

# PVC & HEALTHCARE

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## INTRODUCTION

Polyvinyl chloride (PVC) is a chlorinated plastic polymer adapted for many different uses by the addition of fillers, stabilizers, lubricants, plasticizers, pigments, and flame retardants, depending on the intended application. The use of plasticizers (mainly phthalates) and stabilizers in rather high quantities constitutes a specific characteristic of PVC manufacturing compared to other types of plastic.<sup>1</sup> Lead and cadmium are widely used as PVC stabilizers for many applications, including construction and electric wire coating materials.

PVC is the most widely used plastic in medical products. It accounted for 27% of all plastic used in durable and disposable medical products in the U.S. in 1996. Approximately 445 million pounds of PVC were consumed in the manufacture of intravenous (IV) and blood bags, tubing, examination gloves, medical trays, catheters, and testing and diagnostic equipment in 1996.<sup>2</sup> Tubing, IV and blood bags, and gloves are the primary end-uses for PVC in disposable medical products. Other PVC products used in hospitals, which are not specific to healthcare, include office supplies and construction and furniture products (see Appendix 1 for a detailed list of products).

This white paper examines the life cycle hazards posed by PVC, with an emphasis on di-2-ethylhexyl phthalate (DEHP) exposures to patients and dioxin emissions from medical waste incinerators, and identifies methods and opportunities for reducing PVC use in hospitals.

## PROBLEM STATEMENT

Concerns about the use of PVC in medical care fall into two categories: 1) potential impacts on patient health and safety from the use of PVC containing DEHP and 2) public health and environmental impacts from PVC production, use, and disposal.

### *Patient Health and Safety*

PVC is a rigid plastic. To manufacture flexible PVC medical products, manufacturers add the plasticizer, DEHP.<sup>3</sup> Some flexible PVC medical products contain more than 50% DEHP. DEHP does not chemically bind to the polymer (polyvinyl chloride). Instead, it lies in the polymeric matrix and leaches out under certain conditions, causing direct patient exposures. Because DEHP preferentially dissolves in fat rather than water, blood and feeding formulas contain higher concentrations of DEHP than other fluids, such as saline and amino acid solutions. The largest patient exposures occur during dialysis, extracorporeal membrane oxygenation, exchange transfusions, or repeated blood transfusions in newborns and preterm babies.<sup>4</sup> Total parenteral nutrition (TPN) delivered through PVC tubing may also be a source of very significant exposure to DEHP.<sup>5</sup>

Though data from humans are sparse, the toxicity of DEHP has been extensively studied in various animal species. DEHP or its metabolites may cause toxic effects in various organ systems, depending on amount, route, and timing of exposures. Of particular concern, at exposure levels resulting from medical treatment with DEHP-containing medical devices, is toxicity to the developing male reproductive tract. Recently, the Expert Panel on Phthalate Esters from the National Toxicology Program's Center for the Evaluation of

Risks to Human Reproduction investigated the reproductive and developmental toxicity of DEHP and other related compounds.<sup>6</sup> In their summary statement, the expert panel expressed "serious concern" for the possibility of adverse effects on the developing reproductive tract of male infants exposed to high levels of DEHP from medical procedures such as those used in neonatal intensive care units (NICUs). They also expressed "concern" that the exposure of pregnant and lactating women to ambient levels of DEHP, largely from dietary sources, might adversely affect their offspring. When DEHP exposures from the use of PVC medical devices are added to general dietary exposures during pregnancy, the risk of adverse effects obviously increases. The Panel also expressed "concern" that, if infants and toddlers are exposed to levels of DEHP substantially higher than adults, adverse effects might occur in the developing male reproductive tract.

Additional concerns have been raised about the potential role of DEHP exposure in liver failure frequently encountered by neonates receiving TPN as well as its potential contribution to the development of bronchopulmonary dysplasia in infants ventilated through PVC endotracheal tubes.<sup>7,8</sup> These concerns deserve further investigation and remain unresolved.

Surprisingly, total DEHP exposure from concurrent use of multiple DEHP-containing medical devices has not been quantified. A Health Care Without Harm-sponsored study of PVC use in neonatal intensive care units found approximately 30 devices made of DEHP-containing PVC that are potential sources of DEHP exposure.<sup>9</sup> Routine use of these devices will expose developing male infants to levels of DEHP and/or metabolites at or above levels known to cause testicular toxicity in studies in relevant animal species.

### ***Public Health and Environmental Impacts of PVC Production and Disposal***

#### **PVC, DIOXIN, AND HEALTH CARE INSTITUTIONS**

The public health and environmental impacts of PVC production and disposal result from: 1) release of dioxins and furans generated as by-products during the production of PVC feedstocks; 2) dispersion of plasticizers and metal stabilizers, including lead and cadmium, during use and after disposal; and 3) formation of hydrochloric acid and novel toxic compounds, including dioxins and furans when PVC is burned. PVC

recycling opportunities are limited, and when "recycled" PVC is actually down-cycled into products usually made from other materials, delaying, but not ultimately mitigating, disposal hazards. Efforts to recycle other types of plastics may be ruined by contamination with even small amounts of PVC, making strict segregation of PVC from the plastics waste stream essential, though this is often difficult to achieve in practice.

Chlorinated dibenzo-dioxins and furans are extremely potent, persistent, and bioaccumulative environmental toxicants that contaminate the general food supply. They are unintentionally formed during a variety of industrial processes, including the manufacture of PVC feedstocks and incineration of PVC. They cause their toxic effects at picogram to nanogram per kilogram (kg) body weight levels of exposure and are detectable at levels of concern in the general population and wildlife of most industrialized nations. Inuits and other northern peoples are also significantly exposed through their diet of marine fish and mammals, revealing the capacity of these compounds to travel far from their source.

The draft dioxin reassessment recently released by the US Environmental Protection Agency (EPA) reviews the contribution of PVC manufacturing and waste incineration to dioxin and furan emissions.<sup>10</sup> According to calculations of the Vinyl Institute, reviewed and given a medium confidence rating by the EPA,<sup>11</sup> the production of PVC and its feedstocks result in air releases of 11.2-31.0 grams toxic equivalency (TEQ)<sup>12</sup> dioxins and furans per year. The EPA identifies municipal and medical waste incinerators as the leading sources of dioxin and furan emissions to air in the US: 1,250 and 488 grams TEQ annually, respectively.

Chlorine, carbon, and catalysts must be present in an incinerator in order for dioxins and furans to form.<sup>13</sup> PVC is usually the largest chlorine source in municipal and medical waste incinerators. The relationship between chlorine inputs into an incinerator and dioxin and furan formation, however, depends upon combustion conditions.

For uncontrolled combustion, such as open burning of household waste, landfill fires, or building fires, a direct association between chlorine content of the combusted material and dioxin and furan formation has been established. For example, a study of the open burning of household waste showed that waste containing larger amounts of PVC (4.5% vs. 0.2%) produced substantially

larger amounts of dioxins and furans in air emissions (269 vs. 44.3 microgram/kg waste burned) and ash (7,356 vs. 489 microgram/kg waste burned).<sup>14</sup>

In modern, commercial waste incinerators, the rate at which dioxins and furans are formed and released depends upon chlorine inputs, incinerator design, operating conditions, the presence of catalysts, and pollution control equipment. In its draft dioxin reassessment the EPA concludes, based on studies of modern waste incinerators, that chlorine levels in feed are not the dominant controlling factor for rates of dioxin and furan stack emissions. Instead, according to EPA, the largest determinants are operating conditions — overall combustion efficiency, post-combustion flue gas temperatures, and residence times — and the presence of iron or copper catalysts that support dioxin synthesis.

However, for any given waste incinerator, according to the EPA, conditions may exist in which changes in chlorine content of waste feed will correlate highly with dioxin and furan emissions. These conditions may prevail during start-up or shut-down, changes in waste feed rate, or operational upsets. Although modern commercial waste incinerators are designed and intended to be operated to minimize release of dioxins, furans, and other hazardous air pollutants, they are, nevertheless, a significant source of dioxin and furan releases. For example, the EPA estimates that municipal waste and medical waste incinerators contribute 44 percent and 18 percent, respectively, of dioxin and furan releases to air from quantified sources.

Although the EPA concludes that incinerator operating conditions are the dominant controlling factor for dioxin/furan emissions, there is little doubt that chlorine content of the waste feed also plays a major role. Several laboratory and incinerator pilot studies have found a direct relationship between chlorine loading and dioxin and furan emissions.<sup>15</sup> In addition, the EPA's conclusion appears to rest largely on an analysis of incinerator emissions data by Rigo, et al. (1995), which has serious methodological flaws.<sup>16</sup> It is also important to note that the EPA conclusion refers only to stack gas emissions, which are a relatively small fraction of total dioxins and furans released from incinerators, and does not consider releases in fly ash, bottom ash, and water discharges.

When addressing dioxin and furan formation and emissions, prevention, rather than control, should be

the highest priority. As the US Congress stated in the Pollution Prevention Act of 1990, "pollution should be prevented or reduced at the source wherever feasible" and "disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner."

Moreover, the US is among over 150 nations that recently concluded negotiating an international treaty intended to virtually eliminate production, use, and formation of Persistent Organic Pollutants (POPs), two of which are dioxins and furans.<sup>17</sup>

The primary source of dioxins and furans from the healthcare sector is waste incineration. Chlorine-containing products burned in incinerators provide the chlorine necessary for dioxin and furan formation. Methods for preventing healthcare-related dioxin and furan releases include:

- 1) ceasing all non-essential incineration as a means for chemically and physically transforming waste;
- 2) eliminating large sources of chlorine from incinerator waste feed by a) phasing out the use of PVC, and/or b) separating chlorine-containing products from the incinerator wastestream and sending it directly to a landfill; and
- 3) optimizing incinerator operating conditions for that portion of the waste stream that must be incinerated. Inasmuch as this is an end-of-the-pipe solution, however, it should be considered only as a last resort.

In summary, available data reveal a complex relationship among chlorine feed, design and operating conditions, and dioxin and furan emissions. It is certain that chlorine sources are necessary for dioxin/furan emissions, PVC products are the largest chlorine source, and incinerators with pollution control equipment are significant sources of dioxin/furan releases in stack gases, fly ash, bottom ash, and water discharges. Moreover, even modern, well-designed incinerators do not consistently operate at optimal combustion conditions. For these reasons, along with concern about other hazardous pollutants emitted from waste incinerators — including mercury, particulates, sulfur and nitrous oxides, and hydrochloric acid — Health Care Without Harm has taken the pollution prevention position that PVC use should be minimized, alternatives used when available without compromising patient safety or care, and all unnecessary waste incineration should be avoided.

## DIOXIN TOXICITY

Rain, snow, and dust bring dioxin and furan emissions to the surface of the earth, often hundreds of miles from their point of origin, where they enter the food chain. Because dioxins and furans are environmentally persistent, bioaccumulative, and fat-soluble, their concentration biomagnifies as they pass up the food chain. Human exposure is primarily through food, with major sources including beef, dairy products, fish, pork, and breast milk.

Dioxins and furans are extremely toxic and potent environmental contaminants. They modulate and disrupt multiple growth factors, hormones, and developmental processes. In animals, dioxin causes cancer in multiple organ systems, sometimes at nanogram/kg body weight exposure levels. Prenatal exposure to dioxin in rodents substantially increases the risk of breast cancer later in life.<sup>18</sup> Human epidemiological studies conclude that dioxin causes cancer in humans as well.<sup>19</sup> The EPA draft dioxin reassessment estimates that as many as one in 1000 of the most highly exposed people in the general population are at risk of developing cancer because of dioxin.

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Dioxin also has widespread effects on reproduction and development, as shown in animal and human studies. Nanogram to microgram/kg body weight doses of dioxin on a single day during pregnancy cause permanent disruption of male sexual development in rodents, including delayed testicular descent, lower sperm counts, and feminized sexual behavior.<sup>20</sup> In primates, small dietary exposures to dioxin are associated with an increased risk and severity of endometriosis.<sup>21</sup> A study in humans also shows higher levels of dioxin in women with endometriosis than in a control population.<sup>22</sup>

Dioxin is particularly toxic to the developing immune system. Animal tests show that nanogram/kg doses given 1-4 times during pregnancy cause permanent alterations in the immune system of offspring.<sup>23</sup> Human studies also show an increased susceptibility to infection and changes in immune system parameters as a result of in utero exposure to ambient environmental levels of dioxin and dioxin-like compounds.<sup>24,25</sup> Low levels of exposure during pregnancy also alter thyroid hormone levels in mothers and offspring, perhaps explaining neurological effects, including learning disabilities, that are seen in carefully conducted primate studies.<sup>26</sup>

It is of particular concern that the general population, through ordinary dietary exposures, carries a current body burden of dioxin that is near or above the levels that cause adverse effects in animal tests. Moreover, breast milk contamination is such that the nursing infant, during vulnerable periods of development, is exposed to dietary levels of dioxin as much as 60-100 times that of adult exposures. Nonetheless, breast feeding remains far superior to formula feeding for a variety of reasons, and reducing breast feeding is not the appropriate public health response to a contaminated food supply. Rather, all possible steps should be taken to reduce breast milk levels of this contaminant by eliminating releases of dioxin to the environment.

## SOLUTION:

### ESTABLISH AND IMPLEMENT A PVC REDUCTION PROGRAM

Reducing PVC use in hospitals will involve educating staff on the need for change, gathering data, planning, assessing alternatives, and changing procurement policy. Specific steps include:

- establish a PVC reduction policy,
- educate staff on the lifecycle hazards of PVC and the toxicity of DEHP,
- collect data on PVC use in the hospital through audits and letters to vendors,
- identify PVC-free and DEHP-free alternatives, and
- develop and implement a PVC reduction plan.

#### *Establish a PVC Reduction Policy*

An organization wide PVC reduction policy is an important step towards reduction because it reflects senior management's support for action, signals staff to take the issue seriously, and signals vendors to market PVC-free products. The Tenet Healthcare and Universal Health Services memoranda of understanding with shareholders on reducing PVC use offer examples of model PVC reduction policy language (see Appendices 2 and 3).

Tenet Healthcare, for example, agreed to: "investigate the availability and utility of PVC-free and phthalate-free disposable medical products available in the marketplace"; "seek information on a regular basis from its suppliers of disposable medical products concerning whether their products are PVC-free and phthalate-free"; and "request its suppliers of disposable medical

products to aid in the development of and further advancements in PVC-free and phthalate-free disposable medical products.”

### ***Educate Staff***

Educational programs raise staff awareness of the hazards associated with PVC and DEHP-containing products and establish the reasons why staff should be concerned with the use of these products. Workshops, grand rounds, and conferences are all appropriate forums for promoting awareness of the life cycle hazards of PVC and toxicity of DEHP.

### ***Collect Data***

Data collection through audits and letters to vendors is a critical step because reducing PVC requires knowledge of its use and availability of alternatives. Catholic Healthcare West, for example, requires its group purchasing organization (GPO) to identify products that contain PVC. The principal end uses for PVC products in a hospital are:

- disposable health care products,
- office supplies,
- durable medical products (such as testing and diagnostic equipment),
- construction products, and
- furniture products and furnishings (see Appendix 1 for specific products).

PVC products range from critical healthcare devices, such as disposable intravenous (IV) bags and tubing, to bedpans and notebook binders, as well as basic construction materials and furnishings, such as water pipes and wall coverings.

### ***Identify PVC- and DEHP-free Alternatives***

Disposable PVC health care products divide into five broad categories: bags, tubes, gloves, trays,<sup>27</sup> and catheters. Bags (42.5%), tubes (43.0%), and gloves (12.5%) account for 98% of disposable PVC healthcare products.<sup>28</sup>

A rigid plastic by nature, manufacturers add DEHP to make PVC flexible. DEHP-free PVC medical devices contain alternative softening agents (plasticizers). Non-PVC plastics used in medical devices, such as silicone, polyethylene, or polypropylene, are inherently flexible and do not contain plasticizers. Thus potential risks from plasticizer leaching are avoided.

Citrates and trimellitates have been substituted for DEHP as plasticizers in PVC medical products. Both may leach from PVC, although at different rates, depending on the nature of the solution in the bag. Citrates are less hazardous than DEHP, as indicated by their use as a food additive. Much less is known about the safety/hazards of the trimellitates, though some research indicates that trimellitates leach less than DEHP.<sup>29,30</sup>

PVC bags package IV products, total parenteral nutrition (TPN) and enteral feeding formulas, and blood products (including packed red blood cells, fresh frozen plasma, and platelet rich plasma). PVC bags are also used to collect some bodily fluids. DEHP-containing PVC medical bags first became a matter of concern in the 1970s because of DEHP exposures from the use of blood and TPN bags. This concern led to the development of PVC-free platelet rich plasma bags, fresh frozen plasma bags, and TPN bags as well as a DEHP-free packed red blood cell bag.

Today, PVC-free bags are on the US market for all but one product, packed red blood cells. The PVC-free bags are cost- and technically-competitive with the PVC bags. For the packed red blood cells, a DEHP-free bag is on the market at a slightly higher cost than the PVC, DEHP bag. An unintended consequence of DEHP leaching from PVC bags is it acts as a preservative of red blood cells. DEHP extends the shelf-life of stored red blood cells by stabilizing the red blood cell membrane. The Food and Drug Administration does not regulate DEHP as an additive to red blood cells. The alternative plasticizer used in red blood cell bags is a citrate. Citrates, in fact, have a long history of use as a blood preservative. The shelf-life of blood in citrate-plasticized bags is similar to that of DEHP-plasticized bags.

PVC tubing conveys liquids — such as IV solutions and enteral formula — and gases — usually oxygen — to and from patients. PVC-free or DEHP-free tubing is on the US market for most medical applications. Silicone, polyethylene, and polyurethane are three alternative polymers frequently used in tubing applications. In most applications, at least one of these polymers can compete with PVC in terms of technical performance.

In fact, PVC tubing and catheters are actually poor technical performers in medical treatments that involve contact with human tissue longer than about three to

seven days. The leaching of DEHP not only exposes patients to the plasticizer, but also causes the product to become brittle and subject to cracking. For these reasons products like umbilical vessel catheters and gastrostomy tubes are no longer manufactured from PVC. Recent research suggests that significant levels of DEHP may leach out of nasogastric tubes within 24 hours. An analysis by researchers at Stockholm University of PVC nasogastric tubes used for 24 hours "showed that the section of the tube which had been inside the infant's stomach contained only half as much plasticiser as the rest of the tube. Since this discovery, the [Swedish County] council's medical board decided to substitute polyurethane tubes for the PVC ones."<sup>31</sup>

In terms of economic performance, PVC-free tubing generally costs more than PVC tubing. In the next few years, however, plastics industry analysts expect metal-locene polyolefins (polyethylene and polypropylene are polyolefins) to become cost-competitive with flexible PVC medical products.<sup>32</sup>

Alternatives for disposable **PVC gloves** are also readily available. PVC is used primarily in the manufacture of examination gloves and has little market share in the surgical glove market. Latex is the other dominant material used in the manufacture of examination gloves. However, concerns with latex allergies have led hospitals and manufacturers to consider gloves made of different materials. For example, when Kaiser Permanente decided to phase-out the use of latex gloves it searched for PVC-free gloves, ultimately settling on gloves made of nitrile. While these are more expensive than latex and PVC gloves, Kaiser received a cost-competitive bid due the size of its contract. Reflecting growing demand, a diversity of latex- and PVC-free gloves are on the market today, although costs are slightly higher.<sup>33</sup>

Given the availability of technically-competitive and often cost-competitive alternatives, and the hazards posed by DEHP, Lois Ember of Chemical & Engineering News concluded that:

"Balancing the slight harm to the vinyl chloride industry and the availability of cost-effective alternatives against studies — albeit ambiguous — that show potentially harmful health effects to humans dictates a prudent switch to non-PVC, DEHP-free alternatives."<sup>34</sup>

The environmental and human health advantages of most flexible, PVC-free medical devices are they do not contribute chlorine to incinerators and do not use plasticizers.<sup>35</sup> See Appendix 4 for a list of PVC- and DEHP-free health care products.

**PVC-free construction and furnishing products** are widely available and are often cost-competitive. For example, PVC-free mattress covers and shower curtains are widely available and are cost-competitive with the PVC products. During renovations and new building construction, hospitals should specify PVC-free products. Construction productions, furnishings, and furniture products account for approximately 75% of all PVC end uses (see the Paper on Green and Healthy Buildings).

### *Develop and Implement a PVC Reduction Plan*

A PVC reduction plan should include the following priorities:

1. first, target **disposable healthcare products**, especially within maternity departments, NICUs, and pediatrics, and **office supplies** for PVC elimination;
2. second, purchase **PVC-free furnishings, furniture products, and construction products** when purchasing new furniture, renovating existing departments, or constructing new wings or buildings; and
3. third, when buying new **durable medical products**, specify those that are PVC free.

These reduction priorities are based on the potential for patient exposure to DEHP, potential for the PVC product to be incinerated upon disposal, volume of PVC use, and availability of substitute products.

**Disposable PVC healthcare products** should be the first priority because of the potential for significant patient exposure to DEHP and because they may be incinerated at the end of their useful life. DEHP exposure is critical to consider, especially for fetuses, newborns, and toddlers who may be exposed to levels of DEHP known to cause harm in relevant animal models. Since DEHP is a reproductive and developmental toxicant, DEHP use in maternity departments, NICUs, and pediatrics is of particular concern. For maternity departments, NICUs, and pediatrics, healthcare providers may decide that eliminating DEHP exposures in their particularly vulnerable patients justifies the higher cost for polyethylene, polyurethane, or

silicone tubing. While purchasing DEHP-free PVC products is an option for reducing DEHP exposure, it should only be considered an interim solution because it does not address the life cycle impacts of PVC (see Appendix 5 for a discussion of DEHP reduction options).

**Office supplies** are another priority for elimination because they may be incinerated upon disposal, cost-competitive alternatives are widely available, and hospitals usually can replace them easily under existing contracts.

**PVC furnishings, furniture products, and construction products** should be eliminated from new purchases, building renovations, and new building construction. For most of these products, cost-competitive, PVC-free alternatives are widely available<sup>36</sup> (for more details, see the paper on Green and Healthy Buildings).

**Durable medical products** pose the greatest challenge to reduction due to the lack of knowledge of their PVC content and availability of PVC-free devices. The primary use for PVC in durable medical products is as the housing — the rigid, outer plastic covering — for testing and diagnostic equipment. Since durable medical products have a longer use life than disposable medical products (such as IV bags) and result in little DEHP exposure, they are a secondary target for reduction. A first step in reducing PVC use in these applications would be to require vendors to disclose the PVC content in their equipment.

## **BARRIERS TO PVC REDUCTION**

The primary obstacles to reducing PVC use are:

- lack of knowledge of PVC lifecycle hazards, hospital use of PVC, and the availability of PVC-free products;
- the “grandfathering” of medical products on the market prior to 1976;
- contracts, multi-year, single buyer, and bundled;
- limited number of PVC-free vendors;
- costs of transition and alternatives; and
- market opposition to change.

### ***Lack of Knowledge***

Most hospital staff are unfamiliar with the life cycle hazards of PVC, the extent to which they use PVC and

DEHP-containing products, and the availability of those that are PVC-free, limiting demand for alternatives. In Europe, where awareness of the life cycle hazards of PVC is greater than in the US, demand for PVC-free products is greater.

### ***The “Grandfather” Clause***<sup>37</sup>

Marketing a new medical device requires approval of the Food and Drug Administration (FDA). However, a product that is “substantially equivalent” to devices marketed before May 28, 1976 avoids this strict regulatory scrutiny. The FDA does not require extensive testing of materials used to manufacture medical devices as long as the formulation does not substantially differ from that used prior to 1976. This procedure is not based on a scientific assessment of safety (testing). Rather, it is based on a Congressionally imposed presumption — as stated in section 510(k) of the Food, Drug and Cosmetics Act, as modified by the Medical Device Amendment of 1976 — that products and formulations on the market as of 1976 are presumed safe until proven unsafe. The burden is on the FDA to prove that such medical devices are unsafe before taking regulatory action.

Unfortunately, the law’s grandfathering provision has the effect of discouraging companies from innovating in product formulations. Under existing policies, manufacturers attempt to show that products are made of pre-1976 formulations, since any deviation from traditional product formulas requires more premarket testing and leads to more extensive FDA oversight. A product made of a new polymer would be required to undergo substantial premarket evaluation.

### ***Contracts***

To achieve lower per unit product costs, most hospitals purchase medical products through group purchasing organizations (GPOs). GPOs enjoy economies of scale because of large volume purchases, commit to buy for the long-term (up to eight years), and occasionally agree to “bundled” contracts.

Purchasing through GPOs, however, may reduce purchasing flexibility and create impediments to innovation. By locking into long-term contracts with one vendor, GPOs — and the hospitals they represent — cannot change to another vendor before a contract expires without incurring a significant monetary penalty. Long-term contracts block immediate access to vendors of PVC-free products. For example, of the

three US market leaders in IV products,<sup>38</sup> only B. Braun McGaw markets a PVC-free bag. If a hospital decides it wants to purchase a PVC-free IV bag (and all the accompanying IV products), and its GPO has a long-term contract with Abbott Laboratories or Baxter Healthcare, it cannot purchase the PVC-free IV bag without incurring a monetary penalty.

The industry-wide practice of bundling contracts — where a vendor reduces the price of one product line if a buyer purchases another product line — further ties the hands of purchasers. For example, by switching to a different IV product manufacturer, a buyer may incur greater costs for pharmaceutical products, resulting in a net increase in expenditures.<sup>39</sup> Thus bundling and long-term contracts impede innovation by creating market barriers to new products.

The options available to healthcare organizations locked into long-term contracts include clearly stating their desire for PVC-free products to both their GPO and current vendors and finding individual departments within the hospital where product change is possible, such as NICUs. When contracts expire, healthcare organizations need to voice their desire to GPOs that they want a) single source contracts with manufacturers of PVC-free products or dual source contracts that include a vendor of PVC-free products and b) a clause added to new contracts that allows them to switch to products with better environmental performance.

### *Limited Number of PVC-Free Vendors*

PVC-free products are on the US market in many product categories. However, the number of vendors of PVC-free products within each category may be limited. This is the case with both PVC-free IV bags (as noted above in the "Contracts" section) and PVC-free enteral feeding bags, where only one vendor sells the PVC-free product. The scarcity of vendors selling PVC-free products in the US is in sharp contrast to Europe. For example, at least seven corporations manufacture PVC-free IV bags in Europe,<sup>40</sup> whereas only one manufactures PVC-free IV bags in the US. At least four corporations manufacture PVC-free IV tubing in Europe, whereas none manufacture it in the US.

Corporations that sell in both the European and US markets often choose not to market PVC-free products in the US. Baxter International sells PVC-free IV bags in Europe, but not in the US.<sup>41</sup> B. Braun McGaw,

whose corporate parent (B. Braun) markets PVC-free IV tubing in Europe, does not sell PVC-free IV tubing in the US. Fresenius sells a PVC-free peritoneal dialysis system in Europe, but not in the US. The combination of limited numbers of PVC-free vendors and long-term contracts can limit opportunities for a hospital to purchase a PVC-free product in the US (without incurring a monetary penalty for breaking a contract).

### *Costs*

The potential monetary costs of product change come in two forms: transition costs for employees and potentially higher costs for alternative products. For some products, switching vendors requires training in the use of new equipment. The costs for some PVC-free products may be higher in the short-term but decline in the long-term, as costs of alternatives decrease with improved efficiency in production and through economies of scale.

### *Market Opposition*

Transitioning away from PVC products is made more difficult by the vocal opposition of vested economic interests and their allies. Manufacturers with direct economic interests in continued PVC use include DEHP manufacturers, manufacturers involved in any stage of PVC production, and medical device manufacturers. Trade associations that have expressed support for continued PVC and DEHP use in healthcare include the American Chemistry Council (trade association of the chemical industry), AdvaMed (trade association for medical device manufacturers), and the Vinyl Institute. Think tanks that have expressed support for continued PVC and DEHP use in healthcare include the American Council on Science and Health, Competitive Enterprise Institute, and Reason Public Policy Institute.

Any hospital or healthcare organization that publicly announces a PVC reduction program should expect a visit from a trade association such as the Vinyl Institute or a manufacturer of PVC medical products. The broad arguments against the transition away from PVC and DEHP products are: 1) PVC incineration does not correlate with dioxin emissions and 2) DEHP is safe for use in healthcare products.

PVC advocates rely on the report by Rigo, et al to support their conclusion that PVC combustion does not correlate with dioxin production. This report, as discussed in endnote, has serious methodological flaws.

Other data support a correlation between PVC combustion and dioxin emissions (see "PVC, Dioxin, and Health-Care Institutions" above for more details).

DEHP advocates rely on reports by the American Council on Science and Health (the "Koop Report"),<sup>42</sup> Competitive Enterprise Institute,<sup>43</sup> and Reason Public Policy Institute to support their claim that DEHP is safe for use in medical products.<sup>44</sup> These reports conclude, as succinctly stated in the Koop Report, that "DEHP in medical devices is not harmful to even highly exposed people" (p. 2). The basis for this conclusion, as Schettler revealed in a letter-to-the-editor of *Medscape*, is a selective review of the scientific literature.<sup>45</sup>

When all the scientific literature relevant to DEHP toxicity and exposure was evaluated by the independent Expert Panel on Phthalate Esters from the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction, conclusions that differed dramatically from the Koop Report were reached. As noted above in "Patient Health and Safety," the panel expressed "serious concern that exposure [to critically ill infants from medical devices] may adversely affect male reproductive tract development."<sup>46</sup>

## CONCLUSION

PVC products pose two potentially significant hazards to humans across their life cycle. First, the use of PVC products in medical treatments may result in patient exposure to DEHP, a reproductive and developmental toxicant. Concerns about other potential health effects remain unresolved. Second, the production of PVC and its disposal in incinerators contribute to the formation and emission of dioxins and furans, extremely toxic and potent environmental toxicants.

Health care providers can change the material composition of products and can reduce the use of PVC by demanding safer and cleaner products. The availability of PVC-free umbilical vessel catheters, TPN bags, platelet rich plasma bags, and fresh frozen plasma bags, and DEHP-free packed red blood cell bags are all examples of how the market shifted when health care providers voiced concerns in the 1970s. The medical product market is shifting once again, especially in Europe where PVC-free bags and tubing are widely available. Some manufacturers have chosen to market PVC-free products in Europe, yet continue to sell the

PVC products in the US. The US market shows signs of incremental change, as indicated by Baxter's decision to market PVC-free IV bags in the near future. However, without a clear signal from health care providers that they want PVC-free products, manufacturers will continue to delay the introduction of these products in the US.

## RESOURCES

**European Commission. 2000.** Green Paper on Environmental Issues of PVC.

Webpage: <http://www.europa.eu.int/comm/environment/pvc/index.htm>

**European Commission. 2000.**

Five PVC studies:

1. The Influence of PVC on the Quantity and Hazardousness of Flue Gas Residues from Incineration
2. Economic Evaluation of PVC Waste Management
3. The Behaviour of PVC in Landfill
4. Chemical Recycling of Plastics Waste (PVC and Other Resins)
5. Mechanical Recycling of PVC Wastes

Webpage: [http://www.europa.eu.int/comm/environment/waste/facts\\_en.htm](http://www.europa.eu.int/comm/environment/waste/facts_en.htm)

National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction (CERHR). 2000. NTP CERHR Expert Panel Report on Di (2-ethylhexyl) Phthalate. Webpage: <http://cerhr.niehs.nih.gov/news/index.html>.

Rossi, Mark. 2000. Neonatal Exposure to DEHP and Opportunities for Prevention. Falls Church, VA: Health Care Without Harm. Webpage: <http://www.noharm.org>.

Schettler, Ted. 1999. "Do We Have a Right to Higher Standards? C. Everett Koop, MD and an ACSH panel review the toxicity and metabolism of DEHP." Webpage: <http://www.noharm.org>.

Tickner, Joel, et al. 1999. The Use of Di-2-Ethylhexyl Phthalate in PVC Medical Devices: Exposure, Toxicity, and Alternatives. Lowell: Lowell Center for Sustainable Production, University of Massachusetts Lowell. Webpage: <http://www.noharm.org>.

University of Massachusetts Lowell, Sustainable Hospitals Project. 2000. "Alternative Products." Webpage: <http://www.sustainablehospitals.com>.

US EPA. 2000. Draft Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. Webpage: <http://www.epa.gov/ncea/pdfs/dioxin/part1and2.htm>.

## ABOUT THE AUTHORS

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## ENDNOTES

1. European Commission. *Green Paper on Environmental Issues of PVC* (COM (2000)469). Brussels: European Commission, 2000.
2. Schlechter, M. *Plastics for Medical Devices: What's Ahead?* Norwalk, CT: Business Communications Company, Inc., 1996.
3. Many different plasticizers are used to make PVC flexible. Phthalates are the most common, accounting for 75% of PVC plasticizer use in the U.S. DEHP is the only phthalate plasticizer used in medical products in the U.S. It is also the most widely used PVC plasticizer in the world.
4. Huber, WW, et al. Hepatocarcinogenic potential of di(2-ethylhexyl)phthalate in rodents and its implications on human risk. *Critical Reviews in Toxicology*, 26(4): 365-481, 1996.
5. Loff S, Kabs F, Witt K, et al. Polyvinylchloride infusion lines expose infants to large amounts of toxic plasticizers. *J Pediatr Surg* 35:1775-1781, 2000.
6. See the National Toxicology Program's webpage: <http://cerhr.niehs.nih.gov/news/index.html>.
7. Loff S, Kabs F, Witt K, et al. Polyvinylchloride infusion lines expose infants to large amounts of toxic plasticizers. *J Pediatr Surg* 35:1775-1781, 2000.
8. Latini G, Avery G. Materials degradation in endotracheal tubes: a potential contributor to bronchopulmonary dysplasia. *Acta Pediatr* 88(10):1174-1175, 1999.
9. Rossi, M. *Neonatal Exposure to DEHP and Opportunities for Prevention* (Falls Church, VA: HCWH), 2000.
10. See US EPA, Report #: EPA/600/P-00/001Ab, March 2000
11. The EPA developed a three-part confidence rating scheme: "high" means the estimate is derived from a comprehensive survey; "medium" is based on estimates of average activity and number of facilities or a limited survey; and "low" is based on data judged possibly non-representative.
12. Since the toxicity of the various congeners of dioxins and furans varies, the toxicity of a given mixture of congeners is usually expressed as TEQs, where the most toxic form is assigned a value of one and the relative contribution of others is calculated accordingly.
13. Dioxins/furans form most readily in commercial incinerators as the combustion gases reach cooler temperatures, primarily in the range 200-450°C.
14. Lemieux PM. Evaluation of emissions from the open burning of household waste in barrels. US EPA. EPA/600/SR-97/134, 1998.
15. For example, see: Bruce, et al, The role of gas phase Cl<sub>2</sub> in the formation of PCDD/PCDF during waste combustion, *Waste Management*, 11: 97-102, 1991; Kanters, et al, Chlorine input and chlorophenol emission in the lab-scale combustion of municipal solid waste, *Environmental Science and Technology*, 30: 2121-2126, 1996; and Wagner and Green, Correlation of chlorinated organic compound emissions from incineration with chlorinated organic input, *Chemosphere*, 26: 2039-2054, 1993.
16. In 1995, the Vinyl Institute commissioned a report, prepared for the American Society of Mechanical Engineers, that purported to examine the relationship between PVC in incinerator waste feed and dioxin emissions (Rigo HG, Chandler JA, Lanier WS, *The relationship between chlorine in waste streams and dioxin emissions from combustors*, The American Society of Mechanical Engineers, 1995). After examining data from dozens of burns in a number of municipal and medical waste incinerators, the report concludes that there is no statistically significant relationship between fuel chlorine content and dioxin emissions. The analysis, however, is flawed in a number of significant ways. First, there was no attempt to control for differences in incinerator design or operating conditions so that the question of interest could be addressed independent of other variables. Second, the authors used data collected for regulatory compliance purposes and not intended to examine the relationship between chlorine input and dioxin output. Without actually knowing the PVC content of the waste feed, they were forced to use hydrochloric acid emissions as a surrogate for chlorine loading. Hydrochloric acid emissions can be used to approximate chlorine loading but do not provide precise estimates. Moreover, in the tested incinerators, dioxin concentrations were sampled at various points in the exhaust stream - from boiler outlet to further downstream - predictably a source of variability, since dioxin can be formed at various points in the exhaust, depending on temperature and fly ash composition. This sampling strategy provides a poor estimate of total dioxin emissions to the air and ash. In summary, this analysis relies on data that are poorly suited to answer the question of interest. A more complete referenced discussion of the connection between PVC incineration and dioxin formation may be found in: Thornton J., *Pandora's Poison: Chlorine, Health, and a New Environmental Strategy* (Chapter 7), MIT Press: Cambridge MA, 2000.
17. The POPS Treaty negotiations arose over demands to eliminate global releases of persistent and bioaccumulative chemicals. For example in 1996, the International Experts Meeting on POPS recommended the "Virtual elimination from the environment of POPS that meet scientifically-based persistence, bioaccumulation, and toxicity criteria." Dioxins and furans are two of the twelve priority POPS.

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19. Steenland K, Piacitelli L, Deddens J, et al. Cancer, heart disease, and diabetes in workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin. *J Natl Cancer Inst* 91(9):779-786, 1999.
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26. Koopman-Esseboom C, Morse DC, Weisglas-Kuperus N, et al. Effects of dioxins and polychlorinated biphenyls on thyroid status of pregnant women and their infants. *Pediatr Res* 36(4):468-473, 1994.
27. Trays are used to package surgical instruments, kits for surgical procedures, medical diagnostic kits, and admission kits.
28. Schlechter, M. *Plastics for Medical Devices: What's Ahead?* Norwalk, CT: Business Communications Company, Inc., 1996.
29. Christensson A, Ljunggren L, Nilsson-Thorell C, Arge B, Dichl U, Hagstam KE, Lundberg M. In vivo comparative evaluation of hemodialysis tubing plasticized with DEHP and TEHTM. *Int J Artif Organs* 14(7):407-10, 1991.
30. Quinn MA, Clyne JH, Wolf MM, Cruickshank D, Cooper IA, McGrath KM, Morris J. Storage of platelet concentrates--an in vitro study of four types of plastic packs. *Pathology* 18(3):331-5, 1986.
31. The Federation of Swedish County Councils, *PVC in the Swedish Healthcare System*, Stockholm, 2000.
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35. A few PVC-free products do contain chlorine, including neoprene gloves, which are manufactured from polychloroprene.
36. Currently wire and cable coated with PVC is the most difficult of these products to replace.
37. The source for this section is: Health Care Without Harm, "Citizen Petition before the United States Food and Drug Administration," June 14, 1999 (Falls Church, VA: Health Care Without Harm).
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45. "For example, the panel notes that the target organ for reproductive toxicity in the rat appears to be the testis and that young animals seem to be more sensitive than older animals. Inexplicably, however, the authors then fail to cite a single, readily available study of the effects of DEHP exposure on fetal or neonatal testes. Unmentioned are at least 4 studies demonstrating the particular sensitivity of the immature developing testis to the toxicity of DEHP." Schettler T, "Letter in Response to ACSH Report on Plasticizers," Medscape ([www.medscape.com](http://www.medscape.com)), May 26, 2000.
46. Page 105.

**APPENDIX 1.**  
**POLYVINYL CHLORIDE (PVC) PRODUCTS IN HOSPITALS**

***Disposable Health Care Products***

**BLOOD PRODUCTS AND TRANSFUSIONS**

- apheresis circuits
- blood bags
- blood administration tubing
- extracorporeal membrane oxygenation circuits

**COLLECTION OF BODILY FLUIDS**

- dialysis, peritoneal: drainage bags
- urinary collection bags, urological catheters, and irrigation sets
- wound drainage systems: bags and tubes

**ENTERAL FEEDING PRODUCTS**

- enteral feeding sets (bags and tubing)
- nasogastric tubes, short-term use (usually for neonates)
- tubing for breast pumps

**GLOVES, EXAMINATION**

**INTRAVENOUS (IV) THERAPY PRODUCTS**

- catheters
- drip chambers
- solution bags
- total parenteral nutrition bags
- tubing

**KIDNEY (RENAL DISEASE) THERAPY PRODUCTS**

- hemodialysis: blood lines (tubing) and catheters
- peritoneal dialysis: dialysate containers (bags) and fill and drain lines (tubing)

**PACKAGING, MEDICAL PRODUCTS**

- film wrap
- thermoformed trays for admission and diagnostic kits, and medical devices

**PATIENT PRODUCTS**

- bed pans
- cold and heat packs and heating pads
- inflatable splints and injury support packs
- patient ID cards and bracelets
- sequential compression devices

***Disposable Health Care Products (continued)***

**RESPIRATORY THERAPY PRODUCTS**

- aerosol and oxygen masks, tents, and tubing
- endotracheal and tracheostomy tubes
- humidifiers, sterile water bags and tubing
- nasal cannulas and catheters
- resuscitator bags
- suction catheters
- ventilator breathing circuits

***Office Supplies***

- notebook binders
- plastic dividers in patient charts

***Durable Medical Products***

- testing and diagnostic equipment, including instrument housings

***Furniture Products and Furnishings***

- bed casters, rails, and wheels
- floor coverings
- furniture upholstery
- inflatable mattresses and pads
- mattress covers
- pillowcase covers
- shower curtains
- thermal blankets
- wallpaper
- window blinds and shades

***Construction Products***

- doors
- electrical wire sheathing
- pipes: water and vent
- roofing membranes
- windows

**APPENDIX 2.**  
**TENET HEALTHCARE CORPORATION, MEMORANDUM OF  
UNDERSTANDING WITH SHAREHOLDERS**

**LETTER AGREEMENT CONCERNING SHAREHOLDER PROPOSAL**

This Letter Agreement Concerning Shareholder Proposal is entered into as of July 22, 1999, among the Sisters of St. Francis, Medical Mission Sisters and SEIU Master Trust (collectively, the "Shareholders") and Tenet Healthcare Corporation (together with its subsidiaries, "Tenet"). As used herein, Tenet includes the operations of BuyPower, Tenet's group purchasing operation.

**RECITALS**

- A. Between April 30, 1999, and May 3, 1999, each of the Shareholders submitted an identical shareholder proposal (the "Shareholder Proposal") to Tenet requesting the Board of Directors of Tenet to adopt a policy of phasing out, at all of its health care facilities, the use of polyvinyl chloride ("PVC")-containing or phthalate-containing medical products, where alternatives are available.
- B. Tenet is committed to conducting its business in a socially responsible and ethical manner that protects the safety of its patients and employees as well as the environment. Tenet recognizes that PVC plastic, a component of various medical products, may result in damage to the environment.

**AGREEMENT**

1. Tenet hereby agrees to investigate the availability and utility of PVC-free and phthalate-free disposable medical products available in the marketplace and periodically will review the state of the availability and utility of alternative products as technological advances result in the production of disposable medical products that do not contain PVC or phthalates. Tenet agrees to ask its top 25 suppliers about the availability of new medical products that do not contain PVC or phthalates at least twice a year and to report back the Shareholders at least twice a year on the results of Tenet's inquiry.
2. Tenet will develop an environmentally preferential purchasing policy for PVC-free and phthalate-free disposable medical products and utilize such products to the extent they are of a high quality, are of the same or better functionality as the products being replaced and are readily and reliably available at a reasonable price. Tenet further agrees to notify its vendors concerning its policy. Notwithstanding the foregoing, however, although Tenet will use its reasonable efforts to amend its supply contracts to allow Tenet to use alternative products that meet the above criteria, Tenet shall not be required to use alternative products if doing so violates the terms of such contracts. To the extent possible on commercially reasonable terms, Tenet will use its reasonable efforts to include in its future purchasing contracts a clause allowing Tenet to cease purchasing medical products containing PVC or phthalates under such contracts if there become readily and reliably available at a reasonable price alternative PVC-free and phthalate-free disposable medical products that are of the same or better functionality as the products being replaced.
3. Tenet will seek information on a regular basis from its suppliers of disposable medical products concerning whether their products are PVC-free and phthalate-free and concerning the availability of alternative products.
4. Tenet will request its suppliers of disposable medical products to aid in the development of and further advancements in PVC-free and phthalate-free disposable medical products.

## LETTER AGREEMENT CONCERNING SHAREHOLDER PROPOSAL

This Letter Agreement Concerning Shareholder Proposal is entered into as of July 22, 1999, among the Sisters of St. Francis, Medical Mission Sisters and SEIU Master Trust (collectively, the "Shareholders") and Tenet Healthcare Corporation (together with its subsidiaries, "Tenet"). As used herein, Tenet includes the operations of BuyPower, Tenet's group purchasing operation.

### RECITALS

- A. Between April 30, 1999, and May 3, 1999, each of the Shareholders submitted an identical shareholder proposal (the "Shareholder Proposal") to Tenet requesting the Board of Directors of Tenet to adopt a policy of phasing out, at all of its health care facilities, the use of polyvinyl chloride ("PVC")-containing or phthalate-containing medical products, where alternatives are available.
- B. Tenet is committed to conducting its business in a socially responsible and ethical manner that protects the safety of its patients and employees as well as the environment. Tenet recognizes that PVC plastic, a component of various medical products, may result in damage to the environment.

### AGREEMENT

1. Tenet hereby agrees to investigate the availability and utility of PVC-free and phthalate-free disposable medical products available in the marketplace and periodically will review the state of the availability and utility of alternative products as technological advances result in the production of disposable medical products that do not contain PVC or phthalates. Tenet agrees to ask its top 25 suppliers about the availability of new medical products that do not contain PVC or phthalates at least twice a year and to report to back the Shareholders at least twice a year on the results of Tenet's inquiry.
2. Tenet will develop an environmentally preferential purchasing policy for PVC-free and phthalate-free disposable medical products and utilize such products to the extent they are of a high quality, are of the same or better functionality as the products being replaced and are readily and reliably available at a reasonable price. Tenet further agrees to notify its vendors concerning its policy. Notwithstanding the foregoing, however, although Tenet will use its reasonable efforts to amend its supply contracts to allow Tenet to use alternative products that meet the above criteria, Tenet shall not be required to use alternative products if doing so violates the terms of such contracts. To the extent possible on commercially reasonable terms, Tenet will use its reasonable efforts to include in its future purchasing contracts a clause allowing Tenet to cease purchasing medical products containing PVC or phthalates under such contracts if there become readily and reliably available at a reasonable price alternative PVC-free and phthalate-free disposable medical products that are of the same or better functionality as the products being replaced.
3. Tenet will seek information on a regular basis from its suppliers of disposable medical products concerning whether their products are PVC-free and phthalate-free and concerning the availability of alternative products.
4. Tenet will request its suppliers of disposable medical products to aid in the development of and further advancements in PVC-free and phthalate-free disposable medical products.
5. A representative or representatives of Tenet will be happy to meet with a representative or representatives of the Shareholders by no later than January 31, 2000, at a mutually convenient time and place, to discuss Tenet's progress in achieving the goals set out in this Agreement and to further address the concerns expressed by the Shareholder Proposal.
6. In light of the terms of this Agreement, each of the Shareholders hereby withdraws its request that Tenet

**APPENDIX 3.**  
**UNIVERSAL HEALTH SERVICES,**  
**MEMORANDUM OF UNDERSTANDING WITH SHAREHOLDERS**

Universal Health Services ("UHS") is committed to conducting its business in a socially responsible and ethical manner, which protects patient and employee safety and the environment. UHS recognizes that polyvinyl chloride ("PVC") plastic, a component in various medical products, may result in damage to the environment. In light of these factors and in conjunction with a proposed shareholder resolution filed with the Company on December 21, 1998, UHS plans to investigate the utilization of PVC-containing items in their operations through the following measures:

- 1) The Company will investigate the availability and utility of PVC-free products available in the marketplace and will periodically continue its investigation as technological advances provide cost effective and high quality products. To aid in this process, Health Care Without Harm will provide UHS a list of items potentially containing PVC. Utilizing this information, the company will review its current supplies and request PVC-free alternatives from its suppliers, where appropriate.
- 2) To the extent that it is consistent with high quality and cost effective health care delivery, UHS will continue to explore the use of PVC-free products and utilize such products to the extent they are available. UHS agrees to formally request PVC-free alternatives from its suppliers to aid in the development of further advancements in PVC-free products.
- 3) The Company agrees to meet with representatives of the filing shareholders and Health Care Without Harm prior to June 30, 1999 in order to establish the timetable and benchmarks for the items listed above. UHS agrees to meet with the filing shareholders and other mutually agreed upon parties prior to October 31, 1999 to assess the Company's progress.

The Company and the filing shareholders agree to announce this agreement through a mutually agreed upon joint press release to be distributed on May 19, 1999 in conjunction with the UHS Annual Meeting. The Company's willingness to enter into this agreement furnishes the filing shareholders the sufficient evidence of goodwill on the Company's behalf to allow the removal of the shareholder resolution from the Company's proxy for the upcoming Annual Meeting. The filing shareholders hereby withdraw the shareholder resolution from the company's proxy.

UNIVERSAL HEALTH SERVICES, INC.

CITIZENS FUNDS  
On Behalf of Filing Shareholders

By: \_\_\_\_\_  
Name: Kirk E. Gorman  
Title: Senior Vice President, Chief Financial  
Officer and Treasure  
Date: April 19, 1999

By: \_\_\_\_\_  
Name: Samuel Pierce  
Title: Senior Social Research Analyst  
Date: April 19, 1999

**APPENDIX 4.  
PVC- AND DEHP-FREE DISPOSABLE HEALTH CARE PRODUCTS**

PRODUCTS	PVC-FREE PRODUCTS	DEHP-FREE PRODUCTS
<b>Blood Products, Transfusions, and Extracorporeal Membrane Oxygenation (ECMO)</b>		
Apheresis Circuit		Citrate-plasticized circuit: Cobe
ECMO Circuit		None on the market, although the Cobe apheresis circuit is technically equivalent
Fresh Frozen Plasma and Platelet Bags	PO bag: Baxter Healthcare	
Packed Red Blood Cell Bag		Citrate-plasticized bag: Baxter Healthcare
<b>Collection of Bodily Fluids</b>		
Drainage Bags	PO bag: Dow Chemical Corp. (manufacturers films for use with drainage bags)	
<b>Dialysis Products</b>		
Hemodialysis, Blood Circuits		None on the market, although the Cobe apheresis circuit is technically equivalent
Peritoneal Dialysis, Bags and Tubing	Europe: PVC-free bags & tubing, Fresenius & B.Braun Japan: PVC-free bags, Terumo	
<b>Enteral Feeding Products</b>		
Enteral Feeding Set: Bags	Nylon, EVA, PE laminate bag: Corpak MedSystems	Kendall Healthcare
Enteral Feeding Set: Tubes	Similar product: indwell tubes made from PUR or silicone, many manufacturers	Corpak and Kendall Healthcare
Nasogastric Tubes (for 3 days or less)		
<b>Gloves</b>		
Examination Gloves	Nitrile or other polymers: many manufacturers	
<b>Intravenous (IV) Products</b>		
IV Bags	PP/PE copolymer, polyester, elastomer laminate bag: B. Braun McGaw	
IV Tubing	Europe: EVA or PO, many manufacturers	Budget Medical Products
Total Parenteral Nutrition	EVA bag: Baxter Healthcare	
<b>Packaging, Medical Devices</b>		
Trays for Admission and Diagnostic Kits, and Surgery	Acrylic, polycarbonate, polyester, polystyrene, steel: many manufacturers.	
<b>Respiratory Therapy Products</b>		
Endotracheal and Tracheostomy Tubes	Reusable tubes: many manufacturers; Silicone tube: Biovana Medical Technologies	
Oxygen Masks	Polyester mask: Vital Signs	

Abbreviations: DEHP = di-2-ethylhexyl phthalate; EVA = ethylene vinyl acetate; PE = polyethylene; PO = polyolefin; PP = polypropylene; PUR = polyurethane; and PVC = polyvinyl chloride. Blank cell: no PVC-free or DEHP-free alternative product identified. Sources: The Federation of Swedish County Councils, PVC in the Swedish Healthcare System, 2000; Rossi, Neonatal Exposure to DEHP and Opportunities for Prevention, 2000; Rossi and Muehlberger, Neonatal Exposure to DEHP and Opportunities for Prevention in Europe, 2000; Sustainable Hospitals Project, www.sustainablehospitals.org.

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## APPENDIX 5. DEHP REDUCTION OPTIONS

There are three routes for healthcare facilities to reduce or eliminate DEHP exposure from medical treatments. First, purchase a PVC-free product. Second, purchase a DEHP-free product. Third, purchase a DEHP-plasticized PVC product coated with an alternative substance to reduce DEHP leaching or off-gassing. Purchasing a PVC-free product practically ensures the product is DEHP-free because the alternative polymers — ethylene vinyl acetate, polyethylene, polypropylene, polyurethane, and silicone — do not require plasticizers for flexibility. In addition, PVC-free products avoid the life cycle hazards of PVC, including the use of a known carcinogen in the manufacturing process, vinyl chloride monomer, and the downstream formation of dioxin when vinyl is burned in a medical waste incinerator.

Using a PVC product plasticized with citrates or trimellitates, the primary alternative plasticizers to DEHP in medical products, reduces DEHP exposure but does not address the life cycle hazards of PVC. One option for reducing DEHP exposures is to use DEHP-plasticized PVC products coated with a thin layer of another material that prevents or reduce DEHP leaching. For example, PVC tubing bonded with heparin leaches less DEHP during ECMO than unbonded tubing.<sup>1</sup> While preferable to non-coated DEHP-plasticized vinyl, DEHP-coated products do not address off-gassing nor do they address the life cycle hazards of PVC.

1. Karle V, Short B, Martin G, et al. Extracorporeal membrane oxygenation exposes infants to the plasticizer, di(2-ethylhexyl)phthalate. *Crit Care Med* 25(4):696-703, 1997.