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S.F. No. 979 - Healthy Minnesotans Biomonitoring Program

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Date: March 22, 2006

S.F. No. 979 establishes the healthy Minnesotans biomonitoring program to provide voluntary and confidential community-based monitoring to identify toxic chemicals that may be present in the environment.

Section 1 (144.995) creates the healthy biomonitoring program.

Subdivision 1 states that this act may be cited as the healthy Minnesotans biomonitoring program.

Subdivision 2 defines the following terms: "biomonitoring," "biospecimen," "commissioner," "panel," and "toxic chemical."

Subdivision 3, paragraph (a), requires the Commissioner of Health to establish the healthy biomonitoring program. States that the program shall provide community-based biomonitoring on a voluntary and confidential basis by utilizing biospecimens to identify toxic chemicals in the environment.

Paragraph (b) states that initially the program shall examine breast milk in three economically, racially, and geographically diverse communities and identify any toxic chemical that is present in the breast milk. The commissioner shall expand the program by examining other biospecimens in additional communities as funds become available.

Paragraph (c) states that when a toxic chemical is detected in a participant, the commissioner, in consultation with the Commissioners of Agriculture, Natural Resources,

and the Pollution Control Agency, and other entities, must examine the possible presence of the toxic chemical in the surrounding environment and possible routes of exposure, and must develop recommendations to reduce or minimize possible contamination or exposure to the toxic chemical.

Subdivision 4, paragraph (a), states that participation in the program is voluntary. Participants shall be evaluated for the presence of toxic chemicals. Participants will also receive consultation, health care referrals, follow-up counseling, and offered educational materials.

Paragraph (b) states that the individual results of the participants are confidential and are not to be made public without the written and informed consent of the individual.

Subdivision 5, paragraph (a), requires the commissioner to develop:

(1) model protocols or guidelines that address the science and practice of biomonitoring to be utilized;

(2) guidelines for ensuring confidentiality, informed consent, follow-up counseling and support, and communicating findings;

(3) educational and outreach materials for dissemination to participants and communities;

(4) a training program for health care providers, educators, and other program administrators; and

(5) a designation process for state and private laboratories that are qualified to analyze biospecimens and report findings.

Paragraph (b) authorizes the commissioner to enter into contractual agreements with health clinics, community-based organizations, or experts to perform any of the activities described under this subdivision.

Section 2 (144.996) establishes a healthy Minnesotans biomonitoring program advisory panel.

Subdivision1 creates the advisory panel consisting of two committees, the scientific committee and the community representative committee.

Subdivision 2 describes the membership of each of the committees.

Subdivision 3 describes the duties of each committee.

Subdivision 4 creates immunity for members of the panel.

Section 3 establishes the toxic chemicals that are to be included within the scope of the program.

Subdivision 1 requires the commissioner to identify and list the toxic chemicals that are to be included. States that to be included on the list, the following criteria must be met:

(1) the chemical must be recommended for inclusion by the scientific committee;

(2) the scientific, peer-reviewed data from studies have demonstrated the chemical is known or strongly suspected to negatively impact human health by contributing to an increase in serious illness or mortality;

(3) Minnesotans are exposed to the chemical; and

(4) the chemical is listed as a toxic chemical on either a state of federal list.

Subdivision 2 requires the commissioner to prioritize the toxic chemicals according to the threat the chemical poses to public health. The commissioner shall initially implement the biomonitoring activities with regard to the top 20 toxic chemicals that present the greatest public health risk and add additional chemicals in order of priority to the extent funds are available.

Section 4 (144.998) creates a healthy Minnesotans biomonitoring program account in the state government special revenue fund and states that all funds appropriated are to be deposited in this account. The commissioner is required to seek funding from federal and private sources.

Section 5 (144.999) requires the commissioner to submit a report to the Legislature by January 15, 2008, summarizing the initial activities of the program. Thereafter, the commissioner is required to submit biennial reports describing the effectiveness of the program. The report shall be made available to local public health departments and the general public in a summary format. The report shall be available through the Department's Web site.

KC:ph

Senators Lourey, Kelley, Ranum and Rosen introduced--

S.F. No. 979: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; establishing a healthy biomonitoring program; requiring reports; appropriating money; proposing coding for new law in Minnesota Statutes, chapter 144.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [144.995] [HEALTHY MINNESOTANS BIOMONITORING PROGRAM.]

Subdivision 1. [CITATION.] Sections 144.995 to 144.999 may be cited as the healthy Minnesotans biomonitoring program.

Subd. 2. [DEFINITIONS.] (a) For purposes of sections 144.995 to 144.999, the following definitions apply.

(b) "Biomonitoring" means the process by which the presence and concentration of toxic chemicals and their metabolites are identified within a biospecimen as a means to assess the accumulation of pollutants in a human body.

(c) "Biospecimen" means a sample of human blood, hair, urine, breast milk, body fat, or other body tissue or any other biophysical substance that is reasonably available as a medium to measure the presence and concentration of toxic chemicals.

(d) "Commissioner" means the commissioner of health.

(e) "Panel" means the Healthy Minnesotans Biomonitoring Program Advisory Panel established under section 144.996.

(f) "Toxic chemical" means a chemical:

(1) for which data provided by scientific, peer-reviewed

animal, cell, or human studies have demonstrated the chemical is known or strongly suspected to negatively impact human health by contributing to an increase in serious illness or mortality; and

(2) that has been identified according to section 144.997.

Subd. 3. [ESTABLISHMENT; DUTIES.] (a) The commissioner shall establish the healthy Minnesotans biomonitoring program. The program shall provide community-based biomonitoring on a strictly voluntary and confidential basis by utilizing biospecimens, as appropriate, to identify toxic chemicals that may be present in the environment.

(b) Initially, to the extent that funds are available, the program shall examine breast milk in three economically, racially, and geographically diverse communities and identify any toxic chemical that is present in the breast milk. The commissioner shall expand the program, to the extent that funds are available, by examining other biospecimens in additional communities.

(c) When a toxic chemical is detected in a program participant, the commissioner, in consultation with the commissioners of agriculture, natural resources, and the Pollution Control Agency, and other public or private entities, as appropriate, shall examine the possible presence of the toxic chemical in the surrounding environment and possible routes of exposure and shall develop recommendations to reduce or minimize possible contamination or exposure to the toxic chemical.

Subd. 4. [PARTICIPATION.] (a) Participation in the biomonitoring program is voluntary. All participants shall be evaluated for the presence of toxic chemicals as a component of the biomonitoring process. Participants shall receive consultation, health care referrals, and follow-up counseling and shall be offered educational materials, including, but not limited to, information regarding possible routes of exposure, ways to reduce exposure, and the availability of state and local resources.

(b) The individual results of the program's participants are confidential and shall not be made public without the

written and informed consent of the individual to whom it pertains.

Subd. 5. [PROGRAM GUIDELINES.] (a) The commissioner, in consultation with the panel, shall develop:

(1) model protocols or program guidelines that address the science and practice of biomonitoring to be utilized and procedures for changing those protocols to incorporate new and more accurate or efficient technologies as they become available. The model protocols shall be developed utilizing a peer review process in a manner that is participatory and community-based in design, implementation, and evaluation;

(2) guidelines for ensuring confidentiality; informed consent; follow-up counseling and support; and communicating findings to participants, communities, and the general public;

(3) educational and outreach materials that are culturally appropriate for dissemination to program participants and communities. Priority shall be given to the development of materials specifically designed to ensure that parents are informed about all of the benefits of breastfeeding so that the program does not result in an unjustified fear of toxins in breast milk, which might inadvertently lead parents to avoid breastfeeding. The materials shall communicate relevant scientific findings; data on the accumulation of pollutants; possible routes of exposure; population-based health effects and toxicity; the benefits of linking the accumulation of pollutants to community health; and the required responses by local, state, and other governmental entities in regulating toxicant exposures;

(4) a training program that is culturally sensitive specifically for health care providers, health educators, and other program administrators; and

(5) a designation process for state and private laboratories that are qualified to analyze biospecimens and report the findings.

(b) The commissioner may enter into contractual agreements with health clinics, community-based organizations, or experts

in a particular field to perform any of the activities described under this subdivision.

Sec. 2. [144.996] [HEALTHY MINNESOTANS BIOMONITORING PROGRAM ADVISORY PANEL.]

Subdivision 1. [CREATION.] (a) The commissioner shall establish the Healthy Minnesotans Biomonitoring Program Advisory Panel. The panel shall be composed of two committees, the scientific committee and the community representative committee, with a membership of eight voting members on each committee. The community representative committee shall also include nonvoting members appointed according to subdivision 2, paragraph (d).

(b) The commissioner shall appoint, from the panel's membership, the chair of each of the committees, who shall also serve as cochairs of the panel.

(c) The panel shall meet as often as it deems necessary but at a minimum on a quarterly basis.

(d) Members of the panel and the committees shall serve without compensation but shall be reimbursed for travel and other necessary expenses incurred through performance of their duties under sections 144.995 to 144.997.

Subd. 2. [MEMBERSHIP.] (a) Eight of the voting members shall be appointed by the commissioner, four of the voting members shall be appointed under the rules of the senate, and four of the voting members shall be appointed under the rules of the house of representatives. Nonvoting members shall be appointed by the commissioner according to paragraph (d). All members shall be appointed to the panel by July 1, 2006. Each voting member shall be appointed for a three-year term. All appointments made by the commissioner shall be approved by the governor.

(b) The scientific committee shall be composed of eight members with background or training in interpreting biomonitoring studies or in related fields or science, including, but not limited to, the fields of health tracking, social science, laboratory science, occupational health,

industrial hygiene, toxicology, epidemiology, environmental health, environmental hazards, and public health.

(c) The community representative committee shall be composed of eight members from the following nongovernmental organizations:

(1) one member from a breast cancer awareness organization;

(2) one member from an organization with a focus on environmental health;

(3) one member from an organization with a focus on environmental justice;

(4) one member from an organization with a focus on child environmental health;

(5) one member from an organization promoting breastfeeding;

(6) one member from a labor organization;

(7) one member from private industry with a verifiable and consistent commitment to sustainable core business practices that reduce environmental toxins; and

(8) one member from a public health organization.

(d) The commissioner shall appoint the following additional nonvoting members to the community representative committee:

(1) one representative from the Maternal and Child Health Division of the Department of Health; and

(2) one member from each participating community.

Members appointed under this paragraph may be reappointed at any time and are not subject to the three-year term.

Subd. 3. [COMMITTEE DUTIES.] (a) The scientific committee shall make recommendations to the panel on:

(1) chemicals that should be added to or deleted from the list of chemicals identified under section 144.997;

(2) priorities for biomonitoring in Minnesota;

(3) the adequacy and appropriate interpretation of biomonitoring investigations carried out under the program; and

(4) collecting and analyzing data.

(b) The community representative committee shall make recommendations to the panel on:

(1) study sites or communities for the program;

(2) identifying possible community partners;

(3) training programs and educational and outreach materials; and

(4) dissemination of findings to biomonitoring program participants and to the general public.

Subd. 4. [IMMUNITY FROM LIABILITY.] No member of the panel shall be held civilly or criminally liable for an act or omission by that person if the act or omission was in good faith and within the scope of the member's responsibilities under sections 144.995 to 144.999.

Sec. 3. [144.997] [TOXIC CHEMICALS.]

Subdivision 1. [IDENTIFICATION.] The commissioner shall identify and list toxic chemicals that shall be included within the scope of the healthy Minnesotans biomonitoring program. To be included on the list, all of the following criteria must be met:

(1) the chemical is recommended for inclusion by the scientific committee under section 144.996;

(2) the scientific, peer-reviewed data from animal, cell, or human studies have demonstrated the chemical is known or strongly suspected to negatively impact human health by contributing to an increase in serious illness or mortality;

(3) Minnesotans are exposed to the chemical; and

(4) the chemical is listed as a toxic chemical on either a state or federal list.

Subd. 2. [IMPLEMENTATION.] (a) The commissioner shall prioritize the toxic chemicals under subdivision 1 according to the threat the chemicals pose to public health.

(b) The commissioner shall initially implement the biomonitoring activities of the program with regard to the 20 toxic chemicals that present the greatest public health risk.

(c) The commissioner shall add additional chemicals in order of priority to the extent funds are available.

Sec. 4. [144.998] [BIOMONITORING FISCAL PROVISIONS.]

Subdivision 1. [CREATION OF ACCOUNT.] A healthy

Minnesotans biomonitoring program account is established in the state government special revenue fund. The account consists of money appropriated by the legislature and any other funds identified for use by the healthy Minnesotans biomonitoring program. All interest earned on money deposited into the account shall be retained in the account. Money in the account is appropriated to the commissioner for the purpose of implementing the healthy Minnesotan biomonitoring program.

Subd. 2. [OTHER FUNDING.] The commissioner shall seek funding from federal and private sources.

Sec. 5. [144.999] [BIOMONITORING REPORTS.]

(a) By January 15, 2007, the commissioner shall submit a report to the legislature summarizing the initial activities of the healthy Minnesotans biomonitoring program, including a program description, the methodology used, and the initial outcomes.

(b) Thereafter, the commissioner shall prepare a biennial report describing the effectiveness of the program, including analysis of the health and environmental exposure data collected to adequately monitor the activities under section 144.995. The report shall be made available to local public health departments and the general public in a summary format that protects the confidentiality of program participants. The commissioner shall disseminate the report via the Department of Health's Web site.

Senator ..... moves to amend S.F. No. 979 as follows:

Page 2, line 24, after "exposure" insert "and disease outcomes"

Page 2, line 35, delete everything after "(b)" and insert "Data collected under the biomonitoring program are health data for purposes of section 13.3805 and shall not be made public without the written and informed consent of the individual to whom it pertains."

Page 2, delete line 36

Page 3, delete lines 1 and 2

Page 5, line 34, before the period, insert ", including the tracking of diseases for which there is scientific evidence of an environmental etiology"

Page 6, delete lines 7 to 11

Page 7, line 12, delete "2007" and insert "2008"

Sen. Lowry

National Conference of State Legislatures

ENVIRONMENTAL HEALTH SERIES

Biomonitoring

July 2004, Issue 8

In This Issue

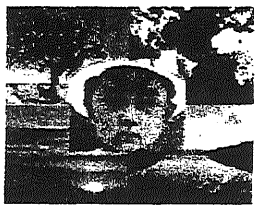
Overview

Biomonitoring, the process of measuring environmental chemicals in people, plays an important role in protecting public health by helping researchers determine what environmental factors influence conditions or diseases such as birth defects, developmental disabilities and cancer. Biomonitoring also is an essential part of the public health response to chemical emergencies, whether accidental or terrorist. Although federal government laboratories can conduct biomonitoring, most state laboratories do not have biomonitoring capacity and lack the resources to develop this capability. A federal effort is currently under way to help states develop this capacity so they can better respond to local environmental health concerns.

What Questions Can Biomonitoring Help Answer?

- Do increased levels of mercury, dioxin or polychlorinated biphenyls (PCBs) in game fish threaten our community's health?
- Have no-smoking policies been effective in reducing tobacco smoke exposure in non-smokers in our state?
- Do pesticides pose a risk to our residents who farm, live near farms, or eat certain types of food?
- In the event of a terrorist or suspected terrorist attack: Did the attackers deliver chemical weapons? Who was exposed and to what? Who needs medical treatment for exposure?

By indicating exactly what chemicals people have in their bodies and at what levels, biomonitoring provides a scientific foundation upon which sound policy decisions can be built. When combined with disease tracking data and environmental hazard information, biomonitoring provides researchers with the tools that will help uncover the environment's role in disease. This, in turn, will help medical and public health practitioners with disease prevention.



Actions taken in 1976 demonstrate the importance of biomonitoring in the decision-making process. Around this time, the Centers for Disease Control and Prevention (CDC) was measuring lead levels in children's blood and found that a very high proportion of children—nearly nine out of 10—had high levels of lead in their bloodstreams (exposure to lead

Serious Diseases, Uncertain Causes

Environmental factors have been linked to diseases such as asthma, leukemia, learning disabilities, cancer and developmental disabilities. Seventeen percent of U.S. children under age 18 have developmental disabilities—such as mental retardation, autism, cerebral palsy and attention deficit hyperactivity disorder (ADHD).[1] Between 5 percent and 10 percent of children who attend public schools have learning disabilities, and ADHD affects another 3 percent to 6 percent. Although the causes of most developmental disabilities are unknown, research suggests that chemicals in the environment—including mercury, lead, PCBs—can cause developmental disabilities in children.[2]

Despite the research advances in environmental health during the last few decades, researchers have not yet found definitive answers to many questions about the health effects caused by environmental factors. Biomonitoring may provide some of the crucial information that is needed to discover the cause of many of these diseases.

can cause behavioral problems and I.Q. loss, even at very low levels). Researchers discovered that leaded gas was the primary cause of these high lead levels. The data helped the U.S. Environmental Protection Agency (EPA) follow through with eliminating lead from gasoline. Lead levels in children dropped dramatically as a result.

Biomonitoring also provides health departments with the tools to investigate clusters of illness like cancer or birth defects.

Federal Activity

CDC currently collects data on human exposure to more than 140 environmental chemicals, including pesticides, PCBs, mercury and environmental tobacco smoke (also called second-hand smoke). CDC releases reports on exposure to environmental chemicals in order to provide unique information to physicians, scientists, and health officials. The data can be used to:

1. Determine which chemicals get inside people and at what levels;
2. Determine the prevalence of people with levels of a chemical that are above known toxicity levels;
3. Establish a baseline that can be used by physicians and scientists to determine whether a person or a group has an unusually high exposure to a chemical;
4. Assess the effectiveness of public health efforts to reduce exposure to specific chemicals; and
5. Set priorities for research on human health effects.

When these data are combined with hazard and health tracking information, it will eventually help physicians, researchers and public health officials prevent diseases that are influenced by environmental factors.

State Activity

To determine the hazard exposure levels at the state, city or community level, states will need to implement their own biomonitoring programs. CDC is working to enable state laboratories to conduct their own testing. Between 2001 and 2003 CDC awarded $10 million in planning grants to states. Only a few received CDC grants to carry their plans forward.

Most states must rely on CDC to investigate chemical accidents or disease clusters and to assist in pursuing research. Unfortunately, CDC has neither the staff nor the resources to address each state's differing needs.

With CDC's assistance, three states are beginning projects that use biomonitoring to study exposure to a number of different environmental chemicals. New Hampshire, for example, plans to test private wells and collect clinical samples to determine if residents have high arsenic levels. Residents will also be informed about arsenic and told how to reduce exposure. Approximately 13 percent of New Hampshire's private wells violate the EPA arsenic standard.

Wisconsin, a fishing-oriented state that has issued statewide advisories to protect residents from exposure to mercury and PCBs in fish, would like to investigate the extent of mercury exposure in its population. This would help to determine if advisories are effective and whether mercury poses a health risk to Wisconsin residents. Wisconsin also is interested in using biomonitoring to address the concerns of farm workers, who are concerned about agricultural chemical exposure resulting from aerial pesticide spraying, working in the fields and drinking contaminated water.

California is the only state to introduce legislation that calls for the creation of a biomonitoring program. In May 2004, Senate Bill 689, the "Healthy Californians Biomonitoring Project," overcame a major hurdle when it passed the Senate—the bill died in the Assembly, however. The legislation called for creation of a pilot program to monitor breast milk in order to determine if environmental contamination is related to the increase in the rates of diseases such as autism or breast cancer. The legislation also called for the creation of other pilot projects

that use various sampling techniques to test for environmental exposures. Further, the bill recommended that protective public health action be taken in response to the data.

To fund the program, the project initially targeted chemical manufacturers and those who release toxic chemicals. These parties were required to pay fees based on their responsibility for the release of toxics into the environment. In order to increase the bill's likelihood of passing the Assembly after it passed the Senate, the funding mechanism was changed so the chemical manufacturers would not be charged—funding instead would come from federal and private sources.

Challenges For Biomonitoring

Industry supports CDC's national effort to monitor human exposure to chemicals because better exposure data can reduce over-regulation and its economic costs to society. However, there are still concerns that monitoring chemicals in humans without knowing what levels may be hazardous will create alarm, leading to unjustified, costly regulations that may not necessarily protect the public. Currently, scientists can test for a large number of chemicals in humans, although for many of these chemicals, the health effects are largely unknown. The scientific rationale for measuring chemicals for which the effects on human health are uncertain but suspected, according to the CDC, is to connect these data with disease tracking data to eventually determine if some exposures are causing health problems, as was the case with lead.

Resources also have been a concern. CDC has not been able to fund all the states that wish to pursue biomonitoring programs, and no state is contributing its own funding, although New York city does fund some of its own biomonitoring program. States that wish to sustain a biomonitoring program may need to combine both state and federal resources—and possibly foundation grants.

Although immediate uses for biomonitoring exist—such as detecting and responding to chemical terrorism and chemical spills, or investigating disease clusters—it also functions as a basic research tool. Determining the exposure levels for many different chemicals today will help determine what further research is needed to determine which, if any, of these exposures poses a health concern. The cost of maintaining a biomonitoring program may eventually be offset by the reduction of disease and its associated social and economic costs.

Biomonitoring in Practice

Washington's Department of Health recently began testing farmworker pesticide handlers to determine if they are overexposed to these hazardous chemicals. The results surprised investigators—nearly one in four farmworkers tested had suffered potentially harmful pesticide exposure (testing discovered low levels of a certain enzyme, which indicates pesticide exposure). Twenty of the 345 pesticide handlers tested had enzyme levels so low that immediate removal from their jobs was required. In response to the preliminary data, the Washington Farm Bureau issued a labor advisory, reminding members to provide information and proper training to pesticide workers and to require worker compliance with safety protocols.

Selected References

Centers for Disease Control and Prevention. *Second National Report on Human Exposure to Environmental Chemicals.* www.cdc.gov/exposurereport, 2003.

Association of Public Health Laboratories. *Biomonitoring: Measuring Chemicals In People.* www.aphl.org/Environmental_Health, 2004.

Notes

[1] Centers for Disease Control and Prevention, Developmental Disabilities Web page, www.cdc.gov/ncbddd/dd/, 2004.

[2] P. Mendola, S.G. Selevan, S. Gutter and D. Rice, "Environmental factors associated with a spectrum of neurodevelopmental deficits," *Mental Retardation and Developmental Disabilities Research Review* 8, 3 (2002): 188-97.

The *Environmental Health Series* is produced by staff from the Environmental Health Project at the National Conference of State Legislatures in Denver. The Centers for Disease Control and Prevention (CDC) reviews each issue for accuracy and scientific integrity. For more information, visit www.ncsl.org/programs/esnr/toxics.htm or call (303) 830-2200.

This issue of the *Environmental Health Series* was researched and written by Glen Andersen.

MINNESOTA MDH DEPARTMENT OF HEALTH

Protecting, maintaining and improving the health of all Minnesotans

Biomonitoring: Measuring environmental chemicals in people

Protecting Minnesota's Citizens

Pesticides

The Midwest is our country's largest agricultural and crop-producing region, which accounts for roughly 65% of total harvested cropland and as much as 60% of total U.S. herbicide use. In 2001-2002, Minnesota farmers used 12 million pounds (active ingredient) of the insecticide, chlorpyrifos. Farmworkers and rural residents are worried about exposure to pesticides, mainly from aerial spraying and from drinking contaminated groundwater. In fact, pesticides are one of the chief groundwater contaminants, and 75% of Minnesotans drink groundwater from community water systems or private wells.

High levels of pesticide exposure can lead to birth defects and neurological disabilities. Infants and young children are most susceptible due to rapid brain development. Some studies using indirect methods have suggested that children living in the Red River Valley have an unusually high rate of neurological and behavioral abnormalities.

The Minnesota Department of Health proposes to study pregnant farmworkers and their newborn babies for levels of pesticide exposure in the Red River Valley. We would link indirect exposure reports with actual measurements of body burden. A pilot study limited to biomonitoring measurements of 25 presumptively exposed pregnant farmworkers (and 25 pregnant urban women) and their newborns is estimated to cost $800,000. If the pilot study were to also follow the development of the babies through their first three years of life to monitor cognitive problems such as attention deficit hyperactivity disorder, the additional cost of the study would rise by approximately $1.4 million.

Arsenic

A third of Minnesota residents depend on private wells for drinking water. Arsenic is a naturally occurring contaminant. About 15 percent of Minnesota wells produce water which exceeds 10 micrograms per liter (parts per billion), the national drinking water standard. Arsenic is more prevalent in western Minnesota, but can occur almost anywhere in the state. Long-term consumption of arsenic above the drinking water standard may increase the risk of health problems of the skin, circulatory system, or the nervous

system, including some forms of cancer. Because private wells are unregulated, these residents may be unknowingly putting themselves at risk.

The Minnesota Department of Health would like to engage in a three-step process to reduce arsenic exposure for residents living in areas known to have unusually high arsenic levels. In the first step, we would survey the residents and measure their body burden for arsenic. Secondly, we would educate them on actions to reduce arsenic. Thirdly, we would again survey the residents and measure their body burden to determine if this voluntary approach is effective in promoting public health.

Methamphetamine

In 2003 and to date in 2004, Minnesota has experienced an average of more than one drug bust daily of a clandestine methamphetamine lab. Most meth labs (75%) have been located away from the largest Minnesota cities, in rural or semi-rural areas. Methamphetamine is made mostly from common household ingredients. When these ingredients are mixed and "cooked" together they make a dangerous drug and harmful chemical mixtures that can remain on household surfaces for months or years after "cooking" is over. Therefore, each drug lab is a potential hazardous waste site, requiring evaluation and cleanup, by hazardous waste (HazMat) professionals.

The State of Minnesota supervises cleanup operations of methamphetamine labs before allowing new occupants to reside at the site. Cleanup can be very expensive, as furniture, draperies, and carpeting usually need to be replaced. Walls, ceilings, and other exposed surfaces often require extensive, repeated cleaning before methamphetamine levels return to safe levels.

The Minnesota Department of Health proposes to conduct biomonitoring studies on new residents in homes that were former meth labs. We would measure the occupants for levels of methamphetamine after various stages of cleanup. We may discover that, while ceilings generally have the highest levels of meth, the risk of exposure might be very low relative to floor surfaces, doors, or windows. If so, then the State of Minnesota may not need to invest in expensive cleanup efforts for ceilings and other relatively inaccessible surfaces. Biomonitoring would also identify disproportionately affected populations. For example, very young children who play on the floor and exhibit a high degree of hand-to-mouth behavior may be particularly exposed to residual methamphetamine. Moreover, infants may be particularly vulnerable due to their rapidly developing brain functions.

News for Leaders in Public Health Laboratories

The APHL Minute

September-October 2004
Issue 5

In This Issue:

The APHL Minute is published by:

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Public Health Laboratories

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Linking Laboratories One by One to Strengthen America's Emergency Response System

Janis Thompson worked as a medical technician in a hospital laboratory for twenty-five years, followed by seven years as an infection control practitioner. In all that time, she said, she and her hospital colleagues "knew very little about what the state public health laboratory did." Aside from regulatory inspections, "I thought that all they did was (test) a few clinical specimens," she recalled.

Unfortunately that perception has been all too common among laboratory workers who are professionally removed from the world of public health. Today, as a training coordinator and program advisor for the Arkansas Department of Health laboratory, Thompson is part of a nationwide effort to reverse those prevailing misperceptions and build statewide laboratory communities that will collectively comprise what has come to be known as the National Laboratory System (NLS). (See page 4.)

As with many recent public health laboratory initiatives, the push for the NLS was accelerated by fears of biological terrorism: almost simultaneously, laboratory leaders envisioned the Laboratory Response Network (see page 5). Quite simply, the first sign of a covert release of smallpox, plague or other *high-consequence* agent is likely to be sick people. And the bulk of infectious disease testing performed in the US is not done in public health laboratories, but in clinical laboratories that are either affiliated with hospitals or see patients (or patient specimens) forwarded by private physicians.

There is a history of collaboration with (public health laboratories and) individual (private) labs, but they are exceptions, not the rules.

–David Sundwall

While every state requires physicians and laboratories to report certain infectious diseases to public health authorities, historically the overall level of disease reporting has been low—perhaps as low as ten percent, according to Toby Merlin, the associate director for laboratory medicine in the CDC's Division of Laboratory Systems (DLS). Better connectivity among laboratories is expected to improve both disease reporting and the referral of disease isolates to public health laboratories for detailed analyses, including molecular comparisons of organisms infecting different patients to discern whether there is a common source of infection.

Public-Private Integration continued on page 4

President's Thoughts

Enhancing Our Partnerships

Dear Members,

I hope you have all had a pleasant summer with some relaxing time away from work.

In the last issue of this newsletter, I wrote about the increasing importance of intrastate coordination among laboratories. I'd like to take up that flag again this month, especially in light of the approaching annual meeting. This co-located annual meeting with the Association of State and Territorial Health Officials, "Communication, Cooperation, Coordination: Building Bridges in Public Health," will highlight many of the key relationships that we all have within our states and with other public health laboratories. Some of the sessions that you can anticipate in St. Paul, MN, in September: "Building Bridges With Sentinel Laboratories – Foundation for the National Laboratory System," "Integration of Current Laboratory Networks," and "Public Health Laboratories – Working to Improve Health Abroad and Enhance Our Partnerships at Home."

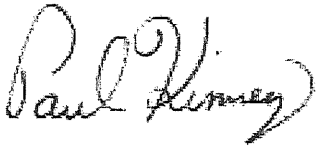
This issue of the Minute contains a number of articles that focus on how essential "connectivity" is to public health practice. In particular, coordination is important for the success of all the national emergency preparedness programs that have a laboratory component—such as the Laboratory Response Network, the Food Emergency Response Network, Biowatch, the Biological Detection System (to name a few!). In a number of states, the public health laboratory director has had to use his or her connections to convene other laboratory and agency directors to assist in these efforts.

In California we now have a quarterly meeting of laboratory directors from governmental (federal, state, county and city) laboratories that we call the Interagency Laboratory Working Group (ILWOG). This group started out two years ago without a name and with only a goal to sort out all the federal programs with laboratory components and local impact. The first meetings brought together four agencies; now we routinely have a dozen or more participate. Key players have been the state public health laboratory (the convener), the civil support team, county and city public health laboratories, the Lawrence Livermore National Laboratory and the local Environmental Protection Agency laboratory. The group has expanded its agenda to include anything that is of interest to our working group members. This has included—but is not limited to—LIMS, data exchange issues, surge capacity, reporting relationships, call down lists and transport of specimens.

Why has this group been successful? Several aspects have worked well for us: the informal nature of the meetings, the ten-minute agency updates on what's new, the laboratory science orientation of the agenda, and the rotating location (each meeting is hosted by a different agency, which then provides a laboratory tour of that facility).

Each state public health laboratory has its own success stories. Many of these are translatable to other states. And one the best ways to learn what has worked for others is to attend our APHL meetings (when possible), to participate in our committee structure and to reach out to your colleagues. I hope to personally welcome you at the 2004 annual meeting at the end of September.

Sincerely,



Paul Kimsey, PhD

EXECUTIVE DIRECTOR'S NOTE

Sharing Innovations, Best Practices

Dear Members,

Ever since the tumult following 9/11 and the 2001 anthrax attacks, APHL has routinely conducted a "lessons-learned" meeting after association events such as board meetings, conferences and symposia, as well as after the conclusion of large-scale projects. Equally important, we began to take stock of our actions whenever we found ourselves in response mode—whether to the FDA's unexpected seizure of newborn screening kits or to the highly publicized release of the March of Dimes' newborn screening recommendations. (See "State of the States" on page 12 for more on this.)

Taking the effort to track these small successes and failures has helped us understand how much we value and rely upon our collaboration with other national organizations, especially when we are in the midst of acting on behalf of members. Because we also rely on member input, this process has helped us recognize just how resourceful our members are, especially when it comes to sharing their laboratory innovations and practices. It's rare that a monthly committee call (any committee, you name it!) won't somehow include some focused or sidebar discussion about how one laboratory has solved such and such a problem...only to have other members ask "hey, can I call you about that after this call is over?" Invariably the answer is yes.

In order to capitalize on this wonderful spirit of sharing, APHL has recently awarded funds through two small grants programs that are supported by our cooperative agreement with CDC: "Public-Private Laboratory Integration" and "Implementing Food Safety Recommendations in States." The first program will help implement innovative project activities that encourage greater public-private laboratory integration, building on the lessons learned from the APHL/CDC National Laboratory System (NLS) demonstration project. For this program, the effectiveness of the enhancements to a state laboratory system will be measured by an increased degree of communication, cooperation, and/or coordination between public health laboratories and private clinical laboratories to address public health threats such as infectious, environmental, or unknown agents of public health concern.

The second program, "Implementing Food Safety Recommendations in States," allows states to improve the food safety capacity of their public health laboratories by implementing recommendations from APHL's report, *A Recipe for Stronger Food Safety Testing Programs*. Some of the funded activities will serve as pilot projects to test their fitness for national use in food safety.

You will find further information about these projects elsewhere within this edition of the *Minute*, but I encourage you to visit our Web site over the next few months. We are creating a new section on the Web to catalog innovative practices in public health laboratories—the new section will appear under the heading "Working Smarter" and will be regularly updated.

The most important lesson we have learned is that we are not alone. There is an entire community of public health laboratory practitioners waiting to help out—you just have to ask.

Sincerely,

Scott J. Becker

Scott Becker, MS

The National Laboratory System: A Work in Progress

Ask laboratory leaders, and they will tell you that there *is* no National Laboratory System (NLS) per se, despite the oft-repeated moniker. Instead, what exists is an ongoing effort, partially funded and otherwise supported by the CDC's Division of Laboratory Systems (DLS), to create well-coordinated networks of laboratories in every US state—in essence a *national laboratory system*. Although the impetus for the project was the need to link private medical laboratories and state public health laboratories to speed the detection and reporting of possible bioterror agents, its scope has expanded significantly. Just this year the DLS—through APHL—awarded roughly $50,000 to each of ten states to carry out specific activities to increase the level of cooperation between the state public health laboratory and a defined subset of laboratories, ranging from hospital labs in Arkansas to water testing labs in Minnesota. While this dedicated support (and past support to NLS pilot projects in Michigan, Minnesota, Nebraska and Washington in 2000) has been a stimulus for innovation, all state public health laboratories—with or without DLS funding—are working toward the same overarching goals.

Innovative Measures to Increase Connectivity

Laboratory program advisors like Thompson recognize the benefits of enhanced laboratory integration as well as the barriers. "Some of the labs have been very receptive (to overtures from the state laboratory)," she said. "Others are more prone to take a wait-and-see approach. Is this going to be regulatory or is it actually going to be beneficial to our laboratory?" To enhance connectivity, Thompson is planning distance-training workshops in laboratory techniques, dissemination of real-time disease surveillance data via a Web site and newsletter, and periodic teleconferences with hospital laboratory staff to discuss common concerns.

In Massachusetts, John Fontana is working on a project intended to strengthen ties between the state public health laboratory and hospital laboratories while simultaneously addressing a long-festering public health problem. Fontana, who directs molecular surveillance activities for the Massachusetts State Laboratory Institute (MSLI), is interested in "giving information back to hospitals" to help them better identify and control a community-associated strain of *Staphylococcus aureus* that is resistant to methicillin treatment. The problem of methicillin resistant *Staphylococcus aureus* (MRSA) is something "we've been staring in the face for years," said Fontana. "It's just not going to go away. It's going to get worse."

Fontana plans to collect MRSA isolates and associated clinical data from hospital laboratories—starting with the University of Massachusetts Memorial Medical Center—and subject them to advanced testing that is beyond the scope of routine hospital testing. The goal is to build a database of MRSA pulsed field gel electrophoresis (PFGE) patterns (essentially DNA fingerprints of the organisms) and drug susceptibility profiles that will help individual hospitals distinguish community-associated MRSA from healthcare-associated MRSA and to detect trends in disease prevalence and drug resistance. "We'll do the PFGE and the analysis, but we'll give (the hospital laboratories) the image database and training so they can monitor MRSA by ward or patient or employee. They can know what's in their hospital and keep track of it."

Some of the labs have been very receptive (to overtures from the state laboratory). Others are more prone to take a wait-and-see approach.
—Janis Thompson

Fontana hopes the hospital laboratories will come to recognize the MSLI as a resource and will ultimately improve MRSA case reporting.

Although Fontana and Thompson have dedicated grant money to pursue their laboratory integration projects, virtually all state public health laboratories are pursuing similar kinds of activities, ranging from shared public-private specimen courier systems to formal agreements to share laboratory space during emergencies that create a surge in demand for laboratory tests.

Joyce Schwartz, the chief laboratory officer for Quest Diagnostics—one of the nation's largest commercial laboratories—well understands the assets that public and private sector laboratories can offer one another. "We touch the

vast majority of practicing physicians in the country between all the commercial labs," she said. "It's the benefit of our access that will hopefully lead the public health agencies to work more closely with us."

On the flip side, Schwartz would like public health laboratories to "off-load more mundane tests" (such as complete blood counts) to commercial labs and to share epidemiological data and validated assays for tests for emerging illnesses like SARS.

Connection with diverse types of laboratories "is just another aspect of preparedness. You don't know if (an infectious or toxic agent) is going to be in the water, food, or livestock."
–Tony Sambol

But Schwartz's viewpoint may still be the minority opinion among private sector, clinical laboratory workers. David Sundwall, president of the American Clinical Laboratory Association (ACLA), said, "We've made the case, at least for ACLA members, that we don't look at our work as competing with public health in any way." Yet he said, "There is a history of collaboration with (public health laboratories and) individual (private) labs, but they are exceptions, not the rules."

Centralization May Be Key

At the national level APHL, CDC, the ACLA and other partners are working on a number of projects to support state laboratory integration efforts. Perhaps the most popular of these is an effort to create a common, mechanized form that can be used in all state and local jurisdictions to detail the detection of a reportable illness, thereby replacing the multiple forms now in use. The CDC's Merlin, who is heading the effort, said a standard form will "lead to better reporting and make it easier on the labs that do the reporting: a classic win-win situation."

A second CDC project is the creation of the National Laboratory Database, which will eventually list all of the clinical laboratories in the country certified under the Clinical Laboratory Improvement Amendments of 1988. It would allow users to search for subsets of laboratories by location, type of testing performed, or other characteristics.

Just this summer the CDC will release findings from a national, formative evaluation of laboratory integration efforts. Based on surveys and personal interviews with public and private laboratory staff, the agency found that having a full-time person to coordinate activities with laboratories outside the state health agency made a huge difference in the level of integration achieved. Eunice Rosner, a CDC health scientist who monitored the evaluation process, noted that a variety of outreach activities—including electronic communication systems, dissemination of new microbiology information, and sending unknown specimens to clinical labs for identification—"all worked pretty well." But, she said, "just having a person working with (the clinical laboratories) seems to be the main indicator of success according to preliminary results; if something comes up, clinical labs have a known person to contact."

Public-Private Integration continued on page 6

The Laboratory Response Network: Ready for the Worst

APHL and CDC established the Laboratory Response Network (LRN) in 1999 to improve the nation's ability to respond to terrorist acts and other public health emergencies. Unlike the nascent National Laboratory System, the LRN has a well-defined operational plan and structure. The network is overseen by the CDC's Bioterrorism Preparedness and Response Program and has three categories of members. A handful of national laboratories operated by the US military, CDC, and other federal agencies have the ability to identify specific strains of the most virulent and highly infectious agents. About 100 reference laboratories, including all state public health laboratories, can definitively confirm the presence of a threat agent, thereby initiating a chain of response. And thousands of clinical laboratories—those that have direct contact with patients—are responsible for identifying suspicious specimens and referring them to a LRN reference laboratory for a reliable diagnosis. Perhaps the network's greatest asset is quality control: all reference and national members must meet stringent requirements for equipment, personnel and use the same validated protocols, giving test results a high degree of accuracy and comparability. Moreover, new tests are continually being brought on-line in anticipation of threats such as SARS and viral hemorrhagic fevers. Since its inception, the LRN has received over $160 million in federal funding.

LETTER TO APHL

Dear Readers: In an email response to a Minute article, Emeritus member James Prier wrote to APHL's executive director, Scott Becker, to enumerate several important points on public-private laboratory integration. This topic is addressed further in the current issue's front-page article, and we thought it timely to share Dr. Prier's insights. APHL welcomes such letters from members.

Dear Scott,

As usual I find the issue of the *Minute* one of the few publications I see regularly that always has matters of interest. The project of public-private [laboratory] integration is of particular interest, since I have spent time as a director of both types.

There are, I believe, two essential elements that are not indicated [in the *APHL Minute* article "Public-Private Laboratory Integration Project 2004," July-August 2004]. One is the reality that this should not be a one-sided approach because the private laboratories have a great deal to teach public laboratories, as well as vice-versa. If a public health laboratory does not comprehend the business of a private laboratory, whether independent or hospital, it will be at a great disadvantage in attempting any significant integration.

The second point is that an important procedural issue is that direct and personal contact between the two is essential before enough factors can be accumulated to effect significant integration of functions. Both state and local public health laboratories in such jurisdictions as New Jersey, Pennsylvania, California, Wisconsin and Florida have done this in the past. Some important guidelines might be obtained from these jurisdictions to establish protocols for pursuing the objective in addition to the specific assignments now in effect in the project.

Just a thought from someone who believes this to be a most important APHL project.

Best regards,
James Prier, DVM, PhD

Forging More Than Just Clinical Connections

Increasingly the scope of laboratory integration efforts is expanding to new realms. Public health scientists realize that animal illnesses or contaminated soil or reservoirs are just as likely to signify biological or chemical terrorism—or other potential public health crises—as human illness.

Tony Sambol, assistant director and program advisor for the Nebraska public health laboratory, recalled an incident that occurred this summer involving a dead rabbit in Lincoln. The state veterinary science laboratory suspected that the rabbit was infected with *Francisella tularensis*: a naturally occurring animal pathogen that is transmissible to people and is on the CDC's Category A (highest priority) list of possible bioterror agents. The veterinary science laboratory contacted a public health veterinarian, who in turn alerted the state epidemiologist. The state public health laboratory confirmed the original diagnosis and reported back to relevant health authorities, which eventually determined that no one had been exposed to the rabbit. "This working together is why we do these (laboratory integration) projects," Sambol said.

Sambol is overseeing a project to extend the use of a device, called STATPack®, to enable secure, real-time video transmissions of laboratory images. Alpha testing has been completed and five hospitals are working with the state public health laboratory as Beta test sites. "Now," said Sambol, "we want to reach out beyond." The plan is to implement the STATPack® system in four new venues: the veterinary diagnostic laboratory

Based on surveys... having a full-time person to coordinate activities with laboratories outside the state health agency made a huge difference in the level of integration achieved.

at the University of Nebraska-Lincoln, the hospital laboratory at Offutt Air Force Base, the food testing laboratory at the Nebraska Department of Agriculture and the state water testing laboratory.

If one of these facilities has "a colony (of organisms) that they believe might be *Bacillus anthracis*, they could send a video picture with all the pertinent facts of the

Public-Private Integration continued on page 7

case to the state public health lab," said Sambol, thus speeding confirmatory diagnosis and emergency response activities. Moreover, he noted, "in the middle of the winter when the interstates are icy and closed, now we have another method to provide consultation."

Connection with diverse types of laboratories "is just another aspect of preparedness," said Sambol. "You don't know if (an infectious or toxic agent) is going to be in the water, food, or livestock."

Minnesota's Louise Liao, who manages the state public health laboratory's environmental testing program, is focused on water. The public health laboratory certifies many of the state's private and municipal water testing laboratories, but "because (certification) is fee-based and because it's regulatory, it does not have a flavor of collaboration," explained Liao.

The public health laboratory would like to work more closely with these environmental testing laboratories, which have their own professional networks for staff development and quality assurance but have expressed interest in workshops to address common deficiencies in analytical techniques. "It's a lot easier to do an inspection when the lab is already doing everything right than to punish them when they've never been trained," said Liao.

The carrot for collaboration is training in *E. coli* testing. Environmental testing laboratories routinely test for the presence or absence of *E. coli* in drinking water—where even minute amounts of the fecal coliform are not allowed—but are eager to learn to *quantify* the amount of *E. coli* in swimming beach water—where anything under 200 to 235 colony-forming units per 100 milliliters water is considered safe. Liao explained that "just in the past two to three years, there's been tremendous interest in swimming beach water nationwide. In a couple years, the US Environmental Protection Agency will require that swimming beaches be monitored for E. coli . . . and environmental testing labs are eager to provide high-quality analyses."

In addition to training on the test methods, the public health laboratory will train on the quality assurance systems and, said Liao, "that training will carry over to all of the environmental testing that the lab does on behalf of the residents of the state."

As with all laboratory integration projects, a hoped-for by-product is greater referral of abnormal test results to the state public health laboratory so that emerging public health threats are identified quickly.

The ultimate goal, Liao said, is "a collaborative relationship where we all benefit from each other's strengths." ■

RFP Template for LIMS Now Available

A Request for Proposal (RFP) template for the acquisition of a Laboratory Information Management System (LIMS) is now available for the APHL membership to use in their LIMS procurement process. Patina Zarcone, APHL informatics and LIM systems manager, along with representatives from 8 member laboratories (Arizona, Alaska, Iowa, Vermont, Washington, Virginia, Missouri, Massachusetts) have created a template RFP that can be customized with state specific procurement regulations and can be used by public health laboratories in their acquisition process. Massachusetts, Iowa and Alaska provided real RFPs for the workgroup to use as examples. For more information or to obtain the template electronically, contact Patina Zarcone at pzarcone@aphl.org or 617.569.9612.

SEE PAGES 8-9 FOR ARTICLES ON THE **LIMS DESIGN PROJECT,** THE **NATIONAL HEALTH INFORMATION INFRASTRUCTURE CONFERENCE,** AND **LIMS AND APHL: A HISTORY OF COLLABORATION, RESEARCH, AND INNOVATION.**

LIMS Design Project:

Empowering Public Health Laboratories

In August 2004, APHL, the Public Health Informatics Institute (the Institute), and twenty-three state and local public health laboratories launched the final phase of a project to provide the membership with the necessary information to develop long-term strategies for laboratory information management systems (LIMS) solutions. The two-year project, supported by The Robert Wood Johnson Foundation, cost approximately $1.5 million. It is the hope of APHL, the Institute, and the members of the collaborative project that the design project will result in savings to public health laboratories worth many times that amount.

Public health agencies looking to develop effective information systems can no longer afford to work in silos.
–David Ross
Public Health Informatics Institute

In this phase of the project, the Institute will conduct a detailed analysis of the LIMS market, including forecasted costs, growth, and demand for LIMS, and the strengths and weaknesses of different approaches to LIMS development and purchase. The information will empower public health laboratories to make informed decisions about the options available: build, buy, or collaboratively develop LIMS with other public health laboratories. In addition, it will provide APHL with the information needed to meet its strategic goal of moving public health laboratories to the cutting edge in the capture, processing, and communication of laboratory information vital to public health.

Also in this phase of the project, the participating laboratories will complete the collaborative development of LIMS logical design specifications that meet the needs of all public health laboratories. In previous phases, the project participants have collaboratively defined common requirements and developed design specifications for the most critical LIMS business processes.

"Public health agencies looking to develop effective information systems can no longer afford to work in silos, nor can they afford to leap to the technology solution without first having a common understanding of the health problem and how the work gets done," said Institute Director David Ross, ScD. "By developing a shared definition of the problem and collaboratively developing the requirements and logical design specifications, APHL and public health laboratories are tackling the problem of redundant health information systems that lack interoperability. The end result of the collaborative requirements and logical design projects will be more effective, more cost efficient LIMS that have better data flow among public health laboratories and to federal agencies, and will improve their capacity for mutual assistance in a crisis."

The public health laboratory LIMS project began in October 2002 with a group of 16 state and local public health laboratories collaboratively defining common requirements. The Institute provided facilitation and expertise in business processes and requirements development. APHL published the resulting public health laboratory LIMS requirements document, which details 500 requirements, in November 2003. A number of public health laboratories across the country have used the requirements to guide their LIMS development or purchase. A document with the logical design specifications for the most critical business processes, collaboratively developed by public health laboratories in twenty-five states and one city, will be published by APHL in fall 2004. A document detailing the design specifications for the remaining business process will be ready in early 2005.

For more information on these initiatives, contact Patina Zarcone, APHL informatics and LIM systems manager, pzarcone@aphl.org. ■

National Health Information Infrastructure Conference

Cornerstones for Electronic Healthcare

"The Secretarial Summit on Health Information Technology launching the National Health Information Infrastructure 2004: Cornerstones for Electronic Healthcare" was held in Washington, DC, in July. Over 1,500 people representing the private and public healthcare industry attended the summit. In the opening speech, Health and Human Services Secretary Tommy G. Thompson stated, "Health information technology can improve quality of care and reduce medical errors, even as it lowers administrative costs. It has the potential to produce savings of ten percent of our total annual spending on health care, even as it improves care for patients and provides new support for health care professionals."

A report, "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care," ordered by President George W. Bush in April, was presented by Dr. David J. Brailer, a recent appointee as national coordinator for health information technology. The report lays out the broad steps needed to achieve current, accessible electronic health records for Americans. A fact sheet on the report, as well as a complete list of the four major collaborative goals and twelve strategies for advancing national healthcare IT efforts, can be found at www.hhs.gov/news/press/2004pres/20040721.html.

The 2004 conference was a continuation of the work initiated at the previous year's conference. Individuals had the opportunity to participate in formal work groups, as well as provide feedback on a national action plan. Participants attended general plenary sessions presented by experts in healthcare fields and met in topic breakout groups to consider recommendations in eight key areas: personal health, governance, incentives, standards and architecture, confidentiality, ethics, privacy, and access, measuring progress (metrics), population health and clinical research.

On the final day of the conference, the recommendations from each topic breakout session were reported to an official hearing of the National Committee on Vital and Health Statistics, the statutory advisory body to the Department of Health and Human Services. The conference recommendations and other materials are available at www.hsrnet.net/nhii/materials.htm.

For more information regarding informatics initiatives at APHL, contact Patina Zarcone, APHL informatics and LIM systems manager, pzarcone@aphl.org ■

LIMS and APHL: A History of Collaboration, Research, and Innovation

August 2003
APHL makes the PHII LIMS Vendor Assessment available to the APHL membership

September 2003
PHII hands "Public Health Laboratories Take the Next Step: A Collaborative Approach to Laboratory Information Management Systems Design" to APHL

November 2003
APHL publishes "Requirements for Public Health Laboratory Information Management Systems (LIMS)" and APHL/CDC LIMS Conference "Setting an Action Agenda for Public Health Laboratory Information Management Systems"

April 2004
PHII and APHL co-publish the research brief "Batteries Not Included: Understanding the total cost of ownership for a commercial off-the-shelf public health laboratory information management system"

May 2004
APHL co-sponsors the CDC PHIN Stakeholder's Meeting "Connecting for the Public's Health." Patina Zarcone, APHL informatics and LIM systems manager, co-chairs conference

July 2004
APHL board of directors approves continued partnership with PHII in the Phase II LIMS Design Project

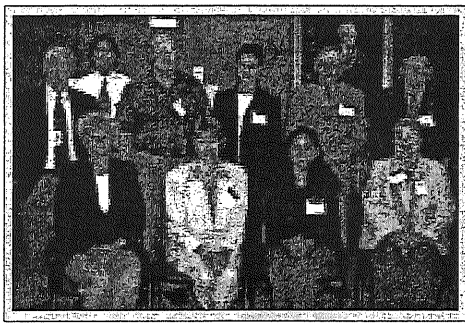
August 2004
Phase I LIMS Design Project documents given to APHL for publication, dissemination, and stewardship

Environmental Health

Pushing for State Biomonitoring Programs: *Laboratorians, Legislators Discuss Needs*

This summer, APHL contracted with the National Conference of State Legislatures (NCSL) to begin educating state legislators about biomonitoring. NCSL is a bipartisan organization that serves legislators of the states and territories; it provides research, technical assistance and opportunities for policymakers to exchange ideas on pressing state issues. APHL has exhibited at four NCSL national meetings, where attendees are often surprised to learn that they have a public health laboratory in their state—a fact that highlights the need for educational outreach efforts.

NCSL convened a roundtable meeting of five states from the upper Midwest biomonitoring consortium on July 14, 2004. Legislators and laboratory directors from Minnesota, Iowa, North Dakota, South Dakota and Wisconsin attended the event, "Meeting Public Health Priorities: Biomonitoring and Public Health Laboratories." Hosted at the Minnesota Department of Health, legislators particularly enjoyed the tour of the state laboratory. Andrea Lipman, of the CDC, explained the federal role in building environmental capacity in public health laboratories; Mary Gilchrist, director of Iowa's Hygienic Laboratory, described the role of state public health laboratories in environmental health. Bonna Cunningham (ND) and Louise Liao (MN) covered the upper Midwest consortium's accomplishments and goals. Then, Glen Andersen of NCSL provided case studies and challenges related to jump-starting state biomonitoring programs, and Nicole Vasquez, staff consultant to the California Senate Health and Human Services Committee, outlined the California biomonitoring bill. She supplied copies of her bill, the first in the nation to explore using biomonitoring to assess exposure to environmental chemicals. At the end of the day, participants discussed what state policies would be needed to achieve biomonitoring.



Standing: Norman Crouch (MN), Glen Andersen (NCSL), Sen. Ralph Kilzer (ND), Bonna Cunningham (ND), Rep. J.A. Hines (WI), Mike Smith (SD). Seated: Rep. Jean Wagenius (MN), Sen. Becky Lourey (MN), Nicole Vazquez (CA), Mary Gilchrist (IA).

Ways to Obtain Funding

- Orchestrate grant-writing through partnerships with legislatures and public and private organizations.
- Estimate public employee health insurance impacts, such as effects of secondhand smoke.
- Work with medical and public health schools to begin quantifying prevention cost savings that may result from biomonitoring.

How to Get the Word Out about Biomonitoring:

- Educate legislators.
- Profile a human-interest story that connects West Nile virus and insecticide use to biomonitoring.
- Sell biomonitoring as a "push for the future."

What Next?

- Adjust biomonitoring/consortium concept from federal to state focus.
- Invite legislators to visit laboratories and create a coordinated biomonitoring plan.
- Consolidate ideas in state and among consortia, with feedback from legislators.
- Get invited to Health, Education, Environment, and
- Appropriations Committee meetings.
  Start developing state legislation.

NCSL featured biomonitoring in a three-page *Environmental Health Series* publication (July 2004, Issue 8. See www.aphl.org/Environmental_Health/index.cfm#biomon.), and a one-page issue brief on biomonitoring was created and sent to legislators interested in health issues in all the states. Legislators may reach out to laboratories as a result of this piece, and may have basic questions about the lab and detailed questions about state interests around biomonitoring.

Since windfalls of money rarely occur, a good biomonitoring plan would utilize available resources and require minimal additional costs. It would also demonstrate state needs and priorities and would track national global concerns.

Take the first step: invite a state legislator to tour your lab! For more on NCSL, visit www.ncsl.org.

Discounts Available, Chemical Terrorism Consumables

APHL arranged discounted rates for state public health laboratories on chemical terrorism consumables from Agilent Technologies and PerkinElmer Life and Analytical Sciences.

Agilent agreed to give state public health laboratories an eight percent discount on consumables ordered through its Customer Contact Center, and an eleven percent discount on consumables ordered online. Shipping and handling will be included at no additional charge for online purchases exceeding $500 in cost.

PerkinElmer will provide a ten percent discount on selected supply and accessory items for Atomic Absorption (AA), Inductively Coupled Plasma (ICP) and Inductively Coupled Plasma-Mass Spectroscopy (ICP-MS) product lines, as well as selected consumable and minor accessory products in the GC, GC-MS, KC, Thermal, Elemental, IR, UV, Fluorescence and Polarimetry product lines. A minimum purchase of $100 is required for phone orders; there is no minimum order for online purchases.

Agilent Technologies, Inc.
Little Falls Site
Attn: Customer Care Center
2850 Centerville Rd.
Wilmington, DE 19808-1610

Tel: 800.227.9770, option 1 then 1
Fax: 302.633.8901
Web orders: www.agilent.com/chem/store

PerkinElmer Life and Analytical Sciences
710 Bridgeport Avenue
Shelton, CT 06484

Tel: 800.762.4000
Fax: 203.944.4905
Web orders: http://las.perkinelmer.com/content/shopOnline.html

For information regarding regional and technical assistance contacts, contact Lauren DiSano, ldisano@aphl.org, 202.822.5227, ext. 204.

Environmental Health Committee Meeting

APHL's Environmental Health Committee held its annual meeting in Washington, DC, on June 10-11. During a strategic planning session, members established a list of issues affecting environmental health, and then prioritized them to clarify the group's annual work focus. (See sidebar.)

The committee discussed how to address major drives effectively and aimed to resolve the lab-specific environmental health issues. The committee identified more than fifty action items to address these concerns. The goals behind the action items are to aid in the identification of partners, facilitate increased environmental health information-sharing among laboratories, increase technology transfer and communication involving environmental health issues at the federal, state and local levels, clarify the roles of laboratories and individuals involved in environmental health, and facilitate the issuance of position papers on a number of issues, such as the laboratory role in biomonitoring for public health tracking.

EH Committee Priorities

Priority issues:
- Environmental protection
- Emergency response
- Biomonitoring

Additional lab-specific issues:
- Emergency preparedness and response for chemical terrorism
- Clarification of the state public health laboratory role in environmental testing
- Limited general/operational funding for environmental health
- Quality assurance issues
- Meaningful data issues
- Long-range planning for workforce and equipment/facilities
- Development of stronger partnerships with the EPA

The committee will also release position statements on priority issues, and is currently drafting a statement on the laboratory role in biomonitoring for environmental public health tracking.

In addition to the planning session, the committee heard a number of presentations on ongoing activities:
- Environmental Public Health Tracking Meeting
- NCEH/ATSDR Advisory Committee Meeting
- Status of environmental health grants, accreditation issues and the Congressional budget.
- APHL's new membership structure
- Current draft of the Environmental Laboratory Certification Survey
- Biomonitoring Advocacy Project
- EPA Water Alliance Report and current environmental health data exchange issues
- Massachusetts Environmental Public Health Tracking Program.

For more information on APHL's environmental health program, contact Jennifer Liebreich, 202.822.5227, ext. 236, jliebreich@aphl.org. ■

Did you know...?

A Glance at the Numbers

Safe Drinking Water Act Survey

Forty state and territorial public health laboratories serve as the state Safe Drinking Water Act primacy laboratory in *some* capacity, either for chemistry, microbiology, or both.

40

Environmental Triage Survey

A ten-question survey administered in May 2004 attempted to assess current preparedness and capacity of state public health laboratories to handle numerous unknown samples, as well as to gauge the willingness of labs to commit funds toward the construction of triage units in the future. Seventy-eight responses were received from FERN laboratories, LRN laboratories, state environmental laboratories, safe drinking water primacy laboratories and state public health laboratories.

83% **Eighty-three percent** recommended that unknown/potentially unknown samples should be screened for energetics, explosives, radiation and off-gassing of organics/specific hazardous chemicals prior to arrival at a laboratory or triage unit.

28% If a triage unit were available, **twenty-eight percent** reported expecting to process less than one unknown sample per day. Interestingly, **twenty-six percent** expected to process more than twenty samples per day.

34% **Thirty-four percent** would be willing to spend $100,000 to construct a triage unit at their facility; **nine percent** would spend $250,000; and **no respondents** would spend $500,000 or $1,000,000.

For additional information, including the complete results of this survey, contact Lauren DiSano, ldisano@aphl.org, 202.822.5227 ext. 204.

Newborn Screening

State of the States:

Newborn Screening Programs Need Funding to Expand Testing

Newborn screening is the process of using a simple blood test to identify many life-threatening congenital and genetic illnesses before any symptoms begin. In the US, state public health laboratories screen ninety-seven percent of the more than four million children born every year for various disorders.

On June 29, 2004, *The Today Show* featured Dr. Jennifer Howse, president of the March of Dimes (MoD), during a four-part series on newborn screening. The disparity in state screening panels, lack of a national standard, and varying health outcomes among states were major themes. During one of the segments, MoD released their report card on state newborn screening programs. The MoD advocated for the screening of nine specific disorders, plus hearing loss.

After discussion with members of the APHL Newborn Screening and Genetics in Public Health Committee, the board and staff, APHL narrowed its points to one main message: *Newborn screening protects children's health; accurate testing is an important part of the process.* APHL developed a media release, newborn screening messages and a one-page newborn screening fact sheet for laboratory directors to quickly respond to media inquires in light of the MoD report. The newborn screening messages focused on four main issues:

1. **System is essential**–newborn screening is a system, which involves testing, confirmation, notification, follow up, training and education.
2. **State laboratories are critical**–they conduct almost all the testing in the US, and assure quality test results in collaboration with the CDC.
3. **Process is dynamic**–advancing technology makes expanded screening possible. More than thirty states' public health laboratories utilize tandem mass spectrometry (MS/MS) in their program.
4. **Funding is needed**–funding must cover comprehensive, coordinated program of testing intervention, follow up, training and education.

Funding for newborn screening programs in state public health departments is crucial. In 2003, Senators

Christopher Dodd (D-CT) and Mike DeWine (R-OH) introduced the "Newborn Screening Saves Lives Act of 2003," after requesting that the Government Accountability Office (GAO) assess what states are doing in regards to newborn screening: to access the GAO report, visit www.gao.gov/new.items/d03449.pdf. The legislation provides resources for education and training initiatives for health care professionals, state laboratory personnel, families and consumers. The legislation was recently introduced in the House on June 2, 2004, as "Newborn Screening Saves Lives Act of 2004" - H.R. 4493 (see http://thomas.loc.gov).

Currently, thirty-five states use MS/MS to screen newborns for various disorders[1]. Thirty-two states use MS/MS to screen for mandated disorders. Eighteen states test for 30 or more disorders, an additional eight states test for 21-29 disorders and two for 11-20 disorders. Of the remaining states, which test for ten or fewer disorders, six are already testing for MCAD, a potentially devastating metabolic disorder mentioned in several recent articles and one of the nine metabolic conditions recommended by the March of Dimes. Since MCAD testing requires use of tandem mass spectrometry, the technology used to identify a wide range of other genetic and metabolic disorders, states with MCAD capability are positioned to expand their test panel to include other disorders.

Newborn screening protects children's health; accurate testing is an important part of the process.

In 2001, the American College of Medical Genetics, under contract with Health Resources and Services Administration, Maternal and Child Health Bureau, convened an expert panel group to review available information on newborn screening and to make recommendations based on the best scientific evidence and analysis of that information. The recommendations will create a model decision matrix based on specific criteria challenging newborn screening programs and outline a uniform panel of conditions for screening. They also will address model policies and procedures and minimum standards for state newborn screening programs that range from screening systems to the primary care community and specialists. The review process and the resulting recommendations are expected to be completed in 2004. The new HHS Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children intends to use the recommendations from the report on a uniform panel of conditions for screening as the foundation for discussion at future Advisory Committee meetings.

Every state newborn screening program participates in the Newborn Screening Quality Assurance Program (NSQAP) at CDC. NSQAP is a voluntary, non-regulatory program to help state health departments and their laboratories maintain and enhance the quality of test results. The program is operated in partnership with APHL, and provides services to more than sixty-nine domestic newborn screening laboratories, manufacturers of diagnostic products, and laboratories in fifty-three countries. NSQAP has been the only comprehensive source of essential quality assurance services for dried-blood-spot testing for over twenty-five years. The Quality Assurance/ Quality Control/ Proficiency Testing Subcommittee of the APHL Newborn Screening and Genetics in Public Health Committee provides guidance for NSQAP on procedures, policies and activities for the quality assurance of laboratory testing. The subcommittee, in collaboration with NSQAP, is working to create a US map grid of the methods (by analytes) states are currently using for their newborn screening programs.

For more information, contact Jelili Ojodu, APHL's newborn screening and genetics program manager, 202.822.5227 ext. 235, jojodu@aphl.org ■

[1] Testing is mandated but not yet implemented in three states.

Food Safety

APHL Awards $250,000 to State Labs

APHL is pleased to announce that approximately $250,000 in funding has been awarded for a grant, "Implementing Food Safety Recommendations in States." The APHL/CDC grant allows states to improve the food safety capacity of their public health laboratories by implementing recommendations from APHL's report, *A Recipe for Stronger Food Safety Testing Programs*. Some of the funded activities will serve as pilot projects to test their fitness for national use in food safety.

Arkansas will purchase a real-time polymerase chain reaction (PCR) cycler to reduce the time needed to identify organisms in clinical specimens during both routine and outbreak testing, and an ultra-low freezer for long-term sample and isolate storage.

Iowa will begin performing real-time PCR for Norovirus detection by purchasing PCR equipment, and will use it to validate a new real-time PCR method.

Michigan's pilot project will encourage the submission of PulseNet-tracked isolates to the state public health lab by providing clinical laboratories with appropriate prepaid express mailers, improving submission rates and building stronger ties with clinical labs.

North Dakota will purchase a real-time PCR cycler to improve testing time and capacity for Norovirus. It will also conduct a study to verify the performance of a latex slide test for *E. coli*, and validate a real-time PCR procedure for *E. coli* testing.

Pennsylvania will cut the time needed for PFGE testing in half for both surveillance and outbreak purposes by obtaining a network server and the software needed to allow more employees to access the CDC National Database simultaneously.

Rhode Island will expand its ability to test for foodborne pathogens under biological containment by acquiring a bench-top hood, and will also use funds for staff training in food microbiology.

Virginia will purchase equipment for use in developing a DNA-sequence database and strain library to cluster and track foodborne pathogens, as well as use funds to improve foodborne specimen submissions by creating a new submission form and distributing specimen collection kits and prepaid mailing labels.

For more information about the grant, contact Jeremy Gillissen, APHL's food safety program manager, at 202.822.5227 ext. 245 or jgillissen@aphl.org. ■

Infectious Diseases

IOM Meeting on Pandemic Influenza

The Institute of Medicine's (IOM) Forum on Microbial Threats hosted a public workshop, *Pandemic Influenza: Assessing Capabilities for Prevention and Response,* on June 16-17, 2004, at the National Academy of Sciences in Washington, DC. The workshop's aim was to inform forum members of the likelihood of an influenza pandemic and to examine the issues that must be resolved to prepare and protect the global community. APHL member Dr. Pete Shult, from the Wisconsin State Laboratory of Hygiene, was invited to participate in a panel discussion focusing on response and planning. Shult addressed the role of state public laboratories in influenza surveillance, monitoring performance of rapid flu tests, subtyping, and the dangers of not responding quickly to an outbreak.

Emerging Infectious Disease Framework Subcommittee Created

In February 2004, the APHL Infectious Diseases Committee recommended that a subcommittee be convened to develop a framework for public health laboratories to use in planning and responding to emerging infectious diseases. In June, the new Emerging Infectious Disease (EID) Framework Subcommittee met at APHL headquarters to create a checklist of criteria that state public health laboratories can use to plan for and respond to new diseases. Some of the topics covered in the checklist include specimen transport, safety, communication and regulatory requirements. The subcommittee is chaired by Dr. Jane Getchell (DE) and members include: Dr. Eunice Froeliger (VT), Dr. Jan Nicholson (CDC), Dr. Elizabeth Delamater (TX), Dr. Sydney Harvey (LA County), Dr. Pete Shult (WI), Dr. Leslie Wolf (NC), Ms. Maureen Sullivan (MN) and Dr. Steve Gradus (Milwaukee). Once completed, this document will be shared with all APHL member laboratories.

Public Health-Clinical Laboratory Relationships Subcommittee Created

One of the APHL Infectious Diseases Committee's strategic objectives is to enhance relationships with commercial, private and hospital laboratories. To further this objective, a new subcommittee was created to define and clarify joint concerns related to infectious disease detection and surveillance; it will also review examples of existing public-private laboratory networks and effective state laws, and will explore the need for

collaborations at the federal/national level. After this work is complete, the subcommittee will provide recommendations, which can be implemented by public and clinical laboratories, CDC, and national organizations such as APHL, the American Clinical Laboratory Association (ACLA) and the American Society for Microbiology (ASM). The subcommittee is chaired by Dr. Richard Harris (WY) and members include: Dr. Patricia Somsel (MI), Dr. Mike Loeffelholz (AR), Dr. David Sundwall (ACLA), Dr. Mike Pentella (IA), Dr. Joyce Schwartz (Quest), Dr. Carol Kirk (WI), Ms. Bonna Cunningham (ND), Ms. Shoolah Escott (NLTN), Dr. Toby Merlin (CDC), Ms. Paula Snippes (MN), Mr. Doug Drabkowski (APHL), and Dr. Vickie Baselski (University of Tennessee). This subcommittee will coordinate with CDC and APHL staff and member activities focused on public-private laboratory partnerships.

2004 National TB Controllers Workshop

The National TB Controllers Association (NTCA) held their annual meeting in June in Atlanta, GA. This year's workshop, "Critical Partnerships for TB Elimination," focused on the laboratory. APHL member Dr. Nancy Warren (PA) served as the association's representative on the planning committee; at the workshop, NTCA president Kim Field recognized APHL for its participation. A number of state public health laboratorians attended the meeting.

Plenary sessions focused on TB genotyping, the intersection of program and laboratory, and new technologies. Poster sessions provided opportunities to share state-specific examples in these areas. Dr. Eric Blank, director of the Missouri state public health laboratory, presented the recently published TB report, *Task Force on the Future of TB Laboratory Services*. Blank discussed the principles, benchmarks, and implementation of the report and outlined the steps that APHL and NTCA need to jointly take in order to enact the recommendations. Dr. John Dyke from the public health laboratory of the Michigan Department of Community Health stressed the critical importance of interactions between laboratories and TB programs, highlighting examples of how public health laboratories can help TB controllers link more effectively to clinical testing sites. Overall, the workshop emphasized the importance of the laboratory in the diagnosis and treatment of tuberculosis.

In addition to the plenary and poster sessions, the meeting also hosted several breakout sessions, including the first meeting of the CDC/NTCA TB Genotyping Advisory Committee, a quarter of which consists of laboratorians.

FDA Waives Two More Rapid HIV Tests

The Food and Drug Association (FDA) has just granted Clinical Laboratory Improvements Amendments of 1988 (CLIA) waived status to two more rapid HIV tests: the Orasure OraQuick rapid HIV Test for oral fluids and the Uni-Gold Recombigen HIV Test. These tests are now available for broad use outside of the traditional laboratory setting. This change allows the tests to be used by anyone who possesses a CLIA certificate of waiver, including physicians' offices, health clinics, mobile health centers and community-based organizations. However, there are no federal requirements for personnel, quality assessment, or proficiency testing. Organizations with a CLIA certificate of waiver need only to follow the manufacturer's instructions on how to perform the test.

The Orasure OraQuick rapid HIV Test for use with oral fluid was granted waived status on June 25, 2004. The test, which detects the presence of antibodies to HIV-1, was previously only CLIA-waived for whole blood venipuncture and fingerstick. The oral fluid test uses a porous pad to collect an oral fluid specimen and can produce results in twenty minutes. The manufacturer claims that the test is 99.6% sensitive and 100% specific. The CDC is currently providing training for this test to those community-based organizations that it funds. For further information on the Orasure OraQuick rapid HIV Test, visit www.orasure.com.

The Uni-Gold Recombigen HIV Test was granted waived status on June 28, 2004. This one-step rapid test screens for HIV-1 antibodies, providing results in ten minutes, and is currently FDA approved for serum, plasma and whole blood from venipuncture. Trinity Biotech, the manufacturer of the Uni-Gold rapid HIV test, claims that the test is 100% sensitive and 99.7% specific. Trinity Biotech has just completed clinical trials for a fingerstick whole blood method and is now pursuing FDA approval. For further information on the Uni-Gold Recombigen HIV Test, visit www.trinitybiotech.com.

Contact Anthony Tran, APHL's HIV, STD, TB program manager, with any questions, at atran@aphl.org or 202.822.5227 ext. 229. ■

NLTN

Antimicrobial Susceptibility Testing Programs Reach Thousands

The CDC's Division of Laboratory Systems, Laboratory Practice Training Branch, identified a need for widespread antimicrobial susceptibility training (AST) in the US. Janet Handler, a senior specialist in clinical microbiology for the Division of Laboratory Medicine at UCLA Medical Center in Los Angeles, CA, was hired to develop and conduct training across the country.

Over the past two years, the National Laboratory Training Network (NLTN), with Janet Handler as the speaker, presented **78 programs** on various aspects of antimicrobial susceptibility, reaching **13,281 people** across the United States. Every state had participants. The NLTN also reached the Bahamas, France, Ontario, Canada, New Zealand and Venezuela. Various training modalities were used, including seminar workshops, wet workshops, audio teleconferences, train-the-trainer programs, and combination internet-teleconferences.

Course participants included public health personnel, clinical laboratory staff, epidemiologists, reference laboratories personnel, CLIA inspectors, CDC and APHL employees.

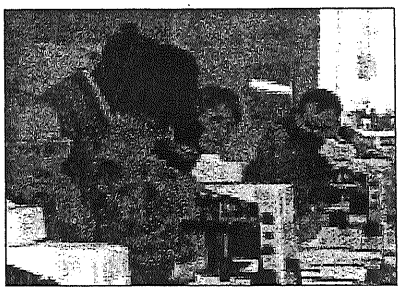
The numerous AST programs offered:

- Antimicrobial Susceptibility from a Public Health Perspective
- MRSA, VISA, VRSA, CAST issues of S. Aureus
- NCCLS Standards
- Advances in Antimicrobial Susceptibility Testing
- Infectious Disease Surveillance, a Team Approach
- Methicillin Resistance Staphylococcus Aureus in HI
- National Antibiotic Susceptibility Testing for Public Health Labs
- NACMID-NLTN Antimicrobial Resistance Around the World, a Laboratory Perspective
- Antimicrobial Resistance Testing: Train the Trainer
- Important Considerations for Detecting and Reporting Antibacterial Resistance
- Antimicrobial Resistance: Detection and Reporting from a Clinical and Public Health Perspective
- NYC/ASM-NLTN – Testing Bacteria Not Addressed
- Antimicrobial Susceptibility Testing for the Smaller Laboratory – What You Need to Know
- Microbial Hot Topics: A Hands on Training Workshop

The combined effort of the NLTN offices over the last two years has had a tremendous impact on helping people understand antimicrobial susceptibility testing and has helped to improve reporting practices in the United States. Evaluations to date indicate that participants intend to make changes in practice after attending NLTN programs. The CDC Laboratory Practice Training Branch and the NLTN plan to conduct outcome evaluations that will identify and quantify improvements resulting from this extensive educational outreach.

Food Safety Discussed at VA Public Health Series Course

In July, public health laboratorians from sixteen states gathered at a one-week Public Health Series laboratory course, "Laboratory Investigation of Foodborne Illness." The program was co-sponsored by the National Laboratory Training Network's Boston office, and the Virginia Division of Consolidated Services. Lectures and laboratory exercises took place in Virginia's new training facility. Faculty drawn from academic food safety programs, CDC, FDA, USDA, FBI and the public health laboratories discussed technical aspects of current and future methods to investigate foodborne illness. Speakers addressed the problem of isolating microorganisms from complex matrices, the use of molecular techniques to demonstrate viruses and parasites in food, the use of chrome agars, and rapid testing for staphylococcal enterotoxin.



Participants pictured from left to right: Chris Malota, TX; Marcus Head, USDA; Denise Toney, VA; Barbara Cote, VT; Mike McDermott, OK.

Attendee Achievements

- Gained hands-on experience identifying coccidian parasites with both conventional and fluorescent microscopy.
- Learned to consider certain legal issues when called as an expert witness.
- Enjoyed access to the instruments and expertise of six manufacturers.
- Tried out the BAX, Dynal Biotech, and MATRIX MicroSciences systems.
- Watched the LightCycler, SmartCycler and Luminex systems demonstrate pathogens in food.
- Studied case examples of actual outbreaks in which the role of the laboratory was described.
- Participated in molecular epidemiology discussions with a specific emphasis on PulseNet.

Timely recognition of organisms associated with foodborne disease is an important function of the public health laboratory. This course provided a rare opportunity for hands-on training in both traditional and molecular methods. ■

NLTN Library Expands Collection

Recently the NLTN lending library acquired **fifty** new training resources for its collection.

A few of the additions:

DNA from A to Z

The Emergence of Zoonotic Diseases

Bioterrorism: Close Encounters of the Lab Kind

To borrow materials, log on to **www.nltn.org** and select **"Lending Library."**

Center for PHL Leadership

Tackling the Chattahoochie:

Center Launches Public Health Laboratory Directors' Orientation

Being a public health laboratory director requires considerable skill at balancing a boatload of priorities. Even a seasoned laboratory director can get bogged down in setting, shuffling, and re-shuffling priorities. So what do you do when you are a new—or a nearly new—public health laboratory director?

The need to craft a formal process to provide mentorship and orientation for new laboratory leaders has been identified repeatedly over the last decade. This need became a priority when an APHL survey of laboratory directors identified an impending leadership vacuum. In a concerted effort to equip emergent leaders for their responsibilities, the National Center for Public Health Laboratory Leadership (NCPHLL) developed a new laboratory directors' orientation program. Seven public health directors agreed to pilot this program through its trial run.

Duane Boline (KS), Mary Celotti (VT), Jack DeBoy (MD), Romesh Gautom (WA), Maurice Knuckles (DC), Mike Loeffelholz (AR) and Victor Waddell (AZ) participated. Eric Blank (MO), served as a mentor and advisor, and Eva Perlman, senior director for professional development, and Pandora Ray, staff associate from NCPHLL, represented APHL staff.

The program is comprised of three components and encompasses three full days. On the first day, the lab directors tackled a team-building exercise, "Navigating the Waters of Leadership and Teamwork." In a hands-on approach, the team explored elements that impact both individual and team performance: they used an assessment tool developed by Team Management Systems that couples an actual rowing activity with a period of review and discussion. After this activity, concepts from a completed homework assignment were applied to the process. Facilitators guided the group of novice rowers through the process, which, in the case of the aforementioned directors, resulted in the boat slicing smoothly through the muddy waters of the Chattahoochie River—albeit if only for a brief moment!

The Practical Guide for the Public Health Laboratory Leader was provided in draft form to each of the participants.

It is intended to be a living document, a work in progress. This guide was developed with the hope of being equally useful to the new, nearly new, or seasoned laboratory leader. Each participant was asked to carefully review the contents of the guide to identify any gaps, and provide feedback and comment.

On the second day of orientation, a media workshop presented by the Merrick Communications Group tested the participants individually. Each director was given the principles and concepts of effective communication during a crisis situation and was charged with developing message points. Each then participated in a simulated interview that was videotaped for critique and analysis. After the analysis, the individual participated in a second interview in an attempt to incorporate the lessons learned from the first exercise. Each person kept their videotapes sessions as a learning tool for future review and practice.

This session was followed by an orientation to APHL. Carol Clark, chief operating officer, outlined the mission, vision, strategic plan and organizational structure. Clark reviewed the member services and categories, governance structure, and the APHL Annual Report, which profiles the accomplishments of the organization. Then Eric Blank provided a historical perspective of the association. Betty Franko, director of the Georgia state public health laboratory, joined the group to provide her perspective and anecdotes. This session was followed by a question and answer opportunity. Duane Boline, director of the Kansas state public health laboratory, stated that this orientation session "answered a lot of questions that I have had for years."

For the third day of orientation, the group convened at the CDC. Key CDC representatives met with the public health leaders throughout the day, including Eric Sampson and Andrea Lipman from the **National Center for Environmental Health**; Ed Thompson, deputy director for the **Public Health Service**; and from the **National Center for Infectious Diseases**, Jan Nicholson, Debbie Deppe, Donald Sharp and Richard Skibicki. Over lunch, the group spoke with Bob Martin and Toby Merlin of the **Division of Laboratory Systems** (DLS).

After lunch, Bob Martin and Karen White discussed their interaction with the public health laboratories. **Office of Terrorism Preparedness and Emergency Response** representatives Charles Schable, Alison Johnson, Ted Jones and Amy Loy described their role and fielded questions from the group. The final group to introduce themselves and report on the status of their projects were staff from the **National Center for HIV, STD and TB Prevention**, including Dale Hu, Tom Folks, Marcia Kalish, Steve McDougal, Bharat Parekh, Mark Rayfield, Tom Shinnick and Craig Studer.

At the close of the program, laboratory director Maurice Knuckles said, "This was invaluable. Just knowing who to call when you have a question makes your life easier."

The organizers of the orientation program extend special thanks and appreciation to Carol Cooke and Andrea Pratcher, DLS, for their tremendous and tenacious dedication to delivering on a wish list of CDC speakers. ■

FELLOWSHIPS

Welcome Class X Fellows!

APHL is excited to announce the induction of the tenth class of the Emerging Infectious Diseases (EID) Laboratory Fellowship Program. Of nearly 250 candidates, sixty were invited to interview in Atlanta, June 14-15. Following interviews, thirty-eight fellows (twenty-seven training fellows with bachelor's or master's degrees and eleven post-doctoral research fellows) accepted positions in the program. Eighteen of the Class X fellows have been assigned to fifteen different state laboratories. APHL is thrilled to work with three first-time host laboratories this year: Arkansas, New Jersey and Texas. Additionally, twenty fellows have been placed in CDC laboratories. We are looking forward to another productive year of fellowship activities.

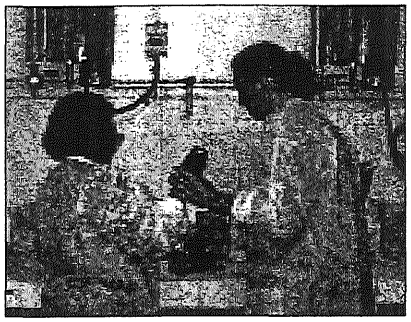
Selection Committee members and state laboratory representatives at sessions of the EID interview program. Linette Granen, APHL; Beth Hochstedler, Iowa Hygienic Lab; Liliane Stark, Florida DOH; James Beebe, Colorado DPHE.

Lab Director Orientation, continued

Around the World with Class IX

Training fellow **Abigail Viall** continues her work in Haiti on a Lymphatic Filariasis noncompliance study. She helped with census-taking and serum collection in four new sentinel sites. She also spent time testing a survey she designed that will be administered in a case-control study. Viall reactivated her National Science Foundation fellowship grant to prolong her stay at the CDC and continue the projects she has initiated there. She insists, "Only someone who has found the working environment to be incredibly stimulating and enjoyable would choose to stay – and use his or her own funds to do so!"

Research fellow **Juliet Bryant** traveled to Monrovia, Liberia, for two weeks in response to a suspected outbreak of yellow fever. She worked with the Liberian Ministry of Health, providing technical assistance and training in serological diagnosis of yellow fever virus to laboratory technicians. The need for increased laboratory training in Liberia was affirmed at a March meeting of UNICEF, WHO, Medicins Sans Frontieres, and the CDC. Developing in-country diagnostic capacity for yellow fever virus was recognized as a key priority for outbreak preparedness and emergency response. In addition to training, Bryant assisted in conducting an overall assessment of laboratory procedures yielding recommendations for strengthening diagnostic capacity for infectious diseases in Liberia. Bryant gained experience transporting reagents and diagnostic specimens across international borders and regarded the trip as an "opportunity to learn about and discuss problems in disease surveillance with officials from the WHO, UNICEF, USAID, and other NGOs."



Class IX Research Fellow Juliet Bryant assists local laboratory staff in Monrovia, Liberia.

Other Fellowship News

Class IX training fellow **Joan Kenney**, from the New Mexico State Laboratory, worked with Indian Health Services to help train environmental health employees from nine different tribes. The workshop focused on mosquito collecting, rodent trapping, tick/flea collecting and burrow swabbing. Kenney expressed that "the level of interest in the room was very encouraging, as was the involvement of CDC liaisons from the University of New Mexico."

A fellowship candidate discusses laboratory opportunities with Helen Deng, of Arkansas Department of Health during EID Fellowship interview sessions.

Yuping Ran, Class V international fellow, won first prize at the Chinese-American Microbiology Society (CAMS) 2004 Annual Meeting for his poster "Discovery of Two Morphotypes of Penicillium marneffei that Differ in Virulence and Proteinase Production." The conference took place during the 104th General Meeting of the American Society of Microbiology in New Orleans.

Jill Thompson, Class IX training fellow from the New York State Department of Health, participated in a vancomycin-resistant Staphylococcus aureus (VRSA) outbreak in New York. This was only the third outbreak of this kind in the United States. Thompson and her group tested over 100 primary samples and isolates throughout the April outbreak.

Class VI international fellow **Alejandro Castello** tested samples from a rotavirus gastroenteritis outbreak in Jamaica. Castello was tasked with establishing the presence of rotaviral antigens and trying to grow virus from serum samples. The results of this investigation were presented at the 53rd Epidemic Intelligence Service Conference, in Atlanta, GA, and the 3rd International Conference on Vaccines against Enteric Diseases, in Montego Bay, Jamaica. ■

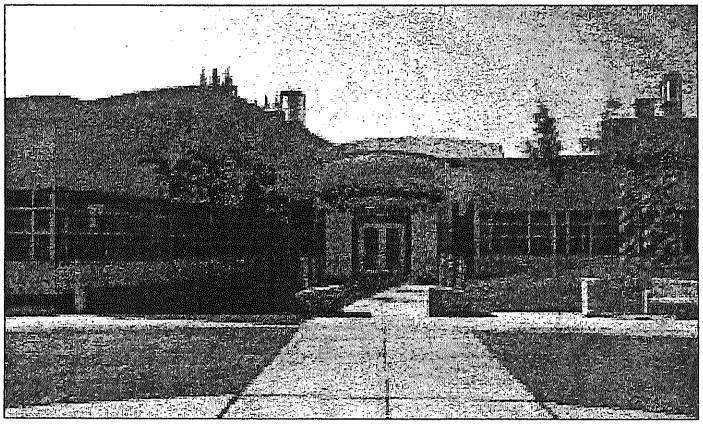
MEMBER NEWS

Alaska Laboratory Tests Blubber, Bear, and Mummy Hair

Everything seems larger-than-life in Alaska: the sky, the fauna, the lengthy stretches of darkness and light, the land itself. The state that calls itself *the last frontier* is more than double the size of Texas and one-fifth the size of the lower forty-eight states combined.

Bernard Jilly, director of the state's public health laboratory for the past 5 years, said sometimes the challenges of working in Alaska seem larger as well. Consider recruitment. Altogether only about 630,000 people call Alaska home. And, until this year there was no in-state bachelor's-level medical technician program. "We mostly have to import staff from the lower 48," said Jilly, who is currently in the market for an environmental health fellow.

Or consider specimen submissions. If there is a tuberculosis (TB) outbreak in a remote village, it can take a week or longer for sputum specimens to reach the main public health laboratory in Anchorage. It is not unusual for specimens to travel via all-terrain-vehicle or snow machine to another village to reach a dirt landing strip and a single-engine aircraft, then to be flown two to three hours to one of only 12 cities with a runway large enough to accommodate a jet, and finally flown via Alaska Airlines to Anchorage. Of course, said Jilly, "weather can play a significant role. Juneau, for example, tends to fog over a lot. If this happens, air traffic may be stalled for a week or so."



Entrance to Alaska public health laboratory in Anchorage.

Similarly, all supplies and laboratory equipment must come from at least as far away as Seattle and withstand temperatures as low as –40 degrees Fahrenheit during winter transit. "Packaging and shipping costs tend to be pretty expensive," Jilly observed.

But if the challenges are sometimes amplified by weather and terrain, so too are the rewards. Said Jilly, "Nobody's neutral about Alaska; you either love it or you hate it. . . . I fell in love with Alaska the first day I set foot in it."

Today the former pathology professor, who spent years in Chicago, works from a three-year-old, 36,000 square-foot facility that sits alongside protected wetlands on the northeast edge of Anchorage with an expansive view of the Chugach Mountains. He oversees a staff of fifty scientists—about thirty-five in Anchorage and another sixteen at a virology laboratory on the grounds of the University of Alaska in Fairbanks.

Despite the immense dimensions of the state, Jilly said, "Alaska is like a small city." Most residents live within thirty miles of Anchorage and "everyone's on a first name basis because we all meet each other at the grocery store." This collegiality carries over into the laboratory, which has a close working relationship with the state medical examiner—who is co-located in the Anchorage facility—law enforcement officers, and military personnel. The state public health laboratory is the reference laboratory for local military bases as well as the Navy hospital in Okinawa, Japan.

Last year when the state began surveillance for West Nile virus—a serious threat because of Alaska's large and locally revered flocks of ravens and eagles—the military collected mosquito pools and sent samples down to its lab in the continental US for analysis, while the state laboratory tested human and avian samples.

As elsewhere, the main laboratory workload reflects the prevailing health concerns of the population; in this case with a heavy emphasis on sexually transmitted diseases, hepatitis, TB, and botulism. (Alaska has by far the highest

rate of foodborne botulism in the country, primarily due to the popularity of fermented native foods.) The single highest volume procedure performed by the laboratory is the Aptima™ test for nucleic acid detection of gonorrhea and chlamydia in urine specimens (which are stable for up to a month and present few shipping problems.)

But, this being *the frontier*, laboratory work can sometimes veer off into the bizarre, at least by the standards of the lower 48. Shortly before Thanksgiving last year, Jilly received seventy-five pounds of fermented whale blubber—a delicacy in the bush—to test for botulism. "Of course," said Jilly, "that came in late on a Friday afternoon." The Fairbanks branch of the state laboratory commonly receives fox, wolf, and even bear heads to test for rabies. And it is not unusual for the laboratory to perform brucellosis testing on serum or organs from caribou, walrus and seal.

...I fell in love with Alaska the first day I set foot in it.
—Bernard Jilly, PhD

Just last year the laboratory started a chemistry program, so far devoted to forensic toxicology, chemical terrorism and biomonitoring. One of the state's first biomonitoring projects is a study of mercury levels in local populations that consume large quantities of fish. Although the study is ongoing, preliminary data—based in part on measurements from ancient, mummified hair—show little change in mercury levels over at least the past thousand years. (Even timescales are larger in Alaska.)

In some ways, though, Jilly's shop shares the frustrations and aspirations of public health laboratories nationwide. What is the biggest challenge facing the Alaska public health laboratory? "The first thing out of any laboratory director's mouth when you ask that question," he said. "Money, money, money."

Like many states, Alaska is undergoing fiscal retrenchment. The Alaska laboratory has suffered a 25% cut in general state funds on top of about a 15% reduction in federal bioterrorism grant funds and a 7% reduction in tuberculosis grant money. About a sixth of the laboratory's technical staff has been eliminated. "We've been really decimated," said Jilly.

But assuming the fiscal situation improves, plans are afoot for laboratory enhancements. Jilly has set aside $1 million for a laboratory information management system that will enable real-time, Web-based specimen tracking and reporting. Said Jilly, "I personally feel that electronic connection here in Alaska is essential to our survival because of the physical challenges of a state like this. I'd like to push the IT (information technology) envelope as far as we can." Already the laboratory is working with the medical examiner to do remote autopsies.

Jilly also plans to "exploit rapid molecular technologies to the maximum." "If it takes a week to get a specimen here," he explained, "you don't want to wait another week to get an answer."

Looking at the big picture, Jilly observed that "we went from a rather sleepy infectious disease laboratory to a really cutting-edge, state-of-the-art facility." Now, he said, even on the frontier it's time to "go into the twenty-first century full speed ahead." ■

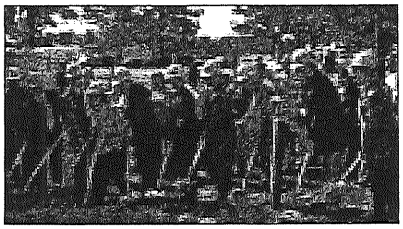
Arkansas Breaks Ground for New Public Health Laboratory

Arkansas officials broke ground for a new public health laboratory in August. At the ceremony, Governor Mike Huckabee stressed the need for the new facility: "The aftermath of the terrorist attacks on our country helped us to understand that a laboratory building, designed to allow testing for agents such as anthrax and smallpox, is urgently needed. We're also seeing an onslaught of newly discovered infectious diseases... It's clear a state-of-the-art laboratory is a necessity for Arkansas."

Dr. Mike Loeffelholz, laboratory director, pointed out that it is also important to recognize that the laboratory protects the health of Arkansas citizens every day by insuring that the food and drinking water are safe to eat and drink, that highly infectious diseases are promptly recognized and controlled, and that all newborns are tested for genetic defects.

This is a great day for public health in Arkansas. –Fay Boozman, PhD, director, Arkansas Department of Health

Quick Facts:



Location: just south of the present Health Department headquarters in Little Rock, AR
Funding: a bond issue financed by fees charged by the Health Department
Construction time: September 2004 - December 2005
Cost: approximately $23 million dollars
Size: approximately 80,000 square feet
Laboratory employees: 140
Architectural services: The Wilcox Group of Little Rock, AR, and the Lord, Aeck and Sargent of Atlanta, GA
Engineering services: TME of Little Rock, AR, and Nabholz Construction Company ■

Discussing Labs with Legislators

This summer APHL staff exhibited on behalf of public health laboratories at the National Conference of State Legislatures' (NCSL) Annual Meeting and Exhibition in Salt Lake City, UT. NCSL is a bipartisan organization that provides state legislators and staff with research and technical assistance. Each year NCSL convenes at an annual meeting attended by thousands of legislators and staff.

Over the past four years, APHL has conversed with legislators from almost every state about the importance of public health laboratories. Many legislators are unfamiliar with the laboratories and are intrigued by the number of services and protections offered to the community. A small number of legislators are old hands: these politicians have toured their own public health laboratory, or can offer the name of their state's laboratory director, or know instantly which current legislative efforts involve the well-being of laboratories.

APHL has perceived an enormous value from these casual discussions with legislators, finding that most are very interested—in both a personal and political capacity—in the issues that laboratorians deal with every day. For more information about NCSL, visit www.ncsl.org.

Brokopp to Lead CDC's Select Agent Program

APHL member Charles Brokopp, DrPH, has been selected as the director of the select agent program within CDC's Office of Terrorism Preparedness and Emergency Response. Brokopp has been the director of Utah's Division of Epidemiology and Laboratory Services for ten years, and has extensive experience with public health and environmental health issues. During his twenty-nine years in public health, Brokopp has worked closely with many local, state, federal and private public health and environmental organizations.

Rapid HIV Test Technical Advisor/Trainer Urgently Needed

APHL is seeking a qualified laboratory scientist for a short-term 2-month assignment in Namibia. The ideal candidate will have a background and experience in rapid HIV testing, quality assurance, and training. Experience in a cross-cultural setting, preferably in Africa, will be advantageous.

All interested parties should contact Yvette Benajmin, director of global health, at 202.822.5227, ext. 246, or ybenjamin@aphl.org

Profiles in Public Health Laboratories Series

LA County Laboratory: *Surviving in the City of Angels*

Director

Sydney Harvey, PhD – a molecular biologist and former owner of Irvine Diagnostic Services (now a part of Quest Laboratory).

Location

Heart of the music district in downtown Los Angeles near the Dorothy Chandler Pavilion.

Facility

"We're bursting at the seams." The laboratory occupies the top two floors of the 14-story Department of Health Services Building in a space designed to accommodate about a third of the current laboratory staff. Because the building has no freight elevators, a carbon dioxide tuberculosis incubator is "sitting on the loading dock with no way to bring it up." Fortunately, the laboratory will move to a larger, renovated county building in 2005.

Staff

145 – Bigger than most state laboratories.

Relationship to the State Laboratory

No regulatory oversight from the state public health laboratory.

Distinguishing Characteristics

- Laboratory Response Network reference laboratory responsible for confirmatory testing of certain suspected agents of bioterrorism for all of California south of San Luis Obispo and outside of San Diego.
- One of only 40 Level 2 chemical terrorism response laboratories nationwide.
- Accredited by the College of American Pathologists with distinction.
- Open for business at least six days a week, Monday through Saturday.
- Became a PulseNet member (capable of performing a DNA fingerprinting method on foodborne bacteria to help pinpoint the source of foodborne disease outbreaks) before the state public health laboratory.

Highest Volume Testing

Roughly a quarter of the laboratory workload is fee-for-service testing for private community health centers, which generates several million dollars in revenue each year. Much of this work is sexually transmitted disease testing.

Biggest Recent Success Story

Survival. Because LA County owns six hospitals and four comprehensive health centers—each with its own clinical laboratory—the public health laboratory has been viewed "as just another clinical lab." Several years ago the laboratory was stripped of its entire environmental chemistry program as equipment and staff were relocated to the county agricultural laboratory. Just this past year, the laboratory has faced a renewed effort to "force (it) into the mold of the clinical labs" as part of a grand consolidation scheme. Harvey's extensive private sector experience has enabled her to make a case for the unique value of the public health laboratory. County authorities "are beginning to understand a little bit more how we're different.," she said. "That to me is a success right now."

I always wanted a laboratory of my own ever since I was 6 years old, ever since I first knew about microbes. Don't ask me why.

–Sydney Harvey, PhD

Biggest Challenge

Staffing. "Up until five years ago, I did not have a single position that did not require a license (from the California Laboratory Field Services Office). You don't find a person . . . who wants to come into a public health lab and train for six months at the bench and sit for a state exam to get a license after already completing a PhD. It's a lot easier to go to a local biotech company and they pay a lot more."

Vacancies 12

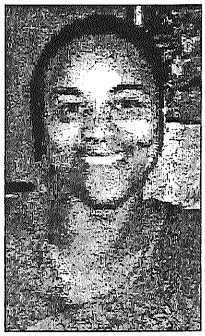
Goal

To become "one of the best public health laboratories in the US. If we're not there, we're awfully close." ■

Staff News

Lauren DiSano, MHS, is APHL's new environmental health program manager, effective July 1. Over the past year, DiSano worked on water security issues at the EPA while serving as an Association of Schools of Public Health fellow. Previously, she earned a master's degree at the Johns Hopkins School of Public Health, Department of Environmental Health Sciences, and a bachelor's degree at James Madison, Department of Health Sciences. DiSano has also worked in environmental community development at the Herring Run Watershed Association.

Diane Johnson, MPH, became APHL's global health program manager on August 9. Johnson will be responsible for the day-to-day activities of the association's involvement with the President's Emergency Plan for HIV/AIDS Relief (PEPFAR). Johnson comes from Inflexxion, Inc., where she provided management, coordination, and negotiating skills on the safe use of pharmaceuticals to address public health concerns. She earned a master's degree at the University of North Carolina at Chapel Hill, Department of Maternal and Child Health, and a bachelor's degree from Brown University, Department of Biocommunity Health. Johnson has also worked at the Institute of Medicine, on the Food and Nutrition Board, and currently publishes as a freelance journalist in an urban magazine, *Sage Advice, Urban City Magazine*, published quarterly out of New York City. ■



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The Association of Public Health Laboratories (APHL) is a national non-profit dedicated to working with its members to strengthen public health laboratories. By promoting effective programs and public policy, APHL advocates for public health laboratories with the resources and infrastructure needed to protect the health of U.S. residents and bolster and coordinate disease surveillance.

This publication was supported by Cooperative Agreement Number 5U90TP 319019 and 319522 from the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the official position of APHL officers, members, staff or partners.

To submit an article, for subscription, or to contact Emily Mumford, e-mail emumford@aphl.org

Biomonitoring and Public Health Tracking

Samuel Yamin, MPH
Public Health Scientist
Minnesota Center for Environmental Advocacy

Biomonitoring

Assessment of human exposure to environmental pollutants by measuring levels of chemicals or breakdown products in blood, urine, or other body fluids and tissues.

Environmental Public Health Tracking

Collection, integration, and analysis of data on human exposures to environmental pollutants and on diseases caused or aggravated by those chemicals.

Objectives

- Characterize relationship between hazardous chemicals and disease.
- Guide and evaluate prevention strategies and regulations.
- Provide the public with solid information.

Reference: Pew Environmental Health Commission, 2000.

Biomonitoring: Federal Program

- Mercury, lead, other metals
- PAHs
- Dioxins
- PCBs
- Phthalates
- Organochlorine insecticides
- Organophosphate insecticides
- Herbicides
- Other chemicals

Reference: Centers for Disease Control and Prevention

Biomonitoring: Example projects in other states

- Illinois: Children's blood lead levels.
- Wisconsin: Methylmercury from fish consumption.
- Other states: Lead, mercury, nitrates, pesticides, arsenic, industrial chemicals.

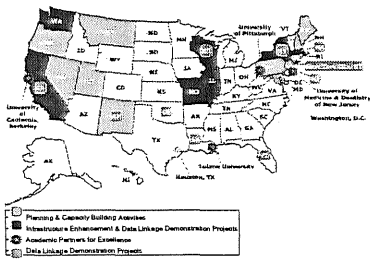
Reference: Centers for Disease Control and Prevention

Environmental Public Health Tracking: Federal Program

Centers for Disease Control and Prevention (CDC) goal is to facilitate establishment of a nationwide biomonitoring and environmental public health tracking network.

Reference: Centers for Disease Control and Prevention

State environmental health tracking programs currently funded by CDC



Reference: Centers for Disease Control and Prevention

Env. Health Tracking: Example projects in other states

- Wisconsin: Childhood cancer, asthma and other respiratory disease, neurological disorders.
- Illinois: Cancer, birth defects, blood lead.
- Missouri: Cancer, birth defects, blood lead, asthma.

Reference: Centers for Disease Control and Prevention

Usefulness for Minnesota

- Determine which pollutants people are likely to be exposed to.
- Improve tracking of diseases, and integrate results with biomonitoring data.
- Catch up to other states and contribute to development of nationwide network.

What could be investigated in MN

- Exposures: mercury, lead, pesticides, air pollutants, persistent chemicals, drinking water contaminants.
- Diseases: birth defects, developmental disorders, asthma and other respiratory disease, cancer, neurological disorders.

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Jo Anne Zoff Sellner
Director

Senate

State of Minnesota

S.F. No. 2899 - Controlled Substance Electronic Reporting System

Author: Senator Linda Berglin

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) KC

Date: March 24, 2006

S.F. No. 2899 establishes a controlled substances reporting system that would require dispensers of controlled substances to electronically report specified information to the Board of Pharmacy.

Section 1 (152.126) establishes the prescription electronic reporting system.

Subdivision 1 defines the following terms: "advisory committee," "board," "controlled substances," "dispense," "dispenser," "prescriber," and "prescription."

Subdivision 2 requires the Board of Pharmacy to establish by January 1, 2008, an electronic system for reporting prescribing information for all controlled substances dispensed within the state. Permits the Board to contract with a vendor to establish and maintain this system.

Subdivision 3 establishes an advisory committee of seven members appointed by the Board. Describes the members of the committee and the committee's duties.

Subdivision 4 requires each dispenser to submit the following data to the Board or the Board's designated vendor:

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) name of the patient for whom the prescription was written;

(6) date of birth of the patient fro whom the prescription was written;

(7) date the prescription was written;

(8) date the prescription was filled;

(9) name and strength of the controlled substance;

(10) quantity of controlled substance prescribed;

(11) quantity of controlled substance dispensed;

(12) days supply based on the directions for use on the prescription; and

(13) any other information deemed necessary by the Board.

The dispenser is required to submit this data by a procedure and in the format established by the Board. A dispenser is not required to submit this data for individuals residing in a skilled nursing facility or a intermediated care facility.

Subdivision 5 requires the Board to develop and maintain a database of the reported data and use the data for the identification of:

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) prescribers who may be prescribing controlled substances in an unprofessional or unlawful manner;

(3) dispensers who may be dispensing controlled substances in an unprofessional or unlawful manner;

(4) individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of dosage for those controlled substances; and

(5) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers.

Subdivision 6, paragraph (a), except as allowed under paragraphs (b), (c), and (d), classifies the data submitted to the Board as private data on individuals.

Paragraph (b), if the Board, after reviewing data submitted, determines that there is reasonable cause to believe that a violation of law or a breach of professional standards has occurred, permits the Board to notify the appropriate law enforcement and professional regulatory authorities and provide the relevant data to the appropriate authority.

Paragraph (c) permits the Board to provide the data submitted for public research and policy or education purposes so long as any information that is likely to identify the patient or other person who is subject to the data has been removed.

Paragraph (d) authorizes the following persons to access to the data in the same or similar manner and for the same or similar purposes as those persons authorized to access similar private data on individuals under state and federal law:

(1) a prescriber to the extent the information relates to a current patient;

(2) a dispenser to the extent the information relates to a current patient;

(3) an individual who is the recipient of a controlled substance prescription for which data was submitted;

(4) personnel of the Board assigned to conduct investigations related to controlled substances laws;

(5) personnel of the Board engaged in the collection and analysis of controlled substance prescription information;

(6) authorized personnel of a vendor under contract to the Board who are engaged in the collection and analysis of the data collected;

(7) a designated representative of a health related licensing Board;

(8) law enforcement officials engaged in a bona fide investigation of a specific licensee; and

(9) personnel of the medical assistance program assigned to use the data collected to identify recipients whose usage of controlled substances may warrant restriction to a single primary care physician, a single outpatient pharmacy, or a single hospital.

Paragraph (e) states that the Board may not release the data submitted unless it is provided with evidence that the person requesting the information is entitled to receive the data.

Subdivision 7 states that a dispenser who knowingly fails to submit data to the Board as required or who has access to the data and knowingly discloses the data in violation of state or federal law is subject to disciplinary action by the appropriate health-related licensing board.

Subdivision 8 requires the Board to evaluate the prescription electronic reporting program to determine if the program is cost effective and submit the evaluation to the Legislature by January 15, 2009. The Board may contract with a vendor to design and conduct the evaluation.

Subdivision 9 authorizes the Board to promulgate any rules necessary to implement this section.

Section 2 requires the Board of Pharmacy to apply for any applicable federal grants or other nonstate funds to establish and fully implement the program.

KC:ph

Senator Berglin introduced–

S.F. No. 2899: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; establishing a controlled substances reporting program; providing for disciplinary action; proposing coding for new law in Minnesota Statutes, chapter 152.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[152.126] ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING PROGRAM.**

Subdivision 1. **Definitions.** For purposes of this section, the terms defined in this subdivision have the meanings given.

(a) "Advisory committee" means the Prescription Electronic Reporting Advisory Committee established under subdivision 3.

(b) "Board" means the Minnesota State Board of Pharmacy established under chapter 151.

(c) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to 6, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12.

(d) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30.

(e) "Dispenser" means a person authorized by law to dispense, pursuant to a valid prescription, a controlled substance. A dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care.

(f) "Prescriber" means a licensed health care professional who is authorized to prescribe a controlled substance under section 152.12, subdivision 1.

(g) "Prescription" has the meaning given in section 151.01, subdivision 16.

Subd. 2. **Establishment of a prescription electronic reporting program.** (a) The board shall establish by January 1, 2008, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state.

(b) The board may contract with a vendor to establish and maintain the electronic reporting system.

Subd. 3. **Prescription Electronic Reporting Advisory Committee.** (a) The advisory committee consists of seven members appointed by the board to three-year terms. The board shall include at least one representative of:

(1) the Department of Health;

(2) the Department of Human Services;

(3) each health-related licensing board that licenses prescribers;

(4) a professional medical association, which may include an association of pain management and chemical dependency specialists;

(5) a professional pharmacy association; and

(6) a consumer or patient rights organization.

(b) The advisory committee shall advise the board on the development and operation of the electronic reporting system, including, but not limited to:

(1) technical standards for electronic prescription drug reporting;

(2) proper analysis and interpretation of prescription monitoring data;

(3) standards for clinically appropriate prescribing and dispensing of controlled substances; and

(4) an evaluation process for the program.

Subd. 4. **Reporting requirements.** (a) Each dispenser must submit the following data to the board or its designated vendor:

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) name of the patient for whom the prescription was written;

(6) date of birth of the patient for whom the prescription was written;

(7) date the prescription was written;

(8) date the prescription was filled;

(9) name and strength of the controlled substance;

(10) quantity of controlled substance prescribed;

(11) quantity of controlled substance dispensed;

(12) days supply based on the directions for use listed on the prescription; and

(13) any other information deemed necessary by the board.

(b) The dispenser must submit the required information by a procedure and in a format established by the board.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for individuals residing in licensed skilled nursing or intermediate care facilities.

Subd. 5. **Use and analysis of data by board.** The board shall develop and maintain a database of the data reported under subdivision 4 and shall use the database for the identification of:

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) prescribers who may be prescribing controlled substances in an unprofessional or unlawful manner;

(3) dispensers who may be dispensing controlled substances in an unprofessional or unlawful manner;

(4) individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of dosage for those controlled substances; and

(5) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers.

Subd. 6. **Access to prescription electronic reporting program data.** (a) Except as indicated in paragraphs (b), (c), and (d), the data submitted to the board under subdivision 4 is private data on individuals as defined in section 13.02, subdivision 12.

(b) If in the course of reviewing data submitted under subdivision 4, the board determines there is reasonable cause to believe that a violation of law or a breach of professional standards has occurred, the board shall notify the appropriate law enforcement and professional licensing, certification, or regulatory authorities, and provide all relevant data to the appropriate authority.

(c) The board may provide data submitted under subdivision 4 for public research, policy or education purposes, to the extent that any information that is likely to reveal the identity of the patient or other person who is the subject of the data has been removed.

(d) The following persons may access the data submitted under subdivision 4 in the same or similar manner, and for the same or similar purposes, as those persons who are authorized to access similar private data on individuals under federal and state law:

(1) a prescriber, to the extent the information relates specifically to a current patient of the prescriber, to whom the practitioner is prescribing or considering prescribing any controlled substance;

(2) a dispenser to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance;

(3) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4;

(4) personnel of the board specifically assigned to conduct investigations related to controlled substances laws under the jurisdiction of the board;

(5) personnel of the board engaged in the collection and analysis of controlled substance prescription information as part of the assigned duties and responsibilities of their employment;

(6) authorized personnel of a vendor under contract to the board who are engaged in the collection and analysis of the data collected under subdivision 4 as part of the assigned duties and responsibilities of their employment;

(7) a designated representative of a health-related licensing board responsible for the licensure, regulation, or discipline of prescribers or dispensers provided that the requested data relates to a bona fide investigation of a specific licensee;

(8) federal, state, and local law enforcement authorities engaged in a bona fide investigation of a specific person; and

(9) personnel of the medical assistance program assigned to use the data collected under this section to identify recipients whose usage of controlled substances may warrant restriction to a single primary care physician, a single outpatient pharmacy, or a single hospital.

(e) The board shall not release data submitted under this section unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

Subd. 7. **Disciplinary action.** (a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.

(b) A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of healthcare data shall be subject to disciplinary action by the appropriate health-related licensing board.

Subd. 8. **Evaluation and reporting.** (a) The board, in consultation with the advisory committee, shall evaluate the prescription electronic reporting program to

determine if the program is cost-effective. The board may contract with a vendor to design and conduct the evaluation.

(b) The board shall submit the evaluation of the program to the legislature by January 15, 2009.

Subd. 9. **Rules.** The board may promulgate rules necessary to implement the provisions of this section.

EFFECTIVE DATE. This section is effective July 1, 2006, or upon receiving sufficient nonstate funds to implement the prescription electronic reporting program, whichever is later. In the event that nonstate funds are not secured by the Board of Pharmacy to adequately fund the implementation of the prescription electronic reporting program, the board is not required to implement section 1, without a subsequent appropriation from the legislature.

Sec. 2. **FEDERAL GRANTS.**

The Board of Pharmacy shall apply for any applicable federal grants or other nonstate funds to establish and fully implement the prescription electronic reporting program.

EFFECTIVE DATE. This section is effective the day following final enactment.

From: Alfred Anderson, MD [mailto:aanderson@medpainmanagement.com]
Sent: Friday, March 10, 2006 10:25 AM
To: DICK AULD
Subject:

I have had the opportunity to review the SF 2899 and HF 3264 bills which deal with a controlled substance reporting program. While it might be useful for a treating doctor to have the ability to track a patient who would abuse scheduled medication, these bills emphasize scrutiny over the prescribing doctor. I oppose these bills for the following reasons:

Subd 3 refers to "standards of prescribing" which are unwritten and undetermined due to the enormous variability of patient response to a given medication. Therefore, this could not be fairly assessed by the Advisory Committee.

Subd. 4. requires the information on the prescriber and the dispenser. These practitioners are already under scrutiny by regulatory agencies. Physicians, pharmacists, third party payers, patients, and family members of patients, are all able to report unprofessional prescribing to the appropriate agency. The board receiving the complaint then applies procedures based on complete information .These bills do not consider the specialty of the doctor, or the diagnosis of the patient, information which is necessary to determine appropriateness of prescribing.

Regarding the Advisory Committee, it appears to be dominated by members who would have no expertise in management of pain or medication required.

It was the understanding of the pain associations that this was to be a tool for the prescribing doctors, in which the doctor could call up the information on a specific patient. Since the patient is the only person who is not presently monitored regarding the chain of custody of a scheduled medication, this bill should deal specifically with that issue.

I am very concerned that these bills, if passed into law, would have chilling effect on the treatment of pain. This would encourage the use of invasive procedures such as implantable devises and the overuse of injection procedures for conditions which could be more effectively treated with scheduled medications.

Alfred V. Anderson M.D.
Medical Director
Medical Pain Management.
St Louis Park, Mn.

Richard Auld

From: Belgrade, Miles J [MBELGRA1@FAIRVIEW.ORG]
Sent: Wednesday, March 08, 2006 10:47 AM
To: Richard.Auld@state.mn.us
Cc: drenner@mnmed.org
Subject: Bill

I have reviewed the Bill to establish a controlled substances reporting program. While I am sure most physicians would welcome an ability to track their patients' use of controlled medicines, this bill is so problematic that I cannot support it.

First, the stated objectives for the all schedules prescription reporting program go way beyond patient care and physician tracking of their patients' meds. None of the five stated uses of the program are to aid physicians' care of patients or selection of patients for opioid prescriptions or continuation of prescriptions. The purposes as stated are to monitor physician and pharmacy prescribing practice and to identify unprofessional and unlawful prescribing or dispensing (uses 1-4); and to identify forged or altered prescriptions (use #5). It is not at all clear that such a reporting system would be able to identify forged prescriptions. Thus this data and the board are designed for law enforcement, and to catch physicians and pharmacies who are not adhering to some (yet unwritten or unidentified) guidelines of prescribing practice.

Secondly, The make-up of the "advisory" board consists of individuals who (with perhaps one exception) have no pain management knowledge or expertise, no knowledge or expertise about medications or clinical problems (e.g. members from: board of helath, dept of human services, the public, an advocate, members of licensing bodies, etc). Such individuals have no basis by which to judge the proper prescribing of opioids and other controlled medicines.

Thirdly, The database provides no clinical context by which to judge the prescribing process. Cancer, hospice, terminal patients, acute pain, chronic pain, mental illness, etc are all unidentified.

Finally, I am concerned that such a database and advisory board structure will definitely have a chilling effect on the use of opioid analgesics for all patients with pain. There is a serious question here of the intent of the individulas who are promoting this bill which will likely place interventional pain treatments at center stage when the medicine options create barriers. Are the promoters of this bill going to see an increase in their interventional business because there is greater reluctance to use medicine to treat pain? This is a secondary gain that needs to be addressed.

Sincerely,

Miles Belgrade, M.D.
Medical Director,
Fairview Pain & Palliative Care Center
University of Minnesota Medical Center, Fairview

Richard Auld

From: Elliott, Tom E. [telliott@smdc.org]
Sent: Tuesday, March 14, 2006 9:24 AM
To: 'Richard Auld'
Subject: RE:

Hi Dick,
Thank you for asking my opinion regarding the prescription electronic reporting program proposed by the Minnesota legislature. First, I agree completely with Miles Belgrade's assessment. This is a terribly flawed program that will not achieve its goals, serve patients or society, and will waste tax payers money.
Here are a few of my specific comments:

Line 2.19: "(2) Proper analysis and interpretation of prescription monitoring data." Unfortunately, this will not be possible without substantial clinical data.

Line 2.20: "(3) Standards for clinically appropriate prescribing and dispensing of controlled substances." Also, not possible. Without considerable clinical data this assessment is not possible. Furthermore, there are no 'standards for clinically appropriate' prescribing of opioids.

Lines: 3.12-13: "(2) Prescribes who may be prescribing controlled substances in an unprofessional or unlawful manner." The data will not make this goal possible.

Lines: 3.14-15: "(3) Dispensers who may be dispensing controlled substances in an unprofessional or unlawful manner." Again the data to be collected will not detect these behaviors.

Lines: 3.16-19: "(4) Individuals receiving prescriptions for controlled substances from prescribes who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of dosage for those controlled substances." The database will not permit detecting these goals either. Furthermore, there are no 'recognized standards of dosage' for these drugs. This is a terribly flawed approach.

In closing, I would be very disappointed if our government chooses to pursue this plan, which is frightfully flawed and a terrible waste of our tax payers money.
Best regards,
Tom

-----Original Message-----
From: Richard Auld [mailto:Richard.Auld@state.mn.us]
Sent: Thursday, March 09, 2006 3:09 PM
To: Elliott, Tom E.
Subject:

Tom, sorry there so many messages from me, but I just got the file numbers for the bill in the Senate and House. The Senate is sf 2899, with Sen. Linda Berglin as chief author (651) 296-4261. The House is hf 3264, with Re. Jim Abeler as chief author (651)296-1729, and Rep. Tom Huntley as the second author (651 296-2228. Thanks again. Dick

Drug Crime Is a Source of Abused Pain Medications in the United States

Joranson DE, Gilson AM. Drug crime is a source of abused pain medications in the United States.
Journal of Pain and Symptom Management. 2005; 30(4):299-301.

To the Editor:

The International Narcotics Control Board consistently reports that, despite an extremely large number of transactions, little or no narcotic drugs are diverted from licit international trade into illicit channels.[1] Most diversion occurs within countries, where governments attempt to prevent diversion during the manufacture and distribution of controlled substances to the retail level (e.g., pharmacies and hospitals). In the United States, diversion occurs despite a closed distribution system of licensing, security, and record keeping.

Public dialogue about prescription drug abuse in the United States focuses largely on inappropriate physician prescribing and patient misuse.[2,3] National media reports and high-profile charges against physicians enhance the perception that physician prescribing for pain is the main cause of increases in opioid analgesic abuse.

An important but mostly overlooked diversion source involves thefts, including armed robberies, night break-ins, and employee and customer pilferage. The Controlled Substances Act makes thefts of controlled substances from Drug Enforcement Administration (DEA) registrants a federal crime, and requires pharmacists, manufacturers, and distributors to report significant thefts and losses.

The authors submitted a Freedom of Information Act request to the DEA to obtain data from Form 106 "Report of Theft or Loss of Controlled Substances." An electronic database was provided with annual data for 2000--2003. Each incident of theft/loss included the number of dosage units, as well as the generic name, trade name, dosage strength, and formulation of the controlled substance. We evaluated six opioid medications used for moderate to severe pain that we have studied previously:[4] fentanyl, hydromorphone, meperidine, methadone, morphine, and oxycodone.

The database contained analyzable data from registrants in only 22 Eastern states, representing 53% of the U.S. population. A total of 12,894 theft/loss incidents were reported in these states between 2000 and 2003. Theft/losses were primarily from pharmacies (89.3%), with smaller portions from medical practitioners, manufacturers, distributors, and some addiction treatment programs that reported theft/losses of methadone.

Over the 4-year period, almost 28 million dosage units of all controlled substances were diverted. The total number of dosage units for the six opioids is as follows:

- 4,434,731 for oxycodone
- 1,026,184 for morphine
- 454,503 for methadone
- 325,921 for hydromorphone
- 132,950 for meperidine
- 81,371 for fentanyl

The number of dosage units diverted varied considerably from year to year and from drug to drug (see Table 1). The greatest increase in theft/loss between 2000 and 2003 was for fentanyl (161.3%); however, fentanyl comprised the smallest amount compared to other opioids. The second largest increase (147.2%) was for hydromorphone, but represented only 2.45% of all dosage units lost in 2003. Morphine was the only opioid showing a decrease (257.4%). There was an 18.5% increase in losses of oxycodone; however, the proportion of oxycodone losses, compared to losses all controlled substances was slightly lower in 2003 than in 2000, as was the case for meperidine and methadone.

Comment

This exploratory study suggests that theft is an important source of prescription opioids diverted into the illicit market. In 2003 alone, a total of 7,652,099 dosage units of controlled substances were stolen/lost, of which 1,834,717 (24.0%) dosage units were the six opioid analgesics. As a comparison, hydrocodone, an opioid analgesic frequently prescribed but not indicated for moderate to severe pain, accounted for 3,995,402 dosage

Table 1

Number of Dosage Units for Selected Opioid Analgesics Listed in the U.S. DEA's Theft/Loss Database[a]

Year and Total Annual Dosage Units Lost or Stolen	Fentanyl	Hydromorphone	Meperidine	Methadone	Morphine	Oxycodone
2000, $n = 6,404,965$	17,644 (0.28)	75,965 (1.19)	32,447 (0.51)	99,073 (1.55)	491,356 (7.67)	1,052,305 (16.43)
2001, $n = 8,640,891$	5,759 (0.07)	28,400 (0.33)	36,966 (0.43)	82,521 (0.96)	172,387 (2.00)	979,683 (11.34)
2002, $n = 5,157,442$	11,867 (0.23)	33,739 (0.65)	25,850 (0.50)	166,288 (3.22)	153,222 (2.97)	1,155,471 (22.40)
2003, $n = 7,652,099$	46,101 (0.60)	187,817 (2.45)	37,687 (0.49)	106,621 (1.39)	209,219 (2.73)	1,247,272 (16.30)
Percentage change, 2000–2003	161.3	147.2	16.2	7.6	−57.4	18.5

[a]Values are expressed as number (percentage) of dosage units lost or stolen.

units (52.2%) lost or stolen in 2003 more than twice the amount of the six study drugs combined.

We conclude that pain medications, regardless of schedule, are being stolen from the drug distribution chain prior to being prescribed, contributing to their illicit availability, abuse, and associated morbidity and mortality. National discussion about pain medication abuse and diversion should be better informed by reliable information about whether abused drugs are coming from those registered to handle controlled substances lawfully or from those who engage in criminal activities.[5]

If we accept uncritically that drug diversion stems only from prescriptions, we risk distorting our view of the medical profession and patients through a lens of substance abuse, which further weakens physicians' desire to treat pain and worsens patient access to pain care. We must eliminate the impact of illegal actions on law-abiding physicians and patients.

The unchecked flow of pain medications diverted from nonmedical sources will not be addressed if diversion control focuses only on prescribers and patients. Instead, this may provoke greater scrutiny of the medical system rather than street level pharmacy crime. To achieve a positive regulatory environment for pain management and palliative care, diversion control efforts must target the correct sources and not subject law-abiding prescribers and patients to unwarranted scrutiny. Once identified, diversion sources should be addressed in a public health context, and in ways that are appropriate and proportional; vulnerabilities in the distribution system may require improved security, while responses to individual practitioners should be based on standards of professional conduct, reserving criminal prosecution for intentional diversion.

Better use must be made of existing national drug abuse databases[6] to put an evidence-based face on how abused prescription pain medications are obtained. A balanced response to diversion must be the goal, in which the collective resources of education, prescription monitoring, professional discipline, and law enforcement are correctly targeted without interfering with legitimate medical practice and patient care.

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References

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2 Cicero TJ, Inciardi JA. Diversion and abuse of methadone prescribed for pain management [letter]. JAMA 2005;293(3):297--298.

3 Drug Enforcement Administration - Office of Diversion Control. The diversion of drugs and chemicals - A descriptive report of the programs and activities of DEA's Office of Diversion Control. Washington, DC: Drug Enforcement Administration, 1999. Available from: http://www.deadiversion.usdoj.gov/pubs/program/activities/index.html. Accessed October 6, 2005.

4 Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997--2002. J Pain Symptom Manage 2004; 28(2):176--188.

5 Brushwood DB, Kimberlin CA. Media coverage of controlled substance diversion through theft or loss. J Am Pharm Assoc (Wash DC) 2004;44(4):439--444.

6 The Council of State Governments. Trends alert: Drug abuse in America - Prescription drug diversion. The Council of State Governments, Lexington, KY, 2004.

Table 1. *Characteristics of State Prescription Drug Monitoring Programs*

State	Year Implemented	Controlled Substance schedule(s) monitored	Type of monitoring system	Administrative Agency
California[a]	1940	II	Electronic and triplicate form[b]	Pharmacy and law enforcement
Hawaii	1943	II	Electronic	Law enforcement
Idaho	1967	II, III and IV	Electronic	Pharmacy board
Illinois	1961	II	Electronic	Public health
Indiana	1995	II	Electronic	Law enforcement
Kentucky	1999	II, III, IV and V	Electronic	Public health
Massachusetts	1992	II	Electronic	Public health
Michigan[c]	1989	II	Single form	Commerce
Nevada	1997	II, III, and IV	Electronic	Pharmacy board and law enforcement
New York[d]	1977	II	Electronic	Public health
Oklahoma	1991	II	Electronic	Law enforcement
Rhode Island	1979	II, III	Electronic	Public health
Texas[e]	1982	II	Electronic	Law enforcement
'ah	1997	II, III, IV and V	Electronic	Commerce's Licensing Division
Washington[f]	1987	Determined by disciplinary authority	Triplicate form[b]	Public health

[a]California is currently testing an electronic monitoring program for Schedule II controlled substances. Until the pilot program is completed on July 1, 2003, pharmacies will also have to continue submitting copies of the triplicate forms to the state monitoring agency.

[b]A triplicate prescription form is a paper prescription form issued by the state to prescribers, who must use it when writing prescriptions for covered controlled substances. The prescriber keeps one copy after writing the prescription, and the pharmacist keeps a copy when the prescription is filled and sends the third copy to the state PDMP.

[c]In 2001, Michigan enacted legislation to convert is PDMP to an electronic monitoring program. Until the new electronic system is implemented, the program will continue to require pharmacies to submit copies of state-issued official prescription forms for schedule II controlled substances.

[d]As of January 1, 2002, New York switched to an electronic monitoring system from a paper-based system using a triplicate form. The new electronic system is supplemented by a state-issued, single-copy prescription form that includes a number of security features to prevent counterfeits.

[e]Beginning in September 1999, Texas permitted pharmacies to submit prescription data electronically rather than submitting paper copies of prescription forms. In March 2002, Texas switched from triplicate to single-copy forms with a number of security features to prevent counterfeits. The requirement to submit prescription forms to the state agency will continue until the electronic system is fully implemented.

[f]The Washington program applies only to licensed practitioners whose prescribing practices require monitoring because of past drug abuse or inappropriate prescribing The drugs the program covers vary, depending on the prescriber, from one controlled substance to all prescriptions.

Source: National Alliance for Model State Drug Laws. Information is current through February 4, 2002.

FACT SHEET ON THE NEED FOR A STATE PRESCRIPTION DRUG MONITORING DATABASE

1. Diversion and abuse of legally manufactured prescription drugs is a pressing national issue. The Office of National Drug Control Policy (ONDCP) cites that in 2002, 6.2 million Americans abused prescription drugs.

2. Prescription drug abuse rank second behind marijuana.

3. Chronic pain is prevalent in 15% to 30% of the population. In the last several years there has been an increasing interest in the provision of better pain therapies.

4. This interest in managing chronic pain has led to the increased prescribing of controlled substances.

5. With the prevalence of chronic pain ranging from 15% to 30% in the United States (25 to 45 million people), the prescription drug abuse or misuse is seen in 18% to 24% (approximately 5 million to 9 million persons).

6. The diversion and abuse of prescription drugs are associated with incalculable costs to society in terms of addiction, overdose, death, and related criminal activities.

7. The DEA has stated that the diversion and abuse of legitimately produced pharmaceuticals constitute a multi-billion dollar illicit market nationwide. OxyContin sells on the street for about $40 per pill.

8. Patients may be receiving Schedule II, III, and IV prescriptions from multiple practitioners who are unaware that others are prescribing for the patient.

9. Drug spending is skyrocketing. Significant amounts of Medicaid funds are spent on drugs that are abused.

10. Significant amounts of state funds are being spent for drug abuse and addiction treatment.

11. The incidence of drug diversion is on the rise. According to the GAO, problems are shifting from states with monitoring programs to neighboring states without a monitoring program.

12. Physicians are becoming more hesitant to prescribe pain medications. Legitimate patients are being under-treated due to the hesitancy.

FACT SHEET ON NASPER

1. When the 109th session began in January 2005, National All Schedules Prescription Electronic Reporting Act (NASPER) was reintroduced in the Senate with eight co-sponsors and in the House with 35 co-sponsors. It unanimously passed the Senate's Health, Education, Labor and Pensions Committee on May 25, 2005, and the House Energy and Commerce Committee on July 20, 2005. The full House of Representatives unanimously passed the bill on July 27, 2005; and the Senate followed with unanimous approval on July 29, 2005.

2. The bill, H.R. 1132 was signed into law on August 11, 2005.

3. H.R. 1132, "the NASPER Act" calls for each state to establish a prescription drug monitoring program.

4. The purpose of the NASPER Act is to combat the abuse and diversion of prescription drugs by establishing a grant program that would support expansion, in number and effectiveness, of State prescription drug monitoring programs. The bill will also facilitate the interoperability of State systems to detect more rapidly drug diversion and abuse that crosses State lines.

5. The NASPER Act does not mandate that states implement a monitoring program. Rather, it gives each state the option to create such a program and the funding to do so.

6. The NASPER Act creates a set of standards for creating prescription-drug monitoring programs that will allow each state to share critical drug information with its neighbors in order to reduce drug abuse and the diversion of prescription drugs across state borders.

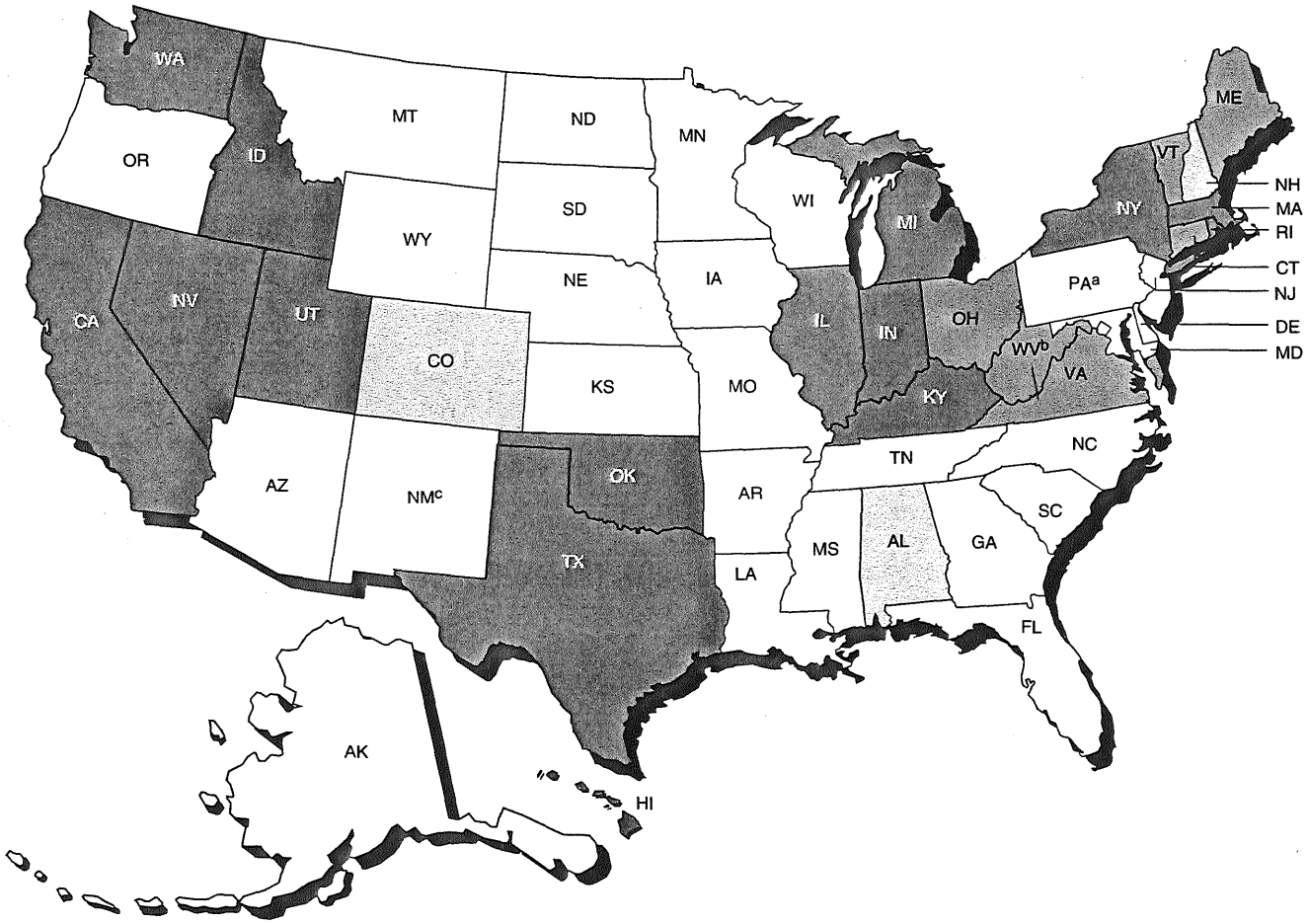
7. The NASPER Act authorizes grants to states from the Department of Health and Human Services ("HHS") to fund programs that create or update electronic monitoring programs for prescription drugs.

8. A state can become eligible for such a grant simply by passing legislation establishing a prescription drug monitoring program consistent with the parameters of the NASPER Act.

9. NASPER authorizes $15 million to be appropriated in Fiscal Year 2006 and 2007. In each Fiscal Year 2008, 2009, and 2010, another $10 million is authorized.

10. The Minnesota program must be in place legislatively before we can apply for federal funding.

Figure 1: Status of Prescription Drug Monitoring Programs, by State, April 2002



States that have prescription drug monitoring programs

States that have recently introduced legislation to establish a program

States that have a task force and are considering legislation to establish a program

States that do not have prescription drug monitoring programs

[a]Pennsylvania does not have a PDMP, but requires pharmacies to submit data to the state attorney general's office.

[b]West Virginia terminated its PDMP in 1998 and has enacted legislation in 2002 to create a new program.

[c]New Mexico terminated its PDMP in 2000.

Source: National Alliance for State Model Drug Laws, 2002, and discussions with officials in New Mexico, Pennsylvania, and West Virginia.

Testimony
SF 2899
Thomas P. Flynn, MD
Medical Oncologist, Minneapolis, MN

- Thank you for the opportunity to present my perspective to the committee
- I have been a practicing oncologist in MN for 25 years, and as such am involved in managing cancer-related pain on a nearly daily basis. I come to you as an individual practitioner, although I expect my views are held by many in my specialty.
- Much work has been done in recent years to educate physicians on the appropriate management of pain in cancer patients on both a national and local level. Such efforts have been stimulated, in part, by studies which have revealed that such pain is often under treated, and under treatment in part can be linked to physician concerns about outside scrutiny of the use of controlled substances.
- This bill has the potential to undo much of that effort.
- I oppose passage of SF 2899 for several reasons, as follows:
- The bill provides for monitoring of prescriptions for these medications on a purely numeric basis, devoid of any clinical information
- The specter of such outside monitoring, without any consideration of the clinical situation, and the potential for reporting of such incomplete data to law enforcement and regulatory agencies will, in my opinion, lead to under prescribing and thus under treatment of pain
- Such under treatment of pain will then lead to more patients coming to ERs and being hospitalized for the control of their pain, increasing the cost of health care.
- Other mechanisms already exist to monitor for inappropriate prescribing and use of medication, such as through the Board of Medical Practice and other licensing and regulatory boards. In these settings all the appropriate clinical information is considered.
- Particularly for cancer patients experiencing pain near the end of life, there is often a need to alter pain treatment regimens frequently, with increasing doses or changes to other narcotics. The monitoring as proposed in this legislation would take into account the number of days supply based on the directions for use. Physicians may then be reluctant to issue new prescriptions when needed before the prior Rx "runs out" leading to inadequate pain control
- The bill provides that an advisory committee, composed largely of individuals with no real expertise in pain management, be charged to provide advice on "standards for clinically

appropriate prescribing and dispensing of controlled substances". There is no way to come up with such standards based on a numeric monitoring system. The variability among patients in doses and schedules needed for the appropriate use of pain medications is enormous. I have had patients who required hundreds of milligrams of morphine every day for months to control their pain, where others may require a tiny fraction of that.

- As a physician practicing in my specialty, I think this bill creates a process which is an unnecessary intrusion into the physician-patient relationship.
- As I have outlined, there is good reason to believe that, while the reporting program may identify a few providers who are prescribing inappropriately or a few patients who are using these medications in inappropriate ways, the harm to patients who suffer from inadequate control of their pain will be too high a price to pay.
- Thank you for your attention.

Senate Counsel, Research, and Fiscal Analysis

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Senate

State of Minnesota

S.F. No. 641 - Mercury Elimination

Author: Senator John Marty

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) KTC

Date: March 22, 2006

S.F. No. 641 requires the removal of dental mercury before cremation and requires dentists to install amalgam separators.

Section 1 (149A.95, subdivision 7) requires dental mercury or amalgam to be removed from a dead body by a licensed mortician or dentist before the body is cremated.

Section 2 (150A.23) requires every dental office in Minnesota to install an amalgam separator that is approved by the Minnesota Dental Association by July 1, 2007. The following offices can apply for an exemption to this requirement:

(1) a site where all the dentists are specialists who do not place or remove amalgam;

(2) a site where the dentists attest on a signed form that they do not place or remove amalgam;

(3) a site scheduled to close after January 1, 2007;

(4) a site owned and operated by a nonprofit organization where dentists provide dental care on a voluntary basis; and

(5) a mobile or portable dental office that can show that it is minimally engaged in amalgam placement or removal or that it is impractical to install a separator.

KC:ph

Senators Marty and Lourey introduced--

S.F. No. 641: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; requiring removal of dental mercury before cremation; requiring dentists to install amalgam separators; amending Minnesota Statutes 2004, section 149A.95, subdivision 7; proposing coding for new law in Minnesota Statutes, chapter 150A.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2004, section 149A.95, subdivision 7, is amended to read:

Subd. 7. [HANDLING OF DEAD HUMAN BODIES.] (a) All crematory employees handling dead human bodies shall use universal precautions and otherwise exercise all reasonable precautions to minimize the risk of transmitting any communicable disease from the body. No dead human body shall be removed from the container in which it is delivered to the crematory without express written authorization of the person with legal right to control the disposition. If, after accepting delivery of a body for cremation, it is discovered that the body contains an implanted mechanical or radioactive device, that device must be removed from the body by a licensed mortician or physician prior to cremation.

(b) If, after accepting delivery of a body for cremation, it is discovered that the body contains dental mercury, the mercury or amalgam must be removed from the body by a licensed mortician or dentist before cremation.

Sec. 2. [150A.23] [AMALGAM SEPARATOR REQUIREMENT AND EXEMPTIONS.]

(a) By July 1, 2007, every dental office located in the state must have installed an amalgam separator approved by the Minnesota Dental Association to capture amalgam waste generated in the dental office.

(b) A dental office listed in this paragraph may apply for an exemption from this section:

(1) a clinical site where all of the dentists are specialists who do not place or remove amalgam. Those specialists are:

(i) orthodontists;

(ii) periodontists;

(iii) endodontists;

(iv) oral and maxillofacial surgeons;

(v) oral and maxillofacial radiologists; and

(vi) oral and maxillofacial pathologists;

(2) a clinical site where the dentist or dentists attest on a signed form that they do not place or remove amalgam;

(3) a site that is scheduled to no longer be used as a dental office after January 1, 2007;

(4) a site owned and operated by a nonprofit organization, where dentists provide dental care on a voluntary basis; and

(5) a mobile or portable dental office that can show it is minimally engaged in amalgam placement or removal or there are reasons why it is not practical for the mobile or portable dental office to install an amalgam separator.

Senator ..... moves to amend S.F. No. 641 as follows:

Delete everything after the enacting clause and insert:

"Section 1. **[115A.933] AMALGAM SEPARATOR REQUIREMENT AND EXEMPTIONS.**

(a) By July 1, 2007, every dental office located in the state must have installed an International Standardization Organization certified amalgam separator to capture at least 99 percent of amalgam waste generated in the dental office.

(b) A dental office listed in this paragraph may apply for an exemption from this section:

(1) a clinical site where all of the dentists are specialists who do not place or remove amalgam. Those specialists are:

(i) orthodontists;

(ii) periodontists;

(iii) endodontists;

(iv) oral and maxillofacial surgeons;

(v) oral and maxillofacial radiologists; and

(vi) oral and maxillofacial pathologists;

(2) a clinical site where the dentist or dentists attest on a signed form that they do not place or remove amalgam;

(3) a site that is scheduled to no longer be used as a dental office after July 1, 2007;

(4) a site owned and operated by a nonprofit organization, where dentists provide dental care on a voluntary basis; and

(5) a mobile or portable dental office that can show it is minimally engaged in amalgam placement or removal or there are reasons why it is not practical for the mobile or portable dental office to install an amalgam separator.

(c) The commissioner of the Pollution Control Agency shall enforce this section pursuant to sections 115.071 and 116.072.

Sec. 2. Minnesota Statutes 2004, section 149A.95, subdivision 7, is amended to read:

Subd. 7. **Handling of dead human bodies.** (a) All crematory employees handling dead human bodies shall use universal precautions and otherwise exercise all reasonable precautions to minimize the risk of transmitting any communicable disease from the body. No dead human body shall be removed from the container in which it is delivered to the crematory without express written authorization of the person with legal right to control the disposition. If, after accepting delivery of a body for cremation, it is discovered that the body contains an implanted mechanical or radioactive device, that device must be removed from the body by a licensed mortician or physician prior to cremation.

(b) Before cremating a body that contains dental amalgam fillings, the person responsible for the cremation shall either:

(1) remove the dental amalgam fillings from the body and properly dispose of them; or

(2) have in place equipment to capture the mercury from emissions before release into the air."

Amend the title accordingly

Mercury-Free Minnesota

Clean Water, Safe Fish, Healthy Kids

2005 Policy Goals

Mercury pollution should be reduced from all sources, including coal-burning power plants and taconite processing, which are the two largest sources of mercury in the state. Minnesota should also continue to be a leader in reducing mercury use in products, by making sure that all vaccines used in the state are mercury-free. Public education efforts by state agencies should be increased, to provide adequate information about the health effects and sources of mercury.

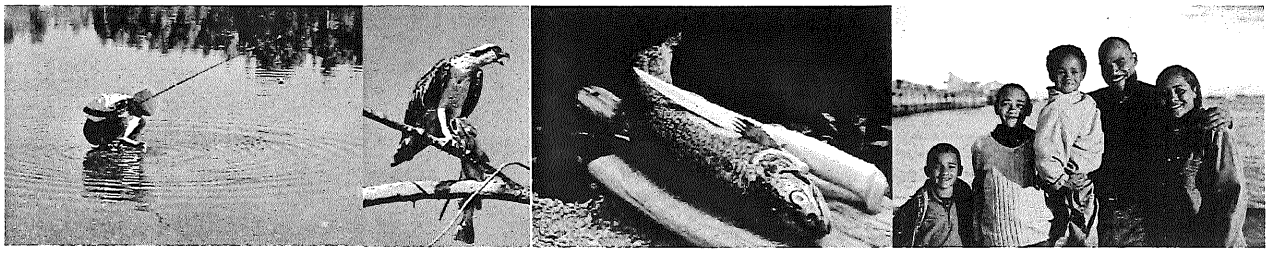
The Problem

Mercury has contaminated Minnesota's waters and fish. Minnesota has issued a statewide advisory limiting the number of walleyes and other game fish that people should eat from our 12,000 lakes.

Mercury is a potent neurotoxin that causes learning and developmental disabilities in children. The EPA reported in January 2004 that *1 in 6 U.S. women* of childbearing age have mercury in their bodies at levels that may adversely affect their unborn child.

The primary sources of mercury in Minnesota are coal-burning power plants and taconite processing. There are many mercury-containing products, including vaccines and dental amalgams, which also pose serious risks.

Since mercury is unquestionably bad for our health and the technology exists to create clean energy and mercury-free products, we should put safety first and choose safer alternatives.



www.MercuryFreeMinnesota.org

Mercury-Free Minnesota is working to achieve the following goals in 2005:

Reduce Emissions from Power Plants

As the single largest source of mercury emissions in Minnesota, coal-burning power plants should be required to do their fair share to reduce mercury emissions. Coal-burning power plants must meet emissions standards currently achieved by the best performing control technologies on the market.

Research & Develop Control Technology for Taconite Industry

Taconite processing releases a large amount of mercury, both from taconite ore and from coal. A research and development program should be established to develop technology to capture mercury emissions from this industry.

Make Vaccines in Minnesota Mercury-Free

All vaccines given in Minnesota shall be mercury-free unless a mercury-free version is not manufactured or not obtainable by best efforts. All persons receiving vaccinations should be informed if their vaccines contain mercury and the hazards posed by mercury, especially the hazards posed to fetuses and children.

Increase Public Education Efforts on Fish Consumption Advice

The Department of Health, Department of Natural Resources, the Pollution Control Agency and the Office of Environmental Assistance should create a plan to ensure that the public is provided adequate notice of and education about the sources and health effects of mercury.

Mercury-Free Minnesota

Clean Water, Safe Fish, Healthy Kids

Mercury-Free Minnesota is made up of more than 30 environmental, conservation, health, and faith groups working with government agencies, legislators, industries, and the public to phase-out harmful mercury emissions in Minnesota, find safer alternatives, and protect human health and the environment.

Go to *www.mercuryfreeminnesota.org* to find out more about us and how you can help to make Minnesota Mercury-Free!

Information on Mercury in Dental Offices & Crematoria

Michael Brakke, Senate Staff

Dental amalgams emit mercury into the environment in two ways:

- without the proper equipment, excess scrap or waste mercury that is not used in the filling process enters the waste stream, and is eventually emitted when burned in treatment plants. In 2000, this accounted for about 3% of the state's total mercury emissions.
- amalgam that has been installed into an individual's mouth is burned if that individual is cremated, whereby it enters the environment. In 2000, this accounted for about 2% of the state's total mercury emissions.

SF 641 would eliminate these two sources of emissions, and would effectively reduce Minnesota's total mercury pollution by approximately 5% per year.[1] At a time of impaired waterways and the Pollution Control Agency's stated goal of 93% reductions in total mercury emissions, eliminating 5% of the problem is a significant step forward.

I. Amalgam waste

Historically, amalgam waste that is generated from the placement and removal of fillings is caught by a chairside trap. This mercury is then discharged to a vacuum filter and eventually a sewer, where it goes to a wastewater treatment plant. The solid amalgam is either spread on land, buried in a landfill, or incinerated. The greatest concern occurs with incineration as the mercury is released from the amalgam (which is environmentally stable when still a solid due to its combination with other ingredients such as zinc, copper, and silver) and is able to pollute the waterways.

This problem is significant enough that the Minnesota Dental Association (MDA), in conjunction with Metropolitan Council Environmental Services (MCES), implemented a voluntary mercury reduction program to address pollution concerns coming from the dental office waste stream. Participants were encouraged to install separators that trap the amalgam through a filter on the oral evacuation system, with the collected amalgam waste then being shipped to a specialized mercury waste facility that recycles the mercury or disposes of it properly. All separators that are approved by the program are required to remove at least 99% of the waste. The approved separators vary widely in cost, from $300 to over $2,000.

The program began two years ago, with the objective of maximum participation by February 2005 in mind. The program has been a success, though the goal of 100% voluntary implementation has not been met. According to the MDA and MCES, of the 1,850 clinics in the state, 75% had already installed, committed themselves to install, or were exempt as of February 2005 (dental offices that do not use amalgam are exempt). This bill would require the installation of certified amalgam separators in dental offices that have yet to comply with the voluntary program, which was supposed to be consummated by February 2005.

II. Crematoria

Cremation can have negative environmental impacts as artificial substances in the body are incinerated. The most significant pollutant to be emitted from crematoria is mercury.

Many more individuals are choosing cremation every year, so the issue of emissions from crematoria is becoming more important. The percentage of the deceased that are cremated varies significantly by state and country. In the United States, approximately 26% of dead bodies were

[1] "Mercury Reduction Progress Report to the Minnesota Legislature" Minnesota Pollution Control Agency, October 2005.

cremated as of 2002. Minnesota is above the national average with about 33% choosing cremation in 2002; this is expected to increase to almost 50% in ten years. Some other countries have even higher cremation rates, especially the United Kingdom (71% and rising) and Japan (98%).

The potentially harmful impacts of cremation result from the burning of substances that are not naturally in the body. According to the Cremation Association of North America (CANE), pacemakers and other battery-powered devices are already removed prior to burning due to the risk of explosion. Also, radioactive implants are usually removed based on their half-life and type. However, any other parts, such as dental amalgams or artificial limbs, are not removed unless requested by the family.

Mercury is a significant, and as of yet unaddressed, cremation-related environmental threat. Crematoria contribute to the problem primarily through the burning of dental amalgams that are 50% elemental mercury.[2]

In Minnesota, 2% of mercury emissions are attributed directly to crematoria. However, even this amount is not insignificant, as relatively small levels of mercury can impair local waterways. For example, only one gram of mercury deposited from the atmosphere into a 20-acre lake each year is generally sufficient to contaminate fish from that lake so that they are no longer safe to eat.[3] In 2000, by comparison, total mercury emissions from Minnesota crematoria were estimated to be about 80 pounds, or 36,287 grams.[4]

Mercury is considered to be the greatest pollution threat from crematoria. However, there are not yet any federal standards on mercury emissions from crematoria in the United States. Under Section 129 of the Clean Air Act the U.S. EPA is required to set standards for a variety of air sources, including crematoria. However, the deadline for these standards has been continually pushed back.

Europe has been more proactive with regard to controlling mercury emissions from crematoria. Early in 2005, Great Britain announced strict regulations to require that all crematoria install mercury filtering equipment by 2012. Currently, 16% of the United Kingdom's mercury pollution is attributable to crematoria, and without controls officials warn that it will become the single largest source of mercury pollution in that country by 2020.[5] Norway and Germany also have some limits on crematoria emissions at either the national or local levels.

With the rate of cremation increasing rapidly in Minnesota and the rest of the United States, controls on mercury pollution from crematoria would be wise policy. SF 641 would require crematoria to address the problem of mercury emissions, through either a removal of the amalgam prior to cremation or installation of acceptable emission controls.

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[2] http://www.cdc.gov/oralhealth/factsheets/amalgam.htm
[3] http://www.newmoa.org/Newmoa/htdocs/prevention/mercury/mercurylake.pdf
[4] "Mercury Reduction Progress Report to the Minnesota Legislature" Minnesota Pollution Control Agency, October 2005.
[5] "Crematoria Warned Over Mercury" BBC January 11, 2005

Minnesota Funeral Directors Association

Oppose Senate File 641

Mercury Filling Legislation

- This legislation would require funeral directors or dentists to remove tooth fillings containing mercury from bodies that are to be cremated. This would mandate the **desecration of human bodies for no scientifically supported reason and place an unnecessary financial burden on grieving families.**

- Research from the federal EPA,-see CANA press release- www.cremationassociation.org/html/pressrelease6.html, the Minnesota Pollution Control Agency, and a comprehensive study of a 40-year-old, high-utilization crematory definitively show that **crematories' emission of mercury into the environment is statistically insignificant.**

- To extract mercury fillings from a dead body, the body would first have to be x-rayed to identify the fillings requiring extraction. No funeral home or crematory has x-ray or imaging capabilities, so the **bodies would need to be transported to and from an imaging facility** at additional cost and time to the family or county.

- Mercury-filling extraction **involves complicated, invasive surgery** that no funeral director is trained to do. The extraction would need to be performed by a person trained in dental surgery, which would **add to the cost and timing of cremations.**

- The embalming process hardens a body's tissue, muscle, and epidermis (skin). **Performing a surgical procedure on an embalmed body would be extremely difficult,** even for a trained surgeon. (An estimated 44% of bodies that are to be cremated are embalmed, which Minnesota law requires under certain conditions.)

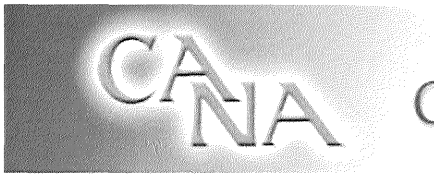
- Mercury-filling extraction would needlessly and substantially disfigure a dead body, which could be traumatic for a grieving family. Cremation is simply another form of disposition and does not imply that the body is any less valued by surviving friends and family.

- Funeral homes and crematories have no provisions for the proper disposal of mercury fillings. Installing **a mercury-waste disposal**

system would be expensive and add to the cost of cremations.

- Minnesota law requires counties to pay for the funeral and disposition services of indigent people. An estimated 27% of such "county burials" involve cremations, and a third of those are embalmed, so **the additional expenses of mercury-filling extraction would add to counties' financial obligations.**

If you have additional questions or are in need of additional information, please contact Paul Cassidy of Leonard, Street and Deinard at 612-720-7261.



Cremation Association of North America

Press Release

Contact: Paul F. Rahill
President
Matthews Cremation Division
407/886-5533

For Immediate Release

EPA Publishes New Mercury Data for Human Crematories and Recommends No Regulations

Press Release

Contact: Paul F. Rahill
President
Matthews Cremation Division
407/886-5533

For Immediate Release

EPA Publishes New Mercury Data for Human Crematories and Recommends No Regulations

The Cremation Association of North America's (CANA) contribution to the development of accurate and reliable environmental data has been acknowledged by the United States Environmental Protection Agency (US EPA). CANA is cited as the reference by the US EPA for human cremation statistics for the United States. Also, the joint test project performed and co-financed by CANA and the US EPA is now the national reference for mercury and other pollutants from human crematories ("EPA National Emissions Inventory"). The following statement was published in the Federal Register volume 69:

"In considering the nature of human crematories since the previous OSWI Federal Register notices were published, EPA has come to the conclusion that the human body should not be labeled or considered "solid waste." Therefore, human crematories are not solid waste combustion units, and are not a subcategory of OSWI for regulation. If EPA or States determine, in the future, that human crematories should be considered for regulation, they would be addressed under other authorities."

The US EPA based their recommendations of no regulations for human and animal crematories on actual data collected for a wide variety of pollutants including mercury. The US EPA determined (based on 1999 CANA cremation rates) that all US crematories, together, would have produced a total of 238 lbs. of mercury emissions in 1999. If we update the mercury emissions levels to include **both** the US and Canada using **2004** cremation rates, the mercury emissions would be approximately 320 lbs. . With 2050 crematories operating in the US and Canada, this would average out to about 0.15 lbs of mercury emissions per crematory per year. If you could capture 100% of the mercury from a crematory processing an average of 400 cremations per year, for one full year, the total mercury captured would be the smaller than a typical household sugar cube.

Mercury enters the cremation cycle, and therefore crematory emissions, is through silver amalgam dental fillings found in some dead human bodies.

Silver amalgam fillings contain mercury alloys that when exposed to the intense heat of the cremation process results in the volatilization of mercury and its emissions into the atmosphere.

How ever the use of Silver amalgam tooth fillings containing mercury is in significant decline. It is estimated that at one time silver amalgam represented almost 90%. Within the last 10 years, this has declined by 38% (United States Center for Disease Control), a significant decrease.

The recommendation by the US EPA has been open for comments for a period that ended February 7, 2005. Comments received will be considered and a final determination will be made in November 2005. Overall, CANA's visibility and credibility as the industry experts continues to grow with these types of outcomes and dividends for the cremation industry.

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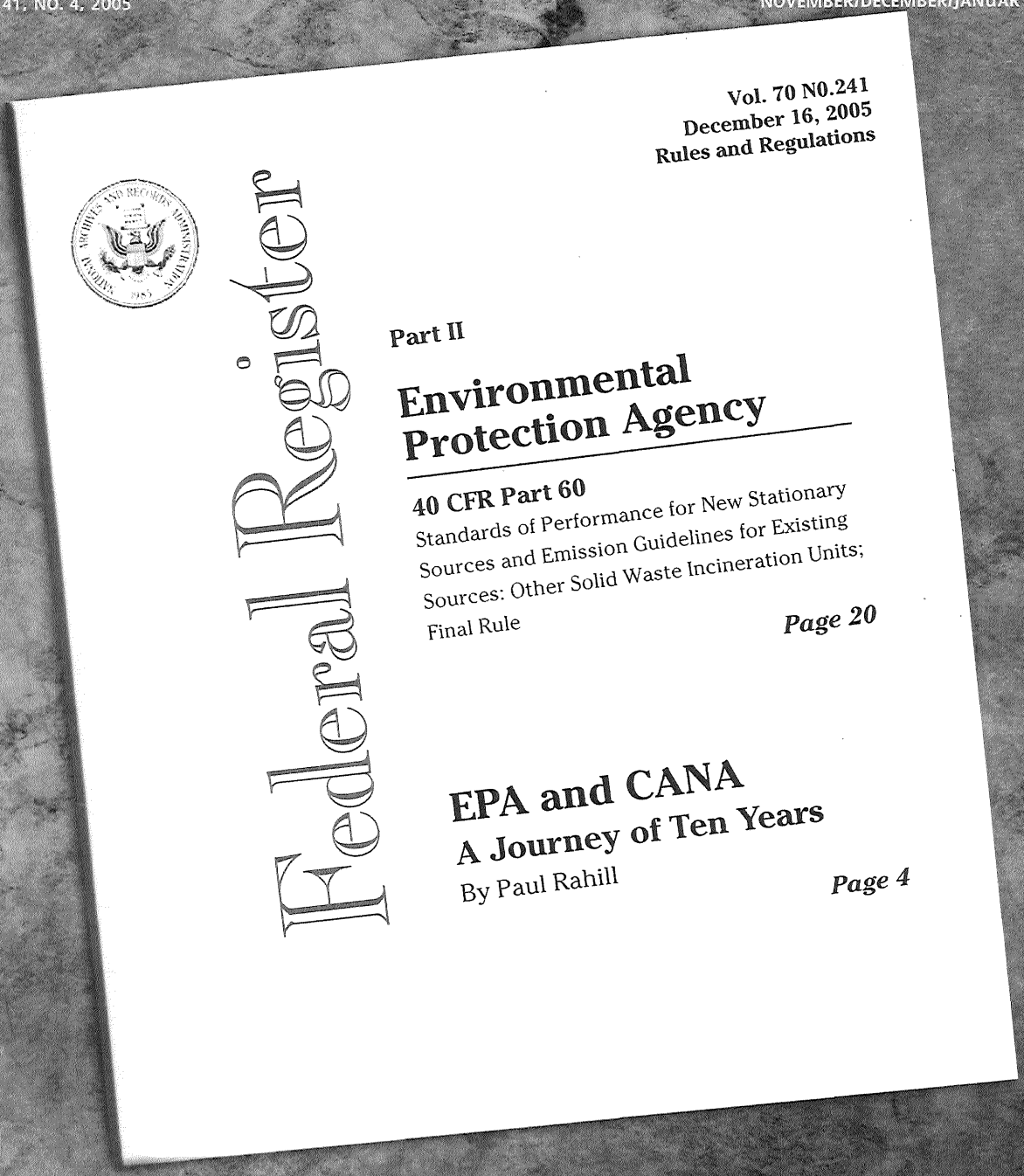
THE CREMATIONIST OF NORTH AMERICA

VOL. 41, NO. 4, 2005 NOVEMBER/DECEMBER/JANUARY



EPA and CANA
A Journey of Ten Years
By Paul Rahill *Page 4*

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Environmental Journey

By Paul Rahill,
Matthews Cremation Division

A Journey of Ten Years . . .

The regulation development process for human and animal crematories that began in 1996 was originally estimated to take four years to complete. At the start of this journey, the US EPA did not have any regulations covering the design, installation and operation of human or animal crematories, leaving this process to the individual states and provinces to deal with as they may. The EPA regulation development plan was originally designed to include varied public and private groups, giving them the opportunity to express their concerns, provide their input and make recommendations that would shape the outcome of the future regulations.

This process, worked by consensus amongst teams, proved to be very slow in producing tangible results. Adding frustration to the process was the surprising lack of credible data on crematory emissions available through the US EPA and its sources. Two years after the teams began to meet, EPA felt it best to reorganize and called upon only those participants it felt could move the process along in a positive and productive manner.

This void of crematory emissions data concerned the members of the newly reorganized "Subteam 1," which included representatives from CANA's environmental team. This Subteam was tasked with making recommendations to the EPA's Work Group leaders on how to proceed with developing regulations, but without accurate emissions data this proved to be a challenge. The options available to the team were not great. The team could propose moving forward with developing regulations based on best estimates of crematory emissions or recommend crematory specific testing be performed before any regulations were considered.

The risk of basing long term regulations for crematories on inadequate and inaccurate data was too great for the death care industry and the Subteam to consider. Whether based on best guess or facts, regulatory change for crematories would certainly result in significant cost increases to the industry and the public, not to mention the inconvenience that would be caused by the inevitable closing and consolidating of crematories that could not economically meet new regulations.

With the overshadowing negative attitudes by the public towards the general funeral service industry and the belief that both costs and inconvenience would increase, the mandate for CANA's representatives on Subteam 1 was clear; it must take a proactive role on behalf of its members and the public they serve. This mandate was not only to insure that cremations be readily available at reasonable costs but also that the commitment to clean air for the living not be compromised through unnecessarily weak or

over-ambitious regulations. With this mandate, the EPA Subteam headed by Paul Rahill and Dale Walter (IEE-Industrial Equipment & Engineering, ALL Crematory, Matthews) proposed to e US EPA that extensive environmental esting be performed prior to developing any Federal environmental regulations for crematories.

Environmental Testing like that propose d by the Subteam is very expensive under any circumstances, but when the testing will be used to guide US EPA regulations, only environmental testing contractors approved by US EPA can be used, increasing costs dramatically. The direct costs to perform the testing required for this critical evaluation would be approximately $300,000. In addition to this was the significant pre-test engineering and technical preparation services, most of which was donated Matthews Cremation.

During this regulatory development process, crematories were only one of many "industries" being reviewed by the US EPA. Quite honestly, crematories were a low priority and the likelihood of obtaining precious test funding from EPA was slim at best. The Subteam then proposed a very unique matching funds idea: EPA would pay half the cost of testing, evaluation and reporting and the balance would be raised by CANA, its members and affiliated death care groups with an interest in the outcome. This proposal intrigued EPA and they soon agreed to this idea. Under the proactive adership of then CANA President John le of Pinecrest Cemetery Company Ottawa, Canada, the task of raising the capital needed for testing began.

CANA was established in 1913 for the purpose of promoting professional standards related to cremation practices throughout North America. There are approximately 1200 members who are engaged in serving the cremation families through Funeral Homes, Cemeteries, Societies, as well as associated service providers. In addition, there are many vendor members to the industry who are also dedicated to indirectly serving families through their clients. This venture with EPA would require a coordinated effort of all parties to successfully meet the challenges ahead.

As with previous testing performed by the members of the Subteam it was determined that it would be advantageous to test different casket and container types at different temperatures to see what effect these variables had on the tested emissions under a very strict test setting. The types of containers were basic (minimum) cardboard cremation containers, cloth covered caskets and particle board/wood caskets. The three temperature ranges selected were the three most common found in North America, 1400°F, 1600°F and 1800°F. The location selected by the US EPA was a CANA member, The Woodlawn Cemetery located in the Bronx, New York. One of the reasons Woodlawn was selected was because their cremation equipment was typical to what could be routinely found operating throughout North America.

US EPA originally decided on 12 tests with the assorted containers and caskets at two temperature levels. CANA however requested a total of 18 tests be performed at three different temperature levels and agreed to pay for the additional testing above the cost sharing arrangement in order to obtain the most detailed and accurate data for the industry. EPA hired the two independent testing contractors whom they knew well and had utilized in other testing projects. After considerable pre-test preparations, testing began on June 11, 1999 and concluded on June 17, 1999.

The cremations were performed at each of the three levels of temperature with data collected and samples taken by the assembled group of technicians and scientists. Pollutants tested for included visible emissions (smoke), particulate matter, carbon monoxide, nitrogen oxides, sulfur dioxide, hydrogen chloride, metals, dioxins and furans. This data collected was unprecedented and would later be utilized to establish baselines by which crematory emissions impact would be evaluated. The conclusion of the test company was clear.

"In general, no correlation was observed between either body characteristics or container type and emissions. Overall emissions tended to increase with increasing temperature."

By October 1999 with the testing complete, data verified, analyzed and documented with the reports written by the test companies and submitted to US EPA, crematories had slipped from a low priority to a very low priority. It was no coincidence; the encouraging test results had contributed to a lower sense of urgency. Crematories, both human and animal would be placed on a back burner at EPA, but not to be forgotten.

Final Regulations were eventually proposed in November of 2004. This was followed by a nationwide public comment period of almost one year allowing anyone; public, industry or agency to submit objections to US EPA for consideration where their basis would be considered before the final regulations would be adopted. Only two comments were received during the one year period and EPA's position remained unchanged.

EPA stated, "Final regulations for other solid waste incineration (OSWI) units were signed by the EPA's Administrator on November 30, 2005, and can be found at http://www.epa.gov/ttn/oarpg/new-.html or see an excerpt on page 20 of this

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ENVIRONMENTAL

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magazine. Regarding the status of human and animal crematories, EPA did not change its position with respect to these sources between proposal and promulgation and they are not regulated as part of the final OSWI regulations or any other existing Clean Air Act Section 129 incineration regulation."

Human Crematories: "We noted in the preamble to the proposed rules that in considering the nature of human crematories . . ., EPA has come to the conclusion that the human body should not be labeled or considered solid waste. Therefore, human crematories are not solid waste combustion units, and are not a subcategory of OSWI for regulation. Moreover, we state in the preamble to the final rules that as stated in the preamble to the proposed OSWI rules, if EPA or States determine in the future that human crematories should be considered for regulation they would be addressed under other authorities."

Animal Crematories: "In the preamble to the proposed rules, we noted that (1) emissions from these units are very low when compared to other solid waste combustion units. The emissions levels from uncontrolled animal crematory units are, in fact, less than emissions after controls from other types of incinerators that are regulated . . .; (2) EPA is concerned about biosecurity within the agricultural sector; (3) In many areas there is also a lack of reasonable and economic alternatives (e.g., rendering, composting, burial) to incineration.; and (4) EPA has determined that the adverse impacts associated with regulation of animal crematories outweigh the benefits of regulation and these units are not included as a subcategory of OSWI for regulation at this time. We state in the preamble to the final rules that EPA has not changed our decision to exclude animal crematories and pathological waste incineration units, based on our analysis of their emissions and the adverse impacts that would occur if these units were regulated under the final OSWI rules, . . . At this time, EPA has no plans underway to regulate human or animal crematories."

15 years after the 1990 Clean Air Act and 10 years after the regulation development process began in earnest, crematories have been tested, reviewed and evaluated with a final determination of no federal regulations planned and none recommended to the States.

Next Steps must be considered though, as problems still exist for current and future crematory operations. In anticipation of US EPA developing federal regula-

CONTINUED ON PAGE 20

tions, many States moved forward on their own and developed regulations without the benefit of the comprehensive test data that was later available from the EPA testing. As a result, several states and provinces have regulations that actually appear to increase the pollutant emissions from crematories as well as increase the fuel consumption of crematories and the production of greenhouse gases.

CANA must now adopt a new mandate which will be a "win-win" for all parties involved. This will require industry leaders to meet with environmental authorities from the States and Provinces to review US EPA's data. This will create goodwill and provide a greater understanding on how crematories actually function. At the same time, CANA's leaders must discuss how state and provincial regulations might be updated to reduce emissions by lowering operating temperatures to those levels that achieved the best results during the tests.

This change, which is supported by US EPA's own published test data, is good for the environment, which is good for us all. Reducing operating temperatures will also increase safety for those who operate cremation equipment and safety must always be a top concern for all crematory operations. Reducing temperatures also reduces fuel consumption and equipment maintenance costs which benefits the consumer by controlling the escalation of operating costs for crematories.

The journey has been long, expensive and frustrating at times, but much has been learned and gained along the way. Finding and maintaining the delicate balance between the environment and the consumer will always be a challenge but may not be as difficult as once thought. Many interests are common, yet this journey is far from over.

MERCURY UPDATE

Crematories represent *0%* of the total inventory for national mercury emissions rates according to US EPA and their Best Point Estimates.

Most recently, US EPA updated their National Emissions Inventory and, based on actual data from testing they participated in, all US crematories combined in 1999 produced a total of 238 pounds of mercury.

The most notable way that mercury enters the cremation cycle, and therefore crematory emissions, is through silver amalgam dental fillings found in many dead human bodies.

Silver amalgam tooth fillings containing mercury have been common for many years, but their use appears to be in significant decline. Within the last 10 years, the percentage of fillings containing mercury has already declined by 30%, a significant decrease.

Although concern for the environment has always been a priority for the dental industry, the primary driver of this trend is actually found in the mirror, appearance. Composite resins blend better with the color and appearance of natural teeth. All these changes in dental practices and consumer preferences have resulted in significantly less mercury entering the cremation stream and thereby reducing mercury emissions by reducing mercury input.

Environmental Protection Agency

40 CFR Part 60/Vol 70 No 241
December 16, 2005
Rules and Regulations
Page 74881

9. Various Other Applicability Issues
Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Other Solid Waste Incineration Units; Final Rule

excerpt . . .

Human Crematories. Two commenters objected to the exemption of human crematories from the proposed rules. Both commenters argued that the incineration of human bodies emits significant quantities of mercury and other hazardous air pollutants. One commenter objected to EPA's conclusion that human bodies are not solid waste and noted that EPA defines solid waste under the SWDA as any "discarded material." The definition also clarifies that a material is "`discarded" if it is `burned or incinerated."

Clean Air Act section 129 regulations deal solely with solid waste combustion units. As noted in the preamble to the proposed rules, in considering the nature of human crematories, EPA has determined that the human body should not be labeled or considered "solid waste." Therefore, human crematories are not solid waste combustion units, and are not a subcategory of OSWI for regulation.

We disagree with the commenter's assertions that human bodies are discarded and that CAA section 129 rules must consider a material to be "discarded" if it is "burned or incinerated." The definition of "discarded" referred to by the commenter is found in 40 CFR part 261, which defines "hazardous waste" for the purpose of implementing the hazardous waste program authorized by the SWDA. In defining "hazardous waste," 40 CFR part 261 also defines "solid waste" and elaborates on the meaning of "discarded," which is a term used in the definition of solid waste. However, in doing so, 40 CFR part 261 states explicitly in 40 CFR 261.1(b)(1) that this definition of solid waste is only for the purpose of materials that are hazardous wastes. Much of the complexity and specificity of the 40 CFR part 261 definitions is needed to assure that hazardous waste is properly identified, tracked, transported, and disposed of, and is not inappropriately discarded

or abandoned. The 40 CFR part 261 details on the meaning of solid waste and discarded are not found in solid waste definitions within the Resource Conservation and Recovery Act (RCRA) rules pertaining to nonhazardous wastes (e.g., 40 CFR part 240 through 40 CFR 259). The regulatory definitions of "solid waste" and "discarded" found in 40 CFR part 261, therefore, do not apply to nonhazardous solid wastes. Section 129 of the CAA regulates only nonhazardous solid wastes. As described in previous **Federal Register** notices pertaining to the proposed and final CISWI rules (64 FR 67104, November 30, 1999 and 65 FR 75342, December 1, 2000) EPA has adopted, under the joint authority of the CAA and RCRA, a definition of solid waste that is used solely to identify nonhazardous solid waste for the regulatory programs authorized by CAA section 129, such as the final CISWI and OSWI rules. The definition of discarded cited by the commenter is not applicable to CAA section 129 rules. However, as stated in the preamble to the proposed OSWI rules, if EPA or States determine in the future that human crematories should be considered for regulation, they would be addressed under other authorities.

Animal Crematories. One commenter expressed support for the proposed decision to exclude animal crematories as a regulated subcategory of the proposed OSWI rules and supports the proposed exclusion of pathological waste incineration units. The commenter pointed out that the other alternatives to incineration, such as rendering, burial, composting or feeding of the carcass to exotic animals does not address the need for disposal of animal carcasses with an infectious disease. Another commenter contended that animal crematories are solid waste incineration units that must be regulated under CAA section 129.

EPA has not changed our decision to exclude animal crematories and pathological waste incineration units, based on our analysis of their emissions and the adverse impacts that would occur if these units were regulated under the final OSWI rules, as fully described in the preamble to the proposed rules and in the response to comments document.

CLEAN WATER ACTION ALLIANCE

March 27, 2006

Sen. Becky Lourey
Minnesota State Senate
75 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

Dear Sen. Lourey and Members of the Senate Health and Family Security Committee:

On behalf of the more than 60,000 members of Clean Water Action Alliance of Minnesota, I appreciate the opportunity to comment on Sen. Marty's legislation to reduce mercury pollution from dental uses (SF 641). Because this toxin is a major public health issue and water pollutant, one of Clean Water Action Alliance's highest priorities is to reduce mercury pollution from all sources. Therefore, we support Sen. Marty's legislation to reduce mercury pollution from dental uses and hope that the bill is passed out of the Senate Health and Family Security Committee.

Mercury, a potent neurotoxin that causes learning and developmental disabilities in children, is contaminating Minnesota's waters and fish. Accumulation of mercury in the body is especially harmful to women and children. A mother can pass this contaminant on to her baby during pregnancy and later during breastfeeding. A woman's exposure to mercury *before* pregnancy is important, too, so women who may become pregnant should follow the same precautions as pregnant or nursing women.

The EPA reported that *1 in 10* U.S. women of childbearing age have mercury in their bodies at levels that may adversely affect their unborn child. The Minnesota Department of Health advises children and women who may become pregnant to limit the fish they eat from *any* Minnesota lake.

Although most of the focus regarding mercury pollution reductions has been on the largest source, coal-burning power plants, dental use is still an important source that needs to be addressed. According to the Minnesota Pollution Control Agency's (MPCA) 2005 Mercury Reduction Progress Report, dental preparations and crematories emitted 163.2 pounds of mercury in 2000 and are projected to have emitted 164 pounds of mercury in 2005. This is greater than the 2003 mercury emissions of Xcel Energy's Allen S. King coal-burning power plant (72.60 pounds).

It is Clean Water Action Alliance's hope that the Senate Health Committee members vote to protect the health of our kids today, by passing Sen. Marty's legislation out of committee. Thank you for your time.

Sincerely,

Marie E. Zellar
Executive Director, Clean Water Action Alliance

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