

**REGULATORY REVIEW
and
RECOMMENDATION**

REGARDING

**BABY WALKERS PURSUANT TO THE
HAZARDOUS PRODUCTS ACT**

Mechanical and Electrical Hazards Division
Consumer Product Safety Bureau
Product Safety Programme
Healthy Environments and Consumer Safety Branch
Health Canada

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EXECUTIVE SUMMARY

Infants in baby walkers are able to move quickly and may be exposed to hazards that can result in severe injury or death. Although the most frequent hazard associated with baby walkers is the risk of injuries caused by falling down stairs, there are also risks related to the issue of proximity. Baby walkers provide infants with access to areas and items they would not be able to reach under normal circumstances, such as cups of hot liquid or heavy lamps on tabletops and counters. This proximity poses a number of potential hazards to infants, who may pull down objects that could cause burns and scalds, or abrasions and bruises.

At present, there are no regulations governing the importation, sale or advertising of baby walkers in Canada. In 1989, representatives of the baby walker industry in Canada addressed the risk of injuries known to be associated with these products by voluntarily adopting a safety standard for baby walkers. Voluntary adherence to this standard became a de facto ban and was effective for many years in restricting the sale of baby walkers in Canada.

Recently, however, there has been increasing evidence that baby walkers are slowly making their way back into the Canadian marketplace. Although the major retailers continue to respect the de facto ban, small retail outlets and independent operators are selling increasing numbers of baby walkers in Canada. This has raised serious concerns about the potential safety of Canadian children, and Health Canada decided it was time to revisit the issue of baby walkers to determine the most appropriate regulatory course of action to manage the risks associated with these products.

This Regulatory Review and Recommendation is based on an earlier draft document entitled *Regulatory Proposal Regarding Baby Walkers, January 22, 2003*. In its current form, the document examines data about injuries associated with the use of baby walkers and investigates the control measures adopted by other countries. It also takes into account the recommendations of paediatricians, medical associations and other groups with regard to regulations and bans on baby walkers. It reviews the results of a Risk Analysis (2002), and considers the findings of a Cost Benefit Analysis (2002), which weighed the merits and drawbacks of different control measures for baby walkers, ranging from no controls to regulated safety standards, to an outright ban.

The paper determines that there are two regulatory approaches to baby walkers that warrant consideration from Health Canada. One is to adopt the U.S. safety standard for baby walkers as a regulation for all baby walkers imported, sold or advertised in Canada. The other is to implement an enforced ban on the importation, sale and advertising of all baby walkers in Canada.

The U.S. safety standard for baby walkers was devised by the American Society for Testing and Materials (ASTM) in 1997. Adherence to the standard is voluntary in the U.S., but industry compliance is very high and there has been a significant drop in the number of baby walker injuries resulting from falls down stairs in the United States. However, there are still reports of infants in ASTM-compliant baby walkers falling down stairs and sustaining life-threatening injuries. In addition, the safety standards of ASTM-compliant baby walkers do not address the risk of injuries related to the issue of proximity.

Health Canada's Cost Benefit Analysis acknowledges that ASTM-compliant baby walkers are likely safer than non-compliant models. However, adopting the ASTM standard as a regulation for baby walkers in Canada would lead to more baby walkers in Canadian households than current numbers, and the absolute number of baby walker injuries in Canada would increase.

Many background papers express serious concerns about the safety of baby walkers and a number of reputable organizations and associations, as well as many paediatricians, have called for a ban on these products. It is clear that the design of baby walkers is not compatible with the developmental abilities of infants. Infants in baby walkers are simply not able to comprehend and evaluate the potential hazards associated with the use of these products. Moreover, infants in baby walkers are able to move at speeds that exceed one metre per second, and this outpaces the reaction time of supervising caregivers.

Therefore, this paper recommends that the most appropriate regulatory option with regard to baby walkers is to protect the health and safety of Canadian children by banning these products altogether from the Canadian marketplace.

1. PURPOSE AND INTRODUCTION

1.1 Purpose

The purpose of the Regulatory Review was to investigate safety issues surrounding baby walkers from as many perspectives as possible, and to analyze the potential effectiveness of various regulatory options that might address the risks associated with these products. The goal was to determine the most appropriate regulatory scheme to govern the importation, sale and advertising of baby walkers in Canada, pursuant to Section 6(2) of the *Hazardous Products Act*.

1.2 Definition of Baby Walker

From a regulatory perspective, it is necessary to define “baby walker” as precisely as possible to ensure that this product can be distinguished readily from other items available on the Canadian market.

For regulatory purposes, Health Canada is using the following definition when referring to baby walkers:

“Baby walkers that are mounted on wheels or any other device permitting movement of the walker and that have an enclosed area supporting the baby in a sitting or standing position so that their feet touch the floor, thereby enabling the horizontal movement of the walker.”

A small sampling of definitions used by other organizations to describe baby walkers includes the following:

Canadian Juvenile Products Association (CJPA)

“ ‘Baby walker’ means any device, which, in one or more of the “manufacturers’ positions”(sic), becomes a wheeled vehicle that enables an infant to move in any direction, propelled by the infant standing or sitting in the device.”

American Society of Testing and Materials (ASTM)

“ ‘Walker’—a mobile unit that enables a child to move on a horizontal surface, when propelled by the child sitting or standing within the walker, and that is in the manufacturers’ recommended use position.”

Australian Consumer Affairs Division

“A ‘baby walker’ is a mobile device that assists infants to walk at an early age. Baby walkers comprise a frame mounted on wheels or castors, having a system to support an infant in a standing position so as to assist the infant to have walking mobility.”

1.3 Background

Infants in baby walkers are able to move quickly and may be exposed to hazards that can result in severe injury or death. Although the most frequent hazard associated with baby walkers is the risk of injuries caused by falling down stairs, there are also risks related to the issue of proximity. Baby walkers

provide infants with access to areas and items they would not be able to reach under normal circumstances, such as cups of hot liquid or heavy lamps on tabletops and counters. This proximity poses a number of potential hazards to infants, who may pull down objects that could cause burns and scalds, or abrasions and bruises. The proximity provided by baby walkers might also give infants access to materials that could be toxic if ingested, such as medications and cigarette butts.

In 1989, the Consumer Product Safety Bureau, (then under the Department of Consumer and Corporate Affairs), was instrumental in convincing Canadian industry to adopt a safety standard (1) on a voluntary basis to address the risks posed by baby walkers. The standard resulted in a de facto ban, and this proved successful in restricting sales of baby walkers in Canada for many years. Between 1989 and 2000, the trading of baby walkers in Canada was limited essentially to:

- second-hand sales at flea markets and garage sales;
- used products passed on from family members and friends; and,
- cross-border shopping between Canada and the United States.

During this period, there was a gradual decrease in the number of baby walkers traded, and hence used in Canadian homes. According to the Canadian Hospital Injury Reporting and Prevention Program (CHIRPP)(2), the percentage of reported injuries associated with baby walkers among children aged 5-14 months decreased from 6.5% of all injuries in 1990 to 2.1% of all injuries in 1999.

Health Canada's Consumer Product Safety Bureau (CPSB) estimates that the level of compliance with the voluntary ban in Canada has been in the order of 90% (3). This is comparable to compliance levels observed with products that are regulated under the *Hazardous Products Act*. In this regard, Health Canada's information and education efforts, along with industry's voluntary ban on the sale of baby walkers, have been recognized as a success story. The decrease in the sale and use of baby walkers correlates with a reduction in the number of baby walker injuries and deaths reported to the CPSB.

Recently, however, Health Canada Inspectors have observed that stores and street vendors in Canada appear to have increasing numbers of baby walkers for sale. Past and current data on sales of baby walkers in Canada are not available, but the observations by Health Canada's Inspectors indicate that baby walkers may be making their way slowly back into Canadian homes.

The major Canadian retailers and chain stores, such as Sears Canada, the Bay and Wal-Mart (4), continue to respect the de facto ban and do not sell baby walkers. However, some Canadian importers and distributors have approached Health Canada with questions that suggest there may be a renewed interest among some of the major retailers in selling these products.

At the same time, baby walkers *are* being sold in Canadian stores other than the major retailers.¹ Small chain stores tend to sell the brand name baby walkers that are found in the United States, and most of these models comply with a safety standard established by the American Society of Testing and Materials (ASTM). Details pertaining to the U.S. ASTM safety standard for baby walkers are outlined later in this report under sub-heading 3.1.2.

In addition, small-scale sales of non-ASTM-compliant baby walkers² are taking place on street corners in cities across Canada. In some cases, individuals use their personal vehicles to import baby walkers directly into the country. The baby walkers for sale in small boutiques, flea markets and street corner outlets in Canada tend to be models manufactured in Europe and Asia.

Health Canada has received calls and inquiries about baby walkers from the public. The nature of the inquiries illustrates that many Canadians are under the impression that baby walkers had been banned in Canada (5).

2. METHODOLOGY

In light of this background information, Health Canada officials decided to conduct a thorough examination of issues surrounding baby walkers as a means of determining the most appropriate regulatory scheme for these products.

To provide direction for this undertaking, Health Canada established a Steering Committee, comprised of representatives from its Regional offices, Health Surveillance and Epidemiology Division, and Product Safety Laboratory. The Committee was Chaired by the author of this Report and the names of members are listed in Appendix A, along with the names of other Health Canada officials who acted as consultants during this process.

The Steering Group devised a methodology, which involved the following steps:

- Conducting research into a number of areas, including current safety standards for baby walkers in different countries, types and severity of injuries associated with baby walkers, and the positions taken by paediatricians and other stakeholders regarding the use of baby walkers;
- Sponsoring a question about paediatricians' experiences in treating baby walker injuries as part of the Canadian Paediatric Society's monthly survey of its members;
- Obtaining and examining a copy of the specifications in the U.S. safety standard for baby walkers, as devised by the American Society for Testing and Materials (ASTM);
- Purchasing seven models of baby walkers (three that were ASTM-compliant, three that were not, and one described as a hybrid of baby walker and ride-on toy) for testing at Health Canada's Product Safety Laboratory;
- Conducting and photographing a series of tests to investigate the stopping behaviour of baby walkers under varying sets of circumstances;

¹ KIDZ, Super Stores, 5 Branches, where baby walkers were being sold. CPSB. n.d.

² Inspector reports North Bay complaint re: baby walkers sold on street corner, and August 12, 1999 incident involving a fall down stairs. Complaint received in internal database, and a series of responses by email.

- Commissioning a Risk Analysis that applied a risk management approach to issues concerning baby walkers;
- Commissioning a Cost Benefit Analysis that investigated the relative merits and drawbacks of four different regulatory approaches related to baby walkers;
- Preparing a preliminary Option Paper as a draft for a formal paper, which would analyze the results of each study, culminating in a recommendation to Health Canada management regarding the most appropriate regulatory approach for managing the risks associated with the use of baby walkers in Canada.

These steps led to a recommendation, as detailed in Section 7 of this Report, that Health Canada should implement an enforced ban on baby walkers in Canada.

3. THE FINDINGS FROM RESEARCH, STUDIES AND TESTS

3.1 Safety Standards for Baby Walkers in Canada and other Countries

3.1.1 Canada

Current Situation: There are no legally binding requirements governing safety standards for baby walkers in Canada.

Background: Members of the Canadian Juvenile Products Association (CJPA) (1) adopted a safety standard for baby walkers in 1989 on a voluntary basis. The standard specifies labelling, instructional and performance requirements for baby walkers sold in Canada. One of the requirements is that baby walkers sold in Canada must have a minimum width (90 cm) to prevent them from passing through a standard door frame.

Widespread voluntary compliance with the standard resulted in a de facto ban on baby walkers in Canada. Given that the large size of such baby walkers made them impractical and unattractive to consumers, and that profit margins from the sales of baby walkers were low, retailers stopped importing, advertising and selling these products in Canada.

When the de facto ban first came into effect, the Canadian Juvenile Products Association (CJPA) represented the baby walker industry in Canada and took responsibility for managing the voluntary withdrawal from the marketplace of baby walkers that did not meet the safety standard. In 1997, the CJPA folded. Many of its former members have since joined the Juvenile Products Manufacturers Association (JPMA) in the United States, but there is no Canadian association to assume responsibility for managing the de facto industry ban on baby walkers in Canada.

3.1.2 United States

Current Situation: Baby walkers in the U.S. must comply with specific requirements regarding labelling and the prevention of mechanical injuries (e.g., the pinching of fingers). There is also a safety standard to address the risk of falls down stairs, but adherence to this standard is voluntary.

Background: In 1992, the Consumer Federation of America, the American Pediatric Society and other groups petitioned the U.S. Consumer Product Safety Commission (CPSC) to ban baby walkers. The

CPSC initiated a rulemaking proceeding on baby walkers by publishing an Advanced Notice of Proposed Rulemaking (ANPR) on August 2, 1994 (5). The ANPR was in large part a response to concerns about reports of children in baby walkers falling down stairs.

The American Society of Testing and Materials Subcommittee on baby walkers then revised an existing ASTM standard by adding new performance requirements designed to prevent falls down stairs. The new requirements were published in 1997 (6). They stated that in order to meet the ASTM safety standard, baby walkers must have *either*:

- a base too wide to fit through a standard doorway (i.e., being not less than 900 mm); *or*,
- a specified level of stability *and* a gripping mechanism to stop the baby walker at the edge of a step.

From 1995 to 2000, the number of baby walker-related injuries to children younger than 15 months of age, who were treated in hospital emergency rooms in the United States, dropped by 63%. ASTM-compliant baby walkers now account for 98% of the baby walkers available in the U.S. For this reason, the U.S. Consumer Product Safety Commission terminated the mandatory rulemaking proceeding on baby walkers.

Officials from Health Canada's Consumer Product Safety Bureau (CPSB) have strong reservations about the effectiveness of the braking devices on ASTM-compliant baby walkers when these products are used in the home. The reservations are supported by the results of tests conducted by the CPSB (7) at Health Canada's Product Safety Laboratory. The test results are summarized in Appendix D. It should be kept in mind that the Canadian climate and way of life often require homes that have basements, and therefore, stairs.

Also, there has been a recent trend in Canadian housing design towards a more open concept with wider stairs that have no surrounding doorways and nothing to which a protective gate might be attached. In this environment, the width requirement of the ASTM standard would not address the risk of children in baby walkers falling down stairs.

Health Canada officials have noted as well that the ASTM safety standards for baby walkers do not address the issue of proximity, which poses a significant risk of injury to children.

3.1.3 Australia

Current Situation: On September 1, 2000, the New South Wales Department of Fair Trading introduced a regulation that all baby walkers sold in the State of New South Wales must comply with Clauses 6.1 and 6.4 of the U.S. Baby Walker Standard (8). This regulation specifies labelling and information standards and stability performance standards for baby walkers. The Australian Commonwealth Consumer Affairs Division is considering the possibility of implementing the regulation on a nation-wide basis.

Background: Over the years, a number of organizations, including the Victorian Injury Surveillance System at Monash University, the Australian Consumers' Association, and the South Australian Injury Surveillance and Control Unit, have called for a nation-wide ban on baby walkers in Australia. The widely demanded ban in this country may have stalled as a result of influential opinions (9) suggesting that the problems associated with baby walkers were due to inappropriate use rather than the product itself.

3.1.4 New Zealand

Current Situation: There has been a requirement since March 2002 that all baby walkers in New Zealand must comply with a mandatory product safety standard.

According to a press release issued by the Ministry of Consumer Affairs in October, 2001:

“From 1 March 2002, all baby walkers must have safety features that help stop them from tipping over and from toppling down stairs. Baby walkers sold by second-hand dealers must also have these features.

All baby walkers will also have to be sold with safety warnings on them. These warnings will be about supervising babies in baby walkers, using baby walkers on flat, clear surfaces, and keeping babies away from fires, other heat hazards, and stairs.” (9)

The Ministry’s press release also offered the following advice to consumers:

“Remember, even with extra safety features, no product is 100 percent safe when it comes to babies. They can easily get into tricky and dangerous situations.” (9)

In reference to baby walker standards, a press release from the Commerce Commission of New Zealand stated:

“A product that complies with the American standards (ASTM F977-00) and/or carries a JPMA logo (Juvenile Product Manufacturers Association) would also indicate compliance with our standards.” (11)

Background: In 1997, New Zealand’s Ministry of Consumer Affairs developed fact sheets relating to the safe use of baby walkers and hints for buying these products. In December of 2000, the Ministry released a Discussion Paper that examined options for addressing baby walker safety, and this led to the declaration of a mandatory product safety standard for baby walkers in New Zealand.

3.2 Data on Baby Walker Injuries

3.2.1 Information from the CHIRPP Database

In 1990, Health Canada established the Canadian Hospital Injuries Reporting and Prevention Program (CHIRPP). CHIRPP is a surveillance program that collects detailed information on injuries treated in the Emergency Departments of 14 hospitals across Canada, including 10 paediatric hospitals.

Information in the CHIRPP database reveals that between April 1990 and April 2002 (2), there were 1,935 baby walker injuries reported among children aged 5-14 months. Of these injuries, 85.5% happened when a child in a baby walker fell down stairs. Of the children injured in this manner, 8.4% were admitted to hospital.

Other falls in or from a baby walker accounted for 8% of the reported injuries and 4.4% of the reported injuries occurred because the child could reach something or pull something down. The remaining injuries (2.1%) happened in various other ways.

There is little question that the home represents the highest risk area for potential baby walker incidents involving injury or death. The CHIRPP Canadian data (2) illustrate that 92.9% of child injuries related

to baby walkers happened in the child's home. A small portion (6.5%) happened in other people's homes and a few injuries occurred elsewhere (0.6%).

Given that the majority of baby walker injuries are attributed to falls down stairs, it is apparent that open stairways represent the greatest hazard for children in baby walkers within the home environment. According to information in the CHIRPP database, other baby walker injuries in Canadian homes have been attributed to the following:

- mechanical injuries as a result of children pulling furniture over, pulling down small appliances, or colliding with objects;
- ingestion of foreign objects, potential poisons, cigarettes;
- burns from stoves, fireplaces, heaters, irons; and,
- scalds as a result of children being able to reach and pull down items (e.g., hot tea or soup, electric kettles, deep fryers, electric fry pans) either directly or by pulling on a cord or table cloth.

Although scalding injuries associated with baby walkers are relatively rare when compared to baby walker injuries resulting from falls down stairs, the scalds are often quite severe. According to information in the CHIRPP database, 41% of the children with baby walker-related scalding injuries were admitted to hospital, and the remaining 59% all required medical follow-up. The severity of these scalds is underscored by the fact that the proportion of children admitted to hospital due to baby walker scalding injuries was two and a half times greater than for other CHIRPP-reported scalds to children of the same age.

During a presentation to Health Canada's Research Forum in November 2002 about baby walker injuries in the CHIRPP database, Dr. Susan Mackenzie, a Senior Epidemiologist with Health Canada, made the following observation:

“It's hard to resist suggesting that the use of baby walkers should be discouraged, especially as they do not appear to offer any benefit to a child's development. More aggressive parental education, or banning the sale of baby walkers are possible interventions. There are alternatives to the walkers commonly in use: stationary activity centres allow a child to maintain an upright posture and provide various items for play. And there are new walkers with features intended to help prevent falls down stairs. If these are effective, the biggest category of walker injuries may be prevented. However, children using these new walkers would still be at risk for scalds and burns from pulling things down.” (2)

3.2.2 Reports of Deaths Associated with Baby Walkers in Canada

In November of 2001, Dr. Susan Mackenzie, a Senior Epidemiologist with Health Canada, sent a request to all Chief Coroners and Chief Medical Examiners in Canada asking for information about any inquests into deaths associated with baby walkers from 1994 on.

Three jurisdictions each reported one death associated with baby walkers, one of which occurred in 1983. The other two reported deaths occurred in 1998 and 2000. This information should not be interpreted as an official record of the number of deaths in Canada associated with baby walkers. There

may have been additional deaths, as the request for information was informal and some jurisdictions did not respond.

In 1984 an Ontario's Verdict of Coroner's Jury looked into the death of a 6 month old infant. The verdict of the coroner's jury was "Accidental: due to a fall down the stairs in a walker." Further, the jury unanimously agreed that after making a series of recommendations stated "However, we have come to the conclusion that the above recommendations would not remedy the situation. The walker is a non-useful, lethal toy and should be banned completely."

3.2.3 Survey of Canadian Paediatricians

In January 2002, the Canadian Paediatric Society (CPS) sent a survey question about baby walker injuries to 2273 member paediatricians across Canada. The Injury and Child Maltreatment Section, Health Surveillance and Epidemiology Division, Health Canada, sponsored the question, which was designed to complement information obtained from the CHIRPP database.

According to the survey results, 7.1% of 1,214 respondents recalled treating one or more children younger than 18 months of age for injuries associated with baby walkers during the previous year. Some of the paediatricians provided specifics about the number of cases they had seen, and the tally indicates that survey respondents treated a minimum of 132 children younger than 18 months of age for baby walker injuries in 2001 (12).

3.2.4 Data from the U.S. and Australia

According to a Policy Statement published in 2001 by the American Academy of Pediatrics (AAP) (12), the number of baby walker injuries reported to the U.S. Consumer Product Safety Commission (CPSC) decreased from 20,100 in 1995 to some 8,800 injuries in 1999. This decrease may be explained in part by the introduction of stationary activity centres in the marketplace as well as the new ASTM-compliant baby walkers. The fact remains, however, that many of the reported injuries were relatively severe and some were fatal. Thirty-four deaths associated with the use of baby walkers were reported to CPSC during the years 1973 through 1998.

The AAP Policy Statement contained the following statistics about baby walker injuries in the U.S.:

"Reported injuries are overwhelmingly caused by falls, either from the walker or with the infant remaining in the walker. Stairs are implicated in 75% to 96% of cases and in almost all of the severe injuries. A small number of pinch injuries to fingers and toes occur. Burns account for 2% to 5% of walker-related injuries. Walkers have also been associated with poisonings of infants under 1 year of age. These burns and poisonings are attributable to the increased access to these hazards afforded by an infant's increased mobility in a walker. Although submersion is not a commonly reported mechanism of non-fatal injury, 4 of the 11 deaths reported between 1989 and 1993 were from drowning (in a pool or toilet), 4 were from suffocation (compression of the neck against the feeding tray) and 3 were from falls." (12)

A study of 271 baby walker injuries treated in the emergency room at Children's Hospital in Columbus, Ohio between 1993 and 1996, found that 96% of the injuries resulted from a fall down stairs, mostly in

the home. Another finding was that more than 75% of these injuries occurred while the child was being supervised (13).

In an Australian study of 133 cases of baby walker injuries reported to the Royal Children's Hospital, Preston and Northcote Community Hospital and Western Hospital, the findings showed that 91% of the injuries occurred in the home, and 77% were the result of a fall (14).

3.3 Positions Taken by Paediatricians and Medical Associations

In Canada

In 1985, the Canadian Paediatric Society (CPS) released a Position Statement indicating it did not recommend that baby walkers be used in Canada. The CPS reaffirmed its position in 2000 (15).

In 1986, the Ontario Medical Association (16) called for a ban on the sale of baby walkers, due to the high incidence of injuries associated with their use.

In the United States

The failure of voluntary initiatives in the U.S. prompted the American Academy of Pediatrics (AAP) to call for a ban (17)³ on the manufacture and sale of baby walkers in 1993. The Academy repeated its call for a ban in September 2001 (12), when its Committee on Injury and Poison Prevention published a Policy Statement concluding that:

“Because data indicate a considerable risk of major and minor injury and even death from the use of infant walkers, and because there is no clear benefit from their use, the American Academy of Pediatrics recommends a ban on the manufacture and sale of baby walkers.”

The AAP also issued a Fact Sheet in 2003 called “Baby Walkers are Dangerous!” (**Error! Reference source not found.**), which urged readers to throw away their baby walkers. The Fact Sheet stated that:

“Most walker injuries happen while adults are watching. Parents and other caregivers simply cannot respond quickly enough. A child in a walker can move more than 3 feet in 1 second! Therefore, walkers are never safe to use, even with close adult supervision.”

Framingham Paediatrics of Massachusetts issued the following statement and advice about the use of baby walkers:

“The most common injury seen with walker use is head injury. This is due to falls down stairs or tipping over. Even if your stairs are gated they may fail when bumped into by a moving walker. Walkers may tip over on uneven floors, carpet edges or raised thresholds. The severity of head injuries in walker falls is due to the exposure of the head above the walker. While the rest of the body is shielded by the walker, the head is left unprotected and can hit the floor with full force. Skull fractures commonly result from walker falls. There are now good alternatives to walkers. The exersaucer™ is a stationary seat in which the child can spin around and play with toys that are attached to

³ American Academy of Pediatrics recommends a ban on the manufacture and sale of mobile infant walkers. CPSC Product Safety Letter, April 5, 1993

the tray in front of them. The treadmill is also stationary and allows the child to run on a revolving tread. If you have a walker or are given one as a gift, please return it to the store with this article.” (19)

In Australia

In an article assessing the potential effectiveness of the baby walker regulation in New South Wales, the *Medical Journal of Australia* (0) published the following observations:

“The New South Wales regulation has the potential to eliminate only about half the baby-walker injuries. Banning baby walkers altogether is preferable.”

“An inadequate mandatory standard has an added disadvantage—once in place it will be assumed to be effective until proved otherwise. The term of the proposed mandatory standard is five years, and it will be reviewed about 12 months before the expiry date. There are no details of the review process in the proposal. In the meantime, if, instead of a ban, the NSW regulation is applied nationwide, about 125 babies will be unnecessarily injured each year.”

“If there was a total ban on baby walkers, there are options for a stationary activity centre (i.e. a baby walker without wheels which allows the user to rotate) and walkers that travel a short distance only from the initial starting point.”

3.4 Positions taken by Independent Groups

The organizations referenced below comprise a small sampling of the many groups and associations that have issued statements that either call for a ban on baby walkers, or emphasize the importance of addressing dangers associated with the use of these products.

In 1993, the Victorian Injury Surveillance System at Monash University (0) in Australia called for a nation-wide ban on baby walkers. The Australian Consumers’ Association joined the call in 1995, as did the South Australian Injury Surveillance and Control Unit in 1996. In June 2000, the Queensland Injury Surveillance Unit stated that the “sale and use [of baby walkers] should be actively discouraged.” (0)

In February 2000, Safekids New Zealand (20) recommended that:

- a mandatory ban on the sale of baby walkers be put in place immediately to prevent more dangerous baby walkers from entering the New Zealand community; and
- a national recall of baby walkers be considered, in an attempt to reduce the numbers of dangerous baby walkers that are already in New Zealand’s communities.

Later that year, Safekids New Zealand responded to the December 2000 Discussion Paper on Baby Walker Safety issued by the New Zealand Ministry of Consumer Affairs by noting that:

“During February 2000, Safekids (along with the support of many other national and local organisations) launched a campaign to actively ban baby walkers from sale in New Zealand.

While we accept that the less restrictive option of a mandatory standard should be tried, Safekids believes that an unsafe goods notice or compulsory product ban and recall

should be initiated if the mandatory standard fails to reduce baby walker injuries. This view is consistent with both the European Union ^{xvi} and Kidsafe Australia ^{xvii} who accept that a product ban is a viable alternative if a mandatory product safety standard fails to reduce the incidence and severity of baby walker injuries.” (21)

Safe Kids Canada called for a ban on baby walkers in a Position Statement published on May 27, 2003. The Statement concluded that:

“A mandatory ban in Canada would close the door to the sale of these products and send a clear signal to current and potential consumers and vendors of the considerable risk of injury and even death from the use of infant walkers. Stationary activity centres should be promoted as a safer alternative to baby walkers with wheels if a caregiver or parent wishes to use this type of product.” (22)

In November 1997, three groups held a joint press conference in Brussels to call for a revision of the draft European standard entitled “Baby Walking Frames Safety Requirements and Test Methods.” The three groups involved in the press conference were:

- ANEC, the European association for the coordination of consumer representation in standardization; (24)
- The European Consumers’ Organization (BEUC), a Brussels-based federation of independent national consumer organizations from all Member States of the European Union and from other European countries; and,
- International Testing (IT)

An excerpt from the ANEC Web site characterized the call for a revised European standard for baby walkers as a success story:

“Most parents in Europe consider baby walkers as a safe place to put their small children. Research undertaken by European consumer organisations, however, showed that baby walkers on sale in the EU might seriously harm young children. The European standard on baby walkers did not take into account that a young child in a baby walker has an increased mobility and reach, causing severe accidents. On the initiative of ANEC, the standard on baby walkers was changed to include the stair fall hazard and the increased mobility of the child.” (24)

In the United Kingdom, the Chartered Society of Physiotherapists called for a ban on baby walkers at its annual conference in May 2000, claiming that these products were responsible for injuring 4,000 babies in the UK every year (25). In addition, the Royal Society for the Prevention of Accidents (RoSPA) has published a Home Safety Policy Statement that actively discourages the use of baby walkers due to the high number of “accidents” associated with their use, and the lack of any evidence that they assist a baby’s development (26).

The following excerpt was taken from an unpublished short report on the Web site of Flinders University Research Centre for Injury Studies, National Injury Surveillance Unit (NISU) of Australia. The report used available data in answering a specific question for one of NISU’s clients and should not be viewed as a detailed piece of research.

“NISU was asked to address the question of whether baby walkers present a higher level of risk than other nursery products. Society already has recognised the need to prevent access to products, which are not within the capabilities of the user. For example, driver’s licences are not issued until 16 years of age in any state and there is a move to introduce a uniform 18-year-old limit. Small parts in toys are a recognised hazard and labelling warns parents not to provide access to such toys among children less than three years of age. The paradox of the baby walker is that it specifically targets a product at an age group that does not have the developmental capabilities to use it safely and by the time perception improves to the point where children can safely use a baby walker, they no longer need it. It can therefore be argued that a case could be made that the product causes injuries in that its design fails to adequately take into account the developmental abilities of the targeted user. Baby walkers carry a risk of injury, which is considerably elevated compared to other nursery products. Baby walkers fail to take into account the developmental abilities of the prime user, which directly contributes to injury. The design of the baby walker can therefore be considered faulty.” (28)

Health Canada’s research found only a few papers that defended the use of baby walkers, and in general the defence was based not on safety considerations, but on the perception that these products could be a developmental aid for infants.

3.5 Findings from Studies Commissioned by Health Canada

3.5.1 Risk Analysis

Dr. Michael Parkes of the Reference Centre for Community Safety Research, Carleton University, carried out a risk analysis that identified and assessed risks related to the use of baby walkers in Canada. After studying potential hazards as well as the range and severity of possible injuries, Dr. Parkes made the following observation about the use of baby walkers:

“It is concluded that a demonstrable risk exists for the population of Canadian infants in the 5- to 14-month inclusive age group. Most injuries associated with baby walkers are caused by falls, primarily down stairs. The risk is particularly apparent for wheeled walkers of older design. The demonstrable risk associated with their use makes it difficult not to condemn them as potentially dangerous, no matter what kinds of design modifications are made, or what warning labels are attached.” (14)

An Executive Summary of Dr. Parkes’ Report is presented in Appendix B.

3.5.2 Cost Benefit Analysis

Andrew MacDonald of the Economic Analysis and Evaluation Division, Healthy Environments and Consumer Safety Branch, Health Canada, analyzed the various costs and benefits associated with four different control measures for baby walkers, including:

- An enforced ban
- Regulation
- Maintaining the status quo (voluntary compliance with the existing safety standard)

- No regulation

Mr. MacDonald's report noted that the most common mechanism of injury associated with baby walkers (falls down stairs) frequently yields serious head injuries such as concussion, skull fracture or inter-cranial haemorrhage. In 2001 Canadian dollars, the cost of illness for each case has been valued at roughly \$6,000, \$11,000 and \$54,000, respectively. The report also noted that scalds and burns were other frequent injuries associated with baby walkers, and the costs for these ranged from roughly \$20,000 to \$30,000 per injury.

After assessing the relative merits and drawbacks associated with each of the four regulatory options related to the control of baby walkers, Mr. MacDonald reached the following conclusion:

“When the net benefits of an option are greater than zero, an option is efficient. In this particular case, only one of the four options, “enforced ban,” clearly meets this criterion. The “Regulation” option is difficult to quantify, as the increase in walker availability will likely result in an increased number of injuries and deaths, resulting in a negative benefit. The “status quo” option fails the criteria, as benefits approximately offset costs. Further, as the voluntary ban becomes less well respected, disbenefits may arise. The last option of “no regulation” fails the efficiency criterion because costs (in terms of adverse health effects) exceed benefits.

In the case of baby walkers, an enforced ban is the preferred option, with the greatest net benefit to Canadians.” (28)

An Executive Summary of Mr. MacDonald's Cost Benefit Analysis is presented in Appendix C.

3.5.3 Baby Walker Testing

The Mechanical and Electrical Division of Health Canada's Consumer Product Safety Bureau conducted a series of more than 200 tests on seven models of baby walkers at Health Canada's Product Safety Laboratory. The tests were designed to gain a general understanding of the stopping behaviour of baby walkers under different circumstances and at varying speeds and angles of approach towards steps.

One important finding was that the braking ability of baby walkers that comply with the U.S. ASTM safety standard, was hampered significantly when the tests were conducted on a flooring surface contaminated with talcum powder or very small amounts of water.

The test report prepared by André St-Laurent, Product Safety Senior Engineering Consultant, concluded that:

“This series of tests has shown that braked baby walkers can demonstrate a significant ability to stop at the edge of a step; it has also shown that contamination of the friction surfaces can have a significant but as yet unquantified effect on the braking performance. The data do not show conclusively whether this significant braking ability is sufficient to protect children in all, or even most, real-life instances.”(29)

An Executive Summary of the Baby Walker Testing Report is presented in Appendix D.

4.0 ANALYSIS OF THE OPTIONS

Taken together, the findings from the studies, survey and other research activities became the basis for developing and analyzing six options that Health Canada might consider with regard to the regulation of baby walkers in Canada.

4.1 Option One: Maintain the Status Quo

Context: At present, major retailers do not sell baby walkers in Canada because the industry voluntarily adopted a safety standard in 1989, and this became a de facto ban. The voluntary ban was generally well respected for a number of years, but the agreement not to sell baby walkers has started to erode. Baby walkers that comply with the U.S. ASTM safety standard are for sale in small and medium-sized retail outlets in Canada. Other models that are not ASTM-compliant are being sold at flea markets and on street corners.

Maintaining the status quo is likely to result in the increased use of baby walkers in Canada. This option contains no provisions to prevent a return of commercially available baby walkers, and does not prohibit the passing down of baby walkers within families or the cross-border importation of baby walkers by individuals.

Cost Benefit Considerations: Health Canada's cost benefit analysis noted there had been an observable decline in baby walker injuries after the voluntary ban was implemented. In 1990, baby walker injuries accounted for 6.5% of all childhood injuries in Canada; that fell to 2.1% by 2000. The voluntary ban reinforced to Canadians the idea that baby walkers are hazardous, however, the availability of ASTM-compliant baby walkers may give Canadian consumers the impression that these products are now safe. Therefore, maintaining the status quo would yield few, if any, incremental benefits.

The cost benefit analysis stated that the incremental costs to industry and government would be low to nil if the voluntary ban were continued, however, the erosion of the voluntary ban may yield disbenefits with increased usage of baby walkers and increased numbers of injuries.

Enforcement Perspective: When the standard for baby walkers was adopted voluntarily in 1989, the Canadian Juvenile Products Association (CJPA) monitored compliance on the part of its members, and managed such matters as the voluntary withdrawal of non-compliant products from the marketplace. The CJPA is now defunct, and there is no other Canadian association that would assume this responsibility.

The major weakness of the status quo is that adherence to the standard is voluntary and therefore, is not enforceable. Retailers, importers and independents could continue to sell baby walkers with impunity. It would be necessary for Health Canada to continue monitoring injuries associated with baby walkers, and a consumer education program would also be required.

Overall Perspective: The voluntary ban adopted by Canadian industry in 1989 has, for all intents and purposes, collapsed. Maintaining the status quo would not address the current issues and problems associated with baby walkers, and would likely permit the situation to deteriorate further. Since compliance with the standard is voluntary, the standard could not be enforced and increasing numbers

of baby walkers would come onto the market in Canada. Some of these would fulfill the ASTM requirement for stability and a gripping mechanism to stop baby walkers at the edge of steps, but tests conducted at Health Canada's Product Safety Laboratory illustrated that contamination of flooring surfaces can hamper the braking ability of these products. Compliance with the ASTM standard does not fully address the risk that children in baby walkers may fall down stairs. In addition, all baby walkers pose risks related to proximity, regardless of whether or not they comply with the ASTM standard.

Option One is not recommended because adherence to the standard is voluntary and the status quo fails to address safety concerns adequately.

4.2 Option Two: No Regulation

Context: This option proposes that the regulation of baby walkers is unnecessary and that Health Canada could address safety issues effectively through other means, such as a communications strategy, education and information campaign. For example, Health Canada could devise a testing program for baby walkers and publicize the results as part of a campaign to raise awareness and reduce the risks associated with these products.

Cost Benefit Considerations: Health Canada's cost benefit analysis concluded that allowing baby walkers free access to the Canadian marketplace with no governing standards or regulations would produce no incremental health benefits.

While there would be no regulatory burden on industry and no cost to government, an unregulated market would likely see per capita morbidity and mortality rates, and all associated costs, similar to those found in the U.S. In 1999, there were approximately 8,800 emergency room admissions for children younger than 15 months for baby walker injuries in the United States (12). As Canada is roughly one-tenth the size of the U.S., this could translate into approximately 880 injuries to Canadian children per year if baby walkers were widely available in Canada. The resulting disbenefit of greater numbers of injuries to Canadians indicates that "no regulation" is an unsatisfactory option.

Enforcement Perspective: Enforcement is non-existent under this option. Public awareness campaigns could provide some benefits.

Overall Perspective: This option is not recommended because it would result in significantly higher numbers of injuries to Canadian children.

4.3 Option Three: Memorandum of Understanding

Context: A Memorandum of Understanding (MOU) would involve negotiating a voluntary agreement with the retailers and importers of baby walkers. The MOU could be an agreement to adopt the U.S. standard and sell only ASTM-compliant baby walkers, or it could be an agreement that all signatories would refuse to import or sell baby walkers, regardless of their origin or design.

A Memorandum of Understanding is a viable option when there is a general consensus to follow a set of rules or guidelines that creates a level playing field for an industry, and when there is a very good likelihood that industry would adhere to it. The MOU can also be an effective strategy if an existing regulation is already in place as a fallback position, or if a regulation is being developed for future implementation.

It would not be difficult to arrange a Memorandum of Understanding to adhere to the ASTM standard for baby walkers among major industry representatives in Canada. Members of the U.S. Juvenile Products Manufacturers Association (JPMA) already adhere to the ASTM standard, and the majority of Canadian industry representatives joined the JPMA when the Canadian Juvenile Products Association folded in 1997. Independents who sell baby walkers that do not comply with the ASTM standard would not be affected by the MOU, and would continue to sell their products at flea markets and on street corners.

Given that the existing voluntary ban on baby walkers in Canada has started to collapse, it is reasonable to assume that it would be extremely difficult to arrange a new voluntary ban on baby walkers through a Memorandum of Understanding.

Cost Benefit Considerations: Health Canada's specialist did not prepare a cost benefit analysis for this option. It would be difficult to identify specific costs and benefits associated with a Memorandum of Understanding, as these would depend upon a number of variables, including the articles of agreement contained in the MOU, and the extent of industry adherence to the articles.

Enforcement Perspective: The chance of success with a MOU is greatly reduced if all industry representatives do not become signatories. It would be impossible for Health Canada to identify and reach an agreement with all potential sellers of baby walkers, because the industry is too segmented and there are too many independent operators.

Under a Memorandum of Understanding, Health Canada's inspectors would have no authority to remove non-compliant products from the marketplace and there would be no recourse for Canadian consumers who have bought faulty products.

When members of the Canadian Juvenile Products Association (CJPA) voluntarily adopted the de facto ban on baby walkers in Canada in 1989, the association monitored the marketplace and assumed responsibility for the compliance of its members. The major companies, which were all association members, developed new products (i.e., exersaucerTM-type products) to provide caregivers with an option that reduced potential hazards to children.

This situation worked well for a number of years, but the association had no jurisdiction over the independents that began selling baby walkers on street corners or at flea markets. The CJPA is now defunct and the marketplace has changed to the extent that a voluntary agreement could not be effective. A MOU is not enforceable, and independents would continue to sell baby walkers, regardless of their design, as long as there are profits to be made and no regulations to follow.

Overall Perspective: A MOU is not considered to be a viable option. It would be unenforceable and would continue, regardless put the safety of Canadian children at risk by permitting the sale of baby walkers

4.4 Option Four: Adopting the U.S. ASTM Standard as a Regulation in Canada

Context: Adopting the specifications of the U.S. ASTM F977-00 standard as a regulation would permit the entry of ASTM-compliant baby walkers into the Canadian marketplace. This would harmonize the Canadian market with its U.S. counterpart, although compliance with the ASTM

standard would continue to be voluntary in the U.S., while it would become a legal requirement for baby walkers sold in Canada.

This option would provide a means to remove non-ASTM-compliant baby walkers, such as the models commonly sold on street corners and in small boutiques, from the Canadian marketplace. However, it would also permit a greater influx of baby walkers into Canadian homes through all primary and secondary retail outlets, and this would result in a greater number of baby walker injuries to Canadian children.

Under a regulatory scheme, Health Canada would be required to monitor the marketplace and conduct compliance testing. Non-compliance would result in product recalls, and Health Canada's Inspectors would have the authority to remove non-compliant products from stores if such products were not removed on a voluntary basis.

A regulation would provide more control over the sale of baby walkers, but would also require more vigilance and additional resources on the part of Health Canada. For instance, Health Canada would have to test baby walkers on a yearly basis, or perhaps more frequently, in order to ensure a level of confidence in their performance. This activity would require that Regional Product Safety Officers monitor the market, gather samples for testing and have them transported to the testing facility. Staff at Health Canada's Product Safety Laboratory would have to develop testing methods and carry out the tests on baby walkers. In addition, Product Safety Officers would have to take appropriate follow-up action if the tests revealed that there were problems associated with any of the products.

Adopting an industry standard is generally an efficient approach to regulating a product. In most cases, it ensures industry buy-in to the proposed regulation, since industry already complies with the standard. This approach usually achieves most of what is being sought. It should be noted, however, that there could be a risk of trade complications if the U.S. ASTM standard was changed and the Canadian government did not amend its regulation to mirror the change.

Cost Benefit Considerations: The cost benefit analysis acknowledged that ASTM-compliant baby walkers are likely safer than non-compliant models. Consequently, it might be reasonable to expect fewer injuries per baby walker if the ASTM standard was adopted as a regulation in Canada. However, since their wide availability would lead to more baby walkers in Canadian households than the current number, and since it is impossible to identify all non-compliant products that could enter the country, the absolute number of baby walker injuries would likely increase. Furthermore, use of ASTM-certified baby walkers still represents an estimated 12% to 14% of all baby walker injuries in the U.S. (28) A regulation cannot anticipate all hazards or all use and misuse scenarios, and the ASTM standard does not address the potential risks related to proximity, including burns and scalds.

A regulation would impose high incremental costs to government, particularly Health Canada and the Canada Customs and Revenue Agency. Regulatory and enforcement costs would be high, due to the greater scrutiny that would have to be applied to assess whether a baby walker meets the regulatory requirements and is acceptable for importation or sale. There would also be a necessity for an ongoing education campaign to promote the safe use of baby walkers.

Enforcement Perspective: One of the major benefits to a regulatory approach is that it is enforceable. It would be illegal to sell baby walkers that do not comply with the regulation, and Health Canada's

Inspectors would have the authority to ensure that non-compliant products are removed from the marketplace. Prosecution would be an enforcement option.

The regulation of baby walkers would ensure a certain level of compliance with the ASTM safety standard, but it would be impossible to identify all non-compliant products that enter the country.

Overall Perspective: Health Canada's series of tests illustrated that ASTM-compliant braked baby walkers demonstrate a significant ability to stop at the edge of a step. However, the tests also demonstrated that contamination of flooring surfaces could have a significant effect on the braking performance. The data did not show conclusively whether the braking ability of ASTM-compliant baby walkers was sufficient to protect children in all, or even most real-life instances.

If a child in a baby walker tips over and falls down stairs, the risk of injury and the potential for a severe injury are high, regardless of whether or not the baby walker adheres to the ASTM standard. Also, the ASTM standard does not address the risk of baby walker injuries due to proximity, including scalds, burns, bruises and abrasions.

If Health Canada approves the sale of ASTM-compliant baby walkers, parents and caregivers may gain a false sense of security about the level of risk associated with these products. The introduction of ASTM-compliant baby walkers into the Canadian marketplace would require an extensive information campaign to educate parents about the importance of vigilance when these products are used. A regulation would result in higher numbers of baby walkers in Canadian households and would lead to higher numbers of injuries to Canadian children. This would call Health Canada's credibility into question.

Although a regulation would be enforceable, it would be very difficult to identify and remove all non-compliant baby walkers from the Canadian marketplace. Moreover, it would be very difficult to revert to a ban once a regulation has been put into place. A regulation to adopt the ASTM standard would be preferable to the existing situation in Canada, but this option would not fully address Health Canada's concerns about the safety of baby walkers.

4.5 Option Five: Develop a Unique Canadian Regulation

Context: This could involve either developing a unique Canadian regulation, or adopting the ASTM standard and modifying it for use in Canada. Either way, this option would require extensive product testing and full enforcement.

It would not be practical to develop a unique Canadian regulation. The process would be costly and the concept would not be well received by industry. A unique Canadian product would not find a market elsewhere and the quantities produced and sold would be too small to be profitable. A modification of the ASTM standard as a Canadian regulation would present similar problems, and could also be viewed as a barrier to trade.

Cost Benefit Considerations: When addressing the costs and benefits of a regulatory approach to baby walkers, Health Canada's analyst focused on a regulation that would adopt the existing U.S. ASTM standard. It would be difficult to assess costs and benefits related to the development of a unique Canadian regulation, as the specifications of such a regulation have not been identified and are therefore unknown.

Enforcement Perspective: The enforcement approach for a unique Canadian regulation would be similar to the approach described with regard to adoption of the ASTM standard as a regulation. However, it should be noted that under a unique Canadian regulation, ASTM-compliant baby walkers could not be sold legally in Canada. Determining the distinction between Canadian-compliant baby walkers and U.S. ASTM-compliant models would tax enforcement personnel.

Overall Perspective: This option would be impractical and is not recommended.

4.6 Option Six: Enforced Ban

Context: An enforced ban would make it illegal to import, sell or advertise baby walkers in Canada. This would give Health Canada's Inspectors the authority to seize any new or used baby walkers offered for sale anywhere in the Canadian marketplace.

The option to "ban" is a preferred option where a regulation would not provide an adequate margin of safety, and the risk of injuries associated with the product can be very serious, life threatening or cause death.

Cost Benefit Considerations: Health Canada's cost benefit analysis for this option acknowledged that it is difficult to estimate the potential number of injuries that could be avoided through confiscation of baby walkers under a ban. It did note, however, that the potential costs associated with baby walker injuries (in 2001 Canadian dollars) could range from \$6,000 for each concussion to \$54,000 for each inter-cranial haemorrhage, and could run as high as \$20,000 to \$30,000 for each injury involving scalds or burns. The analysis noted as well that the potential for fatalities related to the use of baby walkers is always present, and that the few avoided cases that may result from product confiscation could yield significant economic benefits.

The analysis went on to note that offsetting costs to industry and government for an enforced ban would be low, as there is currently no production and only limited sale of baby walkers in Canada. There would be no incremental foregone revenue to industry, and no incremental costs of production. A positive, but small cost would apply to government if an enforced ban were administered, including the cost of a one-time campaign to educate the Canadian public.

Enforcement Perspective: From an enforcement viewpoint, a ban presents the fewest challenges when compared to the other options. If baby walkers were banned under the *Hazardous Products Act*, the importation of these products into Canada would not be permitted. Shipments could be stopped going to importers and prevent anyone from bringing baby walkers into the country for personal use or to sell in secondary markets. Health Canada's Inspectors would have the authority to confiscate all new and used baby walkers offered for sale anywhere in Canada.

The cost of enforcement would not have a significant impact on resources. At present, there are only limited quantities of baby walkers on the market, since the primary retailers have continued to respect the voluntary ban and do not carry these products. It should be noted, however, that Health Canada has received queries indicating that some of these retailers may have a renewed interest in selling baby walkers. If Health Canada were to decide that banning baby walkers is the most appropriate regulatory approach, it would be advantageous to implement the decision sooner rather than later in order to prevent the importation of product that would have to be confiscated at a later date.

Overall Perspective: A ban is definitive in its approach and should be used only in cases demanding the ultimate response where safety is an issue. The data presented throughout this report illustrate that injuries associated with baby walkers can be very serious, life threatening and can cause death. A ban would respond to the issues surrounding baby walkers in all avenues of efficiency. There would be no exceptions and enforcement would be effective. There would be no issues related to recalls, defects, compliance testing or non-compliance. Health Canada's Inspectors would have the authority to confiscate all baby walkers offered for sale, and Canada Customs would have no difficulty in discerning whether or not a product is permissible.

A ban would send a clear message not only to importers, but also to parents and caregivers, that baby walkers present demonstrable and unacceptable risks to the safety of children. However, it must also be acknowledged that banning baby walkers would reduce consumers' choices and would take away the right of Canadians to own a product that is sold legally in the United States and elsewhere.

Since the safety of children cannot be addressed adequately by a regulation and the risk of injury or death associated with baby walkers remains high, a ban on baby walkers would be the most effective regulatory approach to manage the risks associated with these products.

5.0 CONCLUSIONS ABOUT THE OPTIONS

The analysis indicates that there is only one option that warrants consideration from Health Canada. That is to ban the importation, sale and advertisement of baby walkers in Canada. The remaining options present numerous difficulties that would frustrate proper control and enforcement while failing to address the fundamental safety issues adequately.

6.0 APPLICATION OF THE PRECAUTIONARY APPROACH

The precautionary approach (30), as set out by the Regulatory Affairs and Orders in Council Secretariat of the Privy Council Office, recognizes that the absence of full scientific certainty shall not be used as a reason to postpone decisions where there is a risk of serious or irreversible harm. Even though scientific information may be inconclusive, decisions have to be made to meet society's expectations that risks be addressed and living standards maintained. It is legitimate for Canada to make such decisions and it is legitimate that decisions be based on Canadians' chosen level of protection.

It is recognized that injuries associated with baby walkers still occur in Canada. It is reasonable to assume that if standards for baby walkers become regulated and the product becomes more widely available, the number of baby walkers in Canadian households would rise. This would lead to increased numbers of baby walker injuries, and would compound the existing risk of serious or irreversible harm. The potential risk associated with the use of baby walkers requires the application of a precautionary approach when deciding which regulatory option would be the most appropriate with regard to baby walkers.

7.0 CONCLUSIONS AND RECOMMENDATION

An enforced ban on baby walkers is the only logical approach to take because it is the only regulatory option that would protect the health and safety of Canadian infants effectively. This conclusion is supported by evidence documented throughout this Report, including research findings and the results of the Risk Analysis and Cost Benefit Analysis, as well as Health Canada's tests investigating the stopping behaviour of ASTM-compliant baby walkers.

The ASTM safety standard requires that a baby walker must have *either* a specified level of stability *and* a gripping mechanism to stop it at the edge of a step, *or* a width of at least 900 millimetres to prevent it from passing through a standard doorway.

Health Canada's tests on ASTM-compliant baby walkers with gripping mechanisms demonstrated the inability of these models to attain a 100% non-failure rate with regard to tipping over and falling down stairs. Even though the ASTM-compliant baby walkers have demonstrated a significant braking ability under laboratory conditions that makes them far superior to the older style of baby walker, no model could be considered to be absolutely safe in the home environment where there may be many uncontrolled and unforeseen circumstances. If a jumping infant causes a baby walker to tip over and tumble down stairs, the risk of serious injury to the child would remain high, whether or not the baby walker in question complies with any particular standard.

It would not be viable for Health Canada to consider adopting the width requirement of the ASTM standard as the basis for a baby walker regulation in Canada. There has been a recent trend in Canadian housing design towards a more open concept with wider stairs that have no surrounding doorways and nothing to which a protective gate might be attached. In this environment, the ASTM width requirement would not address the risk of children in baby walkers falling down stairs.

It should also be kept in mind that the Canadian climate and way of life often require homes that have basements. This is unlike the situations in the southern U.S., Europe, New Zealand and Australia, where house construction and attitudes to home ownership are different. Therefore, it is not appropriate for Canada to adopt the regulatory approach to baby walkers that is used by these other countries.

Finally, there is nothing in the ASTM safety standard that addresses the risk of baby walker injuries due to the issue of proximity, including the risk of scalds, burns, bruises and abrasions if a child is able to reach up and pull down hazardous objects.

The demonstrable risk associated with baby walkers makes it difficult not to condemn them. They are faulty products in that their design provides babies with increased mobility and proximity, thereby exposing them to a range of potential hazards they are unable to comprehend or evaluate. An infant in a baby walker is able to move at speeds that exceed one metre per second. This outpaces the reaction time of supervising caregivers, and the majority of baby walker injuries have occurred under parental supervision.

This Report recommends that Health Canada should reinforce its commitment to the health and safety of children by banning all baby walkers from the Canadian marketplace as a precautionary measure. An

enforced ban on baby walkers is the option that would reduce the risks associated with these products to the greatest extent possible.

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APPENDIX A

The Health Canada Steering Committee for the Regulatory Review

Michel P. Baillot, Chair

Tanya Evans, British Columbia and Yukon

Walter Golebiowski, Alberta & Northwest Territories

Rick Grabowecky, Manitoba and Saskatchewan

Wendy McNalley, Ontario and Nunavut

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Sylvia Weihrer, Project Officer, Health Canada

Margaret Herbert, Manager, Injury Section, Health Surveillance and Epidemiology Division, Population and Public Health Branch

Dr. Susan Mackenzie, Senior Epidemiologist, Health Surveillance and Epidemiology Division

Studies Commissioned by Health Canada for the Regulatory Review

Application of a Risk Management Approach to the Decision Concerning Baby Walkers, Dr. Michael Parkes, Carleton University

Cost Benefit Analysis for Baby Walkers, Andrew MacDonald, Economist, Economic Analysis and Evaluation Division, Office of Policy Coordination and Economic Analysis, Healthy Environments and Consumer Safety Branch

Baby Walker Testing Report, André St-Laurent, Senior Engineering Consultant, Product Safety, Health Canada

APPENDIX B

Risk Analysis Executive Summary

The application of the risk management decision-making process and related activities to the potential baby walker ban includes several distinct phases: Risk Identification, Risk Assessment and Risk Response.

Risk Identification includes the identification of the issues, setting and context for the decision. The following issues relating to baby walker safety were identified as significant:

1. the potential hazard represented by baby walkers to the infant population, especially in the age group 5 to 14 months inclusive;
2. the range of injuries possible;
3. the lack of evidence that baby walkers promote development;
4. the effect of the voluntary ban;
5. availability in Canada of baby walkers from street corner vendors and in certain retail boutiques or consignment shops; and
6. support for a legislated ban of baby walkers internationally.

Risk Assessment includes an environmental scan and determining the types and categories of risk, organizational issues and local issues. Canadian data on the subject from CHIRPP are not representative and make determining risk difficult. Nevertheless, the data are useful in providing a description of the circumstances of injury:

- Of the 1,790 CHIRPP injuries involving baby walkers over the period 1990 to 2000, 1,542 were recorded as resulting from falls down stairs in baby walkers. Of these, 12.8% were kept in the Emergency Department for observation, were admitted or transferred.
- The peak occurrence was at 7 to 10 months of age.¹
- About 86% of the injuries happened when a child in a walker fell down stairs.
- Concussions were 2.9 times more frequent among children who fell down stairs in walkers than among children with other head injuries. Facial fractures had a ratio of 3.4 times and intra-cranial injuries were five times more frequent in the falls down stairs than in other CHIRPP data.

In addition, according to a 1984 Ontario Verdict of Coroner's Jury, there was one recorded death in Ontario.

Injuries associated with the increased mobility and height of a young child in a walker were not frequent but could be severe, especially the scalds suffered by children who pulled down hot liquids on themselves.

¹ This figure compares favourably with 1994 CPSC study results that show the range of children injured to be 4 to 24 months with a median age of 8 months, and 95% of victims under 15 months. Parkes, M. Dr. *Application of a Risk Management Approach to the Decision Concerning Baby Walkers*. Ottawa, ON: Carleton University, February 2002.

Risk Analysis Conclusions

It is concluded that a demonstrable risk exists for the population of Canadian infants in the 5- to 14-month inclusive age group. Most injuries associated with baby walkers are caused by falls, primarily down stairs. The risk is particularly apparent for wheeled walkers of older design. The demonstrable risk associated with their use makes it difficult not to condemn them as potentially dangerous, no matter what kinds of design modifications are made, or what warning labels are attached.

APPENDIX C

Cost Benefit Analysis Executive Summary of Options

A baby walker risk assessment was prepared for the Product Safety Programme using data from CHIRPP. CHIRPP receives reports from 15 hospitals across Canada, 10 of which are pediatric hospitals. The data using data from CHIRPP and a 1984 Ontario Verdict of Coroner's Jury revealed that between 1990 and 2000, 1,790 injuries involving baby walkers were reported, with one death recorded in Ontario. The majority of baby walker injuries resulted from falls down stairs; the CHIRPP data for this period indicated that 1,542 (86%) were from this type of injury. As these data come from a period when baby walkers were not prevalent in Canada, due to a voluntary ban, this is an underestimate of the number of injuries that would occur if walkers were more readily available in the country. It would be safe to assume that the number of injuries and deaths with market availability of walkers would be *at least* as great as when they are not available; that is, at least 1,790 injuries over 10 years, or 179 per year. When examining the injury and death statistics of all infant products, baby walkers are consistently at the top as the most serious. These figures represent an underestimate given that the CHIRPP database does not represent all injuries.

Given the hazards associated with the use of baby walkers, Health Canada is exploring options to control their use in Canada. The following sections outline the benefits and costs for four potential options: enforced ban, regulation, status quo and no regulation.

1.0 Enforced Ban

Alternate control measures will have different benefits and costs. An enforced ban would result in the highest net benefits (benefits less costs) to Canada. Such a measure would make it illegal to import, sell or advertise baby walkers in Canada, and would give inspectors the right to confiscate any new or used baby walkers from primary retailers and any that appear on the secondary markets (e.g. flea markets and street corners).

Benefits

It is difficult to estimate the potential number of baby walker incidents resulting from such an outcome. However, the most common mechanism of injury (falls down stairs) frequently yields serious head injuries such as concussion, skull fracture or inter-cranial hemorrhage. In 2001 Canadian dollars, the cost of illness for each case has been valued at roughly \$6,000, \$11,000 and \$54,000, respectively. Scalds and burns are other frequent injuries in baby walkers, ranging from roughly \$20,000 to \$30,000. Cost of illness data are typically underestimates of the true willingness to pay to avoid injury, as factors such as any averting behaviour, pain and suffering and other out-of-pocket expenses are not included. The potential for fatalities is always present; the value of a young child's life was valued at roughly \$1

million.¹ It stands to reason that the few avoided cases that may result from product confiscation could yield significant economic benefits.

Costs

The offsetting costs to industry and government would be low as there is currently no production and only limited sale of baby walkers in Canada. There would be no incremental foregone revenue to industry, and no incremental costs of production. A positive, but small, cost would apply to government if an enforced ban were administered, including a one-time campaign to educate the Canadian public.

2.0 Regulation

Setting performance standards would require baby walkers to conform to specifications for safe usage. However, as it is impossible for regulators to consider all potential outcomes in the use of a product, it is unlikely to present the same benefits as an outright ban.

Benefits

Baby walkers that comply with ASTM standards are likely safer than non-compliant ones. Consequently, it might be reasonable to expect fewer injuries per baby walker. However, since their wide availability would lead to more baby walkers in Canadian households than the current number, and since it is impossible to identify all non-compliant products that could enter the country, the absolute number of injuries will likely increase. Furthermore, use of ASTM-certified walkers still represents an estimated 12% to 14% of all baby walker injuries in the US.² As confiscation rights would extend only to non-compliant products, there would be a greater number of baby walkers in the Canadian marketplace.

Standards can be developed to guard against the most common hazards, such as not allowing a baby walker to fit through a standard door opening.³ However, since not all doorways are of a standard dimension, such as the wide entrances to sunken rooms, the standard could not be as effective as an outright ban. Not all hazards, or use and misuse scenarios, can be conceived and protected against with a standard, and standards provide no deterrence from burns or scalds. Benefits would be difficult to quantify. Although potentially safer baby walkers would be on the market, there would be many more of them, combined with non-compliant products. It would not be unreasonable to assume that more injuries would result, although it would be difficult to determine how many.

Costs

From the status quo situation, standards would impose high incremental costs to government, particularly Health Canada and Canada Customs and Revenue Agency. Regulatory and enforcement costs would be high, due to the greater scrutiny that must be applied in assessing whether a baby walker

¹ Carlin, Paul S. and Robert Sandy. Estimating the implicit value of a young child's life. *Southern Economic Journal*, 1991; 58(1): 186–202.

² 1999-2000 Baby Walker Special Study and 2000-2001 Baby Walker Special Study. Cost Benefit Analysis prepared by Andrew MacDonald for the Economic Analysis and Evaluation Division, Healthy Environments and Consumer Safety Branch.

³ The ASTM F977-00 baby walker standard only addresses falls down stairs. This does not address reaching and mobility in a kitchen or elsewhere where a child can knock things down or pull things off.

meets standards and is acceptable for importation or sale. There would also be a necessity for an ongoing education campaign to promote safe use.

3.0 Status Quo/Voluntary Standard

Currently, there is no production of baby walkers in Canada because of an industry voluntary standard to ban them in the country. This has generally been well respected; a complication now arises in that new baby walkers are slowly becoming available on the primary and secondary Canadian retail markets, with the availability of ASTM-certified baby walkers through “big name” manufacturers in the US. Major retailers generally respect the voluntary ban, but outlets such as flea markets and street vendors are less strict (and/or perhaps less aware). Given that the ban was voluntary, there is nothing to prevent a return of commercially available baby walkers.

Benefits

There was an observable decline in baby walker-related injuries after implementing the voluntary ban. In 1990, baby walker injuries accounted for 6.5% of all childhood injuries; that fell to 2.1% by 2000. Furthermore, the voluntary ban reinforced to Canadians the idea that baby walkers are hazardous and may have increased consumer knowledge that they should not be used. The availability of ASTM-certified baby walkers in the US may give consumers the impression that these products are now safe. Continuing the voluntary ban would yield few, if any, incremental benefits, as the status quo would be maintained.

Costs

The voluntary ban has one major weakness: it is voluntary and, hence, not enforceable. For several years, the voluntary ban was respected by industry, but has recently shown signs of breaking down as baby walkers are slowly becoming available on the Canadian retail market. Erosion of the voluntary ban may yield disbenefits with increased usage and accidents.

If the voluntary ban were continued, the incremental costs to industry and government would be low to nil as there would be no change to the status quo.

4.0 No Regulation

Benefits

Allowing baby walkers free access to the Canadian marketplace with no governing standards or regulations would produce no incremental health benefits.

Costs

While there would be no regulatory burden on industry, and no cost to government, an unregulated market would likely see per capita morbidity and mortality rates, and all associated costs, similar to those in the US. It is reasonable to expect major manufacturers to market a uniform product across North America. The resulting imposed disbenefit of greater injuries to Canadians indicates that “no regulation” is an unsatisfactory option. Consequently, it is not under consideration.

Cost Benefit Conclusions

We considered four possible control measures for baby walkers in this economic assessment: an outright ban, regulation, status quo and no regulation. Each option has varying degrees of benefits and costs.

When the net benefits of an option are greater than zero, an option is efficient. In this particular case, only one of the four options, “enforced ban,” clearly meets this criterion. The “Regulation” option is difficult to quantify, as the increase in walker availability will likely result in an increased number of injuries and deaths, resulting in a negative benefit. The “status quo” option fails the criteria, as benefits approximately offset costs. Further, as the voluntary ban becomes less well respected, disbenefits may arise. The last option of “no regulation” fails the efficiency criterion because costs (in terms of adverse health effects) exceed benefits.

In the case of baby walkers, an enforced ban is the preferred option, with the greatest net benefit to Canadians.

APPENDIX D

Baby Walker Testing Executive Summary

Laboratory Testing of Baby Walkers

The M & E Hazards Division tested baby walkers to gain a general understanding of

- the ASTM F 977 steps test,
- the stopping behaviour at speeds other than that at which the ASTM step test is conducted since studies, out of the UK in particular, indicated that children can travel significantly faster¹ than the speed at which the ASTM step test is conducted, and
- the stopping behaviour at varying angles of approach to the edge of the test platform since sunken living rooms and open staircases—popular features of contemporary Canadian homes—present very wide openings and the possibility for a baby walker to approach the opening at a relatively shallow angle.

Testing was based on the ASTM F 977-00 Standard Consumer Safety Specification for Infant Walkers. The procedures were adapted for testing at different approach velocities from approximately 0.7 to 1.8 m/s (2.4–5.8 f/s) and at approach angles of 15°, 30°, 45° and 90°. Tests were also conducted in which the friction characteristic between the baby walkers' friction pads and the test platform were reduced with talcum powder or water. Three baby walkers equipped with friction pads were tested.

For the steps test, the ASTM standard specifies that a baby walker, initially at rest on the flat, horizontal test surface, be accelerated toward a step by a 371 mm (14.6 in.) free fall of a 3.6 kg (8 lb.) mass attached to the baby walker. According to ASTM, this free fall accelerates a baby walker to a velocity of approximately 1.2 m/s (4 f/s) which is based on measurements of children in baby walkers. Tension in the string between the weight and the baby walker helps to maintain tracking. Free-falling weights are a generally repeatable method of accelerating an object. Friction pads or other means must stop the baby walker before it falls off the step.

Three baby walkers equipped with friction surfaces were available for testing. A total of 13 tests were conducted under ASTM-specified conditions on these baby walkers. The first baby walker was tested three times, had an average measured velocity 0.96 m/s (3.1 f/s) and did not tip in any of the tests. With an average velocity of 1.00 m/s (3.3 f/s), the second baby walker failed to stop in all three attempts. The third unit, with an average velocity of 1.04 m/s (3.4 f/s), did not tip in any of the seven tests to which it was subjected.

When tested at velocities approaching 1.2 m/s (4.0 f/s), only the first baby walker demonstrated the ability to stop before falling off the test table.

Of the many ways of examining the collected data, a logistic regression can be applied, looking simply at whether or not a baby walker fell off the test table. Viewed as a population, Figure 3: shows, for all the

¹ Technical reference unavailable.

data collected at 90°, a 50% probability that a baby walker will fall off the test platform at approximately 1.1 m/s (3.6 f/s). For the 45° tests, the 50% probability of falling off the test surface occurs at approximately 1.5 m/s (4.9 f/s). For the 15° tests, the regression shows an inverse relationship between the probability of a baby walker falling off the test platform and the event velocity. Although this behaviour would seem to reduce concerns for the dangers of wide openings and approaches at shallow angles, it may not be an indication of a safer situation for baby walkers but rather an indication of artificiality of the test condition.

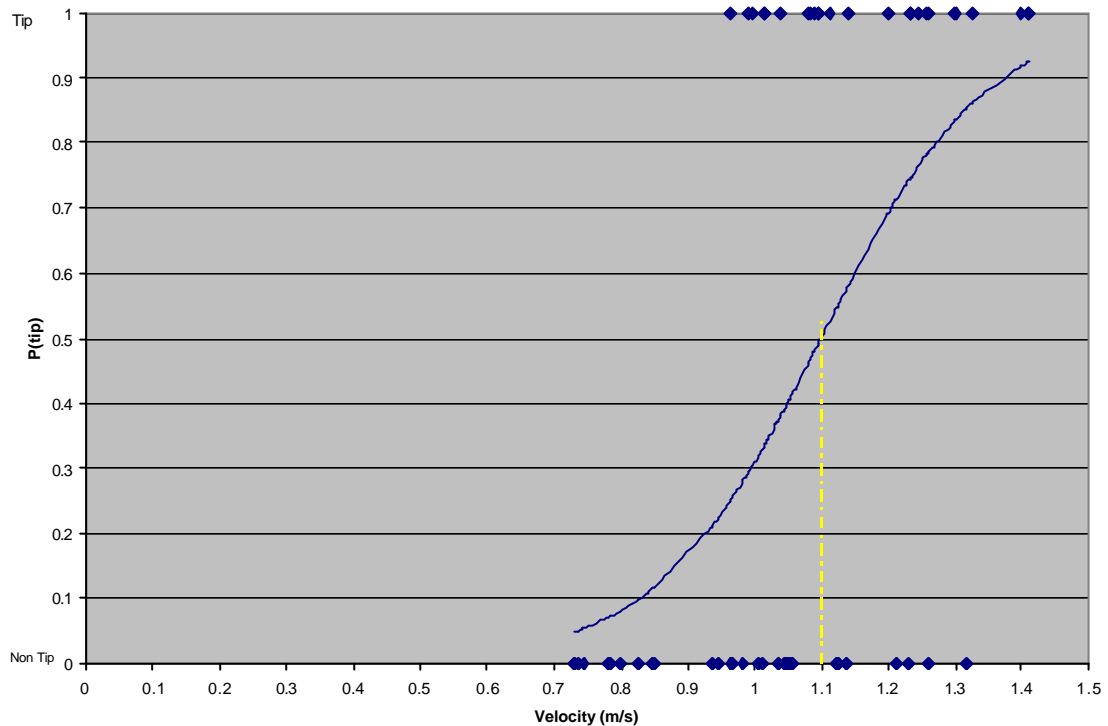


Figure 3: Logistic Regression of All 90° Data

Surface contamination and varying friction characteristics are difficult problems to address. Indeed, the contamination of braking surfaces is an issue not currently contemplated by the ASTM standard.² Means by which these might be controlled are not immediately apparent from this test series and if the braking performance cannot be controlled in a laboratory situation, it is difficult to imagine continued reasonable performance in a home. The tests with surface contamination (talcum powder, water) did exhibit a significantly reduced baby walker braking performance.

This series of tests has shown that braked baby walkers can demonstrate a significant ability to stop at the edge of a step; it has also shown that contamination of the friction surfaces can have a significant but as yet unquantified effect on the braking performance. The data do not show conclusively whether this significant braking ability is sufficient to protect children in all, or even most, real-life instances.

² At the October 2002 meeting of ASTM Committee F15.17 on Walkers, a modification to ASTM standard F977 was approved requiring that manufacturers add instructions to regularly clean friction components to maintain stopping performance.