CDC
CENTERS FOR DISEASE CONTROL

May 10, 1991 / Vol. 40 / No. 18

MMWR
MORBIDITY AND MORTALITY WEEKLY REPORT

Effectiveness in Disease and Injury Prevention

Inappropriate Use of Transillumination for Breast Cancer Screening — Wisconsin, 1990

The overall effectiveness of early breast cancer detection efforts requires the appropriate use and maintenance of dedicated radiographic mammography systems. However, the effectiveness of early detection efforts can be compromised if proven technology is improperly used and/or maintained or if ineffective technology is successfully marketed as an equivalent or superior alternative to mammography. This report summarizes state and federal responses to the inappropriate use of a nonradiographic imaging technique in a breast cancer screening service advertised and used in Wisconsin in 1990.

In June 1990, the Radiation Protection Section, Division of Health (DOH), Wisconsin Department of Health and Social Services, was contacted by a local public health department inquiring about the efficacy of breast examination using a transillumination light scanning (also known as diaphanography) device. The inquiry was prompted when the local health department learned that such a device was being used in communities to screen women for breast cancer. In response, the Radiation Protection Section obtained information about the equipment and procedure from the manufacturer.

In July, the DOH Cancer Control Program learned that a Wisconsin company had placed a newspaper advertisement promoting a mobile van-based breast cancer screening service. The advertisement, which promoted "mammography screening" in large block letters, described a "non x-ray, painless and rapid breast screening technique." Subsequently, the DOH located the van parked outside a shopping mall in a small town in south-central Wisconsin; "mammography screening" appeared on large signs across the van. Company staff explained that their breast screening procedure entailed shining visible and infrared light through the breast to visualize internal tissues and that the results were recorded on videotape for interpretation by a physician in another state.

Breast Cancer Screening — Continued

The DOH contacted the National Cancer Institute (NCI), the Food and Drug Administration (FDA), and CDC to inquire about the efficacy and uses of transillumination. Both NCI and CDC emphasized that the efficacy of transillumination of the breast as a screening test for early breast cancer detection had not been demonstrated and that the technique could not be legitimately labeled as "mammography." The FDA confirmed that, although marketing of the device was allowed through the grandfather provisions of the federal Food, Drug, and Cosmetic Act,* FDA had not approved the device or its labeling or allowed the device to be marketed as being comparable to or as a substitute for mammography. Based on the promotional materials provided by the Wisconsin DOH, FDA began an investigation.

The Wisconsin-based company had been marketing the device and services to employers in the state. As part of its marketing strategy, the company had used the "Worksite Breast Health Programs" planning packet that had been developed by the DOH and distributed in April to Wisconsin employers of more than 500 persons. At least one employer had planned to offer the mobile clinic's "radiation-free" screening to its employees that fall.

On September 6, Wisconsin state officials alerted the U.S. Department of Health and Human Services of the inappropriate marketing of the device in Wisconsin. In late September, the NCI's Office of Cancer Communications reported on the limitations of transillumination for early breast cancer screening (*1*).

The DOH continued to work with local, state, and federal health officials to monitor breast cancer screening activities (*2*). As a result of these efforts and the FDA's investigation, federal marshals seized the device in Markesan, Wisconsin, on December 6, based on charges that the device violated the federal Food, Drug, and Cosmetic Act. The government's complaint specifically objected to the device's labeling, which included statements that represented or suggested that the device was adequate and effective as 1) a screening method for the early detection of breast cancer, 2) an alternative to radiographic mammography for the detection of breast cancer, and 3) a means to accurately and reliably differentiate benign breast conditions from breast cancer.

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Editorial Note: In many states, breast cancer-control programs promote screening and attempt to monitor and improve the quality of mammography. However, efforts to increase the use of mammography create an opportunity for promotion and inappropriate use of less effective imaging techniques as breast screening methods. In Wisconsin, the advertising strategy used by the company not only promoted transillumination as superior to mammography but also exploited some women's fears of radiation and the potential discomfort from the breast compression required in mammography.

In transillumination, light is shone through the breast to illuminate its interior structure (*3*). By using beams of light in the red and near-infrared spectrum, transillumination produces an image of breast tissue on film, usually through video

*21 U.S.C. 301 et seq.

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systems that permit simultaneous recording and viewing on a monitor. This technique is based on the principle that different types of tissues (i.e., cancerous and normal tissues) will manifest different patterns of light scatter and absorption; therefore, the transmission of light through the breast will vary in identifiable ways. Within the breast, adipose breast tissue typically absorbs less light and thus allows greater light transmission. Both glandular breast tissue and cancerous tissue absorb more light and allow comparably less light transmission; however, the increased vascularity of carcinoma yields comparably lower light transmission than normal glandular breast tissue.

Transillumination has at least four important limitations as a method for breast cancer screening. First, transillumination is not sufficiently sensitive or specific to be an acceptable screening technique for breast cancer (*4*). Second, transillumination is especially ineffective in detecting small (<1 cm) tumors. Third, the sensitivity of transillumination is substantially diminished for tumors near the chest wall and for women with dense breast tissue, because dense breast tissue produces greater light scatter. Fourth, transillumination cannot distinguish clearly between the increased vascularity associated with cancer and the increased vascularity associated with different areas of normal breast structure, some benign breast conditions, and internal hemorrhage associated with recent biopsy.

The only recognized imaging techniques for the early detection of breast cancer are radiographic examinations with screen-film mammography and xeromammography. Although other breast imaging techniques (e.g., sonography, thermography, magnetic resonance imaging, and transillumination) have been investigated for their screening potential, such techniques have not yet achieved the levels of sensitivity and specificity of conventional approaches (*5*). Both sonography and ultrasound may be used as diagnostic adjuncts to mammography; however, the adjunctive benefits of thermography and transillumination have not been established. The FDA's Obstetrics and Gynecology Devices Advisory Panel recently considered the clinical utility of breast transilluminators and concluded that, except in investigational settings, the devices do not provide meaningful clinical information and should not be used in the clinical evaluation of breast tissue, neither alone nor in conjunction with other techniques (*6*).

Emphasis on improving the quality of mammography is increasing. The American College of Radiology's Mammography Accreditation Program has increased the general awareness and practice of procedures that improve the quality of mammography (*7*). In addition, some states (*8*) and the FDA, CDC, and NCI are supporting activities that focus on improving the quality of mammography, and as of January 1, 1991, Medicare coverage for screening mammography is contingent on the supplier's meeting quality assurance requirements (*9*). This report underscores the importance of collaboration among state-based cancer-control programs, radiation-control programs, and state agencies to ensure that ongoing breast cancer screening programs meet existing quality standards.

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Breast Cancer Screening — Continued

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Epidemiologic Notes and Reports

Outbreak of Relapsing Fever — Grand Canyon National Park, Arizona, 1990

On June 21, 1990, 11 days after returning from the Grand Canyon North Rim (GCNR), a 61-year-old California resident developed an acute illness lasting 2 days, characterized by fever, shaking chills, headache, myalgias, and drenching sweats. During the next 2 weeks, he had three febrile relapses and was hospitalized. Physical examination and laboratory studies were nondiagnostic. However, during a fourth recurrence of fever and prostration, examination of a peripheral blood smear revealed spirochetes, consistent with the diagnosis of relapsing fever. The patient was treated with tetracycline and recovered.

One additional confirmed case with onset July 5 and one suspected case with onset July 12 were reported in Arizona residents. All three patients had stayed overnight in cabins at the GCNR.

Beginning July 6, 1990, visitors to the GCNR were notified of the risk for exposure to tickborne relapsing fever (TBRF). A survey of 244 employees at the GCNR identified two persons who had had recurrent febrile symptoms compatible with TBRF. One had been hospitalized with meningismus and cerebrospinal fluid pleocytosis. A retrospective mail and telephone survey of 6993 visitor groups, representing more than 10,000 persons who stayed in park cabins during the 1990 season, identified 14 cases of laboratory-confirmed (four cases) or clinically defined (10 cases) relapsing fever* in park visitors from nine states, Canada, and Germany. Seven of the 14 patients had been hospitalized.

An environmental investigation revealed rodent nests likely to harbor vector ticks above the ceilings and below the floors of many of the cabins at the GCNR. During August, all cabins were sprayed with acaricides. National Park officials plan to inspect

*A confirmed case was defined as illness occurring within 3 weeks of exposure in any person who had been a resident or overnight visitor at the GCNR from May 15 through August 15, 1990, from whom spirochetes were visualized on a Wright- or Giemsa-stained blood smear, or in whom antibody to *Borrelia hermsii* was demonstrated by enzyme-linked immunosorbent assay. A clinical case was defined as illness in a resident or visitor during the same dates who had fever and three of four characteristic symptoms (chills, sweats, myalgias, or headache) *and* in whom a history of clinical remission followed by relapse was reported.

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all buildings, remove rodent nests, and make structural changes to prevent rodent access and nesting in attics and crawl spaces before the park opens for the 1991 season.

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Editorial Note: This outbreak is the first recognized occurrence of TBRF at GCNR since 1973, when an interstate outbreak of 62 confirmed or suspected cases occurred in employees or visitors who had stayed in cabins at GCNR (*1*). TBRF is endemic throughout much of the western United States; sporadic cases occur each summer and fall. The disease is caused by infection with the spirochetes *Borrelia hermsii* or *B. turicatae*; *B. hermsii* was identified in 1973 at the GCNR (*1*). The soft ticks of the genus *Ornithodoros*, which transmit the illness, usually feed on rodents and frequently infest rodent nesting material (*2*). The ticks are reclusive, usually feeding at night for only 5–20 minutes. Their bites are painless and frequently go unnoticed (*3*). Most infections with *B. hermsii* are acquired by persons vacationing in mountain cabins where rodents have nested (*1–7*).

Because onset of illness occurs 4–18 days after infection, patients infected with TBRF in tourist areas where the disease is endemic often develop symptoms after they have returned to areas where TBRF is not suspected. TBRF that is undiagnosed and untreated may cause recurrent febrile illness for weeks to months before the illness resolves. Neurologic sequelae, such as aseptic meningitis and cranial nerve palsy, occur in a small proportion of patients. Serologic testing by enzyme-linked immunosorbent assay is available at CDC's Division of Vector-Borne Infectious Diseases, Center for Infectious Diseases, through state health departments and may aid with a diagnosis when symptoms are suggestive of TBRF but laboratory results are equivocal. Following infection, paired serum specimens often demonstrate diagnostic levels of antibody to *B. hermsii* or *B. turicatae*.

The 1973 outbreak was associated with epizootic plague (*2,4*), which caused a marked decrease in rodent populations that serve as the usual hosts for the vector tick and resulted in increased feeding of ticks on humans. Recent observations suggest that a decline in rodent populations occurred in 1990, which may similarly have increased the risk for human exposure.

Prevention strategies for TBRF focus on avoiding tick bites and preventing rodents from nesting in human shelters in areas where TBRF is endemic. "Rodent proofing"—structural changes that prevent rodent access to the foundations or attics of homes and vacation cabins—reduces human contact with ticks that transmit the disease.

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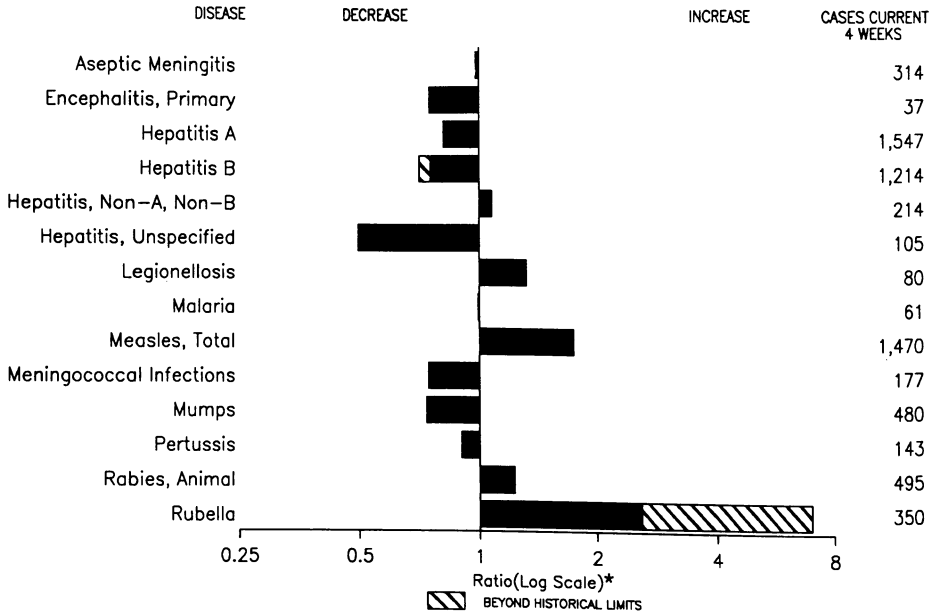
FIGURE I. Notifiable disease reports, comparison of 4-week totals ending May 4, 1991, with historical data — United States



*Ratio of current 4-week total to the mean of 15 4-week totals (from previous, comparable, and subsequent 4-week periods for the past 5 years). The point where the hatched area begins is based on the mean and two standard deviations of these 4-week totals.

TABLE I. Summary — cases of specified notifiable diseases, United States, cumulative, week ending May 4, 1991 (18th Week)

	Cum. 1991		Cum. 1991
AIDS	13,976	Measles: imported	52
Anthrax	-	indigenous	4,079
Botulism: Foodborne	6	Plague	-
Infant	17	Poliomyelitis, Paralytic*	-
Other	4	Psittacosis	33
Brucellosis	16	Rabies, human	-
Cholera	8	Syphilis, primary & secondary	14,838
Congenital rubella syndrome	7	Syphilis, congenital, age < 1 year	9
Diphtheria	1	Tetanus	10
Encephalitis, post-infectious	25	Toxic shock syndrome	121
Gonorrhea	195,023	Trichinosis	8
Haemophilus influenzae (invasive disease)	1,294	Tuberculosis	6,698
Hansen Disease	36	Tularemia	24
Leptospirosis	27	Typhoid fever	102
Lyme Disease	1,384	Typhus fever, tickborne (RMSF)	24

*No cases of suspected poliomyelitis have been reported in 1991; none of the 6 suspected cases in 1990 have been confirmed to date. Five of the 13 suspected cases in 1989 were confirmed and all were vaccine associated.

TABLE II. Cases of selected notifiable diseases, United States, weeks ending May 4, 1991, and May 5, 1990 (18th Week)

Reporting Area	AIDS	Aseptic Meningitis	Encephalitis		Gonorrhea		Hepatitis (Viral), by type				Legionellosis	Lyme Disease
			Primary	Post-infectious			A	B	NA,NB	Unspecified		
	Cum. 1991	Cum. 1991	Cum. 1991	Cum. 1991	Cum. 1991	Cum. 1990	Cum. 1991	Cum. 1991	Cum. 1991	Cum. 1991	Cum. 1991	Cum. 1991
UNITED STATES	13,976	1,673	198	25	195,023	234,349	8,782	5,536	1,007	503	388	1,384
NEW ENGLAND	627	73	10	-	5,009	6,336	197	302	41	13	33	52
Maine	22	4	3	-	44	89	6	8	2	-	-	-
N.H.	16	4	-	-	117	83	17	9	4	-	1	4
Vt.	8	10	-	-	16	24	9	3	3	-	-	1
Mass.	348	25	5	-	2,047	2,458	106	235	25	11	30	34
R.I.	19	23	-	-	400	371	30	12	5	2	2	13
Conn.	214	7	2	-	2,385	3,311	29	35	2	-	-	-
MID. ATLANTIC	3,897	200	18	7	23,883	32,852	664	464	89	12	110	1,063
Upstate N.Y.	556	106	8	5	4,292	4,683	408	215	56	6	41	849
N.Y. City	2,045	9	-	-	8,935	14,174	25	6	-	-	3	-
N.J.	924	-	-	-	3,764	5,351	114	128	16	-	13	214
Pa.	372	85	10	2	6,892	8,644	117	115	17	6	53	-
E.N. CENTRAL	1,060	299	53	6	37,319	44,744	1,007	679	136	21	72	55
Ohio	244	98	14	2	11,765	13,802	160	167	71	9	39	34
Ind.	87	36	6	1	3,770	3,609	157	82	1	1	6	-
Ill.	450	54	11	3	11,220	13,606	409	86	15	1	2	-
Mich.	197	101	20	-	8,740	10,717	137	217	41	10	18	21
Wis.	82	10	2	-	1,824	3,010	144	127	8	-	7	-
W.N. CENTRAL	391	115	10	3	9,185	12,334	1,017	233	112	10	16	9
Minn.	92	22	5	-	948	1,492	133	23	8	1	4	2
Iowa	32	26	-	1	646	923	25	13	6	2	1	5
Mo.	207	45	3	2	5,542	7,203	244	163	94	5	6	-
N. Dak.	4	-	-	-	23	57	20	3	2	1	-	-
S. Dak.	1	4	2	-	128	73	419	2	-	-	3	-
Nebr.	17	7	-	-	664	625	143	13	1	-	2	-
Kans.	38	11	-	-	1,234	1,961	33	16	1	1	-	2
S. ATLANTIC	3,330	418	34	7	58,230	65,107	616	1,220	151	108	59	65
Del.	27	8	1	-	785	1,044	5	21	3	2	-	12
Md.	354	50	4	-	6,017	6,541	125	169	29	6	15	27
D.C.	198	12	-	-	3,553	3,944	37	42	1	1	-	-
Va.	287	67	9	-	5,582	6,052	67	78	9	81	4	10
W. Va.	12	2	1	-	424	456	9	28	1	3	-	3
N.C.	159	43	12	-	10,942	10,845	70	209	64	-	8	8
S.C.	106	12	-	-	4,308	5,186	19	290	15	2	7	1
Ga.	476	37	5	1	14,939	14,644	67	145	10	-	4	2
Fla.	1,711	187	2	6	11,680	16,395	217	238	19	13	21	2
E.S. CENTRAL	389	98	9	-	17,321	19,082	79	480	128	3	25	40
Ky.	63	23	2	-	1,747	2,303	10	65	5	2	13	14
Tenn.	114	25	4	-	6,701	6,448	49	358	117	-	6	22
Ala.	128	33	3	-	4,312	5,840	19	56	6	1	6	4
Miss.	84	17	-	-	4,561	4,491	1	1	-	-	-	-
W.S. CENTRAL	1,277	136	16	1	22,242	24,418	1,209	585	30	75	15	28
Ark.	57	27	2	-	2,321	3,200	126	42	1	2	2	9
La.	216	23	4	-	5,075	4,593	46	87	1	3	5	-
Okla.	47	1	3	-	2,182	2,187	124	88	15	8	4	18
Tex.	957	85	7	1	12,664	14,438	913	368	13	62	4	1
MOUNTAIN	389	63	10	1	3,977	4,986	1,526	359	50	75	30	3
Mont.	10	2	-	-	28	56	51	31	3	4	1	-
Idaho	8	-	-	-	57	34	26	31	-	-	3	-
Wyo.	6	-	-	-	43	68	75	5	-	-	-	3
Colo.	157	19	2	1	1,096	1,392	193	55	14	10	5	-
N. Mex.	38	8	-	-	353	419	481	72	7	25	1	-
Ariz.	73	18	8	-	1,514	1,944	455	74	5	30	10	-
Utah	19	8	-	-	123	152	115	17	9	6	4	-
Nev.	78	8	-	-	763	921	130	74	12	-	6	-
PACIFIC	2,616	271	38	-	17,857	24,490	2,467	1,214	270	186	28	69
Wash.	182	-	4	-	1,530	2,292	231	178	62	9	1	-
Oreg.	72	-	-	-	677	891	139	118	46	4	1	-
Calif.	2,290	244	32	-	15,148	20,728	2,016	884	151	172	25	69
Alaska	8	8	2	-	261	427	69	11	9	1	-	-
Hawaii	64	19	-	-	241	152	12	23	2	-	1	-
Guam	-	-	-	-	-	94	-	-	-	-	-	-
P.R.	490	87	-	1	216	347	40	146	48	18	-	-
V.I.	3	-	-	-	222	169	-	4	-	-	-	-
Amer. Samoa	-	-	-	-	-	43	-	-	-	-	-	-
C.N.M.I.	-	-	-	-	-	78	-	-	-	-	-	-

N: Not notifiable U: Unavailable C.N.M.I.: Commonwealth of the Northern Mariana Islands

TABLE II. (Cont'd.) Cases of selected notifiable diseases, United States, weeks ending May 4, 1991, and May 5, 1990 (18th Week)

Reporting Area	Malaria	Measles (Rubeola)					Menin-gococcal Infections	Mumps		Pertussis			Rubella		
		Indigenous		Imported*		Total									
	Cum. 1991	1991	Cum. 1991	1991	Cum. 1991	Cum. 1990	Cum. 1991	1991	Cum. 1991	1991	Cum. 1991	Cum. 1990	1991	Cum. 1991	Cum. 1990
UNITED STATES	318	273	4,079	3	52	7,494	862	156	1,641	34	716	1,046	242	552	292
NEW ENGLAND	25	-	14	-	4	125	61	-	11	7	103	128	-	1	3
Maine	1	-	-	-	-	27	4	-	-	-	12	4	-	-	-
N.H.	2	-	-	-	-	8	6	-	3	1	12	10	-	1	-
Vt.	1	-	5	-	-	1	9	-	-	-	3	5	-	-	-
Mass.	13	-	5	-	2	5	32	-	-	4	68	100	-	-	-
R.I.	5	-	-	-	-	26	-	-	2	-	-	-	-	-	1
Conn.	3	-	4	-	2	58	10	-	6	2	8	9	-	-	2
MID. ATLANTIC	33	154	2,384	-	2	682	88	3	142	5	74	272	9	187	2
Upstate N.Y.	11	-	1	-	-	258	49	2	51	4	47	222	4	173	1
N.Y. City	3	75	900	-	-	81	2	-	-	-	-	-	-	-	-
N.J.	14	-	196	-	1	68	15	-	47	-	1	13	-	-	-
Pa.	5	79	1,287	-	1	275	22	1	44	1	26	37	5	14	1
E.N. CENTRAL	25	-	51	-	4	2,588	123	6	155	6	138	259	147	162	16
Ohio	6	-	-	-	1	210	40	5	32	2	65	48	147	147	-
Ind.	1	-	-	-	-	244	8	-	5	4	27	38	-	1	-
Ill.	9	-	24	-	-	1,097	40	-	65	-	19	94	-	3	14
Mich.	8	-	25	-	-	337	28	1	47	-	19	32	-	11	-
Wis.	1	-	2	-	3	700	7	-	6	-	8	47	-	-	2
W.N. CENTRAL	10	-	18	-	2	346	48	2	60	-	51	29	-	8	-
Minn.	2	-	3	-	2	118	10	-	5	-	16	-	-	4	-
Iowa	2	-	15	-	-	21	3	2	13	-	4	3	-	3	-
Mo.	4	-	-	-	-	59	21	-	15	-	19	20	-	1	-
N. Dak.	1	-	-	-	-	-	1	-	-	-	1	1	-	-	-
S. Dak.	-	-	-	-	-	12	1	-	-	-	1	1	-	-	-
Nebr.	-	-	-	-	-	91	3	-	3	-	4	1	-	-	-
Kans.	1	-	-	-	-	45	9	-	24	-	6	3	-	-	-
S. ATLANTIC	69	34	267	-	9	467	158	40	589	2	38	88	1	12	12
Del.	1	1	19	-	-	9	-	-	2	-	-	2	-	-	-
Md.	22	31	115	-	-	55	18	13	129	-	7	22	-	9	1
D.C.	4	-	-	-	-	8	-	-	17	-	-	13	1	1	1
Va.	10	1	18	-	3	41	13	4	23	-	5	9	-	-	-
W. Va.	1	-	-	-	-	6	5	1	11	-	6	8	-	-	-
N.C.	2	-	1	-	-	3	36	-	86	-	7	13	-	-	-
S.C.	5	-	12	-	-	1	21	20	179	-	-	4	-	-	-
Ga.	8	-	-	-	-	18	34	-	12	-	6	10	-	-	-
Fla.	16	1	102	-	6	326	31	2	130	2	7	7	-	2	10
E.S. CENTRAL	4	-	4	-	-	55	60	60	92	-	21	35	80	80	1
Ky.	1	-	-	-	-	3	24	-	-	-	-	-	-	-	-
Tenn.	1	-	4	-	-	19	17	60	77	-	10	13	80	80	1
Ala.	2	-	-	-	-	8	19	-	3	-	11	20	-	-	-
Miss.	-	-	-	-	-	25	-	-	12	-	-	2	-	-	-
W.S. CENTRAL	19	-	-	-	5	935	67	28	201	-	17	14	-	1	1
Ark.	1	-	-	-	5	11	12	12	35	-	-	1	-	1	1
La.	3	-	-	-	-	-	16	1	12	-	7	2	-	-	-
Okla.	1	-	-	-	-	131	8	-	6	-	10	11	-	-	-
Tex.	14	-	-	-	-	793	31	15	148	-	-	-	-	-	-
MOUNTAIN	12	14	270	-	10	382	38	3	92	10	103	87	-	1	23
Mont.	1	-	-	-	-	1	5	-	-	-	-	3	-	-	13
Idaho	1	-	-	-	2	19	7	-	5	-	18	11	-	-	6
Wyo.	-	-	-	-	-	3	1	-	3	-	3	-	-	-	-
Colo.	3	1	1	-	1	55	8	2	26	10	50	48	-	-	3
N. Mex.	1	1	80	-	3	72	5	N	N	-	14	6	-	-	-
Ariz.	5	12	177	-	-	123	8	-	40	-	8	10	-	-	-
Utah	1	-	2	-	4	2	-	-	11	-	10	5	-	-	-
Nev.	-	-	10	-	-	107	4	1	7	-	-	4	-	1	1
PACIFIC	121	71	1,071	3	16	1,914	219	14	299	4	171	134	5	100	234
Wash.	9	-	1	-	3	38	28	4	73	1	48	31	-	-	-
Oreg.	2	1	15	2§	5	133	27	N	N	-	28	14	-	-	-
Calif.	106	70	1,053	-	7	1,663	157	6	209	3	66	73	4	98	229
Alaska	-	-	-	1§	1	77	6	3	7	-	4	-	-	-	-
Hawaii	4	-	2	-	-	3	1	1	10	-	25	16	1	2	5
Guam	-	U	-	U	-	-	-	U	-	U	-	-	U	-	-
P.R.	1	-	26	-	1	698	15	1	8	-	12	4	-	1	-
V.I.	-	-	-	-	-	2		1	5	-	-	-	-	-	-
Amer. Samoa	-	U	-	U	-	-	-	U	-	U	-	-	U	-	-
C.N.M.I.	-	U	-	U	-	-	-	U	-	U	-	-	U	-	-

*For measles only, imported cases includes both out-of-state and international importations.
N: Not notifiable U: Unavailable †International §Out-of-state

TABLE II. (Cont'd.) Cases of selected notifiable diseases, United States, weeks ending May 4, 1991, and May 5, 1990 (18th Week)

Reporting Area	Syphilis (Primary & Secondary)		Toxic-shock Syndrome	Tuberculosis		Tula-remia	Typhoid Fever	Typhus Fever (Tick-borne) (RMSF)	Rabies, Animal
	Cum. 1991	Cum. 1990	Cum. 1991	Cum. 1991	Cum. 1990	Cum. 1991	Cum. 1991	Cum. 1991	Cum. 1991
UNITED STATES	14,838	16,755	121	6,698	7,326	24	102	24	1,764
NEW ENGLAND	402	660	6	169	156	-	9	2	5
Maine	-	5	3	-	-	-	1	-	-
N.H.	10	32	1	-	3	-	-	-	1
Vt.	1	1	-	1	2	-	-	-	-
Mass.	200	238	2	97	77	-	8	2	-
R.I.	16	2	-	18	28	-	-	-	-
Conn.	175	382	-	53	46	-	-	-	4
MID. ATLANTIC	2,547	3,585	19	1,558	1,818	-	13	-	542
Upstate N.Y.	103	260	10	108	175	-	5	-	192
N.Y. City	1,292	1,714	-	937	1,091	-	2	-	-
N.J.	471	557	-	293	300	-	5	-	250
Pa.	681	1,054	9	220	252	-	1	-	100
E.N. CENTRAL	1,673	1,155	24	767	673	1	11	-	28
Ohio	222	176	16	108	91	-	2	-	4
Ind.	39	11	-	47	40	-	-	-	-
Ill.	822	430	4	422	354	-	3	-	6
Mich.	422	393	4	155	162	1	5	-	3
Wis.	168	145	-	35	26	-	1	-	15
W.N. CENTRAL	253	146	25	180	175	5	2	2	230
Minn.	26	36	7	33	28	-	2	-	85
Iowa	22	14	5	26	21	-	-	-	46
Mo.	162	70	6	81	83	5	-	2	6
N. Dak.	-	1	-	2	9	-	-	-	22
S. Dak.	1	1	1	13	4	-	-	-	46
Nebr.	7	4	1	6	11	-	-	-	8
Kans.	35	20	5	19	19	-	-	-	17
S. ATLANTIC	4,487	5,237	9	1,215	1,310	2	21	13	453
Del.	56	67	1	9	16	-	-	-	51
Md.	371	415	-	111	108	-	6	1	165
D.C.	291	322	-	72	42	-	1	-	5
Va.	385	286	2	111	111	-	4	-	91
W. Va.	10	6	-	34	25	-	1	-	25
N.C.	654	608	4	132	164	1	-	9	-
S.C.	545	295	-	139	157	-	-	1	36
Ga.	1,078	1,186	-	253	189	-	4	2	68
Fla.	1,097	2,052	2	354	498	1	5	-	12
E.S. CENTRAL	1,549	1,399	6	370	591	2	-	3	54
Ky.	31	26	3	103	143	1	-	1	13
Tenn.	577	582	3	42	178	1	-	-	18
Ala.	550	410	-	123	174	-	-	2	23
Miss.	391	381	-	102	96	-	-	-	-
W.S. CENTRAL	2,654	2,712	4	681	852	9	3	4	251
Ark.	179	179	2	64	81	4	-	-	14
La.	833	819	-	49	129	-	1	-	3
Okla.	57	80	2	42	70	5	-	4	77
Tex.	1,585	1,634	-	526	572	-	2	-	157
MOUNTAIN	218	311	13	159	139	4	4	-	53
Mont.	1	-	-	-	10	3	-	-	11
Idaho	3	5	-	2	3	-	-	-	1
Wyo.	1	1	-	2	1	1	-	-	30
Colo.	25	24	1	6	6	-	-	-	1
N. Mex.	13	18	5	9	31	-	-	-	1
Ariz.	155	213	3	88	67	-	3	-	8
Utah	4	3	4	25	3	-	-	-	-
Nev.	16	47	-	27	18	-	1	-	1
PACIFIC	1,055	1,550	15	1,599	1,612	1	39	-	148
Wash.	54	170	1	105	101	1	-	-	-
Oreg.	28	45	-	34	44	-	2	-	1
Calif.	966	1,318	14	1,372	1,376	-	36	-	143
Alaska	3	6	-	20	19	-	-	-	3
Hawaii	4	11	-	68	72	-	1	-	1
Guam	-	1	-	-	15	-	-	-	-
P.R.	162	150	-	71	29	-	-	-	12
V.I.	74	1	-	1	3	-	-	-	-
Amer. Samoa	-	-	-	-	11	-	-	-	-
C.N.M.I.	-	-	-	-	20	-	-	-	-

U: Unavailable

TABLE III. Deaths in 121 U.S. cities,* week ending May 4, 1991 (18th Week)

Reporting Area	All Causes, By Age (Years)						P&I**
	All Ages	≥65	45-64	25-44	1-24	<1	Total
NEW ENGLAND	598	439	89	44	9	17	53
Boston, Mass.	170	106	31	19	2	12	18
Bridgeport, Conn.	36	24	7	2	2	1	4
Cambridge, Mass.	19	16	3	-	-	-	3
Fall River, Mass.	27	25	1	-	1	-	-
Hartford, Conn.	51	37	10	3	-	1	2
Lowell, Mass.	30	24	4	2	-	-	4
Lynn, Mass.	22	18	3	1	-	-	-
New Bedford, Mass.	27	24	3	-	-	-	2
New Haven, Conn.	41	25	7	6	2	1	3
Providence, R.I.	39	30	5	4	-	-	4
Somerville, Mass.	5	5	-	-	-	-	-
Springfield, Mass.	36	28	7	-	-	1	1
Waterbury, Conn.	34	28	2	4	-	-	7
Worcester, Mass.	61	49	6	3	2	1	5
MID. ATLANTIC	2,682	1,685	535	300	71	91	153
Albany, N.Y.	54	42	8	1	1	2	7
Allentown, Pa.	14	10	4	-	-	-	-
Buffalo, N.Y.	110	68	30	4	3	5	7
Camden, N.J.	30	15	8	4	2	1	4
Elizabeth, N.J.	25	17	5	3	-	-	2
Erie, Pa.†	44	35	6	2	1	-	-
Jersey City, N.J.	56	34	11	6	3	2	3
New York City, N.Y.	1,341	805	273	196	34	33	60
Newark, N.J.	63	30	19	8	2	4	4
Paterson, N.J.	38	22	10	4	2	-	1
Philadelphia, Pa.	429	260	88	36	15	30	30
Pittsburgh, Pa.†	62	37	16	5	1	3	5
Reading, Pa.	54	38	7	7	2	-	8
Rochester, N.Y.	148	107	21	8	3	9	8
Schenectady, N.Y.	32	23	6	3	-	-	1
Scranton, Pa.†	32	28	-	3	1	-	2
Syracuse, N.Y.	75	60	12	2	1	-	6
Trenton, N.J.	33	21	4	6	-	2	3
Utica, N.Y.	21	17	4	-	-	-	-
Yonkers, N.Y.	21	16	3	2	-	-	2
E.N. CENTRAL	2,144	1,344	430	202	106	61	104
Akron, Ohio	54	36	14	2	-	2	-
Canton, Ohio	33	30	3	-	-	-	5
Chicago, Ill.	415	172	87	71	62	23	14
Cincinnati, Ohio	158	97	44	11	2	4	13
Cleveland, Ohio	170	100	28	30	10	2	2
Columbus, Ohio	149	105	27	13	3	1	3
Dayton, Ohio	113	86	19	4	3	1	3
Detroit, Mich.	209	122	48	23	7	8	2
Evansville, Ind.	62	51	10	1	-	-	5
Fort Wayne, Ind.	54	32	16	4	2	-	2
Gary, Ind.§	U	U	U	U	U	U	U
Grand Rapids, Mich.	70	50	12	3	2	3	11
Indianapolis, Ind.	195	119	41	17	10	8	11
Madison, Wis.	35	25	8	1	1	-	1
Milwaukee, Wis.	128	103	14	8	1	2	12
Peoria, Ill.	51	38	8	1	-	4	1
Rockford, Ill.	55	42	11	-	2	-	5
South Bend, Ind.	36	23	8	3	-	2	2
Toledo, Ohio	90	60	21	7	1	1	9
Youngstown, Ohio	67	53	11	3	-	-	3
W.N. CENTRAL	719	541	94	48	21	15	35
Des Moines, Iowa	65	53	10	1	1	-	5
Duluth, Minn.	24	21	-	1	2	-	1
Kansas City, Kans.	26	18	3	5	-	-	1
Kansas City, Mo.	86	62	18	3	1	2	4
Lincoln, Nebr.	44	33	7	3	1	-	4
Minneapolis, Minn.	168	130	13	15	6	4	6
Omaha, Nebr.	63	51	8	2	-	2	6
St. Louis, Mo.	129	96	14	9	5	5	5
St. Paul, Minn.	53	38	8	4	1	2	2

Reporting Area	All Causes, By Age (Years)						P&I**
	All Ages	≥65	45-64	25-44	1-24	<1	Total
S. ATLANTIC	1,494	885	334	170	52	49	97
Atlanta, Ga.	162	91	33	29	4	5	7
Baltimore, Md.	209	127	39	28	8	7	24
Charlotte, N.C.	85	55	21	8	1	-	4
Jacksonville, Fla.	123	72	28	12	1	8	11
Miami, Fla.	105	53	32	18	2	-	-
Norfolk, Va.	78	47	17	11	2	1	7
Richmond, Va.	80	43	21	7	3	6	6
Savannah, Ga.	69	48	11	5	4	1	9
St. Petersburg, Fla.	73	42	20	7	1	3	4
Tampa, Fla.	182	121	43	11	4	1	19
Washington, D.C.	297	163	64	31	22	17	6
Wilmington, Del.	31	23	5	3	-	-	-
E.S. CENTRAL	739	472	165	65	22	15	44
Birmingham, Ala.	102	67	20	8	6	1	3
Chattanooga, Tenn.	53	38	10	4	1	-	4
Knoxville, Tenn.	99	61	26	9	2	1	3
Louisville, Ky.	105	69	17	11	4	4	16
Memphis, Tenn.	165	101	45	12	3	4	7
Mobile, Ala.	100	65	20	10	4	1	2
Montgomery, Ala.§	U	U	U	U	U	U	U
Nashville, Tenn.	115	71	27	11	2	4	9
W.S. CENTRAL	1,352	848	257	144	68	35	87
Austin, Tex.	65	40	10	11	3	1	2
Baton Rouge, La.	39	25	7	4	3	-	3
Corpus Christi, Tex.	40	28	9	2	1	-	2
Dallas, Tex.	223	132	43	24	16	8	11
El Paso, Tex.	66	47	9	5	2	3	4
Ft. Worth, Tex.	81	57	16	4	4	-	4
Houston, Tex.	272	128	66	46	17	15	20
Little Rock, Ark.	81	51	15	9	2	4	7
New Orleans, La.	165	111	24	20	9	1	-
San Antonio, Tex.	194	138	39	10	6	1	18
Shreveport, La.	33	25	6	-	1	1	4
Tulsa, Okla.	93	66	13	9	4	1	12
MOUNTAIN	829	528	157	77	37	30	50
Albuquerque, N.M.	105	77	13	6	6	3	8
Colo. Springs, Colo.	40	29	5	4	1	1	1
Denver, Colo.	131	82	29	12	4	4	14
Las Vegas, Nev.	152	91	34	16	8	3	8
Ogden, Utah	16	12	2	1	1	-	3
Phoenix, Ariz.	178	102	37	20	9	10	2
Pueblo, Colo.	17	13	2	2	-	-	1
Salt Lake City, Utah	43	24	4	7	1	7	2
Tucson, Ariz.	147	98	31	9	7	2	11
PACIFIC	1,791	1,200	314	171	55	48	101
Berkeley, Calif.	20	11	3	4	-	2	-
Fresno, Calif.	109	75	15	4	7	8	7
Glendale, Calif.	16	14	1	1	-	-	4
Honolulu, Hawaii	76	46	15	12	1	2	5
Long Beach, Calif.	93	64	10	13	1	5	8
Los Angeles, Calif.	350	206	68	49	19	6	11
Oakland, Calif.§	U	U	U	U	U	U	U
Pasadena, Calif.	42	32	8	-	-	2	2
Portland, Oreg.	120	93	18	6	2	1	4
Sacramento, Calif.	158	103	36	12	2	5	12
San Diego, Calif.	158	103	34	12	6	2	18
San Francisco, Calif.	184	116	29	34	5	-	6
San Jose, Calif.	153	108	26	9	3	7	11
Seattle, Wash.	169	117	29	10	7	6	7
Spokane, Wash.	66	52	11	1	1	1	2
Tacoma, Wash.	77	60	11	4	1	1	4
TOTAL	12,348††	7,942	2,375	1,221	441	361	724

*Mortality data in this table are voluntarily reported from 121 cities in the United States, most of which have populations of 100,000 or more. A death is reported by the place of its occurrence and by the week that the death certificate was filed. Fetal deaths are not included.

**Pneumonia and influenza.

†Because of changes in reporting methods in these 3 Pennsylvania cities, these numbers are partial counts for the current week. Complete counts will be available in 4 to 6 weeks.

††Total includes unknown ages.

§Report for this week is unavailable (U).

Relapsing Fever — Continued

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Gastroenteritis Associated with Consumption of Raw Shellfish – Hawaii, 1991

On January 2, 1991, 12 of 24 persons who attended one or more of three New Year's celebrations in Honolulu, Hawaii, had onset of gastrointestinal illness. An investigation by the Epidemiology Branch of the Hawaii Department of Health (HDOH) determined that the only common foods shared by participants were oysters and clams provided by one distributor.

Each of the attendees was interviewed regarding clinical manifestations and food consumption. Twelve persons reported having had diarrhea, vomiting, or abdominal cramps within 24 hours after attending one or more of the gatherings. The most common symptoms reported were diarrhea (75%), nausea (75%), abdominal cramps (67%), myalgias (67%), fever (58%), and vomiting (33%). The median duration of illness was 12–14 hours; no cases associated with secondary transmission were reported.

The only food items common to all three parties were oysters and clams served raw at two of the gatherings and both raw and grilled at the third. Fifteen (94%) of 16 attendees who ate any raw seafood ate both raw clams and oysters. Persons who became ill were more likely to have eaten raw clams (11 of 15 vs. one of nine; odds ratio [OR] = 22.0; 95% confidence interval [CI] = 1.6–667.1) or raw oysters (11 of 16 vs. one of eight; OR = 15.4; 95% CI = 1.2–447.7). Illness did not occur in the one attendee who ate only raw oysters or the five attendees who ate only grilled seafood. No other foods or beverages were associated with illness.

The implicated oysters had been harvested at two sites in Virginia, purchased through a Virginia dealer, and passed through two Massachusetts dealers before air-freight shipment to Hawaii. The clams were traced to a Massachusetts dealership that routinely received shellfish from clam diggers based in Rhode Island and Massachusetts. Although the tag on the implicated clams listed the harvest site as Narragansett Bay, Rhode Island, the Massachusetts seafood dealership reported that it had inadvertently mislabeled the tag and that the clams had actually been purchased from a fisherman who had harvested the product from an approved area off the New Bedford, Massachusetts, coast. Further examination of the dealership's records indicated discrepancies between the harvest and shipping dates of the implicated product, and the Division of Food and Drugs of the Massachusetts Department of Public Health could not verify the dealership's claims.

Samples of oysters from the implicated lot were tested for bacterial pathogens by the HDOH. These tests identified 80 colonies of *Escherichia coli* per 100 g, 230 colonies of *Vibrio parahaemolyticus* per 100 g, and isolated colonies of *V. vulnificus* and *V. fluvialis*. In addition, samples of clams and oysters from the implicated lots were analyzed for five indicators of fecal contamination by the Department of Environmental Sciences and Engineering at the University of North Carolina at Chapel Hill. The results by the most probable number method for clams and oysters, respectively, were 230 and 20 colonies of fecal coliforms per 100 g, 375 and 23 colonies of

Gastroenteritis — Continued

Clostridium perfringens per 100 g, <20 and 20 colonies of *E. coli* per 100 g, <30 and <30 colonies of enterococci per 100 g, and 1475 and 250 plaque-forming units of male-specific coliphage per 100 g. Results of electron microscopy and tissue culture for enteroviruses are pending at CDC. At the Massachusetts Department of Public Health, an analysis of clams collected from the implicated dealership, but with different lot numbers from those implicated in the outbreak, detected <20 colonies per 100 g of fecal coliforms.

On January 16, 1991, state and territorial health departments were notified of the outbreak in Hawaii and the potential for similar outbreaks in other locations.

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Editorial Note: Raw shellfish have been implicated as a vehicle for transmission of numerous enteric pathogens, including Norwalk virus, calicivirus, small round viruses, hepatitis A virus, and *Vibrio*, *Campylobacter*, *Salmonella*, and *Shigella* species (*1,2*). In this outbreak, the short incubation period, short duration of illness, and mild symptoms suggest a viral etiology.

In a 1982 survey in New York, clams or oysters from northeastern coastal waters were implicated in 103 outbreaks of gastroenteritis involving 1017 persons (*3*). In these outbreaks, steamed as well as raw shellfish were implicated. No bacterial pathogens were isolated, but Norwalk virus was implicated by seroconversion testing in five of seven outbreaks.

In this outbreak in Hawaii, the etiologic agent was not identified. Based on the small number of detected colonies of *Vibrio* (commonly identified in seawater) and the clinical symptoms, these agents were not considered the cause of the outbreak (*4*). However, the relatively high levels of *C. perfringens* and male-specific coliphage detected suggest that the clams had been contaminated with high levels of fecal waste before harvesting. Because the levels of fecal coliforms (230/100 g) and *E. coli* (<230/100 g) detected in these shellfish met Food and Drug Administration (FDA) shellstock standards, microbiologic examination of shellfish for these traditional indicators may be inadequate to assess the risk for viral contamination, especially in shellfish harvested during winter months from cold marine waters. New, more sensitive diagnostic techniques to detect viral pathogens in shellfish are under development (*5,6*). Efforts are also in progress to develop improved indicators (e.g., bacteriophages of enteric bacteria) of enteric virus contamination of shellfish and shellfish harvesting waters.

This outbreak illustrates the need for timely reporting of outbreaks of shellfish-related illness to facilitate rapid tracing of sources of contaminated seafood. Although this outbreak occurred in Hawaii, the implicated shellfish were traced to sources on the northeastern U.S. coast. Because clams and oysters from these areas are routinely distributed throughout the United States within days of harvesting, the potential exists for outbreaks of gastroenteritis in multiple locations. However, no other shellfish-related outbreaks associated with these lots of shellfish have been reported to FDA or CDC.

Gastroenteritis — Continued

Although the National Shellfish Sanitation Program and related state agencies have promulgated comprehensive guidelines for tagging shellfish and tracing its interstate transportation, this outbreak demonstrates that some shellfish dealers do not adhere to these guidelines. Previous outbreaks of shellfish-associated gastroenteritis have also been associated with inappropriately tagged shellfish (*1*). Because of the need for more effective control measures to ensure a safe seafood supply, the FDA, through the Interstate Shellfish Sanitation Conference, is developing additional requirements for tagging and product identification.

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Measles Outbreak — New York City, 1990–1991

In March 1990, a large measles outbreak began in New York City. Through December 1990, approximately 2500 cases and eight measles-associated deaths were reported. However, since January 1991, transmission has increased; through May 7, more than 2000 cases and nine deaths were reported to the New York City Department of Health (NYCDH) in 1991.

Preliminary data are available for the first 2084 cases reported in 1991. Of these patients, 1383 (66%) were <5 years of age, of whom 735 (53%) were <12 months of age. Most cases have occurred among black and Hispanic children; more than 70% of cases have been reported from the Bronx and Brooklyn. Transmission has also occurred among prisoners in the city jail system and among both patients and medical staff in some local hospitals.

To control the outbreak, NYCDH officials have recommended an additional dose of measles vaccine for 6- to 11-month-old children, have made walk-in immunization services available, are vaccinating eligible children in emergency rooms, and have mounted a citywide multimedia "stop measles" education and information campaign. In addition, New York state health officials have implemented emergency regulations that require health-care workers to demonstrate proof of measles immunity, have integrated immunization services with certification for the Special Supplemental Program for Women, Infants, and Children, and are implementing requirements for hospitals and licensed health-care facilities to offer immunization to all children served.

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Measles – Continued

Editorial Note: Characteristics of the current measles outbreak in New York City are similar to recent outbreaks in other large metropolitan areas of the United States, including Chicago, Houston, and Los Angeles (*1–3*). These outbreaks have involved predominantly unvaccinated preschool-aged black and Hispanic children and represent the failure of current immunization strategies to achieve high vaccination coverage levels among preschool-aged children in urban areas.

Investigations in cities experiencing measles outbreaks indicate that as few as 50% of children have been vaccinated against measles by their second birthday and as few as 25% of children are up-to-date for all immunizations at age 2 years (*4*). The National Vaccine Advisory Committee (NVAC)* has issued recommendations to improve vaccine coverage levels among preschool-aged children (NVAC, unpublished data, 1991). These recommendations are being reviewed by federal, state, and local health agencies.

CDC is assisting the NYCDH in determining the extent of the current measles outbreak.

References

1. CDC. Update: measles outbreak–Chicago, 1989. MMWR 1990;39:317–9,325–6.
2. CDC. Measles–United States, 1989 and first 20 weeks 1990. MMWR 1990;39:353–5,361–3.
3. CDC. Measles–Los Angeles County, California, 1988. MMWR 1989;38:49–52,57.
4. CDC. Measles vaccination levels among selected groups of preschool-aged children – United States. MMWR 1991;40:36–9.

*In 1987, the Secretary of Health and Human Services chartered the NVAC to advise and make recommendations to the director of the National Vaccine Program. Its mission is to encourage the adequate supply of safe and effective vaccines, recommend research priorities that enhance the safety and efficacy of vaccines, and develop goals and recommend initiatives for effective use of vaccines.

The *Morbidity and Mortality Weekly Report* is prepared by the Centers for Disease Control, Atlanta, Georgia, and is available on a paid subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

The data in this report are provisional, based on weekly reports to CDC by state health departments. The reporting week concludes at close of business on Friday; compiled data on a national basis are officially released to the public on the succeeding Friday. Accounts of interesting cases, outbreaks, environmental hazards, or other public health problems of current interest to health officials, as well as matters pertaining to editorial or other textual considerations should be addressed to: Editor, *Morbidity and Mortality Weekly Report*, Mailstop C-08, Centers for Disease Control, Atlanta, Georgia 30333; telephone (404) 332-4555.

☆U.S. Government Printing Office: 1991-531-130/42003 Region IV

HHS Publication No. (CDC) 91-8017