DRAFT

PRIVILEGED AND ~~CONFIDENTIAL~~ MEMORANDUM

TO: President Clinton
FR: Ira Magaziner, Chris Jennings
RE: **Biotech Industry and the Health Security Act**
cc: Hillary Rodham Clinton

January 6, 1994

Prior to the holiday break, you read an article in the Philadelphia Inquirer about the biotechnology industry and its concerns about the Health Security Act. You asked, "**Isn't there something we can do about this?**"

The short answer to your question is yes. Our more detailed response can be found starting on page 4 of this memo. Preceeding this section is some background information on the biotech industry and on the relevant (and rationale behind) the provisions of the Health Security Act.

BIOTECH BACKGROUND

Biotechnology pharmaceutical products have great potential to develop cost-effective "breakthrough" drug treatments and cures for diseases afflicting millions of Americans that are costing billions of dollars. Because the biotech industry is the most heavily R&D investment-oriented of all drug manufacturers and because it allocates much less of its dollars on marketing, it is frequently (and understandably) cited as the shining star of the pharmaceutical industry.

Contributing to the industry's positive perception is the fact that the biotech industry has a relatively solid track record of not increasing prices significantly above inflation, is pricing its products at levels that largely mirror the prices that other Western countries pay, and is one of the most internationally competitive industries in the U.S. As a result, there is no question that we should avoid unfairly burdening a R&D-intensitive industry that may well produce great economic and health care dividends.

While the biotech industry has great potential, it is important to note that there are also significant fears that the manufacturers of these products will "launch" their products at prices that will threaten the solvency of private and public insurance plans. A number of examples have been cited in recent years that illustrate pricing behaviors that support these fears.

Moreover, since many health care experts believe that pharmacological interventions will represent a larger and larger slice of the medical utilization pie in the years to come, there is concern that prescription drug costs will be excessively burdensome on the purchasers of health care. The primary concern is that "breakthrough" drug products, i.e. those that have no significant therapeutic alternatives, will have little or no competition in the private or public sectors to pressure companies to be price sensitive.

The Clinton Health Security Prescription Drug Proposal

The challenge of health reform as it relates to prescription drugs has always been to achieve the balance of providing prescription drug coverage for all Americans at an "affordable" price, while retaining adequate incentives for R&D investment for the industry.

The Health Security Act has attempted to achieve the appropriate balance by providing for a significant drug benefit for every American ($250 deductible and 80 percent coverage). To address the prescription drug cost issue the legislation (1) specifically rejected price regulation of drug products and relies on market purchasing techniques for the under-65 population, (2) provides for a breakthrough drug review board that will evaluate and publish (but not regulate) new drug prices that it concludes are excessive, and (3) holds down Medicare costs by providing for a Medicare rebate for the drugs it purchases (much like the current Medicaid drug rebate program) and provides authority for the Secretary to negotiate new drug prices (just as she has the authority now for drugs covered under the drug immunization bill.) **It is important to note that, even with these provisions, our current estimates project that the industry will benefit from the new prescription drug coverage provisions to the tune of increased expenditures over baseline of between $5 and 10 BILLION A YEAR.**

Industry, Consumer, and Congressional Response to Proposal

Pharmaceutical Industry Response

The pharmaceutical industry has raised serious concerns about the Medicare rebate, the breakthrough drug advisory board, and the provision that provides the authority for the Secretary of Health and Human Services the ability to negotiate over the price of new products. The industry argues that the bill's provisions create an environment that serves as a disincentive for capital investment.

The evidence on the investment issue is mixed. There is no question that the biotech industry is being told by many investors that the Administration's proposal is making it much more difficult to attract capital. Understandably, this information is driving many within the biotech industry to allocate a great deal of resources and time in opposing the Medicare drug cost containment provisions of the Health Security Act. **It is interesting to note, however, that a just released Ernst and Young analysis of biotech investment has concluded that from 1992 to 1993 "financing is up 21 percent" from $2.65 billion to $3.2 billion.** (Please also see attached articles which also seem to confirm this conclusion.)

While the industry has been very active and effective in raising strong concerns about the cost containment provisions of the Health Security Act, it has not acknowledged the many concessions the Administration gave during the development of the proposal. The bill explicitly rejected price controls, rejected the ability of the Medicare program to use a formulary, phased out the Medicaid prescription drug rebate program, provided a huge new market by requiring that every American have drug coverage, created new incentives for the covered Medicare population to purchase Medicare-certified HMO benefits (which are privately administered plans that use formularies), and modified the charge of the drug advisory board to review prices in relation to all other medical interventions (a provision that the biotech industry virtually wrote). All of these provisions were high priorities for the industry. **Regardless, however, there is no question that the industry has taken the position that they need to push for changes on Capitol Hill to ensure investment dollars and that they believe their chances for success are quite good.**

Consumer Groups Response

Representatives of consumer groups almost universally support the pharmaceutical coverage and cost containment provisions in the Health Security Act. Families USA, AARP, the National Council of Senior Citizens, Consumers Union, the AIDS Action Council, the National Organization of Rare Diseases, and other advocacy groups representing tens of millions of Americans have written in to specifically endorse the prescription drug cost containment provisions. In so doing, these groups have specifically **rejected** the industry's position that the cost containment provisions will reduce investment in the treatments and cures that would benefit the people they represent. In fact, some of the groups -- such as Consumer Union -- have concluded that we have gone too far towards the industry's position. In addition, the community pharmacists (the National Association of Retail Druggists and the National Association of Chain Drug Stores) are perhaps our strongest provider group advocates in the nation.

Congressional Response

The Congressional response has, in large part, reflected the concern outlined by the biotech industry. A number of Members, including key Members on major Committees of jurisdiction, have expressed significant interest in coming up with biotech industry inspired alternatives to the current prescription drug cost containment structure. On the other side of the debate, Senator Pryor's staff has expressed concern about being able to retain the current provisons of the bill, which the Senator generally supports (although he wishes that they were stronger on the cost containment front.) The reality appears to be, however, that the Committees will need to have some leeway to make changes to attract the votes we need to get the Health Security Act out of Committee. The key to doing anything will be to make changes that still retain the support of the aging advocate organizations (and hopefully not overly alienating the pharmacy groups.)

What Can Be Done to Address the Concerns of the Biotech Industry?

The short answer to your question is that there are options that are now being reviewed by Administration and Congressional representatives that the the biotech industry finds quite appealing; in fact, the industry has played a significant role in developing them. In brief, these proposals would replace the current Medicare cost containment provisions with contracts to private (primarily managed care) purchasers who are now administering prescription drug benefits for private insurers. (These purchasers control costs primarily through the use of drug formularies, prior authorization techniques, and generic substitution.) The biotech industry is attracted to these approaches because smaller, private sector purchasers are much less intimidating to them and their investors than large Government purchasers (e.g., Medicare).

These alternative proposals have potential, are worth pursuing, and have already found some responsive ears on Capitol Hill. Even staff from Members traditionally not sympathetic to the industry (e.g, Senator Pryor and Congressman Wyden) have expressed interest. Having said this, there remains many unanswered questions, including:

(1) Since different purchasers would provide different benefits (because their formularies would not cover the same medications and their copayment structures would likely be different), how would Medicare beneficiaries and (most importantly) their advocates react to receiving benefits that could be portrayed as not uniform?

(2) If we enacted these alternatives, are we prepared to deal with the possibility that the pharmaceutical industry will step up their attacks on the use of "restrictive" formularies through the media and potentially the courts and, in effect, leave both the private and public sectors unprotected against increasing pharmaceutical costs?

(3) How would the community pharmacists (so far, our strongest, organized provider proponent) react (we suspect negatively) to a proposal which, in essence, immediately relies on privately administered managed care purchasing techniques as a mandatory part of the Medicare program with which they believe they are not yet able to compete? Perhaps more importantly, how would we assure that selective contracting with pharmacists assured convenient access to pharmacies for elderly populations, particularly those living in rural areas?

(4) How would we assure that the costs of the Medicare program are generally consistent with our current cost estimates, which already are quite imposing? and

(5) Since the portrayals by the biotech industry may well overstate the negative economic impact the current legislation may have (or is) having on the industry, should we send a signal that we are supportive of an alternative before we have had a chance to adequately evaluate the economic and political consequences of it?

SUGGESTED ADMINISTRATION POSITION FOR NOW

In light of the outstanding questions about the alternatives now being developed by the biotech industry and the Congress, we would advise that the Administration signal a willingness to be open to options that meet the broad goals of assuring a solid drug benefit, restraining excessive cost increases, and retaining incentives for investment in R&D. In fact, we would recommend specifically acknowledging the option that is being propounded by the biotech industry as one that is potentially constructive and worthy of serious consideration.

THE PRESIDENT HAS SEEN 12/2093

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Isn't there something
we can do about this?

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The Philadelphia Inquirer
50 cents outside the eight-county Philadelphia metropolitan area
Friday, November 26, 1993

Clinton's health-care plan is cramping this industry's style.

Biotech holding back on progress

By Donna Shaw
INQUIRER STAFF WRITER

In Maine, tiny ImmuCell Corp. is delaying research on a medicine for infants who suffer from life-threatening dehydration.

In North Carolina, Macronex Inc. is reluctantly wooing Japanese and European investors so it can continue its work on treatments for asthma and rheumatoid arthritis.

In California, Cryopharm Corp. has sold its blood-storage technology to a Swedish company and laid off 20 of its 50 employees. The savings will allow Cryopharm to fund its key research on preventing viral contamination of donated blood.

Across the country, research scientists at the nation's fledgling biotechnology firms complain of spending less time in the laboratory and more time raising cash.

Money, they complain bitterly, should be easier to find for one of the few remaining bright spots in American industry, an industry the Clinton administration says it wholeheartedly supports, both for its science and its well-salaried jobs.

But now, say the executives, what should be the end of one financial downturn, the recession, is being stalled by yet another force: the President's proposed health-care plan.

"The administration wants to control what it sees as serious profiteering by the pharmaceutical industry, but this will have the most dramatic effect on biotechnology," said Forrest H. Anthony, chief executive of Avid Therapeutics Inc., a West Philadelphia company that specializes in anti-viral drugs for hepatitis B and other ailments.

"I can't imagine a biopharmaceutical company not being negatively

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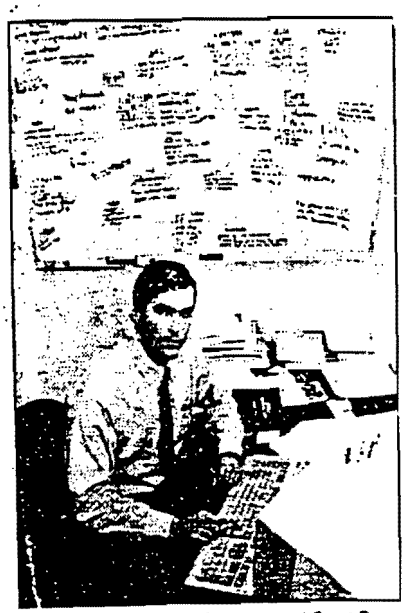
Biotech firms grow cautious over Clinton plan . . .

A18



For The Inquirer / Scott Perry

Michael Brigham, chief financial officer at ImmuCell, of Portland, Maine, fears "that innovation will not be paid for."

BIOTECHNOLOGY from A1

affected by what's going on," added Stanley Crooke, chief of Isis Pharmaceuticals in Carlsbad, Calif.

Isis, which is pioneering technology to turn off the cellular reactions that cause disease, has scaled back its work on cancer and AIDS.

"In an industry where uncertainty is the rule and we ask investors to invest in a dream, any enhanced level of uncertainty is highly, highly detrimental," Crooke said.

In Princeton, Cytogen Corp. recently slashed 88 of its 225 jobs, many of them in research, and "mothballed" human testing of its diagnostic products for breast and lung cancers. It was all to save money by narrowing the company's focus, said Thomas J. McKearn, Cytogen's president and co-founder.

How much of this is attributed to the Clinton plan? "Approximately all of it," he said.

"The public in general will probably never know what the cost of this is," he said. "How do you quantify the benefits we would have seen had we continued? But new drugs that would

A major source of the industry's ire is the Clinton plan's provision for an advisory committee to examine "the reasonableness of launch prices of new drugs that represent a breakthrough or significant advance over existing therapies."

The committee would have no power to set prices, but the mere specter of such a panel is scaring off already jittery investors, say leaders of the biotech industry. That's because investors view the committee as a mechanism to control prices.

"When these sorts of price controls are even talked about, we can't raise money. ... And the danger is that America may blow its chance to retain the lead in biotechnology," said Anthony, who co-founded Avid in 1991 with Baruch Blumberg, winner of the Nobel Prize for medicine for his discovery of the hepatitis B virus and work on an early vaccine.

Robert M. Goldberg, a research fellow for the nonprofit Gordon Public Policy Center at Brandeis University, fears that companies will switch to less innovative projects rather than risk failure in the costly breakthrough arena.

"Many important research projects that could save and enrich the lives of millions will be delayed, shelved or sold overseas," he wrote in the center's September Policy Bulletin.

To be sure, biotechnology is not for the faint of heart — and its periodic setbacks in the lab, combined with the poor economy, have sent many an investor fleeing for cover. Generally, these companies burn enormous amounts of money — so much that they even have dubbed it the "burn rate" — just to stay in operation until they have products to market.

So far, only a handful have received U.S. government approval to sell any genetically engineered products. The industry — nearly 1,300 companies employing 97,000 people — is billions of dollars in the red.

Countering the risks, though, is the tantalizing prospect of curing cancer, AIDS, Alzheimer's disease and more, based on disease-fighting substances found in living cells. That potential — not to mention potentially huge profits — still attracts the more adventurous investors.

James McCamant, editor of the Medical Technology Stock Letter in Berkeley, Calif., believes that, in large part, biotech's financial difficulties stem from a self-fulfilling prophecy.

"The industry has exaggerated the problem ... to make sure nothing is in the final [health-reform] plan," he said, "and that, in turn, has hurt their stocks."

McCamant says he sees nothing in the Clinton plan that will maim biotechnology. The breakthrough-drug committee "will simply codify what's being done anyway," because the government already negotiates for cheaper drug prices, he says.

"We remain convinced that the biotechnology stocks have again entered the upside of a major cycle," he writes in the most recent issue of his newsletter, which touts biotech stocks.

The White House, too, vigorously defends the plan, saying there is nothing in it to hurt biotechnology.

Administration officials, speaking on the condition that they not be identified, said the breakthrough-drug committee, as proposed by Clinton, would have the power to write reports, but "not one single ounce of authority to bring down prices."

"I just can't imagine that people are relying on this provision to decide whether to invest money," said one official.

At the same time, the official acknowledged that he'd heard reports of biotech firms being unable to get funding while investors waited to see what happened to the legislation.

On Nov. 2, a delegation of biotech executives met at the White House with Ira Magaziner, a main architect of the Clinton health plan, to discuss their concerns. Carl Feldbaum, president of the Biotechnology Industry Organization (BIO), said the 90-minute session ended in "a stalemate."

Magaziner was sympathetic and insisted that Clinton wished to encourage innovation, "but that alone," said Feldbaum, "will not encourage our capital markets."

In visits to biotech companies across the country, Feldbaum said, he has seen a change among chief executives.

"They're postponing hiring new

. . Putting expansions and breakthroughs on back burner

new facilities, and, in some rather dramatic cases, they are cutting off new lines of research," he said.

Among those cutting back are:

ImmuCell Corp. The Portland, Maine, company is testing a potentially life-saving drug that would prevent diarrhea in AIDS patients and infants — two groups for which dehydration can be fatal. But even though the government has the drug on the regulatory fast track for AIDS applications, there's simply no money right now to proceed with the parallel research on babies.

"If we had the money, we'd be pushing at least two other [research] programs," said Michael Brigham, ImmuCell's chief financial officer. "... I think that the difference now is this pricing fear, that innovation will not be paid for."

BioCryst Pharmaceuticals The Birmingham, Ala., company was on the verge of becoming a publicly owned corporation in June, which would have meant a large influx of cash, but its financiers backed out at the eleventh hour. BioCryst is working on cancer, psoriasis, multiple sclerosis, lupus and diabetes.

Frederick Dechow, BioCryst's chief executive, said the public offering went sour after the first outline of the Clinton plan was made public. "Investors didn't know how to react," he said. He feels, though, that investors are starting to come back to biotech, partly because they are betting that the breakthrough-drug committee will be eliminated from the final plan.

Alkermes Inc. The Cambridge, Mass., company is holding off on some renovation and expansion, and sending fewer people to professional conferences, according to spokeswoman Donna LaVoie, "mainly because of the current environment."

She acknowledges that such cost-consciousness has some merit, but says it's also making the company "very conservative about the programs we accelerate." Alkermes specializes in new methods of targeting drugs to specific areas of the body, as well as neurodegenerative diseases.

Macronex Inc. To continue work on asthma and rheumatoid arthritis, Dennis Burns, president and chief executive of the Morrisville, N.C., firm, said he's been forced to look overseas for money. "I judge there is interest there," he said.

Cryopharm Corp. The Pasadena, Calif., company resorted to layoffs and the sale of its blood-storage technology to a foreign company to continue its research on methods of preventing AIDS-contaminated blood from reaching patients. Spokesman Roger Hackett sees the Clinton plan as well-intentioned, but says the administration simply doesn't understand how the private sector works.

"From a personal perspective, the most damaging thing about the proposal is that there is no hard and fast proposal," he said.

Feldbaum, the BIO president, says the industry has essentially given up on talking to the White House. He'll now switch lobbying efforts to Capitol Hill, where the Clinton plan likely will undergo extensive revision before a vote.

"We've identified 77 members of Congress on key committees," Feldbaum said. "We'll meet with every one before Christmas."

January 1994 Ernst & Young Analysis:

BIOTECHNOLOGY INVESTMENTS
($ millions)

	1993	1992
Initial Public Offerings	$475	$830
Follow-on	920	820
Venture financing	410	365
Private financing/Debt financing	435	250
PIPE(1)	355	10
Other Creative financing	610	375
Total	$3,205	$2,650

Notwithstanding appearance of "frozen" capital markets, financing is up 21%. (1)Private Investment in Public Entity with discount.

"This year, the industry started to see the positive results of increased activity in strategic partnerships and collaborative agreements, between many biotech firms with larger drug companies, which helped to bolster businesses and streamline development efforts," according to G. Steven Burrill, national director, Manufacturing/High Technology Services of Ernst & Young.

"The biotech industry is poised for a healthy 1994 in spite of the rapidly changing health care and political environment worldwide," Burrill added.

Source: HealthWire, Ernst & Young

BioWorld Today

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BTG Raises $37.5M Via Financing Arm

By Karl A. Thiel
Special to BioWorld

Bio-Technology General Corp. (BTG) on Monday announced the closing of a $37.5 million placement made through Bio-Cardia Corp., a new, independent company that is essentially an off-balance sheet financing vehicle for BTG.

The $37.5 million was raised through the private placement of 375 BTG units priced at $100,000 each. The financing was arranged by D. Blech & Co.

Each unit consisted of four shares of Bio-Cardia common stock and 15,000 warrants to purchase BTG common stock (NASDAQ:BTGC) at $5.49 per share. The warrants are exercisable for five years. BTG also plans to register the warrants with the Securities and Exchange Commission within nine months so they can be publicly traded.

BTG maintains a four-year option to repurchase all outstanding shares of Bio-Cardia stock at 125 percent to

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British Teams ID New Genes

By Michael Kenward
Special to BioWorld

LONDON — The flurry of discoveries of new genes for inherited disease continued right up to the end of 1993, with two announcements concerning research supported by Britain's Medical Research Council. In one announcement, a consortium of researchers at the MRC Molecular Haematology Unit in Oxford, the Institute of Medical Genetics in Cardiff and two groups in the Netherlands said that it had identified a gene for the inherited disease tuberous sclerosis.

The second announcement, regarding a family of genes thought to control sperm production in humans and several animals, came from the MRC's Human Genetics Unit and the Fertility Problems Clinic of the Department of Surgery at Edinburgh University in Scotland. Both discoveries were published in last week's issue of *Cell*.

See British, Page 4

Biotech Financing Boom Continued in December

By Brenda Sandburg
News Editor

December was the third-best month of 1993 for biotechnology financings, with companies raising a total of $275 million in public and private placements. Only in January and November, with hauls of $520 million and $391 million respectively, did biotechnology companies reap more money.

As in November, public offerings far outpaced private investments in December, public offerings raised $189.58 million, while private placements brought in $85.01 million.

Here are summaries of transactions for the month.

IPOs

- Human Genome Sciences Inc. (NASDAQ:HGSI) of Rockville, Md., completed its long-awaited initial public offering on Dec. 2, grossing $27 million on the sale of 2.5 million shares at $12 per share.
- Texas Biotechnology Corp. (ASE:TXB.E) of Houston

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Agouron Gets Rights To Protease Inhibitors from Lilly

By Brenda Sandburg
News Editor

Agouron Pharmaceuticals Inc. has acquired from Eli Lilly and Co. exclusive worldwide rights to two classes of non-peptidic HIV protease inhibitors that the companies have been co-developing under a 1988 agreement.

In return, Agouron (NASDAQ:AGPH) will provide Lilly with proprietary details of the three-dimensional atomic structure of an enzyme that Agouron said "plays an essential role in the life cycle of an undisclosed, but clinically important, family of pathogenic viruses unrelated to HIV." Neither the enzyme nor the viruses it targets were disclosed.

Under its original agreement with Lilly, Agouron had the right to either a two digit royalty on Lilly sales of the

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Mucin-based Cancer Vaccine Enters Clinical Trials

By Karl A. Thiel
Special to BioWorld

Researchers at the Pittsburgh Cancer Institute (PCI) announced last week that they are beginning clinical trials of a novel synthetic peptide cancer vaccine following FDA approval of their investigational new drug application on Dec. 13.

According to Olivera Finn, director of PCI's immunology program, the vaccine differs from previous agents in that it directly provokes the response of killer T cells rather than stimulating antibody production. This cell-mediated immunity, Finn said, is much more effective against cancer than the more common antibody-based therapeutics. In addition, she said the immune response created by the vaccine is "more specific than we've previously seen with other cancer vaccines."

The agent is developed from an abnormal form of mucin found on the surface of breast, colon and pancreatic cancer cells. Mucin is a complex of proteins and sugars found on the surface of both healthy and cancerous cells. In the case of cancer cells, however, the mucin's sugar molecules are incompletely formed, revealing a limb of an inner protein that is normally hidden. These abnormal mucins can themselves evoke the response of killer T cells, but according to the PCI researchers, their effect is highly inefficient.

Mucin Peptides and an Adjuvant

The vaccine consists of concentrated mucin peptides and an adjuvant to attract immune cells. The antigen-presenting cells that are the basis of most vaccines rely on a major histocompatibility complex (MHC) not universal to all patients, so such therapeutics are only effective on patients with the right MHC.

Finn told *BioWorld*, however, that the synthetic peptide vaccine presents a repeated chain of antigens that do not depend on a particular MHC; instead, they bind with T cells at several sites, creating greater stability. Theoretically, therefore, all patients exposed to the vaccine should develop a killer T cell response. According to Finn, the agent greatly increases both the odds that the right immune cells will encounter the mucin protein and the efficiency of the whole process.

The PCI researchers will be evaluating the effect of the agent in 30 patients with widespread, incurable breast, colon or pancreatic cancer. The vaccination will be given in a series of three doses, each three weeks apart. After nine weeks, X-rays and physical examinations will be used to assess shrinkage of tumors. Blood tests and biopsies will be used throughout the course of the study to evaluate anti-mucin immune response at the vaccination site. The vaccine can be given on an outpatient basis, and according to Michael Lotze, co-director of PCI's Biological Therapeutics Program, is less dangerous than surgery and less toxic than chemotherapy or radiation therapy. Clinicals began Dec. 22. ■

NCI To License Plant-Derived Compounds for Treating HIV

By Brenda Sandburg
News Editor

The National Cancer Institute (NCI) will be seeking licensees for three plant-derived compounds that have stopped HIV replication *in vitro*. The compounds include michellamine B, calanolide A and prostratin.

They are among four compounds discovered through NCI's natural product screening program that the institute's Division of Cancer Treatment has approved for preclinical development over the past few years. A fourth compound, conocurvone, derived from *Conospermum* (a flowering shrub in Australia), was recently licensed to AMRAD Corp. Ltd., a consortium of four biomedical research organizations in Victoria, Australia (see *BioWorld*, Dec. 20). NIH has not yet published a *Federal Register* notice seeking a licensee for the other three compounds.

Found Only in Cameroon

Michellamine B, derived from *Ancistrocladus korupensis*, a vine that has been found only in Cameroon, is the furthest along in development. It entered toxicity testing in rodents and dogs late last year. The vine was first collected in 1987 by Duncan Thomas, who was then a botanist with the Missouri Botanical Garden.

Gordon Cragg, chief of NCI's Natural Products Branch, said this is a new species of plant that is not very abundant. He noted that NCI has been working with a group at Purdue University, the Missouri Botanical Garden, and scientists at the University of Yaounde in Cameroon to develop cultivation of the plant in Cameroon.

Of the other two plants, calanolide A is derived from the Malaysian plant *Calophyllum lanigerum* and prostratin comes from the western Samoan plant *Homalanthus nutans*. Cragg said the latter was collected from traditional healers in Samoa, who use it for the treatment of yellow fever.

Cragg told *BioWorld* that NCI's initial natural products collection program, conducted from 1960 through the early 1980s, gathered material primarily from temperate regions of the world — the U.S., Canada and Europe. In the 1980s, NCI began collecting material from tropical areas. Cragg said that under the new program the institute has screened more than 40,000 plant extracts, 12,000-13,000 marine organisms and 15,000-20,000 microorganisms for AIDS and cancer. ■

December

Continued from Page 1

raised $24 million (3.55 million units at $6.75 each) on Dec. 16;

• Viagene Inc. (NASDAQ:VIGN) of San Diego garnered $18 million (2 million shares at $9 per share) on Dec. 16; and

• SangStat Medical Corp. (NASDAQ:SANG) of Menlo Park, Calif., grossed $11 million (1.57 million shares at $7 per share) on Dec. 14.

Follow-ons and other Public Offerings

• PerSeptive BioSystems Inc. (NASDAQ:PBIO) of Cambridge, Mass., raised $50.6 million in a special purpose offering to fund its new R&D spinoff, PerSeptive Technologies II Corp., on Dec. 21;

• Calgene Inc. (NASDAQ:CGNE) of Davis, Calif., gained $9.2 million in a shelf offering (750,000 shares at $12.30 per share) on Dec. 17;

• NeoRx Corp. (NASDAQ:NERX) of Seattle raised $16 million in a follow-on offering (2 million shares at $8 per share) on Dec. 14;

• Shaman Pharmaceuticals Inc. (NASDAQ:SHMN) of South San Francisco, Calif., garnered $19.55 million in a follow-on offering (2.3 million shares at $8.50 per share) on Dec. 3; and

• Biomira Inc. (NASDAQ:BIOMF) of Edmonton, Alberta, raised $14.2 million (U.S.) in a follow-on offering (2 million shares at $7.5 per share) on Dec. 2.

Private Financings

• Insmed Pharmaceuticals Inc. of Charlottesville, Va., raised $1 million on Dec. 22 from the sale of series A preferred stock;

• Cell Therapeutics Inc. of Seattle raised $13.9 million on Dec. 22;

• Biostar Inc. of Saskatoon, Saskatchewan, brought in $8.2 million (U.S.) in its first round of equity financing on Dec. 17 (5.45 million shares at $1.50 each);

• Alexion Pharmaceuticals Inc. of New Haven, Conn., garnered $5 million on Dec. 16;

• Alliance Pharmaceutical Corp. (NASDAQ:ALLP) of San Diego grossed $16.4 million through the private placement of approximately 2.2 million shares at $7.50 each on Dec. 14;

• Receptagen Ltd. of Vancouver, British Columbia, completed a private placement of $7.5 million (U.S.) in special warrants on Dec. 14;

• Diatech Inc. of Londonderry, N.H., garnered $11.5 million in private financing on Dec. 3;

• Xytronyx Inc. (ASE:XYX) of San Diego grossed $1.28 million in a private placement of units on Dec. 3 and an additional $1.23 million in a separate private placement on Dec. 29; and

• Somatix Therapy Corp. (NASDAQ:SOMA) of Alameda, Calif., raised $11.7 million through the private placement of 2 million shares at $5.85 each on Dec. 2. ■

Life Technologies Licenses PCR

Life Technologies Inc. announced Monday that it has been granted a license by Roche Molecular Systems Inc. (RMS) and The Perkin-Elmer Corp. to manufacture and sell RMS's thermostable enzymes and products, including the Taq DNA polymerase enzyme, for use in the polymerase chain reaction (PCR) process.

The licensing agreement is a non-exclusive contract valid for the life of Hoffman La Roche's PCR patents. PCR, a nucleic acid amplification process, is a widely used research tool that enables researchers to generate a vast number of copies of specific DNA sequences within a short time. Both RMS and Perkin Elmer, the exclusive distributor of Roche's PCR products for applications other than *in vitro* diagnostics, will receive unspecified royalties from Life Technologies' (NASDAQ:LTEK) sale of PCR products.

Life Technologies said the licensing agreement will allow it to offer "an integrated and cross-qualified line of PCR application products." Previously the company was able to sell products for use only before or after the PCR process, and could only market the Taq DNA polymerase enzyme for applications other than PCR (such as DNA sequencing and labeling). The company had been marketing the enzyme prior to Cetus Corp.'s PCR patent in 1989; the Taq enzyme was first derived in 1966. ■

HemaCare Files Phase III IND for Immupath

HemaCare Corp. announced Monday that it has filed an investigational new drug application with FDA to begin Phase III clinical trials of its passive hyperimmune therapeutic Immupath.

According to the company, the proposed study would examine the efficacy of Immupath "to prolong survival and to improve immune competency" in AIDS patients with CD4 cell counts of between 50 and 400 cells/cubic millimeter. HemaCare (NASDAQ:HEMA) stressed that Immupath, derived from the plasma of asymptomatic HIV-positive individuals, is inherently non-toxic and contains a wide variety of anti-HIV antibodies that could overcome the difficulty of viral mutation encountered by other agents.

Last September the Los Angeles company received conditional approval from the California Department of Health Services, Food and Drug Branch, to begin Phase III testing of Immupath in approximately 600 patients (see *BioWorld*, Sept. 16). The company has been testing Immupath since 1990.

Agouron

Continued from Page 1

protease inhibitors or up to 50 percent of Lilly pre-tax profits if Agouron co-developed the compounds. The exchange of technology, announced last week, involves no payment of royalties or other continuing financial obligations between the two companies.

Agouron of La Jolla, Calif., said it will present preclinical data on the orally active HIV protease inhibitors on Jan. 12 at the Hambrecht & Quist conference in San Francisco. Agouron's director of corporate communications, Donna Nichols, said the company hopes to have one or two compounds in clinical trials in the second half of 1994.

Peter Johnson, Agouron's president and chief executive officer, said the protease inhibitors in the company's portfolio include compounds "that display desirable pharmacological properties *in vivo* and anti-HIV activity *in vitro* which is equal to or greater than that of any other HIV protease inhibitor yet reported."

According to Agouron, about 10 companies have reported on approximately 10 to 20 compounds. Hoffmann-La Roche Inc., Merck & Co. Inc. and Abbott Laboratories are among the companies developing protease inhibitors. Vertex Pharmaceuticals Inc. and Wellcome plc also are collaborating on the development of orally active protease inhibitors. ■

British

Continued from Page 1

Tuberous sclerosis affects about 10,000 people in Britain. Many cases are due to new genetic mutations, but in families with one affected parent, children have a 50 percent chance of inheriting the disease. Its symptoms include learning difficulties, epilepsy and a range of other medical problems, including tumors (usually non-malignant) in various organs.

Working with families with a history of tuberous sclerosis, the researchers used positional cloning to isolate the gene of chromosome 16. Peter Harris, leader of the MRC's team, said that in the short term, the goal is to develop a test for tuberous sclerosis. "In the long term, it will lead to a better understanding of this disorder, which may result in the development of treatments for this distressing condition," he said.

The researchers also believe the gene may be involved in regulation cell growth and may play a more general role in the development of tumors.

The second announcement concerned work on men with severe sperm-production problems. Screening in the Fertility Problems Clinic at the Western General Hospital showed that 15 percent of these men carried a mutation or deletion in the Y chromosome known as the azoospermia factor (AZF). Ma Kun, a student in the MRC's Human Genetics Unit, identified the gene family most likely to be AZF. The team, led by Anne Chandley and Howard Cooke, also established the genetic sequence of some members of the family.

It turns out that the gene in question is involved in the production of 'information' protein in the cell. Mutations in this gene may cause a loss of information that, in turn, could reduce sperm formation in a significant number of men with no other apparent cause of infertility.

Members of the same gene family also exist in other species, including mice, gorillas, sheep and bulls.

Chandley said the discovery of the gene could be the first step toward diagnosing male infertility through DNA analysis. "We hope that in the long term, understanding the gene function will help us to devise novel methods of male contraception as well as finding ways to treat male infertility," she said. ■

BTG

Continued from Page 1

200 percent of the invested amount, determined by the length of time the shares have been outstanding. Prior to any repurchase of Bio-Cardia stock, BTG keeps the exclusive right to commercialize any of the products developed under the agreement.

Leah Berkovits, BTG's manager of administration, explained that the creation of Bio-Cardia allows BTG to fund product development without affecting the company's cash reserves.

Bio-Cardia was formed in April 1993 when BTG's original offering memorandum was circulated. The financing closed Dec. 31.

Bio-Cardia has licensed seven early stage BTG products and will repay BTG $3.7 million over the next four years in return for BTG's research, development, preclinical and clinical development of the licensed cardiovascular, neonate pulmonary and ophthalmic products.

Berkovits told *BioWorld* that the company expects payments of $10 from Bio Cardia million during 1994.

Under the agreement, BTG of Iselin, N.J., maintains exclusive rights to the products. The agreement covers Imagex, its product for blood clot detection, which is currently in Phase I trials; Oxsodrol BPD, a product for the inhibition or prevention of broncho-pulmonary dysplasia that recently completed Phase I clinicals; and Biolon, a visco-elastic product approved in Canada and several European countries that is used as a lubricant during ophthalmic surgery.

The agreement also covers four products in preclinicals: Bio Flow, for prevention of re-occlusion/restenosis; Factorex, an anti-coagulant; Bio Lase, an acute re-occlusion inhibitor; and Oxsodrol CVD, a re-occlusion/restenosis inhibitor.

BTG's stock closed unchanged on Monday at $5.25 per share. ■

BioWorld
Financial Watch

Monday
Dec. 13, 1993

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1993 Tops 1992 for Biotech Investments

By Lisa Piercey
Business Editor

The total amount of money invested in public and private biotechnology companies in 1993 has now climbed to roughly $3 billion. That number tops 1992's total of roughly $2.8 billion and the year ain't over yet.

In 1993 — a year that saw stocks hit by high-profile product and earnings disappointments and uncertainty about health-care reform, a year in which companies were forced to raise money in a buyers' market and watch their market capitalizations drop to all-time lows, and a year in which the already competitive playing field was crowded with a record number of new start-ups — the biotechnology industry managed to pull a rabbit out of the hat once again.

"When you add it all together, we're having a stronger year in 1993 than we did in 1992," said **Ed Cahill**, managing director of investment banking at **Alex. Brown & Sons** in Baltimore, Md. "Claims of the capital market no longer supplying money to the industry are clearly exaggerated."

Although the numbers are impressive, post-offering market capitalizations for companies completing public offerings in 1993 are the lowest in three years. The average post-money valuation for a company completing an initial public offering (IPO) in 1991 was $106 million, in 1992 it was $87 million and in 1993 it dropped to $72 million.

Average post-money valuations for companies completing follow-on offerings also decreased: from $277 million in 1991 to $174 million in 1992 to $149 million in 1993. (See the December 6 issue of *BioWorld Financial Watch*, pages 5-6, for data.)

In addition, the composition of investment in biotechnology changed markedly from 1992 to 1993 — now, more of the money raised for public companies is being raised at a discount to market prices.

In 1992, initial public offerings and follow-on offerings raked in approximately $1.85 billion (66 percent of the $2.8 billion total). According to **Recombinant Capital**, a financial consulting firm in San Francisco, the rest of 1992 broke out as follows: financing of private companies by venture capitalists and corporations totaled $530 million (19 percent), offerings of debt totaled $50 million (2 percent), R&D partnerships totaled $148 million (5 percent) and corporate investments in both private and public companies totaled $210 million (8 percent).

> ***"Claims of the capital markets no longer supplying money to the industry are clearly exaggerated."***
>
> **Ed Cahill**
> Managing Director, Alex. Brown & Sons

1993's year-to-date total of $3 billion in investments breaks down in the following manner: $1.4 million came from public offerings (46 percent), $604 million (20 percent) from venture capitalists' and others' investments in private companies, $482 million (16 percent) from private financings of public companies and $201 million (7 percent) from offerings of debt. According to Recombinant Capital's records, another $335 million (11 percent) came from corporate investments in both public and private companies.

The most dramatic difference between 1992 and 1993 was the increase in private deals done by public

See 1993 Tops 1992, Page 2

10 BIGGEST GAINERS FOR THE WEEK

(By Percent)		(By Dollars)	
Matritech	+35	CellPro	+2.50
Coll Res	+24	Genetics Inst	+2.25
Chantal	+20	Affymax	+1.75
TSI Corp	+19	Idexx Labs	+1.74
Atrix Labs	+15	Lifecell	+1.25
Genzyme Tr	+15	Target Ther	+1.25
Lifecell	+15	Matritech	+1.00
Future Med	+12	Genzyme Tr	+1.00
Biocircuits	+12	Cephalon	+1.00
Affymax	+12	Atrix Labs	+0.88

10 BIGGEST LOSERS FOR THE WEEK

(By Percent)		(By Dollars)	
Enzymatics	-40	Chiron	-5.75
Alpha 1 Bio	-23	Alpha 1 Bio	-4.38
Immunex	-20	Immunex	-4.25
Cellular Prod	-20	Amgen	-3.25
Argus Pharm	-19	Human Genome	-2.75
Liposome Tech	-19	Liposome Tech	-2.38
Cantab	-19	Appl Im Sci	-2.13
Somanetics	-18	Aphton	-2.00
Appl Im Sci	-18	MGI Pharma	-1.75
Syntro	-18	Genetic Ther	-1.63

1993 Tops 1992

Continued from Page 1

companies (both through the sale of restricted stock and through so-called "PIPE" — Private Investment in Public Entity — deals involving the sale of discounted stock that is freely tradable upon delivery). The change is a reflection of the highly competitive environment in the public equity markets and the tenacity of cash-starved biotech companies.

"What this year demonstrates is that when times are tough you have to be creative," said **Peter Drake**, director of equity research at **Vector Securities International** in Deerfield, Ill.

> ***"I think $1-2 billion a year is about what is reasonable to expect from the capital markets for the biotech industry."***
>
> **Peter Drake**
> **Director of Equity Research, Vector Securities International**

Despite the recent increase in public offerings ($199 million in October and $260 million in November), 1993 was a year bereft of a true "financing window," according to Drake. "A window is a sellers' market. This is still a buyers' market," he said. In fact, Drake said the last time biotech companies enjoyed a sellers' market was in early 1992. He calls heavy months like January 1993 ($452 million in public offerings) financing "opportunities," not financing "windows."

Sustainable Rate of Financing

1993, with its sober but steady inflow of money, may establish a new, more sustainable standard for investment in the sector in years to come. The phenomenal boom in biotech financing seen in 1991 ($3.5 billion in public offerings and $675 million invested in private companies) may not be repeated any time soon, if ever.

"1991 is history," said **Grant Heldrich**, general partner at **Mayfield Fund**, a venture capital firm in Menlo Park, Calif. "What we are seeing now is much healthier. The frothy, extreme environment is gone. Even though valuations are lower, the quality of companies is higher."

Investors and analysts may have become more realistic about the risks and long time frames involved in drug development.

"I think $1-2 billion a year is about what is reasonable to expect from the capital markets for the biotech industry," said Drake.

Fred Frank, senior managing director of investment banking at **Lehman Brothers** in New York, agreed, characterizing 1993 as a "satisfactory year." He added that while the overall stock market is hitting all-time highs, biotech stocks are still down (on a non-weighted basis) about 15 percent for the first 11 months of 1993.

At the same time, Frank noted that money is flowing into mutual funds at a rate of $8-9 billion per month; this is money that fund managers will need to put somewhere. In that environment, the still-undervalued biotech stocks may look attractive. Mutual fund investment could continue to fuel public equity offerings through the first quarter of 1994.

Alex. Brown's Cahill said that investors seem genuinely optimistic. "We're clearly not looking at a market that has keeled over and died.

"Investors are continuing to accept the proposition that once these (biotech) drugs reach the market they will be attractive economically," he said. "And my hunch is that it's going to get better in 1994." ■

CORRECTIONS:

The December 6 issue of *BioWorld Financial Watch* contained several errors. First, the chart depicting money raised by biotech as of Nov. 30, 1993, should have shown the total for "PIPE Deals" as $469 million, not $483 million.

Also, due to our misapprehension of the strict definition of a "PIPE" deal, the label for that category in the same chart would more accurately be termed Private Financings of Public Companies (since all of the deals tallied did not involve freely tradable stock, the primary feature of a PIPE deal).

Second, shares outstanding if **ImmunoGen Inc.**'s currently pending follow-on offering is completed would be 13 million (14.7 million fully diluted). Finally, **MedImmune Inc.**'s stock dropped $11.25 immediately after the FDA meeting referenced in the front page article. The $15.75 drop cited was the stock's drop for the entire week.

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HRC Memo File

PRIVILEGED AND ~~CONFIDENTIAL~~ MEMORANDUM

TO: Hillary Rodham Clinton
FR: Chris Jennings
RE: **Biotech Industry and the Health Security Act**
cc: Melanne

January 6, 1994

Prior to the holiday break, the President read an article in the Philadelphia Inquirer about the biotechnology industry and its concerns about the Health Security Act. He asked, "**Isn't there something we can do about this?**"

Ira asked me to prepare some information for him to respond the the concerns raised by the President. The following is, in essence, that memo.

The short answer to the President's question is yes. The more detailed response can be found starting on page 4 of this memo. Preceeding this section is some background information on the biotech industry and on the relevant (and rationale behind) the provisions of the Health Security Act.

BIOTECH BACKGROUND

Biotechnology pharmaceutical products have great potential to develop cost-effective "breakthrough" drug treatments and cures for diseases afflicting millions of Americans that are costing billions of dollars. Because the biotech industry is the most heavily R&D investment-oriented of all drug manufacturers and because it allocates much less of its dollars on marketing, it is frequently (and understandably) cited as the shining star of the pharmaceutical industry.

Contributing to the industry's positive perception is the fact that the biotech industry has a relatively solid track record of not increasing prices significantly above inflation, is pricing its products at levels that largely mirror the prices that other Western countries pay, and is one of the most internationally competitive industries in the U.S. As a result, there is no question that we should avoid unfairly burdening a R&D-intenstive industry that may well produce great economic and health care dividends.

While the biotech industry has great potential, it is important to note that there are also significant fears that the manufacturers of these products will "launch" their products at prices that will threaten the solvency of private and public insurance plans. A number of examples have been cited in recent years that illustrate pricing behaviors that support these fears.

Moreover, since many health care experts believe that pharmacological interventions will represent a larger and larger slice of the medical utilization pie in the years to come, there is concern that prescription drug costs will be excessively burdensome on the purchasers of health care. The primary concern is that "breakthrough" drug products, i.e. those that have no significant therapeutic alternatives, will have little or no competition in the private or public sectors to pressure companies to be price sensitive.

The Clinton Health Security Prescription Drug Proposal

The challenge of health reform as it relates to prescription drugs has always been to achieve the balance of providing prescription drug coverage for all Americans at an "affordable" price, while retaining adequate incentives for R&D investment for the industry.

The Health Security Act has attempted to achieve the appropriate balance by providing for a significant drug benefit for every American ($250 deductible and 80 percent coverage). To address the prescription drug cost issue the legislation (1) specifically rejected price regulation of drug products and relies on market purchasing techniques for the under-65 population, (2) provides for a breakthrough drug review board that will evaluate and publish (but not regulate) new drug prices that it concludes are excessive, and (3) holds down Medicare costs by providing for a Medicare rebate for the drugs it purchases (much like the current Medicaid drug rebate program) and provides authority for the Secretary to negotiate new drug prices (just as she has the authority now for drugs covered under the drug immunization bill.) **It is important to note that, even with these provisions, our current estimates project that the industry will benefit from the new prescription drug coverage provisions to the tune of increased expenditures over baseline of between $5 and 10 BILLION A YEAR.**

Industry, Consumer, and Congressional Response to Proposal

Pharmaceutical Industry Response

The pharmaceutical industry has raised serious concerns about the Medicare rebate, the breakthrough drug advisory board, and the provision that provides the authority for the HHS Secretary the ability to negotiate over the price of new products. The industry argues that the bill's provisions create an environment that serves as a disincentive for capital investment.

The evidence on the investment issue is mixed. There is no question that the biotech industry is being told by many investors that the Administration's proposal is making it much more difficult to attract capital. Understandably, this information is driving many within the biotech industry to allocate a great deal of resources and time in opposing the Medicare drug cost containment provisions of the Health Security Act. **It is interesting to note, however, that a just released Ernst and Young analysis of biotech investment has concluded that from 1992 to 1993 "financing is up 21 percent" from $2.65 billion to $3.2 billion.** (Please also see attached articles which also seem to confirm this conclusion.)

While the industry has been very active and effective in raising strong concerns about the cost containment provisions of the Health Security Act, it has not acknowledged the many concessions the Administration gave during the development of the proposal. The bill explicitly rejected price controls, rejected the ability of the Medicare program to use a formulary, phased out the Medicaid prescription drug rebate program, provided a huge new market by requiring that every American have drug coverage, created new incentives for the covered Medicare population to purchase Medicare-certified HMO benefits (which are privately administered plans that use formularies), and modified the charge of the drug advisory board to review prices in relation to all other medical interventions (a provision that the biotech industry virtually wrote). All of these provisions were high priorities for the industry. **Regardless, however, there is no question that the industry has taken the position that they need to push for changes on Capitol Hill to ensure investment dollars and that they believe their chances for success are quite good.**

Consumer Groups Response

Representatives of consumer groups almost universally support the pharmaceutical coverage and cost containment provisions in the Health Security Act. Families USA, AARP, the National Council of Senior Citizens, Consumers Union, the AIDS Action Council, the National Organization of Rare Diseases, and other advocacy groups representing tens of millions of Americans have written in to specifically endorse the prescription drug cost containment provisions. In so doing, these groups have specifically **rejected** the industry's position that the cost containment provisions will reduce investment in the treatments and cures that would benefit the people they represent. In fact, some of the groups -- such as Consumer Union -- have concluded that we have gone too far towards the industry's position. In addition, the community pharmacists (the National Association of Retail Druggists and the National Association of Chain Drug Stores) are perhaps our strongest provider group adovacates in the nation.

Congressional Response

The Congressional response has, in large part, reflected the concern outlined by the biotech industry. A number of Members, including key Members on major Committees of jurisdiction, have expressed significant interest in coming up with biotech industry inspired alternatives to the current prescription drug cost containment structure. On the other side of the debate, Senator Pryor's staff has expressed concern about being able to retain the current provisons of the bill, which the Senator generally supports (although he wishes that they were stronger on the cost containment front.) The reality appears to be, however, that the Committees will need to have some leeway to make changes to attract the votes we need to get the Health Security Act out of Committee. The key to doing anything will be to make changes that still retain the support of the aging advocate organizations (and hopefully not overly alienating the pharmacy groups.)

What Can Be Done to Address the Concerns of the Biotech Industry?

The short answer to the President's question is that there are options that are now being reviewed by Administration and Congressional representatives that the the biotech industry finds quite appealing; in fact, the industry has played a significant role in developing them. In brief, these proposals would replace the current Medicare cost containment provisions with contracts to private (primarily managed care) purchasers who are now administering prescription drug benefits for private insurers. (These purchasers control costs primarily through the use of drug formularies, prior authorization techniques, and generic substitution.) The biotech industry is attracted to these approaches because smaller, private sector purchasers are much less intimidating to them and their investors than large Government purchasers (e.g., Medicare).

These alternative proposals have potential, are worth pursuing, and have already found some responsive ears on Capitol Hill. Even staff from Members traditionally not sympathetic to the industry (e.g, Senator Pryor and Congressman Wyden) have expressed interest. Having said this, there remains many unanswered questions, including:

(1) Since different purchasers would provide different benefits (because their formularies would not cover the same medications and their copayment structures would likely be different), how would Medicare beneficiaries and (most importantly) their advocates react to receiving benefits that could be portrayed as not uniform?

(2) If we enacted these alternatives, are we prepared to deal with the possibility that the pharmaceutical industry will step up their attacks on the use of "restrictive" formularies through the media and potentially the courts and, in effect, leave both the private and public sectors unprotected against increasing pharmaceutical costs?

(3) How would the community pharmacists (so far, our strongest, organized provider proponent) react (we suspect negatively) to a proposal which, in essence, immediately relies on privately administered managed care purchasing techniques as a mandatory part of the Medicare program with which they believe they are not yet able to compete? Perhaps more importantly, how would we assure that selective contracting with pharmacists assured convenient access to pharmacies for elderly populations, particularly those living in rural areas?

(4) How would we assure that the costs of the Medicare program are generally consistent with our current cost estimates, which already are quite imposing? and

(5) Since the portrayals by the biotech industry may well overstate the negative economic impact the current legislation may have (or is) having on the industry, should we send a signal that we are supportive of an alternative before we have had a chance to adequately evaluate the economic and political consequences of it?

SUGGESTED ADMINISTRATION POSITION FOR NOW

In light of the outstanding questions about the alternatives now being developed by the biotech industry and the Congress, I would advise that the Administration signal a willingness to be open to options that meet the broad goals of assuring a solid drug benefit, restraining excessive cost increases, and retaining incentives for investment in R&D. In fact, I would recommend specifically acknowledging the option that is being propounded by the biotech industry as one that is potentially constructive and worthy of consideration. Ira, or some other Administration official, could send a general signal of responsiveness at an upcoming February conference in late February.

Having said this, it is premature to take an active position of support for any alternative until we fully understand its policy, economic and political implications. Even more important, it would not make sense to move any further toward the drug industry's position until it becomes absolutely certain that any such changes don't simply become the next starting point for negotiations with the industry.

7218 Harlem

THE WHITE HOUSE

WASHINGTON

January 22, 1994

MEETING WITH SPEAKER FOLEY AND MAJORITY LEADER MITCHELL

DATE: January 24, 1993
LOCATION: Oval Office
TIME: 3:00 pm
FROM: Pat Griffin

I. PURPOSE

- To refocus the Congressional Leadership on health care.
- To jointly develop a specific legislative action timetable and strategy that, while somewhat flexible, will provide the Administration, the Leadership and the Committee Chairmen the guidance and discipline necessary to pass a signable bill.
- To attempt to get the Leadership to agree to establish a mechanism that simultaneously coordinates ongoing policy and strategic modifications between Committee Chairs.
- To outline the role the Administration currently plans to play in the legislative process and to seek feedback to it.
- To obtain guidance about how we can best ensure a successful follow-up meeting with the Leadership and the five Committee Chairs of primary jurisdiction over health legislation.

II. BACKGROUND

Looking at the constrained legislative calendar, noting that Members are diversely positioning themselves as it relates to health care, and keeping in mind the politics of any election year, it is clear that the Congress must be kept on a tight and well orchestrated timetable in order to produce a product that achieves the universal coverage/affordability marker that has been laid out by you and the First Lady. The Congress will not be responsive to this challenge unless the Leadership is invested and has agreed upon a reasonable timetable and strategy that, while somewhat flexible to currently unforeseen developments, serves to discipline the process. This meeting has been designed to facilitate this outcome.

AGENDA ITEMS

1. Timetable. Develop an agreed upon and fairly specific (but internal) timetable for Congressional actions (i.e, Committee mark-ups, floor schedule, conference, etc.) and a strategy about how best to stick to the schedule. (Inherent in this discussion is an understanding that, even if you, the Speaker and the Majority Leader are in agreement, the strategy must also be sold to -- and accepted by -- the five Chairmen as well.)

   The easiest way to get a timetable agreed upon is to work backward with the Speaker and the Majority Leader. While the best outcome would be to have a bill to your desk by the August recess, a much more realistic goal is to have it pass both chambers and be in conference by that timeframe. (Attached is a one page legislative calendar that outlines such a scenario.)

   Although finalizing a conference agreement and passing it through both Houses will be extremely challenging, the most difficult hurdle will be getting the bills into conference. As such, the primary focus of your conversation should be on how best to get the bills out of the Committees and onto the respective chamber floors for a vote on an acceptable legislative product. (A background on this process is attached for your review.) Any significant delay in this process will serve to either make it impossible to complete Congressional action prior to adjournment or will produce a substandard product (because opponents will have greater leverage in undesirably modifying the bill.)

2. Process Strategy to Work Within Timetable. There is no question that many House Members live in fear of being whip-sawed by the Senate if they are forced to move first and take a tough political vote on health care, particularly in this election year. They have no interest in witnessing a repeat of what they feel they went through in last year's budget process.

   To be responsive to the understandable concerns of the House, we recommend that you push the idea of a simultaneous, bicameral Committee and floor vote strategy. If the Senate Finance Committee, and thus the Senate as a whole, delays their action well beyond House Committee/floor action, we fear that there is a realistic possibility that the House will report out bills that they believe will not place them in a political vulnerable position (i.e., a significantly and unacceptably watered down bill).

There is little doubt that our simultaneous Congressional action recommendation conflicts with the institutional history of the Senate and the make-up of the Finance Committee, and it will be difficult to implement. Having said this, we believe it is still essential to attempt this because (1) we believe that a bill you are satisfied with might not be produced without this approach and (2) even suggesting it at least signals to the House that we are sensitive to their legitimate concerns.

Consistent with the concept of working concurrently with the Committees is a need to coordinate substantive policy modifications with the Committee Chairmen. If Committees report out completely opposite approaches, marrying the policy within the Rules Committee (and on the floor in the Senate) will be made extremely difficult. The only people who have a chance to even raise this Committee coordination concept with the Chairmen are their Leaders. We recommend that you raise this concept with Speaker Foley and Majority Leader Mitchell as something that seems desirable and ask them whether they believe it is feasible. **The optimal outcome from this proposal would be an agreement to establish a bicameral, Committee Chairmen coordination mechanism.** A chamber specific coordination approach would still be a great step forward.

3. Administration Role. It is important that you and the First Lady define the role you feel would be best to play throughout the legislative process, with a particular emphasis on the next two months or so. In so doing, you may wish to describe how you feel that the most useful contribution you can make to the work of the Congress is to keep the public debate focused on the fact that there is a health care crisis and that employer-based universal coverage is the only viable solution.

We would recommend that you reiterate that you have no desire or intention to micromanage the process because you feel it would be counterproductive for the Administration to be involved in the day to day actions/decisions of Committees. This does not mean the Administration is not engaged in the work of the Committees; it does mean, however, that it is a role that is primarily technical and behind the scenes until later in the process. You want to make sure, as we suspect is true, that they agree with this strategy.

4. Preparation for Chairmen's Meeting. The meeting should not conclude until you discuss how best to prepare for the next meeting with the Committee Chairmen. We would recommend that you seek their advice about the most appropriate timing, setting, and agenda of the Chairmen's meeting. You may also wish to solicit Leadership's assessment of where the Chairmen stand on the ability to report out comprehensive health reform bills.

IV. PARTICIPANTS

The President
The First Lady
Speaker Foley and his staff, George Kundanis
Majority Leader Mitchell and his Chief of Staff, John Hilley
Pat Griffin
Harold Ickes
Ira Magaziner
Steve Richetti
George Stephanopoulos
Melanne Verveer

V. SEQUENCE OF EVENTS

Members and staff arrive at 3:00.

The President opens up meeting and calls on the First Lady to make a few remarks about how appreciative she has been for all the past advice and how much we will need the Leadership's assistance throughout the upcoming challenging process.

The President briefly outlines the four agenda items that he would like to discuss and opens up the discussion with the Speaker and the Majority Leader.

VI. PRESS PLAN

Closed press. (White House photographer will be present.)

~~POSSIBLE~~ HEALTH CARE TIMETABLE:

January 1 to January 31

Activities:

- Committee Staff/Meetings with Administration (ongoing)
- **President convenes meeting with Leadership**
- State of the Union
- Hearings continue
- Meeting with Chairmen

February 1 to March 31

Activities: Recess: February 14 - February 22

- Hearings continue
- Subcommittee mark-up begins (House Committees)

April 1 to May 31

Activities: Recess: March 28 - April 10; May 27 - June 7

- House full Committee mark-ups
- Senate Finance and Labor Committee mark-ups
- Leadership reconciliation of different bills (if bills reported out)
- House Rules Committee mark-up

June 1 to ~~June 30~~ July

Activities:

- House and Senate/House Rules mark-ups (if not done already)
- House floor consideration and final vote
- Senate floor amendment marriage (between Labor & Finance)
- Senate floor ~~consideration~~

July 1 to August 14

Activities: Recess: July 1 - July 10; August 15 - September 6

- Senate floor vote no later than mid July
- House and Senate conference commences no later than late July

August 15 to October 7 (Target Adjournment Date)

Activities:

- Conference Report/House and Senate floor vote
- Final passage

Presidential Mtg File

January 31, 1994

MEETING WITH DEMOCRATIC LEADERSHIP AND HEALTH CHAIRMEN

DATE:	February 3, 1994
LOCATION:	Roosevelt Room
TIME:	5:15 pm
FROM:	Pat Griffin

I. PURPOSE

- To reiterate need to complete floor action on health care by both chambers by no later than the July 4 recess.
- To outline the "botom line" provisions that must be part of the final bill presented to you.
- To open up discussions among the 5 primary Committees of jurisdiction about how best to achieve your bottom line goals, to develop a coordination process between the Committees, the Leadership and the Administration, and to determine how the Administration can be most helpful in this process.
- To discuss a strategy of how best to deal with other important health care "players" within the Congress, (e.g. Subcommittee Chairmen of Committees of jurisdiction, advocates of major alternatives, Republicans, influential swing voters, and Chairs of other Committees of limited jurisdiction.

II. BACKGROUND

Within the last week, either by phone or in person, you have talked with the Democratic Leadership and Chairs of the Congressional Committees of primary jurisdiction over health care. However, you have not had the opportunity to hold a discussion with all the Chairs in the same room and you have yet to outline the substantive "bottom line" issues you believe are imperative to designing a bill that is acceptable to you. Such a discussion is advisable in order to give some helpful parameters to the Chairs during their upcoming mark-up process AND to get any early warning signs about the extent to which your priorities are going to cause the Chairmen any difficulties.

All the Chairs, with the exception of Senator Moynihan, gave the impression that they could live with the July 4th timetable for getting the bills into conference. This week we are trying to make certain that he, too, is on board so the part of this meeting dedicated to timetable is as limited as possible.

III. AGENDA ITEMS

1. Timetable and Strategy for Achieving Goal. There is no question that many House Members live in fear of being whip-sawed by the Senate if they are forced to move first and take a tough political vote on health care, particularly in this election year. They have no interest in witnessing a repeat of what they feel they went through in last year's budget process.

   To be responsive to the understandable concerns of the House, we recommend that you push the idea of a simultaneous (or as close to simultaneous as possible), bicameral Committee and floor vote strategy. In your discussions last week with the House Leadership, the Chairmen agreed to coordinating amongst themselves and the Administration. **The optimal outcome from this meeting, therefore, would be an agreement to establish a bicameral, Committee Chairmen coordination mechanism.**

2. "Bottom Line" Issue Discussion. To help outline the skeleton of the bill you would like to see reported out of Committees and passed on the respective floors, we recommend that you use this meeting as an opportunity to outline your bottom line provisions to the participants AND to open up a discussion about how to achieve support for these provisions. If they are consistent with what Ira has forwarded you previously, they are:

   (1) **Universal coverage** by the end of the decade that utilizes an employer-based system.

   (2) **Comprehensive benefits** that are defined.

   (3) **Insurance market reforms** -- community rating, banning underwriting, and promoting large risk and purchasing pools -- to put an end to insurance discrimination.

   (4) **Cost containment** that has an enforceable backstop.

3. How to Deal with Other "Players" Discussion. These Chairmen are, first and foremost, concentrating on how they can report out decent health reform bills out of their Committees. Understandably, the players they are most interested and concerned about, therefore, are their swing votes in Committee and, in the Senate, on their Repubublican possibilities. You may wish to ask the Chairs about how best the Administration can help them help us.

IV. PARTICIPANTS

The President
The Vice President
The First Lady
The Speaker
Majority Leader Gephardt
Majority Leader Mitchell
Chairman Moynihan
Chairman Kennedy
Chairman Rostenkowski
Chairman Dingell
Chairman Ford
Pat Griffin
Harold Ickes
Chris Jennings
Jack Lew
Ira Magaziner
Steve Ricchetti
George S.
Melanne Verveer

V. SEQUENCE OF EVENTS

Members and staff arrive at 3:00.

The President opens up meeting and calls on the First Lady to make a few remarks about how appreciative she has been for all the past advice and how much we will need the Leadership's assistance throughout the upcoming challenging process.

The President briefly outlines the three agenda items that he would like to discuss and opens up the discussion. Probably the most useful discussion would one that focuses on the Members current feelings about the Administration's bottom line issues.

VI. PRESS PLAN

Closed press. (White House photographer will be present.)