FOIA Number: 2016-0970-F

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	To Jane Rothe Hagge (3 pages)	09/20/1999	b(6)

COLLECTION:
Clinton Presidential Records
Staff Secretary
Sean Maloney (Chron File (Sept 99))
OA/Box Number: 14867

FOLDER TITLE:
Tuesday, September 21, 1999

2016-0970-F
rs3006

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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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)]

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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 PRESIDENT HAS SEEN

9-21-99

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new election

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9-21-99

Report by U.N. Agency Asks Trade Opening to 3d World

New Emphasis Sought in World Negotiations

By ELIZABETH OLSON

GENEVA, Sept. 20 — Industrial nations must relax trade barriers and open their markets to the developing world, lest these third world countries be forced to rely on unpredictable foreign capital for economic growth, the United Nations trade and development agency said here today.

A study of some 40 developing countries showed increased trade deficits and declining economic growth, the agency, the United Nations Conference on Trade and Development, said in its annual report. It urged that the concerns of poorer countries be the centerpiece of forthcoming global trade negotiations, contending that market access, not foreign capital, was the key to growth.

Its concerns were seconded by the World Bank, which backed a far-reaching trade round today — including agriculture and construction, areas of prime interest to emerging economies — to start at the World Trade Organization's ministerial meeting in Seattle in November.

Joseph Stiglitz, chief economist for the World Bank, speaking to reporters at a meeting on developing countries that was organized along with the W.T.O., said that the "liberalization of agriculture should be a priority." Cutting back farm subsidies, a sensitive political issue, particularly in Europe, is on the agenda of the next round of trade negotiations, which is expected to last three years.

World Bank research indicated that a 40 percent reduction in global agricultural export subsidies would be as effective as an equal percentage reduction in manufacturing tariffs.

In the United Nations agency's annual review, Rubens Ricupero, head of the agency, said it had found that economic growth in the 1990's was an average of two percentage points below what it was two decades ago. At the same time, trade deficits were, on average, three points above their 1970's mark.

"Here we have the worst of two worlds," said Mr. Ricupero, a former Brazilian Finance Minister. "We have had a deterioration in trade balances, and a very sharp deterioration in trade deficits, whereas economic growth has been going downward."

The "disturbing trend," he maintained, stems in large part from the sluggish growth in industrial economies, especially Japan and European Union nations. That, combined with other factors like trade barriers, has made it hard for developing countries to increase their exports enough to cover balance-of-payment deficits, which have been created by a surge of imports.

Predicted gains by third world countries from trade liberalization have not materialized in many cases, the 146-page report said. Instead, there has been increased poverty and unemployment.

Mr. Ricupero urged the advanced economies to "work harder to convince a sometimes skeptical public that there are direct benefits, in terms of more jobs and rising incomes, from expanding trade" with developing countries.

Opening market access to them means lowering tariffs and dismantling agricultural subsidies, which total some $350 billion — twice developing nations' agricultural exports from 1996 to 1998, according to the report. It cited European Union producers of dairy products, who despite having the world's highest costs, have retained a 50 percent share of the world market.

Among other impediments to trade by third world countries, the report cited the use of health and safety standards to control imports, antidumping procedures and increasing export restraints.

The New York Times

TUESDAY, SEPTEMBER 21, 1999

COMMITTEE ON
INTERNATIONAL RELATIONS

COMMITTEE ON
THE JUDICIARY

ROBERT WEXLER
CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
19TH DISTRICT, FLORIDA

September 21, 1999

9-21 99
To Lea. affrs
for Appropriate
Handling

The Honorable William J. Clinton
President of the United States of America
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Clinton:

We are writing to you once again to register our continued concern over judicial irregularities in Argentina evident in the case of the Buenos Aires Yoga School (BAYS).

Our concerns about this issue have not wavered, and we remain fearful for the more than 300 families whose lives stand in legal limbo in Argentina. Unfortunately, the Argentine government has offered little response and none with any clarification on the case.

This past May, a Congressional Staff Delegation went to Argentina to take a closer look into this issue. The Delegation found many legal and judicial irregularities. Details of their findings were unveiled at a briefing sponsored by House Human Rights Caucus entitled "Judicial Corruption in Argentina." The briefing detailed judicial abnormalities and police atrocities in Argentina. The Argentine Ambassador, Diego Guelar, was invited to testify but did not appear nor excuse himself.

Human rights advocates in Argentina have come forward to denounce acts committed by the Argentine judiciary. Nobel Peace prize winner Adolfo Perez Equivel has called for the impeachment of investigative judge, Dr. Julio Cesar Corvalan de la Colina, for his ruling of insanity in the case against two of BAYS members. Another human rights group, Madres de Plaza de Mayo, concluded that Judge Corvalan de la Colina's ruling is in violation of Article 16 of the International Treaty on Civil and Political Rights. The human rights group, Abuelas de Plaza de Mayo, concurs and believes the actions taken by Judge Corvalan de la Colina are similar to those acts committed against citizens during Argentina's "dirty war" when individuals were stripped of their civil rights.

213 CANNON BUILDING
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2500 NORTH MILITARY TRAIL
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(561) 988-6423 FAX

MARGATE CITY HALL
5790 MARGATE BLVD
MARGATE, FL 33063
(954) 972-6454
(954) 974-3191 FAX

We cannot express how important it is that Argentina follow the rule of law. We beseech you to take the opportunity to discuss the BAYS case with President Menem and persuade him of the unwavering commitment of the United States to human rights and justice throughout the world.

With warm regards,

Robert Wexler, M.C.

John Conyers, Jr., M.C.

Tony P. Hall, M.C.

John Lewis, M.C.

Robert A. Underwood, M.C.

THE PRESIDENT HAS SEEN
9-21-99

k Times

Sunday, September 19, 1999

Review

Sandy Interview

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Against the Tide

A Pause on the Way To Asia's Century

By DAVID E. SANGER

CHRISTCHURCH, New Zealand

ASIA at the end of this decade was supposed to be all about microprocessors, not machetes.

Instead, the country that only four years ago was the hottest emerging market in Southeast Asia — Indonesia — now looks like a candidate for national disintegration. High-tech firms that were building next-generation power plants and wiring the country's 13,000 islands for cell phone networks fear that East Timor is just the beginning. Even Indonesians who are appalled at the military-sanctioned killings in East Timor wonder whether the arrival of international peacekeepers could inspire dreams of independence across the archipelago.

Head due north to China, which two years ago seemed to soaring as fast as Japan was falling, and you discover a lot of angst. Two years ago the country skillfully sidestepped the Asian economic crisis. But by the time President Jiang Zemin and President Clinton met here in New Zealand to patch up an acrimonious year, the corridor talk suggested that China's luck had run out.

After two decades of spectacular growth, China's leaders are beginning to admit that they cannot stop the deflation and mushrooming unemployment that are now drowning the country's economy. And military strategists are asking whether economic insecurity makes it more likely that China's leaders will be tempted to lash out against Taiwan.

The Asian Century wasn't supposed to start like this.

In scores of books with titles like "Asia Rising," and in the Clinton Administration's own optimistic imaginings of a "Pacific Community" a few years back, the Asia of the turn of the century was supposed to be a place where booming growth created a web of economic integration. That, in turn, was supposed to set loose an unparalleled era of political cooperation.

Now the theory is being put to its greatest test. Will Asia's finely-honed instincts for amassing greater prosperity — especially after a bruising economic crisis — ultimately restrain all these festering conflicts? Will they make Indonesia's military leaders think twice, or lead the pragmatic Chinese to ignore Taiwan's provocative rhetoric about virtual independence?

Or was the world fooling itself when it imagined, just a few years ago, that the cross-border teamwork that enabled Indonesians, Malays, Taiwanese and Chinese to build Toyotas together would eventually translate political stability?

Those Toyotas and the country that finances them — Japan — may hold the key to those questions. If Tokyo recovers from its own lost decade quickly enough to pump new money and dynamism into the region, it

Continued on Page 4

Rethinking Population At a Global Milestone

Against the Tide: A Pause on the Way to Asia's Century

Continued From Page 1

could speed an economic recovery — and create a greater incentive for nations to resume the business of business.

Handled deftly, even the Timor crisis might contain an opportunity to tie the region together. "You sense everywhere that we're at a critical moment for the whole region, said John Howard, the Prime Minister of Australia, a country that spent years trying to integrate itself with Asia and now finds itself in the uncomfortable position of acting as the largely white, Anglo-Saxon nation leading the peacekeeping brigade into East Timor. "Ten years ago," he said, "it would have been unimaginable that the diverse nations of Asia would come together to stop a humanitarian disaster like this one."

Mr. Howard is right — Asia has no equivalent of NATO, no institutions like the European Union, and until a few weeks ago its leaders always reflexively rejected the idea of getting involved in a neighbor's internal affairs. It was an inchoate sense that the entire region's future was at stake that led the Philippines, Malaysia, the United States, New Zealand and others last week to say they would contribute troops to restore order in East Timor, even at the risk of tangling with the powerful military of the world's fourth most populous nation.

But the Prime Minister's countrymen are also right when they fret about the emergence of a new "arc of instability," running from a collapsing North Korea through China, across Indonesia and into India and Pakistan, where nuclear calamity always seems a firefight or two away.

THIS image of two Asias — one that has abandoned ideological conflict to build more clean-rooms and laptops, and one that brutally fights for advantage in Timor and Kashmir — captures a vast region's dual realities.

Outside Jakarta, newly middle-class workers assemble personal digital assistants, even while the marauding militias in East Timor, some 1,400 miles away, sow terror and threaten an unpleasant welcome for international peacekeepers. Many Indonesians, in short, have a stake in stability and their own slice of the global economy. Many do not.

In their more candid moments during Mr. Clinton's Timor-obsessed travels Down Under last week, the President's foreign policy advisers conceded they have no idea how the experiment of nudging Asia to police its own will work out.

Perhaps, one of Mr. Clinton's top aides said, the effort to force Indonesia to respect the results of a United Nations-supervised referendum on independence will be seen in a few years as a critical victory for democracy in Asia, a logical extension of the movement that flowered in South Korea and Taiwan in the mid-1980's. Or it may be, he added, that it will be seen as "the moment when all of Asia's new instincts about stability and economic integration are overwhelmed" by the old ghosts of political disintegration.

Indonesia may be among the trickiest corners of Asia to conduct this experiment, and China may be among the safest.

Until two years ago, Indonesia was held together chiefly by rising prosperity. Indonesians overlooked the massive corruption and special deals cut for Mr. Suharto's family and friends. But the Asian economic crisis triggered Mr. Suharto's downfall. That left a desperately weak government and a divided military. Mr. Suharto's successor, B. J. Habibie, concluded that he had to get the Timor problem off his plate, and allowed a referendum in which East Timor chose independence.

Parts of the Indonesian military rebelled, unwilling to give up a territory they seized a quarter century ago, even if the resulting chaos threatened huge economic sanctions.

Paul Wolfowitz, the former American ambassador to Indonesia, believes that Mr. Habibie's sudden reversal last weekend, his decision to allow in the U.N. peacekeepers, reflected Indonesia's surprise at the foreign reaction to the East Timor killings and its "fear of being punished by the outside world." But that is balanced, he believes, by another fear — "a legitimate one, that East Timor might lead to the breakup of the country," especially if people think Indonesia's next president, to be elected soon, did not win the post legitimately.

China's leaders, on the other hand, have been forced to live and breathe the logic of economic reality. A rising standard of living is the Communist Party's last claim to legitimacy. And that means convincing investors that the country has its economic and political act together.

Taiwan has always been an open sore, of course, and if it declared independence from the mainland China's leaders would have to respond, probably with force. Some in the Chinese leadership argue that such a moment is fast approaching. But so far, at least, the forces of economic rationality have won the day, arguing that China needs Taiwan's wealth and its huge investments on the mainland more than it needs Taiwan's real estate. And the only way to keep the cash flowing is to maintain the status quo, complete with the ambiguity about Taiwan's political status.

The Administration still clearly believes that the lure of economic prosperity can be used to keep weapons holstered. It turned off International Monetary Fund and World Bank aid to India and Pakistan when they tested nuclear weapons, then turned it back on at the first sign that the two sides would back away a bit.

And on Friday President Clinton announced the most extensive easing of sanctions on the ultimate rogue state — North Korea — in return for a temporary accord to stop shooting long-range missiles over Japan. It's a big risk: No one knows if the North is serious about the deal, or if the benefits Washington offers — consumer goods and investment from America — can cut through four decades of paranoia.

"It's probably not as powerful a tool as we'd like it to be," said former Secretary of Defense William Perry, architect of the strategy. "But it's worth a try."

Long Live the Writers of Banal Slogans!

BEIJING

AT a loss about what to chant for Communist China's 50th birthday Oct. 1?

The Communist Party provided 50 suggestions, among them:

- Warmly hail the great successes in China's reform and opening up and socialist modernization drive!
- Strive to build China into a prosperous, powerful, democratic and culturally advanced socialist country!
- Hold high the great banner of Deng Xiaoping Theory and put forward the cause of building socialism with Chinese characteristics into the 21st century!
- Seize the current opportunity, continue the reform, open China wider to the outside world, promote development and maintain stability!
- Emancipate the mind, seek truth from facts and firmly promote reform and opening up!
- Adhere to the basic economic system with public ownership dominant and diverse forms of ownership developing side by side, and "to each according to his work" as the main distribution form and with other forms as well!
- Promote political restructuring, develop socialist democracy, and improve the socialist legal system!
- Adhere to and improve the system of multi-party cooperation and political consultation under the leadership of the Communist Party of China!
- Rely on the working class wholeheartedly!
- Respect knowledge, value talented people, and carry out the strategy of invigorating the nation through science and education!
- Implement family planning, protect natural resources and the environment, and carry out the strategy of sustainable development!
- Adhere to the goal of serving the people and socialism, to the policy of letting a hundred flowers blossom and a hundred schools of thought contend, and promote socialist science, literature and art!
- Develop public health and physical culture and improve people's physique!
- Uphold the policy of "peaceful reunification, and one country, two systems" and fulfill the great cause of reunification of the motherland!
- Unite as one, fear no difficulties, struggle hard, be persistent, dare to win!
- Long live the great Marxism, Leninism, Mao Zedong Thought and Deng Xiaoping Theory!

Withdrawal/Redaction Sheet
Clinton Library

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Holstein
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EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON ENVIRONMENTAL QUALITY
WASHINGTON, D.C. 20503

THE PRESIDENT HAS SEEN
9-21-99

'99 SEP 20 PM2:09

September 20, 1999

MEMORANDUM FOR THE PRESIDENT

FROM: GEORGE T. FRAMPTON, JR. GTFJr.

SUBJECT: INFORMATION ON THE ANTIQUITIES ACT AMENDMENT

This is in response to your request for additional information on the effect of the pending House bill to amend the Antiquities Act under which you created the Grand Staircase-Escalante National Monument. Specifically, you asked whether the bill's new "consultation" requirements would prevent presidential action.

The bill, H.R. 1487, has been reported by the House Resources Committee and may come to the House floor as early as this Wednesday. The reported bill is a compromise version of a much more onerous bill originally introduced by Congressman Hansen; the compromise was brokered by a Democrat, Congressman Bruce Vento.

The bill language is attached. It requires that the President, to the extent consistent with protection of the historic and scientific interests on the land involved, (1) solicit public "participation" and comment in the development of a monument declaration; (2) consult with the Governor and congressional delegation of the State in which the lands are located, to the extent practicable, at least 60 days in advance of the declaration; and (3) consider any information available in existing land management plans before making a declaration.

Even if read narrowly, the bill typically would require at least a sixty-day consultation period with the Governor and congressional delegation, and some kind of written public comment process including public "participation," i.e., probably a public hearing or hearings. Even if the hearing and comment process (presumably through the federal register) were to be pared down, it is unlikely such a process could be completed in less than three to four months or longer.

Moreover, the Committee Report authored by the Republican majority on the committee attempts to interpret these requirements to be virtually identical to those imposed by the original bill, i.e., to "follow the general public participation pattern [used by federal agencies] when preparing Environmental Impact Statements". If so interpreted by the courts in this vein, the bill could require a one- to two-year process. (Presidential actions including those under the Antiquities Act have consistently been held by the courts to be exempt from NEPA.)

Whether read broadly or narrowly, it is certain that the bill would give opponents of any future national monument proclamation new "hooks" for litigating the monument's validity, by claiming that statutory procedures were not fully followed. Such litigation could be expected to cloud any future monument proclamation for years thereafter. For example, even without any

such "hooks" in the current statute (or in past court rulings rejecting monument challenges), a US District Court in Utah has recently indicated its willingness to strike down your Grand Staircase-Escalante Monument proclamation. We assume that if this occurs the decision will be reversed by the Court of Appeals, which has summarily reversed this same judge before on similar issues. But future challenges under HR 1487 would be much harder to dismiss so cavalierly.

Thus the bill would clearly complicate and undercut – if not seriously diminish – a unique presidential authority that has remained untouched for nearly a hundred years and has been used over a hundred times by nearly every president to create a huge and successful conservation legacy. For this reason, in my view it clearly merits a veto threat. In addition, the bill is an obvious attempt to impeach your Utah proclamation and make it much more difficult for you to exercise this authority again, should you choose to do so.

A pending Senate bill, S. 729, has already been the subject of a senior advisors veto threat during hearing testimony. (It has not yet been reported by the Energy Committee.) That bill, however, is much more draconian in seeking to virtually cripple the Antiquities Act.

I met last week with Congressman George Miller. He has agreed to lead a fight against the bill notwithstanding Congressman Vento's original support in light of the restrictive committee report language. He made it clear that strong opposition from the Administration is important to the success of his strategy.

Cc: John Podesta
Larry Stein
Jack Lew
Elgie Holstein
Lisa Kountoupes

GTF/dss
Attachments

SECTION 2 OF THE ACT OF JUNE 8, 1906

(POPULARLY KNOWN AS THE ANTIQUITIES ACT OF 1906)

CHAP. 3060.—AN ACT For the preservation of American antiquities.

* * * * * * *

[SEC. 2. That the] *SEC. 2. (a) The* President of the United States is hereby authorized, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and may reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected: *Provided,* That when such objects are situated upon a tract covered by a bona fide unperfected claim or held in private ownership, the tract, or so much thereof as may be necessary for the proper care and management of the object, may be relinquished to the Government, and the Secretary of the Interior is hereby authorized to accept the relinquishment of such tracts in behalf of the Government of the United States.

(b)(1) To the extent consistent with the protection of the historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest located on the public lands to be designated, the President shall—

(A) solicit public participation and comment in the development of a monument declaration; and

(B) consult with the Governor and congressional delegation of the State or territory in which such lands are located, to the extent practicable, at least 60 days prior to any national monument declaration.

(2) Before issuing a declaration under this section, the President shall consider any information made available in the development of existing plans and programs for the management of the lands in question, including such public comments as may have been offered.

(c) Any management plan for a national monument developed subsequent to a declaration made under this section shall comply with the procedural requirements of the National Environmental Policy Act of 1969.

THE PRESIDENT HAS SEEN
9-21-99

'99 SEP 17 PM 7:15

THE WHITE HOUSE

WASHINGTON

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Cahill
Shea
Podesta

SEPTEMBER 17, 1999

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: **MARY BETH CAHILL**
MAUREEN SHEA

SUBJECT: **SELECTION OF THOSE TO OFFER PRAYERS AT RELIGIOUS LEADERS BREAKFAST**

SEPTEMBER 28 RELIGIOUS LEADERS BREAKFAST: In preparation for the breakfast, we are seeking your advice regarding those to be asked to make the opening and closing prayers. We would anticipate following past tradition, with open press for your first remarks and the opening prayer, and closed press thereafter.

In the last two years, we have had three Protestant ministers and one rabbi offer the prayers. Of the three ministers, one (James Forbes) is African-American and another (Thom White Wolf Fassett) Native American. The rabbi is a gay woman.

In addition to the old friends and leaders invited this year, we have included a number of people from communities touched by the hate crimes and violence of the past year. This would be an excellent opportunity to push once again for passage of hate crimes and gun control legislation. (The list of acceptances to date is attached.)

RECOMMENDATION:

Opening Prayer: Sister Nancy Sylvester is this year's President of the Leadership Conference of Women Religious. An old friend of both Melanne and Maureen, she is the former head of a social justice lobbying organization founded by nuns, Network.

Closing Prayer: Rev. Byung Chill Hahn is the pastor of the Korean United Methodist Church in Bloomington, Indiana where university student Won-Joon Yoon was killed leaving the church by a white supremacist.

Other Suggestions:

Dr. Laila Al-Marayati: a Muslim, Dr. Al-Marayati is one of your three appointees to the International Religious Freedom Commission.

9-21-99

Rabbi Brad Bloom: his synagogue and library in Sacramento were destroyed in the recent firebombing.

Rev. Suzan Johnson Cook: served on your Race Initiative Board and is African-American

Rev. Dr. James Dunn: this would be a nice gesture as we are still trying to schedule your attendance at his tribute dinner October 4.

DECISION:

_____Approve **_____Approve as amended**

ACCEPTANCES TO DATE

Dr. Laila Al-Marayati – Muslim Women's League – CA
Bishop Vinton Anderson- Second Episcopal District, AME - DC
Rev. Wendell Anthony – Fellowship Chapel Baptist Church – MI
Rev. Joseph Barlow – MOSES - MI
Rev. David Beckmann, President – Bread for the World - MD
Rev. Paul Beeman, President of the Board – Parents and Friends of Lesbians and Gays – WA
Bishop Charles Blake – West Angles COGIC – CA
Rabbi Brad Bloom - Congregation B'nai Israel - CA
Sr. Mary Louise Brink, Mother General – Sisters of Charity of Halifax
Rev. Dr. Amos Brown – National Baptist Convention - CA
Rev. Jamal Bryant – NAACP Youth & College Division – MD
Commander John Busby – The Salvation Army - VA
Rev. Calvin Butts, Abysennian Baptist Church - NY
Rev. Dr. Joan Brown Campbell, General Secretary – NCCC- NY
Revs. John and Diana Cherry – Heart Church Ministries - MD
Sanford Cloud, Jr., President – National Conference for Community and Justice - NY
Doug Coe – National Prayer Breakfast – VA
Rabbi Zev Cohen – Congregation Adath Yeshurun – IL
Rev. Suzan Johnson Cook – Bronx Christian Fellowship – NY
Chaplain Jeni Cooke- Director - National Chaplain Services - Department of Veterans Affairs – VA
Sr. Carol Coston, OP, Director – Partners for the Common Good 2000 –TX
Rev. Tyrone Crider – New Hope Baptist Church – IL
Dr. Stewart Cureton – National Baptist Convention, USA – SC
Dr. C. Mackey Daniels – Progressive National Baptist Convention – KY
Chaplain Jewelnel Davis – Columbia University – NY
Father Robert Drinan – Georgetown University Law Center - DC
Dr. James Dunn – Baptist Joint Committee – DC
Rabbi Jerome Epstein – United Synagogue of Conservative Judaism – NY
Dr. Randel Everett – Columbia Baptist Church - VA
Dr. Thomas White Wolf Fassett – United Methodist Board of Church and Society – DC
Rev. Dr. Floyd Flake – Allen AME Church - NY
Rev. James Forbes, Senior Pastor – Riverside Church - NY
Rev. Dr. Robert Franklin – Interdenominational Theological Center – GA
Rabbi Menachem Genack – Union of Orthodox Jewish Congregations of America - NY
Charles Gould, President – Volunteers of America - VA
Sr. Jeannine Gramick, SSND – National Coalition of American Nuns – MD

Rev. Claudie Grant – President's Commission on Employment of People with Disabilities - DC
Rev. Lucia Guzman, Executive Director – Colorado Council of Churches - CO
Rev. Byung Chill Hahn – Korean United Methodist Church - IN
Rabbi Kenneth Hain, President – Rabbinical Council of America - NY
Janet Hall - VA
Dr. Brian Harbour – First Baptist Church – TX
Rev. Dr. Louis-Charles Harvey – Metropolitan AME Church – DC
Ralph Hardy – Church of Latter-day Saints - DC
Imam Johnny Hasan – The Islamic Center - AR
Rev. Otto Hentz, SJ – Georgetown University - DC
Rev. Dr. H. Beecher Hicks – Metropolitan Baptist Church – DC
Rev. Rickey Hicks – Connor Chapel AME - AR
Rev. Julius Hope – Midwest NAACP Regional Director - MI
Dr. Alvin Jackson – National City Christian Church – DC
Rev. Reginald Jackson – Black Ministers Council of NJ - NJ
Bishop Frederick James – AME Church – SC
Father Mychal Judge, Chaplain – NYC Fire Department - NY
Dr. Firuz Kazemzadeh, Secretary for External Affairs – Baha'is of the US – CA
Dr. Nazir Khaja, President of Board – American Muslim Council - CA
Rev. Dr. Barbara King – Hillside Chapel – GA
Rev. Bernice King – Greater Rising Star Baptist Church – GA
Rev. Clifton Kirkpatrick, Stated Clerk – Presbyterian Church USA - KY
Rev. Samuel Billy Kyles – Monumental Baptist Church – TN
Rev. Arthur Liolin – Albanian Orthodox Archdiocese in America – MA
Bishop Eddie Long – New Birth Missionary Baptist Church - GA
Rabbi Harold Loss – Temple Israel - MI
Dr. Gordon MacDonald, Fellow – Trinity Forum– MA
Father John Madden, Pastor – Our Lady of Jasna Gora - MA
Rev. Anthony Mangun – Pentecostals of Alexandria – LA
Dr. Kevin Mannoia, President – National Association of Evangelicals
Rev. Jack Marcom, Senior Pastor – Ft. Washington Baptist Church - MD
Dr. K. Bruce Miller – Mt. Vernon Baptist Church –VA (VP)
Imam W. Deen Mohammed – Muslim American Society – IL
Nancy Parris Moskowitz – Jewish Community Centers of Great Los Angeles – CA
Rev. Otis Moss – Olivet Institutional Baptist Church – OH
Rev. Michael Murray, President – Black Ministerial Alliance - IA
Dr. Vasudha Narayanan – Department of Religion, Univ. of FL – FL
Ms. Joanne Negstad, President – Lutheran Services in America - MN
Bishop Chandler Owens, Presiding Bishop – Church of God in Christ – GA

- Rev. Ronald Patterson – United Methodist Reporter - TX
  Dr. Jan Paulsen – President of the General Conference -Seventh-day Adventist Church – MD
  Rev. Michael Piazza, Senior Pastor – Cathedral of Hope - TX
  Imam Hasan Qazwini – Islamic Center of America - MI
  Capt. (Rabbi) Arnold Resnicoff, USN, Chaplain of US European Command
  Russell Robinson – Willow Creek Community Church - IL
  Rev. Dr. Paul Sherry – United Church of Christ – OH
  Dr. Muzammil Siddiqi, President – Islamic Society of North America - CA
  Rev. Barbara Skinner – Skinner Farm Leadership Institute – MD
  Chief Jacob Swamp, President – Tree of Peace Society - NY
  Sr. Nancy Sylvester, President – Conference of Leadership of Women Religious – IL
  Rev. Walter Thomas – New Psalmist Baptist Church - MD
  Dr. Robert Thurman – Columbia University (Buddhist) – NY
  Rev. Carlton Veazey – Religious Coalition for Reproductive Choice - DC
  Rabbi Robert Wexler, President – University of Judaism – CA
  Dr. Philip Wogaman – Foundry Methodist Church – DC
  Rabbi Marjorie Yudkin – Beth Chaim Reform Congregation & Chairs Social Action Committee for Reform Rabbis – PA
  David Zwiebel – Agudath Israel of American - NY

I R P S

9-21-99

C Jennings
Can we do anything
about this —
BC

nh

BARRY H. GRAYSON, D.D.S.
Associate Professor of Clinical Surgery (Orthodontics)
Institute of Reconstructive Plastic Surgery
New York University Medical Center

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

Dear President Clinton,

It was indeed an honor and pleasure to meet with you and our mutual friend Dr. Jim French following your radio address on August 12th 1999. In our discussion regarding Kelly's denial of coverage by her insurance company for her surgical and orthodontic care, I mentioned Bill HR-49 (The Children's Deformities Act). Unfortunately, due to time constraints I was unable to discuss with you the national policy of the American Cleft Palate-Craniofacial Association which states that the evaluation and treatment of patients with craniofacial birth defects is best provided by an interdisciplinary team working in a coordinated fashion. This team consists of members of the profession of medicine, surgery, dentistry and allied health disciplines.

The orthodontic component of Kelly's treatment was a prerequisite for the attainment of a favorable surgical result. Careful pre-operative planning and orthodontic treatment is necessary for a functional and aesthetically pleasing correction of many congenital facial deformities. Insurance companies and HMOs routinely deny services rendered by all members of the treatment team as being related to an underlying "cosmetic problem".

Please be kind enough to review the enclosed documents from the American Cleft Palate-Craniofacial Association that substantiate the need to provide insurance coverage for the interdisciplinary team of clinicians that, working together, provide care to the child or young adult born with a craniofacial anomaly.

Again, it was a great pleasure to meet with you and Jim at the White House and an honor to have been entrusted by you and your family with the care of Kelly.

Sincere and warm regards,

Barry

Barry H. Grayson DDS

Copied
Jennings
Podesta

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NEW YORK UNIVERSITY
SCHOOL OF MEDICINE

Institute of Reconstrúctive Plastic Surgery
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PRESIDENT WILLIAM CLINTON

New York University
A private university in the public service

Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies

Summary of Recommendations

Official Publication of the American Cleft Palate-Craniofacial Association

April 1998

INTRODUCTION

In 1991, the American Cleft Palate-Craniofacial Association (ACPA) received funding from the Maternal and Child Health Bureau[1] to develop standards for the special needs of children born with cleft lip/palate and other craniofacial anomalies. Following a consensus conference and widespread peer review process, the ***Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies*** *was developed and published. A summary of the recommendations of this report follows.*

SUMMARY

PARAMETERS FOR EVALUATION AND TREATMENT OF PATIENTS WITH CLEFT LIP/PALATE OR OTHER CRANIOFACIAL ANOMALIES

The complex needs of a child with a cleft lip/palate or any other craniofacial anomaly are best met by a dedicated cleft or craniofacial team of health care providers with special expertise and experience in the care of such disorders. The professionals on these teams provide care regularly for a reasonable number of patients in a facility with the resources necessary for such care.

Audiologic Care

Individuals with craniofacial anomalies may have congenital abnormalities of the auditory structures and an increased incidence of ear disease. These children are at high risk for hearing disorders that may occur intermittently or become permanent, and that vary from mild to severe. Hearing loss can have a significantly adverse influence on speech and language development, educational and psychological status, and eventually on social and vocational status. For these reasons, these children require ongoing audiologic surveillance beginning at one month of age and continuing through adolescence. Tympanometric and audiometric measures should be obtained. Treatment may involve myringotomies and placement of ventilation tubes, hearing aids, auditory training systems, bone conduction amplification, and external, middle, and inner ear surgery.

Cleft Lip/Palate Surgery

In addition to primary surgical closure of the cleft lip and cleft palate which is initiated within the first 12 months of age, many patients will require secondary surgical procedures involving the lip, nose, palate, and jaws that usually are staged from infancy through adulthood. In all cases, surgical techniques should be individualized according to the needs and condition of the patient. Surgical procedures should be coordinated to minimize the number of anesthetic exposures and hospitalizations. Evaluation of complications (morbidity and mortality) of cleft lip and palate repairs should be completed on an annual basis and subject to peer review. The major factor in the quality of surgical outcome is the skill, training, and experience of the cleft care team. An anesthesiologist knowledgeable and experienced in pediatric anesthesia must be present for all surgical procedures. Additional procedures for cleft lip/palate may include pre-surgical maxillary orthopedics, lip adhesion, pharyngoplasty, tonsillectomy/adenoidectomy, orthodontic maxillary expansion, alveolar bone grafting, nasal reconstruction including nasal septal surgery, and jaw surgery in conjunction with pre- and postoperative orthodontics.

Craniofacial Surgery and Maxillofacial Surgery

The complex nature of many types of craniofacial anomalies often necessitates multiple operative procedures at different stages of growth and development. Reduction of morbidity and mortality from craniofacial operations requires establishment of a dedicated surgical team, frequent performance of operative procedures, and adequate support facilities. Longitudinal follow-up is necessary for these patients, at least into adolescence, even when the intervention has been successful with respect to the anatomic defect. Specific components of the pre-, peri-, and postoperative evaluations of craniofacial surgery should be based upon the type of anomaly and the craniofacial zone(s) affected. Treatment involves reconstructive surgery to the craniofacial region, and may include hard and soft tissue remodeling, reconstruction, grafting, distraction, and implantation. Secondary procedures are often necessary due to the effects of growth, attainment of maturity or persistent residual deformities. An anesthesiologist knowledgeable and experienced in pediatric anesthesia must be present for all surgical procedures.

Dental Care

Patients with craniofacial anomalies require dental services as a direct result of the medical condition, and dental treatment is an integral part of the habilitative process. Provision of dental services for these patients includes not only primary care but routine maintenance throughout life. The necessary procedures focus on monitoring craniofacial growth and dental development, on maintaining a healthy dentition and periodontium, and on correcting jaw relationships and dental occlusion when necessary in order to achieve optimal function and appearance. Dental care begins once the primary dentition erupts and continues into adolescence. Treatment requires diagnostic records (study models, cephalometric radiographs, photographs, and, at times, computer imaging) to monitor dentofacial growth and dental development, preventive and restorative dental treatment, and, when indicated, orthodontic treatment, alveolar bone grafting, orthognathic

(jaw) surgery, and prosthetic and periodontal interventions.

Genetic/Dysmorphology Services

A comprehensive clinical genetic evaluation is a key component in the management of patients with congenital craniofacial anomalies and should include diagnosis, recurrence risk counseling, and counseling regarding prognosis. Complex syndromes involving craniofacial anomalies may not fully express clinical manifestations that can be recognized in the first year of life. Thus, genetic screening and follow-up evaluations will be necessary for some patients until puberty. Patients who are first seen by the team at later ages should also be evaluated.

Nursing Care

Nursing assessment, interventions, and ongoing follow-up evaluations are integral to the long-term care needs of the child or individual with congenital craniofacial anomalies and the family. Assessments of feeding, interventional teaching, and follow-up of nutritional and growth assessments are examples of the nursing services provided. In addition to these direct nursing services, members of the craniofacial team bear the responsibility for education of hospital and community nurses in feeding and other aspects of the special care that may be required.

Otolaryngologic Care

Comprehensive care of children with craniofacial anomalies typically requires long-term monitoring of the ears, nose, and throat due to the prevalence of ear disease, ear malformations, and upper airway problems. Physical examinations and airway assessments begin perinatally for patients with airway compromise or within the first 6 months of life for those with stable airways and continue through adolescence. Such assessments may require endoscopy, radiologic studies, airflow studies, CT scans, MRI's, and polysomnography. Structural and functional laryngeal problems may exist in these patients, and may require medical as well as surgical treatment. Adenoidectomy and/or tonsillectomy may be indicated for airway obstruction but only after careful velopharyngeal functional assessment. Other oropharyngeal and laryngotracheal procedures may be necessary as well.

Pediatric Care

Pediatric care provided within the context of the team, along with a primary care physician, is fundamental in assuring that the health needs of the child with craniofacial anomalies are fully identified and appropriately treated. Physical examinations should be provided on a regular basis, parental questions regarding health issues should be addressed, and referrals to appropriate specialists should be made in cooperation with the primary physician.

Psychological and Social Services

Accomplishing the goals for treatment of the patient with craniofacial anomalies requires periodic assessment of psychological needs of both the parent and family. Psychological tests must be administered and interpreted under the supervision of a licensed psychologist, preferably a person familiar with craniofacial anomalies and related speech and hearing disorders. Psychosocial screening interviews should be conducted periodically to assess parental competence and nurturance, child management skills, parent-child relationships, and the emotional and behavioral adjustment of the child. The high rate of learning disorders in children with craniofacial conditions requires that each child be screened for potential learning disorders beginning in infancy until cognitive competence has been established. Each family should be referred for psychological evaluation and, as appropriate, intervention when problems are identified through the screening procedures.

Speech-Language Services

Children who have craniofacial anomalies are at high risk for speech-language disorders. Evaluation of speech and language development provides information that is needed by the team in the planning of treatment, including surgical, dental, and speech management, and in the assessment of treatment outcome. Speech-language evaluations should occur within the first year of life, and then often enough to assure adequate documentation of each child's progress and to develop appropriate recommendations for intervention. Evaluation of velopharyngeal function, conducted with the participation of the team speech-language pathologist, is required for many patients and may include articulatory performance, aerodynamic measures, videofluoroscopy, nasopharyngoscopy, and nasometric studies.

[1] Maternal and Child Health Bureau, Title V, Social Security Act, Health Resources and Services Administration, U.S. Public Health Service, Department of Health and Human Services, Grant #MCJ-425074.

Copies of the entire document, ***Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies*** may be obtained by contacting:

American Cleft Palate-Craniofacial Association
1829 East Franklin Street, Suite 1022
Chapel Hill, North Carolina 27514
(919)933-9044
Fax (919)933-9604

The American Cleft Palate-Craniofacial Association

The American Cleft Palate-Craniofacial Association (ACPA) was founded in 1943 by a group of Pennsylvania dentists who attended a course at Penn State on the construction of speech appliances for children with cleft palate. The purpose of the organization, as stated in the original Preamble to the Constitution, was to "encourage...the improvement of scientific clinical services to persons suffering from cleft palate and associated deformities." It was apparent from the first meeting that improving services was largely dependent on cooperation and communication among the three primary disciplines involved in the treatment of cleft lip and palate: surgeons, dentists, and speech pathologists.

Today, the Association has a membership of over 2,600 in 40 countries. Membership is open to qualified individuals who are involved in the treatment and/or research of cleft lip, cleft palate, and other craniofacial anomalies. Members represent over 30 health care disciplines. Their mission is *"to optimize care of persons affected by craniofacial anomalies through education, stimulation of research, and the promotion of interdisciplinary collaboration and team care."*

For more information on cleft lip/palate, craniofacial anomalies, and team care contact:

OUR NEW ADDRESS
Am. Cleft Palate-Craniofacial Assn.
104 South Estes Drive, Suite 204
Chapel Hill, NC 27514
(919) 933-9044

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Printed in the United States

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FACT SHEET

About the Association

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The Association holds a general scientific meeting of the membership every year. Over 100 papers are presented at the annual meetings on such subjects as intervention outcomes, cleft lip and palate surgery, craniofacial surgery, psycho-social development, genetics, and bone grafting.

The official publication of ACPA is the bi-monthly *Cleft Palate-Craniofacial Journal*. It is an international, interdisciplinary, professional journal reporting on clinical and research activities in cleft palate and other craniofacial anomalies, together with research in related laboratory sciences.

The Association is governed by a 16-member Executive Council which establishes Association policy. The council is supported by 21 committees and a staff of five.

Officers of the Association are:

President	Marilyn C. Jones, M.D., Children's Hospital of San Diego, San Diego, CA
President-Elect	John E. Riski, Ph.D., Scottish Rite Children's Medical Center, Atlanta, GA
Past President	Katherine Dryland Vig, F.D.S., D'Orth, Ohio State University, Columbus, OH
Vice President	Don LaRossa, M.D., Children's Hospital of Philadelphia, Philadelphia, PA
Vice President-Elect	Leslie A. Will, D.M.D., M.S.D., Harvard School of Dental Medicine, Boston, MA
Secretary	Kim S. Uhrich, M.S.W., C.C.S.W., University of North Carolina, Chapel Hill, NC
Treasurer	Michael J. Buckley, D.M.D., M.S., University of Pittsburgh, Pittsburgh, PA
Historian	Donald V. Huebener, D.D.S., St. Louis Children's Hospital, St. Louis, MO
Editor	Jerald Moon, Ph.D., University of Iowa, Iowa City, IA
Executive Director	Nancy C. Smythe, ACPA/CPF National Office, Chapel Hill, NC

About the Cleft Palate Foundation

The Cleft Palate Foundation was founded by its parent Association in 1973 to be the public service arm of the professional Association. Its primary purpose is "to enhance the quality of life for individuals with congenital facial deformities and their families through education, research support, and facilitation of family-centered care."

The Foundation's major activities include the operation of the CLEFTLINE and the dissemination of publications. The CLEFTLINE is an 800 toll-free service providing information and referral to parents of newborns with cleft lip, cleft palate, and other craniofacial anomalies, and to affected adults. Referrals are made to cleft palate/craniofacial teams and to parent support groups. Brochures and fact sheets on various aspects of cleft lip, cleft palate, and other craniofacial anomalies are provided free to families.

The Foundation also conducts parent/patient liaison projects, public education activities, and awards annual research grants to junior and senior investigators.

The Foundation is supported solely through tax-deductible contributions. It is governed by a six-member Board of Directors and supported by seven committees.

Officers of the Foundation are:

President	Earl J. Seaver, Ph.D., Northern Illinois University, DeKalb, IL
Secretary	Kim S. Uhrich, M.S.W., C.C.S.W., University of North Carolina, Chapel Hill, NC
Treasurer	Michael J. Buckley, D.M.D., M.S., University of Pittsburgh, Pittsburgh, PA
Executive Director	Nancy C. Smythe, ACPA/CPF National Office, Chapel Hill, NC
Honorary Chair	Stacy Keach, Malibu, CA

About Cleft Lip and Palate

Cleft lip and cleft palate comprise the fourth most common birth defect in the United States. One out of every 700 newborns are affected by cleft lip and/or palate.

A cleft lip is a separation of the two sides of the lip. The separation often includes the bones of the upper jaw and/or upper gum. A cleft palate is an opening in the roof of the mouth in which the two sides of the palate did not fuse or join together as the unborn baby was developing. Cleft lip and cleft palate can occur on one side (unilateral cleft lip and/or palate) or both sides (bilateral cleft lip and/or palate). Because the lip and the palate develop separately, it is possible for the child to have a cleft lip, a cleft palate, or both cleft lip and palate.

Cleft lip and palate are congenital or birth defects which occur very early in pregnancy. The majority of clefts appear to be due to a combination of genes and environmental factors. The risks of recurrence of a cleft condition are dependent upon many factors which include the number of affected persons in the family, the closeness of affected relatives, the race and sex of all affected persons, and the severity of the clefts.

Children born with a cleft frequently require a number of different types of services, e.g., surgery, dental/orthodontic care and speech therapy, which need to be provided in a coordinated manner over a period of years. This coordinated care is provided through interdisciplinary cleft palate/craniofacial teams — professionals from a variety of health care disciplines who work together on the child's rehabilitation.

For information, call the CLEFTLINE: 1-800-24-CLEFT.

Roberto Podesta RS

9-21-99

copied Podesta

9-21-99

Senator Pete Domenici – appropriations issues

Energy and Water (Domenici is the Subcommittee Chairman):

Wetlands riders: The House has objectionable riders that short circuit the Corps of Engineers wetlands permit review process. We have a senior advisers veto threat on the provisions (backed up by a 183-245 vote). The Senate does not have the riders and you should urge Domenici to insist on the Senate position so that he can get a signable Energy and Water bill.

Solar and Renewable Energy: The 1999 enacted level is $336 million and the request is $398 million for solar and renewable energy, which is a major component of the Climate Change Technology Initiative. Both the House and Senate cut below the request (-$89 million and -$97 million respectively) and below FY 1999 (-$27 million and -$35 million respectively). These levels would severely cripple advances in these technologies and their ultimate implementation. We need you to ask for more than the House and Senate.

Spallation Neutron Source (SNS): The House level for the SNS is $68 million ($146 million below the request, $51 million below FY 1999 and $119 million below the Senate). If the House mark prevails, there is a good chance that the project would be severely delayed or abandoned. Urge Domenici to insist on the Senate position.

Next Generation Internet (NGI) : Neither the House or Senate funds the $15 million request for the NGI. Urge funding.

Interior (Domenici will be an Interior bill conferee):

Baca Ranch: We would like to work with Domenici to authorize the purchase and find the $100 million for purchase of the ranch. Unfortunately, the House and Senate are reallocating the $40 million that we got appropriated for this purpose in FY 1999.

Indian issues: The House version of the Interior bill provides $2.4 billion for the Indian Health Service, a 7% increase over FY 1999 and only slightly below the request. The Senate bill provides $72 million less then the House. Urge Domenici to press for the House level. These reductions underfund women's health, information systems, dental health, mental health, public health nursing and sanitation improvements. The Bureau of Indian Affairs receives $1.79 billion in the House and $1.81 billion in the Senate, both about 3% above FY 1999 but over $.1 billion below the request. Press for at least the Senate level, particularly for Indian school construction. We also prefer the House levels and lack of restrictions on funding for the Special Trustee for American Indians.

Lands Legacy: Of your $1 billion Lands Legacy Initiative, $797 million is in the Interior bill. Neither the House nor Senate fund it at levels above FY 1999. While the Senate is $38 million above the House, even the Senate level of $286 million is $29 million below FY 1999.

9-21-99

Objectionable riders: The Senate has numerous objectionable riders such as grazing permit restrictions (overriding environmental rules), the Hutchison amendment prohibiting oil valuation changes (still pending on the Senate floor), a permanent override of the hard rock mining five acre millsite limitation and other provisions. The House does not have such riders. We have a senior advisers veto threat on the Senate riders.

Millennium: Neither the House nor Senate funds this important initiative designed to rehabilitate and restore nationally significant historic buildings, cultural artifacts and collections. Seek Domenici's help to fund this $30 million request (the same as the FY 1999 level).

National Endowment for the Arts: While both the House and Senate are well below the request, you could thank him for supporting the Senate amendment to increase funding to a level $5 million over FY 1999 and urge him to press for at least the Senate level (compared to a House level which is at the FY 1999 level of $98 million).

Defense (Domenici is a conferee):

F-22: Ask for his help on funding the F22 (the House bill terminates the program).

Spectrum: Oppose efforts by industry to modify the spectrum sale provision in a way that would cut the savings in half.

Agriculture (Domenici is not a conferee but he could call Stevens and Cochran):

Sanctions: Urge Domenici to call Stevens or Cochran to get them to drop or fix the Ashcroft/Hagel language that would require congressional approval of agricultural or medical products sanctions against foreign governments.

6837

9-21-99

THE WHITE HOUSE

WASHINGTON

September 20, 1999

'99 SEP 20 AM 7:49

ACTION

MEMORANDUM FOR THE PRESIDENT

FROM: SAMUEL BERGER
NEAL LANE

SUBJECT: Increasing Industry Participation in Vaccine Development -- A Proposal

Copied
Berger
NSC WW Desk
Lane
Podesta

Purpose

To decide whether to call a White House meeting to develop incentives to promote private sector investment in vaccine development for diseases of developing countries -- and whether to announce this initiative in your UNGA address.

Background

Your May 28 Weekly Economic Briefing contained an analysis entitled, "Have Drug Companies Abandoned Critical R&D?" It focused on the need for motivating pharmaceutical companies to invest in the development of drugs and vaccines that primarily affect the world's poor, such as malaria, tuberculosis (TB), dysentery, and others. You indicated interest in pursuing the issue.

AIDS, TB, and malaria alone kill over seven million people each year -- mostly in developing countries. Effective vaccines will be the best public health solution for all three of these diseases. Unfortunately, the pharmaceutical industry, being profit-driven, will not undertake costly research without the expectation of adequate financial return. We need to determine what the administration can do to expand development of vaccines by motivating industry to come to the table.

cc: Vice President
Chief of Staff

9-21-99

Malaria Vaccine -- One Example

There are major international efforts, mainly led by the United States, United Kingdom, the World Health Organization, and nongovernment organizations, to develop a malaria vaccine. The United States Government now spends over $50 million/year specifically on malaria vaccine research (80 percent from the National Institute of Health). The Gates Foundation has set aside $50 million new money for malaria vaccine research as well. However, while the primarily government-based research is moving ahead, the development of vaccines for malaria is being virtually ignored by the pharmaceutical industry, which cites competing, more profitable pursuits.

Imperative?

New drugs and vaccines cannot be readily developed by the public sector alone. We need the product development capabilities of the private sector to build on the basic science often done by government and academic institutions. We must find ways to encourage pharmaceutical companies to invest in vaccine (and drug) development for important tropical diseases -- especially those like malaria, TB, and AIDS for which there is high need but for which market forces have failed to spur the development process.

Possible Solutions

The pharmaceutical industry has proposed a number of solutions, including increased national allocation of funds, the use of World Bank loans, the creation of national health trust funds, grants by foundations, and the creation of a global vaccine fund.

- Jeff Sachs from Harvard has proposed that donor countries pledge <u>now</u> to purchase vaccines for tropical diseases when they are eventually developed. This could provide a financial incentive for the pharmaceutical companies, but would not require actual funding until an actual vaccine is available. This is one of a number of interesting new ideas, although it is unclear whether there will have to be a commitment to a specific dollar amount, and how many other countries could be expected to contribute.

- Nancy Pelosi has submitted a bill, HR 1274, the "Lifesaving Vaccine Technology Act," which would provide a 30 percent tax credit on research and development expenditures on vaccines

9-21-99

for malaria, TB, HIV, and any other disease that kills more than one million annually. We understand that John Kerry intends to introduce the bill in the Senate. This bill has been estimated to have a cost of only $10 million/year, however, there is some controversy as to whether it would provide any increased incentive.

Foundations are increasingly pivotal. Bill Gates has just informally committed $750 million over 5 years for a Children's Vaccine Trust Fund to buy existing vaccines for poor countries. He intends to produce a developing country market for existing vaccines and then entice pharmaceutical companies to develop new ones. Gates wants to create a credible and sustained demand for vaccines, just like for his computer software.

good if it helps

Cross-Cutting Domestic PhRMA Issue

It is important to recall that the pharmaceutical industry has now initiated a multi-million dollar campaign against your Medicare prescription drug benefit initiative. While we do not believe that this should preclude your efforts to encourage the industry to be more proactive on the international front in developing needed medications, we believe that it is important to realize that a meeting early next year has the potential to coincide with potential tensions on the domestic front with the industry.

Conclusion

Market forces alone will not ensure vaccine development for diseases like malaria, TB, and AIDS in a timely fashion. New research must be done and new and innovative partnerships among government, industry, foundations, the UN, and others must be sought. Notwithstanding the debate we are currently having with the drug industry on Medicare, the time may be right to add the Administration's weight to encourage the drug industries to increase their participation in vaccine development.

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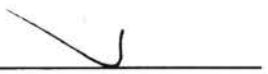
RECOMMENDATIONS

1. That you call for a special White House summit on vaccine development in the first quarter of 2000. During the summit you would meet with pharmaceutical company chief executive officers, foundation heads, members of Congress, academic experts, and other interested parties to hear their concerns and ideas for workable economic and technical solutions to promote private sector investment and new public/private partnerships to develop vaccines for TB, HIV/AIDS, malaria, and other diseases of the developing world.

Approve 

Disapprove _____

2. That you announce your intention to call the meeting during your September 21 UN General Assembly speech.

Approve 

Disapprove _____

Attachment
Tab A May 28 Weekly Economic Briefing

THE PRESIDENT HAS SEEN
6-3-99

SPECIAL ANALYSIS

Have Drug Companies Abandoned Critical R&D?

Tropical diseases long ago conquered in developed nations still kill and disable millions of people in the developing world—and some may be re-emerging in the United States and other advanced nations. Yet pharmaceutical companies appear to have abandoned R&D for these diseases. Can policymakers motivate profit-driven firms to invest in the development of drugs that primarily benefit the world's poor?

Malaria and market failure. The resurgence of diseases, increasing drug resistance, adverse effects, and the need for simpler treatment protocols point to the need for greater R&D in new drugs for diseases found in the developing world. For example, a resurgence of increasingly drug-resistant malaria around the world, including some cases in the United States, is afflicting up to 500 million people and ~~killing up~~ to 2.7 million each year. Yet in 1997 a consortium of leading pharmaceutical companies refused to support a proposed joint project to develop new treatments for the world's most threatening tropical diseases, particularly malaria.

A retreat to proven formulas. Other diseases besides malaria, including tuberculosis, dysentery, and meningitis, lack adequate treatment in poor countries. Instead of researching new treatments for these diseases, however, pharmaceutical companies have chosen to refine proven and profitable products. Of the more than 1,200 new pharmaceutical chemicals commercialized between 1975 and 1997, only about 30 percent were therapeutic innovations. Only 13 of these 1,200 were specifically for tropical diseases, and a mere 4 of these 13 resulted directly from R&D by the pharmaceutical industry rather than by the military or other organizations. This record stands in marked contrast to the pharmaceutical industry's crucial contributions to fighting endemic tropical diseases between 1910 and 1970.

Business as usual. Economic factors are a key explanation for the industry's current indifference to tropical diseases. A typical R&D program costs about $160 million and takes 8 to 12 years to complete. Profit-driven pharmaceutical companies will not undertake such costly research without the expectation of an adequate financial return to justify the risk and expense. In addition, heightened merger activity in the pharmaceutical industry in the late 1980s may have put pressure on management to focus on the proven profitable segments of the market, such as infectious diseases, cardiovascular conditions, and cancer—to the exclusion of even the most endemic of tropical diseases.

The attractiveness of the U.S. market. The sheer size of the U.S. market encourages profit-oriented pharmaceutical companies to develop drugs aimed at diseases that are more common here than elsewhere. But the United States is also a particularly lucrative market for international pharmaceutical companies because prices can be set freely in this country. By contrast, countries with a centralized health care system can exact price concessions from the companies. With the payoff

THE PRESIDENT HAS SEEN
6-3-99

to pharmaceutical R&D arising disproportionately from profits in the U.S. market, it is not surprising that companies' R&D programs are heavily weighted toward diseases that are prevalent here.

Intellectual property issues. Drug companies are among the most enthusiastic proponents of intellectual property protection. The importance of patents, which grant innovators a period during which they can exploit a new drug monopolistically, is well-known. Yet for diseases that afflict the very poor, even the guarantee of a temporary monopoly on the entire world market, enforced by an intellectual property regime, could be an inadequate incentive to incur the risk, research cost, and production cost of a vaccine or cure. In such cases, intellectual property protection would be only a partial solution.

* **The most cost-effective foreign aid?** Some economists have recommended that leading governments guarantee an adequate market for an effective malaria vaccine, should it be discovered, by pledging to purchase the vaccine for mass distribution in needy areas. Under reasonable cost estimates, the vaccine could be provided for every child born in Africa for a very small fraction—between 1½ and 6 percent—of the current amount of all the foreign aid they receive.

Conclusion. The drought of industry research for tropical diseases endemic among the poorest nations may be reversible. Providing adequate economic incentive by guaranteeing a market for vaccines or cures may be one effective—and humane—government solution. Other solutions, such as demanding intellectual property protection from recipient countries, may be insufficient if those who need the treatment are simply too poor to afford it.

THE PRESIDENT HAS SEL

6-3-99

cc: Chris Jennings
Fyi

[redacted]

Steinberg/NSC

can we get AID to do anything about this - maybe we could get G-8 cooperate on this

STEINBERG/NSC

CAN WE GET AID TO DO ANYTHING ABOUT THIS, IMAGINE WE COULD GET G-8 TO COOPERATE ON THIS

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