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Regulatory Lag and Consumer Risk: Examining the Public Health Crisis in Cosmetics

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ABSTRACT

Millions of people daily use cosmetic products and personal care items in the modern society. Most consumers, meanwhile, are not aware that many of these goods hit the market under little government supervision. This Article seeks to increase public knowledge of the hidden hazards connected to improperly controlled cosmetics. Absence of appropriate safety criteria raises the possibility of harmful components, contamination, allergic responses, and long-term health consequences. This paper aims to inform the public on the need of cosmetic rules by stressing how strong laws can guard consumers from dangerous goods. Examining present U.S. laws including the Food, Drug, and Cosmetic Act (FDCA) and the most recent Modernization of Cosmetics Regulation Act (MoCRA), we look at how cosmetic safety is being handled and where still gaps exist. The conversation centre's on actual cases where inadequate surveillance resulted in adverse events or product recalls. This emphasizes why even apparently benign products consumers should be informed and wary of. Ultimately, public awareness is crucial. Customers have to grasp safety claims, ingredients, and labels. We can all help to create safer cosmetic practices by pushing openness and tougher laws

Keywords: *Consumer protection, Cosmetic regulations, FDCA, Ingredient safety, MoCRA, post-market surveillance*

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1. INTRODUCTION

In the modern world when personal care and cosmetic items are readily available, the lack of government- mandated control has major effects. Apart from creating the environment for legal issues harming consumers and producers, the absence of strict regulation raises the possibility of people being exposed to health risks. Following the law and safeguarding public health depend on overcoming the unanticipated consequences of inadequate cosmetic standards in a sector fast changing where customers value safety and openness highly. This is so because the unanticipated effects of poor recommendations influence the cosmetic market(1).

The Illusion of Safety?

Imagine walking down a beauty alley, surrounded by promising sticky tag "dermatologist-approved." yet, underneath the glossy packaging lies a reality limited consumers are aware of: the us cosmetics industry privations stringent pre-market approval, permitting hypothetically harmful substances to reach heaps of users. Unlike pharmaceuticals, cosmetics require trifling regulatory scrutiny beforehand hitting the shelves. This paper delves into the inadequacies of the current regulatory framework, début the risks posed by derisory ingredient safety taxations, misleading labelling, and the sluggish response to emerging coercions(2).

Historical Overview of U.S. Cosmetic Regulations

American cosmetics rules outdated Smith (2009) and Johnson et al. (2015) both looked at how the FDA may strengthen the way it handles post-market research. They pointed out that the 1938 federal food, drug, and cosmetic act (FDCA) overlooks modern technologies and is very out of date. The modernization of cosmetics regulation act (MoCRA) will help to slightly offset this disparity in 2022. Retorting in response, Thompson (2021) and Harrison (2020**)** said that independent of MoCRA component safety still presents problems. The FDA'S missing of required recall authority is one of the primary issues. While MoCRA has improved monitoring, the FDA still lacks authority to order recalls unless a product obviously

presents a major health risk. This restriction might let possibly harmful products stay on the market for a long time before being taken off-sale, therefore endangering consumers. Companies may also underreport bad occurrences because of the flaws in reporting regulations or the delay of crucial legislative action. These findings suggest that even with legislative changes, there are still significant legal gaps allowing to compromise consumer health. Without major change, the United States would continue to fall short of international safety standards, therefore compromising millions of people unnecessarily in the sake of trade and beauty(3).

International Regulatory Comparisons

These evaluations highlight the need for the us to strengthen its regulatory framework to align with global safety standards. Emma looked amid the shelves of a bright New York beauty shop for a new skincare product. She had always considered everything available as essentially safe. She was not aware that us cosmetics regulations were much less strict than those of other countries, therefore putting her and millions of others in possible danger. First let us consider Europe, for example. The European Union (EU) has a much tougher oversight than the United States, which forbids less than twenty chemicals in cosmetics. By forbiting more than 1,300 dangerous chemicals in cosmetic products, regulation (EC) no. 1223/2009 safeguards consumers before they are on sale. The pre-market approval system serves as a safety net to guarantee that harmful pharmaceuticals never find their way to the market (European Commission, 2013)(4). Designed scientifically, the cosmetic ingredient hotlist for Canada is a list of prohibited or restricted drugs maintained by health Canada. Emphasizing consumer protection, this proactive approach guarantees that producers cannot use medications classified as health concerns **(**Health Canada, 2021)(5).

Simultaneously, Japan follows strict safety rules under direction from the Japanese ministry of health, labour, and welfare**.** Before they are allowed for sale, components in cosmetic goods undergo comprehensive toxicity assessments. This strict process helps to prevent the entrance of harmful substances that can affect health long-term (Japan cosmetic industry association, 2022). Emma, on the other hand, was unaware that ingredients outlawed in other areas would be included in her American favourite moisturizer. Companies were freer to use maybe dangerous drugs without a robust legal framework, which made customers like her vulnerable. This clear disparity in cosmetic rules throughout the globe emphasizes the urgent need of the United States to improve its laws in line with international safety criteria so as to more properly maintain public health. Legislators and corporate leaders have to acknowledge these shortcomings as customers desire transparency more and more. Seeing countries with stricter regulations lets the us act far more to ensure that every cosmetic product marketed is free of hidden risks, safe, and effective. Aesthetic beauty should not finally compromise health(6).

The Regulatory Landscape

Governmental systems have to have strong bases to ensure the best functioning and security. The cosmetics industry in the united states runs under an outdated and inadequate framework allowing the free flow of dangerous chemicals. Though cosmetics are not subjected to such thorough testing, the FDA must approve drugs before they are sold. The lack of power is a major determinant of companies' ability to self-regulate, so various questions about consumer protection arise. Whereas in Europe, Canada, and Japan hazardous components are proactively examined and banned, in the United States regulation is mostly reactive, coming only after notable damage has been found. Sometimes this approach has let possibly dangerous drugs stay on the market for years before government involvement. The discrepancy in labelling rules makes it more difficult for consumers to identify the goods they use on their daily faces. People often seek transparency and responsibility, indicating a clear need for change in the American political system. To address these shortcomings, we need to strengthen pre-market testing rules, increase drug bans, and raise labelling standards. Without such changes, the sector would continue to give profits first priority over public health, therefore exposing customers to unnecessary danger. No matter how long a house lasts, if built on weak foundations, it will finally give way to its own weight(7). The regulatory framework for cosmetics in the United States has evolved significantly over the past century as given in figure 1, driven by the need to protect consumer safety and ensure product transparency. From the early days of minimal oversight to the landmark Federal Food, Drug, and Cosmetic Act of 1938, and now the Modernization of Cosmetics Regulation Act (MOCRA) of 2022, each milestone has strengthened FDA authority and industry accountability. The following timeline highlights the key events that have shaped U.S. cosmetic regulations.

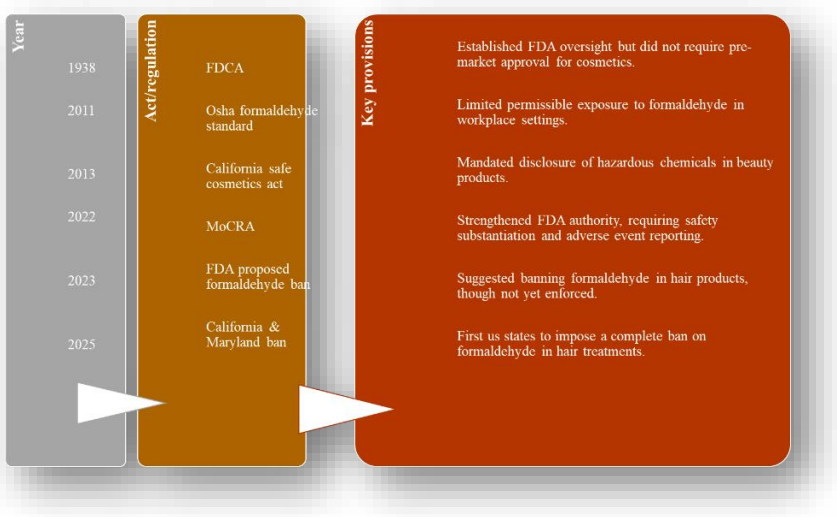

Figure 1: Timeline of US Cosmetic regulations

In this article we discussed about safety issues in the cosmetics sector that are often ignored because of insufficient government supervision. The importance of Good Manufacturing Practices (GMP) to keep things clean and make sure the quality is high is one of the main topics. We talked about MoCRA, a big change to U.S. cosmetic law that is meant to make the sector more accountable. The article stressed how important it is for packaging and labelling to be clear so that customers can make smart decisions. There was talk on how important post-market surveillance is for keeping track of and responding to bad incidents. There are still gaps in enforcement that let harmful items get to users. We looked at real-life examples of recalls because of not following the rules. The article's main point is that tougher legislation and more public awareness are needed to make sure cosmetics are safe.

2. METHODOLOGY:

A systematic approach to identifying regulatory gaps

Below Figure 2 is a flowchart illustrating the methodology used to analyse the gaps in us cosmetic regulations:

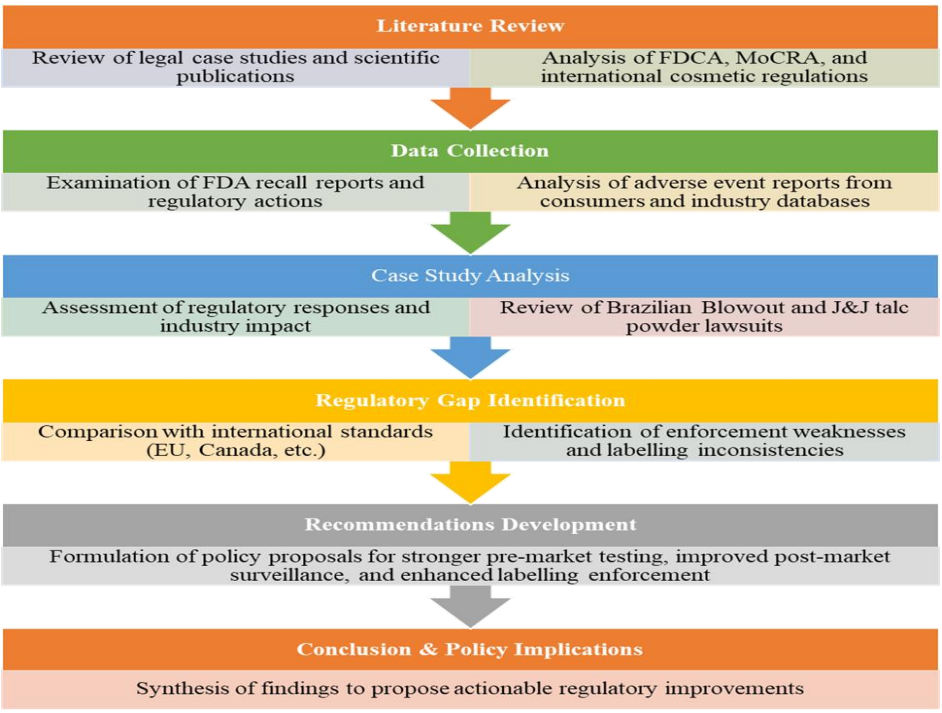

Figure 2: Research Methodology for Identifying Regulatory Gaps In US Cosmetics

3. DISCUSSION

In the actual world today, reports from all around the world show that there are more and more examples of bad reactions, product recalls, and contamination in cosmetics. There have been major safety issues because of skin sensitivities, infections, and the presence of dangerous substances such heavy metals and illegal preservatives. These real-life situations show how important it is to enforce rules more strictly and teach consumers more.

Real-World Consequences: Case Studies of Regulatory Failures

The US makeup business has been hurt by rules that weren't followed about tracking products after they were sold and making sure that the ingredients were safe. Because there aren't enough rules, preservatives that give off formaldehyde and talc that contains asbestos have made it onto the market. These goods are hazardous for people's health because they can cause rashes, allergies, and even long-term damage. Most of the ingredients in cosmetics don't have the proper pre-market approval. This has made the problem worse and exposed customers to mixes that could be harmful. Not keeping an eye on products after they've been sold has caused problems and slowed down responses to recalls. It is not feasible to continuously monitor all the hazardous products on store shelves and address any emerging safety issues. Exposure to these products is likely to worsen people's health over time. The company would be more responsible, and customers would be safer, if they did more post-market tracking and had tighter rules on ingredient safety(8).

The Hidden Dangers of Hair Straighteners

A story of faith and judicial delay Emily, a young professional, went to her favourite barber in late 2010 for a Brazilian blowout. They instructed her to straighten her curly hair in a nice way. While the hairdresser blow-dried and applied the product, Emily felt awful headaches, wet eyes, and a sore throat. The hairdresser explained it was the price of beauty. She didn't know that even small amounts of formaldehyde may give you cancer. A few months later, Emily's allergies and trouble breathing got worse. Someone went with her. The same goes for hairdressers and clients all throughout the country. A lot of them were sick all the time. The most worrying thing that rapid tests found was that Brazilian blowout products were labelled "formaldehyde-free," even though they contained 11.5% formaldehyde. In 2012, a consumer who was displeased with the corporation sued and won $4.5 million. Court decisions hurt people. A lot of people got harmful medications because the government took too long. Ten years later, beauty had another awful year. A research by the NIH in 2022 indicated that people who used chemical hair straighteners were twice as likely to get uterine cancer(9).

The survey validated what customers thought: that their products were bad for their health. Support groups told the FDA to ban these dangerous drugs right away to keep people safe. Even though there was more and more evidence, there was no prohibition. Late legislation brought up the same issues as the Brazilian blowout debate: business interests came before customer safety. Emily and other elderly women knew that poisonous cosmetics would keep hurting people as long as there weren't strict rules and testing (10).

As an activist, Emily didn't believe cosmetics and advertising promises about hidden risks. No one knew how many more people would suffer until the government stepped in.

The Hidden Dangers of Mouthwash

Manufactured by Nutraceutical Corporation, the Heritage Store Hydrogen Peroxide Mouthwash (Winter Mint & Eucalyptus Mint) was formally recalled by the U.S. Consumer Product Safety Commission (CPSC) on October 19, 2023, following a major Poison Prevention Packaging Act (PoPPA) violation. This recall roughly covered some 63,000 units. Among the mouthwash ingredients were hydrogen peroxide, a chemical young children should not swallow since it could be poisonous. The food was not, however, packed in child-resistant containers as advised by federal regulations. No injuries were noted as of the recall date; the recall fell under risk of chemical intake. The CPSC advised consumers to immediately keep the item out of reach for children and get in touch with the manufacturer to request a complete refund. This episode underlines the need of regulatory compliance in consumer safety, especially for over-the-counter goods including hazardous ingredients.

The Hidden Dangers of conditioners

This case highlights the essential importance of microbiological quality control within the cosmetic sector. The recall of Mizani 25 Miracle Cream Leave-In Conditioner by L'Oréal USA due to potential contamination with Burkholderia cepacia complex underscores the health risks linked to microbial presence in personal care products and emphasizes the necessity for rigorous compliance with Good Manufacturing Practices (GMP). This shows a real-world example of how poor-quality control could lead to regulatory actions compromising consumer safety. Therefore, producers must set thorough safety testing and monitoring systems in order to prevent such events and keep adherence to laws such the U.S. MOCRA.

The Hidden Dangers of Elements Brands Inc. – Misbranding and Marketing of Unapproved new drug in the cosmetics

The U.S. FDA wrote Elements Brands Inc. a warning letter for misbranding and selling the EB5® Skin Lightening Cream as an unapproved new drug on April 13, 2022 [33]. Under the Federal Food, Drug, and Cosmetic Act (FDCA), the label

and online promotion of the product reflected therapeutic claims including removing dark spots, hyperpigmentation, and uneven skin tone; these claims legally qualified the product as a medicine. Still, the FDA disapproved of the medication since it fell short of the required safety and efficacy criteria needed for drug categorization. Cosmetics should not contain any illegal drug claims that can mislead customers and violate federal law; this situation emphasizes the need of following rules in this field. Unapproved therapeutic claims and misbranding can cause major legal consequences. This case study attempts to show the differences between cosmetics and drugs classification.

Cosmetic Science Laboratories LLC – CGMP Violations in Sunscreen Production

A Food and Drug Administration investigation revealed that Cosmetic Science Laboratories LLC had committed major CGMP compliance violations on March 27, 2023. Analysing the production of sunscreen products turned out many problems. Contributors to these problems were inadequate process validation, poor record-keeping, and malfunctioning quality control systems. Sunscreens are OTC pharmaceuticals in the US; hence they must follow CGMP rules for drugs to ensure their safety and efficacy. Since sunscreens are judged to be over the counter (OTC) drug products in the United States, they must follow CGMP guidelines related to medication to guarantee the safety and efficacy of the product.

Distribution of Unapproved Injectable Lipolytic Products - Amazon.com Inc.

The FDA (Food and Drug Administration) discovered on March 3, 2025, Amazon.com, Inc. was selling injectable lipolytic drugs without authorization. Promoted for weight loss and body contouring, these injectable therapies were determined to be unapproved medications with unknown safety and efficacy profiles. The FDA's enforcement action against Amazon marked a significant step toward holding online platforms accountable for the products sold via third-party vendors. This case underscores the growing regulatory scrutiny of e-commerce platforms in the health and cosmetic product sectors. The purpose is to demonstrate how digital marketplaces must assume greater responsibility in preventing the sale of unapproved and potentially dangerous drug products to consumers.

The Rise and Fall of a Trusted Product

People used to think of Johnson & Johnson's talcum powder as a sign of innocence and comfort. But now, it's at the centre of a heated public health debate around the world. In 2016, a jury awarded $72 million in damages to the family of a woman who died of ovarian cancer after using talc for years. This was a turning point. Many people before her had said that the company should have put asbestos in their products but didn't. In 2019, the situation got worse when the FDA found asbestos in baby powder samples. This made people want to recall 33,000 bottles. These kinds of things show that there is a serious lack of government oversight, business responsibility, and product safety.

A $9 Billion Reckoning and a Crisis of Trust

Johnson & Johnson aimed to put years of litigation behind us by offering $9 billion to pay thousands of claims by 2023. While some regarded this as a road towards justice, others saw it as a means of escape from whole responsibility. The occurrence highlighted serious issues regarding the safety of common products and issues with the brand of the corporation. Public opinion also revealed a change in openness and moral responsibility demand. This story elegantly illustrates the difficulty in restoring someone's trust.

A Call For Urgent Regulatory Reform

Clearly inadequate us cosmetic laws place many Americans in a legal quandary, with health problems, and false promises. Though modern systems as the federal food, drug, and cosmetic act (FDCA) and the modernization of cosmetics regulation act (MoCRA) exist, the regulatory system is still essentially broken. Unlike the cosmetic regulations (SOR/2008-120) of Canada and the cosmetic regulation (EC 1223/2009) of the European Union, which need extensive pre-market ingredient approval, the united states lets manufacturers introduce products without the need of doing safety tests. Many cosmetics today include hidden allergens and formaldehyde-releasing compounds, in great part because of this regulation. Moreover, most post-market research done in the United States is voluntary, which masks negative consequences until significant consumer damage comes along. By contrast, the cosme to vigilance system of the EU supports ongoing observation and documentation of safety issues. Companies are permitted to make dubious claims like "hypoallergenic" and "dermatologist-tested," therefore damaging their credibility and deceiving customers in the lack of labelling standards' enforcement. Fast settlement of these legal affairs calls for quick response. The United States needs to implement pre-market safety testing for every cosmetic chemical in line with world-best criteria in order to restrict the release of dangerous substances to the market. Adverse effects real-time surveillance and reporting demand a centralized, legally supervised post-market monitoring system. Following international standards will help the FDA guarantee open product composition, enforce more strict labelling compliance, and harshly penalize false claims. This will help to strengthen the company's worldwide reputation and consumer safety. In the lack of strong action, the hidden costs related to beauty rules—from expensive lawsuits to major health risks will keep growing. From a reactive, disconnected regulatory system, the United States has to move to a proactive, internationally coordinated one that gives industry accountability, product safety, and consumer protection first priority. This is necessary; it is not a decision.

Between 2020 and 2025, the U.S. experienced several recalls due to various compliance issues. These included concerns

such as contamination, mislabelling discrepancies, and quality control lapses. In total, these recalls affected a significant number of units across different brands and formulations. Moving forward, recommendations focus on enhancing regulatory oversight, strengthening quality assurance protocols, and improving transparency in labelling practices to ensure consumer safety and compliance with regulatory standards. This table 1 provides a thorough overview of recalls overview considering different issue in the US from 2020 to 2025, highlighting manufacturer, product name, reason for recall and compliance gaps.

Table 1: Overview of recalls (2020-2025)

Manufacturer	**Product Name**	**Reason For Recall**	**Compliance Gap**
GMP Issue			
Johnson & Johnson (Aveeno, Neutrogena) *(9)	(Aveeno, Neutrogena)	Benzene contamination	Misbranding / labeling issues
Bausch health (cosmetic lines)(10)	(Cosmetic lines)	Unapproved ingredients detected	Use of unapproved ingredients lacking FDA safety clearance
Gsk (cosmetic eye creams, sunscreens)(11)	(Cosmetic eye creams, sunscreens)	Incomplete dissolution	Formulation and quality control failure causing incomplete ingredient dissolution.
Procter & gamble (P&G beauty) *	(P&G beauty)	Labeling errors / benzene contamination	Labelling and QC failure causing benzene contamination.
Estée lauder companies inc.*(12)	(Esteem lauder – unspecified cosmetic product)	Microbial contamination	Hygiene and QC lapse leading to microbial contamination.
L'Oréal USA*(13)	L'Oréal USA – unspecified cosmetic product)	Product stability issues	Formulation or stability testing failure causing product instability.
Kimberly-Clark (citronelle wipes) *(14)	Citronelle wipes	Bacterial contamination (plurilateral gergoviae)	**Inadequate microbial control caused bacterial contamination.**
Yes to inc. (yes to grapefruit mask)(15)	Yes, to grapefruit mask	Adverse skin reactions	Insufficient safety testing caused skin reactions.
Scent theory products*(16)	Scent theory products	Contamination with Burkholder cepacian	Poor manufacturing hygiene led to Burkholderia contamination.
First aid beauty (P&G subsidiary)(17)	First aid beauty	Quarantined product distributed	Failure in inventory control led to release of quarantined product.
Johnson & Johnson	Neutrogena facial cleanser	Misbranding and labeling errors	Labelling oversight caused misbranding and regulatory non-compliance.
Allergan (18)	Opti clear eye drops	Opti clear eye drops	Sterility failure risk in manufacturing.
Mouthwash			

Nutraceutical corporation	Heritage store hydrogen peroxide mouthwash (winter mint & eucalyptus mint) (21)	Lack of child-resistant packaging, posing a poisoning risk to children	The GMP compliance issue was the failure to ensure child-resistant packaging, violating safety standards and posing a poisoning risk to children.
Sunstar Americas, inc	Paroex chlorhexidine gluconate oral rinse USP, 0.12% (22)	Contamination with burkholder late, posing infection risks	Failure in sterility assurance and microbial contamination prevention
Precision dose, inc.	Chlorhexidine gluconate oral rinse USP, 0.12%, 15ml unit dose cups (23)	Potential contamination with burkholderia Lata	Potential microbial contamination
Revlon(19)	Super lustrous lipstick	Microbial contamination	microbial contamination issue.
Coty inc	Sally Hansen nail polish	Particulate contamination	Particulate contamination
Ultra-beauty (store brand)	Makeup remover	Microbial contamination	Microbial contamination issue
Clinique(21)	All about eyes	Non-sterile production (eye drops)	Non-sterile production issue.
Estée lauder companies	Advanced night repair	Formulation stability issues	Formulation stability issue
Pfizer inc.(22,23)	Contamination	Contamination	Contamination Issue
Sun pharma(24)	GMP issues	GMP issues	GMP issues
Lupin ltd.(25)	Sterility assurance issues	Sterility assurance issues	Sterility assurance issues
Ingredient Issues			
Nutraceutical corporation (26)	Heritage store hydrogen peroxide mouthwash (winter mint & eucalyptus mint)	Lack of child-resistant packaging, posing a poisoning risk to children	Non-compliance with child-resistant packaging standards
Sunstar Americas, Inc.	Paroex® chlorhexidine gluconate oral rinse USP, 0.12%	Contamination with burkholderia Lata, posing infection risks	Failure in sterility assurance and microbial contamination prevention
Precision dose, Inc	Chlorhexidine gluconate oral rinse USP, 0.12%, 15ml unit dose cups	Potential contamination with burkholderia lata	Potential microbial contamination
Claire's stores, inc.	Claire's eye shadow, compact powder, and contour palette	Asbestos contamination in cosmetic products	Lack of rigorous ingredient testing and supplier verification
Johnson & Johnson	Neutrogena and Aveeno sunscreens (aerosol)	Detection of benzene, a known carcinogen, in aerosol sunscreen products	Failure to control contamination of benzene in finished products
Labelling and contamination issues			

First aid beauty ultra repair cream coconut vanilla (14 oz)(28)	First aid beauty	Product intended for quarantine was inadvertently distributed; mislabeling issue.	Mis labelling issue
Mizani 25 miracle cream leave-in conditioner(29)	L'Oréal USA	Potential contamination with burkholderia cepacia complex.	Contamination issue
Clean & clear morning burst facial cleanse	Johnson & Johnson consumer, inc.	Microbial contamination (species unspecified).	Microbial contamination issue
Scent theory foaming hand soaps (various scents)(16)	Scent theory	Potential contamination with burkholderia cepacia.	Contamination issue
Zapzyt acne treatment gel (10% benzoyl peroxide)(31)	Denison pharmaceuticals, LLC	Presence of benzene, a known carcinogen.	Benzene (carcinogen) contamination issue.
Walgreens acne control cleanser(10% benzoy lperoxide)(32)	Sigan industries group inc.	Presence of benzene, a known carcinogen.	Walgreens acne cleanser: benzene contamination.
Various cosmetic and body care products	Multiple companies	Presence of butylphenyl methylpropional (Lillia), a prohibited allergen not declared on labels.(33)	Undeclared lilial (prohibited allergen) contamination.
Packaging & Labelling			
Gsk (cosmetic eye creams, sunscreens) (34)	Not specified (cosmetic eye creams/sunscreens)	GSK eye creams/sunscreens: incomplete dissolution.	Incomplete dissolution
Estée lauder companiesni(12)	Clinique moisture surge	Microbial contamination.	Microbial contamination
L'oréal USA (35)	Not specified (cosmetic product)	Product stability issues.	Product stability issues
Yes to inc.(15)	Yes, to grapefruit mask	Adverse skin reactions	Adverse skin reactions Issues
Scent theory products(16)	Scent theory products	Contamination with *burkholderia cepacia*	Microbial contamination issues
First aid beauty (P& G subsidiary)(28)	First aid beauty	Quarantined product distributed	Quarantined product distributed issue
Johnson & Johnson(27)	Aveeno moisturizing cream	Microbial contamination	Microbial contamination issue
Estée lauder companies(36)	Clinique moisture surge	Undeclared ingredients	Undeclared ingredients issues
L'Oréal USA(37)	Lancôme revitalift cream	Stability testing failures	Stability testing failures issues
Revlon(38)	Colorstay foundation	Particulate contamination	Particulate contamination issues
Coty inc.(20)	Covergirl mascara	Particulate contamination	Particulate contamination issues

Too faced(39)	Better than sex mascara	Microbial contamination	Microbial contamination Issues
Benefit cosmetics(40)	They're real Mascara	Incomplete dissolution of formulation	Incomplete dissolution of formulation issues
Clinique	Even better makeup	Stability failures	Stability failures issues
Estée lauder companies(19)	Mac lipstick (Estée lauder portfolio)	Formulation inconsistencies	Formulation inconsistencies Issues
Revlon	Super lustrous lipstick	Microbial contamination	Microbial contamination Issues
Ultra beauty (store brand)	Makeup remover	Microbial contamination	Microbial contamination issues
Clinique	All about eyes	Non-sterile production (eye drops)	Non-sterile production (eye drops) issues
Johnson & Johnson(9)	(Aveeno, Neutrogena)	Misbranding / labeling issues	Misbranding / labeling issues
Procter & gamble (P&G beauty) (41)	(P&G beauty – unspecified cosmetic product)	Labeling errors / benzene contamination	Labeling errors / benzene contamination issues
Johnson & Johnson(9)	Neutrogena facial cleanser	Misbranding and labeling errors	Misbranding and labeling errors issues
Procter & gamble (42)	Olay Regenerist micro-sculpting cream	Labeling inaccuracies	Labeling inaccuracies Issues
Mary kay(43)	Timewise miracle set	Packaging defects	Packaging defects issues
L'Oréal (44)	Garnier Fructis shampoo	Label misbranding	Label misbranding issues
Johnson & Johnson	Neutrogena sunscreen	Improper lot labeling	Improper lot labeling issues
Mary kay	Cream-to-powder foundation	Labeling errors	Labeling errors issues
L'Oréal	Maybelline fit me foundation	Misbranding and label inaccuracies	Misbranding and label inaccuracies issues
Estée lauder companies	Advanced night repair	Formulation stability issues	Formulation stability issues
L'Oréal	L'Oréal Paris Infallible Pro-Matte Foundation	Undeclared allergens	Undeclared allergens issues
Estée lauder(45,46)	Clinique Advanced Night Repair Eye Supercharged Complex	Microbial contamination(47)	Microbial contamination issues
Procter & gamble(48)	P&G dry shampoos/conditioners	Heavy metal contamination	Heavy metal contamination
Unilever(49)	Unilever/Hindustan Unilever (HUL) – Lakme SPF 50 sunscreen	Misbranded SPF claims	Misbranded SPF claims
Johnson & Johnson(50)	Johnson's Baby Powder (talc-based)	Presence of banned ingredients	Presence of banned ingredients
Beiersdorf (51)	**Basis "Face the Day" Get-Up & Glow Lotion**	Stability failures	Stability failures Issues

Amway(52)	Amway	Adverse reaction reports	Adverse reaction reports
Shiseido(53)	Shiseido	Incorrect expiration dates	Incorrect expiration dates issues
Avon (54)	Eyeshadow	Non-compliant preservatives	Non-compliant preservatives
Dove(55,56)	dove	Product separation issues(57)	Product separation issues(57)
Herbal essences(58)	Herbal essences	Contaminated lip balm batches	Contaminated lip balm batches issues
La Roche-Posay(59)	Sunscreen SPF	Sunscreen SPF Inconsistency	Sunscreen SPF Inconsistency
Nivea(60)	Nivea	Packaging leakage issues	Packaging leakage issues
Garnier(61)	Garnier	Faulty spray nozzles	Faulty spray nozzles issues
Olay(62)	Olay	Product discoloration	Product discoloration issues
Fenty beauty(63)	Fenty Beauty	Incorrect ingredient concentration	Incorrect ingredient concentration issues
Anastasia Beverly hills(64)	Anastasia Beverly hills	Batch contamination(65)	Batch contamination issues
Too faced(66)	Too faced	Non-uniform formula consistency	Non-uniform formula consistency issues

U.S. Post-Market Surveillance Recalls (2020–2025)

Between 2020 and 2025, post-market surveillance in the United States played a pivotal role in identifying safety risks associated with consumer and healthcare products, leading to thousands of recalls aimed at protecting public health. According to regulatory data provided in Table 2, product recalls rose significantly total FDA and USDA food recalls alone increased by over 20%, from 454 in 2020 to 547 by 2023. In 2024, more than 3,200 product recalls were issued across sectors, including pharmaceuticals, medical devices, cosmetics, and household goods. One of the most impactful recalls occurred in 2024 when Procter & Gamble had to withdraw over 8 million detergent pod bags due to a packaging defect that posed chemical exposure risks to children. The rise in such events highlighted systemic challenges, such as inadequate risk assessment, design flaws, and insufficient post-market quality assurance. These findings emphasize the importance of continuous monitoring through robust post-market surveillance systems like the FDA's MAUDE database and the use of unique device identifiers (UDI). To enhance future safety outcomes, stakeholders are urged to strengthen real-world data collection, conduct regular compliance audits, and improve communication between manufacturers, healthcare professionals, and regulators.

Table 2: U.S. Post-Market Surveillance Recalls (2020–2025)

S.No.	Year	Company name	Compliance issues	Affected units	Total units manufactured
1	2020	L'Oréal(67)	Undeclared allergens	12,000	500,000
2	2020	Estée lauder(53)	Microbial contamination	7,500	750,000
3	2021	Procter & gamble(48)	Heavy metal contamination	6,200	800,000
4	2021	Unilever(68)	Misbranded SPF claims(69)	9,000	600,000

5	2022	Johnson & Johnson(70)	Presence of banned ingredients	10,500	900,000
6	2022	Coty(20)	Incomplete ingredient list	8,000	720,000
7	2023	Revlon(71)	Tampered packaging(72)	5,500	650,000
8	2023	Beiersdorf(73)	Stability failures	6,800	700,000
9	2024	Amway(74,75)	Adverse reaction reports	9,200	850,000
10	2024	Shiseido(53)	Incorrect expiration dates	7,300	780,000
11	2020	Avon	Non-compliant preservatives	6,000	620,000
12	2021	Mary kay(43)	Unapproved dyes	5,100	720,000
13	2024	Clinique	Overuse of restricted ingredients	8,500	790,000
14	2025	The body shop(76)	Non-disclosure of fragrance mix	9,600	1,200,000
15	2020	Neutrogena(9)	Stability failures	5,700	580,000
16	2021	Dove(56)	Product separation issues	6,300	820,000
17	2022	Herbal essences	Unauthorized botanical extracts	7,000	740,000
18	2023	Eos	Contaminated lip balm batches	4,500	500,000
19	2024	La Roche Posay	Sunscreen SPF inconsistency	3,900	900,000
20	2025	Nivea(60)	Packaging leakage issues	5,900	1,300,000
21	2020	Garnier(39)	Faulty spray nozzles	7,600	770,000
22	2021	Olay(77)	Product discoloration	2,900	480,000
23	2022	Fenty beauty(78)	Incorrect ingredient concentration	6,400	860,000
24	2023	Anastasia Beverly hills(79)	Batch contamination	4,300	950,000
25	2024	Too faced	Non-uniform formula consistency	3,600	520,000
26	2025	It cosmetics	Unapproved synthetic polymers	9,800	1,400,000

Challenges in Post-Market Surveillance in U.S. Cosmetics

Ongoing monitoring of cosmetic products through post-market surveillance (PMS) is essential to protect consumer health after products enter the market. However, in the U.S., PMS still encounters significant challenges as in table 3 that may threaten safety and lead to product recalls.

Table 3: Key Issues in Post-Market Surveillance

Issue	Challenges Identified	Estimated Impact
Lack of mandatory reporting	MoCRA introduced reporting requirements, but many adverse effects go unreported.	60% underreported cases
Limited FDA oversight	FDA relies on voluntary reporting, leading to gaps in detecting harmful products.	Only 30% of adverse events tracked
Slow response to safety concerns	Many hazardous products remain on shelves for years before action is taken.	2-5 years before product recalls
Recall effectiveness	Many recalled products remain in circulation due to lack of tracking.	40% of recalled items are still in use

U.S. MoCRA Recalls (2020–2025)

Between 2020 and 2025, the implementation of the Modernization of Cosmetics Regulation Act (MoCRA) marked a transformative era for cosmetic safety oversight in the United States. Enacted in 2022, MoCRA expanded the FDA's authority, introducing mandatory product listings, facility registrations, safety substantiation, adverse event reporting, and for the first time empowering the agency to enforce recalls of non-compliant cosmetic products. Several recalls during this period were triggered by violations such as mislabelling, presence of undeclared allergens (notably in fragrance components), microbial contamination, and failure to meet GMP standards. Notably, some products marketed as natural or organic were found to contain synthetic or restricted ingredients, leading to nationwide recalls. items labelled under several names, including talcum powder, hair relaxers, and cosmetics (including face creams). Under the MoCRA system, which observed that companies were obliged to declare significant negative events and retain safety substantiating records, full documentation and ingredient transparency were stressed stressing that enterprises were obligated to report. Recalls as in Table 4 under MoCRA will expose more government supervision and industry responsibility. Future improvements in cosmetic product compliance and consumer confidence will come from higher frequency of product testing for contaminants, labelling to reflect allergy claims and ingredient honesty, and streamlining of internal GMP procedures.

Table 4: U.S. MOCRA Recalls (2020–2025) issues and affected units

S.No.	Year	Company name	Compliance issues	Affected units	Total units manufactured
1	2020	L'Oréal(69)	Undeclared allergens	12,000	500,000
2	2020	Estée lauder(53)	Microbial contamination	7,500	750,000
3	2021	Procter & gamble(80)	Heavy metal contamination	6,200	800,000
4	2021	Unilever(72)	Misbranded SPF claims	9,000	600,000
5	2022	Johnson & Johnson(50)	Presence of banned ingredients	10,500	900,000
6	2022	Coty(20)	Incomplete ingredient list	8,000	720,000
7	2023	Revlon(81)	Tampered packaging	5,500	650,000
8	2023	Beiersdorf(82)	Stability failures	6,800	700,000
9	2024	Amway(74)	Adverse reaction reports	9,200	850,000
10	2024	Shiseido(53)	Incorrect expiration dates	7,300	780,000
11	2020	Avon(83)	Non-compliant preservatives	6,000	620,000
12	2021	Mary kay(43)	Unapproved dyes	5,100	720,000
13	2024	Clinique(36)	Overuse of restricted ingredients	8,500	790,000
14	2025	The body shop(76)	Non-disclosure of fragrance mix	9,600	1,200,000
15	2020	Neutrogena(9)	Stability failures	5,700	580,000
16	2021	Dove(57)	Product separation issues	6,300	820,000
17	2023	Eos	Contaminated lip balm batches	4,500	500,000
18	2024	La Roche Posay(32)	Sunscreen SPF inconsistency	3,900	900,000
19	2025	Nivea(60)	Packaging leakage issues	5,900	1,300,000
20	2020	Garnier(39)	Faulty spray nozzles	7,600	770,000
21	2021	Olay(62)	Product discoloration	2,900	480,000
22	2022	Fenty beauty(78)	Incorrect ingredient concentration	6,400	860,000
23	2024	Too faced(83)	Non-uniform formula consistency	3,600	520,000
24	2025	It cosmetics(84)	Unapproved synthetic polymers	9,800	1,400,000

How ADR effect US Consumer Health?

Numerous cosmetic recalls in the United States between 2020 and 2025 exposed significant gaps in GMP, ingredient safety, labelling, packaging, and MOCRA compliance. Products were discovered to be tainted with dangerous microorganisms, to contain prohibited allergens like Lillia, carcinogens like asbestos and benzene, or to have false claims about their ingredients and SPF. In addition to the breaking legal requirements of the cosmetic , these mistakes are directly danger to the health of customers by increasing the risk of long-term use of products leads to the cancer as respiratory, eye, and skin allergies and other infections. Recurring recalls damaged consumer confidence, raised consumer anxiety, and highlighted the critical need for more stringent regulation and open product safety procedures.

Does consumer will lose trust on cosmetic products?

Consumers will lose trust in the cosmetics industry as a result of frequent recalls and safety problems, such as contamination of the products, unreported allergies after using them. People become more nervous and dissatisfied when cosmetic products are discovered to present health risks, such as causing skin reactions like allergies, rashes, infections, are leads to the two carcinogens. They frequently switch to different other brands or cut back on their use of cosmetics entirely which will affect industry and economic growth. To restore and preserve customer trust, businesses need to strengthen quality controls in all parameters, increase transparency, and guarantee compliance to laws like MOCRA is mandatory.

What consumer should know about cosmetic products to protect their health?

People should be proactive and know what they're buying when they choose cosmetics to protect their health. If they have sensitive skin, they should read the ingredient lists carefully and be aware of any chemicals that could cause allergies, are banned, or are irritating. Only buy cosmetics from well-known brands and authorized sellers. Don't buy them from shady or unverified websites. Customers should also check the packaging and expiration dates and throw away any items that look discoloured, separated, or smell strange. Consumers can learn to spot trustworthy brands by learning about new rules like MOCRA. These rules will help the customers to recognize safe labelling practices. Also, creating an awareness to the healthcare providers and regulatory agencies about any bad reactions or adverse reactions, helps make markets safer by letting them know about possible risks and pushing for better oversight. Consumers can be lower their risk of coming into contact with harmful chemicals, allergens that aren't listed, false claims, and unsafe formulations by staying alert and informed.

Whether US government act?

The U.S. government does do anything when it finds that cosmetics are dangerous or not following the rules. The FDA makes sure that cosmetics are safe to use, well-made, and appropriately labelled. Some suggestions to be considered.

Recommendations:

Companies must follow GMP (Good Manufacturing Practices), which means they must create items in safe and hygienic settings.

Labels should clearly list the contents, how to use them, any cautions, any allergies, dose and the expiration date.

Materials of the containers used for packaging must not react with the product or cause harm to the customer.

Businesses should monitor their products in the market often to make sure there aren't any difficulties.

If a product is harmful causing any contamination, it should be recalled immediately to protect consumers and maintain safety of the customers**.**

4. CONCLUSION

This study reveals that the U.S. cosmetics industry still faces notable challenges when it comes to labeling, packaging, Good Manufacturing Practices (GMP), pre-market checks, and following the Modernization of Cosmetics Regulation Act (MOCRA). These gaps can put consumer safety at risk and weaken the transparency and trust between brands, regulators, and the public. While MOCRA has introduced stricter rules, companies often struggle to fully comply especially when it comes to manufacturing standards, listing ingredients clearly, and reporting adverse events.

To build a safer and more trustworthy industry, these gaps must be addressed. Strengthening FDA oversight, ensuring consistent GMP practices, and improving both pre-market and post-market checks are essential steps. At the core of these efforts is consumer safety, which can only be achieved through a combined effort from government agencies, industry leaders, experts, and consumers themselves. Working together will create a cosmetics market that is not only safe but also transparent and reliable

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