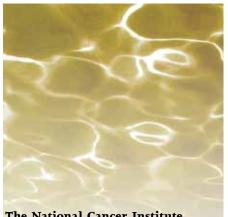
# The Faring of FORMALD LANGE Carol Lynn Green

## A year of key developments and the wait for the National Academy of Sciences' peer review of EPA research.

In the past 12 months, formaldehyde – and the health risks associated with long-term exposure to it – has been considered by prominent domestic and international science research agencies. Scientific reports have been issued and regulatory classification decisions made. Yet, at this moment, the science surrounding formaldehyde exposure and the likelihood that formaldehyde causes leukemia and other cancers – and if so, how – remains somewhat unsettled. This may not be the case for long, however, as the National Academy of Sciences (NAS) begins its formaldehyde evaluation. Following is a synopsis of the year's key formaldehyde developments impacting

funeral service.



The National Cancer Institute (NCI) issued the embalmers study in November 2009, following its May '09 release of its formaldehyde plant workers study.

NCI calls itself "the world's pre-eminent cancer research organization." Created by the United States Congress in 1937, it is authorized to conduct, foster, fund and disseminate the results of cancer research conducted worldwide and provide training in cancer diagnosis and treatment.

In November 2009, following a 20year hiatus, NCI researchers issued a report that examined embalmers and the link between formaldehyde exposure and leukemia, brain cancer and other types of cancer to which embalmers may be exposed because of the use of formaldehyde-based embalming products. This study was the first to relate cancer risk to length of employment, work practices and estimated formaldehyde exposure levels in funeral service. NCI observed an association between embalming and death from myeloid leukemia, with the greatest risk among those who had practiced embalming for more than 20 years. Deaths from myeloid leukemia were also related to greater estimated formaldehyde exposure. According to NCI's definition, leukemia is a cancer that starts in bloodforming tissue such as bone marrow and causes large numbers of blood cells to be produced and enter the bloodstream.1 In the United States in 2009, there were 44.790 new leukemia cases and 21.870 leukemia deaths.

The 2009 report follows NCI's last study of funeral directors and embalmers, reported in 1990. Both reports examine the same group of funeral service professionals, who died between 1960 and 1986. Funeral directors who died from brain tumors, nasopharyngeal cancer and leukemia (case subjects) were compared to a

group of randomly selected funeral directors from the same data (control group) but who died from other causes.

For the current study, NCI conducted interviews of next of kin and co-workers of both case subjects and the control group to estimate a number of measures of formaldehyde exposure. NCI also conducted studies in preparation rooms at Cincinnati College of Mortuary Science to investigate the amount of formaldehyde generated by different procedures of the embalming process.

Although the current NCI embalmers study sheds some light on the risk to embalmers of long-term formaldehyde exposure, it does not explain how formaldehyde causes cancer. It is not surprising, therefore, that NCI concluded that further research of leukemia risk in relation to specific embalming practices and exposures was needed to help explain cancer risks related to formaldehyde.

In May 2009, NCI issued its third reported study of formaldehyde plant workers, finding that formaldehyde plant workers exposed to short-term concentrations of formaldehyde concentrations that were greater than 2 parts per million (the Occupational Safety and Health Administration's short-term exposure limit for a 15-minute period) were more likely to die from cancers of the blood and lymph system than similar plant workers exposed to lower concentrations of formaldehyde. The study followed plant workers employed before January 1, 1966, at 10 formaldehyde-using and -producing plants.

Like the embalmers study, the results were inconclusive; the study did not find a connection between formaldehyde exposure and leukemia. In fact, the overall risk of myeloid leukemia for plant workers had declined from NCI's previous report. In the report conclusion, NCI ac-





knowledged that "[f]urther studies are needed to evaluate the risks of leukemia and lymphatic tumors in other formaldehyde-exposed populations and to assess the biological plausibility of a causal association." In other words, like the later embalmers study, NCI called for more research.

#### The International Agency for Research on Cancer (IARC) concludes that formaldehyde causes leukemia (November 2009).

IARC describes its mission as promoting international collaboration in cancer research, with an emphasis on "elucidating the role of environmental and lifestyle risk factors" in the causes and prevention of cancer. It was established in 1965 by a resolution of the World Health Assembly as an extension of the World Health Organization. Today, there are 21 IARC-member countries; the United States is a founding member.

In November 2009, with both NCI studies and other recent research papers in hand. IARC concluded that there was sufficient evidence to establish an association between formaldehyde and leukemia in humans. Not surprisingly, IARC's determination was met by widely differing responses from organizations with differing missions. Following the IARC pronouncement, Jennifer Sass, a senior scientist with the National Resources Defense Council (NRDC), said: "The link with leukemia means that the overall impact of formaldehyde on human cancers is much greater than previously thought... From here on out, formaldehyde's link to leukemia simply must be considered by environmental and public health agencies, and it increases the imperative that strong protections for the public be adopted quickly."3 NRDC calls itself "the nation's most effective environmental action group, combining the

grass-roots power of 1.3 million members and online activists with the courtroom clout and expertise of more than 350 lawyers, scientists and other professionals."

In sharp contrast, the Formaldehyde Council Inc. (FCI), of which NFDA is a member, considered the IARC review too limited in time and scope to adequately address the new science issues involved. FCI pointed out that the IARC formaldehyde working group participants were almost evenly split and that the formaldehyde decision was not unanimous.4

FCI's review of the available formaldehyde documentation revealed that the results of an unpublished study on a small number of Chinese industrial workers influenced IARC deliberations. Some members of the IARC working group urged that the results of the Chinese study be replicated before determining that there was an association between formaldehyde and leukemia. FCI represents the leading producers and users of formaldehyde in the United States. Formed in 2004, FCI's mission is to encourage accurate scientific evaluation of formaldehyde and formaldehyde-based materials and communicate sound scientific information relating to the uses, benefits and sustainability of formaldehyde products.

#### The National Academy of Sciences begins to review formaldehyde (December 2009).

NAS is a society of "distinguished scholars engaged in scientific and engineering research" to further science and technology and their use for the general welfare. Created by President Abraham Lincoln in 1863, NAS is charged with investigating, examining, experimenting and reporting on any scientific subject whenever any government department calls on it.

On Christmas Eve 2009, the U.S. Environmental Protection Agency (EPA) formally asked NAS to serve as the peer reviewer of the EPA's draft risk assessment of formaldehyde. Since 1997, the EPA has been engaged in reviewing formaldehyde in order to keep its IRIS (Integrated Risk Information System) database current. Sen. David Vitter (R-LA), who put a hold on the nomination of Paul Anastas to head the EPA's Office of Research and Development, had encouraged the EPA to get NAS involved in the IRIS process. Once the EPA agreed to NAS involvement, Vitter lifted his

hold and Anastas was confirmed by unanimous consent in the Senate. The EPA's IRIS database is a human health assessment program that evaluates human health effects that may result from exposure to chemicals. IRIS provides the health-related science that supports the EPA's regulatory activities, so it is an important component of EPA decision-making.

#### When will formaldehyde's fate be determined, and what should funeral directors do in the meantime?

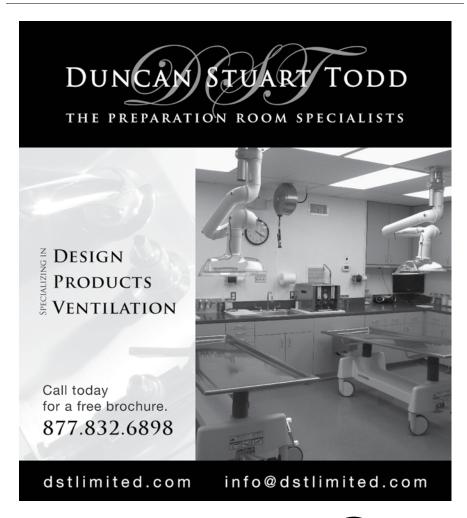
The EPA has stated that formaldehyde assessment and possible regulation is a priority for the agency. Under IRIS procedures, revised in 2009, the EPA ordinarily gives peer reviewers nine months for review, and it has expressed confidence that NAS can complete its work on that schedule. Once NAS receives the EPA's draft IRIS profile, expected by the end of May, NAS' formal nine-month peer review period begins. NAS has scheduled a two-day meeting in June to hear from the EPA and the public about the draft profile and to make final selections for its academic peer review committee.5 In the meantime, regulatory decisions by the EPA and OSHA are on hold, pending the NAS determination.

Keep in mind that current debate over the long-term health effects associated with formaldehyde does not mean that formaldehyde is safe or not. It does mean that the science surrounding the longterm exposure to formaldehyde is complex and evolving.

Under these circumstances, NFDA advocates that funeral directors take precautions whenever they use formaldehyde in the preparation room. As in the past, NFDA urges each funeral director to become familiar with the Formaldehyde Best Management Practices (BMPs) approved by the NFDA Executive Board in 2009 and to implement the BMPs in all preparation rooms.

The first formaldehyde best practice is to "ensure adequate and effective ventilation in the preparation room." The key to effective formaldehyde control in the preparation room is good ventilation, and good ventilation is the cornerstone of the formaldehyde BMPs. NFDA's ventilation consultant has completed his preparation room ventilation study, and his report will be available soon. The consultant has recommended five key ventilation criteria for an effective preparation room ventilation system. NFDA is sure that the study will be an im-

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portant resource for funeral directors, as one of its key objectives is to make the recommendations easy to implement and cost effective for both existing and new funeral homes.

The second formaldehyde BMP is to "select and use the proper embalming product," including formaldehyde-free products. Recently, NFDA's Executive Board approved a broadbased and long-term embalming project to test any formaldehyde-free embalming product on the market. The testing will be conducted by licensed embalmers at several of the leading mortuary schools in the United States, including Cincinnati School of Mortuary Science and Pittsburgh Institute of Mortuary Science. Any manufacturer with a product that contains no formaldehyde will be eligible to participate.

NFDA is closely following these formaldehyde developments and is poised to provide information and guidance, and take action on behalf of funeral directors should advocacy be required. NFDA will actively engage with the EPA and OSHA should they propose more restrictive regulations on the use of formaldehyde.

NFDA remains committed to the edu-

cation of funeral directors about formaldehyde and cancer. Most significantly, as reflected in the formaldehyde BMPs, the ventilation study and the embalming project, NFDA is committed to ensuring that funeral directors have the best and most effective tools available to control and reduce formaldehyde exposure. The issues relating to formaldehyde's safe use and its regulation go to the core of funeral service and how the profession is practiced. It is important that you are informed and take the steps needed to reduce formaldehyde exposure in the preparation room. NFDA stands ready to help. Be sure to visit NFDA's formaldehyde Web page (www.nfda.org/funeral-profession/newsevts/ 1902.html?task=view) for resources and the latest formaldehyde developments. \*

<sup>1</sup> NCI Leukemia Home Page (www.cancer. gov/cancertopics/types/leukemia).

<sup>2</sup> Funeral service professionals were selected from NFDA registries (6,651) and from licensing boards and state funeral directors associations, New York State Funeral Director Association registries (1,678) and California State Department of Health. Division of Funeral Directors

and Embalmers (5,665), for a total of 13,994 individuals. The subjects' vital statistics and, if deceased, cause of death were identified by searching state vital statistics offices. Death certificates were obtained for 6.808 individuals.

<sup>3</sup> "IARC confirms link between formaldehyde and leukemia" (www. huffingtonpost.com/jennifer-sass/iarc-confirmslink-betwee\_b\_347069.html; posted 11/5/09).

4 www.formaldehyde.org/\_base/pdf/newsroom/ IARC-NTP-Statement-FINAL.doc. On April 22, 2010, the National Toxicology Program (NTP) issued its draft profile of formaldehyde. This begins a period of public review of the profile, followed by a decision by the HHS secretary as to whether formaldehyde is a carcinogen and will, for the first time, be listed on the agency's 12th Report on Carcinogens. The secretary's decision is expected by the end of 2010.

<sup>5</sup> www8.nationalacademies.org/cp/ CommitteeView.aspx?key=DELS-BEST-09-07.

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