As we saw last week, the chlorine industry needs to expand the production of polyvinyl chloride plastic (PVC, or “vinyl”) to maintain the profitability of chlorine production. As other high-volume chlorinated chemicals (such as pesticidal DDT and ozone-depleting CFCs) are phased out because they are toxic, long-lived and dangerous to living things, the chlorine industry hopes to expand the uses of PVC plastic as a profitable “sink” for surplus chlorine.

However, there is mounting pressure to phase out PVC itself because it is a bad actor in at least two major ways: (1) burning PVC in building fires, or in waste incinerators, releases dioxin, one of the most toxic chemicals ever identified, and (2) soft PVC products are made soft by the addition of phthalates (pronounced “thalates”), a class of toxic chemicals that causes a variety of health problems in laboratory animals. (See REHW #603, #661.)

The current concern about soft PVC products is their use in medical supplies and equipment. Approximately 25% of medical plastics are made from soft, phthalate-containing PVC, including intravenous (IV) bags, blood bags, tubing, gloves, and catheters. Phthalates can leach out of the plastic into fluids that end up in patients. As a result, many patients are exposed to levels of phthalates that have been shown to cause health problems in monkeys and other animals.

A large coalition of health care advocates, called Health Care Without Harm (HCWH) is asking hospitals, physicians, and nurses to apply the principle of precautionary action to medical uses of soft PVC products.

The precautionary principle says, (1) people have a duty to take anticipatory action to prevent harm; and (2) the burden of proof of harmlessness of a chemical lies with the proponents, not with the general public; and (3) people using a particular toxic chemical have an obligation to examine a full range of alternatives.

To apply the precautionary principle to medical uses of soft PVC, the debate cannot focus on how much exposure to phthalates is safe (which is a “risk assessment” question). Instead, the debate must center on finding safer substitutes.

Safer substitutes would include those that do not leach toxicants and do not create dioxin when burned. Comparative risk assessment can make a useful contribution to identifying preferable substitutes.

A careful examination of alternatives is precisely what the chlorine industry seeks to avoid. Their primary strategy has been to bog down the debate in interpretations of the toxicological evidence -- the “dueling risk assessments” strategy invented long ago by the tobacco industry.

The main front group for this strategy has been Elizabeth Whelan’s American Council on Science and Health (ACSH). ACSH receives 76% of its funding from industry sources, including Exxon, the largest phthalate manufacturer in the world.[1]

ACSH hired Dr. C. Everett Koop, Ronald Reagan’s Surgeon General, to spearhead ACSH’s “blue ribbon” panel of 17 “experts,” most of whom have ties to the chemical industry, examining PVC safety. Koop and ACSH concluded that vinyl toys and medical devices are not harmful.

In its extensive critique of Koop’s study, Health Care Without Harm pointed out that ACSH only weighed the risks and benefits of medical products made flexible with DEHP (a toxic phthalate -- see REHW #661), while ignoring the available alternatives -- cost-competitive non-PVC products that are perfectly good substitutes. For instance, Koop said, “removing the phthalate [from the PVC product] would actually pose a significant health risk to individuals who depend on these devices [IV bags].” Koop ignored the fact that an FDA-approved phthalate-free IV bag produced by McGaw already has about 20% of the IV bag market.[2]

With safer alternatives available, how can anyone justify exposing patients to a chemical of dubious safety like DEHP, which the U.S. Environmental Protection Agency [EPA] classifies as a probable human carcinogen?

In a recent study, the Center for Sustainable Production at the University of Massachusetts Lowell found readily available alternatives for most PVC medical equipment: “A review of the literature, coupled with supplier interviews, suggests that PVC alternatives are widely available for use in most medical devices and can be cost-competitive. Several U.S. and European medical device manufacturers already have developed government approved PVC-free alternatives for IV bags, tubing, and platelet storage, some of which command a substantial share of their product market.”[3]

Under the precautionary principle, the onus is on medical device manufacturers to use the safest alternatives. Baxter Healthcare recently signed a Memorandum of Understanding with shareholders who had filed a resolution asking the company to phase out PVC.[4] According to the Memo, Baxter is “committed to exploring and developing alternatives to PVC products and to developing and implementing proposed timetables for substituting its current containers for intravenous (“IV”) solutions with a container that does not contain PVC... In the future, Baxter will update the shareholders on the steps to be taken towards replacing its global line of PVC-containing products other than IV containers with non-PVC alternatives.”[5] As indicated above, the transition away from PVC will occur more rapidly with some medical products than others.[5] Baxter has already eliminated PVC in applications such as blister packaging and drip chambers. The company began to produce non-PVC IV bags as early as 1975, when it introduced a PVC-free platelet container. Soon a polyolefin (PVC-free) bag was developed for use with antibiotic formulations.[6] The search for alternatives appears to have accelerated recently, most likely due to PVC-free market pressures. In 1997, Baxter acquired Bieffe, a European manufacturer of PVC-free IV bags.

Although Baxter is seeking alternatives to PVC, it continues to defend the material. K.Z. Hong, Baxter’s technical director, says PVC “has more than 40 years of safe and effective clinical use working in its favor.” If that is true, then why did Senate Majority Leader Trent Lott in 1998 try to re-write product liability laws to exempt Baxter from lawsuits? The WASHINGTON POST reported that the “last-minute Baxter exemption” would have protected the company from “lawsuits that consumers could bring against makers of defective and dangerous products.” Baxter spokeswoman Deborah Spak told the POST the company had been seeking an exemption for IV bags for more than a year, because “some of our suppliers had indicated they had concerns about continuing to supply us” if they were not exempted from lawsuits.[7] As Baxter has acknowledged, “in the past 35 years approximately 5 billion patients have experienced exposure to DEHP in the one-to-ten milligram per day range for one to ten days per year. An additional 3 million patient years of chronic exposure at 5 milligrams per day, for one to ten years per patient, have also been accumulated.”[8]

No one is suggesting that essential medical devices be yanked out of patients’ arms before safer alternatives are available, which is why the shareholders asked Baxter to produce timetables for the elimination of PVC from its products.

Health and environmental considerations are generating competitive pressures within the chemical and plastics industry which will likely lead to a broader phase-out of PVC. Exxon is already phasing out its North American PVC business and investing in new-generation metalloocene polyolefins -- the polymer expected to substitute for flexible, phthalate-containing PVC in a variety of applications. As PLASTICS NEWS recently reported from Flexpo 99, the annual flexible polymers conference, “designer, cost-competitive specialty PVC-free device polymers are beginning to challenge PVC in medical, film and sheet, wire and cable, roofing membranes and other markets. As one industry official put it, “As polymer scientists, we may feel these...
While the medical device debate is important, the vast majority of phthalates -- the most widespread pollutants on the planet -- are used in other applications, including many building materials. (See REHW #603.) In order to solve the many environmental problems posed by PVC (including the spread of dioxin, phthalates and other additives) governments must develop broad-based materials policies to aid (and, if necessary, force) businesses to develop and select safer alternatives. (Without governments to establish a level playing field, corporations that cut corners on environmental values gain an unfair advantage in the marketplace, inducing competitors to cut the same corners.)

In Europe, specific materials policies against flexible PVC are beginning to emerge. For instance, in late June, a sustainability report by the German Federal Environmental Agency (UBA) recommended the phase-out of soft PVC.[10] This followed a recent proposal by the Danish Government to restrict and tax the use of PVC. In addition, the UK Department of Environment, Transport and the Regions recently published a buyers' and suppliers' guide, which advises against the use of PVC. The second environmental assessment report by the European Environmental Agency (EEA) lists various problems with PVC.[11]

During the past year, several large companies such as Nike have pledged to phase out PVC. Others include Visa International (which issues 580 million plastic credit cards each year),[12] Firestone (one of the nation's largest manufacturers of roofing products)[13] and large communications firms such as German Telekom and Nippon Telegraph and Telephone.

If we can get people better materials for sneakers and credit cards, shouldn't doctors and nurses be able to provide their patients with the safest materials available?

The question of what to do in the face of uncertainty regarding harm from toxic exposures cannot be solved by science alone. It also requires ethical motivation and common sense.

--by Charlie Cray


