

Impact of Regulation on Contact Dermatitis

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KEYWORDS

- Contact dermatitis • Regulation • European Union
- Metals • Occupational contact dermatitis

Contact dermatitis is an inflammation of the skin as a result of contact with 1 or more substances. This localized inflammation can be triggered by various metals, ingredients in cosmetics, plants, detergents, and many other materials people come into contact with frequently or occasionally. Contact dermatitis can be subdivided into three types: irritant, allergic, and photo.¹ Inflammation in all forms of contact dermatitis is primarily in the epidermis and outer dermis. Acute signs and symptoms often include: erythematous papules and plaques, weeping vesicles, burning (irritant contact dermatitis [ICD]), and pruritus. These signs and symptoms may take days to weeks to heal after the offending exposure is terminated and may evolve through stages of subacute, chronic, and lichenified dermatitis.²

Contact dermatitis is a serious public health and dermatologic concern. The prevalence of contact dermatitis in the United States was estimated to be 13.6 per 1000 population according to the National Health and Nutritional Examination Survey using physical examinations by dermatologists of a selected sample of Americans.³ The American Medical Care Survey estimated that for all American physicians dermatitis is the second most common dermatologic diagnosis proffered. Dermatitis accounts for 9% of visits to dermatologists.

Allergic contact dermatitis (ACD) is the cutaneous manifestation of the allergic response to an allergen. ACD is a type IV delayed hypersensitivity reaction that involves a cell-mediated response that has both an induction stage in which the immune system is sensitized and an elicitation stage whereby the allergic response is triggered.² Allergy to a substance may develop at any age in

life. Allergy is long lasting whereby subsequent contact with the allergen will usually produce an inflammatory reaction.

ICD results in inflammation after the release of proinflammatory cytokines by skin cells (mainly keratinocytes). Irritants may be chemical or physical with inflammation intensifying after repeated or prolonged exposure to the offending substance. Epidermal cellular changes, skin barrier disruption, and the release of cytokines are the 3 main pathophysiologic changes seen.²

Photo contact dermatitis (PCD) occurs only when skin together with the offending substance is exposed to ultraviolet or visible light. PCD can further be divided into photoallergic and phototoxic from exposure to a topical allergen and irritant respectively.¹

Distinguishing between the various types of contact dermatitis can be a daunting task; history and patch testing aid in this distinction. Substances may act as both an irritant and an allergen.

BUREAUCRACY AND LEGISLATION

This article does not review workers' compensation or regulation of clinical trials but instead focuses on other issues of regulation in the field of ACD.^{4,5}

Bureaucracy is often thought as "endless red tape malevolently contrived by petty, self-serving, and small minded bureaucrats."⁶ The bureaucratic perspective ignores the wider social environment and tends to protect its internal activities from public scrutiny and control.⁷

A bureaucracy should be efficient because it benefits from economies of scale and avoids duplication of effort while maintaining standards of

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quality. Bureaucracies exist for want of a better method to provide large scale delivery of services.⁶

Rules reduce variability and set patterns of behavior.⁶ People tend to complain about either a lack of rules or too many rules. Workers tend to apply or ignore rules arbitrarily because of rule inflation, whereby they do not know which rules are operational and which are historical.⁶ There is also the concept that those at the top of the bureaucracy think, whereas those beneath follow orders or procedures.⁶ In a bureaucracy no one takes responsibility for a decision unless forced to. Problems that require decisions are forced up a long chain of command. One part of the bureaucracy may have the authority but another part has responsibility to address a problem.⁶ Bureaucracies typically take a long time to make a decision, with the process itself being sacrosanct. The myriad regulations seem unapproachable for those not part of the bureaucracy.⁸

Dermatologists crossing the Atlantic may think they have entered a strange new world when they arrive at their destination. American dermatologists going to the European Society of Contact Dermatitis meetings hear dermatologists frequently advocate more government regulation particularly of allergens in consumer products in a continent where patch test allergens are abundantly available. European dermatologists coming to the American Contact Dermatitis Society meetings will find only 29 allergens that are Food and Drug Administration (FDA) approved to help dermatologists diagnose complex cases of ACD. European dermatologists quickly learn that CLIA (the Clinical Laboratory Improvement Amendments) and HIPAA (the Health Insurance Portability and Accountability Act) do not facilitate the clinical practice of medicine and that honest dermatologists live in fear of a Medicare auditor coming to their office and telling them, "I'm from the government and I'm here to help." In 1986 President Ronald Reagan called this phrase "the nine most terrifying words in the English language." This article will review governmental regulations—some helpful for patients and workers and some not helpful for dermatologists in their quest to assist patients with contact dermatitis.

REGULATION OF ALLERGENS

It should be fundamental that dermatologists who are the experts in contact dermatitis provide their clinical knowledge for the most useful legislation for patients and consumers.

Regulation has been useful in reducing nickel allergy in Europe. It is less certain that regulation has reduced ACD to chromate, thiurams,

methylchloroisothiazolinone/methylisothiazolinone (MCI/MI), and methyldibromo glutaronitrile (MDBGN).

The European Union (EU) Dangerous Substances Directive has specific concentration limits on strong skin sensitizers such as formaldehyde, glutaraldehyde, acrylates, and isocyanates. The Directive requires that allergens present in concentrations of more than 0.1% be labeled.⁹

CHROMATE

For nearly 20 years the Nordic countries have had legislation limiting hexavalent chromium in cement to fewer than 2 ppm. Danish legislation has required that iron sulfate be added to cement manufactured there to produce this low concentration. This resulted in a reported decrease in the prevalence of chromium allergy among construction workers in Denmark. A similar reduction in chromate dermatitis has been reported in Singapore, attributed to a change in the manufactured constituents of cement which also resulted in a reduction of hexavalent chromate levels without legislation.¹⁰

COSMETICS AND PRESERVATIVES

The United States was the first country with compulsory cosmetic labeling except for professional products used by beauticians. Europe currently has the most highly developed set of legislation regarding contact dermatitis.^{11–17}

The FDA regulates the labeling of cosmetics and requires safety and efficacy data on new products that are claimed to have preventive or health benefits. The FDA maintains a voluntary registration program whereby cosmetic manufacturers may register their finished products and ingredients with the FDA. The Office of Cosmetics and Colors also contains a database on cosmetic complaints that it receives in its Cosmetic Adverse Reaction Monitoring Program. Under the Fair Packaging and Labeling Act and Federal Food, Drug, and Cosmetic Act all cosmetics and over-the-counter (OTC) drugs must be accurately labeled with regard to the net quantity of contents. Cosmetic ingredients must be named in descending order of predominance. Fragrances do not have to be specified. Active ingredients must be listed in alphabetical order separately from the inactive ingredients for OTC drug products. A manufacturer may petition the FDA to allow the listing of an ingredient as "other ingredients" if it believes that the ingredient is a trade secret. This status is not routinely granted.¹⁸

Cosmetics are to some extent legislated through the Federal Food, Drug, and Cosmetic Act issued

by the FDA and US Department of Health and Human Services.¹⁸ All preservatives for cosmetic use are evaluated by the Cosmetic Ingredient Review, which has representatives from industry, the FDA, and consumers.¹⁸ In the United States, the Personal Care Products Council (formerly called the Cosmetic, Toiletry and Fragrance Association [CTFA]) reviews existing literature on ingredients and makes voluntary recommendations to the industry.

Cosmetics and preservatives are regulated by the EU's Cosmetic Directive.¹⁸ It is expected that many companies will follow the same regulations for all countries and will follow the EU's Cosmetic Directive. Canada has said that it will follow this directive. The International Nomenclature for Cosmetic Ingredients (INCI) is based on the CTFA nomenclature used in the United States and must be used in the EU. The Scientific Committee on Consumer Products (SCCP) makes recommendations to the EU commission.¹⁸

PRESERVATIVES

MDBGN was originally restricted to a maximum concentration of 0.1% in both leave-on and rinse-off products in 1986 by the EU Scientific Committee on Cosmetology, but in view of increasing frequency of ACD to MDBGN in the next 2 decades, the EU Cosmetics Directive restricted its use to 0.1% in rinse-off products only since 2005 and then prohibited it from rinse-off products as well in 2007.¹⁹ A significant decrease in positive patch reactions to this allergen has been seen in the EU since this legislation along with a significant decrease in the proportion of patients for whom a positive patch reaction to this allergen is of current relevance.¹⁸ It took 4 years and 4 different opinions from the SCCP to ban this preservative followed by a period of time for the industry to change to alternative preservatives and a total of 6 years to remove this allergen.¹⁸

The EU Cosmetics Directive prohibits the use of Kathon CG/Euxyl K100 (MCI/MI = 3:1) in concentrations above 15 ppm. The chemical industry then began to produce MI separately without MCI in different concentrations or in combination with other preservatives. MI has recently been approved for use in cosmetic products.¹⁸ MI may elicit and possibly induce ACD. The Personal Care Products Council recommends a concentration of no more than 7.5 ppm in cosmetic leave-on products and 15 ppm for cosmetic rinse-off products.¹⁸

PRESERVATIVE LABELING

Even in highly educated unilingual countries, half the population has difficulty reading cosmetic

labels because of the small size of the letters and the long chemical names.²⁰ Poorly educated patients and consumers have more trouble reading labels.²⁰ Patients found it easier to identify fragrance on labels than formaldehyde or MDBGN. The SCCP advisory to the EU commission has expressed concern regarding very long and difficult INCI names assigned to well known allergens. They suggested that more easily recognized names might be of assistance to consumers.

Preservatives may be mislabeled in up to half of consumer products.²¹ Some products do not contain labeled preservatives, but more commonly unlabeled preservatives may be found in products. A preservative may be found in the fragrance added to a product. Unlabeled formaldehyde is a concern.²² Manufacturers state that formaldehyde may be produced via post-formulation reactions, may occur as contamination in the early stage of formulation, and may occur in urea or glycerin used in the formulation of products.²¹

FRAGRANCE

Fragrance is the most common cosmetic allergy found when patients with dermatitis are patch tested in the United States and many other parts of the world.^{23,24} Fragrance chemicals are ubiquitous in our environment and can be found in a wide range of products including household, industrial, and cosmetic. Widespread use is a major contributing factor in the role of fragrance in ACD.

Fragrance mix I (FM I), and Myroxylon pereirae (MP) are 2 of the main screening chemicals used in standard patch test series. The 8 chemicals that compose FM I are: isoeugenol, hydroxycitronellal, cinnamal, cinnamic alcohol, eugenol, α -amyl cinnamal, geraniol and oak moss absolute (*Evernia prunastri*). Patch testing with FM I has been reported to detect up to 70% to 80% patients who are allergic to fragrance. Fragrance allergy correlates with exposure to products containing FM I constituents.²⁵ MP is also known as balsam of Peru and is a complex mixture of natural fragrance resins with more than 250 constituents.²⁶ MP has a patch testing sensitivity of up to 50% in patients with fragrance allergy. A second fragrance mix (FM II) was developed as a result of large multisite studies to further aid in the diagnosis of fragrance allergy. FM II contains the following additional 6 compounds: hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC or Lylal), α -hexyl cinnamal, citral, citronellol, coumarin, and farnesol.^{27,28}

Over 4000 different chemicals are used in artificial fragrance products, yet most of these have never been tested for human toxicity.²⁹

Sensitization to fragrance is thought to occur primarily in non-occupational settings, commonly after the use of cosmetic products both scented and unscented. A frequent primary site of dermatitis in patients with fragrance allergy is the hands; this possibly reflects the diminished barrier function of skin after exposure to irritants allowing penetration and sensitization to occur.³⁰ Occupations reported to have ACD and ICD to fragrance include hairdressers, aromatherapists, bakers, confectioners, coal miners, and workers in the cosmetic manufacturing industry.^{30,31} Buckley and colleagues³¹ concluded that health care workers also have an increased risk for fragrance allergy because of frequent hand washing with soaps and antiseptic solutions. Buckley and colleagues also found that retired individuals have the highest overall risk for fragrance allergy. This risk was exaggerated even more in health care workers with advanced age, suggesting that factors from their workplace environment contributed to potential sensitization. Students with a median age of 21.3 in the Buckley study had lesser prevalence of fragrance allergy, thought to be because of their younger age and less cumulative exposure to fragrance containing products.

Almost all fragrance allergic patients have non-occupational exposure, regardless of their occupation. Assessing occupational exposure is a difficult process. The International Fragrance Association has set advisory limits on the nature and concentration of sensitizing fragrance chemicals added to cosmetics. Household chemicals are still a concern for sensitization of individuals. Employers should make an attempt to provide employees with products that are fragrance free.

Fragrance composition in cosmetics may be indicated simply by the word *parfum* even in the EU, but 26 fragrance allergens must be identified in the EU if 1 of the fragrance substances is present at more than 10 ppm for leave-on products and more than 100 ppm for rinse-off products, even though some of these fragrances may be of little or no importance as contact allergens.⁹ It remains to be seen how quickly regulations will be updated to reflect updated data on current and emerging contact allergens.³²

PARAPHENYLENEDIAMINE

Contact dermatitis to hair dye is a widely recognized clinical problem. Aromatic amines such as paraphenylenediamine (PPD) and paratoluenediamine are common causes of allergic contact sensitization leading to severe dermatitis with facial edema. PPD and other phenylenediamines

in cosmetic products are for application to hair only and not to skin.

A review of the literature suggests that contact allergy to PPD may occur in 0.1% to 2.3% of the general population.³³ Sosted and colleagues³⁴ conducted an interview-based study of 4000 Danish adults, with a median age of 16 years at first exposure and found that 74.9% of female respondents had dyed their hair at some time compared with 18.4% of male respondents. In this study 5.3% of individuals reported an adverse skin reaction consistent with that of an allergic reaction to the dyes.

Another cohort study of 2545 individuals from Thailand's general populous concluded that 2.3% had an allergic reaction to PPD on patch testing. Five hundred nine patch-test negative individuals who then used hair dye for 6 months were compared with a control group of 514 who did not use hair dye during this same 6 month interval; the study found that 1% of individuals who used the dye reacted to PPD.³⁴

Data from these various studies highlight the importance of phenylenediamines as a contact allergen globally and affirm that it should continue to be included among standard series of contact allergens.

Hairdressers are commonly affected by occupational skin diseases (OSD) as a result of their repetitive exposure to water, shampoos, hair dyes, and other allergens. In hairdressers ICD predominates over ACD. Hand dermatitis is endemic among workers, hairdressing ranking in the top 5 occupations associated with OSDs in some European studies. Though the actual prevalence of OSDs is difficult to determine some estimates are as high as 50% with skin pathology beginning as early as the first year in this profession. Studies show that apprentices are disproportionately affected. An Australian study showed 97% of hair dressers affected with OSDs were apprentices; a study preformed in London showed that 30 of 33 junior hairdressers had hand dermatitis. This disproportionality is thought to reflect the large amount of wet work done by apprentices. OSDs are considered "part of the job" for hair dressers.³⁵ With regard to skin changes, irritant changes tended to occur early, whereas sensitization had a tendency to occur later in their careers. Cutaneous adverse effects to PPD are significantly more prevalent in hairdressers than in the general population.

PPD was prohibited in Germany in 1906 and in the middle of the century in Sweden and France. The EU Cosmetics Directive allows PPD in hair dye products with a concentration limit of 6%.³⁶ Hair dye allergy remains a problem in Europe.

In 1933, more than a dozen women were blinded and 1 woman died after using permanent mascara—Lash Lure which contained PPD. This was the first product seized under FDA authority. The FDA Act of 1938 prohibited marketing of hair dyes for eyelash and eyebrow tinting. An eyelash dye containing PPD is still marketed in Europe.^{18,37}

Dermatologists have advocated that PPD in black henna tattoos be regulated in the United States particularly for children. The American Contact Dermatitis Society, The Society of Pediatric Dermatology and the Advisory Board of the American Academy of Dermatology advocate against the use of PPD in these tattoos.³⁸

METALS

Metals and metal salts are a frequent cause of ACD because of the repeated and sometimes constant contact with the skin. Metals may also cause urticaria and an acute hypersensitivity with respiratory symptoms.

Metals such as nickel (Ni) and mercury (Hg) have long been a recognized cause of ACD. Chromium (Cr) and cobalt (Co) are also widely known causes of ACD. Recently gold (Au) and palladium (Pd) have become more accepted as patch test allergens.³⁹ Many metals produce *in vitro* production of both Th1 and Th2 type cytokines in peripheral blood mononuclear cells in patients with patch test reactivity to the same metal.⁴⁰

Hg-induced ACD was reported as early as 1895. Hg compounds are readily absorbed through the skin when applied topically and accumulate in the body.⁴¹ FDA regulation of Hg compounds in cosmetics limits them to cosmetics applied to the eye area, at a concentration which cannot exceed 65 ppm.⁴¹ Use of Hg compounds is only permitted when no alternative is available.⁴¹ Chemical forms of Hg that are known to cause sensitization include phenyl mercuric salts, Hg from broken thermometers, and organic forms such as thimerosal and merbromin. Cross-reactions between inorganic and organic forms have been reported. Thimerosal is the most common form of Hg that causes ACD. Thimerosal can be found in numerous topical medications, cosmetics, and is a declining preservative in vaccines. Dental amalgams also contain Hg, occasionally leading to localized oral lichenoid reactions.⁴² Although patch test reactions to thimerosal are frequently encountered, a careful history will often show that the positive result is not related to the current dermatitis of the patient.³⁹

Cobalt (Co) is essential to animal life; it is the main component of vitamin B12. Co is abundant

in the environment. Industrially it is used in an alloy with Ni, chromium, and iron. Additionally its oxidized form is found in many paints and pigments. Exposure to Co is mainly found in those who wear costume jewelry and individuals who have occupations such as cement working and bricklaying.³⁹ Many patients with an allergy to Co are also allergic to Ni; it is thought that this is co-sensitization. As a result of this co-sensitization, allergy to either metal will be heightened if a patient is sensitized to the other.⁴³

Pd is becoming an increasingly popular metal in the jewelry industry; in part because of the popularity of white gold which may contain up to 20% Pd. Pd is also used in dental alloys, telecommunications products, and temperature solders. In metal patch testing series Pd is tested as palladium chloride 1% in petrolatum. Allergy to palladium chloride has been documented but in almost all cases patients reacted to another metal, causing most authors to feel that the initial positive result is a cross-reaction.⁴⁴ Although the incidence of patients reacting to Pd is increasing, it is difficult to discern the relevance of Pd sensitization.

Metal-induced ACD can be reduced through stricter government regulations, avoidance, and patient education.

Nickel

Ni is the most common cause of metal-induced ACD. Ni is a component of many different types of metals including white gold, Ni plating, gold plating, Monel solder, and stainless steel, making Ni extremely difficult to avoid.

The North American Contact Dermatitis Group consistently ranks Ni the most frequent allergen causing positive patch test reactions. Ongoing efforts to diminish the amount of Ni in products that are in direct and prolonged contact with skin have led to an increase in the use of other metals in alloys used in jewelry, dentistry, and orthopedics.⁴⁰ This effort may lead to an increase in ACD to other metals.⁴⁰

The incidence of Ni allergy is more in women; this is attributed to increased prevalence of ear piercing and the donning of jewelry.⁴⁵ Allergy to Ni may predispose individuals to hand dermatitis. One literature review stated “previous or concomitant Ni sensitivity also appears to worsen the prognosis somewhat” of hand dermatitis.⁹ ACD to Ni is a significant dermatologic problem in most of the world.

The Nickel Directive was adopted by the EU in 1994, prohibiting trade with products that released more than 0.5 μg per cm^2 per week of Ni. Denmark and Sweden limited Ni in objects in contact with

the skin in 1989. Reduced sensitization to Ni among Danish children and German women younger than 30 years has been reported subsequent to these regulations^{4,46,47} In contrast, 6% of children's clothing fasteners still contain Ni in the United States and may be a source of sensitization to Ni for young children.⁴⁸

Latex

In 1989 the FDA was alerted to adverse reactions to natural latex medical devices.⁴⁹ Two years later the FDA issued a Medical Alert to the medical community on the problem of natural latex allergy. The agency issued guidance for protein content labeling for medical gloves in 1995. The FDA has yet to approve a latex skin testing reagent, so in vitro tests remained important for the diagnosis of latex allergy in the United States. Latex skin testing reagents have been available in Europe for years and are regarded as the preferred method to diagnose latex allergy.⁵⁰ In 2000 the European commission recommended that the contact of proteins in rubber latex gloves be reduced mainly by leaching.⁵⁰ Manufacturers were also encouraged to reduce the content and use of thiurams, which are considered to be the most frequent contact sensitizers in rubber gloves. Subsequently the frequency of sensitization to thiurams has declined in Denmark from 1995 to 2004.⁵⁰

PATCH TESTING

The only FDA approved patch test system in the United States is the Thin Layer Rapid Use Epicutaneous Test which consists of 29 allergens. The lack of other FDA approved antigens for patch testing is a concern for American but not European physicians performing patch testing.⁵¹⁻⁵³ The rationale for the stringent requirements of the FDA for patch testing allergens is obscure^{54,55} and may lessen the enthusiasm of American dermatologists for more regulations related to contact dermatitis testing.

The FDA "Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test" provides guidance to applicants on the content and format of the chemistry, manufacturing, and controls. "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use" (revised Form FDA 356h) is required for an allergenic extract or allergen patch test. This action is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiatives and the FDA Modernization Act of 1997, and is intended to

"reduce unnecessary burdens for industry without diminishing public health protection." As part of the application for patch test allergens the manufacturer must provide a manufacturing flow chart, floor diagram of the general layout of the facilities, and a comprehensive list of all additional products that are manufactured or manipulated in the areas used to produce the drug substance that is the subject of the application.

OCCUPATIONAL SKIN DISEASES

There are at least 14 federal regulations and 3 agencies that are involved in the regulation of occupational skin exposures in the United States. The Environmental Protection Agency (EPA) requires reporting of health effects information on chemicals. The Toxic Substances Control Act requires manufacturers and distributors to provide toxicity data to the EPA. The EPA maintains a chemical substance inventory of thousands of chemicals employed in commerce. The employer is required to provide on the material safety data sheets (MSDSs) or alternate form of warning the measures such as protective clothing that are required to control worker exposure. The EPA has the authority to ban hazardous chemicals for certain uses. The EPA is mandated to control the use of pesticides, including use of personal protective equipment and safe use of pesticides.

The Occupational Safety and Health Administration (OSHA) is part of the Department of Labor and has the most direct contact with workplaces in the field through its field inspection compliance activity which is directed at the reduction of workplace injuries and illnesses.

OCCUPATIONAL CONTACT DERMATITIS

OSDs may be caused by biologic, chemical, and physical insults. The most common manifestations of OSDs are ICD and ACD. The dermatologist's role includes not only diagnosis and treatment, but also determination of the etiologic agent and prevention of future occurrences. The National Institute for Occupational Safety and Health (NIOSH) offers an occupational dermatoses program and photo library for physicians on its Web site: <http://www.cdc.gov/ocderm.html>.⁵⁶

Epidemiologic data show that contact dermatitis is the most common OSD, making up 90% to 95% of all reported cases. The US Bureau of Labor Statistics conducts approximately 160,000 annual surveys of employers from private industries in the United States and tabulates all occupational skin disorders.^{57,58} In 2006 the incidence of skin diseases was reported to be 4.5 per 10, 000

full-time workers. Questions that can assist in the diagnosis related to occupation include: (1) Are there workplace exposures to potential cutaneous irritants or allergens? (2) Is the clinical appearance consistent with contact dermatitis? (3) Is the anatomic distribution of dermatitis consistent with cutaneous exposure in relation to the job task? (4) Is the temporal relationship between exposure and onset consistent with contact dermatitis? (5) Does the dermatitis improve away from exposure to the suspected irritant or allergen? (6) Are non-occupational exposures excluded as probable causes? (7) Do patch tests or provocation tests identify a probable causal agent?⁵⁹

Avoiding future contact with offending substances is an important aspect in preventing OCD. Other strategies in prevention include identifying irritants and allergens, subsequently substituting chemicals that are less irritating or allergenic, and using protective equipment. Additional methods to assist in prevention include emphasizing both personal and occupational hygiene, and increased awareness of potential irritants or allergens in the workplace.⁶⁰

The goal of the US Public Health Service for 2010 is to reduce national OSDs to an incidence of less than 46 per 100,000 full-time workers. This goal has been established in *Healthy People 2010: National Health Promotion and Disease Prevention Objectives*. Both ACD and ICD are considered priority research by NIOSH.⁶¹ OSDs have an important public health impact because they are frequent, often have a poor prognosis, and have a significant economic impact when affected individuals cannot continue their chosen vocation.

MATERIAL SAFETY DATA SHEETS

MSDSs are widely used across North America, Europe, and increasingly in other parts of the world to catalog information on chemical compounds and mixtures. MSDSs serve to communicate potential hazards in workplaces. They are produced by chemical suppliers and are distributed to employers who are required by law in most parts of the world to inform and train employees. MSDSs help to identify hazardous ingredients in products and their specific toxicologic properties. MSDSs provide information such as handling procedures, health effects, chemical reactivity, and first aid that helps both employees and emergency personnel to handle these products in a safe manner.

MSDSs were developed after Congress passed the Occupational Safety and Health Act in 1970 which also led to the development of OSHA. The

first major regulatory document released by OSHA was the Hazard Communication Standard (HCS). In addition to MSDS, HCS contained 5 other sections including: (1) chemical labeling, (2) hazard determination, (3) trade secrets, (4) employee training, and (5) written implementation program. Despite these regulations MSDSs have often been criticized in the medical literature over their effectiveness as a tool for workplace hazard and health communication.⁶² OSHA permits exclusion of information deemed solely by the manufacturer as not hazardous or protected as a trade secret.⁶²

American workers are more aware of MSDSs than workers in other countries where MSDSs were not regulated until more recently.⁶² The preparer of MSDSs is required to update the MSDS if he/she becomes newly aware of any significant information but there is no requirement to actively review the literature for new information on health effects of ingredients.⁶³

In Australia, sensitizers present at a concentration of more than 1% and irritants present at a concentration of more than 20% must be listed on the MSDSs.⁶⁴ A study of MSDSs for cases of OCD in Australia found that irritants were often correctly listed but that allergens were correctly listed less than half of the time following these Australian regulations.

Sensitizers may be important causes of ACD at concentrations of less than 1% and would not be listed on American MSDSs. Data about skin sensitization are required for Canadian MSDSs. EU legislation requires that sensitizers present at a concentration of more than 0.1% be listed. Not all metal working fluid ingredients known to cause ACD are classified as sensitizers in the EU and their declaration is not required in these fluids.⁶⁵

Though research suggests that MSDS are inaccurate and usually incomplete, they are still considered vital to employee health and safety. Lack of enforcement by employers coupled with inaccuracy, incompleteness, and incomprehensibility make MSDSs inadequate as a prevention tool. Many MSDSs are written with highly technical language which many employees do not understand. In 2002 Bernstein cited 4 major limitations of MSDSs as: (1) omission of vital information regarding generic chemical names, (2) omission of potential respiratory and skin sensitizing agents that are known to induce reactions through a specific immune response, (3) failure to update current permissible exposure levels (PELs) for 212 agents that are higher than the PELs set by OSHA in 1989, and (4) failure to require documented clinical information regarding specific occupational lung or cutaneous diseases

associated with a specific agent.⁶⁶ Health care professionals and safety personnel should be aware of the multitude of problems that plague MSDSs.⁶³

When updated and properly constructed MSDSs have the potential to play an important role in evaluating patients with dermatitis that is potentially related to his or her occupation. Guidelines set forth by the US federal government do not require certain information that may be vital for the correct diagnosis. Health care professionals must be able to correctly interpret MSDSs to better treat patients with occupationally derived dermatitis.

The Globally Harmonized System for the Classification and Labeling of Chemicals (GHS) is a combined system of Safety Data Sheets and labeling that will supersede the MSDS. The GHS was established to provide an internationally agreed system for hazard classification of chemical products.⁶⁷ Hazards for chemical products are also communicated through this system to those involved with the transport of dangerous goods, consumers, emergency personnel, and employees.^{67,68} Chemicals are classified according to their physical, environmental, and toxicologic hazards. Toxicologic endpoints used include: acute toxicity, irritation, corrosivity, sensitization, carcinogenicity, mutagenicity, reproductive toxicity, and chronic or repeat dose toxicity. Goals of the GHS are to enhance protection to both mankind and the environment. Methods used in the GHS include: (1) providing an internationally comprehensible system for hazard communication, (2) providing a recognized framework for countries without an existing system, (3) facilitating international trade in chemicals whose hazards have been properly identified and assessed on an international basis, and (4) reducing the need for testing and evaluation of chemicals.⁶⁷ The GHS was formally adopted by the UN Committee of Experts for the Transport of Dangerous Goods in December of 2002. The first and second revised editions of the GHS document were published in 2005 and 2007 respectively.⁶⁸ The GHS lists sensitizers present at a concentration of more than 0.1%.⁶⁷ To date the GHS has been implemented in 65 countries.⁶⁸

ROLE OF AMERICAN ACADEMY OF DERMATOLOGY AND AMERICAN CONTACT DERMATITIS SOCIETY

The American Contact Dermatitis Society (ACDS) was born from the American Academy of Dermatology's (AAD's) Committee on Contact Dermatitis. The ACDS is a professional organization of dermatologists, allergists, researchers, and other

health care professionals dedicated to improving patient care, with regard to contact dermatitis and OSDs. Patient care is improved by promoting investigative research, stimulating and gathering information on contact dermatitis and related topics. ACDS also provides a forum to facilitate the exchange of information among health care professionals, and encourages physician courses at national scientific meetings and regional dermatology training centers.

Since its inception in 1989 the ACDS has focused on meeting the challenges of its mission through education, research and teaching, and service. A joint effort between ACDS and the Mayo Foundation is Contact Allergen Replacement Database to enhance patient education. This database allows ACDS members to customize cross-reactivity of chemical groups and compose patient specific lists that are free of the patient's allergens. Dermatitis, the official journal of the ACDS highlights scholarly research and presentations from semiannual meetings. The ACDS Web site also has a wealth of information including lectures on patch testing, self-assessment questions from past issues of Dermatitis, and documentation on the diagnosis and importance of inflammatory skin diseases.

ACDS works together with the AAD to increase the awareness of contact dermatitis and OSDs. The American Academy of Dermatology Association has a legislative team to monitor and lobby on issues that specifically affect dermatology. The focus of this legislative team is on patient safety, research, Medicare reform, and scope of practice. Together the ACDS and AAD strive to improve health care policy on both a state and national level.

SUMMARY

It is essential that government, industry, and dermatologists work together to enhance regulatory methods to control and prevent contact allergy epidemics. Increased knowledge and awareness of OSDs by dermatologists and other health care professionals will assist in achieving national public health goals.

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