<table>
<thead>
<tr>
<th>DOCUMENT NO. AND TYPE</th>
<th>SUBJECT/TITLE</th>
<th>DATE</th>
<th>RESTRICTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>001. memo</td>
<td>Glenda Bean to Rasco re Early Childhood Commission/expired terms (partial) (1 page)</td>
<td>10/02/1995</td>
<td>P6/b(6)</td>
</tr>
</tbody>
</table>

**COLLECTION:**
Clinton Presidential Records  
Domestic Policy Council  
Carol Rasco (Miscellaneous)  
OA/Box Number: 7237

**FOLDER TITLE:**

**RENSTRCTION 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 and such employees [(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 WHITE HOUSE
WASHINGTON

THE PRESIDENT HAS SEEN
10-13-95

Weasi
Mr. Scott

What
about this? Can
we go to Britain.
I need this
Thursday, 23rd,
Kerry.
Formal Self-Introductions by Members of the
Presidential Advisory Council on HIV and AIDS

27 July 1995, Washington, DC

Good Morning. My name is Bruce Weniger. I am a physician engaged
in public health and epidemiologic research with the Centers for
Disease Control and Prevention, where I have worked since 1980 and have
been involved full-time since 1988 in conducting international HIV/AIDS
research and training, with a focus on the epidemic in Asia and South
America. I founded and was the first director of the HIV/AIDS
Collaboration, a joint U.S.-Thai government AIDS research center in
Thailand.

As a federal employee working on AIDS, I want to make it clear
that I am not here officially representing my agency, nor necessarily
speaking official policy. Indeed, the President has asked us
individually to contribute our advice and counsel on what's right and
what's wrong with the Government's efforts, and what it should be doing
differently, and I hope my international perspective and candid
observations from inside the AIDS bureaucracy will fulfill his mandate
to us.

I am honored to be a part of this properly diverse group, each
with our own unique experiences and insights on the many front lines of
the campaign against this epidemic. I look forward to being educated
by your own individual knowledge in the many aspects of confronting
this disease. I hope we can work together to develop for the President
a consensus of thoughtful assessments of what the major problems are,
reflecting all the constituencies represented here, and to suggest both
practical strategies and visionary paths of leadership for his
consideration.

The particular area on which I would like to focus is scientific
research. Clearly, effective treatments for all those who are now
infected that would permit a normal lifespan free of AIDS disease, and
a real cure, should always remain a fundamental research priority for
this nation. When such drugs come, God willing, they are sure to be
expensive, and for many, many countries less fortunate than our own,
may be unaffordable. Thus, if we are ever to be successful in
preventing infection among the roughly 40,000 Americans who acquire HIV
every year, and the millions who become newly-infected worldwide each
year, I believe we desperately need certain tools now critically lacking. These are: 1. a chemical product -- a microbicide -- which women (and men) could use to protect themselves from infection during sexual intercourse, without necessarily requiring the cooperation or even the knowledge of their sexual partner, who may be unwilling or unable properly to use a condom, and 2. we need a vaccine to prevent AIDS.

Unfortunately, the efforts to develop such technologies are in a crisis stage. The pharmaceutical-biotechnology industries on whom we depend to create such products are dropping out of the effort, or not even bothering to try because of a variety of formidable obstacles -- principally economic, but also legal, regulatory, and bureaucratic. To solve this impasse, a number of respected scientists and public health experts have recently suggested new targeted, goal-oriented, empirical, trial-and-error approaches, similar to what was used to develop the polio vaccine, but which, astonishingly, to this day have not yet been tried for AIDS: The idea is, basically: that government provides some seed money and scientific and fiscal oversight, and works on some legislative and regulatory problems, but otherwise gets out of the way to let a consortium of the applied research community and the private sector get the jobs done with a minimum of bureaucratic red tape and delay. Delay in developing these products means lives will needlessly be lost in the years ahead, just as surely as we all now recognize the lives that were needlessly lost from the delay a decade ago in responding to the threat to the nation's blood supply.

Presidential leadership would be essential for such an approach that requires bridging the public and private sectors and research community. I can think of no greater tribute to the memory of Jonas Salk, who spent the final years of his life struggling to develop an AIDS vaccine using the empirical approach that has been suggested, than for our President to declare a national goal for the development of these technologies by the 50th anniversary of the success of Dr. Salk's polio vaccine, which would be the year 2005. This goal would involve the Government's reaching out to the private sector and other nations to join in such a targeted effort, and the marshaling of the federal research, public health, and regulatory establishments to overcome obstacles and weaknesses to meet these national objectives.

Thank you.
HIV VACCINES - ACCELERATING
THE DEVELOPMENT OF PREVENTIVE HIV VACCINES
FOR THE WORLD

SUMMARY REPORT AND RECOMMENDATIONS
OF AN
INTERNATIONAL MEETING

MARCH 7 - 11, 1994
BELLAGIO, ITALY

Sponsored by
The Rockefeller Foundation
Preface

This report provides a brief summary of an international meeting convened by the Health Sciences Division of the Rockefeller Foundation in Bellagio, Italy, March 7 - 11, 1994. The purpose of the meeting was to investigate the state of progress towards the development of preventive HIV vaccines appropriate for use in developed and developing countries, and to explore possible routes for accelerating the development of HIV vaccines. Twenty-four individuals attended the meeting in their personal capacities, not as representatives of particular institutions. Participants came from 12 countries and had backgrounds in vaccine development, AIDS research and care, international health, international finance, pharmaceutical and non-pharmaceutical industries, and public-private collaborations. This report reflects the consensus of the meeting, but does not attempt to represent the views of each of the participants. A draft was circulated to all participants for comments, however, final responsibility for its contents rests with the writers of the report, Jane Rowley and Seth Berkley.
HIV VACCINES - ACCELERATING
THE DEVELOPMENT OF PREVENTIVE HIV VACCINES
FOR THE WORLD

SUMMARY REPORT AND RECOMMENDATIONS
OF AN
INTERNATIONAL MEETING

MARCH 7 - 11, 1994
BELLAGIO, ITALY

Sponsored by
The Rockefeller Foundation

Table of contents

Executive Summary ................................................................. 1
Introduction ............................................................................. 3

1 The need for and ideal characteristics of a preventive HIV vaccine ................................. 4
   1.1 The need for a preventive HIV vaccine .............................................. 4
   1.2 Ideal technical characteristics of a preventive HIV vaccine ...................... 5

2 Current efforts to develop HIV vaccines ............................................................................. 6
   2.1 Progress in HIV vaccine research ..................................................... 6
   2.2 Progress in HIV vaccine development .............................................. 7
   2.3 Financial resources ............................................................................ 8

3 Obstacles to developing and making HIV vaccines available ........................................... 10
   3.1 Obstacles to vaccine development .................................................... 10
   3.2 Obstacles to vaccine availability ....................................................... 12

4 Accelerating the development of HIV vaccines ................................................................. 12
   4.1 The need for a new initiative ............................................................. 12
   4.2 Characteristics of a new initiative ..................................................... 14
   4.3 Activities of a new initiative ............................................................. 15

5 Future Activities ............................................................................. 17

Table 1 ......................................................................................... 19
Table 2 ......................................................................................... 20
Table 3 ......................................................................................... 21
Annex 1 List of meeting participants ............................................................................. 25
Executive Summary

The epidemic of HIV-1 continues to spread throughout the world despite current prevention efforts. Between 1993 and 2000 the World Health Organization projects that at least 26 million people will become infected with HIV-1 – an average of 10,000 people a day over the 7-year period. While a substantial increase in the financial and human resources available for prevention activities would reduce the number of new infections, there is a growing realization that the current range of prevention activities will not be able to halt the epidemic. Other measures are urgently required. The development of safe and effective preventive HIV-1 vaccines would dramatically improve the prospects for controlling the HIV epidemic provided they be made accessible to those at greatest risk of infection.

Meeting participants acknowledged the unprecedented effort that has been made by the scientific community to understand the biology and pathogenesis of HIV since its discovery as the etiologic agent of AIDS in 1984. In addition, there has been considerable interest shown by national and international public and private sector institutions in the development of HIV vaccines. These ongoing efforts, while constrained by budgetary and human resource limitations, have lead to major advances in scientific knowledge, and there are now encouraging signs that the development of a preventive HIV vaccine may be possible. A number of obstacles, however, hinder product development, and make it unlikely that a vaccine appropriate for use throughout the world will be developed and made available in a timely fashion unless remedial actions are taken. In 1993 over US$ 1.5 billion was spent worldwide on HIV prevention and over US$ 5 billion on HIV-related health care. Yet, in the same year less than US$ 160 million was invested worldwide by the public and private sectors in HIV vaccine research and development. This was considered insufficient given the current and rising health, humanitarian, social, and economic costs of the HIV epidemic. The investment of additional resources was viewed as potentially making a significant difference, especially if targeted at the critical gaps in current development efforts.

The national research agencies of the developed countries have been playing a key role in vaccine research. Product development activities, however, have been left almost exclusively to the pharmaceutical and biotechnology companies. In the current environment the incentives for industry to invest substantially in the development of a preventive HIV vaccine are limited – there are a number of other products with more attractive investment prospects. To overcome this market failure and ensure more active industry participation, positive steps will need to be taken.

The dominance of the national research agencies of the developed countries (and the pharmaceutical and biotechnology companies) in HIV vaccine research and development has meant that current efforts are directed almost exclusively towards vaccine products catering to the needs of the developed world. This emphasis raises cause for concern about the ultimate provision of an HIV vaccine to those in greatest need - over 90% of new infections are occurring in the developing world. For example, the industry investment in product development has, in general, been targeted at those vaccine approaches that are perceived as the safest, and has been based upon the sub-types of HIV-1 found in developed countries. Approaches that have technical characteristics that may make them better suited for use in developing countries are not being pursued aggressively. The rationale is that proving efficacy of a vaccine is the priority, following which other products will be developed in a sequential fashion. Given the many scientific uncertainties remaining, participants at the Bellagio meeting concluded that the development and testing of multiple empirical approaches in a parallel fashion, rather than
sequentially, will be a faster route to the development of safe, effective, and inexpensive vaccines appropriate for widespread use. The primary focus of current efforts on the sub-types of HIV-1 found in developed countries may also delay the evaluation of candidate vaccines by restricting the sites where clinical trials can be performed.

The unique nature of the HIV epidemic and its devastating potential consequences led the participants at the Bellagio meeting to conclude that a new global initiative with the primary mandate of accelerating the development of preventive HIV vaccines appropriate for worldwide use should be established. A new global HIV vaccine initiative was viewed as the most effective method to accelerate the development of safe and effective preventive HIV vaccines in the shortest time possible. The initiative should focus on reducing the obstacles to vaccine development and filling the gaps in the current effort. By focusing on the obstacles and gaps, the initiative was seen as complementing, not competing with, existing national and international activities. Success in developing an HIV vaccine will require the involvement of both the public and private sectors. Collaborative ventures between the private and public sectors have been fruitful in a number of other sectors in galvanizing product research and development, while still respecting corporate profit motives and independence. A range of potential models and sources of funding for the new initiative was suggested. A small funding secretariat, or task force, with an international scientific steering committee was viewed as the most appropriate structure.
Introduction

The continued spread of HIV-1 presents a serious threat to public health and economic development throughout the world. The World Health Organization (WHO) estimates that 14 million people had been infected with HIV by 1993, and projects that at least another 26 million will become infected by the year 2000. The available evidence suggests that all infected individuals will ultimately suffer from AIDS, and that all individuals with AIDS will die within a few years, unless much better means are found to slow disease progression. Already HIV is a leading cause of adult and infant mortality in a number of urban centers in both developed and developing countries, and by 1990, according to World Bank estimates, HIV was the leading cause of disability-adjusted life years lost among young adult males living in developing countries.

The recognition of the potential impact of the epidemic led to the mobilization of financial and human resources to slow the spread of the virus. Information and education campaigns designed to modify practices placing individuals at risk of acquiring and transmitting infection along with the provision of condoms and the screening of blood, have played an important role in reducing the rate of spread of the virus. Despite these global efforts, currently estimated to cost over US$ 1.5 billion a year (US$ 200 million [13%] of which was spent in developing countries), the virus continues to spread - even in populations exposed to extensive prevention programs. New prevention measures are urgently required.

Key to the successful prevention of many other infectious diseases has been the development and distribution of safe, effective, and inexpensive vaccines. Vaccines have played a pivotal role in eradicating smallpox worldwide, in eliminating polio from the Americas, and in controlling measles in a number of countries. The development and distribution of a safe, effective, and inexpensive vaccine to prevent HIV infection probably represents the best hope of controlling the global HIV/AIDS pandemic.

There are many scientific challenges that will need to be overcome before a preventive HIV vaccine is developed. The development of a vaccine, however, is only the first step. Experience with drugs and vaccines for other diseases suggests that measures will need to be taken to ensure that once a vaccine is developed that it is accessible to those at risk of infection throughout the world with the least possible delay.

This report broadly summarizes the deliberations of an international meeting convened by the Rockefeller Foundation in March 1994. The meeting, held in Bellagio Italy, was attended by 24 scientists, public health specialists, industry and private sector representatives serving in their personal capacities. The document is divided into five sections: the need for and ideal characteristics of a preventive HIV vaccine; current efforts to develop HIV vaccines; obstacles to developing and making HIV vaccines available; accelerating the development of HIV vaccines; and future activities.

---

1 Throughout this document the term HIV refers to HIV-1. The focus of the meeting was on HIV-1, rather than HIV-2, as HIV-1 accounts for over 90% of all HIV infections, is spreading faster, and is more easily transmitted than HIV-2.
1 The need for and ideal characteristics of a preventive HIV vaccine

1.1 The need for a preventive HIV vaccine

The last decade has witnessed the rapid spread of HIV throughout the world. By mid-1993 the WHO estimated that worldwide over 14 million people have been infected with HIV since the beginning of the epidemic. The vast majority of these infections, over 11 million, were in the developing world, and in some urban centers in sub-Saharan Africa it is estimated that already 1 in 3 adults is infected. Serological data record a rapid rise in the prevalence of HIV in many developing countries. For example, estimates of the number of infected individuals in Thailand increased 10-fold between 1990 and 1993 - from 50,000 to 500,000.

Over the last decade financial and human resources have been mobilized to slow the spread of the virus by modifying those practices that place an individual at risk of infection. Despite these global efforts, currently estimated to cost US$ 1.5 billion, the WHO projects that between 1993 and 2000 at least another 26 million people will become infected, over 90% of them in the developing world. In other words, over the 7-year period between 1993 and 2000, an average of 10,000 people each day will be infected with HIV. Even with an immediate 10- to 15-fold increase in the amount spent each year on AIDS and STD services in the developing world (an estimated annual expenditure of between US$ 1.5 billion and US$ 2.9 billion), the WHO projects that the number of new infections by the year 2000 would be reduced by at most 50%. In other words, substantially increasing the financial and human resources available will not be sufficient to halt the spread of the epidemic.

The development of safe and effective preventive HIV vaccines appropriate for use in developed and developing countries would dramatically improve the prospects for controlling the epidemic. The development of a vaccine would also be of enormous help in reaching those populations that might not otherwise be accessible to behavioral prevention efforts. Often those at highest risk of infection are alienated from society, are of low social status, have little education, or are illiterate, making them difficult to target with behavioral prevention efforts. Furthermore, it is possible that more virulent sub-types of HIV may evolve over time - another factor highlighting the importance of developing and ensuring that preventive HIV vaccines are made available as soon as possible.

Meeting participants regarded the development of preventive HIV vaccines appropriate for worldwide use as of the utmost urgency for a variety of reasons.

- Public health: HIV is one of the most deadly human viruses known - the available data suggest that it is 100% fatal - and at present there is no cure. While the current range of prevention activities are slowing the rate of spread of the epidemic they will not be able to halt its spread even with a substantial increase in investment. In countries where the epidemic is already established, all sexually active individuals who are not monogamous, or those who have partners who are not monogamous, are at risk of infection. The demand for health care from infected individuals is placing a substantial burden on health care systems that are already over-extended. For example, in a number of urban hospitals in sub-Saharan Africa over 70% of hospital beds are occupied by HIV-positive individuals. The negative consequences of the epidemic for public health are further compounded by the impact the epidemic is having on the rate of spread of other infectious diseases, such as tuberculosis.
• **Humanitarian and social:** Much of the burden of HIV is placed upon those least able to cope with it: the poor, the marginalized, and the young. Africa, the region with the weakest economy in the world, has over 60% of the current HIV burden. In many areas individuals who are not in a position to adopt risk-reduction measures, such as young women, are placed at a high risk of infection, not because of their own activities, but rather by the activities of their partner. Premature mortality and AIDS-related morbidity among adults are also having a serious impact on child welfare. For instance, the WHO estimates that in the 1990s there will be over 10 million AIDS orphans in Africa.

• **Economic:** AIDS primarily affects young adults in the most productive age groups and as a result the indirect costs associated with the epidemic are significant. The reduction in the supply and productivity of labor from HIV-related mortality and morbidity, and the financial burden of paying for HIV-related treatment and other needs have serious economic consequences for households, productive enterprises, and countries. In the case of affected households the illness or death of a productive member can tip vulnerable households into poverty. The direct costs of the epidemic are also substantial. By 1993, HIV-related medical care costs in the developed countries had already reached US$ 4.8 billion a year and US$ 340 million in developing countries – figures that will continue to rise in the foreseeable future.

The participants at the Bellagio meeting also expressed concern about the long-term financial sustainability of the current range of prevention activities. Behaviour modification activities are both costly and labor intensive and will almost certainly need to be continued indefinitely to ensure that newly sexually active individuals are educated and to reinforce the knowledge of those already sexually active. The limited impact that prevention activities appear to be having on the rate of spread of HIV, and the decreasing prominence of HIV and AIDS as a health and development issue in developed countries, however, may lead donors to reassess their financial commitment to prevention, with serious consequences for prevention activities in the future.

### 1.2 Ideal technical characteristics of a preventive HIV vaccine

A preventive HIV vaccine intended for use throughout the world ideally would have the following technical characteristics:

- **Protection:** Able to stimulate the production of durable, functional protective immune responses against most, if not all, sub-types of HIV\(^2\) to which an individual is likely to be exposed, and from all potential routes of exposure. The mobility of people (and therefore viruses) highlights the need to protect individuals not just from the sub-types currently circulating where they live but also from those they may encounter in the future.

---

\(^2\) Isolates of HIV from different geographic regions, from different individuals in the same region, and even from a single infected individual often carry distinctly different genetic sequences. Isolates can be grouped by genetic relatedness; nine groups or sub-types of HIV-1 have been identified so far. In North America one sub-type (B) is prevalent in the infected population. In a number of regions, however, several different sub-types can be found.
• **Safety:** Safe in both the short and long term. Safety concerns include reversion to infectious HIV, oncogenic potential, and immunosuppression in those vaccinated. The vaccine should also be safe to deliver without prior screening for HIV infection (i.e., the vaccine should not induce any adverse reactions when given to HIV positive individuals). Although complete safety is the ideal, the risk to benefit ratio in populations at high risk of infection may justify the use of a vaccine that has some risks or before every aspect of safety has been exhaustively evaluated.

• **Delivery:** Provide long-lasting protection with a minimum number of doses (preferably one), have a long shelf-life, be heat stable, and be simple to administer (preferably oral).

• **Unambiguous marker for seroconversion:** Provide health care professionals with a marker which enables seroconversion due to vaccination and seroconversion due to infection to be distinguished rapidly, easily, and inexpensively.

• **Cost:** The final price of the vaccine should be such that it will be affordable for wide-scale distribution to all at risk of infection throughout the world.

2 Current efforts to develop HIV vaccines

2.1 Progress in HIV vaccine research

Since the discovery of the etiologic agent of AIDS there has been an unprecedented scientific effort to understand its structure, function, pathogenic mechanisms, and routes of transmission. More advances have been made over the last decade on this virus than on any other organism in history, and new advances are being announced each week. The information from the ongoing research efforts has provided the essential underpinning for efforts to develop preventive vaccines and treatments for those infected. This worldwide effort has led to the design of a number of different candidate vaccines which are currently being explored in the laboratory and in animal models (see Table 1). These include:

• Peptides based on key portions of HIV structural proteins;
• Protein subunits based on HIV structural genes;
• Virus-like particles and other particles including pseudovirions;
• DNA that encodes one or more HIV proteins;
• Live recombinant viral and bacterial vectors that express one or more HIV proteins;
• Whole killed virus;
• Live attenuated virus.

In addition, a number of new adjuvants and delivery methods are under evaluation.

A number of key scientific challenges, however, remain. These include:

• **The nature of the immune response required to prevent HIV infection:** Infection may occur by both cell-associated and free-virus particles, and either through mucosal or systemic routes of exposure. Whether specific mucosal immune responses will be required to prevent infection and how best to stimulate them remains unknown.
The nature of the immune response required to prevent HIV diseases: At present, the methods of HIV clearance following natural exposure have not been demonstrated. By analogy with other viral diseases, neutralizing antibodies and cytotoxic lymphocytes responses are thought to be important, but neither has been shown definitively to confer protection against HIV disease progression in infected individuals.

The immunological importance of the different sub-types of HIV: The genetic diversity of the viral sub-types found worldwide is large. At present the immunological importance of the different sub-types is not known. The WHO Network for HIV Isolation and Characterization is collecting and analyzing samples from around the world to improve current understanding of this issue.

Animal models: There is no readily available reliable animal model of HIV disease. SIV in monkeys has some potentially important differences from HIV, and HIV infected chimpanzees do not develop disease.

Endpoints for vaccine efficacy trials: There is doubt about what endpoints to use for vaccine efficacy trials owing to the uncertain relationship between surrogate markers of disease progression (CD4 count, viral burden) and subsequent disease progression, and the long latency period between infection and development of disease.

Meeting these challenges will provide a major impetus to the development of preventive HIV vaccines. The meeting participants, however, felt that it was important that product development work and the clinical trials of candidate vaccines should not be overly delayed by the unsolved scientific challenges. Vaccine development and the clinical testing of other viral vaccines have occurred despite the existence of profound scientific challenges and much has been learned from this work. In the case of HIV, where no good correlates of protection have been identified and there is no readily available reliable animal model, there is no substitute for scientifically and ethically sound human trials. While there are certain characteristics of HIV that warrant caution, the consensus was that new information will rapidly be generated from trials in humans regardless of whether or not the candidate vaccine was successful in protecting a large percentage of volunteers.

2.2 Progress In HIV vaccine development

Product development efforts have focused predominantly on three vaccine strategies – peptides based on key portions of HIV structural proteins, protein subunits based on HIV structural genes, and live recombinant viral or bacterial vectors that express one or more HIV proteins. In the last few years over a dozen products have entered Phase I clinical trials (small-scale safety and immunogenicity trials) (see Table 1) and two products have entered phase II (large scale safety and immunogenicity trials). The majority of the products currently being tested are based upon key portions of the HIV envelope protein (gp160 or gp120). Products based on a highly immunogenic portion of the HIV envelope, the V3 loop, as well as products based on recombinant viral vectors using pox viruses to express the HIV envelope, are also undergoing Phase I clinical investigations. None of the Phase I trials have demonstrated any problems with safety and in several trials, virtually all of the volunteers who received a series of injections produced antibodies capable of neutralizing laboratory strains of HIV. The trials, however, involve small numbers of volunteers and have a limited time period of observation. The long term side-effects and duration of immunity remain to be determined.
Phase III studies (large-scale efficacy trials) have not yet been initiated but are expected to begin in 1995. To prepare for these trials national governments and the WHO are developing the necessary infrastructure in various countries. These efforts include: the characterization of HIV sub-types found in possible trial populations, the training of investigators, the determination of the seroincidence of HIV, general strengthening of the infrastructure and field management capacity to undertake vaccine trials, and the development of the political support necessary for the conduct of such trials.

Product development efforts have focused on a small number of the potential vaccine approaches. The participants at the Bellagio meeting expressed concern about the lack of attention being given to other approaches. A number of approaches are not currently being "championed", including the two classical strategies, whole killed virus and live attenuated virus (Table 1). These strategies, and in particular, the live attenuated virus approach, are perceived as potentially less safe. However, a WHO expert committee that reviewed this issue in June 1993 concluded that the live attenuated approach "should be intensively explored". While ethical principles must not be compromised, the participants noted that the high risk of infection in some populations may justify the use of vaccine approaches that could potentially be less safe. For example, a vaccine with a risk of a serious adverse reaction of 1 in 100,000 may be considered better than no vaccine by a population with a high risk of infection, or better than an alternative vaccine that has a lower risk of adverse reactions but is less efficacious. Live attenuated or whole killed vaccines, if found to be efficacious, could represent viable cost-effective approaches under some circumstances.

The meeting participants also noted that product development efforts have focused on the subtype of HIV found almost exclusively in North America and Europe – subtype B (see Table 1). Candidate vaccines representing sub-types prevalent in the developing world, and candidates based on multiple sub-types are not being widely developed. While the immunological importance of the different sub-types has not yet been determined, the current focus of development activities on subtype B could present problems when it comes to carrying out efficacy trials and may result in substantial delays in the evaluation of candidate vaccines. In the absence of more information on the immunological importance of the different sub-types of HIV, it is important that vaccine trials are carried out with prototype vaccines based on the viral sub-types found in the trial site; otherwise, it will be difficult to evaluate the significance of a negative result. There are, however, only a small number of population groups (primarily intravenous drug users and individuals living in some resource-poor inner city areas) with high enough rates of infection with subtype B to carry out efficacy trials using realistic sample sizes. Some clinical trials can almost certainly be done more effectively and expeditiously in developing country populations with a high incidence of infection.

2.3 Financial resources

A review of recent activities in both the private and public sectors suggests that in 1993, less than US$ 160 million was spent worldwide on HIV vaccine research and development (see Table 2). This represents less than 10% of the total amount spent on HIV/AIDS-related research and development. It is a fraction of the amount spent in 1992 on HIV prevention (US$ 1.3 billion in developed and US$ 0.2 billion in developing countries) and on HIV-related health care (US$ 4.7 billion in developed and US$ 0.34 billion in developing countries), and a very small fraction of the
amount spent on health research. The most recent survey of expenditures on health research conducted by the Commission on Health Research for Development estimated that in 1986 US$ 30 billion was spent worldwide on health research, of which less than 5% (US$ 1.6 billion) was spent on developing country-oriented research. Between 1986 and 1993 the total amount spent each year on health research increased markedly. This means that in 1993 expenditures on HIV vaccine research and development represented substantially less than 0.5% of the total global health research budget.

Public sector

The public sectors of the major developed countries are the main source of funding for HIV vaccine research and development. In 1993 it is estimated that they provided over 80% of the total global expenditure in this area, or between US$ 125 million and US$ 130 million (see Table 2). Their efforts to fund research on HIV and AIDS are constrained, however, by overall budgetary and human resource limitations, and the competing demands of other important diseases affecting human health. There is also competition for funds earmarked for HIV/AIDS research between basic research activities directed at increasing current understanding of the virus, activities directed at developing therapeutics to treat those currently infected, and activities directed at developing a preventive HIV vaccine. Of the three, preventive vaccine development has received the smallest proportion of the available funding. For example, in 1993 less than 10% of the US government's budget for HIV/AIDS related research and development activities was spent on preventive vaccines (see Table 2).

Within the public sector, the national health research agencies control the majority of the funds, and hence expenditures are also influenced by their general mission - to promote the health of persons living in their own country. The development assistance agencies, whose mandate is directed towards those living in developing countries, have not been active funders of HIV vaccine research and development to date.

Private sector

The private sector is an important source of funds for health research. The Commission on Health Research for Development estimated that in 1986, the private sector accounted for over 40% of the total amount spent on health research (US$ 13 billion out of US$ 30 billion). Estimates of the amount invested by the private sector in research and development activities related to preventive HIV vaccines are difficult to make. Results from an informal survey of the key players, however, suggest that in 1993 pharmaceutical and biotechnology companies invested less than US$ 25 million in preventive HIV vaccines, or under 15% of the total expenditure.

Both large pharmaceutical companies and the small biotechnology companies have been active players to date in HIV vaccine development. Funds for investment by the large companies come, in general, from within the company. The small biotechnology companies, however, rely primarily on venture capital for funding which, in general, has a limited time horizon for investment without quantifiable success. The prospect of price controls on health care in the United States is also making preventive vaccines a less attractive investment prospect.

The resources that have been invested by industry in the development of preventive HIV vaccines have been targeted predominantly at those approaches perceived as being safest (i.e., least likely to have untoward side effects and, consequently, with less potential for litigation should such
effects emerge), and have been based on the sub-type of HIV found in the US and Europe (i.e., greater likelihood of receiving a return on investment).

The meeting participants concluded that the current level of investment in research and development on preventive HIV vaccines was insufficient given the future health, humanitarian, social, and economic costs of the HIV/AIDS pandemic. The investment of additional resources was viewed as potentially making a significant difference, especially if targeted at the critical gaps in current development efforts.

3 Obstacles to developing and making HIV vaccines available

3.1 Obstacles to vaccine development

In the industrialized countries, vaccine development is almost exclusively a commercial enterprise. The resources, expertise and experience for product development, preparation for licensure application, and manufacturing lie predominantly in the private sector. As a result, whatever research priorities are set by the public sector, the ultimate decision to develop and manufacture a vaccine for general use rests in the hands of the private sector and, in particular, the large vaccine companies, most of which are also large pharmaceutical companies.

The decision to invest in the development of a new product reflects a careful assessment of a variety of external and internal factors that determine the opportunity costs of investing in the product, the risks involved in developing and marketing the product, and its potential profitability. Three key external factors are the state of science, the size of the market, and the public policy environment. Internal factors include the skills base of the company, and the fit with the current research and development portfolio.

In the case of HIV, the current level of investment by the private sector suggests that, at present, industry does not regard the development of a preventive HIV vaccine as a very attractive commercial enterprise. The opportunity costs of investing in the vaccine are not insignificant - the development of an HIV vaccine will almost certainly require a substantial investment of financial and human resources over an extended period of time. The risks are also great. There is no guarantee that a preventive HIV vaccine can be developed, and even if a company did develop a vaccine the size of the market and the price the market will bear are both uncertain, as are the potential liability costs.

State of the science

The rapid scientific advances made in the last decade provide the essential underpinning for efforts to develop preventive HIV vaccines. There is, however, no guarantee that it will be possible to develop a preventive vaccine, and in the interim there are a number of important scientific challenges that need to be met (see Section 2:1). These uncertainties make investing in an HIV vaccine a risky prospect.
Market considerations

Estimates of the size of the market for a preventive HIV vaccine are difficult to make as there are many uncertainties, including the acceptability of the vaccine to the population; the perceived risks of acquiring HIV; the amount people or institutions will pay for a vaccination course; the willingness of different institutions to cover the costs of a vaccination course for those who cannot afford to pay; and national government vaccine policies.

In the developed countries, in the absence of broad recommendations for vaccination the greatest demand for a preventive vaccine will come from those individuals who regard themselves as at high risk of infection. Estimates of the percentage of the population who regard themselves as at high risk of infection are small. The experience with the use of hepatitis B vaccine in health care providers and homosexuals also confirms the difficulty of expecting a broad voluntary uptake. Among population groups identified as at high risk of infection, such as sexually active homosexuals and intravenous drug users, it is likely that only a proportion of individuals will come forward to be vaccinated even if the vaccine is free or highly subsidized. Individuals may not identify themselves as at risk of infection, and in areas where intravenous drug use is illegal or homosexuality is stigmatized, they may not be willing to step forward to be vaccinated. Even if all homosexuals and intravenous drug users were vaccinated, the number of vaccination courses required is not large. Assuming 2% of adult males are sexually active homosexuals, and 0.1% of the adult population uses intravenous drugs, then less than 5 million full courses would be required to vaccinate all members of these two groups in the developed world, and probably less than 150,000 courses a year to vaccinate all individuals entering the two groups. Heterosexuals with multiple sexual partners and certain cadres of medical professionals (e.g. surgeons) have also been identified epidemiologically as being at high risk of infection. The prevailing view is that only a very small proportion of heterosexuals consider themselves at risk of infection. It is difficult to predict, however, how the general heterosexual population will respond to the availability of a preventive HIV vaccine.

The developed countries account for only 15% of the world's population and 7% of new births. In other words, the potential demand for an HIV vaccine is substantially greater in the developing world than in the developed world. The resources to purchase a preventive HIV vaccine, however, lie disproportionately within the developed countries and will continue to do so for the foreseeable future in the absence of international subsidies. In general, the countries with the highest incidence of HIV and hence with the greatest need for a preventive vaccine are also among the poorest. For example, the total per capita expenditure on health care in sub-Saharan Africa (including both public and private funding but excluding South Africa) in 1990 was US$ 13.5 and in India US$ 21, a fraction of the amount spent in Europe or North America. Comparable figures for France and the United States were US$ 1,945 and US$ 2,763 respectively.

Public policy environment

The meeting did not focus on the public policy environment in detail. The general view, however, was that the current public policy environment for vaccine development was not favorable. Positive steps will have to be taken if pharmaceutical and biotechnology companies are to be encouraged to commit more fully their expertise, experience and resources to the development of a preventative HIV vaccine. This is especially true if industry is to be encouraged to invest in vaccines that will meet the technical requirements of the developing world.
Interventions to encourage industry participation are basically of two types – those that reduce the prelicensure costs and risk of developing a vaccine candidate, and those that make the environment for vaccine manufacturing more hospitable. Incentives could include improving the legal and regulatory environment, reducing the potential costs of liability exposure, or ensuring the availability of patent protection for those working on preventive HIV vaccines. Other incentives include:

- financial assistance with research and development in the form of grants, cooperative research and development agreements, tax credits, or other fiscal incentives;
- access to pilot production facilities;
- assistance with access to clinical and field trial sites;
- financial assistance with clinical trials and field testing;
- harmonization of international regulatory procedures for vaccine approval;
- assistance in the assembling intellectual property rights;
- guaranteed procurement of vaccine;
- establishment of an HIV vaccine injury compensation program.

3.2 Obstacles to vaccine availability

Ensuring that once a safe and efficacious preventive HIV vaccine is developed that it is made available promptly to those individuals at high risk of infection is of utmost importance. Experience with drugs and vaccines for other diseases (e.g. hepatitis B), however, suggests that worldwide availability will not occur without specific attention being given to the needs and requirements of developing countries. Issues relating to the manufacture, purchase and distribution of HIV vaccines will need to be addressed and steps taken in advance to ensure that extended delays do not occur. WHO, UNICEF (United Nations Children’s Fund), and a number of other international agencies have extensive experience with these issues from working on the worldwide Expanded Programme on Immunization.

4 Accelerating the development of HIV vaccines

4.1 The need for a new Initiative

The participants at the meeting expressed concern about the direction and pace of current efforts to develop a preventive HIV vaccine that would be appropriate for use in developed and developing countries. This concern reflected an assessment of a number of issues:

- There is no coordinated international strategy backed with adequate resources for the development of preventive HIV vaccines appropriate for use throughout the world. This has meant that there are important gaps in the overall picture of vaccine development.
- The financial resources for preventive HIV vaccine research and development are limited (presently estimated at under US$ 160 million a year) and come primarily from the public sector of the major developed countries. These resources are invested almost exclusively in vaccine candidates and approaches that are directed at meeting the needs of the developed countries, and stress research rather than vaccine development. The vast
majority of infected individuals, however, live in the developing world, and it is here that the epidemic is spreading most rapidly.

- Most of the research funding from the public sector is done through researcher originated mechanisms. Although this is an excellent way to make new scientific breakthroughs, it is not necessarily the most effective way to develop a particular product.

- The expertise and resources for vaccine product development reside overwhelmingly in the larger commercial vaccine companies. The opportunity costs of investing in HIV vaccines, the perceived returns to investment and the potential costs (including liability) have meant that only a few companies are investing substantially in preventive HIV vaccines.

- Small biotechnology companies have been active players in vaccine development to date. They are, however, constrained by their reliance on venture capital for funding which, in general, has a limited time horizon for investment without quantifiable success.

- The limited resources being invested in HIV vaccine research and development has meant that HIV vaccine development is following a sequential, not a parallel approach. Given the many scientific uncertainties remaining, the development and testing of multiple empirical approaches in a parallel fashion, rather than sequentially, will be a faster route to the development of safe, effective, and inexpensive vaccines appropriate for widespread use.

- Vaccine approaches perceived as more speculative are not being actively pursued by commercial vaccine companies, even though they may offer other desirable attributes, such as the potential for higher efficacy or use with fewer doses.

- Candidates developed from sub-types of HIV found in areas where most new infections are occurring are not being aggressively developed in parallel to the developed country prototypes, even though many scientists are of the opinion that efficacy testing can be done much more effectively and expeditiously in high HIV-incidence developing country sites.

- Scientists and public health officials from developing countries have little involvement in, or influence on, the decision-making process for the development of preventive HIV vaccines.

The participants concluded that a new global HIV vaccine initiative should be established with the primary mandate of accelerating the development of preventive HIV vaccines. The main role of the initiative should be to redress system or market failures with respect to product development and its activities should focus on reducing the obstacles to vaccine development and filling the gaps in the current effort. By focusing on the obstacles and gaps, the initiative would complement, not compete with, the existing efforts in HIV/AIDS vaccine development, such as national programs and private sector vaccine development. The initiative was seen as providing support to a number of parallel development efforts prior to the time when a definite choice between alternative strategies can be made. A secondary goal of the initiative would be to work with organizations such as WHO, UNICEF, and other national and international agencies, to ensure that once a vaccine is developed that it is made available for use throughout the world with the least possible delay.
4.2 Characteristics of a new initiative

The participants felt that the new initiative must have a well defined mandate, and must work closely with and be responsive to the needs of industry, national research agencies, national governments, and international agencies.

Other characteristics identified were:

- The ability to mobilize the collective efforts of a number of different sectors of the world economy – national governments, private companies, non-governmental organizations, and international organizations.
- The ability to act decisively, rapidly and to be flexible.
- The ability to undertake innovative development projects entailing calculated scientific and financial risks.
- A commitment to the highest scientific standards and full respect for ethical considerations and human rights.
- A finite lifespan.

The final form of the initiative and its sources of funding will need to be developed in consultation with the anticipated major collaborators. The advantages and disadvantages of various models for the new initiative were discussed at the Bellagio meeting. Models discussed include (see Table 3):

- Task force;
- Donor collaboration;
- Private consortia;
- Public/private consortia;
- Not-for-profit institute.

Experiences with specific programs were also discussed. Particular attention was given to the Children’s Vaccine Initiative (CVI), as in many ways the role of the proposed initiative is analogous to the role CVI is playing in the development of childhood vaccines.

The view of the meeting was that a small secretariat, or task force, with an international scientific steering committee would be an appropriate structure. The secretariat would strive to accelerate the development of preventive HIV vaccines both by working with other organizations to reduce the disincentives and by targeting research funds at the critical gaps in product development as identified by the scientific steering committee. The secretariat would carry out no research of its own but rather would contract research out to companies, universities and government laboratories throughout the world.

The meeting participants felt that it was essential that the initiative have its own mandate and governing structure. It was recognized, however, that given the time delay and resources required to establish a new organization, it might be appropriate for the initiative to be housed, at least initially, in an existing organization. Potential homes for the initiative include the World Bank,
another multilateral agency, the new UN AIDS program (once established), or an international foundation.

Possible sources of funding for the secretariat and its associated activities were discussed. Sources mentioned included multilateral agencies, national agencies with interests in health or international development, philanthropic organizations, pharmaceutical and biotechnology companies, and the general public. An innovative model of a stock corporation owned by a number of pharmaceutical companies, multilateral agencies, private funders and developing country governments, and receiving developed country co-funding or loan guarantees for bonds sold on commercial markets, was offered as one possible funding approach. This approach has the advantage of not requiring substantial public sector funding unless the effort is ultimately unsuccessful. Another approach discussed was obtaining new public funding through a special appropriation by national governments.

The importance of both the private and public sectors playing an active role in the new initiative was stressed. The success of any new initiative will depend upon the willingness of both sectors to be involved. Collaborative ventures between the private and public sectors have been fruitful (eg. Sematech, Airbus) in a number of other sectors in galvanizing product research and development, while still respecting corporate profit motives and independence.

The value of both developed and developing country governments being actively involved was also emphasized. The need for a preventive HIV vaccine is greatest in parts of the developing world and, as a result, it is important that the requirements of these countries are taken into account. As well, the testing of candidate vaccines may be conducted more efficiently in high-incidence settings in developing countries than in developed countries. Those countries that participate in clinical trials should receive full credit for their part of the partnership in the development of an HIV vaccine. Involvement in the new global initiative may also assist countries by stimulating their own capacity to conduct vaccine research and clinical trials, and produce and deploy vaccines – an important additional benefit.

4.3 Activities of a new Initiative

To achieve the initiative's goals, it was envisaged that a number of different activities would need to be carried out in close collaboration with the appropriate national and international agencies. The exact activities will need to be decided following discussions with potential collaborators. Among the activities identified during discussions at the Bellagio meeting were:

- Developing and disseminating a scientific strategic plan for vaccine development and candidate assessment; monitoring progress towards accomplishing the plan and closing the remaining gaps.

- Mobilizing additional financial resources that can be used to accelerate the development of preventive HIV vaccines.
• Encouraging the development of vaccine approaches that are not actively being pursued and new approaches that could be appropriate for eventual use in developing countries by providing financial resources and other types of incentives (see section 3.1). This might include directly funding vaccine companies to undertake particular steps in developing promising vaccine candidates.

In addition the initiative will need to work with other national and international agencies to:

• Ensure the active participation of individuals from all areas of the world in the planning, conduct, and evaluation of research and development for HIV vaccines. Provide additional financial and human resources to strengthen local capacities where necessary.

• Encourage and facilitate collaboration between the public sector and the private sector.

• Monitor the worldwide progress of promising vaccine approaches and candidates, and the global capacity to conduct safety and efficacy testing of vaccine candidates.

• Encourage national and international authorities to consider and resolve issues identified by the private sector as disincentives to vaccine development in general, and to HIV vaccines in particular, such as:
  
  - The commercial unpredictability arising from the lack of efficient mechanisms for dealing with liability and compensation for vaccine injury not associated with manufacturer negligence;
  
  - The lack of consistent international guidelines on issues relating to safety and efficacy testing, and licensure of vaccine candidates against HIV;
  
  - The lack of harmony among international regulatory agencies;
  
  - The commercial unpredictability arising from the lack of recommendations for vaccine use.

• Ensure HIV vaccines will be accessible and affordable for those at risk of infection. Activities that the initiative may need to consider undertaking include:

  - Identification of potential markets for vaccines in developed and developing countries and the creation of markets where they do not exist by ensuring that funds will be available for vaccine procurement (options include exploring the possibility of using the World Bank's International Development Association loans as a way of guaranteeing a hard currency market for HIV vaccines that meet certain specifications).
  
  - Development of plans for ensuring the financing of adequate supplies of vaccine for use in developed and developing countries once licensed for use.
  
  - Strengthening the capability for self-reliance in vaccine quality assurance, vaccine "finishing" and in manufacturing where appropriate and necessary.
  
  - Development of strategies for technology transfer if and when it becomes feasible.
5. Future Activities

The pace of scientific progress and recent research findings are encouraging that an HIV vaccine can be developed. While this is not certain, the rapid rate of spread of the HIV epidemic, the gravity of its potential consequences, and the limited impact of current prevention efforts, highlight the importance of mobilizing additional resources for HIV vaccine research and development. The HIV epidemic is truly a global epidemic, and as a result the development of preventive HIV vaccines will benefit the human race.

The organizations currently engaged in HIV vaccine research and development all have mandates that limit the scope of their vaccine research and development agendas. To date, the major source of funding for vaccine research has come from the public sectors of the developed countries and the vast majority of these funds have been administered by agencies with a domestic focus. The development assistance agencies, whose mandate is directed towards those living in developing countries, have not been major funders. Product development has been left almost exclusively in the hands of the private sector where the expertise and resources lie. In the current environment, however, the risks and potential returns from investing in the development of HIV vaccines are not sufficient for the private sector to make a substantial commitment to vaccine development. Without the expectation of adequate returns it is unrealistic to expect commercial vaccine companies to divert resources in favor of the development of a vaccine merely for the good of the public. Commercial manufacturers cannot be expected to bear the sole responsibility of developing high-risk, low-priced products. As a result, the public sector will need to reduce the disincentives for industry to invest if a vaccine is to be developed with the least possible delay.

The successful development of a preventive HIV vaccine will almost certainly depend upon the involvement of both the private and public sectors from around the world. In the current environment, no one government or company has the resources and incentive to take on the challenge of developing an HIV vaccine alone. The potential resources, however, that could be mobilized if the public and private sector of different countries were encouraged to work together would be substantial. Within the public sector, the development of an HIV vaccine is of importance for a number of different agencies, including those with concerns in health, economic development, and international development.

The participants at the meeting concluded that the establishment a new global HIV vaccine initiative with the primary mandate of accelerating the development of preventive HIV vaccines would be the most effective method of ensuring that a safe and effective preventive HIV vaccine appropriate for worldwide use is developed and made available in the shortest time possible. The establishment of a new global initiative backed with sufficient resources could potentially alter the future course of the HIV epidemic, save the lives of large numbers of people, and reduce the economic consequences of the epidemic. Such a global partnership would be a winning situation for all involved.
Due to the important implications of starting a new initiative and the resources that will be required, participants considered that the plan needed further discussion to define more accurately the steps that will need to be taken. In particular, additional guidance will need to be sought from the private sector. For the short term the meeting recommended that:

- The concept of the establishment of a new initiative should be discussed with potential collaborators;
- A preliminary scientific research agenda should be developed;
- A proposal detailing the scientific and business plan of the initiative, organizational structure, and funding mechanism should be developed.

The participants at the Bellagio meeting considered that the development of preventive HIV vaccines appropriate for worldwide use was of great urgency and deserving of extensive support. The World Bank's 1993 World Development Report concludes that "Historians will look back on the latter half of this century as having had one great medical triumph, the eradication of smallpox, and one great medical tragedy, AIDS." Perhaps it is not too late for the world to rise to the challenge of averting this tragedy.
Table 1. Investment in preventive vaccine product development by approach and virus sub-type. Vaccine approaches are ordered from left to right according to perceived safety.

<table>
<thead>
<tr>
<th>Sub-type</th>
<th>Peptides</th>
<th>Protein subunits</th>
<th>Virus-like particles and other particles</th>
<th>DNA</th>
<th>Live recombinant vectors</th>
<th>Whole killed</th>
<th>Live Attenuated</th>
</tr>
</thead>
<tbody>
<tr>
<td>B*</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>+</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>+/-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C</td>
<td>+/-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>D</td>
<td>+/-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>E</td>
<td>+/-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>F</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>G</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Virus sub-type B predominates in North America and Europe.

0 No product in development
+/- Product in development but not yet in human trials
+ Product currently in Phase I/II trials in humans
<p>| Source: Data from multilateral and national programs, and personal communications from commercial and philanthropic organizations. |</p>
<table>
<thead>
<tr>
<th>Model</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Task Force</strong></td>
<td><strong>Task Force for Child Survival and Development</strong></td>
</tr>
<tr>
<td></td>
<td>- An international effort to enhance worldwide immunization of children</td>
</tr>
<tr>
<td></td>
<td>and to reduce the burden of infection and malnutrition in children.</td>
</tr>
<tr>
<td></td>
<td>Founded by the WHO, UNICEF, UNDP (United Nations Development Programme),</td>
</tr>
<tr>
<td></td>
<td>World Bank, and Rockefeller Foundation, it has a free standing</td>
</tr>
<tr>
<td></td>
<td>secretariat housed at the Carter Center in the United States.</td>
</tr>
<tr>
<td></td>
<td><strong>The International Task Force on Hepatitis B Immunization</strong></td>
</tr>
<tr>
<td></td>
<td>- An international effort to make hepatitis B vaccine affordable for</td>
</tr>
<tr>
<td></td>
<td>wide-scale use and to integrate the vaccine into national immunization</td>
</tr>
<tr>
<td></td>
<td>programs in areas where hepatitis B is hyperendemic. The task force is</td>
</tr>
<tr>
<td></td>
<td>composed of independent professionals working in the areas of hepatitis</td>
</tr>
<tr>
<td></td>
<td>B and international health. The operating agency for the task force is</td>
</tr>
<tr>
<td></td>
<td>PATH (the Program for Appropriate Technology in Health) which is</td>
</tr>
<tr>
<td></td>
<td>based in the United States.</td>
</tr>
<tr>
<td><strong>Donor collaboration</strong></td>
<td><strong>The Children's Vaccine Initiative (CVI)</strong></td>
</tr>
<tr>
<td></td>
<td>- An international effort to harness new technologies to advance the</td>
</tr>
<tr>
<td></td>
<td>immunization of children throughout the world. The CVI was founded by</td>
</tr>
<tr>
<td></td>
<td>the WHO, UNICEF, UNDP, World Bank, and Rockefeller Foundation and has</td>
</tr>
<tr>
<td></td>
<td>recently moved its headquarters to the WHO. The founders recognized</td>
</tr>
<tr>
<td></td>
<td>that other entities needed to be involved which led to the formation of</td>
</tr>
<tr>
<td></td>
<td>the CVI consultative group which is composed of representatives of</td>
</tr>
<tr>
<td></td>
<td>national immunization programs, multilateral, governmental, and</td>
</tr>
<tr>
<td></td>
<td>nongovernmental organizations, and commercial and public-sector vaccine</td>
</tr>
<tr>
<td></td>
<td>manufacturers. The activities of the CVI are carried out by task</td>
</tr>
<tr>
<td></td>
<td>forces and product development groups.</td>
</tr>
<tr>
<td></td>
<td><strong>Consultative Group for International Agricultural Research (CGIAR)</strong></td>
</tr>
<tr>
<td></td>
<td>- An informal association of 41 public and private sector donors that</td>
</tr>
<tr>
<td></td>
<td>supports a network of 18 international agricultural research centers.</td>
</tr>
<tr>
<td></td>
<td>Donors give to the center of choice. The association has two</td>
</tr>
<tr>
<td></td>
<td>secretariats – technical (provided by the FAO) and management (provided</td>
</tr>
<tr>
<td></td>
<td>by the World Bank). In 1992 the financial resources available to the</td>
</tr>
<tr>
<td></td>
<td>18 centers totaled US$ 335 million.</td>
</tr>
<tr>
<td></td>
<td><strong>Global Environmental Facility (GEF)</strong></td>
</tr>
<tr>
<td></td>
<td>- An umbrella administrative mechanism for a wide range of environmental</td>
</tr>
<tr>
<td></td>
<td>financing operations housed at the World Bank. The GEF was launched in</td>
</tr>
<tr>
<td></td>
<td>May 1991 as a three-year pilot project with commitments from</td>
</tr>
<tr>
<td></td>
<td>participating governments totaling US$ 1.4 billion. The funds are to</td>
</tr>
<tr>
<td></td>
<td>be used to make grants and concessional loans to finance projects in</td>
</tr>
<tr>
<td></td>
<td>developing countries, generating global environmental benefits not</td>
</tr>
<tr>
<td></td>
<td>possible under normal lending operations of the multilateral financial</td>
</tr>
<tr>
<td></td>
<td>community. The GEF is managed by the three sponsoring agencies: the</td>
</tr>
<tr>
<td></td>
<td>World Bank, UNDP, and UNEP (United Nations Environment Programme).</td>
</tr>
</tbody>
</table>
Private consortia

Inter-Company Collaboration for AIDS Drug Development
- A collaboration of 15 pharmaceutical companies engaged in ongoing HIV antiviral research. The collaboration was formed to facilitate the conduct of early human effectiveness trials of antiviral drugs by better enabling companies to conduct independently early stage combination studies of their respective investigational antiviral AIDS compounds.

Electric Power Research Institute (EPRI)
- A consortia of 720 U.S. electric utilities founded in 1972 with the objective of applying science and technology to the benefit of consortia members and their customers. The consortia is funded by member contributions and in 1990 had a budget of US$ 360 million. EPRI functions primarily as a secretariat and contracts research out to other organizations.

Microelectronics and Computer Technology Corp (MCC)
- A consortia of 21 U.S. electronics, high-tech, and aerospace firms formed in 1977 to enhance competitiveness in information technology. The consortia acts as a central research laboratory for its members with over 90 % of its work completed in MCC laboratories. MCC is funded primarily by contributions from its member companies and had a budget of US$ 65 million in 1990.

Public/Private consortia

Semiconductor Research Corporation (SRC)
- A consortia founded by 7 U.S. device companies and 4 U.S. integrated computer-device companies in 1982. The SRC coordinates efforts that bring academics and industrial scientists together to work on problems in microstructure sciences, manufacturing sciences, and design science. The SRC maintains no laboratories or working scientists of its own. Instead it focuses on merging the efforts of industrial and academic scientists through its committees. After a program has been agreed upon, the SRC provides funds received from member companies to universities and also serves as the administrator of programs funded by government agencies. SRC's budget for 1990 was US$ 35 million.

Sematech
- A consortia of 17 U.S. semiconductor and computer companies and the U.S. government formed in 1987 to conduct research and development that would provide the U.S. semiconductor industry with the domestic capability for world leadership in manufacturing. The consortia receives funding from member companies and the U.S. government. In 1990 the total budget reached US$ 200 million, over 50 % of which was provided by member companies.

Research in Advanced Communications for Europe (RACE)
- A consortium formed in 1985 to develop the technology base for integrated broadband networks in Europe. Over 100 organizations and the European Commission are members and it has an annual budget of around US$ 650 million. The project was scheduled to last for 10 years.
Optical Technology Research Corporation (OTRC)
– A consortia of 18 Japanese companies formed in 1986 to develop and produce second-generation optoelectronic integrated circuits. OTRC carries out its own research and has an annual budget of US$ 6.7 million. The project was scheduled to last for 10 years.

Airbus
– A consortia of 4 European companies formed to create a partnership that could compete head-on in the world aircraft market. Funding is provided by the companies, government subsidies, and now from sales of aircraft.

<table>
<thead>
<tr>
<th>Not-for-Profit Institute</th>
<th>The Population Council</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>– An international not-for-profit organization applying science and technology to the solution of population problems in developing countries. The Council, based in the United States, solicits funds required for its work. More than half of the Council’s funds come from governments and United Nations agencies.</td>
</tr>
</tbody>
</table>

Program for Appropriate Technology in Health (PATH)
– An international not-for-profit, non-governmental organization focusing on the effectiveness, availability, safety, and appropriateness of technologies for health and family planning in developing countries. Support comes from a wide variety of funding sources including international health and family planning agencies, national governments, private foundations, and corporations. PATH is based in the United States.

The National Foundation for Infantile Paralysis
– A foundation established in the 1930’s in the U.S. to develop a vaccine against polio. Funds were raised through public appeals (e.g. the March of Dimes) and from wealthy donors. The funds were used to sponsor basic research and once clear leads were identified to fund vaccine development. As vaccine candidates became available for human trials, the foundation assisted in the development of guidelines for conducting trials and also provided financial support.

The Concept Foundation
– A foundation established by the WHO’s Special Programme for Research and Training in Human Reproduction (WHO/HRP) to hold and manage intellectual property rights to new products emerging from WHO/HRP research. The Concept Foundation is based in Thailand.
ANNEX 1

LIST OF MEETING PARTICIPANTS

HIV Vaccines - Accelerating the Development of Preventive HIV Vaccines for the World

March 7-11, 1994
Belagio, Italy

Jorge Barrientos
Manager for Health
Population, Health and Nutrition
S-11129
The World Bank
1818 H Street, NW
Washington, DC 20433
United States

Peter Carpenter
Mission+Values Institute
1 Larch Drive
Atherton, CA 94027-2125
United States

Seth Berkley, M.D.
Associate Director
Health Sciences Division
The Rockefeller Foundation
420 Fifth Avenue
New York, NY 10018
United States

Marcus Conant, M.D.
Conant Medical Group
350 Parnassus, Suite 808
San Francisco, CA 94117
United States

Natth Bhamarapravati, M.D., D.Sc.
Center for Vaccine Development
Institute of Sciences and Technology for Development
Mahidol University at Salaya
25/25 Phutthamonthon 4
Nakhon Pathom 73170
Thailand

Jose Esparza, M.D.
Chief, Vaccine Development
Global Program on AIDS
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

Colonel Donald Burke, M.D.
Walter Reed Army Institute for Research
1600 East Gude Drive
Rockville, MD 20850
United States

Donald Francis, M.D., D.Sc.
Department of Clinical Research
Genentech, Inc.
460 Point San Bruno Blvd.
South San Francisco, CA 94080
United States
Tony Garland, Ph.D.
Senior Technical Advisor
Research, Development and Medical Division
The Wellcome Foundation, Ltd.
Langley Court
Beckenham, Kent BR3 3BS
United Kingdom

Richard Mahoney, Ph.D.
Vice-President
Program for Appropriate Technology in Health
4 Nickerson Street
Seattle, WA 98109
United States

Jaap Goudsmit, Ph.D.
Human Retrovirus Laboratory
Academic Medical Center at the University of Amsterdam
Department of Virology, LI-1577
NL - 1105 AD Amsterdam
The Netherlands

Edward Mbidde, M.D.
Director
Uganda Cancer Institute
P.O. Box 3935
Kampala
Uganda

Margaret Johnston, Ph.D.
Acting Deputy Director
Division of AIDS
National Institute of Health
6003 Executive Boulevard
Solar Building
Rockville, MD 20892
United States

Dennis Panicali, Ph.D.
President and CEO
Therion Biologics Corp.
76 Rogers Street
Cambridge, MA 02142-1119
United States

Takashi Kitamura, M.D., Ph.D.
Director, Department of Virology
National Institute of Health
1-23-1, Toyama, Shinjuku-ku
Tokyo 162
Japan

John Petricciani, M.D.
Vice President for Regulatory Affairs
Genetics Institute
87 Cambridge Park Drive
Cambridge, MA 02140
United States

Professor Jean-Paul Levy
Directeur
Agence Nationale de Recherches sur le SIDA
66 bis, Avenue Jean Moulin
75014 Paris
France

Peter Piot, M.D., Ph.D.
Director, Division of Research and Intervention Development
Global Programme on AIDS
World Health Organization
CH-1211 Geneva 27
Switzerland
AIDS VACCINES
Are Researchers Racing Toward Success, Or Crawling?

In 1990, AIDS researchers and stock analysts hailed Repligen Corp., a Massachusetts biotechnology firm, as a leader—many said the leader—in the race to develop a vaccine against HIV. Not only was Repligen collaborating with top AIDS researchers and publishing impressive scientific papers, the start-up had won financial backing from pharmaceutical giant Merck & Co. A 1990 investors’ guide from Shearson Lehman Hutton predicted that if human tests of the vaccine went well, Repligen and Merck might ask the U.S. Food and Drug Administration to license it as early as the end of 1994.

Fast forward to 19 July 1994. On that day, Repligen announced that, because of a "lack of available funding," it was axing its HIV vaccine research and development program. One way of interpreting this startling turnaround is to assume it’s a normal development in a long-distance race; after all, the early leaders in the New York City marathon seldom stay the course. A more skeptical view, however, holds that there never was a "race" to make an AIDS vaccine.

That view may seem as surprising as Repligen’s fade-out, but a growing number of AIDS researchers have come to this depressing conclusion. Jaap Goudsmit, a leading AIDS researcher at the University of Amsterdam, says of the alleged race, "I haven’t seen it." Wayne Koff, former head of the AIDS vaccine program at the National Institute of Allergy and Infectious Diseases (NIAID), who is now developing an AIDS vaccine at New York’s United Biomedical Inc., says the idea of a “race” is largely "a game" played at scientific meetings. "There’s a lot of noise and a lot of posturing"—and little else, says Koff.

The reason pharmaceutical companies aren’t pouring dollars and energy into AIDS vaccines the way they would into a hot new mood-elevating drug is simple: The AIDS vaccine market in developed countries is likely to be much smaller than early estimates indicated. As a result, only a handful of companies are committed to the search, mostly biotech start-ups. And most of these companies are taking the same narrow approach, which limits the chances of success, say Koff and Goudsmit.

Not everyone accepts this downbeat view. But even congenital optimists must have found it difficult to smile about the AIDS vaccine "race" in June, when two NIAID advisory panels decided that even the two most promising experimental vaccines are not ready for large-scale testing (Science, 24 June, p. 1839). NIAID director Anthony Fauci says the discussions by those panels "laid naked what a paltry effort" is being made to develop AIDS vaccines. "When all of the clothes get ripped away, what do we have?" asked Fauci.

Not a super market
Economics clearly isn’t the only factor that is discouraging companies from entering the search for an AIDS vaccine. Another is the fact that the science is very tough. Animal models used to test AIDS vaccines have severe limitations; the genetic diversity of HIV may require an effective vaccine to be based on many viral strains; and no researcher has successfully demonstrated which immune responses correlate with protection from HIV.

Yet even with these high scientific hurdles, you might think the market for AIDS vaccines would have companies salivating. And early estimates did get their juices flowing. In Shearson Lehman’s 1990 report, analysts estimated the market in the United States and Europe would include more than 67 million people, including homosexuals, intravenous drug users, health-care workers, prisoners, and college-age heterosexuals. If, on average, 15% to 20% of these people took a vaccine priced at $150, it could be a $1.6-billion-plus market.

Yet those estimates are rapidly deflating. In July the Rockefeller Foundation released a report, "Accelerating the Development of Preventive HIV Vaccines for the World,"
The University of Amsterdam's Goudsmit argues that this "'50s technology" is "the first thing that should have been done." (Therion is, to a limited degree, pursuing a live, attenuated HIV vaccine, and Immuno recently has begun developing a whole, killed one.)

Not only are most experimental vaccines taking the same genetically engineered approach, they are focusing on a single strain of the virus: the B subtype, which predominates in Europe and the United States, but not in the developing world. This focus may result in vaccines with little relevance to many of the poor countries where HIV is spreading rapidly. Although one immune response might protect against different genetic subtypes of HIV, Bellagio participants felt that vaccines would be more likely to work if they were based on the viruses found in the population where they are being tested. But until now, companies have been reluctant to make different vaccines for different populations. Their strategy is to prove they could protect against the B subtype and then, if necessary, make vaccines from other subtypes. Epidemiologist John McNeil of the Walter Reed Army Institute of Research says that when he and his colleagues gave several companies HIV strains from Thailand hoping someone would make a vaccine, "for the first 18 months to 2 years, we basically didn't have anyone who was willing to do anything."

The real race
As story after story like McNeil's piles up, those in the field are discovering that the race for an AIDS vaccine is really a crawl. The Rockefeller Foundation's Seth Berkley, an internist and epidemiologist who organized the Bellagio meeting, says that not long ago, he thought the AIDS vaccine search was on track. "I had assumed—and I feel like a fool to say this—that the vaccine effort was taken care of and that everything was going great. But as I began to look at it closely, I saw that the vaccine effort was in trouble. And the situation was getting worse, not better, in terms of incentives for industry and the attention paid to the developing world."

To address those problems, the Bellagio report calls for a global HIV vaccine initiative. Though the report doesn't detail what the initiative would look like, it floats several ideas, including a task force, a consortium, or a nonprofit institute. Berkley says his next steps are to develop a scientific plan laying out specific gaps and a business plan with estimated costs. "More has to be done," says José Esparza, who heads AIDS vaccine development at WHO. "If we maintain the present level of effort, we're not going to have a vaccine in a reasonable amount of time." And that could be a disaster, because the one thing AIDS vaccine developers are truly racing against is time.

-Jon Cohen
It takes two people to have sex, but only one to slow the spread of sexually transmitted diseases and acquired immunodeficiency syndrome (AIDS). A man can use condoms, but a woman's choices are limited. The most glaring gap in AIDS prevention is the lack of a method a woman can use when she suspects her partner may have a sexually transmitted disease or human immunodeficiency virus (HIV) infection and she cannot compel him to use a condom.

The paper by Weir et al. on a reduction in cervical gonorrhea among sex workers (prostitutes) in Cameroon using nonoxynol-9 and the letter by Feldblum and Weir reporting a protective effect of nonoxynol-9 against HIV infection are important steps forward. It is to be hoped that such publications will lead to more aggressive research strategies.

Nothing is being done in this field today that was not clearly understood and advocated by some people in the mid-1980s. The primary question has always been, Can an acceptable, effective, and potentially cheap microbicidal agent be developed for vaginal use that will kill HIV but not damage the epithelium of the reproductive tract of either partner?

The risks of sexually transmitted diseases and AIDS are cruelly stacked against women. Sexually transmitted diseases present fewer symptoms but carry more long-term sequelae in women than in men; sexually transmitted diseases and HIV pass more easily from men to women than vice versa, so even though the average man has more sexual partners than most women, women acquire HIV at an earlier mean age than men; and women can pass sexually acquired infections and HIV to the next generation during pregnancy, delivery, or breast feeding. Sexual injustice and violence against women are common, and sexually transmitted diseases and AIDS spread most rapidly where women are most disadvantaged: among prostitutes it is those who charge most who are most likely to get infected. The female condom is a welcome new choice for women that should slow HIV transmission, but it cannot be used without the man's knowledge.

Chemical methods that can be controlled by women are likely to have a powerful effect on the spread of HIV for several reasons. They could be distributed rapidly and cheaply by well understood social marketing techniques. They have the potential to slow HIV transmission directly and to reduce other sexually transmitted diseases that are cofactors in transmission. Women make a heavier investment in reproduction than men and therefore are often more cautious in their reproductive behavior: in Rwanda, three-quarters of women with whom AIDS prevention was discussed chose a method they could control alone.

It has been suggested that a vaginal microbicide might be less effective than condoms but so simple to use that some couples would stop using condoms and consequently expose themselves to a greater risk of HIV infection. One US study, however, found that women who used spermicides or a diaphragm had a lower sexually transmitted disease reinfection rate than those whose partners used a condom, suggesting that compliance may be more important than effectiveness in slowing transmission. Simple analysis demonstrates that unless very implausible variables are put into models of HIV transmission, the addition of a woman-controlled method will have a welcome positive impact on slowing the spread of infection. The consistent experience of family planning is that contraceptive prevalence is most likely to reach useful levels when many methods are available through a variety of channels, and the same generalization seems likely to apply to sexually transmitted diseases and HIV prevention.

Sadly, the global AIDS pandemic has often been associated with poor decision making and political cowardice, and the scientific community has stumbled several times on the path toward vaginal microbicidal agents. Rosenberg and colleagues provided clinical evidence in 1987 that nonoxynol-9 in a vaginal sponge slowed the transmission of gonorrhea and chlamydia among Thai sex workers. When a similar study was conducted among women sex workers exposed to HIV in Kenya, however, an increased risk of genital ulcers and possibly of HIV transmission was observed. Although it was a small study with a limited design (only case subjects used the intravaginal sponge, the vehicle for treatment), the study was convincing enough to stop policymakers from recommending the sponge as a prophylactic; however, it also seems to have slowed research in this field when in fact it should have accelerated it. Most drugs are toxic in high doses, and the sponge used in Kenya contained 10 times as much nonoxynol-9 as the suppository used in Cameroon. Frequent repeated use of high doses of nonoxynol-9 is associated with signs of damage to the vaginal epithelium.

In the Cameroonian study, 303 sex workers were counseled to use suppositories containing 100 mg of nonoxynol-9 and to ask their partners to use condoms every time they had sex. The results were analyzed according to self-reported use of both methods, condoms or spermicides alone, or nothing at all. Few gonococcal infections occurred in the group that used both methods consistently, and for every 1% increase in the use of condoms or spermicides alone the risk of gonorrhea was reduced. The effectiveness of nonoxynol-9 in low doses is encouraging. Feldblum and Weir's reanalysis of previous data from Cameroon is the strongest evidence to date that nonoxynol-9 can deter HIV transmission; it suggests that the Kenyan study was misleading because the high doses used damaged the genital epithelium, increasing the risk of HIV acquisition.

Many chemical entities kill HIV in vitro. A recent paper draws attention to a new entity, gramicidin, that is 1000 times as effective as nonoxynol-9 against HIV. The vaginal pH and the buffering capacity of the product are important variables that must be taken into account in determining the survival of the virus. In addition to nonoxynol-9, chlorhexidine, benzylkonium chloride gossypol, and even dextran sulfate are effective in vitro and have regulatory approval for use in humans. It would be prudent to conduct a coordinated program of international research on more than one product and formulation. Focus groups could be used to test the acceptability of delivery vehicles (pessaries, films, foams, etc.) among both sex workers and women in domestic sexual partnerships. Acceptable formula-
tions should then be tested at a number of concentrations, initially in female volunteers not exposed to the risk of sexually transmitted diseases or HIV, to screen for evidence of damage to the vaginal epithelium in the way pioneered by Roddy et al.13

Short-term policymaking and careful analysis of the next steps in research must be set in the framework of the continued exponential growth of HIV infection in many parts of the world. Even in the United States, HIV-infected women are among the most rapidly growing groups affected by the disease.17 Globally, the largest number of cases are the result of heterosexual transmission. By the turn of the century, it is projected that HIV will infect more people than died as combatants and civilians in World War II. From a public health perspective, a modest reduction in HIV transmission brought about by a vaginal microicide made available today might save as many lives as a more effective method (e.g., a vaccine) made available in 10 years' time, when there might be 5 or 10 times as many infected people.

Should a vaginal microicide be marketed on the basis of in vitro effectiveness against HIV and evidence that it does not damage the epithelium, or should new and existing compounds be withheld until convincing clinical trial data on their effectiveness are available? Specifically, should 100-mg nonoxynol-9 suppositories (which are approved by the Food and Drug Administration [FDA] and commercially available) now be recommended on the basis of Feldblum and Weir's reanalysis? If not, what data are needed and how will they be obtained?

At the least, just as the FDA has developed an accelerated route for testing AIDS therapies, it should accelerate the review process that will allow the labeling of a vaginal microicide as protection against HIV. Weir et al.'s study is important because it presents an ethically acceptable model for testing the effectiveness of a microicide: either everyone in a population at high risk of HIV infection is counseled to use both condoms and the microicide and then groups are separated and analyzed by self-reported use or everyone is counseled to use condoms and then the microicide and a placebo are allotted randomly. Elias and Heise calculate that a study of a new product that was 70% effective in slowing HIV transmission, when used in a population with a 2% to 3% annual seroconversion of HIV infection, would require a sample of approximately 1000 women.14 In the interests of US women and the global community, it would also be prudent to explore other entities and formulations. It might cost $2 million and take 12 to 24 months to select and develop new entities and perhaps another $2 million and as long again to complete clinical trials.

The National Institutes of Health, the US Agency for International Development, the World Health Organization (WHO), and the Medical Research Council in the United Kingdom have all discussed vaginal microbicides. The WHO Global Program on AIDS has acknowledged the need for research, and the Population Council is giving the topic priority. Nevertheless, an appropriately financed and coordinated research program is not yet in place. Those who control resources should either change their policies to recommend low-dose vaginal preparations on the basis of available data or immediately put in place the money and personnel needed to gather more data so a policy decision could be reached by early 1995.

Many lives might have been saved if such work had been initiated earlier, and the lack of decisive action is unacceptable when for every year we wait there may be twice as many HIV-positive individuals in vulnerable groups.  

Malcolm Potts

The author is with the Department of Social, Community and Behavioral Health Sciences, School of Public Health, University of California, Berkeley.

Requests for reprints should be sent to Malcolm Potts, MB, BCh, PhD, Department of Social, Community and Behavioral Health Sciences, School of Public Health, University of California, Berkeley, CA 94720.

References

To: Jim Dorskind
From: Julie Demeo
Re: Letter to Coordinate
Date: October 11, 1995

Carol would like a letter from the President to be sent to the six people listed in the attached document.

These six people were original appointees to the Arkansas Early Childhood Commission by Governor Clinton in 1989, when Governor Clinton first created the Commission. According to Carol, this is a Commission that Bill Clinton worked hard to create and cares about a great deal.

Carol would like a letter of thanks to go to each Commission member listed, since their terms have expired. The letter should:

* Thank them for their years of service and dedication
* Mention the fact that Bill Clinton created this commission and they were original appointees.
* Thank them for their support for the program and for their assistance in developing the early childhood services throughout the state.

Thank you!
THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY

CAROL H. RASCO
Assistant to the President for Domestic Policy

To: Julie

Draft response for POTUS and forward to CHR by: ____________________________

Draft response for CHR by: ____________________________

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

Please advise by: ____________________________

Let's discuss: ____________________________

For your information: ____________________________

Reply using form code: ____________________________

File: ____________________________

Send copy to (original to CHR): ____________________________

Schedule ? : □ Accept □ Pending □ Regret

Designee to attend: ____________________________

Remarks: Please coordinate with ____________________________

Jim Bosshard

Thanks.
<table>
<thead>
<tr>
<th>DOCUMENT NO. AND TYPE</th>
<th>SUBJECT/TITLE</th>
<th>DATE</th>
<th>RESTRICTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>001. memo</td>
<td>Glenda Bean to Rasco re Early Childhood Commission/expanded terms (partial)</td>
<td>10/02/1995</td>
<td>P6/b(6)</td>
</tr>
</tbody>
</table>

**COLLECTION:**
- Clinton Presidential Records
- Domestic Policy Council
- Carol Rasco (Miscellaneous)
- OA/Box Number: 7237

**FOLDER TITLE:**

**RESTRICION 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(5) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(5) of the FOIA]
  - b(6) 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].
MEMORANDUM

TO: Carol Rasco
FROM: Glenda Bean
DATE: October 2, 1995
RE: Early Childhood Commission/expired terms

We have a group of Commissioners whose terms have expired. All of these Commissioners were original appointees in 1989 to the Commission. I wanted to inform you of this in case you wanted to send a letter from the President thanking them for these years of service. They have been faithful supporters of the program and have assisted us in developing the early childhood services throughout the state. We will be recognizing them at the Commission meeting on November 21, 1995 and the letters can either be presented to them at that time or they can be directly mailed to their homes. Thanks for your consideration.

Phyllis Perry Brents
Linda Harris
Barbara Meadows
Dr. Bettye Caldwell
Center for Applied Research & Evaluation
Arkansas Children’s Hospital
800 Marshall St.
Little Rock, AR 72202-3591

Cheryl Stuart
P.O. Box 875
Lewisville, AR 71845

(also retired from DCFS)

Arkansas Early Childhood Commission
101 East Capitol, Suite 106
Little Rock, Arkansas 72201
(501) 682-4891 Fax (501) 682-4897
To

Date 10/10  Time 11:50

WHILE YOU WERE OUT
M. Leon Kolenkiewics
of Carrying Capacity Network

Phone (202) 296-4548

<table>
<thead>
<tr>
<th>Area Code</th>
<th>Number</th>
<th>Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>TELEPHONED</td>
<td>PLEASE CALL</td>
<td></td>
</tr>
<tr>
<td>CALLED TO SEE YOU</td>
<td>WILL CALL AGAIN</td>
<td></td>
</tr>
<tr>
<td>WANTS TO SEE YOU</td>
<td>URGENT</td>
<td></td>
</tr>
<tr>
<td>RETURNED YOUR CALL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Message

Sean letter on Oct. 6 requesting meeting w/ POTUS.

Operator
Draft response for POTUS and forward to CHR by: [Signature]

Draft response for CHR by:

Please reply directly to the writer.

(copy to CHR) by: [Signature]

Please advise by:

Let's discuss:

For your information:

Reply using form code:

File:

Send copy to original to CHR: [Signature]

Schedule?: □ Accept □ Pending □ Regret

Designer to attend:

Remarks:

---

Monique A. Miller
Executive Director

2000 P Street, N.W., Suite #240
Washington, D.C. 20036
(202) 296-4549
FAX (202) 296-4809
Toll Free (800) 466-4866
e-mail: ccm@igc.apc.org
October 6, 1995

Ms. Carol H. Rasco
Assistant to the President
for Domestic Policy
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Ms. Rasco:

As you may be aware, Carrying Capacity Network has long been concerned with problems caused by population growth and, in particular, problems caused by current levels of mass immigration into the United States. You may also be familiar with the authoritative work on immigration which we published last year, "The Immigration Briefing Book." This book has become a widely relied-on source for information about immigration from a variety of perspectives.

In response to the expression of increasing concern by Americans in general and by minorities in particular that current levels of immigration are far too high, Carrying Capacity Network has decided to sponsor the Diversity Coalition for an Immigration Moratorium. As you can see from the attached letterhead, this Coalition has support from a broad range of notable Americans and more individuals and organizations are signing on everyday. The list includes an immigrant Nobel Laureate and minority leaders from all major racial and ethnic groups.

Members of the Board of Advisors Diversity Coalition will be in Washington, D.C. beginning Thursday morning, October 12 for a news conference on Capitol Hill. They will remain in Washington through Friday afternoon, October 13, 1995 to meet with members of Congress. We very much hope that this group of distinguished minority Americans will also be able to secure an appointment to meet with President Clinton to express their concerns and demonstrate the broad support for immigration reduction among minorities and other Americans. Please
contact me regarding a possible appointment with the President as soon as you can.

Thank you very much for your consideration of this matter.

Sincerely,

Monique A. Miller
Executive Director

encl.: Letter to President Clinton
   The Diversity Coalition for an Immigration Moratorium
October 6, 1995

President Bill Clinton
The White House
Washington, D.C. 20500

Attn: Scheduling Officer

RE: The Diversity Coalition for an Immigration Moratorium -- Request for an Appointment

Dear Mr. President:

I am writing to respectfully request a meeting with you to introduce to you members of The Diversity Coalition for an Immigration Moratorium. The Diversity Coalition for an Immigration Moratorium counts among its members an immigrant Nobel Laureate, minority and immigrant leaders including activists and university professors, national minority organizations, and other Americans of diverse racial and political backgrounds from across the country.

The Diversity Coalition has requested that you, together with Congress, adopt an immediate five-year moratorium with an all-inclusive ceiling of 100,000 per year on legal immigration, followed by a long-term cap set at a sustainable level. The Coalition's position reflects the opinion of a majority of Americans, including a large majority of Hispanics, that a reduction in immigration is necessary. The initial moratorium would give us a chance to address existing social and economic problems in the United States. It would also allow time to develop a national policy which will set an immigration level consistent with the national interest while at the same time streamlining deportation and asylum proceedings and enforcing immigration laws to drastically reduce illegal immigration.

The Coalition is concerned that legal immigration levels of almost one million per year, the highest in U.S. history, have had a disproportionate, and in some cases devastating, impact on American minorities. African-Americans and Hispanic-Americans, in particular, are concentrated in inner cities and low-skill occupations, precisely those areas most adversely affected by the arrival of unprecedented numbers of
The Diversity Coalition brings together ethnically and racially diverse groups and individuals who share a common interest in reducing immigration into the United States to a sustainable level.

National Board of Advisors*

Jagdeep S. Bhandari, Ph.D.
Duquesne University

Nicolaas Bloembergen, Ph.D.
Nobel Laureate
Harvard University

Jim Brady
State Chair, United We Stand America-Wyoming

James Coleman
Former member,
Black Education Commission,
L.A. School District

Maria Hsia Chang, Ph.D.
University of Nevada, Reno

Benny Chien
Former President, Californians for Population Stabilization

Susan Croyer

Cherokee Nation

Jim Brady
State Chair, United We Stand America-Wyoming

James Coleman
Former member,
Black Education Commission,
L.A. School District

Maria Hsia Chang, Ph.D.
University of Nevada, Reno

Benny Chien
Former President, Californians for Population Stabilization

Susan Croyer

Cherokee Nation

Robert Doore
Blackfeet Tribe

Jesse Laguna
Sponsor, Proposition 187

Dennis Lambert
Chippewa Tribe

Vishwas More
Member, Board of Governors,
California Community Colleges

Angie Morfin
Founder, Latino American Coalition for Immigration Control

Frank L. Morris, Ph.D.
Dean of Graduate Studies and Research, Morgan State
University

Willis Papillion
Board Member, California Black Republican Council

Billy E. Reed
President, American Engineering Association

Wilfredo Torres
Director, Comité Contra La Migration, Extranjera A Puerto Rico

Leea Whitefeather
Founder, Washington Citizens for Immigration Control

Gil Wong
Chairman, Asian Americans for Border Control

S. Miles Woods, Ph.D.
Retired Professor Emeritus, Chemistry

*Partial listing; affiliations for identification purposes only

The Diversity Coalition for an Immigration Moratorium

Yeh Ling-Ling
Coalition Representative
Phone: 510-376-4766

P.O. Box 1991
Orinda, CA 94563
Fax: 510-631-9757

THE DIVERSITY COALITION FOR AN IMMIGRATION MORATORIUM

MISSION STATEMENT

The Diversity Coalition for an Immigration Moratorium brings together many groups and individuals whose activities and backgrounds may be diverse, but who share a common interest in reducing immigration into the United States to a sustainable level. High levels of immigration have adverse effects on all citizens, but minorities, the poor and disadvantaged in particular bear a disproportionate burden. Therefore, our mutually shared objective is to substantially reduce high levels of legal immigration.

The approximately one million legal immigrants entering the United States each year compete directly with minorities and other citizens and legal residents for jobs, education and other opportunities, thus undermining efforts by the poor, homeless and unemployed to improve their status and prospects. Multi-billion dollar annual costs and other burdens are also incurred at all levels of government because of such large-scale immigration. The results are disadvantageous for both the new arrivals and those already here, and the consequences of excess immigration will only worsen unless action is taken now.

Therefore, Congress and the President should adopt an:

1. Immediate Five-Year Moratorium on Immigration

This moratorium would allow time to develop a national policy which will reduce immigration to a sustainable level as soon as possible as well as to streamline deportation and asylum proceedings, and enforce immigration laws to drastically reduce illegal immigration. During the moratorium, a maximum of 100,000 foreign nationals would be granted lawful permanent residence in the U.S. per year. Entry would be restricted to spouses and unmarried minor children of U.S. citizens, and include some refugees and asylees -- all under the all-inclusive 100,000 annual ceiling.
2. **Long-term Ceiling on Legal Immigration**

During the five-year moratorium period, the government should develop and adopt a responsible long-term immigration policy. That is, the policy should take into consideration our economic needs, our labor market conditions, our resource availability, and the public costs of providing infrastructure to newcomers.

Members of The Diversity Coalition for an Immigration Moratorium are committed to working together toward implementation of these policy goals at the earliest possible date.

1. The Diversity Coalition for an Immigration Moratorium was established as an affiliate of Carrying Capacity Network to provide an effective voice for our diverse community regarding immigration issues, in response to the fact that polls show a majority of the members of all major ethnic groups favor reduced immigration.

2. Legal immigration includes all foreign nationals granted permanent residence -- family-based, employment-based, refugees, asylees, and all legal permanent residents.
CLINTON’S COCAINE BABIES

Why Won’t the Administration Let Us Save Our Children?

CHARLES MOLONY CONDON

Nothing could be more heart-breaking than the sight of a baby born with an addiction to cocaine. There is very little doctors and nurses can do to ease the pain of these innocent newborns, whose mothers’ use of hard, illegal drugs during pregnancy constitutes nothing less than blatant child abuse.

Walk into the neonatal unit of any hospital in America, and you will see crack-cocaine babies. Some cry and shake uncontrollably. They refuse to take food. Many die.

And those who survive are far more likely than other children to be sentenced to lives of behavioral problems, birth defects, and learning disabilities.

Nationwide, one in 10 children born has been exposed to cocaine in the womb. This condition affects 350,000 babies a year. Our society can address this problem effectively. We can significantly reduce this type of child abuse. Unfortunately, the policy of the Clinton administration is to protect, not the children, but the “rights” of the mothers to escape the consequences of their actions.

Several years ago, when I was serving as a circuit solicitor in South Carolina, I became aware of the growing problem of crack-cocaine babies at Charleston’s Medical University of South Carolina (MUSC). My office worked with the hospital to aggressively confront pregnant women with the consequences of their drug use. Over a five-year period, we presented all pregnant mothers who tested positive for cocaine use with a choice: Either seek drug treatment or face arrest and jail time.

This became one of the first “crack-baby” intervention programs in the nation. And the program worked. Scores of women agreed to enter rehabilitation and stayed off drugs for the remainder of their pregnancies. Before-and-after statistics present a clear picture. Before the sanctions took effect, 24 pregnant mothers a month tested positive for cocaine. Virtually none of them was willing to seek help voluntarily. Then, beginning in 1989, when we launched a tough amnesty program, the number testing positive for cocaine dropped to five or six a month. Prenatal visits as well as live births at the hospital stayed the same. Other states were looking at our success as a model.

Tragically, the cocaine-baby program, which was clearly saving lives, was effectively shut down by the Clinton administration. Under the president’s direction, a swarm of federal officials came to Charleston making unfounded allegations of discrimination and accusing the hospital of violating the “privacy rights” of the addicted mothers. The Clinton administration warned us that a private civil-rights suit was pending, and threatened to cut off $54 million in federal assistance, or about 60 percent of the facility’s annual budget. Last year, the hospital finally relented, ending the successful intervention program.

Now, once again, the babies cry out in agony. And once again, hospital staff with no legal recourse must watch pregnant women knowingly cause neurological damage to their unborn children. MUSC nurse Shirley Brown expressed the frustration eloquently: “You just have to sit around with your hands tied and watch them destroy a baby.” Indeed she is right. If this is what President Clinton has in mind when he calls for a return to individual and community responsibility, then this administration faces a profound moral crisis.

Administration officials and representatives of the American Civil Liberties Union (ACLU) called the cocaine-baby program punitive, discriminatory, and invasive. In fact, it was none of the above.

By the late 1980s, nurse Brown and her staff noticed an increasing number of pregnant women coming to the hospital—not for prenatal care, but because of hemor-
quickly agreed to enter the program once they saw we were serious. Only two continued to refuse help, and they were ultimately placed on probation. The cocaine-baby program was not a punitive "lock-up" program, but an amnesty program. And it was working.

Also, there is absolutely no evidence that it scared anyone away from prenatal care. Remember, very few of these women came to the hospital in the first place to take advantage of prenatal services. They came because of urgent medical problems related either to their pregnancy or to their addiction.

Opponents of our cocaine-baby program continually failed to understand that prosecutorial action, like a thermostat, can be constantly adjusted. Charges can be dropped at any time. We can add conditions. The system has a great deal of flexibility that can be used to motivate irresponsible people to take responsible action. Many public defenders (though they are not likely to admit it publicly) thought the cocaine-baby program was a great idea.

**THE SPECTER OF DISCRIMINATION**

Cocaine addicts need a strong motive to mend their ways. And most drug and law-enforcement officials also agree. A federally funded research survey showed that about 30 percent of those who enter public drug-treatment programs do so only because of direct or indirect legal pressure. The Office of National Drug Control Policy noted in a 1992 report that "the criminal justice system can steer offenders toward drug treatment as a condition for deferred prosecution."

The Clinton administration, however, seemed utterly unconcerned with common sense or practical solutions to a problem that is literally destroying the lives of adults and infants. Within a matter of weeks, HHS also sent investigators from its Office of Civil Rights. They alleged that the program was discriminatory toward blacks. Marie Chretien, a regional manager in the Office of Civil Rights, claimed in a letter to the hospital that its substance-abuse policy "may result in an adverse disproportionate impact on African-American women."

It is true that most of the women treated were black. The hospital serves a primarily indigent population, and most of the patient population is black. The South Carolina Drug Prevalence Study showed blacks were more likely to use cocaine than whites.

"Ask Police Chief Greenberg, who is also African American, if this policy was discriminatory. He would be among the first to tell you that cocaine use is much more common in South Carolina among blacks than whites—and that the black community was benefiting most from the prenatal program. "[The program's opponents] don't care about the race issue. They're just using this as a tactic," Greenberg says. "I was glad that somebody was finally doing something to help kids in the black community. It was giving kids a chance who otherwise would not have anything close to an equal playing field. At least at the point of birth, that child ought to be given the best opportunity for a full and productive life."

In spite of all this, the HHS civil-rights office threatened in a letter last June to cut off federal money to MUSC unless it backed away from its aggressive treatment program. "It is the government's obligation to ensure that federal funds do not support a program which discriminates," Chretien wrote in the letter. "This obligation entails making a formal determination of whether there is a violation of the Title VI regulation ... and if negotiations for voluntary compliance fail, the initiation of administrative enforcement proceedings to terminate federal financial assistance."

What continues to amaze me, as the state's chief law-enforcement officer, is the groundlessness of the discrimination charge. In October 1993, the liberal, feminist Center for Reproductive Law and Policy asked a federal judge to issue an injunction against the hospital to suspend the drug-testing program. The judge declined, finding no basis for the discrimination charge.

It's no coincidence, by the way, that shortly after the feminist group failed in its lawsuit, investigators from the Clinton administration swooped down on the Medical University. I am convinced their plan was coordinated with HHS officials. So is the hospital. "It was obvious to us there was collusion between the center and all the federal agencies that came down on us," says the university's president, Dr. James Edwards.
but Olarieston Police Oller Reuben Greenberg insists

the program has benefited blacks most of all.

Whether HHS officials would have followed with their own lawsuit is unclear. Almost certainly they could not have won in court. But they didn’t need to. The hospital, dependent on federal funding, never had a chance. HHS agents made an ex parte decision that the program was discriminatory. And so they exercised the federal version of the golden rule—that is, they’ve got the gold, so they make the rules.

The Clinton administration was willing to withhold millions of dollars from the Medical University, stop all of its Medicaid assistance, shut down its children’s hospital and its cancer center, discontinue dozens of medical services from radiation oncology to pediatric surgery, close down its 558 beds, and force the hospital to turn away its patients—all to end a program that offended the liberal sensibilities of Donna Shalala and Bill Clinton. A gun was held to the hospital’s head, and for the protection of all the other patients, the hospital had to agree to give up.

Unfortunately, this saga isn’t over yet. The Office of the Solicitor and virtually everyone else involved in the hospital’s prenatal drug policy is being sued by the Center for Reproductive Freedom on behalf of five women who tested positive for cocaine.

They want $3 million. It’s a complicated suit, but it boils down to a claim that the program violated their right to privacy. In fact, the so-called constitutional right to privacy does not protect the results of a drug screen, especially not in this case.

First of all, you don’t have a right to use crack cocaine: it’s a felony. Second, all of the women knew about the amnesty program—there were public-service announcements about it. The women voluntarily came to the only hospital in the state that sponsored it. They were counseled about the consequences of testing positive, and they all signed consent forms before being screened.

UGLY LESSONS

Medical personnel are held legally accountable for the health of both mother and unborn child throughout the pregnancy. In fact, malpractice insurance exists to support the obligations of primary-care providers in just such cases. If a fetus is damaged by inadequate, mistaken, or negligent medical practice, the hospital would quickly face lawsuits. So how is it that we have no legal means to keep mothers from seriously damaging or destroying their own babies? “If the mother is not going to be held responsible,” says nurse Brown, “then I don’t think any nurse or physician giving obstetrical care should have to be held liable.”

The Clinton administration apparently believes that infants have no rights at all until the umbilical cord is cut. But the U.S. Supreme Court has never said that the states do not have a compelling interest in protecting the health of the unborn in the third trimester when they can live outside the womb. Indeed, case law in South Carolina and elsewhere suggests that society does have certain obligations to the unborn child, certainly at very advanced stages of development. South Carolina courts have interpreted “person” to include a viable fetus.

We put tremendous resources into prosecuting child-abuse cases because of the great damage done to children, and we make no apologies for that. The cocaine-baby program we started in South Carolina was, most of all, a child-abuse prevention program, protecting the smallest and the most innocent of children.

President Clinton and his messengers appear to be fundamentally unconcerned with the hundred of thousands of cocaine-addicted women who stagger into the delivery units of hospitals across the land. The only remedy they offer to the horribly damaged children who result from this madness is to increase the flow of Medicaid dollars, provided by taxpayers, to pay a price so large that it is literally impossible to calculate. And the greatest frustration of all is knowing that this increasingly expensive tragedy can be prevented. One of the most basic responsibilities a mother has is her child. If a mother injected cocaine into the tiny arm of her infant, causing permanent brain damage or death, certainly that mother would be arrested and prosecuted.

Yet that is exactly what addicted mothers do when they consume cocaine throughout their pregnancy. In South Carolina, we tried to do something about it. The program we created was working. Now it is no more. And as long as powerful federal bureaucrats continue to manipulate federal funding to serve a bizarre agenda that is deaf to the cries of damaged babies, there is nothing more we can do.

Why is the Clinton administration stopping us from protecting our children?
rhaging or other acute problems related to their pregnancies. In the course of treatment, many of these women tested positive for drug use, usually cocaine. Thus the program grew out of a deep concern among the hospital staff for the welfare of both mother and child.

At first, the hospital tried to educate the women about the damage they were causing to themselves and to their unborn babies. Sadly, hospital workers could not convince many of the expectant drug-addicted women to enter a drug-treatment program. Most wouldn't even return for any type of prenatal care at all. The women—mostly poor and uneducated—received free counseling. They were offered free drug treatment and free prenatal care, but few participated in the program voluntarily.

At the same time, the delivery and treatment of crack babies was putting a tremendous strain on hospital resources, as well as on the moral sensibilities of hospital personnel. Normal neonatal delivery costs can be as low as $500 per baby, but the costs of cocaine babies and the intense postnatal care they require have increased tremendously. The hospital has seen bills reach $750,000. Most are born to welfare mothers, so Medicaid and the hospital were picking up the bill. According to the General Accounting Office, a single cocaine baby can run up a lifetime tab of $1 million in medical and educational costs.

At the time we launched the cocaine-baby program in Charleston, I was circuit solicitor. Last year, I was elected attorney general for South Carolina, and now view the problem from a statewide perspective. Hospitals across our state see drug-damaged babies with growing frequency. In every major city in the country, hospitals have units devoted to crack mothers and crack babies. But no one dares to forcefully address the causes of the problem. We are merely watching it happen and paying an increasingly high price in dollars and human suffering. We saw an opportunity to make a difference.

**LOCAL SUPPORT**

During the operation of the cocaine-baby program in Charleston, everyone concerned was brought to the table—social workers, people from Charleston County Substance Abuse, drug-rehabilitation specialists, law-enforcement officials, hospital officials, and my office, which was willing to prosecute when necessary. We all agreed on one principle: We needed a program that used not only a carrot, but a real and very firm stick.

Those who argued most forcefully for the cocaine-baby program were people who dealt with drug addiction every day: the rehabilitation specialists. They told us that "unless you have sanctions in place, unless you understand the basic irresponsibility of these drug-addicted women, it won't work."

Working closely with Chief Reuben Greenberg of the Charleston Police Department, we set up an amnesty program with sanctions for those who don't abide by the rules. Whenever a prenatal patient tested positive for drugs, hospital staff first counseled the mother about what she was doing to her unborn baby. They presented her with a letter from the solicitor's office explaining that she faced arrest and prosecution (crack cocaine use is a felony in South Carolina) if she refused treatment. The solicitor's office then promised to drop all charges if the woman successfully completed a drug-treatment program. We saw this as a child-abuse prevention program with a goal of producing a healthy child.

We had solid legal grounds to act in this manner, especially in the third trimester of the pregnancy. During the final trimester, the fetus is regarded as viable, that is, capable of sustaining life on its own, and is therefore granted significant protections under both federal and state law. Indeed, the viable fetus is a person under the law. In this legal context, we offered pregnant women immunity from prosecution, free medical services, and free access to a program of drug rehabilitation. All we asked of them in return was to enter the program in good faith and to stop abusing their unborn children with illegal drugs.

Politically correct resolutions by the American Medical Association and the American Pediatrics Association denounced the policy as punitive and unwise. The National Institutes of Health also sent down some officials, who made the incredible claim that the hospital was conducting coercive experiments on pregnant women. Then the Clinton administration, ideologically driven by the absurd notion that a woman's privacy rights override a mother's most basic responsibility to her own child, would not allow us to protect the lives of the babies or their self-destructive mothers, Donna Shalala, Secretary of Health and Human Services, sent an investigative team from the department's ethics division. One HHS official, without offering any evidence, claimed the program had a "chilling effect on minority pregnant women seeking prenatal health care."

Of course, the cocaine-baby program was not punitive. The program was not designed to put people in jail. It was a humanitarian effort to save lives through tough, decisive action under urgent circumstances. In fact, the women involved in the program almost invariably avoided jail.

Most of the pregnant women who tested positive for crack cocaine (after they understood their options) agreed to enter the drug program. The small number who refused the program were indeed arrested, but nearly all of their cases were dismissed because the women
TO: Kevin Thurm
FAX #: 690-7755

FROM: CAROL H. RASCO

NUMBER OF PAGES (including cover sheet): 5

COMMENTS: Please prepare a memo re: attached by Friday 10/13. Both The President & First Lady have asked Care about it. Thanks. If you have any problems with the fax transmission, please call Julie at (202)456-5565.

The document accompanying this facsimile transmittal sheet is intended only for the use of the individual or entity to whom it is addressed. This message contains information which may be privileged, confidential or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, copying or distribution, or the taking of any action in reliance on the contents of this communication is strictly prohibited.

TRANSMISSION REPORT

THIS DOCUMENT (REDUCED SAMPLE ABOVE) WAS SENT

** COUNT **
# 5

*** SEND ***

<table>
<thead>
<tr>
<th>NO</th>
<th>REMOTE STATION I.D.</th>
<th>START TIME</th>
<th>DURATION</th>
<th>#PAGES</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>96907755</td>
<td>10-11-95</td>
<td>15:08</td>
<td>4:44</td>
<td></td>
</tr>
</tbody>
</table>

TOTAL 0:04.'44" 5  XEROX TELECOPIER 702C
The cocaine baby myth
A study at NCTR challenges assumptions of harm.

BY MARY LEVERIT

If a mother is properly nourished and healthy, but takes cocaine during pregnancy, the drug does not appear to harm her baby unless it's taken in very high amounts. That is the surprising conclusion reached by scientists at the National Center for Toxicological Research, which has been testing the effects of cocaine on pregnant monkeys and their babies.

For humans, the NCTR results undercut popular supposition about the effects of cocaine on so-called "crack babies." While it is clear that many babies born to cocaine users are born small and at high risk for problems, the NCTR project indicates that the smallest cocaine babies do not necessarily suffer a combination of bad health outcomes such as low birth weight and premature birth. Researchers say the smallest cocaine babies appear to be experiencing the same problems seen in human babies who were born premature and/or small for gestational age.

STUDY SUGGESTS:
BABIES' PROBLEMS NOT CAUSED BY COCAINE

who abuse cocaine enter the world at-risk, with severe physiological handicaps, the study suggests that those problems are not caused directly by the cocaine.

It was not the outcome Dr. Merle Paule, the project's director, had expected. "It totally surprised us," he said.

"We've looked at babies being born in cocaine in vitro, and what we're finding is that if the mother is otherwise healthy, as our animals are, the drug doesn't appear that disruptive."

So how to explain the often terrible effects seen in human babies who are born to mothers who've been abusing cocaine, especially premature birth and accompanying low birthweight?

Paule theorizes the problem with humans is that using cocaine leads to other risky behaviors. Pregnant women who use cocaine tend to become indifferent to proper nutrition and prenatal care, while increasing their consumption of alcohol and tobacco—all activities well known for their potential adverse effects on a fetus.

Paule and other researchers now believe it is the cumulative, indirect effect of those behaviors that denies babies a normal development. The chemicals in the cocaine itself, his study suggests, have

When cocaine is withdrawn from the animals, he said, "We do not see any adverse effects." Paule conducted the experiment using Rhesus monkeys, pri­mates whose physiology closely resembles that of humans. Working under funding from the National Institute on Drug Abuse, he began administering daily doses of cocaine to female monkeys, first to see how much of the drug, if any, actually reached the fetus.

Blood tests revealed that about one-third of the cocaine administered to the mother was getting to her baby. "We found," says Paule, "that cocaine virtually sails across the placenta."

Next, Paule divided his test monkeys into three groups: One received a daily high dose of cocaine—the human equivalent of about one-fourth of a gram per day; another was given about a third that amount; and the third, control group, received no cocaine at all.

The scientists wondered whether the monkeys, particularly the ones receiving the high dose, could even carry their pregnancies to term.

All did. More amazingly, none of the babies was born prematurely and all were normal in measurements of reflexes, body length, and head size, a measure which is believed to correspond with brain development.

With subsequent funding, Paule took the experiment further, beginning the administration of cocaine before the monkey says, "But again, we determined that even under this amazing insult, the babies showed no significant decrease in body weight, gestation length, reflexes, or head circumference—anything we could measure."

Only when Paule pushed the doses of cocaine to what he called "high, unusually strident exposure levels" (the human equivalent of up to 1.5 grams per day), did he begin to see negative effects. Babies were born significantly smaller and shorter than normal with smaller-than-normal heads. At those doses, Paule found, "the cocaine was a problem, in and of itself."

As the infants bred in these experiments grew, Paule began studying how they perform. "Most of our efforts now are trying to assess how these animals use their higher

only

breds under these highly specialized conditions, many of them entering the developmentally crucial stage of adolescence, funding to continue the experiment is in doubt, due to federal budget cuts. Paule's task in the study at this point is to find a way to keep it going.

He's optimistic some funding source will be found, mainly because of the tremendous impact cocaine is having on the country, and the number of children being born to users.

Cocaine is now estimated to have been used by about 10 percent of the U.S. population, with about 5 million of that number deemed to be regular users. Besides warning women about the hazards of abusing cocaine, Paule believes his findings can bring
NOTE TO CAROL RASCO

On Monday, October 16, we sent your office a response to the South Carolina Attorney General Charles Condon article on cocaine babies that appeared in the journal *Policy Review*, which accused this Department of shutting down a program designed to help the unborn children of cocaine-addicted pregnant women. The article distorted the role of HHS in ending a policy of referring these women for arrest and prosecution if they refused treatment, and I would like to take this opportunity to highlight our main criticisms of the article.

- The Department is required by law to investigate promptly any complaint of a failure to comply with Title VI of the Civil Rights Act of 1964. The Department did not go in to help pregnant women "escape the consequences of their actions," as the article implies. Rather, after receiving information, through the Center for Reproductive Law and Policy (CRLP) and an article in the *New York Times*, indicating that all or virtually all of the women subjected to arrest and prosecution were African-American, the Department conducted a preliminary review.

- The Medical University of South Carolina's (MUSC) decision to terminate its practice of referring patients for arrest and prosecution was a voluntary agreement offered by the hospital, and did not follow any threats by the Department to cut off federal funding. HHS, as required upon any complaint of discrimination, conducted a fact finding review and gathered preliminary information that indicated a possible violation of Title VI. The Department notified MUSC that we would be initiating a formal investigation to determine whether the policy was administered in a non-discriminatory way. The hospital then offered voluntarily to end the referral process. This offer came prior to further investigation or any final findings.

While an ultimate finding of a violation of Title VI could have led to a termination of federal funding to the hospital, at the time MUSC made its voluntary offer, a long process of findings and steps would still lie ahead before any such decision could be made.

- It is not true, as the article claims, that the Department was "unconcerned" with the health of the pregnant women and their fetuses. In fact, the Department accepted the hospital's voluntary agreement only after consulting with the Public Health Service to ensure that the agreement would not inadvertently restrict or foreclose other aspects of any future drug abuse treatment program. The Department also offered to provide technical assistance in the implementation of MUSC's program to ensure that they were in compliance with Civil Rights laws.

Please do not hesitate to call me if I can be of further assistance.

Kevin Thurm
RESPONSE TO CHARLES CONDON ARTICLE ON COCAINE BABIES

BACKGROUND

This memorandum is in response to your inquiry regarding Charles Molony Condon's article entitled "Clinton's Cocaine Babies", Policy Review 12 (Spring 1995). Mr. Condon's article is a complete distortion of the role that the Department of Health and Human Services' (HHS) took in examining the Medical University of South Carolina (MUSC) Interagency Policy.

On January 21 1994, the New York Times carried a story on a controversial prenatal substance abuse program established by MUSC. Under the MUSC Interagency Policy on Cocaine Abuse During Pregnancy, women who entered the hospital for prenatal care and allegedly fit a certain profile were tested for substance abuse. Women who test positive were referred for drug counseling, and those who failed to attend those sessions, or who subsequently tested positive for drugs were referred for arrest and prosecution. Allegations were raised that the program was discriminatory in its adoption and implementation, that it was violating human subjects research requirements, and that the confidentiality of patients was being violated. In response to these allegations, the Secretary asked the Inspector General to coordinate an HHS inquiry. A three-part investigation was conducted by the Office of Inspector General (IG), the Office for Civil Rights (OCR) and the National Institute of Health's (NIH) Office for Protection from Research Risks (OPRR). This memorandum focuses on the OCR investigation which resulted in an agreement whereby the MUSC discontinued the portion of its policy referring women for arrest and prosecution. For further discussion of the OPRR and IG investigations regarding the Interagency Policy and for a summary of the Center for Law and Reproductive Policy's private suit, please see attachment A.

OCR INVESTIGATION OF MUSC

OCR's investigation was one part of a three-part examination of the MUSC Interagency Policy. As stated above, the policy provided that MUSC staff would identify from among patients presenting at the hospital for prenatal and obstetrical services those suspected of engaging in illegal drug use. Those patients who tested positive for drug use were referred for drug treatment. Those who failed to complete treatment or who subsequently tested positive for drugs were referred to law enforcement officials for arrest and prosecution.

In early 1994, OCR received information indicating that the implementation of the MUSC Interagency Policy had resulted in a situation in which all or virtually all of the women subjected to arrest and prosecution were African American. The information included allegations in a suit filed by the Center for Reproductive Law and Policy in October 1993, which challenged the Interagency Policy on a variety of grounds, including a claim that its adoption
and implementation were racially discriminatory in violation of the 14th Amendment's Equal Protection Clause.

The HHS regulations implementing Title VI of the Civil Rights Act of 1964 (Title VI) provide that OCR will make a prompt investigation whenever a compliance review, report, complaint or any other information indicates a possible failure to comply with these regulations.

In February 1994, OCR conducted a fact finding review to gather information regarding the Interagency Policy to determine if it violated Title VI. By letter dated April 7, 1994, OCR notified MUSC that the preliminary information gathered indicated a possible violation of Title VI and that OCR was initiating a formal investigation to determine if the policy was administered in a nondiscriminatory manner, particularly with respect to the referral of patients to law enforcement officials for arrest and prosecution.

MUSC responded to OCR's April 7 letter by offering to refrain voluntarily from referring patients for arrest and prosecution. It is important to note that at this time, OCR had not completed its investigation, nor had it made any final findings. However, the policy underlying Title VI emphasizes that voluntary compliance is to be preferred to termination of federal funds, and informal resolution is to be preferred to formal enforcement. Consistent with this policy and to conserve its own resources and those of recipients of federal funds, OCR routinely enters into agreements to resolve investigations informally on the basis of offers by recipients to change policies in a way that will obviate the need for further investigation.

MUSC as an agency of the government of South Carolina had legal representation, and attorneys for the state were involved throughout OCR's investigation. There was no basis for OCR to believe that MUSC's offer was anything other than a voluntary good faith offer to resolve the matter informally. Accordingly, after consulting with the Public Health Service to ensure that the agreement would not inadvertently restrict or foreclose other aspects of any future drug abuse treatment program, OCR accepted MUSC's offer. Effective September 8, 1994, OCR and MUSC entered into an agreement, whereby OCR ended its investigation based on MUSC's agreement to discontinue the referral for arrest and prosecution portion of the policy. OCR reserved the right to investigate at a later date any Title VI issues left unresolved by the private litigation. The litigation is still pending at this time.

At no time did OCR seek to preclude MUSC from proceeding with their efforts to refer patients for drug treatment. In fact, OCR offered to provide technical assistance in the implementation of their program to ensure that MUSC was in compliance with Title VI. OCR's
sole concern was that the program be operated in a nondiscriminatory manner.

MUSC and Attorney General Charles Molony Condon have subsequently indicated that the imminent threat of termination of federal funds forced MUSC's decision to drop the referral for arrest and prosecution portion of the Interagency Policy. This hardly seems credible. Termination of federal funds could not have taken place until: MUSC had been advised of an actual failure to comply with Title VI, and it had been determined that voluntary compliance was not possible; there had been a finding on the record after opportunity for administrative hearing of a failure to comply; and, there had been appropriate notice to the relevant committees of the Congress. MUSC could also appeal findings to the courts, and it would have the option of coming into voluntary compliance at any time during any of these proceedings. All these requirements are stated in Title VI and its implementing regulations and were presumably known to MUSC at the time it made its offer to OCR. Since its establishment as a separate Department in 1980, HHS has never been required to terminate funds to a recipient on the basis of Title VI.

MUSC, however, may have had other reasons for dropping the most controversial aspect of the Interagency Policy. These reasons may include the following:

- Certain activities conducted under the Interagency Policy were subsequently determined by the National Institute of Health's (NIH) Office for Protection from Research Risks (OPRR) to have constituted human subject research (see attachment A). The research failed to comply with HHS regulations regarding experimentation on human subjects.

- The use of the coercive power of the criminal laws to address drug related issues of maternal and child health has been opposed by leading public health groups, including the American Medical Association, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American public Health Association, the Southern Regional Project on Infant Mortality (an initiative of the Southern Governors' Association and the Southern Legislative Conference), the American Society on addiction Medicine, the March of Dimes, the National Association for Perinatal Addiction Research and Education, the National Council on Alcoholism and Drug Dependence, the Association of Maternal and Child Health Programs, Coalition on Alcohol and Drug Dependent Women and their Children, and the staff of the Center for the Future of Children. Thus, MUSC may have been anticipating major criticism of this aspect of its policy.

- MUSC may also have been concerned about alleged gaps between its stated policy and its actual practices. The
Center for Reproductive Law and Policy has alleged that MUSC's practices were more coercive in practice than the Interagency Policy would formally suggest.

- MUSC may have been concerned about the quality of its research design, the adequacy of informed consent, and the availability of suitable drug treatment programs. These were issues that surfaced as a result of examination and criticism of its program.

- MUSC may have been concerned that the OCR investigation would have determined that the policy in its implementation was discriminatory.

In any event, OCR did not concern itself with any of these points except the last. OCR's investigation was not premised on any policy position regarding the validity of testing pregnant women, but only as to whether the procedures were carried out in a nondiscriminatory manner. At no point did OCR seek to intimidate MUSC by threatening to terminate funds into relinquishing its rights to have OCR make a determination whether its actions were discriminatory and to contest that determination if it went against them. Indeed, given the safeguards built into Title VI, MUSC could not have reasonably concluded that any such attempt would be successful. Instead, OCR accepted what it understood to be the voluntary good faith offer of MUSC to resolve the matter informally and agreed not to take further action.

As indicated previously, OCR did not concern itself with matters that were not strictly relevant to its inquiry regarding possible discrimination in the MUSC program. However, this memorandum would not be complete without noting that the Charles Condon article that gave rise to concerns about the HHS and OCR role in the matter not only distorts the HHS role but presents, at best, a very one-sided account of a variety of issues related to the MUSC policy. Accordingly, we have provided as attachment B a copy of the response of the Center for Reproductive Law and Policy to Mr. Condon's article. While we do not necessarily agree with every aspect of this response, we believe it provides important information about other sides of the issues raised by this controversy.
The National Institute of Health's (NIH) Office for Protection for Research Risks (OPRR) reviewed MUSC's Interagency Policy for adherence to Federal rules pertaining to experimentation with human subjects. In accordance with their compliance oversight procedures, OPRR requested and received from MUSC its response to charges that the University violated Federal human subjects protections. The University argued that its prenatal substance abuse policy is not research at all, but simply a treatment program, and as such, is not subject to the NIH rules. OPRR enlisted the aid of expert consultants to determine whether the Interagency Policy is subject to and in compliance with the human subjects rules.

OPRR issued a finding on September 30, 1994. OPRR determined that certain activities related to the Interagency Policy constituted human subject research under HHS regulations at 45 CFR 46.102(d), (f).

In particular, OPRR found that the report authored by MUSC personnel and published in The Journal of the South Carolina Medical Association (Horger, Brown, & Condon, 1990, 527-531) at a minimum, reflected retrospective human subjects research. It was OPRR's determination that this research should have been submitted to the MUSC Institutional Review Board for prior review and approval.

The authors characterized the above referenced report as "preliminary" and announced their intention to report further "after 12 months' data collection" (Horger et al, 1990, page 531). OPRR found that, from the time at which the authors formed this intention, the activity constituted prospective human subjects research.

OPRR found that the failure by MUSC personnel to submit these activities for prior IRB review and approval constituted serious failure to comply with the requirements of HHS regulations and the MUSC assurance of compliance with the regulations.

OPRR placed a restriction on MUSC under which corrective actions are required to ensure adequate protections for human subjects in MUSC research.
The Office of Inspector General

Confidentiality of Substance Abuse Records

Federally-assisted substance abuse treatment centers are prohibited from disclosing patient treatment records unless the patient consents or the statute or implementing regulations otherwise provide for the disclosure (42 U.S.C. § 290dd-2; 42 CFR Part 2). Patient consent must be in writing, and contain various elements, including the identity of the organization or individual to whom the disclosure is made, the purpose of the disclosure, and a description of the information to be released. When appropriate, information may be disclosed to officials within the criminal justice system who have made participation in the substance abuse treatment program a condition of the disposition of criminal proceedings against the patient. In this regard, the HHS regulations specify that appropriate disclosure might be made to "a prosecuting attorney who is withholding charges against the patient." (42 CFR § 2.35 (a) (1)). Again, however, such disclosures require written consent of the patient.

The Office of Investigations within the Office of Inspector General contacted the three substance abuse treatment centers to which patients were referred under MUSC's Interagency Policy, and requested that the centers to verify that any disclosures of patient records to law enforcement authorities under the program were consistent with the above confidentiality rules. The Inspector General's office's review of the centers' responses indicated that the treatment centers were mindful of applicable confidentiality rules, and that they were abiding by them. Accordingly, no investigation of this matter was opened.
MEMORANDUM

TO: All Interested Parties
FROM: Lynn M. Paltrow
DATE: May 5, 1995

MISINFORMATION ABOUT THE SOUTH CAROLINA POLICY

Over a five-year period, we presented all pregnant mothers who tested positive for cocaine use with a choice: Either seek drug treatment or face arrest and jail time.

Under the Policy as initially conceived and implemented, women who tested positive for cocaine while pregnant were arrested and taken to jail. These women were not given the option of seeking drug treatment. Instead, they were arrested and jailed while they were still pregnant even though no prenatal care or drug treatment was available in jail. When they went into labor, they were brought to the hospital in shackles. One of our clients was handcuffed to her bed during the entire time she was in labor. After giving birth, she was returned to jail without her newborn. Other women were taken out of their hospital beds days or even hours after delivery, arrested, handcuffed and taken to filthy jail cells where they awaited disposition of their cases. One woman in jail was told to sit on a towel because she was still bleeding after giving birth.

As one woman explained:

Not too long after Hurricane Hugo, in late September or early October 1989, I began experiencing premature labor pains. At that time I was about seven or eight months along in my pregnancy. I went to Medical University, where I was admitted. I was given drugs to control the premature labor pains, and was told I would have to stay overnight. The next day, Nurse Shirley Brown came into my room.

I had never met her before. She told me that I was going home soon. Then she began asking me various questions like most social workers. When she asked about any problems I might have, I confided in her that I had a problem with drug use. She told me to get dressed, and left the room.
The next time the door opened, it was a couple of police officers, in uniform,
telling me that I was under arrest, and reading me my rights. I was totally
shocked, and didn’t understand why I was being arrested.

The officers put handcuffs on me, and had me sit in a wheelchair. One officer
put his jacket over my hands to hide the handcuffs, but then I was wheeled out
through the hospital with several officers in uniform. Everyone we passed was
staring at me – this pregnant woman being escorted out of the hospital by all
these officers. I wasn’t allowed to make any phone calls, and didn’t know
what I was being arrested for. I was taken to the county jail and kept in a
holding cell until my bond hearing later that day.

At my bond hearing, I finally found out that I was arrested for distributing
drugs to a minor. Even though it was my first arrest ever, the judge refused
to release me on my own recognizance and set bail for $180,000. Because I
could not make such a high bail, I was returned to the county jail, issued a jail
uniform, and placed in a cell.

Each week, I was transported from the jail in handcuffs and leg shackles to
Medical for my prenatal care appointments. It was very embarrassing to be
seen in public this way. I learned later that news of my arrest had been on the
front page of our local newspaper. I was totally embarrassed. Once, when I
was at the clinic for my appointment, a nurse asked the jail officer if my
shackles could be removed, but otherwise I was always in handcuffs and
shackles even at the doctor’s.

Almost three weeks after I was first arrested, I went into labor. I was again
transported in handcuffs and leg shackles to Medical. I went through all my
labor and delivery handcuffed to the bed. For the two days I was in labor, I
couldn’t get up and walk around, or change positions, or really do anything to
make it easier on me. After two days, the doctors performed a cesarian
section. My little girl was born healthy and has remained so. She is now five
and a half years old, and is doing well in school.

At some point, the Policy was revised so that some women were told that they would
not be arrested if they did what they were told. It appears that in practice they were arrested
if they did not comply with the wishes of one particular nurse, Shirley Brown. Nurse Brown
has no specialized training in addiction medicine, but was empowered by the Policy to give
an ultimatum: either stop using drugs immediately and go to the treatment program she
arbitrarily selected or go to jail. Some women were arrested despite the fact that they were
making every effort to comply with all of the Nurse Brown’s demands.

Until 1994, there was not a single drug treatment program in the state of South
Carolina designed to meet the needs of pregnant and parenting women. In fact, a 1991
Federal General Accounting Office Report found that the State of South Carolina, "did not
have any specific or unique treatment services for pregnant women and mothers with young children. The South Carolina State Council on Maternal, Infant and Child Health ("MICH Council") also concluded that "specific resources designed to meet the needs of women of childbearing age, especially pregnant women, are not widely available." MICH Report Vol. II at 2.

And the program worked. Scores of women agreed to enter rehabilitation and stayed off drugs for the remainder of their pregnancies. Before the sanctions took effect, 24 pregnant mothers a month tested positive for cocaine. Virtually none of them was willing to seek help voluntarily. Then, beginning in 1989, when we launched a tough amnesty program, the number testing positive for cocaine dropped to five or six a month. Prenatal visits as well as live births at the hospital stayed the same.

There is no evidence that the Policy worked. As the American Academy of Pediatrics has concluded, "punitive measures taken toward pregnant women, such as criminal prosecution and incarceration, have no proven benefits for infant health." American Academy of Pediatrics, Committee on Substances Abuse, Drug-Exposed Infants, 86 Pediatrics 639, 641 (1990). See also U.S. Department of Health and Human Services, Center for Substance Abuse Treatment, Pregnant Substance-Using Women Treatment Improvement Protocol, Series No. 2 (1993) ("TIP") ("there is no evidence that punitive approaches work").

State, federal and private researchers have all concluded that punitive approaches frighten women away from needed treatment. This undermines both maternal and fetal health. For example, two reports from the Federal General Accounting Office have concluded that women are deterred from drug treatment and prenatal care by threats of

---

1 United States General Accounting Office Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, ADMS Block Grant, Women's Set-Aside Does Not Ensure Drug Treatment for Pregnant Women, GAO/HRD-91-80, at 12, 15 (May 1991) (hereinafter "GAO II") (emphasis added). Moreover, state officials reported that federal funds to encourage states to use a 10% women's set-aside for substance abuse treatment of pregnant women and women with dependent children were not used for this purpose but rather for treating women in general. Id.

2 "The MICH Council was created in 1986 by the South Carolina General Assembly to improve the planning and coordination of maternal, infant and child health services." The MICH Council, as a collaborative effort of the public and private sectors, includes the commissioners for state health, human services, and education agencies; representatives of medical schools; schools of public health; health care providers; voluntary organizations; and gubernatorial appointees. The MICH Council is staffed by and housed in the Governor's Office. State Council on Maternal, Infant and Child Health Office of the Governor, 1991 South Carolina Study of Drug Use Among Women Giving Birth, Volume II, Prevention and Treatment Services (Feb. 1992) at 1 (hereinafter "MICH Report").

3 According to the MICH Report, "[t]rainers to treatment for women include the use of male-oriented therapies in most programs, lack of adequate child care, inadequate financial resources and limited transportation." MICH Report Vol. II at 2. These barriers prevent women from obtaining appropriate treatment. Id. at Appendix, "Alcohol and Drug Treatment Services Available for Pregnant Women."
prosecution: "The threat of prosecution poses yet another barrier to treatment for pregnant women and mothers with young children. These women are reluctant to seek treatment if there is the possibility of punishment, which may include incarceration." GAO II at ___.

The MICH Report similarly observed that "for pregnant women in particular, the fear of criminal prosecution may prevent them from seeking appropriate treatment and health care services." MICH Report Vol. II at 10.

Mr. Condon's only "evidence" that "the program worked" is an article he co-authored, Edgar O. Harper, III, Shirley Brown, and Charles Moloney Condon, Cocaine in Pregnancy: Confronting the Problem, 86 J.S.C. Med. Ass'n. 330 (Oct. 1990) (hereinafter "Cocaine in Pregnancy") As Dr. John Jeurgens, Chairman, Institutional Review Board for Human Subjects Research, University of Mississippi, explains:

The published article is a classical example of the worst kind of research conducted by individuals who have not had sufficient, if any, training in research design and methodology and who are not qualified or competent to conduct legitimate research. Had this article been submitted to a peer-reviewed journal it would have been rejected on several bases, including but not limited to: 1) sloppy and inadequate methodology; 2) inadequate control of possible confounding factors that could dramatically affect the results; 3) inadequate description of the data analysis; 4) inappropriate conclusions based on the data analysis; and, most importantly, 5) the lack of informed consent and the unconscionable and unethical coercive nature of the study, which invalidates the data.

The article in fact purports to show only two things: 1) that the number of positive drug tests for cocaine decreased during the first several months of the Policy and that the raw number of births at the hospital was comparable to the number of births there during the previous years. The quality of the research is so poor that even these claims are, in fact, without support. In addition, there is no data of any sort that we know of that even purports to support the claims that 1) infant health was improved, 2) that money was saved, 3) that

---

4 See also United State General Accounting Office Report to the Chairman, Committee on Finance, U.S. Senate, Drug-Exposed Infants: A Generation at Risk, GAO/HRD-90-138 (June 1990) at 39 [hereinafter "GAO I"] ("some women are now delivering their infants at home in order to prevent the state from discovering their drug use.

5 See William Miller, et. al, Urine Drug Screen for Drug Abuse in Pregnancy: Problems and Pitfalls, 4 WII 152,153-54 (1994) (using Cocaine in Pregnancy and concluding that [there is no evidence that the incidence of drug use among the pregnant population decreases with any type of legal coercion, only that the incidence of positive drug screens may decrease. The decrease in positive urine drug screens can be achieved easily by not using substances within the known time frame to obtain positive results, substituting urine samples, or increasing oral fluid intake just before the test thereby diluting the urine. All of these can result in a negative test result.

women went into treatment and stopped their drug use, or 4) that women were not deterred from getting prenatal care.

We do know from our clients that many were deterred from getting prenatal care and from seeking help.

Now, once again, the babies cry out in agony. And once again, hospital staff with no legal recourse must watch pregnant women knowingly cause neurological damage to their unborn children.

1) Several weeks ago we asked an MUSC staff pediatrician if she had heard of any increase in so-called "crack babies" since the end of the Policy was stopped by MUSC and she said no.

2) In fact, it appears that the majority of women affected by the Policy were not identified while pregnant, but after they gave birth, there are a number of legal options available to health care providers including civil commitment proceedings and civil child abuse reports.

3) As discussed below, there is no evidence at this time that prenatal exposure to cocaine causes neurological damage.

At first, the hospital tried to educate the women about the damage they were causing to themselves and to their unborn babies. Sadly, hospital workers could not convince many of the expected drug-addicted women to enter a drug treatment program.

At that time there were no drug treatment programs set up to address the needs of pregnant and parenting women. MUSC was aware of the lack of services in the community and within their own hospital.

Those who argued most forcefully for the cocaine-baby program were people who dealt with drug addiction every day: the rehabilitation specialists.

It is our understanding that no one with any training in treatment of addicted women participated in the development of the Policy. Moreover, despite the existence of a well-developed body of research on programs that do work for pregnant women, no one involved with the Policy appears to have bothered to obtain any of this information nor did any of their so-called educational activities reflect any of this knowledge or experience.

---

The only remedy they offer to the horribly damaged children who result form this madness is to increase the flow of Medicaid dollars, provided by taxpayers, to pay a price so large that it is literally impossible to calculate. And the greatest frustration of all is knowing that this increasingly expensive tragedy can be prevented.

1) None of our clients have horribly damaged children.

2) It is unclear what "remedy" Mr. Condon is referring to. There is significant evidence that providing appropriate prenatal care and drug treatment for pregnant and parenting women is much less expensive than jailing women and treating children in neonatal intensive care.

Second, all of the women know about the amniocentesis program -- there were public-service announcements about it, the women voluntarily came to the only hospital in the state that sponsored it, they were counseled about the consequences of testing positive, and they all signed consent forms before being screened.

1) The public service announcements did not air until sometime after the program had been started and many women in fact did not know about the Policy before they went to the only hospital they could go to. Indeed, it is hard to imagine that those who did see the 30-second television announcement could possibly have understood the Policy and that by seeking medical care they risked losing their privacy and going to jail.

2) In order to be admitted to the MUSC all patients must sign a general consent form that permits drug-testing and HIV testing. These general forms do not explain the Policy or the consequences of a positive drug test result.

3) MUSC was the only program in the city that took high risk indigent pregnant women. All pregnant women with drug problems were referred there.

4) Any counseling that did, in fact, occur was done by people without specialized training in substance abuse.

Other states were looking at our cocaine-baby program as a model.

Despite Mr. Condon's extensive efforts to promote the Policy nationwide, to our knowledge, from 1989 until the present not a single state or locality outside of South Carolina has adopted the Policy. Indeed, the South Carolina legislature has repeatedly rejected proposals to make the Policy statewide law and every locality in the state except for Greenville has also refused to adopt the Policy as a model.

MEDICAL MISINFORMATION
Nothing could be more heart-breaking than the sight of a baby born with an addiction to cocaine.

"[A]t this time it is inaccurate to describe a cocaine-exposed newborn as crack-addicted."

Barry, Zuckeran, M.D., Chief of the Division of Developmental and Behavioral Pediatrics at Boston City Hospital, Drug Exposed Infants Understanding the Medical Risk, 1 the Center for the Future of Children 28 (1991).

Nationwide, one in 10 children has been exposed to cocaine in the womb. This condition affects 350,000.

The number cited by Mr. Condon were originally presented by Dr. Ira Chasoff as 375,000 infants exposed prenatally to all illegal substances not just cocaine. More-importantly exposure does not mean harm and does not constitute a "condition."

While cocaine use in pregnancy raises legitimate public health issues, it is wrong to suggest that every child prenatally exposed to cocaine will be injured. Indeed:

Expectations of universal and permanent damage to children prenatally exposed to cocaine rest not on scientific findings but on media "hyper" fueled by selective anecdotes. For example, the early reports of adverse effects of prenatal exposure to cocaine, including neurobehavioral dysfunction, a remarkably high rate of SIDS (Sudden Infant Death Syndrome), and birth defects, were initial observations that constitute the legitimate first step in the scientific process. However, these unreplicated findings were uncritically accepted by scientists and lay media alike, not as preliminary and possibly unrepresentative case reports, but as "proven" facts .

Deborah A. Frank, et. al., Children Exposed to Cocaine Prenatally: Pieces of the Puzzle, 15 Neurotoxicology and Teratology 298, 299 (1993) (citations omitted)."
It is possible that a child exposed prenatally to cocaine will suffer no ill effects. The effects of substances on fetal development depend on dose, timing and duration of exposure, genetic or other biological factors as well as other influences. Indeed, the available evidence from the newborn period is far too slim and fragmented to allow any clear predictions about the effects of intrauterine exposure to cocaine on the course and outcome of child growth and development.

Linda Mayes et al., The Problem of Prenatal Cocaine Exposure: A Rush to Judgment, 267 JAMA 406 (1992). See also In re Tanya P., No. 530069-93 (N.Y. Sup. Ct., Feb. 24, 1995) Slip op. at 34 ("Review of all these materials compels the conclusion that, at least at this time, there is insufficient evidence relating crack or cocaine use to fetal endangerment or perinatal death to justify involuntary retention, even in the absence of the legal rights based arguments already discussed.")

It is also wrong to suggest that any harm suffered by a child whose mother used drugs during pregnancy is causally connected to the prenatal drug exposure. Current research does not shed much light on the subject of which particular substances contribute to later disability. Polydrug exposure, impoverished home life, and chaotic communities make it impossible to attribute developmental effects to one particular drug. The research has not controlled for other important variables, such as the role of the father, the mother's personality, her health, and her access to social support.

Diana Krouse, Complex Developmental Issues of Prenatal Drug Exposure, 1 The Center for the Future of Children 36, 46 (1991). As a result, "Identifying a mother's cocaine use as the single most important variable in poor infant outcome at this time is both scientifically impossible and medically irresponsible." 19 Steven Kandall et al., Illicit Drugs in America: History, Impact on Women and Infants, and Treatment Strategies for Women, 43 Hastings L. Rev. 615, 638 (1992).

While reports in the scientific literature provide ample ground for concern about

* See e.g., Liza Chassoff, Drugs, Alcohol, Pregnancy and the Newborn, 266 JAMA 1567 (1991) ("[a]n important issue to keep in mind . . . is that not all drug-exposed infants demonstrate effects of intrauterine cocaine exposure . . . ").


* See also Barry Zuckerman et al., Crack Kids, Not Rumps, 95 Pediatrics 957, 938 (1995); ("[T]he most substantial difference was among young children living in poverty who were more likely than their more advantaged peers to suffer from low birthweight, prematurity, malnutrition, anemia, and postnatal lead poisoning, and congenital infections.").
potential health effects, and form an appropriate basis for additional research — they do not provide a basis for criminal penalties.

Cocaine additives need a strong motive to mend their ways. And most drug and law-enforcement officials also agree. A federally funded research survey showed that about 30 percent of those who enter public drug-treatment programs do so only because of direct or indirect legal pressure. The Office of National Drug Control Policy noted in a 1992 report that "the criminal justice system can steer offenders toward drug treatment as a condition for deferred prosecution.

Very little research on coercive treatment for women especially pregnant women has been done. An analysis of the studies in this area concluded that:

There is a lack of rigorous data to substantiate the effectiveness of compulsory treatment in general . . . . The general failure to define outcome parameters by which to assess mandatory treatment is even more obvious in the case of pregnancy because of the conceptual fuzziness characterizing the whole venture. . . . Indeed, in the current context of the scarcity and poor quality of drug treatment programs for women/mothers, a debate over mandatory treatment is symbolic at best and is meaningless in practical terms.


LEGAL MISINFORMATION

Illegal drugs during pregnancy constitutes nothing less than blatant child abuse.

This is wrong as a matter of law. Every appellate court and numerous trial courts in the country have held that a pregnant woman's use of illegal drugs does not constitute child abuse or any other crime. Indeed, the lower courts in South Carolina have repeatedly rejected application of the child abuse statute to pregnant addicts.11

11 As the court in Whitner v. State, 93-CF-99-347, slip op. at 4 (S.C. Ct. C.P. Nov. 22, 1993) cont. granted (June 30, 1994), observed, "[a]ny appellate court in our nation has interpreted its child abuse laws to apply to a woman who takes illegal drugs during pregnancy." See also Richard v. South Carolina, 94-CF-04-138, slip op. (S.C. Anderson, Sept. 9, 1994) (granting habeas corpus relief to reverse conviction for child abuse because "[t]he legislature choose [sic] to use the word 'child' in the current statute, this court must interpret the statute to exclude its application to a fetus"), State v. Caudle, 93-GS-04-756, slip op. (S.C., Anderson Nov. 29, 1993) (granting indictment for child abuse of woman who allegedly used drugs while pregnant, finding that the plain and ordinary meaning generally given to the word 'child' does not include "fetus"); Lester v. State, 93-CF-23-2984 (S.C. Greenville, Nov. 22, 1993) (granting post-conviction relief on same grounds as the Whitner case); Tolliver v. State, No. 90-CF-23-5178, slip op (S.C. Greenville Aug. 10, 1992) cont. denied (S.C. Mar. 10, 1993) (granting post-conviction relief for a woman who pled guilty to child neglect finding that application of statute to a woman who used drugs while pregnant violated statute's plain meaning and legislative
We had solid legal grounds to act in this manner, especially in the third trimester of pregnancy. During the final trimester, the fetus is regarded as viable, that is, capable of sustaining life on its own, and is therefore granted significant protections under both federal and state law. Indeed, the viable fetus is a person under the law.

The U.S. Supreme Court in Roe v. Wade, 410 U.S. 113 (1973) held that a fetus is not a person under the law.

South Carolina courts have interpreted "person" to include a viable fetus.

In three cases, two involving wrongful death and one involving a man who caused the death of a viable fetus by severely beating a pregnant woman, State v. Horne, 282 S.C. 444, 319 S.E.2d 703 (1984); Hall v. Murphy, 236 S.C. 257, 113 S.E.2d 790 (1960); and Fowler v. Woodward, 244 S.C. 608, 138 S.E.2d 42 (1964) the South Carolina Supreme Court held that a viable fetus could be covered by the respective statutes. No court in South Carolina, however, has interpreted these cases to mean that a viable fetus is a person for purposes of South Carolina law in general. Instead, in addition to numerous lower court decisions, both the state Department of Social Services and the Governor's Maternal Infant and Child Health Council have concluded that a viable fetus is not a person for purposes of South Carolina and federal law.

The New York-based center, an affiliate of the ACLU, asked a federal court to issue an injunction against the hospital to suspend the drug-testing program. The judge declined, finding no basis for the discrimination charge.

On February 12, 1994 the Federal District Court denied Plaintiffs' motion for a preliminary injunction. The court made no specific finding on the discrimination claim nor any other. Rather the court seemed most influenced by the Defendants' claim that an injunction was unnecessary because the women had a choice to go to other hospitals in town. The Court relied on this argument despite testimony from Dr. Birgit Pots who testified that MUSC was the only hospital that would take drug addicted pregnant woman on medicaid and despite the defendants repeated admissions that "The Medical University Hospital remains the only facility within at least a 50 mile radius which offers obstetric care for indigent medicaid sponsored patients." Horger et al., Cocaine in Pregnancy at 520.

Opponents of our cocaine-baby program continually failed to understand that prosecutorial action, like a thermostat, can be constantly adjusted. Charges can be dropped at any time. We can add conditions.

First, prosecutors may not threaten prosecution simply because they think it will lead to good public health policy. It is the legislature not individual prosecutors that decide what behavior shall be punishable as a crime. Once a prosecution is before the court the prosecutors do not have control. In Greenville, South Carolina prosecutors implemented a policy similar to Charleston’s. Like Charleston’s this policy purports to be designed to get women into treatment not jail. However, women have been sentenced to as long as eight years in jail.

For example, on April 20, 1992, based on the advice given her by court-appointed counsel, Ma. Cornelia Whitner entered a guilty plea to the charges of child abuse based on a single positive drug test at the time she gave birth. Ms. Whitner had gotten into an outpatient treatment program. State v. Whitner, 92-GS-39-670 Transcript of Record (S.C. Ct. Gen. Sess. Pickens County Apr. 20, 1992). At the sentence hearing, Ms. Whitner said, “I need some help, your honor.” Her attorney explained that the defendant had “an addiction problem,” that she has been receiving drug counseling, that she had been off drugs since February, and that her child was currently in good health. Both the attorney and Ms. Whitner reiterated that Ms. Whitner needed and wanted in-patient treatment. Id. The judge responded, “I think I’ll just let her go to jail.” Ms. Whitner was sentenced to the State Board of Corrections for a period of eight years. The Whitner case will be argued before the State Supreme Court on May 31, 1995.

RACE DISCRIMINATION

They alleged that the program was discriminatory toward blacks. Marie Christien, a regional manager in the Office of Civil Rights, claimed in a letter to the hospital that its substance-abuse policy “may result in an adverse disproportionate impact on African-American women.”

It is true that most of the women treated were black. The hospital serves a primarily indigent population, and most of the patient population is black. The South Carolina Drug Prevalence Study showed blacks were more likely to use cocaine than whites.

Mr. Condon suggests that the fact that the Policy was applied almost exclusively to African-American women is an innocent byproduct of demographic factors over which they had no control. This is obviously untrue. First, although Mr. Condon claims that South Carolina law requires the reporting and arrest of all pregnant women who threaten harm to their fetuses, the Interagency Policy was implemented and enforced at only one place in the entire city of Charleston—MUSC, the institution that serves a predominantly African-American community. Second, despite the well-established harmful effects of heroin, alcohol, cigarettes, and other drugs on fetal development the Policy singled out cocaine, a drug used disproportionately by African-American women. Third, it appears that almost all of the women who were actually arrested and taken to jail pursuant to the Policy were African-American. This case provides perhaps the closest parallel to Yick Wo v. Hopkins, 118 U.S. 356 (1886) in recent history. Fourth, applying the Arlington Heights v. Metropolitan Housing Dev. Corp., 429 U.S. 252 (1977) standards, the Policy departed from
normal hospital procedures and normal substantive criteria.

THE MEDICAL COMMUNITY'S POSITION

Politically Correct Resolutions by the American Medical Association and the American Podiatric Association denounce the policy as passive and unwise.

Every leading public health group opposes the use of the criminal laws as dangerous to both maternal and child health. See, e.g., State v. Luster, 419 S.E.2d 32, 35 (Ga. App. 1992), cert. denied, S92C1020 (June 4, 1992) (viewing addiction during pregnancy as a disease and addressing the problem through treatment rather than prosecution is the approach "overwhelmingly in accord with the opinions of local and national medical experts").

Fearing the effects of such policies on the public health, virtually every leading public health organization has published a policy or recommendation opposing the prosecution of pregnant women who use drugs, including the American Medical Association,13 the American Academy of Pediatrics,14 the American College of Obstetricians and Gynecologists,15 the American Public Health Association,16 the Southern Regional Project on Infant Mortality (an initiative of the Southern Governors' Association and the Southern Legislative

13 "Pregnant women will be likely to avoid seeking prenatal or postnatal care for fear that their physician's knowledge of substance abuse or other potentially harmful behavior could result in a jail sentence rather than proper medical treatment.

14 "Actions of coercion to obtain consent or force a course of medical and maternal freedom of choice, threaten the doctor/patient relationship, and violate the principles underlying the informed consent process.

15 "Recognizing that pregnant drug-dependent women have been the object of criminal prosecution in several states, and that women who might need medical care for themselves and their babies may not feel free to seek treatment because of fear of criminal prosecution related to illicit drug use ... [the Association] recommends that no punitive measures be taken against pregnant women who are users of illicit drugs when no other illegal acts, including drug-related offenses, have been committed.

Conference), the American Society on Addiction Medicine, the March of Dimes, the National Association for Perinatal Addiction Research and Education, the National Council on Alcoholism and Drug Dependence, the Association of Maternal and Child Health Programs, Coalition on Alcohol and Drug Dependent Women and Their Children, and the staff of the Center for the Future of Children.

16 "[S]tates should adopt, as preferred methods, prevention, intervention, and treatment alternatives rather than punitive actions to ameliorate the problems related to perinatal exposure to drugs and alcohol." Southern Legislative Summit on Healthy Infants and Families, Policy Statement 8 (Oct. 1990).

17 "Criminal prosecution of chemically dependent women will have the overall result of deterring such women from seeking both prenatal care and chemical dependency treatment, thereby increasing, rather than preventing, harm to children and to society as a whole." American Society of Addiction Medicine, Policy Statement on Chemically Dependent Women and Pregnancy, A.S.A.M., Sept. 1989 at 49.

18 "Punitive approaches to drug addiction may be harmful to pregnant women because they interfere with access to appropriate health care. Fear of punishment may cause women in need of prenatal services to avoid health care professionals." March of Dimes, Statement on Maternal Drug Abuse 1 (1990).

19 "[F]rom a health-care perspective, it appears likely that criminalization of perinatal drug use will be counterproductive. It will deter women who use drugs during pregnancy from seeking prenatal care which is important for the delivery of a healthy baby. The threat of criminal prosecution alone will not deter women in most instances from using drugs during pregnancy. These women are addicts who become pregnant, not pregnant women who decide to use drugs and become addicts." National Association for Perinatal Addiction Research and Education. Criminalization of Prenatal Drug Use: Punitive Measures Will Be Counterproductive (1990).

20 "[A] punitive approach is fundamentally unfair to women suffering from addictive diseases and serves to drive them away from seeking both prenatal care and treatment for their addictions and other drug addictions. It thus works against the best interests of infants and children by involving the sanctions of the criminal law in the case of a health and medical problem." National Council on Alcoholism and Drug Dependence Policy Statement, Women, Alcohol, Other Drugs and Pregnancy (1990).

21 "The threat of criminal prosecution prevents many women from seeking prenatal care and early intervention for their alcohol or drug dependency, undermines the relationship between health and social service workers and their clients, and denies women from receiving accurate and essential information to health care providers. The consequence is increased risk to the health and development of their children and themselves." Association of Maternal and Child Health Programs Law and Policy Committee, Statement Submitted to the Senate Finance Committee Concerning Victims of Drug Abuse: Resolution on Prosecution (1990).

22 "The criminal prosecution of addicted women solely because they are pregnant is both inappropriate and counterproductive. There is no evidence that a policy of criminal prosecution will either prevent perinatal drug exposure or improve children's health. Rather, prosecution of alcoholic and drug dependent women will very likely deter them from seeking both prenatal care and treatment for their addiction, resulting in increased risks to the health and well-being of women and their children." Coalition on Alcohol and Drug Dependent Women and Their Children, Statement Concerning Prosecution (1990).

23 "A woman who uses illegal drugs during pregnancy should not be subject to special criminal prosecution on the basis of allegations that her illegal drug use harms the fetus." Center for the Future of Children, The Future of Children at 16 (1991) ("I[n]d we believe that requiring health providers to report pregnant women to law enforcement agencies constitutes an undue threat to both the pregnant woman and her fetus.")
THE LITIGATION

In the spring of 1993, the Center for Reproductive Law and Policy was asked by a local public defender to help represent two women being prosecuted pursuant to the Policy. Crystal Ferguson and Theresa Joseph were arrested for delivery of drugs to a minor. After a motion to dismiss the charges against the women was filed and an American Public Health Association amicus brief in support of the defendants was submitted to the court, the solicitor’s office voluntarily withdrew the charges.

Both publicly and in their own documents the solicitor’s office stated that they were dropping the charges because they expected the trial court to hold that the drug delivery statute did not apply to a pregnant woman’s addiction to drugs. By dropping the charges the solicitor’s office prevented the defendants from obtaining a ruling that the drug delivery statute was being misused under the Policy. In addition, the Solicitor could avoid a precedent setting ruling against it but continue to arrest and threaten prosecution under a statute they knew did not apply.

Foreclosed from this avenue of redress the two women who were prosecuted decided to go ahead with a civil suit — the only way they could now seek justice for what had happened to them. In October of 1993 therefore, the Center filed on their behalf a federal civil rights suit for injunctive relief and damages to try to get the Policy stopped. The complaint alleged that by obtaining and disclosing plaintiffs’ confidential medical information, threatening plaintiffs with criminal charges that are not authorized by statute, using that intimidating threat to force women to accept inappropriate and possibly harmful treatment, carrying through on the threats and jailing pregnant and post-partum women, and applying the Policy almost exclusively to African-American women, defendants violated plaintiffs’ constitutionally protected freedoms including the right to privacy in medical information, the right to refuse treatment, the right to due process under law, the right to procreate and the right to equal protection under the law.

If the defendants real goal had been to get women to go to treatment there were other alternatives. It is well established that women will go if appropriate treatment is available. Even if they thought some women would have to be forced to go there were mechanisms including civil commitment proceedings and family court orders as a condition of retaining child custody that they could have used.

During preparation of the civil law suit an expert in the filed of informed consent reviewed the material available on the Policy and said that it appeared to him that the Policy also constituted illegal research on human subjects. After several months of thorough research on this question a related complaint was filed with the Office for Protection from enforcement for prosecution will reduce the likelihood that these women will seek medical care during pregnancy”). See also Recommendations 8-9 (1991).
Research Risks at the National Institutes of Health (NIH), arguing that the Policy constituted research on human subjects in violation of federal law. It argued that MUSC staff, without patient consent, collected the data on the women and then published their results in a medical journal without prior Institutional Review Board review or approval. See Horger, et al., Cocaine in Pregnancy: Confronting the Problem, 86 Journal of South Carolina Medical Association 527 (Oct. 1990). MUSC used these women, without their consent, to test the hypothesis that threatening and arresting pregnant addicts will get them to stop using drugs.

Following both the lawsuit and our related complaint to NIH, the Department of Health and Human Services' Office for Civil Rights (OCR) independently began an investigation of MUSC for violating Title VI: the law that prohibits race discrimination by programs receiving federal funds. Apparently to avoid a full scale investigation, on September 8, 1994, MUSC signed an agreement with OCR in which it agreed to discontinue most of the Policy.

Indeed, among the articles Amici cite is Committee on Obstetrics: Maternal and Fetal Medicine, Cocaine in Pregnancy, ACOG Committee Opinion No. 114 at 2-3 (Sept. 1992) which conclude that:

Some public officials believe that imposing criminal sanctions will deter substance abuse by pregnant women. However, the Committee on Obstetrics: Maternal and Fetal Medicine believes that the problem is addressed more effectively as a health issue than as a legal problem.
Ms. Carol H. Rasco  
Assistant to the President for Domestic Policy  
Old Executive Office Building  
1700 Pennsylvania Avenue, Room 213  
Washington, DC 20500  

Dear Carol:  

It was wonderful to see you the other day, as always.  

I do appreciate your help in bringing this to the First Lady's attention.  
I think, for a number of reasons, this would be a good thing not only for  
Drew but for the First Lady as well.  

Sincerely yours,  

Thomas H. Kean  

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

Dear Hillary:

It is my great pleasure to invite you to be Drew's graduation speaker at our commencement. It will take place at 10:00 a.m. on Saturday, May 18, 1996. This invitation comes with the unanimous support of students in all three of our schools.

I suspect that you know quite a bit about our University. It is historically connected to the Methodist Church, although at this point in its history it serves students of all faiths and denominations. We are the only small, highly selective, independent institution in New Jersey, and our proximity to Newark, New York and other major cities guarantees us a very diverse student body. Previous commencement speakers in the years I've been at Drew have included David Halberstam, Olympia Dukakis, Mario Cuomo and Thomas Pickering. Approximately 5,000 people usually come to our graduation which is normally covered by the New York Times as well as various New York and sometimes Philadelphia television stations. Morristown Airport is five minutes from the campus--Newark Airport about 25 minutes so access is not difficult.

Were you to accept, the gratitude of the University students would only be exceeded by that of its president.

With warmest regards,

Thomas H. Kean

P.S. There is tremendous interest on campus on Beijing and its follow-up. I've already done three forums all well attended here on campus.