Exhibit 3
Supporting Letters

July 24, 2007

ANDREW C. VON ESCHENBACH, M.D.
Commissioner, Food and Drug Administration
Parklawn Building, Room 1471
5600 Fishers Lane
Rockville, MD 20877

Dear Dr. Von Eschenbach:

In November, 2006, the National Toxicology Program issued a final report, making an authoritative statement confirming the potential for exposures to Di(2-ethylhexyl)phthalate (DEHP) in medical devices to undermine the normal development of the male reproductive tract. Yet, many medical device manufacturers are failing to disclose DEHP content on product labels. As a result, healthcare providers and institutions are severely handicapped in their efforts to prevent exposures to DEHP for vulnerable populations. **We are writing in support and endorsement of the enclosed petition, requesting that the Food and Drug Administration initiate a rulemaking or issue a guidance requiring medical device manufacturers to consistently label all medical device products containing polyvinyl chloride (PVC) that may expose patients to DEHP.**

The FDA's Public Health Notification issued in July, 2002, urged health care providers to reduce the use of DEHP-containing devices for certain patient groups. Since then, health care institutions nationwide have been struggling to follow FDA recommendations to adopt safer alternative products. Since the FDA has failed to finalize guidance to industry regarding DEHP, and failed to require labeling, many manufacturers are not labeling their DEHP-containing devices. The absence of DEHP labeling has made it difficult and time consuming for practitioners and supply staff to follow the FDA recommendations. In failing to mandate DEHP labeling by manufacturers, or to require its phase out, this has, in effect, shifted the costs of the transition to the health care sector and extended the timeframe that patients, including the most vulnerable neonatal populations, receive DEHP exposures during critical health care treatments. In some cases, it may make it impossible to fully comply with the FDA's own July 2002 Public Health Notification. For instance, many smaller scale health care operations and offices that lack the research and logistical staff of larger institutions are left unable to effectively implement the FDA's recommendations.

As the attached statements from hospitals indicate, DEHP labeling would help make it possible for hospitals to transition to safer alternatives and to maintain DEHP-free treatment for vulnerable populations in the face of a marketplace that is constantly changing and introducing new products. Healthcare providers and their institutions strive to provide the safest level of care for their patients. Labeling of DEHP-containing devices is a missing link needed to enable providers to implement your advisory, and provide the protection from potential harm to developing males and other vulnerable patients that the FDA has recommended.

Last spring, over 100 hospitals signed the Health Care Without Harm pledge committing to phase out the use of PVC/DEHP medical device products. In December, 2006, the American Medical Association passed a resolution, that in part, 'encourages hospitals and physicians to

reduce and phase out polyvinyl chloride (PVC) medical device products, especially those containing Di(2-ethylhexyl)phthalate (DEHP), and urges adoption of safe, cost-effective, alternative products where available (Res. 502, A-06).

This issue is crucial for the health of infants, children, and pregnant women -- the populations that NTP and FDA have identified as most vulnerable to DEHP exposures. We are joined in our concerns by the signatories below, representing health professionals across the country. Please act to mandate labeling for medical device products containing DEHP. Thank you for your time and attention to this matter.

Sincerely,

American Medical Association (AMA)
American Nurses Association (ANA)
American Public Health Association (APHA)
Association of Women's Health, Obstetric and Neonatal Nurses (AWOHNN)
Physicians for Social Responsibility (PSR)
American College of Nurse Midwives (ACNM)
Health Care Without Harm

JANUARY 15, 2007

TO: FOOD AND DRUG ADMINISTRATION

REGARDING: LABELING OF MEDICAL DEVICES CONTAINING DEHP

It was during my tenure as the Pediatric Intensive Care Unit (PICU), Clinical Nurse Specialist, at Doernbecher Children's Hospital that I first became aware of the potential risks of medical devices containing DEHP. The hospital, a part of the Oregon Health & Sciences University, is a full-service children's hospital in the Pacific Northwest, and offers a comprehensive program of specialties with full-spectrum pediatric care for hospitalized children.

In 2002, shortly after the FDA's Public Health Notification on DEHP, our Pediatric Intensive Care Unit enlisted the help of the Oregon Health Care Without Harm to complete an assessment of current uses of DEHP medical devices and educate other departments including ECMO and NICU on the issues surrounding DEHP. As part of our efforts we conducted educational workshops, inviting other hospitals as well, to discuss the science and risks around DEHP. We also began researching available alternatives. Becoming educated on the subject was relatively easy, however identifying available alternatives, even though they existed, was not. One of the biggest challenges we faced was deciphering which of the products contained DEHP and which did not. Many of these products are not labeled and PICU/NICU staff spent countless hours on the phone with medical device manufacturers trying to obtain the information.

Requiring medical device manufacturers to label these products would allow healthcare purchasers to quickly identify which products do or do not contain DEHP. This would translate into more staff time and resources that can be focused on the quality of care provided to patients. It has been 5 years since the FDA's public health notification and we have made strides towards DEHP free, however lack of comprehensive labeling has been a hindrance in our efforts. I strongly urge the FDA to consider a mandate calling for manufacturers to label all devices with labels indicating that is does or does not contain DEHP.

Sincerely,

Mary Frances D. Pate, DSN, RN
Assistant Professor, School of Nursing
Oregon Health & Science University

PREMIER

Statement of the Safety Institute, Premier Inc. to the Food and Drug Administration
Regarding the Labeling of Medical Devices Containing DEHP
April 2, 2007

On behalf of Premier Inc., and its Safety Institute, we are writing in support of efforts to minimize patient exposure to medical devices containing a potential toxicant, di(2-ethylhexyl) phthalate (DEHP). Premier Inc. is the largest healthcare alliance in the United States and with 1,700 hospitals and more than 43,000 other healthcare sites is dedicated to improving patient outcomes while safely reducing the cost of care.

DEHP is often added to polyvinylchloride (PVC) plastic products during manufacturing to make them more flexible. Animal studies have indicated that DEHP exposure may be linked to liver, kidney and lung damage. In addition, high levels of DEHP have been shown to adversely affect the development of the male reproductive system in animal studies.

The November 2006, National Toxicology Program's (NTP) Center for Evaluation of Risks to Human Reproduction expert panel issued a monograph confirming an earlier 2002 NTP report indicating that there is sufficient evidence that DEHP is a potential reproductive toxicant to neonatal males.

Research has shown that the chemical can leach from medical devices resulting in elevated and potentially harmful exposure to patients. A 2005 study from Harvard School of Public Health in collaboration with the U.S. Centers for Disease Control and Prevention confirmed that there was a direct relationship between the levels of DEHP in the urine of neonates and the intensity or amount of exposure to DEHP-containing medical devices.

We would like to commend the FDA for taking two very significant steps in reducing patient exposure to DEHP. First, the Center for Devices and Radiologic Health issued a public health notification on July 12, 2002 on *PVC Devices Containing the Plasticizer DEHP* that provided advice on steps that healthcare providers can take to reduce the risk of exposure to DEHP in certain patient populations and medical procedures. Based on this public health notification, our members initiated programs to identify non-DEHP devices and selectively use DEHP-free devices on high risk populations, including the neonates.

Second , the FDA, on September 6, 2002 publishing draft guidance on *Medical Devices Made with PVC using DEHP* for public comment that included recommendations for "ways that manufacturers may reduce or eliminate potential risks associated with DEHP," for example, to "minimize exposure to DEHP as a design requirement" or to "clearly indicate through user labeling that device contains DEHP."

However, more than four years have passed since the FDA issued the public health notification and the draft guidance recommending manufacturers to label devices that have DEHP, making it difficult for healthcare providers to identify these devices to reduce exposure among high risk populations.

FDA has initiated other label requirements to protect the public health, such as the requirements for labeling devices and packages that contain Natural Rubber Latex (21 CFR 801.437) and we would like to see the FDA apply similar labeling requirements for products containing DEHP.

So, we urge the FDA to implement a requirement for labeling of DEHP-containing medical devices to reduce patient exposure to DEHP and improve patient safety.

Premier's Safety Institute will continue to provide publicly available resources on DEHP on its Web site at www.premierinc.com/safety to include DEHP-free product lists and relevant information from the FDA.

Sincerely,

Gina Pugliese, RN MS
Vice President
Safety Institute, Premier Inc.

STATEMENT OF MILLER CHILDREN'S HOSPITAL
TO THE FOOD AND DRUG ADMINISTRATION
REGARDING LABELING OF MEDICAL DEVICES CONTAINING DEHP

We are writing to FDA today to request that you require labels for medical devices that contain di-ethyl hexyl phthalate (DEHP).

Miller Children's Hospital, established in 1970, is a not–for–profit children's hospital located on the campus of Long Beach Memorial Medical Center. The 281–bed hospital cares for children of all ages, from newborns to young adults, as well as expectant mothers.

Miller Children's Hospital is one of only two children's hospitals in Los Angeles County. We have cultivated a regional and national reputation for our quality of care, compassionate medical and nursing staffs, and parents and medical professionals have come to know us and trust us over the years.

We are home to one of the largest Neonatal Intensive Care Units (NICU) in California, treating more high-risk infants daily than any other hospital in Los Angeles, Orange and San Diego counties. In addition, our Pediatric Intensive Care Unit (PICU) provides comprehensive care for the most serious pediatric cases, many of which come to us through our new pediatric Emergency Department – one of few in the area that meets special criteria for providing pediatric emergency and trauma care.

Today, we admit more than 8,000 youngsters annually, see more that 120,000 children in our outpatient clinics, treat more than 25,000 in our Emergency Department and care for more than 1,000 newborns in our Neonatal Intensive Care Unit, many of whom are referred to from other institutions.

We are the major pediatric teaching hospital for the School of Medicine at University of California, Irvine, and are one of the 10 largest pediatric training programs in the country. We're staffed around the clock with residents and supervising physicians experienced in the practical application of the most advanced medical techniques. Miller Children's Hospital's educational and research programs keeps it at the leading edge in prevention, diagnosis and treatment of illnesses and injuries, and in the enhancement of children's health.

We provide this background because as a national leader in pediatric care, Miller Children's hospital is justifiably proud of its work caring for children. It is important for us to have every tool at our disposal to continue our excellent service. This should include the labeling of DEHP-containing medical devices.

Our own experience sheds light on the difficulty hospitals face when trying to protect patients from DEHP exposure. Our Central Supply Manager reports that her queries to medical device manufacturer customer service representatives about DEHP content in their products yields the response that the customer service reps don't even know what she is talking about. They don't know what DEHP is, which requires a referral to technical support and leads to precious lost time.

We cannot be advocates for patient safety when vital information is unavailable. To not have information about DEHP content in devices that are commonly used in patient care is an injustice to both patients and to healthcare providers.

As of November 2006, the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction has finalized its findings on DEHP. These conclusions speak for themselves:

* Serious concern that certain intensive medical treatments of male infants may result in exposure levels of DEHP that affect development of the male reproductive tract.

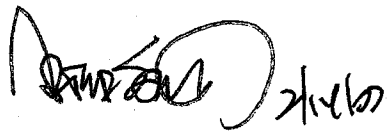
* Concern for adverse effects on development of the male reproductive tract in male offspring of pregnant and breastfeeding women undergoing certain medical procedures that may result in exposure to high levels of DEHP.

* Concern for effects of DEHP exposure on development of the male reproductive tract for infants less than one year old.

Miller Children's Hospital is a national leader in caring for ill neonates. The lack of labels for medical devices containing DEHP make it more difficult for Miller Children's Hospital to provide the absolute best care for our patients.

We support the petition from Health Care Without Harm to require labeling, and look to the FDA to provide leadership in this area. Please keep us informed about the actions you take in this area.

Very truly yours,



Arthur Strauss,MD
Chair, Healthy Initiatives Group
Miller Children's Hospital
Long Beach, CA

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April 5, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Request for FDA Regulation to Label Medical Devices That Leach Phthalate Plasticizers

To Whom It May Concern:

As an organization involved in the health care supply chain, Novation, LLC, the health care contracting services company of VHA Inc. and the University HealthSystem Consortium (UHC), two national health care alliances, supports the Food and Drug Administration's (FDA) development of a regulation to require manufacturers to label polyvinyl chloride (PVC) plastic medical devices that can leach di-ethylhexyl phthalate, or DEHP. Regulated, mandatory labeling for PVC/DEHP products will help implement the FDA's recommendations, improve patient safety and address concerns regarding exposures to PVC/DEHP. Currently, the FDA supports voluntary PVC/DEHP labeling, but does not require it. Mandatory labeling will complement the FDA's existing DEHP Public Health Notification and will help health care providers better inform practitioners about potential risks, enable easier selection of PVC/DEHP-free products for vulnerable patients and improve patient care.

The National Toxicology Program (NTP) is one of the most credible sources on the concern of PVC/DEHP exposure, and it has asserted that decreasing or eliminating human exposure to chemical agents in medical devices could help reduce some human diseases and disability. In 2006, an NTP expert panel completed the second assessment of risks related to PVC/DEHP exposure from medical procedures over a five year period. Again the panel expressed concern about the potential harm to the human reproductive system and the developmental effects of PVC/DEHP exposure to vulnerable patient populations undergoing medical procedures.

Although the FDA's own analysis urges health care providers to seek alternatives to PVC/DEHP devices, there is no clear-cut, thorough way to implement the process. The FDA guidance clearly focuses on providing information on safety issues but it does not address the user issue of ensuring a product is not given to a high-risk patient.

In addition, providers struggle to track latex, PVC and DEHP devices through their inventories, as the information is not always readily available from the manufacturer. Although Novation and other organizations including H2E and Sustainable Hospitals maintain separate listings for PVC/DEHP alternatives, there is no national repository of the information, and this creates a barrier for health care providers trying to obtain the knowledge they need to provide optimal care. To get around this barrier, many health systems must create and manage their own listings or contract with a third party to synchronize their data with the manufacturer, distributor or other entity. This is a costly and complex undertaking for providers and has the potential to generate errors by adding another layer to the process of tracking PVC/DEHP medical products.

In closing, consistent labeling of all PVC/DEHP medical devices will improve patient safety and adverse event reporting, prevent errors and provide better health care information to caregivers and patients.

We hope the information shared will prove useful and we look forward to working with you on this issue. Thank you for the opportunity to reiterate our strong support for mandatory labeling for safer patient care. If you have questions or comments, please contact Novation's Christine Miller, R.N., senior clinical manager, safety at 972-581-5644 or email her at cmiller@novationco.com.

Sincerely,

Joellyn Willis

Joellyn Willis
President

December 20, 2006

Statement of Magee-Womens Hospital of UPMC
Pittsburgh, PA

To: Food and Drug Administration

Regarding: Labeling of Medical Devices Containing DEHP

To Whom It May Concern:

Magee-Womens Hospital of UPMC delivers over 9,000 babies a year in Pittsburgh, PA. Over a year ago, we became aware of the toxic effects of DEHP in neonatal intensive care units to vulnerable babies. After a full assessment with an expert in our neonatal intensive care, we were able to virtually remove DEHP in our NICU and other nurseries. It took considerable effort from our nurse clinicians to get the information needed on all of the plastic used with the infants.

Lack of appropriate labeling on devices utilizes nursing time away from the bedside to make sure that it does not contain DEHP. This labeling should be the obligation of the medical device manufacturers rather than hospital/nurses seeking the information from them when a device comes in unlabeled. This should not be an ongoing issue for hospital staff and we recommend that manufacturers be required to label all devices with labels indicating that is does or does not contain DEHP.

Sincerely,

Joyce H. Lewis, RN MNed
Consumer Educator
Director, Community & Government Affairs
300 Halket Street
Pittsburgh, PA 15213

Statement of Abington Memorial Hospital
Abington, PA

To: Food and Drug Administration

Regarding: Labeling of Medical Devices Containing DEHP

To Whom It May Concern:

Abington Memorial Hospital is committed to working to minimize exposure to potentially toxic or harmful products. We are very concerned about the effects of DEHP on our most vulnerable patients, premature infants in our neonatal intensive care unit.

We are guided by the studies recommending that PVC-containing DEHP should be replaced with alternative materials. The FDA draft guidance recommends that manufacturers disclose the presence of this chemical in the device's labeling. Such labels and disclosure can assist healthcare professionals in making informed decisions.

In the interest of patient safety we ask the FDA to require labeling of DEHP containing devices. Device labeling is the only sure way of communication with end users as to what is contained in the devices.

Thank you for your consideration of this important issue.

Sincerely,

Meg McGoldrick
Chief Operating Officer
Abington Memorial Hospital
Abington, PA
Phone: 215-481-2007
Fax: 215-481-4014
mmcgoldrick@amh.org

January 15, 2006

Statement of Oregon Health & Science University's School of Nursing
Portland, OR

To: Food and Drug Administration

Regarding: Labeling of Medical Devices Containing DEHP

To Whom It May Concern:

It was during my tenure as the Pediatric Intensive Care Unit (PICU), Clinical Nurse Specialist, at Doernbecher Children's Hospital that I first became aware of the potential risks of medical devices containing DEHP. The hospital, a part of the Oregon Health & Sciences University, is a full-service children's hospital in the Pacific Northwest, and offers a comprehensive program of specialties with full-spectrum pediatric care for hospitalized children.

In 2002, shortly after the FDA's Public Health Notification on DEHP, our Pediatric Intensive Care Unit enlisted the help of the Oregon Health Care Without Harm to complete an assessment of current uses of DEHP medical devices and educate other departments including ECMO and NICU on the issues surrounding DEHP. As part of our efforts we conducted educational workshops, inviting other hospitals as well, to discuss the science and risks around DEHP. We also began researching available alternatives. Becoming educated on the subject was relatively easy, however identifying available alternatives, even though they existed, was not. One of the biggest challenges we faced was deciphering which of the products contained DEHP and which did not. Many of these products are not labeled and PICU/NICU staff spent countless hours on the phone with medical device manufacturers trying to obtain the information.

Requiring medical device manufacturers to label these products would allow healthcare purchasers to quickly identify which products do or do not contain DEHP. This would translate into more staff time and resources that can be focused on the quality of care provided to patients. It has been 5 years since the FDA's public health notification and we have made strides towards DEHP free, however lack of comprehensive labeling has been a hindrance in our efforts. We strongly urge the FDA to consider a mandate calling for manufacturers to label all devices with labels indicating that is does or does not contain DEHP.

Sincerely,

Mary Frances D. Pate, DSN, RN
Assistant Professor, School of Nursing
Oregon Health & Science University
3455 SW Veterans Hospital Road, SN-5S
Portland, OR 97239-2941
Phone: 503-494-3816
Fax: 503-494-3878

Statement of Good Shepherd Medical Center

To: Food and Drug Administration

Regarding: Labeling of Medical Devices Containing DEHP

To Whom It May Concern:

I have not had many issues with our suppliers.

Our GPO is Amerinet and they are very much in favor of promoting H2E and the studies they support. Our hospital tries to stay in guidelines with in using our GPO suppliers. When ever I have asked our suppliers for information on products containing DEHP or labeling they comply with information rapidly. Owens & Minor, our distributor, also is on board with the H2E program and support it. Kendall and Hospira have been very supported also.

Sincerely,

Sue Gardner, CRSCT, CHPM
Materials Management, Manager
Good Shepherd Medical Center
sclevel@gshealth.org
Phone: 541-667-3613
Fax: 541-667-3612
Pager: 541-667-3700, # 338

Statement of Evergreen Healthcare
Kirkland, WA

To: Food and Drug Administration

Regarding: Labeling of Medical Devices Containing DEHP

To whom it may concern:

Our Pediatric and Neonatal Intensive Care Unit learnt of the concerns from DEHP in 2003 and we decided to eliminate it from our supplies as soon as possible. Fortunately we have a very dedicated equipment manager who put a lot of energy into researching this. However, it still took over a year to eliminate DEHP from all our NICU/Pediatric supplies. This would have been a much easier process to facilitate if the medical device companies had been more open and transparent with their labeling regarding DEHP. There is also some literature promoted by some of these companies that tries to dispel the safety issues raised about DEHP.

Both the healthcare industry and our suppliers should be practicing the "precautionary principle" when it comes to using potentially toxic substances and we should be using the products that are the safest for our patients. The equipment of choice should be the most environmentally safest. Therefore, healthcare institutions should have the most accurate access to the information (in the form of labeling of medical supplies) that allows them to use their medical equipment and 'do no harm'.

Respectively submitted, yours sincerely,

Jim Overton RN
Evergreen Healthcare
NE 128th St
Kirkland, WA 98034

February 10, 2007

Statement of Children's Hospital and Regional Medical Center
Seattle, Washington

To: Food and Drug Administration

Regarding: Labeling of Medical Devices Containing DEHP

To whom it may concern:

Seattle Children's is a well known and respected regional medical center serving patients and families in Washington, Alaska, Montana, Idaho and parts of Wyoming for the past 100 years. In 2003, we first became aware of the toxic effects of DEHP, contained in many of the medical supplies that we use every day and in some of our most life-saving procedures. Ironically, the potential toxicity of DEHP is greatest in our sickest patients – infants in the intensive care unit. We have taken immediate steps to identify and eliminate products containing DEHP as soon as, and wherever possible. Even with a few dedicated staff, a receptive purchasing department (the cost of DEHP-free supplies can be more than those not containing this chemical) and vendors, we are still working hard to remove all such equipment and devices from our hospital. Our efforts to do this work would have been greatly facilitated had the medical device companies been more open and transparent with their labeling of DEHP containing products, or better yet, taken the initiative to make DEHP-free products available.

Not unlike the similar health risk of latex containing products (companies are now regulated to identify if there is any latex in products/packaging), the same should hold true for DEHP. In order for us to provide the safest care, we need accurate information (in this case, in the form of contents labeling of medical supplies) that allows us to make the best decisions in product selection and purchase.

It is our belief that the healthcare industry and our suppliers should be practicing the "precautionary principle" when it comes to using potentially toxic substances by complete and accurate labeling of all products. This will allow us to provide the safest - care for our patients with the least impact on the environment (which in and of itself impacts future patients/care). Healthcare institutions must have the most accurate information that allows us to 'do no harm' while caring for the children in our hospital

Sincerely,

Sue Heffernan, RN, MN, BC
CNS, Nursing Professional Development
Richard Grady, M.D.
Interim Chief, Pediatric Urology
Laura Hart, M.D.
Attending, Pediatric Urology
Children's Hospital and Regional Medical Center
4800 Sand Point Way NE
Seattle, WA 98112

KAISER PERMANENTE®

STATEMENT OF KAISER PERMANENTE
TO THE FOOD AND DRUG ADMINISTRATION
REGARDING LABELING OF MEDICAL DEVICES CONTAINING DEHP

Kaiser Permanente (KP) is the nation's largest not-for-profit health care system serving 8.4 million members in 9 states and the District of Columbia. 6.4 million Californians are KP members. KP is the largest not-for-profit, non-governmental employer in our 2 largest markets, the San Francisco Bay Area and Los Angeles. In California, KP employs approximately 120,000 technical, administrative and clerical employees and caregivers, as well as 10,000 physicians representing all specialties. In 2005, total annual revenue was $31 billion.

Kaiser Permanente's vision for environmental stewardship aspires to provide health care services in a manner that protects and enhances the environment and the health of communities now and for future generations.

In practical business terms, this means KP tries to avoid purchasing materials and medical devices that are carcinogenic, mutagenic or toxic to reproductive systems. We are working to implement a comprehensive chemical policy that calls for transparency and accountability on behalf of suppliers and manufacturers. We believe that where there is credible evidence that a material we're using may result in environmental/public health harm, we should strive to replace it with safer alternatives that meet our performance criteria.

In our effort to source safer products, KP has a robust chemicals disclosure document that is required for all large national contracts. The disclosure asks for information on persistent bioaccumulative toxic (PBT) compounds as well as carcinogenic, mutagenic and reproductive (CMR) toxins. We have learned the process requires comprehensive vendor education and aggressive demands for safety and ingredient information.

However, many chemicals of concern are not listed on OSHA Material Safety Data Sheets due to trade secret caveats or to small concentrations that exempt manufacturers from reporting despite evidence that some of these chemicals may cause harm at low doses. In many cases, even with the purchasing power represented by KP's size in the marketplace, it is difficult to get the information we require.

The National Toxicology Program's findings on di-ethyl hexyl phthalate (DEHP) are one example where KP has concluded there is sufficient evidence that DEHP is a potential reproductive toxicant to neonatal males. Accordingly, KP undertook thorough investigations of products already in use in KP Neonatal Intensive Care Units (NICUs) and subsequently completed field evaluations of identified non-DEHP products. Today,

non-DEHP alternatives have replaced DEHP products in all neonatal applications for which they are available in KP's 34 NICU units.

We are proud of our phase-out of DEHP devices, but it must be said that the process would have proceeded much more quickly if labeling of DEHP devices was required by FDA.

In 2002, FDA itself recommended health care institutions reduce the exposure of certain populations to medical devices containing DEHP. However, FDA has not required medical device manufacturers to label devices, making it difficult for purchasers and clinicians alike to identify products that contain this chemical of concern. We know from experience that the lack of labeling makes it difficult, if not impossible, for frontline health care staff to know whether or not a medical device may contain DEHP, thus preventing them from implementing the FDA recommendation and protecting the at-risk patient populations they serve.

For these reasons, we support a mandatory labeling requirement of DEHP-containing medical devices by the FDA.

Sincerely yours,

Lynn Garske
Environmental Stewardship Manger
Kaiser Permanente

Catholic Healthcare West
CHW

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San Francisco, CA 94107-1739
(415) 438-5500 *telephone*
(415) 438-5724 *facsimile*
www.chwHEALTH.org

STATEMENT OF CATHOLIC HEALTHCARE WEST TO THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING OF MEDICAL DEVICES CONTAINING DEHP

February 9, 2007

Founded in 1986, Catholic Healthcare West (CHW) is a system of 42 hospitals and medical centers in California, Arizona and Nevada, with corporate headquarters in San Francisco. CHW is the eighth largest hospital system in the nation with 44,000 employees, 7,817 active physicians, 6,860 acute care beds, and 906 skilled nursing beds.

We submit this letter to the Food and Drug Administration with the hope that FDA will exercise leadership by mandating the labeling of medical devices that contain the phthalate DEHP (di-ethyl hexyl phthalate).

CHW has been concerned with DEHP exposure in our facilities for many years. In May 2000, the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (CERHR) produced its first draft report on DEHP.

In response to this report, as you well know, FDA issued a Public Health Notification on DEHP in July 2002. The Public Health Notification recommended that healthcare providers use alternatives to DEHP products where procedures using DEHP could result in excessive exposures. The Public Health Notification also recommended that manufacturers reformulate their products to reduce or eliminate DEHP; and it recommended that manufacturers label their products.

However, FDA did not require labels, which has made it difficult for clinicians to protect patients from exposure.

One of CHW's values is Stewardship, which we describe as cultivating the resources entrusted to us to promote healing and wholeness. At CHW, we have engaged in long-standing advocacy efforts with our suppliers to ensure that products used in the hospital setting are safe for patients, employees, and the environment.

In November 2005, CHW announced the award of a five-year, $70 million contract to B. Braun Medical Inc. for the supply of intravenous (IV) bags, solutions, and tubing to our system's hospitals that are free of both DEHP and polyvinyl chloride (PVC). CHW's President and CEO, Lloyd H. Dean, noted that the reason was that "the care and safety of our patients is our first priority."

In November 2006, the National Toxicology Program's CERHR finalized its report on DEHP, retaining the key findings from its earlier draft. This includes "serious concern"