

because at best one person on average has been made ill. We recognize that our procedure generated highly uncertain estimates of the number of illnesses. The use of recalls to estimate reported and unreported illnesses probably generated a distribution of illnesses below the "true" distribution, because many illnesses occur that are not linked to recalls and are never reported. We were not able to determine even the approximate size of the underestimation from this procedure.

We estimated the monetary value of the health benefits from CGMP regulations by multiplying the number of illnesses prevented by the health costs associated with an illness. The health benefits associated with preventing an illness come from: (1) Preventing the loss of productivity, (2)

the reduction in pain and suffering, and (3) the reduction in expenditures on medical treatment. We measured lost productivity indirectly with measures of functional state, which includes measures of physical function. We estimated the losses caused by pain and suffering with a symptom-problem index. We used direct measures of medical costs, such as payments to physicians and hospitals.⁴

Table 8 of this document contains summaries of our measures of the health effects potentially caused by known instances of defective products associated with poor manufacturing processes. We estimated the health loss per day for the different levels of illness severity by summing the lost productivity (as measured by functional state) and the loss from pain and

suffering (as measured by the symptom-problem index⁵). These losses per day can be interpreted as the difference between a day of normal health, where normal is defined as the population's health not affected by these products, and a day of suffering from the health conditions caused by these defective products. The numerical scale is a relative baseline that rests on the notion of a quality-adjusted life day (QALD). The QALD for a day of normal health equals 1; the QALD for death equals 0. The loss of QALDs per illness equals the daily loss multiplied by the number of days the illness lasts. We converted QALDs to dollars by multiplying the index numbers by the value of a statistical life day and adding the direct medical costs.

TABLE 8.—SUMMARY OF HEALTH EFFECTS BASED ON POTENTIAL ILLNESS ASSOCIATED WITH RECALLS BETWEEN 1990 AND 1999

Problem	Class of recall	Number of recalls	Outcomes	Frequency of illness (percent)	Quality adjusted life day	Duration of illness (days)	Medical cost (\$ per event)	Health cost (\$ per event)
Hypervitaminosis A ...	1	2	100	0.472	3	84	936
Salmonella	1	4	Mild	93.8	0.473	2	0	534
			Moderate	5	0.473	5	800	2,223
			Severe	1.2	0.563	17	9,100	14,859
			Reactive arthritis (short term).	2	0.42	25	100	6,438
			Reactive arthritis (long term).	1	0.42	5,223	400	1,320,252
	2	4	Death	0.04	9,100	5,009,100
Klebsiella pneumonia	1	1	Severe	85	6,235	10,650
			Death	15	6,235	5,006,325
Selenium poisoning ...	1	1	Low doses	50	0.482	3	84	954
			Severe	35	0.482	3	2,578	4,448
			Death	15	2,578	5,002,578
Stannous fluoride	1	1	Acute	100	0.473	3	84	938
	2	1	0.473	3	84	938
Eosinophilia-myalgia syndrome.	1	7	Mild	47	0.482	5,223	1,176	1,515,863
			Moderate	50	0.482	60	84	17,484
	2	41	Severe	10	14,964	27,394
Glass fragments	2	1	Dental injury, simple	50	0.231	1	139
			Dental injury, complicated.	12	3,741
			Oral emergency	12	3,741	6,428
			Tracheo-esophageal obstruction.	25	290
			Esophageal perforation.	1	14,964	23,343
Hypervitaminosis D ...	2	1	100	0.473	3	168	1,022
Pyridoxine (vitamin B6).	2	2	100	0.482	30	168	8,868
Super-potent zinc	2	1	Mild	50	285
			Moderate	40	596
			Severe	10	1,247	3,347
Niacin	2	1	100	84	4,258
Yellow #5 (undeclared).	2	5	Mild allergic reaction	90	0.44	2	0	529
			Severe allergic reaction.	10	2,494	3,346

⁴ The cost of a hospital day is from the Health Care Financing Agency's Indicator Tables. It is the amount per patient day in 1997, adjusted to 1999 dollars. See Ref. E17.

⁵ Functional Status Code is a measure of lost mobility (MOB), physical activity (PAC) and social activity (SOC). Lost MOB might mean an inability to drive a car. Lost PAC might mean walking with physical limitations. Lost SOC might mean self-care

is not possible. Symptom-problem health utility index is a weighted measure of the cost of each symptom. For example, a sick or upset stomach has a utility weight of .290.