This folder contains selected back-up materials from letters that have already gone out (you have the incoming & out-going letters already). You may want to pass it along to your next intern in case these issues come up again.

June 21, 1995

BARMUS

Ms. Carol H. Rasco
Assistant to the President
for Domestic Policy
The White House
Washington, DC 20500

Dear Ms. Rasco:

Thank you for your response of June 16 to my letter concerning mammography risks. You state that experts believe the breast cancer death rate dropped 4.7% between 1989 and 1992 because of increased use of mammography. However, the American Cancer Society's publication "Cancer Facts and Figures" contradicts this by showing that in 1980 breast cancer incidence was 109,000, and mortality 36,000. By 1987, the incidence had risen to 130,000, and mortality to 41,000. By 1993, the incidence was 182,000, and mortality 46,000 (see enclosure). Thus, a drop in the breast cancer mortality rate did not occur.

It is remarkable that developed countries which promote mammography screening have the highest breast cancer mortality rates, as revealed by the British Medical Journal of October 15, 1994 in an article entitled "Breast Cancer--Epidemiology, Risk Factors, and Genetics" (see enclosure).

The National Cancer Institute, in its publication of December 30, 1993, "Research to Improve Methods of Breast Cancer Detection," stated that mammography cannot distinguish with certainty benign from cancerous lesions, and of the women in the U.S. who undergo surgical breast biopsies based on mammography findings, the majority (80%) do not have cancer. Therefore, scientists are now exploring novel nonionizing imaging technologies (see encl.).

It is unfortunate that, until now, women have been misinformed about mammography efficacy and about the risks involved in subjecting their particularly radiosensitive breasts to radiation.

Sincerely,

Bruno Barmus

Enclosures

Bruno Barmus
1234 Aulepe Street
Kailua, HI 96734-4101

EXCERPTS

The American Cancer Society
Cancer Facts and Figures
Breast Cancer
1980-87-93

ncidence 1980
109,000

About 109,000 new cases of breast cancer and 36,000 deaths from the disease are expected in 1980. Breast cancer remains the foremost site of cancer death in American women. It also strikes men, but this accounts for less than one percent of all breast cancers.

Mortality 1980
36,000

****

cidence 1987
130,000

Incidence: An estimated 130,000 new cases in the United States during 1987. About one out of 10 women will develop breast cancer at some time during her life.

Mortality: An estimated 41,300 deaths (41,000 females; 300 males) in 1987, in females, second only to lung cancer, now the foremost site of cancer deaths in women.

Mortality 1987
41,000

****

:idence 1993
182,000

Incidence: An estimated 182,000 new cases among women in the United States during 1993. Approximately one of every nine women will develop breast cancer by age 85. About 1,000 new cases of breast cancer will be diagnosed in men in 1993. Breast cancer incidence rates for women increased about 2% a year since the early 1970s, but have leveled off since 1987 at about 107 per 100,000. Some of the recent rise in rates is believed to be due to marked increases in mammography utilization, allowing the detection of early stage breast cancers, frequently before they would become clinically apparent. Other reasons for a long-term increase in breast cancer are not yet understood.

Mortality: An estimated 46,300 deaths (46,000 women, 300 men) in 1993; in women, the second major cause of cancer death. Although incidence rates are increasing, early detection and improved treatment have kept mortality rates fairly stable over the past 50 years.

Mortality 1993
46,000

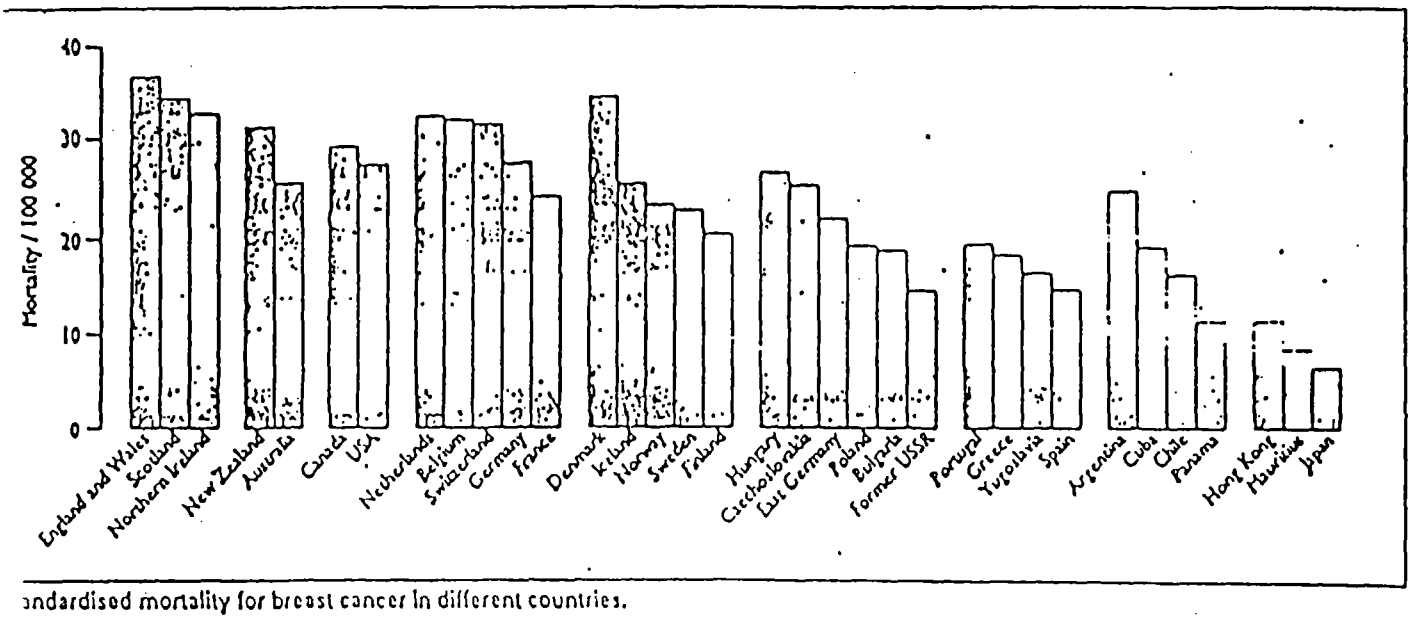
Statistics Reveal Mammography Risks

It is remarkable that developed countries which promote mammography screening have the highest breast cancer mortality rate. Japan sees no neen for mammography screening promotion, because its breast cancer mortality rate is the lowest in the world. Recent Canadian studies indicate that for women 50 and older mammography screening reduces the breast cancer mortality rate. Yet, from 34 countries, the Netherlands have the fifth highest breast cancer mortality rate in spite of the fact that they offer mammography screening every two years as a free service for women staring at age 50. England, where mammography screening is free, has the highest breast cancer mortality rate. The USA and Germany, have the same breast cancer mortality rate--tenth highest.

BREAST CANCER—EPIDEMIOLOGY, RISK FACTORS, AND GENETICS

BMJ VOLUME 309 15 OCTOBER 1994

K McPherson, C M Steel, J M Dixon



andardised mortality for breast cancer in different countries.

EXCERPTS

CANCER FACTS

National Cancer Institute • National Institutes of Health

Research To Improve Methods of Breast Cancer Detection

The National Cancer Institute (NCI) funds numerous research projects to improve conventional mammography and develop alternative imaging technologies to detect and characterize breast tumors.

****

Mammography also cannot distinguish with absolute certainty benign from cancerous lesions. For such reasons, scientists are exploring novel nonionizing imaging technologies including magnetic resonance imaging (MRI), ultrasound, optical imaging, and other technologies. The NCI-funded studies encompass basic technology and instrumentation development through preclinical and clinical testing. These studies aim to define the precise role of the technologies in detecting and characterizing breast tumors.

****

Breast Biopsies

Imaging is also being tested as an aid in performing biopsies. Of the women in the United States who undergo surgical breast biopsies, the majority (80 percent) do not have cancer. As an alternative to surgery, mammography-guided, stereotactic needle breast biopsy is being studied for women with nonpalpable lesions.

****

THE WHITE HOUSE

WASHINGTON

June 16, 1995

Mr. Bruno Barmus
1234 Aulepe Street
Kailua, Hawaii 96734-4101

Dear Mr. Barmus:

Thank you for writing about mammography and breast cancer. The President is committed to the fight against breast cancer and has made improving women's health a high priority of his Administration.

As you point out, the incidence of breast cancer among American women has increased. However, the breast cancer death rate dropped 4.7% between 1989 and 1992, the most recent years for which data is available. Although there is no evidence that mammography is responsible for the rising incidence of breast cancer, experts believe that increased use of mammography screening is one of the factors that has reduced the death rate. This is because mammograms can detect breast cancer in its early stages, when treatment is easier and more effective.

You also mention the possibility that women carrying the "A-T gene" may face increased danger from mammograms. Research is currently underway to evaluate this possibility, and the National Cancer Institute is monitoring the issue carefully.

Thank you again for writing. Please be assured that the Clinton Administration is working to eradicate this terrible disease.

Sincerely,

Carol H Rasco

Carol H. Rasco
Assistant to the President
for Domestic Policy

MEMORANDUM

To: Carol H. Rasco

From: Karen Guss

Date: June 14, 1995

Re: Letter from Bruno Barmus

I contacted Dr. Edward Sondik, Acting Director of the National Cancer Institute, to discuss the Barmus letter. He informed me that Mr. Barmus writes to him about breast cancer very, very frequently, and suggested that your reply be brief and to the point so as not to encourage Mr. Barmus to add you to his list of regular correspondents. Dr. Sondik's advice struck me as very wise and I have drafted your reply accordingly.

To Lon
From Kare

Please file w/
Records Mgmt.
after CSR signs.

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY

CAROL H. RASCO
Assistant to the President for Domestic Policy

To: KAREN GOSS

Draft response for POTUS
and forward to CHR by: _____

Draft response for CHR by: X 6/19

Please reply directly to the writer
(copy to CHR) by: _____

Please advise by: _____

Let's discuss: _____

For your information: _____

Reply using form code: _____

File: _____

Send copy to (original to CHR): _____

Schedule ? : ☐ Accept ☐ Pending ☐ Regret

Designee to attend: _____

Remarks: _____

June 3, 1995 JUN 7 1995

Ms. Carol H. Rasco
Assistant to the President for
Domestic Policy
The White House
Washington, DC 20500

Dear Ms. Rasco:

Mammography Risks Outweigh Its Benefits

Mammography screening continues to be promoted nationwide as a life-saving procedure. It was introduced in the 1960s, at which time women were assured that it was safe and reliable and would reduce breast cancer deaths by 30%. However, statistics show that this has not happened. A woman's lifetime risk of developing breast cancer was 4.9% in 1940, but increased steadily after mammography screening was introduced. By 1987, it was 11.2% (see enclosure).

The latest U.S. Cancer Statistics Review 1971-1991, published on November 15, 1994 by the National Cancer Institute, showed that the highest female cancer incidence and mortality rates apply to breast cancer (see enclosure).

In my opinion, greater consideration must be given in every decision to administer radiation to a woman's breast, and women must be made aware of the very real risk that any ionizing radiation exposure may as well induce cancer as detect it.

A study which was published on December 20, 1991 by the New England Journal of Medicine claimed that more than 1 million American women who carry a single copy of a defective gene are at an increased risk of cancer from medical X-rays. It was suggested that doctors cover all women's breasts with lead shields during X-rays and use non X-ray tests whenever possible (see enclosure). Yet, mammography exposes a woman's particularly radiosensitive breast to radiation without considering the risks involved.

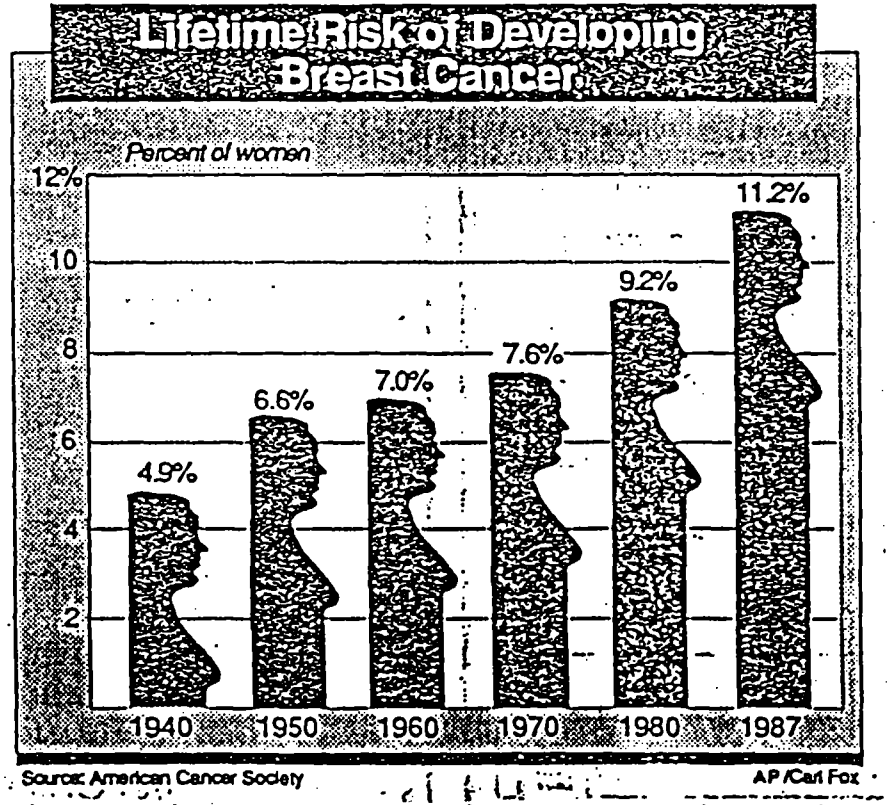
Mammography screening has been promoted since the 1960s. Yet, until now, no breast cancer mortality statistics were ever published to substantiate mammography efficacy.

Sincerely,

Bruno Barmus
1234 Aulepe Street
Kailua, HI 96734-4101

Enclosures -3

cc: Mrs. Hillary Rodham Clinton
The White House
Washington, DC 20500



The American Cancer Society stated in 1991 that the average woman ran a one-in-nine risk of developing breast cancer.

CANCER FACTS

National Cancer Institute • National Institutes of Health

SEER Cancer Statistics Review 1973-1991

14. Which cancers show the highest incidence rates (based on all ages combined) for the period 1987-1991?

(Rates are per 100,000 and are age-adjusted to the 1970 U.S. population. Unless otherwise specified, rates are given for all races, both sexes.)

	Age <65	Age 65+	All Ages
All Sites	198.1	2,145.4	390.4
SITE			
Prostate (men)	26.7	1002.2	123.0
Breast (women)	72.8	444.7	109.5
Lung and Bronchus	28.4	329.9	58.2
Colon and Rectum	18.1	323.1	48.2

16. Which cancers show the highest mortality rates (based on all ages combined) for the period 1987-1991?

(Rates are per 100,000 of the entire U.S. population and are age-adjusted to the 1970 U.S. population. Unless otherwise specified, rates are given for all races, both sexes.)

	Age <65	Age 65+	All Ages
All Sites	74.9	1,066.3	172.8
SITE			
Lung and Bronchus	22.9	290.0	49.3
Breast (women)	16.6	125.8	27.3
Prostate (men)	2.9	232.3	25.6
Colon and Rectum	6.4	135.3	19.1
Ovary (women)	10.0	58.6	14.8
Pancreas	3.1	57.2	8.4

Breast cancer risks rise

Study finds new gene, X-ray link

By Judy Foreman
Boston Globe

BOSTON — More than 1 million American women who carry a single copy of a defective gene are believed to be at five to six times the normal risk of breast cancer, researchers said yesterday. The gene appears to make carriers — men as well as women — at increased risk for cancer from medical X-rays.

It has long been known that having two copies of this "bad" gene puts a person at 100 times the normal risk of developing cancer.

Since most carriers of the gene do not know they have it, the researchers told The Associated Press, their work suggests that doctors should cover all women's breasts with lead shields during X-rays and use non-X-ray tests whenever possible.

The new study, published today in the New England Journal of Medicine, shows that having just one copy of the bad gene significantly increases the risk of breast cancer, which this year will strike 175,000 women. It also raises a man's overall risk of cancer 3.8 times and a woman's overall risk 3.5 times.

Overall, about 2 million to 3 million Americans — about 1.4 percent of the population — are believed to carry one copy of the bad gene. It is dubbed the A-T gene because it causes the inherited disorder ataxia-telangiectasia if a person has two copies of the gene, one from each parent.

A woman is likely to be a carrier of the A-T gene if she is a close blood relative of someone with ataxia-telangiectasia. So far, there is no screening test to identify people who carry the A-T gene.

The gene, said lead researcher Dr. Michael Swift, professor of medicine and chief of medical genetics at the University of North Carolina, appears to trigger cancer by making carriers particularly prone to damage from ionizing radiation, including X-rays.

Whether mammograms, which do use X-rays, specifically increase the risk of breast cancer in women carrying this gene has not yet been shown, the researchers said.

But the link between radiation and breast cancer is so striking in women carrying this gene, they said, that any woman who is a carrier should consider skipping mammograms and instead have periodic breast exams performed by a highly trained examiner, the researchers said.

FDA LANGUAGE

[Zoe: This is what we're working with right now. Again, Chris Cerf in the Counsel's office has approved it, but it hasn't gone through editing or through the Staff Secretary yet. Still, at least the policy is cleared off. Let me know if you need more information. -Seth]

Dear _____:

Thank you for writing to me regarding the proposed effort to limit teenagers' access to tobacco products. I have heard from many concerned individuals on this issue, and your input has been essential to our efforts to address the health needs of all Americans.

Clearly, adults are capable of making their own decisions about smoking. Overwhelming evidence has shown, however, that children are particularly susceptible to tobacco marketing. Some 3,000 young people take up smoking every day, and millions will ultimately lose their lives to it. If we are to ensure a healthy future for our children, we must act now to stop smoking among children.

I have therefore authorized the Food and Drug Administration to initiate a broad series of steps to limit both minors' access to tobacco as well as the promotion and advertising that enhances the appeal of tobacco products among teens and children. Under the proposed regulations, young tobacco purchasers will be required to prove their age with identification. Secondly, cigarette vending machines, which circumvent any ban on sales to kids, will be prohibited. Additionally, tobacco advertising will be prohibited in areas near schools and playgrounds and in publications that reach substantial numbers of young Americans. Finally, the tobacco industry will fund and implement an annual campaign to teach children the dangers of tobacco use.

These proposals do not constitute a ban on smoking or a threat to the First Amendment. Rather, these are common-sense steps that will help us forge a better future for our children. I appreciate knowing your views on this issue, and I hope you will work with us as we seek to create a healthier America.

Sincerely,

Bill Clinton

July 21, 1995

The Honorable Eugene E. Davidson
Member of the House of Representatives
of the State of Tennessee
Nashville, Tennessee 37243-0166

Dear Gene:

Thank you for writing to me to express your concerns about Food and Drug Administration Commissioner Kessler and the tobacco and vitamin industries. I appreciate knowing your views.

I have consistently stated that the federal government in general and the FDA in particular can do a better job of pursuing their regulatory responsibilities with less micro-management and intrusiveness. Working with Vice President Gore and the FDA in these efforts, I have recently introduced a series of regulatory reforms designed to make the agency more outcomes-oriented than process-limiting. Earlier this year, I released a report outlining specific reforms the FDA would implement to make the agency more responsive to the people it serves.

I believe that more can and should be done. But the FDA must continue to play its essential role in ensuring the safety and efficacy of drugs and devices and in maintaining the high quality of our foods.

Your comments are helpful, and I will keep them in mind as my Administration moves forward in addressing these important issues. I'm glad you took the time to write, and I hope to hear from you again in the months to come.

Sincerely,

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

OFFICE OF THE SECRETARY
OFFICE OF LEAD-BASED PAINT ABATEMENT AND POISONING PREVENTION

CONNOR

RONALD J. MORONY, ACTING DIRECTOR (202) 755-1785

FAX TRANSMITTAL

RECEIVER'S NAME: Joe - Norberg

RECEIVER'S FAX NO.: 1-56 - 7931

RECEIVER'S PHONE NO.:

SENDER'S NAME: Sharon Wade

SENDER'S PHONE NO.: 755-1805, ext. 114 755-1785

NUMBER OF PAGES, INCLUDING COVER SHEET: 11

6.14.95
DATE

IN REPLYING BY FAX, OUR NUMBER IS (202) 755-1000)
(COMMERCIAL AND FTS)

COMMENTS

Per request: Sending more than you want — hope it covers everything you need.

U. S. Department of Housing and Urban Development
Washington, D.C. 20410

OFFICE OF LEAD-BASED PAINT ABATEMENT
AND POISONING PREVENTION

June 14, 1995

TO: Zoe Neuberger
White House Office of the First Lady

FROM: Sharon Macda
HUD Office of Lead-Based Paint

RE: Response to Letter to First Lady

Thanks for calling. Attached is a list of current accomplishments. Some are fairly technical, but Fiberlock Technologies will be very interested in this information. I am also sending you a copy of Secretary Cisneros' speech on lead paint poisoning at a national convention last year.

BASIC FACTS ABOUT CHILDHOOD LEAD POISONING

- lead paint poisoning is the number one preventable childhood health problem in America.

- 1.7 million children, under the age of 6, living primarily in urban inner cities, are at risk for lead poisoning; in some neighborhoods, 75% of the children have elevated blood lead levels. The majority are young African American and Hispanic children who have no choice about the poor condition of their housing.

- elevated blood levels in young children result in behavioral problems, learning disabilities, and even permanent brain damage in worst cases.

I was also able to find out specifics about Fiberlock:

FIBERLOCK TECHNOLOGIES, INC, CAMBRIDGE

- Large "environmental control and containment systems" firm; began selling asbestos control products in 1978.

- They have expanded to include products that can cover (encapsulate) and seal in the lead-based paint that has previously been put on walls.

We have a large three ring binder with their product information in our office if you want further information. Let me know if you need any additional information.

U. S. Department of Housing and Urban Development
Washington, D.C. 20410

OFFICE OF LEAD-BASED PAINT ABATEMENT
AND POISONING PREVENTION

HIGHLIGHTS OF RECENT HUD ACCOMPLISHMENTS (and work in progress)

Task Force Created by Secretary Cisneros pursuant to recent legislation; forty-one member, diverse citizen group which has reached consensus recommendations on standards for lead hazard reduction and financing. Report will be available by the end of June, 1995.

Guidelines New revised Guidelines on the Evaluation and Control of Lead-Based Paint Hazards in Housing to be available in July, 1995. This is a major technical document providing detailed lead inspection and hazard reduction protocols.

Regulations Proposed regulations on notification and disclosure of lead-based paint hazards at time of sale or lease (pursuant to section 1018 of Title X) published November 2, 1994. Publication of final rule scheduled for September, 1995.

Grant Program Sixty-four grants totaling $279 million have been awarded to 56 States and localities to assist lead-based paint hazard control in privately owned low and moderate income housing.

This program is building capacity at the State and local levels and is encouraging States to establish certification programs for lead-based paint contractors.

Technical Studies

American Society of Testing and Materials (ASTM). With HUD financial support, the National Institute of Standards and Technology (NIST) has coordinated the largely volunteer efforts of members of the American Society for Testing and Materials (ASTM) to develop standards related to the detection and reduction of lead-based paint hazards. Several standards have been issued; others are in preparation.

Evaluation. The National Center for Lead-Safe Housing, under HUD sponsorship, is conducting a very intensive evaluation of the effectiveness and

cost of the methods being used by HUD grantees to reduce lead-based paint hazards in privately owned housing occupied by low-income households. This is a long-term study. Preliminary results will be available in 1996, but the final report will not be complete until 1999.

Research on relationship between lead in house dust and children's blood lead. The University of Rochester, with HUD funding, conducted an important empirical study to measure the statistical relationship between dust lead and blood lead. This research has implications for policy of both EPA and HUD. The report is available from the National Center for Lead Safe Housing.

Research on the effectiveness of in-home education on specialized cleaning. The University of Rochester, with HUD funding, is completing a study of the effectiveness of educating families on special dust-lead cleaning practices as a method of reducing children's blood leads. The report will be available later this year.

Survey on public awareness of lead-based paint hazards. In December 1994, the Bureau of the Census, with HUD funding, conducted a national survey to determine the level of awareness of lead-based paint hazards. The survey will provide baseline data to determine the impact of hazard disclosure at the time of real estate transactions, which is required by section 1018 of Title X. The Department is required under section 1061 of Title X to report to the Congress on the effect of section 1018. In analyzing the data, HUD will seek to identify improved ways of informing population groups that are least informed. Another survey is planned for 1996, after the disclosure requirement is expected to take effect.

Study of XRF and test-kit reliability. The Environmental Protection Agency (EPA) and HUD supported a major field evaluation of the performance characteristics of portable X-ray fluorescence analyzers and chemical spot test kits in the detection of lead in paint. The report on the study should be available in June 1995.

Continuing evaluation of XRF's. HUD, in cooperation with EPA, is continuing to evaluate the performance characteristics of specific makes

and models of portable X-ray fluorescence (XRF) analyzers, as requested by manufacturers, and will publish the findings in a consistent format that will assist users in the operation and/or purchase of the instruments.

XRF operators registry. The National Lead Abatement Council, under a HUD grant, is developing a registry of proficient operators of X-ray fluorescence (XRF) analyzers. The registry, which is scheduled to be available late in 1995, is intended as a guide for users of lead-based paint inspection services.

Research on encapsulants. HUD and EPA have sponsored laboratory studies of the performance of various coating materials using tests suggested by the ASTM working group that is developing standards for encapsulants. The results of the research are being used by ASTM.

Manual on operations and maintenance. The National Institute of Building Sciences is preparing a manual of best practices for controlling lead-based paint hazards when performing routine maintenance work on buildings. The manual should be available in June 1995.

Clearinghouse and hotline. HUD is contributing to the support of the National Lead Information Center, which operates a clearinghouse and hotline under an agreement with EPA.

Model lead-based paint provisions for housing codes. HUD is funding The National Institute of Building Sciences to develop model provisions for State and local housing codes that incorporate best lead-based paint hazard control practices. This is a two-year project that will begin in July 1995.

U. S. Department of Housing and Urban Development
Washington, D.C. 20410-4000

OFFICE OF THE ASSISTANT SECRETARY
FOR PUBLIC AFFAIRS

Alliance To End Childhood Lead Poisoning
Washington, DC
May 17, 1994
Secretary Henry G. Cisneros

Thank you for that kind introduction, Bart. It is a pleasure to join you for your second annual conference.

I want to commend the Alliance to End Lead Poisoning for convening this conference and for the tremendous work you are doing to help eliminate the number one environmental health threat to America's children: lead poisoning.

The Alliance, which represents a broad coalition of over 40 organizations, has brought the issue of lead poisoning to the forefront of our national awareness, tackled tough issues, served as a moving force behind Title X of the 1992 Housing Act, and has become a formidable player in helping the Federal government and Congress find ways to make the housing stock "lead safe."

The Alliance's advocacy impacts the lives of thousands of children in America who are healthier as a result of your efforts.

In fact, all of you who here today are dedicated to lead poisoning prevention -- at the state, local or federal level -- you, too, also deserve thanks for your tireless, important work.

You are the unsung heroes in the war against lead poisoning of children. It is reassuring to see so many concerned individuals come together on an issue that can -- and must be -- resolved for the sake of our children, our society and our nation's future.

The problem

Lead poisoning in America is a serious concern. While lead-based paint was banned from residential use in 1978, the fact remains a vast majority of Americans still live in homes built before the ban.

The greatest threat is to poor, minority children who live in older, often poorly maintained buildings where lead-based paint is peeling or cracking. In some inner-city communities, the percentage of lead-poisoned children exceeds 75 percent.

This is simply unacceptable. These are the same communities where increased poverty and unemployment leads to violent crime and drug use.

We all know that high-level exposure -- from ingesting lead dust or paint chips -- can trigger convulsions, coma, and if undetected, can even cause death in children. At low-levels, exposure can cause children to suffer from mental retardation, reading and learning disabilities, impaired growth, reduced IQ, hearing loss, reduced attention span, and behavior problems.

Lead poisoning can result in lower educational achievement, high dropout rates, higher truancy and juvenile delinquency, all of which threatens our nation's future economic competitiveness and the health of our society.

Lead poisoning is just another problem that stunts children's growth and development, especially when you consider all the problems confronting children in low-income communities and in distressed public housing. Some live in places unfit for human beings, in unsafe or inadequate housing because that is all they can afford.

Ending childhood lead poisoning is an important part of our efforts to improve the environment in which we and our children live. The conference theme of "Building a Lead-Safe Future" therefore challenges us to share ideas and forge partnerships here so that we can build a better future for our children.

The Clinton Administration wants to nurture healthy communities in every possible way, and reducing lead-based paint in the nation's housing will bring us closer to that goal. We share your concern and we want to help you win the battle.

In the past half decade, the concern about lead poisoning of our children has received national attention. In response to these concerns, Congress has directed HUD, most notably in Title X of the 92 Housing Act, to carry forth the nationwide effort to eliminate childhood lead poisoning.

Certain members of Congress deserve special praise for their role in the passage of the series of legislative initiatives that culminated with Title X: Senator Barbara Mikulski, Senator Paul Sarbanes, Senator Alan Cranston, Congressman Henry B. Gonzalez, Congressman Henry Waxman, and Congresswoman Marge Roukema.

HUD is now moving forward in the battle to eliminate lead poisoning:

- First, we are aggressively stepping up our lead-based paint abatement and testing efforts for public housing. We developed the first-ever -- and much needed -- guidelines for lead-based paint testing and abatement. These guidelines are now being used in our Modernization programs because it is the most informative source of good practices for lead detection and abatement. By the end of the year, we will be publishing a technical guide that will be the next breakthrough in this area.

- Since FY 92, in just two years, we have awarded $137 million in lead abatement grants to 13 states, 11 cities, and 5 counties.

- This program is the first national effort to provide funds for the abatement and hazard reduction of low-income private housing, an area largely neglected until this program was created. All the grant funds are being used to assist low-income residents, many of whom are minorities, making this program a perfect fit in this Administration's pursuit of environmental justice.

- Every homebuyer and renter of a pre-1978 house will receive a warning and a brochure describing dangers of lead paint.

- In addition, the Department has created a Task Force on Lead-Based Paint Hazard Reduction and Financing to make recommendations to HUD and EPA on how to reduce lead paint hazards in privately owned housing.

- This 42-member group, chaired ably by Cushing Dolbeare (you may wish to acknowledge her here), consists of staff from federal and local governments, non-profit groups, community and resident groups, private industry groups, and a public housing resident, Helen Walker. (You may wish to acknowledge her here.)

- At HUD, we recognize the human face of the problem. That is why we asked Helen Walker, who lives in Bronx New York public housing, to join our task force. Three of Helen's five children were diagnosed with lead poisoning while living in public housing. Helen Walker went through an incredible ordeal with her children, who fortunately are now doing much better. The task force greatly appreciates her invaluable insights.

- Last November, EPA Administrator Carol Browner, HHS Secretary Donna Shalala, and I met to establish a unified federal approach to the problems of lead-based paint.

- HUD is continuing to work closely with HHS and EPA to coordinate the government-wide response to lead paint hazards.

- HUD initiated a new program in our fight against childhood lead poisoning. The Youth Apprenticeship Demonstration Program will provide opportunities for youth living in distressed public housing to focus on professional job training and employment opportunities. Young residents will work to improve public housing, including lead-based paint abatement activities.

- As we move forward together to reduce the threat of lead in the nation's housing, I'd like to offer you another powerful tool in your crusade, and that is national service..

- This year, the first 20,000 members of AmeriCorps, President Clinton's new national service program, will help to meet educational, public safety, human and environmental needs in our communities.

- AmeriCorps participants will work directly with community members, getting exactly the kind of real results that matter most to our children and you.

- In fact, during last summer's pilot AmeriCorps program, one of the 16 service projects was devoted entirely to preventing lead poisoning. In a nine-week period, 58 Summer of Service participants in New York City educated 18,000 low-income families about the dangers of lead paint poisoning and referred 3,000 children for testing.

- The possibilities for AmeriCorps programs in this area are endless, and the administration can support your ideas and efforts in a number of ways. But, ultimately, you must make it happen. I urge you to find ways to use national service to make a safer, healthier, better future for our children.

Challenges we face in the battle to reduce lead poisoning

The Department is concerned and committed about reducing childhood lead poisoning -- and we want to be full partners in all lead poisoning prevention measures. Like you, we want to make sure that the children in America are being protected, the work is done safely, and that funding is being wisely spent.

But we have a tough road ahead of us in lead paint abatement. First, the Clinton Administration's commitment to reducing the deficit has challenged all federal agencies to do more with less funding.

Secondly, at both the local and federal level, we need to implement the law wisely, so that we do not exacerbate existing problems within our communities.

For example, in pursuing elimination of lead based paint, we must ensure that housing discrimination does not occur to families with children or in our inner-city neighborhoods.

In pursuing our goal to eliminate lead-based paint hazards, we may run the risk of exacerbating insurance redlining in our older cities, areas in which lenders or insurers refuse to conduct business. Our efforts to protect children from lead-based paint might create another potential problem: landlords discriminating against families with young children out of fear of liability.

Thirdly, our nation lacks a broad and solid infrastructure to implement the lead laws. We have learned here, as elsewhere, that it is much easier to pass laws than it is to implement them. In many states, we do not have qualified testers, trained lead abatement workers, and knowledgeable contractors to ensure that lead reduction will be safe, effective and efficient.

With your help, that deficiency is now being corrected. But we must recognize that we are in a transition period.

We must work together to expedite state implementation of contractor certification programs so that our children will be protected from lead poisoning.

We cannot underestimate the difficulties of the challenges that are ahead. We still have a long way to go before lead poisoning is a thing of the past, which is why we **must** work together in creative partnerships -- from the grassroots movement through the private sector and the local state and federal government -- to protect our children's health.

Conclusion

This administration is committed to being a creative partner with all of you in this vital effort.

We must be true to principles upon which this nation was founded and to Thomas Jefferson's principle: "Equal rights for all; special privileges to none," in order to create a more just society, a society where no children are exposed to hazardous lead paint nor poisoned by it.

Where every child in America has equal opportunity to nurture and develop their talents. A society where every child lives in decent, safe and affordable housing in thriving, healthy communities. Reducing lead-based paint in homes offers a great opportunity to create jobs, train workers, preserve affordable housing, ensure that environmental justice takes place, and can stabilize and empower neighborhoods.

As President Clinton said in his State of the Union address:

> "Let's give our children a future. Let us take away their guns and give them books. Let us overcome their despair and replace it with hope. Let us, by example, teach them to obey the law, respect our neighbors, and cherish our values. Let us weave those sturdy threads into a new American community that can once more stand strong against the forces of despair and evil because everyone has a chance to walk into a better tomorrow."

And let's never give up on the fight to end lead poisoning and other societal problems that endanger the safety of our children today. We -- all of us in this room -- have a responsibility to build a better future for our children -- our nation's most valuable resource. Thank you very much.

###

GREEN

National Center for Injury Prevention and Control
Division of Violence Prevention

The Centers for Disease Control and Prevention (CDC) has focused on violence prevention since the early 1980s, when efforts included the prevention of youth violence, including homicide, assault, suicide, and suicide attempts. Early in 1994, CDC was funded to strengthen efforts to prevent family violence. The Division of Violence Prevention in CDC's National Center for Injury Prevention and Control has four priority areas for violence prevention: youth violence, family and intimate violence, suicide, and firearm injuries.

Violence in the United States

- In 1992, homicide claimed the lives of over 25,000 Americans. Suicide was responsible for the deaths of 30,500 Americans.
- Homicide is the second leading cause of death for our nation's young people aged 15 to 24. It is the leading cause of death for young black men and women aged 15 to 34.
- For every violent death, there are at least 100 nonfatal injuries caused by violence.
- In 1992, 5,373 women in the United States were murdered. Six of every 10 of these women were killed by someone they knew. Of those who knew their assailant, about half were killed by their spouse or someone with whom they had been intimate.
- Researchers have estimated that in 1985 more than 1.8 million women were assaulted by male partners or cohabitants.
- In 1992, there were over 37,700 firearm-related deaths, including 17,800 firearm-related homicides, 18,200 suicides, and 1,400 unintentional deaths related to firearms.

Current Activities of the Division

The Division of Violence Prevention supports both intramural and extramural projects and activities to prevent violence. These activities focus on primary prevention of violence through a public health approach that complements the approaches used by criminal justice, education, and the many other disciplines that work in this area. The projects supported by the division include:

- A surveillance study on the magnitude, characteristics, and costs of the injuries and disability caused by firearms and on the types of firearms that inflict these injuries
- The development of an improved system of collecting data on the behaviors (threatened violence, hitting, gun use) and outcomes (injuries, deaths, psychological problems) associated with family and intimate violence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

- A case-control study to identify potentially modifiable causes of serious attempted suicide among adolescents and young adults aged 12 to 34
- A project to investigate the relationship between exposure to urban violence among African-American children, their behavior, and psychological stress
- Evaluation of the benefits, costs, and consequences of interventions to prevent injuries and deaths due to violence, including
  - Mentoring programs for children and adolescents
  - Conflict resolution and social and cognitive skills education for children and adolescents
  - Peer mediation by students trained to help resolve conflict nonviolently
  - Mentoring programs for abused pregnant women
  - Programs to prevent dating violence on high school and university campuses
  - Training for health care providers on identifying victims of domestic abuse
  - Job training and placement
  - Public education and awareness programs
- Community demonstration programs to identify successful community interventions for preventing violence; determine if multifaceted community programs can reduce violence; and build the capacity of state and local agencies and organizations to deliver violence interventions.

State and Local Injury Prevention Grants

NCIPC provides financial and technical support to state and local health departments in their efforts to prevent violence. These programs define and track injuries, develop interventions, mobilize broad coalitions for intervention and public education, and evaluate prevention effectiveness.

Publications

The Prevention of Youth Violence: A Framework for Community Action identifies promising activities to prevent youth violence.

Youth Suicide Prevention Programs: A Resource Guide assesses programs to prevent suicide among adolescents and young adults.

Information on injury topics is available through CDC's automated Injury Information Line, (404) 488-4677.

Fact Sheet: Prevention of Youth Violence

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

The Problem

- Homicide took the lives of 7,354 young people, ages 15-24, in 1990 alone. For each of these deaths, there are at least 100 nonfatal injuries each year.
- Young people are disproportionately represented among perpetrators and victims of violent assault.
- Violence is not just a minority problem--*all* communities are affected.
- Homicide is the leading cause of death for young African-American men and women 15-34 years of age with homicide rates for young black men exceeding rates for young white men by as much as eight times.
- In 1990, firearms accounted for 77% of the homicides among young men. Nearly 20% of high school students in a national survey reported they had carried a weapon at least once in the previous 30 days.

The Public Health Approach

- Violence is a public health problem because of its tremendous impact on the health and well-being of our youth. CDC has worked in the area of violence prevention for the last 10 years.
- Although we do not have the answers yet to preventing youth violence, the problem is too urgent to wait for perfect knowledge. The public health approach, which identifies patterns and risk factors and implements interventions and evaluates effectiveness, has worked with many health problems and will work with violence also.
- Poverty, discrimination, and lack of opportunities for education and employment are important risk factors for violence and must be addressed as part of any comprehensive solution to youth violence. The public health approach complements and stimulates these efforts, but does not replace them.
- The public health approach is multidisciplinary and enlists many strategies and approaches that are necessary in dealing with such a complex issue as violence.

CDC's Program to Prevent Youth Violence

- As the lead agency in injury control, CDC plays a key role in coordinating activities and programs in the Public Health Service to prevent youth violence.
- The central focus of CDC's activities is on community demonstrations of multiple interventions (such as mentoring, conflict resolution training, and peer education) and evaluation research. Other efforts include data collection and analysis, research on risk factors, training, and developing public awareness of the problem and solutions.
- CDC seeks community input into all aspects of its violence prevention activities.
- Other CDC activities include

  Homicide Surveillance Summary (published in *MMWR*)

  Youth Risk Behavior Surveillance System (monitors priority health-risk behaviors related to violent and unintentional injuries as well as other behaviors among youth)

  Firearm Injury Surveillance Study

  Extramural research on injury topics including violence

  Grants to states and communities to conduct injury programs and surveillance

  Prevention of Youth Violence: A Framework for Community Action: a manual for community organizations on organizing activities to prevent youth violence.

  Development of a national plan for injury control that includes the prevention of violence.

For more information, call (404) 488-4646

The Prevention of Youth Violence: A Framework for Community Action

The constant reports of violence in our communities, schools, and homes confirm what we already know--there is an epidemic of violence in our nation. The tragic accounts are frightening--and ***preventable***.

As concerned citizens, we can take positive action to change the trend toward violence. This manual provides ideas, suggestions, and hope. It explains

- what communities can do to help prevent youth violence
- actions that communities are taking ***now*** to prevent violence among their youth
- how to get started in preventing violence in your community

The Prevention of Youth Violence: A Framework for Community Action provides you with descriptions and contacts for approximately 80 violence prevention programs in diverse communities across the United States.

The manual will be useful to

- organizers of community programs who may be interested in youth violence prevention
- agencies in public health, social services, and law enforcement that want to do something to prevent youth violence

STRATEGIES IN THE FRAMEWORK THAT MAY HELP PREVENT YOUTH VIOLENCE

The CDC manual on youth violence prevention presents many types of activities. We cannot say with scientific certainty that they all work. Few of the strategies have been fully evaluated, but they have promise and are being tried by communities around the country. The strategies are divided into three groups: educational approaches, legislative or regulatory change, and environmental modification.

Educational Approaches:

- ***Mentoring*** is the one-on-one pairing of adults with youths in order to give young people wholesome role models, supportive attention, and guidance.

- ***Conflict resolution training*** teaches young people to manage potentially violent situations through peaceful, nonviolent means.

- ***Training in social skills*** helps young people relate to others in positive and friendly ways. These skills include maintaining self-control, communicating, forming friendships, resisting peer pressure, and establishing good relationships with adults.

- ***Education to prevent injuries from firearms*** provides youths with the information necessary to avoid injuries if firearms are present.

- ***Parenting education*** is training to improve parenting skills, which in turn improves the parent-child interaction and supports family life and development.

- ***Peer education*** uses the powerful influence of other youths to persuade and encourage adolescents to resolve conflicts peacefully.

- ***Public information and education*** raise awareness of youth violence in the community, provide basic information on prevention, and help modify the social and behavioral norms of the community.

Legislative/Regulatory Change:

Communities may choose to enact new laws or regulations concerning access to guns or alcohol or they may choose to strictly enforce existing regulations...

- ***Regulations of the use of and access to weapons*** prohibit weapons in schools or set requirements concerning gun ownership or storage.

- ***Regulations of the use of and access to alcohol*** prevent the sale of alcohol to minors, may prohibit or control the sale of alcohol at special events at which youths are likely to be present, and may require that beverage servers and sellers be trained to identify minors and those who have had too much to drink.

Environmental Modification:

- ***Changes in the social environment*** in which the child or adolescent lives can relieve or eliminate problems that foster violent behavior now or later in life. Some avenues for changing the social environment are providing lay home visitors who teach parenting skills and encourage a nurturing environment for children, preschool programs (like Head Start), therapeutic and group counseling activities for children and adolescents who may be at risk for behaving violently, recreational activities, and work or academic experiences.

- ***Changes in the physical environment*** can help make the occurrence of violence less likely. These changes include improving visibility in public areas, increasing the use of an area by community people, controlling access to certain areas, and creating a sense of ownership of an area by community members.

YOUTH VIOLENCE WILL NOT JUST GO AWAY. ALL OF US NEED TO DO SOMETHING NOW.

If you would like a free copy of *The Prevention of Youth Violence: A Framework for Community Action*, please write to

Division of Violence Prevention
The National Center for Injury Prevention and Control
Mail Stop K60
4770 Buford Highway NE
Centers for Disease Control and Prevention
Atlanta, GA 30341-3724

INJURY CONTROL

- Firearm Injuries and Fatalities

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

The Problem

- In 1991 there were over 38,000 firearm-related deaths. These included:
  - nearly 18,000 firearm-related homicides
  - over 18,500 firearm-related suicides
  - over 1,400 unintentional deaths related to firearms
- In 1989, there were over 240,000 nonfatal firearm injuries.
- In 1985, firearm injuries cost over $14.4 billion in direct costs for hospital and other medical care and in indirect costs for long-term disability and premature death.
- At least 80% of the economic costs of treating firearm injuries are paid for by taxpayer dollars.

Homicide

- More than 60% of homicides are committed with a firearm.
- Since the mid-1980s, homicide rates have increased by 41% in Americans 15 to 24 years of age. Over 90% of the increased number of homicides was committed with firearms.
- Firearm assaults on family members and other intimate acquaintances are 12 times more likely to result in death than are assaults using other weapons.
- In 1991, 5745 women were murdered. Firearms, usually handguns, were the weapon most commonly used.

Firearms and Adolescents and Young Adults

- In 1991, firearm injuries were the second leading cause of death for young people, 10 to 24 years of age and the third leading cause of death for persons aged 25 to 34.
- Firearm injuries are responsible for more deaths to U.S. teenagers than all natural diseases combined.
- Since 1985, the risk of dying from a firearm injury has increased at least 77% for teenagers 15 to 19 years of age.
- The 1990 CDC Youth Risk Behavior Survey showed that 4.1%, or 1 in 24 students, carried a firearm for fighting or self-defense during the 30 days preceding the survey. In the 1991 survey, this percentage increased to 5.5%, or 1 in 18 students.
- Over 25% of those who died from firearm injuries in 1990 were 15 to 24 years old.

Suicide

- People living in households in which guns are kept have a risk of suicide that is 5 times greater than people living in households without guns.

- In 1991, 3,109 persons aged 15-24 committed suicide using a firearm, representing almost 17% of all suicides by firearm that year.

Unintentional Firearm Injuries

- In 1991, there were 837 unintended firearm deaths among persons aged 10 to 29, accounting for 58% of all unintentional firearm deaths in the nation that year. Unintentional firearm deaths are those that occur when the person firing the gun does not intend to harm another.

Prepared by:

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CDC

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MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

Current Trends

Homicides Among 15–19-Year-Old Males — United States, 1963–1991

In 1991, nearly half (13,122 [49%]) of the 26,513 homicide victims in the United States were males aged 15–34 years. In addition, among males in this age group, homicide accounted for 18% of all deaths and was the second leading cause of death (Table 1). During 1963–1991, the pattern of homicide rates changed substantially; the change was greatest for males aged 15–19 years, for whom rates increased substantially (Figure 1). This report summarizes these trends and presents strategies for violence prevention and intervention.

Mortality data were obtained from CDC's National Center for Health Statistics; population estimates were projected from census data. Arrest rates were calculated using data from the U.S. Department of Justice.

From 1985 to 1991, the annual crude homicide rate for the United States increased 25% (from 8.4 to 10.5 per 100,000 persons). The homicide rate for persons aged 15–34 years increased 50% during this period (from 13.4 to 20.1 per 100,000), accounting for most of the overall increase. Rates increased for both sexes and all 5-year age groups within the 15–34-year age group. For persons in other age groups, rates were relatively stable from 1985 to 1991: for persons aged ≤14 years, 1.9 and 2.4, respectively; for persons aged 35–64 years, 8.8 and 9.1, respectively; and for persons aged ≥65 years, 4.3 and 4.1, respectively.

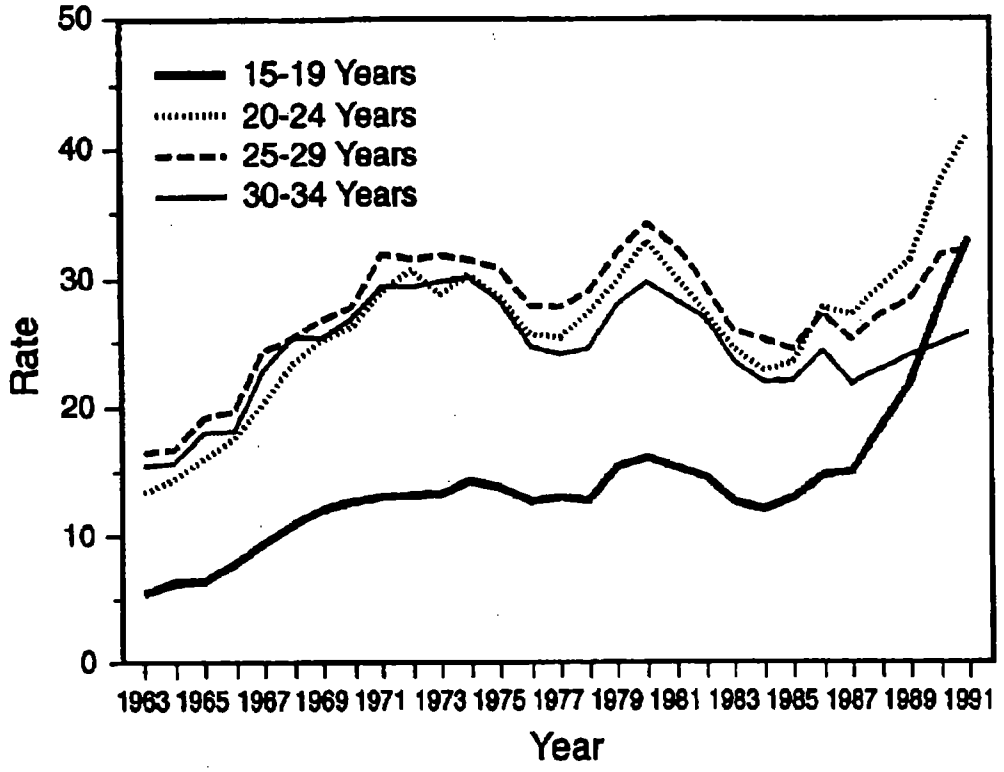
From 1963 through 1985, annual homicide rates for 15–19-year-old males were one third to one half the rates for the next three higher 5-year age groups (Figure 1). How-

TABLE 1. Leading causes of death for males aged 15–34 years — United States, 1991

Cause	No.	(%)
Unintentional injury	23,108	(32)
Homicide	13,122	(18)
Suicide	9,434	(13)
Human immunodeficiency virus infection	8,661	(12)
Cancer	3,699	(5)
Other	13,234	(19)
Total	**71,258**	**(100)**

Homicides — Continued

FIGURE 1. Age-specific rate of homicide for males aged 15–34 years, by age group and year — United States, 1963–1991



*Per 100,000 population.

ever, during 1985–1991, annual rates for males aged 15–19 years increased 154% (from 13.0 to 33.0), surpassing the rates for 25–29- and 30–34-year-old males, even though those rates increased 32% (from 24.4 to 32.3) and 16% (from 22.1 to 25.7), respectively. The homicide rate for 20–24-year-old males increased 76% (from 23.4 to 41.2) from 1985 through 1991.

During 1985–1991, age-specific arrest rates for murder and nonnegligent manslaughter increased 127% for males aged 15–19 years, 43% for males aged 20–24 years, and declined 1% and 13% for males aged 25–29 and 30–34 years, respectively (*1,2*). In 1991, 15–19-year-old males were more likely to be arrested for murder than males in any other age group.

Reported by: Div of Violence Prevention, National Center for Injury Prevention and Control, CDC.

Editorial Note: The increase in the annual homicide rate for 15–19-year-old males during 1985–1991 was a dramatic change from the pattern during 1963–1984. Although the immediate and specific causes of this problem are unclear, the increase in the occurrence of homicide may be the result of the recruitment of juveniles into drug markets, the use of guns in these markets, and the consequent diffusion of guns to other young persons in the community, resulting, in turn, in more frequent use of the guns for settling disputes (*3*). Among 15–19-year-old males, firearm-related homicides accounted for 88% of all homicides in 1991 and 97% of the increase in the rate from 1985 through 1991. Factors underlying the immediate precursors may include poverty, inadequate educational and economic opportunities, social and family insta-

Homicides — Continued

bility, and frequent personal exposure to violence as an acceptable or preferred method of resolving disagreements (*4,5*).

Although the most effective strategies to prevent youth violence have not been determined, efforts to prevent this problem should employ established principles of health promotion and should emphasize the use of multiple complementary interventions (*6,7*). These interventions include

- **Strengthening the science base for prevention efforts.** Strategies and methods to prevent violence in youth should be rigorously assessed (*6*).
- **Establishing primary-prevention programs.** Primary prevention aims to prevent the occurrence of violence rather than focusing on known perpetrators and victims after the occurrence of violence. This strategy addresses all forms of violence (e.g., spouse abuse, child abuse, and violence among youth) and could affect both potential perpetrators and victims.
- **Targeting youths of all ages.** Violence-reduction efforts should address the needs of infants, children, and older youths. Measures that have been successful in reducing violent behavior and its precursors in these age groups (*8–10*) should be considered when developing new programs.
- **Involving adults (e.g., parents and other role models).** They influence violence-related attitudes and behaviors of youth and should be provided the appropriate knowledge and skills to function as role models.
- **Presenting messages in multiple settings.** Lessons in one setting (e.g., a school) should be reinforced in other settings in which children and youth congregate, including homes, churches, recreational settings, and clinics.
- **Addressing societal and personal factors.** Societal factors (e.g., poverty, unemployment, undereducation, and social acceptance of violence [*4,5*]) should be addressed simultaneously with efforts to affect personal behavior change through activities such as home visitation, school-based training, or mentoring.

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Bicycle-Helmet Use

Nationwide, 75.3% of students had ridden a bicycle during the 12 months preceding the survey. Of these students, 92.8% rarely or never wore a bicycle helmet (Table 2). Black male students (97.6%) were significantly more likely than white male students (90.8%) to rarely or never wear a bicycle helmet. The prevalence rate of rarely or never wearing a bicycle helmet ranged from 82.0% to 98.0% (median: 95.7%) among the state surveys and from 71.2% to 98.4% (median: 95.5%) among the local surveys (Table 3).

Riding with a Driver Who Had Been Drinking Alcohol

During the 30 days preceding the survey, approximately one third (35.3%) of students nationwide had ridden with a driver who had been drinking alcohol (Table 2). Hispanic male students (45.1%) were significantly more likely than white male students (34.7%) to report this behavior. Riding with a drinking driver was significantly more likely among 12th-grade male students (42.5%) than among 9th- and 10th-grade male students (30.0% and 33.0%, respectively). State survey prevalence rates ranged from 22.6% to 51.9% (median: 36.4%), and local survey prevalence rates ranged from 23.9% to 45.7% (median: 32.0%) (Table 3).

Behaviors that Contribute to Intentional Injuries

Carrying a Weapon

Nearly one fourth (22.1%) of students nationwide had carried a weapon (e.g., a gun, knife, or club) during the 30 days preceding the survey (Table 4). An estimated 92.0 weapon-carrying incidents occurred monthly per 100 students. Across all racial/ethnic and grade subgroups, male students were significantly more likely than female students to have carried a weapon. Weapon-carrying was significantly more likely among black female students (18.9%) than among white and Hispanic female students (6.9% and 11.5%, respectively). Prevalence rates ranged from 16.2% to 33.0% (median: 24.4%) among the state surveys and from 19.1% to 35.3% (median: 23.7%) among the local surveys (Table 5).

Nationwide, 7.9% of students had carried a gun during the 30 days preceding the survey (Table 4). Across all racial/ethnic and grade subgroups, male students were significantly more likely than female students to have carried a gun. Black male and black female students (20.9% and 3.8%, respectively) were significantly more likely to have done so than were white male and white female students (12.0% and 1.2%, respectively). State prevalence rates ranged threefold from 5.8% to 17.4% (median: 10.2%), and local prevalence rates ranged more than twofold from 6.6% to 14.0% (median: 10.0%) (Table 5).

Engaging in a Physical Fight

Among students nationwide, 41.8% had been in a physical fight during the 12 months preceding the survey, and 4.0% had been treated by a doctor or nurse for injuries sustained in a physical fight during the same time period (Table 6). An estimated 136.8 physical fighting incidents occurred per 100 students per year. Across all racial/ethnic and grade subgroups, male students were significantly more likely than female students to have been in a physical fight. Participation in a physical fight was significantly more likely to have occurred among black female students (41.8%) than

among white female students (29.5%) and among 9th-grade students (50.4%) than among 10th- (42.2%), 11th- (40.5%), and 12th- (34.8%) grade students. Black male students (8.5%) were significantly more likely than black female students (4.3%) and white male students (4.2%) to have been injured in a physical fight. Among the state surveys, the prevalence rate of physical fighting ranged from 29.8% to 60.8% (median: 40.0%), and the prevalence rate of injurious physical fighting ranged from 2.4% to 12.2% (median: 4.4%) (Table 7). Among the local surveys, the prevalence rate of physical fighting ranged from 35.2% to 51.4% (median: 42.9%), and the prevalence rate of injurious physical fighting ranged from 4.5% to 9.3% (median: 6.3%).

School-Related Violence

Nationwide, 4.4% of students had missed at least 1 day of school during the 30 days preceding the survey because they felt unsafe at school or felt unsafe traveling to or from school (Table 8). Both Hispanic and black male and female students were significantly more likely than white male and female students to miss school because they felt unsafe, and 9th-grade female students (6.4%) were significantly more likely than 12th-grade female students (2.7%) to miss school for this reason. Ninefold differences were observed in the prevalence rates from the state surveys, which ranged from 2.5% to 23.1% (median: 5.4%) (Table 9). Nearly threefold differences were observed in the prevalence rates from the local surveys, which ranged from 6.8% to 17.5% (median: 10.5%).

The prevalence of weapon-carrying on school property during the 30 days preceding the survey was 11.8% nationwide (Table 8). Across all racial/ethnic and grade subgroups, male students were significantly more likely than female students to have carried a weapon on school property. Black female students (11.9%) were significantly more likely than Hispanic female (6.6%) or white female (3.4%) students to have done so. Prevalence rates among the state surveys ranged from 7.9% to 19.3% (median: 12.3%) (Table 9). Prevalence rates among the local surveys ranged from 8.3% to 22.5% (median: 11.7%).

Nationwide, the prevalence of students who were threatened or injured with a weapon on school property during the 12 months preceding the survey was 7.3% (Table 8). White male students (8.1%) and black female students (9.8%) were significantly more likely than white female students (4.4%) to have been threatened or injured with a weapon. Male students in grades 10–12 (9.1%, 9.5%, and 7.6%, respectively) were significantly more likely than female students in the same grades (5.4%, 4.8%, and 3.3%, respectively) to have experienced this. Prevalence rates among the state surveys ranged from 5.8% to 15.2% (median: 8.3%) (Table 9). Prevalence rates among the local surveys ranged from 8.9% to 16.3% (median: 10.8%).

Nationwide, 16.2% of students had been in a physical fight on school property during the 12 months preceding the survey (Table 8). Across all racial/ethnic and grade subgroups, male students were significantly more likely than female students to have been in a physical fight on school property. Black male and female students (28.6% and 15.5%, respectively) were significantly more likely than white male and female students (22.5% and 6.8%, respectively) to have experienced this. Male and female students in grade 9 (33.2% and 12.7%, respectively) were significantly more likely to have been in a physical fight on school property than those in grades 11 (20.0% and 7.0%, respectively) and 12 (16.5% and 6.1%, respectively). Among the state surveys,

Table 6. Deaths and death rates for the 10 leading causes of death in specified age groups, by race and sex: United States, 1992—Con.

[Rates per 100,000 population in specified group. For explanation of asterisk preceding cause-of-death codes, see Technical notes]

Rank order[1]	Cause of death, race, sex, and age (Ninth Revision, International Classification of Diseases, 1975)	Number	Rate
	Total black, all ages[3]		
...	All causes	269,219	850.5
1	Diseases of heart .390–398,402,404–429	75,600	238.8
2	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues .140–208	58,401	184.5
3	Cerebrovascular diseases .430–438	17,044	53.8
4	Homicide and legal intervention .E960–E978	12,318	38.9
5	Accidents and adverse effects .E800–E949	11,820	37.3
...	Motor vehicle accidents .E810–E825	5,071	16.0
...	All other accidents and adverse effects .E800–E807,E826–E949	6,749	21.3
6	Human immunodeficiency virus infection .*042–*044	11,378	35.9
7	Diabetes mellitus .250	8,653	27.3
8	Pneumonia and influenza .480–487	7,074	22.3
9	Certain conditions originating in the perinatal period .760–779	6,176	19.5
10	Chronic obstructive pulmonary diseases and allied conditions .490–496	5,857	18.5
...	All other causes .Residual	54,896	173.4
	Black, 1–4 years		
...	All causes	1,799	73.2
1	Accidents and adverse effects .E800–E949	574	23.3
...	Motorvehicle accidents .E810–E825	191	7.8
...	All other accidents and adverse effects .E800–E807,E826–E949	383	15.6
2	Congenital anomalies .740–759	208	8.5
3	Homicide and legal intervention .E960–E978	185	7.5
4	Human immunodeficiency virus infection .*042–*044	100	4.1
5	Diseases of heart .390–398,402,404–429	95	3.9
6	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues .140–208	62	2.5
7	Pneumonia and influenza .480–487	56	2.3
8	Certain conditions originating in the perinatal period .760–779	43	1.7
9	Anemias .280–285	40	1.6
10	Chronic obstructive pulmonary diseases and allied conditions .490–496	28	1.1
...	All other causes .Residual	408	16.6
	Black, 5–14 years		
...	All causes	1,876	33.7
1	Accidents and adverse effects .E800–E949	738	13.3
...	Motor vehicle accidents .E810–E825	356	6.4
...	All other accidents and adverse effects .E800–E807,E826–E949	382	6.9
2	Homicide and legal intervention .E960–E978	260	4.7
3	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues .140–208	159	2.9
4	Congenital anomalies .740–759	91	1.6
5	Diseases of heart .390–398,402,404–429	82	1.5
6	Chronic obstructive pulmonary diseases and allied conditions .490–496	47	0.8
6	Human immunodeficiency virus infection .*042–*044	47	0.8
8	Suicide .E950–E959	34	0.6
9	Anemias .280–285	33	0.6
10	Pneumonia and influenza .480–487	19	*
...	All other causes .Residual	366	6.6

Rank order[1]	Cause of death, race, sex, and age (Ninth Revision, International Classification of Diseases, 1975)	Number	Rate
	Black, 15–24 years		
...	All causes	8,982	168.4
1	Homicide and legal intervention .E960–E978	4,625	86.7
2	Accidents and adverse effects .E800–E949	1,684	31.6
...	Motor vehicle accidents .E810–E825	1,117	20.9
...	All other accidents and adverse effects .E800–E807,E826–E949	567	10.6
3	Suicide .E950–E959	536	10.0
4	Diseases of heart .390–398,402,404–429	305	5.7
5	Human immunodeficiency virus infection .*042–*044	286	5.4
6	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues .140–208	276	5.2
7	Anemias .280–285	86	1.6
8	Chronic obstructive pulmonary diseases and allied conditions .490–496	80	1.5
9	Congenital anomalies .740–759	70	1.3
10	Pneumonia and influenza .480–487	57	1.1
...	All other causes .Residual	977	18.3
	Black, 25–44 years		
...	All causes	38,573	377.3
1	Human immunodeficiency virus infection .*042–*044	8,456	82.7
2	Homicide and legal intervention .E960–E978	5,713	55.9
3	Diseases of heart .390–398,402,404–429	4,363	42.7
4	Accidents and adverse effects .E800–E949	4,065	39.8
...	Motor vehicle accidents .E810–E825	1,932	18.9
...	All other accidents and adverse effects .E800–E807,E826–E949	2,133	20.9
5	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues .140–208	4,034	39.5
6	Cerebrovascular diseases .430–438	1,174	11.5
7	Suicide .E950–E959	1,085	10.6
8	Chronic liver disease and cirrhosis .571	927	9.1
9	Pneumonia and influenza .480–487	705	6.9
10	Diabetes mellitus .250	549	5.4
...	All other causes .Residual	7,502	73.4
	Black, 45–64 years		
...	All causes	63,401	1,309.9
1	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues .140–208	19,244	397.6
2	Diseases of heart .390–398,402,404–429	18,358	379.3
3	Cerebrovascular diseases .430–438	3,625	74.9
4	Diabetes mellitus .250	2,509	51.8
5	Accidents and adverse effects .E800–E949	2,225	46.0
...	Motor vehicle accidents .E810–E825	910	18.8
...	All other accidents and adverse effects .E800–E807,E826–E949	1,315	27.2
6	Human immunodeficiency virus infection .*042–*044	2,213	45.7
7	Chronic liver disease and cirrhosis .571	1,584	32.7
8	Chronic obstructive pulmonary diseases and allied conditions .490–496	1,341	27.7
9	Pneumonia and influenza .480–487	1,080	22.3
10	Homicide and legal intervention .E960–E978	1,018	21.0
...	All other causes .Residual	10,204	210.8

See footnotes at end of table.

April 4, 1995,

Dorothea Green PA-c

5511 Hammersmith Drive

W. Bloomfield, Michigan 48322

810 788-3426

Dear Hilary Clinton,

I am writing this letter because I am interested in your health care plan. You addressed our National Organization last May in Texas the AAPA. After the meeting you asked us to write our congressmen to support your plan. Which I did. I wrote my senators and representatives. In September I attended another meeting in Washington D.C.. the CCOW conference for Physician Assistants. While attending this meeting we spent a day at the Capitol, meeting with represenatives and sentors.

Two Bills at the time were very important to me as a clinical PA.and also as a faculty member at the University of Detroit-Mercy PA program. The first bill S.834 Which deals with reimbursement of PA services;the second bill is F495 Labor HHS appropriations H.R. 46067 which allocates 6.354 million dollars for grants to P.A.educational programs I would like to know what happen to these bills.

Also I am moderator of the African American Caucus of the American Academy of Physician Assistants and I am planing two panel discussions at our national meeting in Las Vegas on May 29, May 31and June 2, 1995. We are focusing on two issues this year.

One issue is health care reform and how it affects the African American Community Good or Bad. The other issue is Violence in our community and how it affects African Americans.

I am very interested in any imput you or members of your office can give me. I am also trying to get speakers to participate in a panel discussions on these topics. If you could help me in any way please write me or phone immediately. If it would be possible for you to set up an interview with our group to give us an update on these issues as you did last year in Texas it would be appreciated.

Thank you for your cooperation and help.

Yours truly,

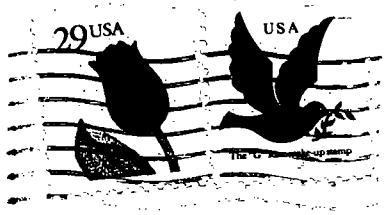
Dorothea J. Green P.A.-c

Moderator of the AA caucus of the AAPA

DM30185

DOROTHEA GREEN, PA-C
5511 HAMMERSMITH DR
W BLOOMFIELD MI 48322-1455

ROYAL OAK, MI
PM
05 APR
1995



Ms Hilary Clinton
White House
Old Executive office Bld.
Washington D.C.
20500-0001

LEWIS

FACSIMILE TRANSMISSION REQUEST

IT COULD BE YOU

==========

DATE: 6/21/95

543-6493

ADDRESSEE: Judithanne Scourfield **FROM:** Robert Gooding

PHONE: (202) 456-5578 **PHONE:** (202) 690-8264

TOTAL PAGES: C+ 13 **FAX NUMBER:** (202) 690-7675

REMARKS:

PLEASE CALL: _____ **at** _____ **for pick-up**

CALL _____ **on** _____ **to confirm receipt of this fax**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Director
Executive Secretariat
Washington, D.C. 20201

MEMORANDUM FOR JUDITHANNE SCOURFIELD

Enclosed is a draft response to Ms. George Lewis of Metafusion, Inc. Ms. Lewis wrote to the First Lady to share her concerns regarding Medicare coverage of parenteral nutrition for dialysis patients. I have also enclosed a letter to Ms. Lewis from Bruce C. Vladeck, Administrator of the Health Care Financing Administration, on the same subject.

Joyce G. Somsak
Director

Enclosures

Dear Ms. Lewis:

Thank you for your letter regarding parenteral nutrition for Medicare dialysis patients. I appreciate your sharing your concerns.

Medicare covers parenteral nutrition only under very limited situations. I understand that a representative of the Health Care Financing Administration (HCFA) met recently with a member of your company and Bruce Vladeck, Administrator of HCFA, corresponded recently with you on the requirements for coverage of this benefit this issue and the issue of prior inappropriate approvals of parenteral nutrition. Given the technical requirements for coverage, I would encourage you to continue your discussions on this issue with Mr. Vladeck and his HCFA staff.

I enjoyed your note regarding your name. I bet you really made your father proud to have you both share the same name.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

JUN 20 1994

Ms. George Lewis
Metafusion, Inc.
3 Church Circle, Suite 103
Annapolis, Maryland 21401-1933

Dear Ms. Lewis:

Thank you for taking the time to share your concerns with me regarding parenteral nutrition for Medicare dialysis patients.

Parenteral nutrition is covered as a prosthetic device, which means that Medicare pays for the service only when there is evidence presented that the patient suffers from a permanent functional impairment of the GI tract. The durable medical equipment (DME) carriers have recently published specific medical criteria which can be used to demonstrate such impairment. These criteria are generally accepted in the medical community; I understand that only a very small number of individuals are expected to meet them. The average dialysis patient, according to the experts we have consulted, does not usually demonstrate this type of impairment.

The underlying policy for coverage of parenteral nutrition has not changed in recent years. We are well aware, however, that the Medicare coverage rules for parenteral nutrition, as well as for other types of prosthetics and durable medical equipment, were not always correctly applied. Before 1993, durable medical equipment claims were paid by over 35 carriers all of which handled many other types of claims as well. Because the total numbers of DME claims were small, relatively little attention was paid to this specific benefit with the result that actual practice varied from one carrier to another. In order to ensure better handling of claims, the Health Care Financing Administration (HCFA) in 1993 transferred all responsibility for payment of DME claims to four DME Carriers.

As best we can tell, established HCFA policy has been followed by your carrier since this transition. Patients who were receiving coverage for parenteral nutrition before the transition to DME carriers were temporarily "grandfathered;" claims from these grandfathered patients are still being paid and will continue to be paid for at least another four months during which we are receiving comment on written clarification of national policy. This explains why many of your patients continue to have their claims paid even though new patients are not being certified for this service.

While I certainly regret the disruption experienced by local suppliers, HCFA cannot continue to certify and pay for parenteral nutrition for those dialysis patients who do not meet the medical necessity criteria.

You may be already aware that HCFA staff met with a representative of your company, as well as other companies, and Congressman Robert Livingston to discuss concerns about patient coverage. I am enclosing a copy of a recent letter to Congressman Livingston for your information.

Thank you for writing me. I appreciate your interest and concern.

Sincerely,

Bruce C. Vladeck
Administrator

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES
BUREAU OF PROGRAM OPERATIONS

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207
Refer to BPO-B22

MAY 23 1995

The Honorable Robert L. Livingston
U.S. House of Representatives
Washington, D.C. 20515-1801

Dear Mr. Livingston:

I am writing to address the concerns raised by INTRX, NutraCare, and Metafusion regarding parenteral nutrition for dialysis patients during the meeting held in your office on March 24, 1995.

Let me assure you, as mentioned in the meeting, parenteral nutrition for dialysis patients is still a covered service if the patient meets all of the medical necessity requirements listed in the regional medical review policies. These three suppliers, especially Mr. Celanos of INTRX, raised three main concerns which we have addressed below:

One Hundred Percent of Parenteral Nutrition for Dialysis Patients Claims in Region C are now Being Denied

We contacted our lead regional offices to gather claims information specific to these three suppliers. A summary of the information is attached. As you can see, these suppliers are continuing to receive payment for some beneficiaries. In addition, they are receiving denials in regions other than Region C. All denials were a result of lack of medical necessity documentation. Because parenteral nutrition is covered under the prosthetic device benefit, Medicare does not cover supplemental nutrition, even if it is medically necessary, unless the nutrition replaces a malabsorbing GI tract. Therefore, medical necessity documentation, such as lab tests, must prove that the patient has a malabsorption problem due to a functional impairment of the GI tract (a statement that there is malabsorption in the intestines alone does not justify medical necessity.)

Most of the suppliers' paid claims are for "grandfathered" patients. A grandfathered patient is one who had been receiving parenteral nutrition prior to the transition to the regional carriers. The regional carriers continue to pay for parenteral nutrition for these patients. Grandfathering, however, is due to end when new, revised parenteral nutrition regional policies are implemented in the near future. The new policies will specifically address the tests or other evidence generally needed to justify medical necessity of parenteral nutrition for dialysis patients. Until this time, we do not anticipate any changes in the way medical necessity is evaluated by the regional carriers.

Region C has Changed its Parenteral Nutrition Policy

As we have communicated to Mr. Celanos, the parenteral nutrition policy has not changed from what is published in the current supplier manual; however, we recognize that the application of the policy in Region C has recently changed. In the past, the Medical Director at Region C, Dr. Tallon, used criteria outside the scope of the regional policy to determine medical necessity for parenteral nutrition for

dialysis patients. After Dr. Tallon resigned in September 1994, the regional carrier employed an interim Medical Director until Dr. Paul Metzger permanently filled the position in January of this year. Both the interim medical director and Dr. Metzger evaluated (and continues to evaluate) medical necessity documentation according to the published regional policy. This method of evaluation has always been applied at the other regional carriers (A, B, and D).

One of our main goals in creating the regional carriers was to increase consistency in applying medical policy and medical review criteria, including those pertaining to parenteral nutrition for dialysis patients. We are achieving that goal by working closely with the Medical Directors in each Region, who regularly consult with physicians, suppliers, and other industry representatives when developing regional medical review policy.

HCFA Should be Responsible For the Actions of Dr. Tallon

While it is unfortunate that Dr. Tallon inappropriately certified some patients for parenteral nutrition for dialysis patients therapy, we cannot continue to inappropriately certify and pay for parenteral nutrition for dialysis patients in these cases. Recognizing we are responsible for the inappropriate certifications, we agreed with Region C to continue to reimburse suppliers for these patients throughout the approved period. After this period is expired, the dialysis patient will again be evaluated for parenteral nutrition therapy. We also agreed that no overpayments will be collected from suppliers for claims submitted and paid for services rendered during the certified period of time.

I appreciate your interest in and concern for our Medicare customers, including suppliers of parenteral nutrition for dialysis patients. Because of similar concerns, we have been meeting with some other parenteral nutrition suppliers to discuss many of these same issues. In fact, Mr. Jimmy Perren of NutraCare was in attendance at one of our recent meetings. I assure you we are making every effort to keep lines of communication open among suppliers, the regional carriers, and ourselves.

Sincerely,

Gary P. Kavanagh
Deputy Director

Attachment

NutraCare				
Region	*Number of Beneficiaries*	*Submitted Charges*	*Allowed Charges*	*Comments*
A	52	$89,027	$58,320**	Denials resulted from a lack of documentation presented for new patients.
B	0	N/A	N/A	N/A
C	28	$723,820	$149,044	Denials resulted from a lack of medical necessity documentation.
D	0	N/A	N/A	N/A

Metafusion, Inc.				
Region	*Number of Beneficiaries*	*Submitted Charges*	*Allowed Charges*	*Comments*
A	242	$721,890	$78,506**	All denials resulted from a lack of documentation presented for new patients
B	10	$14,705	$0	Denials resulted from a lack of medical necessity documentation. Some $ was paid incorrectly and the carrier has requested a refund (not shown as allowed).
C	2	$35,495	$0	Denials resulted from a lack of medical necessity documentation.
D	0	N/A	N/A	N/A

INTRX				
Region	*Number of Beneficiaries*	*Submitted Charges*	*Allowed Charges*	*Comments*
A	94	$241,764	$14,323**	Denials resulted from a lack of documentation presented for new patients.
B	6	$127,833	$8,664	Denials resulted from a lack of medical necessity documentation. Some $ was paid incorrectly and the carrier has requested a refund (not shown as allowed).
C	51	$2,625,659	$774,195	Denials resulted from a lack of medical necessity documentation.
D	2	$120,450	$61,093	Denials resulted from a lack of medical necessity documentation.

** These figures represent amounts paid to the supplier (usually the allowed charge less any deductible and coinsurance).

13.41 PARENTERAL NUTRITION

HCPCS Codes

B4164 Parenteral nutrition solution: carbohydrates (dextrose), 50% or less (500 ml = 1 unit) - homemix
B4168 Parenteral nutrition solution; amino acid, 3.5%, (500 Ml = 1 unit) - homemix
B4172 Parenteral nutrition solution; amino acid, 5.5% Through 7%, (500 ml = 1 unit) - homemix
B4176 Parenteral nutrition solution; amino acid, 7% through 8.5%, (500 Ml = 1 unit) - homemix
B4178 Parenteral nutrition solution: amino acid, greater than 8.5% (500 Ml = 1 unit)- homemix
B4180 Parenteral nutrition solution; carbohydrates (dextrose), greater than 50% (500 ml=1 unit) - homemix
B4184 Parenteral nutrition solution; lipids, 10% with administration set (500 ml = 1 unit)
B4186 Parenteral nutrition solution, lipids, 20% with administration set (500 ml = 1 unit)
B4189 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 10 to 51 grams of protein - premix
B4193 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, 52 to 73 grams of protein - premix
B4197 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, 74 to 100 grams of protein - premix
B4199 Parenteral nutrition solution; compounded amino acid and carbohydrates with electrolytes, trace elements and vitamins, including preparation, any strength, over 100 grams of protein - premix
B4216 Parenteral nutrition; additives (vitamins, trace elements, heparin, electrolytes) homemix per day
B4220 Parenteral nutrition supply kit; premix, per day
B4222 Parenteral nutrition supply kit; home mix, per day
B4224 Parenteral nutrition administration kit, per day
B5000 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, renal - amirosyn rf, nephramine, renamine - premix
B5100 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, hepatic - freamine hbc, hepatamine - premix
B5200 Parenteral nutrition solution: compounded amino acid and carbohydrates with electrolytes, trace elements, and vitamins, including preparation, any strength, stress - branch chain amino acids - premix
B9004 Parenteral nutrition infusion pump, portable
B9006 Parenteral nutrition infusion pump, stationary
B9999 NOC for parenteral supplies
E0776 IV pole

References: Coverage Issues Manual 65-10

Benefit Category: Prosthetic Device

Definitions

Parenteral nutrition is the provision of nutritional requirements intravenously.

Intradialytic Parenteral Therapy (IDPN) is parenteral nutrition delivered during hemodialysis.

Indications

Parenteral nutrition is covered for a patient with severe permanent disease of the gastrointestinal tract which prevents absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status.

Coverage and Payment Rules

General

The patient must have a permanent impairment. Permanence does not require that the impairment necessitating therapy will persist throughout the patient's remaining life. If the judgement of the attending physician, substantiated in the medical record, is that the impairment can reasonably be expected to exceed three months (ninety days), the test of permanence is considered met. Parenteral nutrition will be denied as non-covered in situations involving temporary impairments.

The patient must have a condition involving the gastrointestinal tract which significantly interferes with the absorption of nutrients. Parenteral nutrition is non-covered for the patient with a functioning GI tract, whose need for parenteral nutrition is due to lack of appetite or a cognitive problem.

The patient must require intravenous nutrition to sustain life. Adequate nutrition must not be possible by dietary adjustment, oral supplements, or tube enteral nutrition.

Intradialytic parenteral nutrition (IDPN) provided for patients without a significant gastrointestinal disease, but with impaired nutrition due to a poor appetite, will be denied as non-covered. Parenteral nutrition is covered in dialysis patients with a clearly documented, clinically significant gastrointestinal condition which has resulted in malnutrition that cannot be corrected by dietary means and can be corrected with the prescribed parenteral nutrition regimen. In these circumstances, the prescribed parenteral nutrition is usually administered daily. Parenteral nutrition administered only during dialysis in these patients would rarely be medically necessary. Detailed documentation would be required to justify IDPN.

Less than daily parenteral therapy or parenteral therapy without amino acids may be indicated in some patients with massive bowel resection (>75%) and extreme Short Bowel Syndrome (SBS) and subsequent parenteral nutrition therapy, who undergo a "bowel adaption." After several months, the bowel adaption can make some parenteral nutrients, such as calories and protein, or daily parenteral infusion unnecessary, even though parenteral water, electrolytes, some vitamins or less than daily amino acid supplements are still essential. Continued parenteral nutrition is covered in these patients if, after a documented one year period of daily full parenteral nutrition and subsequent bowel adaption, the beneficiary's weight and strength continues to require modified parenteral nutrition. This modified solution or administration plan is only covered in patients where extreme short bowel and partial bowel adaption is documented.

If the coverage requirements for parenteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

No more than one month's supply of parenteral nutrients, equipment or supplies is allowed for one month's prospective billing. Claims submitted retroactively, however, may include multiple months.

The ordering physician is expected to see the patient within 30 days prior to the initial certification or required recertification (but not revised certifications). If the physician does not see the patient within the time frame, he/she must document the reason why and describe what other monitoring methods were used to evaluate the patient's parenteral nutrition needs.

Covered parenteral nutrition services provided by a SNF to a Part A patient are billed by the SNF to the intermediary. No payment from Part B is available to a SNF when the SNF furnishes parenteral nutrition services to a beneficiary in a stay covered by Part A. If a beneficiary is not covered by Part A, but is eligible for Part B coverage, parenteral nutrition services are covered under Part B, regardless of whether they are furnished by a SNF or an outside supplier.

Nutrients

A total calorie intake of 20 to 35 cal/kg/day is considered sufficient to achieve or maintain appropriate body weight. The ordering physician must document the medical necessity for a caloric intake outside this range in an individual patient.

The ordering physician must document the medical necessity for protein orders outside of the range 1.0-1.5 gm/kg/day, dextrose concentrators less than 10%, or lipid use greater than 12 units per month.

The medical necessity for special parenteral formula (B5000-B5200) will need to be documented in each patient. If the medical necessity for these formulae is not substantiated, payment will be based on the allowance for the least costly alternative.

Equipment and Supplies

Infusion pumps (B9004 through B9006) are covered for patients in whom parenteral nutrition is covered. Only one pump (stationary or portable) will be covered at any one time. Additional pumps will be denied as not medically necessary.

Coding Guidelines

When homemix parenteral nutritional solutions are used, the component carbohydrates (B4164, B4180), amino acids (B4168, B4178), additives (B4216), and lipids (B4184, B4186) are all separately billable. When premix parenteral nutrition solutions are used (B4189 through B4199, B5000 through B5200) there must be no separate billing for the carbohydrates, amino acids, or additives (vitamins, trace elements, heparin, electrolytes). However, lipids are separately billable with premix solutions.

When an IV pole (E0776) is used in conjunction with parenteral nutrition, the XA modifier should be added to the code.

Documentation

The certificate of medical necessity (CMN) for parenteral nutrition may be completed by someone other than the ordering physician. However the CMN must be reviewed for the accuracy of the information and signed and dated by the ordering physician to indicate agreement. (See "Documentation" and "Certificate of Medical Necessity Forms," Sections 12.4 and 12.7, for more information on orders, CMNs, medical records, and supplier documentation.) The CMN for parenteral nutrition is DMERC 10.vv (where vv represents the current version number of the CMN).

After the initial certification of parenteral nutrition items, recertification is required after 3, 9, and 24 months of therapy to document the patient's continued need for therapy. After two years, the need for further recertification will be determined on a case-by-case basis. If parenteral nutrition services are not medically required for two consecutive months, a new initial certification would be required and the required recertification schedule would start again.

A revised certification would be required when:

1. Nutrients billed with a different code are ordered or
2. Calories per day are changed, or
3. Number of days per week administered is changed, or
4. There is a change by more than one liter in the daily volume of parenteral solutions, or
5. There is a change from home-mix to pre-mix or vice versa. A revised certification does not change the schedule for the required recertification.

For the initial certification and for the revised certifications or recertification involving a change in the order, there must be additional documentation to support the medical necessity of the following orders, if applicable.

1. The need for administration of parenteral nutrition less than daily (see below),
2. The need for special nutrients (B5000-B5200),
3. The need for total caloric intake less than 20 or greater than 35 cal/kg/day,
4. The need for protein less than 1.0 or greater than 1.5 mg/kg/day,
5. The need for dextrose concentration less than 10%,
6. The need for lipids more than 12 units per month.

When parenteral nutrition less than daily is initially ordered, additional documentation must be included with the claim. This information must include:

1. The diagnosis relating to the need for parenteral nutrition,
2. A copy of the test or operative report substantiating the diagnosis,
3. A nutritional assessment by a dietician,
4. Weights over recent months with a statement of whether any weight loss was due to fluid loss rather than loss of lean body mass,
5. Laboratory test results (with dates) documenting impaired nutritional status,
6. For IDPN, a measure of the adequacy of dialysis (i.e., KT/V) determined during the prior month on the patient's current dialysis regimen, and
7. A description of the efforts made to increase oral caloric intake or use tube enteral nutrition.

If less than daily, parenteral nutrition is approved initially, recertification at 3 months must include the following information obtained during the third month therapy:

1. Repeat nutritional assessment by a dietician,
2. Patient weight, and
3. Laboratory test results (with dates) documenting changed nutritional status due to parenteral nutrition.

When a certification is required, the claim must include a copy of the CMN, if filed hard copy. If the claim is filed electronically, the information on the CMN must be transcribed exactly into the GU0 record. (See the *DMEPOS National Standard Format Matrix* for details.) The HA0 record can be used for additional narrative documentation that will not fit on the GU0 record.

Effective Date: Claims received by the DMERC on or after October 1, 1993.

METAFUSION, INC.

3 CHURCH CIRCLE, SUITE 103
ANNAPOLIS, MD 21401-1933
1-800-334-8691 (410) 263-2060
FAX (410) 263-2355

April 17, 1995

First Lady Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mrs. Clinton:

As a female owner of a small Maryland health care company and knowing your concern for Health Care in this country, I am writing to you to share my concerns over a problem we are experiencing with Medicare/HCFA that impacts on the health of dialysis patients.

We have been supplying a therapy for over 8 years to patients who are on dialysis and can not absorb enough nutrients through their gastrointestinal tract to maintain their weight, strength and to sustain their lives. This therapy, called Intradialytic Parenteral Nutrition (IDPN) has been a covered therapy for more than 10 years under the Prosthetic Device Benefit (section 1861(s)(8) of the Social Security Act). To qualify as a prosthetic device, an item or service must replace the function of a body organ. For parenteral nutrition, the function replaced is the absorptive capacity of the gastrointestinal tract.

The problem has arisen since Medicare/HCFA instituted regionalization (DMERCS). Though HCFA maintains that the policy for payment of IDPN claims has not changed, the medical directors of the DMERCS have formulated their own interpretation and have denied payment across the board for any IDPN claims submitted after regionalization. As a Maryland corporation, we had to transfer to the DMERCS in January of 1994. Any of our patients that began therapy in or after January, 1994, have been denied coverage, even though these patients have the same medical conditions as patients that were paid before the DMERCS were instituted. If these qualified patients are denied this therapy, it has been documented that their risk of death increases by 50%, however, without reimbursement to cover our costs, our small company is on the verge of being put out of business and we will not be able to provide this life sustaining therapy to our patients, many of whom will lose their lives needlessly.

Since you have shown such concern for the rights of small business, for the health and welfare of the average citizen, and for reform in the health care industry, I desperately ask for your assistance. The insurance companies that administer payment for the DMERCS are paid by how many claims they process, so it is in their best interest financially to deny payment and force the claims into review, fair hearings and ALJ's, all of which they again get paid for processing. This is one of the reasons for the high cost of health care. You may also find it interesting that Travelers Insurance who administered claims for Region A DMERCS paid their CEO $52 million in 1994, yet denied payment on all of our new claims for a service that not only sustained but improved the quality of life for many patients. A few day's stay in the hospital can cost Medicare more than a month's IDPN treatment, yet without IDPN many of these patients will be in the hospital, if they remain alive. We are very careful in making sure that all the patients we supply meet the criteria stated in the HCFA manual and the

dietitians and the doctors prescribing IDPN for these patients have ruled out all other possible safe avenues for sustaining the patient's life.

This matter has become critical for our company and without some immediate relief for our claims that have been stalled in the review process we will be out of business in 30 days. We haven't even gotten to the fair hearing process on most of our patients and after that the ALJ's are backed up at least 18 months.

In order to keep this letter brief, I have only given you highlights of the situation. However, to illustrate the seriousness of this situation, I am enclosing copies of a few letters to and from Medicare and some other documentation that has been compiled by the Coalition for Renal Nutrition, a group of other small suppliers, Doctors and clinicians that we have joined in an effort to resolve this problem with Medicare, though presently to no avail. We are very concerned about what will happen to our patients if we can no longer provide this life sustaining therapy for them and I would appreciate the opportunity to meet with you or your staff concerning this issue.

Very truly yours,

George Lewis

George Lewis, President

Enc.

P.S. I really am a female - as a last daughter I was named after my father

Coalition for Renal Nutrition, Inc.

• P.O. Box 484 • Lima, PA 19037 • 610-494-8700

April 7, 1995

HAND DELIVERY

Helen L. Smits, M.D.
Deputy Administrator
Health Care Financing Administration
700 East High Rise Building
6325 Security Boulevard
Baltimore, MD 21207

Re: Coalition for Renal Nutrition, Inc. -- Medicare Coverage and Payment for Intradialytic Parenteral Nutrition Therapy

Dear Dr. Smits:

The Coalition for Renal Nutrition, Inc. (the "Coalition") is an association of health care providers and others engaged in the provision of intravenous therapy, including intradialytic parenteral nutrition ("IDPN") therapy. We are writing to bring to your attention serious concerns relating to Medicare Part B payment denials for virtually all IDPN claims submitted on behalf of nongrandfathered patients (i.e., patients not receiving IDPN therapy prior to the transition to regional carriers) by each of the four Durable Medical Equipment Regional Carriers ("DMERCs").

This situation is particularly troubling because the Health Care Financing Administration ("HCFA") is on record as confirming that the Medicare program covers IDPN therapy for beneficiaries meeting applicable medical necessity criteria, and that the DMERCs are addressing our concerns.*/

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*/ See, e.g., letter to J. Darrell Boyd, President, National Infusion, from Carol Walton, Director, Bureau of Program Operations, HCFA (Mar. 12, 1995) (Tab A); letter to The Honorable Curt Weldon, House of Representatives, from Bruce C. Vladeck, Administrator, HCFA (Aug. 9, 1993) (Tab B); letter to Michael Reiner, Haemotronic Ltd., from Robert E. Wren, Director, Office of Coverage and Eligibility Policy, Bureau of Policy Development, HCFA (Sept. 7, 1993) (Tab C); letter to J. Darrell Boyd, National Infusion, from Carol J. Walton, Director, Bureau of Program Operations, HCFA (Jan. 19, 1994) (Tab D).

Although each of the DMERC Supplier Manuals provide that IDPN is a covered benefit, the DMERCs' medical review staffs have adopted unduly restrictive and clinically unsupportable medical review criteria that have resulted in denial of virtually all IDPN claims. These denials have subjected many dialysis patients to serious medical risk by forcing some providers to cease accepting Medicare beneficiaries needing IDPN. In addition to harming dialysis patients who need IDPN, this situation has been extremely detrimental to legitimate providers of this therapy as they have been providing unreimbursed services for all IDPN cases for which they have been providing services. This situation, which has now persisted for well over a year -- despite the consistent efforts of providers to resolve this matter through the DMERC medical directors, HCFA's Office of Coverage Policy and Bureau of Program Operations, and members of Congress -- requires a swift and global response to resolve the arbitrary and erroneous claims denials, and to develop clinically sound, workable medical review criteria that can be implemented by each of the DMERCs in processing IDPN claims. We would note that Dr. Metzger, Medical Director for the Region C DMERC, has told providers that he would approve payment of IDPN claims if given proper direction from HCFA.

As a result, we seek your immediate assistance in directing the DMERCs to process and pay IDPN claims in accordance with the well-established policy which provides coverage for IDPN therapy for Medicare beneficiaries meeting applicable medical necessity criteria.

Accompanying this letter is a clinical overview of IDPN therapy in which we clarify some of the common misconceptions about malnutrition in renal patients (Section I). This clinical framework is consistent with the Coalition's goal of providing medically necessary nutrition therapy to renal patients. Among other things, we explain that daily tube feedings are often contraindicated in the dialysis population. Following this discussion are copies of selected journal articles referenced in the paper addressing IDPN therapy results.

Second, we have included in Section II a brief summary of the Medicare statutory and HCFA and carrier manual provisions governing IDPN therapy, which establish unequivocally that parenteral nutrition provided to end-stage renal disease ("ESRD") patients is a covered benefit, and that there has been no legal change in the scope of coverage as a result of the transition to DMERCs.

Third, we will document improper and inconsistent claims processing determinations and highlight our procedural and substantive concerns with the review and fair hearing process (Section III). Fourth, we provide proposed Medicare coverage criteria to facilitate IDPN claim reviews (Section IV), and an IDPN Patient Information Form (Section V) which we believe the DMERCs should utilize to provide a consistent and clinically appropriate review of all IDPN claims, including those which have been reviewed and denied since the transition to DMERCs. Lastly, we include standards of practice for IDPN (Section VI) which reflect current clinical practice guidelines for IDPN therapy.

We appreciate your consideration of this important issue. We understand that HCFA and the DMERCs are in the process of clarifying the Medicare coverage policy for parenteral and enteral nutrition, including IDPN therapy. We believe our efforts to resolve the serious problems being experienced with IDPN claims should be addressed as part of this ongoing effort as soon as possible. Robert Tallon, M.D., M.P.W., of Strategic Healthcare Management, will be contacting your office to schedule a meeting with you and your staff to discuss our concerns. In the meantime, if you have any

questions concerning this matter or require further information, please contact Jerry Francesco on behalf of the Coalition at (610) 494-8700.

Sincerely,

COALITION FOR RENAL NUTRITION, INC.

HAEMOTRONIC, INC.
HOME HEALTHCARE RESOURCES INC.
INTRX HEALTHCARE
IV SERVICES LTD.
I.V. SPECIALISTS, INC.
METAFUSION, INC.
NATIONAL INFUSION SERVICES
NUTRACARE
PENTECH INFUSIONS, INC.
PROFESSIONAL INFUSION SERVICES, INC.
TOTAL RENAL CARE, INC.
VIVRA/ASSOCIATED HEALTH SERVICES
Y MEDICAL ASSOCIATION, INC.

Attachments

cc (w/ attachments): Mr. Thomas Hoyer, HCFA (VIA HAND DELIVERY)
Ms. Carol J. Walton, HCFA (VIA HAND DELIVERY)