

FOR IMMEDIATE RELEASE:
February 29, 2000

CONTACT: Mary Plock
202-434-7240
Mplock@himanet.com

INTERNATIONAL AGENCY FOR CANCER RESEARCH SUPPORTS SAFETY OF VINYL MEDICAL PRODUCTS

Sound Science Prevails in Review of Widely Used Material

February 29, 2000 – WASHINGTON, D.C. – The Health Industry Manufacturers Association (HIMA) applauds the International Agency for Research on Cancer (IARC) for its recent decision to downgrade Di-(2-Ethylhexyl) Phthalates (DEHP) to “not classifiable as a human carcinogen.” Formerly, DEHP had been classified as a “probable human carcinogen.” IARC, part of the World Health Organization, is internationally renowned for the high caliber of its scientific expertise. IARC’s decision reflects the overwhelming body of evidence that endorses the safety of this softener, used in numerous vinyl medical products critically important to patients.

“IARC’s careful and informed review of relevant data represents a major victory for sound science. For more than 40 years, DEHP has been used safely and effectively in a variety of medical applications,” said James Benson, HIMA’s executive vice president, technology and regulatory affairs. “Anesthesia tubing, blood bags, IV sets and other vinyl products are essential to delivering quality patient care.”

In light of IARC’s commendable review, Benson called upon the National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction, the FDA’s Center for Devices and Radiological Health and the European Union – all of which are currently assessing DEHP – to use similar scientific judgment for their own evaluations of the softening agent.

“IARC’s determination confirms the findings of hundreds of studies of DEHP,” Benson noted. “Clearly, the overwhelming evidence to date reveals the safety record for DEHP in medical products.”

In 1999, the American Council of Science and Health, under the leadership of former Surgeon General C. Everett Koop, conducted an extensive review of the safety of DEHP in medical devices and found “that DEHP, as used in medical devices is not harmful to humans even under

-more-

chronic or higher-than-average conditions of exposure. DEHP confers considerable benefits to certain medical devices and procedures and its elimination without a suitable substitute could pose a significant health risk to some individuals.”

“Of additional concern, is that the continued unfounded allegations against DEHP already settled by both science and experience is diverting valuable resources from more deserving medical research,” stated Benson. “Enough is enough. While it is the nature of science to multiply questions, patients – with real concerns and real health problems – need real treatment today.”

Vinyl medical products have undergone the FDA’s rigorous review and approval process that carefully considers scientific data and patient benefits. IARC’s recent action sets the standard for NTP, FDA and other scientific and regulatory bodies that sound science should be the definitive arbiter of patient access to critically important life-saving medical products. “The DEHP experience has shown that, whether the issue is materials safety, FDA approval or Medicare coverage, there are real costs to demanding too much data. Patients can be denied access to important medical technologies, and resources could be better spent on research or raising the standard of care,” said Benson.

IARC’s full report on DEHP can be accessed at the following Web site:

<http://193.51.164.11/htdocs/announcements/vol77.htm>.

###

The Health Industry Manufacturers Association (HIMA) is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the \$68 billion of health care technology products purchased annually in the United States, and nearly 50 percent of the \$159 billion purchased annually around the world.