

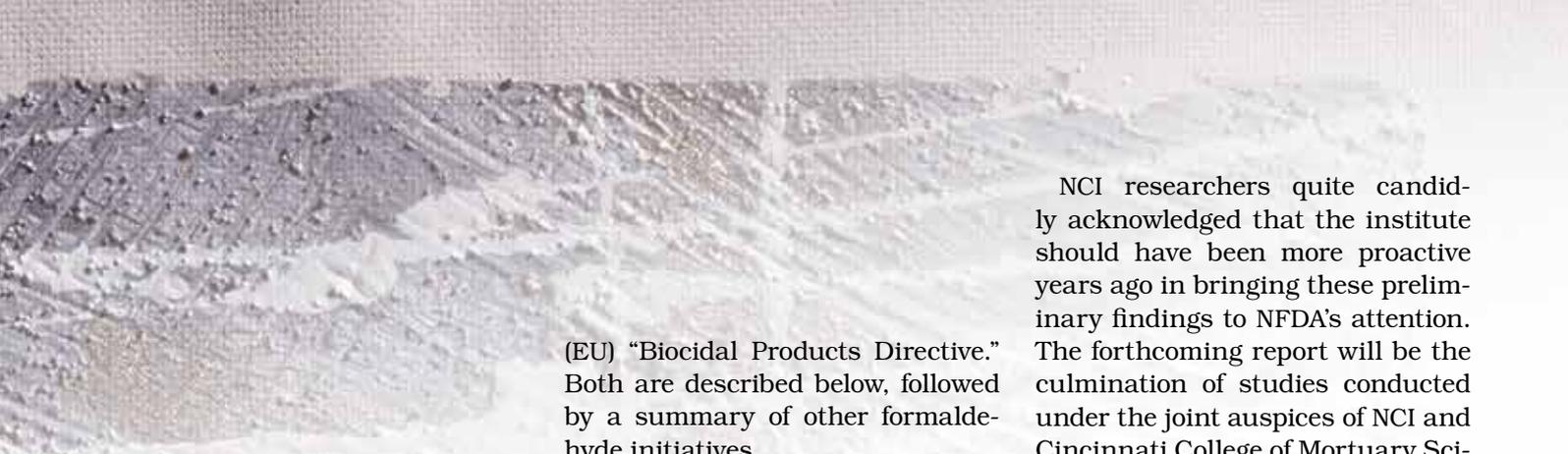
# DEATH KNELL FOR FORMALDEHYDE

Carol Lynn Green and John H. Fitch Jr.

**An update on key domestic and international studies and regulatory activities that might affect the fate of formaldehyde and its use in embalming**

**T**he worldwide review of formaldehyde and the risks it poses is continuing. While the short-term health effects of exposure to formaldehyde are generally well known, there has been less certainty about the potential long-term effects of formaldehyde exposure, particularly the risk of nasopharyngeal cancer, a rare cancer found in the upper part of the throat behind the nose; brain cancer; and leukemia. Epidemiological studies from the 1990s and before found a heightened risk of death from these cancers in funeral directors. However, to date, scientists have been unable to explain the link between formaldehyde exposure and cancer.

Scientists in the United States and abroad are renewing their studies of the long-term health impact of formaldehyde use and exposure, trying to determine whether formaldehyde causes cancer and, if so, the mechanics of that phenomenon in the human body. The results of these studies will be extraordinarily important for funeral service, as the conclusions could result in far more restrictive (or at least different) standards for the continued use of formaldehyde in embalming, lead to substantive changes in funeral service as we know it or even sound formaldehyde's death knell.



What are the consequences for funeral directors should scientists determine that formaldehyde causes cancer? Will formaldehyde become unacceptable in embalming? Will green burial or cremation without embalming become the predominant focus of funeral service? Will formaldehyde-free products, such as AARDBalm or Champion's Enigma line of embalming products, gain greater acceptance? Will work practices in the preparation room need to change to provide greater protection to funeral directors and their employees?

These and other important questions of impact to the future of funeral service must be answered. And although answers are not yet available, know that NFDA is closely following these important matters and is poised to provide information to you and take action on your behalf should advocacy be required. We will keep you informed as these developments take shape. Let us know if you have questions or comments, and stay tuned!

### **Formaldehyde Under Review**

Described in this article are the key domestic and international studies and regulatory activities that might affect the fate of formaldehyde. We want you to be familiar with these developments because of their significance for your health, your employees' health and your business. From the perspective of funeral service, the two most important formaldehyde-related developments are the U.S. National Cancer Institute's (NCI) "Funeral Director Study" and the European Union's

(EU) "Biocidal Products Directive." Both are described below, followed by a summary of other formaldehyde initiatives.

### **NCI Funeral Director Study**

NFDA has learned that later this year, NCI expects to publish a decades-long research study evaluating whether formaldehyde used in the preparation room causes cancer. The timing of the study's release is now a year overdue. However, when issued, NCI's "Funeral Director Study" will be especially significant for NFDA and its members, as it is expected to reflect important new findings about the consequences of formaldehyde use in embalming.

NCI is also finishing two other studies of the impacts of formaldehyde exposure on formaldehyde plant workers. It is expected that together, these formaldehyde studies, involving both professionals and industrial workers, should enable NCI to compare and contrast different kinds of formaldehyde exposure experienced by workers in different fields. As the leading government cancer research agency in the United States since its establishment in 1971, NCI and its studies carry much weight.

NFDA initially met with NCI scientists Richard Hayes and Robert Hoover in January 2008. We learned then of NCI's plans to issue an updated funeral directors report<sup>1</sup> based on NCI research of work practices in funeral homes and the extent to which use of various products containing formaldehyde, such as cavity and arterial fluids, osmotic gels, hardening compounds and drying powders, causes exposure to high levels of formaldehyde.

NCI researchers quite candidly acknowledged that the institute should have been more proactive years ago in bringing these preliminary findings to NFDA's attention. The forthcoming report will be the culmination of studies conducted under the joint auspices of NCI and Cincinnati College of Mortuary Science, which had led NCI to suspect, as long ago as the 1990s, that there was a causal connection between formaldehyde use in the preparation room and some forms of cancer. We continue to be in communication with NCI about its study.

To update its 1990 report,<sup>2</sup> NCI studied 24 embalmings conducted at Cincinnati College of Mortuary Science under controlled conditions – in each instance varying ventilation, solution strength and type of case (intact or autopsied). The embalmings were segmented into work practices, and formaldehyde air emissions from each of the various work practices were tested. Nearly 1,300 interviews were conducted with next of kin and co-workers to elicit information as to work history, number of embalmings (autopsied/intact body) and ventilation in order to determine cumulative formaldehyde exposure, average formaldehyde concentration, eight-hour time-weighted average and highest-peak formaldehyde exposure.

NCI's preliminary studies support the conclusion that preparation room work practices and product substitution can result in significant reduction in formaldehyde exposure. Interestingly, NCI determined that the application of osmotic gel and hardening compounds, and the excessive use of formaldehyde-containing disinfectants produced far greater formaldehyde emissions than use of cavity or arterial embalming fluids. NCI also found that good ventilation and avoiding spilling and splashing embalming fluid were the most

significant factors contributing to reduced formaldehyde exposure. Prior to the release of NCI's report, FDA has issued Formaldehyde Best Management Practices, with specific recommendations for reducing formaldehyde exposure (see page 52).

### **EU Biocidal Products Directive**

In 1998, the EU issued the "Biocidal Products Directive," effective in 2000. The directive was intended to protect human health and the environment and to establish a single system for biocide regulation throughout the entire EU by developing a process for authorizing and marketing products containing biocides, such as disinfectants, preservatives and pesticides. A biocide is a substance intended to destroy or render harmless an organism by chemical or biological means. The EU had found major differences in the ways member states regulated biocides and a general lack of information about their potentially harmful effects.

The directive operates as a market mechanism, prohibiting the sale and distribution of formaldehyde in embalming products (and other chemicals considered biocides) unless formaldehyde is registered, its health effects studied and the EU member country assigned to review formaldehyde health effects data and each additional country in which the embalming product will be sold determine that formaldehyde use in embalming is free of risk to human health and the environment.

The EU has established stringent scientific standards for registration of uses of toxic chemicals, including formaldehyde. For formaldehyde use in embalming to continue to be practiced in Europe, a scientific "dossier" was required for submission by November 1, 2008, with approval by Germany, the assigned reviewer, prior to May 2010. In the event that formaldehyde in embalming products fails to receive EU approval, formaldehyde-containing embalming products will

be banned from sale and distribution in the EU.

Embalming products have been designated Product Type 22, "embalming and taxidermist fluids," described as "products used for the disinfection and preservation of human or animal corpses." The Dodge Company, Ltd., in Great Britain, and Omega Holdings (ESCO and Gold Crest in Europe), which together have registered to defend formaldehyde-based embalming products in the EU,<sup>3</sup> met the November 1, 2008, deadline for submission of their technical dossier for formaldehyde-containing embalming products. The EU's actions in considering and rendering a health and safety judgment on formaldehyde-based embalming products are sure to have repercussions in the United States.

### **Other Initiatives**

There are other pending formaldehyde-based initiatives as well. After more than 10 years of study, the U.S. Environmental Protection Agency (EPA) plans to issue a draft formaldehyde risk assessment as a substitute for the current assessment in its Integrated Risk Information System (IRIS). IRIS is widely used by federal and state agencies to set regulatory action levels. Regardless of when it finalizes its formaldehyde risk assessment, the EPA is expected to rely on the NCI findings. The agency is also considering placing restrictions on allowable formaldehyde concentrations in pressed-wood products. And, significantly, the EPA has requested that the National Academy of Sciences reviews formaldehyde health effects, including a resolution of conflicts in the existing data about formaldehyde. Two Department of Health and Human Services (HHS) agencies have also announced their plans to revisit formaldehyde risk. The HHS National Toxicology Program will publish a revised formaldehyde cancer risk assessment in its forthcoming 12th Report on Carcinogens, and the HHS Toxic Substances and Disease Registry

is considering whether to update the toxicological profile for formaldehyde, last revised in 1999, to reflect more recent studies.

Individual states, too, are assessing formaldehyde and determining how it should be regulated. The Texas Commission on Environmental Quality issued a final formaldehyde development support document to be used, when final, in permit and other regulatory evaluations. This document will assist Texas regulatory agencies in evaluating the potential for adverse effects resulting from exposure to formaldehyde concentrations in the ambient, or outside, air. In both Massachusetts and Vermont, toxic use reduction/formaldehyde ban laws are now under consideration by state legislatures.

The EU's regulatory classification of formaldehyde is also under review. In 2004, the International Agency for Cancer Research (IARC), an agency of the World Health Organization, revised the classification of formaldehyde, labeling it a known carcinogen and raising it to the highest cancer risk category, an IARC Group 1 carcinogen, from a Group 3 probable carcinogen, the lowest risk category for suspected carcinogens. IARC will review this decision in October 2009.

Based on the IARC's revised formaldehyde classification, in 2005, France proposed that the EU render a formal determination that formaldehyde causes cancer. Should the EU reclassify formaldehyde as a known carcinogen, this determination will likely guide forthcoming regulatory decisions affecting formaldehyde use in the EU. In 2006, the German Federal Institute for Risk Assessment (Germany is the reviewer for formaldehyde-based embalming products) issued a white paper assessing the carcinogenicity of formaldehyde, which supported France's request for reclassification of the chemical as a carcinogen.

### **Conclusion**

Today, organizations around the

world are considering the health effects and risks associated with formaldehyde, including its use in embalming. Formal reports of pending formaldehyde research and risk assessment will be forthcoming. These studies foreshadow potentially significant implications for formaldehyde, including possible findings documenting a link between formaldehyde exposure and cancer. Following issuance of these studies, the United States and international bodies will consider taking action that could impact formaldehyde, how it can be regulated and whether it can be used, under any scenario, short term and long term. States, too, will consider additional regulation and legislation. In that regard, state associations will want to be informed of any subsequent state actions once these reports and findings have been issued. Please be sure to keep us advised. Such findings could directly influence regulation and use of formaldehyde-based embalming products in the United States and consequently the future of funeral service.

NFDA is closely monitoring all of these actions, both national and international, and will actively engage the issue with the EPA and OSHA should they propose more restrictive regulations on the use of formaldehyde in embalming. Contact NFDA at 800-228-6332 with questions

and comments. NFDA will keep you informed of developments. \*

#### Footnotes

<sup>1</sup> A leading NCI formaldehyde researcher based in the Netherlands spoke publicly about the NCI study at an international formaldehyde conference in Barcelona, Spain, in September 2007 ([www.formaldehyde-europe.org/pages/International\\_Formaldehyde\\_Sci.135.0.html](http://www.formaldehyde-europe.org/pages/International_Formaldehyde_Sci.135.0.html)). We learned about the Barcelona forum and requested a meeting with NCI.

<sup>2</sup> For the 1990 study, NCI identified the cause of death of more than 4,000 funeral directors who died between 1975 and 1985 by reviewing death certificates and lists provided by state funeral directors associations, state licensing boards and NFDA. NCI compared the number of funeral director deaths with the expected cause of death of the United States general population and then examined specific types of cancer deaths.

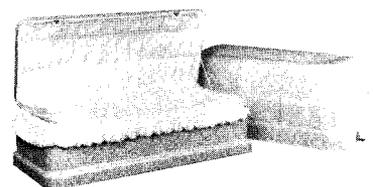
<sup>3</sup> AARDBalm, Ltd. (UK), has applied to defend iodine, with Sweden assigned as the reviewing member state. The Dow Chemical Company and BASF have applied separately to defend glutaraldehyde for disinfection, but no company is defending glutaraldehyde for embalming use. Consequently, it appears that glutaraldehyde-based embalming products will be banned in the EU.

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