

Forum

A New Soot Standard?

In the air pollution arena, the spotlight is now shining on a series of studies conducted over the past 5 years which indicates that thousands of deaths a year are caused by inhaling tiny particles of soot, emitted mainly from industrial sites.

If evidence from the studies, conducted by the EPA, NIEHS, and Harvard School of Public Health, proves conclusive, the federal government will have to rewrite the standard for particle pollution, a legal limit which currently allows an estimated 50,000 to 60,000 deaths a year. Rob Brenner, director of the Air Policy Office in EPA's Office of Air and Radiation, said in a recent *New York Times* article, "We have a real concern about the new data. If it turns out that recent analyses show that particles are the much more significant problem than they seemed to be, our efforts to control particles and our acid rain initiatives will not be enough. We will have to do more."

Environmental groups and others claim that research dollars and regulatory efforts aimed at pollution control have focused on other types of pollution such as ozone and sulfur dioxide and, that of the air pollution efforts aimed at particles, most goes to devices such as scrubbers on power plants that catch only large particles (those larger than 10 microns, as opposed to soot particles which are 10 microns or smaller in diameter).

Evidence of health effects of the particles, including deaths among children with respiratory problems, adults with asthma, and the elderly with illnesses such as bronchitis and emphysema, is based on epidemiological studies. One study, which looked at adjusted mortality rates of 8000 adults in 6 communities for 16 years, found a "strong association" with exposure to particles. A second study, also conducted by the Harvard School of Public Health, tracked the relationship of acid

rain and respiratory infections in children in 24 communities in the United States and Canada.

Some scientists believe that epidemiological evidence alone is not enough to prove a conclusive cause-and-effect relationship between particle exposure and health effects, and that further research, including exposure studies, is warranted before the legal standard is adjusted.

Many hope the emergence of these data will prompt EPA to perform some of the needed research and reformulate a new particle standard, which by law should have been reviewed and updated last year. However, EPA policy officials predict that any action soon is unlikely, citing lack of manpower in EPA laboratories.



A Hero's Welcome. Students in Ghana greet former President Jimmy Carter.

Guinea Worm Gone

The elimination of smallpox in the 1970s was one of the most dramatic public health

achievements of the 20th century. Today, international public health workers are confident that another devastating illness will be eradicated before the year 2000. Dracontiasis, also known as "guinea worm infection," should succumb to a combination of environmental intervention and public health education by 1995. If the prediction is realized, guinea worm infection will be only the second disease to be eradicated.

Dracontiasis is caused by a human parasitic nematode, *Dracunculus medinensis*, common in rural areas of India, Africa, and Pakistan. The larvae of the worm are carried by water fleas that infest drinking water supplies in predominantly rural areas. People are infected by drinking water contaminated with the larvae. These larvae incubate in their human hosts for a year, then transform into a thin worm that grows to a length of two to three feet. When mature, the worm bores out of the body through the skin. The worms produce new larvae that then taint the drinking water, repeating the cycle of infection.



Unwelcome guest. Larvae of guinea worms live in their human hosts for a year before the two- to three-foot adult worms bore out through the skin.

Neither the worms nor the larvae are transmitted person to person, and the worms can only reproduce in their human hosts.

Donald Hopkins, who retired as deputy director of the National Centers for Disease Control and Prevention and is now with former President Jimmy Carter's private health program, Global 2000, has waged a quietly effective, personal campaign against the disease for many of the past 25 years.

Hopkin's eradication strategy includes two simple but remarkably effective objectives. First, all persons in epidemic areas are given fine mesh cloth and taught to filter their drinking water. Second, health education programs are implemented to encourage persons to stay away from the community water supply when the worms are emerging from their bodies. As a result of this approach the number of persons newly infected with guinea worm has decreased from about one million per year to a few hundred thousand per year over the past three years. If the present trend in disease incidence continues, the disease will be eradicated within three to five years.

Former President Carter has helped raise over \$40 million in contributions from a variety of sources to support the eradication campaign. He also visited epidemic areas in eastern Africa in August to call attention to the international effort. Carter's prestige and influence in developing nations have lent importance and credibility to the guinea worm eradication effort among high-level government officials and among the residents of the epidemic areas.

If the project is successful, a low-technology, environmental public health intervention strategy will be responsible for the eradication of one of the most gruesome parasitic diseases known.

EPA Nominations Made

President Clinton has made nominations to fill key assistant administrator positions in the program offices at the Environmental Protection Agency. After the candidates are confirmed by the Senate, they will manage the implementation of the categorical environmental protection activities defined in federal law.

Lynn Goldman has been nominated as assistant administrator for prevention, pesticides, and toxic substances. Goldman, a toxicologist with the California Department of Health Services, will manage EPA's programs in pollution prevention, pesticides, and toxics programs. Toxics programs include the activities authorized under the Toxic Substances Control Act and Federal

Insecticide, Fungicide, and Rodenticide Act. Goldman served as a counselor to the National Toxicology Program.

Mary Nichols, an attorney with the National Resources Defense Council in Los Angeles, has been nominated as assistant administrator for air and radiation. She will manage the implementation of the Clean Air Act amendments, the radon and other radiation programs, and the indoor air pollution control activities at EPA. Nichols was California Secretary of Environmental Affairs and chair of the California Air Resources Board from 1979 to 1982.

Robert Perciasepe has been nominated as assistant administrator for water. Perciasepe, Secretary for the Environment in Maryland, will manage the EPA programs authorized by the Clean Water Act and the Safe Drinking Water Act. These federal statutes are due to be reauthorized by Congress and have major impacts at the state and local levels.

The nominee for assistant administrator for solid waste and emergency response is Elliot Laws. Laws, an attorney in private practice in Washington, DC, will administer the Superfund hazardous waste program and the federal activities related to the disposal of municipal solid waste. The Superfund Program has been widely criticized by community groups, industry, and environmentalists and is scheduled for reauthorization in the next session of Congress. Laws has considerable federal experience as a litigator in the Department of Justice Land and Natural Resources Division from 1985 to 1987 and in the Office of Enforcement and Compliance Monitoring at the EPA.

Bailus Walker has withdrawn his candidacy for assistant administrator for Research and Development. Walker, dean of the School of Public Health at the University of Oklahoma, cited unreasonably long delay in the nomination and clearance process and his commitment to the university in the letter explaining his withdrawal. Administration officials have not yet proposed another candidate, and it is not known when an administrator of this important program office that manages the engineering and health research activities for EPA will be named.

New NIH Director

Harold Varmus, a cell biologist from the University of California at San Francisco, was nominated by President Clinton on

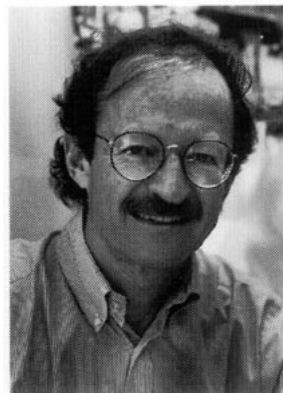
August 4 to direct the National Institutes of Health. In announcing the nomination, Secretary of Health and Human Services Donna Shalala described the appointment as "absolutely first rank."

As the director of NIH, Varmus will manage the largest and most complex biomedical research effort in the world. The NIH is made up of 24 institutes, centers,

and divisions. Among these are the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and a clinical center at its 300-acre headquarters in Bethesda, Maryland, and the National Institute of Environmental Health Sciences in Research Triangle Park, North Carolina. The NIH has about 15,000 employees and an annual budget of about \$11 billion. Approximately 80% of the NIH budget supports research and training grants to scientists throughout the United States.

American preeminence in medicine and human biology and physiology is attributed largely to the NIH program of extramural research grants and intramural science that have been developed over the past 40 years.

Varmus takes over NIH at a critical period. Each week brings a report of major new findings in the fundamental mechanisms of disease and in the treatment of previously intractable conditions. But even as these achievements are announced, NIH is not prospering as it has in the past. Traditionally, Congress exempted the NIH from budget cuts often exacted on other domestic programs. In the 1980s, the NIH budget increased dramatically; in the past two years this trend has not continued. The NIH appropriation has not kept pace with inflation. Thus, the number of new grant applications funded by NIH has not grown, and university-based scientists are frustrated by the fact that their research proposals receive high marks in peer review yet are not funded by NIH. Support for fundamental, nontargeted research, long a staple of the NIH grant system, has decreased as NIH is pressed to be more responsive in applying research to the resolution of the immediate health needs of victims of AIDS and of women, the elderly, and the poor. Allegations of scientific fraud on the part of a few NIH and NIH-supported researchers and recent reports of sexual harassment and failure to promote minorities and women have eroded some of the public's confidence in science and in the management of NIH.



Harold E. Varmus—Nobel Prize winner seeks change for NIH.

Varmus's record of achievement suggests that he will meet the challenges confronting him as new director. In 1989, Varmus was awarded the Nobel Prize in Medicine for discovering oncogenes and describing their role in the molecular biology of cancer. His research interests also include viruses involved in human disease. In addition to his research, Varmus taught several basic science courses to students at the UC-San Francisco Medical School. He studied English at Amherst as an undergraduate and received a master's degree in English literature from Harvard before graduating from medical school at Columbia University. Varmus spent two years at NIH in the 1970s as a clinical associate in the National Institute of Arthritis and Metabolic Diseases.

In what may become a blueprint for the administration of the NIH under his leadership, Varmus co-authored a forceful plea to President Clinton and Vice President Gore for support for science in the 22 January 1993 issue of *Science*. In a Policy Forum article, Varmus stressed the potential benefits of science in resolving the health, environmental, and economic problems facing the nation. He went on to make 11 specific recommendations to help realize the potential of science. Some of these recommendations included developing an economic strategy to encourage investment in biomedical research, encouraging technology research in the private sector, and stimulating alliances between industry and academia, establishing NIH as an independent federal agency, and strengthening the position of the presidential advisor on science and technology. The nomination of Varmus must be approved by the Senate. If confirmed, he will be in a powerful position to implement his recommendations at NIH.

Varmus will have one important ally in his new position. In July, the Senate confirmed President Clinton's appointment of Phillip R. Lee as assistant secretary for health in the Department of Health and Human Services. Lee will be Varmus's immediate superior in the Public Health Service. Lee returned to Washington (he was assistant secretary for health in the Johnson administration) from the UC-San Francisco where he directed the Institute of Health Policy. Earlier, Lee was dean of the medical school where Varmus taught and conducted research. Lee has a long history of contributions in the field of health care policy research. He has been deeply

involved in developing the health care reform agenda for the Clinton administration.

Arsenic and New Data

Exposure to high levels of inorganic arsenic through inhalation or ingestion causes cancer, a fact that was never challenged at the July 28-30 International Conference on Arsenic Exposure and Health Effects. Hours of conference presentations and debate centered instead on ways to use data on documented health effects from high arsenic exposures to predict effects at the lower levels commonly seen in U.S. communities. Keynote speaker Warner North of Decision Focus, Inc., emphasized that there are significant, unresolved issues "in extrapolating from worst case scenarios" and suggested it may be necessary to move beyond standard risk assessment methods when evaluating the carcinogenicity of arsenic. Arsenic exposure occurs most commonly in the U.S. from dietary intake, soil or dust around old mine and smelter operations, coal fly ash, and the use of arsenical pesticides.

An arsenic standard for drinking water must be proposed by September 1994 to satisfy a court order against EPA. Charles Abernathy, a toxicologist with the Risk Assessment Branch of EPA and co-chair of the conference, said that a crucial component of EPA's risk assessment is Taiwanese research which links skin cancer to high levels of arsenic in drinking water. More recent studies in Taiwan also found internal organ cancers (e.g., bladder and kidney cancers) in the population studied.

The lead author of the Taiwanese studies, C.J. Chen, presented new data showing not only cancer but also an elevated risk of ischemic heart disease among residents of southwest Taiwan who drank water with high levels of arsenic. Previous studies of well water in this area of Taiwan found arsenic levels between 10 and 1820 micrograms per liter ($\mu\text{g}/\text{l}$).

The current U.S. standard for arsenic in drinking water is 50 $\mu\text{g}/\text{l}$. Several EPA representatives indicated that an EPA risk assessment, based on the Taiwan skin cancer data, would likely result in a proposed standard of 2-5 $\mu\text{g}/\text{l}$ of arsenic; the number would be even lower if the internal organ cancers are part of the equation.

Requiring all water systems in the country to comply with a 2 $\mu\text{g}/\text{l}$ standard would cost \$6.3 billion, according to J. Alan Roberson of the American Water

Works Association (AWWA). The highest impact would be on Western states, where water generally has higher arsenic levels.

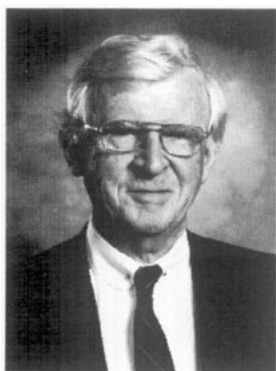
Other water utility speakers urged EPA to seek an extension of its deadline to accumulate more scientific and economic feasibility data, arguing that the population in Taiwan is significantly different from the U.S. population. Chen agreed that diet and socioeconomic characteristics between his study population and the typical U.S. community vary, but said his studies provide persuasive evidence that inorganic arsenic causes human cancer.

Conference attendees agreed that much more research needs to be conducted on the mechanism of arsenic carcinogenicity, especially in the areas of pharmacokinetics and metabolism. There is convincing data that inorganic arsenic causes human cancer, but no animal model has been able to reproduce the effect. A key research question, participants agreed, is the dynamic of how much inorganic arsenic is ingested, how much is delivered to internal organs, and how much is converted to methylated forms and excreted.

A heated topic of debate was whether there is a linear dose-response relationship for arsenic or if instead there might be a threshold at which ingested arsenic fails to cause a cancer risk. Roberson told *EHP* that the EPA drinking water standard for arsenic could remain unchanged if there is a threshold for cancer at 50 or 100 $\mu\text{g}/\text{l}$. Allan Smith of the University of California, Berkeley, on the other hand, has argued that the available evidence does not support a threshold theory. He told the audience, "Until you have studies at low dose rates you have to extrapolate." [See Smith AH, "Cancer Risks from Arsenic in Drinking Water," *EHP* 97: 259-267 (1992).]

Co-chair Abernathy believes the conference met its aim: to allow rational discussion of the Taiwan data among people with diverse views, ranging from analytical chemists to water works engineers to environmentalists. The conference "made clear the uncertainties of the economic impact and health impact of regulating arsenic," Willard Chappell of the University of Colorado, Denver, told *EHP*. Chappell urged EPA to consider all new research data when making its regulatory decisions, warning, "billions of dollars are at stake here."

The three-day conference was sponsored by the Society of Environmental Geochemistry and Health, the Agency for Toxic Substances and Disease Registry, EPA, the American Water Works Association, Atlantic Richfield Co. (ARCO), the American Mining Congress, the Electric Power Research Institute, the International



Phillip R. Lee—a deep interest in health care reform.

UC-San Francisco

Committee on Metals in the Environment, and U.S. Borax. Among the 145 conference attendees were representatives of FDA, the Canadian government, various state and local water utilities, environmental agencies, energy utilities, and scientists from the United States, Taiwan, Mexico, Chile, Canada, Australia, and Europe.

A Win for Wetlands

On August 24, an interagency working group composed of nine federal agencies, including EPA, the Department of Agriculture, and the Army Corps of Engineers, announced a new wetlands initiative touted as fair, comprehensive, and ending years of gridlock.

"The new agreement is a significant advance in protecting American wetlands, which are currently being lost at a rate of nearly 300,000 acres per year," said EPA Administrator Carol Browner. "The agreement is fair to landowners at the same time that it protects our water quality and wildlife."

The interagency working group was formed in response to a request from seven U.S. senators that the White House take the lead in resolving the contentious wetlands issues that have been the heart of controversy for years. The interagency group has been meeting since June, hearing farmers, environmentalists, developers, and scientists.

"This wetlands policy is meaningful reform—for the environment and for the farmers and ranchers of America," said Agriculture Secretary Mike Espy. "It is a fair and flexible policy that simplifies the process of identifying wetlands and provides farmers a simpler method for identi-

fying federal requirements for wetland conservation."

The new wetlands initiative includes more than 40 changes to current policy. Some parts of the plan will take effect over the next several months; other parts take the form of legislative recommendations for Congress as part of the reauthorization of the Clean Water Act, which will be addressed this fall. Specifics of the wetlands plan are:

- Close a loophole that allowed destructive activities such as draining to go unregulated,
- Establish a new appeals process so that farmers and landowners can seek review of permit decisions without going to court,
- Impose deadlines on permit decisions,
- Establish the Soil Conservation Service of the Department of Agriculture as the lead agency for wetland determinations on agricultural lands,
- Withdraw a proposed rule that would have left Alaskan wetlands unprotected,
- Increase emphasis on state, tribal, and local government roles, as well as voluntary wetlands protection programs with landowners.

The new initiative has been well received thus far. Gerald Digerness, president of the National Association of Conservation Districts and a dairy farmer, said, "After years of confusion and conflict regarding wetlands protection and regulation, America's conservation districts welcome what appears to be a fair, flexible, and technically feasible approach that recognizes the environmental, economic, and social benefits of these valuable resources."



Wetlands drying up. A new federal initiative would stem the current loss of nearly 300,000 acres per year.

Brain Food

Children are often told how important it is to eat their spinach and broccoli in order to get their vitamins. For pregnant women and women of childbearing age, the Food and Drug Administration will soon take that advice a step further when it begins fortifying the food supply with folic acid, a B-vitamin found in spinach, broccoli, and other foods, which could cut the rate of neural tube birth defects by 70% and significantly decrease the incidence of other birth defects.

"This is the most important medical finding of the 20th century," said Godfrey Oakley, director of the birth defects division at the U.S. Centers for Disease Control and Prevention in Atlanta, speaking of folic acid's role in preventing birth defects. "It's like the Salk vaccine—its that magnitude of importance," said Oakley.

The decision to fortify products including enriched flours, rice, and cornmeal was made in response to evidence showing that even women with well-balanced diets are not getting enough folic acid, which is broken down at an increased rate during pregnancy. Neural tube disorders, including spina bifida and anencephaly, occur 20–24 days after conception when tissues forming the neural tube (which gives rise to the brain and spinal cord) fail to close. Since many women may not even be aware of the pregnancy at this point, it is vital that they receive folic acid even before becoming pregnant. Folic acid has no effect after the defects have occurred.

The push for fortification of food with folic acid has been slowed somewhat by concerns that it can make detection of pernicious anemia, a rare blood disorder which can cause nerve and brain damage, more difficult. Scientists at CDC have responded that these concerns can be alleviated by controlling the amounts given.

Not only does folic acid prevent neural tube disorders, it may also protect against potential harmful side effects to children from *in utero* exposure to methanol. Folic acid is critical in the detoxification of methanol, which is currently being considered by government and industry as an alternative fuel. In cases of folic acid deficiency, formate, a metabolite of methanol, accumulates in the blood, creating a pH imbalance which can cause toxicity [see Forum, *EHP* 101(2)].

Milwaukee's Water Woes

Anyone who lives in metropolitan Milwaukee knows what contaminated water can do to a community. What was probably one of the world's most massive documented outbreaks of waterborne illness occurred this spring when cryptosporidia,

an organism that causes incapacitating diarrhea in humans, found its way into Milwaukee's water system. Ironically, the outbreak may have come about in part because of attempts by the city to improve the water supply.

An EPA assay found an unacceptably high level of lead in the water earlier in the year and, in an effort to eliminate the lead, Milwaukee's water department was trying a new filtering chemical, aluminum hydroxychloride, in place of alum. Alum, although it is the standard filtering chemical used, can cause lead to leach from pipes. Milwaukee's water and health authorities think that climatic variations, including spring runoff, wind, and temperature, combined with Lake Michigan's usual north-to-south current, may have swept a plume of sediment—and a bolus of cryptosporidia—toward the water intake, where the new filtering chemical may have affected the pH of the water, creating a more amenable environment for the virus.

For the first three weeks in April, the city cautioned its one million citizens not to drink the city's water, which is drawn from Lake Michigan and treated in municipal plants. The warning came too late for many, who were afflicted by severe diarrhea that lasted a week or more. Even after the population stopped using the water, the parasite continued to spread by its secondary, fecal-oral, path with new cases continuing to appear well into May.

The city's department of health estimates that more than 400,000 person-days

of work were lost. More than 4000 people required hospitalization, and some of those infected died. "Cryptosporidia kills by rapid dehydration," says Dennis Juranek, chief of epidemiology in the parasitic diseases branch at the Centers for Disease Control and Prevention. "Patients can lose 10 or 20 liters of fluid a day."

With no preventive vaccine and no effective drug therapy, those stricken could only wait out the infection, drinking fluids, and trying to be punctilious about hygiene. Although cryptosporidial infections do no lasting harm to people in good health, they can be fatal to those who are immunocompromised, such as cancer patients undergoing chemotherapy, organ transplant recipients taking antirejection medication, or patients with AIDS or other conditions that suppress the immune response.

While it's certain that some died from the infection, precise mortality figures won't be available until some time next year, according to Wisconsin state epidemiologist Jeffrey Davis. "When the parasite was found in a person who had an underlying disease, it's hard to determine whether death came as a direct result of cryptosporidia or from other causes," Davis said.

Months after the water system was flushed and cleansed with high concentrations of chlorine, Milwaukee's city council is still assessing the epidemic, spending over a quarter million dollars on consultants and studies to learn what went wrong and how to prevent recurrences.

Published reports blame the epidemic on runoff from Wisconsin dairy farms, sweeping cryptosporidia's sporelike oocytes into the rivers that flow eastward into Lake Michigan, from which Milwaukee draws its water. Urban-versus-rural feeling has begun to stir between prosperous Milwaukee and the rural dairy farmers, some of whom say the city is blaming them unfairly and underestimating their contribution to the state's economy. But the simplistic explanation of dairy farm runoff may tell only part of the story.

Cattle aren't the only animals that harbor cryptosporidia, says Juranek. Deer and elk, among other mammals that live along the rivers in the watershed, could have been the source of the parasite. Meat-packing plants in urban Milwaukee might also have been responsible, with waste running untreated into storm sewers. Furthermore, the parasite, which can survive outside a living host for 6–12 months if the environment is moist, may hide in the sediment of Lake Michigan.

The water-intake for the water plant affected by cryptosporidia is located about 3/4 miles offshore, just south of the point where the river empties into the lake. Beach samples taken along the shore show that a plume of turbid river sediment spreads into the lake. The city's careful water-treatment procedures probably kept cryptosporidia to a minimum. However, cases that occurred in the past may have been misdiagnosed.