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Dockets Management Branch
The Food & Drug Administration
Dept. of Health & Human Services, Rm 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket # 99P-1340/CP1

Dear Sir or Madam,

On May 1999 the Environmental Health Network (EHN) submitted a petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 specifically states:

"Each ingredient used in a cosmetic product ~~shall be made~~ and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning – the safety of this product has not been determined." "

99P-1340

C683

As the petition shows, "Eternity" contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have the right to know the ~~statutes~~ status of safety testing of the ingredients in products such as "Eternity"

So that we can protect ourselves & our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrances materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain. Like tobacco smoke, the harmful chemicals in these products may affect the health of many people including: people with Asthma, chemical sensitivities, immune disorders and chronic fatigue. Children are particularly vulnerable. When I am exposed to fragrance products such as "Eternity" I experience an aggravation of an existing seizure disorder & other neurological problems such as heart arrythmia, dizziness weakness incoherence, headache, disorientation, burning skin & more. This limits my ability to go places and be around people wearing fragrances which permeate everything they come in contact with.

Please act on behalf of the millions of people who have suffered physical illness & injury as a result of fragrance exposure at work, school, or in social settings. Toxic chemicals in fragrances have already ruined countless lives.

Sincerely,

Cary Terrell

'nvironmental Access Research Network

CONTROLLED PERFUME STUDY REVEALS ADVERSE IRRITANT, RESPIRATORY, AND NEUROLOGIC EFFECTS

by Cindy Duehring

Environmental Access Profile Vol. 8, No. 8 (1998)

"Acute Toxic Effects of Fragrance Products," by Drs. Rosalind C. Anderson and Julius H. Anderson, Anderson Laboratories, Inc., West Hartford, Vermont. Published in *Archives of Environmental Health* 53(2): 138-146 (1998).

A large portion of the general population experiences adverse respiratory, irritant, or neurological reactions to the fragrances which permeate society's products. A survey of 1,027 households sampled randomly in North Carolina found 10.5% (108) of them had one or more individuals who experience adverse reactions to perfumes. In addition to the above, researchers note that "intolerance to fragrance products is also a frequent complaint of individuals who suffer multiple chemical sensitivity as a result of toxic exposure at the workplace, and exposure to pesticides or remodeling, as well as of individuals who suffer multiple chemical sensitivity of diverse etiologies."

In this study, the researchers assessed the ability of fragrance products to cause acute toxic effects in mammals using the standardized ASTM-E-981 toxicological test method to determine pulmonary (lung) irritation and sensory irritation. This standardized mouse test for the determination of potency of airborne irritant chemicals was used because it already has a large database of toxicologic information with extensive quantitative correlation between the effects of irritant chemicals on mice and on humans. The ASTM-E-981 has been recommended by other investigators as a "screening tool for the assessment of products that might contribute to toxicity of indoor air pollution via off-gassing. Inasmuch as mice are less sensitive than most humans to irritant airborne chemicals, there is little risk of false positive results." The Functional Observation Battery (FOB), a neurobehavioral screening tool similar to that used by the U.S. Environmental Protection Agency (EPA) was also employed to assess adverse neurological effects of the fragrances. These researchers used an exquisitely designed laboratory and test protocol to rule out possible confounding factors. They even ruled out possibilities of colony viral or bacterial infections through periodic testing by personnel at the Department of Comparative Animal Medicine at the Massachusetts Institute of Technology in Cambridge, plus quarterly on-site inspections by a clinical laboratory animal veterinarian.

Five fragrance products (4 different brands of cologne plus one toilet water with up to four different commercial samples of each product), were tested on 186 groups of mice, with 21 sham tests on unexposed control groups. Respiratory movement and rate were recorded with a miniature microphone for computerized evaluation and quantitative statistical analysis of the frequency and severity of respiratory effects, based on the ASTM protocol to designate criteria for sensory and pulmonary irritation. An adaptation of the computerized system was also used for a comparative evaluation of airflow limitation. A 15-minute baseline control reading was established for each animal using pure zero-grade medical air blown through the glass test chamber. Then a small vial containing cotton-tipped applicators that had been sprayed with the perfume was opened in the glass chamber where the volatilized perfume mixed with the pure medical air, was carried through the mouse exposure chamber, and was exhausted outside the bulding. After 60 minutes of perfume exposure, the mice were given another 15-minute recovery period with pure zero-grade medical air.

The testing was conducted over a three-year period in two different labs, yet the pattern of symptoms' onset and development remained consistent, and the researchers found "statistically significant acute toxic effects for sensory irritation, pulmonary irritation, airflow limitation, and/or neurotoxicity for each of the fragrance products. The doses required for these results varied from very low to very high. In many cases, we observed the effects at the lowest dose tested." The test dosages ranged from 0.05 to 3.0 grams of fragrance products. As

TO REQUEST A PHOTOCOPY OF THIS STUDY: Send $2.40 and request C68/ANDERSON (8 pp.) to EARN, PO Box 1089, Minot, ND 58702 or CIIN, PO Box 301, White Sulphur Springs, MT 59645. Due to copyright law only one photocopy of requested material per person can be provided at cost, which includes the publisher's fee. CANADA/MEXICO add $1.50. All other foreign countries add $2.50.

FOR A COMPLETE LISTING OF BACK ISSUES OF *ENVIRONMENTAL ACCESS PROFILES*: Send an S.A.S.E. to EARN, PO Box 1089, Minot, ND 58702. The entire set of profiles is available for a discounted price.

opposed to the sham controls, breathing immediately became abnormal when the fragrance was introduced, starting with initial sensory irritation gradually progressing to airflow limitation. When the exposures ceased, the breathing patterns and rate gradually returned to normal.

Using the FOB, EPA-trained technicians evaluated the animals for adverse neurological effects and injuries 15 minutes after the exposure ceased. The mean neurotoxicity score for 83 sham control mice exposed only to zero-grade medical air was 4.6. In contrast, the fragrance-exposed mice had a significant increase in severe behavioral abnormalities, with some mice scoring in excess of 100 points. Abnormal responses included altered posture, gait, and muscle tone; tremors; abnormal repetitive movements; increased responsiveness to stimuli; abnormal reflexes and grip strength; and balance problems.

Response to stimuli was "markedly exaggerated in most fragrance product-exposed mice. The following repetitive phenomena occurred: severe lip smacking; eye, ear, or tail twitching; and rapid circling around the cage, oblivious to obstructions (e.g., other mice). Technicians documented many extreme examples of these abnormalities in video recordings. Many of the observations met statistical significance at the .01 or .001 levels, according tot he Z test for comparison of two groups. Some mice developed facial edema [swelling], piloerection [hair erection due to stimulation and contraction of certain muscles], localized cyanosis [slightly bluish, grayish, slate-like, or dark purple discoloration of the skin due to presence of abnormal amounts of reduced hemoglobin in the blood — which could conceivably have significance for possible porphyric effects of the chemicals, as disrupted porphyrin metabolism results in disrupted heme production which can lead to reduced hemoglobin in acute attacks], severe lacrimation [tearing], exopthalamus [abnormal protrusion of the eyeball], severe vocalization, paralysis of one or two limbs, coma, convulsions, or death. Overall, five mice died in the 186 experiments with five fragrance products. The mice died in response to exposures to high sample weights of fragrance products #2, 3, and 4....No deaths occurred among the 123 sham-exposed animals."

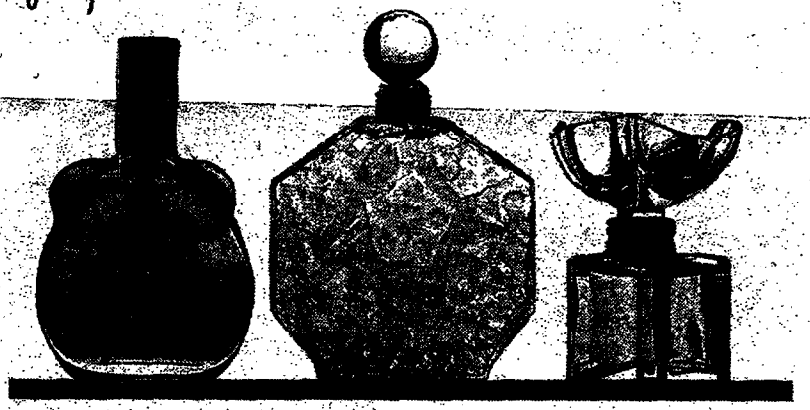
Repeat exposures (two per day for two days with a minimum of two hours between exposures) produced no increased symptoms in sham controls, but caused increased neurotoxicity after each fragrance product exposure, indicating the possibility of "so component of increasing sensi ity to the fragrance product en sions, perhaps even tin dependent sensitization." The searchers stated, "We believe tl these behavioral changes flected toxicity in selected areas the nervous system, rather th nonspecific effects (e.g. gene anesthesia, anoxia), becau some functions were decreas whereas others were unchange Also, no evidence of significa anoxia was present. "It is n known just how much one ca extrapolate neurotoxicity da from mice to humans. In senso irritation and pulmonary irritatio tests, we deal with direct intera tions of airborne chemicals wit receptors on cell surfaces, bu with neurotoxicity we are presum ably dealing with a much mor complex process. Some toxin might be absorbed into the circu latory system and distributed t the nervous system via blood Some chemicals can enter th nervous system apparatus, an metabolites of some commor volatile organic chemicals accu mulate in the nasal mucosa. The deaths observed in a few of these mice merely represented severe effects; they did not constitute any basis for extrapolation of the death phenomenon per se to man. The mechanism for these deaths in our study was unclear."

Inhalation excitotoxicity, or excess excitatory neurotransmitter firing from chemical stimulation of the olfactory nerves, can also cause a variety of specific neurologic effects, and in extreme cases can also produce convulsions. Previous challenge inhalation research with objective quantitative electroencephalogram assessment of cognitive evoked potentials (otherwise known as event-related potentials) has confirmed this process is at work in patients with MCS, and neurologic impairment

Halifax raises stink over heavy users of perfume in public, on job

Aug 2, 1999 Mn Star Tribune

By Larry M. Greenberg
Wall Street Journal



Perfume sales have dropped sharply as a result of Halifax's campaign against the use of strongly scented products in public.

HALIFAX, NOVA SCOTIA — The perfume industry's worst nightmare is unfolding in the scenic port city of Halifax.

A school sends a substitute teacher home to shower off her perfume before she can return to work. Hospitals order patients to towel down if they're too heavily scented. A church asks parishioners to leave their "fragrant offerings" at home.

The fight against perfumes and scented products is a small but impassioned one. And nowhere else has it advanced quite as far as in the seaside provincial capital, population 350,000. Most of Halifax's public institutions, and a growing number of its private businesses, come right out and ask people to abstain from using perfume. Some even require that they be "scent-free."

"Wow. They're way ahead of us," said Claudia Miller, associate professor of environmental and occupational medicine at the University of Texas Health Science Center, in San Antonio, and coauthor of a book on chemical sensitivities. Halifax "is doing something that's beyond what any other community is doing."

The incidence of environmental illness and chemical sensitivities hasn't been widely studied, but anecdotal evidence suggests some asthma patients and others do suffer respiratory reactions to chemicals in perfume and other scented products.

Wider response

While only a smattering of schools, clinics and other public buildings in the United States have acted on calls for scent-free environments, there has been a wider response in Canada. In Ottawa, for example, public buses ask riders to leave scents at home. A high school outside Toronto is going fragrance-free.

In comparison, Halifax, perched on the edge of the continent and hit by a steady sea breeze, has become fixated on smells. At the Rebecca Cohn Auditorium, home to Symphony Nova Scotia, signs in the lobby request that patrons make it a fragrance-free evening. The Halifax Chronicle-Herald newspaper prohibits its 350 employees from using perfume, after-shave, scented deodorant, shampoo and even strong-smelling mouthwash on the job. Andrea Garson, the newspaper's personnel manager, said, "It's no different from a business' vacation policy. Either you abide by it or you don't work there."

Antifragrance policies are the norm at most of the city's workplaces, said Alexander Ross, a top manager at the Halifax operation of Convergys Corp., a Cincinnati supplier of telephone customer-service. Within a month of opening the 1,400-employee center last fall, Convergys declared it a scent-free environment, acting on a request from several employees.

Reminders pop up on computers when employees log on, and warning signs are posted in restrooms. Violators are sent home to take a shower, on unpaid time.

Why have Haligonians so readily embraced the antifragrance movement?

There are a few theories. One is what Canadians generally see as their greater willingness to sacrifice individual rights for the public good — especially as compared with, say, Americans.

Another possibility is a frightening incident in 1991 that few people in Halifax have forgotten: Hundreds of staff members at the Camp Hill Medical Centre fell ill from what was widely regarded as poor indoor air quality.

The hospital says it doesn't know what caused their sickness but acknowledges there were problems with the ventilation system, including that it was sucking in fumes from the kitchen dishwasher. It has since repaired the system. But many of the workers remain sick to this day.

Not law yet

In the years after that episode, labor unions began demanding cleaner air in other hospitals, and soon schools, government buildings and other public places began voluntarily posting fragrance-free notices. The bans, however, haven't been enacted into law.

Still, as the city's antifra forces move off the fring into the mainstream, perf are getting a glimpse o worst-case future. So fa don't like what they see.

"At first I thought it was pest in a teapot. I mean, the be serious, right?' said Patri roll, general manager of Klein Cosmetics (Canada) I Oakville, Ontario, licensee fashion designer. "Then I looking at our numbers. Ou Scotia business has certain nated and probably de which is not the case for the the country."

Maxwell Moulton, princ Halifax's Clayton Park Junic School, says students w comply with a strict fragran "If I have two kids a wee come with any smells on, busy week," he said.

Offenders are sent ho shower. About 80 percent fax schools have some f scent-free policy, accordin Halifax school board.

"You're going to have a ation that is not accustor using scented products," M said. "It will become quite not to buy them."

Retailers already can m the effects. Marilyn Peller grance manager for Mills Br an upscale apparel store city's bustling, historic dow says perfume sales have fal by about a third compare five years ago. As scent-fre cies have proliferated, she the store has shrunk its pe selling space by 25 percent.

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