INTERNATIONAL CENTER FOR TOXICOLOGY AND MEDICINE

TESTIMONY

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INFORMATION ON FUNGI/MOLD TOXICITY

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Dr. Cheung is a graduate of Loyola College in Baltimore and received his Medical degree from University of Maryland Medical School. His first residency and board certification was in Internal Medicine from University of Maryland Hospital. He later received his Master's in Public Health degree in Environmental Science from Johns Hopkins. He returned for further Postgraduate training (and received his second board certification) in Occupational Medicine from Thomas Jefferson University in Philadelphia. After completing his first medical residency, he worked in the Emergency Department setting (full time and part time) for eight years and since beginning his training at Johns Hopkins has been working full time in Occupational and Environmental Medicine for the last ten years.

From June 2000 to December 2003, he was designated as the State Medical Director for the State of Maryland agencies and State employees and in that capacity has worked closely with the State of Maryland (and local municipalities and many large corporations) in building a safe, healthful and productive workplace. Dr Cheung's subspecialty is Indoor Environmental Quality/ Risk communication/ Medical Advisory services. He has worked collaboratively with management, employees, unions, other environmental professionals, parents and other stakeholders. He has experience working on issues of Indoor Environmental Quality focusing on molds and microbial issues in commercial buildings, manufacturing plants, schools, and various public and residential facilities.

Notably**, Dr. Cheung was on the Governor's Task Force on Indoor Air Quality**. The multidisciplinary Task Force met for ten months reviewing the latest literature, data, testimonies of experts and patients, best practices, etc and generated a set of recommendations to the Governor and the State Legislature on July 1st, 2002.

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INFORMATION ON FUNGI/MOLD TOXICITY

Molds have been around since the beginning of time. The many health effects have been known for decades if not centuries. Even the Bible/ Old Testament refers to this issue (Leviticus). Molds are the most typical form of fungi found on earth, comprising a very large percentage, approximately 25%, of the earth's biomass. Other fungi include yeast and mushrooms. Molds are ubiquitous on our planet and play a vital role in the earth's ecology by decomposing organic substances necessary for sustaining plants and animal life. Molds reproduce via spores. All mold needs to germinate and grow is a readily available food source, water and time. Molds are incredibly resilient. The spores are able to travel through the air, capable of resisting dry, adverse environmental conditions, and hence capable of surviving a long time. Aside from their essential role in aerobic decomposition, fungi are used in foods such as cheese, soy sauce and wine. At least 120 important pharmaceutical agents have been derived from fungi including penicillin, cyclosporin, ergotamine and chemotherapeutic drugs.

Floods, leaking pipes, leaking windows, and leaking roofs are all potential sources of moisture that can lead to mold amplification. Prolonged increased ambient humidity, e.g., inadequate ventilation, inadequate conditioning of air, improper drying of flooded areas, etc, can also lead to mold growth. Lifestyle choices such as overpopulating a residence, keeping a house closed up without running A/C or a dehumidifier, a hot tub inside the house without an adequate exhaust, the presence of multiple indoor houseplants and poor housekeeping habits can also lead to mold growth.

In a well constructed home without water contamination, the level of airborne indoor fungi generally are a reflection of outdoor sources. Indoor sources such as plants, pets, and molds carried on footwear and clothing can also contribute to indoor levels. There is even a known relationship between the number of children and the amount of mold. Thoroughness of house cleaning and the presence of sink traps such as carpeting can also affects these levels. Mold is everywhere. Every piece of lumber, plywood, pressed wood, gypsum board, and other materials that are used in construction is populated from the onset with mold. This does not pose a problem unless a source of moisture facilitates proliferation of the dormant spores. Outdoor concentrations vary widely by geographic location and can vary significantly depending on the seasons, temperature changes, humidity, wind, and time of day. Mold counts as high as over 50,000 spores/ M3 (cubic meter of air) and over 555,000 spores/ M3 have been noted in the outdoor environments of St. Louis, Missouri and Santa Barbara, California respectively.

Studies of air concentration differences revealed an average exposure concentration of 120 million spores/ M3 in farms with no complaints. Indoor concentrations in spawning sheds on mushroom farms have been reported to be as high as 100,000 spores/M3. Commercial composting activities have yielded airborne concentrations of mold greater

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than 8 million spores/ M3. This is in contrast to data found in a large study of 9619 indoor air samples/ concentrations across the Country where the average is noted to be only in the tens and hundreds CFU (colony forming units)/ M3. The highest level found was noted to be approximately 13,000 CFU/M3 (Shelton et al). A review by Gots, Pirages and Layton of 31 studies (with 820 residential units) that included ambient indoor and outdoor air concentrations found an average indoor level of 1252 CFU/ M3.

Medical Issues:

A small percentage of people may experience symptoms such as mucous membrane irritation, runny nose, and upper airway congestion when exposed to excessive mold growth in a building. Less common symptoms such as breathing difficulties may also occur. The types and severity of symptoms depend in part on the types and extent of the mold present, the extent of the individual's exposure, and the susceptibility of the individual (for example, whether they have pre-existing allergies or asthma). In general, excessive exposure to mold may produce health problems by several primary mechanisms, including: (1) allergy or hypersensitivity, (2) irritant effects, (3) infection, and (4) toxic effects. The first three of these mechanisms have been known for decades or are transient in nature and because of time constraints, will not be addressed in my testimony this evening. I will be happy to take questions on them later if we have time.

Toxic Effects or "Toxic Mold"

The term "Toxic Mold" is not a scientific term. More on that later. Recently, there has been increased concern related to exposure to specific molds, which produce toxic substances called mycotoxins. Mycotoxins are secondary metabolites that may be produced by molds under the right temperature, the right nutrient source, the right amount of water and other right conditions. Isolation of mycotoxins in laboratory conditions does not necessarily correlate with production by the mold in the environment. Currently, over 350 mycotoxins have been identified.

In 1994, a series of events took place that shifted the public's perception from generic sick building syndrome to toxic mold threat. In Cleveland, Ohio, 10 infants became seriously ill with pulmonary siderosis and hemorrhage, 2 of whom died. The Center for Disease Control and Prevention (CDC), which conducted two studies on this issue at the time, initially concluded that there was a linkage between inhalation of Stachybotrys mycotoxin and one cluster of cases. However, the CDC was not able to confirm or report this association in the second study. In further review of the first study, the CDC's internal panel of reviewers concluded that there was insufficient evidence of <u>any</u> association between exposure to Stachybotrys or other toxic fungi and the infants' conditions. An external panel of experts also reviewed the study and again concluded that there was insufficient evidence of an association. Despite this retraction by the

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CDC, the concept of “toxic mold” was here to stay. Of course, the retraction never made the news.

What do we know about mycotoxins? Mycotoxins have been known to induce animal and human disease by way of ingestion of contaminated feed. Disease of trichothecene toxins initially were reported in Eastern Europe and Russia, where clusters of Stachybotryotoxicosis occurred in individuals who had contact with grain or hay and who lived in areas where Stachybotryotoxicosis was enzootic in horses. The condition occurred in individuals who were malnourished and who had consumed at least 2 KG of contaminated grain. The condition was characterized by pharyngitis, chest pain, dermatitis, epistaxis and leukopenia. Diseases of horses and pigs have been attributed to mycotoxins. Many mycotoxins when tested are toxic to animals but have no effects on humans, e.g., those produced by *Penicilium Roquforti*, the mold that makes Roquefort and blue cheese.

In 1987, a cluster of gastroenteritis secondary to ingestion of bread contaminated with Aspergillus and Fusarium occurred in India. Several mycotoxins were isolated from samples of the wheat. A similar outbreak occurred in China after ingestion of contaminated rice. These outbreaks were related to ingestion of heavily contaminated grain, which resulted in exposure that is many orders of magnitude above any inhalation that might occur. Mycotoxins are found in spores, which are ubiquitous, therefore, all of us are exposed to some level of mycotoxins on a daily basis. They are also found in many food sources including, meats, dairy products, fruits, juices, cheese, wine, cereal, wheat products, etc. The FDA allows certain levels of mycotoxins in our foods, e.g., peanut butter, wheat, etc.

Why is the concept of toxic mold a misnomer? In science, all substances can be toxic at the right dose. For example, salt or water can be deadly if the dose is sufficiently high. Just because the mold can produce this secondary metabolite, the mycotoxins, absent sufficiency of dose are not toxic. We have to be exposed and then absorb the right dose. Keep this concept of dose and toxicity in mind. Mycotoxins are low molecular weight compounds that are not volatile, that is, they do not vaporize or “off-gas” into the environment, nor do they migrate through walls or floors independently. Spores are the vehicles for transport and, thus, inhalation.

For mycotoxins to have human health effects, there must be an actual presence of the mycotoxin, a pathway of exposure from source to susceptible person, and absorption of a toxic dose over a sufficiently short time period. To analyze this, we know how much mycotoxin a spore can maximally carry. Extrapolating from animal data on certain Stachybotrys mycotoxins, we can calculate the equivalent air concentration that is required to produce the dose that was instilled into the more sensitive study animals, mainly rats, mice and guinea pigs. The calculated airborne equivalent concentration in humans is upwards of millions to 10 billion spores/ M3. These concentrations are

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improbable and inconsistent with reported spore concentrations. For example, the observed airborne concentrations in a large nationwide investigation of 9619 indoor samples from 1717 buildings, when Stachybotrys was detected in indoor air (6% of buildings surveyed) the median air borne concentration was 12 CFU/ M3 (95% CI 12 to 118 CFU/ M3).

We know that the FDA allowable level of Aflatoxin, a mycotoxin produced by Aspergillus, is set at 20 ng/ gm of food material. From this we can extrapolate the number of airborne spores that would be required to deliver that level of allowed Aflatoxin. It is upwards of 10^{8} in spores/ M3. Another mycotoxin, Deoxynivalenol or DON, is permitted in consumable wheat products by the FDA at 1000 ng/ gm. By the same method of calculation, we would need an air concentration of 10^{10} (10,000,000,000) spores/ M3. Reviewing these numbers, one can see that it is extremely improbable to develop mycotoxicosis from inhaled airborne mold found indoors. In other words, using what is permitted for human consumption, the level of mycotoxins permitted in food are hundreds of millions of times more than could ever be in indoor air. It is illogical to allege that developing mycotoxicosis from breathing indoor air with mold spores in the hundreds or even thousands but not from vastly higher normal daily food intake.

Using human data, we are aware of a number of studies in which individuals were treated with Diacetoxyscrirpenol, a potent mycotoxin, for chemotherapy. These individuals were given a huge dose (4 gms) and did not develop symptoms of mycotoxicity. Calculating the airborne concentration that would deliver this dose would result in a number exceeding both of the above examples, making it almost impossible to achieve from an airborne source.

Epidemiologically, there have not been reports of toxic mold symptoms related to activities such as gardening, camping, logging or mushroom growing where the mold concentrations are significantly elevated. Many articles that allege toxic mold effects suffer from plausibility & validity issues. Many did not consider other factors, did not document levels of exposure, offer no pathway for exposure, or explanation for why no Stachybotrys (the alleged toxic mold) was found in some of the households or could not explain why one gender (men) may be more affected than others. Page and Trout at the National Institute of Occupational Safety and Health (NIOSH) branch of the CDC conducted reviews of the literature and focused on the potential role of Stachybotrys mycotoxins in building related illness. Thirteen articles were analyzed, and the investigators concluded that there was inadequate evidence to support a causal relationship between symptoms or illness among building occupants and exposure to Stachybotrys mycotoxins.

In summary, numerous health claims of mycotoxicity are inconsistent with basic toxicological principles. They have also come under intense medical/ scientific scrutiny

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with numerous critical review articles and consensus papers. It's not that mold never has a health impact; rather, the health claims explosion and public worry far exceeds either provable or likely illnesses. The misperceptions of mold hazards are often a more important solution driver than the risks themselves. These fears can be very expensive and may lead to evacuations, building material deterioration, property damage, breaking of leases and lawsuits or other legal claims. They can also be, and often are, exacerbated by thoughtless or unknowledgeable "professionals."

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