

[Text]

MEDICAL DEVICES

Question No. 554—Mr. Young:

1. (a) In (i) 1980 (ii) 1981 (iii) 1982 (iv) 1983 (v) 1984 (vi) 1985, how many accidents involving the use of medical devices were reported to the Bureau of Medical Devices (b) how many were reported by the product manufacturer or supplier and by hospitals or physicians and other medical practitioners (c) how many reported accidents resulted in (i) physical injury (ii) death?

2. Did the Bureau investigate each reported accident and, if not how many were investigated?

3. Did the Bureau initiate criminal prosecutions as a result of the investigations and, if so, how many?

**Hon. Jake Epp (Minister of National Health and Welfare):**

1 (a) For the six years requested, the numbers of reported device related incidents are:

Number of reports received:

	(i) 1980	(ii) 1981	(iii) 1982	(iv) 1983	(v) 1984	(vi) 1985
	182	285	239	244	324	347

(b)	(i) 1980	(ii) 1981	(iii) 1982	(iv) 1983	(v) 1984	(vi) 1985

Reported by:

	(i) 1980	(ii) 1981	(iii) 1982	(iv) 1983	(v) 1984	(vi) 1985
Product Manufacturers or suppliers	8	7	3	2	13	35
Hospitals	19	37	40	39	127	78
Physicians	12	26	48	86	32	94
Other medical staff	110	174	111	89	121	112
General Public	33	41	37	28	31	28

(c) (i) and (ii) The classification system for reported accidents includes those that actually resulted in death or physical injury and those that have the potential to do so. The system addresses actual and potential accidents equally but does not differentiate between the two.

2. Every reported accident is investigated but the depth and completeness of each investigation depends upon the severity of the hazard and the assigned priority.

3. Criminal prosecution constitutes only one of a range of possible remedial and corrective measures available to the Bureau. Over the six-year period in question the Bureau has implemented all of the following measures, except criminal prosecution:

Order for Return

Remedial Measures	Addressed to
A. Advisory measures, including:	Manufacturers
1. Medical Devices Alerts	To transfer technological know-how developed by the Bureau, to suggest new methodologies, to advise on compliance with the Act and regulations, etc.
2. HPB Information Letters	
3. Safety Guidelines	Users
4. Standards	To make users aware of hazards, to correct misunderstandings, to provide education and training to prevent misuse and human error.
5. Individual letters	
6. Scientific publications	
B. Directives or recommendations for device improvements or manufacturing changes.	Manufacturers, when the Bureau considers the hazard or ineffectiveness to arise from design errors or improper manufacturing.
C. Directives or recommendations for labelling improvements.	Manufacturers, where the directions for use or other labelling are considered inadequate.
D. Regulatory and compliance measures including:	Manufacturers, when a serious and present hazard is discovered, or co-operation is not forthcoming, or the device is fraudulent, etc.
1. stop sale by manufacturer	
2. recall or corrective action	
3. seizure of stock	
4. refused entry to Canada	
5. criminal prosecution	

[English]

**Mr. Speaker:** The question as enumerated by the Parliamentary Secretary has been answered.

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QUESTION PASSED AS ORDER FOR RETURN

**Mr. Doug Lewis (Parliamentary Secretary to President of the Privy Council):** Mr. Speaker, if Question No. 370 could be made an Order for Return, the Return would be tabled immediately.

**Mr. Speaker:** Is it the pleasure of the House that Question No. 370 be deemed to have been made an Order for Return?

**Some Hon. Members:** Agreed.

[Text]

RESIDENTIAL REHABILITATION ASSISTANCE PROGRAM

Question No. 370—Mr. Malépart:

1. In (a) Canada (b) each province (c) each municipality (d) each regional country, what amounts were (i) spent in 1984 (ii) allocated for 1985 under the Residential Rehabilitation Assistance Program for the rural or urban segment of the program?

2. In (a) Canada (b) each province, what amounts were (i) spent in 1984 (ii) allocated for 1985 for co-operative housing under the RRAP program?

3. Under the Rental Assistance Plan, what amounts were (a) spent in (i) 1983 (ii) 1984 (b) allocated for 1985 in each province?

4. (a) Under the program provided for in Section 56.1 of the *National Housing Act*, how many housing units were built in each province in 1984 (b) what amount was (i) spent in 1984 (ii) allocated in 1985, in each province and in Canada, for public housing, co-operative housing and non-profit organizations?

Return tabled.