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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.