MedicalAlley

PFAS Task Force White Paper

June 2025

Executive Summary

This paper outlines the critical role of PFAS (per- and polyfluoroalkyl substances) in medical devices and the potential impact of broad bans on these chemicals. PFAS, particularly fluoropolymers, are essential for the functionality of various medical devices, including stents, catheters, surgical mesh, pacemakers, heart patches, CPAP machines, prosthetics, surgical instruments, and asthma inhalers. Despite some PFAS chemicals posing health risks, fluoropolymers have been found to be biologically benign and crucial for medical applications. Banning all PFAS from medical devices would jeopardize the care for millions of Americans who rely on these devices. Consequently, public health regulators in the US and Europe have reconsidered overall PFAS bans to allow exceptions for these essential chemicals.

This paper examines the use of PFAS in society and medical devices, highlighting the adverse effects of overly broad restrictions on healthcare quality and costs. It emphasizes the need for legislators and regulators to consider the significant impact of sweeping PFAS bans on life-saving medical technology.

Key Takeaways

1. Broad bans on PFAS would threaten the safe operation of crucial medical devices while jeopardizing care for millions of Americans.

2. There are 15,000 distinct types of PFAS. Some are more benign than others and they should be regulated differently.

3. Public health regulators have reconsidered overall PFAS bans to allow exceptions for essential chemicals in medical devices.

4. A rush to embrace chemical alternatives to PFAS without thorough testing may result in new problems and regrettable substitutions.

5. Patient safety is the overarching concern of medical device manufacturers.

Broad Bans on PFAS Would Threaten Crucial Medical Devices

A key ingredient in life-saving medical devices has been placed in the crosshairs by government regulators, jeopardizing the ability of doctors to care for millions of Americans.

State and federal policy makers are targeting a class of 15,000 chemicals known as PFAS, or per- and polyfluoroalkyl substances. Though some of these 15,000 chemicals carry identified health risks, a smaller subsection of these PFAS chemicals has been found to be more biologically benign. This subsection of PFAS chemicals includes substances, known as fluoropolymers, that are crucial to the proper functioning of medical devices such as stents, catheters, surgical mesh, pacemakers, heart patches, CPAP machines, prosthetics, surgical instruments, and asthma inhalers.

Banning all PFAS from medical devices would threaten care for the Americans who receive 300,000 newly implanted pacemakers or defibrillators per year; 75 million annual endoscopies; 4.8 million laparoscopic procedures per year; as well as the 1.7 million Americans with amputated limbs who rely on prosthetics.

Because of these serious healthcare consequences, public health regulators in the US and Europe who had considered overall PFAS bans have now dropped or altered those plans to allow an exception for the crucial chemicals to continue to be used in medical devices.

This paper will examine PFAS use in society at large and in medical devices in particular. It will explain why overly broad PFAS restrictions would affect both the quality and cost of healthcare for hundreds of millions of Americans. Legislators and regulators should consider the dire effect that sweeping PFAS bans would have on everyday life saving medical technology.

The first PFAS was discovered by accident on April 6, 1938 by a chemist in New Jersey who was trying to develop a new refrigerant for DuPont. When he chilled a lab gas in a cylinder with dry ice, the unexpected result was a white powder that was heat resistant, chemically inert – and one of the most slippery materials ever discovered.

Legislators and regulators should consider the dire effect that sweeping PFAS bans would have on everyday life saving medical technology.

At first the new substance was used for the most urgent concern in the United States at that time – helping to build the first atomic bomb for the Manhattan Project. After World War II, though, new manufacturing methods and broader uses were developed, and one version of the chemical discovery was branded and popularized as Teflon. By the 1950s, that chemical, as well as derivatives such as Scotchgard, became widely used additives for many consumer products and manufacturing processes.

What made PFAS chemicals so valuable was their unique physical and chemical properties. They repelled water, oil, and stains; strongly resisted fire and heat; offered excellent lubrication; remained durable even after intense use; and withstood extremely harsh conditions.

Thousands of chemical variations were developed, and PFAS soon became a signature component of modern life. For consumers, there was widespread use in cooking pans, food packaging, clothes, carpet, furniture, sheets, pillows, mattresses, cosmetics, and sunscreen. In industry, the chemicals were used to put humans on the moon via Apollo space missions, in the clouds via jet manufacturing, at sea through shipbuilding, and across the Earth via cars, trucks, trains, buses, motorcycles, and bicycles. It became a key ingredient in firefighters' foam, jackets, pants, and gloves.

Today, an estimated 32 million Americans live with an implanted medical device.

One other big use was healthcare. A subset of PFAS fluoropolymers (Polymeric PFAS) made possible the development of medical devices for millions of people with no other alternative.

The human body is extremely sensitive. We survive only when a complex network of 78 organs can interact in precise ways through a limited range of temperature, chemical balance, and electrical signals. It's a kind of internal symphony that requires instruments to be in constant tune with each other – our bodies have learned to reject all but a select few foreign substances.

As a result, the creation and deployment of man-made medical devices has become one of modern society's most complicated engineering challenges.

Today, an estimated 32 million Americans live with an implanted medical device. The American Medical Association says about one of every 10 Americans will have a device inside their bodies at some point during their lifetimes.

Many of these devices are made possible with fluoropolymers, a chemically distinct subset of PFAS. Fluoropolymers carry the durability, chemical stability, and unique dielectric properties to work successfully inside the human body. They are the crucial additive that helps to reduce infection, friction, and blood clots. They do not dissolve in water and there is no evidence that they accumulate in a person's bloodstream. They mitigate the risk of medical complications. They ensure against device failure and allow specialized equipment such as catheters to perform longer because they clog less often. With fluoropolymers boosting equipment resilience and durability, patients require surgery less often to replace medical devices.

Because fluoropolymers were the best available substance for the job, countless medical devices have been designed around them. The World Health Organization estimates there are 2 million different kinds of medical devices on the global market, categorized into more than 7,000 groups.

There is no running total of how many devices rely specifically on fluoropolymers because, for decades, the chemicals were an expected part of the manufacturing process. Engineers and public health agencies simply believed they were the best chemicals for the job – the ubiquitous use of PFAS in medical devices is testament to their indispensability. Medical devices are subject to regulation in every major market. The regulatory review process typically includes scrutiny of a battery of preclinical tests, including biocompatibility, which are often based upon international standards. The review of many devices also includes data from human clinical studies.

It's important to note that PFAS in medical devices today have been reviewed by regulators before being approved or cleared for market, and they are subject to surveillance and a continuing review even after they are in the field.

Clinical studies of patients with implanted medical devices that used fluoropolymers have found no chronic toxicity or links to cancer, and no reproductive, developmental, or endocrine toxicity. Other studies concluded fluoropolymers are nontoxic, do not bioaccumulate, and "have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS."

Over time, however, evidence mounted that those other forms of PFAS were accumulating in the environment and posing health risks. The same chemical properties that made PFAS so valuable – longevity, impermeability, resistance to change – also made them resistant to degradation and difficult to remove. By the 1970s, studies detected PFAS in the blood of workers who manufactured it. By the 1990s, PFAS variants were found in the blood of the general population. By the 2000s, scientists had concluded that PFAS were "ubiquitous environmental contaminants, which persist and may bioaccumulate through the food chain." The most common pathways for human PFAS contamination were through food, drinking water, and dust.

PFAS is at the center of a major reform effort by regulators and industry.

PFAS chemicals today are found throughout our oceans, lakes, rivers, and seafood. Scientists have detected it in the bodies of 98 percent of Americans. In 40 studies over five years, every mother's umbilical cord tested positive for PFAS – 30,000 samples – meaning humans start life today with the chemical in their bodies. The Environmental Working Group estimates more than 200 million Americans are drinking water tainted with non-polymeric PFAS, which is soluble in water.

What started as a miracle material is now referred to more often as a 'forever chemical' and environmental hazard. Some types of PFAS at certain levels have been linked to adverse health effects, including cancer, decreased fertility, and childhood developmental delays.

Now PFAS is at the center of a major reform effort by regulators and industry. In the past two decades, the Environmental Protection Agency has increased restrictions on the manufacture, use, and import of the chemicals. In 2006, the agency asked eight major companies to commit a 95 percent reduction in PFAS manufacturing emissions, and the companies reported compliance. Under an agreement between the federal government and industry, the variety of PFAS that made Teflon using PFAS, specifically the surfactant Perfluorooctanoic Acid (PFOA),was eliminated by 2014.

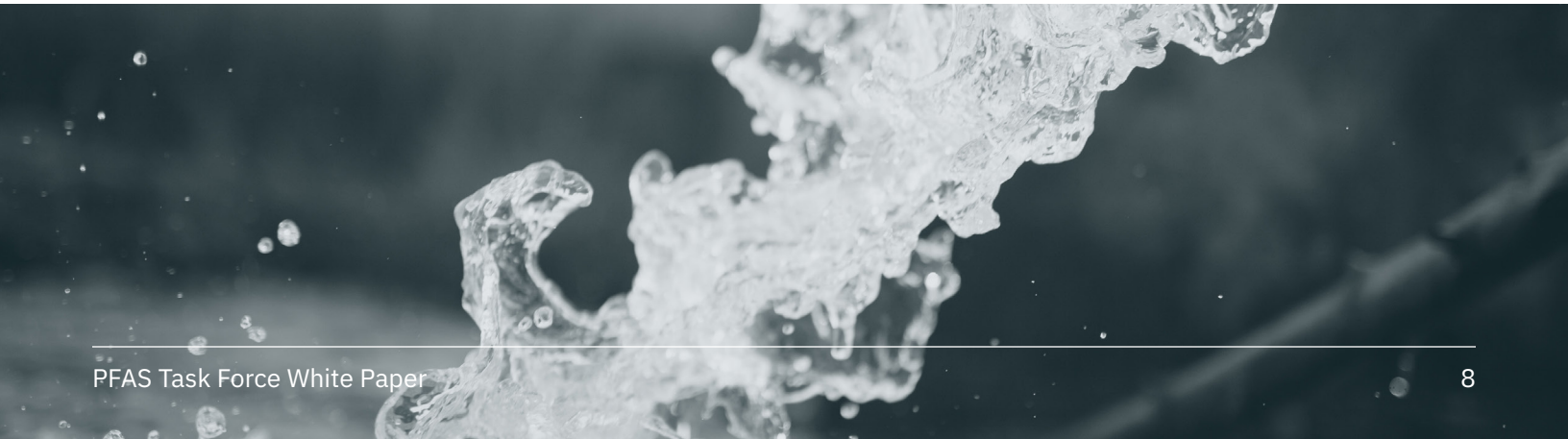
At the same time, lawyers filed more than 15,000 claims against the main US manufacturers of PFAS, including 3M, DuPont, and its spinoffs Chemours and Corteva. So far, the companies have paid more than $11 billion of damages to settle 600 claims for PFAS contamination, with the biggest settlement to help test and filter public water supplies for hundreds of communities. Court actions are far from over – environmental lawyers say PFAS contamination claims, including actions filed by the attorneys general of 31 states, could eventually surpass the amount spent by Big Tobacco to settle lawsuits in the 1990s. The cleanup in drinking water alone is estimated to cost as much as $400 billion. That's more than 30 times greater than the entire annual budget of the US Environmental Protection Agency.

Faced with mounting regulatory and courtroom pressure, 3M, one of the biggest US manufacturers, has announced it is exiting the PFAS business by the end of 2025. Political pressure is rising for increased regulations of international PFAS manufacturers, especially in Europe.

For the first time in history, medical device developers are contemplating a future with restricted supplies of PFAS.

The industry is researching chemical alternatives, but the process is lengthy and complicated. Replacement of PFAS with another substance would require extensive testing by the device manufacturer and detailed review by regulators. Substituting a new material on an existing device can have significant consequences on biocompatibility, safety, and performance. Clinical trials may be required, and risk management documentation can be extensive. Substituting one material for another in medical devices also complicates supplier contracts and qualifications; production processes and sterilization validations; and data collection to meet regulatory requirements. The process is complicated and would likely have an impact upon the cost of healthcare.

Though prior studies found that fluoropolymers themselves were nontoxic, other researchers noted that it was difficult to manufacture that class of PFAS without creating environmental issues. Public pressure is rising to reevaluate all PFAS use.



Like medical device manufacturers, public health regulators are finding that it's not easy to replace fluoropolymers. The European Union considered a sweeping ban on PFAS, but scientists found that there currently are no feasible chemical alternatives for many types of equipment, including implantable medical devices; tubes and catheters; propellants and coatings for metered dose inhalers for asthma; and diagnostic laboratory testing. EU researchers conceded that no obvious PFAS substitutes exist for hernia meshes; wound treatment products; sterile and protective packaging for medical devices; and some forms of contact lenses.

As a result, European regulators are considering plans to enact a PFAS ban while carving out an exception of at least five years, and possibly as long as 12 years, for implanted medical devices. That would give manufacturers and regulators more time to see if PFAS alternatives are possible. Tightened PFAS restrictions also are being enacted in Australia, France, and Japan, but medical devices so far have been exempted.

Similar exceptions for medical devices have been approved by several states in the US. Maine, for example, announced in 2021 the world's first sweeping PFAS ban covering all consumer goods, but amended it two years later to allow exemptions for medical devices and other products where PFAS is designated as a Currently Unavoidable Use. Minnesota also carved out an exception for products regulated by the FDA. Since 2007, 30 states have approved 154 PFAS policies, many banning once-common uses in clothing, cookware, cosmetics, and menstrual products, but all allowing continued use in medical devices.

With regulatory pressure increasing and suppliers of PFAS decreasing, medical device manufacturers now are expected to embrace a costly and time-consuming seven-step process:

1. Identifying all existing devices that contain or are built with PFAS.

2. Evaluate whether PFAS alternatives are possible.

3. Determine whether chemical alternatives would affect device performance, patient safety, and clinical evaluations.

4. Determine how any chemical change would be viewed internationally by different regulators in different states and countries.

5. Test, verify, and validate the substituted materials in the modified devices.

6. Conduct studies.

7. Analyze, compile, and submit all the data to regulators for review and approval.

It all adds up to a vast and costly web of work that will take years to complete.

It's not easy to replace fluoropolymers.

Medical device manufacturers are committed to saving lives. What kind of PFAS regulation makes sense?

1. We believe patient safety and survival should be the overarching concern. As a result, it's crucial to differentiate between types of PFAS. Regulators should focus restrictions on PFAS uses that pose the most risk to the environment, not the uses on medical devices that save lives. It's crucial to carve out an "Essential Use" exemption if there is no clear and reliable alternative for PFAS in medical devices.

2. We believe any regulatory change should come with realistic phase-in periods that recognize the extensive testing and approvals that are required with any significant alteration in a medical device. Uniform national standards make more sense than a patchwork approach of regulations that vary by state.

3. We support robust research programs to develop alternatives to PFAS, especially in less critical applications such as packaging.

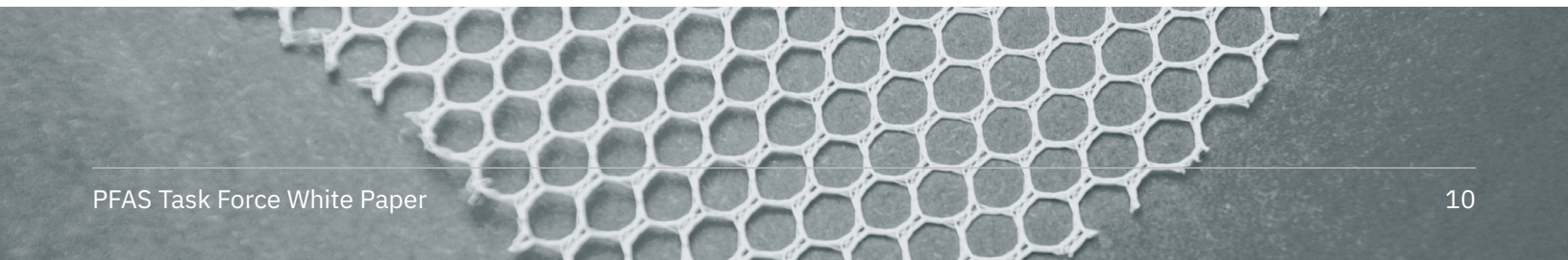
Finally, we support having frank talks about the goals and effectiveness of PFAS regulations. So much of modern healthcare relies on the calculation of relative risk.

Should you crack a rib to restart a heart during emergency CPR? Is it worth undergoing a brutal regime of chemotherapy and radiation treatment to beat back your cancer? What about a surgery that offers the best chance of a cure but poses a realistic chance of leaving you dead on an operating table?

Similar risk calculations can be applied to the use of fluoropolymers in medical devices. **Right now, these chemicals are helping to keep millions of people alive in dire health situations. Can we search for better alternatives? Yes. Should we stop using a crucial component in the meantime? No.**

For decades, America's medical device manufacturers have proven they are global leaders in the field. With the concerns about PFAS, and an anticipated declining supply, industry has put high priority on finding chemical replacements that will deliver safe, reliable, and effective care. There is a great opportunity for green chemistry innovations and using new AI technologies to develop PFAS-free materials, but our engineers need the time for research and development.

With one of the world's foremost groupings of healthcare brainpower, Medical Alley is ready to serve as an innovation hub for the coming advances in technology, business, and regulation of medical devices.



References

Pg. 4 - Heart Rhythm 2024 Spotlights New Developments in Cardiac Implantable Electronic Devices and Other Treatments - https://www.hrsonline.org/news/hr24-spotlights-new-developments-cieds/#:~:text=CIEDs%20have%20evolved%20to%20be,in%20the%20U.S.%20alone1

Pg. 4 - GI endoscopies make up 68% of all endoscopies in U.S.: 5 market trends - https://www.beckersasc.com/gastroenterology-and-endoscopy/gi-endoscopies-make-up-68-of-all-endoscopies-in-u-s-5-market-trends/#:~:text=There%20are%2075%20million%20endoscopies,68%20percent%2C%20are%20gastrointestinal%20endoscopies

Pg. 4 - Global Laparoscopy and Endoscopy Devices Market, 2025 - Focus on Surgical Procedures (Cholecystectomy and Hysterectomy) and Product Types (Arthroscopes, Neuroendoscopes, Cystoscope, and Bronchoscopes) - https://www.globenewswire.com/news-release/2018/09/19/1572863/0/en/Global-Laparoscopy-and-Endoscopy-Devices-Market-2025-Focus-on-Surgical-Procedures-Cholecystectomy-and-Hysterectomy-and-Product-Types-Arthroscopes--Neuroendoscopes-Cystoscope-and-Bro.html

Pg. 4 - 29 Limb Loss Statistics, Facts & Demographics - https://promedeast.com/limb-loss-statistics/#:~:text=Approximately%201.7%20million%20people%20in,being%20for%20the%20upper%20limb

Pg. 4 - Roy J. Plunkett - https://www.sciencehistory.org/education/scientific-biographies/roy-j-plunkett/

Pg. 5 - Guide for Investigating Historical and Current Uses of Per- and Polyfluoroalkyl Substances at Department of Energy Sites - https://www.energy.gov/sites/default/files/2023-02/Final%20PFAS%20Investigation%20Guide%20Final%20%28002%29_0.pdf

Pg. 5 - The History of Teflon™ Fluoropolymers - https://www.teflon.com/en/news-events/history

Pg. 5 - The Happy Accident Behind the Invention of Scotchgard - https://www.invent.org/blog/inventors/patsy-sherman-samuel-smith

Pg. 5 - Implantable Material and Device Regulation - https://journalofethics.ama-assn.org/issue/implantable-material-and-device-regulation

Pg. 6 - World Health Organization, Medical Devices - https://www.who.int/health-topics/medical-devices#tab=tab_1

Pg. 7 - A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers - https://pubmed.ncbi.nlm.nih.gov/29424474/

Pg. 7 - A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers - https://pubmed.ncbi.nlm.nih.gov/35678199/

References

Pg. 7 - Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) - https://www.niehs.nih.gov/health/topics/agents/pfc#:~:text=Per%2D%20and%20polyfluoroalkyl%20substances%20(PFAS,degrade%20easily%20in%20the%20environment

Pg. 7 - History and Use of Per- and Polyfluoroalkyl Substances (PFAS) found in the Environment - https://pfas-1.itrcweb.org/wp-content/uploads/2020/10/history_and_use_508_2020Aug_Final.pdf

Pg. 7 - Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins - https://onlinelibrary.wiley.com/doi/10.1002/ieam.258

Pg. 7 - Perfluorinated Substances in Human Food and Other Sources of Human Exposure - https://link.springer.com/chapter/10.1007/978-1-4419-6880-7_4

Pg. 7 - Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma - https://pmc.ncbi.nlm.nih.gov/articles/PMC8096365/#:~:text=Per%2D%20and%20polyfluoroalkyl%20substances%20(PFAS,PFOA)%20exposure%20and%20kidney%20cancer

Pg. 7 - 'Forever chemicals' detected in all umbilical cord blood in 40 studies - https://www.theguardian.com/environment/2022/sep/23/forever-chemicals-found-umbilical-cord-blood-samples-studies

Pg. 7 - EPA: Toxic 'forever chemicals' levels in drinking water should be much lower - https://www.ewg.org/news-insights/news-release/2022/06/epa-toxic-forever-chemicals-levels-drinking-water-should-be-much#:~:text=EWG%20estimates%20that%20more%20than,the%20reproductive%20and%20immune%20systems

Pg. 7 - Our Current Understanding of the Human Health and Environmental Risks of PFAS - https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas

Pg. 7 - Fact Sheet: 2010/2015 PFOA Stewardship Program - https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program

Pg. 7 - 2010/2015 PFOA Stewardship Program - 2014 Annual Progress Reports - https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/20102015-pfoa-stewardship-program-2014-annual-progress

Pg. 7 - Ban on Teflon Chemical Led to Fewer Low Weight Babies - https://www.nytimes.com/2017/11/30/well/ban-on-teflon-chemical-tied-to-fewer-low-weight-babies.html#:~:text=Beginning%20in%202003%2C%20its%20use%20was%20gradually,data%20on%20birth%20weights%20from%20a%20government

Pg. 8 - 'Forever Chemical' Lawsuits Could Ultimately Eclipse the Big Tobacco Settlement - https://time.com/6292482/legal-liability-pfas-chemicals-lawsuit/

References

Pg. 8 - 3M reaches $10.3 billion settlement over contamination of water systems with ‘forever chemicals’ - https://apnews.com/article/pfas-forever-chemicals-3m-drinking-water-81775af23d6aeae63533796b1a1d2cdb

Pg. 8 - More than half of US State Attorneys General have taken action against PFAS manufacturers and key users - https://www.saferstates.org/press-room/more-than-half-of-us-state-attorneys-general-have-taken-action-against-pfas-manufacturers-and-key-users/

Pg. 8 - ‘Forever chemicals’ are everywhere. The battle over who pays to clean them up is just getting started - https://www.politico.com/news/2022/09/13/the-battle-over-who-pays-to-clean-up-chemicals-00056136

Pg. 8 - PFAS & Their Uses - https://pfas.3m.com/pfas_uses#:~:text=Exit%20all%20PFAS%20manufacturing%20by,an%20orderly%20transition%20for%20customers.

Pg. 8 - Market share of the leading fluoropolymer producing companies worldwide in 2022 - https://www.statista.com/statistics/1391676/fluoropolymer-market-share-worldwide-by-producer/

Pg. 8 - PFAS and Medical Devices - https://www.battelle.org/insights/faqs/pfas-and-medical-devices

Pg. 8 - Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS? - https://pubmed.ncbi.nlm.nih.gov/33043667/

Pg. 9 - ANNEX XV RESTRICTION REPORT - https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea

Pg. 9 - ECHA publishes PFAS restriction proposal - https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal

Pg. 9 - Can you get rid of forever chemicals? More countries are finding out - https://globalaffairs.org/commentary-and-analysis/blogs/pfas-forever-chemicals-countries-regulations

Pg. 9 - PFAS in Products - https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/index.html

Pg. 9 - Maine Modifies Its Sweeping PFAS Law - https://www.pillsburylaw.com/en/news-and-insights/maine-pfas-law.html

Pg. 9 - What Minnesota’s ban on ‘forever chemicals’ means for manufacturers - https://www.manufacturingdive.com/news/minnesota-13-forever-chemicals-pfas-law/690568/

Pg. 9 - Safer States: Bill Tracker - https://www.saferstates.org/bill-tracker/?toxic_chemicals=PFAS&safer_solutions=All&states=All