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Random Letters [Folder 1] [2]

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Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Personal letter from inmate re: Cure for HIV/AIDS (2 pages)	00/00/0000	b(6)
002. forms	re: Laboratory reports / results (4 pages)	00/00/0000	b(6)
003. letter	re: Tax status for ProjectChange International [Personally Identifiable Information] (1 page)	07/27/2000	b(6)

COLLECTION:
Clinton Presidential Records
National AIDS Policy Office
Sandra Thurman
OA/Box Number: 40014

FOLDER TITLE:
Random Letters [Folder 1] [2]

2018-0764-F
jm2020

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

15
Sched Diplomacy

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Regions

U.S. PEACE CORPS

Alan Feuerborn
Peace Corps Volunteer
P.O. Box 133
Kisumu
Kenya

alan_feuerborn@hotmail.com
tel: (254) (035) 41574

August 21, 2000

President Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C.

Dear Mr. President and Family,

Jambo! (Hello) My name is Alan Feuerborn and I am a Peace Corps volunteer stationed in western Kenya in a town named Kisumu. Thank you for allowing me to serve my country in this role.

East Africa has been hit hard by the AIDS epidemic, poverty, and general decline in industry since the East African economic community collapsed years ago.

My primary project is computer literacy at the Ramogi Institute of Advanced Technology (RIAT). I am teaching computer basics to junior college students along with school's staff.

Secondary projects include working with unwed mothers and street kids to help them learn computers as well. And I have just begun working with an NGO that is assisting local artisans to sell their crafts to the West. The focus of this NGO is to develop women and men who otherwise would be left behind.

With the help of other Peace Corps volunteers, we have been educating all of the above people about HIV / AIDS and Life Skills. Last month, Ambassador Carson handed out HIV / AIDS training certificates to my RIAT students.

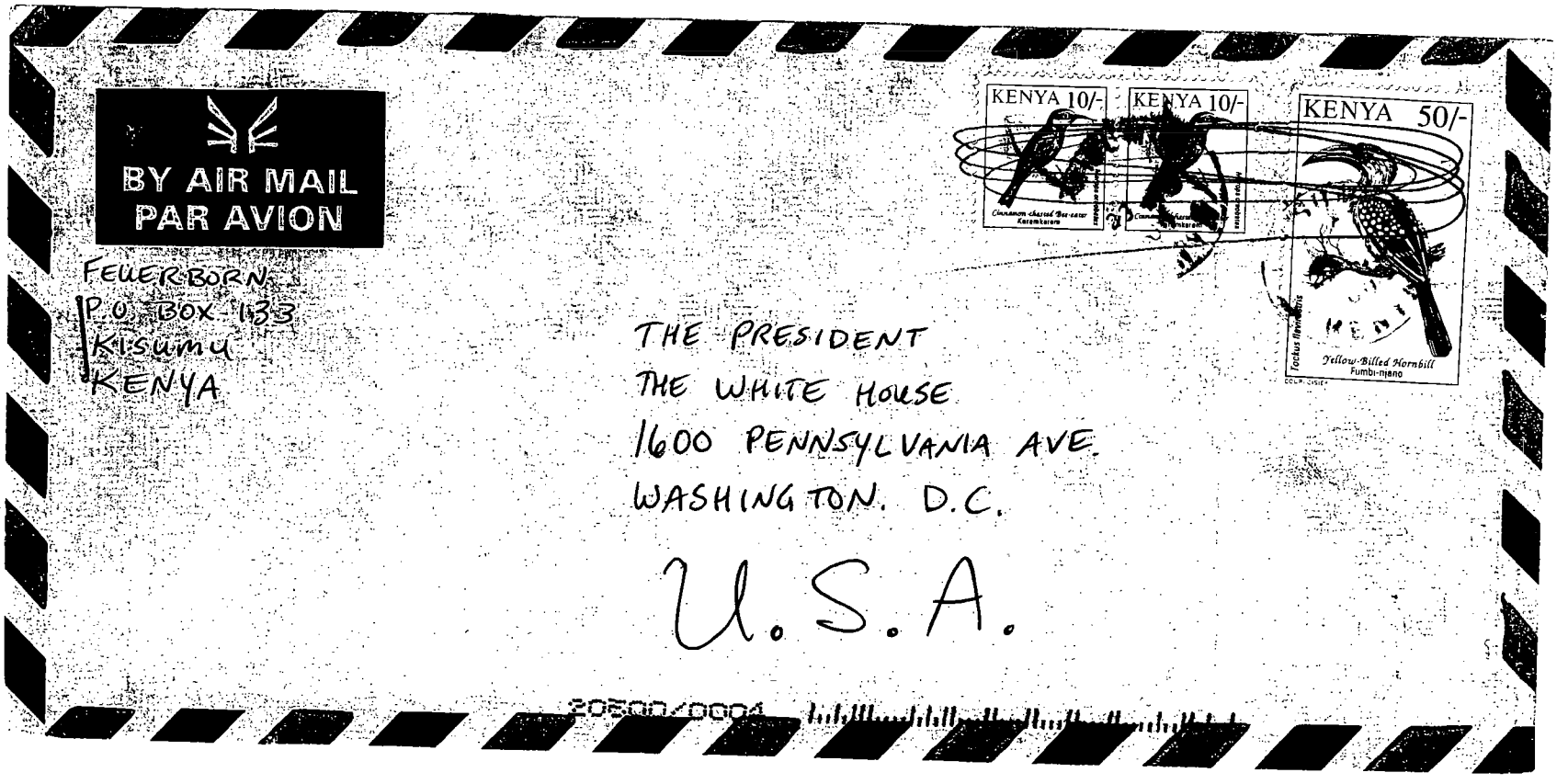
Please accept an open invitation for you and your family to visit us here in Kisumu. Your presence would help promote Information Technology, women in development, and most importantly AIDS awareness and education. I met Director Mark Schneider during his visit to Kenya, and he emphasized these topics as priority areas of development.

Any month is a good month to visit – may be even early next year? Weather on the equator is pretty constant. Bring cool clothes.

Warm regards,

Alan Feuerborn

Alan Feuerborn


BY AIR MAIL
PAR AVION
FEUERBORN
P.O. BOX 133
KISUMU
KENYA
THE PRESIDENT
THE WHITE HOUSE
1600 PENNSYLVANIA AVE.
WASHINGTON. D.C.
U.S.A.
KENYA 10/-
KENYA 10/-
KENYA 50/-
Yellow-Billed Hornbill
Fumbi-njano

October 6, 2000

TO: Cheryl Bauerle

From: Ken Bernard

Cheryl:

The Europe Directorate suggested that we forward the incoming correspondence to your office for further action.

Embassy of the United States of America

September 22, 2000

24 Grosvenor Square
London W1A 1AE

The White House
National Security Council
Attention: European Directorate
Old Executive Office Building
Washington, DC 20504

Dear Sir/Madam:

Enclosed please find a paper by Sir Kenneth Stuart that he has requested be sent to the White House. Ambassador Lader has asked that I forward it.

Thank you for your co-operation.

Sincerely,

Louise B. Bigott
Staff Assistant

3 The Garth
Cobham
Surrey KT11 2DZ
Phone: 01932863826
FAX: 01932860427
Email: ken stuart@lineone.net

1 Sept 2000

The Hon Philip Lader
Ambassador of the United States of America
24 Grosvenor Square
London W1A 1AE

Dear Ambassador Lader

The statement made by President Clinton in his 19 August introduction to the "Global AIDS and Tuberculosis Relief Act of 2000" must be the most important call for international action on AIDS made by any world leader.

The enclosed paper is relevant to and strongly supportive of the President's statement. I think that the issues raised in my paper merit a wider readership than is likely to be achieved by its publication in a conventional medical journal.

I trust that you yourself might find it of interest; and I would welcome the opportunity to discuss with you its publication and how it might be best utilized to promote the objectives set out in the President's statement.

Yours Sincerely

Kenneth Stuart

Kenneth Stuart

The HIV/AIDS Pandemic:

Human Rights, Societal and Developmental Issues

Professor Sir Kenneth Stuart

Chairman, Commonwealth Health Research Inter-regional Consultation

August 2000

Summary

This paper quotes examples from the long list of past and contemporary national accords that have historically linked health to human rights. It describes the dimensions of the global threat posed by the current HIV/AIDS pandemic and its continuing global acceleration in spite of worldwide educational, public health, scientific and research efforts to contain it.

It draws attention to the likely reasons why these efforts have had only a limited success in restraining the rate of spread of the pandemic. It suggests, in particular, that it is their failure to address the associated societal, human rights, educational, poverty and related issues, against which the pandemic is unfolding, that have accounted for their lack of success; that it is these societal issues which chart an almost unavoidable route to the high-risk behaviours which account for HIV infection and spread; and that it is these issues which constitute the root causes of the pandemic.

It stresses the essential nexus between these issues and the pandemic; it points out that they are most marked in the countries in which the pandemic is spreading most rapidly; that concurrent national or international strategies to deal with them would be essential pre-requisites for the success of any HIV/AIDS control programmes, however well designed; that these societal issues are outstripping individual national capabilities to deal with them; that they call for wide international collaboration and responses.

It concludes that, in spite of the urgency of the need for such international action, there are still roles for special-interest community groups and for governmental and non-governmental organisations.

And, while recognising that educational campaigns by such groups are liable to run up against entrenched taboos or conflicting cultural norms, it acknowledges that the significant drops in infection rates recently achieved in Senegal and Uganda are evidence that such campaigns, appropriately structured, vigorously administered and promotive of the appropriate societal transformations, can work.

It recognises likely roles for youth-led peer-directed educational initiatives.

"One cannot, one must not, approach public health without looking for its human rights component." *Elie Wiesel, Nobel Peace Prize Laureate*[1]

Health and Human Rights

The perception that protecting human rights is essential for promoting health is not new. Health as a human right had been affirmed by Aristotle[2] more than two thousand years ago: "If we believe that men have personal rights at all as human beings, they have an absolute right to such measure of good health as society and society alone is able to give them." This affirmation has featured in a number of international covenants on political, social and cultural rights.

Article 25 of the Universal Declaration of Human Rights, which many have ranked as equal in importance to Magna Carta, specifically emphasised societal responsibility for health: "Everyone has the right to a standard of living adequate for health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services."

This concern for human rights is repeated in the American Declaration on the Rights and Duties of Man (Article XI): "Every person has the right to the preservation of health through sanitary and social measures relating to food, clothing, housing and medical care to the amount permitted by public and community resources."

When the World Health Organisation was established in 1948 its frequently quoted remit was: " the attainment by all peoples of the highest levels of health," health being defined in its constitution as a "state of well-being and not merely the absence of disease or infirmity." This definition not only extended health far beyond medicine, it openly acknowledged that, despite the public belief to the contrary, medical care, important is it clearly is, may be outweighed by societal factors as a contributor to health.

That there is a strong moral responsibility for national governmental address to the social factors that adversely affect health was implicit in Sir Douglas Black's seminal study on socially stratified inequalities in health in Britain in 1980[3] and in Sir Donald Acheson's follow-up inquiry on the same subject in 1998[4]. It was equally implicit in the 1988 report

by the United States Institute of Medicine[5], which defined the mission of public health as "ensuring the conditions in which people can be healthy."

In spite of this long historical concern about societal obligations and social influences on health, national health planners world-wide have nearly always placed greater emphasis on medical interventions than on societal influences which operate upstream of medical interventions.

HIV/AIDS: Its accelerating global threat

HIV/AIDS is a global problem of a new order. Early on it was recognised that it was calling into question fundamental aspects of personal and social life. It was called a challenge to the moral capacity of our societies; it was predicted that how we responded to it would be the standard by which we would be judged by history; WHO declared, and current indications still are, that the personal and collective response to the pandemic would be more determining of its future than any narrowly defined scientific response.

With its more recent spread to India, China, and Eastern Europe, it is now present in or threatens nearly every country in the world. Its containment already defies and is causing seismic shifts in all our accepted paradigms of public health management and disease control. The latest estimates by UNAIDS and WHO are that more than 33 million people were living with AIDS at the end of 1998. It causes 2.5 million deaths a year, more than twice as many as the million deaths from malaria; it is outstripping national abilities to cope with it and is already outpacing international responses. And yet some experts say we are only a tenth of the way into the epidemic.

With more than 95% of AIDS infected people living in the developing world, which has also experienced 95% of all AIDS-related deaths, AIDS has become a poor person's disease – taking a heavy toll on life expectancy and in many countries reversing the gains of the past three decades. A loss of 17 years' life expectancy is projected for nine countries in Africa with an HIV prevalence of 10% or more – Botswana, Kenya, Malawi, Mozambique, Namibia, Rwanda, South Africa, Zambia and Zimbabwe – down to 47 years in 2010, back to the life expectancy of the 1960's.

Although not so rapid its continuing spread in the developed world has also brought a distinct, at first muted, but now rapidly deepening sense of foreboding, a foreboding fuelled by the fact that, in spite of international efforts and enormous expenditures of money, the gap between the expanding pandemic and global responses is widening rapidly and dangerously. In addition, the lethal partnership that has been formed between AIDS and tuberculosis, the growing emergence of drug resistance by both and the ease with which they can be spread worldwide by international air travel add even more threatening dimensions to the hazards that each of these disorders already presents individually to global public health.

Public Health, Behavioural and Related Issues

When the challenge of HIV/AIDS was presented to an unprepared world in the early eighties the response of WHO and the international community was based on what was then known of HIV/AIDS and on the then generally accepted public health practices. The three central elements of this response were information and education, health and social services, medical procedures and scientific research – on vaccine preparation and drug manufacture. A fourth element, not yet part of the standard lexicon of public health, but added later, was the need to ensure that HIV infected people and people with AIDS were not discriminated against[6]. These strategies became the template on which national AIDS programmes were implemented, monitored and evaluated.

Another difficulty that countries had to face was the coordination of national action on HIV/AIDS, which was for some time a 'homeless' problem. The ministry of health, almost invariably the lead ministry in national AIDS programmes, lacked both the skills and the mandate for either studying or addressing the non-medical societal issues that relate to AIDS – youth, education, finance, housing, social services – all of which lie outside the normal areas of responsibility of the ministry of health and within sectors that had no primary responsibility for health. The ministry of health could raise but could not answer the question of "What must be done?"[7]

WHO and national AIDS strategies admittedly experienced a number of successes. Imaginative educational and informational programmes were introduced; high-risk behaviour was modified in many countries – most of which set up effective inter-ministerial and interdisciplinary AIDS committees. It soon became evident, however,

that standard public health approaches, epidemiological studies of high-risk behaviour, and advice against such behaviour, important as they clearly are, were not enough. The pace of spread of the disorder, far from being slowed, was accelerating.

The main reason why strategies for dealing with the behavioural aspects of the pandemic have had only limited success is that they were developed in almost complete isolation from the societal issues against which the pandemic was unfolding. The perception of human behaviour and human values as essential elements in the complex calculus of health is critical. Even with non-infectious diseases like heart disease, obesity, the consequences of smoking, hypertension, it is likely that it is the failure of world health planners to come to grips with their social or human behavioural aspects which has accounted for their relentless global spread.

Scientific Advances and Limitations

The greatest successes of international AIDS programmes have been in the scientific field. A vaccine (maybe more than one) is near; and advances in treatment have transformed what, for those who could afford or would receive it, was an almost invariably early fatal condition into an essentially chronic disorder.

But, at least with respect to the scientific studies of AIDS, what Leo Tolstoy had to say about science is probably relevant: "Science is meaningless because it gives no answer to our question, the only question important for us: what shall we do and how shall we be?" Nobel Laureate Macfarlane Burnett[8] has also commented on the limitations of science. While acknowledging the importance of laboratory sciences and the way they helped to control disease, he has emphasised that the major health issues of the future would be influenced not by laboratory medicine and basic science but rather by observational and social studies.

WHO has recently negotiated with a number of pharmaceutical companies a substantial reduction in the costs of HIV/AIDS drugs to developing countries. This will clearly bring significant benefits to the countries concerned and to those individuals who are fortunate enough to receive treatment. It is already evident, however, that for many reasons – personal and national unavailability of drugs even at reduced costs, problems of

distribution, monitoring and health services infrastructure – reduction of drug costs per se is unlikely to significantly influence the course of the pandemic.

Human Rights, Societal and Developmental Issues

It was Jonathan Mann[9], Director of WHO's initial Global Programme on AIDS, who first put the spotlight on the human rights and societal issues with which the HIV/AIDS pandemic is linked - pointing out that they were highly specific within each society and yet fundamentally similar around the world. "The major societal risk factor for vulnerability to HIV is to belong – before AIDS appeared – to a group which was discriminated against, marginalized, stigmatised and excluded from society." He also emphasised that "we are not speaking here about discrimination against HIV-infected people with AIDS, we are identifying discrimination as a cause – at the very root of the pandemic." And it has been repeatedly shown that it is poverty and its associated lack of education which are the twin factors that particularly account for discrimination and the exclusion of increasing numbers of individuals and groups from the global conversation – from being able to make and carry out free and informed choices about their behaviour. And dying before your time must surely be the ultimate form of social exclusion and choice limitation.

In the countries in which the HIV pandemic is spreading most rapidly it is poverty and the infringement of human rights that stem from it which are key. The need, for instance, for men to leave their homes in large numbers to work on farms, in copper, gold and diamond mines; for women deprived of male personal and financial family support to have to become sex-workers also in large numbers in order to feed themselves and their children, are compelling determinants for the behaviours that predispose to HIV infection and spread. There are several other examples of societal factors – economic, socio-cultural, political – which predispose to or cause high-risk behaviours.

Recognising the role of poverty in HIV infection and spread, UNDP's 1999 World Development Report[10] points out that poverty is spreading rapidly worldwide – in spite of the burgeoning wealth of individuals (the assets of the world's three richest billionaires exceed the combined GNP of the 48 least developed countries) and nations. The number of extremely poor people in the world has doubled since 1975 and now stands at a staggering 1.3 billion – a not surprising outcome as official development assistance has

been reduced by almost a fifth in real terms since 1992. Mahatma Ghandi called poverty the ultimate form of violence. Indira Ghandi called it the ultimate pollutant.

In industrial countries, too, human poverty and exclusion, the Report adds, are hidden among statistics of success, revealing enormous disparities within countries: "Measured by the human poverty index (HPI-2) one person in eight in the richest countries of the world is affected by some aspect of human poverty: long-term unemployment, a life shorter than 60 years, an income below the national poverty line, or a lack of literacy needed to cope in society."

Nearly 30 years ago the Pearson Commission[11] began its report with the recognition that "The widening gap between the developed and developing countries has become the crucial problem of our times". But over the past three decades the income gap between the fifth of people living in the world's richest countries and the fifth of people living in the world's poorest has widened markedly. It was 74 to 1 in 1997, up from 60 to 1 in 1990 and 30 to 1 in 1960.

The more the gap widens between rich and poor, educated and uneducated – in developed and developing countries alike – the greater the number of people that are being constantly left stranded in the backwaters of progress; and with this gap comes conflicts, human rights infringements and other problems rooted in poverty and inequality. And HIV/AIDS has clearly emerged as one of the greatest of these problems.

A number of conclusions are now inescapable: that an effective strategy for reducing vulnerability to AIDS must have a dual approach – one in which current public health, educational, behavioural and scientific efforts are strengthened and the other in which the underlying societal causes are also directly addressed; that none of these causes – marginalisation, human inequality and insecurity - is inevitable; that with political will and commitment in the global community they can be reversed; that human rights values, on which the Charter of the United Nations and the Universal Declaration of Human Rights are based, could be guidelines for a global strategy to reduce vulnerability to HIV/AIDS.

In this regard it has been gratifying that the new UNAIDS programme has adopted and is beginning to explore how this kind of vulnerability analysis and approach might be applied to HIV prevention worldwide. Indeed, beyond HIV/AIDS, a new movement linking health and human rights has been catalysed, as it is being increasingly recognised that human rights issues provide a better framework for analysis and response to the societal preconditions for health in its broadest sense than any inherited from the biomedical or public health tradition. It brings a new challenge and a new responsibility to public health – beyond its recognised duty "to ensure the condition in which people can be healthy." It broadens its remit to include the civilising role of promoting universal respect for human rights and its related societal transformations.

Calls for International Action

It is these growing global inequalities which are the realities behind the spread of the HIV/AIDS pandemic, and which motivated President Clinton's appeal one year ago for international collaboration for dealing with it; and it is these realities the global community will have to grapple with in responding to his appeal. His appeal had been anticipated by leaders of a number of the world's major development agencies who had themselves already recognised the magnitude of the AIDS threat, the societal factors that underlie it and the urgent need for the international community to come together to address them. Implicit in these appeals is a call for a "Marshall Plan" for the developing world, particularly Africa. Kofi Annan says that "Africa needs more: more assistance, more technology, more investment, more access to world markets, more co-operation and partnership."[12]

Referring to the enormous advances that globalisation has brought, UNDP's 1999 Human Development Report[13] states that "...at a time of such dramatic breakthroughs it is indefensible that human poverty should persist... Narrowing the gaps between rich and poor and the extremes between countries should become explicit global goals.". It proposes seven key agenda items for securing human development, all requiring national and international action. An important one, it states, would be a "Joint World Bank / UN Task Force, which would investigate global inequalities and suggest policies and actions on how they can be narrowed over the next two or three decades".

As early as 1992, at the Earth Summit in Rio de Janeiro, the world's governments had pledged to "mobilise and clarify national and international efforts against AIDS to prevent infection and reduce the personal and social impact of HIV infections."

An Editorial in the 6 May 2000 issue of the New Scientist squarely faces the gathering threat of HIV/AIDS for the entire world community and the urgency of the need for action to contain it: "...what is the bottom line? Without global action and more money, the whole world – not just the developing part of it - is in trouble. The G7 group of seven rich countries, urgently needs to draw up a plan to deal with HIV"[14].

Parenthetically, it is ironical that there should be need for such urgent appeals for comprehensive co-ordinated action by the developed countries for promoting the development of the developing countries, when they (the developing countries) are already the source of an estimated 90% of the world's biological resources.

International Responses

During the past two years alone there have been four major international meetings on HIV/AIDS – two of national and international health planners, scientists and drug manufacturers and two of leaders of the G8 countries.

The first of the two of the former category was held in Geneva in 1998. Its theme was "bridging the gap" between the treatment of the disease in the rich and poor countries. A major late outcome of this Conference was the reduction in drug costs to developing countries achieved through WHO's negotiations with the pharmaceutical companies earlier this year. The second meeting in this category, in Durban in July 2000, set as its goal to "break the silence". In spite of the controversy about the origins of AIDS which marked this Conference, probably its most effective contribution towards breaking the silence was its "shout" to the international community that something can be done.

It highlighted, for instance, the achievements of the HIV/AIDS campaigns in countries like Senegal and Uganda. Senegal began its campaign in 1981, before the virus had got a grip. It has managed to keep its infection rate below 2 per cent. Uganda began its programme in the early 1990's, when 14 per cent of the population was already infected. Now the figure is down to 8 per cent and falling. The successes of both Senegal and

Uganda have been based mainly on their effective promotion of the wider use of condoms.

The first of the two meetings of leaders of the G8 countries was in Cologne in 1999. Its most important outcome was its commitment to a packet of enhanced debt relief for the poorest countries. The second was in July 2000 in Okinawa. The goal, said their Japanese hosts, was to set the stage for "greater prosperity", "peace of mind" and "world stability" in the 21st century.

In their final communiqué of this meeting, G8 country leaders promised to accelerate efforts to implement the agreement reached the year before about debt relief and make a commitment to "tackle the root causes of conflict and poverty... and engage in a new partnership with non-G8 countries, particularly developing countries, international organisations and civil society." They also made a number of specific health pledges: to cut the number of young people infected with HIV by 25 per cent by 2010, to cut tuberculosis deaths by 50 per cent and to reduce the "burden of disease associated with malaria" by 50 per cent by this date. A number of organisations, however, thought that these commitments, certainly those on debt relief, should be taken with a grain of salt – particularly in view of their failure to live up to similar assurances given only a year before. Médicins Sans Frontières noted that developing countries spent twice as much a year in debt repayments as on health and education combined: "We will monitor the G8 to ensure more concrete action and fewer empty promises."

On 19 August 2000 President Clinton signed into law the "Global AIDS and Tuberculosis Relief Act of 2000." In announcing this Act, which has since been termed "A Marshall Plan for AIDS in Africa" he stated that it was a follow-up of the interagency initiative launched by Vice-President Gore and himself in July 1999, "Leadership and Investment in Fighting an Epidemic" (LIFE), for which 100 million dollars had been appropriated annually for 2000 and 2001 "to expand our funding for global HIV/AIDS prevention, care and treatment in the worst affected developing countries."

Acknowledging that "the UN/AIDS programme would need an estimated 1.5 billion dollars annually to establish an effective HIV prevention programme in sub-Saharan

Africa and an additional 1.5 billion annually to deliver basic care and treatment to people with AIDS in the region" he considered that the new Act "takes some of the additional steps to broaden the global effort to combat this world-wide epidemic. It provides enhanced bilateral authorities and authorizes funding for the Agency for International Development's HIV/AIDS programmes...In addition to new funding for UNAIDS programmes and the international AIDS Vaccine Initiative the new Act authorises the creation of a World Bank AIDS Trust Fund that is intended to create "a new multilateral funding mechanism to support AIDS prevention and care programmes in the most grievously affected countries."

"The United States", he continued, "cannot and should not battle AIDS alone. This crisis will require the active engagement of all segments of all societies working together. Every bilateral donor, every multilateral lending agency, the corporate community, the foundation community, the religious community and every host government of a developing nation must do its part to provide the leadership and resources necessary to turn the tide. It can and must be done."

In his concluding comments re-emphasized the urgency he attached to his appeal: "There is currently no vaccine or cure for HIV/AIDS, and we are at the beginning of a global pandemic, not the end. What we see in Africa today is just the tip of the iceberg. There must be a sense of urgency to work together with our partners in Africa and around the word, to learn from both our failures and our successes, and to share this experience with those countries that now stand on the brink of disaster. Millions of lives—perhaps hundreds of millions—hang in the balance. That is why this legislation is so important...We have come to realize that, when it comes to AIDS, neither the crisis nor the opportunity to address it have borders."

Conclusions

Much more is called for than periodic meetings of national or international health planners, scientists or financial leaders, and their episodic knee-jerk responses as and when new statistics trigger yet another round of global HIV/AIDS concerns. What is needed are ongoing strategies for international action across the whole range of issues that can be shown to impact on the pandemic and issue-specific arrangements for sustaining them. Nothing less will suffice. Kofi Annan, before President Clinton, had

emphasised both the urgency and nature of this need when he said: "Time is not on our side, but by acting now, and acting together, we will make a difference."

It cannot be over-emphasised, however, that the range of collaborators that would be called for has never been mobilised in support of any issue – health or otherwise – in the world's history. It will not be easy. A truly unprecedented global response is called for. It is a response that would certainly call for revisions by world decision makers of deeply held views and priorities. Can this happen? The answer must be an optimistic yes. As Barbara Ward said: " The most important change that people can make is to change their way of looking at the world.... Change our fundamental angle of vision and everything changes – our priorities, our values, our judgements, our pursuits." Such a response would clearly open a new chapter in international societal relationships. It could also be viewed as a response, albeit late, to a centuries-old global concern for humanity, equity, justice and human rights. What might be even more important is that the very survival of these values worldwide may well be dependent on the nature of this response.

This does not mean that all initiatives to meet the challenge of the HIV/AIDS pandemic must wait on co-ordinated action by the International community. Individual discrete efforts of non-governmental organisations or special-interest community groups also have roles to play – by educating, raising awareness, and promoting societal transformations. Indeed, any initiative which is likely to favourably influence individual or group HIV-related behaviour, and has credibility in the special context of people's daily lives, should be encouraged and supported.

Admittedly, even the best designed educational campaigns, showing that unsafe sex and high-risk behaviour can kill, are liable to run up against entrenched taboos and adverse cultural norms; but the significant drops in infection rates recently achieved in Uganda, Brazil and Thailand[15] provide evidence that such campaigns, appropriately structured, vigorously run and promoting the requisite societal adaptations, can work.

The recent proposal by the UK based Charity, Students Partnership Worldwide (SPW), for the development of youth-led peer-directed education programmes on HIV/AIDS, is an example of such an initiative[16]. Based on the premises that it is young people who are at greatest risk, that they are more likely to be favourably guided by the advice of their

peers than the prescriptions of adults, and that promoting awareness of the importance of human rights issues could be an important element in AIDS education programmes for and by young people, this SPW initiative is already attracting wide international attention. Demonstration models of such programmes are already being developed by SPW in co-operation with the governments of South Africa, Uganda, Tanzania and Zimbabwe. Plans are underway for the development of comparable programmes in other areas of the developing world.

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[1] Wiesel E, quoted in *Health and Human Rights*, Mann, Gruskin, Grodin and Annas, Routledge 1999, front cover

[2] Aristotle, quoted by Von Warburg W P in A Right to Health? *Aspects of Constitutional Law and Administrative Practice*, Hague, Sijthoff and Noordhoff, 1979

[3] Department of Health and Social Security, *Inequalities in Health*, Report of a Research Working Group chaired by Sir Douglas Black, London, DHSS, 1980

[4] Acheson D (Chairman), *Independent Inquiry into Inequalities in Health:* Report, London Stationery Office, 1998

[5] Institute of Medicine, *Future of Public Health*, 1988

[6] Mann J, *Human Rights and AIDS: The Future of the Pandemic in Health and Human Rights*, Mann, Gruskin, Grodin and Annas, Routledge, p216-226, 1999

[7] Tolstoy L, quoted in Lewis Wolpert's *Samuel Gee Lecture* (1996), Journal of the Royal College of Physicians, 30,2

[8] Burnett M, *Biomedical Research Challenges and Opportunities*, 1981, Perspectives in Biology and Medicine 24, p511-24

[9] Mann J, *Health and Human Rights*, BMJ, 1996, 312, 924-5

[10] UNDP World Development Report, New York, OUP, 1999, p4

[11] Pearson Commission, (Commission on International Development), *Partners in Development*, New York, Praeger, 1969

[12] Annan Kofi, The Commonwealth Lecture 2000, *An Agenda for Africa*, Commonwealth Institute

[13] UNDP World Development Report, New York, OUP, 1999, p9-12

[14] New Scientist 2000, *Rallying Point: If we don't help South Africa Deal with HIV – We'll Live to Regret It*, 166 (2237) p3

[15] UNAIDS/WHO epidemiological fact sheet, 2000 update

[16] Students Partnership Worldwide, Jim Cogan, Director, Summary Paper, *HIV/AIDS: A Youth-led Approach*, May 2000

ELIZA REHABILITATION PROGRAMMES

FOR STREET CHILDREN AND THE HANDICAPPED

P.O. BOX 10507, Nairobi, Kenya, Tel: 02 315103, Fax: 02 244082

Email - Elizango@hotmail.com

Your Ref:

Date: 13th October 2000.

Our Ref:

Sandral Thurman, Director
White House Office of National Aids Policy (ONAP)
736 JACKSON PLACE, NW, SUITE 820
WASHINGTON DC 20503
Phone: 202-456-2439
Fax: 202-456-2438

Dear Sir,

SUBJECT: REQUEST FOR HIV / AIDS EDUCATION & COUNSELLING PROJECT FUNDS

We are writing to you to kindly request for your assistance to facilitate the implementation of our objectives to the needy in HIV / AIDS project.

As a multifaceted orgnaisation a major component is that of street children, **orphans, widows, widowers and the less fortunate** who need HIV / AIDS education, counselling at all level i.e seminars, workshops in primary, secondary schools and other relevant institutions. The organisation strives to give more human dimension to aspects of development with social significance by revitalizing some principles which are disappearing:- dialogue, solidality and community participation. It seek to champion community based projects as a preferred strategy for the positive resolution of problems affecting , **HIV. / AIDS victims, orphans, windows, widowers and the less fortunate.**

As much as we would like to continue caring for them, resources are becoming scarce times are hard and there is a need to rehabilitate, educate and counsul them about, and be aware of HIV / AIDS catastrophy. And having already established a rapport with the children the less fortunate most of whom are a product of **HIV / AIDS** catastrophy, we have resolved to appeal to **your organisation** to kindly assist us for the purpose to release us from this strenuous efforts, and having our orgnaisation registered as a **NON - PROFIT MAKING COMMUNITY BASED NON-GOVERNMENTAL ORGANISATION**, based in Down town River Road. We have pleasure therefore to submit this appeal to you and we shall be more than grateful if you can assist us towards the needy people.

Hoping to hear from you and thanking you in advance.

Yours Sincerely,

James Kihara Warui
Programmes Administrator.

November 2, 2000

Mr. Amador Rodriguez, #669226
2101 FM 369 N.
Iowa Park, TX 76367

Dear Mr. Rodriguez:

Thank you for your recent letter. I apologize for the delay in a response. I do believe that life is indeed precious and very valuable.

We have come a long way in having created effective vaccines to combat the AIDS pandemic, as well as reliable health care opportunities with people living with HIV/AIDS.

Thank you again for your interest.

Sincerely,

Sandra L. Thurman
Presidential Envoy on AIDS &
Director, National AIDS Policy Office

Saved to
(H:) Drive — Interns — Shaira
letter — ONAP response2

MS. SANDRA THURMAN. 10-25-2000
(AIDS CZAR)
1600 PENNSYLVANIA AVE N.W.
WASHINGTON. D.C. 20500-0006
(PEACE BE WITH YOU)(IN JESUS CHRIST NAME)

LIFE IS PRECIOUS. AND SO ARE YOU. SO LET's do PRECIOUS THINGS FOR OUR SURVIVAL:

I HAVE DAYS AND NIGHT's do RESEARCH CONCERNING THE KILLER VIRUS HIV/AIDS AND HEPATITIS (B) (C):

THE TEXAS PRISON ARE INFLICTING THE KILLER VIRUS to ALOT OF INDIVIDUALS WITHOUT THEM HAVING ANY KNOWLEDGE OF THE KILLER VIRUS. INDANGER THE CITIZEN UPON THEIR RELEASE IN WHICH STATE OFFICIALS AS WELL U.S. OFFICIALS ACKNOWLEDGE THE ENDANGER IMPOSING to THEIR CITIZEN. BILL 2076 ONLY PROVIDE A SAFETY HEALTH CARE FOR THE PRISON OFFICIALS BUT WHAT ABOUT THE CITIZEN OF THE UNITED STATES.

RESPECTFULLY SUBMITTED
Amador Rodriguez

Amador Rodriguez, #669226.
2101 FM 369 N.
Iowa Park, TX 76367

November 2, 2000

Mr. Charles Sloan
P.O. Box 43843
Washington, DC 20010

Dear Mr. Sloan:

Thank you for your recent letter. I apologize for the delay in a response. Your suggestion regarding Sustiva for treatment for AIDS vaccine will be directed to the appropriated channels.

We have come a long way in having created effective vaccines to combat the AIDS pandemic, but we are far from eradicating this devastating disease.

Thank you again for your interest.

Sincerely,

Sandra L. Thurman
Presidential Envoy on AIDS &
Director, National AIDS Policy Office

Saved to
(H:) Drive —— Interns — Shaira
letter - ONAP response

9-29-00

WHITE HOUSE OFFICE OF NATIONAL AIDS POLICY

SANDRA THURMAN

DIRECTOR

(1)

I WRITE AS USA VOLUNTEER TO SUGGEST AN IDEA FOR A POSSABLE AIDS VACCINE. IF YOU THINK MY IDEA HAS CREDIBILITY PLEASE FOREWARD IT FOR CLINICAL TRIALS RESEARCH AND DEVELOPMENT.

AIDS VACCINE

(SUSTIVA EFAVIRENZ) + (AZT) + (3TC)

TO MOBILIZE THE BODY IMMUNE SYSTEM TO PROTECT AGAINST HIV VIRUS INFECTIONS AND AIDS DISEASE. ADMINISTER TO HEALTHY PERSONS THE VACCINE WITH SPANSULES EXTENDED RELEASE CAPSULES TO REDUCE SIDE EFFECTS.

Charles O Stone
USA VOLUNTEER

9-29-00

(2)

WHITE HOUSE OFFICE
OF NATIONAL AIDS POLICY
SANDRA THURMAN
DIRECTOR

IF THE "AIDS-VACCINE" I SUGGEST
PROVES SUCCESSFUL I SUGGEST THE
GOVERNMENT MAKE IT AVAILABLE FOR
ALL AMERICANS.

THE - SUSTIVA - AZT - 3TC - COMBO
STOPS THE HIV-VIRUS-REPLICATIONS
AND MUTATIONS AND AS A VACCINE
WILL MOBILIZE THE BODY IMMUNE
SYSTEM TO RESIST HIV VIRUS INFECTIONS
THE VACCINE DOSE STRENGTH
WOULD BE DETERMINED BY
CLINICAL TRIALS.
CHARLES E. KEARNS (USA VOLUNTEER)

(3)

WHITE HOUSE OFFICE
OF NATIONAL AIDS POLICY
DIRECTOR
SANDRA THURMAN

FEEL FREE TO USE THIS LETTER
ENCL. LETTERS ETC ANY WAY
YOU WANT.
PLEASE ACKNOWLEDGE RECIEPT
SOON AND LET ME KNOW
YOUR RESPONSE.

BEST WISHES
Charles E. Sloan
USA VOLONTEER

CHARLES SLOAN
P.O. BOX Y3843
WASH. D. C. 20010

Once Daily

SUSTIVA™

efavirenz

Efficacy

In Study 006, SUSTIVA, in combination with nucleoside analogues (AZT + 3TC) resulted in 75% of patients achieving viral loads below quantifiable levels (BQL, <400 copies/mL), compared to 56% of patients receiving a protease inhibitor regimen (IDV + AZT + 3TC) at 24 weeks.* These differences in the percent BQL were predominantly the result of more patients who received IDV + AZT + 3TC discontinuing the study prior to 24 weeks compared to patients receiving SUSTIVA + AZT + 3TC. These differences in discontinuation rates were predominantly the result of adverse events in the IDV + AZT + 3TC arm. It is difficult to assess the relative efficacy of the treatment arms given the disproportional discontinuations in an open label study.

Flexibility

Combined with nucleoside analogue RT inhibitors and/or a protease inhibitor.

Pregnancy

Pregnancy should be avoided in women receiving SUSTIVA. Barrier contraception should always be used in combination with other methods of contraception.

Convenience

Once-daily dosing, with or without food; high fat meals should be avoided. Bedtime dosing is recommended during the first two to four weeks of therapy.

Reliability

Long half-life (40-55 hours) for sustained plasma levels.

Tolerability

SUSTIVA is generally well tolerated. The most common side effects with the SUSTIVA + AZT + 3TC regimen were: nausea (12%), rash (11%), dizziness (10%), impaired concentration (9%), fatigue (7%), vomiting (7%), insomnia (7%), headache (6%), diarrhea (5%), and abnormal dreams (4%).

Patients should be counseled that nervous system symptoms and rash may occur early in treatment and generally resolve within two to four weeks with continued therapy with SUSTIVA. In controlled clinical trials, 52% of patients experienced nervous system symptoms and 2.6% discontinued therapy as a result. Similarly, 27% of patients experienced rash and 1.7% discontinued therapy as a result. Patients should be cautioned not to operate hazardous machinery or drive automobiles if they experience nervous system symptoms.

EFFECTIVE THERAPY YOU CAN COUNT ON.

SUSTIVA (efavirenz) in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection. This indication is based on analyses of plasma HIV-RNA levels and CD4 cell counts in controlled studies of up to 24 weeks in duration. At present, there are no results from controlled trials evaluating long-term suppression of HIV-RNA with SUSTIVA.

Resistant virus emerges rapidly when non-nucleoside reverse transcriptase inhibitors (NNRTIs) are administered as monotherapy. Therefore, SUSTIVA must not be used as a single agent to treat HIV or added on as a sole agent to a failing regimen. SUSTIVA therapy should always be initiated in combination with at least one other antiretroviral agent to which the patient has not been previously exposed.

*Patients who terminated the study early for any reason or who had a missing HIV-RNA measurement that was either preceded or followed by a measurement above the limit of quantification of the Roche RT-PCR Amplicor™ HIV-1 Monitor Assay were considered to have HIV-RNA above 400 copies/mL at the missing time points.

SUS4e
Printed in U.S.A.

NATIONAL INSTITUTES OF HEALTH
OFFICE OF AIDS RESEARCH

Robert W. Eisinger, Ph.D.
Health Science Administrator

Building 2, Room 4W17
Two Center Drive
MSC 0255
Bethesda, MD 20892
TEL: 301 496 8655
FAX: 301 402 7769
E-mail: be4y@nih.gov

AUG 28 2000

9-29-00

FOR SANDRA THURMAN
C/O WHITE HOUSE

Mr. Charles Sloan
P.O. Box 43843
Washington, D.C. 20010

FROM Charles L. Sloan
VS LUNTEER

Dear Mr. Sloan:

This is in response to your recent letter concerning the use of antiretroviral agents for the prevention of HIV infection.

The National Institutes of Health (NIH) continues to support studies to develop more effective means to prevent HIV infection and AIDS. These studies include efforts to develop improved behavioral interventions, vaccines, therapeutic regimens, and microbicides. Since antiviral drug combinations can have serious side effects, the use of them for preventing HIV infection is not viewed as the most promising method, except when an individual is known to have been exposed to HIV, such as when a health care worker is exposed via a needle stick. The NIH has supported research evaluating the use of anti-HIV agents as post-exposure prophylaxis. For instance, NIH-sponsored researchers at the New York Blood Center are using a mouse model to evaluate the post-exposure use of antiviral agents and human antibodies to prevent HIV infection.

If you would like up-to-date information on current AIDS clinical trials, please contact the AIDS Clinical Trials Information Service through its toll-free number (1-800-874-2572) or visit its web site (www.actis.org).

I hope you find this information useful and thank you for your continued support of the NIH AIDS research program.

Sincerely,

Don Luckett
Program Analyst

I SHARE THIS COPY WITH YOU

NATIONAL INSTITUTES OF HEALTH
OFFICE OF
AIDS
RESEARCH

William E. Paul, M.D.
Director

Building 31, Room 4C02
31 Center Drive
MSC 2340
Bethesda, MD 20892
TEL: 301 496 0357
FAX: 301 496 4843
E-Mail: wepaul@nih.gov

9-29-00

JAN 13 1997

For Sandra Thurman
c/o White House
From Charles Sloan

Mr. Charles Sloan
P.O. Box 43843
Washington, D.C. 20010

Dear Mr. Sloan:

Thank you for your recent letter to Dr. William Paul. I am pleased to hear that you are encouraged by the recent advances made in AIDS research.

The National Institutes of Health (NIH) continue to support efforts to develop and evaluate new combination therapies for HIV infection. The NIH also is involved in a collaborative effort with researchers, physicians, community members, and others outside and within the Public Health Service to review the data accumulated to date on combination therapies for HIV infection and its sequelae. The goal is to develop a set of principles upon which to establish the most effective clinical practices for the treatment of HIV infection. This effort has been given a high priority so that patients and physicians receive the most up-to-date information for choosing the best treatment regimens. The NIH also continues to support the development and evaluation of multiple HIV prevention strategies, including vaccines, behavioral interventions, and other interventions involving the prophylactic use of antivirals and other agents.

Thank you again for your interest in and support of the NIH AIDS research program.

Sincerely,

Don Luckett
Program Analyst

I Share
This Copy
With You

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Communications
Bldg. 31, Room 7A-50
(301) 496-5717
Fax (301) 402-0120
Press Line (301) 402-1663

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

9-29-00

FOR SANDRA THURMAN
WHITE HOUSE
FROM CHARLES SLOAN
VOLUNTEER

August 4, 2000

Ref#: SEG56135

Charles Sloan
PO Box 43843
Washington, DC 20010

Dear Mr. Sloan:

Your letter dated May 4, 2000 to Donna Shalala, Secretary of the Department of Health and Human Services was forwarded to the National Institute of Allergy and Infectious Diseases (NIAID) for reply. The NIAID is the NIH institute with primary responsibility for research on HIV infection and AIDS. We apologize for the delay in our response. Your letter just recently arrived in our office.

Thank you for your suggestion regarding Sustiva for treatment for HIV infection.

For information on approved treatments for HIV infection you may contact the HIV/AIDS Treatment Information Service (ATIS). The address, telephone number, and Web site for ATIS follow:

HIV/AIDS Treatment Information Service
P.O. Box 6303
Rockville, MD 20849-6303
1-800-448-0440
http://www.hivatis.org

With the dedication of medical researchers around the world, we hope to find ways to prevent, treat, and cure this devastating disease.

Sincerely,

NIAID Correspondence Specialist
Office of Communications and Public Liaison

DR. SHARP
THIS COPY
FOR YOU

Professor cautions AIDS may spread in U.S. like Africa

By Robert Stacy McCain
THE WASHINGTON TIMES

Citing U.N. data on HIV infection rates, J. Philippe Rushton, a psychology professor at the University of Western Ontario whose studies of race, behavior and genetics have been attacked by left-wing academics, told a Washington press conference yesterday that blacks in the United States and Canada "are on the brink of an AIDS epidemic" comparable to the crisis in Africa.

A "taboo on discussing the evidence" of racial differences in sexual behavior "tragically . . . is killing people," Mr. Rushton said.

"Right now, about 2 percent of U.S. blacks are living with HIV/AIDS," Mr. Rushton said at the National Press Club. "That was the level of AIDS infection in Africa just 15 years ago. Now African rates are between 8 percent and 20 percent."

If the HIV infection rates for U.S. blacks continue to mirror the spread of the virus among blacks in Africa, Mr. Rushton said, "we are faced with the threat of an African AIDS epidemic within large sections of the black population of the United States, and also in the Caribbean."

As early as 1989, Mr. Rushton said, he "predicted the very situation [of HIV infection among U.S. blacks] we've got today."

The warning came as U.S. health officials convening in South Africa — which has seen an exploding rate of HIV infection in recent years — warned of the global consequences of the AIDS epidemic.

Last month, Health and Human Services Secretary Donna E. Shalala announced the formation of Crisis Response Teams "to help combat the spread of HIV/AIDS among racial and ethnic minority populations."

AIDS is the leading cause of death for black men ages 25-44 in the United States, according to the federal Office of Public Health and Science, while the disease is also the country's third-leading cause of death for black women ages 25-44.

Mr. Rushton's research has been attacked as "academic Nazism" and "racial pornography" by Hampton (Va.) University sociologist Steven J. Rosenthal.

"Rushton is dead wrong," John Moore, chairman of the anthropology department at the University of Florida, said in 1997.

Rutgers University's Transaction Publishers, citing protests, has stopped distribution and destroyed 55,000 copies of a special abridged edition of Mr. Rushton's 1995 book, "Race, Evolution, and Behavior," after review copies of the 106-page booklet had been mailed to scholars around the country.

One chapter of that booklet — titled "Sex, Hormones, and AIDS" — addressed behavior-related racial disparities in rates of infection for sexually transmitted diseases (STDs), which Mr. Rushton attributes to genetic differences.

"Race differences in sexual behavior have results in real life," Mr. Rushton wrote in the booklet, noting that "the 1997 syphilis rate among blacks was 24 times the white rate. . . . Racial differences also show in the current AIDS crisis."

Although he is hesitant to suggest how public policy might apply his findings — "my job is to get the truth out there," he says — Mr. Rushton suggested, "I would have thought the greater threat of AIDS to blacks [would lead to] targeting treatment to the populations that are most at-risk" for infection.

Robert A. Gordon, a sociology professor at Johns Hopkins University who joined Mr. Rushton and others at yesterday's press conference, said efforts to suppress Mr. Rushton's research are the result of "a dogmatic egalitarianism in the social sciences."

7-12-00

HIV IN THE CITIES

A representative sample of homosexual and bisexual men were tested in seven metropolitan areas. The number of men tested and the rate of HIV infection found in each area are listed below.

City	Number tested	Percent infected
Baltimore	357	8.5
Dallas	530	6.5
Los Angeles	509	8.3
Miami	488	5.8
New York	541	12.1
San Francisco Bay area	702	6.2
Seattle	365	2.2

Source: "HIV Prevalence and Associated Risks in Young Men Who Have Sex With Men," Journal of the American Medical Association, July 12

The Washington Times

HIV

From page A1

John Hylton of the Johns Hopkins University School of Hygiene and Public Health says the results are "incredibly significant."

Mr. Hylton, a coordinator for the project, says the report's findings are "especially important because they clearly point to the high level of HIV among the young. They indicate the rates of infection are increasing among minority men in urban areas that aren't thought of as AIDS epicenters, the way San Francisco and New York are."

"We're talking of men who are just becoming sexually active — men who are becoming acculturated into the gay social scene," Mr. Hylton says, implying that this bodes ill for the future.

But the results also are disconcerting because the study's participants presumably have been exposed to "HIV/AIDS prevention educational initiatives while they were growing up," the study points out. The nation became aware of the spreading AIDS epidemic about 1981, and the continuing anti-AIDS campaign began in 1984 and 1985, when the oldest men in the current study were about 7 years old.

Regardless, nearly 1 in 10 (9.7 percent) of the 22-year-old participants tested positive for the virus. None of the 15-year-olds was found to be infected at the time of the testing, which extended from 1994 to 1998.

"Prevalence of HIV was higher among blacks, Hispanics, and men of mixed or other race than among whites. Among men of mixed race, HIV prevalence was higher among those who reported black backgrounds than among those who did not," the study states.

Black people in the study had an infection rate of 16.9 percent, the highest recorded. Thus, the findings "display the large racial gap in the current HIV epidemic in the United States," the report continues.

Forty-one percent of those in the overall group stated they were engaging in unprotected sex, which heightens the risk of becoming infected. Researchers called that fact "sobering," and it led the scientists to declare:

"Considering their youth, the high prevalence of recent unsafe sex, and the high HIV prevalence in [those tested], many of the HIV-negative men are likely to become HIV-infected in the near future."

The researchers said the findings underscore "the need to evaluate and intensify prevention efforts for young [homosexuals and bisexuals], particularly blacks, men of mixed race or ethnicity, Hispanics and adolescents."

A team of 14 specialists and their staffs from around the country conducted the study. It was sponsored by the federal Centers for Disease Control and Prevention. Three state health departments plus seven city and county public health services and three university medical centers participated.

Because youths in the age groups studied are hard to reach by what the report called "traditional household-oriented sampling methods," the researchers took to the streets of seven major cities — Baltimore, Dallas, Los Angeles, Miami, New York, San Francisco Bay area and Seattle. They scoured dance clubs, bars, businesses, bathhouses, health clubs, parks, beaches and social organizations for subjects, often interviewing thousands of embarrassed and sometimes hostile men before identifying homosexuals and bisexuals who fit into the age groups being studied.

They ultimately discovered that the rate of HIV-infection among Seattle's study participants was just 2.2 percent, the lowest encountered. The highest: New York City's 12.1 percent.

The "multisite, venue-based" approach used by researchers in this study sets it apart from others. But it is particularly significant because many of the earlier estimates of HIV's pervasiveness that appeared in the late 1980s were based on surveys of men 30 years old or older.

7-11-00

The Washington Times WORLD

AIDS could kill millions in southern Africa

By Daniel Q. Haney
ASSOCIATED PRESS

DURBAN, South Africa — Life expectancy in countries worst hit by Africa's staggering AIDS epidemic is expected to fall to around 30 years within a decade — the lowest in a century — as the disease kills tens of millions more in its sweep across the continent.

The new estimate, released yesterday, is the latest attempt to quantify the incredible breadth and effect of the epidemic on sub-Saharan Africa, where 15 million have died of AIDS and 25 million more infected people almost certainly will die in the next few years.

"It's hard to comprehend the amount of mortality we will see in these countries," said Karen Stanecki of the U.S. Census Bureau, which compiled the projections.

Miss Stanecki presented the new figures at the 13th International AIDS Conference, a high-profile meeting being held for the first time in Africa, ground zero of the epidemic.

AIDS already has sharply reduced life expectancy in many southern African countries. For instance, in Botswana, where more than one-third of adults are infected with HIV, which causes AIDS, life expectancy is now 39 years instead of 71, as it would have been without the disease. And the numbers are expected only to get worse.

Miss Stanecki projected that by 2010, life expectancy will be 29 in Botswana, 30 in Swaziland, 33 in Namibia and Zimbabwe and 36 in South Africa, Malawi and Rwanda. Without AIDS, it would have been around 70 in many of those countries.

"These are a level of life expectancy that have not been seen since the start of the 20th century," she said.

Speakers at the meeting struggled for superlatives to describe the scope of this disease in the poorest parts of the globe, especially sub-Saharan Africa, where nearly three-quarters of all HIV-infected people live.

Dr. Kevin DeCock of the U.S. Centers for Disease Control and Prevention called the epidemic "Africa's worst social catastrophe since slavery."

Miss Stanecki predicted that by 2003, the populations of Botswana, South Africa and Zimbabwe will begin to fall because of AIDS deaths and dropping fertility resulting from the epidemic. In those countries, the populations will drop between one-tenth and three-tenths of 1 percent. Without AIDS, they would have grown between 1 percent and 3 percent.

Miss Stanecki said this is the first time the Census Bureau has projected negative population growth due to AIDS. The population growth of several other countries — including Malawi, Namibia, Swaziland and Zambia — will be near zero.

Experts note that programs to educate people about condoms and other ways of avoiding infection clearly can work in southern Africa. Because of early efforts, the epidemic never occurred in Senegal, and Uganda has reversed its high infection level.

A DS Envoy: 'A Cashmere Glove Over A Steel Fist'

Thurman Tackles Pandemic With Soft-Spoken Bluntness

By Barton Gellman
Washington Post Staff Writer

BY TOM ALLEN—THE WASHINGTON POST

At the White House Office of National AIDS Policy, Sandra L. Thurman also is working on global AIDS efforts.

NEW YORK—The king of Swaziland shouldered om Rosshirt aside the other day as the White House peechwriter angled toward Sandra L. Thurman. His Majesty Mswati III wrapped Thurman in a warm embrace and called her Sandy. Then came President Paul agame of Rwanda. Then President Jerry Rawlings f Ghana.

When Rosshirt escaped with Thurman downstairs om the Waldorf Astoria's Palm Room, where President Clinton had just spoken to African leaders about IDS, the scene replayed. A Zambian stopped to book spot on Thurman's calendar for President Frederick hiluba. Then it was the foreign minister of Thailand.

Usually, it is an ambassador who has to work a oom, angling for face-time with heads of state. These ays, the world is working its way toward Sandy hurman, for the unlikely reason that she is President linton's personal envoy in the global fight against IDS.

Clinton plucked Thurman, an Atlanta activist and hird-generation Georgia pol, to be director of the Vhite House Office of National AIDS Policy more han three years ago. Last month, amid intensified attention to the pandemic's global toll, he added an international portfolio. The scale of the catastrophe—19 million dead, 34 million dying—has begun o sink in with world leaders, and Thurman aims to elp coordinate the global response.

Smart money said she would not get the job. Secretary of State Madeleine K. Albright and Frank Loy, ndersecretary of state for global affairs, wanted to fill he post with a foreign service officer, reporting to hem. After six months of internal debate, they hought they were winning that fight. In July, Loy announced that the naming of a career ambassador was mminent. The next day, he called a reporter to retract he report.

People have a way of underestimating Thurman, who dresses for society, calls most everyone "love" or dear" and lets her blond hair drape over her shoulders at 47.

"My daddy used to have a saying that I had the heck in the bank before most people realized I had a rain," Thurman recalled.

"Time and time and time again" people mistake her manners for softness, said James Carville, an old flame of Thurman's from their days on former Georgia governor Zell Miller's 1990 campaign. "The State Department and everybody's taken a run at her, and they ain't the better for it. She kind of has a cashmere glove over a steel fist."

Carville demurred about their romance, except to recall that "she dragged me to I don't know how many damn fundraisers" for humanitarian causes.

After five years as executive director of AID Atlanta, a community support and care program for people living with AIDS, Thurman had sweet-talked donors into tripling her budget. She took leave to serve as political director of Clinton's 1992 Georgia campaign, but stayed in health care advocacy until Clinton's second term.

Thurman is blunter, in her gracious southern way, than is common among high-level appointees. She made clear in public, within months of becoming AIDS "czarina," that she strongly disagreed with the president's decision against funding for needle exchanges to prevent the spread of AIDS among drug abusers.

And she did it without making an enemy of Barry McCaffrey, her White House counterpart for drugs, who opposed such funding. Earlier this year, she even lured the retired Persian Gulf War general to a soup kitchen for AIDS patients, where he pronounced the grub "top 1 percent Army mess hall, which I would take as a compliment."

She describes Air Force One, on which she flew most recently to Tanzania and Nigeria with Clinton, as "16 hours trapped with 40 of your co-workers, like a big bus with wings."

"Of course I'm burned out," she said, in mock exasperation. "I've been doing this for 18 years!"

But not too burned out to spend her vacation on the "family disease"—politics. Thurman's mother was a Georgia Democratic Party chairman, and Thurman knows where the power is. Her job at the Los Angeles convention was running credentials. If you wanted someone in, said Sen. Edward Kennedy (D-Mass.), "who [were] you picking up the phone to talk with? Sandy Thurman. She catches you one way or the other."

In her White House office, Thurman has only six staff members to help coordinate AIDS policies that spend billions of dollars across a dozen agencies. Some colleagues in other departments describe her Jackson Place townhouse headquarters as a black hole for paperwork. She has a way of missing meetings, or saying the date is no good, that "stops progress dead in the water" when she does not like the direction her colleagues are going, one of them said.

Thurman said before leaving for Africa last month that she is "very sensitive to the quality of work that comes out of this office" and agreed she might not "move as quickly as people would like." But when she came back she took a steelier line.

"The more I thought about that, the more it ticked me off," she said. "With such a small staff we operate in triage mode, so most of our energy goes where the bodies are dropping fastest. . . . There's a certain level of arrogance to folks thinking what is their priority ought to be [my] priority."

Players

Sandra L. Thurman

Title: Director, Office of National AIDS Policy; presidential envoy for AIDS cooperation.

Age: 47.

Education: Bachelor's degree, Mercer College.

Previous jobs: Director, Office of Citizen Exchanges, State Department; director of advocacy programs, Task Force for Child Survival and Development, Carter Center; executive director, AID Atlanta.

er
Mostly sunny, warm. Low 68.
y: Mostly sunny, igh 84. Low 66.
Page B8
AR No. 213 M2 DM VA

The Washington Post

WEDNESDAY, JULY 5, 2000

Today

DEATH WATCH | *The Global Response to AIDS in Africa*

World Shunned Signs of the Coming Plag

st of three articles

BARTON GELLMAN
hington Post Staff Writer

rom a seventh-floor office in Langley some 13 rs ago, Katherine J. Hall kept vigil on the unrav- g of societies and states.
ıs national intelligence officer at large, Hall su- vised the CIA's taxonomy of upheaval overseas. at signs forecast a government's collapse, an nomy's ruin, a civil war? Hall and her staff had a ch that conventional indicators, heavy on poli- and money, were missing something. In 1990, three years of frustrated lobbying, she and ague Walter L. Barrows got permission to y the burgeoning growth of AIDS.
ıteragency Intelligence Memorandum 91- 05, distributed in classified channels the fol- ng July, foretold one of the deadliest calamities ıman experience. Titled simply, "The Global AIDS Disaster," the report projected 45 million infections by 2000—inexorably fatal, the great majority in Africa. The number beggared comparison. There were not that many combatants killed in World War I, World War II, Korea and Vietnam combined.

Unlike the Black Death in 14th-century Europe, which took half as many lives, the means of controlling AIDS were known. Yet African and foreign governments, the report said, were making no more than a "modest level of effort." This would "have only a marginal effect."

The same might have been said for IIM 91-10005. The document landed near the top of the pile of incoming intelligence at the White House and Cabinet agencies. The reaction, said principal author Kenneth Brown, was "indifference—that's the right word." The authors prepared for the flurry of briefings that accompanies release of a major intelligence product. Save for then-Surgeon General C. Everett Koop and a Pentagon medical unit, no one asked.

Nine years later, a highly public awakening plays out in the Clinton administration, Congress, foreign capitals, the United Nations system and the offices of drug manufacturers. The premise of their new commitments on AIDS is that they are confronted for the first time with the magnitude of the disaster.

Yet for a decade, the world knew the dimensions of the coming catastrophe and the means available to slow it. Estimates ranged widely, but the World Health Organization in 1990 and 1991 projected a caseload, and eventual death toll, in the tens of millions by 2000. Individually and collectively, most of those with power decided not to act.

How and why they made their choices is the subject of this series of articles. It is a story of authentic doubts for a time because the disease concealed itself in years of latency and layers of social

See AIDS, *A12, Col. 1*

BY DAVID SILVERMAN – REUTERS

Jonathan Mann, a leader in the fight against AIDS, quit the World Health Organization in frustration.

"The botton that the epi could rage o Africa [whil could contro here," Mann lamented. "I the rich Unit States . . . D need Africa?

CHARLES SLOAN
P.O. BOX 43943
WASH. D.C. 20010

SANDRA THURMAN
DIRECTOR
WHITE HOUSE OFFICE OF NATIONAL AIDS POLICY
~~THE~~ WHITE HOUSE
1600 PENNSYLVANIA AVE. N.W.
WASHINGTON D.C. 20500

CHARLES SLOAN
P.O. BOX 43843
WASH. D.C. 20010

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AIDS advocates: Orphans are time bomb of epidemic

Pauline Jelinek
THE ASSOCIATED PRESS

WASHINGTON — Orphans are the most ignored victims of the AIDS pandemic and will come back to haunt the world as uneducated, antisocial youths and adults unless they get help, AIDS advocates said Tuesday.

"There are few consequences of the AIDS epidemic that are so tragic as orphans . . . so neglected and . . . so ignored by the international community," said Peter Piot, head of the United Nations AIDS program.

"I believe that no society can really cope with such an enormous number of orphans and of desocialized youth," he told a congressional briefing on the subject. "This is going to have major consequences for the stability of societies."

Officials estimate 16 million children have already lost one or both parents to the disease and that the number could reach 30 million by 2010.

Their problems usually start long before their parents die — when the children leave school to care for the sick or get jobs to support their families. Along with the loss of education and income, the children lose a loving home and suffer the trauma of watching their parents die.

Albina du Boisrouvray of the charity Francois-Xavier Bagnoud Foundation (FXB) said the children are "a time bomb" for their countries because "they will be unprepared to become productive citizens."

The three-hour session organized by the private Global Health Council brought together U.S. governmental agencies and groups from around the world that have been working on the problem.

Sandra L. Thurman, head of the White House office on AIDS policy, said though it has been estimated that Africa alone needs $3 billion a year to fight the disease, the international community has to date given only about a tenth of that.

HERALDO GARCIA
808 N. 20th STREET
Ft. PIERCE FL. 34950-6003

WEST PALM BEACH, FL 334
PM
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33nsA

ATTN: OPD
MRS. SANDRA L. THURMAN
C/O THE WHITE HOUSE
WASHINGTON D.C. 20500

November 1, 2000

Bermard A. Kirshbaum, M.D.
125 Clwyd Road
Bala Cynwyd, PA 19004-2302

Dear Dr. Kirshbaum:

Thank you for your recent letter summarizing several journal articles focusing on ozone therapy as a treatment for HIV infection.

As you know, all drugs seeking approval for treatment of HIV must go through a rigorous clinical trial process. Only after a drug has made it through the clinical trial process and been shown to be safe and effective will the Food and Drug Administration approve it for use in the United States. While this may seem to be a long and complicated process, it is in place to ensure the safety and efficacy of all drugs approved for use in the United States, not only for treatment related to HIV, but for all diseases and conditions. This requirement has resulted in the United States producing the most safe and effective medicines in the world.

While the Office of National AIDS Policy is not able to directly support research or participate in the development and approval process, we would like to forward your letter to the Office of AIDS Research at the National Institutes of Health.

Thank you for taking the time to provide us with this information.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation
Director, Office of National AIDS Policy

Bernard A. Kirshbaum, M.D.
125 Clwyd Road
Bala Cynwyd, PA 19004-2302

Dear Dr. Kirshbaum:

Thank you for your recent letter summarizing several journal articles focusing on ozone therapy as a treatment for HIV infection.

As you know, all drugs seeking approval for treatment of HIV must go through a rigorous clinical trial process. Only after a drug has made it through the clinical trial process and been shown to be safe and effective will the Food and Drug Administration approve it for use in the United States. While this may seem to be a long and complicated process, it is in place to ensure the safety and efficacy of all drugs approved for use in the United States, not only for treatment related to HIV, but for all diseases and conditions. This requirement has resulted in the United States producing the most safe and effective medicines in the world.

I will be pleased to provide a copy of your letter to the FDA for their consideration. Thank you for taking the time to provide me with this information.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation
Director, Office of National AIDS Policy

Reps/murguia/letter/kirshbaum

Memo from

BERNARD A. KIRSHBAUM, M.D.

To: Ms. Sandra Thurman -

Please, Please read the attached letter.

It is fairly brief (only 2 pages) - the bulk of this packet consists of reprints from the medical/scientific literature and laboratory data of patients with AIDS which support the thesis of this letter.

This is serious. It is not a joke; it is not a hoax. All of it is true. I believe that if these concepts are put into practice, they will save millions of lives and billions of dollars.

Bernard Kirshbaum

Matthew - will you respond - thanks!

Bernard A. Kirshbaum, M.D.
125 Clwyd Road
Bala Cynwyd, PA 19004-2302

tel: (610) 668-1456 fax: (610) 668-0748

e mail: kirshbaum2@earthlink.net

4 October 2000

Sandra Thurman, Director
Office of National AIDS Policy
736 Jackson Place NW
Washington, DC 20503

Dear Ms. Thurman:

As you know only too well, AIDS is a costly and frustrating disease. The cost of AZT is approximately $4000 per year to treat one patient, and it has some untoward side effects which make it less desirable. Protease inhibitors, although more effective, are also considerably more expensive, about $18,000 annually per patient, and they also have some known but lesser side effects.

Vaccines for AIDS are still years away from being available, and will be expensive. What can we do for those who are presently infected with this disease?

I would like to propose an agent which is as effective as protease inhibitors, has no (repeat no) side effects if administered properly, and is inexpensive -- about 50 cents per day -- average cost less than $200 per year for each patient treated. A small fraction of the cost of current medications being used in the treatment of AIDS.

That modality is medical ozone. Ozone you say?!! Preposterous, everyone knows it's toxic and you can't use it! -- Please read on:

The generally held belief is that ozone is toxic, but this is true only when it is inhaled. What is generally not known is that ozone can be safely administered into the human body by all other routes, including intra-arterially, intravenously, intramuscularly, even intra-spinally, as well as rectally -- with no side effects so long as one stays within pharmacologic limits. And the results of doing so are highly beneficial.

Ozone is a powerful oxidizing agent which kills a vast array of bacteria, viruses, and other pathogenic micro-organisms on contact. This has also been confirmed for Human Immunodeficiency Virus (HIV), the retrovirus causing AIDS. -- see enclosed copies of reprints from the journal BLOOD, and ANTIVIRAL RESEARCH.

Note that both of these papers appeared in October 1991, and that each group was working independently, without knowledge of each other, and both papers came to the same conclusion, namely: that ozone is effective at destroying intra-cellular as well as free HIV, without damage to the blood cells (no cytotoxicity), and with no alteration in the proteinaceous components of the blood.

The last group of pages are laboratory data on 4 patients who have been treated with medical ozone administered rectally. The graphs of patients "G" and "T" were presented by Dr. Michael Carpendale at meetings of the 11th International Congress of Ozone, held in San Francisco in September 1993, under the auspices of the International Ozone Association. You will note that there was a rise in the CD4 cells counts of both these patients after each course of ozone therapy that they received. Also, patient "T" turned PCR (polymerase chain reaction) negative -- i.e. no viral particles detectable in his blood.

Patients "N" and "L" are known to me. Patient "N" was diagnosed as having AIDS 6 years prior to starting ozone therapy and was being treated with AZT which was making him "sick" and was not helping with his disease. Note that his HIV P24 antigen turned NONE DETECTABLE in his blood (October 11, 1995), $5\frac{1}{2}$ months after starting ozone treatments rectally on May 1st, 1995. I emphasize 1995, because that was the year before protease inhibitors came onto the market.

Patient "L" also had had AIDS for a number of years and was taking a "cocktail" of medications without significant benefit. She stopped those drugs just before having her blood HIV viral load study on June 2nd, 1999, which was reported as 40,570. She started rectal ozone therapy 10 days later (June 12, 1999), and when her blood laboratory study was repeated one month later (July 14, 1999) her viral load was 16,218 -- a 60% drop in one month!

Ozone is also an immunomodulating agent and can up-regulate the immune system, enhancing the formation of interferon and lymphokines which are of additional benefit in treating AIDS. I believe that medical ozone, properly utilized, can play a significant role in the management of AIDS in our own nation, and in the worldwide epidemic of this disease.

If you would like additional information about these matters, kindly contact me. I would be pleased to discuss this with you in greater detail, and can provide additional evidence of the effectiveness of medical ozone.

Sincerely,

Bernard A. Kirshbaum, M.D.
Clinical Professor of Dermatology
Medical College of Pennsylvania

VOL 78, NO 7 OCTOBER 1, 1991

BLOOD

Journal of the American Society of Hematology

T-Cell Chronic Lymphoproliferative Disease

American Society of Hematology
Thirty-Third Annual Meeting
December 6-10, 1991
Denver, CO
(see page 1896 for additional information)

W. B. SAUNDERS COMPANY
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Inactivation of Human Immunodeficiency Virus Type 1 by Ozone In Vitro

By Keith H. Wells, Joseph Latino, Jerrie Gavalchin, and Bernard J. Poiesz

A device was designed to deliver a constant source of given concentrations of ozone to fluids containing human immunodeficiency virus type 1 (HIV-1). Ozone was found to inactivate HIV-1 virions in a dose-dependent manner. Greater than 11 log inactivation was achieved within 2 hours at a concentration of 1,200 ppm ozone. Similar concentrations of ozone had minimal effect on factor VIII activity in both plasma and immunoaffinity-purified preparations of factor VIII treated for the same time period. The data indicate that the antiviral effects of ozone include viral particle disruption, reverse transcriptase inactivation, and/or a perturbation of the ability of the virus to bind to its receptor on target cells. Ozone treatment offers promise as a means to inactivate human retroviruses in human body fluids and blood product preparations.

HUMAN immunodeficiency virus type 1 (HIV-1), the etiologic agent of acquired immunodeficiency syndrome (AIDS), is a lentivirus that completes its replicative cycle by budding through the host cell membrane, acquiring host-derived and virus-encoded components in the process. Subsequent rounds of replication require an intact lipid envelope containing the virally encoded envelope proteins necessary for receptor binding.[1] It has been suggested that perturbation of the HIV-1 envelope may be a suitable approach to inactivating HIV-1.[2] Compounds that fluidize membranes by removing cholesterol (AL721)[3] or by complexing membrane cholesterol (amphotericin B methyl ester)[4] can inhibit HIV-1 replication in vitro. Although their precise mode of action has yet to be defined, these compounds may reduce HIV-1 infectivity by perturbing the envelope of HIV-1. We therefore investigated the activity of another membrane active agent, ozone, on HIV-1 infectivity in vitro.

Ozone, the triatomic allotrope of oxygen, is an extremely potent oxidant that has been shown to possess broad spectrum antimicrobial activity.[5-8] It has been widely used in sewage treatment, in water purification, and in medicine.[9,10] In particular, ozone has been shown to be effective against a number of enveloped and nonenveloped viral species, with enveloped viruses being more susceptible to ozone inactivation than those lacking lipid envelopes.[5,11,12] We report on the in vitro inactivation of HIV-1 in cell culture media and deliberately infected factor VIII preparations at concentrations of ozone that are not toxic to target cells, while maintaining the biologic activity of factor VIII. We also investigated the mechanism by which ozone mediates its antiviral effect.

MATERIALS AND METHODS

Cells and virus. The CD4a$^+$ T-cell line HUT 78[13] was maintained in RPMI 1640 + 10% heat-inactivated fetal bovine serum (FBS) + 1% penicillin/streptomycin (complete RPMI; all from GIBCO, Grand Island, NY) at 37°C, 5% CO_2 humidified atmosphere. HUT 78 cells served as the target cells in the HIV-1 inactivation studies. HUT 78/HIV-1_{AAV} is a cell line stably infected with an isolate of HIV-1 from our laboratory (AAV).[14] HUT 78/HIV-1_{AAV} served as the source of HIV-1 for the inactivation studies. Cell-free conditioned media from HUT 78/HIV-1_{AAV} (HIV-1_{AAV} CM) was harvested by centrifugation (1,200g) and filtered through a 0.45-μm filter (Nalgene, Rochester, NY). This virus preparation was titrated for production of progeny HIV-1 p24 in HUT 78 according to the infectivity assay described below.

Factor VIII. Factor VIII preparations used were either nonconcentrated, frozen, HIV-1–negative human plasma or immunoaffinity-purified human factor VIII (Monoclate; Armour Pharmaceuticals, Kankakee, IL). Factor VIII activity was determined in a one-stage assay.[15]

Ozone generation and delivery. Ozone was generated from medical grade oxygen by electrical corona arc discharge in a commercial ozone generator (Hansler GmbH, Iffezheim-Baden, Germany). Ozone was delivered into cell culture medium or factor VIII preparations through a closed hollow fiber system (Fig 1A) as a stream of ozone/oxygen in carrier nitrogen.[16] The hollow fiber cartridge, virus reservoir, peristaltic pump, and all connecting lines were confined to a laminar flow biohazard hood. Figure 1B shows a closeup diagram of the hollow fiber gas exchange cartridge. The micropores of the hollow fiber are of sufficient size to allow for ozone to diffuse from the extracapillary space into the liquid phase, but small enough to prevent liquid from leaking back into the extracapillary space. Ozone and the liquid phase were pumped in a countercurrent fashion with respect to one another to maximize ozone diffusion. Ozone levels in the system were measured using a Dasibi model 1008 ozone monitor (Dasibi, Glendale, CA).

HIV-1 inactivation studies. For this and all studies described, 300 mL of Hanks' balanced salt solution (HBSS) were passed for 1 hour at a flow rate of 100 mL/min through the hollow fiber cartridge, reservoir, and connecting lines to moisten the fibers and other components. The system was then drained and 450 mL of cell-free HIV-1_{AAV} CM containing one-half of an infectious unit of HIV-1 was added to the reservoir. For our purposes, one-half of an infectious unit is defined as the dilution of virus that yields 50% of the maximum amount of progeny HIV-1 p24 antigen 5 days postinfection in the virus infectivity assay described below. The titration curve for virus used in these assays is shown in Fig 2. As can be seen, the detection of expressed HIV-1 p24 is linear up to a concentration of 1:4 dilution of input virus, with a maximum detection of 3,000 pg of HIV-1 p24. Hence, a dilution of approximately 1:24 of stock virus was used as one-half of an infectious unit.

From the Departments of Medicine and Microbiology/Immunology, SUNY Health Science Center, Syracuse, NY; the Department of Hematology/Oncology, The Brooklyn Hospital, New York, NY; and the Biological Technical Services, Merck Pharmaceutical, Manufacturing Division, West Point, PA.

Submitted June 25, 1990; accepted May 29, 1991.

Supported in part by US Public Health Service Contracts No. HB-67021 and AI-72654 and a grant from Medizone International, Inc.

Address reprint requests to Bernard J. Poiesz, MD, Department of Medicine, SUNY Health Science Center, 750 E Adams St, Syracuse, NY 13210.

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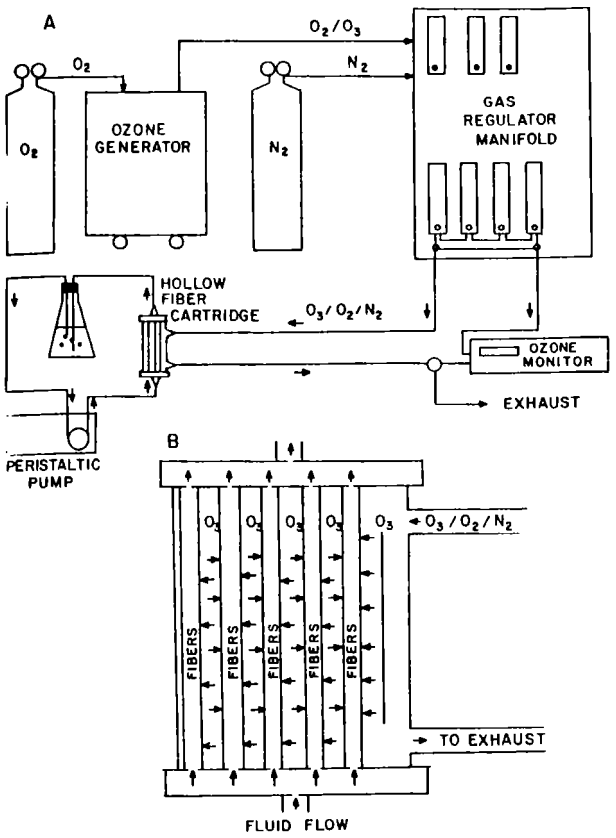

Fig 1. Schematic diagram of ozone generation/delivery system (A) and close-up of gas exchange cartridge (B) showing flow of oxygen, ozone and nitrogen gases, and HIV-1–containing fluids. Note that the input and exhaust ozone is monitored.

A full infectious unit would be a dilution of 1:12. The CM (final protein concentration, 35 mg/mL) was then pumped through the system at a rate of 100 mL/min. Ozone flowed through the extracapillary space of the hollow fiber cartridge at the concentrations and times indicated. To find a threshold virucidal dose of ozone, ozone concentrations were sequentially elevated on an hourly basis (ie, 1 hour at 200 ppm, 1 hour at 400 ppm, etc) (Figs 3A and 4A). The time parameter (abscissa) is a composite of the total time of exposure. For N_2 only experiments, carrier N_2 alone flowed through the cartridge. For pump only experiments, no gas was introduced into the cartridge, although the cartridge ports were opened to filtered room air. At the times indicated, 1 mL samples of treated CM were removed for use in the virus infectivity assay described below.

HIV-1 infectivity assay. One million HUT 78 cells were pelleted in 15-cm[3] sterile tubes and resuspended in 50 μL of HIV-1–containing CM. Cells were exposed to the CM for 1 hour at 37°C and 5% CO_2 in wells of a 24-well plate. Five days postinfection the CM were sampled and assayed for viral p24 using a commercial antigen capture assay (Cellular Products, Buffalo, NY).[1]

In those experiments investigating the degree to which ozone inactivates HIV-1, the HIV-1 infectivity assay was modified.[17] Serial 10-fold dilutions of nonozonated HIV-1 were introduced into the assay system while ozone-treated HIV-1–spiked CM or human plasma was used undiluted. The cultures were assayed for HIV-1 p24 twice a week up until day 28. Results are expressed as a mean of a minimum of six separate experiments, each consisting of triplicate runs. Results are expressed as picograms per milliliter HIV-1 p24 or percent untreated control. The cutoff for positive is 30 pg/mL of HIV-1 p24.

Ozone cytopathic effects. To determine if ozone is causing the formation of products in cell-free CM that are deleterious to the target cells used in the infectivity assays, sham infections were performed. First, cell-free HUT 78 cell culture-CM was filtered and added to the cartridge. It was then treated with either room air, N_2, or 1,200 ppm ozone for 2 hours. Mock infections were then performed by placing 10^6 HUT 78 cells in 50 μL of the above treated CM versus control for 1 hour at 37°C. Cells were then washed and placed into culture at a concentration of 5×10^5/mL. Four days later, cells were pulsed with 1 μCi [^{3}H]-thymidine. Eighteen hours later, cells were harvested, washed, and precipitated with 10% ice-cold trichloroacetic acid for 2 hours on ice. Acid-precipitable material was collected on Whatman GF/C filters (Whatman Intl Ltd, Maidstone, England), washed, and counted. Results are expressed as counts per minute incorporated or a percentage of untreated control. Similarly, cells were assayed for viability via trypan blue dye exclusion.

To further evaluate any potential effects of ozone-treated media on the target cells, which would influence their ability to be infected by HIV-1, we analyzed the effect of the various treated CM on CD4a levels on the HUT 78 cells. HUT 78 cells were exposed for 1 hour at 37°C to media treated as above and were then stained with fluorescein isothiocyanate (FITC)-conjugated OKT4a (Ortho Diagnostics, Raritan, NJ) and analyzed on a Coulter EPICS V Flow Cytometer (Coulter Electronics, Hialeah, FL). Results were expressed as percent cells positive and mean channel number of fluorescence.

Effect of ozone on factor VIII levels and HIV-1 in factor VIII preparations. Frozen factor VIII containing human plasma prepa-

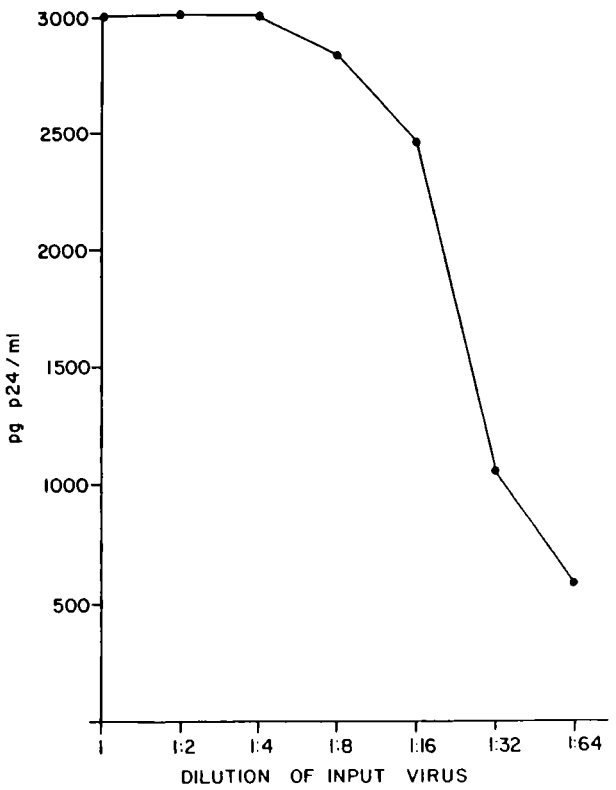

Fig 2. Titration curve of input virus in HIV-1 infectivity assay. Progeny HIV-1 p24 was measured 5 days postinfection by antigen capture assay.

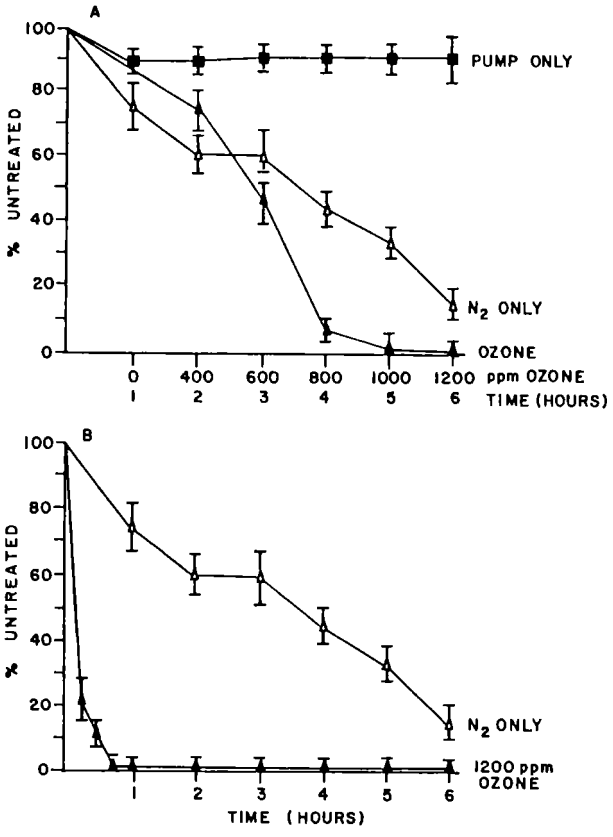

Fig 3. Effect of ozone on HIV-1 infectivity in cell culture medium using an escalating dose regimen (A) and continuous high-dose (1,200 ppm) (B) ozone. Virus infectivity was assayed after treatment with room air (■), nitrogen atmosphere (△), or ozone in carrier gas (▲). Residual infectious HIV-1 levels were assessed using the 5-day HIV-1 infectivity assay. CM from cultures 5 days postinfection were assayed for HIV-1 p24. Results are expressed as a percentage of the p24 produced by cultures infected with nonozonated HIV-1. The results shown are the mean values and ranges from three separate experiments. Each separate treatment (A: pump 1 to 6 hours, N_2 only 1 to 6 hours, escalating dose ozone; B: 1,200 ppm 1 to 6 hours) was tested in triplicate cultures within an individual experiment. Please note that the total concentration of ozone multiplied by time in (A) is 4,000 ppm hours and in (B) is 7,200 ppm hours.

rations were thawed at 4°C in an ice water bath and pooled. Pooled material was separated into two 250 mL aliquots. The first aliquot was diluted with 250 mL Dulbecco's phosphate-buffered saline (PBS) (pH 7.5) and added to the hollow fiber system (final protein concentration, 400 mg/mL). It should be noted that for this particular experiment the hollow fiber system was prewashed with Dulbecco's PBS for 1 hour before addition of diluted factor VIII. A sample of diluted factor VIII was removed and the remaining diluted factor VIII was pumped through the hollow fiber system. One hour, no gas (pump only) and one hour, nitrogen only (N_2 only) samples were removed. Ozone was then flowed through the system at the sequentially escalating concentrations indicated and samples were removed at hourly intervals. All samples were frozen for later assay of factor VIII activity.

The second 250 mL aliquot of factor VIII was combined with 250 mL of cell-free HUT 78/HIV-1_{AAV} containing a full infectious unit of HIV-1. This preparation (final concentration, 435 mg protein/mL) was then added to the hollow fiber system prewashed with HBSS. The HIV-1–containing factor VIII preparation was pumped through the hollow fiber system and sequentially treated with room air only, N_2 only, and escalating ozone concentrations, as above. Samples were removed at the times indicated and 50 μL of this material was used to infect 1×10^6 HUT 78 cells, as described above. CM were sampled 5 days postinfection and assayed for HIV-1 p24.

Next, a similarly prepared aliquot of human plasma diluted in PBS and spiked with HIV-1 (final protein concentration, 435 mg/mL) was treated in the hollow fiber system continuously at 1,200 ppm ozone over 6 hours. At various time intervals, samples were removed and analyzed for either HIV-1 infectivity or factor VIII activity.

Finally, 14 vials of affinity-purified factor VIII were reconstituted with 5 mL of H_2O each and diluted with 80 mL of PBS containing 1% human serum albumin. This mixture was added to 150 mL of HIV-1_{AAV} CM. After circulating this material several times through the moistened cartridge, the final protein concentration was 35 mg/mL (primarily from the HIV-1_{AAV} CM) and the final factor VIII concentration was 10 IU/mL. This material was then subjected to treatment with 1,200 ppm ozone for 6 hours and analyzed periodically for HIV-1 infectivity and factor VIII activity.

Mechanism of ozone inactivation of HIV-1. To ascertain whether ozone inactivated HIV-1 by directly perturbing the lipid envelope

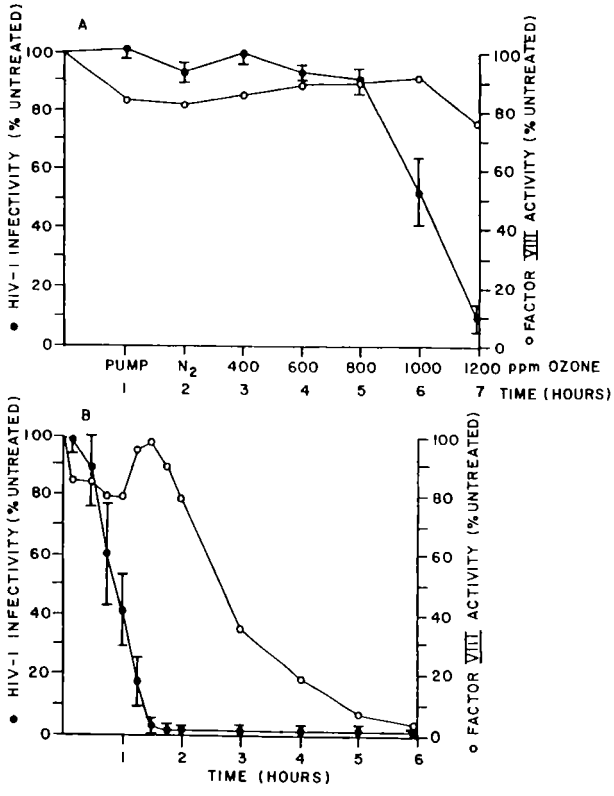

Fig 4. Effect of ozone on HIV-1 infectivity (●) and factor VIII activity (○) in factor VIII plasma using escalating dose (A) and continuous high-dose (1,200 ppm) (B) ozone. Residual infectious HIV-1 levels were assessed using the 5-day HIV-1 infectivity assay. CM from cultures 5 days postinfection were assayed for HIV-1 p24. Results are expressed as percentage of the p24 produced by cultures infected with nonozonated HIV-1. The values are taken from triplicate cultures and are expressed as mean values and ranges. Factor VIII activity was assessed by a one-stage assay and is an average of duplicate determinations. The ranges are so tight that they are not shown. Please note that the total concentration of ozone multiplied by time in (A) is 4,000 ppm hours and in (B) is 7,200 ppm hours.

of the virus, ozone-treated and nontreated HIV-1 preparations were analyzed for the presence of intact virions on sucrose density gradients.[18] Briefly, untreated HIV-1 preparations or preparations treated continuously with 1,200 ppm ozone for 2 hours were concentrated by centrifugation at 40,000g for 2 hours and applied to a 22% to 65% continuous sucrose gradient. Samples were centrifuged at 30,000g for 12 hours. Fractions were collected and analyzed for HIV-1 p24 by antigen capture,[1] for reverse transcriptase,[18] for HIV-1 gp120 and gp41 by Western blot analyses using human polyclonal anti-HIV-1 sera,[1] and for buoyant density by refractometry.[18] Amounts of HIV-1 reverse transcriptase and p24 present as viral cores, intact virions, or soluble proteins were estimated by calculating the surface area of each entity between the fractions with buoyant densities of 1.26 to 1.21; 1.20 to 1.14; and less than 1.14 g/mL, respectively.

Effects of ozone on HIV-1 envelope protein cell surface receptor interactions were assessed in a competitive binding assay using rhodamine-labeled HIV-1 particles.[19] Briefly, HIV-1 particles were banded on a sucrose gradient, concentrated on a glycerol cushion, and labeled with a rhodamine-linked saturated hydrocarbon, 18 carbons long (R-18) (Molecular Probes, Junction City, OR). Labeled particles were then separated from free R-18 by another centrifugation through 30% glycerol onto a 100% glycerol cushion. Labeled virions were then exposed to HUT 78 cells for 30 minutes at 4°C after the target cells had been pre-exposed to ozone-treated or nontreated, sucrose-banded HIV-1 virions, normalized for p24 and reverse transcriptase content. The degree of rhodamine-labeled HIV-1 binding to the target HUT 78 cells was analyzed on the Epics V flow cytometer.

RESULTS

Figure 3A shows the results of an escalating dose regimen on inactivation of cell-free HIV-1. With respect to ozone, the sample was treated sequentially for 1 hour at each of the indicated ozone concentrations. This escalating dose study was designed to define the minimum concentration of ozone at which significant (at least 2 log) virus inactivation was achieved. All curves represent the average of three separate experiments. As can be seen, there was a dose-dependent and time-dependent inactivation of cell-free HIV-1 associated with its passage through this hollow fiber system. The relative contributions of room temperature incubation, mechanical shear, hypoxic atmosphere, and ozone to viral inactivation can be seen in Fig 3A. It is evident that, while ozone is perhaps the major contributing factor to the inactivation of HIV-1 in this system, it is by no means the sole mediator of this event. The results using this escalating dose regimen showed that a threshold dose of 1,200 ppm achieved ≥ 2 log inactivation of virus. The total concentration multiplied by time at this point was 4,000 ppm hours.

Figure 3B shows the results of the time-dependent inactivation of HIV-1 in cell culture medium using 1,200 ppm ozone. As can be seen, 1,200 ppm achieves ≥ 2 log virus inactivation within 45 minutes (900 ppm hours). Inactivation due to room temperature, mechanical shear, and nitrogen atmosphere is only approximately 25% within 1 hour. Hence, ozone is the major contributing factor to virus inactivation at both the higher dose and early time points.

Figure 4A shows the results of the effect of a sequentially escalating dose of ozone on HIV-1 viability and factor VIII biologic activity in an HIV-1–spiked human plasma preparation. As can be seen, there is minimal loss of factor VIII biologic activity associated with ozone treatment at concentrations that eventually inactivate HIV-1. Treatment to a threshold dose of 1,200 ppm results in a 90% inactivation of HIV-1 with only a corresponding 25% loss of factor VIII biologic activity.

Figure 4B shows the results of the time-dependent inactivation of HIV-1 and factor VIII biologic activity in a plasma preparation using continuous 1,200 ppm ozone. As can be seen, 1,200 ppm ozone achieves ≥ 2 log inactivation of HIV-1 by 2 hours while the corresponding factor VIII activity remains high (90%).

Similar results were seen when immunoaffinity-purified factor VIII preparations were inoculated with HIV-1 and treated continuously with 1,200 ppm ozone (Fig 5). In this instance, ≥ 2 log viral inactivation was achieved within 1

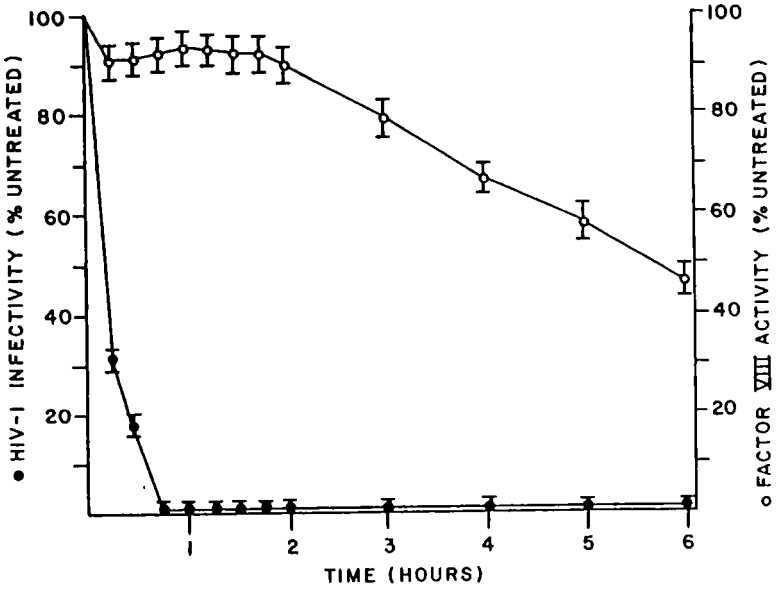

Fig 5. Effect of ozone on HIV-1 infectivity (●) and factor VIII activity (○) in immunoaffinity-purified factor VIII (monoclate) preparations using continuous high-dose (1,200 ppm) ozone. Residual infectious HIV-1 levels were assessed using the 5-day HIV-1 infectivity assay. CM from cultures 5 days postinfection were assayed for HIV-1 p24. Results are expressed as a percentage of the p24 produced by cultures infected with nonozonated HIV-1. The values presented are taken from triplicate cultures and are expressed as mean values and ranges. Factor VIII biologic activity was determined by one-stage assay and is the mean and ranges of triplicate determinations.

Table 1. Comparison of Ozone-Treated HIV-1 With a Titration of Untreated HIV-1 in a 28-Day HUT 78 Cell Culture System

HIV-1 Viral Input*	HIV-1 p24 Assay Result for Each Biweekly 28-Day Culture Sample (day in culture)†								
	1	4	7	10	14	17	21	24	28
3.5×10^{1} ng HIV-1 in CM treated 2 h, 1,200 ppm ozone	–	–	–	–	–	–	–	–	–
3.5×10^{1} ng HIV-1 in human plasma treated 2 h, 1,200 ppm ozone	–	–	–	–	–	–	–	–	–
3.5×10^{1} ng HIV-1 no ozone	–	+	+	+	+	+	+	+	+
3.5×10^{0} ng HIV-1 no ozone	–	+	+	+	+	+	+	+	+
3.5×10^{-1} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-2} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-3} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-4} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-5} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-6} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-7} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-8} ng HIV-1 no ozone	–	–	–	+	+	+	+	+	+
3.5×10^{-9} ng HIV-1 no ozone	–	–	+	+	+	+	+	+	+
3.5×10^{-10} ng HIV-1 no ozone	–	–	–	–	–	+	+	–	+
3.5×10^{-11} ng HIV-1 no ozone	–	–	–	–	–	–	–	–	–
0 ng HIV-1 p24 no ozone	–	–	–	–	–	–	–	–	–

*Total HIV-1 viral input as measured by p24 antigen capture of 50 μL of cell-free HUT 78 HIV-1_{AAV} cell culture CM either undiluted (3.5×10^{1} ng) or serially diluted in virus-negative culture media.

†The mean of six separate experiments each run in triplicate being ≥ 30 pg/mL of HIV-1 p24. All 18 replicates of data points listed as negative were negative, and all replicates of data points listed as positive were positive save for day 24 of the 3.5×10^{-10} cultures, in which the mean was 28 pg/mL and some replicates were positive and some negative. A culture was deemed positive if two successive samples were positive with the second being either four times the first or ≥ 250 pg/mL of HIV-1 p24. All cultures save for the ozone-treated HIV-1, 0 pg HIV-1 p24, and 3.5×10^{-11} ng HIV-1 p24 were positive.

hour, whereas factor VIII activity after 2 hours was approximately 90%.

As can be ascertained from Figs 3, 4, and 5, increasing amounts of protein and possibly other plasma components decreased the virucidal effect of ozone. The HIV-1–spiked material in Figs 3 and 5 has a protein concentration of 35 mg/mL, while the human plasma in Fig 4 has a concentration of 400 (A) or 435 (B) mg/mL.

In an effort to determine the degree of inactivation of HIV-1 by ozone, HIV-1–spiked CM (35 mg protein/mL) and HIV-1–spiked plasma (435 mg protein/mL) were each treated with 1,200 ppm ozone for 2 hours. Fifty microliters of each of these treated materials (initially containing 35 ng of HIV-1 p24) were placed in a 28-day HIV-1 culture assay and compared with a serial dilution of untreated HIV-1 virus. In this experiment the transmission of an 11 log dilution of untreated virus could still be detected, whereas the transmission of ozonated, undiluted HIV-1 in CM or human plasma could not be discerned, suggesting that 1,200 ppm of ozone for 2 hours achieved a minimum of an 11 log inactivation (Table 1).

Studies were performed to evaluate the mechanisms of antiviral action of ozone treatment. There were no appreciable effects of ozone-treated CM on the viability, rates of DNA synthesis, and CD4a levels of HUT 78 target cells exposed in mock infections (Table 2). However, treatment of HIV-1–infected CM with 1,200 ppm ozone did result in a marked decrease in recoverable sucrose-banded virions as measured by reverse transcriptase and HIV-1 p24 analyses (Fig 6). In six separate experiments comparing the surface area under the curve for reverse transcriptase activity and p24 antigen content between media treated and untreated with ozone, the loss of recoverable virions ranged from 75% to 93% with a mean of 85%. Western blot analysis of the fractions in Fig 6 for HIV-1 gp41 and gp120 envelope protein content showed a loss of antigen comparable with that seen with reverse transcriptase and p24 *gag* protein (data not shown). Hence, there was no preferential loss in residual intact virions of envelope antigen or functional reverse transcriptase activity secondary to ozone.

As shown in Fig 6, there was no appreciable accumulation of viral cores in the ozone-treated CM. All of the

Table 2. Effects of Ozone-Treated CM on HUT 78 Cells in a Mock Infection

Condition of CM	CD4a Levels		Cytopathic Effect			
	% Cells Positive	x̄ Channel No.*	Cell Viability ($\times 10^{6}$)	% Control	[H^3] Thymidine Incorporation (cpm)	% Control
No treatment	57 ± 2	84 ± 2	2.89 ± 0.33	100	12,850 ± 1,340	100
Room air (2 h)	59 ± 2	77 ± 2	2.73 ± 0.24	94	10,280 ± 985	80
N_2 (2 h)	58 ± 2	86 ± 2	2.64 ± 0.35	91	10,993 ± 1,002	85
1,200 ppm ozone (2 h)	61 ± 2	89 ± 2	2.73 ± 0.18	94	9,124 ± 878	71

All assays were run six times and results equal mean ± 3 SD.

*Channels are grouped from 1 to 267 and are on a log scale.

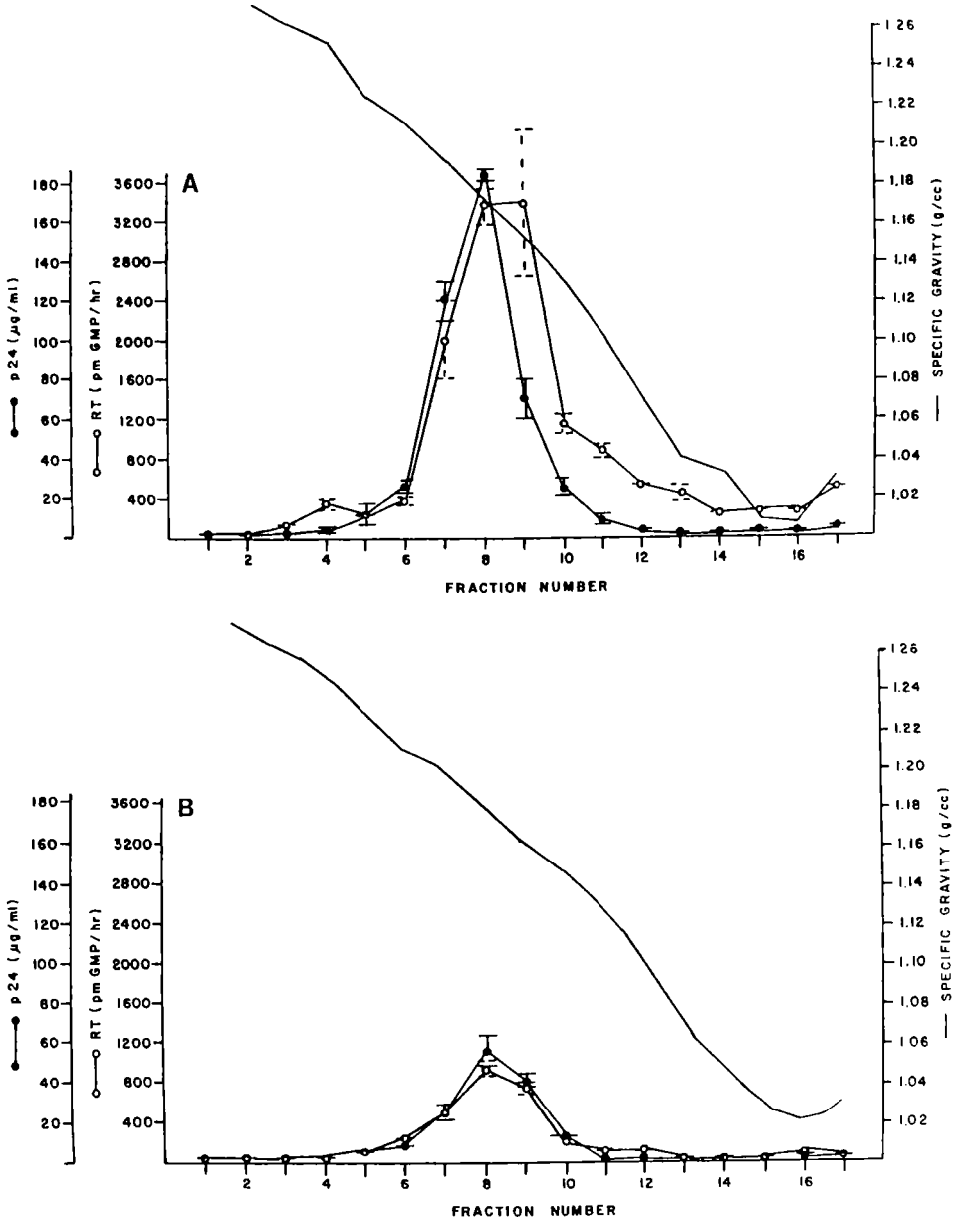

Fig 6. Analysis of fractions from sucrose density gradients of HIV-1–positive cell-free CM untreated (A) or treated with 1,200 ppm ozone (B) for 2 hours. Specific gravity, HIV-p24 (●--●), and reverse transcriptase (○--○) levels are shown. Specific gravity was determined by refractive ind HIV-1 p24 was determined b, IIV-1 p24 antigen capture immunoassay and is expressed as micrograms per milliliter with mean values and ranges of triplicate determinations shown. Reverse transcriptase activity was determined using the template: primer, poly rC:oligo dG, 10 mm Mg^{2+}, and [^{3}H]-GTP. Results are expressed as picomoles per liter o GMP incorporated per hour and are the mean values and ranges from triplicate samples.

missing HIV-1 p24 antigen, but not the reverse transcriptase activity, was recovered in the supernatant after the original high speed pelleting step before sucrose banding (data not shown). This result would indicate that ozone t atment led to complete solubilization of most of the treated HIV-1 particles and that, while key epitopes of solubilized HIV-1 p24 could still be detected in the antigen capture assay, functional reverse transcriptase activity was lost secondary to the oxidation of solubilized enzyme.

Further evaluation of ozone-treated and untreated HIV-1 sucrose-banded virions for their ability to compete against rhodamine-labeled HIV-1 for cell surface receptor binding has shown an impaired ability of ozone-treated virions to c place HIV-1 (Table 3). This experiment was performed twice with similar results. Although further investigation is necessary, the implication is that ozone-treated virions have a diminished capacity to bind to their natural cell surface receptor, CD4.

DISCUSSION

Reducing the infectious risk of human blood products is an area of intense research.[20-22] Inactivation of infectious agents in blood products under conditions that retain their intrinsic protein biologic activities has undergone extensive study. Thermal inactivation of viruses in blood derivatives has been marginally successful, due in part to the thermolability of these components.[23-25] Methods ranging from gamma-irradiation,[26] porous membrane filtration,[27] and solvent/detergent mixtures[28-31] have been investigated. To date, tri(n-butyl)phosphate (TNBP) detergent mixtures have demonstrated a minimum 4 to 5 log 10 reduction in a

Table 3. Effect of Ozone on the Binding of HIV-1 Virions as Measured in a Competition Assay

Condition	Rhodamine-Labeled HIV-1	$\bar{x}$ Channel No.*	$\bar{x}$ Channel No Minus Autofluorescence of HUT 78 Cells	% of Control*
HUT 78 cells	No	81	0	0
HUT 78 cells	Yes	155	74	100
HUT 78 cells preincubated with unlabeled HIV-1 not treated with ozone	Yes	122	41	34
HUT 78 cells preincubated with unlabeled HIV-1 treated with ozone	Yes	143	62	67

*Channels are grouped from 1 to 256 and are on a log scale. Calculation of percentage of control is performed by first converting $\bar{x}$ channel number to an arithmetic value, subtracting autofluorescence of HUT 78 cells, and dividing by the value obtained with HUT 78 cells plus rhodamine-labeled HIV-1.

variety of lipid-enveloped viruses, including HIV-1, vesicular stomatitis virus, and Sindbis virus, with a concomitant high recovery rate of protein biologic activity. Analogous work in chimpanzees with TNBP-treated, exogenously viral-spiked blood samples with hepatitis B and non-A, non-B (Hutchinson strain) viruses has shown similar log reductions. However, methods eclipsing a 6 log viral reduction with a similar protein recovery are still being explored. In addition, methods that obviate the necessity for removal of the inactivating agent (ie, Sephadex G-25) and/or that are compatible with cellular systems would ultimately be preferable.

Ozone has previously been shown to possess potent antiviral activity, especially when used against lipid-enveloped viruses. For this reason we investigated the use of ozone as a potential anti–HIV-1 agent. We used a hollow fiber delivery system that maximizes the surface area available for ozone to interact with the fluid material of interest. The system also allows for the precise regulation of concentrations of ozone to be delivered into the hollow fiber cartridge. Afferent as well as efferent concentrations of ozone can also be monitored to determine if saturating levels of ozone are achieved in the treated material. With regard to laboratory safety concerns, this closed system has proven to be safe and leak-proof, thereby reducing possible exposure of laboratory personnel to ozone and human retroviruses to an absolute minimum.

We first examined the ability of ozone to inactivate cell-free HIV-1 in cell-free CM. These results indicate that ozone has potent anti–HIV-1 activity. Preliminary experiments using an escalating dose regimen indicated that a 1,200 ppm dose of ozone achieved a ≥ 2 log inactivation of virus. The data show that neither incubation of the virus preparation at room temperature and at atmospheric conditions for the duration of the experiment nor mechanical shear created by pumping the virus through the system inactivate the virus to any great extent. However, there was a significant inactivation of the virus due to exposure of virus-containing CM to the stream of carrier nitrogen. Exposure of the virus to pure nitrogen for 6 hours results in an almost 85% inactivation of virus.

During exposure to nitrogen for 6 hours, conditions are completely anoxic and a maximal pH of 8.1 is achieved, whereas with exposure to room air the oxygen concentration is 21% and the maximal pH is 7.58. It is possible that anoxic conditions or pH changes seen with 6 hours of nitrogen exposure contribute to HIV-1 inactivation. Because some HIV-1 inactivation was observed with N_2 alone, it was necessary to determine the proportion of virus inactivation attributable to ozone over the course of a 6-hour treatment. Comparison of the time-dependent inactivation of virus seen with 1,200 ppm ozone with that seen with pure nitrogen clearly indicates that ozone plays the predominant role in achieving virus inactivation for periods up to 6 hours. Ozone inactivation of HIV-1 occurs relatively quickly compared with any inactivation observed with N_2 alone. Inactivation of HIV-1 at 45 minutes is ≥ 2 log when 1,200 ppm ozone is used and only 25% when nitrogen alone is administered.

Investigation of the degree of inactivation of HIV-1 in CM or human plasma by 1,200 ppm ozone for 2 hours indicates a minimum 11 log reduction in viral infectivity, determined by a 28-day culture assay. Therefore, the effects of temperature, N_2, and mechanical shear, which yield an approximate 0.22 log reduction in HIV-1 infectivity, are certainly eclipsed by the 11 log reduction in infectivity achieved by ozone.

We examined the ability of ozone to render blood products, such as factor VIII plasma preparations, free of HIV-1 without seriously damaging their biologic activity. The escalating dose study indicated that, at 1,200 ppm, ozone can achieve a 90% inactivation of HIV-1 in human plasma with only a corresponding 25% decrease in factor VIII biologic activity. Measurement of exhaust ozone levels indicated that saturating levels of ozone in the factor VIII preparations were not achieved in this experiment (data not shown) and, thus, longer exposures of HIV-1–containing factor VIII preparations at the higher ozone concentrations were used to eliminate the virus entirely. Use of 1,200 ppm ozone for a period of 2 hours achieved saturation and resulted in an 11 log inactivation of HIV-1 in the human plasma preparation. Under the same conditions, factor VIII biologic activity was diminished only 10%. Similarly, ≥ 2 log HIV-1 inactivation in immunoaffinity-purified factor VIII preparations occurred within 1 hour of exposure to 1,200 ppm of ozone with an approximately 10% loss of factor VIII.

Comparison of the results of inactivation of HIV-1 by high-dose ozone (1,200 ppm) in cell culture media, monoclate, and factor VIII plasma preparations indicated that a longer exposure time was necessary to achieve total virus inactivation in the plasma factor VIII preparation. The reason for the apparent protection of HIV-1 from the

effects of ozone in this experiment is most likely the increased protein levels in the factor VIII preparation. Such increased protein levels and other plasma components may act to protect the virus from the effects of ozone.[32]

The exact mechanism by which ozone mediates the inactivation of HIV-1 remains to be elucidated. Our preliminary data indicate that, at the concentrations tested, ozone results in the solubilization of virions. However, the reduction in infectious virus (about 10^{11}) was far greater than the observed reduction in detectable virions (about 85%). This finding suggested that, in addition to the physical destruction of HIV-1 virions, there was a far greater functional impairment of these virions in the infectivity assay. Our data do not suggest that there was any obvious effect of ozone-treated CM on the viability and CD4a levels of the HUT 78 target cells used in the assay. Nor do our results indicate any preferential quantitative effect on HIV-1 envelope proteins and reverse transcriptase levels in the virions. However, there was some suggestion of a deleterious effect on virus binding to cell surface receptors.

Ozone may react with the unsaturated fatty acids in the lipid envelope of the virus, thereby increasing membrane fluidity and resulting in viral inactivation. Alternatively, ozone may react with other components in the virus preparation (serum proteins, fatty acids, etc) to produce secondary reaction products, such as hydroxyperoxides, that in turn mediate the actual viral inactivation. Far more extensive analyses of all components of the HIV-1 life cycle will be required to fully elucidate ozone's antiretroviral activity.

Ozone has potent anti–HIV-1 activity in cell culture media and factor VIII preparations. Although the exact mechanism by which ozone mediates its effect remains unclear at this time, it is readily apparent that ozone may be of use in rendering factor VIII and possibly other blood products, both proteinaceous and cellular, free of HIV-1 and other infectious agents.

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Ozone inactivates HIV at noncytotoxic concentrations

Michael T.F. Carpendale[1,2,3] and Joel K. Freeberg[1,3,*]

[1]*Rehabilitation Medicine and Research Services, Veterans Administration Hospital, San Francisco, CA 94121, U.S.A.,* [2]*Department of Orthopaedic Surgery, University of California School of Medicine, San Francisco, CA 94143, U.S.A. and* [3]*Center for Medical Ozone Studies, Bay Medical Research Foundation, San Francisco, CA 94117, U.S.A.*

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Summary

The inactivation of human immunodeficiency virus (HIV) and cytotoxic properties of ozone-treated serum and serum-supplemented media were examined. The titer of HIV suspensions in human serum was reduced in a dose-dependent manner when treated with total reacted ozone concentrations at a range of 0.5 to 3.5 $\mu g/ml^{-1}$. Complete inactivation of HIV suspensions was achieved by 4.0 $\mu g/ml^{-1}$ of ozone in the presence or absence of H-9 cells. In contrast, cellular metabolism, as measured by MTT dye cleavage, and DNA replication, as measured by BUdR incorporation, were enhanced in H-9 cells grown in media treated with quantities of ozone that completely inactivate HIV. The permissively HIV-infected cell line HXB/H-9 was cultured in ozone-treated media for six days with culture supernatants being sampled and assayed on alternate days for HIV p24 core protein. HIV p24 was reduced in all treated cultures compared to control cultures, with an average reduction of 46% [p24].

HIV; Ozone; Noncytotoxic; Virus inhibitor

Current address: Cutter/Miles, 4th and Parker St., Berkeley, CA 94701, U.S.A.

Correspondence to: M.T.F. Carpendale, Center for Medical Ozone Studies, Bay Medical Research Foundation, 425 Divisadero Street, 305, San Francisco, CA 94117, U.S.A.

Introduction

Ozone, the triatomic allotrope of oxygen with a high electrovoltaic potential, has multiple applications as a bactericidal and virucidal agent in sewage treatment, water purification and pharmaceutical manufacture. Ozone effectively inactivates both enveloped and nonenveloped viruses when introduced into suspensions in water (Akey and Walton, 1985; Roy et al., 1981), effluent (Harakeh and Butler, 1985; Katzenelson et al., 1976), and cell culture media (Bolton et al., 1982a; 1982b). Nonenveloped viruses, including poliovirus (Katzenelson et al., 1979), coxsackie virus (Emerson et al., 1982) bacteriophage f2 (Kim et al., 1982), canine hepatitis virus (Bolton et al., 1982b) and rotaviruses (Vaughn et al., 1987) have been substantially inactivated at moderate ozone concentrations, while enveloped viruses have been shown to be susceptible to degradation at lower ozone concentrations. Inactivation of enveloped viruses by ozone has been demonstrated for vesicular stomatitis virus (Bolton et al., 1982a), influenza type A (Bolton et al., 1982b), infectious bovine rhinotracheitis virus (Bolton et al., 1982b), and Venezuelan equine encephalomyelitis virus (Akey and Walton, 1985). The wealth of information demonstrating the effective inactivation of viruses by ozone in vitro led us to conduct a series of experiments to assess the ability of ozone to inactivate HIV relative to measurable cytotoxic effects, as well as examine the effect of ozone on HIV replication in lymphocytic cells.

Materials and Methods

Ozone generation and measurement

Ozone was generated from medical grade oxygen using high voltage corona discharge in an electric ozone generator (Model HC-1000, Griffin Technics, Lodi, NJ), which allows the voltage, flow rate and concentration to be controlled. Tygon® polymer tubing, Teflon® and glass tubing, and silicon stoppers were used throughout the reaction system to insure containment of the ozone and consistency in concentrations. Gaseous ozone concentrations were measured by an ultraviolet light absorption monitor (model EG-2001 AHC, Griffin Technics) capable of continuous measurement of ozone concentrations of 0.1–200 μg/ml.

Aqueous solutions of ozone can be easily quantified by chemical titration (Shechter, 1973). Mixed organic solutions treated with ozone, however, react quickly to form secondary ozonides and peroxides requiring multiple and complex assays for quantitation (Lee et al., 1982). We therefore developed an apparatus for ozone titration employing three parallel gas lines, each receiving equal flow of oxygen/ozone mixture from the ozone generator and monitor, which introduces the gas by bubbling into flasks containing the solution to be exposed, and directs the overflow into flasks containing potassium iodide

solution (Fig. 1). This allows the total amount of ozone introduced into the solution, and the net amount of ozone reacted per unit volume of serum or media to be measured. A given net reacted ozone concentration was reproduced in each experiment by controlling the gaseous ozone concentration, flow rate, and exposure time for the 50 ml volumes of serum or media. Ozonized potassium iodine solution was measured spectrophotometrically using the methods of Shechter (1973) with the modifications of Emerson (1982). Human serum (HIV seronegative, heat inactivated) or RPMI-1640 medium supplemented with 20% human serum was treated in this apparatus with a gaseous ozone/oxygen mixture ranging from 5 to 20 mg/l for various time periods to produce a range of net reacted ozone concentrations. Control media received equal volumes of pure oxygen or were untreated. The pH of the treated media was checked after ozone treatment and was found not to be altered by treatment.

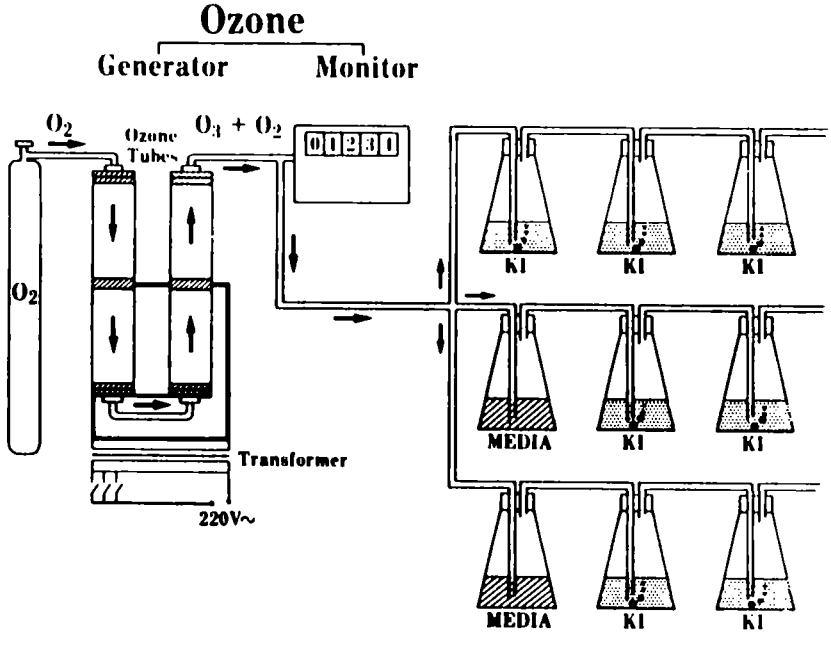

Fig. 1. Ozone generation, monitoring and measurement (reacted). Apparatus for measuring amount of ozone reacted with media and serum. The top line of flasks is used to measure the total amount of ozone introduced into the system. The middle and lower line of flasks are used to treat media or serum. The amount of ozone measured by the second and third flask in the middle or bottom line of flasks is subtracted from the ozone measurement made by the top line of flasks to calculate reacted ozone concentrations in media or serum.

Cells and viruses

HIV-DV, a primary isolate from the peripheral mononuclear cells of a homosexual male with Kaposi's sarcoma, has been described previously (Crowe et al., 1982). HIV was purified from cell-free culture supernatant ($TCID_{50} = 10^{5.5}$/ml) of infected VB T lymphoma cells (Lifson et al., 1986) by ultracentrifugation at 140000 × *g* for 90 min at 4°C. HIV-DV, H-9 T lymphoma cells, HXB/H-9 described previously (Crowe et al., 1982) and VB T lymphoma cells were generous gifts from Dr. Michael McGrath (San Francisco General Hospital Medical Center, San Francisco). All cell cultures were maintained in RPMI-1640 supplemented with 10% fetal bovine serum, 1 mM L-glutamine, 2 mM sodium pyruvate, and 0.5 μg/ml gentamycin (U.C. San Francisco Cell Culture Facility). Peripheral blood mononuclear cells (PBM) were isolated by the Ficoll-hypaque method from a healthy donor negative for HIV antibodies by ELISA, and were cultured under identical conditions with the addition of 10 μg/ml phytohemaglutinin (Sigma, St Louis, MO). Cell lines were maintained in a humidified incubator at 37°C with 5% CO_2.

HIV titer and ozone exposure

Heat inactivated, HIV antibody-negative human serum was treated with ozone to obtain a range of concentrations. Aliquots of purified HIV were added to treated or control solutions (final density of 10^6 infectious units/ml) and exposed for 30 min. Samples from the exposed virus suspension were removed, serially diluted in quadruplicate and titered by addition to microtiter plates containing 10^4 VB cells/well. The presence of infectious HIV was scored by cell fusion and subsequent multinucleated giant cell formation after incubation for seven days.

Ozone cytotoxicity

In these experiments RPMI-1640 medium supplemented with 20% human serum was treated with ozone in the apparatus described while control media received either equal volumes of oxygen for equal time periods or were untreated. Thrice washed H-9 T lymphoma cells or freshly isolated normal peripheral blood mononuclear cells were added at equal volumes (10^5 cells/well) to ozone-treated or control media in 96-well tissue culture plates and incubated at 37°C plus 5% CO_2 for four days, with daily replacement of ozonized or control media. The cells were then resuspended in RPMI-1640 plus 10% fetal calf serum supplemented with 10% (v/v) 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyl tetrazolium bromide (MTT, Sigma), and assayed as described previously (Mossman, 1983). Samples of the control cell suspensions were serially diluted and added to each microtiter plate in order to correlate absorbance values with cell density, and a standard curve was generated for each trial.

DNA replication in identically prepared cultures was quantified by incorporation of 5-bromo-2-deoxyuridine (BUdR, Sigma) using the method of Porstmann et al. (1985). H-9 cells (10^5 cells/well in 96-well microtiter plates) were incubated in ozonized, oxygen-treated, or untreated media supplemented with BUdR at 10^{-5} molar final concentration for 6 h. After centrifugation and cell disruption, BUdR-DNA was quantified by antigen-capture immunoassay utilizing anti-BUdR monoclonal antibody (Chemicon Inc., El Segundo, CA). BUdR-BSA conjugate was quantified at various concentrations in each plate as standards.

Infectious HIV yield

Cocultures were prepared containing 10^6 VB and 5×10^4 HXB/H-9 cells per ml in 5 ml total volume of ozone-treated, oxygen-treated, or untreated RPMI-1640 media supplemented with 20% human serum. After incubation for four days, cells were removed by centrifugation at $1200 \times g$ for 10 min, and virus was concentrated by ultracentrifugation at $140\,000 \times g$ for 90 min at 4°C. The virus pellet was resuspended and titered in VB cell cultures as described above.

p24 Antigen expression in HXB/H-9 cells

The permissively HIV-infected cell line HXB/H-9 was cultured (5×10^5 cells/ml) in ozone-treated, oxygen-treated, or untreated control RPMI-1640 media supplemented with 20% human serum in six-well culture plates. Of the culture supernatant volume 25% was sampled and replaced daily with treated or control media. Samples taken on days 2, 4 and 6 were assayed in triplicate for p24 core protein by antigen-capture assay (Abbot Laboratories) following the manufacturer's instructions. The p24 protein solution supplied with the Abbot assay kit was diluted in ozone-treated media without cells and incubated in parallel with each culture to verify recovery of p24 protein in media.

Statistical calculations

Standard curves of cell number vs. absorbance, or ng/ml of BUdR-BSA vs absorbance, were generated for each MTT or BUdR ELISA and analyzed by linear regression. Only assays with standards yielding r values of greater than 0.994 were included in the final data. Treatment and control populations were compared for significant difference in cytotoxicity and p24 antigen expression by Student's t test.

Results

Inactivation of HIV by ozone-treated human serum

The first experiments conducted were designed to determine if human serum reacted with ozone possesses antiviral properties. The total amount of ozone reacted with a given volume of human serum was measured in the test apparatus. The treated or control serum was placed in microtiter plates, and a concentrated HIV suspension was added to the serum, exposed and titered. Previously published kinetic studies had indicated that 30 min would be a sufficient exposure time for virus inactivation (Katzenelson, 1979). No significant reduction in HIV titers was measured in oxygen-treated or untreated serum. The infectious titer of HIV is reduced 99% in serum reacted with 0.5 μg O_3 per ml of serum, and a six-log reduction is achieved by reacted ozone concentrations of 4 μg per ml of serum (Fig. 2). The logarithmic inactivation of HIV in ozone-treated media is presented as a function of reacted ozone concentration. No detectable infectious units remained at total reacted ozone concentrations of greater than 4.0 μg/ml.

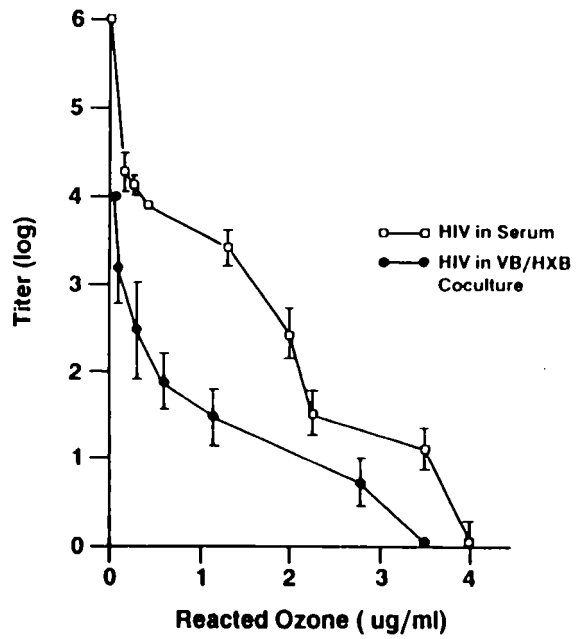

Fig. 2. HIV inactivation in ozone-treated serum and media. Titer of HIV in ozone treated human serum, and infectious HIV titer in VB/HXB cocultures grown in ozone-treated media as a function of the quantity of reacted ozone. Zero reacted ozone concentration is oxygenated and untreated controls. (Error bars represent 99% confidence interval, $n = 3$ replicate experiments.)

HIV infectious yield

In order to determine if HIV is inactivated by ozone-treated media in the presence of cells as well as in purified suspensions in serum, mixed cultures were prepared containing the $CD4^+$ cell line VB and permissively HIV/III_B infected cell line HXB/H9. Mixed cultures of HXB/H9 and VB cells resulted in multiple syncytia, a high degree of cytopathology and rapid increase in viral replication and release (Lifson et al., 1986). These culture conditions were chosen as a maximum challenge to the virus inactivation capabilities of ozone. Supernatants from these cocultures grown in ozone-treated or control media were titered by syncytium formation assay after four days. Infectious titers were reduced in relation to ozone dosage to a similar degree as in purified suspensions, with a complete loss of four-log titer infectivity resulting from pretreatment of media with 3.5 μg/ml of ozone (Fig. 2).

HIV titers in oxygen-treated media were not significantly different from those in untreated media.

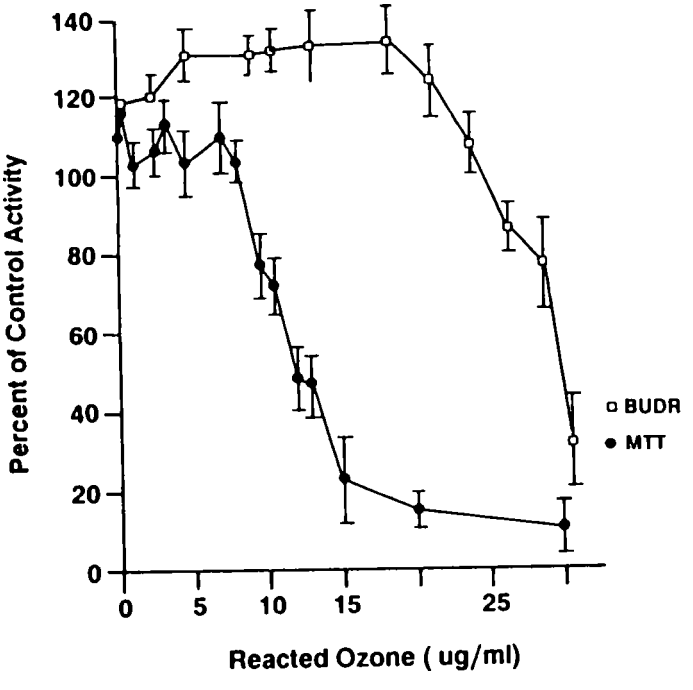

Fig. 3. H-9 cell cytotoxicity in ozone-treated media. Percent of control MTT dye conversion, and percent of control BUdR incorporation as a function of reacted ozone concentration in human serum supplemented media. Zero reacted ozone concentration is oxygenated and untreated controls. (Error bars represent 99% confidence interval of $n = 4$ replicate experiments.)

Ozone cytotoxicity

The ability of RPMI-1640 medium supplemented with 20% human serum to support the growth of H-9 cells and PBM cells when treated with various quantities of ozone was tested in the third set of experiments. In all cytotoxicity tests, ozonized media was replaced daily to assure that the maximum cytotoxicity for a given concentration of ozonized media was insured. The viability of the cells was assessed by the cellular cleavage of MTT dye, an objective method of determining cell viability. BUdR incorporation in H-9 cells was measured in response to ozone-treated media as a non-radioisotopic alternative to the [^{3}H]thymidine incorporation assay for DNA replication (Porstmann et al., 1985). Neither MTT dye conversion or BUdR incorporation were effected by oxygenation of culture media when compared to untreated control cultures. The mean percent of cell survival and BUdR incorporation, relative to controls, is shown for H-9 cells at each ozone concentration tested (Fig. 3). No significant difference was found in the measured MTT dye conversion by H9 cells and PBM cells in response to ozone-treated media (data not shown). MTT vital dye conversion is significantly enhanced in ozone-treated media relative to controls at ozone concentrations that completely inactivate purified HIV suspensions (1–8 μg/ml, $P < 0.01$). BUdR incorporation was enhanced in ozone-treated media over a range of 1–21 μg/ml. Significant reduction of H9 or PBM cell viability is observed at reacted ozone concentrations above 9.5 μg/ml of media, while significant inhibition of DNA replication in H-9 cells is observed at reacted ozone concentrations above 25 μg/ml of media ($P < 0.01$).

HIV replication

The intracellular antiviral properties of ozone-treated medium were investigated by cultivation of permissively infected HXB/H-9 cells for a period of six days with daily replacement of 25% of the treated or control media. Samples of media removed on alternate days were assayed for p24 viral core protein by antigen-capture ELISA. A statistically significant reduction ($P < 0.01$) in p24 antigen expression was measured in supernatants from all treated cultures in proportion to reacted ozone concentration (Fig. 4). Viral core protein antigen levels were not changed in cultures treated by oxygen alone. Cell viability, tested by trypan blue exclusion, was $\pm 10\%$ of control cell viability in all cultures except the maximum treatment dosage (10.2 $\mu g/ml^{-1}$), which showed 87% of control viability. Solutions containing known concentrations of p24 antigen, diluted in ozone-treated media, were measured in this assay system and yielded expected values, excluding the possibility that the p24 antigen was degraded in treated media.

Discussion

In vitro inactivation of HIV has been demonstrated for a variety of agents, including sodium hypochlorite, ethanol, paraformaldehyde, glutaraldehyde, isopropanol, hydrogen peroxide, phenol and nonoxynol-9 (Martin et al., 1985; Spire et al., 1984; Hicks et al., 1985). The addition of ozone to this list is consistent with the oxidative and/or surfactant properties of these agents. Normal human serum did not inactivate HIV in these experiments, in agreement with previously reported results (Banapour et al., 1986), and treatment of serum or culture media with oxygen produced no significant effect on HIV inactivation or cell viability.

In all experiments reported here, treatment of serum or culture media with ozone was completed before the addition of virus or cells. Ozone is a highly reactive oxidizing agent, and these results support the hypothesis that HIV inactivation is effected by secondary reaction products of ozone in serum and media containing 20% serum. The ozonide reaction products of fatty acids have been shown to mimic the direct cellular effects of ozone at concentrations of 10^{-5} to 10^{-4} molar (Rietjens et al., 1987; Cortesi and Privett, 1972). Thin films of virus suspensions in media have been successfully inactivated by less than one ppm of gaseous ozone in roller bottle cultures (Bolton et al., 1982a; 1982b), but it is unclear if direct exposure of virus to gaseous ozone occurred under these conditions. Emerson et al. (1982) found that significantly higher

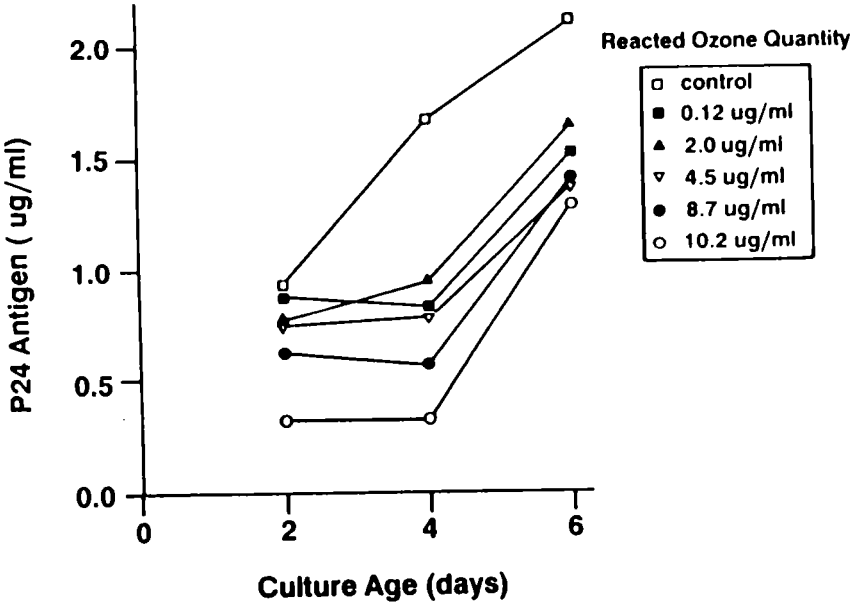

Fig. 4. P24 antigen expression in ozone-treated media. P24 antigen concentration in HXB/H-9 culture supernatants for five ozone treatment quantities and oxygen treated controls. (Values are the mean of duplicate measurements of three cultures for each data point, with a coefficient of variation of $\leq 26\%$.)

dissolved ozone concentrations were required in aqueous systems to inactivate cell-associated poliovirus and coxsackievirus A9 compared to purified virus suspensions. This does not appear to be true for HIV in the HXB-VB cocultures we tested, perhaps due to the high degree of cytolysis in these cultures which allowed greater direct exposure of virus to ozone and/or ozonides.

Ozone had a hormetic effect, i.e., a stimulating effect at low concentrations, on H9 and PBM cells in these experiments comparable to that reported by other agents (Wolff, 1989). The growth of normal PBM cells and H9 lymphoma cells was equally susceptible to inhibition by ozone-treated media as defined by the MTT dye conversion assay. In contrast, Sweet et al. (1980) found that lung, breast, and uterine tumor cells were more susceptible to growth inhibition than lung diploid fibroblasts when exposed to 0.3–0.8 ppm of gaseous ozone. DNA synthesis was unimpaired in H9 cells when grown in less than 25 μg/ml of ozone-treated media in our experiments. This is consistent with the findings of Bolton et al., that labeled thymidine incorporation was not decreased in Madin-Darby bovine kidney cells when exposed to 0.64 ppm of gaseous ozone in roller bottle cultures.

The p24 antigen assay has been demonstrated to be 100-fold more sensitive than reverse transcriptase assays in detecting HIV (Feorin et al., 1987). The p24 antigen in the media supernatant of persistently HIV-infected H9 cell cultures was reduced an average of 46% when grown in ozone-treated medium (range 6–81%). Azidothymidine has been reported to reduce p24 levels in culture supernatants of PBM cells 50% to 95% at drug concentrations of 0.02–0.08 μM (Hartshorn et al., 1987). These ozone-mediated reductions in p24 antigen expression of HXB/H-9 cultures, as well as the reduction of infectious virus titer of mixed VB/HXB cultures described above, were accomplished at ozone concentrations shown here to be nontoxic in uninfected cells. Current models of HIV pathogenesis hypothesize dissemination by both free virus and direct cell–cell transmission (Levy, 1988). An agent or combination of agents which act at multiple sites of viral replication has obvious advantages.

We have demonstrated here an agent which, in vitro, acts to both inactivate cell-free HIV and suppress intracellular replication without apparent cytotoxicity. These results indicate a potential HIV inactivation treatment for blood and blood products. Future research will attempt to elucidate the molecular mechanisms of this phenomenon.

Acknowledgements

This study was partially funded by a grant from the Griffin Foundation to Bay Medical Research Foundation, Center for Medical Ozone Studies. Grateful appreciation is extended to David Griffin and Joseph Giannone. The authors also wish to thank Dr. Michael McGrath, Dr. Lynn Pulliam, Dr. Raxit Jariwalla, and Dr. Steven Harakeh for their helpful suggestions and contributions to this research.

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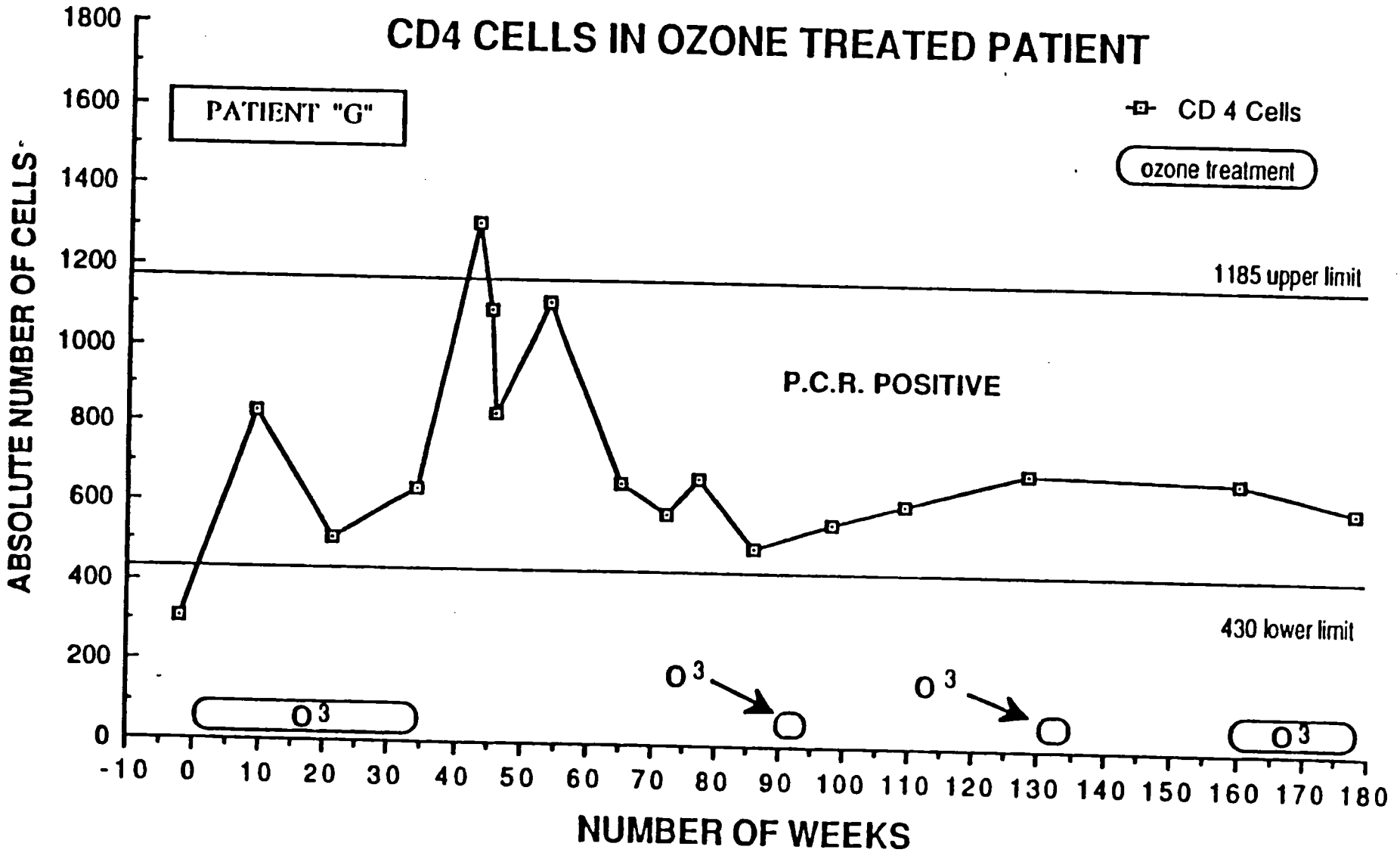
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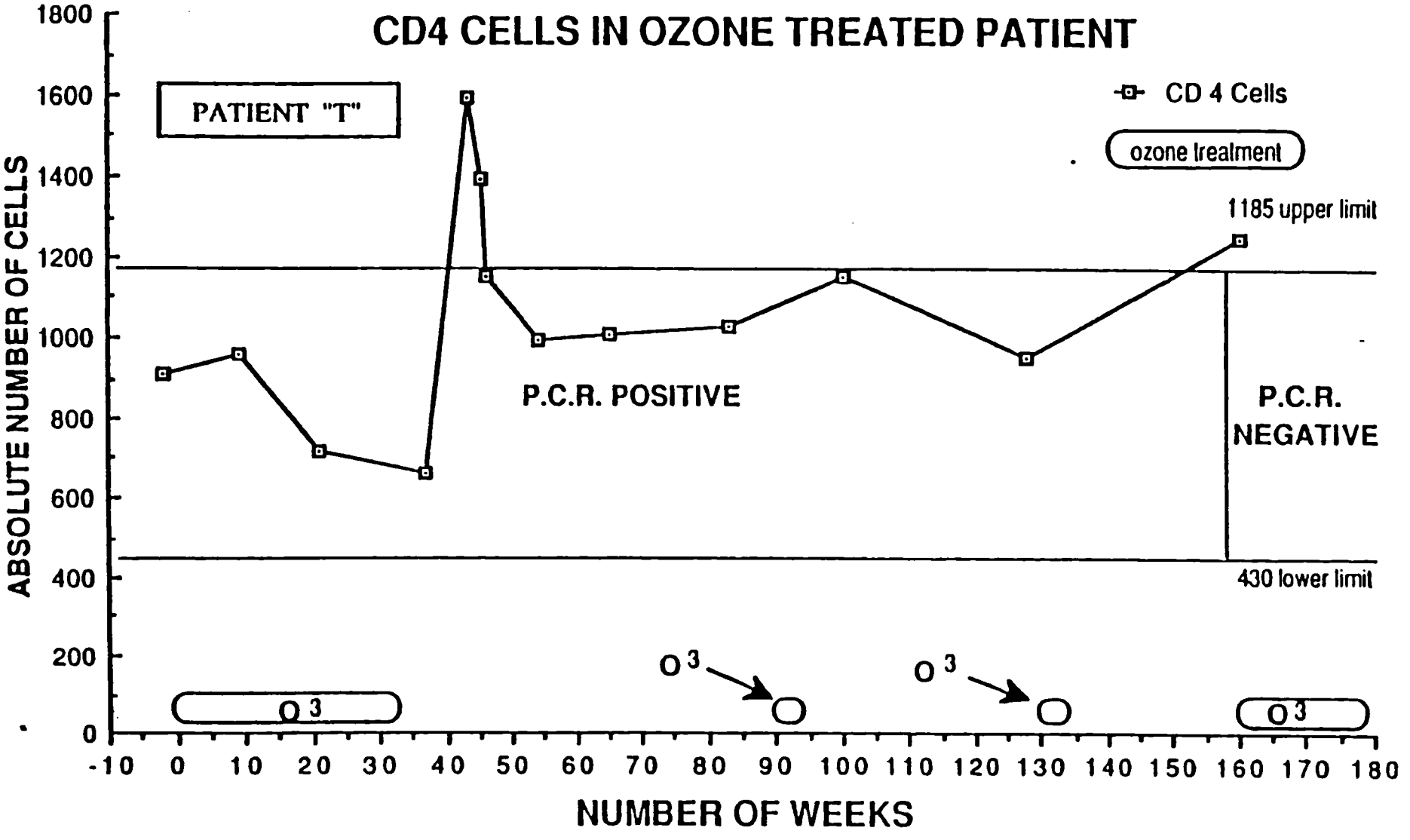
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September 20, 2000

Ms. Cloudine Marcelino
4166 N. 81st Street
Scottsdale, AZ, 85251

Ms. Marcelino:

Thank you for your letter. Your resume looks impressive and I appreciate your interest in the International Fellows Program. Unfortunately, there are certain guidelines that do not allow us to by pass or pardon the routine immigration processes or to seek assistance from the non- citizens. I view of your strong commitment to the cause, I strongly suggest that you apply to other programs that do not require one to be a United States citizen.

I wish you all the best with your efforts to work for the African American children to improve their lives and end their sufferings.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

T.M. Quigg, MD
186 Erie Street, #204
Collingwood, Ont.
Canada L9Y 4T3

Dear Dr. Quigg:

Thank you for your recent letter that discusses your idea for a "super station" designed to help slow the spread of HIV/AIDS in sub-Saharan Africa

The Clinton Administration is very proud of the attention we have helped developed a global perspective on the devastating impact that the AIDS is having. As noted in your letter, particularly hard hit has been sub-Saharan Africa. We have tried to stress the fact that addressing HIV/AIDS is moral responsibility, and that all nations, including the United States, can and should do more.

Your idea of a radio program to focus on AIDS is intriguing. I am glad you have shared your thoughts with the Elton John AIDS Foundation. You may also want to share it with the U.S. Agency for International Development and the United Nations' Global AIDS Programme.

Thank you for being concerned about this disease, and for thinking of new and innovative ways to address it.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation
Director, Office of National AIDS Policy

Reps/murguia/letter/quigg

T.M. Quigg, MD
186 Erie Street, #204
Collingwood, Ont.
Canada L9Y 4T3

Dear Dr. Quigg:

Thank you for your recent letter that discusses your idea for a "super station" designed to help slow the spread of HIV/AIDS in sub-Saharan Africa. I appreciate your sharing this idea with me, and the fact that you have already approached the Elton John Foundation.

The Clinton Administration is very proud of the attention we have helped focus on the devastating impact that the AIDS is having from a global perspective. Particularly hard hit has been sub-Saharan Africa. We have tried to stress the fact that addressing HIV/AIDS is a global responsibility, and that all individuals have a moral responsibility to become involved in the fight against HIV/AIDS.

Your idea of a radio program to focus on AIDS is intriguing. I am glad you have shared your thoughts with the Elton John AIDS Foundation. You may also want to share it with the U.S. Agency for International Development and the United Nations Global AIDS Programme.

Thank you for being concerned about this disease, and for thinking about new and innovative ways to address it.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation
Director, Office of National AIDS Policy

Reps/murguia/letter/quigg

Leah did a draft letter for this that I thought looked good. But I don't have a copy...

Sorry it took so long!

ProjectChange International, Inc.

Promoting Good Health Through Education and Prevention
(A 501(c)(3) Non-Profit Corporation)

August 14, 2000

Sandra L. Thurman
Director, Office of National AIDS Policy
736 Jackson Place, NW
Washington, DC 20503

Dear Ms Thurman,

I hope all is well with you! I have three specific purposes for writing. First, to formally introduce to you our organization, ProjectChange International, Inc (PCI), a nonprofit organization with a mission to improve the health status of the African public, through preventive strategies and capacity building. As you may know communicable and chronic diseases are a major burden that affect the health of many in the developing parts of the world, including Africa. One example is the HIV/AIDS epidemic, a disease with no borders, the realities of which were brought home over the last few weeks as the eyes of the world turned to the XIII International AIDS conference in Durban, South Africa. Our initial goal is to contribute to the international effort to stop the spread of this disease.

My second goal is to formally request your participation on the Advisory Board of PCI. During a discussion with Dr. Elaine Daniels, a Board member, in Wilmington, DE, last week she strongly recommended you as someone who would identify with the goals of PCI, and can help advance them. It will be my pleasure to discuss with you our excitement about and the rationale behind the mission of PCI. I am confident you will find the attached prospectus useful as a reference material regarding the vision, goals and objectives of PCI. We believe that collaboration with specific stakeholders like you is essential to our success. Our primary strategy is to mobilize resources (money, materials, equipment, human resources, etc.) here for our programs in Africa.

PCI is poised for significant growth in the next year, under the stewardship of a competent management team, and dedicated Board of Trustees and Advisory Board. We would like to count you as a partner and supporter of PCI as we implement the various initiatives outlined in the attached prospectus.

P. O. Box 7404 • 2513 Berwyn Road • Wilmington, DE 19810 • USA •
Phone: (302) 478-7273 • Fax: (302) 479-3810 •
info@projectchange.net • www.projectchange.net •

Finally, we are planning the formal launch of PCI, November 17, 2000, in Philadelphia. The event will be our first annual fund-raiser, one of our various strategies to mobilize financial resources to fund our three-part HIV/AIDS program in Africa. This will be a Black-tie event, and promises to be both entertaining and informative. The program consists of a full-day educational symposium, and a dinner fund-raiser to be held that same evening. The proposed feature speaker for the evening is Nobelist Arch Bishop Desmond Tutu. Other participants will include well-known and active local, national and international leaders in business, government, religion, and journalism. I would like to invite you to speak at this event, because I believe that your participation will serve to heighten the impact and significance of our efforts.

Most of the funds raised will be utilized to implement our film project in Nigeria. We have obtained a written commitment from a video production company in Nigeria to develop an HIV/AIDS film to be used as an informational tool throughout the country. The film will utilize local actors/actresses, materials and story line to make it relevant to the Nigerian environment and experience, and will be shown on long-distance buses, schools and other appropriate locations, with an estimated direct reach of over 5 million people annually.

I would also like to invite you to visit our web site, www.projectchange.net, for additional information about PCI.

I look forward with great interest to counting you as a partner in our efforts to improve the general health status of the African public. If you have any questions please contact at (302) 695-4924 (office) or (302) 383-5582 (mobile).

Best personal regards.

Sincerely,

Kelechi Lawrence, Ph.D., MBA
Chairman & CEO

Enclosure.

Kelechi Lawrence, Ph.D., MBA
Chairman & CEO

ProjectChange International, Inc.
Promoting Good Health Through Education and Prevention
(A 501(c)(3) Non-Profit Corporation)

P. O. Box 7404 . 2513 Berwyn Road . Wilmington, DE . USA .
Phone: (302) 478-7273 . Fax: (302) 479-3810 .
kelechi@projectchange.net . www.projectchange.net .

ProjectChange International, Inc.

Promoting Good Health Through Education and Prevention
(A 501(c)(3) Non-Profit Corporation)

Mission

ProjectChange International, Inc (PCI) will be a leader in providing information and support systems that empower Africans to proactively take actions that will curtail their susceptibility to preventable diseases, improve their health and the quality of their lives. A critical element of this vision is the conviction that individuals can, given the proper information and appropriate support, protect themselves from preventable diseases. PCI will also engage in capacity building to address the need for comprehensive health care infrastructures in many African countries.

Goals

We will vigorously pursue our mission by:

- Building an organizational structure adequate to effectively pursue mission
- Mobilizing human, financial and material resources for non-governmental organizations (NGOs) in Africa working to improve the health of the African public
- Collaborating with all stakeholders
- Contributing to the development and maintenance of health care delivery systems
- Engaging in and supporting programs that are consistent with our mission
- Continuing to build a global network of active supporters

Objectives

PCI has targeted Nigeria for the initial implementation of its programs. In March 2000, two members of the Board of Trustees (the Chairman & CEO, Dr. Kelechi Lawrence and Dr. Oluseyi Senu-Oke) visited Nigeria to evaluate government and civil society attitudes about various communicable diseases, including HIV/AIDS. Based on personal observations and feedback from several stakeholders the following objectives were developed:

Information, education and communication – Awareness creation and enhancement are essential to the attainment of a positive public attitude toward disease prevention and treatment. We plan to intensively drive the development of more favorable attitudes through the following specific projects;

- ✓ Implement voluntary counseling and community support centers
- ✓ Promote training of an "army" of local volunteers to serve as peer educators and care givers
- ✓ Sponsor development of culturally sensitive disease-themed films to be shown on long-distance buses, schools, churches and other appropriate locations
- ✓ Periodically convene and support conferences, workshops and seminars as a means to facilitate exchange of information, best practices and networking
- ✓ Encourage community outreach activities

Improved advocacy – We will continue to expand our global network of contacts to include policy makers, journalists and advocacy organizations.

Capacity building – We will address the need for robust infrastructures for health care delivery to the African public by establishing and independently operating fully functional and well equipped diagnostic laboratories in African countries that will;

- Perform monitoring and screening functions for free or at substantially subsidized fees
- Collect pertinent disease data for improved policy and clinical decisions, and tracking of general disease trends
- Provide service to the academic research community with an opportunity to begin to develop and/or strengthen the clinical and basic research infrastructure to attract more international collaborations
- Contribute to the evolution of stronger health care delivery systems in each country

Organizational Structure

PCI is a 501(c)(3) non-profit organization incorporated in the State of Delaware. PCI has a three-tier organizational structure consisting of:

- ★ The Executive Committee which is responsible for routine operations and strategy implementation
- ★ The Board of Trustees with responsibilities for overall governance, policy development and program approval
- ★ The Advisory Board which facilitates strategy development and provides overall advisory support

Accomplishments (selected)

The following specific accomplishments were recorded during the visit to Nigeria, March 2000:

- ❑ Achieved a first-hand assessment of the Nigerian environment
- ❑ Donated hundreds of HIV/AIDS literature and thousands of condoms to the partner NGO, ProjectSheild Inc. in Lagos, Nigeria
- ❑ Established contacts with the National Coordinator of the National Action committee on HIV/AIDS, Professor Ibironke Akinsete
- ❑ Visited the laboratories of Dr. A. S. Akanmu of Lagos University Teaching Hospital and Professor Charles Wambebe, CEO, National Institute of Pharmaceutical Research & Development, and discussed their active research programs on HIV treatment modalities
- ❑ Learned useful insights about the success factors of the Ugandan HIV program from the Ugandan Ambassador to Nigeria, Amb. J. B. Onen

Performance Assurance

PCI will continue to consistently deliver on its goals because it is run by a competent and energetic management team that is familiar with its operating environments, and enthusiastic about making a difference in Africa. Also, PCI is backed by an experienced, hands-on and active Board of Trustees and Advisory Board, and supported by a growing global network of contacts in government, business, international agencies and civil society. PCI will be expeditious in approach and efficient in resource distribution and utilization.

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. letter	re: Tax status for ProjectChange International [Personally Identifiable Information] (1 page)	07/27/2000	b(6)

COLLECTION:
Clinton Presidential Records
National AIDS Policy Office
Sandra Thurman
OA/Box Number: 40014

FOLDER TITLE:
Random Letters [Folder 1] [2]

2018-0764-F
jm2020

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

The University of Texas Medical Branch at Galveston

School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals and Clinics

Department of Microbiology and Immunology

Samuel Baron, M.D.
Professor

September 21, 2000

Dr. Sandra L. Thurman
Director, Office of National AIDS Policy
Presidential Envoy for AIDS Cooperation
White House
Washington, D.C. 20500

Dear Dr. Thurman:

With 6.4 million HIV transmissions each year and the failure of nonoxynol-9 in clinical trials, plus the aversion many young people and others have to using condoms, there is an urgent need both here in the United States and worldwide for practical methods to curtail the HIV epidemic. Our recent findings (enclosed) indicate that certain commercial over-the-counter (OTC) lubricants and vaginal preparations—substances that are widely used and are in the safest USFDA category -- are highly active against HIV under simulated *in vivo* conditions.

These OTC preparations should be considered for clinical trials for the following reasons:

1. They are highly effective against HIV in laboratory studies.
2. Unlike the irritating, nonoxynol-9, they do not attract CD4+ cells.
3. They are widely and immediately available off the shelf.
4. They are inexpensive.
5. Both women and men may use them.
6. Their widespread use to date has not prompted reports of serious side effects.

As you can see from the enclosed articles, we have derived the strategy for using these OTC preparations to protect the vulnerable vagina and rectum from our observations regarding the naturally potent salivary defense, which makes oral transmission rare. Should clinical trials confirm our laboratory experience, by urging wider use of these substances, we may have an immediate and practical opportunity to curtail the uncontrolled epidemic of HIV. We urge you to consider supporting collaborative clinical

ROOM 4.142D MEDICAL RESEARCH BUILDING 301 UNIVERSITY BOULEVARD GALVESTON, TEXAS 77555-1019
(409) 772-2325 FAX (409) 772-5065 E-MAIL: sabaron@utmb.edu

trials with us and with the comparatively small pharmaceutical producers of these preparations. Considering the relatively modest cost and the potentially enormous benefit, this appears to be a rare (if not unique) opportunity, one we should not miss.

Best regards,

Samuel Baron, M.D.
Professor

THE WHITE HOUSE

WASHINGTON

SW Harahap
PO Box 1244/JAT
Jakarta 13012
Indonesia

September 20, 2000

Dear Mr. Harahap:

Thank you for your letter. We appreciate your interest in the HIV and AIDS publications but the Office of National AIDS Policy does not offer such materials. However, I am sending you a copy of the National AIDS Strategy by the White House.

I suggest that you either contact the World Health Organization or the Centers for Disease Control and Prevention directly and enroll with their free publications mailing list. Their contact are as follows:

The World Health Organization
Regional Office for South-East Asia (SEARO)
World Health House
Indraprastha Estate
Mahatma Gandhi Road
New Delhi 110002
India
Website: www.who.org

Centers for Disease
Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30333
U.S.A
Website: www.cdc.gov

I hope that the information I have provided will be of some help and I wish you the best of luck in your efforts.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

Herman M.K. Mukela
Communication Secretary
St. Anthony BWAFWANO OVC H.B.C.
Home Based Care
P.O. Box 23290
Kitwe, Zambia

Dear Mr. Mukela,

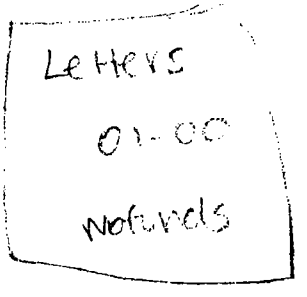
Thank you for your letter of December 17, 1999, which highlighted the developing AIDS/HIV problem in Zambia, specifically referencing the terrible circumstances children must face as a result. I am so thankful that I was able to meet with you and your colleagues at St. Anthony's, and view first hand the devastation your country is facing, during my visit last Spring. I am especially aware of the dire impact that this epidemic is having on the lives of children in Zambia, and throughout the world.

Unfortunately, the Office of National AIDS Policy is unable to allocate funding for specific projects or programs. We do however applaud your efforts to improve the lives of the children who have been hurt as a result of the epidemic, and wish you much success in your endeavor to construct a children's park.

Thank you again for you letter.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy



Christopher Stallard
2874 Payton Road NE
Atlanta, GA 30345

September 15th, 2000

Sandra Thurman
736 Jackson Place
Washington D.C. 20503

Sandra,

Our paths crossed in Bob Dalton's office on June 26th. If you recall, Bob introduced us as you were preparing to leave and my name is Christopher. You piqued my interest that day when I heard you express a desire/intent in creating an international non profit organization.

Allow me to be straightforward from the outset and put the bottom line up front. I too am interested in a greater service to humanity and would like to learn more of your concept.

A little background ... it's been a very busy summer for me here in Atlanta. September marks my third year with CDC. In that time, I have been a key architect in the design and development of the CDC Corporate University, a model for the individual and organizational development of the Public Health workforce. In addition to my programmatic responsibilities administering the School of Public Health Education and Communication, I participate on several workgroups to advance the integration of our programs with other agency initiatives, while building coalitions along the way.

For the 14 years preceding our arrival in Atlanta, my wife Gail and I lived and worked in Europe. To summarize that professional chapter; I held a variety of challenging and complex international human resource management positions. The value I offer is a varied and versatile skill set in strategic organizational development, partnership and coalition development, and international human resource program development. I am an accomplished consensus builder, working individually and in group settings with diverse populations at all levels.

I'm not particularly fond of self promotion in this manner, as these written words of accomplishment do little to convey the nature of my being; caring, concerned and compassionate. These are the virtues that compliment and guide my professional skills.

My wife Gail is my best friend and companion. It seems appropriate to share some of her background with you as well. Gail is the most seasoned, intrepid civilian broadcast journalist working for the United States Army. A "one woman band", she travels the world telling the Army story. This has brought her to virtually every continent and crisis the Army is involved in over the past 15 years, from the raging forest fires in Idaho, to refugee water crisis in Goma, Zaire, and the devastation of hurricane Mitch in Central America. Gail is an award winning talent incredibly gifted at her storytelling craft. In my view, a non profit with a broadcast communication program, is well positioned to capture and convey the personal stories of heroes engaged in the struggle for life, so that others may learn, appreciate and contribute.

In reading your bio and speeches, I have a sense too about your passionate commitment. Sandra, I am very interested to learn more of your international non-profit concept and how I may be of value to your efforts. Both Gail and I are fortunate to have deeply rewarding and gratifying work in the public sector for the past 15 years. But with only one life to live, and a whole world to serve, a transition may well be in order.

I would be more than delighted to hear back from you. If time permits in your busy schedule, perhaps we could meet the next time you are in Atlanta. I may be contacted at work 770-488-1778 or home 404-325-1775.

Regards,

Christopher

Christopher Stallard

THE WHITE HOUSE

WASHINGTON

October 31, 2000

Bernard A. Kirshbaum, M.D.
125 Clwyd Road
Bala Cynwyd, PA 19004-2302

Dear Dr. Kirshbaum:

Thank you for your recent letter summarizing several journal articles focusing on ozone therapy as a treatment for HIV infection.

As you know, all drugs seeking approval for treatment of HIV must go through a rigorous clinical trial process. Only after a drug has made it through the clinical trial process and been shown to be safe and effective will the Food and Drug Administration approve it for use in the United States. While this may seem to be a long and complicated process, it is in place to ensure the safety and efficacy of all drugs approved for use in the United States, not only for treatment related to HIV, but for all diseases and conditions. This requirement has resulted in the United States producing the most safe and effective medicines in the world.

I will be pleased to provide a copy of your letter to the FDA for their consideration.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation
Director, Office of National AIDS Policy

Reps/murguia/letter/kirshbaum

THE WHITE HOUSE

WASHINGTON

October 31, 2000

Salang Bunnag
Police General
Chairman, Salang Bunnag Foundation
919 Cheangwalana 15
Tungsonghong
Lukai, Bangkok, Thailand 10210

Dear General Bunnag:

President Clinton asked me to respond to your recent letter regarding the development of an AIDS-therapy drug called V-1.

All drugs seeking approval for treatment of HIV in this country must go through a rigorous clinical trial process. Only after a drug has made it through the clinical trial process and been shown to be safe and effective will the Food and Drug Administration approve it for use in the United States. While this may seem to be a long and complicated process, it is in place to ensure the safety and efficacy of all drugs approved for use in the United States, not only for treatment related to HIV, but for all diseases and conditions. This requirement has resulted in the United States producing the most safe and effective medicines in the world.

I will be pleased to provide a copy of your letter to the FDA for their consideration.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation, &
Director, Office of National AIDS Policy

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
Marnie Schlesinger	Sandy Thurman
COMPANY:	DATE:
	November 20, 2000
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
212-490-6006	3
PHONE NUMBER:	
RE:	

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Dear Marnie:

Attached please find the letter of invitation and tentative agenda for the World AIDS Day event at the White House. I understand from our public liaison office that Mr. Wiesel is scheduled to be traveling on December 1st. However, his participation in this event would greatly enrich the program.

We realize that this is very short notice but your consideration of our request would be most appreciated.

If you have any questions or need additional information, please let us know. We can be reached at 202-456-2441.

Sandy

736 Jackson Place
Washington, DC 20503
(202) 456-2437
(202) 456-2438 (fax)

THE WHITE HOUSE

WASHINGTON

November 20, 2000

Elie Wiesel
The Elie Wiesel Foundation for Humanity
380 Madison Avenue, 20th Floor
New York, New York 10017

Dear Mr. Wiesel:

It is once again that time of year when we prepare to come together on December 1, World AIDS Day, as a global community united in the spirit of healing and the promise of triumph in our shared struggle against AIDS. This first World AIDS Day of the new millennium is particularly poignant, marking both a time for reflection on how far we have come together and for recommitting ourselves in hope and faith for the journey that still lies ahead.

This year, I would like to invite you to join us here at the White House on November 30th and December 1st for a special gathering that will highlight the role of communities of faith in our fight against AIDS. Specifically, we would greatly appreciate it if you would be willing to join President Clinton, Archbishop Ndungane and Thich Nhat Hanh in offering remarks during our morning event on December 1st. Your participation will greatly enrich our discussions as we explore ways to bridge the gap between policy, faith, and action.

This summit is being supported by the US Agency for International Development (USAID) and the Centers for Disease Control and Prevention (CDC), who intend to produce and widely disseminate materials that reflect the results of our work and broaden the call to people and communities of faith to respond energetically and compassionately to the AIDS crisis.

A draft agenda of this important gathering is attached, and we will be in touch with you soon regarding your availability. Should you have any questions about the Summit, please feel free to contact Cheryl Bauerle in my office at (202) 456-2959.

I do hope that your schedule will permit you to join with me on this very special occasion.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation, &
Director, Office of National AIDS Policy

DRAFT

A CALL TO CONSCIENCE:
THE ROLE OF FAITH IN RESPONSE TO AIDS

White House World AIDS Day Summit 2000
November 30 - December 1, 2000

THURSDAY, NOVEMBER 30TH

12:00PM **Opening Luncheon** (Mayflower Hotel)
Convening Prayer
Welcoming Remarks – Sandra L. Thurman
Epidemic Africa – a film by Rory Kennedy Film
Personal Story – African Woman Caregiver
Opening Plenary Address – Stephen Carter
Present role of facilitator and rapporteur; outcome expected from groups
Adjourn to Small Groups

14:00PM **Small Group Discussions** (plan for max of 15 persons/group)
Personal introductions
Present provoking questions; group discussion
Adjourn

18:00PM **Interfaith Service of Healing, Hope and Remembrance**
(St. John's Lafayette Square)
Greetings: Secretary of State Albright
Preacher: Andrew Young (tentative)

20:00PM **Buffet Dinner Reception - tent.** (Blair House)

FRIDAY, DECEMBER 1ST - WORLD AIDS DAY

9:00AM **Panel Presentation with POTUS - tent.** (location to be determined)
Introductory Remarks by Sandy Thurman
Personal story from John Ibekwe, President of the Nigerian Network of People Living with AIDS
Remarks by Archbishop Ndungane, Episcopal Archbishop of South Africa
Remarks by Thich Nhat Hanh, Buddhist Theologian

12:00PM **Closing Luncheon** (Mayflower Hotel)
Remarks & Acknowledgments – Sandra L. Thurman
Closing Theological Reflection – Margaret Farley
Closing Address – William Foege (tentative)
Sending Forth Prayer
Adjourn

November 1, 2000

Salang Bunnag
Police General
Chairman, Salang Bunnag Foundation
919 Cheangwalana 15
Tungsonghong
Lukai, Bangkok, Thailand 10210

Dear General Bunnag:

President Clinton asked me to respond to your recent letter regarding the development of an AIDS-related drug called V-1.

All drugs seeking approval for treatment of HIV must go through a rigorous clinical trial process. Only after a drug has made it through the clinical trial process and been shown to be safe and effective will the Food and Drug Administration approve it for use in the United States. While this may seem to be a long and complicated process, it is in place to ensure the safety and efficacy of all drugs approved for use in the United States, not only for treatment related to HIV, but for all diseases and conditions. This requirement has resulted in the United States producing the most safe and effective medicines in the world.

While the Office of National AIDS Policy is not able to directly support research or participate in the development and approval process, we would like to forward your letter to the Office of AIDS Research at the National Institutes of Health.

Thank you for taking the time to provide us with this information.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation
Director, Office of National AIDS Policy

Reps/murguia/letter/bunnag

Date

Salang Bunnag
Police General
Chairman, Salang Bunnag Foundation
919 Cheangwalana 15
Tungsonghong
Lukai, Bangkok, Thailand 10210

Dear General Bunnag:

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I will be pleased to provide a copy of your letter to the FDA for their consideration.

Sincerely,

Sandra L. Thurman
Presidential Envoy for AIDS Cooperation
Director, Office of National AIDS Policy

Reps/murguia/letter/bunnag

THE WHITE HOUSE

WASHINGTON

10/12/00
DATE

MEMORANDUM

FOR: ONAP

FROM: HELEN S. CASTLEMAN
DIRECTOR, OFFICE OF AGENCY LIAISON

SUBJECT: REFERRAL OF CASEWORK IN BULK

An unprecedented number of individuals still write the President and the First Lady for help. I know that this has meant a far greater volume of mail for your agency than ever before. I appreciate your continuing cooperation in our efforts to be as responsive as possible.

The attached letters have not received a White House Staff response. I am forwarding this correspondence to your agency for any appropriate action.

Please return the original incoming letter, along with a copy of any written or telephone response, to me at the address below. I also would appreciate your sending a copy of your agency's log of the names and addresses of these individuals. Any misreferrals should be returned to my office. If you have questions you can reach me at 202/456-7486.

Mrs. Helen S. Castleman
Director, Office of Agency Liaison
Room 6, OEOB
The White House
Washington, D.C. 20502

Again, thank you for your continuing help.

The Honorable William J. Clinton
President of the United States
The White House
1600 Pennsylvania Ave. NW
Washington DC

Dear Mr. President:

It has been reported in our country that you have recently signed an Executive Order to help fund and accelerate research of HIV/AIDS. Specifically, you state in Executive Order 13155;

- there is a critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis,
- an effective United States response to the crisis must also focus on the development of HIV/AIDS vaccines to prevent the spread of the disease,
- successful initiative will require effective partnerships and cooperation among governments, inter-national organizations, nongovernmental organizations, and the private sector, and greater consideration should be given to financial, legal, and other incentives that will promote improved prevention and treatment actions

It is in this spirit, that I write to you to share with you my concern about the devastation caused by HIV/AIDS. As you may know the Thai people have suffered greatly from this deadly disease. Even though our country took an aggressive approach to fight this disease early on with education and prevention techniques, and Thailand is often cited as the example in decreasing HIV transmission -- it has taken its toll on our people, as it has throughout the world.

HIV/AIDS has personally touched my life. In my last position as Deputy Chief of National Police and as a Senator of Thailand's upper parliamentary House, many of my police men and women have succumbed or fallen ill to this disease, as well as their families, which are either infected or affected. My foundation, the Salang Bunnag Foundation, has provided for treatment and care for our police force. However, the current treatments have not proven themselves effective. Through my foundation, I continued to search for an effective treatment. It was through my efforts that I came to hear of and finally meet Dr. Vichai Jirathitikal, the inventor of V-1.

The Police General Salang Bunnag Foundation
919 Cheangwalana 15, Tungsonghong, Lukai, Bangkok 10210, Thailand
Tel: (662) 573-1444, 573-4717, 573-9393; Fax: (662) 573-4649
E-mail: info@thaisalang.com; http://www.thaisalang.com

I brought one of my sickest policeman to Dr. Vichai to seek treatment with V-1 (see attached documents). I was amazed at the progress he made in a short time, so much so that I have asked to broaden the scope of the treatment that is being offered. At present ten police officiers are being treated by the V-1 protocol at the Border Police Hospital, the Sawang Nursing Home (under Thai Red Cross), the Ta Reua Hospital and the Royal Thai Police Hospital. Their physical appearance and well being continues to improve. Test results have shown increase in CD4 and CD8, and some patients have already shown a significant drop in viral load.

I feel so strongly about the progress that I have personally experienced and seen that I have made the decision to lend my full support and weight to bringing world attention to V-1 and its beneficial effects on people living with HIV/AIDS. I am personally asking that you consider the background information on V-1.

The time for action is now. HIV/AIDS has taken a terrible and costly toll on our world and its people. In some places the toll has been so great that some countries have been brought to the precipice of destabilization. The only way to defeat this global threat is through global means. Thailand is not in a position to mount this defense alone, but can, with the help of the United States. I have asked the team of V2000, especially Dr. Clavreul, to work diligently, and with all due diligence, to complete the work on V-1 for USA FDA fast-track approval. It is my hope to present V-1 to our King on his birthday, December 5th. I hope that you will make the commitment to lend your personal support to this worthwhile project with worldwide implications, and our King and you can share in bringing this exciting news to the world. This Royal Birthday is particularly significant as it is the King's sixth cycle (seventy second year) birthday, the centennary of the late Queen Mother's birth and the fiftiethth anniversary of the Royal wedding of Their Majesties the King and Queen.

I would respectfully request that you extend all possible assistance to Dr. Geneviève Clavreul, Senior Vice-President Scientific Research and Development for the V2000 Corporation. Please feel free to contact Dr. Clavreul at 626.398.8585 or via email at gmc@v2000co.com should you have any questions or require additional information. Thank you for your time and consideration.

Sincerely,

Salang Bunnag

Salang Bunnag
Police General
Chairman, Salang Bunnag Foundation
Thailand