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247

Open hostility flares on judiciary panel

NEWS

4/20/63

By HARRY McFARLAND
The Associated Press

JUNEAU — Open hostility flared in a House Judiciary Committee meeting when a minority Democrat protested the lack of debate on one bill and the absence of testimony on another.

Rep. Don Clocksin, D-Anchorage, found himself looking at a committee substitute on a measure (HB247) he said

he hadn't read. Judiciary Chairman Charlie Bussell, R-Anchorage, asked immediately for a vote, saying that the information on the bill was contained in the member's packet.

"You're not even going to allow debate?" Clocksin asked.

Bussell said the committee had debated the bill, and the committee substitute was the

result of testimony. The measure was approved on a 4-1 vote.

A second measure (HB163) was introduced to the committee, with Bussell stating he saw no real need to have testimony.

"This is a travesty on the legislative process," Clocksin said. "It's a railroad."

Backed by other members

of the majority — including House Speaker Joe Hayes and House Majority Leader Ramona Barnes, both R-Anchorage — Bussell won his way, and the measure was approved on a 5-2 vote.

After the meeting, an angry Clocksin stormed up to Bussell, using foul language, demanding to know why he was being treated in such a manner.

MAR 29 1983

STATEMENT BY
ARTHUR HULL HAYES, JR., M.D.
COMMISSIONER
FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

OCTOBER 15, 1982

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

I am here today to discuss with you the events surrounding the recent contamination of Extra-Strength Tylenol capsules and to share with you our thoughts and concerns regarding this tragic event. On behalf of Secretary of Health and Human Services Richard Schweiker and myself, I would like to acknowledge the excellent cooperation we have received from industry, State and local authorities, and the Federal Bureau of Investigation who have responded swiftly and effectively to this emergency.

Based on the September 30, 1982 report of deaths in Chicago by a Cook County medical examiner, the manufacturer of Tylenol, McNeil Consumer Products Co. of Fort Washington, Pennsylvania immediately removed the lot from the marketplace nationwide which had been linked to the deaths. On October 1, the manufacturer removed a second lot from the marketplace nationwide which had been linked to an additional death. In the greater Chicago area, all Extra-Strength Tylenol capsules were withdrawn.

At the same time, the Food and Drug Administration (FDA) issued press releases on September 30 and October 1 (a press conference was also held on October 1) advising consumers not to use Extra-Strength Tylenol capsules until circumstances surrounding the deaths could be clarified. Additionally, FDA began sampling Extra-Strength Tylenol nationally on October 1. Sampling in the Chicago area had begun immediately upon learning of the Tylenol-related deaths on September 30.

FIELD ACTIONS

During the next four days, over a million and a half Tylenol capsules were sampled and tested. Over 1,100 FDA field personnel were committed to collecting and analyzing samples of Tylenol capsules and immediately investigating all reports of deaths or illnesses which might have been associated with the use of Tylenol. Samples were collected in practically all of the States and forwarded to our district laboratories for analysis. I would like to make special mention of the enormous task our analysts faced. Each individual capsule was physically examined and its ingredients chemically analyzed. It was truly an extraordinary effort.

In one instance, our field efforts may have, indeed, prevented an additional death. One bottle taken from the shelves by FDA in the Chicago area proved to be contaminated with cyanide. This was the only bottle containing cyanide that was not associated with a death. None of the capsules outside the Chicago area showed cyanide contamination.

In addition, both plants where the lots involved had been produced were inspected to insure that the contaminant had not been introduced into the product during the manufacturing process. The Philadelphia District Office began inspecting the Fort Washington, Pennsylvania plant on September 30 and the Houston District Office inspected the Round Rock, Texas plant on October 1. We concluded that the contamination was the result of tampering after the capsules had been

shipped to distribution points and, most likely, after they reached the retail shelves. Some of the reasons were:

- The only cases of injury and death associated with cyanide-contaminated capsules were in the Chicago area and had all occurred within three days--September 29 to October 1.
- The control numbers directly associated with the injuries and deaths were produced in two widely separated plants at three different times: Fort Washington, Pennsylvania and Round Rock, Texas in January, March, and April 1982.
- There was no uniformity in the amount of cyanide present in the capsules that were analyzed.
- FDA Laboratory testing of capsules containing cyanide revealed that the gelatin capsule begins to deteriorate 6 to 7 days after being in contact with the cyanide, and samples of capsules collected and analyzed by FDA from a Schaumburg, Illinois drug store and FDA analysis of capsules from victims' bottles revealed beginning stages of such deterioration.
- The first two control numbers implicated were both shipped to the Chicago area in mid-August 1982. The third lot was first shipped to distribution points in Pennsylvania in May 1982. Subsequent shipments of code 1801 MA were after that date and therefore all were available for adulteration in Chicago at about the same time.
- The bottle of capsules implicated in one death contained both Regular Strength and Extra-Strength capsules. Only the Extra-Strength capsules contained cyanide. Inspection of the plants revealed distinctly separate processes for the manufacture of the two kinds of capsules and these processes are physically separated one from the other.

-- Local law enforcement agencies have announced that they believe at this time that the tampering took place after the product left the manufacturing plant.

By October 4, FDA also had checked reports of more than twelve deaths or illnesses in areas other than Chicago and none proved to be related to Tylenol. On that same date FDA issued another press release to provide this updated information and to continue to advise against the use of nonprescription Tylenol capsules. Also, from the day the deaths were first reported, my colleagues and I utilized national TV and radio news programs, press conferences and other available means of communication to convey this message to the public.

As authorities continued to investigate the cyanide poisoning deaths in the Chicago area, a report of a Tylenol-related illness involving an Oroville, California man was received by FDA late on Monday evening, October 4. Field investigators were immediately assigned to the area to investigate the incident and acquire samples. Although the man recovered, subsequent analysis of the Extra-Strength Tylenol capsules from the bottle he had used revealed the presence of strychnine. At this time, although all contaminated Tylenol products were Extra-Strength Tylenol, retailers were notified nationwide on October 5 by the manufacturer to withdraw both Extra- and Regular Strength Tylenol capsules from their shelves. FDA also issued another press release on that date summarizing McNeil's announcement regarding the Oroville situation and restating its warning to consumers to avoid Extra-Strength and Regular nonprescription Tylenol capsules nationwide.

As of today, over 150 reports of deaths or illnesses that might have been related to the use of Tylenol capsules have been received by FDA from across the country. We have investigated each of these reports and have been unable to prove that any subsequent cases have been linked to the taking of contaminated Tylenol. We are continuing to monitor and follow up on additional reports we receive.

HEADQUARTERS ACTIONS

In addition to the efforts undertaken in the field and because of the continuing serious emergency involving the tampering with nonprescription drug products, I utilized our existing emergency procedures for headquarters personnel and 24-hour coverage was provided by the staff. I also created a formal emergency Task Force devoted to the Tylenol problem. The group met at least twice daily to review, discuss and direct the activities of headquarters and field personnel.

These events have, quite understandably, generated concern about package integrity and product security. After discussion with the Secretary, I conferred with The Proprietary Association, a trade association which represents a large number of nonprescription drug manufacturers, on October 3 suggesting that they organize an industry task force to address this problem. They agreed to do so and immediately established the Joint Committee on Product Security. I met with the Committee on October 5 to explore measures to improve product packaging in order to discourage tampering.

Further, a special Expert Technical Committee was appointed to develop standards for tamper-resistant packaging. This group met on

October 7 and 11 and reviewed technologies available to deal with this problem, and a number of packaging types were identified as tamper resistant by a definition developed by the group. An integral part of these discussions has been the availability of necessary packaging that are agreed upon. In addition, individual drug companies have been examining their own packaging to determine what can be done to develop and implement additional tamper-resistant procedures. As you know, the Board of Directors of The Proprietary Association met yesterday and received the report from the Expert Technical Committee. I am advised that Mr. Cope will discuss the substance of that report in his testimony.

There is a need for a Federal standard to implement the packaging requirement. Such requirements and their technical feasibility are the subject of discussion within FDA and The Proprietary Association.

Of concern to us has been the development of State and local laws or proposals to require some form of tamper-resistant packaging. These laws or proposals are an understandable response in the face of this tragic situation. It is important, however, that there not be conflicting laws affecting nationally distributed products in such a way that it is impracticable to market such products. Therefore on October 5, Secretary Schweiker requested FDA to immediately begin drafting a regulation that would require some kind of tamper-resistant packaging for nonprescription drugs. The Secretary stressed the need for uniform consistent standards that adequately protect the public while assuring the availability of nonprescription drug products nationwide.

FDA currently possesses the legal authority to promulgate regulations governing the design of containers to discourage or indicate the occurrence of tampering. Specifically, section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. sec. 351(a)(2)(B)] authorizes FDA to issue good manufacturing practice regulations (GMPs) for drug products.

GMPs are those measures that manufacturers take to assure that their drug products are of adequate quality, including measures to assure that products remain of adequate quality throughout the chain of distribution. This GMP authority has been used to require drug containers to guard against foreseeable external factors that could cause product deterioration or contamination. These regulations were not intended to cover tampering. Tampering has been uncommon and sporadic, and has therefore not been considered, until now, to be the type of threat to product integrity for which an industry-wide response is necessary. But, in the light of the recent events in Chicago and Oroville, it is clear that good manufacturing practices should now include the use of tamper-resistant packaging to discourage or indicate the occurrence of tampering. Such packaging is necessary to assure that over-the-counter (OTC) drug products meet Federal requirements for safety, quality, and purity at the time of purchase by the ultimate consumer.

It must be recognized that the initiatives described above will not happen overnight. Although we expect to publish the regulation in the near future, it is going to take time for industry to get the equipment in place in the plants and to begin marketing these products. It

should also be emphasized that a tamper-proof package is not possible. However, we believe that we can improve upon the packaging for these products using existing and developing technologies by making them more resistant to tampering of any sort. At the same time, we must help to educate consumers to be alert to signs that indicate tampering. Our goal in these efforts is to reduce the risk of injuries or deaths to consumers now and in the future. I want to assure you that Secretary Schweiker and I give this matter the highest priority.

CONSUMER INITIATIVES

Initiatives are underway by health professionals, the industry and FDA to develop ways in which we can best inform and educate the public about how critical it is for all of us to be as observant as possible with regard to the condition of the products we buy. We will be building upon our existing programs through cooperation with the private sector to develop ways to disseminate information and to impress upon consumers that they have a personal responsibility to heighten their sense of awareness in this area. In fact, the National Council on Patient Information and Education plans to form a group which will deal with various aspects on patient and consumer responsibility. We are working closely with the Council. The Council, headed by former Congressman Paul Rogers, held its first meeting on October 12, 1982.

INTERNATIONAL COMMUNICATIONS

We also undertook to disseminate information to the international community.

On Friday, October 1, the text of Dr. Novitch's statement at the noon press conference was sent by telegram to the World Health Organization (WHO) offices in Geneva, Copenhagen, and Washington. An all-post telex was sent Friday evening by the Department of State. That evening, a telex explaining events up to that time was also sent to 64 government drug regulatory authorities and WHO.

Over the next two days, we continued to provide WHO and the State Department with additional information as it became available and requested that the various health ministries be provided with this updated information. Another telex was sent to international drug regulatory authorities.

Further, on October 8, we again contacted the State Department updating domestic information on the Tylenol situation, listing the 11 foreign countries in which Tylenol capsule products are manufactured and/or marketed, and providing information on the Johnson and Johnson preferred method of disposing of bottled Tylenol capsules. We provided a list of the 11 foreign affiliates of Johnson and Johnson and explained that these affiliates had already established communications with the local health ministries regarding sales of Extra-Strength Tylenol capsules. We transmitted this same information to WHO Headquarters, WHO regional offices, and the European Economic Community. This information was also transmitted to international drug regulatory authorities.

The willful contamination of products intended to benefit consumers is repulsive to us all. I can assure you that the Secretary and I are personally committed to moving quickly to provide additional safeguards to help protect the public.

Thank you Mr. Chairman. This concludes my prepared testimony. I will be happy to answer any questions you may have.

HHS NEWS

MAR 29 1983

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOR RELEASE AT 8:00 A.M., EST
Thursday, November 4, 1982

Claire Dorrell - (202) 245-6343

HHS Secretary Richard S. Schweiker said today he has formally approved and sent to the Federal Register for publication uniform standards for nonprescription drug manufacturers to follow in providing tamper-resistant packaging for their products--effective within 90 days in many cases.

Manufacturers could choose among various techniques--seals, shrink bands, and bubble or strip packs, for example--but would be required to highlight the barrier with a distinctive design that would be hard to duplicate. Each product would also have to prominently display an advisory that the product should not be purchased or used if the seal or barrier was not intact when the product was bought.

FDA Commissioner Arthur Hull Hayes Jr., M.D., said the regulation "allows manufacturers flexibility as to which methods of tamper-resistant packaging will be used. We realize new methods are being developed all the time, and we want to encourage new protection methods," said Dr. Hayes.

"While it is virtually impossible to make any package tamper-proof, it is possible to manufacture packages in such a way that tampering is much more difficult, and that if a product is tampered with, it can more easily be detected by a careful consumer," Schweiker said. "That is the intent of this regulation."

The regulation is a result of the tampering--the opening and refilling of Tylenol capsules with cyanide after they left the manufacturer--which killed seven people in the Chicago area at the end of September and other reports of product tampering since that time.

The regulation becomes effective in steps. The first effective date, in 90 days, requires tamper-resistant packaging on most nonprescription capsule and

(More)

liquid drugs (including eyedrops), except topical dermatologic products. The new packaging would also be required in 90 days on certain cosmetic products that may be susceptible to tampering, such as mouthwashes.

In 180 days tablets and suppositories--which are considered less susceptible to tampering--would be required to have tamper-resistant packaging, too. The delay is designed to ensure that the more susceptible products, such as liquids and capsules, have priority in obtaining the technology and machinery needed to make them secure.

Also at 180 days, the label statement and the distinctive design for barriers would be required. This delay recognizes the practical difficulties these features may pose, although some manufacturers may be able to beat the deadline by months. In fact some expect to begin marketing products in new tamper-resistant packages within the next few weeks. In 15 months, no over-the-counter drug could be sold without tamper-resistant packaging.

Since the Chicago deaths, FDA and the major manufacturers of nonprescription drugs have been working together to review what technology and machinery is available, and how to most effectively protect the public from product tampering.

"The manufacturers of over-the-counter drugs have been extremely cooperative in moving quickly toward better protection. They have acted responsibly and in good faith, and I believe this regulation will give them the uniform national standards they need," said Schweiker.

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NOTE REGARDING THE FOLLOWING FRAME(S) ON MICROFILM:
COMPLETE DOCUMENT IS AVAILABLE IN ORIGINAL FILES.
TITLE PAGE ONLY HAS BEEN FILMED.

Friday
November 5, 1982

MAR 29 1983

Food and Drug Administration

Part IV

**Department of
Health and Human
Services**

Food and Drug Administration

**Tamper-Resistant Packaging
Requirements; Certain Over-the-Counter
Human Drugs and Cosmetic Products;
Contact Lens Solutions and Tablets; Final
Rules**

§ 11.46.410

ALASKA STATUTES
(Effective January 1, 1980)

§ 11.46.480

Sec. 11.46.480. Criminal mischief in the first degree. (a) A person commits the crime of criminal mischief in the first degree if, having no right to do so or any reasonable ground to believe he has such a right,

(1) with intent to cause a substantial interruption or impairment of a service rendered to the public by a utility or by an organization which deals with emergencies involving danger to life or property, he damages or tampers with property of that utility or organization and causes substantial interruption or impairment of service to the public;

(2) with intent to damage property of another by the use of widely dangerous means, he damages property of another in an amount exceeding \$100,000 by the use of widely dangerous means; or

(3) he intentionally damages an oil or gas pipeline or supporting facility.

(b) Criminal mischief in the first degree is a class B felony. (§ 4 ch 166 SLA 1978)

Cross reference. — As to liability for destruction of property by minors, see AS 11.46.020. Am. Jur. reference. — 34 Am. Jur., Malicious Mischief, § 1 et seq.

STATE OF ALASKA
FISCAL NOTE

Revision Date _____, 1983

| | |
|--|--|
| <p>I. <u>REQUEST</u> <u>Bill/Resolution No.: CS for HB #247(Jud.)</u> <u>Title:..tampering with an item in commerce</u> <u>Sponsor: Rep. Eiska</u> <u>Requestor: Judiciary Committee</u></p> | <p>II. <u>FISCAL DETAIL</u> <u>Agency Affected: Health & Social Services</u> <u>Program Category Affected: Justice</u> <u>BRU, Program of Subprogram(s) Affected:</u> <u>Adult Confinement</u></p> |
|--|--|

EXPENDITURES/REVENUES: (Thousands of Dollars)

| | FY 83 | FY 84 | FY 85 | FY 86 | FY 87 | FY 88 |
|-------------------------|-------|-------|-------|-------|-------|-------|
| OPERATING | | | | | | |
| 100 PERSONAL SERVICES | | | | | | |
| 200 TRAVEL | | | | | | |
| 300 CONTRACTUAL | | | | | | |
| 400 COMMODITIES | | | | | | |
| 500 EQUIPMENT | | | | | | |
| 600 LAND & STRUCTURES | | | | | | |
| 700 GRANTS, CLAIMS, ETC | | | | | | |
| TOTAL OPERATING | | * | * | * | * | * |
| * See Analysis. | | | | | | |
| CAPITAL | | | | | | |
| REVENUE | | | | | | |

FUNDING: (Thousands of Dollars)

| | | | | | | |
|------------------------|--|--|--|--|--|--|
| GENERAL FUND | | | | | | |
| FEDERAL FUNDS | | | | | | |
| OTHER (Specify Source) | | | | | | |

POSITIONS:

| | | | | | | |
|-----------|--|--|--|--|--|--|
| FULL-TIME | | | | | | |
| PART-TIME | | | | | | |
| TEMPORARY | | | | | | |

III. SOURCE OF FUNDS TO OFFSET FISCAL IMPACT OF BILL:

IV. ANALYSIS: Attach a separate page for any Analysis

Prepared By: Roger C. Lange *Roger C. Lange* Phone: 465-3376
 Division: Adult Corrections Date: April 26, 1983
 Approved by Commissioner: Robert Paul Smith, Ph.D. *Robert Paul Smith* Date: 4/28/83
 Department: Health & Social Services

Distribution:

- Original to Legislative Finance
- Copy to Office of Management and Budget (for Legislature introduced bills)
- Copy to Department (for Governor introduced bills)
- Copy to Sponsor
- Copy to Requestor (if different from Sponsor)

3/8/83

FISCAL NOTE

CS for House Bill No. 247 (Jud.)

Page 2

IV. ANALYSIS

There is no statistical data regarding the activity which would become a crime under this act. The Division has no information regarding the annual number of occurrences, arrests, or convictions for tampering with an item in commerce that is a food, drug, device, or cosmetic where physical injury is intended. Therefore, no estimate can be made regarding the fiscal impact of this proposed legislation.

STATE OF ALASKA
FISCAL NOTE

Revision Date , 1983

I. REQUEST
 Bill/Resolution No.: HB 247
 Title: "...tampering with...food, drug..."
 Sponsor: Rep. Liska
 Requestor: House Judiciary

II. FISCAL DETAIL
 Agency Affected: Department of Law
 Program Category Affected: Admin. of Justice
 BRU, Program of Subprogram(s) Affected: Prosecution

EXPENDITURES/REVENUES: (Thousands of Dollars)

| | FY 83 | FY 84 | FY 85 | FY 86 | FY 87 | FY 88 |
|-------------------------|-------|-------|-------|-------|-------|-------|
| OPERATING | | | | | | |
| 100 PERSONAL SERVICES | | | | | | |
| 200 TRAVEL | | | | | | |
| 300 CONTRACTUAL | | | | | | |
| 400 COMMODITIES | | | | | | |
| 500 EQUIPMENT | | | | | | |
| 600 LAND & STRUCTURES | | | | | | |
| 700 GRANTS, CLAIMS, ETC | | | | | | |
| TOTAL OPERATING | -0- | -0- | -0- | -0- | -0- | -0- |
| CAPITAL | | | | | | |
| REVENUE | | | | | | |

FUNDING: (Thousands of Dollars)

| | | | | | | |
|------------------------|-----|-----|-----|-----|-----|-----|
| GENERAL FUND | -0- | -0- | -0- | -0- | -0- | -0- |
| FEDERAL FUNDS | | | | | | |
| OTHER (Specify Source) | | | | | | |

POSITIONS:

| | | | | | | |
|-----------|-----|-----|-----|-----|-----|-----|
| FULL-TIME | -0- | -0- | -0- | -0- | -0- | -0- |
| PART-TIME | | | | | | |
| TEMPORARY | | | | | | |

III. SOURCE OF FUNDS TO OFFSET FISCAL IMPACT OF BILL:

IV. ANALYSIS: Attach a separate page for any Analysis

Prepared By: Richard I. Pegues, Director Phone: 465-3672
 Division: Administrative Services Division Date: March 31, 1983
 Approved by Commissioner: Norman C. Gorsuch, Attorney General Date: March 31, 1983
 Department: Department of Law

Distribution:

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HB 247
Analysis

This bill makes tampering with an item in commerce that is a food, drug, device, or cosmetic a class B felony. There is no history of such tampering occurring in the state. After such tampering as the Tylenol poisoning in Chicago, however, this bill could serve to help prevent future similar occurrences from happening in Alaska by providing strict penalties for any tampering. Prosecutors believe that the incidence of tampering will be slight and, consequently, no measurable fiscal impact will result due to enactment of this legislation.

STATE OF ALASKA
FISCAL NOTE

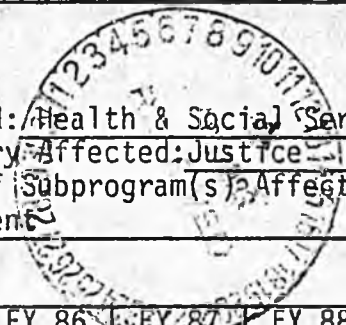
Revision Date _____, 1983

I. REQUEST

Bill/Resolution No.: House Bill No. 247
 Title: "tampering with an item in commerce"
 Sponsor: Rep. Liska
 Requestor: Judiciary Committee

II. FISCAL DETAIL

Agency Affected: Health & Social Services
 Program Category: Justice
 BRU, Program of: Subprogram(s) Affected:
Adult Confinement



EXPENDITURES/REVENUES: (Thousands of Dollars)

| | FY 83 | FY 84 | FY 85 | FY 86 | FY 87 | FY 88 |
|-------------------------|-------|-------|-------|-------|-------|-------|
| OPERATING | | | | | | |
| 100 PERSONAL SERVICES | | | | | | |
| 200 TRAVEL | | | | | | |
| 300 CONTRACTUAL | | | | | | |
| 400 COMMODITIES | | | | | | |
| 500 EQUIPMENT | | | | | | |
| 600 LAND & STRUCTURES | | | | | | |
| 700 GRANTS, CLAIMS, ETC | | | | | | |
| TOTAL OPERATING | | * | * | * | * | * |
| * See Analysis. | | | | | | |
| CAPITAL | | | | | | |
| REVENUE | | | | | | |

FUNDING: (Thousands of Dollars)

| | | | | | | |
|------------------------|--|--|--|--|--|--|
| GENERAL FUND | | | | | | |
| FEDERAL FUNDS | | | | | | |
| OTHER (Specify Source) | | | | | | |

POSITIONS:

| | | | | | | |
|-----------|--|--|--|--|--|--|
| FULL-TIME | | | | | | |
| PART-TIME | | | | | | |
| TEMPORARY | | | | | | |

III. SOURCE OF FUNDS TO OFFSET FISCAL IMPACT OF BILL:

IV. ANALYSIS: Attach a separate page for any Analysis

Prepared By: Roger C. Lange *Roger C. Lange* Phone: 465-3376
 Division: Adult Corrections Date: April 1, 1983
 Approved by Commissioner: Robert London Smith Date: 4/7/83
 Department: Health & Social Services

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