Product Safety

Consumer Products

Personal Care Products

Talc Cancer, Wen Hair Loss Reports Show Weak Reporting to FDA

Cosmetics makers should be required to submit reports of suspected harm from their products to the FDA, researchers who recently analyzed an FDA database and a former commissioner say.

Manufacturers are many times more likely to be alerted to possible health-related problems and reactions than the federal agency, the researchers said.

Bloomberg BNA's own analysis of selected cosmetics-related adverse event reports in the Food and Drug Administration database bears out their argument that the makers get far and away the vast majority of reports of suspected injuries, even potentially fatal ones.

That information may come from complaints by consumers to the company directly, or from court filings of consumers seeking redress in the U.S. judicial system.

Our analysis of adverse events related to ovarian cancer—the most high-profile and serious potential injury currently linked to a cosmetic product—also points to another limitation of the current voluntary reporting system: When a maker does report to the FDA, little information in those reports is made public.

''One can only assume that whatever products are reported on, you need to multiply that out by a large number to understand what the manufacturers are probably getting,'' Dr. Steve Xu, a dermatologist and lecturer at the Northwestern University Feinberg School of Medicine, Chicago told Bloomberg BNA after his review of 13 years worth of summaries of cosmetics-related adverse event reports filed in the database.

Dr. Robert M. Califf, who served as FDA commissioner under President Barack Obama, agreed with Xu that mandatory manufacturer reporting is needed. Reporting is one of the few tools the underfunded FDA Office of Cosmetics and Colors has to gauge the safety of cosmetics, he said.

Voluntary manufacturer reporting, coupled with chronic consumer under-reporting to the FDA, means that potential safety problems aren't flagged, Califf said.

Cosmetics companies don't need premarket approval for selling their products, and don't have to register their products or ingredients. Nor can FDA recall cosmetic products.

''Without a legal requirement for the cosmetics industry to collect or report adverse events or even register marketed products, the FDA must wait for clues to accumulate from voluntary reports suggesting that a product may not be as completely safe as presumed,'' Califf said in an editorial accompanying Xu's study.

''The need to wait for problems to declare themselves overtly before regulatory action can be initiated,'' he said, ''raises important questions about cosmetic safety as well as the safety of health-related products in general.''

Xu's study and Califf's editorial were published in JAMA Internal Medicine.

Ovarian Cancer Reports Johnson & Johnson said in an August 3 securities filing that it is defending itself from about 4,800 plaintiffs who allege its talc products, mainly Johnson's Baby Powder, caused women to develop ovarian cancer.

The company has been hit with more than $600 million in jury awards over the last two years in that litigation, making it easily the biggest-ticket, most publicized cosmetic-linked injury litigation currently underway.

For that reason, Bloomberg BNA examined the number of ovarian cancer reports linked to J&J in the FDA's database, which goes back to January 2004.

Bloomberg BNA's analysis of the summary reports filed thru June 2017 revealed only 131 reports specifically associated with the company's talc products.

Talc reports were few, but many more ovarian cancer reports were plenty: 4,622 in total. When combined with the 131 reports specifically naming J&J, it's roughly the same number of plaintiffs the company is currently facing in court.

In fact, the ovarian cancer figure is so large it amounts to 41 percent of all cosmetics-related reports in the database from January 2013 to June 2017.

But, other than showing their scale, these 4,622 ovarian cancer reports in the database offer only very limited details related to the suspected causes of those consumers' reported health problems..

That's because key information pertaining to all of these summary reports of ovarian cancer is redacted, consistent with FDA disclosure regulations.

Under those rules, when a manufacturer voluntarily submits an adverse event report to the agency, significant information—including the manufacturer's name, the product name, and even the type of cosmetic product involved—are not included in the summary of the report posted in the database.

The rest of the report summaries are redacted, Bloomberg BNA's analysis found.

The maker and product name are revealed in those 131 reports because they were submitted by consumers or doctors directly to the FDA. In such cases, identifying information about the product's user, but not the name of the product or its maker, is removed.

An FDA spokesperson told Bloomberg BNA it couldn't disclose the identity of the manufacturer or manufacturers that submitted the ovarian cancer reports.

The agency confirmed, however, that it received about 4,400 adverse event reports between January

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2014 and March 2017 on ovarian cancer, and that those reports were associated with the use of body powders.

Johnson & Johnson, which denies a cancer connection to its products and is appealing the verdicts against it, wouldn't say whether it submitted the ovarian cancer adverse event reports to the FDA.

However, in an email to Bloomberg BNA, the company said: ''Whenever a Johnson & Johnson company is given notice of an adverse event about any of our products, whether through direct contact with patients, customers or health care providers or through the litigation process, those adverse events are reported to the FDA.''

Wen Hair Loss Reports Despite those assurances from J&J, the large number of ovarian cancer reports, and the relatively small number naming J&J or its talc products, illustrate a problem and a pattern: Cosmetics makers get much more information about potential health problems than regulators.

They also have the power to decide how much, if any, of that data to pass on to the FDA. And when manufacturers do report suspected health problems to the FDA, only very limited information about those reports are made available to the public.

Though not involving nearly the same degree of alleged harm as the cancer that consumers have linked to talc, reports of injury tied to Wen hair products made by Chaz Dean Inc. are also illustrative.

Some 127 people initially reported reactions such as hair loss and scalp irritation from the products to the FDA between February 2011 and July 2016, the agency said on its website.

But during inspections of manufacturing and distribution facilities, the FDA learned of 21,000 more consumer complaints lodged directly with Chaz Dean and distributor Guthy-Renker LLC, the agency said.

Only a small fraction of those reports currently show up in the database, according to Bloomberg BNA's analysis.

Similar to Johnson & Johnson's talc products—though again, on a much smaller scale—private litigation also ensued over the Wen by Chaz Dean products. It resulted in a $26 million settlement, which the U.S. District Court for the Central District of California approved Aug. 21.

The disparity between the amount of safety-related information that makers and the FDA receive is of particular concern to some consumer health advocates because the FDA has so few regulatory options for cosmetics.

''There is really so little power that FDA has, and I think these lawsuits coming up really show why this is such a significant problem,'' Melanie Benesh, legislative attorney with the Washington-based Environmental Working Group, an advocacy organization that works to protect health and the environment, told Bloomberg BNA.

Northwestern Database Analysis As for Xu, the Northwestern University researcher, he and two of his colleagues looked at all cosmetics-related reports filed by consumers or doctors that were available when the database first became public in December 2016.

That included adverse events from January 2004, the oldest data publicly available, to September 2016, which was then the latest data of this type available.

The researchers' study didn't include include a count of the industry-supplied ovarian cancer reports. Those reports, according to the FDA, weren't added to the database until 2017.

Their overall conclusions? For the 13-year period the researchers studied, there were approximately 75,000 total adverse event reports in the database, which also covers food and dietary supplements. Of that total, only 5,144 reports—just a few hundred more than the ovarian cancer reports from industry—were cosmetics-related.

Skin and hair products represented more than half of the cosmetic reports in the database during the time period the researchers studied, Xu said.

Wen hair products were the most frequently reported specific product or brand then in the database. The researchers counted 1,211 reports, he told Bloomberg BNA.

There were so few Johnson and Johnson reports during that time period, that J&J didn't even make Xu's top five list of most recurring names.

Premier Pigments products, mostly tattoo inks, were listed second-most, with 137 reports naming that company.

Brazilian Blowout (97), L'Oreal (89), and EOS (87) rounded out the five names found most often in the database, Xu said.

Despite the low overall reporting numbers, the researcher isn't discouraged.

''There is some data here; it's not of high value yet but it could be,'' he said.

''There has to be broader awareness of this database. Both providers and patients should participate more, and there has to be a legislative mandate for manufacturers to forward reports to the FDA,'' Xu said.

''In the next five to 10 years, hopefully the database can be more useful for epidemiologists and public safety purposes,'' Xu said.

The FDA advised when it made its database public in 2016 that the database has limitations.

The information appears as it was reported to the agency, doesn't represent agency conclusions, and doesn't reflect certainty about whether the product caused the symptoms, the FDA said on its website.

But, though the reports are just raw data as submitted to the FDA, ''they are important because'' they're ''one of the few tools FDA has to monitor possible safety problems with cosmetics,'' Linda Katz, director of the FDA's Office of Cosmetics and Colors, said in a statement issued at the time.

Talc Cancer Study Underway Meanwhile, the FDA says it's revisiting cosmetic talc, in part because of the continuing influx of adverse event reports.

The agency denied a citizen petition in 2014 seeking a label on talcum powder warning of a possible link to ovarian cancer.

''We did not find such a link in our review of the scientific literature at the time,'' Katz said in her same 2016 statement.

The FDA's Office of Women's Health in 2016 funded a talc-related research project that is slated to be finished over the next few years. ''Once the project is completed we will make the results available either through a scientific publication or our website,'' the agency said.

The project is fully funded, FDA told Bloomberg BNA.

Industry agrees that more regulation is needed.

''Despite the very strong safety record of cosmetic products, the Council and its member companies believe more can be done to ensure that FDA has the appropriate authority and resources to regulate our products in the 21st century,'' Lezlee Westine, president and CEO of the Personal Care Products Council, said in a statement responding to the JAMA study and editorial.

The council has advocated for required reporting by manufacturers to the FDA of serious and unexpected adverse health events, she said.

The council's members include Johnson & Johnson and more than 600 other companies that manufacture, distribute, and supply the vast majority of personal care products marketed in the U.S., the group's website said.

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Drug Safety

Bad Reaction to a Drug? FDA Made Side-Effect Database Searchable

If you had a bad reaction after taking a medicine, there's now an easy way to find out whether others experienced the same.

The Food and Drug Administration improved its online database of reports about side effects filed by patients and doctors, making it easily searchable by product, patient age, type of side effect or year it occurred.

It means that, for the first time, the public will have access to data it can make sense of. Previously, inquiring minds needed to know a little about coding to figure out the FDA's adverse-reaction database. And even then, they had to file a Freedom of Information request with the government to get the actual reports and check the information's accuracy.

The FDA said it hopes that the increased transparency will spur patients and doctors to submit more detailed and complete reports. Many patients don't even know they can submit adverse-event reports to the agency.

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Government Operations

Senators Question CPSC Chair Nominee Over Generator Vote

Consumer Product Safety Commission Acting Chair Ann Marie Buerkle defended her decision last year to oppose a draft rule on portable generator safety at her confirmation hearing to head the agency Sept. 27.

Buerkle told the U.S. Senate Committee on Commerce, Science and Transportation that she voted against the proposal because of potential Environmental Protection Agency jurisdiction over the issue.

Eleven deaths from carbon monoxide poisoning as of Sept. 22 have been linked to improper use of portable generators in Florida alone following Hurricane Irma, said Sen. Bill Nelson of Florida, the commerce panel's top ranking Democrat. The storm left millions of people in his state without power.

Nelson and Sen. Richard Blumenthal (D-Conn.) raised Buerkle's lone dissenting vote on the plan, approved by the CPSC by a 4-1 margin last November, to begin mandatory rulemaking to reduce portable generator carbon monoxide emissions.

Buerkle said the CPSC is very involved on the issue. She cited visits by commissioners to manufacturers and CPSC involvement in voluntary standards requiring shut-off valves on generators.

Under questioning from Nelson, Buerkle said she's put forward the name of an official with the Portable Generator Manufacturers' Association, an industry trade group, as a candidate for CPSC general counsel.

Nelson also criticized Buerkle's actions on generators in a Sept. 27 letter he co-wrote with Sen. Tom Carper of Delaware, the top ranking Democrat on the Committee on Environment and Public Works.

Blumenthal called on her to ''fully fund and support research'' into crumb rubber because of concerns that it may cause cancer.

Some senators, including Commerce Committee Chairman John Thune (R-S.D.), asked Buerkle about the role of voluntary and mandatory standards.

Buerkle said Congress has directed mandatory rules for some products. But for most others, the CPSC should pursue voluntary standards, she said.

This achieves ''buy-in'' through the consensus process of standards organizations, she said. ''We find substantial compliance,'' she said.

The commerce panel intends to move quickly Buerkle's nomination, Thune said.

In addition to chair, Buerkle is also up for a new seven-year term on the commission beginning in October 2018, when her current term expires.

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Food

FDA Food Safety Inspection Flaws Cited in Federal Report

Flaws in the FDA's food safety inspection systems raise questions about its future ability to ensure the safety of the nation's domestic food supply, according to a federal report released Sept. 27.

The report, which examined FDA data from 2010 to 2015, raises questions about the agency's progress in preventing and minimizing foodborne illness outbreaks, a major aim of the FDA Food Safety Modernization Act signed into law in 2011.

The law shifted the agency's focus to preventing, rather than responding to, foodborne illness outbreaks.

The FDA is largely on track for near-term inspection goals—including inspections of 21,086 establishments considered at ''high-risk''—but the agency may have trouble meeting progressively shorter inspection timetables mandated by the FSMA for future inspection cycles, the Inspector General for the Department of Health and Human Services said.

The number of facilities inspected by FDA, excluding attempted inspections, also has decreased over time, from about 17,000 in 2004 to 16,000 in 2015, the report said.

Recalls of flour infected with E. coli bacteria that sickened 63 people in 24 states in 2016 were cited as an example of the regulatory flaws. That outbreak was traced to a General Mills facility in Kansas City, Mo., according to the U.S. Centers for Disease Control and Prevention.

''This outbreak—as well as others resulting in large recalls of spinach, tomatoes, lettuce, and alfalfa sprouts—raises questions about FDA's inspections process and its ability to protect the Nation's food supply,'' the report says.

The agency, which has broad regulatory authority over most foods, also was faulted for not issuing prompt warning letters to some violators and failing to conduct timely follow-up inspections in some cases.

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Full report at https://oig.hhs.gov/oei/reports/oei-02-14-00420.asp.

Medical Devices

Apple, Fitbit Will Join FDA Program Meant to Speed Health Tech

A federal agency that regulates apples wants to make regulations on Apple Inc. a little easier.

The Food and Drug Administration, which oversees new drugs, medical devices and much of the U.S. food supply, said Sept. 26 that it had selected nine major tech companies for a pilot program that may let them avoid some regulations that have tied up developers working on health software and products.

''We need to modernize our regulatory framework so that it matches the kind of innovation we're being asked to evaluate,'' FDA Commissioner Scott Gottlieb said in a statement.

The program is meant to let the companies get products pre-cleared rather than going through the agency's standard application and approval process that can take months. Along with Apple, FitBit Inc., Samsung Electronics Co., Verily Life Sciences, Johnson & Johnson and Roche Holding AG will participate.

The FDA program is meant to help the companies more rapidly develop new products while maintaining some government oversight of technology that may be used by patients or their doctors to prevent, diagnose and treat conditions.

Apple is studying whether its watch can detect heart abnormalities. The process it will go through to make sure it's using sound quality metrics and other measures won't be as costly and time-consuming as when the government clears a new pacemaker, for example. Verily, the life sciences arm of Google parent Alphabet Inc., is working with Novartis AG to develop a contact lens that could continuously monitor the body's blood sugar.

Faster Pace ''Historically, health care has been slow to implement disruptive technology tools that have transformed other areas of commerce and daily life,'' Gottlieb said in July when he announced that digital health manufacturers could apply for the pilot program.

Officially dubbed the Pre-Cert for Software Pilot, Gottlieb at the time called it ''a new and pragmatic approach to digital health technology.''

The program is part of a broader move at the FDA, particularly since Gottlieb took over in May, to streamline regulation and get medical products to patients faster. The commissioner said Sept. 19 the agency will clarify how drugmakers might use data from treatments already approved in some disease to gain approvals for more conditions. In July, he delayed oversight of electronic cigarettes while the agency decides what information it will need from makers of the products.

Rules Uncertainy As Silicon Valley developers have pushed into health care, the industry has been at times uncertain about when it needed the FDA's approval. In 2013, the consumer gene-testing company 23andMe Inc. was ordered by the agency to temporarily stop selling its health analysis product until it was cleared by regulators, for example.

Under the pilot, the FDA will scrutinize digital health companies' software and will inspect their facilities to ensure they meet quality standards and can adequately track their products once they're on the market. If they pass the agency's audits, the companies would be precertified and may face a less stringent approval process or not have to go through FDA approval at all.

More than 100 companies were interested in the pilot, according to the FDA. The agency plans to hold a public workshop on the program in January to help developers not in the pilot understand the process and four months of initial findings.

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Drug Safety

Colorado Curb on Edible Shapes Aims to Prevent Candy-Like Appeal

Colorado will prohibit marijuana-laced edibles in the shape of humans, animals, or fruits in an effort to keep them out of the hands of unsuspecting children who might mistake the gelatinous products for candy.

The regulations take effect Oct. 1, Colorado's Department of Revenue announced.

The rule includes ''shapes that resemble or contain characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings,'' the Colorado Department of Revenue said in a statement announcing the rule.

Dispensaries must dispose of non-complaint edible products by Oct. 1.

''This is an important step in maximizing the state's public health and safety by keeping marijuana out of the hands of minors and raising consumer awareness,'' Mike Hartman, executive director of the Colorado DOR, said in a statement.

The rule builds on previous Colorado requirements for edibles, said Jordan Wellington, director of compliance at Vicente Sederberg, Denver, a law firm that specializes in the marijuana industry.

''The state already requires child-resistant, opaque packaging, and it prohibits marketing or packaging that might appeal to young people,'' Wellington told Bloomberg BNA. ''Combined with existing protections, these new regulations will further reduce the likelihood that cannabis-infused edibles will appear attractive to children or be mistaken for non-cannabis products,'' he said. Wellington was a member of the DOR's marijuana enforcement division's working group on packaging and labeling.

The rule also sets new measures for marijuana potency labeling. All medical and retail marijuana, concentrates, and products, including edibles, must clearly mark the THC levels in bold, 10-point font, outlined in a shape or highlighted.

Clear labeling of potency is needed in response to numerous occurrences where individuals, mostly novice or tourist marijuana users, ingest dangerously high levels of THC, unaware of the product's high concentration. ''We want consumers to be educated about the potency of the product they are buying,'' Hartman said.

''Like with alcohol, the regulation of cannabis is an evolving process, and it is clearly preferable to the old system of prohibition,'' Wellington said.

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Drug Safety

Chinese Drugmaker Hit With Warning For Barring FDA Inspector

A Chinese drug manufacturer improperly limited the FDA's inspection of its manufacturing facility, the agency said in a warning letter.

Shandong Vianor Biotech Co. in Linyi, Shandong, limited the Food and Drug Administration's inspection by initially barring the agency's inspector from accessing a room identified as a laboratory. The company eventually allowed the inspector into the room, but the room didn't contain any equipment. The company representative then said the laboratory was offsite and couldn't give the inspector access to it because it wasn't a convenient time. The warning letter, dated, Sept. 12, was posted online Sept. 26.

While warning letters about quality issues at plants are common, warnings about obstructing the FDA's inspections are rarer. This is only the second time in 2017 that the FDA has issued a warning letter to a company for limiting an inspection. The prior warning letter was sent to Shandong Analysis and Test Center in Jinan, Shandong in July for not providing information on drug samples and test results.

Additional Violations Because Shandong Vianor limited the FDA's inspection and committed other violations of current good manufacturing practice (cGMP) regulations, drug products made at the facility are ''adulterated'' under the Federal, Food, Drug and Cosmetic Act.

The other violations include failure to have complete laboratory records and falsifying analytical test results, the warning letter said.

Also, the company's laboratory analysis revealed that a certain drug product was subpotent (the name of the drug was redacted in the letter), even though the certificate of analysis (CoA) provided for the drug showed it within specification, the letter said. Customers and regulators rely on COA for information about the quality and source of drugs and their components.

Additionally, the company doesn't properly maintain and clean equipment, the FDA said. The agency's inspector observed what appeared to be rusted and corroded screws, fluid and debris, and metallic mesh material on the facility's product contact surfaces.

The FDA put the company on an import alert Aug. 22, meaning the agency will automatically detain the company's products at the U.S. border.

Corrective Actions The FDA told the company to correct the violations and respond to the warning letter.

Also, the warning letter said the FDA may withhold approval of any new applications or supplements listing the company as a drug manufacturer.

The warning letter was signed by Thomas J. Cosgrove, director of the FDA's Office of Manufacturing Quality.

The company couldn't be reached for comment on the warning letter.

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The warning letter is at http://src.bna.com/sSX.

Chemicals

Wal-Mart Steps Up Push to Remove Potentially Harmful Chemicals

Wal-Mart Stores Inc. is expanding its program to clean up the products it sells, setting a 2022 target for reducing potentially harmful substances and widening the list of chemicals it wants to avoid.

The world's largest retailer aims to reduce the chemicals in products such as household cleaners, cosmetics,

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skin care and infant items by 10 percent by then, according to a company statement Sept. 27. It's also added some fragrance allergens to its so-called priority list of substances it wants to remove from goods.

The new goal is the latest in the retailer's efforts to respond to consumers seeking greener products and more information about what's in them. Last year, Wal-Mart named eight high-priority chemicals it wants eliminated from the goods it sells, and it's on schedule to have the chemicals listed on its broader priority list labeled online and on packaging next year.

''We're trying to center around a broader approach that emphasizes three elements: building trust, delivering impact and really staying ahead of regulation,'' said Zach Freeze, Wal-Mart's senior director for strategic initiatives for sustainability.

Last month, Wal-Mart also started participating in the Chemical Footprint Project, which helps companies track and eliminate dangerous substances. The program gives Wal-Mart a tool to make further reductions, Freeze said. So far, its suppliers have removed 96 percent of high-priority chemicals by volume weight from consumables products sold in U.S. stores.

Wal-Mart announced in 2013 that it would ask suppliers to find safer alternatives for ingredients in personal care, cleaning and beauty products. Some of its suppliers have recently announced their own initiatives. Unilever and Procter & Gamble Co. both said this year they'll start labeling fragrance ingredients in their products, illuminating an area that's long been opaque.

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Motor Vehicles

Motor Vehicles

Carmax Found to Have Unfixed Recalls in 27% of Autos, Study Says

A review of eight CarMax Inc. locations by safety advocates found more than one-in-four vehicles reviewed had unrepaired safety recalls, including some with air bag inflators linked to deadly malfunctions.

A total of 461 vehicles contained at least one outstanding safety recall that had not been repaired, 41 of which had recalls for which no repair was available, the review by safety advocates found. The study looked at the recall status of about 1,700 used autos listed for sale at eight CarMax dealerships in three U.S. states.

Of those, 45 vehicles contained air bag inflators made by Takata Corp., the company behind the largest auto recall in history, that were subject to recall but had not yet been repaired.

The defects include fire risks and other hazards that have been linked to deaths and injuries, said Rosemary Shahan, president of Consumers for Auto Reliability and Safety Foundation, one of the groups that did the study. The Center for Auto Safety and the MASSPIRG Education Fund, an advocacy group, also were part of the research.

''Yet they continue to sell these to the public and they market them in a very deceptive way,'' Shahan said. ''We are demanding that state law enforcement officials crack down on CarMax and other dealers who are engaging in these practices.''

Selling used cars with unrepaired safety recalls, while not prohibited under federal law, is condemned by auto safety and consumer advocates who say it puts unsuspecting drivers at risk. The practice has also drawn fire from Democrats in Congress who have tried to ban the practice. It's illegal to sell new cars with safety recalls that have not been remedied.

Yet only franchised new-car dealers can complete recall repairs. Independent dealerships such as CarMax cannot.

CarMax said in a statement Sept. 28 that each vehicle listing on its website includes a link to search for open recalls affecting that vehicle. Employees review vehicle recall information with customers and customers sign a form acknowledging they've received NHTSA recall information prior to signing sales paperwork, according to the company.

''We are dedicated to making sure our customers know about open recalls prior to purchase,'' CarMax Chief Operating Officer Cliff Wood said in a statement. ''Nothing is more important than being transparent and honest with our customers.''

Disclosing recall status to consumers is not good enough, said Jason Levine, executive director of the Center for Auto Safety. He cited a pickup truck listed by CarMax that the survey found with six unrepaired safety recalls presenting risks including engine fire and airbag failure.

''This is the sort of situation that disclosure does not fix,'' Levine said in a call with reporters.

New York Probe Some officials have tried to crack down on the practice where they can. More than 100 auto dealers operating in New York state settled with New York Attorney General Eric Schneiderman's office in April after a probe found hundreds of used autos had been sold with unrepaired safety recalls to customers. The dealers agreed to disclose open recalls to future customers and pay a $1,000 fine.

The Federal Trade Commission in 2016 reached settlements with General Motors Co. and two auto dealers over claims that they sold used vehicles with open recalls while also advertising thorough vehicle inspections.

Congressional Democrats have also tried ban the practice but failed in the face of aggressive lobbying by auto dealers, who argue the prohibition would unfairly raise dealership costs and hurt used car values.

According to the study, the groups found an average of about 27 percent of the vehicles in stock across the eight locations had least one unfixed safety recall, more than twice the rate found in a similar study of five CarMax locations in 2015.

The study authors reviewed vehicle inventory listed online by CarMax at the locations, and queried each vehicle's recall status using the National Highway Traffic

Safety Administration's online recall search tool. The survey was conducted Aug. 31 through Sept. 6.

Takata air bag inflators have been linked to more than 100 injuries and at least 18 deaths worldwide for the risk of exploding in a crash. Some 100 million vehicles globally may eventually be recalled for the defective parts. Mounting liabilities from the callbacks pushed Takata to file for bankruptcy in June.

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Intelligent Vehicles

Cadillac Finally Has an Answer To Tesla's Autopilot

Cadillac has finally built a six-second vehicle.

That's how long a driver can spend checking Instagram while the opulent 2018 version of its CT6 sedan drives itself. Then the first of three escalating warnings are triggered. Still, providing a somewhat-safe moment to scan an e-mail is a heroic feat of coding, one that allows the iconic luxury brand to claim parity with similar systems built by Mercedes, Volvo, and most of all, Tesla.

General Motors isn't squandering this fleeting moment of glory. On Monday, it kicked off a coast-to-coast semi-autonomous trip from its New York headquarters—with a state police escort out of town no less—and gave us a seat for the first leg, all the way to the nation's capital. (For speed freaks, the new CT6 is actually a five-second vehicle, as far as getting to 60 mph is concerned.)

Cadillac is marketing the gear—dubbed ''Super Cruise''—as the ''first, true hands-free'' driving application on the road. It's a bold claim for a brand so late to the robo-pilot party, but it's not inaccurate. To date, similar systems have required a little steering feedback to ensure the driver is paying attention—a little hand, if you will. Cadillac engineers went in a different direction, planting a face-detection camera in the top arc of the steering wheel that constantly stares at its commander.

The downside: One gets a creepy feeling of being watched. The upside: One can safely crush a hefty cheeseburger at speeds up to 85 mph.

The Cadillac system will accelerate, brake, and keep a safe following distance per the pre-set cruise speed while carving gracefully through the corners. It wasn't even phased by dark sunglasses, the purported bugaboo of face-scanning tech.

But Super Cruise is far less fun or spontaneous than the name suggests. The hardware—a web of radar-blasting pods and seven cameras, including an infrared unit—only works on freeways with exits and on-ramps, and only when cruise-control is activated and the vehicle is traveling dead-center in a lane. When the stately sled is compliant with those three prerequisites, an instrument panel token prompts that the system is ready and it takes control with a push of a button.

Cadillac says it doesn't want to replace the driver, but rather provide ''the flexibility of choice''

When in doubt, however, the CT6 defers to analog driving. For long stretches between New York's Cadillac House and Washington, on pristine sections of the New Jersey Turnpike, the system stubbornly declined to launch. Meanwhile, changing lanes has to be done the old-fashioned way, and Cadillac warns drivers not to use the system in a tunnel, construction zone, or rainstorm. (Good luck Seattleites!)

While Tesla has swaggered about its self-driving aspirations, going so far as to call its system ''autopilot,'' GM is being far more conservative—playing the sober step-dad to Elon Musk's cool uncle. ''We do not seek to replace the driver,'' said Cadillac President Johan de Nysschen. ''True luxury means the flexibility of choice.''

For a road warrior stuck with a brutal daily commute, Super Cruise will be a balm—smoothing jangled nerves just a tad. But it won't make a driver any more productive or well-rested.

As I zipped out of Manhattan and into New Jersey, jets from Newark Liberty hurtled overhead, filled with passengers binging on Broad City and scrolling through Trump tweetstorms. Down below, I sat behind the wheel with my arms folded, focused on the road ahead. Super Cruise felt like a box of Blue Apron groceries: The meal is meticulously planned and the ingredients prepped, but I still had to cook it.

Cadillac is well aware that Super Cruise is a small step even for an incremental one. The CT6 will be its only vehicle equipped with the self-driving system next year. And unless a customer opts for the most luxurious trim, Super Cruise will cost $5,000 extra.

In short, the burgeoning brand is not banking on Super Cruise to win customers away from BMW, Mercedes, or even Tesla. Few will buy a CT6 because it has a self-driving widget. But the system may keep quite a few potential buyers from ruling out the sedan entirely.

Cadillac chief de Nysschen called self-driving systems a critical step in the brand's ''long journey back to the pinnacle of premium.'' In last year's luxury car market, it was a neat trick. Next year, it's table stakes. Cadillac just anted up.

BY KYLE STOCK

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Automotive Equipment

Polaris 3-Wheeled Slingshot Probed After Deadly Driver Ejection

U.S. auto-safety investigators are probing seatbelts installed in Polaris Slingshot three-wheeled vehicles after a driver was thrown and killed in a crash despite being buckled up.

The Slingshot slid sideways into oncoming traffic while the driver was making a lane change and collided with a vehicle heading in the opposite direction, accord-

ing to a National Highway Traffic Safety Administration summary of the crash. The driver was partially ejected from the Slingshot despite wearing a helmet and using the vehicle's seatbelt, NHTSA said, citing a police report.

Post-crash pictures showed that the Slingshot's seatbelt retractor was ''in a shattered condition with the internal components found outside the retractor body,'' according to NHTSA. The driver died from a severed spinal cord, according to a complaint submitted to the regulator by a person claiming to be the driver's sibling.

Polaris Industries Inc., based in Medina, Minn., didn't immediately respond to an email to its media inbox seeking comment outside of regular business hours.

The probe will cover 4,779 Slingshots from the 2015 model year, when Polaris introduced the three-wheeler that blurred the line between passenger cars and motorcycles. Despite a seated position, steering wheel and seatbelts, the Slingshot is classified as a motorcycle under NHTSA safety regulations.

The agency said it's unaware of any additional seatbelt retractor failures on the vehicles, some of which have previously been recalled for other problems including faulty steering racks, headlights that may shut off while driving and the risk of leaky fuel lines.

Polaris has been dogged by a string of recalls in recent years involving its off-road products, including some for fire hazards.

BY RYAN BEENE

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Pro Bono

Attorneys

Travel Bans Spur Growth for Refugee Aid Group; BigLaw Steps Up

The International Refugee Assistance Project hoped there would be an outcry and support for its mission when the humanitarian and legal aid group found out about President Donald Trump's first travel ban in January.

After getting a leaked draft of the executive order prohibiting travelers from seven mostly-Muslim countries that Trump justified as necessary for national security, IRAP condemned the move as a ''betrayal'' of American values. The group issued a ''call to action'' to its pro bono network of law students and attorneys to be ready to go to the airports if necessary.

But when the project's attorneys headed to the airports after Trump's announcement of the first ban, no one knew what the response to their call to action would be, Henrike Dessaules, IRAP's communications director, told Bloomberg BNA.

''We weren't sure how much people would care about this,'' she said.

The response was overwhelming. IRAP galvanized ''an army'' of over 1,600 volunteer lawyers who descended on airports in Boston, Seattle, Chicago and elsewhere. Those initial days were marked by confusion and, for some attempting to enter the country, crisis.

IRAP attorneys at the airports offered representation to travelers heading to the U.S. who found themselves facing a mid-air policy shift that upended their status and threatened them with detention.

Uncertain Future IRAP couldn't have anticipated how quickly developments have unfolded this year.

These include two Trump travel ban orders by spring and a third that was announced Sept. 24, a flurry of related court challenges and rulings, IRAP's mobilization drive and the outpouring of support, and IRAP's formation of a litigation unit in response to the new workload affecting thousands of refugees.

Then there's the group's travel ban lawsuit that reached the U.S. Supreme Court. The justices had been scheduled to hear *Trump v. Int'l Refugee Assistance Project* on Oct. 10, along with a similar case, *Trump v. Hawaii*.

However, it's unclear what will happen with the cases after the Trump administration's third executive order, which adds two countries that don't have Muslim majorities, North Korea and Venezuela.

The U.S. Supreme Court Sept. 25 dropped the Oct. 10 travel ban case arguments from it calendar and ordered both sides to file briefs Oct. 5 about whether the case is moot in light of the new ban.

The administration said the new ban targets countries that didn't meet ''baseline requirements'' set by the second ban on ''information sharing with the United States regarding terrorism threats.''

''We think this proclamation is merely a continuation of the Muslim ban, and we plan to continue challenging the Muslim ban in all its forms in any we can,'' Dessaules told Bloomberg BNA in a Sept. 25 email.

Core Mission IRAP aims to serve ''the world's most persecuted individuals'' such as refugees and displaced persons, according to its website.

About 35 percent of its cases are done in-house by about 20 employees in New York, Jordan, and Lebanon, Mark Doss, an IRAP supervising attorney, told Bloomberg BNA. The remainder are done by more than 1,600 pro bono attorneys and law students, Doss said.

The group's aim is to help refugees navigate the resettlement process, he said.

This work includes interviewing clients, gathering facts, researching country conditions, locating witnesses and experts, and drafting affidavits and briefs, Doss said.

In 2016, IRAP resettled more than 450 people from countries including Iraq, Syria, Afghanistan, Somalia, Sudan, and Iran, he said.

Evolving Responsibilities IRAP's workload consisted primarily of casework before the travel ban.

But things have ''moved very quickly'' since the start of the year, Mariko Hirose, IRAP's litigation director, told Bloomberg BNA.

Hirose joined IRAP in July after it formed a litigation unit in late spring.

The unit will be ''dedicated simply to litigation,'' Dessaules said.

The Supreme Court might decide the Trump travel ban cases are moot but IRAP is ''preparing for the possibility of further executive actions aimed at curtailing the rights of refugees and immigrants,'' she said.

The January travel order was sweeping and triggered legal challenges. It banned foreign nationals from Iraq, Iran, Libya, Somalia, Sudan, Syria and Yemen regardless of legal status before court challenges derailed it.

A revised order in March removed Iraq and was tailored to address legal questions raised by the first. But that, too, has been challenged and underpins the consolidated case before the justices.

The Supreme Court allowed the ban to take effect in part. The ban expired as to foreign nationals on Sept. 24, but the portion applying to refugees extends until Oct. 24.

The third executive order begins Oct. 18 for all foreign nationals subject to the suspension of entry under section 2 of the March order, and for nationals of Chad and North Korea, and Venezuelan government officials. It will extend indefinitely.

Attorneys Pitch In After the January order, IRAP spearheaded ''self-organized coalitions'' comprised of attorneys from large law firms, attorneys from smaller

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firms, those who specialize in immigration law, and public interest attorneys, Wendy Fu, IRAP's pro bono coordinator said.

These coalitions are ''on call'' and can rally volunteers when there's a need to be at an airport when one of our clients is traveling, Fu said.

They make sure the client gets in safely, makes any connecting flight, and reaches his or her final destination, she said.

The group has hired additional staff, including Fu, and a staff attorney to help with the casework generated by the travel ban, Dessaules said.

''All of the interest and passion that existed in January has sustained itself, it's just more organized,'' Fu said.

IRAP's legal division has been busy with appeals, stay applications, and emergency paperwork relating to its challenge to the second travel order, Hirose said.

It's also been very involved with the Hawaii case, filing friend of the court briefs with the U.S. Court of Appeals for the Ninth Circuit and the Supreme Court, she said.

Fortunately, they've had help from ''about 12″ law firms they've worked with in the past on pro bono matters, Fu said. These firms, including Paul Weiss, Rifkind, Wharton & Garrison LLP, Linklaters, and Beveridge & Diamond PC, have been doing research projects and brief-writing projects for IRAP, Dessaules said.

''They've been doing a ton for us'' and can turn around the work very quickly, Fu said.

Work Won't End Soon The court rulings, including the orders from the Supreme Court, ''have a significant impact on our work, because they dictate which refugees are able to come to the United States while the case is pending before the Supreme Court,'' Hirose said.

''This is an issue that affects nearly 24,000 refugees who have reached the stage of being assured by a resettlement agency,'' she said.

The group anticipates that there will be a continuing need for the litigation department as the administration's position continues to evolve, even if the Supreme Court acts on the case.

''Our mission has always been to do whatever we can to help our clients,'' and this hasn't changed despite the increase in litigation this year, she said.

BY MELISSA HEELAN STANZIONE

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