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# Standing Committee on Environment and Sustainable Development

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**EVIDENCE**

## Thursday, April 26, 2007

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## Chair

**Mr. Bob Mills**

# Standing Committee on Environment and Sustainable Development

**Thursday, April 26, 2007**

● (1110)

[*English*]

**The Chair (Mr. Bob Mills (Red Deer, CPC)):** Order, please.

If we could get started, I'd like to welcome our guests. We will ask you to give about a ten-minute-or-so presentation, if you could try to keep it to that. Then we'll go around with questions from the members.

We'll begin. We'll go in the order they're printed here. We'll start with Mr. Stephen Dibert, please.

**Mr. Stephen Dibert (President, Canada's Medical Device Technology Companies (MEDEC)):** Thank you.

My name is Stephen Dibert. I'm the president and CEO of MEDEC. MEDEC is the national medical device association representing the medical device industry in Canada.

I didn't have a formal submission here for today. I'll just be speaking from some notes. However, I did send in two written letters, one on March 19 and one on April 10, which I assume were circulated.

I'll just go over my background briefly. I've spent my entire career in health care. I have a degree in kinesiology. I was a respiratory therapist for eight years, working in hospitals, and in many cases working with the medical devices that we'll be talking about a little bit later. For the last three and a half years I've been at MEDEC, working with the industry on various issues.

Just quickly on the industry, the medical device industry is a broad industry. It's defined by the Food and Drugs Act here in Canada. It ranges from orthopedics to ophthalmology to cardiac devices, including various hospital products and medical devices and equipment.

The industry is fairly large in Canada. There are 35,000 people who work in the medical device industry in Canada. About 1,500 facilities produce medical devices in Canada. There's a strong Canadian small to medium-sized enterprise base in Canada. We're doing fairly well as an industry.

As MEDEC, the trade association, we have about 100 companies that belong to the association. About one-third of those are those Canadian small and medium-sized enterprises. Again, we look after the needs of our sector through various areas.

I won't be using the entire ten minutes this morning. I'll leave time for the true experts on the science related to the act.

I'm going to begin by saying that MEDEC and our members do support the health objectives of this act. However, we have several concerns. I'll go through those concerns one by one.

The first concern we have is that a ban on phthalates would have a profound effect on patient access to the medical devices and technology that they need, in many cases, to maintain their health and to improve their health. These devices are as simple as oxygen masks and oxygen tubing, IV bags, IV sets, ventilator tubing. These thousands of devices that are used every day in patient care would be severely affected as the act is currently structured.

We're also concerned that the industry would not be able to provide the viable alternatives that would be needed by the patients. They wouldn't be able to do the research, the development, prove the viability, and get the data and the evidence required to bring these new substitutes or alternates to the marketplace.

Our other concerns include the fact that none of Canada's trading partners have banned phthalates relative to medical devices. They have concerns around some of the chemicals that are used, but no one has banned the DEHP that are used in medical devices.

We are concerned about the lack of science, again, on those alternatives. As you're all aware, in our health care system, Health Canada, through the Medical Devices Bureau, which assesses products based on risk, looks at these products for safety and effectiveness, and we're concerned that some of the products wouldn't be able to meet those risk assessments and get to the patients.

The industry is conducting research, and will continue to conduct research, and to look at substitutes and alternatives as they continue. We have one company here with us today, but I've spoken with several others, such as Tyco, Hospira, Becton Dickinson. They continue to do research on looking at alternate products that meet the needs of patients in our health society.

That outlines my major concerns with the act as it's currently worded. I would ask that the committee consider deleting the reference to medical devices in the act so that patients can get access to the much-needed medical devices they require.

That's my presentation. Thank you.

**The Chair:** Thank you very much.

We'll go on to Mr. Jon Cammack, please.

**Mr. Jon Cammack (Vice-President, Technology Resources, Baxter Healthcare Corporation):** Thank you.

Good morning. My name is Jon Cammack. I want to thank you for the opportunity to speak this morning.

Like Stephen, I don't have any formal presentation. I didn't send anything to the committee, but I am going to be speaking from notes.

As just some background on myself, I have a PhD in pharmacology and toxicology. I'm a board-certified toxicologist. I've been with Baxter Healthcare for almost 12 years now. For the last eight-plus years I have chaired AdvaMed, which is the sister trade organization to MEDEC in the United States.

I've chaired AdvaMed's toxicology PVC working group. That working group has been very proactive in partnering, especially with regulatory agencies, on the safety of DEHP and PVC. We worked with Health Canada. We worked with the USFDA and the U.S. national toxicology program on a fairly large industry study that looked specifically at the reproductive and developmental effects of DEHP in developing rodents.

One of the things that Steve stressed is very true. The industry has been very proactive on this issue. We have addressed it head-on.

I am going to spend a few minutes just talking about the science on this topic. I would say if there is any take-away message I would want to leave with you, it's that there is no scientific data that exist right now that indicate that DEHP PVC is harming humans in medical applications—none. There is no science that supports that.

There is a lot of science on the effects of DEHP in animals, and especially in rodents, but for many reasons, that's not applicable to DEHP PVC, as it's used in medical therapy. Again, of anything I would like to leave the committee with, that's what it would be.

I do want to start and just say that in terms of medical products, there are very stringent regulatory requirements that define what kinds of safety studies and what kinds of efficacy studies need to be performed on drugs, devices, and biologics. There are very extensive safety toxicology studies.

There is a certain set of guidelines called ISO 10993 for medical devices. There are ICH, International Conference on Harmonisation, guidelines for drugs. There are special guidance documents for other types of medical products.

This is a very heavily regulated industry and we have to meet very high standards in terms of safety. And all the products that are currently on the market in Canada and countries around the world have gone through these testing criteria. Again, there are very specific toxicology and safety testing requirements.

In terms of DEHP and PVC medical products, I would say, honestly, there is an unmatched product history there. There are over 45 years of clinical use and literally one billion to two billion days of chronic exposure in patients using these products. And as I said earlier, there is no scientific evidence that these products are in any way harming patients at all. It's just the opposite: they're necessary and lifesaving therapies.

I would like to draw your attention to a very recent review that the U.S. national toxicology program conducted. They have a special branch of the national toxicology program that focuses on risks to human reproduction. They have spent the last seven to eight years, again, studying the effects of phthalates, and specifically, DEHP.

● (1115)

There was a lot of information and data that the expert panel reviewed. The overall conclusion was that there was no human data that indicated DEHP exposure from medical products during pregnancy, childhood, or adulthood was causing harm.

Several years ago, the United States FDA did a safety assessment on DEHP PVC medical products. The end result was the derivation of a safety threshold for exposure to DEHP. The overall conclusion from that assessment was that there was little to no risk to human safety with the vast majority of medical PVC use.

Some very specific therapies—such as ECMO therapy, which is used when premature babies are having their blood oxygenated—are listed by the FDA as risk categories, but they did not say that those therapies and products used in them were unsafe.

About two years ago there was a follow-up study on young adults who had been exposed to DEHP during ECMO therapy as premature infants. The intent of that study was to look for any potential adverse effects on the reproductive system. In all those patients who were looked at in this follow-up study, there was no evidence of effects on the reproductive system, reproductive organs, or sexual hormones. That was a very pivotal study.

There has been a lot of focus within regulatory agencies around the world on this topic. I mentioned the FDA assessment. In February 2002, Health Canada published their final safety assessment on DEHP PVC medical products. Their overall conclusion was very similar to the assessments of the USFDA, the U.S. national toxicology program, and the special committee that looks at reproductive effects in humans.

Like the FDA, they also identified special risk categories like ECMO therapy used for premature infants. The FDA safety assessment and the Health Canada safety assessment were finalized before this ECMO follow-up study. That again was a key science-based study that looked at this very unique patient population.

There are other countries, and states within the U.S., that have looked at DEHP and PVC. California is one state that is very environmentally conscious. It has focused on this issue for many years. Approximately three years ago there was a California Assembly bill, Bill 1139, the Lowenthal bill, that called for a ban of DEHP PVC medical products. That bill was absolutely voted down.

The International Agency for Research on Cancer, which is part of the World Health Organization, downgraded the status of DEHP as a chemical that could potentially cause cancer in humans, because of the science. It showed that the way DEHP caused effects in rodents was not able to happen in humans because of the genetic machinery of primates and humans. There were other reasons why they downgraded DEHP, but again they were very science-based.

● (1120)

In Europe, many national European ministries of health have followed that, like the International Agency for Research on Cancer. The Swedish National Board of Health and Welfare is a notable example. It's another very environmentally conscious agency that has downgraded DEHP as a possible human carcinogen, because of the science.

That's a very brief background on the science. There is a tremendous volume of data here.

All that having been said, vinyl DEHP is safe and effective for many medical applications; however, it's not functionally the right material for every medical product application. The industry, including Baxter, has been very proactive for many years in introducing alternative materials. It hasn't been reactive; it has been proactive in the sense of finding the right materials for very unique and specific applications.

The claim made that non-PVC products are safer than PVC products is just not correct. All medical product materials are held to the same regulatory standards. Health Canada doesn't look at a PVC medical product any differently than it does a non-PVC product. It's the same for agencies world-wide. The same standards are applied.

Scientifically it's unclear why there is still a focus here, in light of all the national and international reviews, and especially in the sense that alternative materials are constantly evolving in the industry. Where there are unique functional requirements, those products have been introduced. It's a matter of looking at the right material for whatever the unique clinical application is.

In conclusion, medical products are held to safe and effective standards. Medical applications of PVC and vinyl are recognized by international and national regulatory agencies around the world. The cumulative body of science absolutely supports the safety of DEHP and PVC medical products, and I would submit that public health is not served by uninformed or reactionary policy decisions.

Thank you.

● (1125)

**The Chair:** Thank you.

Marion Axmith, please.

**Ms. Marion Axmith (Director General, Vinyl Council of Canada):** Thank you very much.

Good morning, Mr. Chair and honourable members of the committee.

My name is Marion Axmith. I'm the director general of the Vinyl Council of Canada, which is a council of the Canadian Plastics Industry Association. I've been with CPIA for 24 years and I've worked on the Vinyl Council managing the Vinyl Council for the past 14 years.

Our members include a wide range of companies, from resin producers to additive suppliers, compounders, processors or manufacturers, and recyclers. The Canadian plastics industry is about a $51-billion industry. It employs approximately 150,000 Canadians.

The Vinyl Council members are members of a responsible industry within Canadian society. In 1999 we launched our environment management program to manage and reduce our environmental footprint. The program is a commitment to manufacture vinyl products in a safe and environmentally responsible manner. It is our road map to ensure we protect the environment and health during manufacture, use, recycle, and disposal of our products. We continually improve our performance. We strive for sustainability and we improve our capacity to listen to all our stakeholders.

We are here to speak to you about Bill C-307, which is an act to prohibit the use of three phthalates—BBP, DBP, and DEHP—in certain products. We are here to argue that Bill C-307, in its current form, is not necessary, as it circumvents the existing CEPA process for evaluating the safety of chemicals in Canada.

Incidentally, Canada has one of the best screening processes for chemicals in the world today. As I'm sure you're aware, CEPA has already screened 23,000 chemicals over the past six years or so. They've identified 199 of these for further review, and none of these phthalates, which are the subject of this bill, are on that list. They're not on that list because they have been assessed and they are not substances of concern.

What are phthalates? You've heard Dr. Cammack talk about DEHP, but generally phthalates are a class of compounds used mostly with a plastic called vinyl to make that plastic soft and flexible without compromising the strength of the vinyl. As Dr. Cammack said, DEHP has been used safety in medical devices for almost half a century and it provides many very useful benefits, including flexibility, a resistance to kinking, and the ability to withstand harsh sterilization methods while at the same time remaining very cost-effective.

Of the other two phthalates, BBP is most commonly used in flooring, carpet tile, caulking, and sealants. DBP is actually not used in vinyl at all and it is not found in children's toys. The main use for that one is in adhesives, cosmetics, and mostly nail polish.

On DEHP, Dr. Cammack covered the medical devices side. It is used in some plastic toys, inflatable toys like beach balls or water wings, that sort of toy, but it is not used in toys that are put in the mouth by children.

● (1130)

The product that keeps coming up and keeps getting mentioned is teethers. Most of the teethers made in Canada today are not made from vinyl. They do not have phthalates in them. They're made from silicone. So phthalates used primarily in vinyl are a very important part of our everyday lives.

In the next slide in front of you we've covered most of the benefits of the product, so I'll move directly to page 6.

Industry's perspective is that science should prevail here. We feel it's very important to remove this debate from the political arena and move it to the scientific and medical arena, where it can be properly studied and reviewed. The weight of scientific evidence to date demonstrates that bans on phthalates are unnecessary to protect human health.

As you're aware from your March 20 meeting, Health Canada has expressed concerns about the legislation as it is currently written, and I'd simply like to take you through some quotes that I pulled out of the transcript of that meeting from Mr. Paul Glover, who is the director general of the safe environments program of Health Canada. These are quotes and these are some of the things Mr. Glover said at the March 20 meeting:

> The risks posed by these substances to human health and to the environment were formally assessed under CEPA. The assessments for BBP and DBP were published in 1994 and in 2000 respectively. Both of those were found not to be CEPA-toxic, and therefore no further action was required under CEPA. That was primarily on the basis of exposure, or the lack of it.
>
> ...we also have no long-term safety data on the alternative chemicals used for medical devices. It is important to note that some phthalate-free medical devices have not yet been tested for all of the same indications of use as if they had phthalates in them. Therefore, it may not be suitable to simply substitute these.

So the Vinyl Council would respectfully like to put on the table two proposed amendments to this bill. The first one occurs in clause 3, to amend that, on page 1 of the bill, by replacing lines 9 and 10 with the following:

> the coming into force of this Act in accordance with the Canadian Environmental Protection Act, direct Environment Canada and Health Canada to review the use of the three phthalates: BBP, DVP, DEHP.

The second amendment refers to clause 3 on page 2, by deleting lines 9 and 10, which in effect would delete “medical devices” from the bill.

In summary, I want to stress that the Canadian plastics industry is a very responsible sector. We care deeply about the health and safety of Canadians. The Canadian public is our clientele. Canada has one of the best screening systems in the world for assessing chemicals, and we are asking that CEPA and the CEPA review process be allowed to work. Use this excellent system that the government has put in place.

We cannot make policy based on rumour, innuendo, and fear-mongering. Follow the science, use the excellent CEPA screening system that already exists.

Thank you, Mr. Chair.

● (1135)

**The Chair:** Thank you very much.

We'll go now to Marian Stanley, please.

**Ms. Marian Stanley (Manager, Phthalate Esters Panel, American Chemistry Council):** Good morning, Mr. Chair and honourable members. Thank you for the opportunity to testify before this committee.

My name is Marian Stanley. I'm a chemist by training. I'm a senior director at the American Chemistry Council and I've managed the Phthalate Esters Panel, which is a part of that council, for the last 17 years.

The panel represents the major producers of phthalate esters in the United States and North America. Since its inception in 1973, the panel has demonstrated its commitment to the safe use of its products by sponsoring health, safety, and environmental research.

The panel strongly supports the regulation of chemicals based on sound science. Phthalates are among the most well-studied chemicals on the planet and they have been the subject of hundreds of studies in laboratory animals and numerous government-sponsored assessments in Canada, the U.S., the EU, and Japan. These assessments have studied the risks to human health posed by exposure to phthalates.

The phthalate panel firmly believes the weight of scientific evidence demonstrates that the ban on phthalates proposed in Bill C-307 is unnecessary to protect human health. Bill C-307 proposes to ban butyl benzyl phthalate, dibutyl phthalate, and di(2-ethylhexyl) phthalate in products for use by a child in learning or play and in products that are put in the mouth of an infant when used. At the outset, the proposed ban of these three phthlates in children's toys would do little to protect children's health.

Butyl benzyl phthalate is most commonly used in flooring and insulating sealants. Dibutyl phthalate is used primarily in adhesives as a solvent for organic compounds and in nail polish. These are cellulosic plastics, not vinyl. Another way to think of this, think of screwdriver handles: they are also plasticized by dibutyl phthalate, a cellulosic plastic.

DEHP is used primarily in medical devices, as Dr. Cammack described, and in some soft plastic toys, as Ms. Axmith talked about —swim wings, plastic waterslides, but also in things like raincoats, backpacks, flip-flops, and other products children use in their daily life. These are not intended to be placed in the mouth by children and are safe as they're currently used.

In addition, numerous government risk assessments of these three phthalates have demonstrated that exposure to phthalates in toys and children's products generally poses no significant risk to children. Both the U.S. national toxicology program, the Center for the Evaluation of Risks to Human Reproduction, as Dr. Cammack described, and the European Union have performed risk assessments of these three phthalates proposed to be banned by Bill C-307, and these agencies have found no significant risk to children from exposure to these phthalates.

Similar to its being banned in toys, the proposed ban on DEHP in cosmetics would be of little benefit to human health because DEHP is not used in cosmetics. DEHP is a vinyl plasticizer, and, generally, what I put on my face isn't vinyl. As for dibutyl phthalate, exposure levels to dibutyl phthalate from nail polish are extremely low, such that the risks from exposure to DBP are minimal. For example, dibutyl phthalate exposure levels for the thousands of study participants derived from the U.S. Centers for Disease Control and Prevention biomonitoring data show that levels of exposure to dibutyl phthalate are well within the safety limits set by the U.S. Environmental Protection Agency. These levels already incorporate a number of conservative safety margins. Because the animal data is reviewed, the no-effect level is then assessed, and the "up to 10,000 factor of safety" level is already applied, you've got a built-in precautionary system at work in North American regulatory agencies today.

I'd like to make two points. The measured exposures to dibutyl phthalate and the other phthalates are lower than previous estimates. Additionally, for dibutyl phthalate, the EPA has rereviewed the toxicology data and raised the safety factor for dibutyl phthalate threefold. In effect, that means that a woman using nail polish with dibutyl phthalate would have to use five bottles a day and absorb every single molecule of dibutyl phthalate to reach a level that caused no effect in rodents.

● (1140)

The U.S. Food and Drug Administration, which has regulatory authority over cosmetics, studied the CDC's biomonitoring data in 2001 and said it found no reason for consumers to be alarmed at the use of cosmetics containing phthalates. The FDA continues to evaluate available data on phthalates in cosmetics and has not seen any data that led it to take further steps. Moreover, an extensive 2002 review by the cosmetic ingredient review expert panel—this is an FDA-sanctioned independent body of toxicologists and dermatologists that regularly reviews all compounds used in cosmetics and personal care products—found that dibutyl phthalate and other phthalates used in cosmetics were safe as currently used.

Finally, the 2006 EU risk assessment of dibutyl phthalate mentioned above specifically found no concern for consumers using nail polish containing dibutyl phthalate.

The deck that you all have has a page on DEHP in medical devices. I won't go over that, since Dr. Cammack covered it so very thoroughly, but there are some highlights there for you to read at your leisure. On page seven in the deck that I've given you is a table that summarizes the reviews of the three phthalates that are included in Bill C-307. It looks at the reviews that were conducted in Canada, the European Union, and the United States. So this would be a very quick resource for you.

I'd like to conclude by saying that the extensive science shows that bans proposed in Bill C-307 are unnecessary to protect human health. The government-sponsored risk assessments in North America, Japan, and Europe have demonstrated that human exposure to phthalates in consumer products, including toys and cosmetics, is well below any level that has been shown to cause adverse health effects in laboratory animals, and they are well below government-established safety levels.

Consequently, the effect of these bans on phthalates proposed in Bill C-307 would be to place a significant burden on both manufacturers and retailers of phthalate-containing products and on the consumer and medical patients who rely on the performance and convenience made with phthalates, while it would provide no measurable benefits to human health. For this reason, the phthalate esters panel opposes Bill C-307.

Thank you for your time.

**The Chair:** Thank you very much.

We'll begin our first round. Ten minutes.

Mr. McGuinty.

**Mr. David McGuinty (Ottawa South, Lib.):** Thanks, Mr. Chair.

Thank you very much for coming, ladies and gentlemen.

We have in front of us here on this bill probably a hundred pages of conflicting testimony and evidence. We had Health Canada come here some weeks ago to speak to us about this bill. I think for most Canadians Health Canada has the referee's role, the broker's role, between industrial interests, health interests, and obviously health care interests, in this case.

It's placing us in a very difficult situation, because while we here in the official opposition support the notion that we ought to examine these chemical compounds, we're not in a situation, I think, to recommend to Canadian health care providers that they ought not to be using products that play an indispensable role in health care or in pandemic preparation.

So please help us understand here. How can this bill be amended so that it actually meets the primary interests of this committee and parliamentarians, which is to put the health of Canadians and the safety of Canadians first? I know it's an emotional issue. In part it has been cast as an emotional issue because the bill has been presented as something that talks about things that go in children's mouths. As a father of four children, I'm concerned about what they put in their mouths. Now, as teenagers particularly, other things go in their mouths.

I'm just trying to get a sense here of how this can be amended so that we achieve what the French would call *le juste milieu*, the proper balance. We're not out to commit economic hara-kiri with industries in this product business. We want to see health care go forward, but we want to see health and safety here properly reflected. Can you help us understand, what do we have to do to this two-page bill to make it right?

● (1145)

**Mr. Jon Cammack:** Marion, I think you had suggestions.

**Ms. Marion Axmith:** Mr. McGuinty, as I mentioned in my presentation, I have proposed a couple of amendments to the bill.

Our perspective is that we have a CEPA review process for the review of chemicals, for their risk assessment, and for their risk management. If you, as a committee, have concerns about these substances, refer them back to Health Canada, to Environment Canada, for further assessment. As mentioned, they have already been assessed a number of times.

With regard to Health Canada, Health Canada is, as I'm sure you're aware, the arm of the government that approves the medical devices for use. There is a very stringent screening process for approval of these medical devices, and they have been doing that for decades.

I would just further point out that there is not one documented case of a Canadian being harmed by any of these medical devices. I'll leave it at that.

**Mr. David McGuinty:** So your position, then, for Canadians who are watching and following this debate, is that we should go with the recommendations of the referee, and the referee is Health Canada. You're telling us that the referee came here some weeks ago and told us to restate what you've restated for Mr. Glover—that the risk to human health and environment was formally assessed by CEPA in 1994 and 2000, and that these assessments concluded that none of these products were CEPA-toxic on the basis of exposure. You talked about the fact that substitution may not be possible. That's Health Canada's position.

If that's the case, why do I and all committee members here have a half-dozen environmental groups walking into our offices and sending us briefs saying the exact contrary, saying the exact opposite, saying that the science conducted by Health Canada was faulty, saying that it did not take into account cumulative exposure. Who's right? Who's wrong? Who's spinning? Who's helping us come up with actual balanced decisions here?

**Ms. Marion Axmith:** I know, Mr. McGuinty, that the industries, whether they are the medical devices industry, the vinyl industry, or the phthalate industry, have done their homework, have participated in studies, and have supported studies over many decades.

With regard to the environmental groups that are raising concerns on these substances, I challenge them to come forward with their scientific data and information to support their allegations.

**Ms. Marian Stanley:** Mr. McGuinty, I could give you a brief U.S. perspective. As I said, I've worked with the phthalates panel for 17 years. In the early nineties we were working with Health Canada and getting very comprehensive reviews of the phthalates with Health Canada and Environment Canada.

Now, at the same time, the U.S. had in place review processes, but they were in silos, so we didn't have an agency that put everything together in a comprehensive manner. You've had this for a very long time, and you had that process in place before the European Union even thought about their chemicals program.

Many of the allegations about phthalates and other chemicals are based on hazard and hazard alone. What you need to do in the scientific framework is to look at not only hazard but also exposure. We certainly recently had a case in the U.S. in which a woman was challenged by a radio station to drink water. She died because she drank too much water. In that dose, it was certainly a hazard. In normal everyday doses, water is not, so the risk is low.

We know from measured data now that the exposure to phthalates is very low, certainly well below the level that causes any hazard in animals. We believe also that our current North American regulatory system has a precautionary basis to it, so that human health is well protected.

● (1150)

**Mr. David McGuinty:** Let me maybe put this to you, then, for the last comment. I have a brief here from one particular NGO, which states a couple of things:

> A 2006 U.S. National Toxicology Program...report confirmed that DEHP "poses a risk to human development and reproduction"...
>
> DEHP, BBP, DBP have been added to the California Proposition 65 list of toxic substances.... [Canada's] assessments...failed to include exposure from consumer products, house dust and breast milk, underestimating children's exposure....
>
> The European Union has banned DEHP, DBP, and BBP in all toys and childcare articles, and DEHP and DBP in cosmetics. Other countries that have banned phthalates in children's toys include Argentina, Fiji, Finland, Japan, and Mexico.

It goes on from there.

Are these people wrong?

**Mr. Jon Cammack:** I think that some of the statements you just read were maybe taken out of context. Specifically, the U.S. NTP and the Center for the Evaluation of Risks to Human Reproduction said very conclusively that there is—bottom line—insufficient human data to indicate that there is harm occurring in humans.

It is a raging debate, there's no question about it. From what we have seen directed at the medical products industry, the data we get presented by the environmental groups is based completely on rodent studies that are done in ways that aren't necessarily relevant to how our products are used. By that I mean it may be very, very high doses, for example, of a chemical like DEHP that a rodent is exposed to, and by a route of exposure, very high oral dosing, that may not necessarily be relevant to how a medical therapy interacts with the human body.

I don't think anybody—any scientist or toxicologist—would question that there is very credible rodent data that shows effects of phthalates at very high levels.

**Mr. David McGuinty:** May I ask, has the European Union banned DEHP, DBP, and BBP in all toys and child care articles, and did they ban DEHP and DBP in cosmetics? That's 26 nation-states. Have they banned these products?

**Ms. Marian Stanley:** I'll speak to that.

First of all, those phthalates were not banned in all toys. They were banned prior to the completion of risk assessments. The ban is in toys that can be placed in the mouth, and it's for a five-centimetre-square piece of article.

There's also another part of the European legislation called the CMR list—carcinogen, mutagen, or reproductive toxicant. It is based solely on hazard. So if you have an effect in any animal, and it's deemed to be a level-one or level-two CMR substance, it goes on a list. There are approximately 1,700 substances on that list currently. But if it's placed on that list, it can't be used in consumer products. Now, the irony of that is that dibutyl phthalate is certainly on the CMR list; however, the risk assessment also says there's no problem with its use in cosmetics by the general population.

For DEHP, it's the same thing; it is hazard-based.

**The Chair:** Thank you, Mr. McGuinty.

Mr. Lussier, please.

[*Translation*]

**Mr. Marcel Lussier (Brossard—La Prairie, BQ):** Thank you, Mr. Chairman.

Ms. Stanley, you represent the American Chemistry Council. Are you a chemist?

[*English*]

**Ms. Marian Stanley:** Yes.

[*Translation*]

**Mr. Marcel Lussier:** Have you ever worked in a laboratory where you were called upon to analyze human blood for the purposes of detecting the chemicals that are under consideration today, that is BBP, DBP and DEHP? Have you ever undertaken a chemical analysis in order to determine the concentration of these chemicals in blood?

● (1155)

[*English*]

**Ms. Marian Stanley:** No, my experience as a chemist has been in the chemical industry as an analytical chemist looking primarily at organic compounds. My experience as a chemist has also been within the pharmaceutical industry, working in a laboratory and looking at quality control of pharmaceutical compounds. Additionally, I've done quality assurance in the pharmaceutical industry and have been a technical product manager. I have not worked with blood or urine samples.

[*Translation*]

**Mr. Marcel Lussier:** Have any of the experts before us undertaken a chemical analysis of human blood in a laboratory, in order to detect the chemicals that we are discussing?

Mr. Cammack?

[*English*]

**Mr. Jon Cammack:** Yes, our company has done those studies, many, many of them, and beyond those, we've taken the actual blood samples from animals—again, where a lot of these data are based—and studied the effects of DEHP at the very highest levels in the blood of these most sensitive animal species, rats and mice.

[*Translation*]

**Mr. Marcel Lussier:** That is not my question. I asked you if you have ever done a chemical analysis of human blood.

[*English*]

**Mr. Jon Cammack:** I have not, but my laboratories have.

[*Translation*]

**Mr. Marcel Lussier:** Have you looked at several chemical analyses of human blood in which these three chemicals were detected? Do you have any analyses that prove that there is a low concentration of those chemicals in human blood?

[*English*]

**Mr. Jon Cammack:** Absolutely, no question. And this is published, publicly available data.

DEHP, especially in blood component storage containers, does migrate from the material into the blood. So yes, we've seen that. In fact, current blood banking would not be possible without DEHP plasticized PVC, because that chemical actually has a protective effect on the red blood cell.

[*Translation*]

**Mr. Marcel Lussier:** Have you ever seen analyses of the blood of newborns, where those chemicals are present?

[*English*]

**Mr. Jon Cammack:** My laboratories haven't done that because Baxter doesn't make those products, but those data are published. There is scientific literature that publishes that.

[*Translation*]

**Mr. Marcel Lussier:** When DEHP is detected in the blood along with other chemicals, has anyone ever wondered if one chemical may have an effect on another?

[*English*]

**Mr. Jon Cammack:** I think you are asking if there is migration of a phthalate into the blood, what effect that has on the patient. Yes—

[*Translation*]

**Mr. Marcel Lussier:** If one chemical is mixed with another that is also in the blood, for example BPC and another chemical of some kind, is the combined effect of those two or three chemicals analyzed? Is the combined effect of the three chemicals measured?

[*English*]

**Mr. Jon Cammack:** I'm not sure I totally understand the question, but for a blood bag for current blood banking, the material that's used is DEHP-plasticized PVC. There aren't other phthalates used in those blood bags, so it would be the DEHP, not other chemicals.

[*Translation*]

**Mr. Marcel Lussier:** Ms. Axmith, do you have any data that shows that DEHP in the blood has an effect when it is combined with other chemicals also contained within human blood?

We heard from experts who tabled studies on human blood that contained traces of 26 different chemicals.

Has your group undertaken any studies that consider the effect of DEHP when it is combined with other chemicals?

● (1200)

[*English*]

**Ms. Marion Axmith:** I defer to the scientists and the toxicologists on this, but my understanding, and Marian Stanley can explain further, is that phthalates are not retained in the body. They pass through the body. So if a patient, an infant, a child, an adult, were treated with a device containing DEHP, that substance might go into their body, yes, but it would not be retained in the body. It would be expelled within a certain time period.

I ask Marian to comment on that.

**Ms. Marian Stanley:** Sure. What I'd like to comment on is that what we do know is that from the very extensive Centers for Disease Control biomonitoring program, they have now analyzed well over 100 compounds in both human blood and urine. The preamble to their report states that the presence of a compound does not necessarily mean a diseased state.

The phthalates panel has looked at the action of phthalates as a possible adjuvant to causing allergic reactions. We know that it doesn't have that effect in animals. We know that the national toxicology program has done some work with two phthalates and has found them to be not additive, so there is evidence there to show that phthalates don't interact with other compounds and that they're not additive together.

Additionally, as Marion Axsmith pointed out, they have about a 24-hour transit time in the body and then they are expelled in the urine.

**Mr. Jon Cammack:** Could I make a comment?

I think I understand your question now, so yes, there are constituents of a material that will extract into blood or any kind of solution that a material touches. That's not a unique feature of PVC DEHP. If I had a non-PVC material and put water in it, or blood or anything else, there are going to be chemicals and constituents of this material that come out into solutions. That is a non-unique feature of PVC and DEHP. One of the very powerful things about PVC materials is that they have not only a tremendous amount of study in animals looking at the safety, but there are human clinical data with no evidence of adverse effects. So whether this is a non-PVC material, glass or whatever, in contact with a solution, positively, scientifically, there are things that are coming out of this, going into solution and going into your body.

[*Translation*]

**Mr. Marcel Lussier:** I am disturbed by Ms. Axmith's comments. She said that the chemical remains in human blood for only 24 hours. Therefore, if I do a blood analysis and I find DEHP in that blood, that means that I was in contact with that chemical only 24 hours ago. It's incredible that this chemical was found in the blood of 26 patients tested. That means that we are constantly in contact with that chemical. We're told that it is eliminated quickly, that there is no cumulative effect and there is no reaction between chemicals in the blood. That's what I'm hearing.

[*English*]

**Mr. Jon Cammack:** That's a great question. Different chemicals are handled differently by the body, but right now there is no science that says DEHP or another phthalate from some medical therapy are interacting together and producing a synergistic effect. I think that's what you're asking. There is no data that says that.

There's no data that says any chemical coming from any material in a medical therapy is interacting with other chemicals and producing more pronounced effects than you would get with the individual chemical. Again, that isn't a unique feature of PVC and DEHP. That's how all medical products act when they're in contact with the body.

● (1205)

**The Chair:** Thank you, Mr. Lussier.

Mr. Cullen, please.

**Mr. Nathan Cullen (Skeena—Bulkley Valley, NDP):** Thank you, Mr. Chair.

The first question I have is for Ms. Axmith. Regarding the chemicals that are manufactured, the ones that are in our manufacturing process, do any of them cause cancer? Has there ever been a link? Is it possible for a manufactured chemical to cause cancer in humans?

**Ms. Marion Axmith:** That depends on the chemical.

**Mr. Nathan Cullen:** So yes, in some cases?

**Ms. Marion Axmith:** Possibly, in some cases.

**Mr. Nathan Cullen:** But possibly not ever? Is it possible that no chemicals—

**Ms. Marion Axmith:** No, possibly, in some cases, and not—

**Mr. Nathan Cullen:** I don't know why this is a hard question to answer. Mr. Cammack is nodding, so maybe I'll ask him.

Do chemicals that are manufactured cause cancer?

**Mr. Jon Cammack:** Yes. Just about any chemical in high enough doses can cause cancer.

**Mr. Nathan Cullen:** This is an important premise for us to establish. It's just in case we have any sort of concept that environmental toxins don't cause cancer in humans.

I'll stay with you, Mr. Cammack. Is DEHP a reproductive toxin?

**Mr. Jon Cammack:** DEHP, no question, causes reproductive effects in sensitive rodents, in rats and mice. There are other species that DEHP does not cause reproductive effects in, and other rodent species.

**Mr. Nathan Cullen:** Right. So when the national toxicology program in 2000 said that "...DEHP poses a risk to human development and fertility", and "Based on the science, there is a consensus that DEHP is a reproductive toxin"....

I guess the question is that we keep talking about rodents so much. If a young mother were going into a hospital to deliver a baby and found out that there's a product in there that causes cancer in rodents and there was a substitute that didn't cause cancer in rodents, I'm imagining she'd choose the latter, just in the precautious sort of way that we are with our children. Why would you choose one that's causing cancer in one animal?

**Mr. Jon Cammack:** It's a great point, and I think the key thing that you said is alternative materials. Any reasonable person obviously would choose the non-cancer-causing—

**Mr. Nathan Cullen:** To follow up on Mr. McGuinty's point, I have a list of 14 pages that we submitted for evidence, Mr. Chair, but the translators couldn't handle the scientific terminology. It has been one of our struggles with this particular bill, the poor folks around the Hill who have to work with these words. But there are 14 pages of substitutes available.

I have, at the end of this, another page filled with hospitals all across the United States, and now hospitals in Canada, that are going DEHP-free. Why would a hospital do that if there's no risk?

**Mr. Jon Cammack:** Again, I would say this is something that the medical products industry has been doing for many, many years. Baxter, ourselves, we have many—

**Mr. Nathan Cullen:** You do make products that are DEHP-free, correct?

**Mr. Jon Cammack:** And have for the last 25-plus years.

**Mr. Nathan Cullen:** Let me nail that down just for a second then. The argument was made that this was damaging to the economy, and there was some testimony that people would be unable to get surgeries if this bill were to pass. Do you find that verifiable?

**Mr. Jon Cammack:** That's absolutely verifiable, because currently there aren't alternatives for all medical products that are made with PVC DEHP.

**Mr. Nathan Cullen:** Let me ask you this. If there were a phase-in period that allowed for companies to react, considering the 14 pages of alternatives and Baxter being one of the leading companies in making DEHP-free medical devices to allow industry to adapt, and if, on top of that, there were an exemption, where if there were no reasonable alternative found, government would have another three years to allow industry to find another reasonable exemption—

● (1210)

**Mr. Jon Cammack:** That doesn't make sense to me. Again, the reason to evolve materials is based on the functionality of the material—patient-focused, how it's going to work with the patient—and it should be science-based. Right now, there's absolutely no data that say there should be a full-scale conversion.

**Mr. Nathan Cullen:** I have some words from Dr. Robin Walker, who chaired Canada's own expert advisory panel on DEHP in medical devices. He quotes from the 2002 report, and this is from Health Canada:

> Alternate measures are immediately justifiable and should be introduced as quickly as possible to protect those sub-populations at greatest risk....

That's 2002. And let me just repeat that "immediately justifiable and should be introduced as quickly as possible".

Now, I know government moves slowly and we have many consultation panels with industry, but I have a question for Ms. Axmith. Hearing "immediately justifiable" and "introduced as quickly as possible" in 2002, do you think Canadians will be satisfied with the rate of progress in removing DEHP from medical devices?

No, I directed it towards you, Ms. Axmith.

**Ms. Marion Axmith:** I think on that particular report, where Health Canada was coming from, they did express concern about sensitive sub-populations. And to be precautionary about it, they were recommending that if alternatives exist to treat those sensitive sub-populations, if they're available, they should be used.

Health Canada also stated that under no circumstances should medical treatment be withheld from anyone.

**Mr. Nathan Cullen:** Certainly. Let's put this spectre to rest immediately with respect to this bill. There is no suggestion that someone's going to end up on an operating table and the surgery won't be performed because there simply isn't a medical device available. That's clearly not the intention of the bill. I think we can establish that and admit to it immediately.

**Ms. Marion Axmith:** Of course.

**Mr. Nathan Cullen:** So when I hear that Health Canada asks for.... And the chair of that committee has since been phasing this out in his hospital in the Atlantic provinces, in Nova Scotia, which is one of the have-not provinces faced with certain fiscal restraints. It has been able to do this phase-out. It's an outstanding hospital, as many of my eastern colleagues will contribute to, and becoming better, I would suggest, because they are moving to phase out DEHP from all their products, and they are doing so without any great fiscal penalty to a hospital that is only allowed a 7% overall increase per year. It is doing quite well in managing to do that.

There's great faith expressed in Health Canada and Environment Canada. It's wonderful, because when we asked Health Canada and Environment Canada officials if they had sufficient resources to go about the assessments you have so much faith in, they said no. They simply don't have the human power to go through and do proper assessments of these substances at all possible times.

So my question is this. When Health Canada restricts and limits the focus of its study so that there's no accumulation allowed, the cumulative effect.... How many times in a given day does a human bump into these phthalates? Do we know? We've taken this as a very narrow scope where we say, well, four bottles of nail polish is needed to be consumed and that would be approaching it.

Phthalates don't come just through nail polish. They don't just come through any one substance; they come through many. Has anyone ever done a cumulative assessment of your average human, or particularly of a young child in their daily goings-on, to understand the cumulative effect, the total taken in of phthalates? Has anyone done this?

**Mr. Jon Cammack:** The CDC has done studies like that and has looked at levels in urine.

**Mr. Nathan Cullen:** Was it on children? I just want to be clear. Can you submit that study for this committee?

**Mr. Jon Cammack:** We can send that study to this committee.

**Mr. Nathan Cullen:** I think it's very important.

I have a question about this, though. There was a claim made that there are no phthalates in children's products in Canada; that chewables and these products simply don't contain them in Canada. I just want to make sure I got the testimony.

**Ms. Marion Axmith:** Yes, specifically I made that comment. It was specifically on teethers and soft rattles.

**Mr. Nathan Cullen:** Teethers and...sorry...?

**Ms. Marion Axmith:** Soft rattles.

**Mr. Nathan Cullen:** Soft rattles. What about all chewables, such as rubber duckies and such? Do we know whether there are phthalates in those? I'm just looking to see what assurances we know we have, if we're going to make a claim that this bill is not necessary because they're not in toys. Do we know this?

● (1215)

**Ms. Marion Axmith:** As I said before, they are not in teethers and soft rattles, things intended to be put into the mouths of children.

**Mr. Nathan Cullen:** So things intended—

**Ms. Marion Axmith:** Health Canada—and you would have to ask them for the studies—have been pulling these products off the shelves since 1998 and testing them.

**Mr. Nathan Cullen:** Yes, it's ironic, only because when we had government officials here and asked them what veracity there was to make that claim—how often they are testing; how we know that imports aren't including these, the things in the dollar store.... We have no capacity to know this right now in Canada. So I caution you on making the claim.

I'm reminded, as I was walking here with my colleague today, that there's a great movie that I encourage witnesses and committee members to see, *Thank You For Smoking*. It's this wonderful diatribe and satirical movie about the ability to defend and make sure that things are framed.

The important thing for us to consider here is that I very much appreciate your passion in defending the interest you represent. I will remind committee members as we go through this process of the interests we are meant to represent, and that if there is a precaution out there.... The same argument that was used for so long, initially for smoking and then for second-hand smoking, about sound, scientific evidence just not being there, not being available, was used for decades to prevent action.

If we have substitutes available, which doctors in hospitals right now are saying are available for us to use, and if there is ample evidence showing that there should be some reason for caution over these products and these chemicals, it is beyond me to understand why we wouldn't take the cautious approach and ensure the greatest level of safety for Canadians. It's beyond me.

I'm too far gone in this comment, and I know my time is up, Mr. Chair. I apologize for running over.

**The Chair:** Thank you, Mr. Cullen. I think you have the same passion for this that I have for garbage.

Let's go on with Mr. Warawa, please.

**Mr. Mark Warawa (Langley, CPC):** Thank you, Mr. Chair. I'll be splitting my time with Mr. Allen.

I found the questioning of Mr. Cullen interesting. I think it was a little over the top, though, when he was equating smoking with phthalates in medical bags. I haven't heard of any studies of rats being tested for smoking and the effects of nicotine.

The EU had an emergency ban in 1999 on phthalates. I want to follow up on some of the questioning of Mr. McGuinty. The members of this committee have heard testimony about the risk of phthalates, and have also heard about it in the bill from Mr. Cullen. What do you believe is motivating the environmental NGOs to encourage the passage of this bill? And what do you believe caused the EU to have an emergency ban back in 1999?

**Ms. Marian Stanley:** It started in 1998.

We know that any plasticizer from a vinyl will migrate. There was a program to determine the migration of phthalates from vinyl toys and the level of that migration. In conjunction with that, there was a debate on test methods and a debate on the level that should be allowable.

As with many scientific studies, there were several competing methods. There was a chew and spit method; there was a head-over-heels extraction method, etc.; there were many methods. People couldn't come to a conclusion on how to determine migration limits, so the scientific committee in the EU at the time said they didn't believe there was a risk in phthalates. However, because no agreement could be reached on a migration level, an emergency ban was put in place.

Now, I think a reasonable question is, why were those six phthalates chosen? Those six phthalates were chosen because they were, at that time, undergoing risk assessments and scientific reviews in the EU. There are about 13 phthalates in commerce.

That emergency ban, which is a three-month emergency ban, was renewed 21 times. After the 21st time, there was a determination made in the European Parliament to ban phthalates in toys for very young children.

Subsequent to that ban, the EU risk assessments were published. They were completed in 2003 and finally put into the *Official Journal of the European Union* in 2005, I believe—but we can verify those dates. At any rate, as we've said here, a couple of those phthalates aren't even used in toys—butyl benzyl phthalate, dibutyl phthalate—but they were being studied and were caught up in that ban. DEHP is used more in child care products.

When the risk assessments were finalized and the science came out, the science said there wasn't a concern for risks to children, as the exposure wasn't high enough. At about the same time, the U.S. Consumer Products Safety Commission was involved. They commissioned a chronic hazard advisory panel and did a five-year study—which was probably the most comprehensive study of vinyl toys, because they were petitioned to ban vinyl in toys for children of five and under. They determined that the exposures were so low there wasn't a risk to children. They looked at mouthing behaviour, how children put things in their mouths, and time spent by objects in their mouths. They pulled products off the shelves and tested them. They determined there was no reason for a ban. That was published in 2003. They reiterated in February 2007 that they stood by their conclusions.

I know I threw a little bit of the U.S. experience in there too, but all of that was happening concurrently.

● (1220)

**Mr. Mark Warawa:** I have five children and four grandchildren. With my grandchildren, everything goes in their mouths—anything that's near them—particularly with the young ones.

Do you feel comfortable with your children or grandchildren sticking things in their mouths with the products we have manufactured in Canada? Are you comfortable with the phtalate levels in the regulations we have in place and the way CEPA manages this?

**Ms. Marian Stanley:** Well, I certainly can speak for the U.S. What the CPSC showed was that while children are constantly putting things into their mouths, when they have an array of items, they don't always go for the vinyl toy.

**Mr. Mark Warawa:** Correct.

**Ms. Marian Stanley:** So you're getting an array of things there. The study was done both with parents observing and professional observers. They determined that the amount of time vinyl toys actually went into mouths was very short, and because of that there wasn't a concern.

Would I have a concern giving my children toys in the U.S.? No. Would I have a concern bringing my child into Canada and buying a whole new array of toys made in Canada and giving my child those toys? No.

**The Chair:** Mr. Allen.

**Mr. Mike Allen (Tobique—Mactaquac, CPC):** Thank you, Mr. Chair.

And thank you for your comments.

There are a couple of things I want to pursue a little bit. It's interesting that when we go through this bill next week to decide what we're going to do with it, the evidence that's been given on both sides of this issue is pretty tough to get your head around.

I'm going to go to page 4 of Ms. Stanley's presentation first—it's interesting that it happens on page 4 of both your presentations, Ms. Stanley's as well as Ms. Axmith's—where you use words like “but not those intended to be placed in the mouth”, and “banned by Bill C-307 and have generally found no significant risk”.

And then in Ms. Axmith's presentation it included, “DBP is not commonly used”, and then “soft plastic toys”.

To Mr. Warawa's point in terms of all these things ending up going in the mouth and everything else, I'm a little bit concerned that the words you're using here do not give me a great level of comfort that there is not an impact. Those words you're using just concern me.

When I'm looking at this bill next week, how can you allay my concerns that children are not going to be impacted by this?

**Ms. Marian Stanley:** We use those words because I can't give you an absolute. I haven't gone out and tested every single product on every single shelf, from every single reputable manufacturer, from every single importer.

We know from the Toy Industry Association, certainly in the U.S., that it's not common. These are U.S. manufacturers, large and small. But I can't give you a 100% unequivocal guarantee.

● (1225)

**Mr. Mike Allen:** Okay.

Ms. Axmith, would you want to add anything to that before I ask my next question?

**Ms. Marion Axmith:** With regard to DBP and what is on slide 4, I can't think of a vinyl product where DBP is used.

With regard to DEHP, as we've mentioned, it's products that are inflatable, like beach balls, water wings, and that sort of thing, and raincoats, rain boots.

**Mr. Mike Allen:** Okay. You've both taken me now to my next question. Thank you. It is with respect to the advantages and disadvantages or problems with substitutes.

Mr. Cullen brought up these 14 substitutes. And along his line of questioning when he talked about manufacturing, manufacturing in these chemicals causes cancer. I presume that if we use them in these other products they're a manufactured product and there is a chance that they could also cause cancer. Is that not true?

**Ms. Marian Stanley:** What you have with phthalates are remarkably well-characterized materials.

The International Agency for Research on Cancer, for DEHP particularly, looked at all of the data. And the cancer that was caused was in rodents and in tumours, specifically liver tumours, by a mechanism that the International Agency for Research on Cancer determined wasn't relevant to humans. The metabolism of the rodent and the primate were so different that the cancer issue.... Actually, I think the U.S. is the only country in the world right now that actually hasn't changed its cancer classification for phthalates.

And I think you had another part to that.

**Mr. Mike Allen:** It was just around the substitutes and how—

**Ms. Marian Stanley:** The substitutes. When the Consumer Product Safety Commission did its very extensive study, it said to be very careful about using substitutes. They may not be as well studied and they may not perform as well. Products may be more brittle, and in toys may cause a choking hazard for children.

The way our regulatory system works is that for a test to be valid you've got to give a high enough dose to a rodent to cause an effect. Because of the expense and the ethics of testing, you don't test at 100 different doses. You have orders of magnitude between this. And Dr. Cammack can help me out here, because he's done the testing. You may test at 100 milligrams per kilogram, and then at 1,000 milligrams per kilogram. If you see no effects at 100 milligrams, but you do see effects at 1,000 milligrams, somewhere in there is the real effect level. It may be at 900 milligrams per kilogram.

So our regulatory system right now says that no effect is 100 milligrams per kilogram. We know there is no effect in a rodent now. We're now going to apply a safety factor to that for inter-species. We're going to apply another safety factor to that going from adults to children, and another safety factor may be applied. So you have a very precautionary regulatory system in place.

I don't know if Dr. Cammack wants to add to that.

**Mr. Jon Cammack:** The only thing I would add, and it's a follow-up to Mr. Cullen's comments, is in terms of the alternative materials question, absolutely those products exist. Our industry innovates new materials for new applications, but it's very focused on the functionality. No regulatory agency has indicated or enacted guidance that has forced us to move away from DEHP PVC, and as health care manufacturers of products in that setting, we have a very vested interest, unlike the tobacco industry, in ensuring the health of our patients.

So those alternative materials exist, alternative products. The reason is that's what we do. We evolve materials.

**The Chair:** Thank you, Mr. Allen.

We'll go to Mr. Rota for five minutes, please.

**Mr. Anthony Rota (Nipissing—Timiskaming, Lib.):** Thank you.

Thank you for being here today.

I'm looking at what we have and what I've heard in the past. There are a lot of conflicting reports on these items, and it just confuses things more than anything else. When we look at it, we see precautions for what are called sub-populations, but what I see are pregnant women and children. These are the ones we have to look at, some of our more precious commodities in society; it's our future.

So I get defensive when I hear that it's only one part of the population and it's not really dangerous, that if we give limited doses, it's not a problem, and that's what I'm hearing here.

When we look at children's toys or plastic nipples or bottles, what was the reason for eliminating them on those items? I haven't heard a clear answer on that one.

● (1230)

**Ms. Marion Axmith:** The reason for eliminating phthalate from those items back in 1998—and it was industry that stepped up and voluntarily withdrew phthalate out of teethers and soft rattles—was that it was done as a precautionary measure pending further research. That's a very important part of the statement: “pending further research”.

As Marian Stanley has outlined, further research has been done by the Consumer Product Safety Commission in the U.S. on those kinds of products and they have been deemed safe for continued use. The reason they're not back on the shelves here in Canada is Health Canada has not withdrawn the alert they issued in 1998. They have continued to take those products off the shelves and test them. And alternatives were readily available at that time, so there were products out there that consumers could use, and you know that in the marketplace products get displaced with other products. It happens in the plastics industry all the time. A better product comes along or a more economical product or a product that performs better, and that gets substituted in the marketplace. It's the way of business.

**Ms. Marian Stanley:** I think you referred to bottle nipples and other nipples. I don't believe they were ever phthalate plasticized vinyl. Silicone is more like mom, and that's why they're used.

**Mr. Anthony Rota:** So in children's toys—for example, we talked about the rubber ducky, which is probably one of the basic toys children get when they're younger—now they're banned from there or they have been voluntarily removed from toys that children put in their mouths.

The one statement I'm thinking of, Ms. Stanley, is when you were talking about letting your children or your grandchildren play with the toy. What I heard was that since it's only in limited amounts anyway, it's not as if they're putting it in their mouth and sucking on it and holding it constantly.

There seemed to be a doubt in your mind if a child took a toy, let's say their favourite toy, and kept it in their mouth constantly over a long period of time. All of a sudden that inserted a little bit of doubt in my mind whether you would let your children have that toy that stays in their mouth all the time. Then I started wondering whether it's something we should expose our children to.

**Ms. Marian Stanley:** I know that what the Consumer Product Safety Commission said was that a child would have to keep a vinyl article in his or her mouth for greater than, I think, 95 minutes a day to approach any harm. What they then found in their mouthing study with children is that what children did indeed keep in their mouths for the longest time, their favourite, were the silicone pacifiers. So the behaviour studies didn't show that this is what children were doing. That just wasn't the behaviour.

We know also, at least in the U.S., from the Centers for Disease Control, that the level of phthalates used in toys is virtually non-detectable in the human population. I personally do not have a concern. There are other things I'd be worried about.

**Mr. Anthony Rota:** Maybe I'm not hearing you correctly. If a child holds—

**The Chair:** Be brief. Your time's up.

**Mr. Anthony Rota:** Already? Sorry about that.

I'll ask a very quick question. What I'm hearing is that if a child holds something with phthalimide in it for 95 minutes or more a day, it can be toxic.

● (1235)

**Ms. Marian Stanley:** The other thing the Consumer Product Safety Commission did was a worst-case analysis. They said, okay, we know that what children keep the longest in their mouths is the silicone pacifier. Let's make the assumption that it is vinyl and that it is plasticized, and then let's back-calculate to what the exposure would be. And they said that there's still no risk to children. So again, I personally do not have a concern, because of that worst-case analysis.

**The Chair:** We'll go to Mr. Vellacott.

**Mr. Maurice Vellacott (Saskatoon—Wanuskewin, CPC):** One of the other witnesses—you in the industry, of course, would be aware of this—B. Braun Medical Inc., which is not able to be here today, supplies DEHP-free medical supplies. They produce them. They manufacture uniquely PVC-free and DEHP-free basic IV tubing containers and IV administration kits, some licensed for sale in Canada. The company apparently was represented at the Health Canada stakeholders' forum on DEHP in medical devices.

I gather that some of those particular devices may not be available in Canada. Also, it should be noted that their products contain alternate plasticizers. I think there was a comment made before that some of these alternate plasticizers have not been fully assessed. Has there been some partial assessment of these alternate plasticizers? What's the difference between being fully assessed and maybe being in some manner assessed?

**Mr. Jon Cammack:** Any product that's approved in Canada or in the U.S. or in other regions of the world—again, I talked about the regulatory requirements—has definitely been evaluated if it is approved. The difference between DEHP and most other manufactured chemicals is that there is a tremendous, overwhelming number of studies that have been done on that chemical in cancer studies and reproductive and developmental studies. So there have been many, many more studies done than what would have been done on any other type of plasticizer.

However, again, any product that is on the market has gone through the appropriate amount of testing. B. Braun is certainly not the only company that has DEHP- and PVC-free products. Many companies also offer those types of products where they are appropriate for the clinical applications and where the functional requirements are met.

**Mr. Maurice Vellacott:** So we're saying that if it's on the market, it's had its testing, at least with a certain rigour. Would something along the way kind of give us cause for.... Is there additional testing done at some point when there are concerns raised?

**Mr. Jon Cammack:** The type of testing that has raised concerns about DEHP and rodents—

**Mr. Maurice Vellacott:** No, I'm talking about the alternate plasticizers.

**Mr. Jon Cammack:** I'm going to answer the question.

With DEHP, the types of studies that have been done are very long-term studies, in animals, looking at multiple generations. For alternate plasticizers, as an example, those kinds of studies certainly aren't available in the literature. They're not publicly available. So DEHP, in a sense, is held to a little bit different standard in that respect.

**Mr. Maurice Vellacott:** So the other plasticizers have not been around as long. That's why we don't have this—

**Mr. Jon Cammack:** They haven't been around as long, and because of the length of time it takes to do those kinds of studies, it's very unlikely they would have been performed.

**Mr. Maurice Vellacott:** Okay.

I have one last question. Do I have a minute or two left?

● (1240)

**The Chair:** Yes.

**Mr. Maurice Vellacott:** One minute.

They also state, getting back specifically to Braun Medical, that they unequivocally support Health Canada's position paper on DEHP in medical devices, including the purpose-labelling requirements. They're not advocating a general ban on DEHP in medical devices, but they would like to see measures taken to ensure the use of DEHP-free medical devices in the most vulnerable populations, as defined by the position paper of Health Canada.

Would you be agreeable to that? Would there be an openness—that might be the word—or an agreement, possibly, at some point to that same position, that DEHP-free medical devices be available, particularly for vulnerable populations as defined by the position paper of Health Canada?

**Mr. Jon Cammack:** I'll answer for Baxter, and maybe Stephen can answer for the industry.

My company doesn't make the kinds of products for those very unique, specialized patient populations, like ECMO, where the concern statements by Health Canada were focused. So again, it is in some very unique populations.

But I would say that already, where there are customers who have a specific request or need, or in cases like this where there has been a focus of attention, medical device manufacturers are providing what our customers are asking for. I would only reiterate that it is based on the functional performance and what the clinical application is.

As I understand the bill, there is a lack of science to indicate that there is a need for a general ban or even a general phase-out over time.

**Mr. Maurice Vellacott:** Okay.

Maybe Stephen now...and the others can respond quickly.

**Mr. Stephen Dibert:** Our first position relative to the legislation is to remove the reference to medical devices. However, if there's an amendment or wording that would state that devices that have been proven with science to be safe and effective are viable, then they're free to come to the market and go through the rigorous regulatory process that all other devices that come to the market undergo. And those devices from any companies that bring an advantage, or even a perceived advantage to the marketplace, should do well.

**Mr. Maurice Vellacott:** So there should be no distinctions for vulnerable populations.

**Mr. Stephen Dibert:** Pardon me?

**Mr. Maurice Vellacott:** So no distinctions for vulnerable populations.

**Mr. Stephen Dibert:** Vulnerable populations, again, if the products that are used are scientifically proven to be safe and effective, then there's no problem.

**The Chair:** Thank you, Mr. Vellacott.

Mr. Lussier.

[*Translation*]

**Mr. Marcel Lussier:** Thank you, Mr. Chairman.

I trust that Canadian and American products manufactured by our vinyl or plastics industries are tested for the presence of phtalates, but are imported products also tested?

For example, in my municipality, in my riding, there is a fairly large Chinese community involved in the import/export business. For example, Dollarama stores that sell all kinds of products manufactured in China are doing very well. How do you think those products are monitored?

[*English*]

**Ms. Marion Axmith:** That is an excellent question.

[*Translation*]

**Mr. Marcel Lussier:** But it should be put to the Department of Health.

[*English*]

**Ms. Marion Axmith:** I have wondered many times about that.

It's a challenge for the government to monitor those products that are coming into this country, especially products intended to be used by children. They need to monitor those products. They need to test those products. And perhaps it would be Health Canada that would test those products, take them off the shelves and test those products to see what is in them, because I feel that imported products should meet the same high standards as do the products manufactured in the United States and Canada. Those imported products should be expected to meet those same standards.

That is an excellent question.

[*Translation*]

**Mr. Marcel Lussier:** Ms. Stanley, do you have the same concerns in the United States?

● (1245)

[*English*]

**Ms. Marian Stanley:** It's difficult for me to speak to the plastics industry because I represent the manufacturers of the additive—and only of one particular additive.

I know there are concerns that old technology is used in places like Russia, China, and that they're not meeting the same standards being met in the United States and Canada. Now, where North American companies may have opened up a plant, materials sold into the regions from those plants would meet the same standards as they meet in North America, or in Europe for that matter. But many times it is the state-run agencies or the state-run plants that aren't giving concern to workers, to process, or to the environment.

Certainly I've been in discussions with the U.S. Chamber of Commerce to try to make sure the same standards are met in places like China. It's a challenge.

[*Translation*]

**Mr. Marcel Lussier:** Thank you.

Ms. Axmith, in your brief, you mention resin manufacturers, additive suppliers, plastic compounders, developers and recyclers.

Do you recycle products that are imported from China?

[*English*]

**Ms. Marion Axmith:** Not necessarily. I should clarify that over 70% of all vinyl resin goes into building and construction products, which are used for many decades—many, many, years.

Our particular focus at the present time is in the construction area, when those products come out of use. We're establishing an infrastructure to recapture and recycle those products, but those products would have been made in Canada.

[*Translation*]

**Mr. Marcel Lussier:** Do you know if there are still any phtalates in older recycled products? Do the phtalates present in plastic disappear after 10 or 20 years of use? Does the concentration of phtalates decrease? If not, are they still present in those products?

[*English*]

**Ms. Marion Axmith:** Well, on the technical side, I would defer to Marian. I can tell you, if you're going to recycle a flexible product, you need to recycle it into another flexible product, not necessarily the same product.

Marian.

**Ms. Marian Stanley:** For the last eight years we've been conducting research at Simon Fraser University in Vancouver. We've been looking at the fate of phthalate esters in the environment. We know they biodilute. They do not bioaccumulate. They don't stay in the environment.

We've been looking at about 26 different species. As you go up the species range, you get fewer and fewer phthalates, so they do biodilute. We know they're not around forever.

**Mr. Marcel Lussier:** Thank you.

**The Chair:** We'll go on to Mr. Cullen, please.

**Mr. Nathan Cullen:** Thank you, Chair.

I was asking our research friends a question. I was curious as to whether you could still get a mercury filling in Canada. It's a neuro-disrupter. It's one of the most toxic elements we make. There are those in this room, and there are Canadians today, who are still getting mercury fillings put into their mouths.

The reason I bring it up is that it's an interesting example of the amount of inertia we can have, as a society, as a manufacturing base, as dentists who are concerned about our health and will continue to put a known toxin into our mouths. I think it's instructive about over-relying on government and well-meaning officials to always protect us to the levels we would hope, particularly when we're talking about these vulnerable populations.

I have a question for Mr. Cammack. Does Baxter make—and I hate to quiz you on this, because I know you'll get in trouble if you don't know the answer—cardiopulmonary bypass equipment, transfusion equipment, exchange transfusion, hemodialysis, TPN or lipophilic drug formulations?

● (1250)

**Mr. Jon Cammack:** We do make some of those products, certainly for hemodialysis. We make dialyzers, dialysis tubing, TPN containers and tubing.

**Mr. Nathan Cullen:** Are you making alternatives without DEHP among those products right now?

**Mr. Jon Cammack:** Yes, and we have been for many years. The reason is the functionality. TPN is a good example. It has not been common practice for many years, for Baxter and most of the industry, to store, for example, lipids in PVC, because the PVC withdraws enough DEHP out of the material that it can't act functionally correctly.

**Mr. Nathan Cullen:** Picking up on Mr. Rota's point, this may be a bit of a point of confusion. On the one hand end it seems we've heard testimony today to not worry about these particular chemicals. On the other hand, if they leak out of a product, there is some concern for that, so there's an alternative where those phthalates don't exist in the—

**Mr. Jon Cammack:** Let me be clear. Maybe I didn't say it quite correctly.

It is all about function. It's all about the right material for the right applications.

**Mr. Nathan Cullen:** You're not concerned about the actual health effects of phthalates in medical products?

**Mr. Jon Cammack:** Let me finish. I think it will answer your question.

Let's stay with TPN—you mentioned TPN. If a manufacturer were to store lipids in a PVC DEHP-plasticized container, there would be enough DEHP taken out of the material that the container couldn't function in the way it needs to function properly; it wouldn't vent correctly. So yes, there would be a health risk in that the medical product wasn't acting in the way it needs to act to deliver the therapy.

**Mr. Nathan Cullen:** Aside from that, if someone walking into the hospital with a child who is sick or a mother about to deliver a baby heard that DEHP is an admitted reproductive toxin and that there is exposure to DEHP through medical devices for which we have economic substitutes, and that there's a bill in Parliament that says we shouldn't do this, that we should use those substitutes where available, I think most Canadians would say to pass the bill.

I'd rather have the choice, when going into a hospital, to not have a reproductive toxin or toxins that are known. This has been presented by some here today as some sort of clash between environmentalists and the industry. I don't think the Canadian Cancer Society regularly calls itself an environmental activist, and yet it is supportive of this bill.

Again I appreciate the commitment and passion you all bring to this in wanting to rely on the science. When I look to rely on health concerns, I look to people like the Canadian Cancer Society, which has a deep and vested interest in this issue and no particular ax to grind.

When I look at the ability and availability of the 14 pages of substitutes—just to correct my colleague, Mr. Allen, it wasn't just 14 substitutes, but 14 pages of substitutes—available, clearly with a bill that allows a three-year extension window, and then another one that cabinet can allow if there's an economic hardship realized where there's no substitute available, one starts to wonder what the resistance is. Is this some sort of symbolic resistance to make sure that this doesn't become some thin edge of the wedge?

I'll put this to Ms. Axmith. The assessment we have so much faith in from Health Canada on BBP and DBP didn't include children's toys, didn't include breast milk, consumers products, and cosmetics. It would be rather like doing an assessment on smoking but not taking in any sort of respiratory evidence.

How can we look at an assessment that said this is not CEPA-toxic that is only going to study a narrow portion of the application to humans and say that study is a good study?

**Ms. Marion Axmith:** But if you look at page four of my presentation, we're saying that BBP and DBP are not used in children's toys.

● (1255)

**Mr. Nathan Cullen:** And it doesn't appear in breast milk or in consumer products, dust, or cosmetics?

**Ms. Marion Axmith:** Further—

**Mr. Nathan Cullen:** No, but allow me that question. It appears in these other products; that's guaranteed. Health Canada didn't test for that. You're relying on that report to say exposure is not a risk, when there are products they simply didn't assess. Nor did they assess the cumulative effect on children.

**Ms. Marion Axmith:** Well, you need to speak to Health Canada about that, and about their testing.

**Mr. Nathan Cullen:** But you're relying on the study. Why would you rely on a study that doesn't actually assess all the products that actually have these chemicals in them?

**Ms. Marion Axmith:** Because we operate here in Canada within a regulatory framework, and that framework is the Canadian Environmental Protection Act.

**Mr. Nathan Cullen:** I'm aware of it.

**Ms. Marion Axmith:** We embrace that process.

**Mr. Nathan Cullen:** Even when flawed.

**Ms. Marion Axmith:** Even when flawed.

Perhaps your focus should be on improving that process if you're not happy with it.

**Mr. Nathan Cullen:** The committee just did. We just finished engaging in that very process, and thank you for your testimony.

**The Chair:** Thank you, Mr. Cullen.

Mr. McGuinty, I believe you have a brief question.

**Mr. David McGuinty:** I have a very quick question. I'd like, if I could, to ask the scientists on the panel a very simple question.

I spent years working on environmental issues, and people used to talk about cumulative assessment, cumulative effects assessment in an environmental context. It's a fledgling area, I think we would agree.

But when it comes to the important questions Mr. Cullen is asking here, when we talk about the need for a cumulative effects assessment on a human body or a child's body or an older person's body, do we know how to do that? Is there established scientific protocol that allows us? Or are we now at a phase where we're pushing out the envelope and we need to begin to understand better how to do that? Do we know how to do a cumulative effects assessment of the important issues that Mr. Cullen is raising here? Do we actually know how to do that? Is there a science-based department, ministry, organization that does cumulative effects assessment for these kinds of products?

**Mr. Jon Cammack:** I can speak to medical devices, medical products, and yes, toxicology studies that support approval of these products, if it is a product that's used in chronic exposures and in therapies that have chronic exposures. The types of studies that are done are chronic studies, long-term studies that account for cumulative exposures to whatever you're studying. DEHP or some other plasticizer—

**Mr. David McGuinty:** That's not what we're talking about when we're talking about cumulative exposure, not chronological, not sun exposure over time, which increases your incidence or risk of skin cancer. We're talking about, I think, a multiplicity of exposures, of sources, other than these three particular products that we're examining in this private member's bill. Does the science exist now? Is there a protocol? Is there a practice? Is this happening in industry? Is it happening in government? Is it happening in a regulatory setting?

I'm drawing a distinction here between chronological exposure to one substance and a multiplicity of exposures at one time.

**Ms. Marian Stanley:** I think if you're talking about phthalates, we know, at least in the U.S. from the CDC data—and I'll get to the other thing that I think you're talking about—that for the array of phthalates from the CDC data, the exposures are very low. So if you layer these on top of each other, of phthalates, you're still cumulatively below EPA-set safety levels.

Now, if you're talking about an array of all of the chemicals you're exposed to in your daily life through food, the array of chemicals that you may be exposed to for your contact with daily life, is there some way to do that? I think that may be where you're going. Can you look at every pesticide out there, plus every additive in every other product, and come to some conclusion?

There's work going on in academia in things like gene array studies. But we're not there.

**Mr. David McGuinty:** So let me then put the question this way.

When someone comes to see me and says that the science performed by Health Canada is faulty because it has not included this ascribed notion of the “cumulative”, what do they mean by that? What does an ENGO coming to me and saying that the science is inconclusive: “These assessments, however, failed to include exposure from consumer products...no cumulative assessments of these phthalates was done...”, what are they talking about?

● (1300)

**Ms. Marian Stanley:** If we're talking about just phthalates, by the virtue that we have excretion data through the CDC, we know what the exposure to a fairly wide array of phthalates is. And that exposure, if you took it and you added it all up, you would still be below what's considered a safe daily dose. So I have confidence.

Plus, the CDC is saying that exposure doesn't equate a disease state or harm.

**The Chair:** Thank you.

Are there any comments?

I'd like to thank our guests for being here.

I'd just remind members that if you have any amendments to Bill C-307, we need those as quickly as possible, because we will be looking at this bill on Tuesday.

Thank you.

The meeting is adjourned.

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