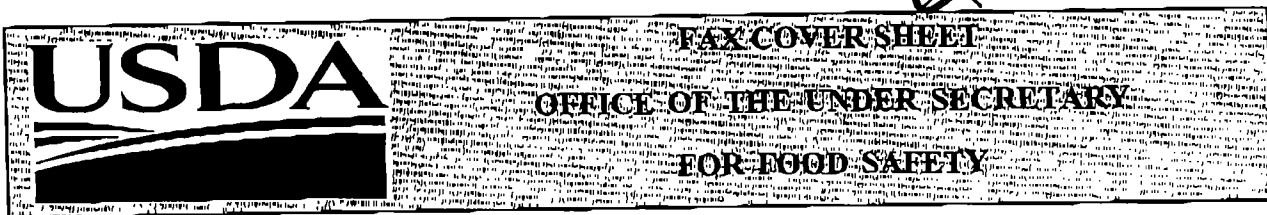


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DATE: DEC 23 NUMBER OF PAGES including cover: 3

TO: TOM FREEDMAN

FAX NUMBER: 456-7431

FROM: ☐ CATHERINE E. WOTEKI, UNDER SECRETARY
☐ KRISTIE D. KELM, SECRETARY
☒ CAREN A. WILCOX, DEPUTY UNDER SECRETARY
☐ _____

COMMENTS: FYI

Telephone (202) 720-0350/51 Fax (202) 690-0820
1400 Independence Avenue, SW - Room 227-E
Washington, D.C. 20250



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

DEC 23 1998

INFORMATIONAL MEMORANDUM FOR THE SECRETARY

THROUGH: Catherine E. Woteki *C. E. Woteki*
Under Secretary
Food Safety

FROM: Thomas J. Billy *T. J. Billy*
Administrator

SUBJECT: Recall of Hot Dogs and other Packaged Meats Because of Possible Contamination
with *Listeria monocytogenes*.

ISSUE:

Bil Mar Foods, a Division of Sara Lee Corporation, is voluntarily recalling specific production lots of hot dogs and other packaged meat products because of possible contamination with *Listeria monocytogenes*. The company issued a press release on December 22 to announce its action.

DISCUSSION:

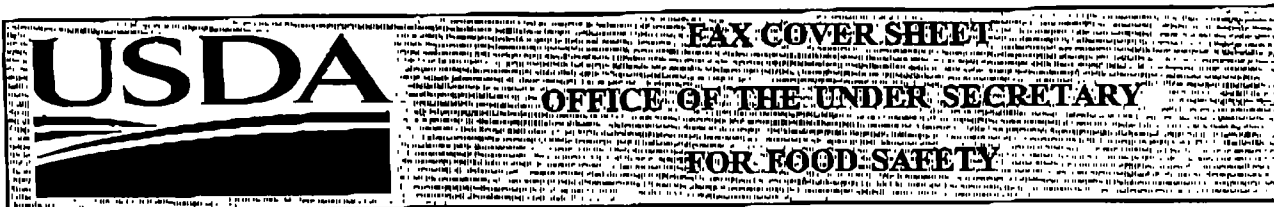
FSIS supports and respects the company's responsible business decision to recall its products on the basis of its own evaluation of available information. This decision is consistent with the principles underlying the Hazard Analysis and Critical Control Point (HACCP) system for food safety.

The products being recalled were produced by the Bil Mar Foods establishment in Zeeland, Michigan, and sold by retail grocery stores and selected food services in the United States. The company is taking this action following discussions with USDA and the Centers for Disease Control and Prevention (CDC). The CDC has indicated that some of the product may contain the serotype 4b, type E (by pulsed-field gel electrophoresis) *Listeria monocytogenes* bacteria. Current information indicates that this strain is uncommon in food and humans.

For almost two weeks, FSIS has been working with the CDC and the Food and Drug Administration in investigating an outbreak of listeriosis that has reportedly caused 40 illnesses and 4 deaths among persons in ten states. Preliminary evidence suggested that the food vehicle for the single strain of *Listeria monocytogenes* bacteria could have been a meat or poultry product contaminated with the bacteria at some point between production and ingestion.

On December 22, the FSIS recall committee met to formalize the company's decision to recall. The recall committee determined that the recall is a Class I recall. FSIS has taken 11 samples of

Liston



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TO: Tom Kresnow / Mary Smith

FAX NUMBER: 406-7431

FROM: ☐ CATHERINE E. WOTEKI, UNDER SECRETARY
☐ KRISTIE D. KELM, ASSISTANT TO THE UNDER SECRETARY
☒ CAREN A. WILCOX, DEPUTY UNDER SECRETARY
☐ JOYCE E. SMITH, ASSISTANT TO THE DEPUTY UNDER SECRETARY
☐ _____

COMMENTS: _____

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1400 Independence Avenue, SW - Room 227-E
Washington, D.C. 20250

USDA Response to Listeriosis

Notwithstanding the good progress on *Listeria monocytogenes* control over the last several years, USDA believes the current listeriosis outbreak presents an opportunity to further strengthen pathogen control efforts from farm to table and further reduce the risk of human illness. *Listeria* has been considered an adulterant in ready to eat products since 1989. The new use of Food Net has enabled cases of listeriosis in geographically dispersed areas to be fingerprinted and identified, and highlights the probable source of a sub-type of the bacteria in a new manner, not possible before its inception.

Actions Taken

- FSIS is currently monitoring three recalls of meat and poultry products. Compliance officers are following up to ensure the recalled ready-to-eat products are removed from distribution channels.
- An interdisciplinary team of scientists is reviewing corrective action plans for the major plant associated with a recall. Inspection and enforcement officials must be satisfied that those corrective action plans are effective before production can resume, and the company is cooperating.
- USDA's Toll Free Meat and Poultry Hotline has handled more than 500 calls on listeriosis since media coverage of the outbreak began. The Hotline is providing advice to consumers on safe food handling, making use of current publications for "at risk" persons as well as the Center for Disease Control's new factsheet on listeriosis (attached).
- USDA is coordinating with CDC and the states to investigate the chain of events that led to illness. FSIS is conducting extensive sampling from plants associated with recalls, and routinely subtypes *Listeria monocytogenes* isolates to determine if they are associated with the outbreak.
- FSIS and FDA are conducting a joint risk assessment for listeriosis under the aegis of the President's Food Safety Initiative. The risk assessment will be germane to all foods and identify new and/or refined risk management steps. Estimated completion date: close of FY 99.
- USDA's Agricultural Research Service is studying the pathogen itself and its characteristics to gain a better understanding of control measures; for example, if the organism has become more heat-resistant, this would influence food processing techniques.

Actions Planned

FSIS is planning two meetings early in February to reevaluate strategies to reduce the number of illnesses associated with *Listeria monocytogenes* in ready-to-eat products.

- On February 9 (tentative), industry representatives will be challenged to address their own pathogen control strategies, particularly in light of HACCP implementation. (Preliminary contacts from some in industry indicate an openness to work cooperatively on these.)
- They will be invited to work cooperatively with FSIS to develop guidance materials for use by industry to help minimize the public health risk from *Listeria monocytogenes*.
- They will be asked to make available "shelf-life" product samples for further analysis. For example, a careful study of the influence of refrigeration time on bacterial load may provide new information relevant to the effectiveness of current processing and labeling procedures, such as "open dating."
- A public meeting will also be held (February 10). The meeting will address:
 - Adequacy of current protocols; i.e., current sampling program, recall procedures, industry procedures, government procedures;
 - Development of industry guidance;
 - Discussion of any commitments from industry at February 9 meeting;
 - Review of public health and scientific picture of *Listeria monocytogenes*, including improvements made possible by FoodNet and PulseNet;
 - Review of FSIS monitoring program for *Listeria monocytogenes* in ready-to-eat products;
 - Review of longstanding educational approach and materials.
 - Review of methodology, testing, sampling, recall procedures;
 - Dissemination of information on FoodNet and PulseNet, demonstration of fingerprinting.
- FSIS anticipates this public meeting will be the vehicle for immediate and longer-term regulatory decisions and strategies for research and education. The public meeting will be announced in the *Federal Register* and through our constituent update.
- FSIS is also using internal analysis to identify preventative control, enforcement, and educational strategies for reducing the number of foodborne illnesses associated with *Listeria monocytogenes* in the future.
- FSIS has already changed its website, and is re-examining its consumer education materials, particularly those for "at risk" audiences, as well as its distribution strategy. FSIS will coordinate education and information/activities with CDC and FDA via the Partnership for Food Safety Education.



L. Skon

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY

TELEPHONE (202) 720-3631

FAX (202) 720-5437

FAX COVER SHEET

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 - ☐ JOHN GIBSON, SPECIAL ASSISTANT
- ☐ GREG FRAZIER, CHIEF OF STAFF
 - ☐ JOSE VENZOR, EXECUTIVE ASSISTANT & BRIEFINGS DIRECTOR
- ☐ PATRICK STEEL, DEPUTY CHIEF OF STAFF
 - ☐ SEAN O'SHEA, EXECUTIVE ASSISTANT
- ☐ TIM GALVIN, SPECIAL ASSISTANT FOR FOREIGN POLICY
- ☒ ERIC OLSEN, COUNSEL TO THE SECRETARY FOR DOMESTIC POLICY
- ☐ JANET POTTS, COUNSEL TO THE SECRETARY
- ☐ LAURETTA MILES, ADMINISTRATIVE ASSISTANT

MESSAGE: _____

FYT

(112)
USDA mulls labeling, testing to control listeria

By Julie Vorman

WASHINGTON, Feb 4 (Reuters) - The federal government said Thursday it would consider warning labels on packages of hot dogs or stricter testing by meat plants to halt the growing number of cases where meat has been infected by bacteria.

A string of recalls for tainted hot dogs, lunch meat and milk have occurred in recent weeks, puzzling U.S. Agriculture Department officials who cannot explain the eruption of cases.

A total of 16 deaths and more than 70 illnesses have been linked to listeria in products made by Sara Lee Corp. The other outbreaks have not caused any reported deaths.

"We're considering everything at this point," Margaret Glavin, associate administrator of the USDA's Food Safety and Inspection Service, told reporters.

A warning label for high-risk consumers is "one of the areas we are exploring," Glavin said. Another option is to require plants to test for listeria, or increase the USDA's current random sampling of meat products for listeria.

Food industry officials contend that more research is needed before the USDA issues any new rules.

The USDA will hold a hearing on Wednesday to gather suggestions from consumer groups and the meat industry.

The listeria bacteria does not harm healthy adults, but can be deadly for unborn babies, small children, the elderly and anyone with a weak immune system.

In 1998, the USDA took a total of 3,547 product samples for listeria from some 2,000 U.S. plants, Glavin said. Ninety of the samples, or about 2.5 percent, tested positive.

Meat plants themselves often test for generic listeria in the air or in floor drains, she said.

Scientists are probing whether longer shelf life of products -- sometimes now extending for months -- might contribute to the problem. Another possibility is that the bacteria has become resistant to high temperatures during processing.

Between 1989, when the USDA launched random testing of listeria, and 1993, U.S. listeria illnesses fell by 44 percent and deaths dropped 48 percent, according to health records.

"Since that time, those numbers have remained down but they haven't continued to drop. It is this concern and the spate of recent problems that is causing us to investigate," she said. The Sara Lee plant in Zeeland, Michigan which produced the products linked to the deaths cannot resume production until it pinpoints the cause of the listeria, the USDA said.

The plant has a history of problems dating back to the summer of 1997, when a series of sanitation "discrepancies" were found by USDA inspectors, Glavin said.

In November 1997, the USDA suspended inspections for a week -- effectively shutting the plant down -- until management took care of sanitation problems.

In July 1998, the Zeeland plant's own environmental tests showed "generic listeria was in the plant, maybe in floor drains," she said.

Glavin defended the USDA, saying it moved swiftly once the U.S. Center for Disease Control found a possible culprit.

On December 15, a USDA team of investigators went to the plant and tested production line samples. Although investigators did not find any contamination, three days later USDA officials suggested a "voluntary withdrawal" of the suspected product.

Sara Lee issued a voluntary recall on December 22. One week later, USDA scientists confirmed a tainted sample from an ill patient's refrigerator was linked to the plant.

Glavin also insisted that the recent outbreak of listeria cases did not reflect on the USDA's tougher food safety measures for raw meat and poultry plants. All large and medium-sized U.S. meat and poultry plants must follow a series of scientific-based checkpoints to prevent contamination.

((Washington commodities/energy desk, 202 898 8467

email: commodsenergy.washington.newsroom@reuters.com))

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113

Listeria outbreaks puzzle USDA, food safety experts

By Julie Vorman

WASHINGTON, Feb 4 (Reuters) - Amid a still-rising death toll from listeria-tainted hot dogs and lunch meat, a consumer group on Thursday demanded that the U.S. Agriculture Department require companies to test the riskiest foods for the fatal disease.

Listeria, a relatively unknown foodborne disease, has been a focus of media attention in recent weeks with a string of outbreaks reported in U.S. delicatessen meats, milk and other refrigerated products that do not need cooking.

At least 16 deaths have been blamed on Sara Lee Corp <SLE.N> hot dogs and lunch meat since August, according to the U.S. Centers for Disease Control, which raised the death toll on Wednesday. The agency is monitoring the outbreak in 14 states.

The spate of recent cases has puzzled regulators, who say there is no obvious reason to account for the increase.

One immediate step that should be taken, according to the Center for Science in the Public Interest, is to require listeria testing by companies of the riskiest food products. "We need better testing of ready-to-eat foods that consumers do not cook," said Caroline Smith De Waal, a food safety analyst with the center. "We are going to ask the USDA to require companies to start this testing for hot dogs, lunch meat, cold cuts and other high-risk foods."

The USDA and the Food and Drug Administration now conduct random testing for listeria. The USDA regulates meat and poultry, while the FDA is responsible for other foods.

Listeria typically affects only infants, unborn babies, the elderly and others with weak immune systems. While less common than the foodborne diseases campylobacter or salmonella, 20 percent of those who get sick from listeria die.

Since December, Sara Lee Corp has recalled an estimated 35 million pounds of hog dogs and luncheon meat, but expects to actually retrieve only about 15 million pounds.

Hormel Foods Corp <HRL.N>, Thorn Apple Valley <TAVI.O> and grocery store chain Winn-Dixie recently recalled products because of suspected listeria. On Tuesday, single-serve cartons of milk sold under the Land O'Lakes brand were also recalled. The USDA described the recent outbreaks across the United States as "unfortunate" and said the illnesses "present an opportunity to strengthen control efforts from farm to table." The USDA's Food Safety and Inspection Service has scheduled a public meeting on Wednesday to take a closer look at how to prevent listeria and ways to improve company recalls.

High on the list is a review of how the USDA randomly samples ready-to-eat products like lunch meat and industry procedures for recalling meat suspected of contamination. The USDA said it would also look at how companies use "sell-by" dates on meat and poultry labels.

Lester Crawford, a former head of the FSIS, said the outbreaks were especially startling because the Centers for Disease Control determined in 1994 that the industry had successfully reduced listeria contamination.

The outbreak comes at a time when the Clinton administration has launched a series of food safety measures, including new requirements that meat plants adopt science-based safety checkpoints. Last week, the FDA's Center for Food Safety ranked listeria as one of its top priorities for research in 1999.

Food safety experts urged the USDA to take a look at whether companies have extended the shelf life of their products too long, which might promote the growth of listeria. The department also needs to closely inspect equipment at meat plants and determine if listeria may be spreading inadvertently through some new processes or through air contamination.

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114
Meat Recall-Investigation, 0463

USDA defends response to tainted meat outbreak

WASHINGTON (AP) Federal food safety officials on Thursday defended their response to an outbreak of tainted meat at a Michigan meat processing plant.

Tainted meat from the Bil Mar plant in Zeeland has been linked to 11 deaths, five miscarriages and stillbirths and about 72 illnesses in 14 states, according to the federal Centers for Disease Control and Prevention.

In Ohio, there have been 23 confirmed cases of listeriosis, including two fetal and four adult deaths. Ohio counties affected are Franklin, Cuyahoga, Hamilton, Lorain, Lucas, Madison, Mahoning, Montgomery, Ross, Tuscarawas and Wood.

Bil Mar, a division of Chicago-based Sara Lee Corp., on Dec. 22 recalled 15 million pounds of hot dogs and other packaged meat products sold under a variety of names. It said they could be tainted with listeria monocytogenes bacteria. The plant remains closed during the investigation.

Listeria are common bacteria but can pose a serious risk to people with weakened immune systems, as well as to the elderly, diabetics and pregnant women.

Officials from the Agriculture Department's Food Safety and Inspection Service began investigating the plant Dec. 15 after consulting with the CDC on a rash of illnesses but did not have evidence of an "intact" contaminated product until several days later, said Margaret Glavin, associate FSIS administrator. "There was a lack of an absolutely firm link with the plant," Glavin said.

Still, Glavin said the agency met with company officials Dec. 18 and asked them to consider taking the product off the market. USDA does not have recall authority.

Sara Lee spokeswoman Theresa Herlevsen denied there was any such meeting.

"We're not aware of any recommendations of a market withdrawal or a recall," Herlevsen said. "It was a voluntary action ... in the absence of any recommendations."

It is not the first food safety issue at the plant, officials said. In 1997, the plant was closed for several days after inspectors found a series of sanitation discrepancies, Glavin said. In July, company officials found evidence of listeria during environmental testing, but at that time, there was no evidence of listeria in the product, officials said.

After the July testing, the company underwent "very aggressive sanitizing and cleaning of all areas," Herlevsen said.

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114 172
Listeria-Tainted Hot Dogs Eluded 'Best' Safeguards, USDA Says

Washington, Feb. 4 (Bloomberg) -- U.S. investigators cannot explain how bacteria responsible for 11 deaths eluded the "best" safety measures and found their way into hot dogs, a federal official said.

The same strain of listeria that killed 11 adults, caused five miscarriages and sickened 72 people since August 1998 also was found in hot dogs from a meat-processing plant owned by Sara Lee Corp. The outbreak is one of the deadliest since 1985.

"We are very concerned that the best (sanitation) practices for preventing listeria contamination don't seem to be adequate," Margaret Glavin, the No. 2 official of the U.S. Agriculture Department's Food Safety and Inspection Service, told reporters in a conference call. "The current state of knowledge on what's the best thing to do isn't good enough."

The outbreak prompted Sara Lee Corp., the largest U.S. processed meat company, and Thorn Apple Valley Inc., a Michigan meat processor, to recall millions of pounds of hot dogs and cold cuts in December and last month.

Symptoms of the infection include fever, muscle aches, nausea and diarrhea. The infection can lead to meningitis and can be especially harmful to pregnant women, newborns, elderly people and people with weak immune systems.

Glavin said the department may increase its random testing program for the bacterium. The department in 1998 tested 3,547 samples of processed meat for listeria at an estimated 2,000 meat plants. Ninety samples were positive.

"We've not made a change in our testing program, but that's certainly one of the things we are considering," Glavin said.

According to the U.S. Centers for Disease Control, investigators have traced a rare strain, serotype 4b, to hog dogs manufactured at Sara Lee's Bil Mar Foods plant in Zeeland, Michigan. In addition, a different strain was traced to unopened packages of deli meats produced at the same plant.

Expanded Recall

On Dec. 22, Sara Lee voluntarily recalled 15 million pounds of its hot dogs and other meat products after the CDC notified the company the products could contain listeria. That was before the government had proof of contamination.

The family of a Tennessee woman who claim she died after eating the company's Ball Park hot dogs sued the company for wrongful death. The suit was filed this week in Cook County Circuit Court in Chicago.

Sara Lee expanded the recall last week to add turkey franks and other products sold to 70 Marketplace retail stores in Illinois, Indiana, Michigan and Ohio. Allen's Pride frozen beef

was recalled from a St. Louis supermarket, and Monarch brand meat products were recalled from two stores in Montgomery, Alabama.

Sara Lee also makes Hanes underwear, Coach leather goods and its namesake frozen desserts. It had \$20 billion in revenue in

114 2/2
fiscal 1998.

Thorn Apple Valley Jan. 22 recalled six months of production of hot dogs and lunch combinations, an estimated 30 million pounds, the department said, after some of the products tested positive for listeria. The company said most of the meat had been eaten or thrown away, making the amount to be recovered much smaller.

Updates on CDC's investigation of listeria can be found at it www.cdc.gov/ website.

--Roger Runnigen in Washington (202) 624-1857, with reporting from Will Edwards in Atlanta/rg

Story illustration: For a graph of Sara Lee's recent share performance: Type SLE US <Equity> GP D <Go>.

Company news:

SLE US <Equity> Sara Lee
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Publisher of

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SUBJECT: Letter on Listeria

COMMENTS:

CSPI

CENTER
FOR SCIENCE
IN THE
PUBLIC INTEREST

Publisher of **Nutrition Action Healthletter**

February 9, 1999

Honorable Dan Glickman
Secretary of Agriculture
US Department of Agriculture
14th Street and Independence Ave, SW
Washington, DC 20250

Dear Secretary Glickman:

I am writing on behalf of CSPI's one million members and subscribers to request that you require additional microbial testing in the meat and poultry HACCP and pathogen reduction program. The latest food poisoning outbreak from *Listeria monocytogenes* (*Listeria*) linked to Sara Lee hot dogs and luncheon meats, which so far has caused at least 75 illnesses and 15 deaths, might have been avoided if the company had been required to test its fully-cooked products for the harmful strain of *Listeria* before the products were released to the public.

Under your leadership, USDA has modernized the meat and poultry inspection system, using a system of preventive controls called "HACCP," combined with performance standards and microbial sampling in slaughter plants. Preliminary data released by the Food Safety and Inspection Service shows that this system has been effective in reducing *Salmonella* contamination rates for some meat and poultry products. In addition to government sampling for *Salmonella*, microbial testing for generic *E. coli* was mandated for all slaughter plants.

We need strong standards to protect consumers from foodborne hazards, and USDA has the toughest standard for *Listeria*: a "zero tolerance." This means that whenever meat or poultry products are found to contain this bacterium, they are subject to a recall. While USDA's random sampling program for *Listeria* has resulted in numerous recalls of contaminated meat and poultry products, the current outbreak demonstrates that random sampling doesn't identify all hazardous products.

Unlike slaughter plants, processing plants are not required to perform any microbial sampling to ensure the effectiveness of their HACCP systems. The Sara Lee outbreak should provide the impetus to correct this serious deficiency in USDA's HACCP and pathogen reduction program. Specifically, CSPI requests that all processing plants that produce hot dogs, cold cuts, luncheon meats, or other fully-cooked meat or poultry products should be required to test their products and their plants for *Listeria monocytogenes*.

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1875 Connecticut Avenue, N.W.
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Michael F. Jacobson, Ph.D.
Executive Director

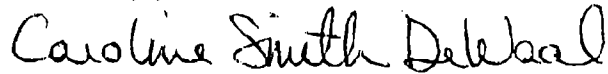
February 9, 1999

Page 2

Requiring processing plants to conduct laboratory tests on ready-to-eat meat products would provide urgently-needed additional protection for consumers against *Listeria* in the food supply. A government mandate is especially important because industry lawyers have been advising meat and poultry companies for years to avoid testing their products for *Listeria*.

Thank you for your tremendous leadership on food safety. Clearly, this tragic outbreak demonstrates that more can and should be done.

Very truly yours,

A handwritten signature in black ink that reads "Caroline Smith DeWaal". The script is cursive and fluid, with the first letters of each word being capitalized and prominent.

Caroline Smith DeWaal

Director of Food Safety

*CW 4/23*

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OFFICE OF THE ADMINISTRATOR



National Highway Traffic Safety Administration, NHTSA
400 7th Street, SW., Room 5220, Nassif Bldg.
Washington, D.C. 20590
FAX #202-366-2106

DATE:

2/9/99

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Ricardo Martinez

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People Saving People



7431

Contact: Julie Vasquez
202-662-0600

Media Advisory

NATIONAL SAFE KIDS CAMPAIGN TO RELEASE NEW FINDINGS REVEALING MOST COMMON MISUSE OF CAR SEATS NATIONWIDE

*Groundbreaking Study Results and Car Seat Check Up Event
Kick Off Child Passenger Safety Week (February 14-22, 1999)*

The National SAFE KIDS Campaign®
1301 Pennsylvania Avenue, N.W.
Suite 1000
Washington, DC 20004-1707
(202) 662-0600
(202) 393-2012 Fax
www.safekids.org

Honorary Chairs
Vice President Al Gore
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C. Everett Koop, M.D.

President
Martin R. Eichelberger, M.D.

Executive Director
Heather Paul, Ph.D.

WHO:

Heather Paul, Ph.D., executive director, National SAFE KIDS Campaign
Ricardo Martinez, M.D., administrator, National Highway Traffic
Safety Administration
Martin Eichelberger, M.D., president, National SAFE KIDS Campaign
Terry Connolly, director, General Motors Safety Center
Inga Wilson, parent of injured child

WHAT:

Children whose car seats are incorrectly used may be at risk for serious injury in the event of a crash, according to the largest national study on car seat misuse to date to be released by the National SAFE KIDS Campaign. Findings from the study, *Child Passengers at Risk in America: A National Study of Car Seat Misuse*, will reveal the most common types of car seat misuse nationwide.

The study results will be highlighted by a Car Seat Check Up event which will be held to educate parents on the proper way to install and use car seats and safety belts.

WHEN & WHERE:

Thursday, February 11, 1999
News Conference: 9:30 a.m. E.T.
Car Seat Check Up: 9:00 - 11:00 a.m.
Curtis Chevrolet, 5929 Georgia Avenue, NW, Washington, D.C.

WHY:

Motor vehicle crashes are the leading cause of unintentional injury-related death among children ages 14 and under. More than 1,800 children die and more than 280,000 are injured each year as motor vehicle passengers.

A b-roll feed including crash demonstrations will go out via satellite on Thursday, February 11, 1999. Contact Julie Vasquez at (202) 662-0600 for technical information.

The National SAFE KIDS Campaign is the first and only national organization dedicated solely to the prevention of unintentional childhood injury — the number one killer of children ages 14 and under. More than 260 State and Local SAFE KIDS Coalitions in all 50 states, the District of Columbia and Puerto Rico comprise the Campaign. Former U.S. Surgeon General C. Everett Koop, M.D., is chairman of the Campaign, and Vice President Al Gore and Tipper Gore are honorary chairs.

-###-

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