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THE WHITE HOUSE
WASHINGTON

JUL 22 1994

Dr. Paul Delay
Senior Technical Advisor
Attn: Working Paper Response
U.S.A.I.D
G/PHN/HIV-AIDS
SA-18, Suite #1200
Washington, DC 20523-1817

Dear Dr. Delay:

My staff and I have had an opportunity review the USAID Working Policy Guidance Paper on HIV/AIDS, and have several comments for your consideration.

The emphasis on research activities designed to elicit more information about behavioral and epidemiologic aspects of the epidemic should be clearly focused on the development of new interventions. One potential area of research not mentioned is transmission of HIV through breast milk, in view of USAID's efforts to promote breast feeding. This may be best coordinated with other research agencies, given the increasing numbers of women of child-bearing age who are HIV positive.

While sexual transmission accounts for 85% of the global cases of HIV infection, contaminated blood supplies, poor infection control and injecting drug practices are also important. These known avenues of transmission should be examined at both the policy and programmatic levels in order to address all aspects of the pandemic. Coordination with the Global Programme on AIDS Blood Safety Initiative and indigenous programs operating at the national and local levels is an essential component of this approach.

The co-sponsored program on HIV/AIDS (WHO/GPA, UNICEF, UNFPA, UNDP and World Bank), is not mentioned in the appendix section #2, Coordination With Other Donors And Federal Agencies. There is no analysis of how USAID, as one of GPA's major supporters, plans to coordinate activities with the development and implementation of this new program.

Mission strategies, as well as headquarters guidance, should be negotiated with the country's national program and national plan as a framework and reference point in order to ensure the success of community based interventions.

It would be helpful to know the criteria for selecting "emphasis" countries. This information would assist in framing the policy analysis, especially in view of USAID's current plan to close or

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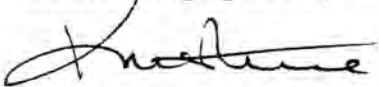
regionalize some of its missions. Will the emphasis countries be selected where the epidemic has not yet peaked or will they be countries where the epidemic is firmly entrenched?

We also encourage you not to disenfranchise any population affected by the pandemic, particularly the gay community, as this population has been severely affected by the pandemic.

US based PVOs should also be encouraged to develop stronger linkages with indigenous PVOs and NGOs in order to coordinate programmatic emphases and avoid duplication of resources.

In summary, I found the draft policy guidance to be well written with evidence of thoughtful work on the part of USAID. I hope you will consider the above comments as constructive input for your final document.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Kristine', with a stylized flourish at the end.

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

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HIV/AIDS WORKING PAPER

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HIV/AIDS WORKING PAPER

EXECUTIVE SUMMARY

As we enter the second decade of the global epidemic of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) we are now witnessing the enormous toll in human suffering and the threat to the economic and social viability, and political stability of many societies around the world. This document is intended to update and refine Agency strategy for HIV/AIDS activities and reaffirms USAID's strong and continuing commitment to providing assistance that will help developing countries address the challenges posed by the HIV/AIDS pandemic.

Estimates prepared by the World Health Organization Global Programme on AIDS (WHO/GPA) indicate that by end of 1994 approximately fifteen million people worldwide will have been infected with HIV (the virus that causes AIDS) and conservative estimates indicate that as many as 30 to 40 million people will be infected with HIV by the year 2000. Sexual transmission of HIV accounts for over 85% of the cumulative adult HIV infections in the world. Analysis of surveillance data indicates that young women are at greater risk of HIV infection than their male counterparts due, in part, to the increased biologic efficiency of sexual transmission from men to women and to the socio-economic status of women in many areas of the world.

Unlike the other major communicable diseases (malaria, measles, infectious diarrhea, etc.), AIDS primarily increases deaths among young adults between the ages of 14 and 49. This generates periods of prolonged morbidity and excessive population losses in the most productive years of life and leaves children orphaned due to HIV-related deaths in the family. Many development gains made within the last decade could be negated as a result of the pandemic.

The impact of HIV/AIDS goes much beyond the health sector and, therefore, must be considered in its broader societal context. Clearly, the health of the population and the impact on health services delivery will be severely affected. In some countries, the major improvements seen in the past two decades in infant and child mortality rates are now being reversed by HIV/AIDS. There are increased demands on health budgets and social service delivery systems (including personnel, hospital beds, drugs, etc.). Primarily as a result of the HIV/AIDS epidemic, there is now a major secondary epidemic of tuberculosis, affecting both HIV infected persons and persons who are not infected with the AIDS virus. In the severely affected countries of Asia and east Africa, approximately 25-30 percent of household income is being devoted for care and support costs for family members with HIV related illness. In east Africa, socio-economic impact studies demonstrate negative impact on specific sectors of the "modern" labor sector, particularly mining, trucking/transportation, and personal services. High rates of HIV infection among police and military personnel could threaten internal and national security. Multiple socio-economic impact studies show that the aggregation of negative impacts at the household and sectoral levels, decreases in overall domestic savings and investment levels, possible

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negative effect of HIV/AIDS on foreign investment decisions, reductions in the volumes of imports and exports with implications for balance of payments and growth, and reduction in receipts from tourism, may all combine to impact on the macroeconomy.

Worldwide, the most prevalent route of HIV transmission is through heterosexual contact. Among the many factors influencing the sexual dissemination of HIV in the developing world, five are particularly important: high risk sexual behaviors, the lack of optimal interventions to limit sexual transmission, high rates of other sexually transmitted diseases (STDs), the socio-economic status of women, and migration. (e.g. urbanization, migrant workers)

The enormous demands for assistance presented by the HIV/AIDS pandemic will exceed currently available resources. Therefore, USAID will have to focus its own efforts, and continue to encourage both improved donor coordination and the provision of assistance by other donors.

USAID will support two major areas of HIV/AIDS prevention activities. Some projects involve the implementation of a significant level of the currently available prevention interventions. These projects should ultimately decrease the number of persons infected by HIV and, thus, decrease the severity of the global epidemic. Other activities supported by USAID are intended to identify and develop new, more effective interventions to continually add to the world's current programs.

It is essential to utilize a rational, transparent, and consistent approach to priority setting for the myriad of possible activities that USAID could support and to maintain an appropriate balance between those programs that implement prevention activities at country level and those projects that seek to identify and validate new interventions. Consideration must be given to cost, duration of activity, anticipated impact, comparative advantage, level of urgency, applicability to current projects, and perceived gaps in implementation or research that are not being addressed by other organizations.

To achieve impact on the global epidemic it will be necessary to provide bilateral support to strategic countries and continue support for coordinated multilateral HIV/AIDS prevention projects. To increase the potential for program impact, and effectively use available resources, USAID will concentrate resources on a limited number of emphasis countries while maintaining more modest programs in others. In both emphasis and non-emphasis countries, USAID will look for ways to strengthen indigenous capacities and leverage public and private resources in order to maintain active HIV/AIDS prevention programs.

The interventions emphasized by USAID's HIV/AIDS prevention activities are in response to clear epidemiological trends, results from behavioral, biomedical, and operations research, and knowledge gained from successful behavior-change interventions conducted to date. USAID HIV/AIDS programs will, therefore, focus primarily on preventing the sexual transmission of

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HIV infection through:

- o- Promoting safe sexual behavior through information, education and communication;
- o- Increasing the demand for, access to, and use of condoms;
- o- Controlling STDs through improving the provision of STD diagnosis and treatment services;
- o- Policy dialogue with host country decision makers.

A community-based approach will continue to be integral to the implementation of USAID's HIV/AIDS prevention strategies. Because the U.S. PVO community is uniquely placed to share their experience and transfer capacity to indigenous NGOs, USAID encourages linkages between the two groups.

In addition to focused HIV/AIDS/STD prevention projects, it will be critical to identify opportunities to integrate prevention activities with other USAID sustainable development efforts, particularly in the health, population and economic growth sectors. USAID will continue to support the efforts of the UN multilateral organizations including GPA/WHO, UNDP, UNICEF, and UNFPA.

Because of the limitations on currently available interventions, it is essential to develop new, more effective interventions in order to adequately prevent and control this epidemic. USAID possesses multiple comparative advantages to contribute to the global armamentarium of prevention tools and methods. The following list of activities represents current fields of pursuit and those areas that appear to be the most promising. The list should remain dynamic. The proportion of support for the development of new interventions will be based, in descending order of priority, on the following criteria:

- o- Research activities that will immediately and directly influence the effectiveness of existing programs. Priority will be given to studies that improve our understanding of the behaviors and epidemiology that are the principal contributors to the transmission of HIV infection. This should also include research activities that will identify more effective ways to change behavior, for example, the evaluation of the role that HIV testing may play on modifying behavior.
- o- Activities that will provide women with improved HIV prevention tools. These include the development of female controlled barrier methods, such as a microbicide, and the identification/development of rapid, simple STD diagnostics, particularly for the syndromic management symptomatic women and the screening of asymptomatic women. Optimizing ways to utilize family planning services is a priority.
- o- Activities that will serve policy dialogue and reform, including modelling and estimating socio-economic impact.
- o- Pilot projects and research to mitigate impact of HIV in severely affected areas. The

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primary thrust of USAID's activities will remain HIV/AIDS prevention. However, in those countries where HIV prevalence is high and the resulting large number of AIDS cases are threatening the integrity of the health care system, there is an inextricable link between prevention and care. The strategic plan will be too focus mainly on support for policy changes that will reduce the constraints and obstacles to community and home-based health care services for individuals and families with HIV infection and AIDS and operational research activities that will provide information on the effectiveness and cost of specific interventions, such as home based/community care and short course therapy for tuberculosis, rather than the general procurement of drugs and supplies for patients.

o- Activities that support the discovery and utilization of a HIV Vaccine. USAID's role should be limited to exploring and facilitating opportunities for field trials of promising vaccines.

As the epidemic continues to expand more rapidly than existing resources, it is crucial that we improve our ability to monitor and evaluate the effectiveness of our prevention interventions. The indicators of progress and success will differ significantly between the short and long term. Because of the epidemiologic dynamics of HIV transmission and the existence of a long term HIV "carrier" state, it is anticipated that, even in the presence of extremely effective prevention interventions, decreases of HIV prevalence will not be measurable for at least 10 to 15 years at a national level.

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HIV/AIDS WORKING PAPER

I. INTRODUCTION

We are now entering the second decade of the global epidemic of human Immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS). No region of the world has been spared. The epidemic continues to exact an enormous toll in human suffering and threatens to compromise the economic and social viability, and political stability of many societies around the world. Particularly hard-hit are the fragile health care and social service delivery systems of many developing countries where demands are great and available resources are easily overwhelmed.

In April 1987, in recognition of the threat to human life and the potential for a broad development impact of the HIV/AIDS pandemic, the U. S. Agency for International Development (USAID) drafted its first comprehensive Policy Guidance on HIV/AIDS. Now, with seven years of experience in over 70 countries, it is appropriate to review and refine this policy. The document that follows replaces that guidance and reaffirms USAID's strong and continuing commitment to providing assistance that will help developing countries address the challenges posed by the HIV/AIDS pandemic.

II. STATUS OF THE EPIDEMIC

Estimates prepared by the World Health Organization Global Programme on AIDS (WHO/GPA) indicate that by end of 1994 approximately fifteen million people worldwide will have been infected with HIV (the virus that causes AIDS) and conservative estimates indicate that as many as 30 to 40 million people will be infected with HIV by the year 2000. Current evidence shows that most, if not all, persons who are infected with HIV will eventually develop AIDS and die. In the near future, prospects are poor for the development of preventive vaccines and/or therapeutic agents which would cure AIDS. In addition, access to drugs which may prolong the life of persons in developing countries with HIV infection is limited by high costs and the necessity for intensive medical monitoring.

In examining the geographic spread of HIV infections around the world, distinct trends in the levels and modes of infection have emerged. In regions with the highest rate of HIV infection, such as in countries in East and Central Africa, the prevalence of infection has reached frighteningly high levels – up to 30% of urban adults in Malawi, Zambia, Botswana, Rwanda, and Uganda. Moreover, HIV infection is becoming newly established in other geographic areas such as West Africa, parts of Latin America, and in Asia. Data from antenatal clinic attenders is considered representative of the general adult community, and HIV seroprevalence rates from 1% to 4% in antenatal clinic attenders are now being seen in urban Honduras, India, and in Thailand, with much higher prevalence rates seen in subpopulations who are engaged in high risk activities, such as commercial sex workers and patients at sexually transmitted disease (STD) clinics. If the epidemic in Asia continues to expand at the rates that are now being

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documented in Thailand, India, and Myanmar, then by the year 2005 the cumulative number of HIV infected persons in Asia will exceed all other continents.

Sexual transmission of HIV accounts for over 85% of the cumulative adult HIV infections in the world. Analysis of surveillance data indicates that young women are at greater risk of HIV infection than their male counterparts due, in part, to the increased biologic efficiency of sexual transmission from men to women and to the socio-economic status of women in many areas of the world. Over 5 million females (40% of the total number of infected adults) are infected world-wide with HIV/AIDS, eighty percent of whom are in sub-Saharan Africa. In some regions the incidence of HIV infections in women is increasing faster than in men, and in some African urban areas, more women than men are infected.

III. THE RATIONALE FOR USAID TO SUPPORT HIV/AIDS PREVENTION AND CONTROL

Unlike the other major communicable diseases (malaria, measles, infectious diarrheas, etc.), AIDS primarily increases deaths among young adults between the ages of 14 and 49. This generates periods of prolonged morbidity and excessive population losses in the most productive years of life and leaves children orphaned due to HIV-related deaths in the family.

Many development gains made within the last decade could be negated as a result of the pandemic. The impact of HIV/AIDS goes much beyond the health sector and therefore must be considered in its broader societal context. Although the developmental impacts of HIV/AIDS are extremely complex, the epidemic is likely to adversely affect society and the human resource base in the following major areas:

o **Health Sector:** Clearly, the health of the population and the impact on health services delivery will be severely affected. In some countries, the major improvements seen in the past two decades in infant and child mortality rates are now being reversed by HIV/AIDS. For example, in Malawi, the infant mortality rate has gone from 150/1000 live births to 167/1000 live births during the past three years, and the child mortality rate from 220 to 250. There are increased demands on health budgets and social service delivery systems (including personnel, hospital beds, drugs, etc.) as a result of HIV/AIDS and the associated opportunistic infections. Studies in east Africa and Asia indicate that by the year 2010, 80 percent of the health care budget of some Ministries of Health could be expended on HIV related treatment costs. As these demands increase, some countries are responding by restricting health care access for those with HIV related illness. Persons with HIV disease are sent home to die with minimal or no health care support. Primarily as a result of the HIV/AIDS epidemic, there is now a major secondary epidemic of tuberculosis, affecting both HIV infected persons and persons who are not infected with the AIDS virus. In countries in east Africa and in Thailand, the annual TB notification rates have doubled in the past three years.

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o Families/Households: Recent studies, which use computer modeling of the epidemic over the next twenty years, combined with information on coping mechanisms of families who have experienced deaths in adult family members and data on actual costs for both formal and traditional health care, indicate a profound impact at the family level. In the severely affected countries of Asia and east Africa, approximately 25-30 percent of household income is being devoted for care and support costs for family members with HIV related illness. If this is combined with the loss of earnings from sick individuals, nearly 75% of the family annual income is lost due to HIV/AIDS. In the second year, with a subsequent loss of another adult and one child from HIV related disease, 100 to 165% of household income is lost. This microeconomic impact will, in turn, affect the status of villages/communities and, ultimately, specific sectors of the macroeconomy. There will be: increased household expenditures and reduced savings and investment; changes in labor allocation decisions and output choices (including moves toward a less labor-intensive production mix); reduced investment in education and reduced educational performance; changes in family structure (particularly an increase in the number of orphans); exhaustion of household ability to cope with adverse conditions such as drought; and reduced food security at the household-level. In Uganda, the ability for the extended family to care for orphans is now seen to be exhausted after two to three years of a significant number of AIDS adult deaths.

o Community: The impact that is seen at the household level extends to the community. There is additional negative impact on community level agricultural productivity and maintenance of community service projects, such as potable water supplies.

o Agricultural sector: Preliminary information demonstrates a movement toward less labor intensive crops and crop production technologies, and reductions in marketed output, with possible implications for food security at the national level. Studies are now being undertaken in the Offices of Health and Agriculture in USAID, in cooperation with the U.S.D.A., to better define this impact.

o Industrial sector: In east Africa, socio-economic impact studies demonstrate negative impact on specific sectors of the "modern" labor sector. This is defined as any industry which employs greater than ten staff. Those sectors most severely impacted are mining, trucking/transportation, and personal services. Further information is needed to determine the extent of possible increases in production costs due to increased morbidity in the workforce, decreased productivity, and increases in employer-funded medical costs; negative impacts on the quantity and quality of labor supply; and negative impacts on investment decisions, including investment in human capital. Anecdotal data indicates that some industries are increasing the ratio of trainees to workers in order to mitigate the effect of loss of employees.

o Political Sector: There are potential impacts on political stability in countries where

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key officials succumb to the disease and potential successors struggle for power; and a possible search for scapegoats that will focus on leaders who fail to stop the epidemic.

o **Security/Military Sectors:** High rates of HIV infection among police and military personnel could threaten internal and national security. In some countries in Africa and Asia, 15 to 40% of military recruits are HIV positive. In specific cadres of the military, such as fighter pilots, the HIV seroprevalence approaches 100%. While the U.S. Government supports demobilization of military forces in developing countries because of the economic drain, this could further exacerbate the HIV/AIDS epidemic through increased transmission by HIV positive military personnel returning to their villages and homes.

o **Macroeconomy:** Multiple socio-economic impact studies show that the aggregation of negative impacts at the household and sectoral levels, decreases in overall domestic savings and investment levels, possible negative effect of HIV/AIDS on foreign investment decisions, reductions in the volumes of imports and exports with implications for balance of payments and growth, and reduction in receipts from tourism, may all combine to impact on the macroeconomy. However, classic macroeconomic indicators, such as Gross National Product (GNP) and Gross Domestic Product (GDP) per capita, may not be useful to truly measure this impact. New paradigms are required to allow for the evaluation of impact of various health problems at the macroeconomic level. Studies are now underway to assess the spectrum of potential monitoring methods.

The potential impacts of HIV/AIDS on development, as well as the impacts of development activities on the spread of the disease, will therefore need to be carefully considered in the formulation of USAID development strategies, objectives, programs, projects and evaluation systems. In sum, given the broad and compelling implications of the HIV/AIDS pandemic on the people of the developing world, its epidemiology, and its potential impact on micro and macro development, USAID will sustain a strong commitment to HIV/AIDS programs.

IV. LESSONS LEARNED

Worldwide, the most prevalent route of HIV transmission is through heterosexual contact. Among the many factors influencing the sexual dissemination of HIV in the developing world, five are particularly important: high risk sexual behaviors, the lack of optimal interventions to limit sexual transmission, high rates of other sexually transmitted diseases (STDs), the socio-economic status of women, and migration. (e.g. urbanization, migrant workers)

A. High risk sexual behaviors include: multiple sexual partners, non-use or ineffective use of condoms within non-monogamous relationships, and frequent use of commercial sex. Success in HIV/AIDS prevention is predicated upon the ability to effectively influence the behavior of large numbers of individuals who engage in these high risk

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sexual behaviors.

B. Limitations of available public health interventions: Sexual abstinence, decreasing the number of casual sexual partners, avoiding the use of commercial sex workers, maintaining faithful monogamous or polygamous relationships, and consistent, correct condom use are the only prevention interventions currently available. However, all of these interventions require significant behavior changes and cultural traditions/practices and political/religious opposition may make timely adoption of these methods difficult. More than any other epidemic in modern history, the global effort to contain and combat HIV/AIDS (at least in the near future) is dependent more upon behavioral modification interventions than upon medical or clinical action. AIDS education and communication programs help to modify behavior. Providing a spectrum of alternative behavior modifications for preventing and controlling the spread of HIV/AIDS is essential. Increasing demand for and access to condoms is a key factor in reducing the transmission of HIV infection. To date, efforts have been most effective when conducted at the sub-national level and when focused on specific communities or target groups. Multiple reinforcing channels of communication aimed at changing knowledge and attitudes toward sexual behavior are preludes to behavior modification. Modifying the social norms combined with awareness of personal risk are the next critical steps.

C. STDs: The presence of sexually transmitted diseases (STDs), particularly those that cause genital ulcers (syphilis, chancroid), increases the efficiency of sexual transmission of HIV by 5 to 20 times. Persons with STDs are logical targets for communication campaigns to induce behavior change to engage in safer sexual practices. Educational campaigns that focus on STD patients can have up to eight times as large a preventive impact as those aimed at the general adult population. Besides primary prevention activities, it is equally important to improve the quality of clinical services, both public and private, for the diagnosis and treatment of STDs to limit the infectivity and duration of active STD infections.

D. Women's status is a significant factor in the sexual transmission of HIV/AIDS. In many societies where men have greater access to economic resources, and where social/religious conventions and legal status maintain gender inequities, women are disadvantaged in their ability to negotiate sexual relations with men. Women and girls with limited education are also less able/likely to respond to information about the disease and to take preventive measures. Addressing the economic determinants of prostitution represents a major challenge for prevention activities to truly be effective.

E. Migration: Often concomitant with development is the rapid movement towards urbanization which is largely fueled by young-adult migrants. Separated from family and traditional values, these migrants are often among the earliest populations to become infected with STDs and HIV. Migrant labor flows also exacerbate the situation by

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Increasing the spread of HIV/AIDS both within and between countries. It is critical that USAID insure that within the design and implementation of its various development projects there are attempts to lessen these potentially adverse impacts on HIV transmission.

V. STRATEGY

The guidance provided by this document is intended to be flexible, building on the lessons learned and enabling USAID to respond quickly to incorporate new advances in HIV/AIDS prevention and control measures as they are developed. In order to remain relevant and useful, this guidance will be reviewed and revised periodically.

The enormous demands for assistance presented by the HIV/AIDS pandemic will exceed currently available resources. WHO now estimates that it would cost between \$1.5 and \$2.9 billion dollars per year to provide adequate support for global HIV/AIDS and STD prevention efforts in the developing world. Currently, less than \$200 million is expended annually in the developing world on HIV prevention. Therefore, USAID will have to focus its own efforts, and continue to encourage both improved donor coordination and the provision of assistance by other donors.

USAID will support two major areas of HIV/AIDS prevention activities. Some projects involve the implementation of a significant level of the currently available prevention interventions. These projects should ultimately decrease the number of persons infected by HIV and, thus, decrease the severity of the global epidemic. Other activities supported by USAID are intended to identify and develop new, more effective interventions to continually add to the world's current programs. The distinctions made between the two areas is admittedly arbitrary. Clearly, all intervention programs, no matter how small or large, should serve as "laboratories" for evaluating effectiveness and should be designed to allow this evaluation to inform future revisions of the project.

It is essential to utilize a rational and consistent approach to priority setting for the myriad of possible activities that USAID could support and to maintain an appropriate balance between those programs that implement prevention activities at country level and those projects that seek to identify and validate new interventions. Consideration must be given to cost, duration, comparative advantage, level of urgency, applicability to current projects, and perceived gaps in implementation or research that are not being addressed by other organizations.

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A. ACHIEVING IMPACT ON THE GLOBAL EPIDEMIC

Achieving impact on the global epidemic will involve bilateral support to strategic countries and continued support for coordinated multilateral HIV/AIDS prevention projects. Based on currently available and projected resources, major, comprehensive country level projects will be limited in number to no more than 20 countries.

1. Bilateral Programs in Strategic Countries:

While a number of USAID-funded and other HIV/AIDS prevention activities to date have shown considerable success in limited populations, in no country has the overall scale of the prevention program been large enough to halt or reverse the course of the epidemic. To increase the potential for program impact, and effectively use available resources, USAID will concentrate resources on a limited number of emphasis countries while maintaining more modest programs in others. In coordination with the host government and other donors, HIV/AIDS prevention programs will be established in these emphasis countries using bilateral and central resources. USAID will establish a set of emphasis countries based on a combination of the following characteristics:

- o Epidemiologic indicators which reflect a high level of HIV infection and/or other STDs, or the likelihood of rapidly increasing levels of HIV prevalence;
- o Demographic and social indicators which indicate potential for high levels of at-risk behavior;
- o Evidence of national commitment to a comprehensive HIV/AIDS control program and the absorptive capacity within the public and private/NGO sectors for increased levels of support for HIV/AIDS prevention activities, considering the role that other donors may play in national prevention campaigns and the perceived deficiencies in the national program; and
- o Mission support for funding of HIV/AIDS prevention programs and the presence of Mission or other appropriate staff to facilitate and implement HIV/AIDS interventions; and

In the selection of these emphasis countries, there will be consideration of their global strategic importance. The emphasis countries should be defined based either on their critical role in the transmission dynamics of the epidemic or because they are representative of the region and are

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potentially valuable for baseline research (either biological or behavioral) and the piloting of prevention interventions.

"Areas of affinity" is the concept that clusters of countries may share characteristics which could affect the spread of HIV and which could positively or negatively influence prevention efforts. These characteristics can include, but are not limited to, religious, cultural, political, or demographic attributes. Trans-national surveys and prevention projects will allow sharing of appropriate resources, such as STD drug resistance data and educational tools, and should impact on the cross border dynamics of HIV transmission.

USAID/Washington will continue to work in settings outside emphasis countries on a more limited scale, responding to requests for technical assistance and other USAID-generated assistance requirements.

In both emphasis and non-emphasis countries, USAID will look for ways to strengthen indigenous capacities and leverage public and private resources in order to maintain active HIV/AIDS prevention programs. The Agency's HIV/AIDS program will continue to be based on bilateral efforts that work in support of host-country, Mission strategic objectives, and overall Agency priorities. Bilateral activities will receive strong USAID/Washington support and technical guidance, and will be conducted in coordination with other donors.

In addition to focused HIV/AIDS/STD prevention projects, it will be critical to identify opportunities to integrate prevention activities with other USAID sustainable development efforts, particularly in the health, population and economic growth sectors. Both the positive as well as negative implications for HIV transmission of USAID's other projects must be considered and addressed. For example, the mainly male migrant work camps that are created during construction projects can foster increased utilization of commercial sex workers. Prevention interventions should be incorporated into these other projects.

The interventions emphasized by USAID's HIV/AIDS prevention activities are in response to clear epidemiological trends, results from behavioral, biomedical, and operational research, and knowledge gained from successful behavior-change interventions conducted to date. USAID HIV/AIDS programs will, therefore, focus primarily on preventing the sexual transmission of HIV infection. However, if significant new technologies become available, these must be considered and appropriately included in current projects. USAID activities will concentrate on:

- o Promoting safe sexual behavior through information, education and communication:
USAID experience with information, education and communication (IEC) initiatives in both health and family planning programs is already being applied to the prevention of HIV/AIDS. Communication programs must strengthen existing societal norms that support an individual's ability to change to healthier,

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lower risk behaviors. Multiple reinforcing channels of communication will be used to enhance audience reach and message effectiveness. They may include:

- interpersonal communication
- institutional networks
- print and audiovisual materials
- mass media

For example, contraceptive social marketing has proven that concepts and products can be presented and successfully adopted by large portions of national populations. Further application of social marketing techniques to prevent HIV/AIDS is needed to achieve overall disease prevention objectives.

In the design and monitoring of communication activities, it is essential improve our understanding of sexual behaviors, especially as they are influenced by community and culture. Behavioral research and surveys will be conducted to refine and evaluate prevention activities.

o Increasing the demand for, access to and use of condoms;

Condom use is considered to be approximately 90 percent effective in preventing HIV infection. Although condom use has risen sharply in countries with high rates of HIV infection, baseline rates of condom use were previously very low. The percent of users in at-risk populations is still unacceptably low. USAID will take the following approaches to increase demand for, access to, and use of condoms:

- coordinate/collaborate with existing population/family planning programs at the country-level;
- encourage collaboration and integration with contraceptive social marketing programs;
- encourage public-private sector partnerships for the marketing and provision of condoms;
- design condom programs that focus on:
 - institutional capacity building
 - condom promotion and proper use
 - condom supply and demand, quality assurance, distribution, and logistics
 - operations research and evaluation; and
- continue to dialogue with governments and to coordinate with other bilateral donors and international agencies in order to ensure the adequate supply and accessibility of affordable, high quality condoms for HIV/AIDS prevention. In specific circumstances, it may be necessary for USAID programs to procure condoms to insure the success of the prevention activities.

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Within USAID's HIV/AIDS programs, comprehensive reviews will be undertaken to assess the status of the entire condom supply operation, from estimating demand through logistics management for distribution, in order to ensure that programs deliver condoms efficiently and effectively to people at risk.

o Controlling STDs through improving the provision of STD diagnosis and treatment services:

Sexually transmitted diseases, such as syphilis and gonorrhea, play a unique role in this epidemic. STD patients are logical targets for communications for behavior change and the physical presence of an STD, particularly those causing genital ulceration, increases the efficiency of HIV transmission by 5 to 20 times. STD prevalence and incidence data also provide insights into the risk of further spread of HIV in a community and can serve as a dynamic indicator of the success of HIV prevention interventions. The goal of any STD prevention/control intervention is to improve the quality of diagnosis and treatment of STDs, to increase access and use of STD services, and to provide targeted education to STD patients. Behavior modification will be a significant focus of USAID's STD control efforts. Interventions that USAID will emphasize include: counseling for risk reduction (including partner reduction), promoting acceptability and correct use of condoms, encouraging compliance with medical prescriptions, notifying and treating sexual partners, training care providers in symptom recognition, assessing risks and changing attitudes. Communication initiatives will foster individual and community recognition of and demand for STD services, and community participation in planning for these services will also be encouraged.

USAID will strive to maximize the availability of appropriate health care services at the point of first encounter with the health care system, by providing prompt treatment with highly effective drugs using a syndrome based approach which does not require sophisticated laboratory support. A concerted effort will be made to establish STD screening capability at sites where women already seek health services. Existing service delivery systems of maternal and neonatal health care, family planning, and HIV/AIDS prevention, which already reach women in large numbers, will be utilized to the extent possible in the diagnosis and treatment of STDs.

USAID will emphasize strengthening STD case management in those groups whose behavior puts them at highest risk of infection. Since STD rates are often higher in urban and peri-urban areas, for example, services will often be concentrated in these areas.

USAID will continue to work closely with other donors and host governments on initiatives that require extensive resources, such as provision of STD treatment

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drugs and diagnostic supplies, to ensure that maximum impact is achieved.

o Policy dialogue with host country decision makers.

Gaining the support of key public and private-sector policy makers for HIV/AIDS prevention efforts is critical. The public-sector should encourage a broad, high-level, multi-sectoral response to HIV/AIDS across the agencies of host countries. Ministries of Education, Agriculture, Planning, Defense, Finance, and Health should all be encouraged to promote the appropriate integration of HIV/AIDS prevention activities. The expertise and influence of private sector representatives, can also be an extremely valuable aspect of achieving effective and comprehensive responses to HIV/AIDS prevention efforts, especially in the work place.

USAID will work with host governments and the private sector to bring about policy changes that address the social and cultural impediments to the successful implementation of HIV/AIDS programs, notably the role and status of women.

To heighten the awareness of key policy-makers as well as bring about policy change, USAID will continue to examine the potential development impact of HIV/AIDS as well as the effectiveness of prevention and control interventions on a given population or region. A critical tool in the policy dialogue is the use of computer models to project the epidemic into the future and to simulate the effect of various interventions. Raising the profile of HIV/AIDS activities will also assist in forging relationships between the public and private sectors to take advantage of the relative strengths of each in gaining a broad public understanding for and acceptance of HIV/AIDS prevention programs.

In addition to raising awareness of the impact of the disease on national development, USAID will work with host governments to better understand the impact that the development process may have on the spread of HIV/AIDS. As a result of an improved understanding of the complex nature of the problem, USAID will work with the public and private sectors to identify, develop and implement effective and symbiotic policies and programs which help to lessen negative impacts of HIV/AIDS.

A.I.D will focus its country activities on the above four interventions. However, as the epidemic evolves, it may be appropriate at the individual country-level to implement additional activities, such as gathering of specific epidemiologic/surveillance data and assisting country health services with management and care issues. This could involve piloting home based community care projects or focusing on the treatment of tuberculosis.

To complement and facilitate the implementation of HIV/AIDS prevention activities,

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public-private sector partnerships will be promoted. Private-sector participation will be encouraged in activities that are less effectively carried out by the public sector or which the public sector does not have the capacity to conduct. Examples of such activities include, but are not limited to, condom social marketing programs, market-research projects, and improving private-sector employee education and STD diagnostic and treatment practices.

A community-based approach will continue to be integral to the implementation of USAID's HIV/AIDS prevention strategies. Community-based groups are effective in working at the grassroots level and can effectively augment and complement public sector efforts in HIV/AIDS prevention. Community-based programs also offer access to hard-to-reach populations which are at high risk of acquiring and transmitting HIV infection, but are often excluded from public programs. Support of community-based programs helps to build indigenous capacities and in turn increases the likelihood that programs will be sustained.

Community-based organizations, including the traditional health care system (e.g. traditional birth attendants and healers), offer the flexibility needed to handle HIV/AIDS issues and, in many areas, operate the only functional health care delivery systems. Therefore, in implementing a community-based approach, USAID will strengthen its support for: local groups/organizations, e.g. women's groups, young farmers clubs; the traditional health care system; and U.S. based and indigenous private voluntary organizations (PVOs) and non-governmental organizations (NGOs). Because the U.S. PVO community is uniquely placed to share their experience and transfer capacity to indigenous NGOs, USAID encourages linkages between the two groups.

The fundamental goal of the Agency's HIV/AIDS-related efforts is to limit the spread of HIV infection in developing countries by building national capabilities to undertake prevention programs that are culturally appropriate. By averting disease, preventive approaches reduce future health expenditures and decrease the direct and indirect socio-economic losses associated with HIV/AIDS.

2. Support for Coordinated Multi-lateral HIV/AIDS Prevention Projects: USAID will continue to support the efforts of the UN multilateral organizations including GPA/WHO, UNDP, UNICEF, and UNFPA. USAID views WHO/GPA's role in providing policy, technical, and strategic guidance as complementary to its program implementation role, and continues to foster collaboration between the two organizations. Recently, as the involvement of the UN system has broadened to include other organizations, USAID has also begun to provide support to HIV/AIDS activities within UNICEF and UNDP to enhance their work. Each of these organizations provide unique strengths and skills which contribute to the control of the global epidemic. It is equally important to improve the coordination between the multilateral and bilateral community to maximize available resources and the effectiveness of all HIV prevention activities.

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**B. IDENTIFY AND DEVELOP
INNOVATIVE PREVENTION
INTERVENTIONS AND METHODS TO
MITIGATE IMPACT**

It is essential to develop new, more effective interventions in order to adequately prevent and control this epidemic. USAID possesses multiple comparative advantages to contribute to the global armamentarium of prevention tools and methods. The goals of USAID's HIV/AIDS research and development activities are to increase the capacity of developing country partners to reduce and ultimately stop the global spread of infection with HIV, and to lessen the adverse impact of HIV/AIDS on health and socioeconomic development. The following list of activities represent current fields of pursuit and those areas that appear to be the most promising. This list is not exhaustive and should remain dynamic. The proportion of support for the development of new interventions will be based, in descending order of priority, on the following criteria:

1. Research activities that will immediately and directly influence the effectiveness of existing programs.

These activities can be accomplished in a relatively short time-frame and have immediate effect on programs. Thus, priority will be given to studies that improve our understanding of the behaviors and epidemiology that are the principal contributors to the transmission of HIV infection. This should also include research activities that will identify more effective ways to change behavior, for example, the evaluation of the role that HIV testing may play in modifying behavior.

The challenges presented by the HIV/AIDS epidemic include the need for USAID to support linkages of biomedical, epidemiologic and behavioral research with operations research to design integrated prevention strategies. Three categories of research will be emphasized:

- (1) research to enhance program effectiveness;
- (2) research to identify more effective ways to change behavior; and
- (3) research to develop prevention technologies specifically adapted for use in developing countries.

Such research will be designed to: increase our understanding of the implications of distribution, occurrence, and persistence of unsafe sexual behavior; determine the most cost-effective mix of strategies for preventing sexual transmission of HIV; determine how to reach more people with fewer resources; and assess the relative effectiveness of alternative strategies for reducing the adverse impact of HIV/AIDS on health and socioeconomic development. In addition, USAID

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will continue to support a world-wide data base on HIV infection rates.

2. Activities that will provide women with improved HIV prevention tools.

These include the development of female controlled barrier methods, such as a microbicide, and the identification/development of rapid, simple STD diagnostics, particularly for the syndromic management symptomatic women and the screening of asymptomatic women. In order to improve women's access to communication campaigns for primary HIV/STD prevention, as well as to STD management, it is necessary to explore methods to increase the use of existing services for women. Optimizing ways to utilize family planning services is a priority.

3. Activities that will serve policy dialogue and reform.

This includes the development and utilization of tools that will project and simulate the epidemic and assess the potential socio-economic impact. Modelling endeavors tend to be relatively low cost and provide powerful arguments for policy makers and assist HIV prevention program managers with defining and prioritizing targeted interventions. A significant tool for policy dialogue is the ability to model and project over time the number of newly infected persons with HIV, the number of AIDS cases, and the potential impact of the epidemic on various sectors of the society. As an aid to the design and ongoing refinement of prevention programs, simulation modelling allows one to assess the impact of different interventions at varying degrees of efficacy. In order to improve planning for future development programs, USAID will also continue to conduct research on the economic, social and political impact of HIV/AIDS on development.

4. Pilot projects and research to mitigate impact of HIV in severely affected areas:

In countries where HIV prevalence is high, USAID may selectively provide limited support for activities that address the needs of HIV infected individuals. The primary thrust of USAID's activities will remain HIV/AIDS prevention. However, in those countries where HIV prevalence is high and the resulting large number of AIDS cases are threatening the integrity of the health care system, there is an inextricable link between prevention and care. The strategic plan will be to focus mainly on support for policy changes that will reduce the constraints and obstacles to community and home-based health care services for individuals and families with HIV infection and AIDS and operational research activities that will provide information on the effectiveness and cost of specific interventions, such as home based/community care and short course therapy for tuberculosis, rather than the general procurement of drugs and supplies for patients.

5. Activities that support the discovery and utilization of HIV Vaccines.

Multiple US Government organizations and private enterprises are involved in the research to

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Identify and develop an effective HIV/AIDS Vaccine. USAID's role should be limited to exploring and facilitating opportunities for field trials of promising vaccines.

Specifically, USAID will continue to support the efforts of other agencies (NIH, CDC, etc) and organizations in developing HIV vaccines and therapeutics by:

- o- continuing to provide support to WHO/GPA which uses these funds in part for the development of vaccine trial infrastructures in developing countries;**
- o- assisting vaccine and therapeutic researchers to identify and work effectively with national counterparts;**
- o- collaborating with investigators conducting clinical trials on HIV vaccines and therapeutics for the purpose of monitoring and preventing adverse effects of these new medical strategies on the implementation and effectiveness of existing prevention strategies; and**
- o- providing technical assistance in program development, operations research, and epidemiology as related to the conduct of HIV vaccines and therapeutics trials in developing countries.**

USAID's extensive field network will also be extremely useful for developing delivery systems and integration into existing health care programs if effective/affordable vaccines and therapeutics become available.

VI. MONITORING AND EVALUATION

As the epidemic continues to expand more rapidly than existing resources, it is crucial that we improve our ability to monitor and evaluate the effectiveness of our prevention interventions. The indicators of progress and success will differ significantly between the short and long term.

A. Short Term (5 years) To ensure the effectiveness of USAID-funded HIV/AIDS prevention activities, systematic assessment of programs will occur on an ongoing basis. All activities will incorporate quantifiable objectives and periodically assess progress in reaching these objectives. This formative information will be used to improve the design and implementation of current and future prevention programs. USAID, in collaboration with WHO, is establishing a standardized set of global prevention indicators to be used by both national HIV/AIDS control programs and the donor community. These indicators will measure:

- o knowledge by the target audience of preventive practices**
- o condom availability and use of condoms in relationships of risk**
- o proportion of the population who report "non-regular" sex partners**
- o the quality of STD case management**
- o the prevalence of specific STDs as proxy indicators for effectiveness of sexual transmission prevention activities.**

These indicators and other evaluation protocols are all intended to monitor the success of various intervention programs within a reasonably short time frame (1-5 years) and

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should be useful in the ongoing redesign of project activities.

In addition to monitoring program performance, USAID will conduct general program evaluation research to examine cross-cutting issues such as: (1) the comparative cost-effectiveness of different alternative AIDS interventions, (2) the effectiveness and impact of different alternative educational and informational approaches, and (3) the effectiveness of vertical (stand-alone) AIDS interventions versus AIDS interventions that are integrated into existing public health services.

B. Long Term (10-15 years)

The ultimate goal for HIV/AIDS prevention activities is demonstrable reduction of new HIV infections. Because of the epidemiologic dynamics of HIV transmission and the existence of a long term HIV "carrier" state, it is anticipated that, even in the presence of extremely effective prevention interventions, decreases of HIV prevalence will not be measurable for at least 10 to 15 years at a national level. Multi-lateral and bilateral donor cooperation should ensure that mechanisms be put into place which will allow for the periodic measurement of HIV incidence and prevalence, but caution must be observed to insure that unrealistic targets are not expected as part of 5 year program outcomes.

APPENDICES:

NOTE TO KRISTINE GEBBIE

SUBJECT: Meeting at USAID on Draft Policy Guidance

The purpose of this meeting was to discuss, in a group setting, the draft USAID policy guidance on HIV/AIDS. Attendees included: NALCOA, Whitman Walker Clinic, USAID Health Policy and HIV/AIDS, Africare, Project Hope, ChildHope, Christian Children's Fund, National Council on International Health, Family Health International, and International Council on Women's Research. The date of the meeting was July 6, 1994.

An overview of the document's history and process of development was given by Dr. Paul Delay. Two fundamental areas in developing this document were looking at project impact and prioritizing finite resources. The main focus for the future will be on USAID funded projects using their best interventions to interrupt transmission and pursue promising new areas related to intervention.

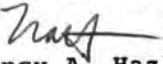
Dr. Neils Dellaire, Senior Policy Advisor for HIV/AIDS, discussed the overall framework for all of USAID's projects under the newly published Guidelines for Development. The four areas USAID will be concentrating on in the future are: stabilizing population growth; promoting health; sustaining the environment and promoting economic growth. Women's reproductive health will be the fulcrum on which all of USAID Population and Health Division will rest. An adjunct to this will be women's and girl's education. Influencing male power relationships and encouraging men to take responsibility for their sexual behavior and child rearing will also be part of this strategy.

Key issues for USAID as a whole were identified as 1) increasing effectiveness through new and major opportunities for impact and 2) to respond to weaknesses in policy. The discussion was then opened to the participants who were asked to comment on the document.

A variety of comments were offered. Most centered around participants areas of expertise. For example, Jim Graham, Whitman-Walker Clinic, was unhappy that the word "gay" was not mentioned anywhere in the document and that this omission effectively "disenfranchised an entire population." Ellen Weiss, International Women's Research Center, requested that language perjorative and stigmatizing to commercial sex workers be changed. There were not substantive comments relating to either the organization or focus of the document.

Dr. Dellaire and Dr. Delay thanked the participants for their comments and thoughtful input. They estimate that the comments will be incorporated and out in a final draft after the Yokohama meeting in August.

NB. This document is in sync with the Wirth strategy paper. Both strategies include prevention of new infections and reduction of personal and social impact although tasks reflect the primary mission of each agency. State is in a stronger leadership position to mobilize and unify national and international efforts through its diplomatic role while USAID is better able to fund and implement service delivery programs in prevention and care.


Nancy A. Hazleton, MPH

HIV/AIDS Working Paper



USAID

June 15, 1994

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APPENDIX 1. OTHER MODES OF HIV TRANSMISSION

Sexual transmission is well-established as the dominant mode of HIV transmission, accounting for almost 85% of all global adult HIV infections. Other modes are: mother to child transmission including breastfeeding; and blood-borne, including transmission related to blood transfusions, injectable drug-use, and contaminated medical and other skin piercing equipment.

Estimates prepared by the WHO/GPA indicate that the number of children worldwide who acquire HIV from an infected mother in utero or during the birthing process is expected to continue rising through the 1990s because of increases in HIV acquisition among women of child-bearing age. Studies have shown that roughly one-third of babies born worldwide to HIV-infected mothers become infected themselves. A proportion of this mother-to-infant transmission occurs during pregnancy and delivery. Preliminary data from Kenya and Rwanda indicates that up to 15% of perinatal transmission may be attributable to breastfeeding. The risk of HIV transmission through breastfeeding is greater among women who become infected during the breastfeeding period. This extremely disturbing information has profound implications on USAID's child survival projects and could lead to modifications in the global recommendations which encourage breast versus formula feeding for infants. The international medical community is now urgently engaged in undertaking further research to better define the efficiency of HIV transmission during breastfeeding.

Transmission through blood transfusion is less prevalent than through sexual transmission, and has been virtually eliminated in industrialized countries. Transmission through blood transfusion continues in many developing countries. Although transmission due to the sharing of needles between injecting drug users is a less prevalent mode of HIV transmission in most developing countries, it seems to be a fairly significant mode of transmission in parts of Southeast Asia accounting for up to 15% of all adult HIV transmission. HIV transmission through the use of contaminated medical equipment, including reused needles, accounts for an unknown, though presumably small proportion of all transmission.

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APPENDIX 2: COORDINATION WITH OTHER DONORS AND FEDERAL AGENCIES

USAID relationships with WHO/GPA, other donors, and other Federal agencies which also provide HIV/AIDS assistance are summarized below.

1. World Health Organization/Global Programme on HIV/AIDS (WHO/GPA):

WHO/GPA was formed in 1987 to provide global leadership and coordination in the development of policies, strategies, guidelines, and evaluation methods for national HIV/AIDS prevention and control programs. USAID played an important role in the formation of WHO/GPA and continues to be its largest financial supporter. The role of WHO/GPA is to plan and coordinate global HIV/AIDS activities to assist national program managers in the development of their national HIV/AIDS plans. The role of USAID is also to assist in the development of national HIV/AIDS plans as well as engage in policy dialogue with decision-makers and assist host-countries in the implementation of their national HIV/AIDS programs. USAID will continue to strengthen bilateral activities to further complement WHO/GPA efforts and to work with WHO/GPA to more efficiently allocate resources at the country-level.

2. Other Donors

While USAID is the largest bilateral donor to HIV/AIDS prevention efforts, a number of other bilateral and multilateral donors (e.g. UNDP, UNICEF) play a major role. USAID's relationship with these donors will be complementary and reinforcing. To further maximize the potential of different donors, USAID will seek new donor relationships or expanded involvement of present donors in providing goods and services in areas in which USAID has no comparative advantage.

3. Other Federal Agencies:

While USAID has a clear mandate as the lead Federal agency in development assistance, other Federal agencies are carrying out developing-country HIV/AIDS activities related to the mandates of those agencies. Most of these activities are research-oriented. In addition to providing resources and personnel for behavioral, operations and epidemiological research, these other Federal agencies (primarily the Department of Health and Human Services and the Department of Defense) conduct epidemiologic and biomedical research which focuses on developing scientific understandings that could enhance the ability to develop appropriate interventions, including vaccines, clinical treatment, virucides, etc. USAID can and should be instrumental in facilitating cooperation between counterparts in developing countries and U.S. researchers in the conduct of vaccine trials and other biomedical research.

THE WHITE HOUSE
WASHINGTON

July 25, 1994

Daniel P. McDougall, MA, CSC
Coordinator
Deaf AIDS Project
4221 Cass Avenue
Detroit, Michigan 48021

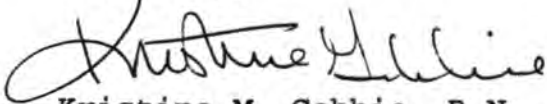
Dear Mr. McDougall:

Thank you for sharing the information about the deaf and hard of hearing community with me. As you know, the Office of National AIDS Policy was created out of the commitment of the President to take positive steps to stop the HIV/AIDS epidemic. As National AIDS Policy Coordinator, I, like you, am devoted to the development and implementation of policies that will stop the spread of HIV.

The deaf community must also be involved in stopping the spread of this disease. I have worked closely with members of the deaf community on increasing the services available to them. The information which you have sent is very valuable to the Office of National AIDS Policy.

Thank you again for sharing the information with me. Please continue to share information with me.

Sincerely,



Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

**AIDS Care
Connection**

MAY 3 | 1994

Helping people with
HIV receive the services
that they need.4221 Cass Avenue
Detroit, Michigan 48201
313.993.1320 Voice
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313.993.1345 Fax

30 May, 1994

Kristene M. Gibbie
National AIDS Coordinator
Office of National AIDS Policy
Executive Office of the President
Washington, DC 20500

Dear Ms. Gibbie,

During a recent conversation with Beth Ann Hazelwood, a well-known advocate of HIV services for the Deaf community in Rochester, New York, I was informed that your office is currently collecting information pertaining to HIV service needs across the country. As the Vice President of the **National Coalition on the Deaf Community and HIV (NCDH)**, I thought I might take a few moments of your time to draw your attention to a gross gap in HIV service delivery in the United States. Specifically, this gap represents the nearly non-existent HIV service delivery system targeting our Deaf and hard of hearing populations in our country: a community that has been estimated at numbers as high as twenty five million.

Since the onset of the HIV pandemic, the vast majority of HIV service delivery systems have assumed that their services adequately addressed the needs of the Deaf and hard of hearing populations (DHHP). This assumption has been based on a series of myths commonly held by the general population. These are:

- ◆ that Deaf and hard of hearing people are simply hearing people that are "broken";
- ◆ that the written word is an effective means toward delivering information and services to Deaf individuals; and
- ◆ that hard of hearing individuals can easily lip-read service providers.

These assumptions, while refuted by researchers in the fields of linguistics and sociology, are still commonly held perceptions of the DHHP. And, while these assumptions may only cause annoyance during daily cross-cultural encounters between hearing and Deaf individuals, the role they play in the provision of HIV services to the DHHP is far more detrimental.

In truth, Deaf and hard of hearing people are not simply hearing people that cannot hear. They represent a complex array of cultures, norms, languages, and communication strategies that are all but neglected in current HIV service delivery systems. Put simply,

*Gus - has 2
mgt deaf/hearing
upgraded people
gotten on the
calendar yet?
9th was running
if names*

*these 2 letters also
need diff replies -
Carlos should start*

- ◆ Deaf people use American Sign Language as their primary mode of communication. Recent studies reveal that the average Deaf High School graduate comprehends written English at a level between the *third and fourth grade*;
- ◆ Hard of hearing individuals (those who do not use American Sign Language, and who generally have more "residual" hearing) lip-read with varying, and unpredictable, levels of success. Previous studies indicate that a proficient lip reader may only "catch" twenty percent of any given sentence.

Given this information, it is easy to understand why members of the DHHP are at increased risk of HIV infection:

While service providers have been basing their service delivery to the DHHP on their perception of its members as a *disabled community*, a more suitable perception of the community is as a *linguistic/cultural minority*.

The impact of this error in judgment is clear: since the beginning of our war on HIV, the DHHP has been completely shut out of the services taken for granted by the population at large. HIV education and risk reduction efforts that are written (i.e.: pamphlets, books, etc.) have had no effect on the community, and face-to-face education, risk reduction, and services for people with HIV have generally not been available in American Sign Language, or in a way that demonstrates cultural sensitivity to the population. As a result, members of the DHHP are still without basic HIV information, and are at increased risk of infection. Furthermore, those Deaf people who are HIV infected face a brick wall when trying to access the service delivery systems already in place.

Exacerbating this problem is the nearly non-existent lack of funding to address the unique service needs of the DHHP. Public and private funding sources continue to perceive the DHHP as a group of "broken" hearing people, and therefore demand statistics representing high rates of infection within the community. The irony is that no system exists to track the rate of HIV infection in the DHHP. Some local testing programs conduct their own tracking, but these do not provide the range of numbers necessary to convince funding sources. Consequently, the handful of service providers scattered throughout the country are caught in a classic "Catch 22" scenario: we cannot develop the services to save the lives of those in our community because we cannot prove they're at risk; however, no one will provide us with the money necessary to track HIV infection in the DHHP.

Consequently, Deaf people *are* dying. A few facts:

- ◆ In Houston, on-going tracking of antibody test results in the DHHP reveal seropositivity rates in that community to be an incredible *22 percent*;
- ◆ There exist few permanent, paid staff positions in the country specifically addressing the HIV service needs in the DHHP. Those that do exist are commonly found in California, however, the needs of the large DHHP's throughout the country go largely un-met;
- ◆ Michigan, while having the seventh largest DHHP, has only one trained and qualified HIV service delivery individual paid to provide services to this community (myself). I provide for the entire state: HIV education/prevention services; pre/post-test counseling; case management; consultation; and administrative functions related to our Deaf AIDS Project. Currently, approximately one half of my salary is funded to serve the DHHP. The balance of my time is funded to serve the hearing community;
- ◆ Every HIV positive Deaf and hard of hearing person in the state of Michigan that I have come in contact with first became aware of his/her seropositivity *after being diagnosed with an AIDS-defining condition*. This situation is not unique to my state.

I could continue with a litany of co-factors and examples of the plight of the Deaf and hard of hearing community in their battle against HIV, but in the interest of space -- and your time -- I would like to summarize my perception as follows.

- ◆ Deaf and hard of hearing people in the United States are at an increased risk for HIV infection, due to the lack of linguistically and culturally appropriate education and risk reduction activities.
- ◆ For the same reasons, HIV positive members of this community progress along the continuum of HIV disease at a quicker rate, and suffer untimely and often un-necessarily gruesome deaths.
- ◆ These trends will continue, as long as public and private funding and administration sources continue to overlook the needs of this language minority.

The appropriate response to the needs of this community is clear. We must recognize that this community is unique, and accept the fact that data paralleling the hearing community is not currently available. We must develop an accurate reflection of the rate of HIV infection in the DHHP. We must decide that it is acceptable to fund Deaf AIDS programs based on the anecdotal information currently available, rather than deny the DHHP access to HIV education and services.

I feel comfortable speaking for the other members of the NCDH board when I offer our collective skills toward your endeavor to address the HIV service needs of our country. Collectively, our board represents the leadership in the field of Deafness and HIV from coast to coast, and I hope that you will consider us your resource toward this end. If you have any questions or comments regarding the information above, please feel free to contact me at the address and phone numbers above.

In advance, I thank you for the time you've taken to review this information, and I wish you the best of luck in your post.

Very Sincerely,

Daniel P. McDougall, MA, CSC
Coordinator
Deaf AIDS Project

To: Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

From: Carlos Velez, J.D. *WAV*
Prevention Cluster Lead

Date: July 18, 1994

Re: Prevention Issues for the Deaf Community

On June 8, 1994 our Office held a meeting with various representatives of the Deaf Community. Various issues were raised in the areas of prevention, services and research. In the area of prevention, the following were raised:

There are no federally funded prevention programs aimed at the deaf community;

There are very few federally funded materials aimed at deaf individuals; and,

Representation of members of the deaf community in the HIV Prevention Community Planning Groups being set up by CDC in all states has been limited or nonexistent.

CDC is providing technical assistance to the Community Planning Groups on how to conduct needs assessments on the prevention needs of the various communities that are at risk for HIV infection. The Academy for Educational Development (AED) is working with CDC to instruct the various Planning Committees on how to plan to develop prevention priorities for their communities. We are currently in discussions with CDC on how to address the needs of various communities that have received little or no attention in the past. One of the primary groups to be addressed will be the deaf community, especially deaf gay men, who are at increased risk for HIV due to their lack of access to information. Their inclusion in the planning process will ensure that deaf individuals in all parts of the country will receive programs that will address their prevention needs.

MAY 31 1994

**AIDS Care
Connection**

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313/993-1345 FAX



FACSIMILE COVER PAGE

To: Kristine Gibbie
Time: 21:46:30
Pages (including cover): 4

From: Routhier-McDougall
Date: 5/30/94

Ms. Gebbie,

I would appreciate a few moments of your time in reading the attached information regarding what I feel is a significant gap in HIV service provision in the United States.

THE WHITE HOUSE
WASHINGTON

July 25, 1994

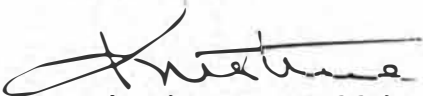
Deborah Steinkopf
Executive Director
P.O. Box 5171
Evanston, Illinois 60204

Dear Ms. Steinkopf:

I'm so sorry that a cancelled flight into Chicago changed my Saturday schedule, so that I was unable to visit the BE-HIV program in Evanston. Ed Obermiller certainly appreciated the opportunity, and has shared your newsletter and other materials with me.

My best wishes to you and those you serve in your community activities. I hope a have a chance to meet with you at some future date.

Sincerely,



Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

cc: John Meyers, Board Chair

THE WHITE HOUSE
WASHINGTON

COPY

July 25, 1994

Ms. Arlene Shipley
850 Waterman Road N.
Jacksonville, FL 32207

Dear Ms. Shipley:

Thank you for sharing Tashia's story with me. It is comforting to know that there are individuals like yourself who are willing to selflessly open their hearts and homes to people living with HIV and AIDS.

As you may know, the Office of National AIDS Policy was created as a result of the President's commitment to take positive steps to end the HIV/AIDS epidemic. The Administration is committed to stopping the spread of HIV, caring for those living with HIV and finding a cure as soon as possible. Our office shares your commitment of making accurate, culturally sensitive, and age-appropriate information available to all groups who seek education on HIV and AIDS.

In your letter you requested information on the Target Family Grant program as well as on any other resources that may be useful to you in your efforts to open a congregate living facility for women and children. The Office of National AIDS Policy does not provide funding for programs and activities. I have shared the information on your letter with the Associate Director for HIV/AIDS at the Health Resources and Services Administration (HRSA), which administers the Ryan White CARE Act funds. His office will be able to provide you information on any funding that may be available for HIV/AIDS related services. You may also be able to obtain more information from the National AIDS Clearinghouse, which maintains a database of available funding sources and can provide you with that information free of charge. The Clearinghouse can be reached toll-free at 1-800-458-5231.

I hope that you will continue your efforts to help children such as Tashia. Only through the work of individuals like yourself will we be able to effectively fight both child abuse and the AIDS epidemic.

Sincerely,



Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

cc: Associate Director for HIV/AIDS, HRSA

M. ARLENE SHIPLEY
850 Waterman Road N.
Jacksonville, Florida 32207

(904) 398-7798

April 25, 1994

Carlos
draft reply



MAY - 5 1994

Ms. Christine Gibbe
Office of AIDS Policy
The White House
Washington, DC 20503

Re: Recent telephone calls regarding Tashia's story

Dear Ms. Gibbe:

Thank you for taking time of your busy day let me share Tashia's story of heroism with you. (Is there such a word as heroinism -- it is sometimes so hard to be politically correct!)

As I discussed with Dr. Barrer, I am the foster mother of a little girl who died one month ago from AIDS. She had AIDS from SEXUAL ABUSE -- because HRS left her in that home, for at least seven years, with many abuse reports, different abusers, with multiple STD's and even with AIDS they put her back in that house. We got her one week after her 9th birthday; her "T" cell was zero at diagnosis and they told us she would not live 4 months. We kept her alive for two years to the day that God gave her to us.

She did not have to die -- but her cries for help were ignored until it was too late: she was ignored, abandoned and erased. No one else would take her, but my husband is a nurse and I am a survivor of 14 years of sexual abuse and one term away from a Masters in mental health counseling (I worked full-time, went to college full-time, cared for my mom with Alzheimers full-time, and cared for this dying child). Obviously I have a very wonderful husband -that is another story!

As I explained, we have applied for a 501(c)3 under Tashia's Guardian Angels, to open a congregate living facility for women and children so that the women do not lose their kids to foster care while they are dying -- the center will include a school and day care so that these kids will have a place to learn and play where they are wanted and loved. Later, a respite center for ALL sick children so their families have rejuvenation time, is planned (my husband and I did not have a night out for 18 months). The foundation will also build a standing AIDS educational museum in Tashia's memory. We will have national experts tell us what to put in each age-appropriate room for the designated audience: children, adults, gays and lesbians, adolescents, religious orientations, and abstinence slants. Using state of the art computers, videos, interactive games, and Tashia's story, etc., any group will have access to COMPLETE information if wanted. So our families may

bring their children, children may stop in alone and teachers may bring students with permissions slips. We will be giving our community a resource for information not presently available. We plan to make this a model for the entire nation. And I hope you will find it within your scope of influence to be of assistance. Your Target Family Grant program or other resources you may know of will be greatly appreciated.

Enclosed are my resume and a proposal to the local school board (it was accepted and I will begin presenting in June). I have also enclosed pertinent newspaper articles pertaining to my foster daughter's life.

The sexual abuse by at many men was not all this child suffered. She was illiterate because she was not sent to school. She had permanent scars on her face and body where she was held to an electric stove as punishment. She was tied to a chair, gagged and locked in the closet all night when her mother went out partying. She was repeatedly beaten and bones broken. But they never broke her spirit. She was diagnosed with at least five personalities from the abuse and you can imagine how hard this made her care. ~~For the first time in her life she was SAFE and happy, only to be dying a horrible, painful death.~~ My husband and I vowed to make what little life she had left as childlike as possible for her, and we did. We took her to Disneyworld, and she asked to come home, that she liked her bedroom better. She was allowed to be a little girl, to play and laugh and sing. People ask me how we could possibly do this -- I tell them that if they had listened to her prayers at night, praying to a God she did not know when she came to us (we had her baptized her first Easter Sunday), and hear all the things she thanked God for, and all the OTHER people she asked God to help, and then see her look at me and say, "Mommy, you make my heart sing!", they would see why we did it.

She did not know she was dying. She knew she had a disease and we spoke to her about the fact that all of us die. But SHE told us at the end. I was privileged to help this child have a final closure with her mother - as Tashia requested - one month before she died. We also adopted her, in God's eyes (articles enclosed) so that she felt safe - and she died twelve hours later. She couldn't wait to see God, and she asked me to help her die. She did not die alone, or afraid, as we promised her.

I believe God intends me to fight for all children now; I plan to tell the world Tashia's story - even though she died, it had a happy ending. She was loved, safe, permitted a childhood and many people helped her dreams come true. I can't, on paper, begin to tell you all of the lessons God let this world learn through the miracles worked in this child's life. My telling her story is already healing the lives of people in our community. It is a story that will continue to bring education, lessons, healing and miracles to our world - it is a story that can make your heart sing!

Knowing the school board will not educate our children properly, I have recently applied and been approved to go into the schools and do peer education for the teachers. By telling Tashia's story, how her life was either enhanced or diminished by the way she was treated (diminished at school), I am able to open up peoples hearts not to fear people with AIDS and to educate that you don't get it passively. I would appreciate the privilege of speaking to the various businesses, churches and organizations with which you are affiliated, or any referrals you might make. If you know of any grant programs that we can apply to for education, or the various programs we are instituting, please let me know.

I am going to all of the local businesses (American TransTech has scheduled two sessions), hospitals, etc. to do in-service AIDS education for their employees using Tashia's story. Last week I spoke at Baptist Hospital and a Mormon church. At Baptist a man called to tell me three people had apologized to him and that he was not going to have to quit his job because of harassment. At the church, after I was finished, a woman got up and disclosed that she had been HIV+ for six years and afraid to tell her congregation -- but after seeing how they responded, she felt she would be loved and accepted! This is what this wonderful child's death is meant to accomplish -- healing lives.

This is the first Mother's Day I will not be with Tashia, so I am traveling to Washington to deliver Mother's Day petition cards to President Clinton for the Mothers' Voices group.

Thank you for your time and consideration.



Arlene Shipley

THE WHITE HOUSE

WASHINGTON

July 25, 1994

James Peinkofer, C.S.W.
University of Rochester
Medical Center
601 Elmwood Avenue
Box 689
Rochester, New York 14642

Dear Mr. Peinkofer:

Thank you for writing and sharing the information on the Deaf AIDS Core with me. It was a pleasure to meet with you on my last trip to Rochester, New York. As you know, the Office of National AIDS Policy was created out of the commitment of the President to take positive steps to stop the HIV/AIDS epidemic. As National AIDS Policy Coordinator, I, like you, am devoted to the development and implementation of policies that will stop the spread of HIV.

The deaf community must also be involved in stopping the spread of this disease. I have worked closely with members of the deaf community on increasing the services available to them. The information which you have sent is very valuable to the Office of National AIDS Policy.

Thank you again for sharing the information with me. Please continue to share information with me.

Sincerely,



Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

To: Kristine Gebbie, RN, MN
National AIDS Policy Coordinator

From: Carlos Velez, J.D. *CV*
Prevention Cluster Lead

Date: July 18, 1994

Re: Prevention Issues for the Deaf Community

On June 8, 1994 our Office held a meeting with various representatives of the Deaf Community. Various issues were raised in the areas of prevention, services and research. In the area of prevention, the following were raised:

There are no federally funded prevention programs aimed at the deaf community;

There are very few federally funded materials aimed at deaf individuals; and,

Representation of members of the deaf community in the HIV Prevention Community Planning Groups being set up by CDC in all states has been limited or nonexistent.

CDC is providing technical assistance to the Community Planning Groups on how to conduct needs assessments on the prevention needs of the various communities that are at risk for HIV infection. The Academy for Educational Development (AED) is working with CDC to instruct the various Planning Committees on how to plan to develop prevention priorities for their communities. We are currently in discussions with CDC on how to address the needs of various communities that have received little or no attention in the past. One of the primary groups to be addressed will be the deaf community, especially deaf gay men, who are at increased risk for HIV due to their lack of access to information. Their inclusion in the planning process will ensure that deaf individuals in all parts of the country will receive programs that will address their prevention needs.

UNIVERSITY OF
ROCHESTER
MEDICAL CENTER

STRONG MEMORIAL HOSPITAL
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING
INFECTIOUS DISEASES CLINIC

*Carlos
Lizaga*

May 31, 1994

Ms. Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator
Office of National AIDS Policy
Executive Office of the President
Washington, D.C. 20500



JUN - 7 1994

Dear Ms. Gebbie:

It was indeed a pleasure both meeting you and interpreting for you at the recent HIV and the Primary Care Provider Conference held in Rochester, N.Y. on May 20th. Your keynote message was thoroughly informative and inspiring.

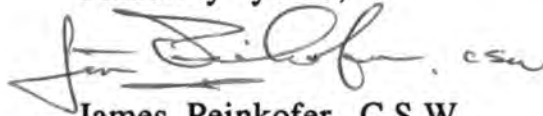
Thank you as well for my opportunity to briefly discuss with you about the HIV education and service needs of the Deaf community both in Rochester and the United States. I was unable to attend your afternoon town meeting as I was presenting a workshop at the provider conference. I understand that questions of services for the Deaf were brought up by audience members there as well.

As you informed me of a meeting you are having very shortly with members of the Deaf community to address HIV-related needs, I have enclosed two pieces of information that you may find helpful. The first is a tearsheet of an article which I wrote for *Public Health Reports* (May/June '94) and received just today. The second sheet describes the work of HIV/AIDS Network for the Deaf (H.A.N.D.), a subcommittee of the Rochester Area Task Force on AIDS, which I chair. In addition to the general information sheet, H.A.N.D. recently received two \$25,000 grants from the

N.Y.S. AIDS Institute. One will produce an HIV prevention/education video in American Sign Language targeting deaf teens and young adults. The second grant is for a interpreter reimbursement pool that HIV positive deaf individuals may utilize for their service needs. Both grants are very important for the large Deaf population in Rochester, and we hope they will have a beneficial outgrowth for the rest of the United States.

Again, it was a pleasure meeting you and if you have further questions or consultative needs, please call.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "James Peinkofer, C.S.W.", with a stylized flourish at the end.

James Peinkofer, C.S.W.
(716) - 275-0533

H.A.N.D.

The HIV/AIDS Network for the Deaf (HAND), is a group of individuals committed to the advocacy and coordination of services and resources, in Monroe County, N.Y. and the nine county catchment area of the Rochester Area Task Force on AIDS (RATFA), for people who are deaf or hard of hearing and living with HIV/AIDS, their families, their significant others and their friends and/or who are in need of other services (prevention, referral, education) related to HIV/AIDS.

The services HAND provides are:

- arranging public relations and media contacts regarding the needs of HIV/AIDS education and service to the Deaf and Hard of Hearing communities.*

- assisting with referrals of clients or other interested persons to Deaf AIDS Core (DAC) and other organizations.*

- providing a forum for networking service agencies and interested persons to the needs of HIV/AIDS education, prevention and care within the Deaf and Hard of Hearing communities.*

- offering guidance and encouragement to persons and agencies involved in HIV/AIDS service.*

Member agencies

*AIDS Rochester, Inc.	(716)-442-2220	(v/tdd)
*Deaf AIDS Core	(716)-235-3849	(tdd)
*Family Service of Rochester	(716)-232-1840	(v)
	(716)-232-1237	(tdd)
*Hillside Children's Center	(716)-256-7500	(v)
*Monroe Co. Assoc. for the Hearing-Impaired	(716)-423-9490	(v)
	(716)-423-9845	(tdd)
*New York State Dept. of Health	(716)-423-8116	(v/tdd)
*Rochester chapter of ADARA	(716)-461-1060	(tdd)
*Strong Mem. Hospital AIDS Center	(716)-275-0533	(v)
	(716)-273-1057	(tdd)
*Substance Abuse Intervention Srvs. f/t Deaf	(716)-475-5002	(v/tdd)

Other member agencies ('93-'94)

*DePaul Mental Health Services	(716)-232-2028 (tdd)
*Lilac Rainbow Alliance for the Deaf (LRAD)	(716)-454-6249 (tdd)
*John L. Norris Alcoholism Treatment Center	(716)-461-4253 (tdd)
*NTID Psychological Services	(716)-475-6770 (tdd)
	(716)-475-6587 (v)

H.A.N.D. Highlights

*10/29/92 - Nine people from various agencies gather as a new committee of the Rochester Area Task Force on AIDS (RATFA) to target the HIV prevention, education, and service needs of the Deaf in Rochester, N.Y.

*12/17/92 - After two months of meeting, the group has raised many issues to work on to bring HIV services to the Deaf. The group is officially named H.A.N.D. (Larry Warnow), from the former HIV/AIDS Service and Education for the Deaf (H.A.S.E.D.). H.A.N.D. agrees to work with and refer to Deaf AIDS Core (D.A.C.) with the understanding D.A.C. will fulfill all HIV educational requests.

*2/18/93 - H.A.N.D. finalizes its goals and mission statement.

*3/18/93 - Members create a section on deaf women for RATFA's Women's Health Care Initiative guidelines focusing on many barriers to care which deaf women experience daily.

*4/22/93 - H.A.N.D. is instrumental in bringing the message of HIV service to the Monroe Co. Association for Hearing-Impaired People (M.C.A.H.I.) 1993 Service Directory for the Deaf. Five pages (including the inside cover) highlight HIV service and educational programs locally.

*7/93 - Two members of H.A.N.D. attend the 1993 National Conference on HIV/AIDS and the Deaf in Los Angeles. Information learned at the conference is gathered and shared with other H.A.N.D. members in the Fall.

*11/17/93 - H.A.N.D. assesses the HIV educational needs of the working Deaf at six major local employers (Kodak, Xerox, etc.). HIV materials written for the Deaf are mailed to the corporation's health centers.

*2/22/94 - H.A.N.D. generates a list of new goals to accomplish for 1994.



Strong Memorial Hospital
AIDS Center

announces:

DEAF ACCESS SERVICES

- CONFIDENTIAL HIV TESTING
- TDD PHONE
- CONFIDENTIAL INTERPRETING
- SIGNING STAFF
- CASE MANAGEMENT FOR ALL

CALL FOR INFORMATION: (716)-273-1057 (TDD)
(716)-275-0526 (voice)

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HIV Education for the Deaf, A Vulnerable Minority

8pgs

HIV Education for the Deaf, A Vulnerable Minority

JAMES R. PEINKOFER, CSW

Mr. Peinkofer is a Social Worker at the AIDS Center of the University of Rochester's Strong Memorial Hospital. Tearsheet requests to James R. Peinkofer, CSW, Strong Memorial Hospital, Box 689, 601 Elmwood Avenue, Rochester, NY 14642; tel. 716-275-0533, TDD 716-273-1057; FAX 716-273-1055.

Synopsis

Large numbers of deaf and hard-of-hearing people are in danger of becoming infected with the human immunodeficiency virus (HIV). The deaf are particularly vulnerable because of language barriers,

their unique culture, and the paucity of community services, educational programs, and general information directed to this population.

The particular barriers that the deaf must face in learning about HIV protection range from inadequate schooling about human sexuality to the scarcity of locally available education programs outside the cities with high rates of HIV infection.

The programs for the deaf in Houston, Los Angeles, and New York City are described as well as the array of national efforts directed to this special population.

THE PORTRAIT of the AIDS epidemic among the deaf differs from that of the hearing community. The deaf lack public forums devoted to educating them about the human immunodeficiency virus (HIV), comprehensible HIV-AIDS brochures in medical waiting rooms, or the empathetic ear of the mental health therapist. For the deaf, these are signs of neglect across a nation.

Little has been published about HIV-AIDS and the deaf (1-5). Even less has been published in the form of specifically directed educational materials. With such a paucity of information, how can the members of the deaf community react to this immense public health crisis?

A Community Examined

The last formal review of the size, distribution, and characteristics of the deaf population in the United States was completed in 1974 by Schein and Delk (6). In "The Deaf Population of the United States" they estimated that, in 1971, the rate of those persons who were prelingually deafened was 203 per 100,000. This group, thought to be the "true deaf," shares a common language—American Sign Language (ASL), as well as a common culture (7-9). Today's deaf community ranges demographically from 350,000 to 2 million as estimated by the National Information Center on Deafness at Gallaudet University in Washington, DC.

Seroprevalence of HIV and the deaf. Generally, studies show 1 out of every 250 people in the United

States is infected with HIV (10, 11). Applying this ratio to the population of deaf Americans shows that a substantial number of people within this group could be infected. In June 1991, Bares estimated the potential number of deaf persons with AIDS in the United States to be approximately 2,640 (1). To date, no statistical data exist regarding HIV transmission within the deaf community, although the National Coalition on the Deaf Community and HIV, Inc. (NCDH) has begun an audit of health care facilities across the nation that are treating deaf persons with HIV or AIDS. Because of information gained during the research for this article, I believe that the 1 to 250 HIV infection ratio is much greater among the deaf; the pertinent factors will be examined later.

General barriers to HIV-AIDS information. Finding resources and information about any medical topic can be done with some ease by the nation's hearing population. Television, books, radio, and other mediums bring HIV-AIDS to society's attention. Yet many barriers prevent even basic information from reaching the community of the deaf. Even though the Centers for Disease Control and Prevention's (CDC) National AIDS Hotline TDD Service has been active for more than 5 years (12), such local community services as TDDs, (Telecommunication Devices for the Deaf) interpreted lectures, captioned video or television programs, and literature which is candidly written currently do not reach a sizable portion of deaf society.

Deaf people depend greatly on visual elements for learning new information. Pictures, slides, videos, and

THE WHITE HOUSE
WASHINGTON

July 25, 1994

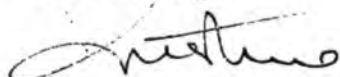
Ms. Joanne Despotes, RN, C.
Midwest AIDS Training &
Education Center
808 South Wood Street (M/C 779)
Chicago, Illinois 60612

Dear Joanne:

I hope you can imagine how upset I was when United cancelled 2 flights, there was no room on American, and I couldn't get to Chicago on time for our meeting and tour! I'm glad Ed Obermiller was there and could be my eyes and ears for the morning.

While I am leaving this National office, I will not be leaving the HIV effort, and I certainly hope our paths will cross again. After August 2, I can be reached at (202) 387-0015. Please give my best wishes to your colleagues at MATEC, and the Chicago area nurses in AIDS care.

Sincerely,



Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

THE WHITE HOUSE
WASHINGTON

July 25, 1994

Mr. W. Bradford Mello, Ph.D.
10905 Amherst Avenue, #843
Silver Spring, MD 20902

Dear Dr. Mello:

Thank you for offering your help to the Office of National AIDS Policy. It is extremely important to have people with all different backgrounds and interests join the fight against AIDS.

Unfortunately, at this time, ONAP is in a transitional period as a result of the resignation of Kristine Gebbie. I will be in touch with you as to when we can work together on the issues we discussed.

I do salute you for offering your help and I look forward to speaking with you in the future. If I can be of service, please contact me at (202)632-1090.

Sincerely,



John Paul Gurrola
Director of Communications
Office of National AIDS Policy

W. Bradford Mello

ADDRESS

10905 Amherst Ave #843
Silver Spring, MD 20902
(301) 946-6811

EDUCATION

University of Oklahoma, Norman, OK
Ph.D. Degree May 1993
Major Communication, 3.85 GPA
Advisor Dr. Dan Nimmo
Emphasis Political Communication & Mass Media

Pennsylvania State University, State College, PA
M.A. Degree August 1987
Major Speech Communication, 3.47 GPA
Advisor Dr. Thomas Benson
Emphasis Rhetoric & Mass Media

Pennsylvania State University, State College, PA
B.A. Degree May 1985, 3.07 GPA
Major Telecommunications

TEACHING EXPERIENCE

University of Maryland, College Park, MD
Position Adjunct Graduate Faculty
Dates Spring 1994
Course Seminar in Political Communication

Catholic University of America, Washington, DC
Position Adjunct Faculty
Dates Spring 1994
Course Public Speaking

Western Maryland College, Westminster, MD
Position Adjunct Faculty
Dates Fall 1993/Spring 1994
Courses Film History
Political Communication

Institute for Experiential Learning, Washington, DC
Position Adjunct Faculty
Dates Fall 1993, Summer 1994
Courses Media and Communications

Montgomery College, Rockville, MD
Position Adjunct Faculty
Dates Fall 1993
Courses Fundamentals of Speech

University of Oklahoma, Norman, OK

Position Graduate Teaching Assistant
Dates August 1989 to July 1993
Courses taught Communication and Society
Principles of Persuasion
Communication and Social Change
Family Communication
Communication and Argumentation
Introduction to Communication

Tidewater Community College, Virginia Beach, VA

Position Adjunct Instructor
Dates Fall 1987-Summer 1988, Summers 89,90
Courses Taught Public Speaking, Oral Communication

Hamilton College, Clinton, NY

Position Instructor
Dates Spring 1989
Course taught Public Speaking

State University of New York--Oneonta, Oneonta, NY

Position Instructor
Dates Fall 1988
Courses taught Introduction to Communication
Oral Interpretation

Pennsylvania State University, State College, PA

Position Graduate Teaching Assistant
Dates August 1985-May 1987
Course taught Public Speaking
Courses assisted Video Field Production
Intermediate Studio Production
Introduction to Mass Communication

SCHOLARLY ACTIVITIES

Dissertation

The Evolution of a Psuedo-Event: The Case of the Memphis Belle. A critical evalutation of the films of the Memphis Belle, the political conflicts they mediated and their social impact.

Invited Presentations

Mello, W.B. (May 17, 1993) Presentation honoring the 50th anniversary of the 25th mission of the B-17 Memphis Belle. Introduced and answered questions regarding the documentary and docudrama feature about the 25th mission. National Archives, Washington, D.C.

Presentations

Mello, W. B. & Marley, C.A. 100 Years of Editorial Cartooning: Two Cartoon "Auteurs" Build Community. Media Forum Series. Accepted for presentation at the 1994 Speech Communication Association Convention, New Orlean, LA.

Mello, W. B. & Marley, C.A. Editorial cartoons: Contributions to consciousness and culture. Media Forum Series. Presented at the 1993 Speech Communication Association Convention, Miami, FL.

Marley, C.A. & Mello, W. B. Political cartoons: Propaganda and palaver. Media Forum Series presentation at the 1992 Speech Communication Association Convention, Chicago, IL.

Mello, W.B. A Symbolic healing occurred in Flint today. Paper presented at the 1991 Speech Communication Association Convention, Atlanta, GA [Competitive Paper]

Bedore, J., Dewitt,B., Mello, W.B., Noggle, G. CNN's first month of Gulf War coverage: A content analysis of hard versus soft news. Paper presented at the 1991 Speech Communication Association Convention, Atlanta, GA [Competitive Panel]

Mello, W.B. (1991). Resistance to early change efforts: The AIDS tragedy. Paper presented at the Sooner Communication Conference, Norman, OK. [Competitive Paper]

Mello, W.B. (1990). Reconceptualizing the double bind: How males are receptive. Paper presented at the Speech Communication Association Conference, Chicago, IL. [Competitive Panel]

Mello, W.B. (1988). The rhetoric of Ordinary People. Paper Presented at the Florida State Film and Literature Conference. [Competitive Paper]

RESEARCH INTERESTS

Political & Mass Communication, Film, Propaganda

GRADUATE COURSEWORK

Seminars

Political Punditry	Propaganda
Political Advertising	Rhetoric and Media
Political Communication and Media	Film History
Communication and Social Change	International Communication
Mass Communication Theory	

General communication courses

Systems and Theories of Rhetoric	History of Communication
Contemporary Issues in Communication	Problems in Speech Education

Research tools and skills oriented courses

Comparative Research Methods	Content Analysis
Rhetorical Criticism	Screen Writing
Film/Video Production	

Advanced Computer Programming for Humanities/Business
Computer Graphics Programming
Spanish Grammar & Conversation

HONORS AND AWARDS

Outstanding Graduate Teaching Award, 1990-1991
Baldwin Award Nominee for outstanding teaching, 1990-1991
Participant in The University of Oklahoma Centennial Leadership
Conference, 1990

PROFESSIONAL SERVICE

Reader for the SCA Student Section, 1991
Delegate to Graduate Student Senate(GSS), 1990-1991
Academic Affairs Committee Chair for GSS, Fall 1990
Communication Graduate Student Association Executive Board, 1990-91

AFFILIATIONS

Speech Communication Association
Southern States Communication Association
Eastern Communication Association
Association of Educators in Journalism and Mass Communication

THE WHITE HOUSE
WASHINGTON

July 25, 1994

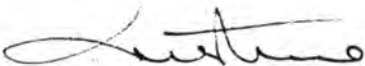
Mr. Timothy McCormick, M.Div.
Executive Director
P.O. Box 148187
Chicago, Illinois 60614-9998

Dear Mr. McCormick:

I'm so sorry that the cancellation of my original flight to Chicago Saturday kept me from visiting Bonaventure House. Ed Obermiller shared with me your handbook on assisted living and his very positive impressions on your program.

My very best wishes to you, your colleagues and clients, I hope we have an opportunity to meet in the future.

Sincerely,



Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

JUL 25 1994

THE WHITE HOUSE

Dear Rod—

I thank you so much for
allowing me to be a part of the
Catholic HIV/AIDS Ministry on
Saturday - and always. Even in
a short time, it was renewing
and uplifting. I know we will
continue to share

Katharine



SEVENTH NATIONAL CATHOLIC
HIV/AIDS MINISTRY CONFERENCE
Loyola University, Chicago ♦ July 21-26, 1994

July 23, 1994

Kristine Gebbie, RN
National AIDS Policy Coordinator

Dear Kristine,

On behalf of our Board of Directors and all of the participants at this Conference, I want to thank you for not only for your words of encouragement and wisdom but also for your tireless and compassionate example. I believe that you have been a real gift to the administration in this new position and have challenged the administration to make the role of the National Policy Coordinator even more effective in the future.

I wish you well especially during these days of transition and leave-taking. I hope that you will continue to keep in contact with us and be a part of our Network.

Blessings and peace,

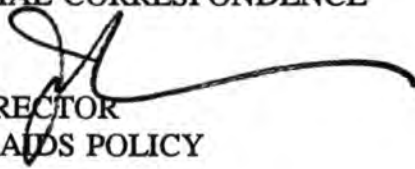
Rev. Rodney J. DeMartini, SM
Executive Director

THE WHITE HOUSE
WASHINGTON

July 25, 1994

MEMORANDUM FOR LORI ABRAMS
OFFICE OF PRESIDENTIAL CORRESPONDENCE

FROM JOHN PAUL GURROLA
COMMUNICATIONS DIRECTOR
OFFICE OF NATIONAL AIDS POLICY



SUBJECT PRESIDENTIAL LETTER

Please process this letter from POTUS to the members of the Harvard Community Health Plan Foundation. If you have any problems, call me at (202)632-1090.

**DRAFT LETTER TO HARVARD COMMUNITY
HEALTH PLAN FOUNDATION FROM POTUS**

July 25, 1994

To the members of the Harvard Community Health Plan Foundation:

I want to commend you on the success of the **FIRST AIDS KIT**. HIV/AIDS is the health crisis of the century. It is an important step when organizations, like the Harvard Community Health Plan Foundation, take the initiative and develop population specific HIV/AIDS prevention information.

At home, at work, and in every aspect of our lives, education can stop the spread of HIV. I am pleased that you obtained input from young people when developing the **FIRST AIDS KIT**. As you know, HIV infection is spreading in the youth of our country at an alarming rate and it must be stopped. By working together we will triumph over this horrible disease.

Once again, I thank you for your efforts and I hope you will continue to be an important factor in the fight against AIDS.

Sincerely,

B.C.



Harvard Community
Health Plan Foundation

MAY 9 1994

May 3, 1994

Kristin Gebbie, RN, MN
AIDS Policy Coordinator
The White House
1600 Pennsylvania Ave. NW
Washington, D.C. 20500

Call Bart 67560
Harford

Charles
Andrew
John

need an idea
for recognition
is the Pres going to
Boston any time
soon?

Dear Ms. Gebbie,

We thank you for the timely response to our FIRST AIDS KIT. We were pleased to discover that you recognize the need to use population specific HIV/AIDS prevention information in the battle against AIDS.

We feel that education is paramount in curbing the spread of HIV among young people. The Harvard Community Health Plan Foundation worked closely with young people in developing the FIRST AIDS KIT. In fact, without the contributions of these young adults, our dream of providing these KITS to those at risk, would never have been achieved.

We would like to take the next step, and offer to you our efforts to send a strong national message regarding targeted AIDS education efforts. National recognition of the young people who contributed to the FIRST AIDS KIT would help raise awareness on the need for additional targeted prevention efforts among all populations.

Whether in the form of a White House ceremony or words of recognition for key individuals who guided our efforts, the FIRST AIDS KIT is a perfect opportunity to send a clear, strong message throughout New England and across the country.

I welcome the opportunity to discuss ways to involve ourselves in supporting the battle against AIDS in the national arena. I look forward to speaking with you soon.

Sincerely,

Susan Pauker, M.D.
Executive Director

THE WHITE HOUSE
WASHINGTON

July 25, 1994

Mr. Ron Spingarn
3420 16th Street, N.W.
Apartment 410
Washington, D.C. 20010

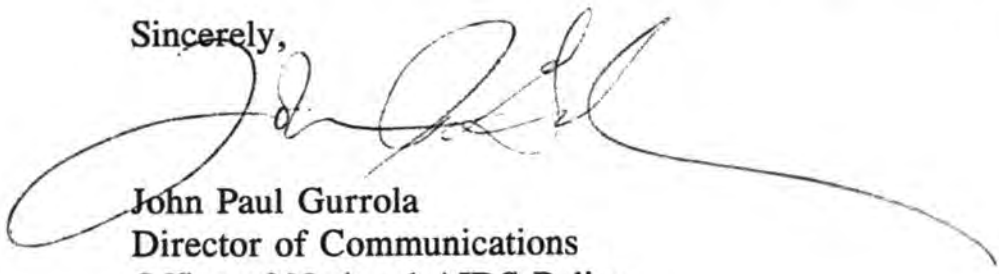
Dear Mr. Spingarn:

Thank you for sending me your Fellowship Project Guidelines. Unfortunately, there is still no established fellowship program for the Office of National AIDS Policy.

At this time, ONAP is in a transition period as a result of Kristine Gebbie's resignation. I will keep you informed of future changes and opportunities.

If I can ever be of service, don't hesitate to call me at (202)632-1090.

Sincerely,



John Paul Gurrola
Director of Communications
Office of National AIDS Policy

To: John Gurrola, NOAP
From: Ron Spingarn, phone: 202-232-8269
re: Fellowship Project Timelines

Sorry for the delay in getting this to you. Because I heard from you and others that you had (and have) a lot of other things on your plate, I put off giving this to you for a while with the hope that things may have settled down a little. I hope that they have.

Here is a rough timeline for the projects I would work on during a 12 month Fellowship with your office, pending approval, of course, from Kristine, you, and the other necessary people.

Please let me know what the status is of the Fellowships. If you'd like, you can reach me via e-mail on Compuserve (ID#74132,1401), America On-Line (ID Name: RSpingarn) or Internet (RSpingarn@aol.com). Thanks.

Jeff
Str
Still to for
no fellowship
program. In a transition
period. Will
let you know.

Date: 5/7/94 Time: 11:07:57

From: R. Spingarn To: John Gurrola

PROJECT TIMELINE (1ST DRAFT)

MONTHS:

Pre-1 1 2 3 4 5-6 7-8 9-10 11-12

Project #1: Survey:

Development - Testing --- Revision --- Conducting ----- Analyzing Results --- Revise Program Plan/Workshop (as needed)

Project #2: Program Plan:

Draft Plan ----- Give to Advisory ----- Revise Program Plan
Committee

Project #3: Workshop

Draft Workshop Curriculum ----- Revise Curriculum -- Pilot Test Workshop

Project #4: Database

Input contact names and information into database -----

Also....

Networking with:

Journalists/Media/Communicators -----

AIDS/Public Health Service Providers -----

Potential Sponsors, Funding Sources, Collaborators -----

Formation of Advisory Committee:

Identify	Select/Invite	Meet and/or	Give Draft Program
Potential	Members	Conference	Plan for Input
Members		Call with	
		Members	

JUL 25 1994

THE WHITE HOUSE

Dear Dr Thompson —

Thank you for showing me
The S.D. center during my visit
to Atlanta - you have a lovely
facility, but more importantly
a caring staff & good programs
My very best wishes to you
all — Christine Delaney

**ITINERARY FOR MS. KRISTINE M. GEBBIE,
RN, MN, NATIONAL AIDS POLICY COORDINATOR****JULY 20, 1994**

9:00 A.M.	ARRIVAL AND PICK-UP AT ATLANTA AIRPORT
9:30 A.M. - 10:30 A.M.	TOUR OF OUTREACH, INC. - MS. SANDRA MCDONALD 3030 Campbellton Road, S.W. Atlanta, GA 30311 (404) 346-3922
10:45 A.M. - 12:00 P.M.	TOUR OF ELYSIUM HOUSE - PAT & KIM (HIV/AIDS HOSPICE) 6490 West Fayetteville Road Riverdale, GA (404) 997-0889
12:00 P.M. - 1:00 P.M.	LUNCH
1:00 P.M. - 2:30 P.M.	TOUR OF GRADY HOSPITAL INFECTIOUS DISEASE CENTER - Dr. SUMNER THOMPSON 341 Ponce de Leon Atlanta, GA 30303 (404) 616-4307
2:30 P.M. - 4:00 P.M.	VISIT TO MOREHOUSE SCHOOL OF MEDICINE - DR. RUDOLPH JACKSON Discussion of African Aids Project. 730 West View Drive, S.W. Atlanta, GA 30314 (404) 752-1400
4:30 P.M.	RETURN TO ATLANTA AIRPORT

DOC:
Alfred
White

(404) 346-3922

JUL 25 1994

THE WHITE HOUSE

Dear Becky -
and everyone at AID Atlanta -
I'm so glad we had the chance
to spend a little time
together - I'm impressed by
all you do. And thank
you for the T-shirt, mug
and lunch! All are appreciated.
My best wishes
Katharine

M. Rebecca Clayton Burton, M.A.
Executive Director
AID Atlanta
1438 West Peachtree St., N.W.
Suite 100
Atlanta, GA 30309-2955

JUL 25 1994

THE WHITE HOUSE

Dear friends at Outreach...
How can I thank you for
the wonderful opportunity
to visit with you? It was
such a pleasure to meet
people taking positive action
in the face of enormous
challenges - and making a
difference! And an extra
thanks for the transportation!
All the best - Christine

Outreach Inc.
3030 Campbellton Road, S.W.
Atlanta, GA 30311

JUL 25 1994

THE WHITE HOUSE

Dear Carl and Kim -
I'm so glad I was able to
visit Elysium House - and
I certainly wish you the
best in your struggles to get
on a firm financial footing.
If this office can help, please
let us know -
Kathleen Sebelius

Carl Mansell and Kimberly K. Partain
Elysium House, Inc.
6490 West Fayetteville Road
Riverdale, GA 30296

JUL 25 1994

THE WHITE HOUSE

Dear Steve —
Thanks for the time on
Wednesday — I appreciated
the chance to learn & get
more about Morehouse's
HIV activities — & to become
re-acquainted.
My best wishes
& welcome

Dr. Stephen Margolis
Professor
Co-Director, A.M.H.P.S. AIDS Research
Consortium
Morehouse School of Medicine
720 Westview Drive
S.W. Atlanta, GA 30310-1495

THE WHITE HOUSE
WASHINGTON

July 25, 1994

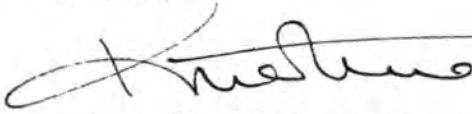
Bonnie Stover, Coordinator
Volunteer Programs / AIDS Services
Los Angeles County/USC Medical Center
1200 North State Street
Los Angeles, CA 90033

Dear Ms. Stover:

Thank you for arranging to send our office the beautiful works of art created by the artists at the 5P21 Art Coalition. I am trying to make arrangements for pieces to be displayed in The White House or at one of the Executive Office Buildings in the complex here. I believe that the artists deserve a great deal of credit for their abilities, energy and creativity.

I hope that you will pass along my appreciation to all the artists involved in your most recent art show - WORDS. Their hard work and the beautiful results are an inspiration to us all.

Sincerely,



Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator



LAC+USC

Los Angeles County
University of Southern California
Medical Center

1200 North State Street
Los Angeles, CA 90033

Phone: (213)

Edward L. Martinez
Executive Director

Sol Bernstein, M.D.
Chief of Staff

County of Los Angeles
Department of Health Services

Kristine M. Gebbie
Executive Office of the President
Office of National AIDS Policy
750 17th Street, N.W.
Suite 1060
Washington, DC 20503

Katherine A. Eaves, R.N.
Acting Director, Nursing Services
and Education

Dear Ms. Gebbie,

It was a pleasure to have you join members of the Art Coalition on June 20, 1994, for breakfast and a tour of the Art Show, WORDS. The artists and invited guests were pleased to have the opportunity to meet with you to express their thoughts and present you with their artwork. They are delighted with your suggestion to have their work displayed in the White House. This is a great honor for the artists representing the 5P21 Art Coalition.

Thank you for so graciously accepting Randy's invitation to meet with us. We deeply regret that you felt the need to resign your position and we wish you much happiness and success in your future endeavors.

Warmest regards,

Bonnie Stover, coordinator
Volunteer Programs \ AIDS services
LAC+USC Medical Center

THE WHITE HOUSE
WASHINGTON

July 26, 1994

Ms. Susan Lowe
4803 Georgia Ave
West Palm Beach, FL 33405

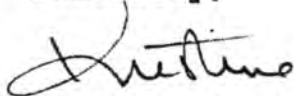
Dear Ms. Lowe:

Thank you very much for your efforts on the "White House Reception of Hope" on July 16, 1994. You gave the time, energy, and allowed those working for you to contribute to the success of the event.

Together, we can continue our progress on increasing awareness, pursuing research, and extending the hand of compassion.

We must maintain hope alive.

Sincerely,



Kristine M. Gebbie
National AIDS Policy Coordinator

THE WHITE HOUSE
WASHINGTON

file

RECEIVED
AUG 2 1994

July 26, 1994

Ms. Bobbie Stasey
728 Val Verde Southeast
Albuquerque, New Mexico 87108

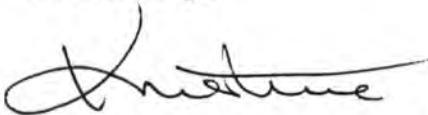
Dear Ms. Stasey:

Thank you for writing and for sending copies of your books Running With the Angels and Just Hold Me While I Cry. The Office of National AIDS Policy was created out of the commitment of the President to take positive steps to stop the HIV/AIDS epidemic. The Office of the National AIDS Policy Coordinator will continue to support the development and implementation of policies that will stop the spread of HIV and provide care for those living with HIV/AIDS. I am inspired and moved by the work that you do to reach out to mothers and offer support.

The Office of National AIDS Policy, which coordinates the implementation of policies in the areas of prevention, services and research, does not carry out programmatic activities of its own. Although we can assist in directing individuals to sources of Federal funding, we do not make determinations as to whether a particular program should be funded. I have shared the information in your letter with the Office of AIDS Coordination at the Centers for Disease Control and Prevention. You may wish to obtain additional information on available sources of funding from the National AIDS Clearinghouse at (800) 458-5231.

Again, thank you for sharing your books with me. I wish you continued success with your future endeavors.

Sincerely,



Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Bobbie Stasey

728 Val Verde Southeast, Albuquerque, New Mexico 87108
(505) 265-6540

June 1, 1994

RECEIVED

Kristine Gebbie
White House AIDS Policy
750 17th St NW, Suite 1060
Washington, DC 20503

JUN - 3 1994

*Tim - draft
reply*

Dear Ms. Gebbie:

I attended the talk you gave at Woodward Hall here in Albuquerque earlier this Spring. I was sitting up close and to your right. I asked you a lot of questions.

The editor of the newsletter for New Mexico AIDS Services asked me if I would write an article for their Mother's Day issue. He said he would like my thoughts on AIDS, in general. I welcomed the opportunity to write an open letter to other mothers who were going through what I had gone through five years ago. Especially to those in rural New Mexico who have no agency available for support. I had been to hear what you had to say, and I was encouraged in an odd sort of way because I heard you talk about "Denial," about "Quality Life," about "Emotional Research vs. Biomedical Research." I agreed with everything you said. And I felt surprised that our Administration has a clear understanding of and is being open about (through your communication) what is needed and what will stop the spread of AIDS.

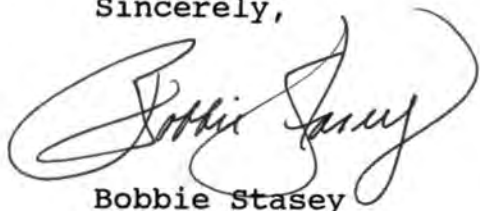
Using my experience and your quotes I came up with the enclosed article. They refused to print it. Whatever their reasons were for not printing the article, I came to the conclusion that, indeed, denial regarding the root cause of AIDS, *behaviors*, runs rampant even within AIDS support agencies.

After my son died, I wrote a book about our family's experience, determined to use the book as a vehicle to talk with groups who wanted to hear the support I wanted to offer. My husband and I emptied savings accounts in order to pay my expenses to travel around the country to do these talks. In the course of the year, I received letters from other mothers and families who shared similar personal experiences with me about the death of their loved ones. I put together a second book, Running With the Angels, the gifts of AIDS, printing their letters. My hope is that people will receive support for what is the most terrifying, painful experience of one's life: losing a child to AIDS.

I would like to continue talking to groups who would like to have me. However, this has become prohibitively expensive. Is there any kind of a grant available to help me continue to share my experience, my hope, to help educate, to offer emotional support to those living with AIDS? I notice there are not many mothers out there doing this. And yet everywhere I go, I hear questions about moms and families: "How did you react when you learned your son had AIDS?" "How do I tell my Mom?" "How did you cope?" Most people with AIDS want a close connection with their families, a place they can go to when they can no longer care for themselves. And in order for people with AIDS to feel safe enough and loved enough to return home to die, an understanding of how to heal past relationships must be offered, judgements about sexuality or drug use must be worked through, a path paved for families to come together at the end of a loved one's life.

I would dearly love to continue offering support in any way possible. Can you offer any suggestions?

Sincerely,

A handwritten signature in cursive script, appearing to read "Bobbie Stasey". The signature is fluid and somewhat stylized, with the first and last names being the most prominent parts.

Bobbie Stasey

Bobbie Stasey
728 Valverde SE
Albuquerque, NM 87108
(505) 265-6540

A MOTHER'S HOPE
by Bobbie Stasey

*"Why weren't they more careful?"
"Why did she have to share that needle?"
"Why was the transfusion tainted?"
"Why did he have sex with someone else
and then pass it on to her?"
"Why did she have a baby when she knew
she was HIV?"*

The bulk of Federal AIDS funds is allocated for Biomedical Research. Next is for Personal Care and Support. The least amount of Federal AIDS funds is for Education and Prevention.

"A vaccine won't save my child. My child is already HIV-positive. I don't care about research anymore! What I care about is how I'm going to care for my child! And who's going to care for me while I'm caring for my child! How do I get help when I feel like screaming! He'll die!

"My child will be the exception. I've read about people with HIV living a long time. If I could just figure out what those people are doing I could make my child do the same thing.

"Wait a minute. I can't make my child do anything. He stopped doing what I told him to do long ago.

"I know. I'll show him the article about that man who's been living symptom-free for more than ten years. If we had ten more years together... I'd get to see what kind of a man he's like at 30.

"And there's this other article about needing to keep a good attitude. The article seems to say that's what's keeping them alive. But Bruce had a good attitude. What a sweet man, so kind and loving and hopeful. But that was a few years ago. Maybe there're some new positive-thinking methods that Bruce didn't know about. Maybe it'll be different for my child. I have to hope. If I stop hoping, he might die. Bruce never gave up hope, and he tried everything.

"This is making me crazy. I can't be thinking like this. This isn't a good attitude.

"I should talk to someone, at church maybe. But who? I can't let Lucy find out. I remember when she said, 'They deserve it.' And if I talk to Lori, she'll tell Lucy and Lucy will tell Joe who works with Sam and then everyone my husband works with will know. I need my husband and Sam needs his work. I need my friends. I need the church.

"I can't handle this right now. I can't let Sam or my child know how scared I am. If we all get scared, then my child might die. I have to be strong.

"I won't tell anyone today. Today my child isn't sick. Only a little tired."

Rural Americans have no safe place to go, no AIDS support services, no significant others support group,

nothing but a nationwide 800 number to call for help. Cities that do have organizations try desperately to reach out to towns that don't. But they are under-funded. Burnout is high for volunteers working with AIDS, and yet all over the country emotional support is provided, essentially, by volunteers. Most people can't and don't get help until their person with AIDS has become symptomatic.

Kristine Gebbie, President Clinton's AIDS Czar, said recently in a talk in Albuquerque, that for those living with AIDS, "Support for living a quality life is under-funded." And about those who have yet to acquire HIV: "A fear-based curriculum does not work. Until the emotional research agenda is at least equal to the biomedical research agenda, this disease will continue unchecked. Our denial mechanism is showing not the fact that we *can't* deal with AIDS, but that we *won't*." Doctors must rediscover that the real work of medicine starts when drugs no longer work.

Once HIV becomes a fact of life within a family unit, that family needs a safe place to turn. They need to learn how to cope with living with AIDS; they need to hear how others are coping. With an opportunity to voice the fearful thoughts in a nurturing, compassionate atmosphere, the fears quiet, allowing a life of quality to emerge. The Social Death prevalent within and around families living with AIDS is horrendous. The priceless commodities of accepting and loving ourselves and each other strengthen a family, bond the family together, rather than tearing it apart in judgement and fear.

Tender compassion for each other, a listening ear, an open heart, a voice that is not silent but strong when ignorance speaks out -- this is what will put a stop to the horrors of AIDS.

If we all must die, then, please God, let us die *not* alone and suffering, but with dignity and respect, loved for who we are. Teach us how to support one another. Give us the strength to speak from our hearts. Help us to know how to help ourselves and others in our fears, our pain, our heartache. Help us to find the good in all of this.

Scientists continue staring at the "smart" behavior of the virus itself under a microscope. Until they are willing to look at the human beings carrying the virus, at the families and loved ones who are caring for each other, and at the behaviors which continue to explode the virus in our midst, then AIDS will be with us... for as long as any one of us has left to live.

Bobbie Stasey is the author of Just Hold Me While I Cry, a mother's life enriching reflections on her family's emotional journey through AIDS, and Running With the Angels, the gifts of AIDS.

Elysian Hills Publishing Company

P.O. Box 40693 Albuquerque, NM 87196

voice (505) 265-9041 fax (505) 265-4401

For orders call: 1-800-368-3208

ABOUT THE AUTHOR: Bobbie Stasey

Bobbie Stasey is married, has one surviving son, three step-children and five grandchildren. She has worked as a hospice volunteer, an Alanon Group Representative, a bereavement counselor, a volunteer to the Aid to Parents of Abused Children, and in the death and dying movement with Dr. Elisabeth Kübler-Ross; she is the New Mexico contact person for the Kübler-Ross Foundation.

Ms. Stasey received her Bachelor of Science degree in 1972, and is a 1989 graduate of the Children's Institute of Literature. In 1988, she won the prestigious Southwest Writers Workshop Non-Fiction award for "Daddy Went Away."

In 1987, with the news that her 24 year-old son was HIV positive, she curtailed her work in hospice to focus on caring for him. Jimmy died in 1989. After two years of grieving, Ms. Stasey wrote JUST HOLD ME WHILE I CRY, an account of her family's emotional journey during the last six months of his life.

Since the book was published, she has facilitated talks in Albuquerque, Birmingham, and Los Angeles, at the AIDS Advocacy/Companion Program in Grand Junction, Colorado, presented "AIDS, A Mother's Perspective" at the National Hospice Organization's Annual Conference in Salt Lake City, and has appeared on numerous radio and TV interviews.

Planned distribution of her new book, RUNNING WITH THE ANGELS, *the gifts of AIDS*, includes the USA, Canada, the United Kingdom, Australia and New Zealand. She is being nominated for the Professional Writers Literary Award, the Western States Book Award and the Editors Book Award.

MS. STASEY IS AVAILABLE FOR INTERVIEWS. PLEASE CALL ED
AT ELYSIAN HILLS PUBLISHING CO. 1-505-265-9041.

Elysian Hills Publishing Company, Inc.

NEWS RELEASE

CONTACT: Elysian Hills Publishing Co. – Ed Dziczek
PHONE: 505-265-9041
FAX: 505-265-4401

FOR IMMEDIATE RELEASE

*Ms. Stasey is available for interview
Photos available*

THE FORGOTTEN VICTIMS OF AIDS

Grieving Family Members Recount “Social Death”

According to Dept. of Health figures, as of September, 1993, the number of acknowledged AIDS cases in the U.S. totalled 339,250. Of these, 4,809 were children under 13, and 43,019 were women. How many of us realize the enormity of the pain and suffering behind these grim statistics? Not only for the patients suddenly handed a death sentence, but also for the families coping with terminal illness and social prejudice.

Author Bobbie Stasey does now. But little did she realize that her work as a hospice volunteer and bereavement counselor was preparing her for the death of her own son to AIDS.

Since her first book, “Just Hold Me While I Cry” was published sharing her family’s emotional journey through her son’s death, she has received letters from all over the country from families going through the same traumas.

Her new book, “Running With the Angels, the Gifts of AIDS”



Author BOBBIE STASEY

(Elysian Hills Publishing Co., 1-800-368-3208) details the true stories of lives touched by AIDS.

Stories of courage, love and miracles. Coping with the epidemic, with “Social Death” and with friends and family members that turn away and disappear overnight.

Ms. Stasey attributes AIDS, uniquely, as the vehicle for teaching unconditional love. As this dread disease marches across the face of the earth, Ms. Stasey continues her mission to reach out to those living with and dying from AIDS and to end their isolation. She personally answers all letters. You may reach her at P.O. Box 40693, Albuquerque, NM 87196.



END

PHOTOS AVAILABLE

MS. STASEY IS AVAILABLE FOR INTERVIEW – CONTACT ELYSIAN HILLS PUBLISHING CO.

P.O. Box 40693 Albuquerque, NM 87196

voice 505-265-9041 fax 505-265-4401
order information 1-800-368-3208

THE WHITE HOUSE
WASHINGTON

July 26, 1994

Mr. Irvin Kalb
Medical Intellectual Property Associates
c/o Arant, Kleinberg, Lerner & Ram
2049 Century Park East, Suite 1080
Los Angeles, California 90067

Dear Mr. Kalb:

Thank you for your letter of April 27 regarding the issue of safe disposal of potentially HIV contaminated menstrual by-products. To my knowledge no data exists to either prove or disprove the theory that menstrual by-products present a risk. The Centers for Disease Control and Prevention (CDC) would not make a definitive statement regarding the potential risk factor of disposing of menstrual by-products without adequate scientific data accompanying such a statement.

However, perhaps CDC could suggest to you a non-government organization that might be willing to explore this further. University research facilities that are privately or federally funded might also be a viable option.

Since my office is not in a position to make a scientific judgement as to the need for or efficacy of your product, I am forwarding your letter to CDC for a more comprehensive response.

Sincerely,



Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

cc: Dr. Curran

MEDICAL INTELLECTUAL PROPERTY ASSOCIATES

c/o Arant, Kleinberg, Lerner & Ram
2049 Century Park East, Suite 1080
Los Angeles, California 90067



MAY 17 1994

*Paul
draft
reply*

April 27, 1994

Ms. Kristine Gebbie
Director Coordinator
President's Commission on Aids
750 17th Street N.W.
Washington, D.C. 20503

Re: U.S. Patent Appln Serial No. 07/963,996
For: BLOOD PRODUCT DISPOSAL SYSTEM AND METHOD
U.S. 5,287,960 Issuing February 22, 1994
Our Docket No. 413025-6988

Dear Ms. Gebbie:

Our "think tank" (Medical Intellectual Property Associates - MIPA) has identified, addressed and solved a major gap in the preventive measures for blood transmitted diseases, particularly Hepatitis and HIV. Your assistant, Ms. Joe Massori, has suggested that I write to you regarding this problem and solution.

I am the past Medical Director of Medical Intellectual Properties Associates, a private "Think Tank" group, that looks at medical-social problems and theories to find practical solutions. I started this informal group about 25 or more years ago with a group of fellow Rand Corporation scientists. About that time we looked for alternative solutions to the use of tampon and sanitary napkins with a view of cutting down on the amounts of landfill volume and sewer solid waste volume. It became very evident that the blood and tissue in these products carried a number of possible organisms, including Hepatitis B virus. We then set about to find a simple inexpensive way to 1) kill the infectious organisms, 2) protect the environment, 3) to assist sanitation personnel (housekeepers in homes, hotels and on aircraft) in handling these waste products while being protected from infection, and 4) eliminating the bulk of waste to sewers disposal plants and land fills. This device was designed at that time.

Ms. Kristine Gebbie
April 27, 1994
Page 2

About three years ago we turned our attention to the disposal device and invented a foolproof, harmless, inexpensive method and device for this purpose. On February 22 of this year we were granted Patent Number 5,287,960, a copy of which is attached. This covers our new menstrual device as well as pads, tampons, sponges, etc.

About two years ago I discussed with the people at CDC the problem of menstrual byproducts being a potential source of infection with the HIV virus. While CDC personnel acknowledged menstrual pads as a potential risk factor, it was our conclusion that they shelved the issue because of a fear of creating a panic and the unavailability at that time of a suitable approach to address this ignored source of contamination.

With the AIDS pandemic underway and with WHO stating that two women are infected with HIV every minute (about 1,000,000 per year - WHO Bulletin on AIDS dated 11/16/1993), it is imperative that this potential source of AIDS be addressed as a solution has now been identified.

I am sending you this letter because the United States is in a position to be a world leader in helping to prevent the spread of AIDS. Enclosed are also articles which, in my opinion, are the best analyses of the extent of the problem. In the absence of a cure, prevention by means of education and changing sexual behavior, including the proper disposal of menstrual blood and tissue contaminated devices, and the use and proper disposal of condoms is our best approach at this time.

We are currently looking for a U.S. commercial partner to manufacture this simple, inexpensive menstrual product disposal system shown in the attached patent. We have spoken to several potential manufacturers and they all ask what does CDC, PHS or OSHA think of this source of infection and our approach to a solution. At the time of writing this letter I have not heard from PHS, CDC or OSHA after having tried to get their opinion, and in the early days of our designing this method and device, their input. This entire effort has been done privately with private funds and no help from any university, government and/or corporation.

For your information, enclosed are 1) articles from 1992 represented in Scientific American Special Issue Medicine 1993 distributed in March 1994, 2) latest AIDS Day by Day March-April 1994, 3) prospects for an HIM vaccine.

Ms. Kristine Gebbie
April 27, 1994
Page 3

Please forgive me if these are "old news", but following my discussion with Ms. Massori, I reviewed the best summary articles I know and selected the attached.

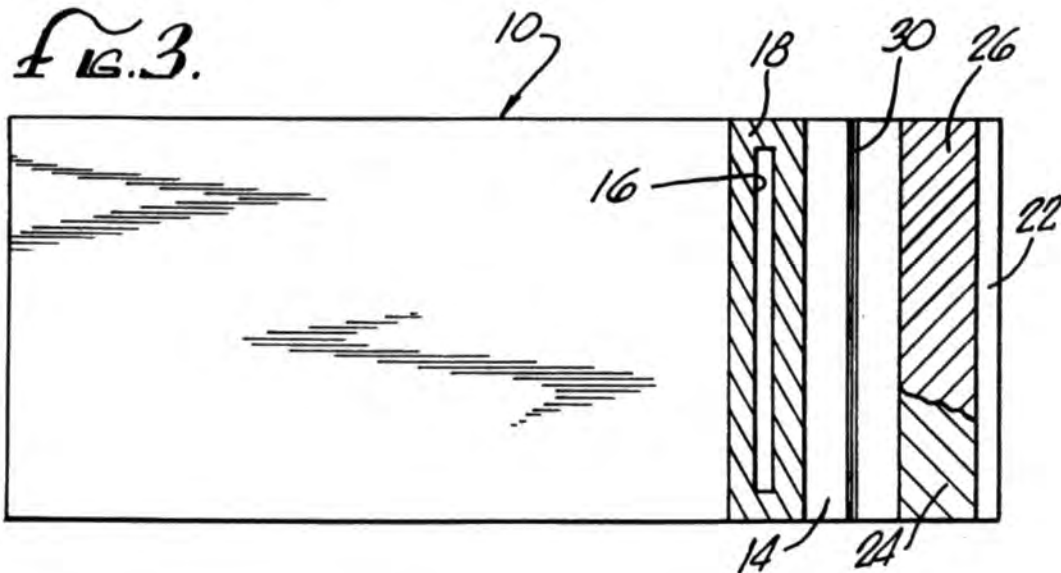
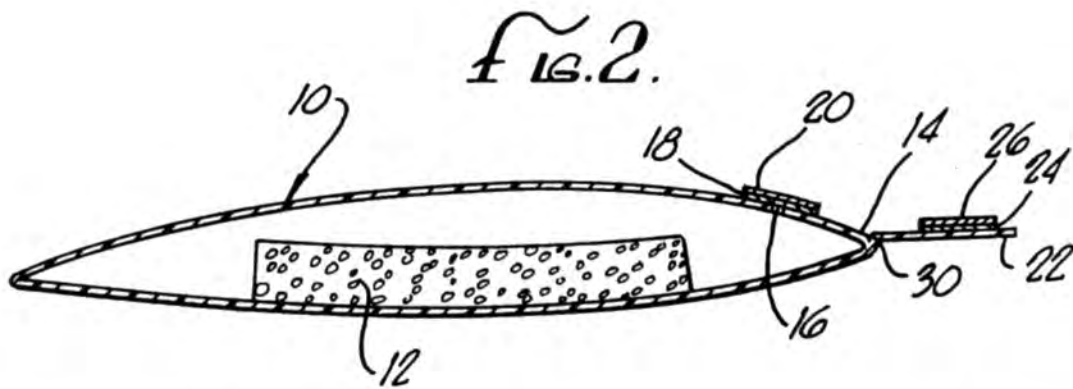
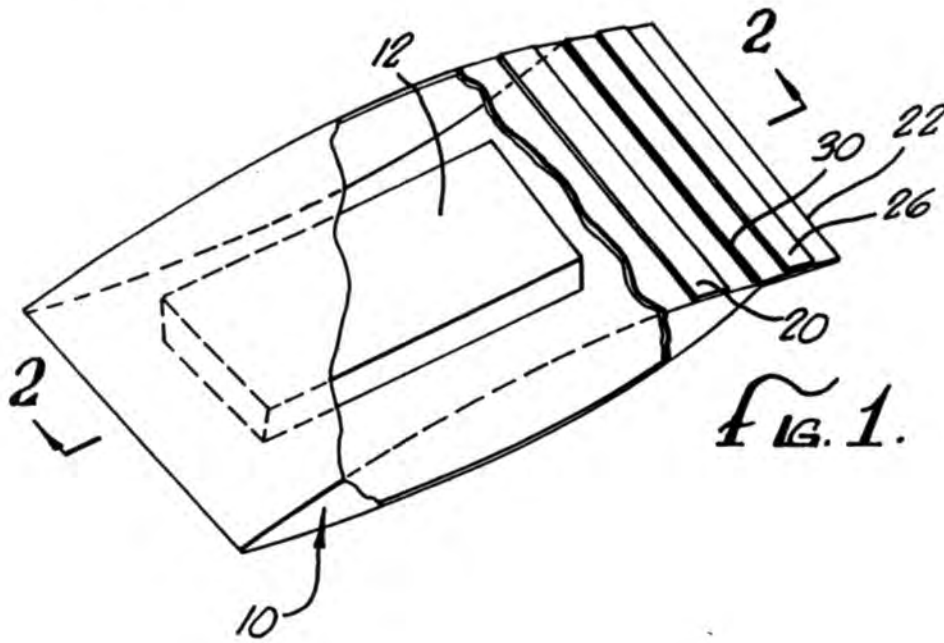
I would be glad to meet with you to discuss recognition of the problem and endorsement of the solution. I am going to be in Washington in May. My wife and I are "homeless" after the January 1994 earthquake and we will be traveling the United States starting on or about May 1st or May 2nd. If you care to reach me I can be reached until that date at (310) 274-7777, Suite 360 or letters can be addressed to me c/o E. Roesch 244 S. Camden Drive, Beverly Hills, California, 90212. Alternatively, you can contact Dr. Michael Ram, MIPA patent counsel, at (310) 557-1511 or the address set forth above.

Very truly yours,



Irvin Kalb

IK:tl
Enclosures





US005287960A

United States Patent [19]

Kalb et al.

[11] **Patent Number:** 5,287,960[45] **Date of Patent:** Feb. 22, 1994[54] **BLOOD PRODUCT DISPOSAL SYSTEM AND METHOD**

[76] Inventors: **Irvin M. Kalb**, 327 Alta Ave., Santa Monica, Calif. 90402; **Robert H. Shaw**, 243 Peck Dr., Beverly Hills, Calif. 90212; **Michael J. Ram**, 1 Horseshoe Rd., Bell Canyon, Calif. 91307

[21] Appl. No.: 963,996

[22] Filed: Oct. 20, 1992

[51] Int. Cl.⁵ B65D 81/18

[52] U.S. Cl. 206/210; 206/440; 383/66; 383/86; 604/385.1

[58] Field of Search 206/438-440, 206/204, 205, 210, 494; 383/66, 86; 604/358, 385.1

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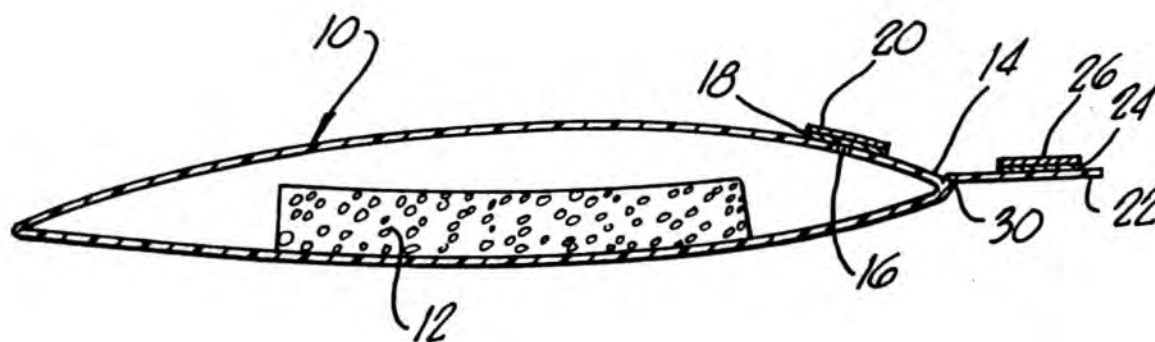
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Primary Examiner—Bryon P. Gehman*Attorney, Agent, or Firm*—Michael J. Ram[57] **ABSTRACT**

The present invention relates to a method for treating and disposing of materials contaminated with blood such as blood soaked menstrual pads or tampons. The invention further relates to a system for decontaminating and disposing of blood soaked products comprising a bag containing a disinfecting material, the bag having a readily openable portion for placing the blood soaked product into the bag and in contact with the disinfecting material and then resealing the bag to prevent its contents from contaminating the surroundings. Once resealed, the seal can not be removed without destroying the seal.

8 Claims, 2 Drawing Sheets

AIDS Day by Day

Intracellular Antibodies

Engineered antibody genes were introduced into cultured cells in a successful attempt to induce expression of an antibody that would be retained in the endoplasmic reticulum. The particular antibody recognizes gp120, which is cleaved from gp160 in the ER. Infection of the experimental cells with HIV-1 resulted in diminished production of gp120 and thus in the release of virus particles that were much less infectious than HIV-1 usually is.

Wayne A. Marasco et al., *Proceedings of the National Academy of Sciences of the USA* 90: 7889-7893, August 1993.

Convergent Combination Therapy

A suggestion that a combination of drugs directed at the same HIV-1 protein might reduce the potential for the development of drug resistance attracted widespread attention when it was made in February by Martin Hirsch and colleagues at the Massachusetts General Hospital. Although one experimental result reported in February has been found to be incorrect, and mutations conferring resistance to both nucleoside and non-nucleoside reverse transcriptase inhibitors can arise, the MGH group said it was still possible that some drug combinations might prolong the benefit of therapy more than others.

Yung-Kang Chow et al., *Nature* 364:679, August 19, 1993.

Emilio A. Emini et al., *Nature* 364:679, August 19, 1993.

Gene Therapy

The NIH Recombinant DNA Advisory Committee approved two proposed gene therapy experiments. Flossie Wong-Staal and her col-

leagues at San Diego have suggested inserting a ribozyme into CD4+ lymphocytes to prevent viral replication. A Seattle group plans to remove CD8+ T cells from AIDS patients, isolate and culture those that target HIV-1, and reinject them in large numbers.

NIH announcement, September 10, 1993.

Aminoglycoside Antibiotics

Neomycin B, tobramycin, and lividomycin A inhibit binding of HIV Rev protein to its viral RNA site. The drugs selectively block Rev function in vitro and in vivo, and solve delivery problems by directly interacting with RNA. Additionally, this approach may impede growth of drug-resistant variants.

Maria L. Zapp et al., *Cell* 74:969-978, September 24, 1993.

Start of Efficacy Trials in Doubt

At NIAID's annual conference on AIDS vaccine development, researchers from Duke, Johns Hopkins, and the Chiron Corp. reported that they had not been able to find any evidence of neutralizing antibodies against field isolates of HIV. They tested several vaccine candidates, all of which have raised antibodies against HIV strains grown on cell lines. Questions were raised about the accuracy of the antibody assay, but Anthony Fauci, head of NIAID, said, "It certainly does make me anxious about going forward with large-scale efficacy trials."

"News & Comment" in *Science*, November 12, 1993.

WHO Wants Vaginal Barrier

Faced with the prospect of two women becoming infected with HIV every minute, at least a million per year, mostly by heterosexual intercourse, and seeing little hope for an effective vaccine before the end of the decade, the World Health

Organization announced that it was attempting to coordinate a research effort to find an intravaginal antiviral foam or gel. Such an agent would be an alternative to condoms and ideally would kill HIV without destroying useful microbes or interfering with fertility. Michael Merson, head of WHO's Global Program on AIDS, said he was hopeful that an effective substance could be developed in two or three years.

WHO announcement, November 16, 1993.

Interleukin-12

Peripheral blood mononuclear cells from many individuals infected with HIV fail to induce T-cell proliferation and IL-2 production in response to synthetic viral envelope proteins or to influenza virus. These responses were restored along with interferon- γ production when cultured cells were stimulated in the presence of IL-12, but IL-12 did not increase IL-2 production in cells from HIV-negative individuals. Restoration of HIV-specific cell-mediated immunity in HIV-infected individuals suggests that IL-12 may be useful in augmenting the diminished immunologic functions associated with HIV infection.

Mario Clerici et al., *Science* 262:1721-1724, December 10, 1993.

Possible CD4 Cofactor

Searching for a cell surface cofactor that, together with CD4, would permit efficient HIV entry and infection, investigators in the laboratory of Ara Hovanessian at the Institut Pasteur have nominated CD26, also known as dipeptidyl peptidase IV. Their argument is based on the fact that this serine protease cleaves substrates at specific amino acid sequences that are highly conserved in the V3 loop, the part of the viral envelope glycoprotein gp120 that is generally thought to be critical in HIV infection.

Christian Callebaut et al., *Science* 262:2045-2050, December 24, 1993.

A diary of discovery, appearing in each issue of SCIENTIFIC AMERICAN SCIENCE & MEDICINE. See "Prospects for an HIV Vaccine," by Dani P. Bolognesi, also in this issue.

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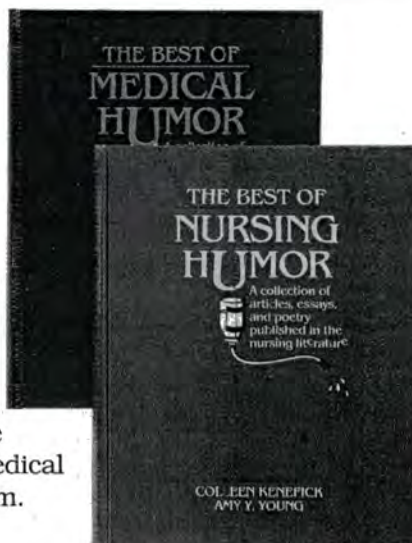
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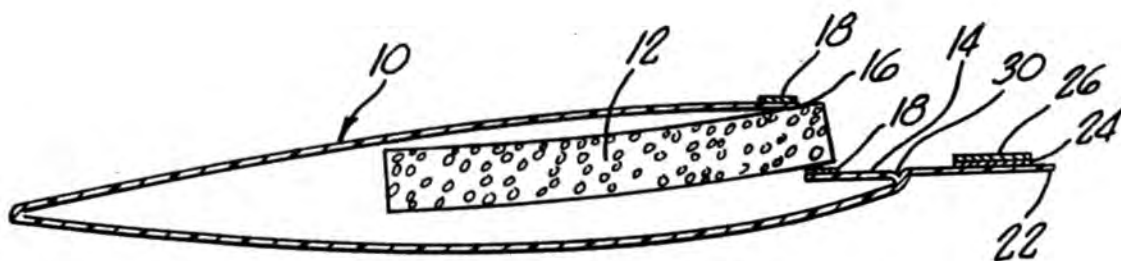


FIG. 4.

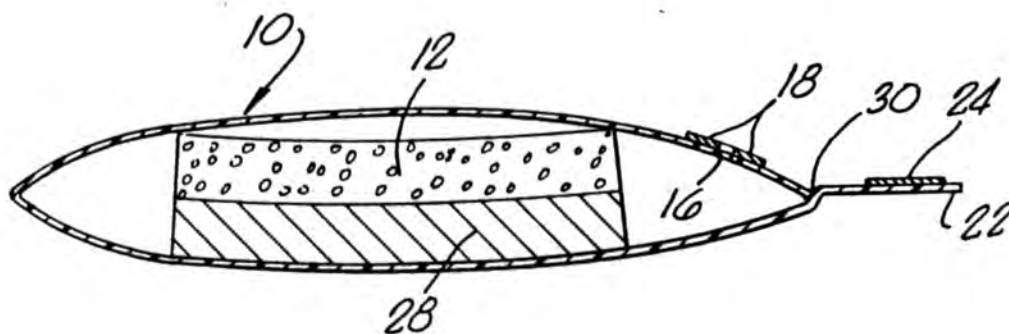


FIG. 5.

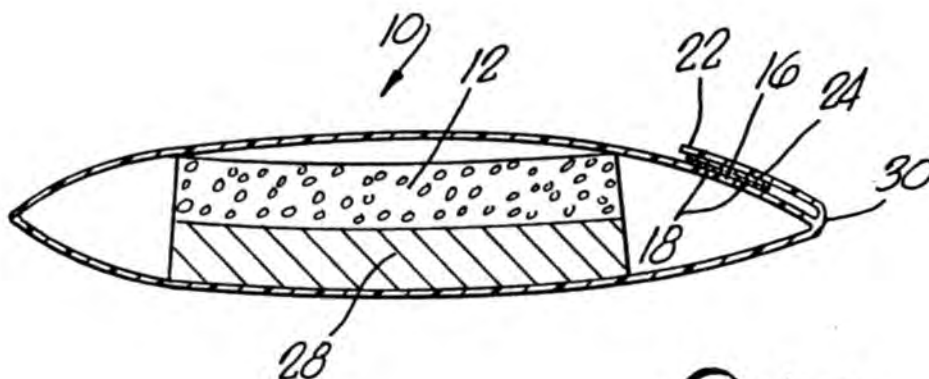


FIG. 6.

BLOOD PRODUCT DISPOSAL SYSTEM AND METHOD

BACKGROUND

The present invention relates to a method for treating and disposing of materials contaminated with blood or blood products and devices and materials for use in the process.

Many diseases are transmitted between humans by contact of open wounds or sores with contaminated blood. Other diseases can be transmitted by insects, such as flies, fleas or mosquitoes, which feed on contaminated blood or materials which contain blood. These insects then contact the open wounds or sores on humans, bite or sting individuals or animals, or, as for example in the case of fleas on rodents, travel into living quarters of humans where the fleas can then transfer to humans, thus transmitting viruses, germs, bacteria, parasites or other disease vectors to the individual. Diseases known to be transmitted by contact with blood or which can be carried by insects are hepatitis, HIV, AIDS, malaria, herpes, human papilloma virus (HPV), and Jacobs Kreutzfelds disease. Many other diseases of unknown etiology are believed to be transmitted by insect bites or contact with infected blood.

Over the last several years considerable efforts have been taken to eliminate or significantly reduce the possibility of transmission of blood bourn diseases by casual contact in the hospital or medical facility environment. Additionally, strict testing and controls have been placed on blood and blood products which are transfused during medical procedures. However, no attempts have been made to eliminate the possibility of the transmission of blood bourn diseases or the contamination of ground water supplies which can be caused by the casual or negligent disposal of menstrual blood. On a monthly basis, millions of women dispose of blood soaked tampons or pads in garbage receptacles or flush them down toilets. These blood soaked materials then end up in land fills or sewer systems where insects and other vermin can contact these blood soaked products. Unfortunately, if the woman's menstrual blood contains germs, bacteria, viruses, or blood parasites, these microorganisms can survive the disposal conditions and can then be transmitted to other humans. This is of particular concern in the case of HIV, hepatitis A, B, or C and HPV which are known to be transmitted in blood and which are believed to survive normal disposal conditions. Additionally, many diseases endemic to the less developed third world but virtually unknown in the developed countries of the world can be readily introduced into those developed countries by a single menstruating woman entering the country from those regions. This is a problem currently unrecognized or unaddressed by the world's public health authorities.

Thus, there is a need for a simple, safe and effective method and system to readily destroy microorganisms carried in menstrual blood and to allow safe disposal of menstrual blood.

SUMMARY

The present invention is directed to methods and devices that respond to these needs and address the deficiencies of the present methods for disposal of menstrual blood.

These needs are met by the present invention which comprises a method of contacting and permeating a

blood soaked pad or tampon with a microorganism destroying compound, such as peroxide releasing compounds, chlorine solutions, chlorine releasing compounds, iodine solutions, and other disinfecting materials, the blood soaked pad or tampon and microorganism destroying compound being sealed within a non-porous container until the infective nature of the microorganism has been eliminated and/or the container and its contents can be safely destroyed. In a preferred embodiment, the method comprises placing a chlorine containing chemical, which can be carried by a porous substrate, into direct contact with the blood containing absorbent pad and sealing the chlorine/pad combination in a leak proof plastic bag.

These needs are further met by products and devices for delivering microorganism destroying materials and containers designed for performing the decontamination process. In a preferred embodiment, the chlorine is delivered from a sodium hypochlorite soaked sponge or a substrate impregnated with or carrying a dry chlorine releasing compound such as trichloro s-triazinetriene.

DRAWINGS

These and other features, aspects and advantages of the present invention will become better understood with reference to the following description, appended claims, and accompanying drawings, where:

FIG. 1 is a partly cutaway perspective top view of the disposal system embodying features of the invention.

FIG. 2 is a cross sectional view of the disposal system of FIG. 1 taken along line 2—2 of FIG. 1.

FIG. 3 is a top view of the disposal system of FIG. 1 after the bag is opened.

FIG. 4 is a cross sectional view of the disposal system of FIG. 1 taken along line 2—2 of FIG. 1 showing the contents of the plastic bag partly removed.

FIG. 5 is a cross sectional view of the disposal system of FIG. 1 taken along line 2—2 of FIG. 1 showing the bag after a blood contaminated pad is inserted therein.

FIG. 6 is a cross sectional view of the disposal system of FIG. 1 taken along line 2—2 of FIG. 1 showing the bag after a blood contaminated pad is inserted therein and the bag is sealed for disposal.

DESCRIPTION

The most common methods for collecting menstrual blood are the insertion of an absorbent tubular tampon into the vagina of the menstruating female or the placement of an absorbent pad external over the opening of the vagina during the period of menstrual flow. The tampon or pad, which is replaced frequently during the period of menstrual flow, usually contains from about 1 cc to about 5 cc of blood or other vaginal secretions, with the normal menstrual flow totaling from about 3 cc to about 10 cc per day with an average flow during each period of menstruation of from about 25 cc to about 55 cc.

Literature has indicated that a 0.1% solution of chlorine, when brought in direct contact with the HIV virus, is adequate to kill the virus. However, to assure complete penetration of the disinfectant into the pad carrying the menstrual blood, a higher concentration of chlorine is beneficial. It has been found that the use of about 5 to about 7.5 cc of a 5% sodium hypochlorite solution or about 0.75 g to about 1.25 g of a dry powdered trichloro s-triazinetriene, which contains 45.77%

chlorine, 90% of that amount being available as free chlorine, when brought into contact with liquid blood soaked into a pad or tampon, and contact is maintained for a minimum of about fifteen minutes, results in most infectious matter in the blood being destroyed or at least incapable of infecting other organisms, thus eliminating or significantly reducing the risk of contamination from the microorganisms in the blood. However, to assure complete decontamination, it is preferred that excess chlorine be used and the blood soaked absorbent material be sealed with the excess chlorine in a closed container, such as a plastic bag, for a period in excess of fifteen minutes. Additionally, the use of peroxide releasing materials is effective against anaerobic bacteria.

FIGS. 1-6 show an embodiment of the system which includes features of the invention, namely a sponge at least partly saturated with a chlorine containing compound, such as sodium hypochlorite, sealed in a plastic bag to prevent evaporation of the water in the solution, oxidation of the chlorine compound or loss of the chlorine. The bag includes means for ready access to the liquid containing sponge when it is time to dispose of a blood containing pad or tampon, and is sized to receive both the blood soaked pad and the sponge. Additionally, the bag is designed to be readily sealed after a pad is placed into it. Preferably, once the bag is resealed, the seal can not be reopened without tearing or cutting the bag, thus preventing access to the contaminated contents.

FIG. 1 shows the liquid and gas impervious bag 10 having a disinfectant containing structure 12 enclosed therein. In a particular embodiment the disinfectant containing structure 12 is a sponge containing a chlorine containing liquid. Spaced a short distance from a first end 14 of the bag 10 is a slit 16. The slit is surrounded on all sides by a first contact adhesive 18 and the adhesive 18 is covered by a readily removable sealing strip 20. As can best be seen in FIG. 3, in a particularly preferred embodiment, the slit 16 does not traverse the entire width of the bag so that the adhesive 18 and sealing strip 20 totally surrounds the slit opening. Above the upper end 14 of the bag 10 is a sealing flap 22 which has, on its upper surface, a second strip of contact adhesive 24 compatible with the first contact adhesive 18, the second contact adhesive being covered by a protective release paper 26. While the use of the second strip of contact adhesive 24 is not necessary for the operation of the system, the use of the two adhesive strips 18 and 24 makes for a more positive sealing of the bag during reclosure as discussed below.

To use the system the sealing strip 20 is removed from the surface of the bag 10 (FIG. 3) and the liquid containing sponge 12 is removed from the bag 10 (FIG. 4). The blood containing tampon or pad 28 is then removed from its collection site, the blood containing surface is brought into contact with the sponge 12 and the sponge 12 and pad 28 are inserted through the slit 16 into the bag 10 (FIG. 5). The release paper 26 is then removed, the sealing flap 22 is folded along the heat seal 30 and the first and second contact adhesives 18, 24 are brought into contact causing an immediate bond between the two adhesives, thus sealing the slit 16 in a leak proof manner (FIG. 6). As soon as the disinfecting material, such as a chlorine containing compound in the sponge 12, comes into contact with the blood in the pad 28, a reaction starts to take place between microorganisms in the blood and the chlorine or other disinfecting material, eventually killing the microorganism.

While a non-porous bag, formed from a plastic material such as a polyethylene, polypropylene or similar materials is preferred, other non-porous materials or combinations of materials may be used. For example, the bag can be formed from a multilayered film material which utilizes a non-porous barrier material such as nylon, saran, or wax. In such an instance, the non-porous barrier material can be coated onto a porous packaging material such as paper, cardboard, or porous polymeric materials such as Tyvek non-woven material. Such a combination of materials has the benefit of being more biodegradable when disposed of in a land fill or less polluting when incinerated.

Additionally, while a first adhesive 18 and sealing strip 20 placed on the wall of the bag 10 are disclosed, other opening means can be used. For example, the bag may include a tear strip imbedded in the wall of the bag 10. Pulling the tear strip creates the opening in the wall of the bag.

The disinfectant containing structure 12 can be formed from various different materials. In a first embodiment the disinfecting agent is a liquid and the carrier is a porous material, preferably spongy in nature so that in use it can be compressed to aid in driving the disinfectant from the carrier into the pad containing the menstrual blood once sealed in the bag. In an alternative embodiment, the disinfectant is a dry material entrapped in a porous structure, coated on a carrier material or formed into a sheet. The sheet of the dry disinfectant material can be formed by casting the material from solution, compressing powdered material or casting the material in combination with a noninterfering binder such as a wax or a water soluble polymer. Where the disinfectant is delivered in a dry form, while contact with dry blood can be effective, the more effective procedure is to use the liquid blood in the menstrual pad to dissolve and/or activate the dry disinfectant.

In a third embodiment the disinfectant containing structure 12 comprises the disinfectant, whether in a liquid or a dry form, enclosed in a frangible package or capsule. In use, the frangible package or capsule is broken while next to or in contact with the blood soaked menstrual pad, thus releasing the contents of the package or capsule onto the menstrual pad. The capsule or package can be loosely contained in the disposable bag, supplied separately, or attached to or incorporated in the bag wall in a manner that will make its contents available when required.

Although the present invention has been described in considerable detail with reference to certain preferred versions and uses thereof, other versions and uses are possible. For example, the primary application is for the disposal of blood containing menstrual pads. However, the invention is applicable to the disposal of other blood containing materials such as bandages, surgical sponges, and the like, or the disposal of materials soaked with other potentially contaminated body fluids such as urine, sputum, or mucous. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.

What is claimed is:

1. A method for the decontamination and disposal of a porous material containing body-fluids comprising:
 - a) supplying a bag having enclosed therein a disinfecting agent, the bag being sealed to prevent the activity of the disinfecting agent from being signifi-

cantly diminished by evaporation or reaction with ambient air,

- b) opening the bag at the time of use,
- c) placing at least a portion of a porous material containing body-fluids in contact with the disinfecting agent to form a combination, the combination being positioned in the opened bag,
- d) sealing the bag to prevent its contents from exiting the bag or ambient air from entering the bag,
- e) causing the disinfecting agent to penetrate the porous material and contact the body-fluids, and
- f) disposing of the sealed bag and its contents.

2. A method of decontaminating the disposing of an absorbent pad containing menstrual blood comprising:

- a) supplying a non-porous bag having a first outer wall and a second outer wall spaced from the first wall, the bag containing an object located between the first outer wall and the second outer wall, the object comprising a disinfecting material, the first outer wall of the bag having an openable portion capable of being opened no greater than a preset length to allow the object located between the first and second outer walls to be removed through the opening thus formed, the bag further having a flap attached thereto, the flap having an inner surface positioned to cover the openable portion after opening, the flap carrying an adhesive strip on the inner surface, the adhesive strip being larger than the largest preset length of the opening, the adhesive being covered by a removable protective film,
- b) creating an opening in the openable portion of the first wall of the bag,
- c) removing the disinfecting material from the bag and bringing the disinfecting material into contact with a pad containing menstrual blood to define a combination,
- d) placing the pad and the disinfecting material combination back through the opening in the bag wall so that the pad and disinfecting material combination is fully contained in the bag,
- e) removing the protective film to expose the adhesive on the flap,
- f) placing the adhesive strip on the flap over the opening in the first wall of the bag so that the adhesive strip completely surrounds the opening, and
- g) disposing of the bag and its contents in a suitable waste receptacle.

3. The method of claim 2 wherein the disinfecting material is chosen from the group consisting of chlorine-releasing materials, peroxide-releasing materials, iodine-releasing materials and a combination of two or more of the chlorine-peroxide- and iodine-releasing materials.

4. The method of claim 2 wherein the disinfecting material is made available in a form chosen from the group consisting of a liquid carried by a porous substrate, a dry form which can be activated by contacting the disinfecting material with moist blood on the pad, and a dry or liquid disinfecting material enclosed in a frangible container.

5. A combination of a container having, a disinfecting agent and a carrier for the disinfecting agent enclosed within the container comprising:

- a bag with means capable of being opened and resealed a single time, the means comprising an openable portion in a first wall thereof and means for sealing the openable portion after opening, the

sealing thereof not being reversible without destroying the sealing means,

the bag being non-pervious to its contents prior to the openable opening portion in the wall, the opening formed being suitable for removal from and reinsertion of the carrier and the disinfecting agent into the bag and being non-pervious to its contents after the opening in the wall is resealed.

6. The container of claim 5 wherein the bag is rectangular in shape, a flap of a fixed width is attached to and extends along a first end of the bag, the width of the flap being the distance from the first end of the bag to an edge of the flap parallel to the first end of the bag, and the bag has a slit of a fixed length in the first wall of the bag, the slit being parallel to the first end of the bag and spaced from the first end of the bag a distance less than the width of the flap, the flap having an adhesive strip applied to a first surface of the flap parallel to the bag first end and being longer in length than the length of the slit, the adhesive located so that the flap can be folded at the juncture of the bag and flap, and, after folding, the adhesive on the flap adheres to the first wall of the bag and completely covers and surrounds the slit.

7. A system for receiving, decontaminating and disposing of a blood-containing menstrual pad comprising:

- a non-porous bag containing structure for opening and resealing the bag a single time, and a disinfecting agent for microorganisms in blood contained in the bag,

the structure for opening and resealing the bag being an openable portion in a first wall thereof and means for sealing the openable portion after opening, the sealing thereof not being reversible without destroying the sealing means,

the bag being non-pervious to its contents prior to opening of the openable portion in the wall, the openings formed being suitable for placing a blood containing menstrual pad into contact with the disinfecting agent in the bag and being non-pervious to its contents after the opening in the wall is resealed,

wherein the disinfecting agent is chosen from the group consisting of chlorine-releasing materials, peroxide-releasing materials, iodine-releasing materials and a combination of two or more of the chlorine-peroxide- and iodine-releasing materials, and

the disinfecting agent is made available in a form chosen from the group consisting of a liquid carried by a porous substrate, a dry form which can be activated by contacting the disinfecting agent with moist blood on the pad, and a dry or liquid disinfectant material enclosed in a frangible container.

8. A process to destroy microorganisms in menstrual blood comprising:

- bringing a pad containing menstrual blood into contact with a disinfecting agent,

placing the pad along with the disinfecting agent into a bag, and

sealing the bag so its contents can not be removed without destructively opening the bag,

the disinfecting agent being initially enclosed in the bag, the bag being openable once to gain access to the disinfecting agent.

* * * * *



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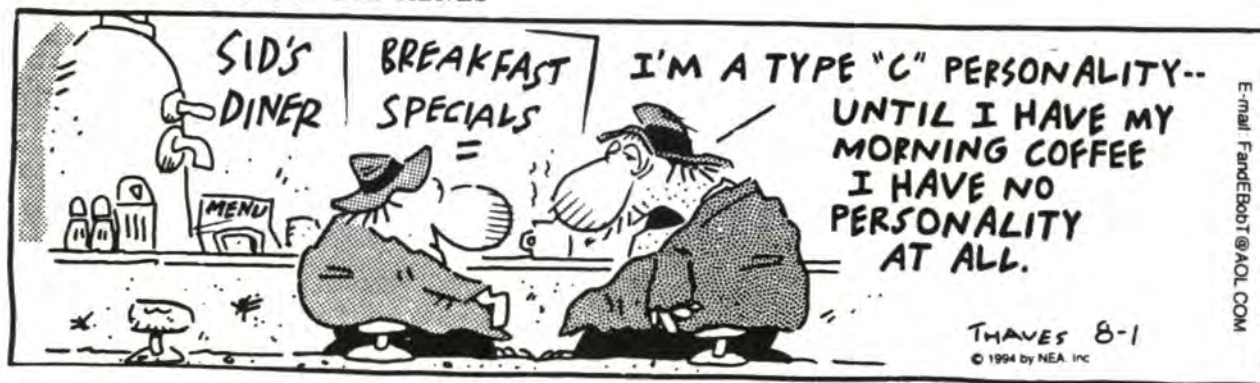
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FDA To Decide Whether Cigarettes Qualify As Drugs—...A Food and Drug Administration scientific advisory panel meets Tuesday to deliberate the nature of cigarettes and to vote for a recommendation that could lead to FDA regulation—(AP 8/1/94)

FDA Approves Tryout of Natural-Filled Breast Implant—...Government regulators are allowing 50 American women to try out an experimental breast implant filled with a natural fat from soybean oil—(AP 8/1/94)

Electromagnetic Fields, alzheimer's Linked—...People with a high occupational exposure to EMFs are at least three times as likely to develop Alzheimer's disease as those without significant exposure—(Richmond Times-Dispatch 8/1/94)

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^For release 9 a.m. EDT<

^FDA Approves Tryout of New, Natural-Filled Breast Implant<

^By LAURAN NEERGAARD=

^Associated Press Writer=

WASHINGTON (AP) - Government regulators are allowing 50 American women to try out an experimental breast implant filled with a natural fat from soybean oil - the first advance in implants since widespread problems with the devices were reported in 1991.

LipoMatrix Inc. said today that its new breast implant should be safer than the silicone-gel and saline implants that thousands of women blame for sickening them - and would be the first implant a mammogram could see through.

The Food and Drug Administration said animal studies show the implants are safe enough for limited testing in women.

"This is a very different implant," said LipoMatrix' president, Dr. Terry Knapp. "It's a natural substance."

Breast implants have been one of the FDA's most wrenching controversies. It banned silicone-gel implants in 1991 for everyone except breast cancer survivors in clinical trials.

Thousands of women claim leaking gel made them ill, in some cases causes crippling autoimmune diseases like lupus. Scientists haven't proven the implants are dangerous, but their manufacturers have agreed to pay \$4 billion to settle 9,000 lawsuits.

And FDA is wrestling with how to regulate saline-filled implants, silicone shells inflated with saltwater that some women say harbor bacteria and fungi that infect them when they leak. Critics say both silicone and saline build up in tissue.

Knapp believes his implant is much safer because it uses triglyceride, a natural fat in the body.

Most people associate triglycerides with heart disease because too much of a certain animal-based triglyceride can clog arteries. Knapp's Trilucent breast implant uses an unsaturated triglyceride from soybean oil, the same kind fed to infants allergic to milk.

Were the implant to leak, animal studies show the body would metabolize and excrete the fat just as it would had the woman eaten the fat, Knapp said in a telephone interview from his headquarters in Neuchatel, Switzerland.

"Hopefully, this will solve the problem for us and it will be a viable alternative," said Sandy Finestone, who heads the Women's Implant Information Network in Irvine, Calif.

However, the implants were developed by scientists at Washington University in St. Louis because mammograms can't adequately penetrate the older implants, meaning early breast cancer could be missed.

Mammograms can penetrate triglyceride just as they penetrate normal breast fat, Knapp said.

The pilot study should give the FDA enough information about the implants' safety and whether they are mammogram-friendly to justify a full-scale clinical trial, said spokeswoman Susan Cruzan.

The FDA also will look at results from trials in Britain, Germany and Italy that began last October. Ninety women there have received the implants without problems, but it's way too early to draw safety conclusions, Knapp said.

Doctors at five U.S. sites will implant 10 women each, who will be followed for one year. The women must already have an implant that needs removing because of leakage or other problems - but cannot have systemic medical problems because the small study is not sophisticated enough to account for major illnesses.

The new implants do have silicone shells, which some women also fear. Knapp said the shells are a special new form of silicone that shouldn't leach into tissues; the study will look at that as well.

Trial sites include: Johns Hopkins University in Baltimore; Stanford University in California; The Breast Center in Van Nuys, Calif.; the University of Florida, Gainesville; and Washington University in St. Louis.

Women interested in participating may call 800-839-3000.
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August 8, 1994

RICHMOND TIMES-DISPATCH

U.S. FOCUS

Electromagnetic fields, Alzheimer's linked

LOS ANGELES TIMES/WASHINGTON POST
NEWS SERVICE

Electromagnetic fields, previously implicated in triggering leukemia, brain tumors and breast cancer, may play a far more important role in Alzheimer's disease, says a University of Southern California researcher.

Results from two new studies indicate that people with a high occupational exposure to EMFs are at least three times as likely to develop Alzheimer's disease as those without significant exposure. Dr. Eugene Sobel has written for the Fourth International Conference on Alzheimer's Disease and Related Disorders in Minneapolis.

By comparison, the cancer risk associated with EMFs is generally believed to be 1.5 to 1.8 times as high among those with occupational exposure.

Sobel and his colleagues also found that dressmakers and tailors were overrepresented among Alzheimer's victims. Further study showed that industrial and home sewing machines produce much larger EMFs than other appliances and that people who use sewing

machines regularly have the greatest exposure of any occupation — as much as three times that of electric power line and cable workers.

Unlike the case for leukemia and tumors, the researchers say they have a biological rationale for how the EMFs produce the suspected Alzheimer's-related defects and animal evidence that supports their observations.

"This opens up a whole new frontier in terms of potential EMF effects," said EMF expert Louis Slesin, editor of *Microwave News*. "EMF has long been a backwater area with a lot of skeptical people taking potshots at the research. . . . This could signal a major change in the way EMF health risks are addressed."

Dr. James Mortimer of the Veterans Affairs Medical Center in Minneapolis said Sobel's findings were very surprising. "Nobody ever even thought it [Alzheimer's] was related to EMF. This is a much stronger finding than the link to leukemia."

Alzheimer's disease afflicts at least 2.5 million Americans and perhaps as many as 4 million, most over age 65.

It is characterized by memory loss, disorientation, depression and deterioration of bodily functions. It is ultimately fatal, causing about 100,000 deaths in the United States each year.

The cause of Alzheimer's is still unknown. Genetics almost certainly play a major role in its onset, experts say, but environmental factors may contribute as well. Most previous studies of environmental factors have focused on chemicals. Sobel's findings offer entirely new possibilities.

Two of the studies were conducted in Helsinki by USC with researchers from the University of Kuopio and Helsinki. The other study was done in Los Angeles. Together, they involved a total of 386 Alzheimer's patients and 475 healthy control subjects. Subjects were divided into two categories — those with medium to high occupational exposure and those with low or no occupational exposure.

Those people with the higher occupational exposure to EMFs were an average of three times as likely to develop Alzheimer's as those with low exposure, Sobel reported. The relative risks were consistent in the three

studies: 2.9, 3.1 and 3 times higher than the low exposure group.

Women were more susceptible to the effects of EMFs: in the three studies combined, women with the higher exposure had a relative risk of 3.8 compared to women with the lowest exposure. In one of the Finnish studies, those women with the highest exposure were 7.3 times as likely as women in the low exposure group to develop Alzheimer's; in the other two studies, the relative risks were 3.3 and 4.2 times as great.

The study was an outgrowth of laboratory findings by one of Sobel's co-authors, neurologist Zoreh Davanipour of Loma Linda University. Davanipour and colleagues found that EMFs increase the number of calcium ions in nerve cells grown in the laboratory.

Calcium is extremely important in the cells because it is directly involved in many biological responses, especially communication among nerve cells. Sobel speculates that increased levels of calcium ions kill the cells. That finding suggests that EMFs could affect neurological diseases, a conclusion that the researchers said seems to be supported by the study results.

DAN QUAYLE

Tonight the Republican Party will finally be allowed to air its health care reform views on television.

Unlike the Clinton case for a government-run system, the Republican ideas won't be showcased in a prime-time special on one of the major networks. Instead, the show will be produced from the U.S. Chamber of Commerce studios and shown only on C-SPAN and via satellite downlink.

The networks declined to sell air time to the Republican National Committee because it was considered "advocacy advertising." Never mind that the RNC was responding in part to those same networks' advocacy journalism in support of the Clinton concepts. America's media elite obviously want to control the debate.

Consider NBC's "To Your Health," a "documentary" aired in late June and funded entirely by the liberal Robert Wood Johnson Foundation, which paid \$3.5 million for the two-hour commercial free special. (The sponsoring foundation, which had earlier spent \$500,000 for four town meetings featuring the first lady, may have broken new ground in the annals of philanthropy by making a grant to a profit-making network news division. Ordinarily, foundations direct their benevolence to nonprofit or charitable causes.)

Hosted by Tom Brokaw, the show was billed by the network as a fair and impartial review of the health care debate. In effect, however, it was little more than an infomercial for government-run health care. Hillary Clinton was Mr. Brokaw's sole guest for the first half-hour. Mr. Brokaw, who flirted with the idea of becoming a member of the Clinton administration, let the first lady give her case

Missing medical pieces from the GOP

with little rejoinder or interruption. It was a blatant bit of pandering.

One of the guests, Daniel Casse, blew the whistle on this stage-managed town meeting in the Wall Street Journal. Mr. Casse, who was invited as an opponent of Mr. Clinton's plan, found himself and a handful of critics vastly outnumbered by "Democratic congressional staffers, union represent-

atives, health care lobbyists sympathetic to the Clinton plan and spokesmen from every conceivable liberal action group."

Ironically, the NBC special portrayed opposition to the Clinton health care plan as caused mainly by conservative radio talk-show hosts such as G. Gordon Liddy and Michael Reagan, the former president's son.

What the mainstream media

can't seem to grasp is that the American people are much smarter than the sophisticates think. They can see through a staged health care discussion. They know when they aren't getting both sides of a story, and they know that too often, to get the other side, they must turn on their favorite conservative talk-show host.

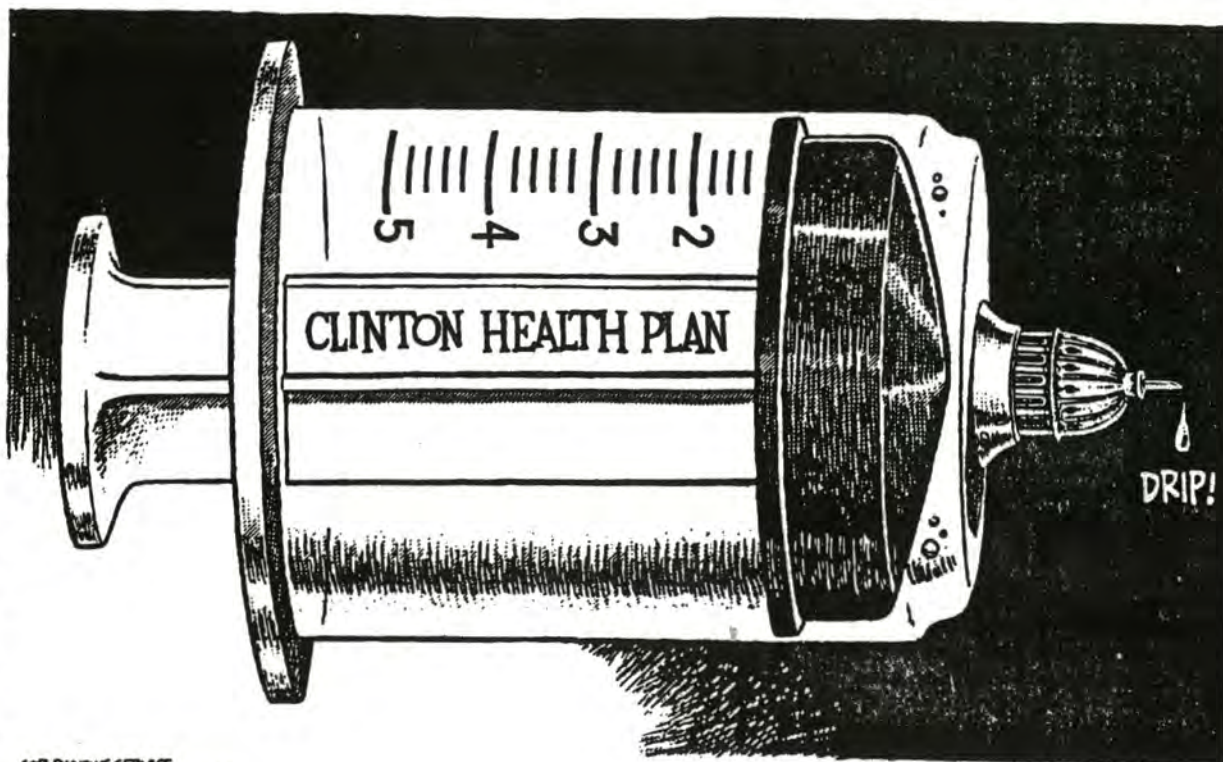
The power of the media elite to

influence and shape public opinion is in decline, because so many journalists have jettisoned their claim to be objective and even-handed. Liberal advocacy by the mainstream media has opened the door to the rising influence of conservatives in such nontraditional media as talk radio.

Rush Limbaugh is, of course, the most famous example. He is now on the receiving end of the media elite's criticism, supposedly because he is too partisan. In fact, with his entertaining, no-holds-barred advocacy, Mr. Limbaugh simply embarrasses the media by exposing how often they are pursuing a liberal political agenda, even as they talk sanctimoniously about fairness and accuracy.

As the health care reform endgame plays out on Capitol Hill, the media will no doubt treat us to stories about heroic congressmen burning the midnight oil through the hot August nights to solve the national health care crisis. But this is a myth. The only crisis Congress is trying to solve now is the electoral crisis its Democratic majority will face in the fall. That's why the horse-trading and vote buying are already under way.

To truly understand the debate, the public will be well-advised to diversify their sources of information. Turn on C-SPAN to learn what NBC left out. And keep those radios tuned in.



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RICHMOND TIMES-DISPATCH

CORRELL

Former Vice President Dan Quayle is chairman of the Competitiveness Center of the Hudson Institute in Indianapolis.

Genetics a key in derailing cancer

By Roger Signor
ST. LOUIS POST-DISPATCH

ST. LOUIS — Doctors here are removing the thyroid gland to keep some patients from developing a potentially lethal form of cancer. It's the first time that a genetic test has been used as the basis for taking out a patient's organ.

Since last year, surgeons at Washington University School of Medicine have removed the thyroid glands from 14 patients in whom a new genetic test predicts that their glands will become malignant.

The doctors described the new test, developed at the medical school, and preventive surgery at an international conference on thyroid cancers in Stockholm.

The use of a genetic test by the researchers in St. Louis to prescribe such radical intervention as excision of an important gland has implications for diseases other than thyroid cancer, experts said.

The thyroid gland makes hormones that help regulate the use of energy.

Other genetic tests may be developed to predict more common cancers, such as breast, colon and ovarian cancers, doctors said.

All patients who have had the surgery in St. Louis, known as a thyroidectomy, have a genetic mutation. A research team led by Dr. Helen Donis-Keller, professor of surgery and genetics at Washington University, perfected the test to detect that mutation last year.

The overall thyroid study is the brainchild of Dr. Samuel Wells, head of surgery at Washington University. With a team of 25 scientists, he has studied 50 families worldwide who carry the thyroid mutation. He has followed the families for 25 years.

The 14 patients from the families range in age from 6 to 20 years. Dr. Wells' project has a \$4 million grant from the National Institutes of Health.

"Excluding factors such as lab errors, there's virtually 100 percent certainty that this genetic test is predictive of people developing thyroid cancer — usually occurring in their teens," Dr. Wells said in an interview.

He estimated that further testing of families in his study will identify up to 100 people who carry the genetic flaw and are candidates for surgery.

Families that carry the gene said they're glad that the test and the surgery are available. Even so, some deal with considerable stress and worry. Now, they anxiously wait to find if any of them — maybe a grandparent or a grandchild — carries the gene.

Dr. Wells said his team of surgeons and geneticists doesn't discuss results of genetic tests with the families. That's left to counselors.

A St. Louis University geneticist said the breakthrough by Dr. Wells' team would soon be followed by other genetic tests that will predict development of more common cancers such as tumors of the breast and colon.

"This [thyroid test] should prevent years of misery and perhaps death in many patients," said Dr. Martin Eswara, assistant professor of genetics.

Dr. Eswara and Dr. Wells agreed, though, that patients and doctors will be more reluctant to prevent cancer by removal of an entire colon or breast.

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^AP-Abortion-Services, Bjt,0391(

^Prayers and Memorial March for Martyred Doctor, Escort(

^With PM-Abortion Shooting, PM-Abortion-Escorts(

^AP Photo PA101(

^By ROBERT DVORCHAK=

^AP National Writer=

PENSACOLA, Fla. (AP) — On a day of marches and mourning, appeals for peace and healing joined prayers for a doctor and his escort shotgunned to death outside an abortion clinic.

"Never return evil for evil," said the Rev. John Beuhrens, president of the 2,000-member Unitarian Universalist Association of North America, at Sunday's interfaith service.

He told the crowd of 350 worshipers to keep their faith strong following Friday's double slaying, saying: "The only thing necessary for violence and evil to prevail is for good women and men to do nothing."

After the service, ministers led marchers through pouring rain to a memorial for slain civil rights leader Martin Luther King Jr. During the block-long procession, the soaked crowd sang "We Shall Overcome."

Prayers were said for Dr. John Britton, 69, and retired Air Force Lt. Col. James Barrett, 74, both shot through the head outside the Ladies Center.

Paul Hill, 40, a former minister who has called the assassination of doctors who perform abortions "justifiable homicide," is charged with two counts of murder and one count of attempted murder.

Britton had replaced Dr. David Gunn, murdered 17 months ago outside another Pensacola clinic. The city has also been the site of four bombings, a destructive raid and countless demonstrations at abortion clinics over the past 10 years.

"Not only our faith but our city has been tarnished," said the Rev. Herb Sadler of the Gulf Breeze United Methodist Church.

"Pensacola has been held up to the world as a place of hate and violence. We know the core of radical fundamentalists who produce these acts do not represent our city and they do not represent our faith," Sadler said.

Earlier Sunday, about 150 people attended a memorial service for Barrett at the Pensacola Unitarian Universalist Fellowship. His wife, June, 68, who was wounded Friday, lit a candle to begin the service.

Barrett's son and daughter were among those who rose from their chairs to praise Barrett's life. Church-goers dabbed their teary eyes with hankies and tissues as five ceiling fans turned silently to ward off the Gulf Coast heat.

"We all know he died doing something he strongly believed in," Bruce Barrett said of his father. "He died with his boots on. He was a soldier in the war for human rights."

Dandy Barrett Witty spoke of her father's service to his country during World War II, Korea and Vietnam, and the contributions he made to Pensacola in the two years he and his wife lived here.

"My dad was a military man, but he believed his primary mission in life was the keeping of the peace," she said, her voice breaking. "He believed that on Friday when he was killed. I would ask that we all continue his work."

To the right of the lecturn in the sparsely decorated room was a bouquet of red roses and white carnations sent by the Ladies Center.

Before the service concluded with the singing of Barrett's favorite hymn, "Amazing Grace," a letter was read from the Rev. Susanne Nazian, president of the Florida Unitarian Universalists Association.

"We join with people of all faiths to condemn these murders. We pray for the healing of the families of the men who were murdered and for the healing of the city of Pensacola," Nazian wrote.

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2 slain at Fla. clinic



THE ASSOCIATED PRESS

VICTIM. Dr. John Bayard Britton was shot outside an abortion clinic.

Anti-abortion militant is in custody

THE ASSOCIATED PRESS

PENSACOLA, Fla. — A former minister killed a doctor in a bulletproof vest and his escort yesterday outside an abortion clinic in Pensacola, police said.

Another escort was wounded in the shotgun attack at the Ladies Center for Abortion, the second such deadly assault in the city in 17 months.

Paul Hill, 40, was chased down within minutes after witnesses pointed him out to police. Hill had openly advocated violence as a divinely sanctioned means of stopping abortions.

"Now is the time to defend the unborn, the same way you'd defend slaves about to be murdered!" he shouted as he was transferred from the police station to jail.

Hill was held without bail on two charges of murder and one of attempted murder. He could also face federal charges under a law enacted in May in response to 1,000 cases of abortion-re-

lated violence since 1977.

Dr. John Bayard Britton, 69, and 74-year-old James Herman Barrett had just arrived for work and were sitting in a pickup truck outside when the gunman approached and opened fire with a 12-gauge shotgun, hitting both men in the head, police said.

Barrett's 68-year-old wife, June, a retired nurse who like her husband worked as a volunteer escort shielding clinic employees from protesters, was also in the truck. She was wounded in the arm and was listed in good condition.

The clinic had been bombed twice in 1984 and vandalized in 1986.

Hill, a former minister with the Presbyterian Church in America and The Orthodox Presbyterian Church, is director of Defeasive Action, an anti-abortion group he founded after Dr. David Gunn was slain outside another Pensacola clin-



THE ASSOCIATED PRESS

ARRESTED. Anti-abortion activist Paul Hill was charged in the shootings.

PLEASE SEE CLINIC, PAGE A9 ►

Groups denounce 'senseless violence'

State advocates on both sides say deaths unjustified

BY TOM CAMPBELL

TIMES-DISPATCH STAFF WRITER

Advocates on both sides of the abortion issue in Virginia denounced yesterday's killings at a Florida abortion clinic, but from different points of view.

"I hold every one of these people responsible for what happened in Florida," said Jill Abbey, director of the Richmond Medical Center for Women, of the abortion protesters who demonstrate daily outside the clinic at Grove Avenue

and the Boulevard.

But people speaking for Virginia anti-abortion organizations said no "mainstream" member of the movement embraces the idea that killing abortionists is justifiable in any way.

The Pensacola killings were "senseless violence," said Ralph Reed, executive director of the Christian Coalition in Chesapeake. "This lone act in no way represents the beliefs and values of the genuine pro-life movement. Killing in the name of life is rank hypocrisy, pure and simple."

Violence "solves no problem. It only creates heartache, misery and pain," said Judie Brown, president of the American Life League, a national anti-abortion group with headquarters in Stafford.

Brown and other anti-abortion leaders distanced the movement from the man

who was accused of the Pensacola killings, Paul Hill, a protester who has argued that killing abortionists is justified.

Brown called Hill "a creation of the tabloid talk-show media. He is not a leader in the pro-life movement."

In Washington, representatives of more than a dozen other anti-abortion groups held a news conference to condemn the killings, saying the "true philosophy of the pro-life movement [is] respect for all life."

The American Center for Law and Justice, a public-interest law firm founded by television evangelist Pat Robertson in Virginia Beach, also condemned the violence.

Tania Blagrove, executive director of the Virginia affiliate of the National Abortion and Reproductive Rights Action League, said, "Anti-choice activists

have failed to make abortion illegal, so they are doing everything they can, including murdering doctors and bombing clinics, to make abortion unavailable."

Abortion protesting at clinics in Richmond and elsewhere in Virginia has been steadfast in recent years, but largely peaceful.

Protesters turn out Monday through Saturday on the sidewalk at the clinic on the Boulevard. And they are routinely outside the Virginia League for Planned Parenthood abortion clinic when it operates, Thursdays and Saturdays, at 517 W. Grace St.

Abbey and Grace Sparks, the Planned Parenthood executive director, said the protesters are orderly, but confront arriving patients with accusations that

PLEASE SEE GROUPS, PAGE A9 ►

Two fatally shot at Florida clinic

▼ CLINIC FROM PAGE A1

ic last year.

Hill decided to give up his ministerial credentials in the Orthodox Presbyterian in 1992, said Ross Graham, spokesman for the church.

"The Christian principle is to do unto others as you would have them do unto you," Hill said in an interview this year. "If an abortionist is about to violently take an innocent person's life, you are entirely morally justified in trying to prevent him from taking that life."

Sgt. Jerry Potts said Hill was a regular outside the Ladies Center and was arrested June 17 for disrupting the clinic.

Police tried to keep an eye on Hill, but "there was no way we could put a 24-hour surveillance on him," Potts said.

The attack came just minutes before an off-duty police officer was to arrive to provide routine security at the clinic, a two-story, wood-frame house on the suburban north side of Pensacola, a conservative city in the Florida Panhandle.

Britton traveled from his home town across the state near Jacksonville to perform abortions in Pensacola after Gunn's murder, according to a profile in February's GQ magazine. He had received threats, including a message left in the office door that read: "What would you do if you had five minutes left to live?"

The Barretts would escort him to the clinic in a minivan with a box containing a gun, according to GQ.

Barrett was a retired Air Force lieutenant colonel and a Korean War veteran. His wife was a retired captain with the U.S. Health Service.

"Jim was doing what he believed in," Mrs. Barrett said in a statement. "He believed in justice and would want justice for Paul Hill. Jim believed in a woman's right to choose."

In June, the U.S. Supreme Court upheld buffer zones around abortion clinics to protect patients and staff members.

Gov. Lawton Chiles pledged yes-

HISTORY OF VIOLENCE

There have been several cases of abortion violence in Pensacola, Fla., preceding yesterday's shooting. They include:

■ Christmas Day 1984

The Ladies Center, another clinic and two doctors' offices were bombed by abortion foes who were convicted and imprisoned. The Ladies Center also was bombed on June 24, 1984.

■ March 1986

Six protesters were arrested after they stormed into Ladies Center, damaging equipment and injuring two women. John Burt, one of the protesters jailed, was a confidant of Griffin.

■ March 10, 1993

Dr. David Gunn was shot dead outside a clinic in the nation's first murder during abortion protest. Michael F. Griffin, 31, is serving a life sentence for the killing.

terday to step up state efforts to protect abortion clinic employees and patients.

"Florida will not tolerate any act of violence or any attempt to make our state the staging ground or headquarters for a campaign of violence and disruption," Chiles said.

Activists on both sides of the abortion debate denounced the shooting, including Operation Rescue, which has orchestrated clinic protests nationally.

"Neither the violent nor the vigilante have any place in the pro-life movement," said the Rev. Patrick Mahoney of Operation Rescue.

The Presbyterian Church in America is "a very strongly pro-life denomination, but we would condemn murder for any cause whatsoever," said Robert Sweet, a spokesman for denomination.

Groups denounce violence

▼ GROUPS FROM PAGE A1

they are killing their babies and about to take part in murder.

"They're nasty," said Abbey. "They like to paint it as a nice peaceful protest. They're not peaceful. They say ugly things. ... It's verbal harassment."

Sparks said the protesters commit "verbal violence. ... When you accuse people of committing murder, when you say children are being murdered, there is a degree of responsibility for the words you use."

"It's hard to respect someone who uses those words, but at the same time says, 'There's no room for violence in this movement,'" Sparks said. "Those words are violent."

Abbey said she feels threatened by the protesters she sees at work. She said the protesters may reject violence, but welcome the impact violence may have on patients and staff.

"I felt threatened today by one of the protesters," she said. The man told her about the killings in Pensacola. "He said something about, 'You don't need to be scared of me, but wait until the violent ones come.' Sounded like a pretty bold threat to me."

Sparks said she is not concerned about violence from the protesters she sees regularly.

But she noted, "There's also an element that's sort of unknown and violent and probably not mentally stable. Those are the people we are concerned about."

The continuing protests here and the news of violence elsewhere take a toll, Sparks said.

"It's a hard way to work. It's hard on staff, it's hard on patients," she said. "But we're not going to stop. ... Our medical people are focused on the need that women have for this service and I'm focused on that, too. And while none of us take foolish chances, none of us are going to run from this."

Staff writer Kathryn Orth contributed to this report.

Dem health bill already needs chicken soup

By **SUSAN MILLIGAN**

News Washington Bureau

WASHINGTON — House Democratic leaders produced their semi-final offer on health care reform yesterday, setting up a nasty confrontation with Republicans and leaving some Democrats wondering if they can back it.

The proposal, unveiled in draft form by Democratic leaders, also skirts the issue of abortion — an element that could stall the bill.

And the package is certain to run into trouble for its inclusion of "employer mandates" requiring companies to pay for part of worker health care — a provision no one on Capitol Hill believes would survive a Senate vote.

Democratic leaders pointedly said their package was not President Clinton's proposal, even submitting a handy chart to congressmen explaining the differences.

But Republicans quickly dubbed the package the "Clinton-Gephardt bill," and said it would not get a single House Republican vote. "The heart of the bill is Clinton and all of the damaging things it would do to America," said House Minority Leader Robert Michel (D-Ill.).

The Democratic proposal, which could come to the House floor as early as Aug. 8, includes "pregnancy-related services," the legislative euphemism for abortion coverage. But aides said the language is temporary while members seek a compromise on the issue.

The package includes universal coverage by 1999 with subsidies for small business and the poor.

New York officials are withholding support, saying it is unclear how the package would affect the state. Rep. Nita Lowey (D-Westchester-Queens) said it appears the package includes spending limits that could cost New York 3,000 hospital residents.

DAILY NEWS • Saturday, July 30, 1994

Health victory urged

Clintons, Gores try to ignite support

FROM ASSOCIATED PRESS REPORTS

INDEPENDENCE, Mo. — Exhorting Americans to "finish Harry Truman's fight," President Clinton stood front and center in the former president's hometown yesterday to demand victory in the long battle for guaranteed health insurance.

"Harry Truman would say: 'The buck stops here.' The buck stops in Congress, and the buck stops with you," Clinton told thousands of cheering supporters massed on Independence Square. "Let's push it over the finish line."

Clinton teamed up with his wife, Hillary, and Vice President Al Gore and his wife, Tipper, for a campaign-style rally designed to ignite a public outpouring of support as Congress nears a critical point in the health care debate.

It was their first joint appearance outside Washington since the campaign, and White House officials clearly were trying to recapture some of the energy and enthusiasm that accompanied the disclosure of Clinton's health care plan last year but later gave way to doubts about the details.

Protesters on hand

Even as Clinton denounced the "hot air and hot signs" characterizing the rancorous health care debate, protesters in the distance chanted dissenting views, waving signs such as, "No to National Health Care" and "It's Socialism, Stupid."

Supporters chanted in return: "Pass It Now! Pass It Now!"

Clinton's audience included busloads of "reform riders" who are riding the Health Security Express bus caravan to Washington to push Congress to enact Clinton-style health reform.

Mrs. Clinton sought to put the focus on the gripping stories of ordinary Americans riding the buses, saying their experiences need to be heard "over all the shouting and the back and forth."

Sixteen-year-old Rachel Crowthers, who rode the bus from Portland, Ore., told the crowd she's been treated "like a second-class citizen" since going on Medicaid to meet her medical bills for cancer treatments.

When protesters booed the soft-spoken girl's speech, Gore told the crowd, "It made me realize how completely out of touch they are with the people of this country. Unbelievable."

The Clinton-Gore team made its stand before the bunting-decorated county courthouse and a statue of Truman, who first proposed his first health care plan in November 1945. Everyone should be guaranteed health coverage "regardless of ability to pay," Truman reasoned.

Clinton told the crowd: "Let's finish Harry Truman's fight. We're halfway home and we can go all the way."

He rejected critics' contentions that his plan to make employers help pay for their workers' insurance was "either socialized medicine, somehow unethical or bad



THE ASSOCIATED PRESS

APPEAL FOR HELP. President Clinton pushed for health care reform at a rally at the town square in Independence, Mo., yesterday.

for the economy."

Hoping to shake off negative perceptions about the Clinton plan, Democratic congressional leaders are trying to fashion a similar alternative that they characterize as less bureaucratic and less burdensome to small business.

In Washington, Senate Republican leader Bob Dole criticized Democrats yesterday for backing "government-knows-best health care" and called for bipartisan talks on a scaled-back reform measure.

Dole said a plan disclosed Friday by House Democrats was the "same song, different verse" as the proposal Clinton submitted to Congress last year.

Intensive lobbying planned

"You can't just change the name and put more government in it," he said.

The House Democratic plan is stripped of some of Clinton's most unpopular proposals but retains his call for businesses to pay 80 percent of the cost of health insurance premiums for workers.

With House and Senate votes expected in the next few weeks, the administration is kicking off an intensive two-week lobbying campaign, including 300 hours of local radio interviews. Each Cabinet member is committing 30 minutes a day to interviews, and the Clintons and Gores plan numerous appearances as well.

House remake of health bill pledges coverage to all by '99

KNIGHT-RIDDER NEWSPAPERS

WASHINGTON — Invoking the legacy of Social Security and other popular safety-net programs, House Democratic leaders yesterday unveiled a retooled and renamed health reform bill that would guarantee insurance for all Americans by 1999.

"It's more than a piece of legislation," said Majority Leader Richard Gephardt, D-Mo. "It's really a piece of the American dream. If we pass it — if we triumph over the special interests and obstructionists — it will be every American's security and dignity as long as they live."

Democratic Whip David Bonior, D-Mich., said the bill would redefine the contract between employer and employee: "Every job would come with health insurance attached."

But as the rallying cry went out to Democratic lawmakers, leaders faced a risky struggle to round up the 218 votes needed for passage.

Many rank-and-file Democrats say the leadership can forget about their votes if the Senate rejects the key financing mechanism of the House bill, a mandate that requires employers to share the cost of workers' health premiums.

The House bill is as close to President Clinton's blueprint as Congress is likely to get.

While it keeps important features

of Clinton's bill, such as the employer mandate and a national benefits package, it scraps the president's requirement that most Americans get their health insurance through huge, government-sponsored co-ops.

The bill also sets up a new Medicare Part C program as an insurance pool open to poor families, the unemployed and people who work for several firms or small businesses. It also allows some people to enroll in a popular federal health care program and others to opt for a medical savings account in lieu of full insurance coverage from an employer.

But many important details remained unresolved. For instance, Democrats have not been able to agree on abortion benefits. The Clinton bill provides full coverage for the procedure, while lawmakers opposed to abortion want to make it optional.

The Democratic leaders' bill almost certainly faces further changes to secure passage. A better sign of what could actually clear Congress might be a Senate plan due out Tuesday that sets a goal of 95 percent coverage by 2000. An employer re-

quirement would go into effect in 2001 if the goal isn't met.

However, Senate sources said Majority Leader George Mitchell, D-Maine, is considering exempting firms with fewer than 25 workers from the employer requirement.

Clinton's bill would have required employers to pay 80 percent of workers' premiums, with subsidies to help small firms. Since there's no chance of that passing in the Senate, Mitchell is trying to design as gentle an employer mandate as possible.

The House Democratic leaders took pains to distance their plan from Clinton's, which has been sliding in opinion polls. They even changed the bill's title from Clinton's "Health Security Act" to the "Guaranteed Health Insurance Act of 1994."

Nonetheless, Clinton embraced the work of the House leaders.

Republicans said the name change was laughable. "The Democratic leaders met with the president and declared his bill dead," said Rep. John Boehner, R-Ohio. "Their new bill happens to have the same elements of the Clinton bill."

More importantly, conservative Democrats seemed unpersuaded. Since comprehensive health reform has very few Republican supporters, Democrats need the support of their party's moderates and conservatives. They didn't seem to be getting it.



Gephardt

Tobacco companies lead in fund-raising in Colo.

DENVER — Tobacco companies have raised more than \$300,000 to try to defeat a Colorado ballot measure to add 50 cents to the price of a pack of cigarettes.

That's nearly 70 percent more than the amount collected by Fair Share for Health, the group that wants to tax cigarettes to pay for health care.

The \$303,627 raised from January through July 29 came from only seven donors — all tobacco companies and trade groups.

Philip Morris U.S.A. kicked in \$118,000, while R.J. Reynolds contributed about \$81,000 to fight the tax. Smokeless Tobacco gave \$25,000. The Tobacco Institute and Brown & Williamson contributed \$20,000 each.

Fair Share raised \$178,877 during the same time period, with the largest contributions coming from the health care industry.

R.M.D. Health Enterprises, P/SL Health Care System, Swedish Medical Center and Children's Hospital all contributed \$10,000 each. The Heart Association and Cancer Society were also major contributors.

DOONESBURY



IT GIVES US AT LEAST ONE MORE CHANCE, AND POSSIBLY SEVERAL CHANCES, TO MAKE OUR CASE AGAIN IN AN OPEN COURTROOM!



Doctors' dispute deepens

Henrico hospital to fight to free cardiac surgeon

BY ANNA BARRON BILLINGSLEY

TIMES-DISPATCH STAFF WRITER

Henrico Doctors' Hospital has joined the legal fray involving a pediatric heart specialist, contending that a former employer's court action could deprive patients in central Virginia of his potentially lifesaving services.

The former employer, the Medical College of Virginia's Division of Cardiothoracic Surgery Inc., has sued Dr. Gary K. Lofland, contending that his attempts to establish a private practice in Richmond violate a noncompete clause in his employment contract.

In documents filed this week, though, Henrico Doctors' contends the noncompete clause is "unenforceable

as a matter of public policy in that, in this unique situation, it denies all of Central Virginia the lifesaving medical services of a uniquely qualified pediatric cardiothoracic surgeon."

Lofland's contract states that, for two years following termination of his employment at MCV, he would not "solicit to render" competitive services within a 50-mile radius of the academic medical center. In a motion requesting an immediate hearing, Henrico Doctors' calls for "temporary and permanent injunctive relief" on the grounds that uncertainty surrounding Lofland's status has deprived critically ill Central Virginia pediatric patients "of necessary services."

A hearing on the case is set for Aug. 19 at 11:15 a.m. Meanwhile, the parents of a local child in desperate need of surgery confirmed that Lofland has set up the

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PLEASE SEE DOCTORS, PAGE A6 ►

▼ DOCTORS FROM PAGE A1

operation for Wednesday at Henrico Doctors'.

The documents filed this week shed more light on what has been a protracted, perplexing — and possibly unprecedented — dispute between Lofland and the physicians' group with which he practiced for five years.

For instance, the documents indicate that Henrico Doctors' this week entered into an employment agreement with Lofland. That agreement, which seems to have come after indications Lofland was seeking employment in another part of the country, is to take effect Monday.

Pending since March, the legal proceedings against Lofland — and his subsequent countersuit against his colleagues — had been more or less a behind-the-scenes battle.

Two surgeries were delayed

The wrangling became public when two surgeries scheduled to be performed by Lofland at Henrico Doctors' last week were abruptly canceled.

The parents of the two children scheduled for surgery were told only that Lofland was involved in a legal dispute.

News of the incident prompted other parents of pediatric heart patients to come forward with compelling tales of how their lives have been affected by the inability to schedule surgery for their children. In many of these cases, Lofland performed the initial surgery when their children were diagnosed with heart defects. The parents fully expected the same physician to perform the necessary subsequent surgery.

What was baffling about the cancellation of the two surgeries last week was that Lofland had performed other surgeries at Henrico Doctors' since his departure from MCV.

No other physician in area

Henrico's filings this week indicate two of those surgeries were emergencies. The legal documents state: "At the present time, there is no physician other than Dr. Lofland at any hospital in Central Virginia who is sufficiently experienced and competent to perform sophisticated cardiothoracic surgery upon pediatric patients."

The papers indicate that in the two emergency situations, transporting the patients to a hospital outside Central Virginia could have proved life-threatening. Also, the documents state, "the families of the pediatric patients who are transported [would] have to bear the expense and additional emotional distress of following their children to a hospital outside of Central Virginia."

According to the papers, "three other pediatric patients required the specialized surgical services of Dr. Lofland although they were not in as immediate exigent circumstances as the first two infants."

'Irreparable harm'

And the legal documents say there are at least nine pediatric patients who will require the services of Lofland in the next several weeks. Henrico Doctors' contends that "without the services of Dr. Lofland, there will be immediate and irreparable harm to not only pediatric patients within Central Virginia ... but also to the hospital and its program of cardiothoracic surgery."

On the other hand, officials at Virginia Commonwealth University, of which MCV is a part, contend that Lofland's private practice will jeopardize their academic medical center's training programs and accreditation.

While Central Virginia needs a pediatric heart surgeon, area physicians say, the volume of patients is not high enough to support more than one such specialist.

VCU has said, "When a specialist takes leave from our program, but refuses to abide by the noncompete clause, he impedes the institution's ability to recruit another specialist who can deliver this type of high-quality care and medical training."

Staff writer Alan Cooper contributed to this report.

Alcoholism's Sad Slide

For those who struggle with a drinking problem, new research shows that depression may be the real culprit

BY COLETTE BOUCHEZ

For most people, de-stressing after a hectic work week, or even a bad day, can safely include knocking back one or more alcoholic drinks. This is not only okay, say most doctors — it might even be a good idea. Indeed, a number of studies released this past year indicate that for most people, moderate amounts of alcohol, even consumed regularly, can have positive health effects, particularly in helping prevent cardiovascular disease.

However, for those afflicted with the disease of alcoholism, drinking is in no way connected to anything positive. Instead, it has been linked to a series of physical and emotional ills, including depression.

"The problem of depression is definitely overrepresented in people with alcoholism, in the sense that the two occur simultaneously much more frequently than one would expect by chance," reports Dr. Patrick McGrath, a psychiatrist and principal investigator in studies on alcoholism and depression currently being conducted at New York State Psychiatric Institute.

"What is less clear," says McGrath, "is whether depression leads to drinking, or the other way around."

There is no definitive answer, but some see a difference between the sexes. Observes McGrath, "Thus far, our studies show that men begin drinking first — perhaps as part of a male-bonding or buddy system — and are hit with depression only after the drinking becomes a problem. In women, the problem begins with depression, which in turn leads to the drinking."

Taking a controversial position, McGrath maintains that pre-alcoholic depression in women may develop as a

result of continually fluctuating hormones that may activate any genes they have inherited for depression. He points to research showing that girls experience a dramatic increase in rates of depression after puberty, while the incidence for boys seems to rise at a more gradual rate. Once the gene for depression has been activated, maintains McGrath, it may help trigger the one for alcoholism.

Other experts in the field take a different view. "My sense is that the depression exists equally in men and women prior to the onset of drinking," says Dr. H. Michael Grant, a psychiatrist at Lenox Hill Hospital who regularly treats alcoholics also suffering from depression.

Grant believes that if hormone fluctuations do play a role in alcohol-related depression, it is simply because they allow women to be more aware of mood changes and, thus, better able to document feelings of depression before excessive drinking begins.

"It's likely that men are not as in touch with their feelings and may not recognize, even in retrospect, mood changes or behaviors that would indicate the presence of pre-alcoholic depression," says Grant.

More readily accepted is the idea that a gene for alcoholism can exist in both sexes, though there is little scientific evidence for this theory. McGrath not only believes that

a gene for alcoholism exists, but that it makes up at least half the risk factor for the disease.

"Besides having family histories that demonstrate generational patterns of alcoholism, we also know that children of alcoholics react differently

on brain-wave tests than children whose parents don't have a drinking problem and, further, that they exhibit certain personality traits that are later linked to alcoholism," according to McGrath. All these indicators show up long before the kids may take a drink, he says.

In other studies, children of alcoholics have been shown to physiologically process alcohol differently. This, says McGrath, may also contribute to addiction.

Grant believes that there are both

biological and sociological factors at work. "For most people," he says, "the onset of alcoholism is likely a combination of family history of the disease plus negative life experiences which have manifested extreme psychological discomfort."

Interestingly, although alcoholism and depression appear to coexist in many patients, and although both diseases seem to have a genetic component, there is no genetic crossover between the two. In other words, a family history of alcoholism will not increase your risk of depression, and vice versa.

However, experts say there is a curious phenomenon that leads many people to inherit both the genes for alcoholism and for depression. Notes McGrath, "For whatever reason, depressed women tend to marry men who are alcoholics, so their offspring are often at even greater risk for having the

two diseases occur simultaneously."

While the cause of alcoholism still remains a mystery, experts tend to agree that treating the depression may be the best way to conquer the disease in men and women. Observes Grant, "We are finding that regardless of which came first — the depression or the drinking — treating the depression usually causes the drinking to stop, or at least makes the pattern easier to break."

The most effective weapons in doctors' arsenals these days are anti-depressant medications, particularly those that affect the levels of the brain chemical serotonin, which has been linked to addictive behavior as well as to depression. The best results appear to be achieved by combining anti-depressants with psychotherapy and the support of self-help groups like Alcoholics Anonymous.

Points out Grant, "The ultimate goal is to reduce the alcoholic's discomfort — whether it be depression or anxiety — and by doing so reduce the need for alcohol."

(Bouchez regularly reports on health for The News.)

Free Treatment Program

Currently, there are a number of studies taking place nationwide that use anti-depressant medications in the treatment of alcoholism.

In New York City, free treatment of this type can be obtained at a new research program conducted by the New York State Psychiatric Institute in conjunction with the National Institutes of Health.

Those who qualify for the study receive a free medical evaluation as well as free medication and counseling. To inquire about eligibility or obtain further information, call (212) 960-5734, Monday through Friday, 9 a.m. to 5 p.m. Daytime or evening treatment hours can be arranged.

— C.B.

JULIE LIEBERMAN





PHS SUPPLEMENT BRIEFS

WEDNESDAY, JULY 27, 1994

Researchers Find Drop in U.S. Blood Lead Levels—...Lead levels in Americans' blood have dropped dramatically since the latter half of the 1970s, researchers from the Centers for Disease Control and Prevention report in the Journal of the American Medical Association—(Richmond Times-Dispatch 7/27/94)

25% Of Aged Mismedicated—...A study suggested more than 6.6 million elderly Americans not in nursing homes are prescribed dangerous or inappropriate medication that can cause people to lose their balance or faint, resulting in serious injury and deaths—(Richmond Times-Dispatch 7/27/94)

FDA Panel To Rule On The Status Of Rogaine—...The Food and Drug Administration advisory panel is expected to recommend today whether Upjohn Co.'s antibalding drug Rogaine should go over-the-counter—(The Wall Street Journal 7/27/94)

FRANK AND ERNEST / BY BOB THAVES



Clippings of interest to the Public Health Service
Compiled by the PHS News Division 202/690-6867



BRIEFLY

COLLECTED FROM WIRE SERVICES
AND TIMES-DISPATCH RESOURCES

Researchers find drop in U.S. blood lead levels

CHICAGO — Stricter environmental rules have largely succeeded in getting the lead out of American blood, researchers say.

Lead levels in Americans' blood have dropped dramatically since the latter half of the 1970s, researchers from the Centers for Disease Control and Prevention said in today's *Journal of the American Medical Association*.

However, the researchers cautioned the metal still can be found in the paint of many older homes and endanger people who live there and inhale or eat paint dust or flakes. Lead also is found in old pipes and contaminated soil.

25% of aged mismedicated?

Study focuses on the elderly not in nursing homes

THE ASSOCIATED PRESS

CHICAGO — More than 6.6 million elderly Americans not in nursing homes are prescribed a dangerous or inappropriate medication every year, researchers say.

Use of such medications can cause people to lose their balance or faint, resulting in serious injury and death. It also can rob them of their ability to think clearly and remember, causing them to wind up in a nursing home.

People receiving such drugs are "often placed at risk for loss of their memory, loss of their balance and mental slowing," said the study's co-author, Dr. Steffie Woolhandler, an associate professor of medicine at the Cambridge Hospital and Harvard Medical School.

The study was published in today's *Journal of the American Medical Association*.

Critics of the study complained its research is outdated and that there is disagreement among doctors about what drugs are inappropriate for elderly people.

Woolhandler cautioned that no one should stop taking a prescription drug without consulting a doctor.

The study, involving 6,171 people over 65, was based on 1987 federal survey data, the most recent available, Woolhandler said.

Previous studies looked at nursing home patients; this was the first attempt to examine the medicines prescribed to elderly people not in institutions, Woolhandler said.

People in the study were considered to be using inappropriate drugs if they were taking any of 20 medications that a panel of independent experts said in 1991 always should be avoided by the elderly.

A total of 23.5 percent of those surveyed were using at least one of the drugs. Extrapolated, that would mean about 6.6 million of the more than 26 million elderly people not in nursing homes were getting inappropriate drugs.

The most common drugs used were the anticoagulant dipyridamole, better known as Persantine; the pain reliever propoxyphene, better known as Darvon Compound; and the anti-depressant amitriptyline, better known as Elavil.

High use rates also were found for the diabetes drug chlorpropamide, or Diabinese; the tranquilizer diazepam, or Valium; the arthritis drug indomethacin, or Indocin; and the tranquilizer chlordiazepoxide, or Librium.

Critics of the study disputed the authors' claim that doctors' prescribing practices have not changed significantly since 1987. And they ar-

gued that not every drug on the list is truly harmful or dangerous.

"Some of the drugs she thinks are unacceptable are considered important by others in the academic field," said Steve Berchem, a spokesman for the Pharmaceutical Research and Manufacturers of America.

MARKETPLACE

FDA Panel to Rule on the Status of Rogaine

By LAURIE MCGINLEY
And ELYSE TANOUYE

Staff Reporters of THE WALL STREET JOURNAL

A Food and Drug Administration advisory panel is expected to recommend today whether Upjohn Co.'s antibalding drug Rogaine should go over-the-counter. Analysts say the chances are good, and the agency is likely to follow the panel's advice.

But there's a problem: Rogaine, a clear liquid that "regrows" hair in men and women, is far from a sure cure. "I call it 'no gain,'" says a 30-year-old congressional aide who has used the drug for five years and says he has less hair now than when he started.

Rogaine already passed the FDA's safety and effectiveness tests when it was approved for prescription use. But FDA officials take another look when a product is to be sold without a doctor's supervision. In the case of Rogaine, the advisory panel will consider what happens when the drug's active ingredient, monoxidil—which in pill form is used to lower blood pressure—is absorbed into the skin. The scientists want to know whether there are any cardiovascular effects when the drug is used topically—especially by an overly enthusiastic consumer.

"You know, a layperson may feel

if a little bit is good, a lot is better," says Murray Lumpkin, a top FDA official.

Only about half the men, and 19% of women, who use Rogaine see moderate hair growth or better, says the company. The drug takes months to produce hair. It doesn't work well for those who have lost a lot of hair. And unless it's rubbed or sprayed on the scalp twice a day every day, the new hair will fall out. "You have to have a motivated population," says Hemant Shah, an independent analyst. "It isn't a one-shot deal."

After Upjohn launched Rogaine for women in 1991 (the drug was approved for men in 1988), Rogaine sales peaked at \$160 million in 1992, well below Wall Street's early expectations of \$500 million a year. Last year, sales fell 31% to \$110 million. Mr. Shah believes the drug's nonprescription sales potential is "limited."

D. Larry Smith, a New York-based analyst, is more upbeat. An over-the-counter Rogaine would be a "huge, huge plus" in sales for Upjohn, he says. And the company says the price tag is likely to be cheaper than the current cost of \$50 to \$60 a month, although it won't say how much cheaper.

MEDICINE

Under federal law, the change in status would protect Rogaine from competition from generic copycats for another three years after the expiration of the patent in February 1996. The company is also testing an antibaldness formula with 5% monoxidil, instead of 2%, the current formulation, and would be available by prescription only.

If its application is approved, Upjohn will also have greater freedom to advertise its product. Advertising for prescription drugs is regulated by the FDA, which generally requires that any print ad or television commercial include relevant warnings about potential side effects. "There's a requirement that balance be given between the good things the drug does and the potentially bad things," says Randy P. Juhl, chairman of the FDA advisory committee that will consider the Rogaine application.

Nonprescription drug advertising is regulated by the Federal Trade Commission, which doesn't require that warnings about side effects be included in ads. But extensive information on labels and package enclosures for such products is mandated by the FDA.

In recent years, the lure of greater revenue has encouraged a growing number of companies to switch their prescription drugs to over-the-counter status. Dr. Juhl's committee today is also likely to make a recommendation on SmithKline Beecham PLC's request to sell Tagamet, its popular anti-ulcer drug, on a nonprescription basis. And on Friday it will review a similar bid by Merck & Co. for Pepcid, another anti-ulcer medication. Both drugs would be marketed as heartburn remedies.

Upjohn is confident Rogaine will pass the safety test. When used topically, only 1.4% of the drug is absorbed, according to a spokesman who says the most common side effect is skin irritation in about 7% of patients. At the meeting today Upjohn will present data showing that 11,000 people who used the drug were found to be as healthy as 11,000 nonusers, according to the Upjohn spokesman.

The company has also tested the drug as a possible treatment for impotence. The theory was that it might help induce erections when applied topically by opening up blood vessels, which is how it lowers blood pressure. But the research was dropped several months ago, the Upjohn spokesman said, because the treatment didn't work in clinical trials.

From the Assistant Secretary for Health, US Public Health Service

Irradiation to Prevent Foodborne Illness:

Foodborne illness is one of the largest preventable public health problems in the United States. Studies by the Centers for Disease Control and Prevention show that foodborne diseases caused by pathogenic bacteria, such as *Salmonella*, *Campylobacter*, *Escherichia coli*, and by *Vibrio*, *Trichinella*, tapeworms, and other parasites, cause an estimated 9000 deaths and from 6.5 million to 81 million cases of diarrheal disease annually. Medical costs and productivity losses also are staggering. The US Department of Agriculture estimates that annual medical and lost productivity costs associated with selected foodborne pathogens are between \$5 billion and \$6 billion. The enormous tragedy is that these losses are preventable when current knowledge and proven technology are applied.

Unfortunately, it has taken a crisis to raise consumer, industry, and lawmakers' awareness. Media scrutiny about salmonella in poultry and the highly publicized deaths of four children and severe illness of 600 people linked to *E coli*-tainted hamburgers have raised serious questions about food safety.

Contamination can occur at any point in the food supply chain, which extends from the farm to the table. The critical link is processing. Ideally, the safety of all food distributed by food processors should be assured. Several measures are available to do so, but none has the potential to be more effective than irradiation.

Food irradiation, like pasteurization of milk, can prevent countless infections because it destroys the pathogens that cause foodborne illness. Irradiation would neither replace good manufacturing practices nor provide the sole answer to foodborne illnesses. But it would add substantially to a farm-to-table approach for food safety.

Irradiation is not a new technology. It is widely used in the United States to sterilize medical supplies, including surgical instruments, implants, gowns, and bandages. Irradiation was first patented for food preservation in 1930 by a French scientist. Research intensified in the United States in the 1940s when irradiation was considered as a means for providing safe food for troops in remote areas. United States astronauts have been eating irradiated food since 1972, when the Apollo 17 crew selected ham as the first irradiated flight meal. Immunocompromised people also benefit from irradiated food because it helps to reduce the risk of bacterial infection.

Today, 38 nations, including the United States, have approved the use of irradiation processing for a wide variety of food products. There is a worldwide research base of 9000 references for food irradiation that covers all aspects of safety and wholesomeness for a wide range of produce, grain, fish, meat, and poultry.

The Joint Expert Committee on the Wholesomeness of Irradiated Foods—convened by the World Health Organization (WHO), Food and Agriculture Organization (FAO), and the International Atomic Energy Agency (IAEA)—concluded in 1980 that the “irradiation of any food commodity up to an overall average dose of 10 kilogray causes no toxicological hazard . . . and introduces no special nutritional or microbiological problems.”

In 1986, a WHO/FAO/IAEA Task Force on the Use of Irradiation to Ensure Hygienic Quality of Food concluded that “at present, and in the foreseeable future, no known technology can guarantee the production of raw foods of animal origin, particularly poultry and pork, without the presence of certain pathogenic organisms and parasites, such as *Salmonella*, *Campylobacter*, *Toxoplasma*, and *Trichinella*. . . [W]here such foods are important in the epidemiology of foodborne diseases, irradiation decontamination/disinfection must be seriously considered.”

After another extensive review of all existing data, WHO released the following updated policy statement on September 23, 1992: “Irradiated food produced under established Good Manufacturing Practices is to be considered safe and nutritionally adequate because:

- The process of irradiation will not introduce changes in the composition of the food which, from a toxicological point of view, would impose an adverse effect on human health.
- The process of irradiation will not introduce changes in the microflora of the food which would increase the microbiological risk to the consumer.
- The process of irradiation will not introduce nutrient losses in the composition of the food which, from a nutritional point of view, would impose an adverse effect on the nutritional status of individuals or populations.”

In 1993, the American Medical Association's Council on Scientific Affairs affirmed food irradiation as “a safe and effective process that increases the safety of food when applied according to governing regulations.”

In 1994, I enjoyed my first irradiated

turkey sandwich. It was delicious! Yet, obvious questions remain. If food irradiation is so great, why isn't every American able to buy irradiated products? And why is there so little agricultural or food processing industry interest in irradiation? Consumer wariness is the most frequently cited reason.

Irradiated chicken and produce have been made available to US consumers recently in a few food markets. The products quickly gained consumer acceptance. The results in these markets, along with marketing research, demonstrate that with a little education, consumers indicate a preference for irradiated food products, and they are willing to pay more for them. Most irradiated foods cost only a few additional cents. Consumers know they are buying a product protected by irradiation because it bears the prominently displayed radura logo along with the statements “Treated with Radiation” or “Treated by Irradiation.”

It may not seem apparent, but food irradiation, like pasteurization and other population-based public health measures, is critical to achieving cost containment in health system reform. Reducing the incidence of foodborne illness is one part of reducing the nation's health care costs. Expensive emergency department charges and other treatment expenses are avoided. Most important, suffering and death are avoided.

It is the US Public Health Service's responsibility to use what we know to protect and improve the health of the public. Each modern food-processing advance—pasteurization, canning, freezing—produced criticism. Food irradiation is no different. It is up to leaders in the health professions to dispel the myths.

The technology of food irradiation has languished too long already. Perhaps our nation has become dangerously complacent about the importance of public health measures. The current health care debate offers us both a mandate and an opportunity to increase the understanding of the importance of public health for ensuring personal health. If this message is lost, our efforts to advance and protect the nation's health will not succeed.

—by Philip R. Lee, MD

Assistant Secretary for Health
Director, US Public Health Service

Editor's Note: Mark Weber, Office of Health Communications, assisted with this report. Direct written inquiries to him at 701-H Humphrey Building, Washington, DC 20201.

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^AP Poll Finds Wide Support for Principle of Universal Coverage(

^With PM-Poll-Method(

^AP Graphic(

^By HOWARD GOLDBERG=

^Associated Press Writer=

NEW YORK (AP) — Although just a third of Americans favor President Clinton's health care plan, his commitment to universal coverage retains widespread support, according to an Associated Press poll.

Seventy-four percent favor giving all Americans health insurance that covers all medically necessary care. Support for universal coverage is even higher among women, blacks, people born in the 1940s and those from lower middle-class families.

The poll of 1,000 adults was taken July 20-24, just after Clinton's suggestion — which he quickly disavowed — that health reform might cover 95 percent of Americans rather than everyone. In the poll, 36 percent deem this an acceptable way to limit costs and 58 percent say it's unacceptable.

The Clinton administration and congressional leaders are considering numerous compromises to make their health care proposals affordable and politically palatable. The poll shows how difficult this is: Even backing off universal coverage by 5 percent disappoints most Americans of all ages, incomes, regions and other categories.

Overall support for reforming the nation's health care system fell to 69 percent from 83 percent in an AP poll six months ago. Those saying the current system works rose to 28 percent from 17 percent in January.

Both telephone polls were conducted by ICR Survey Research Group of Media, Pa., part of ABS Consultants. Results have a margin of error of plus or minus 3 percentage points.

The respondents oppose Clinton's plan by 51 percent to 33 percent, a reversal from January, when 51 percent favored the plan. In the current poll, 7 percent say they favor only parts of the plan, 8 percent say they're not familiar enough to know and 1 percent are uncertain.

An issue that seems to have the public as divided as Congress is the so-called employer mandate. Clinton proposed that employers pick up 80 percent of the cost of coverage for workers and their families. Three congressional committees endorsed that approach, but its fate is uncertain amid fierce lobbying.

In the poll, 48 percent say employers should be required to pay most of the costs of health insurance for all their workers, 46 percent say employers should only be required to offer their workers a chance to buy their own health insurance. The rest don't know.

That support for the employer mandate is somewhat higher than in a comparable poll a month earlier by the Times Mirror Center for The People & The Press.

But uncertainty among the public remains high. Even among those who favor the Clinton plan, which includes the employer mandate, 37 percent oppose that provision.

The poll shows that supporters of the Clinton plan also send mixed signals on the question of universal coverage. Fully 98 percent favor it when asked if the system should give all Americans health insurance. But when the idea is floated of making the plan more affordable by covering only 95 percent of Americans, backers of Clinton's plan are no more likely than others to call that compromise unacceptable.

On July 19, Clinton told a meeting of governors in Boston that "95 percent or upwards" might be enough coverage to fit his definition of universal. Later in the day, aides said he was not backing off his threat to veto any legislation that does not guarantee every American private health insurance that can never be taken away.

APNP-07-27-94 0850ED1(

Mental health question limits proposed

Policy would apply to federal job seekers

BY GIL KLEIN

MEDIA GENERAL NEWS SERVICE

WASHINGTON — The Clinton administration announced yesterday it would limit questions investigators can ask prospective federal employees about mental health treatment.

Tipper Gore, wife of Vice President Al Gore and the administration's point person on mental health issues, told the National Press Club that the new policy is designed to remove the stigma of mental health counseling.

"There's no reason why seeing a psychiatrist makes anyone more of a security threat than seeing an oncologist for colon cancer, an endocrinologist for Graves' disease, or an aller-

gist for severe allergies, as our last three presidents have done," Mrs. Gore said.

"Schizophrenia is no more a character flaw than heart disease," she said.

She cited the case of Vincent Foster, President Clinton's counselor and good friend, who committed suicide while suffering from depression.

"He knew he suffered from depression," Gore said. "Yet he did not seek treatment in part because he thought it would reflect badly on him, and because he was afraid it would jeopardize his security clearance."

She said the new policy would revise questions investigators could ask to focus only on the recent past. Short-term counseling would not have to be reported. Questions that investigators could ask of mental health care providers would be limited to the applicant's ability to perform job responsibilities.

The policy requires no congressional approval and it will go into effect after govern-

ment agencies have had a chance to review it, she said.

Melvin Sabshin, medical director of the American Psychological Association, agreed that "in an overwhelming number of cases, having some kind of treatment is irrelevant to job performance." Yet now, he said, there's a "reflex action that any counseling disqualifies a person for a high-security job."

As the policy stands now, Gore said, once a job applicant admits having seen a counselor or psychiatrist, an investigating agent can ask that counselor any question.

"They ask all kinds of very personal questions that we as Americans concerned with individual rights should abhor," she said.

Under the Clinton proposal, she said, the applicant will give the investigator a waiver saying he can ask certain questions of the counselor and no others. The investigator can ask about treatment of a particular mental disorder as it relates to job performance only, she

said.

Even sensitive CIA and national security jobs would fall under this proposal, she said. Despite the Aldrich Ames spy case, CIA Director R. James Woolsey last week said he wanted to seal off records of employee counseling from counterintelligence officials charged with hunting down moles.

"Common sense tells you that if you had a severe delusional illness where you are detached from reality ... that would be some cause for concern," Gore said. "But that is so different from a broad range of mental disorders that go from depression to bulimia, to learning disabilities to panic and anxiety disorders, which when treated would not cause a person to be a security risk."

She urged private employers to follow the federal government's lead in removing the question "have you ever seen a psychiatrist or have you ever had counseling" from employment applications.

July 15, 1994 / INTERNAL MEDICINE NEWS & CARDIOLOGY NEWS

19



"I notice several of you are reaching for the remote."

Beware the Bombardment Of Health Care Propaganda

Millions of dollars will be spent in the next two weeks to persuade you to help sway maybe 90 votes in Congress on health care issues. As the targets of this advertising assault, you would do well to remember the high stakes and the hidden motives of the people who are trying to recruit you to their side in this fight.

The fate of health care legislation lies largely in the hands of about 60 undecided members of the House of Representatives and perhaps half that many Senators. They are mainly in the center of the political spectrum — moderate and conservative Democrats, concentrated in the South and the border states, along with a smaller number of moderate to liberal Republicans, especially in the Senate.

They are tugged in different directions by ties of party, constituency, philosophy, and political and financial support. They will largely determine whether there are broad, systemic changes in the financing and delivery of health care services, of the scale President Clinton is seeking, or narrower, incremental changes — or nothing.

Any of the outcomes is possible, which is one reason the lobbying and advertising are so intense. The other, bigger reason is that the financial stakes are so enormous for all the interests involved — big and little business, organized labor, senior citizens, doctors, nurses, hospitals, drug companies, universities, and teaching centers — and, not least, insurers.

WITHIN THESE large issues are buried scores of others, any one of which can be enough to move one of the targeted 90 Senators and Representatives from one side to the other. These range from the size of the tobacco tax, to the inclusion or exclusion of abortion, to the latitude a health plan has to screen its own doctors.

My desk — and the desk of every other reporter covering this epic fight — is buried deep with faxes and press releases from groups advocating their side of every one of these questions. Some of them are very straightforward about their sponsorship and their interest; others come disguised in coalitions or committees shielded by layers of camouflage.

All this was predicted months ago by Joseph Califano, who went through an earlier version of this fight when he was Secretary of Health, Education, and Welfare in the Carter administration. Back in February, Califano wrote in *The Washington Post* that, realistically, one "should think of health care reform as throwing a trillion-dollar pot of gold up for



DAVID
BRODER

"At bottom, this is not a political contest between Republicans and Democrats or an ideological one between liberals and conservatives. It's a bare-fisted brawl over who gives to and gets from the rich business of health."

grabs. At bottom, this is not a political contest between Republicans and Democrats or an ideological one between liberals and conservatives. It's a bare-fisted brawl over who gives to and gets from the rich business of health.

"The nastiest street fights," Califano continued, "are likely to come among those who have the most at stake: hospitals (\$409 billion), doctors (\$195 billion), nursing homes and home health care (\$108 billion), pharmaceutical companies (\$100 billion), insurers (\$62 billion), and others such as dentists, podiatrists, optometrists, physical therapists, pharmacists (more than \$100 billion). They can be expected to fight in the back alleys of Capitol Hill with a roughness rarely seen in Washington."

THE FIGHTING has been every bit as intense as Califano predicted, and now it is spreading to the airwaves and the newspapers in an advertising blitz the likes of which few can remember. The most effective lobbying, as all the interest groups have learned, comes from the grassroots — but it does not arise spontaneously. That is why you are being bombarded with pleas to tell Congress you want what they've got, or you don't want this or that done to you or taken away from you. Tell them you want it now, or tell them you wish they'd think about it for another year. Tell them — *tell them!* — tell them.

The first thing to say to the people who are telling you what to tell Congress is that you're fully capable of deciding for yourself what you want your Representative or Senators to do. Then tell them to identify themselves — and their financial interest — clearly. If they won't, you would be wise to ignore them. Third, make them show you how their interest is compatible with your interest. What you want from the health care system may not be what any of them are peddling.

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Rapid Test Could Facilitate Difficult TB Diagnoses

BY JOHN CARPI
New York Bureau Chief

NEW YORK — A rapid test could aid in the detection of the one-third of tuberculosis cases that are difficult to diagnose, Dr. Antonino Cantanzaro said at an update on clinical diagnosis and management of tuberculosis sponsored by Gen-Probe.

The rapid test could differentiate *Mycobacterium tuberculosis* from *M. avium* and *M. intracellulare*, aiding diagnosis in patients with complex cases such as concomitant HIV infection and immunosuppression after transplanta-

tion, said Dr. Cantanzaro, of the division of pulmonary and critical care medicine at the University of California, San Diego, School of Medicine, La Jolla.

One-third of TB cases now tracked by the Centers for Disease Control and Prevention are atypical. "Patients may present with pneumococcal pneumonia that does not reveal underlying TB until 2 weeks after the pneumonia clears, or they may be HIV positive and present with classic TB signs but actually have MAC [*Mycobacterium avium* complex] infection," said Dr. Cantanzaro, who is chairman of the California Tuberculosis Elimination Task Force.

"Most physicians still favor the chest X-ray, and in typical cases that is an excellent diagnostic tool, but in atypical patients lab tests are required," Dr. Cantanzaro added. Standard laboratory TB tests include sputum analysis, acid-fast staining, and the Bactec test, perhaps the most reliable and fastest of the three. Bactec yields results in 10-14 days.

The CDC recommends that *M. tuberculosis* be detected and identified within 2 weeks, with drug sensitivity analysis completed in another 2 weeks. Thomas Shinnick, Ph.D., chief of the Hansen Disease Laboratory at the CDC in Atlanta, said at the meeting.

"Current testing falls well within the CDC's range, but gene amplification techniques will help in making patient management decisions sooner," Dr. Shinnick said.

Gene amplification is the backbone of the new test discussed at the meeting. Gen-Probe, the manufacturer of the test, submitted an application for approval to the Food and Drug Administration this spring.

The test yields results in 24 hours and the cost of the test to laboratories is expected to be between \$30 and \$40, according to Mathew Longiaru, Ph.D., a director at Gen-Probe. That price compares to about \$20 to \$25 for a Bactec culture.

In a study of 594 specimens from 198 patients at Jackson Memorial Hospital in Miami, the test found all 52 patients positive for tuberculosis as confirmed by polymerase chain reaction (PCR) with Southern blot hybridization. The specificity on first assay was 95% and the sensitivity was 84%.

Unpublished data found similar specificity and sensitivity in tests of 500 specimens from 259 patients at the State

One-third of TB cases now tracked by the Centers for Disease Control are atypical.

University of New York Health Science Center at Brooklyn, Marcelino Sierra, Ph.D., director of microbiology at the center, reported at the meeting.

Patient management decisions that might be aided by a rapid test fall into three categories, according to Dr. Cantanzaro. "I think the office-based physician would be better equipped to initiate therapy in suspect patients with the availability of a rapid test," he said. "Those are patients who are not obviously infected but in whom you might want to begin treatment. HIV-infected patients who require a specialized treatment protocol, and patients in whom the distinction between infection with *Mycobacterium tuberculosis* and *Mycobacterium avium* complex is not clear. . . . In the other two-thirds of patients—those with obvious tuberculosis—you don't need a rapid test," Dr. Cantanzaro said.

A rapid test may also challenge some commonly held views about TB infection. When compared with culture, serum, and PCR results, the Gen-Probe and PCR tests indicate persistent infections beyond 10 weeks in some compliant patients. Compliant TB patients who are not infected with drug-resistant strains are thought to be noninfectious after 10 weeks of therapy.

"What this might be telling us is that we need to rethink the concept of when a person no longer is infectious," Dr. Sierra said. "These are much more sensitive assays that can pick up minute amounts of bacterial RNA, indicating that some bacteria are still active and reproducing even after a thorough treatment course."

But the Gen-Probe test does not spot drug-resistant strains. "There are indications that there might be mutation targets to identify for drug resistance, but this is in its infancy," Dr. Longiaru said.

ONCE-A-DAY CARDIZEM[®] CD (diltiazem HCl) 120-, 180-, 240-, 300-mg Capsules

FOR HYPERTENSION OR ANGINA

Brief Summary of Prescribing Information as of April 1993

CARDIZEM[®] CD (diltiazem HCl) Capsules

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker; (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker; (3) patients with hypotension (less than 90 mm Hg systolic); (4) patients who have demonstrated hypersensitivity to the drug; and (5) patients with acute myocardial infarction and pulmonary congestion documented by x-ray on admission.

WARNINGS

Cardiac Conduction. CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time except in patients with sick sinus syndrome. This effect may rarely result in abnormality of heart rates particularly in patients with sick sinus syndrome or second- or third-degree AV block (13 of 3290 patients or 0.4%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.

Congestive Heart Failure. Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (50-60). An acute study of oral diltiazem in patients with impaired ventricular function (ejection fraction 24% ± 6%) showed improvement in indices of ventricular function without significant decrease in contractile function (50-61). Worsening of congestive heart failure has been reported in patients with preexisting impairment of ventricular function. Experience with the use of CARDIZEM (diltiazem hydrochloride) in combination with beta-blockers in patients with impaired ventricular function is limited. Caution should be exercised when using the combination.

Hypotension. Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.

Acute Hepatic Injury. Mild elevations of transaminases with and without concomitant elevation in alkaline phosphatase and bilirubin have been observed in clinical studies. Side effects were usually transient and frequently resolved even with continued diltiazem treatment. In rare instances, significant elevations in enzymes such as alkaline phosphatase, LDH, SGOT, SGPT and other phenomena consistent with acute hepatic injury have been noted. These reactions tended to occur early after therapy initiation (1 to 8 weeks) and have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in some cases, but probable in some (see PRECAUTIONS).

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with 30, 60, and 90-mg prolonged-release capsules, laboratory parameters of renal and hepatic function should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In patients with renal and/or hepatic impairment, the drug should be used with caution. High doses of diltiazem were also used with hepatic damage in single subacute hepatic studies. Oral doses of 120 mg/kg and higher in rats were associated with histopathological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interactions. Significant potential for additive effects, caution and careful titration are warranted in patients receiving CARDIZEM concomitantly with other agents known to affect cardiac conduction and/or conduction (see WARNINGS). Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis in combination with CARDIZEM (see WARNINGS). As with all drugs, care should be exercised when treating patients with multiple medications. CARDIZEM undergoes biotransformation by cytochrome P-450 mixed function oxidase. Coadministration of CARDIZEM with other agents which block the same route of biotransformation may result in the competitive inhibition of metabolism. Especially in patients with renal and/or hepatic impairment, dosages of similarly metabolized drugs, particularly those of low therapeutic ratio, may require adjustment when starting or stopping concomitantly administered diltiazem to maintain optimum therapeutic blood levels.

Beta-blockers. Continued and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers is usually well tolerated, but available data are not sufficient to predict the effects of concomitant treatment in patients with ventricular dysfunction or cardiac conduction abnormalities. Administration of CARDIZEM (diltiazem hydrochloride) concomitantly with propranolol in five normal volunteers resulted in increased propranolol levels in all subjects and bioavailability of propranolol was increased approximately 50%. In vitro, propranolol appears to be displaced from its binding sites by diltiazem. If combination therapy is initiated or withdrawn in conjunction with propranolol, an adjustment in the propranolol dose may be warranted (see WARNINGS).

Digitalis. A study in six healthy volunteers has shown a significant increase in peak diltiazem plasma levels (58%) and area-under-the-curve (53%) after a 1-week course of cimetidine at 1200 mg per day and a single dose of diltiazem 60 mg. Rationale produced smaller, nonsignificant increases. The effect may be mediated by cimetidine's known inhibition of hepatic cytochrome P-450, the enzyme system responsible for the first-pass metabolism of diltiazem. Patients receiving diltiazem therapy should be carefully monitored for a change in pharmacologic effect when initiating and discontinuing therapy with cimetidine. An adjustment in the diltiazem dose may be warranted.

Digitalis. Administration of diltiazem with digoxin in 24 healthy male subjects increased plasma digoxin concentrations approximately 20%. Another investigator found no increase in digoxin levels in 12 patients with coronary artery disease. Since there have been conflicting results regarding the effect of digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing CARDIZEM therapy to avoid possible drug-interactions. (See WARNINGS.)

Anesthetics. The depression of cardiac contractility, conductivity and automaticity as well as the vascular dilation associated with anesthetics may be potentiated by calcium channel blockers. When used concomitantly with anesthetics and calcium blockers should be titrated carefully.

Cyclosporine. A pharmacokinetic interaction between diltiazem and cyclosporine has been observed during studies involving renal and cardiac transplant patients. In renal and cardiac transplant recipients, a reduction of cyclosporine dose ranging from 15% to 48% was necessary to maintain cyclosporine trough concentrations similar to those seen prior to the addition of diltiazem. If these agents are to be administered concurrently, cyclosporine concentrations should be monitored especially when diltiazem therapy is initiated, adjusted or discontinued. The effect of cyclosporine on diltiazem plasma concentrations has not been evaluated.

Ceramide. Concomitant administration of diltiazem with ceramide has been reported to result in elevated serum levels of ceramide (40% to 72% increase) resulting in toxicity in some cases. Patients receiving these drugs concurrently should be monitored for a potential drug interaction.

Carcinogenesis, Mutagenesis, Impairment of Fertility

A 24-month study in rats at oral dosage levels of up to 100 mg/kg/day and a 21-month study in mice at oral dosage levels of up to 30 mg/kg/day showed no evidence of carcinogenicity. There was also no mutagenic response in vitro or in vivo in mammalian cell assays or in vitro in bacteria. No evidence of impaired fertility was observed in a study performed in male and female rats at oral dosages of up to 100 mg/kg/day.

Pregnancy

Category C. Reproduction studies have been conducted in mice, rats and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryonic and fetal lethality. These doses have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefits justifies the potential risk to the fetus.

Nursing Mothers

Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARDIZEM is deemed essential, an alternative method of infant feeding should be considered.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded from these studies.

The following table presents the most common adverse reactions reported in placebo-controlled angina and hypertension trials in patients receiving CARDIZEM CD up to 360 mg with rates in placebo patients shown for comparison.

CARDIZEM CD Capsule Placebo-Controlled Angina and Hypertension Trials Combined		
Adverse Reactions	CARDIZEM CD (n=407)	Placebo (n=301)
Headache	6.4%	5.0%
Dizziness	3.0%	3.0%
Bradycardia	3.3%	1.3%
AV Block First Degree	3.3%	0.0%
Edema	2.6%	1.7%
ECG Abnormality	1.6%	2.3%
Asystole	1.6%	1.7%

In clinical trials of CARDIZEM CD capsules, CARDIZEM tablets, and CARDIZEM SR capsules involving over 3200 patients, the most common events (i.e., greater than 1%) were edema (4.8%), headache (4.8%), dizziness (3.5%), asystole (2.6%), first-degree AV block (2.4%), bradycardia (1.7%), flushing (1.4%), nausea (1.4%), and rash (1.2%).

In addition, the following events were reported infrequently (less than 1%) in angina or hypertension trials: Cardiovascular: Angina, arrhythmia, AV block (second- or third-degree), bundle branch block, congestive heart failure, ECG abnormalities, hypotension, palpitations, syncope, tachycardia, ventricular extrasystoles. Nervous System: Anxiousness, dizziness, depression, gas, abnormal hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tremor. Gastrointestinal: Anorexia, constipation, diarrhea, dry mouth, dyspepsia, dyspepsia, mild elevations of SGOT, SGPT, LDH, and alkaline phosphatase (see hepatic warnings), nausea, vomiting, weight increase. Dermatological: Rash, photosensitivity, pruritus, urticaria. Other: Amblyopia, CPK increase, dyspnea, epistaxis, eye irritation, hyperglycemia, hyperuricemia, impotence, muscle cramps, nasal congestion, nocturia, osteoarthritis, pain, polyuria, sexual difficulties.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: allergic erythema multiforme, exfoliative dermatitis, endocarditis, symptoms, gingival hyperplasia, hemolytic anemia, increased bleeding time, leukopenia, purpura, retinopathy and thrombocytopenia. In addition, events such as myocardial infarction have been observed which are not readily distinguishable from the natural history of the disease in these patients. A number of well-documented cases of generalized rash, characterized as leukocytoclastic vasculitis, have been reported. However, a definitive cause and effect relationship between these events and CARDIZEM therapy is yet to be established.

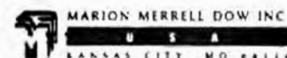
Prescribing Information as of April 1993

Marion Merrell Dow Inc.

Kansas City, MO 64114

card435a

References: 1. Cardizem CD prescribing information. 2. Data on file, Marion Merrell Dow Inc.



TB sweeps school; fear soon follows

THE ASSOCIATED PRESS

WESTMINSTER, Calif. — A tuberculosis outbreak that swept La Quinta High School has spread more than just serious illness. It has made students fearful of being ostracized and wary of who's sitting next to them at lunch.

One misdiagnosed case led to hundreds of the school's 1,350 students being exposed to the disease in the past three years.

"They're scared if they have TB, we won't talk to them, have lunch together," said 15-year-old incoming La Quinta sophomore Ngoc Pham, who is taking summer classes at a nearby school.

Of 1,263 students and recent graduates given skin tests in September 1993, 292 developed redness and swelling indicating exposure to TB. An additional 87 students and staff tested positive last month. Seventeen people have been diagnosed with active tuberculosis, including 14 who had cases resistant to several antibiotics.

During last year's baseball championships, 1994 graduate Steven Lund recalled how another team "wanted to protest about having the game at our field."

Life is difficult

"One of the moms had a surgical mask on her face," said Lund, who tested positive for TB exposure but didn't get active tuberculosis.

Such reactions have made life difficult for La Quinta students, said Dr. Jody Meador, the county tuberculosis controller. "High school is a time when people should be thinking about their futures, their careers, enjoying youth," Meador said.

Officials said the outbreak began three years ago when a 16-year-old student's private doctors misdiagnosed her persistent cough as bronchitis. TB is usually characterized by a persistent, sometimes bloody cough, night sweats, chest pain and weight loss.

"From what we're able to gather, the child was misdiagnosed back in 1991 and was essentially walking around the school with active TB," said Dr. Hugh Stallworth, Orange County's public health director.

After officials confirmed that the unidentified girl, a Vietnamese immigrant, had tuberculosis, they traced 12 other active cases at the school to her or people she had been in contact with.

One of the TB sufferers with a case that didn't respond to several kinds of antibiotics was Debi French, who had to have part of a lung removed.

Positive tests

As doctors tracked all of the people French had come in contact with, they found 25 percent tested positive for exposure to the bacteria, said Dr. Richard Jackson, chief of the state's Division of Communicable Disease Control.

One of those was Lund.

"Debi French was in one of my classes my junior year and my senior year," Lund, 18. "We were in a closed space with her every day."

Orange County now requires all new students be tested for TB exposure.

La Quinta was a good incubator for the disease because students can easily pass its airborne bacteria from one to another when they talk, shout, sing, cough or sneeze. Also, the ventilation system at La Quinta was in need of repair in some rooms. That kept fresh air from circulating efficiently.

Public health leaders said their best weapon is education, especially of doctors.

"If the physician doesn't have TB high on his list, doesn't skin-test for it, doesn't do a chest X-ray, the physician is going to miss it," Stallworth said. "If the physician is not up-to-date on how to treat TB, it's going to be a problem."

Americans May Find Calcium Increases Tough to Swallow

By KATHY SCARBEEK
Staff Writer

BETHESDA, Md. — New recommendations to increase calcium consumption as a hedge against osteoporosis may be a tough prescription for Americans to swallow.

"Recent national surveys show that the average American's diet, regardless of age or sex, contains calcium intakes that are significantly lower" than those prescribed by the National Research Council's recommended dietary allowances (RDAs), according to Dr. John Bilezikian, chief of endocrinology at the Columbia University College of Physicians and Surgeons, New York.

The new recommendations, made by the National Institutes of Health consensus development conference on optimal calcium intake, call for calcium consumption that for most Americans exceeds the RDAs that they are not meeting now. (See chart.)

The panel encouraged dietary sources of calcium, rather than supplements, as preferable for achieving optimal calcium levels. For some, including vegans and those allergic to milk, calcium supplements "may be the preferred way to attain optimal calcium intake."

Dairy products were recognized as major sources because of their high calcium content and frequency of consumption. Other food sources of calcium include some green vegetables, calcium-set tofu, canned fish, seeds, nuts, and some legumes. (See chart below.)

Calcium-fortified foods such as juice, cereal, and bread are "potentially major sources of calcium," said Dr. Bilezikian, who chaired the panel. He noted that one slice of calcium-fortified bread has almost as much calcium as a glass of milk.

Increasing calcium by eating more dairy products tends to increase the intake of fat and saturated fat, the panel warned. High-fat dairy products should be avoided. Skim milk, low-fat milk, and plain yogurt provide the most calcium for their calories and fat, according to the U.S. Department of Agriculture.

Those most likely to have problems meeting the recommendations on calcium intake include:

The elderly. The absorption of one calcium supplement, calcium carbonate, is impaired in the absence of gastric acid. Because many elderly people have decreased gastric acid production, taking calcium carbonate supplements with meals will promote calcium absorption.

Patients who have had kidney stones. The panel urged physicians to use caution in recommending calcium supplements for these patients.

Patients with lactose intolerance. Dr. Peter A. Banks, director of the clinical gastroenterology service at Brigham and Women's Hospital, Boston, warned that some lactose intolerant people who tolerate some milk may have gastrointestinal difficulties if they add an extra glass or two. "If they decide to drink another glass, some will get cramps, diarrhea, and bloating because it puts them beyond their tolerance threshold," he said.

Glucocorticoid users. The panel recommended that oral calcium supplements be considered in all patients receiving exogenous glucocorticoids, which decrease calcium absorption.

Patients with vitamin D deficiency. Older adults, the homebound elderly, and those in long-term care facilities often do not have adequate levels of vitamin D, which is essential for calcium absorption. Vitamin D supplementation to provide 600-800 IU/day improves calcium balance and reduces fracture risk in these groups. Calcium and vitamin D need not be taken together to be effective.

Calcium Intake Recommendations

	Current Recommended Dietary Allowances	NIH Consensus Panel's Recommendations
Infants (0-6 months)	400 mg/day	400 mg/day
Infants (6-12 months)	600 mg/day	600 mg/day
Children (1-10 years)	800 mg/day	800-1,200 mg/day
Adolescents & Young Adults (11-24 years)	1,200 mg/day	1,200-1,500 mg/day
Women (25-50 years)	800 mg/day	1,000 mg/day
Postmenopausal Women 65 & Younger Who Take Estrogen	800 mg/day	1,000 mg/day
Postmenopausal Women 65 & Younger Who Do Not Take Estrogen; All Women Older Than 65	800 mg/day	1,500 mg/day
Men 25-65	800 mg/day	1,000 mg/day
Men over 65	800 mg/day	1,500 mg/day

Source: National Research Council, Recommended Dietary Allowances, 10th edition 1980; NIH Consensus Development Conference.

As Men Live Longer, Osteoporosis Rates May Rise

Osteoporosis may be on the rise among men. "In New York we're seeing a major increase in the number of men with osteoporosis," Dr. John A. Bilezikian said at the consensus conference.

Data to substantiate the purported increase, however, appear to be lacking.

"It's difficult to tell whether [osteoporosis] is on the rise or not," Sandra C. Raymond, executive director of the National Osteoporosis Foundation in Washington, said in an interview. "Very little is known about osteoporosis in men."

There has been a small overall increase in osteoporosis-related hip fractures, she noted. "Which would mean an increase in men as well."

Since osteoporosis usually doesn't oc-

cur in men until they are "very old," continued increases in men's life expectancy will mean an increase in their rate of fractures from osteoporosis. Ms. Raymond said.

Currently, the lifetime risk of sustaining an osteoporosis-related fracture is one in eight in men and one in two in women.

Men comprise 20% of the 25 million Americans with osteoporosis.

In recognition of statistics like these, the consensus conference panel, chaired by Dr. Bilezikian, recommended levels of daily calcium intake for men of all ages that met, and in most cases exceeded, those of the current National Research Council's recommended dietary allowances for calcium. (See chart above.)

The panel's recommendations on cal-

cium intake for men generally reflected its recommended levels for women of the same age.

Increasing the calcium requirement for elderly men "seems prudent," the consensus panel said, adding that more research on calcium metabolism in older men is needed.

Risk factors for osteoporosis in men include alcoholism, a small body frame, and glucocorticoid use.

Osteoporosis in men can be treated with calcitonin injections, the only drug approved by the Food and Drug Administration for treating the disease in men. Ms. Raymond said.

Investigational drugs include sodium fluoride and bisphosphonates.

—Kathy Scarbeck

Food Sources of Bioavailable Calcium

Food*	Calcium Content (mg)
Milk (1 cup)	300
Almonds, dry roasted (1 oz.)	80
Beans, pinto	44.7
Beans, white	113
Broccoli	35
Brussels sprouts	19
Cabbage, Chinese (Pak-choi)	79
Cabbage, green	25
Cauliflower	17
Citrus punch with calcium citrate malate (1 cup)	300
Fruit punch with calcium citrate malate (1 cup)	300
Kale	47
Mustard greens	64
Rutabaga	36
Sesame seeds-no hulls (1 oz.)	37
Spinach	122
Tofu, calcium-set	258
Turnip greens	99
Watercress	28
Yogurt, low-fat (1 cup)	415

*Based on 1/2 cup serving size unless otherwise noted.

Source: C. M. Weaver and K. L. Plawski, Dietary calcium: Adequacy of a vegetarian diet. *Am. J. Clin. Nutr.* (in press).

Louise A. Lynch

Panel Recommendations Projected to Revise RDAs for Calcium Upwards

The consensus panel's recommendations could play a "significant" role in shaping a possible revision of the National Research Council's recommended dietary allowance for calcium.

That's the opinion of Paul Thomas, project director with the Food and Nutrition Board of the private Institute of Medicine in Washington, which is affiliated with the National Research Council and sets the RDAs for calcium and other nutrients.

The recommendations, made by a panel convened by the National Institutes of Health, would be "important" for the board to consider before changing the current RDA for calcium. Mr. Thomas said during an interview.

The panel's calcium intake recommendations meet or exceed current RDAs for calcium. (See chart above.)

RDAs are defined as the levels of intake of essential nutrients judged "to be adequate to meet the known nutrient

needs of practically all healthy persons."

There are several RDAs for calcium, each tailored to age group, sex, and other factors such as pregnancy and lactation.

Although the board hasn't made a firm commitment to revising RDAs for calcium and other nutrients, its "general consensus" is that they should be changed, Mr. Thomas said.

The most recent RDAs for calcium were developed in 1989.

RDAs are the basis for the Food and Drug Administration's reference daily intakes (RDIs), formerly known as recommended daily allowances. RDIs are the reference values for vitamins and minerals used on food and supplement labels, said Mr. Thomas.

Although RDA values for each nutrient are given for several categories of people, there generally is only one RDI per nutrient. The FDA instructs consumers to use it as a general reference.

—Kathy Scarbeck

GI DISORDERS

H. pylori and Ulcers: Nobody's Laughing Now

(Continued from page 1)

bial therapy to eradicate the organism.

The panel's recommendations, soon to be published in the Journal of the American Medical Association, are likely to stand the medical world on its ear. One effect ultimately will be to largely eliminate the management of nonbleeding ulcers from the purview of gastroenterology.

In effect, the new guidelines transform peptic ulcer disease into an easily curable illness readily amenable to management by busy primary care physicians.

"The sun is setting on peptic ulcer disease as we know it," according to Dr. Andrew H. Soll, professor of medicine at the University of California, Los Angeles, School of Medicine.

The consensus panel confirmed that 92% of patients with duodenal ulcer and about 70% with gastric ulcer are infected

with *H. pylori*. The great majority of noninfected ulcers are due to non-steroidal anti-inflammatory drugs.

Eradicate the gram-negative spiral bacterium with a 1- to 2-week course of antimicrobial therapy, and the ulcer relapse rate at 12 months is just 5% or less, compared with up to 90% in patients treated with acute histamine₂-receptor antagonist therapy.

Dr. Marshall made a triumphant return to the annual Digestive Disease Week this year, as lead speaker at the opening plenary session.

But he accused the consensus panel of having gone "only halfway" with regard to *H. pylori* and GI disease, citing the committee's unwillingness to endorse routine eradication of *H. pylori* in infected patients with nonulcer dyspepsia.

Three out of four patients with ulcer-like symptoms turn out not to have an ul-

cer on endoscopy or barium enema. Since a subset of these patients responds favorably to *H. pylori* eradication therapy, and the therapy has relatively few downsides, it's far more cost-effective to dispense with expensive imaging and treat them all, Dr. Marshall argued.

The consensus committee recommended physicians first determine whether a patient with dyspepsia has an ulcer. That costs about \$500. If so, the patient is tested for *H. pylori* at a cost of \$100. If the patient is positive, antimicrobial therapy is given. Thus four dyspeptic patients must be worked up at a cost of more than \$2,000 to find one ulcer to treat.

Dr. Marshall would test for *H. pylori* first. If the test is positive, he treats the infection. Only one in four treated patients will have an ulcer, but perhaps two or three will benefit, and he will have treated all four after spending only \$400 on the work-up.

"This is very controversial. You can be the party-line gastroenterologist and do it the way the consensus committee says, but I think there is common sense support for my algorithm, which is probably what's going to be used in the future in primary care," said Dr. Marshall, now the director of the *Helicobacter pylori* Research Foundation, Charlottesville, Va.

In defense of the consensus committee, its chair, Dr. Tadataka Yamada, stressed that the panel's charge was to make decisions on the basis of the data presented at the consensus conference.

There was "very little evidence of a well-controlled nature" to support eradication of *H. pylori* in patients with nonulcer dyspepsia, said Dr. Yamada, chairman of internal medicine at the University of Michigan Medical School, Ann Arbor.

"It's essentially empiric, anecdotal therapy not based on good science yet," agreed Dr. Nicholas J. Talley, chairman of internal medicine at the University of Sydney Faculty of Medicine.

Urea Breath Test

Urea breath tests offer an effective, noninvasive means of determining whether antimicrobial therapy has been successful in eradicating *H. pylori* but are not yet FDA approved.

These tests take advantage of a unique characteristic of *H. pylori*: To survive in a hostile acid environment, the microorganism secretes urea to raise its microenvironmental pH. No urea on the breath, no more *H. pylori*.

Standard serological antibody tests used to diagnose *H. pylori* colonization have excellent specificity and sensitivity for this purpose. But they are of no use in evaluating the success of eradication after antimicrobial therapy is completed because antibody levels remain high for 6 months or more after the bacterium is gone.

Dr. Yamada said the consensus panel's most important accomplishment was the creation of a detailed list of research priorities. Among these are well-designed studies of *H. pylori* eradication in patients with nonulcer dyspepsia, serious consideration of vaccine development, and exploration of the impact of prophylactic *H. pylori* eradication on future ulcer development in asymptomatic but infected individuals.

A particularly high priority is further study of what Dr. Yamada called the "intriguing and important" association between *H. pylori* and gastric carcinoma.

H. pylori Linked to Growth Deficiencies

NEW ORLEANS — *Helicobacter pylori* infection is associated with diminished growth in children and with reduced adult height, Dr. Michael A. Mendall reported at the annual Digestive Disease Week.

"The possibility that there is a causal association is of great potential public health importance," said Dr. Mendall, of St. George's Hospital Medical School, London.

Two other investigators have previously reported that *H. pylori*-infected children and adults are shorter.

Dr. Mendall studied 401 adults to rule out childhood social class as a possible confounding factor. After adjusting for age, gender, current and childhood social class and living circumstances, and father's occupation, the difference in height between *H. pylori*-positive and *H. pylori*-negative subjects was 1.9 cm among men and 1.1 cm for women.

In another study, Dr. Mendall screened for *H. pylori* in 554 children at ages 7 and 11 in Edinburgh. After adjusting for socioeconomic factors, infected girls grew 1.72 cm less than uninfected girls did during these years. Infected boys grew 0.19 cm less.

Explanations for reduced height in infected adults may include reduced dietary intake due to chronic dyspepsia, and the possibility that chronic infection results in delayed puberty, he said.

—Bruce Jancin

Frugal Approach Pays Off for Eradication

A rational approach to the treatment of *H. pylori* peptic ulcer disease or nonulcer dyspepsia is to select an inexpensive combination of drugs as first-line therapy, reserving the pricier regimens for patients who have failed a course of eradication therapy, Dr. Marshall said.

One popular choice as first-line therapy is 2 weeks of bismuth subsalicylate, tetracycline, and metronidazole. It costs about \$42. Physicians will want to add a standard histamine₂-receptor antagonist to this regimen when treating patients with peptic ulcer, since antisecretory therapy relieves their ulcer symptoms.

Another good first-line combination, particularly for patients with peptic ulcer, is ranitidine, amoxicillin, and metronidazole. This combination runs about \$85 for 2 weeks, has a 75% cure rate, and already includes an H₂ blocker, he said.

The combination of metronidazole, omeprazole, and clarithromycin offers a good cure rate and convenience for a relatively inexpensive price. Unlike other regimens, it is given for 1 week rather than two.

A patient who has failed a course of eradication therapy shouldn't receive metronidazole the second time around, since after the first treatment failure, nearly all *H. pylori* strains are resistant to the drug. A good second-tier therapy is the combination of omeprazole, amoxicillin, and clarithromycin, which costs close to \$200 but has a high cure rate.

A combination that includes bismuth is a poor choice in patients with a complicated ulcer because bismuth blackens the stool, making it hard to monitor occult bleeding. "I'd start the patient on omeprazole, amoxicillin, and metronidazole on day 1 in the hospital," he said. It's effective, and costs \$179 for a 2-week course.

—Bruce Jancin

Reinfection 'Rare' After *H. pylori* Is Treated

BY ERIK L. GOLDMAN
Northeast Bureau Chief

FIVE DOCK, Australia — *Helicobacter pylori* reinfection is unusual in successfully treated patients with duodenal ulcers, indicating that treatment to eradicate this organism can "cure" ulcers, said Dr. Thomas J. Borody, of the Centre for Digestive Diseases.

Dr. Borody and his associates studied 94 patients who had been treated with a three-drug antihelicobacter regimen 4-8 years earlier. They found only two had positive results on carbon-14 urea breath tests indicating reinfection. This suggests a reinfection rate of 0.36% per patient-year.

"Our figures certainly add credence to the original bold statements claiming cure of duodenal ulcer," he said.

One of the reinfected patients was completely asymptomatic, although at gastroscopy the duodenal mucosa was

positive for *H. pylori*. The second complained of dyspepsia, but she reported that it was not as severe as it had been prior to definitive treatment.

Previous reports of recurrence within the first year following treatment probably do not reflect true recurrence but rather recrudescence of the original infection, Dr. Borody said.

"Recrudescence is a well-known phenomenon that occurs almost totally within the first 4 weeks after cessation of ... therapy. Recrudescence of infection 12 months after biopsy-proven eradication ... has yet to be described."

He attributed recrudescence to the presence of small pockets of *H. pylori* in "sanctuary sites" within the atrophic or metaplastic mucosa or in the intracellular spaces (Am. J. Gastroenterol. 89:529-32, 1994).

True reinfection is most likely due to reacquisition of the organism from family members. Though one of the reinfected

patients in this study claimed that none of his close relatives had symptoms of dyspepsia, the other reported that her husband and two sons all complained frequently of this condition.

In an earlier American study, more than 50% of spouses of patients with *H. pylori*-related duodenal ulcers also carried the organism.

The extremely low reinfection rate in this Australian population is consistent with a large study of whites in the United States, which reported a reinfection rate of 0.49% per person per year.

The findings from Dr. Borody's study contradict the notion that immunization against *H. pylori* is a worthwhile approach to preventing duodenal ulcers.

"With the low rate of reinfection reported here in those proven to be *H. pylori* susceptible ... the population that would most benefit from immunization would appear to be difficult to define at this time."

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Life Science
July 27, 1994**SETTLEMENT MADE IN FIRST RESEARCH FRAUD CASE UNDER FALSE CLAIMS ACT;
TWO UNIVERSITIES AGREE TO PAY TOTAL OF \$1.575 MILLION**

Two universities that received federal funds for research that involved falsified data have agreed to repay a total of \$1.575 million to settle the case, the Department of Justice (DOJ) and the Public Health Service (PHS) announced Friday.

Scientific misconduct charges against John Ninnemann, who's research was funded by the National Institutes of Health (NIH) first at the University of Utah and then at the University of California at San Diego, ended in a separate agreement with the Department of Health and Human Services' Office of Research Integrity (ORI) that Ninnemann will send letters of retraction and correction to the scientific journals in which he published the falsified data.

Lyle Bivens, ORI director, said that Ninnemann has not admitted guilt to the government's allegations that he falsified and misrepresented scientific experiments in grant applications, progress reports and publications in the 1970s and 1980s, but that Ninnemann has agreed to be excluded from eligibility for all federal grants, contracts and cooperative agreements for three years; to be excluded from serving on any PHS advisory committees, board or peer review committees for three years; and to submit the letters of retraction and correction.

In the lawsuit, the government sought recovery of damages and civil penalties under the False Claims Act, which imposes liability on persons who knowingly submit false claims to the government or cause false claims to be submitted to the government. The act goes back to the Civil War, when it was passed in response to profiteering. It was modified in the 1980s to encourage whistleblowers.

While Ninnemann actually received \$1,184,750 from NIH, \$400,501 to Utah and the balance to UC San Diego, the settlement for \$1.575 million reflects the government's settlement on what could, under the law, have been a suit for triple damages plus legal costs. Utah's share of the pay back is \$950,000 and UC San Diego's \$625,000.

Of the \$1.575 million, NIH will receive \$1.03 million, and J. Thomas Condie, a former research assistant of Ninnemann's who exposed the fraud, will receive \$311,100 plus \$255,000 to reimburse him for legal expenses.

Condie, who worked for Ninnemann in his university of Utah lab in the early 1980's brought the lawsuit in 1989 under the qui tam provisions of the False Claims Act. Those provisions allow private citizens, known as relators, to bring suit on behalf of the government against parties alleged to have defrauded the government and to share in any awards if the suit is successful.

Page 2 of 2 (LS - WASFAX 7/27/94)

The government took over the case in 1990, alleging that Ninnemann falsely reported to NIH his research results on the causes of immune system suppression after burn injury. On the basis of Ninnemann's false reports, said the Justice Department, Utah received funding from 1981 through 1984 and California from 1984 through 1988.

The complaint also alleged that Utah was aware of Ninnemann's falsifications following a 1983 internal investigation but characterized the problem as "sloppy research" rather than intentional falsification and that the school falsely assured NIH that Ninnemann had corrected any problems associated with his research.

The government alleged that NIH relied on Utah's false representations in permitting Ninnemann to transfer his grant funding from Utah to California in 1984, making Utah liable for the funding California continued to receive for Ninnemann's research. The government also alleged that California was liable for the funding it received because the university failed to carefully monitor Ninnemann's work as it had promised NIH.

As part of the agreement with ORI, the University of California and the University of Utah have agreed to establish programs to prevent future scientific misconduct and to correct deficiencies identified in their institutional policies and procedures for addressing scientific misconduct.

Commenting on the settlement, Assistant Attorney General Frank Hunger, who heads DOJ's civil division, said the case demonstrates DOJ's commitment to safeguarding the NIH investment in biomedical and biobehavioral research. "This settlement proves the False Claims Act is an important tool for the government in fighting fraud in federally-funded scientific research," Hunger said.

Philip Lee, Assistant Secretary for Health and PHS director, said, "I'm pleased with the work of the Department of Justice and ORI in obtaining a settlement that protects the integrity of Public Health Service-sponsored research, corrects the scientific literature and recovers more than \$1 million of NIH grant funds. This use of the false Claims Act should send a signal to grantee institutions as well as to researchers themselves that they are responsible for the accurate reporting of research in grant applications and reports."

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A renaissance liberal: Senator Metzenbaum at the Capitol building in Washington

KATHERINE LAMBERT

Fighting at the Finish

Watchdogs: After 19 years of battling the big, bad world of business, a senator from Ohio hangs it up

BY JOLIE SOLOMON

IT'S TIME THOSE SCAB-LOVING EMPLOYERS understand we're not going to give up those rights!" Ohio Sen. Howard Metzenbaum, 77, stomps down from the podium at a Cleveland union rally and wades into the audience, shaking a fist and exhorting his comrades to fight the good fight: for a striker's rights bill, for health-care reform and for the man running to succeed him. "Get off your botts," shouts the senator. "I didn't spend 12 years of my life fighting Reagan and Bush so I could be replaced by one of their right-wing disciples."

Metzenbaum may indeed see his Senate seat warmed by the despised disciple. His would-be successor, Joel Hyatt, is running behind. But even if the tide turns for Hyatt, a lawyer and liberal who happens to be his son-in-law, no one can really replace Howard Metzenbaum. At a time when most sen-

ators—and most liberals—are known for what they *don't* get done, the departure of one liberal legislator seems like a doubtful occasion for commentary. But Metzenbaum is that rare species, a powerfully effective senator and a powerfully effective liberal. Consumers' groups are mourning Metzenbaum's imminent departure, and business groups are toasting it—even as they note that such an enemy has his uses. "When you raise his name with members, it gets their blood boiling," says Stephen Bok of the U.S. Chamber of Commerce.

A renaissance liberal, Metzenbaum fought the nomination of Clarence Thomas, was the original sponsor of the Brady bill and is trying to get J. Edgar Hoover's name removed from the FBI building. But there will always be congressional champions for such sexy issues. It's in the nitty-gritty, detail-laden battle about business that his

absence will be most obvious. This is the man who forced faltering giants of the 1980s to pay up on retirees' health benefits and companies such as Dillard Department Stores to pay for failing to give notice to laid-off employees. This is the guy who interrupted genial confirmation hearings for Supreme Court nominee Stephen Breyer recently to question a conflict of interest in a pollution case.

Rare package: Some freshmen senators hope to pick up the baton from Metzenbaum: Carol Moseley-Braun, Russ Feingold and Paul Wellstone each cite Metzenbaum's coaching. Still, the Ohio senator has been a rare package deal for his constituents: a self-made millionaire who fights for the union maid and a mince-no-words man whose sense of humor and integrity have made ideological foes such as Orrin Hatch and Alan Simpson into friends.

Metzenbaum made his millions leasing land near airports in the 1940s, when he realized that a growing flood of air travelers would need somewhere to park. While Mike Roush, a small business lobbyist, calls the senator "a pain in the butt," Metzenbaum sees himself as a trustbuster serving small business people, whether it's MCI fighting AT&T or nurse-practitioners tilting at the American Medical Association. He also challenges the equation that an antibusiness liberal is a big spender. By reading the fine print of every bill to root out hidden tax breaks, colleagues say, he has saved billions for taxpayers.

Still, Metzenbaum enjoys needling business and has a talent for finding villains with public appeal. He ranted at baseball executives in Florida this spring for their monopolistic behavior, "plush limos" and high salaries. And he accused Tele-Communications Inc. chief John Malone of trying to create a cable "megamonster" in his proposed merger with Bell Atlantic.

Metzenbaum's success would have been easier to explain in the '70s, when Congress took a more jaundiced view of business. But for most of his 19 years in Washington, the political culture has defined business's interests as almost synonymous with the nation's. So Metzenbaum has pulled off his wins by learning how to play the Senate game. He was nicknamed "Senator No" in the 1980s because he would attach endless amend-

ments to Republican bills he wanted to block. One would have allowed the export of products deemed unfit for U.S. consumption. When Metzenbaum attached a measure banning the export of faulty baby formula, the baby-food makers pulled out and the bill died. The mere threat of a Metzenbaum filibuster can often kill a bill; Republican Alan Simpson compares him (fondly) to a horror-movie monster who is knocked down again and again but "keeps coming back."

Young senators studying Metzenbaum may be able to match his mastery of the written rules. Harder to imitate is his comfort in violating the unwritten rules, particularly the one that says a senator shall annoy neither his constituent nor his fellow senator. Metzenbaum infuriated Ohio workers with his votes for gun control and against the gulf war. In the Senate, he drives even allies crazy, often simply by refusing to stop arguing when a debate reaches the wee hours of a session before a holiday. It's hard for most people to take the criticism Metzenbaum gets. Says Simpson: "We all go around saying it doesn't affect us, then we go home at night and practically suck our thumbs." How does Metzenbaum do it? "He's an unthreatened man."

Cutting edge: Twenty years ago the Senate bid goodbye to another unreconstructed liberal and Senate master, Philip Hart, by naming a Senate office building after him. Metzenbaum, a pricklier personality in a pricklier time, is unlikely to enjoy a similar honor. And as times change, even his record may be challenged. Ben Fischer, Carnegie Mellon professor of labor studies, says Metzenbaum has failed to push the cutting edge of labor issues.

For the moment, Metzenbaum isn't talking about his legacy. But he has told staffers he wants to "go out with a bang." That may be hard, especially since a top priority was the striker-replacement bill. The bill died in early July, but Metzenbaum has said he may find a way to bring it back to life. Can he do it? In June, lobbyists were swearing that Metzenbaum couldn't succeed with another pet project: killing their bill to limit product liability. Among other things, the bill would have barred punitive damages against companies that followed Food and Drug Administration rules; that would have eliminated big awards, for example, to women hurt by breast implants. Then, hours before a critical vote, Metzenbaum and a few colleagues outmaneuvered their opponents, and the bill died. For now. When the bill comes up in 1995, the Senate will debate it without him. ■

Fat-Free or Fat Chance?

Sin Food: A fake revival?

IT WAS JUST A FEW YEARS AGO THAT FOOD makers promised that fake fats would create a new world of guilt-free chocolate cake and french fries. They haven't delivered yet, but that hasn't stopped the industry from continuing its crusade. Last week Nabisco Foods Group unveiled a reduced-calorie fat. Meanwhile, old favorites like Olestra and Simplese continued to struggle. Here's an update from the front:

Salatrim: Nabisco claims it's more like real fat than the others. In other words the reduced-calorie product re-creates the texture of fat and has a better, as they say in the lab, "mouth feel."

Olestra: Hundreds of millions of dollars later, Procter & Gamble is still trying to get the Feds to approve its fake fat, which it hopes to use in fried foods such as potato chips. But it had better hurry—Olestra's patents are running out.

Simplese: Earlier this year, NutraSweet gave up on its version of ice cream called Simple Pleasures. Lousy mouth feel? Perhaps, but the fake stuff is still used in cheese and mayonnaise.

Appetize: Developed by scientists at Brandeis University, Appetize cuts saturated fat in vegetable oil by 50 percent. Look for it in french fries, margarine and ice cream sometime next year.

KAREN SPRINGEN and MARY HAGER



ILLUSTRATION BY CALEF BROWN

The New York Times

Tobacco Industry Ad Is Called Misleading

WASHINGTON, July 26 (AP) — An anti-smoking coalition contended today that the tobacco industry was financing a national advertising campaign to divert attention from illness and death caused by cigarette smoke.

Scott D. Ballin, the chairman of the Coalition on Smoking or Health, said the advertisements being run by tobacco companies were intended to raise doubts about Federal studies linking secondhand smoke to disease and to arouse fear that rights would be violated by a Government anti-smoking campaign.

The coalition involves the American Cancer Society, the American Heart Association and the American Lung Association.

"The tobacco companies continue to believe that if they say something often enough, regardless of whether there is any truth to their statements, they will be able to deceive the public and protect their products" from government control, Mr. Ballin said.

Asked about those assertions, Thomas Lauria of the Tobacco Institute, a trade group, said the advertising campaign by cigarette companies carried only true statements that could be verified.

USA SNAPSHOTS®

A look at statistics that shape the nation

Pushing for smokelessness

Those who strongly agree that smoking should be banned in all public places:

Non-smokers

61%

Smokers

18%

Source: Opinion Research Corporation

By Cindy Hall and Nick Galifianakis, USA TODAY

Richmond Times-Dispatch

A12 WEDNESDAY, JULY 27, 1994

Elders' Remarks on Elders Should Disqualify Her

EDITOR, TIMES-DISPATCH:

Why aren't the news media outraged about Surgeon General Joycelyn Elders' bigoted, misinformed, and tasteless comments and asking for her resignation the way the rest of the country would if it had heard what she said?

Dr. Elders has been quoted in regard to the current administration's spending more on AIDS research than on research on cancer and heart disease, "AIDS destroys our bright young people. Most of the people who die of cancer or heart disease are elderly and will die with something sooner or later."

For her to remain in her position indicates what type of people want to control our health care system so they can determine who is worthy to receive treatment, how much, when, who will live, and who will die.

KARIE DAWKINS.

GLEN ALLEN.

'AIDS cure' videos blasted

By RAFAEL A. OLMEDA

C-2

Daily News Staff Writer

The charlatan peddling a secret potion to cure AIDS has been begging customers to testify for him at a showdown with consumer-fraud investigators today, several former patients say.

Eleodoro Urra is scheduled to meet with city Consumer Affairs Department legal officials who have demanded documentation for his claims.

"He now gets the opportunity to discuss

what he has to back up his claim," said Fred Cantor, a Consumer Affairs attorney.

Urra, 62, plans to bring documents, witnesses and video-taped testimonials to back up his claim that LS-30 cures AIDS.

But one former patient, who identified herself only as Marytza, said the videos, like Urra, can't be trusted.

Several former LS-30 users charge that Urra has been calling patients and asking them to testify on his behalf, promising free medicine in return.

Peter Steiner

WE COULD DELAY UNIVERSAL COVERAGE FOR 6 OR 8 YEARS. BY THEN THE OLD AND INFIRM WILL BE DEAD.



ADVERTISING / By KEVIN GOLDMAN

Marketing Female Condom Is a Challenge

The first female condom is due to reach the U.S. market next month, accompanied by an advertising campaign that must meet the challenge of introducing an entirely unknown product to a skeptical public.

It won't be easy. Sales of over-the-counter female contraceptives have been steadily declining. Sales in supermarkets and drugstores of spermicidal sponges, jellies and foams declined 22% to \$48.5 million in the 12-month period ended June 30, according to Towne-Oller Associates, a unit of Information Resources. And sales of condoms for men were flat in the first four months of 1994, despite a major push from the federal government's public-service announcements that began in January.

Wisconsin Pharmacal's female health division, the maker of the Reality female condom, concedes it faces a major hurdle and says it has decided to focus the first phase of its advertising on educating consumers and not necessarily selling the product. The Jackson, Wis., company wants a Reality buyer to know how to use the product before buying it. The fear is that an uneducated consumer would become discouraged and never buy it again.

To introduce Reality, Wisconsin Pharmacal hired the McAdams Consumer Healthcare Advertising agency, which is producing the first print ads this week that are scheduled to run in the November issues of six to 10 magazines catering

to those who are 18 to 24 years of age. The magazines include Cosmopolitan, Essence and Mademoiselle.

Mary Anne Leeper, president and chief executive of Wisconsin Pharmacal, says she hopes to advertise Reality on television but has no current plans to do so.

The print ads will show closeup photographs of couples with the headline, "Now even if he isn't using a condom, you can." The ad copy says, in part, "Finally the Reality female condom is here. And now for the first time, you have protection of your own. Reality female condoms were designed to help protect you and your partner against sexually transmitted diseases, especially AIDS. They also help prevent unwanted pregnancies." The tagline on the ad is "Make it your Reality."

The ads, which also will run in the September issues of medical magazines, show the package but don't show the product, a recommendation that came from the advertising agency. Sue Forman, senior vice president and creative director at McAdams, says a picture of the product would require too much explanation. "Without lengthy copy of what Reality does, no one has a frame of reference so it could be confusing," says Ms. Forman. "We would rather urge consumers to speak to their doctors or call the toll-free number" included in the ad.

The contraceptive isn't inexpensive. Each Reality condom will cost \$2.70 to \$3. A male condom costs about \$1.

Reality is a polyurethane sheath that is lubricated. It is inserted like a diaphragm into the vagina, where it is held in place by an inner flexible ring. The package provides answers to three questions: "Will it protect me?"; "How do I insert Reality?";

and "What does it feel like during sex?"

The package also includes labeling by the Food and Drug Administration that doesn't please Reality's manufacturers: The female condom has a failure rate of 26%, which is higher than that of other contraceptives.

Ms. Leeper says the company will offer doctors and pharmacists results of other studies. For example, one consultant to the company says the failure rate is 21%.

Ms. Leeper contends that Reality "isn't competing against" other birth-control products. Instead, she says, "I'm competing against perception. My issue isn't competition. My issue is introducing a whole new concept." She adds that other contraceptives may prevent unwanted pregnancies, but aren't effective in halting the spread of sexually transmitted diseases.

Reality is manufactured by a London company, Chartex International. Chartex makes female condoms in 12 countries under the name Femy and Femidom. Ms. Leeper doesn't have exact sales figures, but adds that 48% to 54% of women who bought the product purchased it again.

The ad campaign is no-nonsense even though recent public service announcements and paid ads for male condoms have been peppered with humor. "Humor has no place in this effort," says Ms. Forman. "It isn't appropriate when we're launching a product that no one knows and everyone will have questions about."



Eating Well

Marian Burros

THE Clinton Administration has finally named an Administrator for the Food Safety and Inspection Service, the hot seat at the Agriculture Department. On Aug. 15, Michael R. Taylor, Deputy Commissioner for Policy at the Food and Drug Administration, will become responsible for meat and poultry inspection.

Many highly publicized incidents of illness and death from contaminated meat and poultry have occurred in the last few years, and in an interview this week, Mr. Taylor acknowledged that consumer interests, not politics, must be the overriding concern for his agency.

"There's a long way to go and a lot of contention, but the food industry has got to figure out a way to get food safety off tabloid TV," he said.

One problem Mr. Taylor will have to address first is why the Agriculture Department allows frozen chickens to be sold as fresh.

He must also wrestle with the tricky question of whether to exempt ground beef from the regulations that define "lean" for all other foods.

And he will have to decide if meat and poultry can be irradiated to reduce bacterial contamination.

"I am going over there to carry out consumer protection provisions," Mr. Taylor said. "The focus of my tenure will be to reduce food-borne illness."

Mr. Taylor is moving from an agency where decisions are generally based on public health concerns and consumer protection into an agency that has always worn two hats: food industry advocate and consumer protector.

The agency is constantly criticized by consumer advocates and health professionals who say that it bases decisions on politics rather than science or consumer protection.

Caroline Smith DeWaal, who is the director of food safety for the Center

Tough tasks await new chief of meat inspection.

for Science in the Public Interest, a Washington advocacy group, and has worked with Mr. Taylor on seafood safety, said if anyone can forge a consensus it is he.

"He's trusted not only by us but by the industry," she said.

Janet Riley, a spokeswoman for the American Meat Institute, agreed. "Mike Taylor has a great background in food safety," she said, "but the job has got to be one of the toughest in Washington with all the different pressures from Congress, consumers, labor and the meat industry."

Mr. Taylor said he hopes to bring current scientific thinking to the antiquated system of meat and poultry inspection, adding microbial testing for bacteria to the current system, which now calls only for visual inspection.

It is not a moment too soon, critics say. The public has been bombarded for several years by newspaper and television reports about contaminated meat.

Carol Tucker Foreman, the Assistant Secretary of Agriculture for the Food Safety and Inspection Service during Jimmy Carter's Administration, said the meat and poultry in-

spection system is archaic.

"Public health problems have changed, but the Food Safety and Inspection Service hasn't changed," she said. "Mike Taylor has the ability to get the agency into at least the last half of the 20th century."

Mr. Taylor, who was a lawyer specializing in food and drug law before he went to the F.D.A., says he hopes to do better than that. He has been deeply involved in proposed regulations for seafood based on a system known as Hazard Analysis Critical Control Point, or Haccp (pronounced HASS-ip). This system calls for comprehensive analysis and control of hazards, with monitoring and record keeping.

"My immediate task is to initiate Haccp rule making for meat and poultry," he said. "I certainly hope this fall to have a very credible Haccp proposal out there. A good solid year after the proposal, I hope to have a final rule. I want to send a signal that microbial monitoring is out there, and we've got to come to grips with how best to use it in Haccp."

Many meat and poultry producers use some form of microbial testing in their plants. Yet, even though the National Academy of Sciences said in 1985 that the Agriculture Department should switch to a science-based inspection system — and Agriculture Secretary Mike Espy promised a Haccp program a year ago — the department does not require microbial testing.

But improving the safety of meat and poultry will not include irradiation, Mr. Taylor said. A recent conference on the hazards of the E. coli bacteria that were responsible for the deaths of four children and the illness of 700 people from eating undercooked contaminated hamburgers recommended irradiation of raw meat as a solution. Mr. Taylor says such a solution will not work.

"Because of public fear irradiation