new automotive strategy illustrates how industrial policy, electrification incentives, and trade dynamics are increasingly shaping the safety and execution environment across North American supply chains.

On February 5, 2026, the Government of Canada announced its automotive strategy, designed to secure domestic manufacturing, accelerate electrification, and strengthen Canada's role in the North American and global auto supply chain. Canada will deploy up to $3B from the Strategic Response Fund and $100M from the Regional Tariff Response Initiative to support automotive manufacturing, including EV assembly, battery technology, automation, and advanced parts production.

This announcement reveals the Canadian government's keen interest in diversifying its strategic partners and positioning the Canadian automotive sector for an electric future.

The recall landscape in 2026 will be more concentrated, software-driven, and execution-focused

Recall activity in 2026 is expected to remain volatile and highly concentrated, with fewer campaigns accounting for a disproportionate share of vehicles affected. This concentration increases operational and reputational risk when issues arise and magnifies the consequences of execution failures.

Software-led recalls and OTA-enabled remedies will continue to expand. While these tools enable faster intervention, they also invite greater scrutiny. Regulators, insurers, and courts are more and more focused on time-to-remedy and completion, not simply the announcement of corrective action.

Consumer behavior reinforces this shift. Vehicle owners value connected features that enhance safety, but they also expect transparency, trust, and clear explanations—especially during recall and service events. Inconsistent or delayed messaging can undermine confidence even when the technical fix itself is sound.

Dealers remain central to recall execution. Despite the growth of digital channels, consumers continue to place significant trust in dealers to explain safety issues, perform repairs, and provide pricing transparency. The effectiveness of large recall campaigns increasingly depends on dealer readiness and communication as much as engineering solutions.

Predictions for the future of the industry: 2026 and beyond

Taken together, these trends point to a year in which automotive product safety risk is defined less by isolated failures and more by how organizations operate under pressure. Elevated recall activity early in 2026 underscores that safety challenges remain real and systemic. At the same time, electrification, software dependence, and trade uncertainty are expanding the pathways through which risk can materialize.

Beyond 2026, several structural forces are likely to continue shaping automotive product risk. Electrification will continue to advance unevenly, sustaining portfolio complexity. Software will become a baseline consumer expectation, intensifying scrutiny of digital governance. Trade policy uncertainty and USMCA review will continue to influence sourcing and manufacturing decisions, adding friction to quality and validation processes.

PwC's industry outlook suggests that affordability pressures and uneven electrification are likely to persist through the decade, reinforcing the importance of execution discipline and safety governance as competitive and risk differentiators.

Legal and claims risk will increasingly center on execution: what manufacturers knew, how quickly they acted, how clearly they communicated, and whether remedies were implemented consistently. Regulatory expectations are unlikely to relax materially. Instead, scrutiny will continue to focus on timeliness, documentation, and demonstrable remedy effectiveness. Although the current administration has signaled a preference for reducing regulatory burden broadly, NHTSA's core recall authority and enforcement posture have remained largely intact through Q1 2026; the pace of defect investigations and civil penalty actions has not meaningfully moderated, and manufacturers should plan accordingly.

Consumer trust will be shaped as much by service experience and transparency during safety events as by underlying technical performance.

Manufacturers that treat product safety as an integrated operating discipline—spanning engineering, software governance, supply-chain strategy, dealer execution, and communications—will be better positioned to manage severity, contain losses, and preserve trust.

Those that focus narrowly on recall compliance may find themselves exposed to compounding operational, legal, and reputational risks in a significantly more complex automotive environment. Integrating product safety into a company's operations is no longer a differentiator. It is a prerequisite for managing severity, preserving trust, and containing loss.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.

From product safety enforcement to forced-labor investigations, brands are being held accountable for compliance failures across the entire supply chain.

Consumer products

In March, the Consumer Product Safety Commission (CPSC) announced an $11.5 million civil penalty against a bicycle parts manufacturer. The Commission said the company knowingly failed to immediately report defective cranksets, which posed an unreasonable risk of serious injury or death to consumers.

Under the settlement agreement, the manufacturer must also maintain internal controls and procedures designed to ensure compliance with the Consumer Product Safety Act, conduct internal compliance audits, and submit annual reports regarding its compliance program and internal controls.

The Government Accountability Office (GAO) published a report in February that outlines several steps the CPSC could take to strengthen its oversight of lead and other toxic substances in children's products. The GAO found that the Commission was not conducting the required review of safety standards, among other concerns.

The Trump Administration is bolstering the Federal Trade Commission's (FTC's) focus on "Made in USA" claims. A new Executive Order urges more oversight for online marketplaces and the larger supply chain. It also directs the FTC and other agencies to consider whether more regulations are necessary to ensure companies are in compliance.

The United States Trade Representative (USTR) initiated investigations into 60 countries on the basis of policies around importing goods made with forced labor. The USTR claims that U.S. interests are being hurt because its trading partners lack bans and enforcement actions to keep cheap products made with forced labor out of the market.

Many of the new policies impact not just the manufacturer but extend farther through the supply chain. This creates more risk for brands who will need to ensure that their suppliers and distributors are meeting their obligations.

GAO urges stronger oversight of children's products

In February, the Government Accountability Office (GAO) released a report exploring how the Consumer Product Safety Commission (CPSC) could strengthen its oversight of toxic substances in children's products. The study came after a senator asked for information on how the Commission tests products intended for children ages 12 and under for potential lead contamination and other safety hazards. The senator specifically requested details about how the CPSC oversees third-party labs that conduct testing on children's toys, and whether safety standards need to be updated.

The GAO looked at the CPSC's processes for examining children's products; the agency's plans to adopt an electronic data filing system; how it approves and assesses risks from third-party labs that test children's products; and the steps the CPSC takes to keep safety standards for lead and other toxic substances up-to-date.

The GAO noted that to meet CPSC requirements, manufacturers and importers must have certain toys and children's products tested by labs for lead and other toxic substances before they can enter the U.S. market. However, the large volume of goods entering the U.S. makes it challenging to ensure compliance.

The report said that the CPSC "has failed to review and update its testing requirements for lead despite being required to do so at least every five years." It also stated that the agency lacks any written procedures for monitoring changes related to toxic substances in children's products.

Currently, the CPSC uses a risk-based approach to determine which children's products to examine at U.S. ports for possible toxic substances. This is done in coordination with U.S. Customs and Border Protection systems to identify high-risk products.

Products may be screened with handheld devices for lead and other toxic substances. In addition, officials may review importer documentation to verify that products were tested by third-party labs and meet CPSC safety standards.

The CPSC is launching a new electronic system in July 2026 that will require importers to "e-file" data when goods enter U.S. ports, including product identification and information about where the product was tested. However, there is currently no system to guarantee that importers file timely, accurate data.

The GAO report offers four recommendations to the CPSC. The first is to implement a system to oversee compliance with the new e-filing requirements. The second is to establish a process for using violations data to assess risks associated with independent and government labs. This system is already in place for labs owned by manufacturers. In January, the CPSC withdrew its accreditation for four consumer-product testing laboratories located in China, stating that the labs issued "unreliable or falsified reports, concealed the loss of accreditation by international authorities, and/or certified products that later failed independent safety testing."

The GAO also urges the Commission to review its lead requirements and document a process for completing lead reviews every five years. Finally, the GAO suggests an established process for staying up-to-date on changes related to phthalates and other toxic substances.

After the release of the report, the CPSC agreed with the recommendations and indicated it would implement them.

Manufacturers, importers, distributors, and test labs should monitor for new requirements from the CPSC. The focus on children's safety and the Congressional oversight will make this topic a priority.

Renewed focus on "Made in America" claims

Taking action against companies that make false "Made in USA" claims has been a focus of the Federal Trade Commission (FTC) for several years. In March, the Trump Administration issued a new executive order (EO) and an accompanying fact sheet instructing the agency to prioritize enforcement against deceptive U.S.-origin claims.

While the EO does not change the current legal standard for these claims, it stresses that the FTC will closely monitor for these types of statements and that the agency's scrutiny may go beyond manufacturers to include retailers, marketplaces, and others in the distribution chain.

Among the considerations are whether online marketplaces are properly verifying third-party sellers' country-of-origin claims. If not, the FTC is directed to propose regulations to establish new procedures.

The EO's reach goes beyond the FTC. All agencies with oversight of country-of-origin labeling are instructed to consider drafting regulations to promote voluntary country-of-origin labeling for products made or manufactured in the United States. The order stressed that these actions should be coordinated across agencies so that American businesses receive consistent labeling guidance.

The latest executive action also directs agencies to review "Made in USA" claims in federal procurement. If contractors or vendors have been found to misrepresent the U.S. origin of a product sold to the government, the product is to be removed from government procurement availability and the companies referred to the Department of Justice. The contractors may be subject to actions under the False Claims Act.

Attorneys with Kilpatrick Townsend & Stockton LLP recommend that companies review all origin claims across labels and packaging, websites, advertising, social media, and retailer and distributor listings. They should also be sure they can substantiate claims with documentation proving the source of ingredients or components, location of manufacturing and processing, and overall U.S. content.

The legal experts also advise companies to reevaluate unqualified claims for any products that are not fully made in the U.S. and monitor third-party statements to ensure retailers, influencers, and distributors are not making false claims about their products.

In addition, companies should be ready to respond to agency inquiries—from the FTC as well as any contracting agency—with clear substantiation, thorough internal guidance, and documented review processes.

Regulators investigate use of forced labor

In March, the United States Trade Representative (USTR) launched investigations into 60 of the U.S.'s largest trading partners under Section 301(b) of the Trade Act of 1974. The goal is to determine if the nations have effectively enforced bans on importing goods produced with forced labor. The USTR said countries that fail to prohibit these types of goods could be seen as unreasonable or discriminatory and have a negative impact on U.S. commerce.

While the USTR acknowledged that several trading partners have adopted measures intended to stop the importation or sale of products produced using forced labor, it states that none of them have adopted and effectively enforced a forced labor import prohibition to date.

For example, the EU adopted its Forced Labor Regulation in 2024, but enforcement does not begin until December 2027. The lack of enforcement allows companies to continue to "source, use, and profit" from imported products produced with forced labor, according to the agency.

The USTR is required to seek consultations with trade partners at the start of an investigation. It must also seek public comments and hold a hearing on the matter. The dockets to submit comments or request to appear at a hearing opened on March 12 and closed on April 15.

Trade authorities were looking for input on several issues, including whether any trade partner subject to these investigations maintains or is in the process of establishing a forced labor import prohibition, and whether any such import prohibition is being effectively enforced. The USTR also wanted to know the extent to which the failure of any trade partner to establish and effectively enforce a forced labor import prohibition is unreasonable, discriminates against U.S. goods, or constitutes a persistent pattern of conduct that permits any form of forced or compulsory labor.

Other questions were what action, if any, should be taken to address these issues and the appropriate aggregate level of trade to be covered by any additional duties on products of any trade partner subject to these investigations.

Lawyers with Brownstein Hyatt Farber Schreck LLP suggest that manufacturers, distributors, and other stakeholders who may be impacted by the investigations conduct tariff impact assessments on supply chains and consider a forced labor audit. They also advise companies to diversify or restructure supply chains in anticipation of potential tariff measures and develop risk-mitigation strategies, such as tariff engineering, country-of-origin reviews, or leveraging existing Free Trade Agreements.

By the numbers

In Q1 2026, there were 142 CPSC recalls, a 14.5% increase from 124 events in Q4 2025. This is the highest quarterly total since Q4 2007 and the second-highest in more than 28 years. The number of units recalled rose even more significantly, up 347% to 20.17 million units compared to 4.51 million last quarter. This is the largest quarterly total since Q2 2024.

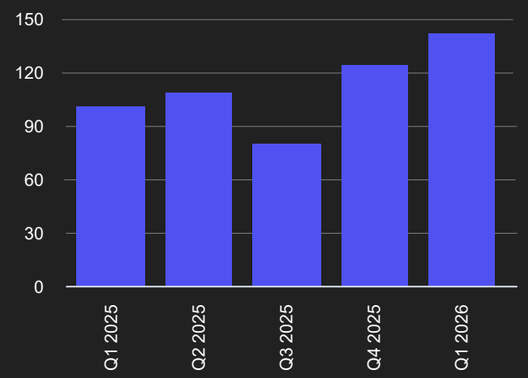
Toys accounted for the most recalls by category in Q1 2026, linked to 25 events, up from 12 last quarter. Children's Products were second, with 21 events. In third was Personal Care with 19 recalls.

In terms of recalled units, Yard & Garden was the top product category with 14.09 million units impacted in Q1. This was predominantly driven by two recalls for grill brushes that had a combined total of 13.40 million units. Personal Care was second by volume with 1.99 million units recalled, including 1.54 million stain removers. Home Appliances were the third-highest product category in Q1 with 1.93 million units impacted across six events.

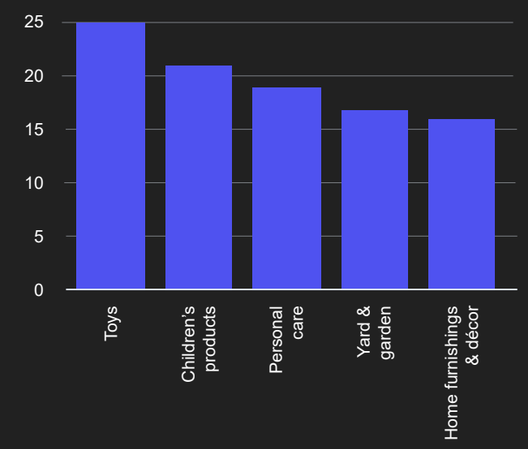
Ingestion was the top consumer products hazard by event in Q1 2026, tied to 22 recalls. Entrapment was second with 20 events as a standalone risk and 26 recalls when other factors such as suffocation and lacerations are considered. Falls as a sole risk and the combination of burns and fire tied for third with 14 recalls each.

Ingestion was also the leading risk by volume, impacting 13.63 million units, primarily linked to products with button cell and coin batteries. Burns as a standalone concern were second by volume, connected to the recall of 2.04 million units. Infection led to the third-highest number of units impacted with 1.54 million, all linked to the stain remover recall.

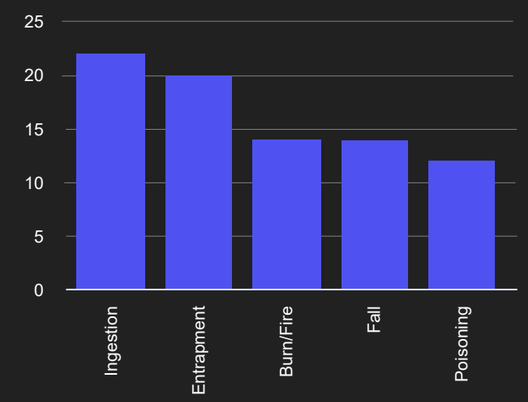
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recall events by risk (top 5)

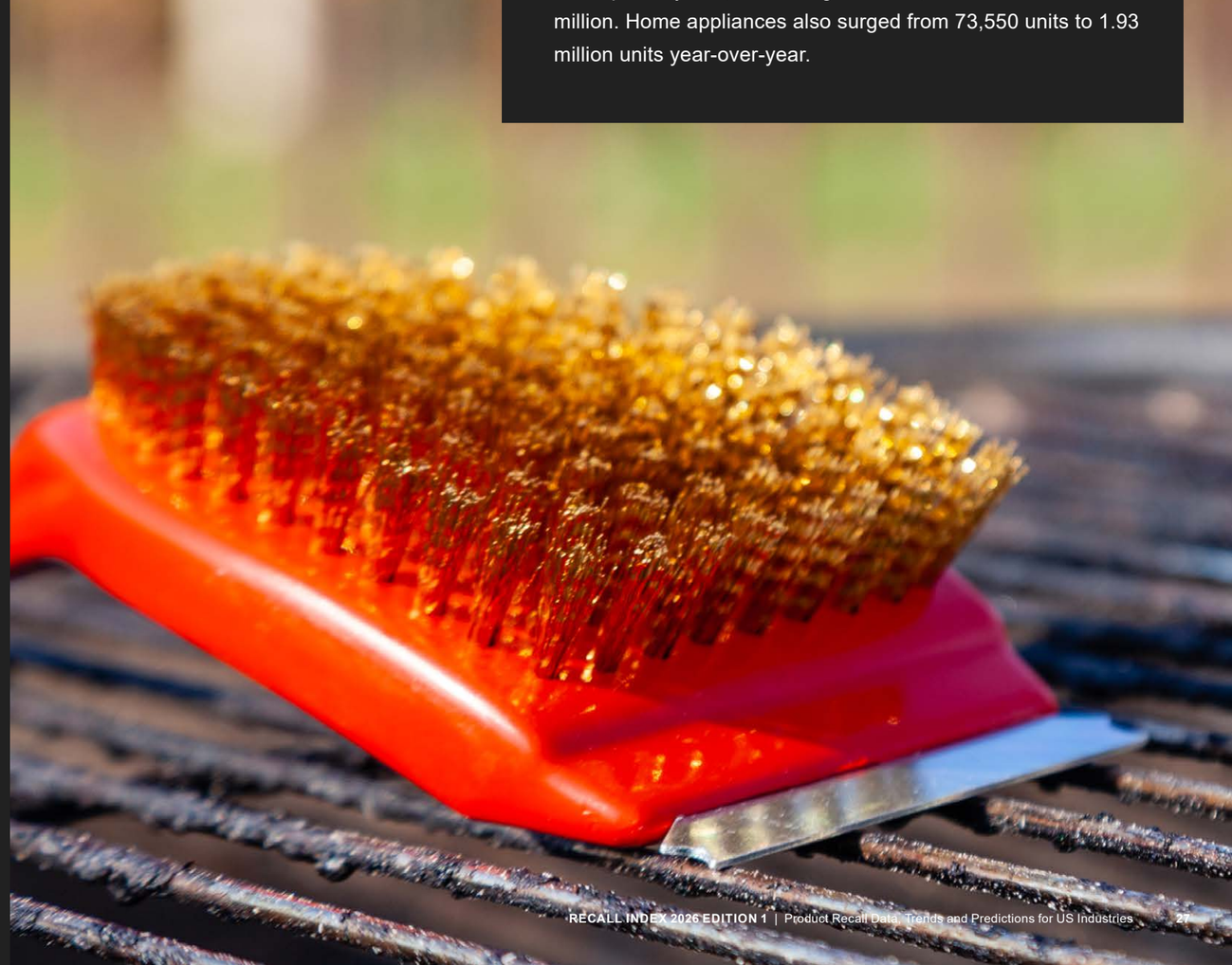


Year-over-year analysis:

Year-over-year, Q1 2026 had more recalls and more units impacted than Q1 2025. Consumer product recalls surged from 101 events to 142. As mentioned earlier, Q1 2026 is the second-highest quarterly figure recorded in over 28 years. In terms of units, Q1 2026 recorded a surge of 334.6% from 4.64 million units to 20.17 million.

Recall events involving Toys reached their highest quarterly figure in over 10 years. They surged from 3 events in Q1 2025, to 25 this quarter. Children's products also recorded a notable increase from 10 recalls to 21, marking their highest Q1 figure in the past 3 years. Personal care products also surged from 6 events to 19.

In terms of units, Yard & Garden reached their highest quarterly figure recorded in 10 years, marking a significant increase from the 1.47 million units in Q1 2025, to 14.09 million. Personal care products and Home appliances marked their highest Q1 figure in the past 3 years, increasing from 114,910 in Q1 2025 to 1.99 million. Home appliances also surged from 73,550 units to 1.93 million units year-over-year.



Beyond the recall: why recalls rarely end product safety risk in 2026

ANNE MARIE ELLIS, *BUCHALTER*

Recall activity remains elevated across the U.S. consumer products industry, but recall numbers alone no longer reflect the full scope of product safety risk. Recalls can trigger a second wave of exposure, which many companies do not anticipate and are poorly prepared to manage.

We are seeing recent recalls morph into securities litigation, consumer fraud claims, indemnity disputes, platform liability questions, and regulatory scrutiny focused not only on the hazard, but also on how the recall itself was designed and executed. Recalls should not be treated as discrete compliance events. Instead, they should be considered the beginning of additional exposure.

Recalls are no longer the end of the story

For many companies, the primary concern after a recall is personal injury litigation stemming from the defect and possibly a lack of insurance coverage. While this may still be true, additional proceedings are now very likely to widen both the scope and duration of exposure.

A recent recall with tag-along investor litigation demonstrates this shift. A company that conducted a recall ultimately faced a follow up investor lawsuit alleging misleading claims about the recall, product safety, and corporate values. The courts' scrutiny focused less on the mechanical defect and more on how the company characterized safety risk, regulatory engagement, and recall impact in its public disclosures. This is not a new problem. In many cases, the defect can be fixed, the messaging cannot.

Once recall statements enter earnings calls or investor decks, they stop being product safety communications and start being securities disclosures. Even though the court found no actionable misstatements, it is still a good reminder that even "puffery" about corporate values, product safety, and product quality can be under a microscope one day.

For companies instituting a recall, planning must account for how recall related information will be communicated across disclosures, earnings calls, and investor messaging. While product safety teams may not control these channels, recall communications do not stay siloed, and statements made elsewhere can quickly shape downstream risk.

Pre-recall warnings remain fair game

Companies often assume that a prompt recall resolves warning based claims, but that belief is proving unreliable. Recent class actions suggest exactly the opposite. Plaintiffs increasingly treat recalls as admissions, arguing that the recall itself confirms earlier knowledge and delayed action.

This is evidenced in the cases involving metal wire grill brushes. Despite coordinated recalls and replacement programs, courts have allowed failure to warn claims to proceed based on allegations about pre recall knowledge, packaging, and marketing. The existence of a recall did little to shield companies from scrutiny of what they knew earlier and how decisively they communicated—or didn't communicate—risk.

In sum, recalls may stop future injuries, but they do little to insulate companies from claims targeting pre recall conduct. Companies cannot simply view recalls as a liability firewall. They must be prepared to address what is on the other side of the wall.

Testing decisions are now litigation decisions

Testing laboratories and certification partners are no longer background players in recall disputes. In fact, they can be an expanding risk area. A recent case involving regulated substances in children's products advanced a claim that testing failures allowed non-compliant goods products into commerce, contributing to downstream recalls and consumer exposure.

While these cases are fact intensive and not always successful, their existence alone signals a shift. This shuttles in an era of upstream accountability, which forces companies to justify not just whether testing occurred, but also how decisions to rely on specific tests, labs, or standards were made.

Testing strategies are no longer a shield for companies. They are evidence. Once litigation begins, how, when, and why a particular lab or method was used may actually matter more than the numerical result.

Recall obligations survive financial distress

Recall obligations can become destabilizing when companies face financial distress. Fire related recalls and injury driven product withdrawals have contributed to Chapter 11 filings, while also complicating remediation efforts once insolvency begins. Courts and regulators have been clear: bankruptcy does not extinguish recall obligations. Instead, it often compresses timelines and introduces competing priorities—consumer remediation versus creditor recovery—at a time when resources are most constrained.

Companies with high volume products, long service lives, or latent hazards should assume that recall exposure would follow them into restructuring scenarios. Firms cannot treat recalls as isolated operational issues. They must view them as long-term liabilities.

Punitive damages awards can turn on recall timing and documentation

A potential underestimated risk in recall related litigation is punitive damages exposure tied to recall execution conduct. Courts have shown diminishing patience for arguments that recalls alone demonstrate responsible behavior, particularly where plaintiffs allege delayed escalation or internally contested decisions.

In recent appliance fire cases, punitive claims have survived motions to dismiss not because recalls failed to occur, but because of when and how decisions were made. Internal emails, escalation timelines, and draft risk assessments—often created well before any recall announcement—can become key pieces of evidence in cases with punitive damage claims.

Firms must realize that recall execution is powerful evidence. Documentation, escalation protocols, and harmful emails matter just as much as the recall notice itself.

E-commerce platforms face exposure

One of the most consequential shifts under way is the erosion of the idea that online marketplaces are peripheral to recall risk. Courts are increasingly willing to treat platforms as sellers or distributors where they control fulfillment, listings, pricing, and customer communications. Marketplaces used to argue that they owed no duty to customers and were a marketplace of ideas, not product sellers. Now that defense may be eroding in many jurisdictions and with CPSC.

This shift has practical consequences. Traditional recall strategies, which are typically grounded in retailer cooperation and point of sale communication, often fail in marketplace environments. Frequently, there is fragmented customer data, shared responsibility, and platform driven messaging that complicate both remedy execution and liability allocation.

Manufacturers that sell through e commerce platforms must think about and plan for recall execution and be aware of other entities that are now in the chain of distribution in a potential product liability lawsuit.

Regulators are now scrutinizing recall abuse

The CPSC has recently focused attention on fraud and abuse within recall programs themselves. False refund claims, serial remediation requests, and manipulated participation data have all drawn agency concern—not because they harm companies alone, but because they undermine consumer safety outcomes.

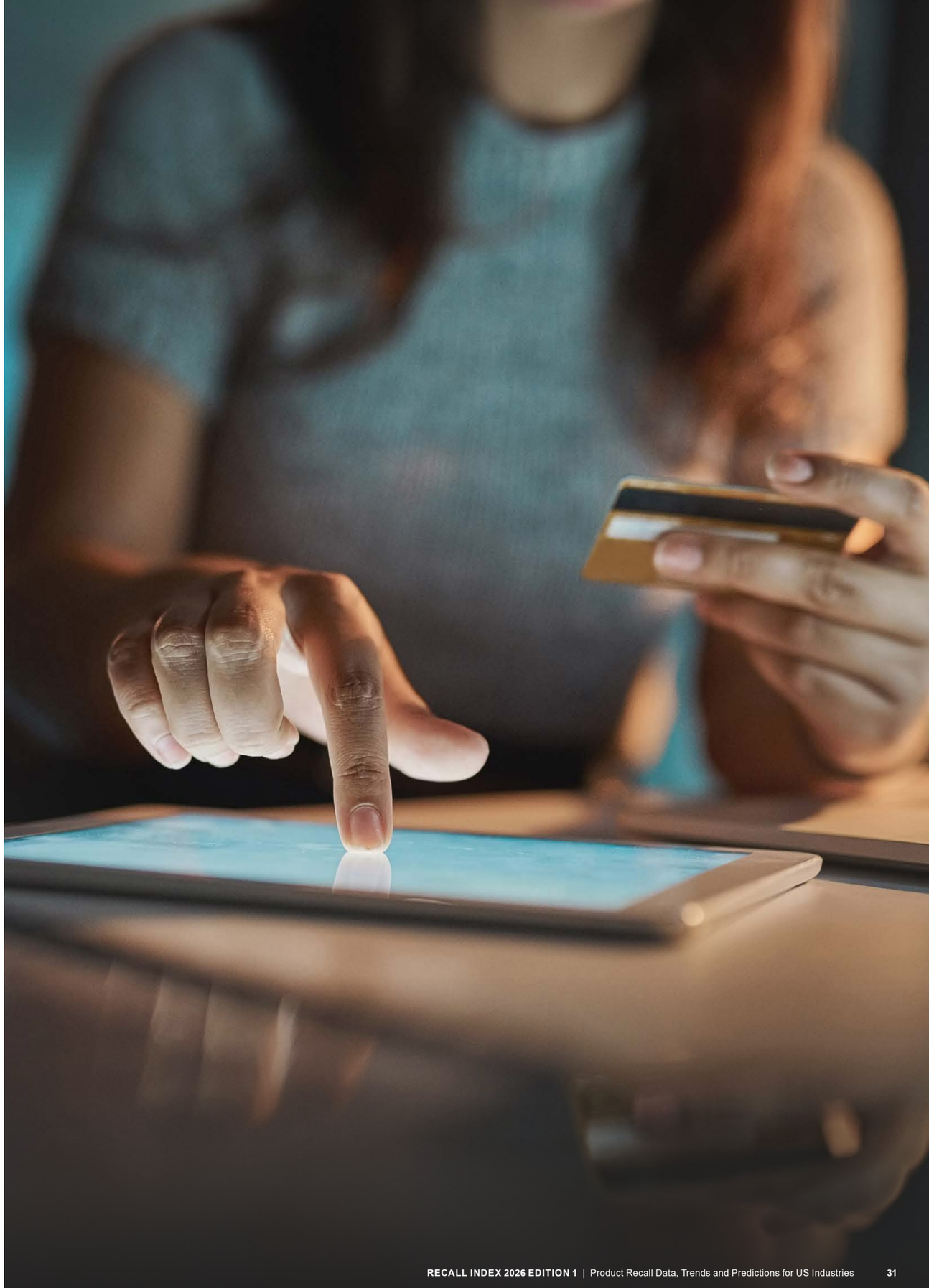
The Commission has signaled that data integrity and program oversight are becoming enforcement priorities. For manufacturers, this means that recall administration, which is often outsourced to third party vendors, can no longer be treated as a purely operational function. Weak controls and poor audit trails now carry regulatory risk of their own.

The hard truth about recall risk in 2026

The bottom line is that recalls no longer just contain risk. They expose it. In 2026 and beyond, effective recall risk management will require more than compliance with regulatory directives. Companies will need to integrate recall processes across product safety, legal, finance, communications, testing partners, and platforms. It demands not only anticipating how regulators think about the issue, but also how plaintiffs, insurers, investors, and courts years later will perceive the recall.

Firms that treat recalls as isolated events will unfortunately learn through litigation that they may have underestimated the timing and the audience. Those that treat recalls with an eye toward a cohesive internal strategy with product safety teams, litigation strategy, financial planning, and governance will have a far better chance of emerging intact.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.



Food and drink

In January, the U.S. Food and Drug Administration's (FDA's) Human Food Program (HFP) released its priority deliverables for 2026. The agency is focused on three main areas: food chemical safety, nutrition, and microbiological food safety.

Some of the key initiatives include research into ultra-processed food and post-market chemical oversight, including monitoring for PFAS and microplastics. Other priorities are food labeling for online grocery platforms, the food traceability rule, and modernizing inspections and oversight.

The agency has already announced some of the specific deliverables, such as new regulatory program standards for produce in February. These requirements will help ensure a consistent foundation across both state and federal produce regulators.

Another important issue is reforming the rules around Generally Recognized as Safe (GRAS) notices for human and animal food substances. A proposed bill was introduced in Congress in February. The measure includes provisions requiring manufacturers to identify "covered GRAS designations" within 90 days and the creation of a Board to review all "covered GRAS designations."

Infant formula safety is also on the HFP's agenda. In February, the FDA promoted updates to its web-based resources for infant formula to increase transparency and make complex information more accessible and user-friendly. This comes after one infant formula manufacturer settled a suit filed by shareholders, promising to invest $40 million over five years into one of its U.S. plants to improve product safety. The same company was ordered to pay $70 million in damages to a group of families in a different suit. The families claimed that the manufacturer failed to warn them about the risk of a potentially deadly bowel disease linked to the formula.

Color additives are another area of interest. As part of the FDA's efforts to phase out petroleum-based colors in food, the agency announced in February that it would exercise enforcement discretion for companies who make "no artificial colors" claims as long as they use colors derived from natural sources. This is a shift from the FDA's previous position.

The agency is also considering changes to labeling and safety requirements around products that contain gluten. The FDA issued a request for information to gather stakeholder input on cross-contamination risks and other concerns.

Evolving FDA policies on colors, allergens and origin claims are raising compliance complexity, and litigation risk, for food and drink brands.

A new rule on voluntary “Product of USA” labeling went into effect in January for food regulated by the U.S. Department of Agriculture (USDA), including beef, poultry, and processed egg products. Producers are subject to stricter requirements and must be able to substantiate claims within 24 hours.

The robust agenda for the HFP and the actions already taken in the first quarter suggest that 2026 will be an active year for the FDA. Stakeholders across the food and drink sector should be prepared for new regulations and processes.

FDA eases enforcement around “no artificial colors” claims

In February, the FDA announced a policy change designed to incentivize food producers to transition from the use of artificial petroleum-based colors to coloring from natural sources. In a letter to the food industry, the agency stated it will exercise enforcement discretion under the Federal Food, Drug, & Cosmetic Act (FD&C Act) for voluntary claims about artificial colors as long as the food does not contain any certified synthetic colors listed in Title 21 of the Code of Federal Regulations, Part 74.

Previously, the FDA only permitted claims such as “made without artificial food colors/colorings,” “no artificial color/colors/coloring,” and “no added artificial color/colors/coloring” if a product contained no added color of any kind, whether natural or synthetic. The agency emphasized that this change does not alter the statutory misbranding standard under the FD&C Act or create new binding labeling requirements.

Lawyers with Skadden, Arps, Slate, Meagher & Flom LLP note that the FDA’s decision may increase litigation risk for food manufacturers. Even if the agency does not take enforcement action around artificial color claims, private suits and state enforcement actions could be brought alleging that “no artificial colors” or similar statements are misleading if the product contains any added color.

The legal experts caution that plaintiffs’ firms have increasingly focused on “purity” and “natural” claims. This creates a risk that plaintiffs could claim that the FDA’s decision to exercise enforcement discretion acknowledges that these claims could be considered false or misleading under a strict interpretation of the law.

The attorneys urge manufacturers to audit product formulations and labels to ensure compliance with both federal law and the most stringent applicable state laws and to monitor pending litigation affecting color additive disclosures and bans. They also recommend companies carefully substantiate labeling claims with robust documentation regarding ingredient sourcing and the nature of color additives used.

In addition, manufacturers should develop internal processes to review marketing claims and respond to pre-litigation demands or regulatory inquiries.

As lawyers with Womble Bond Dickinson LLP state, the FDA’s policy shift does not provide a legal safe harbor for food manufacturers. Companies may still face compliance risks, including potential state law or private litigation exposure.

Regulators exploring stronger disclosure rules for gluten

In January, the FDA issued a request for information regarding labeling and preventing cross-contact of gluten in packaged food. The agency wants to improve transparency in disclosures of established food allergens and other ingredients that impact certain health conditions, such as gluten for those with celiac disease.

This follows the USDA’s Food Safety and Inspection Service (FSIS) action in September 2025 directing its inspection program personnel (IPP) to include gluten in their verification activities for major allergens.

The FDA is seeking stakeholder input regarding adverse reactions due to cross-contact with “ingredients of interest,” including oats and non-wheat gluten containing grains such as rye and barley. It also asks about the severity of and potency of immunoglobulin E-mediated food allergy to rye and barley and concerns with identifying these “ingredients of interest” on packaged food products in the U.S., among other issues.

The FDA said it has received a citizen petition about gluten labeling and has reviewed available data and reports. It found several serious data gaps that limit the agency’s ability to fully evaluate the public health importance of these ingredients.

The comment period ended on April 22, 2026. The FDA is already reporting gluten as an undeclared allergen in some food recalls, including four events in Q1 2026.

Food manufacturers should carefully review their ingredients to determine if gluten is present. They should also audit their manufacturing facilities to assess the risk of cross-contamination for products with and without gluten. It is unclear if the FDA intends to add gluten to its list of major allergens, but companies should consider any changes they may need to implement if that were to happen.

New “Product of USA” labeling in effect

FSIS’s rule regarding voluntary “Product of USA” labeling went into effect on January 1, 2026. It applies to meat, poultry, and processed egg products regulated by the USDA. For single-ingredient products, the animal must be born, raised, harvested, and processed entirely within the U.S. For multi-ingredient products, all preparation and processing steps must take place within the U.S. and every component except spices and flavorings must be sourced domestically.

Previously, companies could label meat or poultry products as a “Product of USA” if they were processed in the U.S., even if the animals were born and raised in another country. In addition, imported livestock that was slaughtered or further processed domestically often qualified.The USDA said the change will strengthen consumer confidence “by aligning with what Americans expect and demand.”

Use of the label is voluntary, but companies that make the “Product of USA” claim must be able to substantiate it. The final rule does not specify the types of records and documentation that must be maintained to demonstrate compliance, though the USDA offers some examples. These include a written description of the controls used in the birthing, raising, slaughter, and processing of the source animals or a written description of the controls used to trace the source animals and all additional ingredients from the time of birth through packaging and wholesale or retail distribution.

Updated FSIS inspection guidance issued in December 2025 instructs inspectors to verify voluntary U.S.-origin claims as part of routine labeling review. Companies must make records available to FSIS field personnel and any authorized USDA official within 24 hours of a request being made. This includes a copy of the final label that is in use, the product formulation, the processing procedure for the product, and any supporting documentation to show that the label complies with relevant federal regulations and policies.

The fact that there is such a short window to provide information to inspectors means that companies need to proactively compile and maintain the proper supporting information so that they are ready if it is requested.

FDA FOOD AND DRINK

By the numbers

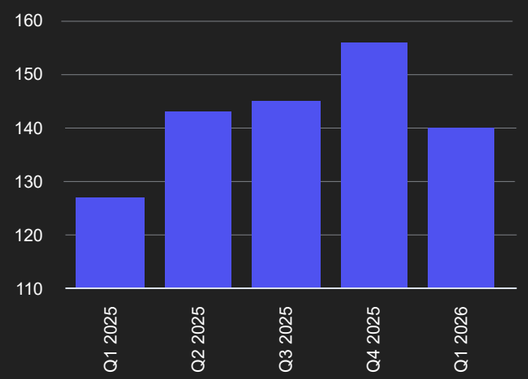
The number of FDA food recalls fell 10.3% in Q1 2026 compared to Q4 2025, decreasing to 140 events. However, the Q4 figure was the highest quarterly total in the past 8 years. The number of units impacted grew 99.5% from 28.76 million last quarter to 57.40 million this quarter. There were seven recalls that affected more than 1 million units.

In Q1 2026, undeclared allergens were the leading cause of FDA food recalls with 57 events, up from 49 last quarter. The most common allergens cited were milk, which was linked to 17 recalls, and soy, which was tied to 14 events. There were four recalls involving gluten. Foreign materials were the second most common cause with 24 recalls. Bacterial contamination had the third-highest number of recalls with 22.

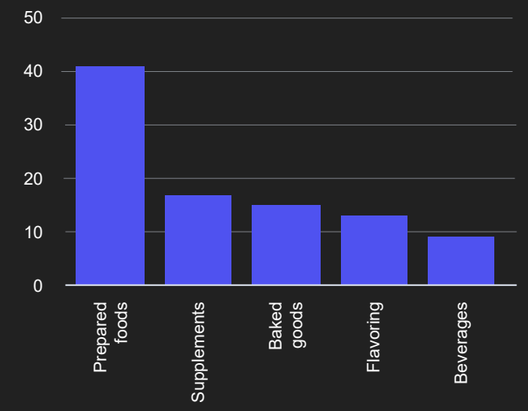
Foreign materials impacted 26.43 million units, the most of any hazard in Q1. This included a recall of prepared food containing glass that affected 19.07 million units. Undeclared allergens were second by volume with 19.26 million units recalled, including a single recall of 18.61 million units for undeclared colors. Bacterial contamination was third and impacted 10.41 million units.

By category, prepared foods led by both recalls and volume in Q1 2026. There were 41 recalls that impacted 44.98 million units, including two large recalls for foreign materials. Supplements were second for both events and units. There were 9.34 million units recalled across 17 events, which included 5.44 million sea moss gel superfood supplements that contained Clostridium botulinum. Baked goods had the third-highest number of events with 15. They also had the third-most units impacted, at 1.19 million.

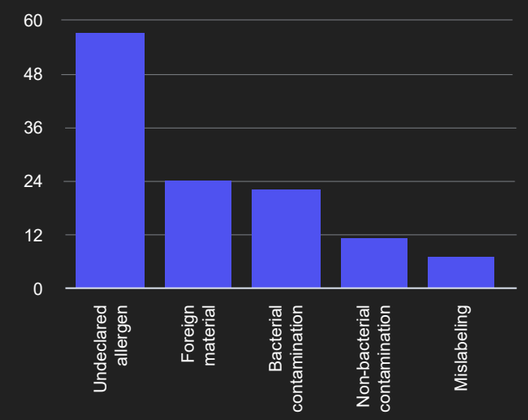
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recall events by risk (top 5)



Year-over-year analysis

Year-over-year, recall events rose from 127 in Q1 2025 to 140 in Q1 2026. This marks a 6-year high for Q1 recall activity. The number of units recalled however declined from 70.25 million to 57.40 million.

Undeclared allergens experienced their highest Q1 figure for the past 8 years with 57 events, with an increase from 50 events in Q1 2025. Recall events involving foreign materials increased slightly from 23 recalls, to 24 in Q1 2026. This marks the highest quarterly level of foreign materials recorded in the past 4 years. Bacterial contamination saw its lowest Q1 figure in the past 3 years with 22 events, recording a decline from 29 in Q1 2025.

In terms of units, Foreign materials surged 423.1% in Q1 2026 with 26.43 million, up from 5.05 million in Q1 2025. Undeclared allergens also saw a significant increase from 1.95 million units in Q1 2025, to 19.25 million. While bacterial contamination was the third-leading concern, it recorded its lowest Q1 figure in the past 3-years with 10.41 million units, marking a decline from 59.65 million in Q1 2025.

By the numbers

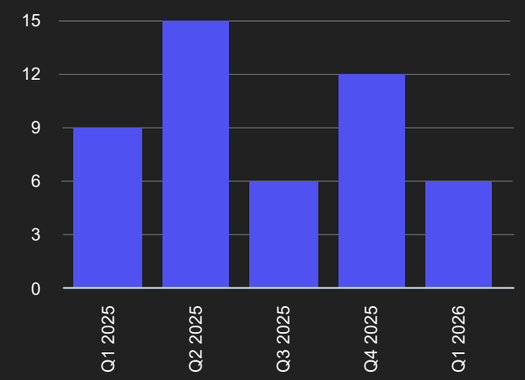
In Q1 2026, the number of USDA food recalls fell by 50% from 12 events in Q4 2025 to six this quarter. This marks their lowest quarterly figure recorded in the past 12 years. In contrast, the number of units impacted surged by 389.6% from 7.58 million pounds last quarter to 37.09 million this quarter. That is the third-highest total in 14 years. The top two quarters each had more than 50 million pounds recalled – Q3 2025 with 58.52 million pounds recalled, and Q2 2016 with 53.35 million.

In Q1 2026, there were two events each for the three causes for USDA recalls: bacterial contamination, no inspection, and foreign materials. Bacterial contamination and no inspection are both on par with the two recalls record apiece in Q4 2025. Foreign material was down from five recalls in the previous quarter.

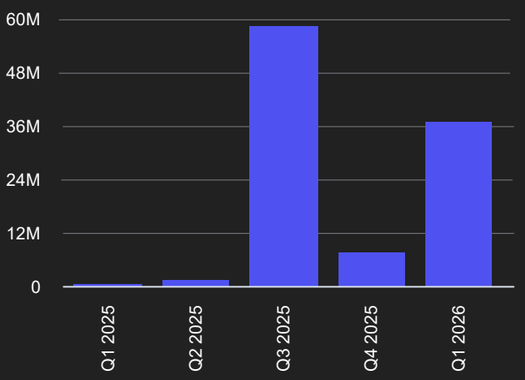
By volume, foreign materials was the leading cause of USDA food recalls, accounting for 37.00 million pounds in Q1, largely due to a single recall of 36.99 million pounds of chicken fried rice products contaminated with glass. No inspection was second by volume with 59,779 pounds. By volume, bacterial contamination was third, impacting 36,632 pounds which is down from 94,440 in the previous quarter,

Poultry and pork each had two recalls in Q1. The total volume recalled was 37.00 million pounds and 55,777 pounds, respectively. Beef and fish were linked to one recall each, ranging from 22,912 pounds for beef and 13,464 pounds for fish. While the one recall for beef is on par with the previous quarter, there were no recalls for fish products in Q4 2025 and they have only recorded seven recall events in the past 14 years.

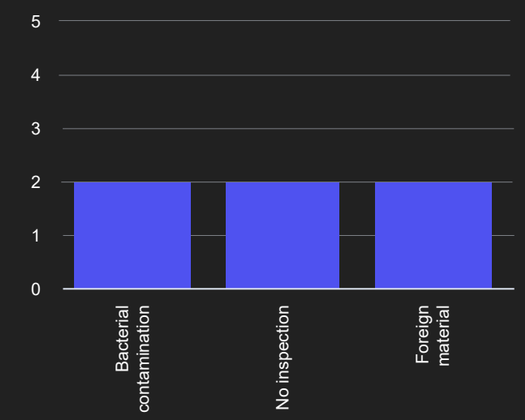
Number of recall events by quarter



Number of pounds recalled by quarter



Number of recall events by risk

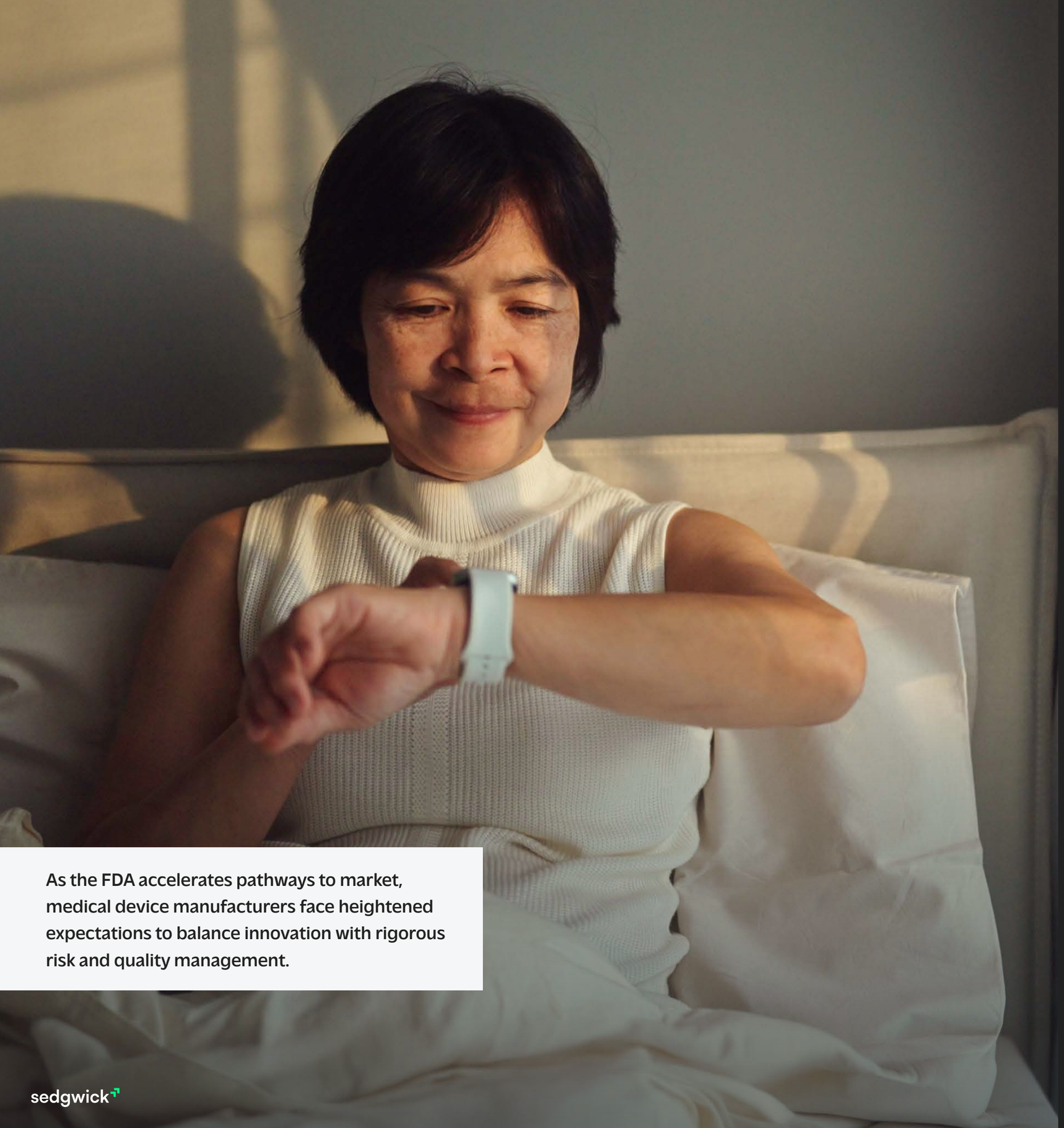


Year-over-year analysis

Year-over-year, recall events fell from 9 in Q1 2025 to 6 in Q1 2026. This marks a 12-year low for Q1 recall activity. The number of pounds recalled however surged from 425,317 to 37.09 million. This subsequently marks a 15-year high for pounds recalled in Q1.

There was very little variance year-over-year in terms of risk. Bacterial contamination was on par with 2 recalls. No inspection recorded 2 events in Q1 2026, which down from a single event the previous year. Foreign material also declined by a single event, recording 3 recalls in Q1 2025 compared to 2 this quarter.

In terms of pounds recalled, foreign materials experienced their highest Q1 figure in the past 15-years. They saw a surge of 511.9% from 72,131 in Q1 2025 to 37.00 million. No inspection saw an increase from 33,899 to 59,779 in Q1 2026. Bacterial contamination saw a noticeable increase from 0 impacted pounds in Q1 2025, to 36,632.



As the FDA accelerates pathways to market, medical device manufacturers face heightened expectations to balance innovation with rigorous risk and quality management.

Medical device

As part of its ongoing efforts to ensure patients have access to innovative products, the U.S. Food and Drug Administration (FDA) published new guidance for general wellness products, which includes many wearable devices such as sleep and activity trackers. The agency expanded the types of devices covered in this category, which means they will not be subject to stricter premarket review and post-market surveillance.

The agency is also trying to make real-world data more accessible for sponsors in their marketing applications. By dropping some of the requirements on micro-level data, the FDA will allow companies to use data from large patient databases that may offer more insights into real-world use. However, strict oversight is still required.

In February, the FDA's new quality management system regulation for medical devices went into effect. This is the first major update in almost 30 years and makes changes to align with global quality management standards and moves to a more risk-based approach to inspections.

While the FDA is taking steps to get medical devices to market more quickly, it continues to focus on safety and risk management.

FDA eases General Wellness product rules

In January, the FDA released updated guidance for low-risk general wellness products. These goods include wearable devices that track sleep and activity, products to coach breathing techniques for relaxation, and products that help the user manage a healthy eating plan.

By definition, general wellness products relate to the maintenance or encouragement of a general state of health. They are not used to treat or diagnose conditions and present a low risk to the safety of users and others.

In its January guidance, the FDA stated that it does not intend to examine this category of products to determine whether they qualify as a medical device under the Federal Food, Drug, & Cosmetic Act (FD&C Act). In addition, it will use enforcement discretion regarding medical device premarket review and post-market regulatory requirements.

Even products that measure factors such as blood pressure or oxygen saturation are exempt from medical device regulation, provided that they meet certain criteria. Among these are that they are non-invasive and non-implanted; are not intended for the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; and are not intended to substitute for an FDA-authorized, cleared, or approved device.

In addition, labeling for general wellness products should not suggest that the product is medical or clinical grade. Manufacturers must not state or imply that the product is a substitute for an FDA-authorized medical device.

Attorneys with Loeb & Loeb LLP note that the guidance classifies more devices that use sensor-based digital health technology into the wellness category. That may create some confusion. For example, the FDA previously classified a blood pressure monitor that had the same features and output measures as a regulated device as a medical device, even if it was not advertised for medical purposes. Now that same device could be considered a general wellness product if it is promoted as such and meets the other criteria listed to qualify.

Legal experts with Sheppard Mullin Richter & Hampton LLP explain the line between products that do and do not fall under FDA device regulation depends on whether the product's claims, advertising, and labeling remain focused on general wellness—such as nutrition, fitness, or sleep. If so, they are not regulated as a medical device. Products that promote disease-specific references or treatment guidance must comply with the FD&C Act rules.

Based on analysis from Arnold and Porter, current FDA administrators want to ease regulation to ensure patients have access to innovative products that leverage new technologies. The lawyers recommend that makers and marketers of general wellness products review the guidance and adjust their compliance and development plans accordingly.

Use of real-world data simplified

In December 2025, the FDA issued new guidance to make the use of real-world evidence (RWE) in medical device applications less burdensome for sponsors. For certain types of submissions, the agency will accept RWE without requiring identifiable individual patient data collected from real-world data sources.

Historically, any RWE submitted in an application needed to include private, confidential information at the individual patient level. This requirement makes it impractical to use most existing large patient databases such as the National Cancer Institute's Surveillance, Epidemiology, and End Results database, as well as those from hospital systems and insurance claims and electronic health record networks. All of these systems contain valuable de-identified, macro-level data which could offer insights into patient outcomes across a wide range of populations and real-world treatment settings that go beyond traditional clinical trials.

Attorneys with Morgan, Lewis & Bockius LLP caution that even with this change, sponsors should still anticipate high standards for data collection and rigorous study design. The FDA recommends that sponsors document how the RWE supports the purpose of their submission and assess the relevance and reliability of the real-world data used to generate the RWE.

In addition, the agency urges sponsors to obtain all information and associated documentation related to the processes, procedures, and methods around data collection and data quality. The FDA states that without this information, it may have less confidence in its ability to trust the data, which will impact the approval of the submission.

The legal experts note that the FDA plans to review the relevance and reliability of RWE submissions on a case-by-case basis and consider the scientific strength and quality of the evidence. The agency has stressed the need for thorough documentation of real-world data sources, study protocols, definitions of all study elements, relevance, and reliability assessments.

Even with the new guidance, there may be situations where an investigational device exemption (IDE) is required for studies using real-world data. The document provides clarification around when this would apply.

While the December publication focuses on medical devices, the FDA intends to consider updating its guidance for drugs and biologics. Device manufacturers and sponsors should determine if the changes will offer any benefits to their submission process. However, they need to be aware of the robust data requirements that still exist.

New process for quality management system inspections

The FDA's updated Quality Management System Regulation (QMSR) took effect on February 02, 2026. The mandatory QMSR helps manufacturers ensure that their products consistently meet applicable requirements and specifications. It is based on a systematic application of risk management through a culture of quality and is consistent with international total product life cycle regulations.

The latest QMSR harmonizes FDA regulations with those used by regulatory authorities in other countries by incorporating the global standard ISO 13485:2016 by reference. The quality management systems for FDA-regulated food, drugs, biologics, and devices are known as current good manufacturing practices (cGMPs). Medical device cGMPs were last revised in 1997.

An overview by experts with Exponent Inc. states that the updated QMSR changes how medical device manufacturers' quality systems may be structured and how inspections will be conducted. It also alters what documentation and risk-based rationale may be needed to defend certain long-standing practices, especially around management oversight, supplier controls, and internal audits.

Some of the key amendments to the QMSR identified by Exponent Inc. include a shift "from prescriptive subsystem requirements toward management responsibility, documented risk-based decision-making, and system effectiveness."

Simultaneously with the regulatory updates, the FDA replaced the Quality System Inspection Technique (QSIT) with a new inspection process that emphasizes a risk-based approach and alters medical device inspections to allow pre-inspection reviews of a firm's inspection and compliance history. In addition, management reviews, internal audits, and supplier audits are now explicitly subject to FDA review.

The update also introduces other applicable FDA requirements such as medical device reporting and reports of corrections and removals as part of the QMSR inspection process, two different inspection models, and more focus on supplier controls to ensure a continuous, risk-informed assessment of the supplier's ability and performance.

Consultants with Exponent Inc. recommend that device manufacturers consider how the inclusion of management reviews, internal audits, and supplier audits could affect the outcome of their FDA inspections.

They also suggest that medical device companies proactively review legacy quality practices, align their documentation with ISO 13485 principles, and prepare their internal records for inspection so that they are better positioned to navigate FDA oversight under the updated regulation.

By the numbers

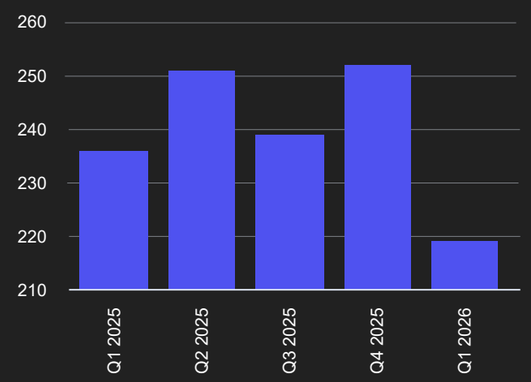
In Q1 2026, the number of FDA medical device recalls decreased by 13.1% compared to Q4 2025, dropping from 252 events to 219. The number of units recalled fell even more dramatically from 331.08 million in Q4 to 146.63 million in Q1, a 55.7% decrease. However, Q4 2025 had the third-highest quarterly unit total in 21 years. While Q1 2026 is lower, it is still above the five-year quarterly average of 112.75 million units. There were 11 recalls that impacted more than 1 million units, including three that affected more than 14.50 million.

Device failure was the leading cause of medical device recalls in Q1 2026, accounting for 41 events, up from 26 last quarter. Software and mislabeling tied as the second-most common concern with 24 events each. Safety issues was third with 19 recalls.

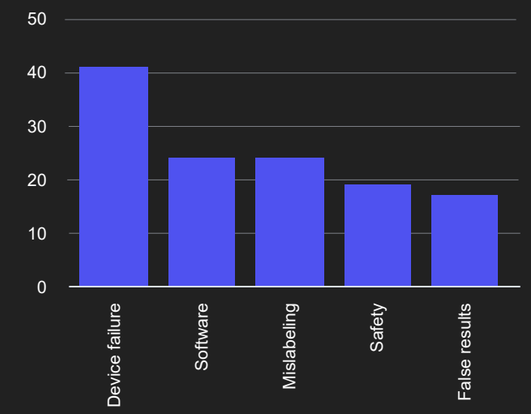
Sterility was responsible for the most units recalled in Q1, with 86.35 million, primarily linked to a large recall of 86.07 million convenience kits of prepacked medical devices. The second-most common reason for medical device recalls by volume was mislabeling. There were 19.60 million units impacted, largely due to a recall of 18.15 million user manuals for devices to measure blood glucose. Leakage had the third-highest number of units recalled, with 16.47 million, including one recall of 14.68 million connectors used in hemodialysis.

There were fewer events and fewer units impacted for both Class II and Class III recalls in Q1 2026 compared to Q4 2025. This quarter had 199 Class II recalls involving 124.05 million units and five Class III events with 2,140 units affected. In addition, there were fewer Class I events with 15, but more units impacted in the category quarter-over-quarter with 22.58 million.

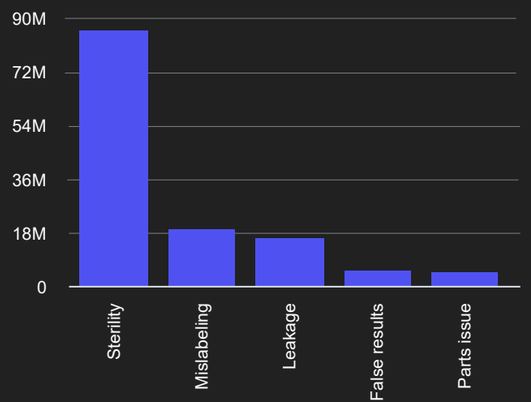
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recalled units by risk (top 5)

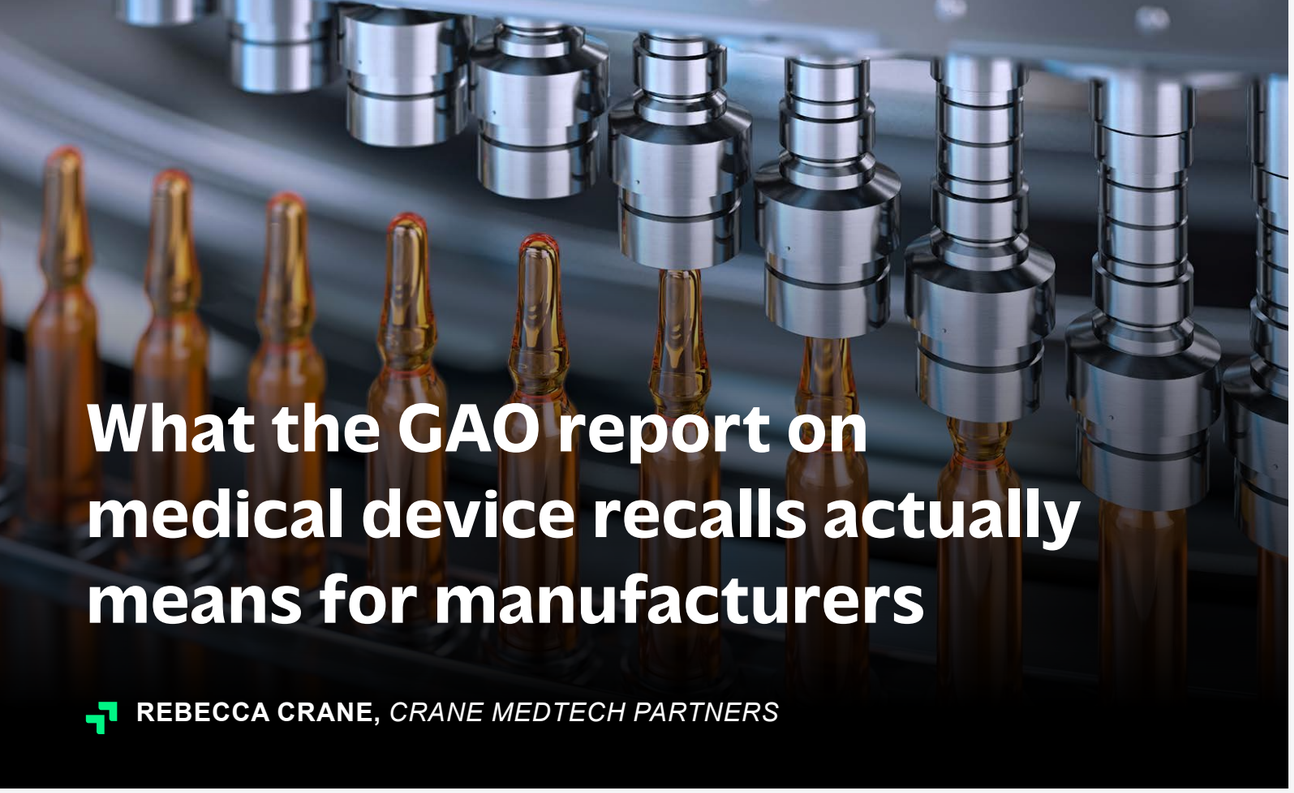


Year-over-year analysis

Comparing Q1 2025 and Q1 2026, the number of recalls was higher in 2025 with 236 events, marking a 3-year low for Q1 recalls in the medical device sector. However, the number of units impacted in Q1 2025 was much less with 18.58 million, compared to 146.63 million. This subsequently marks a 3-year high for units impacted in the first quarter.

In terms of risk, device failure fell 14.6% from the 48 recalls in Q1 2025, to 41. Software also saw a slight decline from 31 events to 24, while mislabeling was on par year-over-year with 24 events.

Looking at impacted units, Sterility hit a 10-year high with 66.35 million units, up significantly from the 1.37 million units recorded in Q1 2025. Mislabeling reached their second-highest level in the past 5-years, and the highest first quarter figure recorded in the past 6 years, with 19.60 million. This was also up considerably from 178,183 in Q1 2025. Leakage marked a 3-year high with 16.47 million units, and recorded its highest first quarter figure for over 10 years.



What the GAO report on medical device recalls actually means for manufacturers

REBECCA CRANE, *CRANE MEDTECH PARTNERS*

Medical device manufacturers should act on the December 2025 report issued by the U.S. Government Accountability Office (GAO) on the FDA's device recall process. The FDA cannot legally mandate what manufacturers do during a voluntary recall, and the agency's capacity to provide guidance during one has declined. The FDA missed its own three-month termination target 74% of the time over the last five fiscal years.

A manufacturer's recall program needs to be built to withstand scrutiny at any time, not only when the agency has capacity to apply it.

What the report found

The GAO's audit covered nearly 4,000 recall events from FY2020 through FY2024, before reductions in force in 2025 decreased agency capacity. Three findings matter most operationally. The first is that staffing constraints have reduced oversight activity. FDA officials told the GAO that staff limitations prevent the agency from reviewing manufacturer Recall Status Reports and conducting in-person recall audit checks. Staff are triaged to Class I events and early recall stages. These factors mean that mid-recall and termination oversight gets deferred.

The second key finding is that reduced staffing further limits the agency's ability to provide timely guidance on voluntary recall strategy, scope, or corrective actions during an active recall. Manufacturers have always needed to own these decisions but the practical gap now is that the agency has even less bandwidth to weigh in when asked.

The third notable conclusion by the GAO is that 74% of recalls exceeded the three-month termination target. In practice, manufacturers may complete a recall, move on, and hear about a gap or disagreement months or years later, well after they considered the event closed.

What findings mean operationally

The GAO's recommendations go to agencies and Congress, but manufacturers need to assess and act on their recall infrastructure now around two key areas.

First, a company's recall strategy needs to stand on its own rationale. Voluntary recalls are manufacturer-led from initiation through execution. A recall is easier to defend when it is backed by strong documented rationale. What data triggered the decision? What analysis supported the retrieval scope? And what corrections were determined necessary and why?

Post-market data received after initiation of the recall may confirm the original scope or indicate it needs to be expanded. The record of when the scope was revisited and what assessment was made needs to withstand later review.

Second, recalls require sustained prioritization and open communication. Gaps in effectiveness checks go unaddressed, second notification waves get delayed, and teams move on before the recall is complete. The recall needs to stay resourced and actively managed through termination, with assigned ownership and regular status reviews.

Maintaining open, proactive communication with the FDA throughout the process, flagging challenges early, and documenting decisions as they are made all help to reduce the risk of surprises down the road.

The recall plan gap

The FDA requires manufacturers to have written recall plans. A plan that has never been exercised against a realistic scenario is not recall ready. These six gaps are where most plans fall short.

The first is **decision-making authority and organizational readiness**. A recall puts the entire organization under pressure at once: quality, engineering, legal, commercial, and customer support all have a role. Often these different business units have competing instincts about scope, notification language, and timing. Organizations need clear and effective processes for identifying, escalating, and assessing the initial signal, whether that is an internal finding, supplier notification, or customer complaint. Without that clarity, decisions get delayed and the organization loses time it doesn't have.

The second common gap is **not placing a product hold across the full distribution chain**. Initiating a recall requires an immediate hold on affected product across the full distribution network: the manufacturer's own distribution centers, field stocking locations maintained by sales reps or logistics teams, distributor warehouses, international distribution centers, customer sites, and in-transit inventory.

The hold needs to identify affected product accurately, by lot number, part number, manufacturing date, or other applicable identifier. An inaccurate scope undermines the recall before it begins. The recall plan needs to map every node and define the hold mechanism for each one. Testing whether a hold instruction reaches all locations and is acted on is a specific part of any tabletop exercise to test a recall plan.

A third gap is **traceability**. Does the company know who has the affected product, where it is, and that the data are current? Traceability for a recall means two things: knowing which units are affected and knowing where each unit is in the distribution chain, tied to the customer and/or clinician who needs to be notified. Both are necessary because a lot number without a customer location leaves the notification list incomplete.

Distribution data is also a snapshot. Devices are in transit, orders are entering the network, and returns may not yet be processed when the recall is initiated. Customers who returned a device may still appear on the notification list and customers who received units the day before may not appear at all yet. For corrections without physical removal, knowing who received the device and whether they still have it is essential.

Distributor records are another specific gap. Distributors either share the list with the manufacturer or notify their customers directly. Either way, that data needs to be quick, comprehensive, and accurate. Manufacturers need to establish expectations with distributors in advance so the right data is available when it is needed.

Customer notification is the fifth recall gap. Companies need to consider reach, accountability, and response tracking. Notification is not complete when letters go out. It is complete when there is documented evidence that the affected customer received the notification and took the required action. The notification plan needs to define the full responsibility chain: who the manufacturer notifies directly, what instructions distributors receive for notifying their customers, and who ensures the patient or end user is informed.

Response tracking is operationally demanding with notifications through multiple channels, each generating a separate data set that must be reconciled back to the master list. Excel files become difficult to manage at scale and reconciliation may require readily available, specialized resources.

Non-response requires additional rounds of follow-up because each unconfirmed notification is an open risk. Documented follow-up attempts on non-responders are what distinguish a diligent recall from an incomplete one. The organization needs a process to manage this data accurately and quickly, and to prioritize follow-up before effectiveness check deadlines.

The sixth gap is **effectiveness checks and post-recall monitoring**. An effectiveness check is documented verification that the recall achieved its objective with the affected product returned, corrected, or quarantined, and affected parties confirmed to have acted or multiple notification attempts made. A low response rate triggers a second notification wave. Stopping at “notifications sent” is not an effectiveness check.

Monitoring also needs to continue after the formal check is complete. Post-recall complaint data may indicate the corrective action did not fully address the root cause. Building a post-recall surveillance step into the associated corrective and preventive action is how that review gets documented rather than missed.

Three things to do now

There are several ways that companies can address these gaps proactively. The first is to map their distribution network and test their hold process. They should identify every node where affected product could be, across their own facilities, field stocking locations, distributors, and international stock, as described in the product hold section above. Test whether a hold instruction reaches all of the nodes and confirm the instruction is acted on. Any gaps this reveals are the same ones that will surface in a real event.

Companies should also run a full-process timed drill. This doesn’t mean just auditing the documentation. They should walk their teams through a scenario from initial signal to effectiveness check against the clock. The decisions that are hard to make under pressure in a drill cause delays in a real recall.

Finally, organizations should review their notification and effectiveness check procedures. Define who is responsible for each step of the notification chain, how downstream accountability is assigned to distributors, and how response data from multiple channels gets tracked and consolidated back to the master list. Define what the company’s effectiveness check will look like in practice: what evidence is collected, over what timeframe, and what triggers the next round of notifications.

Manufacturers know their products and supply chains better than the FDA does. The GAO report shows that agency oversight capacity has declined and it isn’t likely to recover quickly. Whether a given manufacturer’s recall program is built to function without that oversight is the question worth answering before it becomes urgent.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.

Pharmaceutical

In January, President Trump announced the United States' withdrawal from the World Health Organization (WHO). He cited the WHO's "mishandling of the COVID-19 pandemic," among other reasons. As part of the withdrawal, the U.S. will end funding to certain United Nations organizations and review its support to all international organizations.

In a statement, the WHO said the U.S. decision "makes both the United States and the world less safe." It also defended itself against the negative claims in the statement from the White House.

After the U.S. Supreme Court invalidated President Trump's reciprocal tariffs imposed under the International Emergency Economic Powers Act (IEEPA), the president threatened to implement 100% tariffs on branded drugs and their active ingredients for pharmaceutical companies that have not struck deals to lower U.S. drug prices.

According to a statement from the White House, manufacturers who enter pricing agreements and produce their drugs in the U.S. will be exempt from the tariffs. In addition, generic drugs will be exempt for at least one year. Orphan, veterinary, and other specialty drugs are also exempt, provided they meet urgent public health needs or are from countries that have an existing trade deal with the U.S.

The tariffs are scheduled to take effect on July 31, 2026 for large companies that do not negotiate deals with the White House. Smaller companies will have until September 29, 2026. As of early April, 17 drugmakers had reached agreements to receive exemptions.

U.S. regulators were also very active in the first quarter with enforcement actions related to pharmaceuticals. In February, the Federal Trade Commission (FTC) reached a settlement with one of the largest prescription drug benefit managers (PBMs) and their affiliated group purchasing organizations. The FTC alleged that the company, along with two other PBMs, were engaging in anticompetitive and unfair rebating practices that artificially raised the list price of insulin.

From pricing and promotion to safety reporting, regulators are demanding greater transparency and accountability across the pharmaceutical value chain.

The settlement requires the company to adopt fundamental changes to its business practices to increase transparency. The FTC estimates that the actions will drive down patients' out-of-pocket costs for drugs like insulin by up to $7 billion over 10 years and bring millions of dollars in new revenue to community pharmacies each year. A proposed settlement was reached with a second PBM in March under similar terms.

The U.S. Food and Drug Administration (FDA) is also cracking down on illegal activity. In March, the agency sent warning letters to 30 telehealth companies for making false or misleading claims about compounded GLP-1 products offered on their websites.

Compounded drugs are not FDA-approved, yet many of the companies made claims implying the products were the same as FDA-approved weight loss drugs. They also advertised products branded with their company's name or trademark without qualification, which can mislead consumers about where the product is sourced and make buyers think the telehealth company compounded the drug.

The FDA launched a campaign in September 2025 focusing on misleading direct-to-consumer pharmaceutical advertisements. The March communications were the second group of warning letters sent to telehealth firms under that initiative.

In addition to the increased enforcement activity, the agency is working to give the public easier access to information about the safety of FDA-regulated products in the market. It has consolidated several databases and launched a streamlined system to report and monitor adverse events. The new platform will standardize reporting and make it easier to search for information.

The FDA also wants to help manufacturers respond to Form 483 observations, which the agency issues after inspections. It published new guidance on what it expects from companies, with an emphasis on corrective and preventive action plans and improved communication.

Getting products to market quickly while maintaining safety also continued to be a priority for the agency in Q1. It provided clarity around medications to treat pediatric cancer and rare diseases. In addition, there were actions around protections for orphan drugs and a streamlined process to approve individualized therapies for ultra-rare diseases.

The trade implications from the proposed tariffs and the U.S. withdrawal from the WHO are likely to affect the global pharmaceutical sector. Manufacturers, distributors, and marketers also need to be ready for stricter scrutiny from the FDA and increasing demands for greater transparency.

New platform for analyzing adverse event reports launched

In March, the FDA launched its Adverse Event Monitoring System (AEMS), a unified platform for analyzing adverse event reports across FDA-regulated product categories. The system standardizes reporting, improves data quality, and reduces administrative burden through streamlined workflows, AI-based redaction and digitization tools, enhanced analytics, and cross-product surveillance.

Previously, the FDA relied on seven separate databases to process roughly 6 million adverse event reports annually, making cross-system analysis difficult. The agency estimates that AEMS will save approximately $120 million over five years and support near real-time publication of reports rather than quarterly updates.

Four databases have been replaced by AEMS already. The remaining three should be completed by the end of May. The FDA will also migrate historical adverse event data to the new system, decommission certain legacy systems, and roll out enhanced application program interfaces (APIs) and data analytics tools.

In addition to adverse event reporting, AEMS will act as a centralized platform for managing consumer complaints, regulatory misconduct reports, and whistleblower submissions across all FDA centers. By bringing all of these functions together, the agency will be able to conduct more effective safety monitoring, enable trend identification across a range of product categories, and use improved data integration and analysis capabilities to support timely regulatory decision-making to protect public health.

Despite all of the benefits, the FDA does note several limitations to AEMS, including duplicate and incomplete reports; unverified information in the reports; and rates of occurrence cannot be established with reports. In addition, the existence of a report does not establish causation. The fact that a product is named in a report does not mean it caused the adverse event.

The agency expects that the increased transparency provided by the new system will encourage consumers, health care providers, and other members of the public to provide more detailed and complete information in their adverse event reports.

Manufacturers and sponsors should review their processes both for submitting adverse event reports and for responding to them. Real-time access to data and greater transparency create more potential risk to brands.

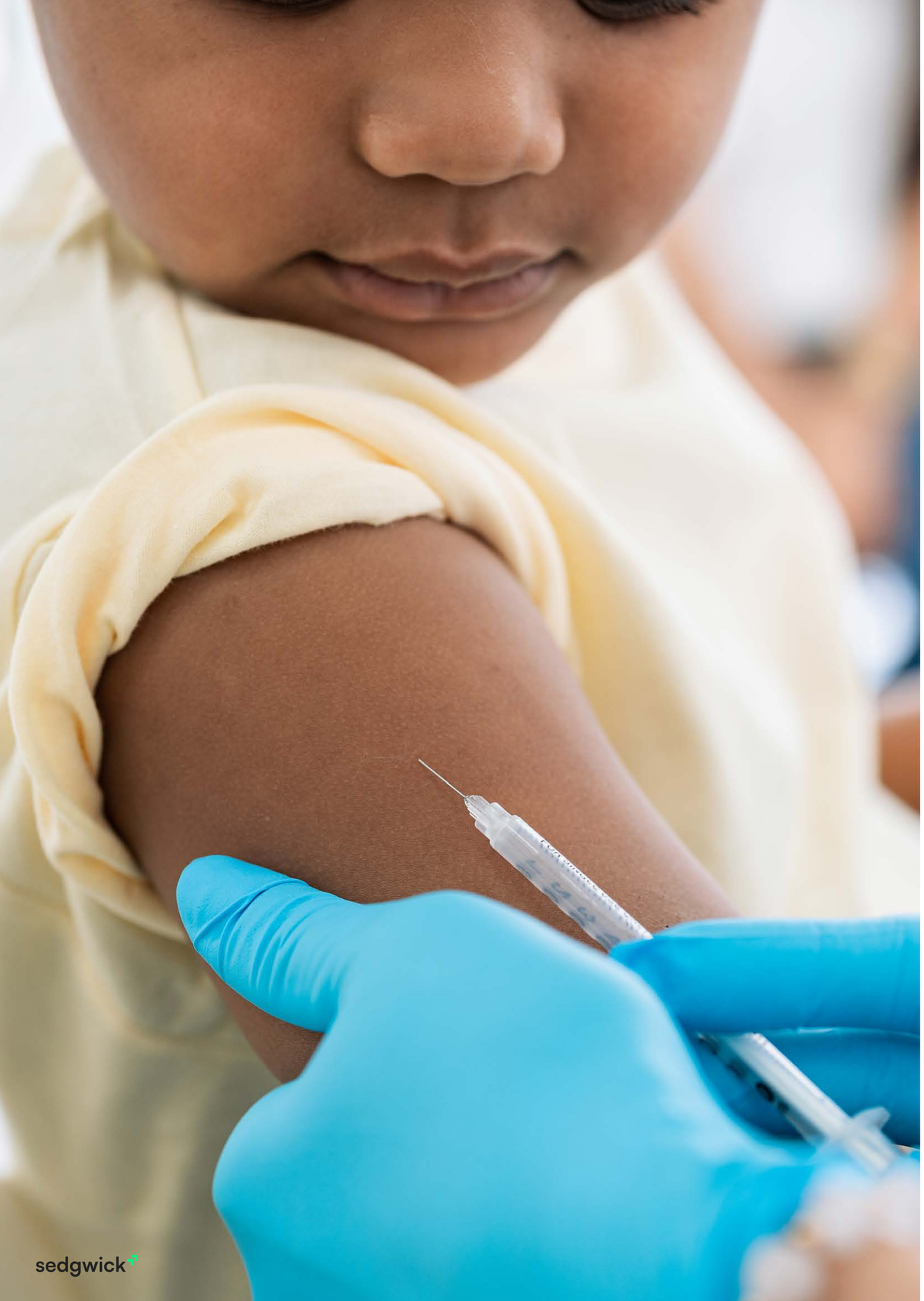
Having a thorough response plan in place will help mitigate regulatory and reputational damage. The FDA has stated that it will use adverse event report information when monitoring the benefit-risk profile of regulated products throughout the entire product life cycle, which could result in post-market actions.

FDA offers guidance on responding to negative inspection reports

In March, the FDA published a draft guidance to help drug manufacturers respond to Form 483 observations related to current good manufacturing practice (cGMP) inspections. These forms are issued to companies when an FDA investigator has observed any conditions that may constitute violations of the Food, Drug, & Cosmetic Act or related regulations.

The latest guidance applies to foreign and domestic human and animal drug establishments manufacturing drugs regulated by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). Combination product manufacturers for which CDER or CBER is the lead center are also in scope.

The guidance emphasizes robust corrective and preventive action (CAPA) plans grounded in root-cause analysis and risk assessment proportionate to patient safety and product quality risk. The FDA advises that plans should include preventive measures, implementation timelines, deliverables, and effectiveness checks. The guidelines also highlight a 15-business-day response window and recommend patient- and product-focused risk assessments for unexpired drugs that have been distributed into the market.



In addition, the agency expects clear communication plans while remediation is underway and recommends the use of a cGMP consultant for data integrity matters. Lawyers with Hogan Lovells note that questions remain around how “effectiveness” will be determined, the scope of investigations for global companies, who “owns” the response in multi-site organizations, and whether consultants should be used for issues beyond data integrity.

The legal experts recommend that manufacturers evaluate their standard processes for responding to a Form 483 response against the latest guidance to see if there are gaps. They also counsel companies to have a 15-business-day response playbook that includes any escalation triggers, team assignments, investigation templates, and consultant criteria.

Furthermore, drugmakers should review their FDA inspection and warning letter history to see if there are recurring issues that the FDA may consider signs of inadequate remediation at the next inspection. In addition, organizations should note that partially implemented, or merely promised, corrective actions may open them up to regulatory action.

While the guidance is nonbinding, it outlines the agency’s expectations for responding to Form 483 observations. The comment period closed on May 8, 2026. Stakeholders should follow any progress on a final draft.

Several measures advance to speed drug development and access

In Q1, regulators and lawmakers advanced several measures intended to expand access and accelerate development for certain drug categories. Congress enacted the Consolidated Appropriations Act of 2026 (CAA), which promotes pediatric cancer and rare disease research, extends FDA authority for rare pediatric disease priority review vouchers through September 30, 2029, and reinforces pediatric study enforcement under the Pediatric Research Equity Act.

The CAA also clarifies orphan drug exclusivity language from “same disease or condition” to “same approved use or indication within such rare disease or condition,” regardless of designation or approval date. Attorneys with Cooley LLP advise sponsors to assess whether these amendments—particularly the explicit scope—could narrow existing or planned exclusivity positions for future drugs.

Another change for the pharmaceutical sector is that the FDA will require more transparency in the marketing applications for some generic drugs. Sponsors will need to submit information about whether the generic drug is quantitively and qualitatively the same as the brand drug, and if not, what the differences are.

In addition to the CAA, the FDA issued a draft guidance in February with a “Plausible Mechanism Framework” for accelerating development of individualized therapies for ultra-rare diseases. The guidance specifically discusses genome editing and RNA-based therapies, though the framework could be applied to other tailored therapeutics.

One of the challenges with developing these types of drugs is that patient populations are small, so sponsors cannot always generate substantial evidence of effectiveness and safety through randomized controlled trials. The framework will allow drugmakers to bypass certain clinical trial requirements.

Manufacturers and sponsors will need to review all the changes to determine which provide benefits and which may require updates to compliance processes and marketing plans.

PHARMACEUTICAL

By the numbers

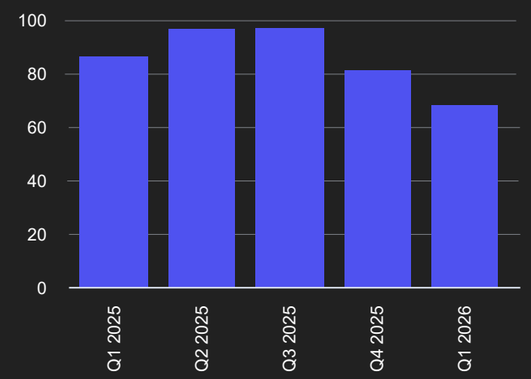
There were 68 FDA pharmaceutical recalls in Q1 2026, down 16.0% from 81 in Q4 2025. The total number of units rose by 2,425.9% from 8.66 million last quarter to 218.83 million this quarter. This is the highest quarterly in the past 4 years and the fourth highest in 20 years. This was driven by a single recall that impacted 212.61 million units. There was one other recall with more than 1 million units, but most events had less than 650,000 and 15 recalls did not report unit totals.

The leading cause of pharmaceutical recalls in Q1 2026 was failed specifications with 24 events, up slightly from 23 last quarter. That was followed by foreign materials with 11 events. Sterility was third and was linked to 10 recalls.

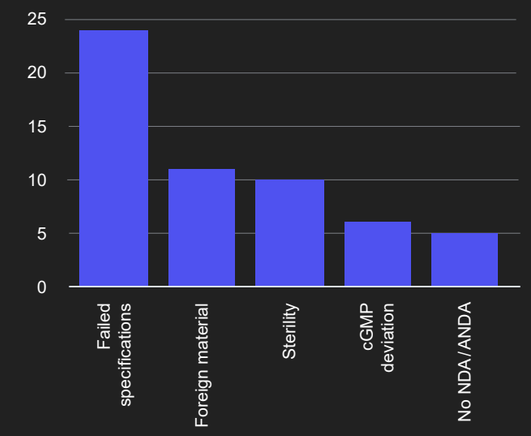
cGMP deviations impacted the most units by volume with 212.62 million, primarily due to a recall of antiseptic towelettes, hand sanitizer, and other products that contain benzalkonium chloride. Sterility was second by volume, affecting approximately 3.87 million units, driven largely by a recall of 3.11 million eye drops. Foreign materials impacted 1.11 million units, the third-highest total of any pharmaceutical risk this quarter.

Class III pharmaceutical recalls were lower by event and volume quarter-over-quarter from Q4 2025 to Q1 2026. This quarter had 11 Class III recalls compared to 14 last quarter. There were seven Class I recalls, up from three in Q4 2025. Class II recalls had fewer events at 50 but significantly more units affected with 218.56 million compared to 6.14 million in Q4.

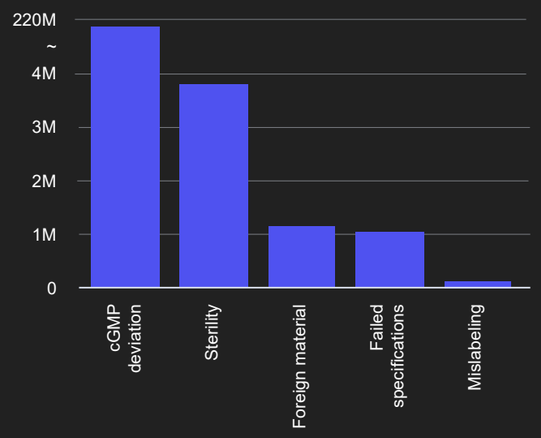
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recalled units by risk (top 5)



Year-over-year analysis

Comparing Q1 2026 to Q1 2025, there were more recalls but fewer units impacted, with 87 pharmaceutical recalls involving 27.74 million units last year. This marks a 5-year low for Q1 recall events, but a 4-year high for impacted units.

While failed specifications were the leading cause with 24 events, it was down from the 27 events recorded in Q1 2025, marking its lowest Q1 figure in the past 3 years. Foreign materials increased from 8 events to 11, experiencing its highest level in the past 6 years. Sterility was up slightly from 9 events in Q1 2025, to 10.

In terms of units, cGMP deviations marked it's third-highest Q1 total in the past 10 years, with 212.62 million impacted products. This has only been exceeded by Q1 2022 with 428.00 million units, and Q1 2018 with 314.70 million. Sterility increased significantly year-over-year from the 209,952 units impacted in Q1 2025 to 3.87 million units this quarter. Foreign materials marked a 5-year high for impacted units in the first quarter with 1.11 million. This surged from 65,847 in Q1 2025.

Enforcement evolved: FDA's new regulatory authorities and technology initiatives signal a higher-risk landscape for pharma in 2026

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The pharmaceutical industry closed out 2025 navigating a paradox that will only intensify in 2026: a leaner FDA—one that shed roughly 3,500 positions—yet one that is simultaneously more sophisticated, more data-driven, and more enforcement-active than in prior years. The explanation for this apparent contradiction lies not in any single development, but in a convergence: the maturation of new regulatory authorities that have expanded FDA's post-market reach, combined with an accelerating investment in artificial intelligence as an enforcement multiplier.

For the pharmaceutical industry, the practical consequence is a materially elevated risk of enforcement action—and the recall exposure and downstream litigation that follow.

The pivot Is visible on multiple fronts

The Q3 and Q4 2025 data make the shift in enforcement clear. Between July 1 and December 3, 2025, the FDA issued 327 warning letters, a 73% increase over the same period in 2024. On a single day in September 2025, more than 60 warning letters went out targeting deceptive direct-to-consumer drug advertising.

In April 2026, the FDA simultaneously contacted thousands of clinical trial sponsors regarding ClinicalTrials.gov reporting failures. This action illustrates what AI-assisted enforcement could look like at scale: a level of data aggregation and coordinated outreach that would have been resource-prohibitive under traditional agency staffing models. The common thread across all these actions is technology and expanded authority working in tandem.

Three developments in particular are reshaping the post-market enforcement environment for pharmaceutical companies. First, the FDA's AI infrastructure is now operational. In June 2025, the agency launched Elsa (Electronic Language System Assistant), a GovCloud-hosted generative AI platform available to all agency employees. The FDA has confirmed that Elsa is being used to identify high-priority inspection targets by analyzing adverse event reports, Form 483 histories, corrective and preventive action (CAPA) resolution rates, and compliance anomalies. In December 2025, the FDA deployed an agency-wide agentic AI tool capable of supporting multi-step workflows across reviews, surveillance, inspections, and compliance functions. Most recently, in May 2026, the FDA announced the expansion of its AI capabilities and the completion of its data platform consolidation—marking another significant milestone in the agency's build-out of AI infrastructure. Together, these tools move the FDA's enforcement targeting from an episodic, resource-constrained exercise toward continuous, data-driven surveillance.

Second, Remote Regulatory Assessments (RRAs) have given the FDA a scalable post-market oversight tool without the scheduling and resource demands of on-site inspections. Under the framework the agency finalized in 2025, RRAs—including mandatory records requests—can be used to evaluate facilities and monitor ongoing compliance.

For pharmaceutical companies, this means the threshold for the FDA to initiate a meaningful compliance inquiry is lower than it has historically been. A data signal flagged by Elsa or an unresolved CAPA identified in historical records can now trigger a remote records request without the lead time and logistical burden of a traditional inspection. The combination of AI-driven targeting and RRA-enabled follow-through gives the FDA a far more efficient enforcement pipeline than it has previously had.

Third, the Drug Supply Chain Security Act's (DSCSA's) enhanced drug distribution security requirements have matured into an enforcement-ready framework. The electronic transaction documentation, product identifier, authorized trading partner, and verification requirements that the industry has been implementing for years are no longer merely operational. They are now an active basis for warning letters and, critically, a rich data resource the FDA can draw on during recalls, product investigations, and enforcement actions.

DSCSA enforcement: a telling case study

One of the most instructive examples of the FDA's more analytically precise enforcement posture came from a December 2025 inspection of a Texas medical spa. During the on-site inspection, FDA investigators conducted what the resulting warning letter described as a "thorough analysis" of the facility's purchase records and patient dispensing records for a branded version of botulinum toxin. They cross-referenced the facility's purchasing data against records obtained directly from the authorized manufacturer and determined that the facility had dispensed significantly more units than its authorized purchases could account for.

The April 2026 warning letter was significant for two reasons. First, it was the first DSCSA warning letter issued to a "dispenser" under the Act—demonstrating that the FDA's DSCSA enforcement is expanding well beyond its traditional targets of manufacturers and wholesale distributors. Second, the forensic precision of the purchase-versus-dispensed-volume analysis reflects a level of investigational rigor that, while not publicly confirmed as AI-assisted, is consistent with the data-aggregation capabilities the FDA has described for its new tools. Whether or not AI played a role in this particular inspection, the action illustrates the kind of rapid cross-record analysis the FDA is now capable of deploying in the field.

Predictions for 2026 and beyond

There are four major trends we are predicting for the remainder of the year and beyond. First, AI-augmented inspections and remote assessments will produce more findings with less warning. As Elsa and related AI tools mature, the combination of continuous data surveillance and lower-friction remote inquiry means companies should expect more targeted enforcement activity—and less lead time before it arrives.

Critically, a data signal flagged by AI does not need to result in a full on-site inspection to carry real consequences. It can trigger a mandatory RRA records request, which is itself a compliance event with defined response obligations and a timeline.

Unresolved 483 observations, aging CAPAs, and inconsistencies in adverse event reporting are the kinds of signals these systems are designed to detect. Companies that have deprioritized remediation of legacy compliance issues should treat that as a near-term enforcement risk, not a deferred one.

The second shift is that DSCSA will become a target for AI analytics and RRA-based inquiry. DSCSA is, at its core, a data generation and utilization mandate. Every transaction in the pharmaceutical supply chain produces serialized records that, in aggregate, map product movement from manufacturer to dispenser.

As the enhanced drug distribution security requirements come into full force, that accumulated dataset becomes exactly the kind of structured, “query-able” information that the FDA’s AI tools are built to interrogate and that RRAs are designed to access remotely.

Supply chain integrity is an intensifying focus for both the FDA and Congress—driven by ongoing concerns about drug shortages, counterfeit products, and foreign manufacturing dependence. DSCSA tracing data offer the FDA a window into supply chain vulnerabilities that no other mechanism currently provides at the same scale and granularity.

Companies should expect DSCSA compliance to attract AI-driven analytics and RRA-based inquiry not only in the traditional enforcement context, but also as part of FDA’s broader effort to monitor and map the pharmaceutical supply chain in near-real time. The Texas spa action, discussed above, is an early signal of what that scrutiny looks like when it arrives.

Our third prediction is that warning letter volume will remain elevated—and escalation risk will rise with it. The 73% jump in warning letters in the second half of 2025 reflects the new enforcement baseline, not an anomaly. As AI-assisted targeting matures, the agency will sustain high enforcement volume even under staffing constraints.

Companies that receive warning letters should respond quickly and thoroughly. The historical pattern in pharmaceutical enforcement is that inadequate or delayed responses substantially increase the risk of escalation to consent decrees, injunctions, or—in the most serious cases—criminal referral to the Department of Justice.

Finally, companies should expect litigation risk to grow alongside enforcement visibility. Heightened enforcement activity generates a richer, more rapidly accessible public record for plaintiffs’ counsel. A warning letter citing cGMP deviations, a DSCSA records deficiency identified during a recall probe, or a Form 483 observation identifying a sterility concern can each serve as an evidentiary foundation for product liability or class action claims.

Companies should document their responses to regulatory findings with the understanding that those records may eventually be reviewed by parties beyond the agency.

Preparing for what is coming

The practical takeaway for the pharmaceutical industry is straightforward: compliance must be continuous rather than episodic and the data companies generate must be as audit-ready as the physical operations that produce it. In an environment where the FDA can cross-reference millions of records faster than a company can convene a response team, preparation is the primary risk management tool.

A less appreciated dimension of that preparation is managing the data risks that flow specifically from the FDA’s use of AI. Elsa and related tools analyze information that companies have already submitted to the FDA or that the agency has collected about them—adverse event reports, 483 observations, CAPA records, complaint handling data, and historical inspection outcomes.

AI tools are designed to cross-reference these data sets across submissions and time periods, surfacing patterns and inconsistencies that sequential human review might not identify. These could include a recurring 483 observation across multiple inspection cycles, a gap between the timeline of a reported adverse event and the company’s CAPA response, or a discrepancy between manufacturing records and product distribution data.

Companies cannot fully predict which data points will trigger AI-driven scrutiny, but they can materially reduce risk by ensuring consistency and completeness across all FDA-facing submissions. Pharmacovigilance data quality deserves particular attention. Adverse-event reporting is a confirmed use-case for Elsa, meaning late, incomplete, or inconsistent safety reports now carry more enforcement exposure than they did when review was resource-constrained.

More broadly, companies should consider conducting internal cross-referencing exercises—reviewing their own 483 histories, CAPA closure records, and adverse event submissions for the kinds of patterns and discrepancies that AI tools are designed to find—before the FDA finds them first.

That broader discipline means addressing open 483 observations before they age into enforcement priorities, ensuring DSCSA transaction records are complete and retrievable, and establishing clear internal protocols for responding to warning letters, RRA records requests, and recall inquiries. The regulatory environment that the FDA’s new authorities and technology investments are creating rewards organizations that treat these obligations as integrated business functions—and is increasingly unforgiving of those that do not.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.

April insights

Automotive:

There were 79 U.S. automotive recalls in April 2026, up 12.9% compared to the Q1 2026 monthly average of 70 events. The number of units recalled by NHTSA decreased from a monthly average of 4.06 million units in Q1 to 3.76 million units in April.

There were 13 equipment recalls, making it the leading cause of events for the automotive sector in April 2026. That was followed by electrical systems with 10 recalls and power trains with six recalls.

Power trains had the most units recalled in April with 1.5 million, primarily tied to a single recall of 1.39 million units. Air bags were second in terms of volume with 491,689 units recalled. Electrical systems were third with 412,707 units impacted.

Consumer product:

There were 62 U.S. consumer products recalls in April 2026, up from the Q1 2026 monthly average of 47 events. The number of units recalled decreased from a monthly average of 6.72 million units in Q1 2026 to 4.13 million in April 2026. There was only one recall with more than one million units.

Yard & Garden was the top consumer product recall category for April 2026 with 16 events. Personal care, Electronics, and Toys tied for second with eight recalls each. In third was Sports & recreation with six events.

Home appliances had the most units recalled in April with a total of 1.8 million due to a single recall of steam cleaners for a risk of burns. Kitchen products were second in terms of volume with 761,00 units. Personal Care was third with 482,770 units impacted.

Food and drink:

FDA

The FDA issued 31 food and drink recalls in April 2026, down 33.6% from the Q1 2026 monthly average of 47 events. The number of units recalled in April decreased to 4.20 million units compared to the Q1 2026 monthly average of 19.13 million.

Undeclared allergens were the leading cause of FDA food recalls with 16 events in April 2026, including five recalls for colors and four for soy. Bacterial contamination, foreign materials, and unapproved food additives were the second-leading causes with three events each. This was followed by quality and excessive substance levels with two recalls apiece.

Undeclared allergens impacted the largest volume of FDA food recalled, accounting for 4.17 million units in April 2026. This included a single recall for 3.60 million units of lemonade for the undeclared presence of Yellow No. 5. This was the only FDA food recall in April to impact more than one million units. Foreign materials were the second-highest concern by volume, linked to 10,534 units. Bacterial contamination was third with 9,688 units impacted

USDA

There were no USDA recalls in April. This compares to a Q1 2026 monthly average of two events impacting 12.36 million pounds.

Pharmaceutical:

There were 34 pharmaceutical recalls in April 2026. This is up 47.8% from the Q1 2026 monthly average of 23 events. In contrast, the number of units recalled fell significantly to 2.81 million compared to the Q1 2026 monthly average of 72.94 million units.

In April 2026, the most common hazard by event was sterility with 13 recalls. Failed specifications were second with six events. This was followed by cGMP deviations and mislabeling with four recalls each.

Foreign materials was the leading pharmaceutical recall risk by volume, impacting 1.17 million units tied to a single recall of contrast solution for imaging. cGMP deviations had the second-highest volume with 607,406 units affected. Sterility was third with 501,120 units recalled.

The FDA classified one pharmaceutical recall in April 2026 as Class I and five as Class III. The remaining 28 recalls were designated as Class II and impacted 2.7 million units.

Medical device:

In April 2026, there were 81 medical device recalls, an increase from the Q1 2026 monthly average of 73 events. However, the number of units recalled fell 35.9% from a Q1 monthly average of 48.88 million units to 31.32 million units in April.

In terms of events, safety was the most commonly cited cause for medical device recalls in April 2026 with 14 events. False results were second with 11 recalls, followed by device failure with 10 events.

Safety was also the leading cause of recalls by volume and impacted 9.05 million units. Outside specifications were the reason for the second-highest number of medical device units recalled with 7.20 million, largely tied to a single recall of 7.17 million sponges with excessive levels of endotoxins. This was followed by device failure with 5.90 million units affected.

The FDA classified eight medical device recalls in April 2026 as Class I. These recalls impacted a total of 14.93 million units. There was one Class III recall in April that affected 52,896 units. The remaining 72 recalls were categorized as Class II and were linked to 16.34 million recalled units.

Conclusion

Challenges remain for companies across all industries. The FDA is considering changes to gluten labeling, which could increase litigation and compliance risks for packaged food companies. The agency also has aggressive plans to change policies dealing with nutrition and food safety—specifically related to chemical and microbiological hazards.

The automotive sector is tracking proposed rules for autonomous vehicles. The lack of consistent regulations is one factor blamed for a slow roll out of self-driving cars.

The Government Accountability Office is urging the CPSC to improve its oversight of toxic substances in children's products. This could lead to more regulations for manufacturers to mitigate the presence of lead and other toxins.

The FDA launched a new system for submitting adverse event reports for drugs, medical devices, and other FDA-regulated products. The platform provides more transparency and real-time information, which could create more exposure, and thus more risk, for reporting companies.

Given the uncertainty, organizations must plan for risks across a variety of areas, including:

- Business interruptions
- Supply chain challenges
- Regulatory and legislative changes
- Financial impacts
- Product updates, upgrades, and warranty work
- Product recalls and market withdrawals
- Data privacy and cybersecurity issues
- Innovation and advancements in technology
- Dynamic consumer demand
- Customer and partner apprehension

Unfortunately, recalls and other incidents are inevitable in today's business environment. Many regulatory agencies recommend, even mandate, that companies have recall, incident response, and/or risk management plans in place as part of their standard business processes. Advance planning means better protection for your customers, brand, and bottom line when product issues do occur.

Whether planning for or actively managing a product safety crisis or other in-market event, leveraging the experience and insight of an external partner can save millions of dollars in regulatory and litigation costs, as well as time and stress on other internal resources. In addition, their expertise will help you honor your commitments to customers, supply chain partners, industry groups, and regulators, while protecting your reputation among the stakeholders that matter most.

Sedgwick Recall

When their reputations are on the line, leading global brands trust Sedgwick Recall. With more than 30 years of experience managing complex product recalls and crisis events across industries and borders, we provide the strategic expertise and operational precision needed to protect consumers and safeguard businesses.

Sedgwick has helped companies in 150+ countries prepare and adapt during some of the most challenging events in their history. Our three decades of global experience executing 8,000+ recalls affecting 500+ million units gives us unparalleled insights that we put to work to help you.

We are the leader in global product recall services. We've managed some of the largest product recalls and are a recognized authority in recall and incident response solutions. We offer a full suite of end-to-end solutions to help businesses navigate complex and evolving regulatory landscapes with confidence. Whether you need help managing the entire process from pre-incident planning to final disposal of a defective product or modular support for any step in between, we work as an extension of your team to resolve issues quickly and in compliance with all regulatory requirements while helping you use your resources wisely.

We also leverage our extensive skills in acting quickly in a crisis to provide expert incident response solutions. Our experienced team helps businesses operate well under pressure to find the best solution for dynamic, evolving situations. We will partner with you throughout the event to assess rapidly changing situations and continually adjust our plans to achieve the best outcome for your business, including rapid notifications, scaling up a multilingual call center, or removing a product from the market.

Sedgwick offers the experience and the global reach to help you with proactive planning to mitigate risk and quick, effective actions in times of crisis.

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

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