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May 22, 2000

Dockets Management Branch
FDA
DHHS, Room 1-23
12420 Parklawn Drive
Rockville MD 20857

RE: Docket #99P-1340/CP 1

Gentlemen:

I am writing to request that you put warning labels on fragrance products. I suffer from MCS (Multiple Chemical Sensitivity) and exposure to perfumes and other scented products worn by others cause me to have headaches, dizziness,confusion and other central nervous system problems.

The fragrance industry should be required to list all of the ingredients on their products. I think the public needs to be warned and educated on the harmful effects of these kinds of products. Many people are under the impression that these products are totally safe and harmless. See the enclosed fact sheet I got from my doctor's office which reveals some of the dangerous ingredients used in fragrance products and the harmful effects.

Sincerely,

Lynnette Ikuta

Lynnette Ikuta

PATIENT EDUCATION: SCENTS MAKE NO SENSE

By Irene Ruth Wilkenfeld
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Popular perceptions are polarized into two sharply opposing camps on the issue of PERFUMES. The aggressive advertisements of today's multi-billion dollar fragrance and cosmetics industry, have lured the "fragrance-faithful" into believing that PERFUME is their passport to a romantic, alluring, fantasy world. Growing numbers of chemically hypersensitive individuals, however, consider perfume a neurotoxic, sensitizing, potent pollutant. Obviously intended to "attract" others, perfume is fast becoming a "turn-off". ***So it's time to explode the myth of the benign synthetic scent.***

More than any other medical specialty, clinical ecology recognizes that low levels of chemicals can adversely affect the body in profound and subtle ways, that have for too long escaped widespread understanding and scrutiny. Yet, regrettably, the environmentally hypersensitive patient does not always find the clinical ecologist's office to be an oasis, free of the involuntary, unsolicited, intrusive exposures to polluting perfumes. The time has come for the clinical ecologist to capitalize on his/her unique position in the medical marketplace and lead by example. The office of an AAEM member should be a safehaven, a place to escape the seductive traps inherent in the mass marketing strategies of the fragrance industry. Environmental physicians should model responsible behaviors (related to indoor air quality), educate their patients about the health risks associated with perfumes, and uncompromisingly ***ban scents*** of all kinds from their premises.

The U.S. FDA acknowledges that the incidence of adverse reactions to perfume products appears to be increasing, as a result of the rising popularity of stronger, sweeter fragrances. Sadly, however, the consumer's ability to identify a specific problematic ingredient is complicated because the word "fragrance" on a cosmetic label can indicate the presence of up to 4,000 separate ingredients. As many as 600 separate chemicals may be used in a single formulation (ex. "Red" by Giorgio Beverly Hills), many of which are protected by "trade secrecy".

Approximately 95% of these ingredients are SYNTHETIC, in this instance, meaning that they are derived from petrochemicals. (Natural ingredients like tuberose or jasmine, cost more than $40,000 a pound. By contrast, synthetic ingredients run less than $10 per pound.) 84% of these ingredients have minimal or no toxicity data, according to the National Academy of Sciences. In 1989, from a list of 2,983 chemicals used in the fragrance industry, the National Institute of Occupational Safety & Health (NIOSH) recognized ***884 toxic substances***. Some of these are capable of causing cancer, birth defects, central nervous system disorders, allergic reactions, skin and eye irritations and provoking chemical sensitivities. And since the average consumer, daily uses some 17 to 21 different scented, cosmetic products (shampoo, conditioner, deodorant, facial soap, etc.), the task of isolating a single "trouble maker" becomes Herculean.

Perfume consists of a combination of natural essential oils and aroma chemicals, in a base of alcohol. Some of these less-than-romantic ingredients include: acetone, galaxolide, hedione, phenyl ethyl alcohol, vertofix, benzyl salicylate, linalyl acetate, benzyl acetate, ***cyclohexanol***, ***linalool***, ***methyl ethyl ketone***, methyl ionone gamma, hexyl cinnamic aldehyde, amyl salicylate, iso bornylacetate, ammonia, ***propylene glycol***, formaldehyde, ***musk ambrette*** and ***benzophenones***.

-***Cyclohexanol*** can cause inhibition of motor activity, flaccidity, spasms and death. It has a depressive action on the central nervous system.

-***Linalool*** has been shown to provoke ataxic gait (characterized by defective muscular coordination), reduced spontaneous motor activity, depression and respiratory disturbances in test animals.

-***Methyl ethyl ketone*** can induce narcosis, stupor, unconsciousness, emphysema, congestion of the liver and kidneys, eye, nose and throat irritation, and numbness of the extremities.

-***Propylene glycol*** is considered an immunotoxic chemical.

-***Musk ambrette*** can cause central and peripheral nervous system damage characterized by degeneration of myelin and selected distal axons and extreme sensitivity to sunlight, in exposed laboratory animals.

-***Benzophenones***, used to help a fragrance last longer, can cause hives.

According to the U.S. Food & Drug Administration, **fragrances are responsible for 30% of all allergic reactions to cosmetics.** Across the nation, increasing numbers of individuals are reporting symptoms linked to perfume exposure, ranging from headaches and sinus pain to anaphylactic shock and seizures. Many are now beginning to recognize the relationship between their "dis-ease" and their ongoing assault by a collage of unknown, unregulated chemicals, capriciously and gratuitously perpetuated by the fragrance industry.

In July of 1990, the Candida Research and Information Foundation (CRIF) of Castro Valley, CA, released the

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preliminary results of their PERFUME SURVEY, mailed to some 10,000 patients, physicians and health food stores. Their goal is to call for the mandatory removal of all neurotoxic chemicals from perfumes. They reported the following figures, indicative of the complaints cited by respondents to their survey:

	OCCASIONAL	OFTEN
headache	87%	54%
spaciness	81%	53%
inability to concentrate	79%	50%
mood changes	72%	43%
dizziness	66%	44%
nausea	66%	44%
short term memory lapse	63%	41%
restlessness, agitation	62%	35%
depression	62%	40%
sleepiness, lethargy	60%	40%
sinus pain	56%	38%

Mary Lamielle, President of the National Center for Environmental Health Strategies (NCEHS) of Voorhees, New Jersey, in a press release (3/27/90) supporting legislation to seal fragrance samples (in magazines, billing statements, etc.), listed the following symptoms induced by fragrances: "watery or dry eyes, double vision, sneezing, stuffiness, allergic rhinitis, sinusitis, tinnitus, dizziness, vertigo, coughing, bronchitis, difficulty breathing, chest tightness, asthma, anaphylaxis; headache, migraine, cluster headaches, seizures, convulsions, fatigue, confusion, disorientation, incoherence, short-term memory loss, anxiety, irritability, depression, mood swings; rashes, hives, eczema, flushing; muscle and joint inflammation, pain and weakness; irregular or rapid heartbeat, hypertension".

In their study, "Patients with Multiple Chemical Sensitivities: Clinical Diagnostic Subsets among an Occupational Health Clinic Population", J. Cone and Associates evaluated workers with Multiple Chemical Sensitivities (MCS). Once they became hypersensitive (as a result of exposures to pesticides, hydrogen sulfide, copy machines, carpeting, etc.) perfume was shown to be capable of provoking a recurrence of symptoms.

According to the U.S. Food & Drug Administration, 72% of asthmatics have respiratory symptoms related to perfume. Chang Shim, M.D. and M. Henry Williams, Jr., M.D., pulmonary specialists, challenged 4 asthmatics with cologne for 10 minutes. Their pulmonary function tests (FEV1) dropped by 18% to 58% below baseline. (Effects of Odors in Asthma, American Journal of Medicine, 1986, 80:18-22.) Study subjects complained of tightness in the chest, shortness of breath, wheezing, a hacking, non-productive cough and nasal congestion, within 1 to 2 minutes of cologne exposure.

In yet another study, reported by NCEHS in March of 1990, when 18 patients (diagnosed with MCS) were subjected to low levels of phenyl ethyl alcohol, at the Smell & Taste Center of the University of Pennsylvania's School of Medicine, these tests subjects exhibited changes in nasal airflow, increased respiration and an elevated heart rate.

One often overlooked mechanism involved in the neurotoxicity of perfumes concerns the LIMBIC SYSTEM of the brain, composed of the hippocampus, amygdala, and other structures closely connected to the hypothalamus. This area of the brain, which forms the rim around the cerebral hemispheres, is directly influenced by an individual's interaction with his/her environment. Any chemicals that cross the olfactory nerve projections in the nose are directly transported (along the rich neural connections that lie between the olfactory system and the temporal regions of the brain) to the limbic region, where they can activate an array of adverse symptoms. The fact that the limbic system and the hypothalamus are dynamically engaged in virtually every aspect of human physiology and behavior, makes any injury to these structures, potentially complicated and serious.

Lesions of the limbic system are associated with irrational fears, feelings of strangeness, feelings of unreality, sadness, disorientation and a sense of being out of touch and out of control. Many who are sensitive to perfumes and other chemical odors, will readily identify with and recognize these cerebral sensations, too often misdiagnosed as "agoraphobia" in the psychologist's office.

Strong odors are believed to be capable of provoking increased electrical activity in the amygdala (involved in feelings and activities related to self-preservation) and in the hippocampus (essential for learning and new memory). Problems in the hypothalamus, the analytical laboratory of the body, will be reflected in changes in body temperature, reproductive physiology, digestion, aggressive behavior, heart rate, blood pressure, immunity and possible anaphylaxis. All this suggests the existence of a direct pathway from the nose and mouth (oropharynx) to the brain, capable of triggering numerous neurological and psychological abnormalities.

In a paper entitled, "The Biopersonality of Allergies and Environmental Illness", presented at the Eighth Annual International Symposium on Man and His Environment in Health and Disease, on February 21, 1990, in Dallas, Texas, Iris Bell proposed that those suffering with Environmental Illness, seem to have an easily sensitized pathway between the nose and the limbic region of the brain. Their pathways are "more easily kindled". This would explain how a small, seemingly insignificant "insult" could result in a proliferation of symptoms and an apparent loss of resiliency or adaptability (SNOWBALL or SPREADING PHENOMENON). Once the limbic system sustains lesions, a formerly well-tolerated, low-

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level exposure to perfume, might result in a cascade of unwelcome sensations.

All this evidence makes it hard to understand the general lack of appreciation regarding the association of perfumes and illness by many conventional physicians. Bronchospasm in workers exposed to TDI (toluene diisocyanate) and certain other industrial chemicals is undisputed among doctors. But when patients complain of reactions to perfume, they are often dismissed as hypochondriacal.

A 1986 congressional committee found that there is a need to educate the medical community about the behavioral symptoms associated with neurotoxicity. This committee concluded that the National Institutes of Health, the American Medical Association and the American Psychological Association, should develop programs to train the medical community to recognize and appropriately deal with the health effects of neurotoxins. I think that, because of its unique orientation, ENVIRONMENTAL MEDICINE CAN BECOME A PIONEER IN THIS CRITICAL AREA.

The long-standing, primary medical prescription for MCS patients has been ***avoidance of incitants***. Theron Randolph's concept of an environmental unit, to achieve "comprehensive environmental control", in diagnosing and treating patients, has always involved placing the patient in a specially structured environment DEVOID of materials that outgas, like perfumes. The clinical ecologist's office should respect this approach, without exception. New patients should be alerted to a strict and enforced "unscented" policy, prior to arriving for their first visit.

The Oriental expression, ***SHIN DO FU JI***, means "Man and Earth are not 2 but 1". This should remind us all, that we cannot expect reliable diagnostic testing or therapeutic healing to succeed in a perfume-drenched, synthetic environment which stresses the body in potentially harmful ways. As a medical trailblazer in the practical prevention of perfume-induced problems, the American Academy of Environmental Medicine can add yet another unique dimension to its already long list of distinguishing, patient services. Prohibit perfumes in your practice and END SCENT SUFFOCATION.

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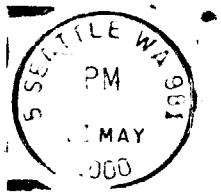

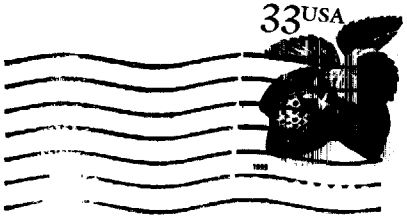

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