Humidifiers Increase Moisture... And Sometimes Bacteria
High-Tech Tools for Food Safety Sleuths
The need for speed in identifying bacterial food contaminants has spawned new techniques such as a DNA probe that FDA scientists developed. Other high-tech tools help analyze food for harmful chemicals.

Ovarian Cancer: Early Detection Elusive
Early detection of ovarian cancer is hard because it seldom produces identifiable symptoms, and pelvic exams may not be any help in determining if ovaries are diseased. Tumor markers and diagnostic ultrasound may aid diagnosis.

FDA Keeps Antennae Out for Insect Fragments
If you can identify the antenna or mandible, you'll know what insect is infesting the food, according to food specialists whose daily task it is to make sure adulterated products never reach the consumer.

New Treatment Lessens Threat of Kawasaki Syndrome
The early signs of Kawasaki syndrome may mimic those of less serious childhood maladies, but left untreated it can be life-threatening. FDA recently approved use of a biologic to prevent coronary artery problems that can result.

Coping with Connective Tissue Diseases
Medications help people manage this group of often painful and life-disrupting disorders, including scleroderma and lupus. Possible causes may be defective genes, hormone overproduction, and environmental agents.

Humidifiers Increase Moisture—and Sometimes Bacteria
Will using a humidifier indoors in winter improve your health? Some experts say the devices make colds less frequent (or at least less bothersome); others point out they're a potential breeding ground for bacteria.
Washington Man Charged
In Sudafed Tampering

Federal agents arrested a 31-year-old Olympia, Wash., man charged with putting cyanide into Sudafed 12 Hour Capsules in a scheme to murder his wife and collect $700,000 on her insurance policy.

The arrest of Joseph Earl Meling, a former sales agent with Prudential Insurance Company in Lacey, Wash., on Aug. 23, 1992, followed a 20-count indictment handed down by a federal grand jury three days earlier. It capped an 18-month joint investigation by FDA, the Department of Justice, the Federal Bureau of Investigation, and local law enforcement agencies into the deaths of Stanley Frank McWhorter, 44, of Lacey, and Kathleen Ann Daneker, 40, of Tacoma, Wash., and the hospitalization of Jennifer Sue Meling, the defendant’s wife.

McWhorter and Daneker died after ingesting cyanide-laced capsules they bought at stores near their homes; Jennifer Meling survived the poisoning she suffered after taking tainted capsules.

The indictment charges Meling with product tampering felonies, which carry maximum sentences of life imprisonment. It alleges that he contaminated the Sudafed capsules with cyanide and returned them to retail stores for purchase by other consumers to conceal the motive behind his wife’s attempted murder.

Meling is also charged with mail fraud for his alleged attempt to collect life insurance on his wife, and for perjury, based on testimony he gave last year in a lawsuit filed by the Daneker and McWhorter families against Burroughs-Wellcome, the drug’s manufacturer. In depositions for the case, Meling denied possessing or using cyanide, but the indictment alleges that he bought the poison at a chemical company a few weeks before his wife ingested the tainted capsules.

FDA Commissioner David A. Kessler, M.D., said the episode holds important lessons for preventing such tragedies in the future. He stressed that federal authorities will relentlessly pursue tampering suspects, but reminded the public that since no product can be made tamper-proof, consumers must be vigilant.

“Consumers must provide the final quality check,” he said. “Be alert when taking medicine. Look at the tablet or capsule or caplet. Examine the package seal. This is simple advice, but it could mean the difference between life and death.”

(See also “Look Twice: How to Protect Yourself Against Drug Tampering” in the October 1991 FDA Consumer.)

The indictment also charges Meling with mail fraud for allegedly staging a burglary of his residence in May 1989 to collect insurance money. The insurer, Pemco of Seattle, paid Meling and his wife $8,892 in 1989, based on Meling’s claims.

FDA Proposes Banning
415 Ineffective Ingredients

To help clear America’s medicine chests of products not proven safe and effective for their stated claims, FDA has proposed banning 415 ingredients from seven categories of nonprescription drugs.
Other ingredients known to be safe, but which would not be allowed for certain claims, could be used as inactive components of some products. For example, peppermint, although not effective as a digestive aid, could be used as a flavoring agent.

Most ingredients affected by the proposal have been in use since before 1962, when a change in the law required manufacturers to submit to FDA proof of the effectiveness of new drugs as well as those already on the market.

At that time, products and ingredients found to be harmful were taken off the market. Products believed to be safe but for which there was no evidence of effectiveness were allowed to remain in use pending studies. However, if not proven effective by the time final rules issue, they will be taken off the market.

In such actions taken, FDA banned 223 ineffective ingredients from 19 product categories in November 1990, and 111 ineffective weight-control ingredients in August 1991.

**Some Tungsten-Halogen Bulbs Need Better UV Shields**

Manufacturers and importers of some tungsten-halogen bulbs in desk lamps should redesign their products to shield users from ultraviolet (UV) radiation, FDA told the firms in a letter last May 15.

The agency took this action after confirming findings in a report from Australia that the bulbs may emit significant amounts of UV radiation. This radiation can increase the risk of skin cancer and can produce sunburn in some individuals after several hours of exposure at close range.

Tungsten-halogen bulbs consist of a tungsten filament inside a quartz envelope filled with a halogen gas. They operate at high temperatures and elevated pressures. (Bulbs with envelopes permanently mounted inside enclosures with glass lenses, such as sealed-beam automobile headlights, pose little or no risk because their enclosures absorb the UV radiation.)

In its letter, FDA asked that the firms:
- design lamp fixtures to include glass or other suitable UV-blocking filters
- provide warnings in the labeling and instructions that filters removed to insert a bulb should be put back on
- provide warnings in the labeling and catalogs that bulbs only be used if they have shields that protect against both shattering and UV radiation.

Lamp fixtures whose UV-radiation emissions create a significant risk of injury are subject to regulatory action under the federal Food, Drug, and Cosmetic Act, the letter said.

**Pewter Baby Cups Recalled**

A Williamsburg, Va., pewter shop recalled two styles of pewter baby cups in August after FDA tests found leachable lead levels that exceeded the agency's safety guidelines.

Shirley Pewter Shop had sold approximately 650 of the 4-ounce cups, according to company president Shirley Robertson. Both styles of the cup have a fluted shape, hand-hammered interior, and horizontal etching at the base and lip. The style for boys (catalog No. 218) has a smooth scroll handle, while the handle on the cup for girls (catalog No. 219) has a more elaborate, scalloped design.

A child drinking regularly from these cups could suffer impaired intellectual development. If the child uses the cup several times a day, for several weeks or months, symptoms such as headaches and seizures could result. These symptoms re-
Updates (continued)

quire prompt medical attention.
For a full refund, including postage, consumers should mail the cups to Shirley Pewter, 1205 Jamestown Road, Williamsburg, VA 23185. People with questions about the recall can call the firm at (804) 229-1378.
(For more information on lead poisoning, see “Getting the Lead Out... Of Just About Everything” in the July-August 1991 FDA Consumer.)

New Scallop Labeling

New labeling for scallops should give consumers a better idea of how much of the product is water.
FDA recently met with industry representatives to discuss the use of sodium tripolyphosphate (STP) for preventing the loss of moisture (called “drip loss”) in scallops. Scallops lose a considerable amount of natural moisture after they have been taken from the water, and STP can help retain the scallops’ original weight. STP has long been on FDA’s generally recognized as safe list of substances.
However, prolonged soaking can result in scallops with excessive water, which adds to the product’s total weight. Consumers buying these water-augmented scallops end up paying for water weight.
Industry representatives agreed to develop data on the effects of using different concentrations of STP and different soaking times. FDA will take these data into account in establishing a comprehensive policy. In the interim, any scallop product with 80 percent water or more should be labeled, “X% Water Added Scallop Product.” (Scallops usually consist of 75 to 79 percent water.) Scallop products exceeding 84 percent water cannot be marketed. In addition, the labeling for scallops treated with STP should say, “Processed with Sodium Tripolyphosphate,” and the ingredient listing on the labels of these products must include water and STP (or other polyphosphates).

University Recalls One Lot Of Transplant Treatment

One lot of Minnesota Antilymphocyte Globulin (MALG), an experimental biologic used to prevent organ transplant rejection, has been recalled by University of Minnesota officials.
University officials, in a letter dated Aug. 14, 1992, instructed clinical investigators not to use the biologic in new patients, to discontinue use of lot No. 50280E, and to return unused vials to the MALG program.
MALG, a product made from horse tissue, was recalled after university officials received reports that the biologic leaked from around vial stoppers, which could lead to bacterial contamination. Officials also received reports of significant adverse reactions, including anaphylactic shock. Some side effects were fatal.
FDA and university officials recommend that patients already taking the product continue to do so because the risks of stopping prematurely outweigh the risks of continuing the regimen.
Under an investigational protocol granted by FDA in 1970, the biologic has been distributed for study to physicians in over 100 medical centers and hospitals. Clinical investigators have been given specific instructions for reporting on patients to the university. These reports will be evaluated to determine what future use of MALG should be pursued.

Little Pesticide Found in Foods

More than 98 percent of foods produced in the United States or imported either had no detectable pesticide or levels below federally permitted limits, according to FDA’s fifth annual report on its pesticide
monitoring program. The findings have improved 1 percent each year since 1990.

No detectable pesticide residues were found in 66.8 percent of all the foods sampled, and residues below the maximum federal limits were found in 31.6 percent.

Domestic samples were taken from 50 states and Puerto Rico, and imported samples from 102 countries. The foods included produce, grains and grain products, fish, shellfish, meats, and dairy products. Fruit and vegetable products together accounted for 72 percent of the domestic samples and 78 percent of the imported samples.

Among the report’s key findings:

• Of the 8,281 domestic samples analyzed, 64.4 percent showed no pesticide residues, while 34.8 percent showed residues below the legally permitted federal limits. Only 0.8 percent were found violative, either because the residue found was from a pesticide not permitted on the food or because it exceeded the legal maximum.

• Of the 9,933 imported samples analyzed, 69.2 percent showed no residues, while 28.5 percent showed residues below permitted limits. Only 2.3 percent were found violative.

The Environmental Protection Agency determines which pesticides may be used on foods. For each usage, EPA sets a tolerance level which is the maximum amount of residue of a pesticide permitted in or on a food. FDA enforces the tolerance levels except in the case of meat, poultry, and certain egg products, which are under the jurisdiction of the U.S. Department of Agriculture.


Free Hepatitis Screening

Free blood tests for hepatitis B and hepatitis C are available at hospitals across the country under a program of the American Liver Foundation.

These screening tests can identify people exposed to either virus who may not be aware of that exposure and of the possibility that they may transmit the liver disease to others.

The screening program started in 40 cities last September and will be offered in another 60 cities in 1993. To find out where the closest screening facility is, call (800) 223-0179 between 8:30 a.m. and 5 p.m. Eastern time.

Hepatitis B and C are transmitted by blood and blood products. Hepatitis B is also transmitted by sexual contact. Sometimes the source of infection is unknown. (Though it’s transmitted in many of the same ways as the AIDS virus, unlike HIV, the hepatitis B virus can survive on counter tops and on such objects as razors and toothbrushes for several days.)

Symptoms of both forms of hepatitis include fatigue, nausea, loss of appetite, and jaundice. But sometimes infection does not cause any symptoms. These illnesses can be fatal or can lead to ailments such as chronic hepatitis and cirrhosis. Hepatitis B is the most identifiable cause of liver cancer in the world.

Among the groups at high risk for hepatitis B and C are intravenous drug abusers, people who have undergone blood transfusion or hemodialysis, and health-care professionals. People who have had multiple sex partners are at higher risk for hepatitis B.

According to the national Centers for Disease Control, each year about 300,000 Americans become ill with hepatitis B and about 170,000 with hepatitis C. CDC says, however, that hepatitis B and C are two of the most underreported and underdiagnosed diseases in this country. About 30 percent of those with hepatitis B and
about 40 percent of those with hepatitis C cannot identify the source of infection.

Screening tests for hepatitis B have been available for several years. FDA approved a screening test for hepatitis C in 1990.

The American Liver Foundation screening program is being funded by the Schering Corporation, with test kits provided by Abbott Laboratories.

(See also "Hepatitis B: Available Vaccine Safe but Underused" in the May 1990 FDA Consumer.)

Directory of Rare Disease Information

The Consortium on Rare Diseases has developed a resource list for use by people with rare diseases and their families to learn about diseases, education, research, voluntary and patient organizations, and treatment and patient care. For more information about the directory, contact FDA’s Office of Orphan Products Development, HF-35, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-4903.

FDA Pubs Available

A number of FDA publications are newly available; all but one are free.

The new FDA Almanac, containing facts and figures about the agency’s responsibilities, costs $19 for a paper copy and $9 for microfiche. To order, write to the U.S. Department of Commerce, National Technical Information Service, Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161; or call (703) 487-4650. Give order No. PB92-182227. Available free are:

Five reprints from FDA Consumer’s “On the Teen Scene” series:
• Eating Disorders Require Medical Attention (FDA92-1194)
• Enjoy, Protect the Best Ears of Your Life (FDA92-1195)
• TSS: Reducing the Risk (FDA92-1196)
• Good News About Good Nutrition (FDA92-2257)
• Using Over-the-Counter Medications Wisely (FDA92-3199)

An English-Spanish bilingual brochure:
• A Health Alert For Hispanic Pregnant Woman: For Your Baby’s Sake, AVOID SOFT CHEESES; Una Importante Advertencia para las Mujeres Hsianas Embarazadas: Para Proteger Su Salud y La De Su Bebé, EVITE LOS QUESOS BLANDOS (FDA92-2256S)

An FDA backgrounder:
• Safe Use of Physical Restraint Devices (BG92-3)

To order single copies, except of the backgrounder, write to FDA, HFE-88, 5600 Fishers Lane, Rockville, MD 20857; or call (301) 443-3170. To order single copies of the backgrounder and up to 100 copies of the reprints and brochure, write to FDA, HFI-40, at the same address. Please include title and publication number with the order. These documents also may be copied without permission.

Info on Aging

Consumers can order free health publications by calling a new toll-free telephone hot line at the National Institute on Aging.

Callers may choose from more than 60 titles—including Who? What? Where?
A geneticist couples two DNA strands, one natural from bacteria and one synthetic, and forms a hybrid that positively identifies a species of food-borne bacteria responsible for causing severe illness and death. In another laboratory, a chemist, using mass spectrometry, tracks the amount of an unwanted chemical in fermented products to parts per billion.

Both are FDA food scientists working on the persistent problems caused by contaminants that sometimes creep into what we eat and drink. Often the problem is bacterial, causing rapid development of illness. Other times it's chemical, with illness occurring immediately or at some future time because of cumulative effects.

Health problems from contaminants in foods are well documented. For example, a particularly virulent species of *Listeria* bacteria causes listeriosis, a disease the national Centers for Disease Control estimates results in 1,850 illnesses and 425 deaths annually in the United States. An example of a chemical problem is the presence of ethyl carbamate, a byproduct of fermentation, in alcoholic beverages and other fermented products. This chemical has been known to cause cancer in laboratory animals.

Up-to-the-minute technology helps food scientists lessen the dangers from these and other food contaminants. (Continued)
FDA’S DNA PROBE FOR IDENTIFYING LISTERIA BACTERIA HAS BEEN ACCEPTED WORLDWIDE.

The Need for Speed

Listeria monocytogenes, the species that causes listeriosis, was the culprit in one of the United States’ most tragic food-borne illness outbreaks. In 1985, 48 people from the Los Angeles area who had eaten soft cheese contaminated with the bacteria died, and 94 others became ill.

More recently, last July food and agriculture ministries in France reported an outbreak of listeriosis that had started four months earlier. At the time of the report, there were 108 cases from all regions in France, including 21 deaths of newborn or elderly persons and five spontaneous abortions. The source of the outbreak had not yet been identified.

Serious complications of listeriosis include meningitis (brain infections) and septicemia (bacteria in the bloodstream). For pregnant women, the disease can be transmitted to the fetus, resulting in similar complications in the newborn, or miscarriage or stillbirth.

At the time of the Los Angeles outbreak, the deadly potential of the bacteria made quick identification imperative so that whatever food was causing the illness could be removed from grocery shelves immediately. But it took nearly a month using traditional laboratory methods to positively determine that L. monocytogenes had caused the illness.

Recognizing the need for a speedier laboratory technique to identify the bacterial species without sacrificing accuracy, Atin R. Datta, Ph.D., a geneticist with FDA’s division of microbiology, and his FDA associates went to work on the problem. Datta’s team developed a synthetic gene probe to positively identify L. monocytogenes, and today, food scientists can identify L. monocytogenes in only two to four days.

FDA’s DNA probe has been accepted worldwide. After researchers in France find the source of the recent listeriosis outbreak there, it is expected that they will use the DNA probe to save time in positively identifying the bacteria.

How the DNA Probe Works

All food, unless it has been sterilized and packaged in a sterile container, contains many types of bacteria. Most are harmless to healthy people, but some, like L. monocytogenes, are capable of causing serious problems. In this procedure, the Listeria class of bacteria is isolated and if L. monocytogenes is present, it can be identified and counted.

In the first part of the DNA probe procedure, Datta spreads a diluted sample of food suspected of containing Listeria on the surface of a selective agar medium (a gelatinous substance). This allows Listeria bacteria to multiply by suppressing the growth of most other bacteria normally present in many foods. Within two days, the Listeria forms colonies on the agar.

When the colonies are formed, Datta presses membrane filter paper onto the agar plates containing the bacterial colonies. This transfers the bacterial colonies to the filter paper, giving the colonies a firm support base for the next step—colony hybridization.

In hybridization, bacterial colonies on the filter paper are treated with microwaves and strong alkaline solutions to break open the cells and release the DNA, uncoupling the natural double-stranded DNA into single strands. Next, synthetically produced, radioactive-labeled, single strands of L. monocytogenes DNA (called gene probes) are added to the bacterial colonies on the filter paper.

If L. monocytogenes is present, the synthetic gene probe finds it among the natural single strands of DNA and binds with it, forming a hybrid DNA molecule. The probe has been designed in such a way that only L. monocytogenes DNA will form the hybrid molecule; other bacterial colonies will not bond to this probe. (See accompanying illustration.)

In the last step of the DNA probe procedure, Datta places a sheet of x-ray film on the filter paper holding the hybrid DNA molecules. Each colony containing hybrid molecules leaves a dark spot on the film. Because each colony has grown from a single cell, the number of dark spots tells Datta how many L. monocytogenes cells were in the original sample.

Other types of DNA probes are used in FDA labs for problems with Shigella, Escherichia coli, and other bacteria that cause food-borne illnesses. They’re all labeled with radioactive material.

Handling radioactive material is a health hazard, and disposal is a costly environmental problem. (Currently, only three locations in the United States have appropriate disposal facilities for low-level radioactive waste.) So Datta and his associates are developing and testing a method that labels DNA probes with a non-radioactive material—horseradish peroxidase.

DNA probes labeled with horseradish peroxidase could be used to detect L. monocytogenes in foods in the same way as radioactive-labeled probes. Once this technique is standardized, Datta believes it will replace radioactive probes, not only for Listeria but also for other food-borne pathogens.

A Look at Mass Spectrometry

In other FDA food laboratories, chemists use mass spectrometry (MS) to do different types of analyses. MS enables
Visible colonies of *Listeria* appear after a dilute food sample is spread on the surface of agar selective for the growth of *Listeria*.

Bacterial colonies are transferred to filter paper.

Bacterial cells are exposed to microwave irradiation under strong alkaline conditions. This treatment opens the cells, breaks the bonds of the double-stranded DNA, separates them into single strands, and fixes them to the filter paper.

Gene probes (single-strand pieces of synthetic *L. monocytogenes* DNA) are added. The synthetic strands are labeled with a radioactive compound so their presence can be detected on x-ray film.

The radioactive gene probes couple with complementary regions of the natural DNA and reform the double helices.

The filter paper containing the hybrid DNA is placed on a sheet of x-ray film.

The radioactivity from the hybrid DNA exposes the x-ray film, and dark spots appear after the film is developed. Each dark spot represents a colony of *L. monocytogenes* and enables the food scientist to know how many bacteria contaminated the original sample.

(Source: *Science of Food and Agriculture, Council for Agricultural Science and Technology*)
GC injection port—A food sample is injected through a self-sealing silicon rubber stopper. The heated injection port vaporizes the sample, turning it into a stream of molecules, and a carrier gas sweeps it into the coiled GC column.

Ion Source—A beam emits electrons that strike the molecules as they clear the GC column, producing ions. An electronic field propels the ions toward the quadrupole.

GC column—The molecules are separated here. The column is coated with a material that interacts with each molecule. The molecules pass through at varying speeds, depending upon their physical or chemical ability to stick to the material in the column.

chemists to identify organic chemicals such as dioxins, pesticides, and naturally occurring toxins. Combining the sophisticated technology of mass spectrometry with chromatographic techniques such as gas, super critical fluid, or high pressure liquid chromatography (see accompanying article), FDA chemists can identify and count chemical contaminants in food.

They do it by introducing a small amount of an extract of a food sample into...
a chromatograph, where chemical contaminants or pesticide residues are separated into individual compounds. (See diagram.) Then, in the mass spectrometer, an electronic beam bombards the separated chemicals, ionizing the molecules (giving them an electric charge) and fragmenting them.

The unique fragmentation pattern of individual ionized compounds allows the computer attached to the mass spectrometer to chart information about each and to identify the unknown chemical by comparing its spectrum, or “molecular fingerprint,” to a known substance. The system also may allow chemists to accurately measure the amount of a chemical contaminant in a sample of food to parts per trillion levels and smaller.

FDA food chemists have developed laboratory procedures using MS to identify and count many kinds of food contaminants. For example, in an MS procedure using a technique called positive ion fast atom bombardment, chemists have characterized 12 of the neurotoxins in “red tide”—algae that bloom and produce toxins. These toxins can concentrate in fish and shellfish that feed on algae blooms. If eaten, the toxin-contaminated fish can cause serious illness and death. State authorities monitor waters and close the areas to fishing immediately when red

**Data System**—This computer controls the entire GC/MS system. It regulates the temperature in the GC, tunes the MS, controls the voltages on the quadrupole, detects the abundance of each ion, and processes the data.

**Quadrupole**—Four conductive rods separate the ionized material according to their mass/charge ratio. Voltages on the rods can be set to allow ions of a particular weight to pass through and ions of the wrong weight to be pumped away by the vacuum system.

**Detector**—All ions that pass through the quadrupole are measured here. The information is then passed on to the computer that records the data and generates charts. Using data from the charts, chemists can identify and quantify unknown substances.
A PEEK IN THE TOOLBOX

FDA food scientists use a number of analytical techniques. Grouped into categories according to their function, these tools and some of their applications are:

■ Chromatography (thin-layer, gas and liquid)
  • separates complex mixtures (food extracts of various types) of similar components by measuring migration rates of component molecules through columns and through coatings on chromatography plates.
  • analyzes food extracts for pesticide residues, chemical contaminants, and natural toxins; analyzes alcoholic beverages, fats, oils, and direct and indirect food additives.

■ Spectrometry (mass spectrometry, nuclear magnetic resonance and electron spin resonance, and infrared and ultraviolet spectroscopy)
  • measures molecules or atoms of food components as they are ionized and fragmented in a magnetic field; as they are polarized in a magnetic field; or as they undergo absorption and emission of energy in irradiation.
  • analyzes food additives, food contaminants, metals, fats, and oils; confirms the identity of pesticides, natural toxins and other chemical contaminants, and food additives and flavors; assists in identifying unknown complex organic structures.

■ Radiotracers
  • measure isotopes that undergo radioactive decay but that, in all other respects, are identical to atoms normally found in chemicals.
  • study food additives, food processing, animal metabolism, and biosynthesis of natural toxins; analyze foods for radioactivity.

■ Gene probes, enzyme catalysis, antibody-antigen interaction, and immunoassays
  • depend on specific properties and interactions of substances being analyzed with antibodies, DNA fragments, and other components.
  • analyze foods for amino acids, sugars, microbial toxins, other natural toxins (e.g., aflatoxins), and pesticides.

■ Analyzers (thermal energy analyzer, amino acid analyzer, and others)
  • are specialized instruments, often automatic, that react to specific components or contaminants in food samples.

■ Electrochemistry (polargraphy, electrophoresis, anodic stripping, voltammetry)
  • separates complex mixtures of components in a food product by use of an electric force field.
  • analyzes food extracts for metals and pesticide residues; identifies preservatives, color additives, and species of fish.

■ Bioassays
  • measure responses of living organisms (from viruses to bacteria, animal cells in culture to primates) to substances being analyzed.
  • analyze food extracts for natural toxins, pesticides, nutrients, and hormones.

■ Computer-assisted analytical workstations
  • control analytical instruments by use of highly sophisticated computers.
  • monitor programs; calibrate, record and store information; maintain diagnostic control over analytical and data-gathering systems.
tide appears.

FDA field laboratories around the country regularly apply MS and other laboratory procedures to identify and measure chemical contaminants in food. The Chicago district, for example, uses MS procedures to test milk and paper milk cartons for dioxin, a chemical contaminant that could migrate into milk from the paper containers (see "Deciding about Dioxins" in the February 1990 FDA Consumer).

FDA and other government agencies have used MS research results to make decisions about food problems. In a food-related crisis in 1989, for example, FDA chemists, working with food scientists from the Centers for Disease Control, needed to identify an unknown impurity in L-tryptophan, a widely used dietary supplement. More than 1,500 persons who had taken the supplement had become ill and 39 died of eosinophilia-myalgia syndrome, a painful muscle and blood disorder. James Sphon, Ph.D., of FDA’s Office of Physical Sciences, says that before starting the isolation and identification process, the mass spectrometrists had very little information about what the substance could be.

An FDA/CDC team developed a chromatographic procedure to show trace organic components in L-tryptophan. Using this procedure, along with epidemiologic data, FDA and researchers from medical centers and industry solved part of the mystery by identifying one impurity, 1,1’-ethylenedibis-L-tryptophan (EBT), that could have been associated with the illness. Several other chemicals have been identified and through ongoing research, scientists will try to find out if these cause or contribute to eosinophilia-myalgia syndrome.

Flaws in Fermentation

FDA has also used mass spectrometry to measure the amount of ethyl carbamate (EC) in fermented products such as soy sauce, wines, or bakery products. EC, a chemical that sometimes forms as a byproduct of the fermentation process, is a suspected human carcinogen (cancer-causing agent).

The problem of carcinogens in fermented products got international attention in 1985 when Health and Welfare Canada reported that its scientists had detected EC in certain alcoholic products at levels that exceeded newly established Canadian guidelines. FDA and the U.S. Bureau of Alcohol, Tobacco, and Firearms (ATF) immediately began sampling wines and whiskeys from domestic and foreign producers to determine the levels of EC. (FDA and ATF share responsibility for regulating alcoholic beverages—FDA regulates their safety and cleanliness; ATF regulates the manufacture, composition specifications, labeling, and advertising.)

As with the Listeria situation, there was a problem of time spent in the laboratory searching for the presence of EC. Before a sample of distilled spirits could be run through the mass spectrometer, chemists had to “clean up” the sample in an unusually extensive, time-consuming procedure.

So William Brumley, Ph.D., formerly with FDA and now with the U.S. Environmental Protection Agency, developed a procedure using a more sophisticated mass spectrometer to shorten the analysis time. Brumley’s procedure not only identifies and measures EC, it also does part of the sample cleanup.

In Brumley’s approach, the MS analysis is carried a step further through an instrument called MS/MS. In this extended step, selected ions are collided with an inert gas. The impact breaks them into smaller, or “daughter,” ions. This breakdown allows a more specific identification of the EC.

This year, John Roach, an FDA mass spectrometrist, began collaborating with scientists from 20 laboratories worldwide to evaluate Brumley’s approach. The collaborative study will determine if the procedure is acceptable for common use within the scientific community.

FDA food scientists continually adapt DNA probes, mass spectrometry, and other procedures to fit the numerous types of food contaminant problems they encounter. (See accompanying article, as well as “A Day in the Life of FDA’s Food Safety Team,” in the September 1988 FDA Consumer.)

Analytical methods used by FDA have been accepted in courts of law, and studies of most have been published in peer review journals. As FDA geneticist Datta and mass spectrometrist Brumley have shown, if new approaches are needed to solve a contaminant problem, FDA scientists can be called upon to develop them. ■

Judith Foulke is a staff writer for FDA Consumer.
In 1991, an estimated 20,700 American women were diagnosed with ovarian cancer.
OVARIAN CANCER

Early Detection Elusive

by Marian Segal

This is the first in a two-part series on ovarian cancer.

She crowned herself "the Queen of Neurosis," but this time, it was not simply an overactive imagination that made her fear for her health. It was symptoms of the ovarian cancer that eventually claimed her life.

Gilda Radner, one of the original Not Ready for Prime Time Players of television's "Saturday Night Live," claimed in her book It's Always Something that she could get neurotic over any health problem. "I hated to be sick and I had an imagination that could turn a stomachache into the plague."

So, she wrote, when a complete physical examination in January 1986 failed to explain the overwhelming fatigue and general malaise she was feeling, she agreed with the doctor that her symptoms might just be from depression; she had, after all, been going through a rough period in both her personal and professional life. It wasn't until October—10 months and several symptoms, diagnoses, and failed therapies later—that cancer of the ovaries was confirmed.

Delay in diagnosing ovarian cancer is not unusual. Early detection is difficult because disease confined to the ovary seldom produces symptoms. And when symptoms do surface, they are often vague and easily mistaken for other, often minor, ailments.

Radner's cancer was not discovered until it had spread to her bowel and liver. She suffered from fatigue, low-grade fever, pelvic cramping, abdominal bloating, gas, and aches and pains in her upper thighs and legs. Loss of appetite and a feeling of fullness, indigestion, nausea, weight loss, and, less often, vaginal bleeding and low back pain are other symptoms.

As the tumor grows, it may press on the bowel and bladder, causing constipation and frequent urination. Malignant cells can break away from the tumor and spread directly to other organs in the abdomen, such as the stomach, colon and diaphragm (muscle separating the chest cavity from the abdomen), causing a fluid buildup that results in swelling and discomfort. The cells can also enter the bloodstream or lymph system and spread to other parts of the body.

Radner wrote that her complaints had been variously attributed to Epstein-Barr virus infection, depression, stress, and anxiety. She had undergone blood tests, a barium enema, and ultrasound (pelvic sonogram). According to Radner, the sonogram, done in the summer of 1986,
showed “congestion” and the “ovaries weren’t exactly in the place they were supposed to be, but that wasn’t serious.” There was no sign of tumor or obstruction.

**Aspirin to Acupuncture**

Attempting to combat her ills through both mainstream and holistic medicine, Radner tried remedies that ran the gamut from aspirin, anti-inflammatories and antidepressants to health foods, vitamins, acupuncture, and colonics (unconventional type enemas).

“Suddenly, I began to wonder how to please so many people,” she wrote. “Do I take the magnesium citrate? What about the coffee enema? Do I do both? Do I do the abdominal massage or the colonic? Do I tell the doctors about each other?”

Then, late in October, an abnormal liver function test prompted more exams. A CAT scan and analysis of fluid from the abdomen confirmed ovarian cancer.

Diagnosed at age 40, Radner was younger than most women with the disease. The chance of developing ovarian cancer increases with age; most cases are found in women 55 to 75 years old. As was true with Radner, however, women with a family history of the disease generally are diagnosed at a younger age.

In 1991, an estimated 20,700 American women were diagnosed with ovarian cancer. It is most common in women living in Europe and North America; Asian women have a relatively low incidence. Although Chinese and Japanese women living in the United States have higher rates of ovarian cancer than their counterparts in Asia, the disease is still less common among this group than among the native white population in the United States. Rates among black women in all parts of the world are low.

Certain factors are associated with an increased risk of getting ovarian cancer.

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*The late Gilda Radner (top center) puts on a funny face in 1975 with fellow “Saturday Night Live” Not Ready for Prime Time Players (clockwise) Garrett Morris, Dan Aykroyd, Jane Curtin, Laraine Newman, Chevy Chase, and the late John Belushi. (Courtesy NBC PHOTO)*
Although the lifetime risk for most women is 1 in 70, it doubles for women who have never been pregnant and women who have had breast cancer.

Women with close relatives who have had ovarian cancer are also at greater risk, reaching perhaps a 1 out of 2 chance in women who have at least two first-degree relatives (mother, sister or daughter) with the disease. This compares with slightly higher than a 1 in 10 chance in women without a family history. Radner wrote that her mother had breast cancer and a cousin had both breast and ovarian cancer. Later, it was learned that other of her relatives had ovarian cancer as well.

The Familial Ovarian Cancer Registry, established in 1981 at Roswell Park Cancer Institute in Buffalo, N.Y., included 2,144 cases of ovarian cancer in 899 families as of April 1992. Despite the familial nature of some cases, familial ovarian cancer is estimated to account for only 5 to 10 percent of the total cases.

Evidence suggests that hormones may influence development of the disease. The risk of ovarian cancer is reduced in women who have had multiple pregnancies and in those who used birth control pills. The Cancer and Steroid Hormone Study by the national Centers for Disease Control and the National Institute of Child Health and Human Services found that use of oral contraceptives for even a few months reduced the risk of ovarian cancer by 40 percent in women 20 to 54 years old.

The study, published in the March 12, 1987, New England Journal of Medicine, found that the longer a woman used birth control pills, the lower her risk of ovarian cancer, and that the protective effect persisted long after stopping the pill. Based on these data, since 1989, the labeling for oral contraceptives has included decreased incidence of ovarian cancer among the non-contraceptive health benefits of the pill.

Search for a Screening Test

According to the registry, more than 90 percent of women diagnosed with ovarian cancer while it’s still confined to the ovary are alive five years after diagnosis. Among women whose cancer has spread beyond the ovary by the time it’s diagnosed, only 25 percent survive five years. However, unlike cervical or breast cancer (which may be detected early by a Pap test or mammogram, respectively), ovarian cancer has no reliable screening test.

“The traditional routine pelvic examination, now relied on as the only screening measure available, is largely ineffective for early detection,” says Grant Bagley, M.D., an obstetrician/gynecologist in the Food and Drug Administration’s Office of Health Affairs. “Often you can’t feel a normal-sized ovary. And even if you can, it’s hard to tell if it’s enlarged because ovaries vary in size from person to person and day to day. Ovarian cancers start very small, and by the time they’re large enough to feel, the cancer is most likely already advanced.” The problem with ovarian cancer, he says, is that “you have to detect very small changes, and these are hard to detect on a pelvic exam because it’s a very indirect examination.”

Researchers are looking for tumor markers—substances that may appear in abnormal amounts in the blood or urine—that may prove useful in developing a screening test.

One marker that has received much attention recently is CA 125, a substance in the blood that is elevated in patients with advanced ovarian tumors. Doctors now measure CA 125 levels in patients treated for advanced disease to determine if the tumor has shrunk or if disease has recurred. Its value in monitoring treatment prompted scientists to study its potential for early detection.

Transvaginal ultrasound is also being studied as a screening tool. With ultrasound, high-frequency sound waves are projected into the body, and the echoes produced are converted by computer into a picture. Unlike abdominal ultrasound, in which the sound wave-emitting device is placed on the outside of the belly, transvaginal ultrasound uses a probe placed in the vagina that can reach within millimeters of the ovaries, producing more detailed images.

“There is uncertainty as to the value of these tools as screening tests and their ultimate impact on mortality,” says John Gohagan, Ph.D., chief of the National Cancer Institute’s Early Detection Branch in the Division of Cancer Prevention and Control. NCI is conducting a clinical trial including 74,000 women aged 60 to 74 to clarify the issue. The trial is designed to assess the value of CA 125 and transvaginal ultrasound for early detection of ovarian cancer and to measure their impact on mortality.

Women in the trial are randomly assigned to either a screening group or a control group of 37,000 women each. The screening group will have periodic pelvic examinations along with CA 125 and transvaginal ultrasound tests. The control group will have routine medical care.

Diagnostic Procedures

If a woman or her doctor suspects ovarian cancer, diagnosis begins with a medical history of the patient, review of her symptoms, and complete physical examination, including a pelvic exam, in which the physician feels the vagina, ovaries, fallopian tubes, bladder, and rectum to check for any growths. A Pap test may also be done because, even though it cannot reliably detect ovarian cancer, it may detect...
The Ovaries—How They Work

The ovaries are located in the pelvis, one on each side of the uterus. About the size and shape of almonds, they are made up of several different cell types. Some carry out the functions of the organ, while others provide physical support. The ovaries have two main functions:

- ovulation (the release of an egg each month)
- production of estrogen and progesterone, hormones that regulate the menstrual cycle and pregnancy and control the development of female physical traits, such as the breasts, pelvic structure, fat distribution, and body hair.

From birth, the ovaries contain the cells that eventually become ova (eggs). Each month, beginning with puberty and until menopause, hormones produced by the pituitary gland in the brain stimulate ovulation (release of an egg), which alternates each month between the two ovaries. (Not all women ovulate every month).

The egg travels through the fallopian tube to the uterus. If it is fertilized, it may grow and develop in the womb. If not, hormone changes cause shedding of the uterine lining, and menstruation begins about two weeks later.

—M.S.
While reaching over a microscope for one of several scientific handbooks, Richard Trauba, a food specialist in the Food and Drug Administration’s Minneapolis district office, says he likes to find antennae because they make his job of identifying insect fragments found in food so much easier.

“Antennae can be very distinguishable,” he says. “If you can find the antenna, you can usually nail down the type of common storage insect.”

Opening the book and pointing to a page of stalk-like stems, some resembling cattails, Trauba says: “Look at all the differences. Some look like spearheads, some like scales. It’s amazing what comes through. ‘Mandibles can also be very distinguishable,”

Trauba continues, “They can come through the milling process without being broken up.”

These very distinguishable parts Trauba extracts from food are small—microscopically so, ranging from one-fourth of a millimeter to 4 or 5 millimeters in length. When you consider a millimeter equals less than four-hundredths of an inch, that’s small.

Then, too, extracting insect fragments from foods in the first place takes considerable skill and experience. Trauba’s interest is more than academic. Working with microscopic insect fragments obtained from food products, FDA scientists are developing evidence for use in enforcing the relevant sections of the Food, Drug, and Cosmetic Act.

(Continued)
According to this law, food is adulterated “if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food or if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.”

**Taking Action**

FDA establishes food defect action levels (DALs) for various food products and various types of insects. For instance, the permissible level of certain insect fragments in 50 grams, or about two cups, of flour is 75 parts. (This is the uppermost level at which fragments pose no health hazard in the product.)

According to Paris Brickey, chief of the microanalytical branch, division of microbiology, Center for Food Safety and Applied Nutrition, Washington, D.C., insect fragments may be unavoidable in foods grown outside, exposed to a certain amount of insect contamination.

Brickey says that the amount of insect fragments permitted by the DALs is not only harmless, but “unavoidable to a certain degree. If weevils attack wheat in the field and breed in the kernels, they aren’t always removed when the wheat is cleaned, so they get ground up into the product. That’s unavoidable.”

But there are times when a product is considered contaminated even if the number of insect fragments it contains falls below the DAL. “Certain fragments come from what we classify as filth insects—such as certain types of flies,” Brickey explains. “They inhabit filthy areas, often feeding on garbage. Some feed on sores and cuts. They can carry microorganisms. We’re not held by defect action levels with these. We’ll take action.”

When there’s an unsanitary practice involved, “we look at it on a case-by-case basis without reference to the numbers,” says Brickey. In such cases, FDA scientists evaluate the type of insects as well as the size of the insect fragments.

“In a milled product, this may indicate whether the insects were of post-milling or pre-milling origin. If they were in the wheat before it was milled and were ground up with the flour, that’s one thing. If they got into the flour after it was milled, there was probably an unsanitary condition,” says Brickey.

The alternative to permissible insect fragment levels, according to Brickey, would be “food so expensive nobody could afford it.”

**Big Role for L.A.**

Trauba estimates that each of FDA’s 18 field laboratories has four scientists who regularly extract and identify insect fragments. He readily concedes a first place to the Los Angeles FDA district office, which has nine entomologists (insect specialists) on its staff.

“Los Angeles has a huge collection of fragment slides. One person works on the slide collection full time, going out to zoos collecting new specimens and things like that. They have some strange stuff out there,” Trauba says.

Los Angeles’ premier position didn’t just happen. It’s the main port of entry for foods imported from Asia, which frequently aren’t processed, packaged and shipped according to U.S. criteria.

Alan Olsen, supervisory entomologist in the L.A. district office, makes it clear that it takes much more than college courses to prepare FDA scientists to find insect fragments in food. Most of these skills are acquired on the job.

“Finding an insect fragment in food will not tell you how the fragment got there. You start with the insect,” Olsen explains, “but you also have to look at the process. We extrapolate back to find out where the fragment came from.

“Was it in the raw material, or did it come after the raw materials were first ground, or much later, after they were extruded through the noodle machine? We have to understand the process and factor it in. We have to know when the product was cooked, ground and formed.”

Olsen explains that entomologists on his staff are educated in the many stages of food processing during their early FDA days, when they accompany inspectors on their rounds. “The scientist helps track down the root of the problem while learning food processing. We’re a team.”

**Extracting Fragments**

According to Olsen, Trauba is one of FDA’s masters at the extraction of insect fragments. Trauba’s initial scientific expertise and college training was in chemistry, and extracting insect fragments from food is reminiscent of a college chemistry experiment.

Before explaining the process, Trauba emphasizes the importance of following the extraction procedures exactly as published by the Association of Official Analytical Chemists (AOAC).

He explains that the AOAC book of
Above, Richard Trauba, a food specialist with FDA’s Minneapolis district office, takes material from a food product in a Petri dish to a microscope where he will analyze it for insect fragments. Below, Trauba holds a beaker of macaroni in an acid solution that will break the macaroni into smaller pieces and break the starches down into sugars. The sugars will then be washed away so that the macaroni can be analyzed for insect fragments.
methods includes directions for separating the filth elements from many food products. “Some of the categories include dairy products, nuts, grains, baked goods, spices, pasta, cereal, egg products, seafood, jams, and jellies—there’s even a methodology for determining if there’s mouse or rat urine on the bagging.”

Sticking strictly to these methods permits foreign businesses to know exactly how their products will be tested, and the likely results once they come under FDA’s jurisdiction. It’s much the same for domestic businesses—everyone is playing with the same deck.

But the trump card for FDA and consumers in using AOAC methods, according to Trauba, is that “all the federal courts accept them as official. There’s never any question. That’s why it’s so important to use the methodology in the book.”

Since he developed the methods adopted by the AOAC for extracting insect fragments burrowed into wheat and oat kernels, Trauba speaks from first-hand experience.

AOAC methods have been around since the 1920s. One reason the courts accept the AOAC standards as authoritative is that they have been “collaborated” or verified by other labs, Trauba points out.

In the collaboration process, a product is “spiked” with a known amount of insect fragments, then sent to 10 or 12 labs throughout the FDA and industry, which conduct identical tests to verify the method. The results are statistically validated, and, if acceptable, the new method is accepted by the AOAC.

Using a packaged macaroni product to demonstrate the extraction process, Trauba makes it seem simple. First, the macaroni needs to be “digested,” as Trauba puts it—that is, broken down enough to free the baked-in fragments, allowing them to be removed.

The macaroni is added to a solution of water and dilute hydrochloric acid and then heated, under pressure, in an autoclave for 30 minutes. The heating eliminates the starches, leaving soluble sugars and carbohydrates.

Pouring hot water over the material in a very fine sieve washes away soluble matter and some, but not all, of what Trauba at this point refers to as “plant material.”

At this stage, the insect fragments are freed but not separated from the plant material. More hot water, mineral oil, and hydrochloric acid are added next. The mixture is placed in a “percolator,” a glass vessel with a drain in the bottom. The mineral oil selectively coats the insect fragments and other animal material, such as hairs and feathers. These float to the surface with the oil.

“When the aqueous phase drains, we wash the ‘percolator’ out with alcohol and drain the contents into a beaker and filter it through paper,” Trauba explains.

The fragments on the filter paper are then ready for identification using a microscope. The viewer compares the fragment with slides or pictures of known insects. Identification of the type of insect from which the fragment came often necessitates the higher magnification of a compound microscope.

Testing some food products calls for additional steps. Although it’s much the same, Trauba warns that as the number of steps in a method increases, so does the risk of losing some insect fragments. “The more mechanical things are involved, the more chance there is of losing tiny fragments. The less manipulation the better.”

Fragment examination is particularly important with imported foods. “We have
no inspection authority to go overseas to see what an industry looks like," says Brickey. "When we get an import in, we have no idea whether the manufacturing process was good or what—that's why we have to rely on the fragment count."

**Exotic Bugs**

The Los Angeles entomologists have discovered and named four new species of beetles and two new species of mites in imported foods. Olsen emphasizes that many food products from tropical areas are so different that they are not covered by standard AOAC methods.

According to Olsen, overseas manufacturing processes can be equally exotic. "This makes it necessary to modify extraction procedures to fit the problem. It is also necessary to be prepared for insect fragments that are far from commonplace," he points out.

On the other hand, Trauba is not concerned about these foreign insect fragments any more than he's concerned about domestic fragments. He says the real, everyday problems he's seen so far have been caused by common storage insects, found the world over.

Although it lacks overseas enforcement and inspection authority, FDA gives considerable attention to food imported from Asia and elsewhere. Trauba, for instance, and other FDA scientists are regularly updated on problem food imports by the agency. (See also "FDA Steps Up Import Safety Program" in the October 1992 issue of *FDA Consumer.*)

Friendly discussions with foreign governments and businesses are starting to pay off. According to Brickey, who serves as an FDA project officer working with the Philippine government, some exporters, tired of having products detained on American docks, are cleaning up their acts.

"I go over to the Philippines at least once a year to talk to government officials, lab personnel, and industry to help them improve their sanitary conditions so they can get their product into our country. . . . We've been somewhat successful. We've signed agreements with some countries."

"You now see more foreign products labeled 'for export,' or 'export quality only,' which means they've taken special care to meet our acceptance criteria. What they sell domestically is another thing."

**Prevention at Home**

Preventing contamination isn't neglected at home, either. Olsen, who works with a national pest control group, says, "I'm big on prevention. The ideal is not to have the problem in the first place."

Both Olsen and John Tisler, chief of the industry activities section at the Center for Food Safety and Applied Nutrition, point out that the voluntary prevention programs only complement law enforcement.

Says Tisler: "FDA's philosophy as a regulatory agency is that the prime responsibility to assure a safe, wholesome product that is properly labeled belongs to the food firms. FDA's job is to evaluate how well the industry is meeting its responsibility and to take the necessary action to assure that the consumer receives only safe, legal products. Voluntary activities—industry initiating preventive or corrective actions—are a parallel course."

There's even a role for consumers. Complaints from the public are taken very seriously. The worst case of insect infestation Trauba ever saw was detected thanks to a tip from a Seattle woman who found an insect part in a can of nuts with a code next to the expiration date indicating that it had been packed in Minneapolis.

Fragment analysis strongly indicated that the insect part was not a chance occurrence—that the plant itself was contaminated. When they went to the plant, Trauba and the FDA inspectors found swarms and swarms of a number of different insects. They soon found the source: When the plant had discontinued making peanut butter and switched to producing canned nuts, the peanut butter assembly line was simply turned off. Open bottles and ingredients were left where they stood causing widespread contamination of everything in the plant. FDA took action, and the plant ultimately was closed.

Bill Wagner is a freelance writer in St. Paul, Minn.
NEW TREATMENT LESSENS THREAT OF Kawasaki Syndrome

by Amy Roffmann New

Toddler with fevers? Only about as common as sand on the beach. But for toddlers with Kawasaki syndrome, fever is just one of the early signs of a very serious illness.

Kawasaki disease, or Kawasaki syndrome, is an infectious inflammatory disease that affects mainly infants and young children. At first, the symptoms—fever, rash, watery eyes, swollen lymph nodes—look like those seen with many of the bugs kids pick up all the time.

But this is no simple bug. It affects many systems in youngsters’ bodies, but damage to the heart and surrounding tissue is of the greatest concern. Left untreated, Kawasaki syndrome can damage the coronary arteries that feed the heart, possibly causing a massive heart attack. Recently, the Food and Drug Administration approved use of a previously licensed biologic, intravenous immune globulin—Immune Globulin Intravenous (Human)—to help minimize the complications of Kawasaki syndrome.

Although there have been rare reports of Kawasaki syndrome in adults, the disease primarily affects children under 5 years old, with most cases affecting 1- to 2-year-olds. The disease affects boys about 50 percent more often than girls, and seems to affect children of Asian descent at a much higher rate than children of African or European descent. “The typical patient would be a 2-year-old boy with high fever,” says Stanford Shulman, M.D., Chief of Infectious Diseases at Children’s Memorial Hospital in Chicago.

There have been three epidemics of the disease in Japan: in 1979, 1982 and 1986. According to surveys of those epidemics, 1 in 250 Japanese children with the disease died from it, and 15 to 20 percent developed heart aneurysms. These abnormal enlargements of blood vessels cause a weakening of the vessel that could burst at any time, threatening the patient’s life.

Kawasaki syndrome is not considered contagious, although outbreaks tend to occur in certain geographic regions. The disease is most common in Asia, particularly in Japan and Korea. In the United States, the incidence in children of Japanese or Korean background is four times greater than in children of European background. This link puzzles researchers. The disease is more prevalent even in Asian children with little or no exposure to the foods or customs of Asian culture.

In Hawaii, the disease is far more common among Japanese-American children. While Japanese-Americans compose one-third of Hawaii’s population, Japanese-American children account for 85 to 90 percent of the cases of Kawasaki syndrome in that state. Most of these children are third- or fourth-generation Americans with little or no Japanese cultural influence in their daily lives. These statistics appear to indicate a genetic factor that researchers are not yet able to explain.

The disease was first described by Tomisaku Kawasaki, M.D., a Tokyo pediatrician, in 1967, but wasn’t reported in English literature until 1974. Fever develops within the first few days of onset of the disease. Many Kawasaki patients experience abrupt spikes in temperature—several spikes a day for five or more days—as the disease begins. Left untreated, the spiking can continue for as long as four weeks.

A measles-like rash usually accompanies the fever, and lymph nodes in the neck swell. Conjunctivitis, characterized by red eyes and swollen eyelids, may also develop in the first few days. The lips, tongue and throat may become red and swollen. One of the most distinguishing symptoms of Kawasaki disease is the redness and swelling of palms and soles within a few days of onset. After a couple of weeks, the skin of the hands and feet begins to peel.

Diagnosis Critical

Early and accurate diagnosis is critical to successful treatment, as the disease can start to damage the heart after just one week of illness.

But diagnosis is difficult. One problem is that the symptoms don’t always appear...
Typical signs of Kawasaki syndrome include red eyes, swollen eyelids, red and swollen lips (top), and later peeling of hands (bottom).
A company based in Austria, has been approved by FDA for use in treatment of Kawasaki disease.

According to John Finlayson, Ph.D., a protein specialist with FDA, “We don’t really understand why immune globulin works, but the major benefit is in minimizing coronary aneurysms.”

The immune globulin is given intravenously in either a single large dose of 2 grams per kilogram of body weight over 12 hours, or four smaller daily doses of 400 milligrams per kilogram (1 kilogram is about 2.2 pounds).

Besides minimizing the potential for cardiac damage, this treatment regimen seems to work to “turn off” the disease. If treatment starts within 24 hours of the onset of the disease, the child is usually feeling much better by the next day.

According to Newburger, aspirin provides both an anti-inflammatory and anti-platelet effect. The anti-inflammatory effect keeps the arteries from swelling, and the anti-platelet effect prevents clots from forming in arteries.

Aspirin is given is fairly high daily doses—from 30 to 180 milligrams per kilogram (for example, 405 to 2,430 milligrams per day for a 30-pound child) of the patient’s body weight—for the first two weeks of the disease. (For comparison, one regular aspirin is 325 milligrams.) The dose is then lowered to 3 to 5 milligrams per kilogram for an additional six to eight weeks.

Patients who have some heart damage may be given low doses of aspirin for several months; those with more severe damage, for years.

Aspirin use in the treatment regimen for children is somewhat controversial. The association between aspirin and Reye syndrome in children with flu and chickenpox has made parents and doctors wary of using aspirin to treat children with any acute illness.

However, no association has been reported between Reye syndrome and the use of aspirin in children with Kawasaki syndrome. Therefore, the benefits of its use in this instance, under a doctor’s direction, outweigh its risks. Children who need to continue low doses of aspirin for long periods after the acute stage of the disease are monitored closely for signs of chickenpox or flu, and the aspirin can be stopped for a few days if a child develops symptoms of these illnesses.

Explicably, a possible connection has been made by some studies between children contracting Kawasaki syndrome and recently cleaned carpets. Researchers at Cornell University Medical Center were the first to find the apparent association in a survey of the families of Kawasaki patients and a separate control group.

Researchers asked questions about other family members with the disease, the type of foods the patient had been eating, and whether or not the child was breast-fed. The only factor that clearly differed between the two groups is that children with Kawasaki disease were more likely to have been exposed to carpets and rugs that had been shampooed, beaten, or vigorously cleaned within a month of the onset of illness. Most cases of Kawasaki syndrome occur between December and May, prompting some experts to recommend that families with infants and toddlers not clean carpets during winter and early spring.

Since the Cornell study, 13 additional studies have tested the connection. “Four studies have found an association between exposure to shampooed carpets and development of Kawasaki,” says Shulman. “Nine of the studies failed to find an association.”

Shulman explains that while the association is generally unproved, it may be valid in certain geographic locations. To be on the safe side, he recommends keeping children away from just-shampooed carpets for 24 to 48 hours.

Long-Term Outlook

According to Newburger, a Kawasaki patient’s long-term outlook depends on how much damage is done to the heart. Patients who receive treatment early will likely suffer no damage to the arteries. More than half the children who do develop aneurysms recover within a year.

Patients who don’t fare as well are those who don’t receive treatment and develop extremely large aneurysms. “The most severely affected patients—those with aneurysms of at least 8 millimeters—those patients will probably not return to normal,” says Newburger.

Because the disease was so recently identified, doctors don’t yet know if there are any long-term effects that aren’t apparent when the acute phase of the disease ends.

While most childhood fevers, sniffles, and watery eyes are no reason for alarm, parents should be aware that accompanied by other symptoms, the illness may require immediate medical attention. Recognized and treated early, Kawasaki syndrome can be stopped before it becomes a life-threatening problem.

Amy Roffman New is a writer in Chandler, Ariz.
Coping With Connective Tissue Diseases

by Marilyn Larkin

"I woke up one morning and noticed that my hands and feet were swollen. I said to myself, 'what is this?" says Carol Grogul, a 29-year-old administrative assistant in a New York City investment company.

She went to work and didn't think much more about it. But over the course of the next few weeks, Grogul began to experience severe pain in her knees and hips.

"One minute I was fine, the next minute the pain was so bad I couldn't move," she recalls.

When her fingers started curling into a claw shape, she became frightened. After seeking help from several doctors to no avail, Grogul was referred to a rheumatologist. The diagnosis: scleroderma (thickening of the skin), also called systemic sclerosis, which is one of a family of disorders known collectively as connective tissue diseases (CTDs). Within a matter of weeks, she was to feel the full brunt of scleroderma’s distressing symptoms.

"Now the skin on my face is so tight I can hardly open my mouth. I have no muscle energy at all. I walk with a cane, like an old woman, and I'm losing my hair," she says.

These severe symptoms followed a bout with kidney failure, also the result of scleroderma. "This disease may not kill you, but you will suffer," she says. "I never have a day when I feel really good, but I just have to keep going."

Seven years ago, when Tina Kline of Clyde, N.C., was pregnant with her second child, she noticed rashes on her knuckles, nose, eyes, and chest—and assumed she was experiencing a reaction to picking strawberries. She also felt completely exhausted, which she attributed to her pregnancy.

"A few days later, my arms would not go over my head. I couldn't get dressed or undressed. My legs were so weak, I had to crawl up the stairs," she recalls.

Tests taken in the emergency department of her local hospital were inconclusive, so Kline was referred to various specialists for additional tests. Ultimately, a rheumatologist made the diagnosis: polymyositis/dermatomyositis (PM/DM)—another CTD with potentially devastating consequences.

Today, at age 36, Kline, who founded a PM/DM support group, is in remission from the disease. But she suffers from bone deterioration, a side effect of the prednisone (a corticosteroid medication) prescribed to lessen her symptoms.

After six weeks, during which she took 60 milligrams of oral prednisone daily, the joints in her legs began to deteriorate. She was hospitalized and given 150 milligrams daily of the immuno-suppressive drug azathioprine (Imuran) to combat the deterioration. However, she continued taking prednisone to treat PM/DM. The disease had also caused her lungs to become infected.

Over the next few years, in a rare instance of widespread joint deterioration, Kline said that her hip and shoulder joints "collapsed," even though prednisone was tapered to lower levels. She has since had her hips and shoulders surgically replaced, and "my knees are next," she says. "There are days when I feel angry and frustrated, sick of having to deal with the disease nonstop, day in and day out," Kline admits. "But I’ve learned to be grateful for what I can do, for whatever physical independence I have."

Immune System at Fault

In scleroderma, PM/DM, and systemic lupus erythematosus (SLE), the immune

Today, Tina Kline, founder of a support group for people with polymyositis/dermatomyositis, looks like almost any healthy 30-something woman as she stands at her kitchen counter slicing vegetables. The PM/DM that first attacked her seven years ago during a pregnancy is in remission. But during her fight with the disease she was confined to a wheelchair, her hips and shoulder joints collapsed, she developed a back hump and distended stomach, and she lost hair and gained 50 pounds.
Distinguishing CTDs

CTDs have some symptoms in common and others that are specific to each disorder. Here’s a look at the most common symptoms of scleroderma, PM/DM and SLE and how they are treated.

- **Scleroderma:** The most common early symptom of scleroderma is Raynaud’s phenomenon (but not everyone who has Raynaud’s phenomenon develops scleroderma). In Raynaud’s phenomenon, the blood vessels of the hands and feet constrict in response to cold exposure, and the affected skin turns white, blue, then red. Vasodilators—drugs that relax and dilate blood vessels—are used to treat this condition.

  Swelling of the hands or feet is managed with diuretics (drugs that help eliminate excess water from the body) or nonsteroidal anti-inflammatory drugs (NSAIDs).

  There are no proven treatments as yet to treat or alter the course of fibrosis, the skin thickening that gives scleroderma its name. Experimental therapies, such as the use of penicillamine, a drug that interferes with collagen production, are being explored.

  Skin sores must be cleansed to prevent bacterial infection, usually caused by staphylococcus bacteria. If infection occurs, it may be treated initially by soaking the affected area in warm water and applying an antiseptic such as hydrogen peroxide or Betadine (povidone-iodine solution). If infection continues, a broad-spectrum antibiotic such as erythromycin may be prescribed.

  ACE inhibitors (a type of blood pressure medication) are frequently prescribed to treat kidney involvement and prevent kidney failure. A variety of experimental therapies are being used to treat involvement of other organs.

  A wide range of over-the-counter and prescription medicines are used to treat less severe symptoms, such as dry, itchy skin and digestion problems.

  Physical therapy may help early in the process to prevent joint contracture. Range of motion exercises can also help protect joints and keep them limber.

- **Polymyositis/Dermatomyositis (PM/DM):** Muscle weakness—particularly in the shoulders, arms and legs—is the hallmark of polymyositis. When the muscle weakness is preceded or accompanied by a red rash on the nose, cheeks, knees, or knuckles and a purple coloring on the eyelids, the disorder is called dermatomyositis. The two are usually grouped together as PM/DM.

  Corticosteroids are the mainstay of treatment, says rheumatologist Kramer. In severe cases, immunosuppressive drugs such as methotrexate or cyclophosphamide may be prescribed. Physical therapy can help prevent muscles from shrinking as they heal.

- **Systemic Lupus Erythematosus (SLE):** Milder symptoms of SLE, such as joint pain, rashes, and mild pleurisy (inflammation of the lung lining) often respond to NSAIDs. Corticosteroids are used to treat more severe symptoms, such as kidney disease, and milder symptoms that don’t respond to NSAIDs.

  Antimalarial drugs may be prescribed to reduce joint swelling, pain and rash, including the patchy, crusty red skin patches associated with this disorder. Immunosuppressive drugs may be used to treat patients with very severe symptoms, such as advanced kidney disease or central nervous system disease.

  SLE patients are advised to avoid the sun, which can precipitate or aggravate a flare-up of the disease. Daily sunblock use is recommended, even for those patients who don’t spend much time in the sun.

—M.L.
system goes awry. (See "Living with Lupus," in the December 1989-January 1990 FDA Consumer.)

"The body ceases to recognize 'self as self,' and mounts an attack against itself," explains Joseph Markenson, M.D., associate professor of clinical medicine at Cornell University Medical College in New York City. In such an "autoimmune reaction" the body produces antibodies—substances normally secreted by certain white blood cells to combat disease-causing viruses, bacteria, and other microorganisms—against its own cells and tissues. This triggers an array of symptoms, from joint pain to rashes to internal organ damage.

These CTDs have been in the news lately because of claims by some women and physicians that silicone leakage from breast implants and collagen injected into the skin to reduce acne scars and wrinkling cause CTDs. Although scientific evidence linking these products with CTDs is not conclusive, the media attention has sparked much curiosity about these disorders.

The fact is, the vast majority of the millions of Americans who suffer from a CTD—many of whom are women in their 20s, 30s and 40s—have no clue why the disease has struck them. This includes an estimated 2 million Americans with rheumatoid arthritis (see "Arthritis: Modern Treatment for that Old Pain in the Joints" in the July-August 1991 FDA Consumer), a CTD that thus far has not been associated with silicone implants or collagen injections. It also includes an estimated 500,000 Americans with SLE or another variant of lupus; 300,000 with scleroderma; and an unknown number who suffer from PM/DM. Many people who have a CTD develop "overlap" syndromes, which means they have symptoms of more than one CTD simultaneously.

CTDs are potentially life-threatening, and even mild cases can significantly impair quality of life. Disabling symptoms interfere with the ability to work or take care of a family. There is also an emotional toll when other people's unfounded fears lead them to treat a person with a CTD as an outcast.

"I know a woman with lupus who lost her job; people in her office wouldn't go near her or let her sit on their chairs," says Ronni Shulman, a 38-year-old public relations consultant from Westchester, N.Y., who has had scleroderma for 10 years. "I've noticed women hold on to their children when I walk by." Yet these disorders aren't contagious or infectious. No one can "catch" them from someone else.

What Causes CTDs?
The causes of CTDs are unknown, although scientists are investigating factors that may play a role in triggering the disorders. Suspected culprits are defective genes, overproduction of hormones, and faulty clearing from the body of antibodies and the substances with which they react.

"There appears to be a combination of some environmental agents acting on certain genetic backgrounds in these diseases," says Fred Miller, M.D., Ph.D., medical officer in FDA's Center for Biological Evaluation and Research, molecular immunology laboratory. He notes that occupational exposure to silica dust and polyvinyl chloride have been associated with scleroderma. Drug-induced lupus, a variant of SLE, can be traced to the use of drugs such as hydralazine (a high blood pressure medication), procainamide (a treatment for irregular heartbeats), and isoniazid (a tuberculosis drug). When a patient stops the suspected drug, lupus symptoms may clear up. But why some people become ill after exposure to these agents remains unclear.

The idea that an environmental agent can trigger a CTD in susceptible people has led to conjecture about a possible link between silicone, collagen injections, and CTDs. Yet the data offered to support a connection are "very sparse and weak," says FDA's Miller. Because FDA feels further study of silicone breast implants is warranted, the agency has restricted the use of these implants to women undergoing breast reconstruction following mastectomy and a limited number of women choosing the devices for augmentation (see "Silicone Breast Implants Available Under Tight Controls" in the June 1992 FDA Consumer).

Many physicians are urging caution with collagen injections. "It [the procedure] worries me a lot," says Judith Anderson, M.D., a hematologist and associate professor of internal medicine in the Division of Hematology/Oncology, Wayne State University School of Medicine. She points out that there is no standardization of the type of collagen used for injection. Most physicians use collagen products made from bovine (cow) collagen. Such products are likely to be properly purified and free of contaminants because they are prepared in large quantities for commercial use.

However, "unethical practitioners" may use collagen from cadavers, which may not be subject to the same high standards of quality control, Anderson says. Cadaver collagen may be contaminated with white cells that can cause an autoimmune reaction in a person who receives collagen injections. There is also potential for viral contamination of cadaver collagen. "If I were a young woman with a cleft chin or wrinkles, I would think 100 times before having collagen injections," she says.

Although patients are given a preliminary injection to test for allergic reaction before undergoing treatment, "that doesn't mean you won't develop problems several years down the road," adds Sara Kramer, M.D., a rheumatologist and instructor of clinical medicine at New York University Medical Center. "My feeling is, if you don't need the procedure for medical reasons, you're better off not having it done." FDA holds that evidence is insufficient to show that collagen injections cause CTDs in people without a history of these diseases. Even so, this does not mean there is no risk of developing CTDs from these injections. The agency has mandated that collagen products' labels carry a warning
Patients interested in participating in clinical trials of investigational therapies for CTDs should talk with their physicians or contact the following organizations:

National Organization for Rare Disorders (NORD)
P.O. Box 8923
New Fairfield, CT 06812-1783
(203) 746-6518

Scleroderma Society
1182 Teaneck Road
Teaneck, NJ 07666
(201) 837-9826

The National Support Group for Dermatomyositis
RD 3, Box 80
Clyde, NC 28721
(704) 627-9908

Lupus Foundation of America, Inc.
4 Research Place, Suite 180
Rockville, MD 20850-3226
(301) 670-9292 or (800) 558-0121

Arthritis Foundation
1314 Spring St., N.W.
Atlanta, GA 30309
(404) 872-7100

The National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse
Box AMS
Bethesda, MD 20892
(301) 495-4484

about the possible association between collagen injections and PM/DM. People considering undergoing the procedure should ask their physicians for the patient information brochure, which lists the possible adverse effects of the products, and discuss these risks with their doctors.

Diagnosing CTDs

One reason it’s so difficult to determine if silicone, collagen injections, or anything else triggers CTDs is that the illnesses themselves are not easily diagnosed. No single test can definitively determine whether a person has a CTD, and symptoms are very often vague, mimicking those of other diseases. As Shulman says about scleroderma, “It’s like the snowflake of diseases—no two cases are alike.”

A CTD is usually diagnosed by the patient’s symptoms, medical history, and the results of a number of tests that assess the status of the immune system and tissues in the body.

• **Blood Tests**: Several blood tests are used to help determine whether a patient has a CTD and, if so, what type. A physician may first order a complete blood count and other standard blood tests. Depending on results, the doctor may also order an anti-nuclear antibody test (ANA). This is a nonspecific test that determines if a patient has auto-antibodies that react with parts of the cell nuclei. However, results may be positive for conditions other than a CTD, such as infectious diseases or endocrine disease.

  Disease-specific antibody tests may also be done. These tests indicate the presence of antibodies for specific CTDs. For example, the anti-DNA and anti-Sm antibody tests are specific to SLE. There are also specific antibody tests for scleroderma and PM/DM. However, many people with CTDs have negative antibody tests. These tests can help confirm a diagnosis in a patient with symptoms or a family history, but can’t be used alone to make diagnoses.

• **Electromyography**: This test assesses the electrical activity in muscles and is used in the diagnosis of PM/DM.

• **Biopsy**: The removal of a small piece of tissue for inspection under a microscope can be a useful diagnostic tool. A biopsy of muscle tissue can help diagnose PM/DM. A biopsy of kidney tissue can give evidence that SLE has affected that organ.

Symptom Management

Just as the causes of CTDs are unknown, so are the cures. All CTDs are chronic, but people may have long periods of remission when they are symptom-free. For this reason, treatment focuses on symptom “management.”

Since few people with CTDs suffer from all symptoms characteristic of a specific disorder, the treatment plan for each patient must be individualized. Because the drugs used to treat severe symptoms can have very serious side effects—such as the bone deterioration Kline developed from taking corticosteroids—physicians continuously weigh the benefits of treating symptoms against the risks of adverse drug effects (see accompanying article, “Distinguishing CTDs”).

Looking Ahead

Studies are under way in medical centers around the country to test investigational therapies for CTDs. These include the use of certain orphan drugs and combinations of new immunosuppressive drugs, biologic agents (antibodies produced in a laboratory), plasmapheresis (removal of plasma from blood cells, and reinfusion), and photopheresis (use of a drug activated by ultraviolet light).

“The upside to all the media attention focused on CTDs lately is increased awareness among physicians and the public about the toll these diseases take on people’s lives,” says hematologist Anderson. She and others hope this will spur greater interest in exploring the causes that underlie these disorders and result in better ways to manage—and even cure—connective tissue diseases.

Marilynn Larkin is a medical writer in New York City.
If you use a humidifier in your home this winter, will your family be healthier? Whether a humidifier will make a difference in your family’s health is a question still under debate in the medical community.

“It’s a continuing argument,” said Sam Barton, a volunteer with the American Lung Association of Northern Virginia. “If you get 10 doctors together and ask them whether they recommend using a humidifier, five would say yes and five would say no.”

Barton noted, for the record, that his family does not use a humidifier. “When wintertime comes and we turn on the furnace, we just set a pan of water on the floor vent,” he explained. “It puts two
If not cleaned properly, the tanks of some humidifiers may provide an ideal breeding ground for bacteria, fungi, and other harmful microorganisms.

The term “humidifier” and “vaporizer” are often used interchangeably. Technically, however, a vaporizer is a type of humidifier that boils water before sending it into the air as steam. (See accompanying article.) The term “humidifier” will be used throughout this article to denote both humidifiers and vaporizers.

What’s Regulated, What’s Not

If you opt to invest in a humidifier, keep in mind that you may be purchasing a device that is not subject to FDA regulation. Many “department store” humidifiers that consumers purchase directly off the shelf are not regulated by FDA because they make no medical claims. Some of these machines do no more than promise to increase the comfort level in your home.

Other “off-the-shelf” units promise to do more, such as produce a “warm soothing steam to help relieve congestion caused by colds and respiratory ailments.” This is a medical claim, and the unit must therefore meet FDA requirements.

Some of these units have the added feature of being able to spray an over-the-counter medication (such as a nasal decongestant or cough suppressant) into the air along with the soothing vapor. Such units are defined in FDA’s regulations as “medicinal non-ventilatory nebulizers” or, more simply, “atomizers.”

Then there are the more highly specialized devices that are used exclusively in medical settings, or that can be obtained for home use only with a physician’s prescription. These FDA-regulated machines are not designed to treat the sniffles, colds, flu, or other common ailments, but serious disorders of the respiratory system such as asthma, cystic fibrosis, and other chronic pulmonary disorders. One such device, called a therapeutic humidifier, adds water vapor to breathing gases—such as oxygen—producing a vapor that pervades the area surrounding the patient, who breathes the vapor during normal respiration.

In addition to its pre-market review responsibilities, FDA also keeps an eye on respiratory medical devices after they reach the market. For example, the agency monitored the voluntary recall of 180 defective water feed sets by a manufacturer in California. The plastic tubes, used to supply distilled water from a container to a respiratory humidifier, were pulled from the market because their self-closing clamps did not work correctly. This defect could have caused the humidifier’s chamber to overfill with water, possibly resulting in a decreased supply of oxygen to the patient.

Is Wetter Better?

A number of studies suggest that relative humidity (air moisture content expressed as a percentage of its moisture-holding capacity) can, in fact, reduce the incidence of respiratory infections and allergies.

In a 1973 study, for example, 800 Army recruits were divided and placed in two barracks, only one of which was humidi-
This vaporizer (a type of humidifier) has a compartment to which medication can be added. The medication, usually an over-the-counter nasal decongestant or cough suppressant, is carried by the steam into the room where the vaporizer is used.
To reduce the possibility of health hazards from dirty humidifiers, the Consumer Product Safety Commission recommends the following precautions:

• Clean your humidifier every day. Empty any leftover water, wipe all surfaces dry with a soft towel, and refill with clean water. Some units may require special maintenance steps, so carefully follow the manufacturer’s instructions.

• Sanitize your humidifier every seven days (or every 14 days if your humidifier has a capacity of five or more gallons). Empty leftover water and fill with a weak bleach solution (one teaspoon of bleach per gallon of water). Let the solution soak for 20 minutes, swishing it around the sides every few minutes. Rinse the tank with water until you can no longer smell bleach. Remove any scale or mineral deposits using a soft brush or towel and a vinegar solution (half vinegar, half water).

• Use distilled or demineralized water to reduce the build-up of scale (which is composed of minerals that have settled out of the water) and the release of humidifier dust (minerals that are released in the mist and settle as a fine, white dust). Don’t use tap water because it contains more minerals. Use demineralization cartridges or filters if they are supplied or recommended.

• Clean or replace sponge filters or belts as needed.

• Sanitize and thoroughly dry the appliance before storing it. Clean it after summer storage, and remove dust on the outside of the unit, too.

—T.C.

Recruits in the humidified barrack had 18 percent fewer infections between January and March than did recruits in the barrack without humidification.

Another study found a significant reduction in respiratory infections among children who attended a humidified school compared with children who attended a non-humidified school. Infections were reduced even further in children in the humidified school whose homes were also humidified.

During the study, the average weekly absentee rate due to respiratory infections was 7.1 percent for children whose schools and homes were not humidified and 1.3 percent for children with humidification at both places.

Most experts agree that some moisture in the air is a healthy thing, and that people seem to be healthiest when the relative humidity hovers in the mid-range—somewhere between 30 and 50 percent. Available data indicates that this “mid-range” of relative humidity tends to shorten the lifespan of airborne bacteria and viruses.

It’s when the relative humidity gets too high or too low that certain bacteria or viruses are likely to thrive and health problems seem most likely to develop.

To keep tabs on the humidity conditions in your home, you may want to buy an instrument called a hygrometer, usually available at hardware stores.

Wintertime Dryness

During winter, when the heat is on, the relative humidity in your house can become very low. This is because heated air can hold much more moisture than cold air. So, as the air in your home heats up, it becomes “thirsty” and begins sucking moisture out of surrounding surfaces: plants, walls, furniture, books, paintings, human bodies, everything.

The moisture that cooking and bathing puts into the air is not likely to offset this drying effect, especially in the colder parts of the country where the furnace runs almost continuously during the winter months.

This is one reason you may find your throat getting parched more often in wintertime, your lips more chapped, and your skin more dry and itchy.

Some people are convinced that prolonged exposure to low relative humidity increases susceptibility to common colds by “drying out” the protective mucus membranes in the nose and throat. There is little evidence, however, to indicate that the mucus membranes of healthy individuals are adversely affected by low relative humidity.

“God has built a humidifier right there in your nose,” said Ali Abrishami, M.D., an allergist in Greenbelt, Md. “There is moisture in your nose, and that moisture goes into the air you breathe.”

Abrishami is not a strong advocate of humidifiers.

“If a patient asks me whether they should use a humidifier, I tell them it can’t hurt, provided they aren’t allergic to molds,” he said. “I tell the patient that it’s not harmful to add moisture to the air if it’s dry.”

“But too much humidity isn’t good either,” he added.
How Humidifiers Work

The Risk Factor

If you want to keep your home’s relative humidity within the “healthy,” 30–50 zone during winter, you may want to take the simple approach and keep a pan of water on your floor vent or your radiator, or maybe just keep a pot of water boiling on the stove.

The other alternative is to invest in a humidifier. But there’s some risk involved here. If not cleaned properly or often enough, the tanks of some models may provide an ideal breeding ground for bacteria, fungi, and other harmful microorganisms that are then sprayed into the air along with all that soothing moisture. And over-using a humidifier can cause the relative humidity to get too high, a situation that can promote the growth of dust mites and fungi (which includes molds) in your house. These organisms are capable of causing severe allergic reactions in susceptible people.

High relative humidity may also prolong the life expectancy of certain viruses that may be in your home.

When It’s Too Wet

The size of indoor populations of allergenic mites and fungi is directly dependent on the relative humidity.

Mites are the culprits behind house dust allergies, and laboratory studies show that these microscopic creatures like life on the moist side; they begin multiplying rapidly as the humidity climbs above 50 percent.

In a two-year study involving 98 houses, fewer than 10 live mites per gram of house dust were found when the relative humidity fell below 40 to 50 percent.

Humidifiers come in all shapes and sizes, from hatbox-sized portable units to furniture-sized consoles. But they all do the same thing: They put moisture in the air. And they do it in one of five ways.

- **Evaporation.** Evaporative units have a fan inside them that blows air through a wet pad, and this moisture-laden air then continues on into the room. ("Wicking" humidifiers do the same thing, only the air is blown through a moisturized filter instead of a pad.) Evaporative units don’t produce a spray and are therefore less likely to spread germs than are units that throw a cool mist into the air. The wet pads, however, can become a breeding ground for bacteria if not cleaned regularly.
- **Steam.** These units, sometimes called vaporizers, boil water and send it into the air as steam. They tend not to put microorganisms into the air; after all, it would take an extraordinarily tough germ to survive the boiling process. Unlike other kinds of humidifiers, they produce little or no “white dust.” Steam units leave the minerals behind when they boil water in their tanks.
- **Warm mist.** These units boil water just like steam vaporizers, only the steam is cooled slightly before exiting the unit, resulting in a “mist” of warm water droplets instead of real steam.
- **Cool mist.** These units break up water into tiny droplets and spray a cool mist into the air. Because the water isn’t boiled, the cool vapor may contain potentially harmful organisms if the tank is not properly cleaned and sanitized.
- **Ultrasonic.** These units use high-frequency vibrations to break up water droplets into an extremely fine mist. The mist produced by these machines contains no molds and comparatively few live bacteria. It is thought that the ultrasonic vibrations may “break up” and shatter living organisms along with the water droplets. However, while these bits of dead microbes may not cause respiratory infections, they may still trigger allergic reactions in sensitive people.

—T.C.
In another two-year study involving two houses, no mites at all were found when the relative humidity fell below 50 percent. Both studies found that mite density was not affected by the age of the house, or by how clean the house was kept.

Mites aren’t the only house guests that enjoy humidity. Fungi, which include molds, usually need relative humidities in excess of 75 percent to grow. They are known to cause allergic reactions such as asthma attacks or rhinitis (an inflammation of the mucous membranes of the nose).

Because they like it wet, most fungi populations stay in areas such as the kitchen and bathroom, unless, of course, you own a humidifier and run it too much in some other room.

For someone allergic to certain molds, running a humidifier (especially in the bedroom at night) can be double trouble: Fungi may grow in the humidifier’s tank and be sprayed into the air for the person to breathe; and the excessively humid environment may cause fungi to begin forming on furniture, walls, carpets, clothes, and other surfaces in the person’s room.

White Dust

If you use tap water in your humidifier, the minerals in the water will be dispersed into the air and coat your floors, walls and furniture with a fine white dust, sometimes called humidifier dust. According to Ken Giles of the U.S. Consumer Product Safety Commission, this white dust may contain particles small enough to enter the lungs.

“The health effects from inhaling humidifier dust are not clear,” said Giles.

“Any impact on human health will depend upon the types and amounts of the minerals found in the water.”

Since the medical community remains unsure about the effects of white dust, play it safe and use distilled water in your machine.

The Whole-House Approach

If you live in a house with forced-air heat, you can add a humidifier to your heating system. It’s an efficient way to go. But some of these systems—if not properly maintained—can breed microorganisms just as easily as stand-alone units. And they have the added feature of being able to spread allergens and pathogens throughout your entire home, not just one room.

If you or someone in your family is sensitive to molds or dust mites, you may want to talk to your family doctor, or even a respiratory specialist, before deciding whether you want to install one of these units.

A humidifier of any kind won’t accomplish much if your house isn’t insulated, or if it doesn’t have a vapor barrier, because the moisture will be lost. (Most houses built before 1950 don’t have a vapor barrier—a layer of plastic, foil, or treated paper on the room side of the insulation.) A humidifier won’t moisturize the air sufficiently in a house that lacks insulation or a vapor barrier. The moisture will simply escape to the outside.

If your house isn’t insulated, you probably don’t need a humidifier. The air exchange rate in a leaky house is usually so great that indoor air doesn’t have time to get too dry or thirsty. Your heating bills may be outrageous, but you at least have the satisfaction of knowing that your relative humidity is probably well within the healthy zone.

Tom Cramer, now with the U.S. Department of Agriculture, wrote this article while on the staff of FDA Consumer.
The Notebook: a potpourri of items of interest gathered from FDA news releases, other news sources, and the Federal Register (designated FR, with date of publication). The Federal Register is available in many public libraries.

- **The first International Latex Conference**, on Nov. 5 to 7 in Baltimore, is co-sponsored by FDA and the national Centers for Disease Control. Health-care professionals, scientists, industry, and regulatory agencies will share information on hypersensitivity reactions to latex medical devices. For more information, contact Crosspaths Management Systems, Inc., Two Wisconsin Circle, Suite 660, Chevy Chase, MD 20815; telephone (800) 527-2847. (Morbidty and Mortality Weekly Report, Aug. 14)

- **Fresh pizzas** topped with previously inspected meat or poultry products were exempted from federal inspection last Aug. 3, by a Food Safety and Inspection Service final rule. The rule will likely increase competition in the school lunch markets where, in the past, only frozen pizzas could be sold. (FR Aug. 3)

- **Salmonella poano** infected an 8-week-old infant in Utah in April 1992. It was only the fourth occurrence of this illness in the United States. The infant, who recovered after a week, contracted the disease from the family’s pet savannah monitor lizard. Pets, especially reptiles, carry a wide variety of diseases. It’s important to wash thoroughly after coming into contact with pets or their environment. (MMWR Aug. 21)

- **The Cardiology Advisory Committee** of the National Heart, Lung, and Blood Institute is meeting Nov. 5 and 6 in Building 31C, Conference Room 8, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892. The meeting is open to the public. For more information, contact Terry Bellicha, Communications and Public Information Branch, NHLBI, Room 4A21, Building 31, NIH, Bethesda, MD 20892; telephone (301) 496-4236. (FR Aug. 24)

- **Swine and ruminant meat products** from the Republic of Ireland and Northern Ireland are no longer permitted into the United States, according to the Animal and Plant Health Inspection Service.APHIS banned the meat products Aug. 18 to make sure swine vesicular disease, rinderpest, and foot-and-mouth disease are not introduced into the United States. (FR Aug. 18)

- **New worker-protection standards** for those who work with agricultural pesticides were issued by the Environmental Protection Agency. The regulations, which took effect Oct. 20, strengthened requirements for warnings about applications, use of personal protective equipment, and restrictions on entry to treated areas. They also added provisions for decontamination, emergency assistance, contact with handlers of toxic pesticides, and pesticide safety training. (FR Aug. 21)

- **A new Farmers’ Market Nutrition Program** for women, infants and children was implemented by the Food and Nutrition Service on Aug. 20. The program will provide participants with fresh, nutritious foods such as fruits and vegetables. Individual state agencies will administer the program. (FR Aug. 20)

- **Ischemic heart disease** (IHD) is the leading cause of death among adults in the United States, accounting for 500,000 deaths in 1989, according to the Centers for Disease Control. IHD, caused by severely clogged arteries that restrict blood flow, declined 24 percent among people 35 and older from 1980 to 1989. In 1980, the death rate was 588.3 deaths per 100,000 population, while in 1988, the death rate dropped to 448.8 per 100,000. (MMWR July 31)

- **Cataract risk** may be increased by cigarette smoking, according to two studies in the Journal of the American Medical Association (JAMA). In one study, men who smoked 20 or more cigarettes a day had nearly twice the risk of developing cataracts as non-smokers. In another study, women who were heavy smokers had a 63 percent greater risk of getting cataracts than non-smokers. (JAMA Aug. 26)
Two Tennessee physicians who were charging AIDS patients a hefty fee for a “secret cure” paid a hefty price themselves for their fraudulent activities.

On May 20, 1992, following a two-day hearing by the State of Tennessee Board of Medical Examiners, Therial L. Bynum, M.D., of Murfreesboro, Tenn., and Everett R. Echols II, M.D., of Shelbyville, Tenn., were found guilty of malpractice, unprofessional conduct, and making false statements. Bynum was also found guilty of offering to treat a disease using a “secret means.” The state revoked Bynum’s license and fined him $5,000. Echols had his license suspended for six months and was fined $3,000. After six months Echols may resume his psychiatric practice, but not his general medical practice.

“Bynum and Echols would diagnose people by looking at them and tell them if they were in ‘Stage I, II, or III of AIDS,’” said Ken Merritt, an investigator from FDA’s Nashville district office. “The cost of treatment would depend on which stage they were in,” he said, “each stage costing $10,000. They guaranteed a cure—even for stage III, at the cost of $30,000.”

The board hearing was the culmination of an extensive investigation by FDA. The Tennessee Board of Medical Examiners Criminal Division, the Tennessee Seventeenth Judicial District Drug Task Force, and the Tennessee Attorney General’s Office provided assistance in the late stages of case preparation and trial.

FDA first heard of Echols and Bynum on June 5, 1991, when an AIDS patient, identified as D.P., from Chattanooga, called the Nashville office, saying he suspected a scam. He said the physicians got his name from an acquaintance of his sister and called him with an offer of a cure, claiming they had cured 27 people so far. They told him they were conducting their treatment program unofficially and needed 100 cures before coming forth with their study results and identity of the drugs involved, which they claimed were FDA-approved.

At FDA’s request, D.P. agreed to work undercover with the agency to expose the fraud.

In accordance with a plan devised by FDA, D.P. arranged to meet Bynum June 15 at Sequatchie County Hospital, where Bynum worked as a temporary emergency room physician, to get more information about the “cure.” Merritt accompanied him, posing as his friend and “financial benefactor” who would be paying for his treatment.

According to Merritt, Bynum spent about a half hour going through the medical records D.P. brought with him and then described the treatment he would prescribe, saying he had to have $10,000 “up front” and another $20,000 within the next two weeks.

“He didn’t do any kind of physical examination,” Merritt said. “He told D.P. he would have to stop taking AZT [an approved AIDS drug] because it would ‘mask’ the effects of the drug he was going to prescribe.”

According to Merritt, Bynum said he didn’t mind revealing the identities of the drugs he was going to prescribe, but that his associate, Echols, feared someone might steal their secret or misuse the drugs, taking them without a doctor’s supervision. Bynum would only say that one of the drugs was made outside the United States by a single manufacturer, which accounted for its scarcity and high cost.

Subsequently, D.P. became ill with AIDS-related symptoms and could no longer participate in the investigation.
In September, however, FDA learned of other complaints about Echols and Bynum from Sheridan Y. Wood, executive director of Nashville CARES, an organization that provides services to AIDS patients.

Wood sent Merritt a copy of a letter she had received from a woman whose son had AIDS. Merritt interviewed the woman, who told him she contacted Echols after hearing about him from another physician.

“She said Echols and Bynum guaranteed a cure for her son, telling her, too, they had cured 27 people,” Merritt said. “She was real excited and hopeful, but when they told her it would cost $20,000, she was let down. At that point, she suspected it was a scam and wrote to Nashville CARES.”

Around the same time, Wood also told Merritt of a complaint she had received from the roommate of a 31-year-old man who died of AIDS. Merritt interviewed the roommate and obtained samples of remaining drugs—tablets and a liquid—that Bynum had prescribed.

“The roommate told me that Bynum had delivered the drugs himself,” Merritt said. “We obtained the original containers with Bynum’s handwriting on them. Laboratory analysis showed the tablets were prednisone [an anti-inflammatory steroid]. We couldn’t identify the liquid at that time, but it was later identified as cyclosporin [an immune system suppressant used after organ transplantation to prevent rejection].”

The roommate also told Merritt that Bynum claimed to have cured 20 people and that he would not reveal the names of the drugs he used because it might compromise his research.

In the meantime, Merritt had learned of and interviewed another AIDS patient, identified as B.A., who agreed to work undercover with the agency to expose the scam.

A plan was devised for B.A. to make an appointment with Echols, saying he was seeking psychiatric counseling. They met Dec. 18, and B.A. told Echols he had AIDS. Echols told him about his and Bynum’s cure. B.A. met with Echols and Bynum again on Jan. 7 and Jan. 10. FDA Nashville district compliance officer Ray McCullough accompanied B.A. on the last visit, posing as his uncle who would be paying for the treatment. At the meetings with Echols and Bynum, B.A. and McCullough wore body wires and pocket recorders.

Both doctors claimed they had cured more than 27 persons of AIDS. They said that with their cure, the patient would still test HIV positive, but the body’s T-cell count would increase and the infection would not spread. (T-cells are critical immune cells that are destroyed by the AIDS virus). They said that if B.A. took their treatment, he would not die of AIDS.

McCullough paid $5,000 for a two-month supply of the drugs, with the promise of another $5,000 for a second two-month supply. Echols and Bynum gave B.A. a prescription for prednisone tablets and a “kit” containing about 50 milliliters of an unidentified liquid, and instructed him to gradually stop using AZT over a period of several days.

The liquid was sent to FDA’s Atlanta laboratory for analysis, where it was identified as cyclosporin.

Merritt, working together with Mike Owens, a criminal investigator with the Tennessee Department of Health, and Herb Glasmeyer, an agent with the Drug Task Force, produced the evidence for the case and presented it to the Tennessee Board of Medical Examiners Feb. 27, 1992.

On March 18, the board suspended both physicians’ licenses, stating that they were “endangering the lives of patients by purporting to treat them with medications that may endanger them.” The final order to revoke Bynum’s license and suspend Echols’ was issued May 20, following the hearing.

Sandy Baxter is a public affairs specialist for FDA’s Nashville district office. Marian Segal is a member of the agency’s public affairs staff.

FDA Insists on Shipshape Pier

“Water, water, everywhere, Nor any drop to drink.”
—Samuel Taylor Coleridge
The Rime of the Ancient Mariner

Some contemporary mariners in Puerto Rico faced the same problem as Coleridge’s ancient mariner, until FDA got the local Ports Authority to clean up Old San Juan Pier 6. The potable (drinking) water system was so insanitary FDA had classified it “Not Approved.”

On Jan. 8, 1991, FDA investigator Jaime Pares conducted a routine inspection of Pier 6, which serves mainly cruise ships traveling between the Caribbean and the U.S. mainland.

Pares found numerous violations of the Public Health Service Act and FDA’s Interstate Conveyance Sanitation regulations, including inadequate storage and protection of the hoses used for potable water; lack of protective outlet caps on five hydrants; and lack of protective housing on two hydrants, which also were installed closer to the pier floor than agency regulations allow.

McCullough paid $5,000 for a two-month supply of the drugs, with the promise of another $5,000 for a second two-month supply. Echols and Bynum gave B.A. a prescription for prednisone tablets and a “kit” containing about 50 milliliters of an unidentified liquid, and instructed him to gradually stop using AZT over a period of several days.

The liquid was sent to FDA’s Atlanta laboratory for analysis, where it was identified as cyclosporin.

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Investigators' Reports (continued)

FDA issued the Ports Authority a notice of adverse findings classifying Pier 6 “Provisional”—meaning the potable water could become contaminated—and calling for corrections and reinspection.

Pares reinspected the area on Dec. 11 and 12, 1991. Accompanied by Pier 6 supervisor Federico Bauza the first day, Pares found improper outlet locations on six hydrants. This allowed drained water to splash the hydrants and, with rising tides, even flow back up the outlets to possibly contaminate the water system.

Pares noted that Hydrant No. 1 leaned over on the floor, keeping the backflow prevention device from working. The hydrant had been out of use for several days after being hit by a cable thrown to anchor a vessel, Bauza said. He asked an employee to stand the hydrant up and clean some trash from the water meter box. When the employee opened the drain valve, rusty water flowed out for six to eight minutes. Questioned by Pares, Bauza acknowledged that this water supply line fed five other hydrants.

Pares told Bauza the hydrant must be flushed daily to prevent water from siphoning back up the hose and possibly causing contamination in the other hydrants. Hydrants and water hoses must be flushed before each use, Pares said.

Written procedures to instruct employees how to operate and flush the lines were unavailable at the pier.

Bauza promised to take corrective action as soon as possible.

When Pares arrived the next day, Hydrant No. 1 was being flushed. But he noted that three water hoses stored on reel carts in the parking lot were exposed to the environment and that the reels weren’t identified with a permanent sign saying, “Potable Water Hose Only,” as FDA requires. The inner plastic lining of two hoses was cracked at the metal coupling end, and one hose had a bent coupling.

The hoses lacked protective outlet caps—a violation noted during the January 1991 inspection.

Pares discussed his observations with Salvador Acobis, an official at the Ports Authority central offices.

Pares reminded Acobis that Pier 6 had been classified “Provisional,” yet some deviations found during the last inspection continued. He pointed out that FDA had held a training seminar in November 1991 for Ports Authority maintenance and area supervisors to help prevent such problems. Acobis said Bauza hadn’t attended the seminar but had been given the written information. Pares warned Acobis about possible legal consequences if the problems weren’t fixed.

Acobis promised to take corrective action during the next few days.
On Dec. 30, 1991, FDA sent a warning letter to Jose Buitrago, executive director of the Puerto Rico Ports Authority. The letter pointed out that despite FDA's repeated admonitions to correct Pier 6's problems and despite FDA's seminar to help Ports Authority prevent such problems, Pier 6 continued to have numerous deficiencies. As a result, the letter advised, FDA classified Pier 6 "Not Approved."

The letter suggested a meeting with Buitrago and said if the problems weren't remedied, FDA would have no other choice but to take legal steps such as injunction.

FDA notified all cruise line agents and the national Centers for Disease Control of the classification. Two cruise lines canceled their Puerto Rico landings, and three lines threatened cancellations.

On Jan. 15, 1992, Miguel Castellanos, chief of the Maritime Bureau of Puerto Rico, wrote FDA that his office had instructed Bauza to take corrective action, but that more time was needed.

Two days later, Pares went back to Pier 6. He found the same violations noted at the December inspection. He also found two more hoses with cracked inner linings, as well as dirt and debris under the hose storage carts.

At Acobis' request, FDA's San Juan compliance branch director Daniel Gonzalez met on Jan. 21 with Acobis and Victor Carrion, supervisor of the Ports Areas.

After discussion of the violations, Acobis promised to take corrective action. Gonzalez asked how much time it would take. Acobis said the work would start that day. Gonzalez said there would be no more letters and that the next FDA step would be to stop the Ports Authority from selling water.

Acobis and Carrion promised to take corrective action.

Gonzalez asked for a written plan, including dates for completion of each action. When Pares inspected Pier 6 on Feb. 3, 1992, he found no violations, and FDA classified the watering point "Approved."

—Dixie Farley

Peroxide Pusher Shut Down

A Wisconsin judge recently ordered a local businessman to stop the illegal activities he had continued to pursue in defiance of FDA regulations.

In his ruling on March 10, 1992, Judge Robert Warren of the U.S. District Court for the Eastern District of Wisconsin enjoined Vital Health Products, Ltd., of Muskego, Wis., and its president, Conrad E. LeBeau, from promoting and selling hydrogen peroxide products for treating serious diseases, including AIDS and cancer.

LeBeau had been distributing "35% Hydrogen Peroxide Solution," "Peroxy Gel," "17.5% Hydrogen Peroxide Solutions and Glycerine," "Lymph System," "Licorice Root," and "White Birch Mineral Water" with promotional materials containing unsubstantiated claims that the products could cure AIDS, cancer, Parkinson's disease, Alzheimer's disease, diabetes, and more than 20 other serious illnesses. He continued to promote and sell his products even after U.S. marshals seized and destroyed thousands of dollars worth of them in 1989 (see "Sale of Peroxy Products Halted" in the December 1990 issue of FDA Consumer).

FDA's Minneapolis district office first learned about Vital Health Products in 1987 from an advertisement the firm had placed in a magazine. An inspection of the company's facility in November 1987 revealed that Vital Health was promoting a hydrogen peroxide product, "Aloe Vera Oxygel," to treat cancer, AIDS and arthritis.

On March 14, 1988, FDA issued a letter to LeBeau warning that "Aloe Vera Oxygel" was an unapproved new drug and was misbranded.

LeBeau responded in writing to FDA's letter on March 22, saying that his company had stopped producing promotional materials that included medical claims for "Aloe Vera Oxygel."

A follow-up inspection of Vital Health in May, however, revealed that while the company had stopped selling "Aloe Vera Oxygel," it had begun to sell two other hydrogen peroxide products: "Peroxy Gel" and "Peroxy Spray."

Both products were labeled as anti-infective agents. During the inspection, FDA investigators collected a brochure titled Hydrogen Peroxide Therapy: New Hope for Incurable Diseases, which claimed that "a hydrogen peroxide ointment such as 'Peroxy Gel' has caused the pain associated with arthritis to disappear, the effects of Down's syndrome to be lessened, and the size of a tumor to be diminished."

An issue of Vital Health News, the company's newsletter, made similar claims and also stated that "Peroxy Gel" was effective against Lyme disease.


A month later, LeBeau sent a letter to FDA asking if Vital Health could continue distributing its products if promotional materials were not mailed with them.

FDA denied the request, stating that as long as the products and promotional materials come together at some point it constitutes labeling.

"The letter was intended to let him [LeBeau] know that he still was not in compliance," said Walter L. Stauffacher, a compliance officer in FDA's Minneapolis district office. "Having the promotional
materials mailed from a different location doesn’t change the name of the game.”

But LeBeau did not comply. FDA investigators obtained Vital Health hydrogen peroxide products through undercover mail-order purchases on Nov. 27 and June 15, 1990.

Three additional undercover purchases made in October and November 1990 netted other Vital Health Products, including “Lymph System,” “White Birch Mineral Water,” and “17.5% Hydrogen Peroxide Solutions and Glycerine.” As before, the labeling for all of the products carried unsubstantiated medical claims.

The products ordered on the last purchase included “35% Hydrogen Peroxide Solution,” “Peroxy Gel,” and “Licorice Root Tea.” The FDA investigator received the products Nov. 29, 1990, but the promotional literature, shipped from a different address, arrived separately on Dec. 1.

A brochure claimed that “hydrogen peroxide can be used in the treatment of numerous disease conditions, including AIDS, Alzheimer’s disease, cardiovascular disease, asthma, influenza, herpes zoster, systemic chronic candidiasis, Epstein Barr Virus, diabetes, multiple sclerosis, rheumatoid arthritis, and Parkinsonism.”

An accompanying newsletter stated that “‘Licorice Root Tea’ effectively treats AIDS, adenalin exhaustion, Addison’s disease, cancer, colds, coughs, drug withdrawal, hypoglycemia, lung problems, and ulcers”; that “‘White Birch Mineral Water’ effectively treats cancer, arthritis, and genital warts”; and that “‘Lymph System’ detoxifies and purifies the lymphatic system.”

“They were marketing and selling products as cures for diseases without having any proof that they worked,” Stauffacher said. “When this happens it’s the consumer who suffers.”

Judge Warren’s ruling also required Vital Health to notify all of its customers and others involved in buying or selling the products that they are illegal and can no longer be distributed.

FDA will continue to monitor the activities of Vital Health and LeBeau.

—Victor Lambert

3,000 Tons of Peanuts Detained

Six million pounds of peanuts were refused entry into the United States last November after FDA inspectors found them contaminated with rodent and insect filth.

“Our worst fears were confirmed that hot summer day in July when we inspected a shipment of imported peanuts waiting for entry,” says Edward Creech, import program manager at FDA’s import office in Norfolk.

Creech, along with two rookie inspectors, examined the nuts after being alerted that a warehouse was holding part of an 8.5 million-pound shipment of shelled peanuts. “One of the warehouses holding the peanuts had checked some of the containers and found rodent and insect filth and called us. The heat of the day and the vermin made crawling around inside those containers almost unbearable for us. Our new inspectors got quite an initiation.”

Creech also received information about the filth contamination from U.S. Department of Agriculture examiners checking for aflatoxin, a cancer-causing mold that forms on some crops.

The huge shipment of peanuts from the People’s Republic of China, Sudan, and Argentina arrived at the Port of Norfolk in four vessels in July 1991. The shipment had traveled a long, circuitous route and had been stored for some time in Rotterdam, the Netherlands. Most of the peanuts had been in storage more than two years.

When the shipment arrived at Norfolk, U.S. Customs agents called FDA’s import office to ask if it should be held at port until it was checked. Because of the size of the shipment and FDA’s previous experience with heavily contaminated nuts from Argentina, FDA instructed Customs to allow the peanuts to be moved to warehouses and held there.

FDA inspected the peanuts for filth and from Aug. 1 to Aug. 21, 1991, collected 15 samples to test for pesticide residues. Two of the samples—both from lots from Argentina—had excessive pesticide residues.

All of the peanuts from China and 7 percent of those from Argentina passed USDA inspection for aflatoxin and FDA’s inspection and sampling for pesticides and filth. Those lots, totaling 2.3 million pounds, were released for sale in the United States.

FDA refused to allow into the United States all 75 thousand pounds of peanuts from Sudan because of adulteration with rodent and insect filth, and 93 percent, or 6.2 million pounds, from Argentina because of filth, violative pesticide residues, and aflatoxin. In all, more than 6 million pounds (73 percent of the 8.5 million-pound shipment) of peanuts were detained.

All of the detained nuts were reexported. According to law, refused shipments may be reexported or destroyed, in both cases under U.S. Customs supervision.

—Judith Foulke
Summaries of Court Actions are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Summaries of Court Actions report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against goods alleged to be in violation, and criminal and injunction proceedings are against firms or individuals charged to be responsible for violations. The cases generally involve foods, drugs, devices, or cosmetics which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce.

Summaries of Court Actions are prepared by Food and Drug Division, Office of the General Counsel, HHS.

Published by direction of the Secretary of Health and Human Services.

**SEIZURE ACTIONS**

**Food/Poisonous and Deleterious Substances**

**PRODUCT:** “Vanilla extract,” and unlabeled “vanilla concentrate,” at Adjuntas, Dist. Puerto Rico; Civil No. 91-2300(GG).

CHARGED 10-17-91: While held for sale, the article labeled “Vanilla extract” contained the poisonous or deleterious substance coumarin, which might render it injurious to health, and contained the added poisonous substance coumarin—402(a)(1), 402(a)(2)(C); the labeling of the article labeled “Vanilla Extract” and the article identified as “vanilla concentrate” contained false and misleading statements of identity since the articles were artificial vanillas; and the articles (artificial vanillas) were offered for sale under the names of other foods—403(a), 403(b); coumarin or substitute coumarin had been substituted wholly or in part for vanilla in both articles—402(b)(2); the article lacking bottle labels but identified as “vanilla concentrate” lacked required labeling—403(f); and the articles failed to conform to the definition and standards of identity for vanilla extract or concentrated vanilla extract—403(g).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66248; S. No. 91-637-103 et al.; S.J. No. 1)

**PRODUCT:** Cocoa liquor product, at Bronx, S. Dist. N.Y.; Civil No. 90 Civ. 2661.

CHARGED 4-19-90: While held by Heisler Food Enterprises, Ltd. (David Heisler), Bronx, N.Y., the article contained rodent filth and mold, and the article had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Pursuant to stipulation of the dealer and the government, the article was condemned and ordered destroyed. (F.D.C. No. 65821; S. No. 90-545-795; S.J. No. 2)

**PRODUCT:** Hot sauce, Mexican, canned, at Chicago, N. Dist. Ill; Civil No. 91-C-6741.

CHARGED 10-23-91: While held for sale, the article was unfit for food due to swollen cans—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66306; S. No. 91-661-261; S.J. No. 3)

**PRODUCT:** Lobster tails, and lobsters, frozen, at Elk Grove Village, N. Dist., Ill.; Civil No. 90 C 6239.

CHARGED 10-26-90: While held for sale, the article contained a decomposed substance—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65959; S. No. 90-575-995; S.J. No. 4)

**PRODUCT:** Mung beans, at Buena Park, C. Dist. Calif.; Civil No. 89-6188.

CHARGED 10-24-89: While held by House of Spices (India) Inc., Buena Park, Calif., the article contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 65760; S. No. 89-566-963; S.J. No. 5)

**Food Additives**

**PRODUCT:** Candy, at Winston-Salem, M. Dist. N.C.; Civil No. 89-6188.

CHARGED 10-24-89: While held by House of Spices (India) Inc., Buena Park, Calif., the article contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 65760; S. No. 89-566-963; S.J. No. 5)
cherry-flavored hard candy with either lemon-flavored or pineapple-flavored hard candy, packaged as civil defense carbohydrate supplements) contained nonconforming food additives (i.e., the cherry-flavored candy contained FD&C Red No. 2, and the lemon-flavored candy contained FD&C Yellow No. 5)—402(c); and the labels of the articles failed to specifically disclose the presence of FD&C Yellow No. 5—403(a)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66210; S. No. 91-605-675 et al.; S.J. No. 6)

PRODUCT: Diet teas of chamomile, cinnamon, lemon grass, and licorice flavors, at Arlington, N. Dist. Texas; Civil No. 4-91-406E.

CHARGED 6-4-91: When imported from Brazil, the articles labeled “Dietic Tea Steviassweet Lemongrass Flavor [or other flavor]... Made in Brazil... Distributed by Steviassweet Co. Inc.,... Arlington, Texas” contained a nonconforming food additive (i.e., steviolide, stevia leaves, or stevia extract)—402(a)(2)(C).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66081; S. No. 91-311-516 et al.; S.J. No. 7)

Drugs/Human Use

PRODUCT: Aspirin, caffeine, butalbital, and codeine phosphate combination capsules, at Memphis, W. Dist. Tenn.; Civil No. 91-2064 HB.

CHARGED 1-22-91: When shipped by Anabolic Inc., Irvine, Calif., the article labeled “Ascomp With Codeine No. 3... Distributed by Econolab, Westland, Michigan... Manufactured by Anabolic Inc., Irvine, Calif.” was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65853; S. No. 90-576-652 et al.; S.J. No. 9)

PRODUCT: L-Ornitbine tablets, L-Glutamine tablets, and L-Phenylalanine tablets, at Chestnut Ridge, S. Dist. N.Y.; Civil No. 91-CIV-5671 (KMW).

CHARGED 8-21-91: While held by Nat-Rul Health Products, Inc., Tappan, N.Y., the articles were new drugs without an effective approved New Drug Application—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66185; S. No. 91-574-767/8; S.J. No. 11)

PRODUCT: Bee propolis capsules, and Nutrapathic Nutra-Mune, Nutrapathic D-Yeast, and ImmunAid products, at Sioux Falls, S.D.; Civil No. 90-4139.

CHARGED 9-20-90: While held by Western Vitamins & Health Products, Inc., Sioux Falls, S.D., the articles (which were labeled “Bee Propolis 500 mg. ... Capsules ... Distributed by Western Vitamins and Health Products, Inc., Sioux Falls, South Dakota,” “Nutrapathic Nutra-Mune [or "D-Yeast"] Parametric Associates, Inc., St. Louis, Mo.”, and “ImmunAid ... Nature’s Way Products, Inc., Springville, Utah” and were accompanied by labeling reading “Western Vitamins and Health Products, Inc. ... be propolis has been called a natural antibiotic. ... Boost Your Immune System ... Americans ... suffering from Candida Albicans ... Fight Back With Nutra-Mune and D-Yeast ... Safeguard A Strong Immune System ... ImmunAid”) were new drugs without effective approved New Drug Applications—505(a); the labeling of the articles was false and misleading in claiming that the articles were safe and effective for their intended uses, as follows: bee propolis—for use as “Nature’s Antibiotic,” as well as in the treatment of throat infections, migraine headaches, ulcers, gum disorders, and coughs; Nutra-Mune—for enhancing the body’s defense system and increasing the body’s ability to detect and eliminate foreign substances that may infect the body (i.e., viruses, fungi and bacteria); ImmunAid—for safeguarding a strong immune system, which representations and suggestions are contrary to fact—502(a); and the labeling of the articles failed to bear adequate directions for use and were not exempt due to their new drug status—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66245; S. No. 91-521-531 et al.; S.J. No. 11)

Medical Devices

PRODUCT: Sun-tanning booth with UVB lamps, at Tampa, M. Dist. Fla.; Civil No. 91-887-Civ-T-98A.

CHARGED 7-18-91 and amended 7-21-91: The article, which had been assembled by Chic Tanning Studio (Andrew R. Priede), Tampa, Fla., using interstate medical-use UVB lamps, fell below its purported quality because it contained UVB lamps that were unsuitable for tanning—501(c); the article’s labeling lacked adequate directions for use and were not exempt due to their new drug status—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 65939; S. No. 90-576-652 et al.; S.J. No. 10)
directions for use and adequate directions could not be written since the UVB lamps used in the product were appropriate for use only upon the advice and direction of a physician—502(f)(1); the article’s labeling lacked adequate warnings against unsafe use—502(f)(2); and the manufacturer of the article had failed to register and no pre-market notification had been received by FDA—502(o).

**DISPOSITION:** Consent—dismantling of article ordered. (F.D.C. No. 65870; S. No. 90-516-919 et al.; S.J. No. 13)

**CRIMINAL ACTIONS**

**DEFENDANT:** Anthony F. Vescio, president of a drug packaging & distribution firm, Niagara Falls, W. Dist. N.Y.; Criminal No. 91-53M.

**CHARGED 3-22-91:** While held for sale, hydralazine HCl tablets (lot 0664)—a non-penicillin drug product—was repacked under circumstances lacking good manufacturing practice (i.e., the facilities were not separate from those used for repacking penicillin, the air-handling systems for penicillin operations were not separate from the air-handling systems used for other drug products, and non-penicillin drug products were not tested for penicillin contamination prior to distribution—501(a)(2)(B); and the above drug product—represented to be a drug recognized in the *U.S. Pharmacopoeia*—fell below the standard of such official compendium because the drug product was contaminated with penicillin—501(b).

**DISPOSITION:** Guilty plea—$1,000 fine. (F.D.C. No. 65701; S. No. 86-479-641 et al.; S.J. No. 14)

**INJUNCTION ACTIONS**

**DEFENDANTS:** Adams Supply Co. (aka Adams No-Mo Supply Co., Adams No-Mo Dog Medicine Supply Co., and Adams No-Mo Dog Remedies), and Kathleen Jeffries, proprietor, Bedford, S. Dist. Ind.; Civil No. IP-89-768-C.

**CHARGED 7-6-89 in a complaint for injunction:** That the defendants purchased interstate arecoline hydrobromide tablets and gelatin capsules, placed the tablets inside of the capsules, and packed, labeled, promoted, and distributed in interstate commerce such drug product as “Adams No-Mo Tape Worm Expeller for Dogs”; that the labeling of such drug product lacked adequate directions for use and could not bear such directions, because the article was not safe for animal use except under the professional supervision of a licensed veterinarian—503(c)(1)(A)(i); and the drug product did not qualify for an exemption because the product label did not bear the veterinary Rx legend and because the drug was not sold only to persons who have a prescription from a licensed veterinarian, to licensed veterinarians for use in their professional practice, or to persons regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary prescription drugs. The defendants had been repeatedly warned that their conduct was illegal, and despite such warnings the defendants continued to sell the product in violation of the law.

**DISPOSITION:** The defendants stipulated to facts which established the elements of proof of violation but raised an affirmative defense that the drug product was exempt. It was asserted that 21 U.S.C. 321(w)(1) included exemptions from the term “new animal drug” which exempted No-Mo Tape Worm Expeller from both the new animal drug requirements and the labeling provisions of 502(f)(1), i.e., that there were two grandfather clauses, as follows: first—drugs generally recognized among qualified experts as safe and effective for their labeled uses do not have to undergo testing and approval; and second—by implication an exception independent of the safe and effective criteria, a true grandfather clause for the drug product which was the same product marketed in the same package with the same instruction sheet from the late 1920s subject to the old act and which, therefore, might still be marketed without interference from strictures of the new act. The government asserted that the defendants’ interpretation of the law could not be supported by either the wording of the statute or by case law.

After a hearing and the submission of post-hearing briefs, the court ruled for the government, saying that even if a drug falls under a definitional grandfather clause, that clause does not act to exempt the drug from misbranding provisions. Since FDA decided in 1978 that arecoline was toxic such that it should be administered only under veterinary supervision, that determination brought the drug under the purview of 21 C.F.R. 201.105, and failure to comply with the regulations caused the drug to be misbranded. Regardless of whether or not No-Mo must be classified as a new drug, the court thought the defendants’ drug product could not escape the requirements for toxic animal drugs. The court also agreed with the government that the government’s construction of the grandfather clause did not interfere with congressional intent.

Accordingly, the court perpetually restrained and enjoined the
defendants from the complained-of violations. The defendants appealed. Subsequently, the court denied a motion for an order suspending the injunction pending disposition of appeal. Ultimately, the appeal was dismissed for failure to pay the required docketing fee in a timely fashion. (In. No. 1212; S. No. 89-440-771 et al.; S.J. No. 15)

DEFENDANT: Bernard Swetts, quality assurance director of a defunct drug firm, Niagara Falls, W. Dist. N.Y.; Civil No. 91-0727E. CHARGED 11-7-91 and amended 12-5-91 in a complaint for injunction: That, while held for sale after shipment of interstate components, the circumstances used for the repacking of drugs at the defendant's firm failed to conform with current good manufacturing practice—501(a)(2)(B); that the strengths, quality or purity of certain repackaged drugs, the names of which were recognized in an official compendium, differed from or fell below the standards in such compendium—501(b); that an FDA inspection revealed the failure to separate penicillin product operations from other drug product operations, to separate penicillin air-handling systems from other air-handling systems, and to test non-penicillin drug products for the presence of penicillin prior to distribution; that FDA had advised that penicillin cross-contamination was of particular concern because even small residues of penicillin can cause serious health consequences; that the defendant had continued to repack non-penicillin drug products with penicillin drug products; and that, if not restrained, the defendant was likely to commit similar offenses in other employment resulting in the adulteration of drugs.

DISPOSITION: A consent decree of permanent injunction enjoined the defendants from the complained-of violations. The defendants from the complained-of violations. The defendants from the complained-of violations. The defendants appealed. Subsequently, the court denied a motion for an order suspending the injunction pending disposition of appeal. Ultimately, the appeal was dismissed for failure to pay the required docketing fee in a timely fashion. (In. No. 1212; S. No. 89-440-771 et al.; S.J. No. 15)

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DEFENDANT: Bernard Swetts, quality assurance director of a defunct drug firm, Niagara Falls, W. Dist. N.Y.; Civil No. 91-0727E. CHARGED 11-7-91 and amended 12-5-91 in a complaint for injunction: That, while held for sale after shipment of interstate components, the circumstances used for the repacking of drugs at the defendant's firm failed to conform with current good manufacturing practice—501(a)(2)(B); that the strengths, quality or purity of certain repackaged drugs, the names of which were recognized in an official compendium, differed from or fell below the standards in such compendium—501(b); that an FDA inspection revealed the failure to separate penicillin product operations from other drug product operations, to separate penicillin air-handling systems from other air-handling systems, and to test non-penicillin drug products for the presence of penicillin prior to distribution; that FDA had advised that penicillin cross-contamination was of particular concern because even small residues of penicillin can cause serious health consequences; that the defendant had continued to repack non-penicillin drug products with penicillin drug products; and that, if not restrained, the defendant was likely to commit similar offenses in other employment resulting in the adulteration of drugs.

DISPOSITION: A consent decree of permanent injunction enjoined the defendants from the complained-of violations. The defendants appealed. Subsequently, the court denied a motion for an order suspending the injunction pending disposition of appeal. Ultimately, the appeal was dismissed for failure to pay the required docketing fee in a timely fashion. (In. No. 1212; S. No. 89-440-771 et al.; S.J. No. 15)
The new food labeling regulations call for food retailers to voluntarily provide shoppers with nutrition information about fresh produce, meat and seafood. This chart is one of a series developed by the Food Marketing Institute and other trade associations to help meet this goal.

### POULTRY NUTRITION INFORMATION CHART

#### CHICKEN

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>Total Calories</th>
<th>Protein</th>
<th>Carbohydrate</th>
<th>Total Fat</th>
<th>Saturated Fat &amp; Cholesterol</th>
<th>Sodium</th>
<th>Vitamin A</th>
<th>Vitamin C</th>
<th>Calcium</th>
<th>Iron</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 oz, edible, cooked, skinless</td>
<td>kcal</td>
<td>g</td>
<td>g</td>
<td>g</td>
<td>g</td>
<td>mg</td>
<td>mg</td>
<td>% U.S. RDA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast, baked</td>
<td>116</td>
<td>24</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>72</td>
<td>63</td>
<td>*</td>
<td>*</td>
<td>5</td>
</tr>
<tr>
<td>Drumstick, baked</td>
<td>132</td>
<td>23</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>79</td>
<td>81</td>
<td>*</td>
<td>*</td>
<td>6</td>
</tr>
<tr>
<td>Thigh, baked</td>
<td>150</td>
<td>21</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>81</td>
<td>75</td>
<td>*</td>
<td>*</td>
<td>6</td>
</tr>
<tr>
<td>Whole, roasted</td>
<td>135</td>
<td>23</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>76</td>
<td>73</td>
<td>*</td>
<td>*</td>
<td>6</td>
</tr>
<tr>
<td>Wing, baked</td>
<td>149</td>
<td>23</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>72</td>
<td>78</td>
<td>*</td>
<td>*</td>
<td>6</td>
</tr>
</tbody>
</table>

#### TURKEY

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>Total Calories</th>
<th>Protein</th>
<th>Carbohydrate</th>
<th>Total Fat</th>
<th>Saturated Fat &amp; Cholesterol</th>
<th>Sodium</th>
<th>Vitamin A</th>
<th>Vitamin C</th>
<th>Calcium</th>
<th>Iron</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 oz, edible, cooked, skinless</td>
<td>kcal</td>
<td>g</td>
<td>g</td>
<td>g</td>
<td>g</td>
<td>mg</td>
<td>mg</td>
<td>% U.S. RDA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast, baked</td>
<td>119</td>
<td>26</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>55</td>
<td>44</td>
<td>*</td>
<td>*</td>
<td>8</td>
</tr>
<tr>
<td>Drumstick, baked</td>
<td>143</td>
<td>24</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>67</td>
<td>80</td>
<td>*</td>
<td>*</td>
<td>13</td>
</tr>
<tr>
<td>Thigh, baked</td>
<td>142</td>
<td>23</td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>66</td>
<td>71</td>
<td>*</td>
<td>*</td>
<td>14</td>
</tr>
<tr>
<td>Whole, roasted</td>
<td>129</td>
<td>25</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>64</td>
<td>59</td>
<td>*</td>
<td>*</td>
<td>8</td>
</tr>
<tr>
<td>Wing, baked</td>
<td>137</td>
<td>26</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>60</td>
<td>76</td>
<td>*</td>
<td>*</td>
<td>8</td>
</tr>
</tbody>
</table>

*Contains less than 2% of U.S. RDA

Serving Size: 3 oz. boneless, cooked, skinless portion roasted, baked, broiled/grilled, microwaved, stir fried, or cooked in liquid—without additional fat, salt, sodium or sauces.

(Data Source: USDA)