POISONOUS PROPAGANDA

GLOBAL ECHOES OF AN ANTI-VINYL AGENDA

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INTRODUCTION

Three Greenpeace campaigners were freed from a Japanese jail on March 29, 1999. They had been arrested 11 days earlier for rappelling down the side of a building at the Tokyo Toy Fair to unfurl a banner that read "Play Safe, Buy PVC Free."[1] This action repeated a stunt played out the previous year at the opening of the International Toy Fair in New York. It became just the latest high-profile twist in a two-year attack on chlorine and chlorine-based products by environmental and activist groups opposed to chemicals called phthalates. Phthalates are liquid organic compounds added to hard polyvinyl chloride (PVC), plastics commonly known as vinyl, to act as softeners or "plasticizers." These substances make the compound more malleable and hence more versatile. Due to their low cost and excellent performance characteristics—including the flexibility they impart to PVC plastics—phthalates are found in a wide range of products. They are used for medical devices, particularly fluid containers, tubing, and gloves; children's toys such as teethers, rattles, and rubber ducks; and household and industrial items such as wire and cable coating, flooring, and clothing. The vast majority of phthalates are used in the production of flexible PVC.

Despite significant scientific evidence to the contrary, activists claim that phthalates are responsible for numerous adverse health effects, including cancer and damage to the human reproductive system. Governments, the media, and retailers have taken these claims seriously. Coordinated and well-crafted stunts and press releases, often promoting unpublished scientific papers, have enabled the campaigners to play all the major interested parties against one another. As a consequence, reams of scientific and statistical documents have been commissioned and produced in evidence, raising concerns and unnecessarily exacerbating fears among consumers.

Yet phthalates have been in widespread use for almost 50 years, and have had particularly close scrutiny and attention paid to them over the last 25. Regardless of the quality of the evidence in their favor, partly because phthalates are used in children's products—particularly for things that children place in their mouths such as teethers—the campaign against them has proven quite powerful. As a direct result of the crusade, several formal and informal bans are being implemented around the world.

That such a frenzy could have been stirred up around phthalates, which from a health and environmental viewpoint must qualify as among the most studied and understood families of compounds, should serve as a dire warning to those who benefit most from these substances—consumers.

This paper explains how a Greenpeace-backed group called Health Care Without Harm (HCWH) has lobbied for the removal of soft-PVC medical devices from hospitals where they perform vital, life-saving functions. Despite billions of patient days of acute and chronic exposure to such products, healthcare suppliers have been put on the defensive. Alternative products, which are inevitably less well-documented and understood, will also be more scrutinized. In this the inevitable logic of the "precautionary" approach has already come to the fore: the fear of phthalates will simply be transferred onto their proposed solution.[2]

THE PRECAUTIONARY PRINCIPLE

Greenpeace's recent campaign against PVC plastics is nothing new. It's one of the many campaigns that environmentalists pursue based on the precautionary principle. This principle holds that lawmakers and others should act to reduce potential risks even when they lack evidence that such risks actually exist and are significant. It departs from the usual scientific rationale in that it reverses the burden of proof. Science proceeds on the basis of evidence, which is a positive finding that is reproducible. The precautionary principle, on the other hand, postulates that all negative assumptions can be considered valid unless the contrary has been proven. This negative proof is impossible to ascertain. The precautionary principle thus contributes to the deconstruction of the process leading to scientific opinion, since it distances conclusions from evidence-based rationale. It further considers that valid decisions can be made on beliefs without requiring solid evidence.

Application of the precautionary principle is becoming widespread. An international agreement on the precautionary principle was reached during the United Nations Conference on the Environment and Development in Rio de Janeiro in 1992, becoming part of Agenda 21. This is laid down for environmental matters within the European Community (EC) in the Maastricht Treaty under Article 130r.[3] Recently, members of the European Commission, the executive body of the European Community, argued for the principle to be extended into the realm of food law.[4]

This paper demonstrates the dangers of blindly following the precautionary principle. The principle is subject to considerable debate, particularly in relation to the tension between demonstrated actual risk and anticipated plausible risk, as well as the problems associated with enforcing what are inevitably variable standards.[5] A further problem of using the precautionary principle is that all results inevitably become provisional.[6] Targets are relative, and no conclusive outcomes can ever be reached, as situations

continuously await clarification through further analysis. In this respect, the investigations into phthalate toxicity have been perfect examples.

Such an approach has also inevitably encouraged the release and use of results before peer-reviewed publication. In addition, frank and open discussions held by interested parties are increasingly entering the public domain through a desire for greater "transparency." But the views expressed through both of these means are not the same as reasoned reflection or verified evidence, and should therefore not be used in the establishment of policy.[7] Of more direct concern to the main subject of this paper has been the fact that some supposed research into the endocrine-disrupting properties of phthalates was released through the media, rather than the academic literature.[8] Indeed, in one such high-profile instance, a full peer-reviewed version of the work has still failed to appear over two years after raising significant concerns through articles in the popular press,[9] despite assurances that the work "is still in the phase of being written up."[10]

Phthalates are among the most studied of organic compounds. There is not validated evidence that they have ever harmed any human being.

Implicit within this approach, however, is the assumption that the precautionary principle is a zero-cost, or a something-for-nothing, option. In reality, apart from the narrow economic costs to those businesses directly concerned, there is a far greater social cost that has yet to be taken into account. At an immediate level, replacing plastic medical devices or toys opens the door to the dangers of injury and infection from replacement materials that are either less flexible or have been subject to less scrutiny. Phthalates are among the most studied of organic compounds. There is not validated evidence that they have ever harmed any human being.

More important has been the amount of time and effort, not to mention the cost, expended by all parties to this dispute. While the attention of large numbers in the scientific community and others has been turned onto these products, countless numbers of people continue dying of diseases for which cures might be found if only the resources expended elsewhere were made available.

Finally, the panic and hysteria that have been created around these issues reflect a far wider loss of trust within society rather than any inherent problem with the products themselves. The real cost will be that of a generation of young people brought up to live in fear of the dangers posed by harmless products, and questioning the ability of science to cast light on such issues. A broader climate of fear is being created which in turn will lead many to an even more misguided assessment of risk and greater inflexibility towards innovation and change.

THE PHTHALATES CAMPAIGN

Polyvinyl chloride (PVC) is a rigid material that can be softened by the addition of plasticizers. These compounds generally have a high boiling

point and, when incorporated into polymers, cause a greater workability of the material by increasing the flexibility of the individual polymer chains. The most commonly used compounds for this purpose are esters of o-phthalic acid, which are more generally known as phthalate esters or simply phthalates**.** Several of these are used as plasticizers in PVC.

Name	Acronym	R[11]
Dibutyl phthalate	**DBP**	**n-C_4H_9**
Dipentyl phthalate[12]	**DPP**	**n-C_5H_{11}**
Butylbenzyl phthalate	**BBP**	**n-C_4H_9 and -C_6H_5**
Di(2-ethylhexyl) phthalate	**DEHP**	**-$C_2H_4(C_2H_5)C_4H_9$**
Di-iso-octyl phthalate	**DIOP**	**-C_8H_{17}**
Di-n-octyl phthalate[13]	**DNOP**	**n-C_8H_{17}**
Di-iso-nonyl phthalate	**DINP**	**-C_9H_{19}**
Di-iso-decyl phthalate	**DIDP**	**-$C_{10}H_{21}$**

Phthalates have been in widespread use for approximately 50 years and have been extensively tested.[14] Due to their low cost and the flexibility they impart to PVC, they are found in products as common and diverse as medical devices such as fluid containers, tubing, and gloves; children's toys including teethers, rattles, and rubber ducks; and household and industrial items such as wire and cable coating, flooring, and clothing.

As a result of their diverse and widespread use and relative resistance to degradation, phthalates are frequently found in the environment.[15] Yet compared to many other commonly used products, such as solvents, they can readily be removed by photochemical, oxidative, and biological processes.[16] They also break down in low-oxygen environments such as sediment, but at a lower rate,[17] and levels in natural waters are reported to be decreasing.[18]

The quantity of phthalate plasticizer added to a PVC product can be determined by measuring weight loss after diethyl ether extraction. For example, at the Laboratory of the UK Government Chemist, over 100 plastic teethers and toys have been assessed for plasticizer content. In these and other investigations, including those of Greenpeace using chromatographic methods, losses of up to 50 percent are fairly common with DEHP, DINP, and DIDP identified as major components. DNOP is not produced on a commercial scale and is difficult to detect in the presence of the multi-component product DINP. DBP and BBP are usually found at levels below 1 percent in toys and are taken to arise as impurities or by-products not intentionally added. However, while it is not difficult to extract phthalates from PVC using a suitable solvent, it is problematic to determine the level of migration of phthalates from PVC into saliva (which does not act as a low molecular weight organic solvent) by chewing.

ALLEGATIONS

Since August, 1996, Greenpeace has been contacting major toy manufacturers around the world requesting meetings to discuss concerns about PVC toys, teethers, baby bottles, and the like.[19] This effort formed part of a wider Greenpeace agenda against PVC in particular and the chlorine industry in general.

On April 23,1997, the European Commission was approached by Danish authorities regarding three emergency notifications taken out five days earlier upon the recommendation of the Danish Environmental Protection Agency.[20] These concerned various teething rings manufactured in China for the Italian company "Chicco–Artsana."[21]

According to these notifications, the analyses showed that the articles released certain phthalates in quantities considered to be unacceptable for babies. The Danish importer had thus withdrawn these products from the market. The manufacturers, who considered that the teethers were in conformity with EC legislation and further presented no danger, nevertheless voluntarily withdrew them from the market on a preventative basis, awaiting the results of further analyses.[22] The results of the manufacturer's analysis, which took into account the latest working draft proposing a test method to determine the migration of phthalates in articles destined for child-use and care, conflicted with that of the Danish authorities.

Reactions by other member states to these notifications indicated important differences regarding test methods used to measure phthalate migration, focusing specifically on such assumptions as period of exposure, contact area, and type of stimulus. An experiment in the Netherlands, which led to reported doses marginally above the tolerable daily intake (TDI), employed questionable methodology, which mimicked chewing through the use of an ultrasonic bath that produces a 55,000 Hz vibration.[23] Not what one would expect from a child's mouth!

Some countries adopted TDIs fixed by the Scientific Committee for Food in its Opinion on phthalates in infant formula, expressed on June 7, 1996.[24] Others, particularly Belgium and the United Kingdom, required the European Commission to ask for the opinion of experts and/or relevant scientific committees at the European level, before proceeding with the matter.

Hence, unable to issue a "serious and immediate risk to health" warning, the European Community's Committee for Product Safety Emergencies referred the matter to the newly formed Scientific Committee on Toxicity, Ecotoxicity, and the Environment. Due to the reorganization of the EC's services subsequent to the 1996 BSE ("mad cow" disease) scare, this committee did not meet for its first plenary session until November 17, 1997.

THE GREENPEACE CAMPAIGN

Encouraged by the Danish notification to the Commission and its impact upon the Italian-owned distributors, as well as the results of the Dutch *in vitro* experiment and longer-standing Swedish concerns regarding PVC use, Greenpeace approached the Commission on the matter.[25] Frustrated by the delay caused, unnecessarily in its view, by the need to substantiate and corroborate scientific data, Greenpeace continued independently to approach politicians and officials in member states at a local, regional, and national level, as well as manufacturers and retailers and their professional associations. It sought to use the various notifications, voluntary withdrawals, and early investigations as proof of a wider concern.

Frustrated by the delay caused by the need to substantiate scientific data, Greenpeace continued independently to approach politicians, manufacturers, and retailers.

On September 17, 1997—100 days before Christmas—Greenpeace launched the "Play Safe" campaign in New York and London.[26] This effort included a list for parents of PVC and non-PVC infant toys, as well as a message outlining the supposed adverse health effects: liver and kidney damage leading to cancer, the mimicking of sex hormones, and reproductive abnormalities.

The campaign was set to target major toy manufacturers such as Mattel and retailers such as Toys "R" Us who were refusing to conform to the scare campaign. The campaign by then was affecting a number of retailers in Denmark, the Netherlands, and Sweden, as well as clients of the Italian suppliers in Spain, Portugal, Greece, and Italy itself.

Greenpeace claimed that they "first drew attention to the problem by releasing a scientific study."[27] This "study" actually amounted to no more than a couple of pages identifying the types and amounts of phthalates contained in PVC.[28] But the level of phthalate contained by a compound is not an indication of the amount that actually leaches from it, and even if this latter quantity can be determined, it remains to be proven whether this poses a risk to human health.

By October, a number of prominent politicians entered the fray, no doubt concerned by increasingly alarmist pronouncements and responses. Austrian Consumer Affairs Minister Barbara Prammer stated that "based on precautionary consumer protection, PVC toys are not desirable."[29] Belgian Minister for Public Health Marcel Colla urged retailers to "voluntarily discontinue marketing these products."[30]

These recommendations further pressured retailers in those countries. Greenpeace's direct action against Toys "R" Us in Austria led the company to withdraw ten specific PVC toys from store shelves.[31] These were subsequently reinstated at the behest of their US headquarters. In Belgium, FEDIS, the retail federation, agreed to immediately withdraw all soft-PVC products designed to be chewed by young children.[32]

Each of these steps, however, simply fuelled further activity and alarmist press releases by the campaigners. In Italy, activists entered the Ministry of Health in Father Christmas costumes carrying boxes full of PVC toys.[33] Three weeks later Health Minister Rosi Bindi encouraged manufacturers to look into alternative materials.

In Germany, the Association of Toy Retailers took the lead and in December called upon its members to withdraw such products. The Federal Institute for the Protection of Consumer Health and Veterinary Medicine urged manufacturers and industry to act responsibly by doing likewise. This recommendation was then followed by statements from the Ministry of Health and the Ministry of Family Affairs suggesting that it would be highly desirable for industry to voluntarily refrain from selling such products.[34]

Nor was it simply trade and retail associations, in addition to Greenpeace, which put pressure upon national ministries. The municipality of Bilbao, in Spain, introduced its own ban.[35] This measure was widely repeated among other local and regional assemblies, including many in Italy, no doubt keen to be seen taking a greater interest in their electorates' well-being than that taken by central government.

Revealing its own uncertainties in February, 1998, the European Commission itself removed all soft-PVC teething toys from its childcare facilities.[36] This move prompted a new and understandable round of calls from campaigners that if the products were not good enough for the Commission, then they should not be inflicted upon the rest of the population.

Relentless pressure by Greenpeace, including the placing of advertisements in newspapers seeking to "name and shame" firms that would not comply, led individual businesses, such as Dutch retailer Bart Smit, to order their shops to remove all listed soft-PVC toys.[37]

Governments and retailers across Europe effectively removed soft-PVC products from store shelves and markets on a "voluntary" basis. The recognition, in one instance at least, was that while the claims against such products had "not been scientifically substantiated," nevertheless "we choose to give our customers the benefit of this doubt."[38]

THE CSTEE INVESTIGATION

It was within this evolving climate that the European Commission invited its new Scientific Committee on Toxicity, Ecotoxicity, and the Environment (CSTEE), at its first plenary meeting in Brussels on November 17, 1997, to give its opinion as to:

- the impact on children's health by the use of soft-PVC containing phthalates in childcare articles and toys, which children of a young age could put in their mouths;

• the limits which ought to be respected in relation to the migration of phthalates from these products; and

• the test method to be followed and the standards or parameters that should be taken into consideration to measure the phthalate migration level.

The CSTEE established a working group, which first met on December 8, 1997. The working group formulated a preliminary position, which was released at the second CSTEE plenary meeting held in Brussels on February 9, 1998. This position related to the six phthalates—DEHP, DNOP, DINP, DIDP, DBP, and BBP—found in infant teething rings and was based on the documents and literature available to it at that time. This document confirmed the existence of different methodologies and highly variable results for the estimation of emission of phthalates from toys. Still, true to the precautionary approach, it used the highest reported emission levels as a baseline and sought to homogenize all available research evidence to an equivalent exposure dose.

The exposure dose was initially based upon the maximal amounts extracted over a 12-hour period from a phthalate-containing PVC toy surrogate of 10 square cm, by a saliva solution under dynamic conditions, and assuming an infant body weight of 5 kg for the risk assessment. This was changed to a more realistic extraction for six hours using an infant body weight of 8 kg at the time of the CSTEE's expression of its formal opinion on the matter at its third plenary meeting in Brussels on April 24, 1998.

A margin of safety was estimated for each phthalate by dividing the No-Observed-Adverse-Effect-Level (NOAEL) values obtained through animal experimentation, by the worst predicted exposure dose. A level of little concern was assumed for exposure situations with margins of safety in excess of 100. This figure derived (according to a recent US study) from allowing a factor of ten for variation between species and a further factor of ten for variation between individuals.[39]

A further opinion, expressed as answers to four new questions put to the committee on the occasion of the CSTEE fourth plenary meeting in Brussels on June 16, 1998, emphasized the need to wait for the outcome of an *in vivo* Dutch study using adult human volunteers, expected later that year. This study was expected to provide more realistic estimates for the quantities of phthalate leached, as well as the duration of exposure.

Predictably, Greenpeace used the launch of investigations by the Commission and the publication of preliminary opinions as a further stick to beat recalcitrant governments, manufacturers, and retailers. Under increasing pressure to "take action," the Commission agreed with the need for a directive specifically to address soft-PVC toys intended for young children and babies.[40]

The Commissioner for Consumer Policy and Consumer Health Protection, Emma Bonino, drew up proposals for an emergency ban, reducing its scope to objects designed to be put in the mouth.[41] Fearing that an outright ban might be successfully challenged in court, however, the Commission voted against it on June 10, 1998, adopting instead a non-binding recommendation on July 1, 1998.

The recommendation covered child-care articles and toys made of soft PVC containing phthalates and intended to be put into the mouth by children under the age of three.[42] It invited member states to take appropriate safety measures while EC legislation for permanent protection was under consideration. Indicating that such products "are considered to be liable to provoke negative health effects at high levels of exposure," it also requested member states to check levels of phthalate migration, comparing these to limits now proposed by the CSTEE. It also effectively conceded the importance of non-scientific factors by indicating that "other Member States had announced that they would act on their own if the Commission does not find a Community solution."[43]

THE MOVING SAFETY MARGIN

One of the major problems throughout this process has been the adoption of continuously shifting baselines and data. The margin of safety, arbitrarily considered as needing to exceed 100 times what is considered safe, is determined by dividing the NOAEL value by the exposure dose. Yet each of these quantities has varied according to particular experiments or has been the subject of systematic revision or reinterpretation. Even taking samples from parallel batches of PVC and using identical techniques can yield low correlative precision due to the uneven release of phthalate particles from within.[44]

In all instances the worst data or the worst-case approach was adopted in order to err on the side of caution, even if the worse-case data was 10,000 times greater than the best case! That approach was considered reasonable as no account was being made for exposure to more than one phthalate in a toy, and for additional exposures through food, air, or dermal contact. Nor was there any allowance for the assumed enhanced sensitivity of young children to these products. The fact that children don't swallow all their saliva was not considered.

Governments and retailers across Europe effectively removed soft-PVC products from store shelves and markets on a "voluntary" basis.

The various opinions did recognize, however, that, where calculable, intake from toys was not the only, nor indeed the major, source of exposure. A European Committee for Standardization draft report in 1997 estimated exposure from toys to be 10 percent of total exposure for a given phthalate.[45] For at least one such compound, BBP, "Food is by far the major source contributing over 90 percent of intake."[46] A UK Ministry of Agriculture, Fisheries and Food information sheet indicates that far from being caused by plastic containers or wrapping, the presence of phthalates in food is due to

general environmental conditions, as core content levels of phthalates in food items often exceed surface content levels.[47] Indoor air provides most of our remaining exposure to phthalates.

In all, well over 100 documents have now been presented to the CSTEE in evidence over the issue of phthalate toxicity. While some are merely member-state notifications of intended action, others are of a more scientific nature. One of the key—and shifting—areas for debate and experimentation has been over what is assumed to be the critical end point of phthalate toxicity. This means an indication as to the type of adverse effect to be expected from each compound.

NOAEL values are determined by administering phthalates in varying concentrations to the diet of test animals, usually rats. Typically, concentrations go up in factors of ten, and after a specified period the animals are analyzed for abnormalities with respect to a control group. The NOAEL value is then taken to be the highest dose producing no statistically significant variation, while the critical end point is the type of variation first noticed. In certain instances Lowest-Observed-Adverse-Effect-Level (LOAEL) values were taken, where appropriate data did not exist.

From early on in the proceedings, the two phthalates to come under most scrutiny were DEHP and DINP. They were the most commonly found phthalates in toys and various child-care articles, but they also each had a margin of safety determined from the start as being below 100. These particular margins were based on the least reliable available data, provided by Greenpeace and the Danish authorities who had initiated the matter, and varied by a factor of 2,500 and 10,000 respectively from other experimental sources.

Initially, DNOP also produced a margin of safety below 100. In its preliminary position of February 9, 1998, the CSTEE declared all three phthalates as giving cause for concern. Later revisions to NOAEL values and exposure doses removed DNOP from the list. By the time of the formal opinion expressed on April 24, 1998, the CSTEE had concluded that only the very low margin of safety for DINP (8.8) caused concern, "since humans appear to be less sensitive towards the critical effect of DEHP [hepatic peroxisome proliferation][48] identified in rats."[49]

ARE PHTHALATES CARCINOGENIC TO HUMANS?

DEHP has been found to be hepatocarcinogenic (liver cancer inducing) in rats and mice.[50] After long-term exposure, peroxisome proliferation (an increase in those parts of cells which generate or break down hydrogen peroxide), which is the most sensitive change found, acts as an early indicator of carcinogenicity.[51] However, there is a marked species variation in response to peroxisome proliferation. Rats and mice are very sensitive, whereas guinea

pigs and monkeys appear to be relatively insensitive or non-responsive, respectively, at dose levels that produce a marked response in rats. Studies on human cell cultures have shown no response.[52]

Yet now, based upon figures 2,500 times greater than from other sources, scaled up by a further safety margin of 100, using the most sensitive critical end point of dubious relevance, DEHP was considered as giving cause for concern. This concern has increased despite the fact that a 1996 risk assessment of DEHP, which reviewed nearly 500 studies, concluded that the threat of human liver cancer is extremely unlikely under any anticipated exposure dose.[53]

Regulation of carcinogens in the United States is still based on the "no-threshold" assumptions adopted over 40 years ago.

Campaigners against phthalates have attached great importance to the fact that the US Environmental Protection Agency (EPA) classified DEHP as a "probable human carcinogen."[54] But this decision was taken over ten years ago and has not formally been reevaluated. Not only has the relevance to humans of liver tumors in rodents induced by peroxisome proliferation become more questionable, our understanding of carcinogenic processes themselves has evolved. Nevertheless, in the mid-1980s, the US toy industry removed DEHP from children's products to maintain consumer confidence until further scientific research could be conducted.[55]

Regulation of carcinogens in the United States is still based on the "no-threshold" assumptions adopted over 40 years ago.[56] Since then, however, not only have we become more conscious of the various non-zero doses that the body can tolerate, our understanding of the biological processes has evolved. In particular, scientists now have a far more sophisticated view than the "one hit, one cancer" approach, which has long been used to determine EPA policy.[57] In addition, according to the biochemist who developed the primary test for carcinogenic substances, Dr. Bruce Ames, about one-half of all chemicals tested, both natural and man-made, are toxic when tested at high doses in either rats or mice.[58]

Recently, the head of the EPA's Science and Policy staff stated in a section of an article published in the *Journal of Regulatory Toxicology and Pharmacology* that, "No evidence exists to suggest that these agents [peroxisome proliferators] are carcinogenic in the human liver."[59] Canada's federal health department, Health Canada, has classified DEHP as "unlikely to be carcinogenic to humans."[60] The European Commission's own official decision states that DEHP "shall not be classified or labeled as a carcinogenic or an irritant substance,"[61] while the World Health Organization Environmental Health Criteria document for DEHP concludes, "Currently there is not sufficient evidence to suggest that DEHP is a potential human carcinogen."[62]

More recently, the World Health Organization's International Agency for Research on Cancer (IARC) downgraded DEHP from a "potential human carcinogen" to one that is "not classifiable as to carcinogenicity to humans."

IARC made this decision because DEHP has only been shown to cause cancer in lab rats and mice. It has not caused cancer in human cultures exposed to the chemical nor has it caused cancer in non-human primates. Accordingly, IARC found that DEHP cancer effects on rats and mice "are not relevant to humans."[63]

For DINP there is a recognition that "different commercial products may vary in composition," which might explain the factor of variation in excess of 10,000 between experiments to measure the exposure dose.[64] It has also been found to cause hepatic peroxisome proliferation in rats, but an even more sensitive critical end point has been established: an increase in liver and kidney weight after being fed significant dietary levels of DINP for up to two years.[65] Scaled up to human levels, this is equivalent to a child consuming a sizeable chunk (50 grams) of plastic each day.[66] As Michael Fumento, senior fellow at the Hudson Institute, has said, "If your child eats toys, phthalates are the least of your worries!"[67]

ARE PHTHALATES ENDOCRINE DISRUPTERS?

If the potential carcinogenicity of phthalates on rodents, in high doses and over long periods of time, were not relevant to obtain desired restrictions upon their use, campaigners had already prepared themselves to move on to a more emotive critical end point. This shifting of the argument had begun through focusing media attention on the most extreme possible outcome, presenting phthalates as so-called "endocrine disrupting chemicals" (EDCs), calling them "gender benders," and claiming that they mimic estrogen.[68] This approach successfully generated shock headlines such as "Human Sperm Count Could Be Zero in 70 Years,"[69] and "Sex Change Chemicals in Baby Milk."[70]

The endocrine system entails a complex set of processes whereby a number of fundamental bodily functions are kept in check through the action of an appropriate balance of hormones. An endocrine disrupter is any chemical that interferes with the synthesis, secretion, transport, binding, action, or elimination of the natural hormones that are responsible for homeostasis, reproduction, development, and/or behavior.[71]

The popularity of the endocrine-disrupter hypothesis stems from the 1996 publication of *Our Stolen Future* by Theo Colborn, Dianne Dumanoski, and John Peterson Myers.[72] This book argued that artificial hormones released into the environment through human activity are responsible for the identification of unexplained phenomena in the endocrine systems of various organisms (particularly aquatic-related life forms). Built upon previous work by Colborn with some of her earlier collaborators,[73] the book contains a foreword by US Vice President Al Gore, and has now been cited as the first reference to the recently released CSTEE Opinion on EDCs, as well as a study by the National Academy of Sciences.[74] Yet its so-called scientific

content has been extensively refuted by many, particularly given that "none of the authors is a real scientist who conducts scientific research or publishes peer-reviewed studies."[75]

Michigan State University Professor of Environmental Toxicology Michael Kamrin reviewed *Our Stolen Future* in *Scientific American*.[76] He described the book as "not scientific in the most fundamental sense." Kamrin argued that "the authors present a very selective segment of the data that has been gathered about chemicals that might affect hormonal functions." Further, the book "obscures the line between science and policy to the detriment of both." Some months earlier, *Business Week* contended that "with its selective use of data, dubious logic and relentless hype, *Our Stolen Future* ends up doing a serious disservice to its own cause."[77]

Greenpeace followed up with its own publication a month later titled "Taking Back Our Stolen Future: Hormone Disruption and PVC Plastic."[78] This publication also repeated a widely criticized study published in the *British Medical Journal* earlier that year, which claimed to provide evidence of a serious decline in the quality of human semen in the United Kingdom.[79] Yet even if this widely disputed claim were to be proven true,[80] it would remain to be demonstrated whether there was any causal connection with the release of artificially produced endocrine-disrupting chemicals.[81]

The authors of the 1992 study that supposedly provided the most conclusive evidence of declining sperm counts, Niels Skakkabaek and Richard Sharpe, have since indicated that the implications of their work have been overstated. In the July 7, 1995, issue of *The Independent*, the two accused Greenpeace of "taking something which is a clearly stated hypothetical link and calling it fact."[82]

Others, such as the CSTEE, meanwhile, have indicated that "the major human intake of endocrine disrupters are naturally occurring estrogens found in foods. This exposure is several orders of magnitude higher than the exposure to pesticide EDCs."[83] Such naturally occurring phyto-estrogens, commonly found in plants and vegetables such as soya, hops, peas, beans, sprouts, and celery, appear to be overlooked by environmental campaigners. Yet researcher S.H. Safe calculated daily human intakes of such estrogens, based on potencies relative to 17 βb-oestradiol. Oral contraceptives are found to represent 16,675 μmg equivalent per day, and postmenopausal estrogen therapy would provide 3,350 μmg per day. By contrast, estrogen flavonoids in food represent 102 μmg per day, while daily ingestion of environmental organochlorine estrogens a mere 0.0000025 μmg![84]

Rather obviously then, substances designed to be endocrine disrupters, such as the birth control pill, use massively higher levels than even naturally occurring disrupters found in produce. Moreover, synthetic-phthalate exposure levels are minuscule when compared to the safe, naturally occurring

levels found in bean sprouts and other produce.[85] However—presumably recognizing the sensitivities of potentially alienating over half the constituency they seek to influence—Greenpeace and other environmentalists chose not to highlight how much the presence of such substances actually stems from the widespread use of oral contraceptives. Nor do they emphasize that naturally-occurring exposure is leagues higher than that from chemicals.

The supposed estrogenic properties of phthalates have recently been thoroughly examined, both *in vitro* and *in vivo*.[86] This research indicates that while some of the shorter chain esters (e.g. DBP, BBP) display a weak effect in some *in vitro* analyses at high concentrations,[87] none of the eight phthalates elicited *in vivo* estrogenic effects based upon both uterotrophic and vaginal cornification tests, which determine the response of the uterus to hormones as well as their ability to induce the estrous cycle. This suggests that metabolic events may inactivate the estrogenic activity of certain phthalates, thereby indicating that while *in vitro* tests may allow prioritization for further testing, they should be used as a complement to *in vivo* testing, which can more accurately model sensitive processes and interactions.[88]

The only logical outcome of adopting the precautionary principle is to accommodate the lowest common denominator.

Several multi-generation fertility studies have been carried out on several different phthalates. Again, some phthalates have produced teratogenic (causing birth defects) and embryotoxic effects at doses well in excess of the NOAEL in continuous breeding studies upon mice. However, the most recent two-generation studies demonstrate that exposure of rats to DINP and DIDP in utero, during lactation, puberty, and adulthood does not affect testicular size nor produce any reproductive fertility effects.[89]

THE CSTEE OPINION ON EDCs

The European Commission's Scientific Committee on Toxicity, Ecotoxicity, and the Environment within DG XXIV has set up a Working Group, which in March of 1999 published its own "Opinion on Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with Emphasis on Wildlife and on Ecotoxicology Test Methods." Unfortunately, the tone of this document is set from its opening line: "There is growing concern on possible harmful consequences of exposure to xenobiotic compounds that are capable of modulating or disrupting the endocrine system."[90] This "growing concern" of "possible" effects now suffices to spur Commission-level action, a trend more recently repeated elsewhere.[91] Indeed, the document somewhat self-consciously justifies itself in part on the basis that "the media and consequently the public at large have [therefore] developed an interest on the subject."[92]

Apart from citing the widely discredited work of Theo Colborn, the document also lends further credence to the disputed claims over falling sperm counts and the rising incidence of prostate cancer. It is likely that Greenpeace and its allies, responsible so far for a substantial element of the

"growing concern," will draw upon the document itself as further evidence of the objectivity of their claims.

While the original intention of the work, as revealed through the various CSTEE plenary meeting minutes, was "to finally produce a report that covers human health and environmental effects of EDCs,"[93] the final product placed a far greater emphasis upon wildlife, "due to the fact that it is where the greatest impact is felt. The human health effects part was therefore correspondingly reduced."[94] In other words, unable to come up with sufficient evidence for effects upon humans, the committee simply decided to play this down rather than highlight the fact.

The document accepts that for humans "a *causative* role…has not been verified," [95] and that "for most reported effects in wildlife the evidence for a causal link with endocrine disruption is weak or non-existing." It states further that "the mechanisms of pollutant-induced reproductive toxicity observed in wild mammalian species generally remain unclear but could also involve endocrine disruption."[96]

Needless to say, many of the purported effects upon wildlife are themselves speculative. Two recent studies in the journal *Science*, for example, have concluded that defects found in frogs throughout the western United States, cited in the CSTEE document,[97] may be caused by a trematode, a simple parasitic flatworm, infecting tadpoles and leading to multiple or malformed hind legs.[98] Some may now argue that chemical pollution was responsible for the increase in water snails, which act as a key host of the parasite. But this is to reveal such views as based upon simple association, rather than the scientific analysis necessary to provide insights into causal mechanisms and metabolic pathways.

REACTIONS TO THE DUTCH "CONSENSUS GROUP" STUDY

The only logical outcome of adopting the precautionary principle is to accommodate the lowest common denominator. This effect was perfectly exposed by reactions to the outcome of the Dutch Consensus Group study, which considered the oral leaching of phthalates using adult human volunteers as subjects.[99] This study coincided with a review of other data made available to the CSTEE subsequent to April 1998. This information included an Austrian investigation that appears to corroborate the results of the Dutch study, as well as the US Consumer Product Safety Commission report on DINP which showed the high levels of release that had previously been used could not be reproduced.[100]

The final report by the Dutch Consensus Group indicated that the possibility of a baby exceeding the recommended limits was "so rare that the statistical likelihood cannot be estimated."[101] It also revealed that previous estimates as to the amounts of time spent chewing on soft-PVC products by

children had been grossly exaggerated, reducing this estimate from six hours to a maximum of three hours exposure. A joint press release issued by Toy Industries of Europe, the European Council of Plasticizers and Intermediates, and the European Council of Vinyl Manufacturers assumed that their position had now been vindicated.[102]

The Greenpeace view on the Dutch study at this stage was predictably antagonistic, arguing that it had failed in its task to develop a standardized procedure for measuring the quantities of phthalates leached from PVC. More pointedly, Greenpeace questioned the integrity of the study group for having representatives from both the toy industry (Mattel) and the chemical industry (Exxon) on its technical committee.[103] Exxon production facilities in particular had been systematically targeted by activists during their campaign, due to the company being the world's single largest producer of phthalates.[104]

Just two months later, however, the CSTEE announced its own views on the new research,[105] and Greenpeace announced itself to be in full agreement.[106] A new and less extreme determination of the NOAEL value for DINP had been made available,[107] but as this yielded a value four times greater than that derived from the earlier research,[108] the CSTEE decided "from a precautionary standpoint" to maintain its use of the pre-existing value in its revised assessment.[109] In other words, the new evidence was quite simply ignored.

In addition, a study that had examined the effects of exposing female rats to DEHP in drinking water from day 1 of pregnancy to day 21 after delivery indicated damage to the testes of the offspring.[110] Despite water intake not having been accurately measured,[111] the derived LOAEL was taken to substantiate an earlier low NOAEL value which had, at the time of the April 24, 1998, opinion, been ignored in favor of that derived from "a well-performed study."[112] Now, however, the critical effect was taken to be the testicular effects which, although known at the time of the earlier opinion, had not been used.[113]

The recalculated margin of safety for DINP, while providing improvement due to the reduction in exposure time, remained below 100, suggesting continued cause for concern. For DEHP the margin of safety was now lower than the previous value. The fact that it could have testicular effects raised greater concerns than the fact that it had liver effects. These views were submitted to the DG XXIV Risk Evaluation Unit, which suggested in January, 1999, "that the Commission should be looking for a phase out of phthalates as soon as possible."[114]

EVER DECREASING CIRCLES

The official view from the Commission was, by now, hardly contentious. After all, since the issuing of the last formal opinion on the matter in November, 1998, a number of member states had finally been convinced by

the various voluntary restrictions in operation, as well as by the actions of environmentalists and consumer groups. These members had started notifying the Commission of their intentions to introduce formal restrictions on such products, particularly those aimed at children under three years of age and intended to be placed in the mouth. These members included Austria, Denmark, Finland, Greece, Italy, Norway, and Sweden, all of which expected to have formal bans in place by the middle of 1999.[115]

It is interesting to note how the gradual collapse of member states across the European Community increased the pressure on America to follow suit. Despite one commentator's view that "[m]ultinational companies are under attack everywhere—but nowhere more than in Europe," it may yet prove to be the case that Europe is just a stepping stone to actions further afield.[116] In the United States, the Greenpeace campaign took a longer time to become effective, in part due to the fact that DEHP had already formally been withdrawn as a precautionary measure in 1986.

Nevertheless, concerned by the direction of events in Europe, US Ambassador to the European Community Vernon Weaver sent a blunt letter to the European Union's Directorate General for External Affairs in February, 1998. It stated that "a sudden ban on products which have been sold for years and which is based on incomplete and perhaps erroneous information could cause trade misunderstandings between the US and the EU."[117]

EUROPEAN UNION BAN ON USE OF PHTHALATES IN TOYS

In December, 1999, the European Commission adopted measures to prohibit the use of phthalate softeners in PVC toys and childcare articles intended to be placed in the mouth by children under three years of age.[118] This decision, based upon the recommendation of the Emergencies Committee of the General Product Safety Directive, applied until March 8, 2000. Since then the temporary ban has been extended and a proposal to formalize this within legislation has been put forward. By then it is intended, and EC representatives have introduced a proposal, to make the ban permanent. In addition, soft-PVC toys (items designed for children under three that, although not designed for teething, could be mouthed by children) will need to carry a warning label indicating the presence of phthalates.

Further, eight member states of the European Union have decided to introduce their own restrictions on the production and sale of such items. This in turn followed from more informal self-regulation introduced by manufacturers, retailers, and trade associations subsequent to their becoming systematically targeted by activists. The measures prohibiting the placing on the market of articles containing more than 0.1 percent by weight of the six phthalates DINP, DEHP, DNOP, DIDP, BBP, and DBP (only two of which actually gave "cause for concern") thus merely formalizes a state of affairs already largely in existence.

The suggestion by Commissioners David Byrne and Erkki Liikanen that "phthalates pose a serious risk to human health," indicates a dishonest or self-deceiving loss of nerve.[119] Was the European Commission relying on a wealth of new and worrying toxicological evidence to justify its actions? Far from it! This paper shows that the latest research from both Europe and America indicated no possibility of actual harm.

Greenpeace chooses to ignore the fact that chlorine is necessary to maintain a safe drinking water supply or that we use chlorine compounds in nearly 85 percent of all pharmaceuticals produced worldwide.

Even the Chair of the Commission's own CSTEE, Professor Jim Bridges of the University of Surrey, has questioned the ban, indicating, "I don't think the science is saying at all that there's an immediate risk."[120] Previously, another CSTEE member had voiced consternation as to the purpose of their deliberations when "risk perception prevails," indicating that "no matter what the scientific input" it would "not be the decisive input anyway."[121]

Why is it then, despite the overwhelming evidence against claims of carcinogenic or reproductive effects in humans, that officials, both in Europe and the US, have nevertheless decided to recommend the removal of such products on a "precautionary" basis?

Clearly Greenpeace, who orchestrated much of the scare-tactics and seemed to relish making inflammatory comments about "corpses" and "Russian Roulette," played a central role.[122] Its attempts to stifle discussion about the issue by asking a participant not to debate it on a BBC Radio 4 programme last year also raises serious doubt as to the organization's belief in, and adherence to, transparent informing of the democratic processes.[123] It also fitted neatly into its longer-term campaign against PVC use in general. However, whilst Greenpeace was a key catalyst, it is ultimately a mere messenger of a far broader process of social transformation which continually lends itself to elevating fears and denigrating our achievements.

Although much of the research and reasoned opinion indicated little cause for concern, the actions taken and policies implemented assumed the worst. This approach suggests that what has changed is not the evidence upon which decisions are made, but rather the confidence of those making them. In the aftermath of the 1996 BSE crisis, the European Commission directorate responsible for Consumer Policy and Health Protection trebled its staff numbers.[124] More importantly, it issued a swathe of documents all referring to the need to adopt a "precautionary" approach in all matters to do with food safety and public health. In effect, officials sought to deflect blame for their handling of the crisis by pointing to the fact that science can never provide definitive answers. But this is hardly a new discovery, let alone one that deserves to be dressed up with the designation of a "principle."[125]

THE US CAMPAIGN

Nonetheless, Greenpeace has launched a similar campaign in the United States. In August of 1998, Greenpeace succeeded in pressuring Nike to

phase-out its use of PVC plastics in its products, noting that the risk came from the "manufacture" and "disposal" of these products. Greenpeace focused on what it claimed to be a release of "supertoxic substances such as dioxin."[126]

Elimination of dioxins is part of Greenpeace's 20-year campaign to eliminate "the use, export, and import, of all organochlorines, elemental chlorine, and chlorinated oxidizing agents."[127] With this campaign, Greenpeace chooses to ignore the fact that chlorine is necessary to maintain a safe drinking water supply or that we use chlorine compounds in nearly 85 percent of all pharmaceuticals produced worldwide.[128] While Greenpeace claims otherwise, at current levels dioxins in the environment do not pose a serious health threat, particularly those derived from PVC plastics.

Fears of dioxins are based upon the fact that through the technical synthesis or incineration of certain chlorinated organic compounds, dioxins can be produced as a byproduct. These have often been referred to as the most toxic man-made chemicals known, although this accolade is considered by many to be a gross exaggeration.[129] Only exposure to quite substantial doses has ever posed a threat to human health.[130]

Substantial scientific evidence supports the view that dioxin contamination in the environment has dramatically decreased over the last twenty years to its lowest level this century,[131] despite a three-fold increase in PVC production.[132] This decline has been helped by the more advanced technology now used for cleaning the products of combustion prior to release into the atmosphere.[133] Nevertheless, part of Greenpeace's US campaign against PVC—which focuses on medical products—consists of highlighting the contribution which hospital waste purportedly adds to atmospheric dioxin levels. In reality, PVC forms but a minor contribution. For example, in the United States, under new pollution control regulations the total annual dioxin emissions from medical waste incinerators will amount to less than 0.3 ounces or 6 to 7 grams of dioxin emissions nationwide. That amounts to less than one percent of all US annual dioxin emissions.[134]

With its dioxin campaign well established, Greenpeace began to focus on additives to PVC—lead, cadmium, and phthalates—a move that enabled them to claim children and the sick were most at risk. Greenpeace turned up the heat on its phthalates campaign in the United States by releasing a new report on phthalates in November, 1998. This amounted to little more than a press release with footnotes,[135] but led to a flurry of toy manufacturers, including Toys "R" Us, issuing assurances of their intentions to phase out the products.[136] During the Christmas shopping season Toys "R" Us gained national headlines in the US by pulling from its shelves any item designed for teething that contained phthalates.

Shortly thereafter, Health Canada issued an advisory calling for soft-PVC teethers and rattles to be removed from shelves, and calling on parents and

childcare facilities to immediately dispose of these toys.[137] Then, on December 2, 1998, the US Consumer Product Safety Commission (CPSC) released the latest results of a study on DINP, revealing the phthalate in children's toys did not pose a significant risk.[138] The CPSC noted in its press release that "the amount ingested does not even come close to a harmful level." That day, the CPSC also requested that industry, "as a precaution while more scientific work is done," remove phthalates from soft rattles and teethers.[139]

GREENPEACE EXPANDS ATTACK ON MEDICAL DEVICES

In those countries where there had been regulatory successes against toys, the campaign now refocused on medical devices. PVC softened with phthalates provides among other products flexible tubing, intravenous bags, catheters, and protective gloves. It allows hospitals access to quality disposable items that are durable, flexible, inexpensive, and safe.[140]

Yet building upon their earlier gains, Greenpeace and others, such as a US coalition called Health Care Without Harm (HCWH), are seeking to limit or prohibit the use of PVC in healthcare facilities. They seek such prohibitions despite no evidence of adverse effects to even those patients receiving dialysis for kidney disease, which is the group most exposed to, and hence supposedly at risk from, such products.[141]

Marketed as a group of health care professionals, HCWH consists of a large number of environmental groups, including Greenpeace, other advocacy groups, and some health professionals and hospitals. Since its inception in 1996, the group has challenged hospitals to stop engaging in any activities, or using products, that release any amount of dioxins. HCWH continued to pressure hospitals in June of 1998, with the release of "Greening Hospitals," a report claiming that US hospitals were creating serious pollution problems because of such things as medical waste incineration (particularly of PVC products) and the mere use of PVC products. Of particular concern, noted the report, was the release of dioxins that incineration and use of these materials produced.

At the time, the American Hospital Association's Communication Director Rick Wade noted, "Incineration remains the most effective means that we have to dispose of medical wastes in hospitals."[142] A representative from US Catholic Healthcare West, which represents 67 Catholic hospitals and is a member of HCWH, noted that they had committed to "drastically reduce if not phase out our use of polychlorinated plastics by year 2000...But the caveat is that we will need to have products at comparable quality and cost."[143] Under pressure, the American Hospital Association eventually joined with the EPA and HCWH in a "memorandum of understanding," through which they pledged to cut hospital waste by 50 percent by year 2010. With this pledge, the American Hospital Association essentially promised to eliminate one of its most important medical tools.

PVC plasticized with DEHP is the only flexible material approved by the European Pharmacopoeia[144] for life-saving medical devices such as blood and plasma transfusion equipment,[145] and it is approved by the US Food and Drug Administration (FDA). The safety of these materials has been confirmed by more than 40 years of use, with five to seven billion patient days of acute exposure and one to two billion patient days of chronic exposure without any indication of adverse effects.[146] But again, companies with a vital interest at stake, both private and public, have proven to be remarkably defensive in their stance.

In a February, 1999, report, "Health Care Alert: Vinyl IV Bags Leach Toxic Chemicals," HCWH claimed that Americans are being poisoned from leaching phthalates from medical devices such as vinyl tubing and blood bags. In reply to the HCWH study, Dr. Bruce Burlington, then-director of the FDA's Center for Devices and Radiological Health, commented, "We believe that IV bags, blood administration sets and the other uses of PVC, including dialysis tubing, are safe."[147] Such FDA approval indicates that phthalates have passed very tough safety standards and rigorous testing to ensure safety. In fact, the FDA demands such high safety standards that the public waits years for the FDA to approve life-saving drugs and medical devices.[148]

Dioxin contamination in the environment has dramatically decreased over the last twenty years to its lowest level this century, despite a three-fold increase in PVC production.

In addition to issuing the report, HCWH coordinated their efforts with shareholders of various medical product companies and hospital management firms to get them to offer proposals for the elimination of PVCs.[149] Baxter was one of the first companies to deal with a shareholder resolution after HCWH issued its report on the "dangers" of vinyl medical products. As a result, Baxter responded to a proposal from three of its institutional shareholders in April, 1999, which requested that Baxter phase out PVC from the company's products. Baxter entered into a "memorandum of understanding" with the shareholders, through which the shareholders withdrew their proposal. In return, Baxter promised to set and follow "a timetable and benchmarks for its future PVC alternative materials development efforts, together with regular updates on its progress," as noted in a Baxter press release. The company further noted, "In instances where the overall performance and safety of another material is proven superior to PVC and regulatory clearance is obtained, Baxter will offer an alternative."[150]

While Baxter promised to simply market alternatives when the quality of the product would produce a demand for them, Greenpeace and others made sure that the headlines read another way. They reported that Baxter agreed to phase out PVCs, holding Baxter up as a model to pressure others to follow suit and build legitimacy for their cause.[151] Some companies did indeed follow Baxter's lead. In October of 1999, Tenet Healthcare Corporation, which owns and operates 126 acute-care hospitals, announced it had reached an agreement with shareholders to develop a purchasing policy giving preference to PVC-free medical products, as long as the alternatives are as good or better.[152] However, following sound science instead of activist pressure,

when a proposal was made at Abbott Laboratories the board of directors allowed the issue to come to a vote, recommending that shareholders vote against the proposal. The board prevailed but also agreed to discuss the issue with the proponents of the proposal.

In the Spring of 1999, The American Council on Science and Health formed a Blue Ribbon Commission, headed by former US Surgeon General C. Everett Koop and including 16 other top scientists and physicians, to study the issue. The panel concluded in June that "DEHP in medical devices is not harmful to even highly exposed individuals." And it concluded, "DINP in toys is not harmful for children in normal use of these toys."[153]

Yet in June, 1999, HCWH released another report, which it had commissioned the Lowell Center for Sustainable Development at the University of Massachusetts to produce. The report offers a well-done analysis of PVC-plasticized products and their alternatives. If one reads the report closely, the findings indicate that sticking with DEHP makes sense. Lacking hard evidence that vinyl products pose any real risk, the paper merely recommends consideration of alternatives based on the precautionary principle. It notes that information about DEHP is based on animal studies and that "inadequate evidence exists to conclude that toxic mechanisms found in laboratory animals do not occur in humans." Hence, it demands what's essentially impossible: that researchers prove a negative—that DEHP doesn't cause health problems. Until they can do so, we should consider alternatives merely because they "have the *potential* [emphasis added] to be safer alternatives to DEHP."[154]

The precautionary standard demands zero risk—a standard no product could meet.

Interestingly, the report notes the potential hazards of the alternative products, illustrating that it's impossible to find any product that meets the precautionary no-risk standard. According to this report, "polyurethanes use several very hazardous intermediaries and create numerous hazardous byproducts." Polycarbonate is "highly toxic phosgene derived from chlorine gas." And polyolefins can be "highly flammable or explosive" and "the burning of these plastics can generate many volatile compounds." Yet, the report continually hits on the point that alternatives exist to PVCs and that we should continue to investigate the transition because of PVC risks. It does not emphasize what should be an obvious and more fundamental point: everything in life has risks. The goal should be to create systems to allow individuals to minimize risks when possible and take risks where necessary to reap certain benefits. Instead the precautionary standard demands zero risk—a standard that no product could meet.

HCWH continues its battle on yet another front, pushing resolutions before the chapters of the American Medical Association (AMA), state legislatures, local governments, and the American Public Health Association. These resolutions focus on policies to eliminate dioxin by calling on hospitals and other institutions to adopt policies that will lead to the elimination of PVC

medical products. Dr. Peter Orris, representative of the American Public Health Association to HCWH, introduced one such resolution before the Chicago Medical Society[155] (which failed) and another before the American Public Health Association. A verbatim version of Orris's Chicago resolution passed the California chapter of the AMA and is now before the national membership of the AMA.[156]

In California, resolutions worked their way from the local level all the way to the California Assembly.[157] This effort started with a resolution in Oakland, a city across the bay from San Franciso. Oakland passed a resolution in February of 1999, resolving to encourage the elimination of dioxins wherever possible; set up a regional taskforce to study dioxin releases and find ways to reduce them; promote the use of alternatives to PVCs; urge hospitals to phase out PVC products where practical; and other similar resolutions.[158] Following Oakland, San Franciso adopted a resolution in April, which set the goal to engage in efforts designed to eventually reduce dioxin emissions to zero. These local resolutions had been driven in part by concerns raised by Citizens for a Better Environment, which suggested that the public was at risk from eating seafood from the supposedly heavily dioxin-contaminated San Franciso Bay.[159] Responding to such claims, the California Assembly considered and passed "Resolution 27—Relative to dioxin."[160] Of note, the Bay Area Air Quality Management District found that the level of dioxin in the Bay area is small (2 percent in Oakland) and that home fireplaces and automobiles accounted for the vast majority of emissions.[161]

These trends against vinyl medical products are quite disturbing given the potential impact on the quality of health care. In addition to contributing to spiraling costs, an unwarranted rush to substitutes would negatively impact the healthcare system by diverting resources from real issues. In the US, 25 percent of all medical devices made with plastic use PVC. The material's unique properties, including durability and transparency, as well as the fact that it will not kink and that it provides a sterile disposable option, are integral to the design and efficacy of a wide range of products. While Greenpeace and HCWH claim that adequate alternatives exist, even Catholic Healthcare West—a member of Health Care Without Harm—noted that they would not phase out the products until suitable alternatives come available. And when addressing vinyl alternatives, FDA spokesman David Feigal notes, "We would need to see substantial amounts of testing to make sure we weren't moving from a product with good characteristics to one that we didn't know much about."[162] Likewise, the American Council on Science and Health noted, "DEHP imparts a variety of important physical characteristics that are critical to the function of medical devices and eliminating DEHP in these products could cause harm to some individuals."[163]

One of those new materials is currently recognized as having odor problems and causing skin irritation.[164] The European Commission's CSTEE has already initiated investigations into the potential problems associated

with the possible replacements.[165] Both adipates and citrates, which have started to be used as substitutes in countries where phthalates are no longer available, have been criticized for appearing to offer insufficient toxicological documentation in the literature to support their use as alternatives.[166] In this, the inevitable logic of the precautionary principle has come to the fore. The fear of phthalates has simply been transferred onto the supposed solution.

One physician expressed his concerns, having spent 16 years using vinyl products as an emergency room doctor:

> In the emergency department, we move fast and don't have time to worry whether we can get our hands on medical supplies and equipment that stand up to the demands of patient trauma....Specifically, I'm concerned by reports that certain activist groups strongly oppose the disposal of these [vinyl medical] products...[O]ther products can't match its tough performance standards—or they would have replaced vinyl by now....[W]ith the spread of new and insurgent infectious diseases, the role of disposables—many of which are made with vinyl—is critical to ensure the safety of patients and health care workers alike. Vinyl is one of the most cost-effective materials used by the medical profession. With health care costs a major issue for our national economy and for millions of Americans, would searching for vinyl substitutes really be the best expenditure of limited resources?[167]

Vinyl medical products are particularly important for blood storage, with 12 million units of blood collected in PVC blood bags each year in the US. At an FDA workshop on the health implications of blood bags a Baxter official noted why PVC bags do so well. In addition to being less expensive, "PVC is one of the few materials that can consistently meet the requirements," which include long shelf life, the ability to withstand extreme low and high temperatures as well as steam sterilization, and the ability to serve as an effective microbial barrier.[168] Companies that have developed or are developing alternative blood bags may benefit from the scare campaign and/or government regulations will enable them to increase market share.[169] However, while substitutes may work adequately for blood plasma, the situation is quite different for the storage of red blood cells. In fact, the shelf life of red blood cells is actually doubled when stored in vinyl bags. The elimination of vinyl bags could contribute to local blood shortages as well as an impending nationwide blood shortage. Even The Lowell Center concluded, "To our knowledge, no commercially available substitutes have been identified for PVC to date in the storage of red blood cells."[170]

One should question switching to more expensive, alternative products about which much less in known, particularly given the state of our blood supply. In recent testimony before a US congressional committee, Dr. Susan Wilkinson, on behalf of the American Association of Blood Banks, noted that the industry receives what "seems to be daily reports of isolated blood

shortages" in various communities and that

> available data suggest that if current trends continue, the [total] demand for blood will surpass the supply as early as the year 2000...The NBDRC [National Blood Data Resource Center] data indicate that 8.6 percent of the more than 2,000 hospitals surveyed postponed surgeries due to a lack of blood and that nearly 25 percent experienced at least one day in which non-surgical blood needs were not met.[171]

Wilkinson noted several reasons for the shortages. Of concern is an FDA policy not to allow any blood donations from among those who traveled to the United Kingdom and spent up to six months there (adding all the trips) between 1980 and 1996. During that period, fears mounted over whether eating British beef was transmitting the deadly "mad cow" disease. Ironically, that health scare is yet another case where so-called consumer activists raised alarm by grossly exaggerating the risks.[172]

An unwarranted rush to substitutes [for PVC] would negatively impact the healthcare system by diverting resources from real issues.

In the final analysis, it is key to remember that the campaign against phthalates forms part of a wider Greenpeace agenda against PVC specifically and chlorine use in general. We should not expect it to end with phthalates. Greenpeace has made it clear that it has no intention of calling a halt to its campaign subsequent to the demise of phthalates, having argued explicitly that "PVC is a poisonous plastic—replacing phthalates won't solve the problem."[173] Hence, once Greenpeace achieves its objective to eliminate vinyl plasticized with phthalates, health care providers should be ready for a new battle regarding the unsuitability of the substitutes.

CONCLUSION

Greenpeace and other environmental groups' success at mobilizing a worldwide campaign, first against toys and then against medical devices in the US, should be a cause for alarm for anyone interested in continued progress in the medical field and any other industry. After 40 years of safe use, environmental activists have mobilized individuals and businesses around the world against what has proven not only an innocuous substance, but a very beneficial product. Using "studies" as short as a few pages in combination with an effective media campaign and mobilization, Greenpeace and its allies have trumped decades of scientific research.

By merely raising the possibility of a risk, they have been able to turn an entire industry sector on its head. They've managed to tap into a widespread and evolving policy based on the assumption that we should regulate any possible risk "just to be on the safe side." What they ignore are the trade-offs. What new risks will immerge from substitutes? How many people might have to die or suffer pain and discomfort from new, less effective products? What beneficial products will we lose? And how much time, energy, and resources will we lose as a society

developing new products, and what other technologic developments will we have to forego as resources are diverted to the unnecessary development of alternatives?

Finally, this issue has broader implications for public policy worldwide. This campaign is clearly not the first environmentalist crusade and clearly it will not be the last—as Greenpeace's anti-chlorine rhetoric has clearly indicated. With each and every campaign, scarce resources are reallocated and fewer are available for the development of goods for the betterment of society.

NOTES

[1] "Japan Frees Greenpeace Volunteers," Greenpeace press release, March 29, 1999.

[2] See, for example, the Scientific Committee on Toxicity, Ecotoxicity, and the Environment (CSTEE), "Opinion on the toxicological characteristics and risks of certain citrates and adipates used as a substitute for phthalates as plasticizers in certain soft PVC products," adopted at the 11th CSTEE plenary meeting (Brussels, September 28, 1999).

[3] Sometimes used interchangeably with "European Union," the term "European Community" (EC) describes the economic union promoting trade between member nations; "European Union" (EU) refers to the political union among European nations.

[4] "The Consumer Committee's Comments on the Commission's Green Paper on the General Principles of Food Law in the European Union–COM (97) 176 final," September 18, 1997, Part IV, paragraph 2.

[5] See R. Von Schomberg, "Report of the House of Lords, Select Committee on the European Communities: EC regulation of genetically modified organisms in agriculture," *The Stationery Office* (London, December 15, 1998), p. 401.

[6] Ibid.

[7] E. Green, "Another casualty in the beef war," *New Statesman*, December 12, 1997, discusses how Jack Cunningham based his decision to ban beef on the bone of a scientific paper which had not been subject to peer review.

[8] Environmental groups cite certain chemicals as "endocrine disrupters," claiming they cause reproductive problems for humans by mimicking human hormones. Claims about endocrine disrupters are discussed in further detail later in this paper.

[9] This statement refers to the work of Dr. Vyvyan Howard, Senior Lecturer in Fetal and Infant Pathology at the University of Liverpool, published in *The Mirror* as, "Human Sperm Count Could Be Zero In 70 Years," June 16, 1997.

[10] Private e-mail communication from Dr. Vyvyan Howard, May 28, 1999.

[11] "R" denotes a carbon side chain, which varies in length for each type of phthalate.

[12] Not used in the United States.

[13] Used as part of an intentional mixture.

[14] For example, the US Chemical Manufacturers Association chartered the Phthalate Esters Panel in 1973. This panel represents members before federal and state agencies in all matters relating to safety and health issues arising out of the use of phthalate esters. Since its inception, the panel has conducted extensive research to evaluate this class of chemicals, and significant research was also undertaken before the panel's formation.

[15] "Phthalates in Paper and Board Packaging," Joint Food Safety and Standards Group food surveillance information sheet number 60, MAFF UK, May 1995, repeated in information sheet number 82 and number 83, "Phthalates in Food," and "Phthalates in Infant Formulae," March 1996.

[16] "British Plastics Federation Statement on PVC Toys and Phthalates," September 17, 1997.

[17] R. Shanker, C. Ramakrishna, and P.K. Seth, "Degradation of Some Phthalic Acid Esters in Soil," *Environmental Pollution*, 39, 1985, pp. 1-7.

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[149] In a press release, Greenpeace notes that an agreement with Baxter International resulted from negotiations not only between shareholders, but also with HCWH, of which Greenpeace is a member.
[150] "Release Issued Jointly by Baxter International Inc., The Retirement Plans for the Employees of the Sisters of Mercy Regional Community Center of Detroit, The Sisters of Charity of Cincinnati, and the Service Employees International Union," Baxter news release, April 6, 1999. Of note, Baxter has an interest in the development of a market for alternatives. It already has invested a reported $35 million developing alternative bags, but because they cost 10 percent more, customers would not buy them.
[151] Greenpeace's press release on the topic read: "Medical Supplies Giant Baxter International to Phase Out Vinyl, Joining List of Companies Going PVC Free," April 6, 1999; and Health Care Without Harm's read: "Responding to Public Concern, Nation's Largest IV Products Manufacturer to Phase Out Vinyl IV Bags," April 7, 1999.
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[153] *A Blue Ribbon Report: A Scientific Evaluation of Health Effects of Two Plasticizers Used in Medical Devices and Toys* (New York: American Council on Science and Health, 1999), p. 4.
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[155] "Resolution No. 98-28, PVC Plastic Use by Health Care Facilities," Chicago Medical Society, Introduced by Peter Orris, MD, Councilor, Wood Street Branch, 1999.
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[158] "Resolution 7477S, Resolution for the City of Oakland, Establishing a Regional Task Force and Policy on Dioxin, Public Health, and the Environment," February 2, 1999.
[159] William Schiffman, "Report Says Dioxin Polluting San Francisco Bay," Associated Press, September 10, 1998.
[160] "House Resolution 27—Relative to dioxin," California House of Representatives, 1999-2000 Regular Session, June 14, 1999; Amended in Assembly July 6, 1999; Amended in Assembly June 17, 1999. The final version of this document was watered down somewhat to garner support for passage. Amendments added the word *potential* before listing health impacts associated with dioxin as well as before the assertion of dioxin contamination in the San Franciso Bay. The amendments also eliminated any terms indicating that dioxin was a carcinogen. The final resolution simply stated that there is an "urgent need to *scientifically determine the extent to which dioxins are a genuine threat to public health and the environment.*" The italicized portion is some of the language added before passage.
[161] *Air Emissions of Dioxin in the Bay Area* (Bay Area Air Quality Management District, 1996).
[162] David Brown, "Campaign Seeks to Eliminate Plastic IV Bags," *Washington Post*, February 22, 1999.
[163] *A Blue Ribbon Report*, p. 4.
[164] PVC Forum No. 3, Sweden, December 1998.
[165] Minutes of the 6th plenary meeting of the CSTEE.
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[167] Thomas R. Bullock, MD, "Vinyl Medical Products, Letter to the Editor," *Hospital Practice*, October 15, 1998.
[168] Steve Tolken, "So Far, Phthalate Alternatives Haven't Inspired Much Demand," *Plastics News*, October 5, 1999.
[169] A Baxter official noted at the FDA workshop that although they think the bags are safe, public fears could give them a "marketing advantage" for their alternatives. Likewise, when discussing the alternative under development by Pall Medsep, the company's representative noted at the meeting, "It may be something that could be mandated, (but) that's unlikely," quoted by Steve Tolken, "So Far, Phthalate Alternatives Haven't Inspired Much Demand."
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