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Ask Economists, Not Hillary, Why Canadian Drugs Cost Less

The Americas

By Michael Walker

Before the U.S. Congress joins the state of Maine on a bus trip north to pick up Canadian drug pricing policies, it should ask a simple question: "Why are drug prices lower in Canada than in the U.S.?" The answer may persuade them to stay at home.

The first step in analyzing the price differential is to learn its true size. Hillary Clinton and Sen. Slade Gorton (Rep., Washington) have each conjured up "Top 10" lists that cherry-pick the drugs with the most glaring price differences between Canada and the U.S. Inspired by such lists, Maine has passed a law to equalize patented drug prices with those north of the border. Meanwhile, Canada's Patented Medicine Prices Review Board, which imposes price controls on branded pharmaceuticals, figures that in 1998 the U.S. price for drugs was 60% higher than at home. However, it is unlikely that the Board's self-congratulatory claim or the makers of Top 10 lists appreciate the complexities involved in international price comparisons of pharmaceuticals.

In 1996, University of Pennsylvania Prof. Patricia Danzon measured prices of drugs in 12 different ways, including by molecular composition rather than brand name, and by gram of active ingredient rather than dosage. By one of the measures, the price index for Canadian drugs was actually 3% higher than in the U.S. Indeed, commonly used drugs such as Eltroxin, Atenolol, Doxycycline, Ranitidine and Diazepam are several times more expensive at the retail level in Canada than in the U.S.

Furthermore, because regulatory approval is slower in Canada, innovative and high-priced drugs may be included in the U.S. price index before they are included in Canada's. In the U.S., many of these drugs are priced at a premium to existing drugs but nevertheless earn significant market share. Recent examples include Viagra, Vioxx and Celebrex. For any given year, the U.S. price index will include several such new drugs but the Canadian index will not.

But if drug prices are 60% higher in the U.S., it does not follow that the Board deserves the credit. When it was set up in 1987, U.S. drug prices were already 36% higher than Canadian prices. While the Board might like the credit for Canada's 24% price improvement up to 1998, the fact is it has simply been a part of a generalized widening of price differentials between the countries.

According to Statistics Canada, the real price level of U.S. gross domestic product in 1998 was 25% higher than in Canada. In 1987, the difference was only 6%. This 19% widening of the gap between Canadian and U.S. real price levels explains all but 5% of the increasing pharmaceutical price difference between the two countries.

In discussing why American pharmaceuticals cost more in America than in Canada, we must note that there is nothing, in this regard, different about drugs or about Canada. Many products of intellectual property, made in America, are sold for lower prices in foreign countries. And many, in particular, are sold more cheaply in Canada.

As an example, the CD-ROM version of Intuit's Quicken Basic 2000, a popular personal financial planning software package, costs $34.95 from the company's web site. However, the Canadian version, purchased from the company's Canadian web site, costs the equivalent of $20 before the ubiquitous federal sales tax. AOL charges $21.95 for unlimited monthly Internet access in the U.S., but AOL Canada charges less than $16 for the same service. Intuit's and AOL's American customers pay premiums of 70% and 40% respectively. (Inclusion of sales taxes does not alter the substantive result since the allegation is that somehow a market failure produces higher U.S. prices.)

The point here is that these are software-related products with very low manufacturing and distribution costs. The price differences cannot be caused by supply costs to the two markets. Nor do we have a "Patented Software Prices Review Board" to claim credit for the price differential. But government has nevertheless had a hand in producing the lower Canadian prices.

> *The 19% widening of the gap between Canadian and U.S. real price levels explains all but 5% of the increasing pharmaceutical price difference between the two countries.*

Because of bad government policies the Canadian dollar has collapsed to 67 U.S. cents from 87 cents over the past decade. Canadians' personal incomes have declined 24% versus those of Americans, and U.S. producers wishing to hit the price point that will maximize the value of their sales therefore charge Canadians less for their products. As a Congressional Committee found, and for the same reason, American drugs are also priced at a lower level in Mexico. While poor economic performance elsewhere is the main determinant of drug price gaps, there is a peculiarly American aspect to the story that must be noted, and that is the litigious atmosphere in the U.S. marketplace.

Prof. Richard L. Manning, while at Brigham Young University, produced a Journal of Law and Economics study in 1997 that showed that one-third to one-half of pharmaceutical price differentials in 1990 were due to the higher cost of legal liability protection in the U.S. It is not unreasonable to extrapolate his result to goods generally. Canada, unlike the U.S., does not see multibillion dollar liability suits. In Canadian courts, personal injury compensation is capped at C$250,000 and judges rarely award large liability settlements. In short, Americans pay in higher prices for the liability-law circus going on in their courts. Peter Huber, in his 1988 book on the liability revolution, estimated those costs at $300 billion a year. The liability crisis is worse today.

U.S. politicians wanting lower pharmaceutical prices should start with meaningful tort reform rather than Canadian drug-price controls, which cannot have been a significant influence on drug prices. Even if they were, they represent the sort of bad public policy that has left Canada with a weak dollar and a decade of stagnant living standards.

The inventive effort that creates the drugs that benefit Canadians and Americans alike is financed largely by resources generated in the U.S. Canada has always been reluctant to make its contribution to this effort and for many years simply stole the patents under Canadian federal law. Neither U.S. nor Canadian consumers would be well-served by the importation of this outlook, even if, in the short run, there was a slight reduction in the price of the top 10 drugs.

Mr. Walker is executive director of the Fraser Institute in Vancouver. John Graham, a senior analyst at Fraser, contributed to this article.

THE WALL STREET JOURNAL
FRIDAY, MAY 19, 2000

5-22-00

L Jennings
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comments to this
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9-14-00

Trade Bill For China Clears Hurdle

By David Rogers
Staff Reporter of The Wall Street Journal

WASHINGTON—The China trade bill cleared a last major hurdle as the Senate rejected a move by Beijing's critics to threaten U.S. sanctions if China continues to sell other countries sophisticated weapons technology.

Both the White House and the business community had lobbied strongly against the provision, and the 65-32 vote to table the measure greatly enhances the chances for final passage of the bill to grant Beijing its long-sought goal of permanent normal trade relations with the U.S.

The House approved the measure in May; by avoiding changes now, supporters hope to be quickly able to send the legislation to President Clinton, possibly next week. "This was the last stand of opponents to PNTR," said Sen. Robert Torricelli (D., N.J.).

China trade is a top priority for Mr. Clinton, who sees it as part of his political legacy. After intense lobbying, only nine Senate Democrats opposed the administration on the tabling motion, and the healthy margin of victory capped an eight-year campaign by Mr. Clinton to push Congress and his party toward a greater openness to global trade agreements.

Business groups seemed mostly relieved to have escaped what would have been an embarrassing setback. "It would have been a major, major loss," said Cal Cohen, president of the Emergency Committee for American Trade. The Business Roundtable described yesterday's vote as a "green light to the Senate to move quickly to pass PNTR."

For Republicans, the choice wasn't easy. The GOP appeared torn between its distrust of the president's China policy and its desire to please its own corporate backers. While many would have been delighted to have imposed a regime of new sanctions and reporting requirements on Mr. Clinton, the burden would have fallen more on the next president, when Republicans hope to be back in the White House.

The amendment's chief sponsor, Sen. Fred Thompson, is a party star and the man who led the Senate investigation of China's role in alleged campaign-finance abuses during Mr. Clinton's 1996 presidential campaign. As chairman of the Senate Governmental Affairs Committee, the Tennessee Republican also has criticized the White House on how it controls the export of U.S. technology to Beijing, often by companies that were generous political contributors.

Mr. Thompson was scathing in his criticism of business leaders for pressuring lawmakers to play down the proliferation issue. "They resent it when we who have been elected by the entire population—people who are not corporate leaders—address ... matters of national security," Mr. Thompson said. "These little people who strut around here making implied threats ... need to be taken down a notch or two."

Joining him on the floor, Sen. Robert Byrd (D., W.Va.) said "our lips quiver" at the threats from the business lobby. "What weak dishwater is the excuse that we cannot add anything to the House-passed bill?" asked Mr. Byrd. "What a sorry spectacle is a Senate completely cowed by the possibility that we might upset the Chinese."

Mr. Thompson conceded that substantial authority already exists to impose sanctions for weapons proliferation, but he said a more extensive reporting requirement needs to be imposed that "makes it a little more difficult to game the system."

A senior administration official argued the result would have been counterproductive, however. The proposed standard of evidence of a violation—"credible information"—is too low and would trigger needless action, the official said. While Mr. Clinton or a future president could waive imposing sanctions, that by itself also removed any threat to China. "Sanctions are most effective when there is the threat of sanctions," the official said.

Sens. McCain, Schumer to Unveil Bill To Ease Generic Drugs' Entry to Market

By Laurie McGinley
Staff Reporter of The Wall Street Journal

WASHINGTON—In a new bid to reduce prescription-drug costs, Sens. John McCain and Charles Schumer will unveil legislation today designed to make it easier for generic drugs to enter the market.

The measure would discourage or end several practices that makers of brand-name drugs use to stave off competition from generic rivals, according to Sen. Schumer (D., N.Y.). In an interview, he said ending these "patent abuses" was a fresh approach to reducing drug prices—one that didn't require price controls or government regulation but instead ensured quicker access to cheaper generic drugs. "Everyone agrees that innovation should be rewarded, but that after that, there should be competition," he said.

The legislation has little chance of being adopted in the time remaining to Congress this year, Sen. Schumer and aides to Sen. McCain (R., Ariz.) acknowledged, and there was no House sponsor lined up yesterday. But the bill is fresh evidence of continued efforts to rein in drug costs in ways opposed by drug companies, and Sen. Schumer predicted it would be a major priority next year.

The bill had early support from a wide range of political interests. It has been endorsed by the Health Insurance Association of America, which represents health insurers; the Consumer Federation of America, and Consumers Union. HIAA President Chip Kahn said the bill would reduce insurers' drug costs and thus the premiums paid by consumers.

The legislation would bar makers of brand-name drugs from filing "frivolous" patents on nonessential items, such as dosage or tablet size, in order to block the approval of a rival drug by the Food and Drug Administration. It would prevent citizens' petitions, which are used by consumers and drug makers to raise questions about a drug, from delaying the approval of a generic version unless there was proof that health and safety issues were involved. "These petitions," said the bill summary, "often take up to two years to answer and create a logjam in the generic approval process."

In addition, the legislation would make it more difficult for makers of brand-name drugs to pay generic-drug competitors to delay their entry into the market—a practice currently being investigated by the Federal Trade Commission.

The Pharmaceutical Research and Manufacturers of America, the brand-name-drug industry's main trade group, wouldn't comment; a spokesman said the group hadn't yet seen the bill.

9-14-00

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Should we
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9·29·00

States Prove Unpredictable in Aiding Uninsured Children

By JENNIFER STEINHAUER

In Alaska, health care officials found that the best way to get children enrolled in a federal health insurance program was to give their parents information encased in an imitation caribou-skin tote bag. Louisiana had a tireless advocate for the program, and made things easy for parents by giving them stamped self-addressed envelopes to return their applications.

In Arizona, the Legislature forbade groups to try to enroll people through the public schools, and the state has lagged behind dozens of others in the number of children it has insured. California is the among the worst states in enrollment; a 27-page application was just one of many problems there.

Three years ago, Congress provided $4.2 billion to the states to provide health insurance for the millions of children whose parents were too poor to afford commercial plans but who made too much to qualify for Medicaid. Now, a majority of the states are in danger of forfeiting their shares of the federal money, because they have not been able to get their versions of the program, the Children's Health Insurance Program, up and running.

But what separates those states that have managed to enroll children into health insurance programs from those that did not in many ways defies convenient leaps of logic and, in many cases, the expectations of experts of the program.

Geography did not dictate the outcome. Often states that failed miserably adjoined states with highly successful programs. Nor did the difference always prove to be related to partisan politics.

And while states that have fared best often share a few crucial factors — like a person or group obsessed with getting the plan rolled out, or simpler application forms — just as often it was an odd legislative twist of fate that determined whether or not the program was a success.

"All of this just shows how weird policy can be," said Rhea Williams-Bishop, a coordinator in the South for the Children's Defense Fund. "Putting it in place and implementing it are really two different things, and one quirky event can really change the situation."

Leaders in some 40 states that are in danger of losing federal financing for the program said they were simply not able to find enough children to enroll, or argued that when they tried to ferret out children, they found many who were eligible for Medicaid and enrolled them in that program instead. But it is also clear that some states made a much more concerted effort early on.

Alaska was never expected to be among such states. Experts did not expect a rural state, with a large Native American population and broad swaths of hard-to-travel land, to set any records in enrollment.

As it turned out, Alaska was among the top six states in signing up uninsured children, according to figures from the Children's Defense Fund, which has closely monitored enrollment. Like many other states, Alaska chose to expand its Medicaid program with the new federal money rather than to start a new program from scratch. But it packaged it in a whole new way.

"We wanted to create a program that didn't feel like government," said Karen Pearson, the deputy director of the division of public health in the state's health department.

The program got a very private-insurance sounding name — Denali KidCare — named after the mountain. The state hired a marketing expert, rather than telling a totally inexperienced state employee to create advertising, as many states have done. The move resulted in a snappy advertising campaign distributed where potential beneficiaries actually lived.

Many new staff members were hired, in part to shave away at the entrenched Medicaid culture — one that discourages people from signing up for benefits rather than recruiting them, Ms. Pearson said. And the state quickly teamed up with the Alaska Native Tribal Health Consortium, which runs Native American hospitals, to reach out to those potential enrollees. Incentives were put together that were ethnically specific, like the imitation caribou tote bags.

So far, the state has enrolled 38,980 children, 20,000 above its expectations. Sherry Gutierrez, who supports three children in Fairbanks on about $1,800 a month, said she was thrilled with the program.

"There were some years that I was eligible for public assistance but I stayed away from getting it because it seemed like a lot of the health care professionals treated you badly," Ms. Gutierrez said. "I didn't want my kids to feel that. With Denali, they treat it much more like health insurance."

Another fairly rural state, with a large Indian population and among the highest number of uninsured children, is Arizona, where the insurance program has gone quite another way. The biggest barrier there, pediatricians, advocates and government officials agreed, were a few powerful state legislators who opposed the program, calling it federal interference, in spite of strong support from the governor and the public.

Indeed, the measure was killed in the Legislature, only to be revived in a quick special session with one caveat that has kept enrollment figures low: the state could not give contracts to public schools to enroll students, one of the most successful methods of recruitment.

"That had a chilling effect," said Frank Lopez, a spokesman for the Arizona Health Care Cost Containment System. "School districts were hesitant to do anything in our outreach efforts."

Efforts to overturn the ban have been unsuccessful.

"I think citizens around the state have tried to do enrollment, and the state has made a reasonable effort to simplify the process," said Carol Kamin, executive director of the Children's Action Alliance of Arizona, an advocacy group. "But the bottom line is that in order to do outreach, you have got to go to where the kids are, and schools are, after all, where they are."

One of the most successful programs in the nation is in New York, where a state program that predated the federal one became a model for other states, and where the state often recruits in schools.

Eva Then of Washington Heights in Manhattan signed up when she came to register one of her three children for school, and saw the Children's Aid Society handing out fliers. She had already been through three efforts to wind her way through the Medicaid application procedure. "I came home and told my mother I couldn't believe they gave my children insurance because it was too easy," she said.

In Arizona, State Senator Russell Bowers, a major proponent of the ban on school outreach, defended his position, saying: "I feel schools are for education. I am not interested in contracting for health care in schools."

Mr. Bowers, a Republican, acknowledged that his position was hugely unpopular, even in his own district, but he said, "If the whole state wanted to do something and I felt it was wrong, I still would vote no."

To generate opposition, someone sent fliers around the state insisting that federal health insurance for children would require that sixth-grade girls have pelvic examinations.

Those same fliers were also distributed throughout Texas, where a few opponents of the program in the Legislature also slowed the program's start. The number of uninsured children in Texas is among the nation's highest.

"We had a tough fight trying to get a good plan," said Carl Rush, chief operating officer of Family Health Foundation in San Antonio. "There are elements who think this is the thin edge of the wedge of socialized medicine."

It did not help matters that the Texas Legislature meets once every two years and had just adjourned in 1997 after Congress passed the measure. Other states had similar calendar problems.

States that turned over much of the enrollment process to community-based groups also tended to do best.

Texas, California and some other states were dogged by fears among legal immigrants that their status would be challenged if they accepted a public program. This was especially true in California.

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The New York Times
THURSDAY, SEPTEMBER 28, 2000

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THE PRESIDENT HAS SEEN
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Ex-Rivals Unite in Wider Health-Insurance Plan

By LAURIE MCGINLEY
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—Former enemies in health-care reform battles put aside their differences to propose steps to cut the ranks of the uninsured—largely through expanding Medicaid and creating a tax credit for employers.

"Political gridlock should no longer be an option" in dealing with the problem of 43 million uninsured Americans, said Ron Pollack, executive director of Families USA, a liberal advocacy group that backed the Clinton administration's failed health-overhaul effort in 1993 and 1994.

He was joined by the Health Insurance Association of America, which helped doom the Clinton health-care overhaul plan by airing the "Harry and Louise" television ads, and the American Hospital Association, which is less ideologically driven than the other two groups.

Estimate of Costs

The plan, a framework rather than a detailed proposal, could help as many as 23 million low-income Americans who lack insurance, the groups said. They didn't provide an official cost estimate but said costs could reach $23 billion a year, an amount they said was affordable given the bulging federal surpluses.

But Congress may not agree, considering competing requests for big-ticket projects, including a prescription-drug benefit for Medicare, the federal program for the elderly.

In developing the plan, the three groups agreed that it shouldn't disrupt existing coverage and should build on existing structures, such as Medicaid, the state-federal program for the poor and the disabled, and the Children's Health Insurance Program, which covers low-income children who aren't eligible for Medicaid.

Focus of Plan

The focus is on people with annual incomes of as much as 200% of the federal poverty level. Under current law, eligibility for Medicaid varies from state to state. But generally, people with children are eligible only if their incomes are well below the federal poverty level. In 32 states, a parent who works at a minimum wage job, making $5.15 an hour, makes too much money to qualify for Medicaid if he or she works full time, according to Families USA's Mr. Pollack. People without children are eligible only if they are disabled as well as poor. For a family of three, for example, the cap would be $28,300. Under the plan:

- Medicaid would be expanded for all people with incomes of as much as 133% of the federal poverty level, or $18,820 for a family of three. The federal government would provide the states with additional funds.
- States would be encouraged to provide coverage for parents and childless adults with incomes between 133% and 200% of the poverty level through Medicaid or a program like the Children's Health Insurance Program. The federal government would increase its matching rates to the states.
- Employers would receive a tax credit to help make company coverage more affordable for low-income workers. For example, a business that pays 70% of the premium for its workers would receive a tax credit to pay all or part of the remaining premium for low-income workers who couldn't pay their share.

Mr. Pollack, who favors aggressive government action on health matters, and HIAA President Chip Kahn, an advocate of private-sector solutions, said the proposal wasn't the ideal one for either one.

But they said coverage can be expanded only if interest groups compromise.

The proposal is a sharp break in another way. It would provide coverage to low-income individuals without children. Currently, most childless couples, no matter how poor, are excluded from Medicaid coverage in most states.

Reactions Vary

Chris Jennings, a top health-care adviser to President Clinton, called the proposal encouraging.

But Neil Trautwein, director of employment policy for the National Association of Manufacturers, called it a "big-government approach."

At the other end of the spectrum, Jamie Court, a Santa Monica, Calif., consumer advocate, said the plan wouldn't work because insurers would block any meaningful cost containment.

THE WALL STREET JOURNAL
TUESDAY, NOVEMBER 21, 2000

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

Personal

October 27, 2000

Bruce / CHRIS
WHAT DO YOU THINK OF THIS
TOO

The Honorable John D. Podesta
Chief of Staff to the President
The White House
Washington, DC 20500

Dear Mr. Podesta: John -

The purpose of this letter is to provide ONDCP's perspective on Medicaid's Institution for Mental Diseases (IMD) exclusion and its deleterious effects on access to drug treatment for some of the most needy in our nation, particularly poor women with children. Many of these women are unable to participate in Welfare to Work initiatives due to substance use disorders. The Department of Health and Human Services is currently studying this issue and Secretary Shalala will be making a decision shortly.

HCFA's current interpretation of the IMD exclusion prohibits Federal Medicaid payments for treatment of substance abuse disorders for individuals between the ages of 22 and 64 in facilities with more than 16 beds. The policy has resulted in the Federal government paying for treatment in expensive inpatient hospital-based settings and has jeopardized access to medical care for poor women and their children because the exclusion prohibits payments for primary health care services for clients in an IMD.

The policy has slowed progress on welfare reform. Counties are required to refer individuals for treatment if they cannot work due to substance use disorders. Residential treatment programs, unlike outpatient programs, generally provide intensive therapeutic services appropriate for individuals with the most severe addiction problems – like those who currently remain on welfare.

In many cases addiction is preventing welfare recipients from making progress in their lives – from breaking the familial legacy of abuse and welfare dependency. Changing the IMD will primarily help women and children – it will give them a fighting chance to become productive members of society.

ONDCP recommends a simple administrative change -- removing "substance abuse" from HCFA's definition of mental disorders in the IMD exclusion, as has been done for other brain disorders. ONDCP has communicated its assessment and recommendation with Secretary Shalala (attached). We have the opportunity to make a momentous change in the way we serve the most needy among us. There is little time remaining. We should seize this opportunity.

V R

Respectfully,

A huge legacy for drug treatment.

Barry R. McCaffrey
Director

10-12-00

Copied Jennings Podesta

James J. Mongan

The Forgotten Uninsured

It would seem to take a real effort in a presidential election year to lose track of an issue affecting 44 million Americans—one out of seven. And yet this appears to have happened, almost effortlessly, with regard to the issue of health coverage for the uninsured.

To be fair, both candidates have touched lightly on the issue, with small proposals designed to make the voters think they have done something big. George W. Bush has served up an anemic proposal of tax credits (a $2,000 credit toward a $6,000 policy for a family of four with an income of $30,000). His proposal would cover only a small number of the uninsured, simply because, for most of the uninsured, it is akin to throwing a five-foot rope to a man in a 20-foot-deep hole. Al Gore has put forth a better, though quite limited, expansion of current public programs for some low-income children and their parents, which would reach a modest number of the uninsured.

But the remaining 35 million or 40 million uninsured are lost in this presidential campaign. This seems particularly mysterious when the economic circumstances would finally seem to have given our country the chance to deal with the issue.

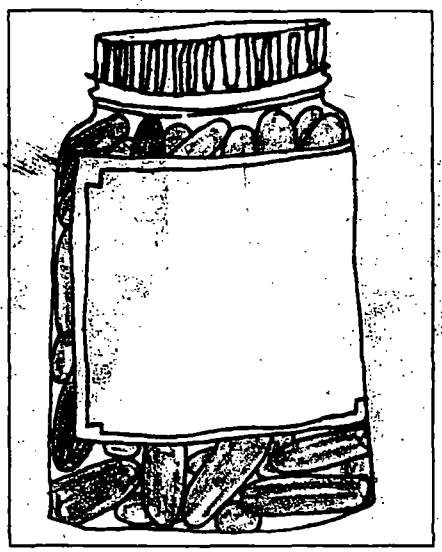
Most thought that the major obstacle to covering the uninsured was the need to find about $60 billion a year for an adequate, near-universal, program. Although poll after poll finds that the majority of Americans favors universal coverage, that majority disappears when people are asked if they support the individual or employer taxes needed to pay for coverage.

You might think the existence of large and unprecedented surpluses would point the way toward a solution. But even in the face of a combined federal surplus estimated at $4.2 trillion over the next 10 years, the uninsured seem to have fallen by the wayside. There are many ideas for the use of this surplus, but the uninsured remain largely unmentioned as potential beneficiaries of what would need to be only about 15 percent (or $600 billion) of the surplus over the next decade.

If certain elements of both the Democratic and Republican proposals were improved, expanded and funded with 15 percent of the surplus, we would have a health reform plan covering most of the uninsured without new taxes. The ingredients are there now to achieve near universal coverage. But the current proposals are underfunded, partial solutions that will not have a significant impact on the problem.

Understanding why the presidential candidates have been so unwilling to put forth broader proposals might be helpful in finding this "lost" issue again before the current election season is over. I would suggest three possible reasons:

- Politically, health care for the uninsured brings the Democrats back to what is perhaps their biggest domestic policy debacle of recent decades, the loss of the Clinton health plan—and the loss of 40 years of control of the House, which followed. They are not eager to revisit their Waterloo. For Republicans, this issue inevitably brings with it the smell of bigger government and a mighty competitor to the tax cuts that all but define their current ideology.
- Practically, many Americans do not understand, or choose not to understand, the impact of being uninsured. Many assume that the uninsured get care when they need it, and in a sense they are right—but also very wrong. For some acute, visible episodes such as childbirth or a broken leg, almost everybody does get treatment. What is not well understood is that the uninsured often do not receive care for many serious illnesses such as cancer, diabetes and hypertension, and in many instances defer care until their illness has reached an advanced stage. Ignorance of the consequences of being uninsured should no longer be an excuse for inaction.
- Philosophically, some in this country still oppose a more adequate social insurance safety net and seem to see it as inimical to the essary incentives of a robust competitive ronment. A prominent conservative economist, when asked why the richest nation on earth could not afford health insurance for all its citizens, responded archly, "Maybe not having universal coverage is the reason that we are the richest nation on earth."



BY KATY KELLY

The implication was that having adequate health insurance for all would sap our economic vigor and ruin our economy—that a robust economy depended upon the misfortune of the uninsured. But surely this is not a vision of America that either George Bush or Al Gore could or should defend. There is a better and more traditional vision—that we are a compassionate nation and will be even more productive as we provide education health care for all our citizens.

The American people should press the candidates to find this lost issue of the uninsured and return it to the national spotlight, where it belongs.

The writer, associate director of the White House domestic policy staff in the Carter administration, is president of Massachusetts General Hospital.

THE WHITE HOUSE

WASHINGTON

9-13-00

September 12, 2000

JP | C Jennings
I'd really like to do something on this — How much of this can we do —
BC

MEMORANDUM FOR THE PRESIDENT

FROM: SIDNEY BLUMENTHAL SB

SUBJECT: COLON CANCER

You have a great opportunity to save lives that would be lost to colon cancer, the number-two cancer killer of both men and women. When colon cancer is detected through early screening survival rates increase enormously. Currently, only about a third of colon cancers are diagnosed in the early stage, before the cancer has begun to spread. Less than 25 percent of Americans over 50 years of age are currently being screened according to American Cancer Society guidelines. The American Cancer Society estimates that colon cancer mortality could be cut in half within two years through screening awareness programs and mandating insurance companies to cover screenings for those individuals with average-risk (that is, those 50 years old or older).

copied Podesta Jennings

On Sunday, October 8, an alliance of foundations and groups devoted to fighting colon cancer will hold a rally on the Mall, a walk-a-thon and a concert by Paul Simon. The leaders of the event are Katie Couric, Rosie O'Donnell, Dennis Franz, and Lilly Tartikoff. Major corporations (Chrysler, US Airways, Sony, Viacom, NBC, Aetna, Merck, Dreamworks, etc.) are lending support. This high profile event would provide the occasion for a radio address on Saturday, October 7, on meeting the challenge of colon cancer. (Loretta Ucelli supports a radio address on this topic.)

Policies you could propose include:

(1) Increasing public awareness by increasing funding for the Centers for Disease Control and Prevention. In FY 2000, the CDC received a bare $2.8 million for promoting screening, the Colo-rectal Cancer Awareness Program. An increase

to $25 million would begin to change nationwide participation rates. It would continue the effort started by the First Lady in September 1998, when she joined with Katie Couric at the White House to call attention to the importance of colon cancer screening.

(2) Support enactment of the Eliminate Colo-Rectal Cancer Act (HR 1816/S 1044) and the Cancer Screening Coverage Act (HR 1285/S 1641) that would provide access to screening for individuals with private health insurance who are currently prevented from getting screening. Some plans deny coverage to average-risk individuals and others even deny it to high-risk individuals. A majority of new cases of colon cancer are diagnosed in individuals considered to be at average risk. Both bills have bipartisan sponsorship. The Eliminate Colo-Rectal Cancer Act is co-sponsored in the Senate by Senator Ted Kennedy and Senator Jesse Helms.

(3) Support coverage under Medicare for colonoscopy screening for average-risk individuals. Currently, Medicare covers only high-risk individuals for this essential procedure.

(4) Support, once again, a real Patients Bill of Rights that establishes the right of access, for the first time, to clinical trials (including those under the auspices of the FDA), specialists, and a grievance and appeals process for those who have been unfairly denied care.

Colon cancer, of all cancers, is the one that can be defeated most directly and immediately. Bipartisan support exists for new policy. The insurance companies' exclusionary coverage is unacceptable and unpopular. The results of taking action are indisputable.

Withdrawal/Redaction Marker
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Laurie Garrett to Sydney Blumenthal re: address (partial) (1 page)	06/27/2000	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20147

FOLDER TITLE:
POTUS Notes [Folder 8]

2012-0463-S
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RESTRICTION CODES

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

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

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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]

P6/(b)(6)

[001]

8-17-00

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Podesta

June 27, 2000
Sydney Blumenthal
The White House
Washington, D.C.

Dear Sydney,

What a happy coincidence it is that you ran into Bink last week. I thought many times about writing you a note of commiseration when you were an unfortunate victim of attention but thought you wouldn't remember me. I was, after all, a "mere teenager" when you were serious college students. I still think fondly of times in Chicago and Cambridge.

Bink said that you were interested in seeing the uncorrected galleys of my new book, BETRAYAL OF TRUST: THE COLLAPSE OF GLOBAL PUBLIC HEALTH, which is due for release by Hyperion on August 22nd. I have enclosed two copies,.one for you, the other for The President. I look forward to hearing what you think of it.

It's a hefty book, as was my last one, THE COMING PLAGUE, so I have drawn up some talking points to summarize the material. This may help you cut to the chase.

The key themes of BETRAYAL OF TRUST are:

- Public health versus individualized medicine approaches to populations.

Western models of individualized medicine are too costly, offer little benefit in terms of life expectancy and fail to address the fundamental roots of bad health in poor countries (e.g. unclean water, lack of vaccines, etc.)

- The revolution now under way in biology/pharmaceutics/Big Medicine/genome.

These will be of NO benefit to the majority of the world's population because the fruits of this intellectual/industrial revolution will be unaffordable. Most drugs are already unaffordable, and increasingly inappropriate. The technological innovations most desperately needed are not being pursued because they are not immediately profitable.

- Public health systems are extremely fragile.

Public health systems are among the first government functions to suffer under societal stress. Examples given supporting this assertion are contemporary India, all the former Soviet nations and central Africa, all based on first hand observation and reporting. (For this book I did on-site research on five continents, spanning five years.)

- An exhaustive history of U.S. public health.

The history illustrates that public health is strongest and most effective when local class/wealth disparities are lowest., and when there is a large self-interested middle class. In contrast, today on both a global and

US domestic scale we are witnessing a record wealth gap, with most of the world's wealth concentrating in a population of less than 1% of the world. Such a gap poses a significant threat to public health. The book explains why, drawing heavily from an encapsulated 300 year history of New York City public health efforts.

- Antigovernmentalism.

The rampant antigovernment fervor in the U.S. targets, among other things, such public health programs as vaccination of children and registration of infant birth defects.

- Illicit drug use.

Public health has never been able to deal well with illicit drug and alcohol issues. In most cases this has reflected strong political support for criminalization of substance abuse, versus treatment. As a result, the population as a whole has found its health threatened by needle-borne diseases (hepatitis B, C, and D; HIV), and by illnesses amplified in sites of incarceration of drug users (TB, HIV).

- Race.

In the U.S. public health has a sorry racial legacy that it has never successfully addressed. As a result, African Americans and, to a lesser degree, Hispanics and Native Americans are severely alienated from the system, and least likely to participate in population-based control efforts, such as mass immunizations, HIV education campaigns, STD efforts, well baby programs, and the like.

- Marginalization.

Globally the health and human rights arguments hold up most strongly in countries which, like the U.S., have significant minority populations that have undergone several generations of economic and political segregation and/or perceived oppression.

- Ideology.

Ideology generally imperils public health. The very large chapter on the former Soviet nations details examples of Communist-inspired programs and belief systems that resulted in disastrous public health programs, most of which in some form persist today. In Western countries various Judeo-Christian beliefs have often clashed with public health efforts, particularly in terms of mass vaccination, STD control and substance abuse programs. In India religious programs clash with health ones on a daily basis.

(Overall I think I should note that personally I have NO ideological axe to grind, nor do I believe that my personal political views fit neatly into any category. Readers will find BETRAYAL OF TRUST tough on Communism, Hinduism, global corporate capitalism, religious fundamentalism...in short, on any "ism" that seems to get in the way of a population's health interests.

And readers will find that I am critical of academic public health "pie-in-the-sky" ideas that arise from Marxist or managed care ideologies. Endorsing this book risks no political nod: it is, however, a clear endorsement of public health. And I have taken pains not to appear partisan in a Democrat v Republican sense, though the Reagan Administration—by historical necessity— comes under sharp attack.)

- The discipline has lost its way.

Public health, as a discipline and practice, lost its way during the Western health transition (post WWII, going from infectious diseases to CVD and cancer), largely because the infectious models of disease

prevention didn't translate neatly to the chronic disease paradigm. And the chronic disease paradigm was, with the exception of tobacco, approached as a matter of individual behavior. Thus, public health became not the Great Protector, but the Great Chastiser, telling people that they were personally responsible for their own illnesses (diet, exercise, alcohol, etc.) . Because the data upon which such behavioral messages rested was often contradictory the public eventually stopped listening, or simply heeded selectively. Thus, in the US, for example, Americans reduced their cholesterol intake but increased their overall caloric intake, becoming a majority-obese nation.

- Managed care.

As executed in the US, managed care has proven another significant challenge to public health. Details provided. Economics, as a discipline, has only recently (over the last decade) addressed public health and medical issues aggressively, presenting strong financial arguments in favor of preventive and population based approaches to health. DALYS analysis has revolutionized thinking in the area, especially at World Bank and WHO. But governments largely make decisions about health spending based on different priorities, and health functions as a completely insane market. In Europe and North America this means spending is skewed towards massive outlays for end stage disease intervention. In poor countries corruption, military priorities and singular epidemics (e.g. TB and HIV) can tilt all public health spending away from basic infrastructural needs.

- Bioterrorism.

Concern about deliberate release of agents intended to imperil the public's health has spawned a virtual bioterrorism prevention industry in North America and Europe. A backlash has also emerged, claiming the threat is overblown and represents a post-Cold War paranoia. Public health is challenged by the issue in two key ways: (1.) it must insist that its role in local bioterrorism detection and response is paramount, and resist efforts to militarize the issue or to yield all control to law enforcement; but (2.) by collaborating with law enforcement, it may risk public credibility, particularly in minority communities, and it must take great pains to keep its relationship with military and law enforcement authorities cordial, but at arms length. If public health is perceived to be too cozy with law enforcement it risks losing all support among communities that feel themselves most targeted by military or police forces.

- Microbe Trafficking.

Globalization of microbes, as well as of ailing refugee and immigrant populations, necessitates more international thinking about disease control. National programs will find themselves increasingly overwhelmed by challenges "from outside" (e.g. contaminated imported foods, traveling businessmen carrying drug resistant microbes, exported livestock and pets), and find that country-of-origin programs make more sense.

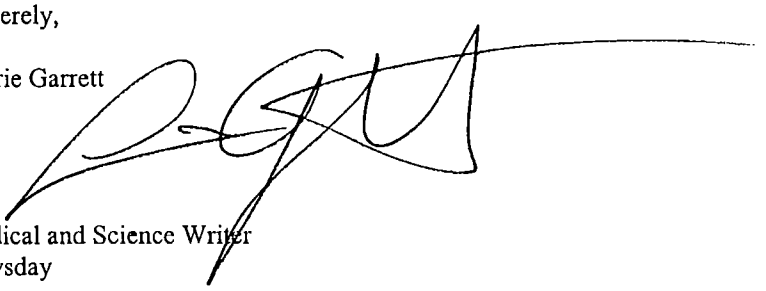
- International pharmaceutical practices.

Drug companies will increasingly become foci of tension as drug resistance against affordable agents mounts, and life expectancies are impacted. HIV is a big lesson in this regard. And in the case of HIV, pressure in the wealthy world skewed resources away from public health approaches to the disease (e.g. vaccine R&D, prevention campaigns and contact tracing) towards the search for a cure. Today, as a result, we are saddled with an extraordinarily costly drug regimen of only minimal efficacy and are playing catch-

up in pursuit of both a vaccine and effective prevention interventions for countries with heterosexual adult infection rates in excess of 5% of 18-50 year olds. From a global point of view, we sacrificed public health for individualized medical attention that has proven to be the most costly ever offered as a "solution" to an infectious disease.

Sincerely,

Laurie Garrett



Medical and Science Writer
Newsday

9-26-00

THE WHITE HOUSE

WASHINGTON

'00 SEP 22 P7:14

copied Chow Podesta

September 22, 2000

MEMORANDUM TO THE PRESIDENT

FROM: Barbara Chow

SUBJECT: DPC Weekly Report

1. Drunk Driving -- .08 BAC: This week, the Department of Transportation's (DOT) National Highway Transportation Safety Administration released two separate studies reaffirming the need for a national standard for impaired driving at .08 blood alcohol content (BAC). The first study detailed how critical driving skills are seriously impaired at higher BAC levels, and the second study found that the 3 year-old .08 BAC law contributed to a 13.7 percent decline in drunk driving deaths in Illinois. The .08 BAC issue has been the major sticking point on the FY 01 Transportation Appropriations conference report, which is now set to merge with the VA-HUD conference report. The Transportation appropriations conference committee chairman, Frank Wolf, has remained a steadfast supporter of the .08 BAC measure. MADD and DOT both believe that there is a good possibility of getting the measure included in the final bill.

2. Education - - Fattah Commission on Educational Equity: You recently spoke with Congressman Fattah about his interest in establishing a National Commission on Educational Equity. He has asked you to create this commission by executive order. We met with him this week to discuss his ideas and received a draft copy of his proposal. The main purpose of the commission would be to galvanize a public debate on inequities in school financing and determine the role the federal government could play in eliminating these disparities. We are reviewing his proposal and will make a recommendation to you in the near future.

3. Education - - Vouchers: This November California voters will vote on Proposition 38, which would give approximately $2.6 billion in taxpayer money to provide a $4,000 voucher to parents toward private or religious school tuition. A report by professors at Stanford and UC Berkeley shows that the premises of the education measure is flawed. In addition to the fact that the program is not limited to impoverished families and would aid the affluent, it is unlikely that enough students could leave the public school system in order for the state to break even on the cost of the program. Currently, there are about 672,000 seats in private schools. In order for California to break even, they would need enough private school seats for 1.5 million children.

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4. Health Care - - Nursing Home Quality: Following last week's radio address, your nursing home staffing and accountability initiative was transmitted to Congress. Congressman Rush Holt, with the blessing of Congressmen Gephardt and Waxman, introduced the legislation on Thursday. Senator Grassley and Senator Breaux are expected to introduce a version of it as well. Senator Grassley intends to add this initiative to the provider giveback legislation that is expected to move out of the Finance Committee as early as late next week. The proposal has been extremely well received by both consumer and provider groups as achieving the appropriate "carrot and stick" balance necessary to improve quality and enhance accountability in nursing homes.

5. Health Care - - Long-term Care Tax Credit Update: This week we met with Speaker Hastert's staff to discuss the prospect of working together to pass your $3,000 long-term care tax credit in exchange for our support for an enhanced tax deduction for the purchase of private long-term care insurance. We indicated our interest in working collaboratively as long as we could ensure that only high quality private insurance products were eligible for the tax deduction. Speaker Hastert's staff was very receptive, but noted Congressman Archer's longstanding opposition to such tax credits. We subsequently had a positive conversation with Senator Grassley, who has already introduced a similar legislative package, which he hopes will emerge from the Senate Finance Committee. Chip Kahn, the President of the Health Insurance Association of America, pledged his strong commitment to working with the Administration to push the Congress to pass this legislation before adjournment.

6. Tobacco - - Enforcement of State Laws Forbidding Sales to Minors: Every state is required to have a law outlawing tobacco sales to minors, and they must conduct unannounced inspections of retail outlets to ensure that they are following the law. These provisions, known as the Synar amendment for sponsor Mike Synar, were enacted in 1992. Each state has individual, year-by-year targets to meet, and by 2003, every state must ensure that less than 20 percent of its retailers sell tobacco products to minors. Last week, HHS notified four states (AK, PA, WV, WY), plus the Virgin Islands of a preliminary finding that they failed their yearly target. The Marshall Islands failed to comply with unannounced inspections. This is an improvement from last year when 7 states (DE, IA, MO, MN, OR, RI, WY) plus D.C. failed their targets. The states and jurisdictions may enter into an appeals process before the Secretary makes a final determination. As required by current law, unless the Secretary finds extraordinary circumstances, these states would lose 40 percent of their Substance Abuse Prevention and Treatment block grant (these funds would be distributed to other states). The Secretary has continued to indicate the Administration's willingness to work with Congress to develop a more flexible system of penalties for enforcing noncompliance while maintaining our commitment to reducing youth smoking. Since this long-term solution is not likely to be enacted this year, an alternative penalty is included in the Labor/HHS appropriations bill. In lieu of losing Substance Abuse funds, states must agree to commit additional state funds to ensure compliance with state laws prohibiting the sale of tobacco products to minors. The amount to be committed is equal to one percent of each state's block grant allocation for each percentage point by which it missed its target rate.

The Synar program has been successful in achieving its goals: all states now have laws making it illegal to sell or distribute tobacco to minors and all have developed methods for

9-26-00

measuring statewide compliance and conducting unannounced inspections. State surveys found average retail sales rates to minors fell from approximately 40 percent in FY 1997 to approximately 19 percent in FY 1999. HHS expects all states to meet the goal of less than 20 percent of retailers selling tobacco to minors by 2003; FY 1999 surveys show 24 states have already achieved this goal.

7. Welfare - - Individual Development Accounts: This week, HHS will award Individual Development Account (IDA) grants to 25 new communities and 16 renewal communities and states for the second year of the five-year IDA demonstration program. As part of your FY 2001 budget, you proposed funding the third year of IDAs at the full authorized level of $25 million. For the past two years, Congress has only appropriated $10 million. You also proposed allowing low-income families to use IDAs to save for a car that will help them get or keep a job. Last February, you highlighted this proposal as part of a comprehensive package of transportation actions to help low-income families get on the road to work and opportunity. However, the authorizing committee's staff (Gregg) objects to this provision. We will continue to explore other avenues to get this done this year.

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PRESCRIPTION DRUGS

Advocacy Groups Pleased with NEC/DPC Report on Prescription Drugs. The report on why Sen. Roth's low-income prescription drug proposal does not work for most Americans provides valuable ammunition for the public debate over prescription drugs. Groups plan to use this information to make the case for providing a universal, voluntary and affordable benefit under Medicare, rather than a private insurance-based benefit targeted only to low-income beneficiaries.

II. CONSTITUENT OUTREACH AND OTHER ISSUES:

ASIAN PACIFIC AMERICAN OUTREACH

Advisory Commission on Asian American and Pacific Islanders Holds Town Hall Meeting in New York. With close to 500 people in attendance and a dozen downlink sites in cities throughout the Eastern region, the 15-member Commission heard testimony from 75 to 100 individuals on issues of concern to the Asian Pacific American community. Some raised very strong concerns about the Wen Ho Lee case, but 95% of the testimony covered issues such as education, health care, language barriers, immigration, and hates crimes. The Commission did issue a statement expressing concern regarding the handling of the Lee case and stated that general civil rights and racial profiling are issues they will be including in a report to you due by the end of the year.

BUSINESS OUTREACH

Briefing with Business and Labor Representatives on Hollings Legislation. OPL hosted a meeting for various business community and labor representatives regarding Foreign Telecom Investment. This measure is currently before Congress and will particularly affect mergers such as the proposed one between Deutsche Telecom and VoiceStream. Chuck Brain, Gene Sperling and Karen Tramontano briefed the group on the Administration's opposition to this legislation.

DISABILITY OUTREACH

Disability Community Angered by Nursing Home Proposal. Your Saturday Radio Address announcement to seek $1 billion for staffing of nursing homes met with a rapid and impassioned flurry of email and phone communications. For years, advocates have been calling for more resources and support for home and community-based services. Although the Administration has made modest gains in this area, including a $50 million commitment announced by Vice President Gore on July 25, advocates view the $1 billion investment as a disproportionate focus on the nursing home industry that will draw resources away from community-based long-term care providers. Although advocates do not propose neglecting nursing homes, they view evidence of bed sores and malnutrition as reasons to help provide the services and supports people need to live more comfortably in the communities of their choosing.

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9-26-00

ASSESSMENT OF THE EARLY TREATMENT FOR HIV ACT OF 1999

Summary: The Early Treatment for HIV Act of 1999 (HR 1591/S 902) would create a new optional Medicaid eligibility category for low-income individuals infected with HIV. The legislation would allow non-disabled individuals with HIV to obtain Medicaid coverage without having to meet the SSI definition of disability. HIV-infected individuals in states electing this option would qualify for coverage if their income and resources do not exceed the level used to determine Medicaid eligibility for disabled individuals. Preliminary CBO estimates on this legislation are $1.4 billion over five years and $4.6 billion over ten. HCFA's Office of the Actuary has not scored this bill.

Issues:

- **General concern about disease-specific Medicaid coverage expansions:** The Administration has traditionally been hesitant to support disease-specific expansions of the Medicaid program because they create inequities between individuals with different diseases. We did, however, propose legislation that would provide an optional Medicaid eligibility category for low-income individuals diagnosed with breast or cervical cancer in the Budget.

Suggested Response:

- Generally concerned about opening the door (more) on disease-specific Medicaid coverage. However, we have proposed and enacted demonstrations that will provide hard evidence of the cost savings and/or health benefits of early coverage. These include:

  - **Medicaid 1115 demonstrations for persons with HIV/AIDS:** HCFA is currently working with several States to develop budget neutral Section 1115 waiver proposals that would provide Medicaid coverage to individuals living with HIV. HCFA released guidance in May on the information States can provide HCFA to facilitate the review process of HIV/AIDS 1115 waiver proposals. These waivers will allow States and HCFA to test the health and budget impact of expanding Medicaid to cover additional individuals with HIV. In February, HCFA approved the first HIV/AIDS demonstration waiver in Maine. The waiver is to be budget neutral and will provide coverage to approximately 300 individuals with family income up to 300% FPL. The demonstration will allow the State of Maine and HCFA to test the health and budget impact of 1) covering this population earlier in the disease process, and 2) allowing individuals currently on Medicaid who wish to return to work to maintain their health insurance coverage.

  - **Ticket to Work and Work Incentive Improvement Act Demonstrations:** The Jeffords-Kennedy bill, enacted in December 1999, created a $250 million demonstration to provide health coverage to individuals whose disabilities are not yet severe enough to qualify them for SSI or Medicaid. HCFA recently released a solicitation inviting States to participate in the demonstration. This demonstration represents another avenue through which States can seek to expand coverage to people with HIV/AIDS.

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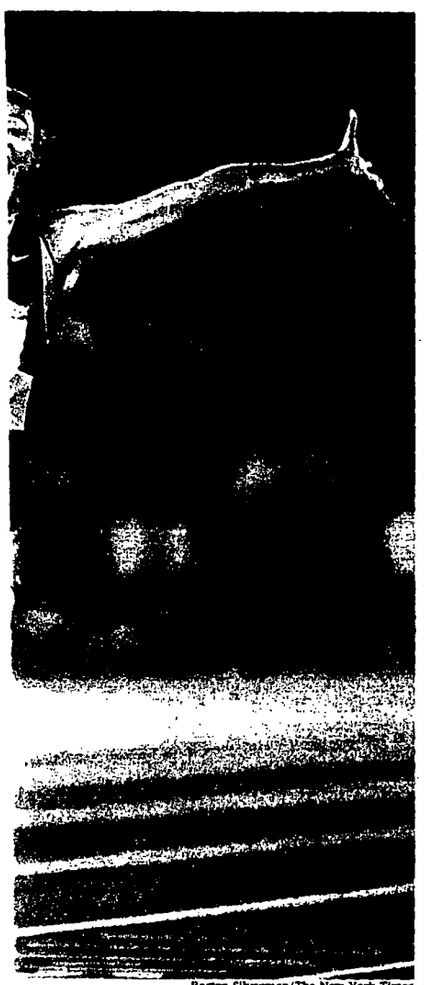

Barton Silverman/The New York Times

he Bahamas' Chandra Sturrup, left, was sixth.

Jones and Greene

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or those s a dad- ugh life s name, baseball uttal. park in onstruc- explained "When ay, 'He

a bounding spring as if the track were a trampoline. Essentially, the race was over in the first five meters. She accelerated into her long searing stride and skipped across the finish line in 10.75 seconds, the fastest time in the world for a woman this year and the preamble to her attempt to become the first female athlete in track and field to win five gold medals in the same Olympics.

This was the first time American athletes had won the men's and women's 100-meter sprints since Lewis and Florence Griffith Joyner were awarded first place at the 1988 Summer Games in Seoul, South Korea. Lewis actually finished second in that race but was later declared the winner after Ben Johnson of Canada was stripped of his gold medal for testing positive for anabolic steroids.

So dominant was Jones's performance tonight that her margin of victory — 37-hundredths of a second — was the greatest in the Olympic 100 meters since Marjorie Jackson of Australia won a hand-timed race in 1952. Tonight, Ekaterini Thanou of Greece finished far behind in 11.12 seconds for the silver, and Tanya

Continued on Page 48

U.S. and Others Press for Cuts In Price of Oil

Officials Also Discuss Strategy on the Euro

By JOSEPH KAHN

PRAGUE, Sept. 23 — The top financial officials of the United States, fresh from an unprecedented synchronized plunge into world oil and currency markets, joined other rich nations today in vowing to fight what they described as double jeopardy for the global economy.

In a communiqué issued after Group of 7 financial leaders met here, ministers said they would monitor currency markets to see whether they needed to follow Friday's coordinated central bank action to shore up the euro, Europe's battered common currency, with further interventions. But they used stronger language on oil prices, saying it was "crucial for the world economy" that oil-producing nations take steps to reduce prices, which have tripled since early 1999.

"Oil prices are the largest dark cloud in the blue sky of the global economy," Treasury Secretary Lawrence H. Summers said after the Group of 7 meetings, speaking of a recent run-up in the price of crude oil to a 10-year high of more than $30 a barrel. "Prices need to return to a more historical range."

The Clinton administration's decision on Friday to tap the Strategic Petroleum Reserve to help dampen oil prices won praise in the communiqué. Other Group of 7 nations are considering releasing oil from their reserves, and ministers discussed ways of breaking oil distribution bottlenecks and ways of putting diplomatic pressure on the Organization of Petroleum Exporting Countries, officials said in describing the talks.

The attempts to correct currency and oil prices cast the United States, which often argues that such markets should take care of themselves, as an aggressive interventionist, evoking expressions of surprise from other Group of 7 ministers. Several said Friday's concerted buying of euros and selling of dollars, yen and other currencies had gone smoothly,

Continued on Page 6

Further Steps Taken To Lower Oil Prices

The administration took several more steps to cushion the oil market against shortages and to soften the shock of higher prices on consumers. President Clinton also directed the Department of Health and Human Services to release $400 million to help poor families buy fuel, a record allocation for the program.

Article, Page 22.

40 STATES FORFEIT HEALTH CARE FUNDS FOR POOR CHILDREN

$1.9 BILLION TO BE SHIFTED

New York and 9 Other States That Spent Allotment Will Get Unused U.S. Aid

By ROBERT PEAR

WASHINGTON, Sept. 23 — Forty states will soon lose hundreds of millions of dollars of federal money that was supposed to provide health insurance to children in low-income families, federal and state officials say.

The money — 45 percent of the $4.2 billion provided by Congress — remains unspent by the states after three years. It will be given to New York and nine other states that used their full allotments of federal money under the Children's Health Insurance Program, which was created by Congress, with much enthusiasm and fanfare, in 1997.

"We would like to be able to keep that money and use it to provide health care to children," said Helene Robinson, director of the state program in Louisiana, which expects to lose $63.7 million, or 63 percent of its federal allotment of $101.7 million.

California and Texas account for more than half of the unspent money — $590 million and $446.3 million, respectively. Together, they have 29 percent of the nation's 11 million uninsured children.

Health care for children has become a major issue in the presidential campaign. Vice President Al Gore, the Democratic nominee, says Gov. George W. Bush, the Republican candidate, has a dismal record of providing health insurance to children in Texas.

Mr. Bush rejects the criticism. Texas officials say 100,000 children have enrolled in the new program since they began taking applications in April.

Dan Bartlett, a spokesman for the Bush campaign, said Mr. Gore "should address the problems on his own watch." Mr. Bartlett said that the number of uninsured children nationwide had increased since the Clinton administration took office, and Census Bureau reports show that the 11 million figure is up from 9.6 million in 1993.

States have until Sept. 30 to spend the money they were allotted. In interviews with The New York Times, officials in 20 states gave these reasons for failing to use their full allotments:

¶Some states took a year or more to start enrolling children.

¶Some were reluctant to put up the state money they had to spend to obtain the full amount of federal

Continued on Page 34

THE PRESIDENT HAS SEEN
9-29-00

CHRISTOPHER REEVE

President William Clinton
Executive Office of The President
C/o Betty Currie
Fax: (202) 456.1210
The White House
Washington DC 20500

Dear Bill:

Thank you so much for the birthday greetings. I remember the last time we met, just before your 50th. Even though I'm now two years away from facing that number, I'm beginning to feel that there is nowhere to run and nowhere to hide. The only thing to do of course is to have a blowout party and move on.

I've been meaning to write you for some time to thank you for your public endorsement of the new NIH guidelines. As you know, the NIH is already funding human ES research in labs across the country. I think the delay in bringing the bill to the floor is working in our favor: by the time it comes up for a vote scientists will have made so much progress that it will be more difficult for the opponents to defeat it.

Thank you for listening, for caring, and responding to the needs of so many over the last eight years. The whole country will miss you.

Sincerely,

Christopher

Christopher

9/29/00

After you have seen we will send to Cohen.

Copied Jennings Podesta
Original to Cohen for reply

C.

BEDFORD, NEW YORK 10506

11 Great Hill Farms Road, Bedford, New York 10506
Phone 914-764-0074 Fax 914-764-1301

Christopher Reeve Paralysis Foundation

Fax

To: President William J. Clinton **From:** Christopher Reeve

Fax: (202)456.1210 **Pages:**

Phone: **Date:** 9-25-00

Re: **CC:** –

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10-2-00

THE WHITE HOUSE

WASHINGTON

00 OCT 1 PM4:38

October 1, 2000

MEMORANDUM TO THE PRESIDENT

FROM: Chris Jennings

Cc: Bruce Lindsey

RE: Status of Arkansas / UAMS State Medicaid Amendment

This memo is written as a follow-up to Bruce Lindsey's memo regarding the Arkansas state plan amendment to provide supplemental payments for outpatient services at University of Arkansas for Medical Sciences (UAMS). The State and UAMS have raised concerns that the upcoming upper payment limit regulation that we are considering (see memo submitted on September 29) will prohibit their proposed financing mechanism and its associated revenue for UAMS.

After reviewing their situation and the draft regulation, it does appear that the Arkansas financing proposal – like all other approved UPL arrangement – would have to be phased out. However, because of the way that we are structuring the regulation, the State and UAMS would receive the benefit of their financing plan for a full two years. Our draft proposal would give states that have been approved in between last year and the effective date of the regulation two years to prepare to comply with the regulation. Since Arkansas's amendment is scheduled to be approved on December 7, it will qualify for this transition.

In addition, the State may benefit from proposals in the Medicare provider payment restoration package that would raise the State's Medicaid disproportionate share hospital (DSH) allotment. In fact, just this last week, the House Commerce Committee marked up its provider payment restoration package that would raise Arkansas's Medicaid disproportionate share hospital (DSH) allotment.

Yesterday, I reviewed the status of the legislation and regulation with Medicaid Director Ray Hanley. He was surprised and pleased to learn that the draft regulation would benefit Arkansas and UAMS for two years. Although he stated that they would, of course, prefer a permanent funding stream from UPL, he felt that UAMS would be quite satisfied with this approach. He also was encouraged about the House Commerce Committee action.

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Jennings
Podesta

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THE WHITE HOUSE

WASHINGTON

September 21, 2000

MEMORANDUM FOR THE PRESIDENT

FROM: BRUCE R. LINDSEY

RE: HCFA REGULATIONS AND UAMS

The University of Arkansas for Medical Sciences (UAMS) is in financial crisis. UAMS has run a deficit for 8 straight quarters, FY 2000 ended with a $20 million shortfall, its line of credit has been exhausted, substantial layoffs have already taken place reducing services, and there are concerns about its ability to meet payroll next quarter. Chancellor Harry Ward is retiring October 16, 2000 and a new chancellor, Dodd Wilson, M.D., will begin on that date. Additional new leadership and new procedures are rapidly coming on board with multiple steps being taken to rectify the situation.

The causes for the crisis are many including the general nation-wide tightening of healthcare expenditures, slow UAMS reaction to the new fiscal realities, an enormous load of uninsured patients, and the perennial under-funding of UAMS by the General Assembly.

Early last fall a UAMS team composed of Rick Smith, M.D., Ray Scott, Tom Butler, and Barbara Eyman (Washington-based attorney) begin work on multiple mechanisms to develop new sources of support for UAMS through the Medicaid system. With the assistance and support of the Arkansas Medicaid Program, two state plan amendments were proposed to use UAMS' general revenue as match in order to access federal funds in the form of a State Operated Teaching Hospital payment. One of these plans for an inpatient payment of $2.4 million/year has been approved by HCFA. The other outpatient plan for $34 million/year is in the final stages of review by HCFA, which is expected to allow the plan to take effect in December. These plans are very small in relation to how other states are using Medicaid funds for their teaching hospitals, especially those that care for many indigent patients.

While Arkansas was pursuing these state plan amendments, HCFA became concerned about how some states were using the same mechanism, the "Upper Payment Limit" methodology, to draw down federal funds. The Medicaid Administrator, Timothy Westmoreland, has announced his agency's intention to issue regulations to severely curtail a state's ability to receive these funds. HCFA does not appear, in principle, to object to how Arkansas is proposing to use its funds, it is simply trying to close what it considers a loophole in the federal regulations. While these new regulations will not prevent Arkansas' plan from initially taking effect, they will end Arkansas' ability to

fund UAMS through this mechanism unless the rules are crafted with some attention to the state's plight.

HCFA has said that it is "modeling" new rules and is eager to release them. Some states such as California, which accesses $1.1 billion/year through this mechanism, are likely to remain relatively untouched while other states will likely be severely restricted by the new rules. From UAMS' point of view, it is imperative that the new rules make some allowance so that the state may continue to use this mechanism.

UAMS has proposed several options that would allow HCFA to issue its new rules limiting inappropriate use of the Upper Payment Limit methodology while at the same time allowing Arkansas and states in similar situations to continue to use this mechanism. UAMS, however, believes that without some direction from us, HCFA will move forward with new regulations limiting Arkansas' ability to use this mechanism.

Harry Ward, Rick Smith and others have requested a meeting with you to discuss this problem. Governor Huckabee, former Senator Pryor, former Senator Bumpers and others have written you urging some relief. If you don't have time to meet with UAMS officials, maybe a meeting with Chris would suffice.

cc: Chris Jennings

202-456-6703

Tuesday 1pm

National Organization for Rare Disorders, Inc.®

NORD • 100 Rt. 37, P.O. Box 8923 • New Fairfield, CT 06812-8923
(203) 746-6518 • FAX: (203) 746-6481
TDD: (203) 746-6927
http://www.rarediseases.org • e-mail: orphan@rarediseases.org

Bill

out of th... into it

copied Jennings Podesta

Augu...

9-20-00

C Jennings

can we do anything on this? —

BK

promises that will in the needs and interests in mind?

Earlier this year NORD members, in an effort to bring our issues to these same politicians, asked Congress to appropriate just *one dollar* for every rare disease patient in the country; a miniscule request that would amount to a mere $25 million for FDA's *Orphan Product Research Grant Program*. In 1999, Congress appropriated $1,793 billion for AIDS/HIV research, $475 million for breast cancer, $269 million for heart disease, $186 million for stroke, $163 million for lung cancer, $140 million for asthma, and $132 million for Parkinson's disease, **and only $11.5 million for research on new treatments for all 6,000 rare "orphan diseases".**

NORD's argument stated the facts:

- There are an estimated 25 million Americans with more than 6,000 rare disorders.
- Each disorder affects fewer than 200,000 people in the United States, but combined together rare diseases affect about nine percent of the population.
- These 6,000 disorders are neglected diseases that desperately need research.
- The commercial sector is usually not interested in pursuing this research because the potential markets for new treatments are too small.
- ***If the government doesn't support research on rare disorders, who will?***

In response to our plea, Congress appropriated only $1 million additional dollars for the orphan disease research program---**a total of $12.5 million to be shared by 6,000 diseases in FY 2001**. NORD members were told to be grateful for this one million dollar increase, as Congress could have reduced the appropriation instead of increasing it!

(OVER)

202-456-6703

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http://www.rarediseases.org • e-mail: orphan@rarediseases.org

...out of the darkness, into the light...®

Ms. Kathy L McClanahan
McClanahan Graphics, Inc.
President
405 W Searcy St
Heber Springs AR 72543-3842

August 2000

Dear Kathy:

With the election season upon us, national and local politicians are making promises that will hopefully secure more votes for their cause. As someone who is interested in the needs and concerns of the rare disease community, do these politicians have your best interests in mind?

Earlier this year NORD members, in an effort to bring our issues to these same politicians, asked Congress to appropriate just *one dollar* for every rare disease patient in the country; a miniscule request that would amount to a mere $25 million for FDA's *Orphan Product Research Grant Program*. In 1999, Congress appropriated $1,793 billion for AIDS/HIV research, $475 million for breast cancer, $269 million for heart disease, $186 million for stroke, $163 million for lung cancer, $140 million for asthma, and $132 million for Parkinson's disease, **and only $11.5 million for research on new treatments for all 6,000 rare "orphan diseases".**

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(OVER)

What can be done to show Congress that funding for rare disease research is just as important as celebrity led causes? It's all about numbers! By increasing the numbers of members that NORD represents, politicians will know how many voters NORD represents, how many people in their home district have a rare disease, and how many of these voters actually care whether the politician voted for or against public health programs and medical research funding.

There is strength in numbers. If a health problem affects only a small number of people, politicians assume it is not a "major" health threat. NORD's role is to remind government officials that no matter how rare a disease may be, it is a "major" health threat if you or your loved one happens to have it! A NORD membership gives you much more than three newsletters each year. It gives you **a voice in public health debates**, it puts your concerns on the public health agenda, and it says to politicians and government servants, **"I am here. Don't forget about me"**.

Medically disenfranchised people with rare diseases are usually the exception to the standard rules. NORD must assure that the rules are made broad and inclusive enough to encompass all of our concerns, no matter which diagnosis we have. Until we have celebrities raising money for our cause, or demanding the attention of politicians, we must rely on the support and commitment of our members.

We thank you for joining in NORD's cause, and we urge you to ask your friends and family to become supporters of NORD's work.

Warmest regards,

Abbey S. Meyers
President

P.S. Please take this opportunity to become a NORD member, renew your NORD membership, or make an additional contribution to help NORD increase funding for medical research on all 6,000 rare diseases.

cc: Blumenthal
Jennings

THE WHITE HOUSE
WASHINGTON

I think this is good. 9-13-00

September 12, 2000

JP | CJ Cox

I'd really like to be somebody on this — how much of this can we do —

BL

MEMORANDUM FOR THE PRESIDENT

FROM: SIDNEY BLUMENTHAL

SUBJECT: COLON CANCER

You have a great opportunity to save lives that would be lost to colon cancer, the number-two cancer killer of both men and women. When colon cancer is detected through early screening survival rates increase enormously. Currently, only about a third of colon cancers are diagnosed in the early stage, before the cancer has begun to spread. Less than 25 percent of Americans over 50 years of age are currently being screened according to American Cancer Society guidelines. The American Cancer Society estimates that colon cancer mortality could be cut in half within two years through screening awareness programs and mandating insurance companies to cover screenings for those individuals with average-risk (that is, those 50 years old or older).

copied Podesta Jennings

On Sunday, October 8, an alliance of foundations and groups devoted to fighting colon cancer will hold a rally on the Mall, a walk-a-thon and a concert by Paul Simon. The leaders of the event are Katie Couric, Rosie O'Donnell, Dennis Franz, and Lilly Tartikoff. Major corporations (Chrysler, US Airways, Sony, Viacom, NBC, Aetna, Merck, Dreamworks, etc.) are lending support. This high profile event would provide the occasion for a radio address on Saturday, October 7, on meeting the challenge of colon cancer. (Loretta Ucelli supports a radio address on this topic.)

Policies you could propose include:

(1) Increasing public awareness by increasing funding for the Centers for Disease Control and Prevention. In FY 2000, the CDC received a bare $2.8 million for promoting screening, the Colo-rectal Cancer Awareness Program. An increase

to $25 million would begin to change nationwide participation rates. It would continue the effort started by the First Lady in September 1998, when she joined with Katie Couric at the White House to call attention to the importance of colon cancer screening.

(2) Support enactment of the Eliminate Colo-Rectal Cancer Act (HR 1816/S 1044) and the Cancer Screening Coverage Act (HR 1285/S 1641) that would provide access to screening for individuals with private health insurance who are currently prevented from getting screening. Some plans deny coverage to average-risk individuals and others even deny it to high-risk individuals. A majority of new cases of colon cancer are diagnosed in individuals considered to be at average risk. Both bills have bipartisan sponsorship. The Eliminate Colo-Rectal Cancer Act is co-sponsored in the Senate by Senator Ted Kennedy and Senator Jesse Helms.

(3) Support coverage under Medicare for colonoscopy screening for average-risk individuals. Currently, Medicare covers only high-risk individuals for this essential procedure.

(4) Support, once again, a real Patients Bill of Rights that establishes the right of access, for the first time, to clinical trials (including those under the auspices of the FDA), specialists, and a grievance and appeals process for those who have been unfairly denied care.

Colon cancer, of all cancers, is the one that can be defeated most directly and immediately. Bipartisan support exists for new policy. The insurance companies' exclusionary coverage is unacceptable and unpopular. The results of taking action are indisputable.

5-26-00

Doctor Yes

How Is Merrill Lynch Limiting Health Costs? By Expanding Benefits

Its Generous Plan Includes More Scrutiny of Care Provided to Employees

Exercise Pool Gets an OK

A1

By Carol Gentry
Special to The Wall Street Journal

There are health plans, and there are health plans. And then, there is Merrill Lynch & Co.'s health plan.

By just about any standard, the financial-services giant is generous in what it covers. For example, it sets no limits on how long its employees can get care in a mental hospital—an approach virtually unheard of elsewhere.

The company regularly retools its coverage to accommodate special needs. For a secretary rendered mute by Lou Gehrig's disease, it approved a synthetic speech machine that costs $6,000.

Early Detection

Even when Merrill Lynch turns down a request, it can do so in an unusually forgiving way. A disabled former employee suffering from multiple sclerosis asked Merrill to cover construction of a large swimming pool, so he could get exercise therapy. Can't do that, Merrill said, though we will cover a pool 4 feet by 6 feet.

But here's the really odd part: The company says its approach appears to be saving money. Adjusted for inflation, its health costs have declined even while benefits have expanded. And Merrill spends less per employee than many similarly sized companies. In fact, a half-dozen other corporations have copied its health plan, and the government will run a pilot project of it for thousands of federal workers this summer.

The story of how the nation's largest investment firm built its own benefits program rather than use an off-the-shelf plan challenges many of the assumptions that led employers into managed care. Instead of controlling costs by restricting employees' access to specialists or brand-name drugs, Merrill says it saved money by focusing on the quality of care and early detection.

The Company's Role

The company's experience also illustrates a fact that gets lost in the managed-care debate: If you work at a big company, it's probably your boss, not your HMO, who calls the shots. While small employers usually have to buy a standard health plan with preset limitations, large companies can act as their own insurer. They can make decisions about coverage and hire an insurer to act as the middleman and pay the claims.

Many corporations are content to delegate authority over the scope of coverage to insurance administrators, says Kenneth J. Reifert, director of global benefits for Merrill Lynch. "They want to distance themselves from a tough decision."

Merrill Lynch's different route dates back to 1987, when William Schreyer, chief executive at the time, underwent open-heart surgery. Shortly thereafter, he brought in a young cardiologist, Lonny Reisman, to screen Merrill executives for heart problems.

Soon after Dr. Reisman arrived, he met with Herbert Allison Jr., who was then Merrill's head of human resources and later became its president. Mr. Allison asked Dr. Reisman his opinion of the company's cost-containment strategy. "I think it stinks," Dr. Reisman says he told him. "You're completely missing the point. It isn't about resource consumption, it's about clinical excellence." He suggested that if Merrill focused on improving quality of care, the company could solve its cost problems.

Mr. Allison introduced him to the then-director of health benefits, Mr. Reifert, and the two visited insurance contractors nationwide, conducting random audits of staffers' medical care. Records showed employees with untreated sky-high blood pressure or out-of-control glucose levels. Some Merrill employees had spent days in the hospital being treated for the wrong disease. Ominous results on screening tests weren't always followed up.

'A Blank Check'

Meanwhile, insurers' prices were soaring. "We were giving them a blank check," Mr. Reifert says.

He and Dr. Reisman tried to recruit HMOs as partners for a quality-improvement project. But they couldn't get the HMOs' attention.

So Merrill formed a coalition with other major employers to lobby health plans to put more emphasis on monitoring quality. The bird dogs for the group were Dr. Reisman, who by now was a full-time consultant to Merrill employed by the William M. Mercer consulting company, and his colleague at Mercer, Charles Blanksteen.

The two started a company to serve as an incubator for the quality-improvement project. With encouragement and money from Merrill and venture capitalists, the firm evolved to become the closely held Active Health Management Inc.

They began by examining the treatment given to Merrill employees and dependents who had generated more than $50,000 in claims in a year. They checked on whether those patients had been properly diagnosed, were being given the best

Please Turn to Page A16, Column 1

possible treatment (whatever the cost) and were being monitored properly.

When the answer was no, the patient's doctor would get a call from a Merrill medical consultant with a few tactful suggestions. Then, Dr. Reisman would check on the patient from time to time.

But Active Health and Merrill Lynch managers concluded they needed to intervene much sooner—not after a heart attack, but when a patient with angina went untreated; not after a stroke, but when a patient failed to fill a prescription for blood-pressure medicine. What they needed was computer software to alert them to danger signals, so they could alert the patient's physician. Active Health developed a program that could take in data from throughout the system—doctors, laboratories, hospitals and pharmacies—and flag mistakes, misdiagnoses and disasters waiting to happen.

Next, Merrill needed a national insurer to handle payment of bills and follow up on hazards the computer flagged. The big insurers declined, but there was another possibility: String together Blue Cross and Blue Shield networks across the country, under the leadership of Empire Blue Cross and Blue Shield of New York. Michael Stocker, Empire's CEO, was enthusiastic.

Merrill Lynch officials decided that while Empire would handle bill payment, they would determine what the coverage should be. The company said it would abide by the principle of following the advice of the best medical experts.

That strategy sometimes puts the company in a lonely position. Most insurers, for example, don't cover behavioral therapy for children with autism, saying it's the province of education, not health care. Merrill Lynch covers the treatment in some early cases where experts say such therapy can bring lasting improvement.

Merrill Lynch doesn't coerce patients into taking a generic drug if the doctor wants them to have a brand name. "We want patients to get what the doctor is prescribing," says Shari Goldfarb, a vice president for global benefits.

When Viagra came out, the company that manages Merrill's prescription-drug program called Mr. Reifert's staff to say that a lot of companies weren't covering the anti-impotence drug. After checking with Active Health, Merrill gave the go-ahead. "Impotence is a medical condition," says Louis DiMaria, vice president and manager of international benefits planning. "So we're covering it. Simple."

Merrill Lynch's plan sets no arbitrary limits on the number of home-health visits or the number of days for inpatient hospital care for mental health, substance abuse or rehabilitation. Coverage remains at 100% as long as doctors consider the treatment medically necessary and the patient is improving.

Most insurers set caps on those services because they have been overused by hospitals and because the treatment for such problems wasn't clear-cut. But Mr. Reifert says it's now clear that psychiatric problems can stem from biochemical irregularities. So why would the company cover them differently than physical ailments?

It doesn't make sense to kick patients out of the hospital when they're making progress, adds John Brence, a vice president for global benefits. The same logic governs home visits, he says. If there are set limits, "sooner or later, somebody's going to need care beyond that," he says. "And if they don't get that care, they're going to get sicker and end up going back to the hospital."

Merrill Lynch insists it knows where to draw the line. When some New York employees asked for acupuncture coverage, the staff and its Active Health physicians said OK—but only if it's done by an acupuncturist with traditional medical training.

When a request came in for a new type of mammogram that was still being tested, Active Health suggested Merrill say no. There were still too many problems to trust its reliability, they said.

Employees who aren't satisfied with answers from benefits managers can appeal to a panel from Merrill's human-resources staff. But employees say Merrill goes to extraordinary lengths on their behalf.

Once, Merrill sent a Learjet, staffed with a surgeon, from Germany to Kenya to pick up a manager's desperately ill wife stricken while on vacation with a blood clot on the brain. Mr. Reifert blanched at the price—almost $100,000—but paid it at the recommendation of Merrill Lynch's medical director, Donald Gemson, who decided that Kenya and neighboring countries lacked the imaging equipment and experienced surgeons required to the treat the problem. The patient recovered.

Employees have heartily endorsed Merrill's health plan and its quality-monitoring system, tested in 1998 and fully implemented in January 1999. In the mid-1990s, many of them had gone to managed-care plans to get away from deductibles, paperwork and coverage of only 80% of the bill. But when they heard that the new Merrill plan had none of those features, and still covered three out of four doctors and nine out of 10 hospitals, they jumped back in. Now 80% of the company's employees are on the new plan.

Insurance industry groups say that HMOs and other insurers have already used technology to develop quality-monitoring systems, and private employers don't need their own system. "This isn't anything new," said Charles N. Kahn III, president of Health Insurance Association of America.

But Active Health says the Merrill system is far ahead of the usual insurance company efforts because it focuses only on quality, not on cost, and because it has such a huge database. Thus, Active Health was warning doctors about drug interactions and other risks with the heartburn drug Propulsid more than a year before the manufacturer acknowledged them and pulled it off the market in March.

In some ways, Merrill's generous coverage is an extension of similar policies that go back decades. The company opened its first on-site health clinic more than 50 years ago, and it now has clinics at 10 Merrill locations, designed to save workers time and increase the chance that problems will be detected early.

Karen Scales, who works in Merrill's New York headquarters, saves about four hours a month by getting her allergy shots downstairs. But she values the clinic for more than convenience: Her first skin cancer was spotted there, and she was referred to Memorial Sloan-Kettering Cancer Center, which has now removed three. Ms. Scales says she "never, ever would have gone" for screening if it hadn't been so convenient.

While the clinics rang up 80,000 visits last year, they account for less than 2% of Merrill's $130 million a year in medical spending. The lion's share goes into the health-insurance system.

So what evidence is there that Merrill's approach saves money? The company's medical cost per employee last year, including workers' own contributions, was roughly $3,600—about 25% less than the average found in a benchmarking study of 54 large employers by the Towers Perrin consulting company last summer.

Merrill Lynch has fewer retirees to cover than many large corporations, such as auto makers, Mr. Reifert says, so it's possible there are other factors at work. But he also notes figures that show Merrill Lynch's health insurance costs per capita dropped slightly between 1995 and 1999 when adjusted for medical inflation during that period.

The company also has found that the rate of large claims (more than $50,000) has been steadily declining. There were 2.2 claims per 1,000 people covered in 1999, vs. 3.3 per 1,000 in 1995. Meanwhile, the average for a high-cost claim remained stable at around $100,000.

Mr. Brence calculates that the reduction in high-cost cases saved Merrill $6.5 million in direct medical costs over the five-year period—not to mention the reduction in suffering and time lost for employees.

After seeing Merrill's experience, other companies have signed up for the Active Health/Empire system, including Marriott International Inc., Sears, Roebuck & Co. and Circuit City Stores Inc.

The plan puts "dollars in the right place," says Gary Krueger, manager of group benefits for Circuit City, "as opposed to buying something that's just managing access to care."

The quality-monitoring system also caught the federal government's interest. This summer, the government will begin a pilot project, to last at least a year, using the system for 40,000 federal employees in New York and an undetermined number of other workers elsewhere in the country.

2/2

Jennings

VP should look at this —
which federal employees
& how many are in the
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5-26-00

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6-22-00

U.S. 15th in Health Care, WHO Study Says

Ranking Is Attributed to Method Used in Medical Financing

By David Brown
Washington Post Staff Writer

Although the United States spends considerably more on health care per person than any other nation, it ranks only 15th among countries of the world on an overall index designed to measure a range of health goals, according to a broad new assessment released yesterday by the World Health Organization.

The American method of financing medical care is one reason the U.S. health system lags behind those of Japan, most European countries, Canada and Australia, according to the report. A less-than-optimal life expectancy here is another.

On the other hand, the United States leads the world in the "responsiveness" of its health system, a category the study's authors used to measure how respectfully people are treated and how efficiently their medical care proceeds.

"I think this is profoundly important," said John M. Eisenberg, head of the federal Agency for Healthcare Research and Quality, which is concerned with measuring performance and outcome in medical care. "It's an important alarm for Americans to look at and realize how much better we can do."

The United States ranks 24th in the world in life expectancy. It ranks 32nd in the degree of variation among the population in life expectancy, which means that a sizable percentage of Americans die prematurely.

In spending, however, the United States is without peer. Nearly 14 percent of its gross domestic product is spent on matters of health, more than any other country. Its per capita spending on health—from government, business and individual consumers combined—is $3,724 a year, about a thousand dollars more than the $2,644 being spent by its nearest competitor, Switzerland.

In a complicated measure of health system "performance," the study found that the United States could get more for its dollar if the money were spent differently. With an "efficiency" score of 84 percent, it is behind virtually all of Europe (which France leads) as well as Israel, Morocco, Chile, Saudi Arabia and Costa Rica.

"On a global scale, that [score] is pretty good," said Julio Frenk, a WHO physician and epidemiologist who is one of the chief authors of the study. "But it says the U.S. could still get 16 percentage points ahead with the same resources. It is clear that there is room for improvement, even without spending anything more."

The WHO report is the product of two years' work by hundreds of physicians, economists, statisticians, demographers and anthropologists. It is the first systematic attempt to go beyond impression and anecdote in measuring how well one system works compared with another.

"It started with the frustration of trying to answer questions from governments about this or that latest fashion in health sector reform," said Christopher J.L. Murray, a WHO epidemiologist and the other principal author of the study.

The WHO evaluation is composed of five gauges of health system performance.

The first is the "disability-adjusted life expectancy" (DALE), which is conventional life expectancy, discounted by years of ill health. The latter is a way of including in the measurement the burden of disease a population lives with (but doesn't die from). The global leader in DALE is Japan, at 74.5 years. For the United States, the DALE is 70 years.

The second is child survival. Most people born survive into adulthood. Consequently, the mortality of people in their first five years of life is an index of the health inequality in a population.

The third is the "responsiveness" of the health system, which reflects the quality of human interaction between health care providers and patients. Its components include respect for individuals and their freedom of choice, the confidentiality of records, the promptness of attention when one is ill and the quality of facilities.

The fourth component measures how well different subgroups of a population—women, the elderly, the poor, minority groups—are treated when it comes to the things that make up "responsiveness."

The final component measures the fairness of health care financing. "Perfect fairness" is defined as every household devoting the same percentage of its non-food spending on health care—regardless of how large or small its income is, or how sick or well its members are.

All five of the gauges involve value judgments. However, the judgments were not reached arbitrarily. They are consensus views derived from the results of surveys of thousands of people in dozens of countries. There is, for example, near universal agreement that out-of-pocket payment at the time of illness is an undesirable and unfair way to finance health care.

Embedded in the 51 pages of tables in the 215-page report are myriad insights into national success, failure and opportunity.

Oman, with $334 in per capita health spending, ranks No. 1 among the world's nations in life expectancy for its investment. In 25 years, Murray said, that Persian Gulf state has reduced its child mortality from about 1 per 4 children born to the current rate of 18 deaths per 1,000 births.

Chile and Lebanon have virtually the same per capita spending (about $570 a year), but the former ranks 33rd in overall "performance"—or health attainment for its investment—while Lebanon ranks 91st. Part of the reason is that Lebanon has a highly unregulated health care system built around the private provision of care, which decreases its population-wide efficiency.

A generation ago, China emphasized disease prevention and universal primary care. (It was one of the first Third World countries to eradicate smallpox and was famous for its "barefoot doctors.") With the arrival of a market economy in the 1980s, medical care became financed largely by out-of-pocket payment by consumers. Today, it ranks 188th out of 191 nations in the WHO assessment's "fairness of financing" measure.

The erosion of organized planning for health may be one reason China's life expectancy has barely budged in the past 20 years, despite the huge growth in its national wealth, a traditional driver of health improvement, Frenk said.

Ranking Care

The World Health Organization ranked the health systems of member nations by the level and distribution of health, as well as factors such as confidentiality, promptness, personal respect and fairness of methods for financing health care.

Overall health system attainment, top 25 nations

1. Japan
2. Switzerland
3. Norway
4. Sweden
5. Luxembourg
6. France
7. Canada
8. Netherlands
9. United Kingdom
10. Austria
11. Italy
12. Australia
13. Belgium
14. Germany
15. **United States**
16. Iceland
17. Andorra
18. Monaco
19. Spain
20. Denmark
21. San Marino
22. Finland
23. Greece
24. Israel
25. Ireland

The Washington Post
Wednesday, June 21, 2000

6-22-00

JP | BReed | CJennings

can we do anything
w/ this —

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Ask Economists, Not Hillary, Why Canadian Drugs Cost Less

The Americas

By Michael Walker

Before the U.S. Congress joins the state of Maine on a bus trip north to pick up Canadian drug pricing policies, it should ask a simple question: "Why are drug prices lower in Canada than in the U.S.?" The answer may persuade them to stay at home.

The first step in analyzing the price differential is to learn its true size. Hillary Clinton and Sen. Slade Gorton (Rep., Washington) have each conjured up "Top 10" lists that cherry-pick the drugs with the most glaring price differences between Canada and the U.S. Inspired by such lists, Maine has passed a law to equalize patented drug prices with those north of the border. Meanwhile, Canada's Patented Medicine Prices Review Board, which imposes price controls on branded pharmaceuticals, figures that in 1998 the U.S. price for drugs was 60% higher than at home. However, it is unlikely that the Board's self-congratulatory claim or the makers of Top 10 lists appreciate the complexities involved in international price comparisons of pharmaceuticals.

In 1996, University of Pennsylvania Prof. Patricia Danzon measured prices of drugs in 12 different ways, including by molecular composition rather than brand name, and by gram of active ingredient rather than dosage. By one of the measures, the price index for Canadian drugs was actually 3% higher than in the U.S. Indeed, commonly used drugs such as Eltroxin, Atenolol, Doxycycline, Ranitidine and Diazepam are several times more expensive at the retail level in Canada than in the U.S.

Furthermore, because regulatory approval is slower in Canada, innovative and high-priced drugs may be included in the U.S. price index before they are included in Canada's. In the U.S., many of these drugs are priced at a premium to existing drugs but nevertheless earn significant market share. Recent examples include Viagra, Vioxx and Celebrex. For any given year, the U.S. price index will include several such new drugs but the Canadian index will not.

But if drug prices are 60% higher in the U.S., it does not follow that the Board deserves the credit. When it was set up in 1987, U.S. drug prices were already 36% higher than Canadian prices. While the Board might like the credit for Canada's 24% price improvement up to 1998, the fact is it has simply been a part of a generalized widening of price differentials between the countries.

According to Statistics Canada, the real price level of U.S. gross domestic product in 1998 was 25% higher than in Canada. In 1987, the difference was only 6%. This 19% widening of the gap between Canadian and U.S. real price levels explains all but 5% of the increasing pharmaceutical price difference between the two countries.

In discussing why American pharmaceuticals cost more in America than in Canada, we must note that there is nothing, in this regard, different about drugs or about Canada. Many products of intellectual property, made in America, are sold for lower prices in foreign countries. And many, in particular, are sold more cheaply in Canada.

As an example, the CD-ROM version of Intuit's Quicken Basic 2000, a popular personal financial planning software package, costs $34.95 from the company's web site. However, the Canadian version, purchased from the company's Canadian web site, costs the equivalent of $20 before the ubiquitous federal sales tax. AOL charges $21.95 for unlimited monthly Internet access in the U.S., but AOL Canada charges less than $16 for the same service. Intuit's and AOL's American customers pay premiums of 70% and 40% respectively. (Inclusion of sales taxes does not alter the substantive result since the allegation is that somehow a market failure produces higher U.S. prices.)

The point here is that these are software-related products with very low manufacturing and distribution costs. The price differences cannot be caused by supply costs to the two markets. Nor do we have a "Patented Software Prices Review Board" to claim credit for the price differential. But government has nevertheless had a hand in producing the lower Canadian prices.

> *The 19% widening of the gap between Canadian and U.S. real price levels explains all but 5% of the increasing pharmaceutical price difference between the two countries.*

Because of bad government policies the Canadian dollar has collapsed to 67 U.S. cents from 87 cents over the past decade. Canadians' personal incomes have declined 24% versus those of Americans, and U.S. producers wishing to hit the price point that will maximize the value of their sales therefore charge Canadians less for their products. As a Congressional Committee found, and for the same reason, American drugs are also priced at a lower level in Mexico. While poor economic performance elsewhere is the main determinant of drug price gaps, there is a peculiarly American aspect to the story that must be noted, and that is the litigious atmosphere in the U.S. marketplace.

Prof. Richard L. Manning, while at Brigham Young University, produced a Journal of Law and Economics study in 1997 that showed that one-third to one-half of pharmaceutical price differentials in 1990 were due to the higher cost of legal liability protection in the U.S. It is not unreasonable to extrapolate his result to goods generally. Canada, unlike the U.S., does not see multibillion dollar liability suits. In Canadian courts, personal injury compensation is capped at C$250,000 and judges rarely award large liability settlements. In short, Americans pay in higher prices for the liability-law circus going on in their courts. Peter Huber, in his 1988 book on the liability revolution, estimated those costs at $300 billion a year. The liability crisis is worse today.

U.S. politicians wanting lower pharmaceutical prices should start with meaningful tort reform rather than Canadian drug-price controls, which cannot have been a significant influence on drug prices. Even if they were, they represent the sort of bad public policy that has left Canada with a weak dollar and a decade of stagnant living standards.

The inventive effort that creates the drugs that benefit Canadians and Americans alike is financed largely by resources generated in the U.S. Canada has always been reluctant to make its contribution to this effort and for many years simply stole the patents under Canadian federal law. Neither U.S. nor Canadian consumers would be well-served by the importation of this outlook, even if, in the short run, there was a slight reduction in the price of the top 10 drugs.

Mr. Walker is executive director of the Fraser Institute in Vancouver. John Graham, a senior analyst at Fraser, contributed to this article.

5-22-00

L Jennings
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TC

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jennings
Podesta

CJ Jennings
Why are we saying
not an Executive order?
What do we have by
doing it?

May 22,

Mrs. Ro
The Car
One Cop
Atlanta

Dear Rosalynn:

Thank you for your letter seeking an executive order to boost immunization rates among children and adolescents. I have shared your letter as well as Dr. Cook's with my health care advisor, Chris Jennings, and asked him to respond to you directly.

As you may know, my fiscal 2001 budget proposes almost $1 billion for childhood immunizations, including the Vaccines for Children program and CDC's discretionary immunization program. My Administration is working hard to ensure that all our nation's children are protected against preventable diseases, and I was glad to get your ideas on how we can further advance this crucial goal.

I'm glad to know that you enjoyed your time at the White House -- I loved seeing all the kids! Hillary and I hope to see you again soon, and we send our best.

Sincerely,

Bill

AP letter
has been prepared
for Donald Cook

cc:
Jennings,
w note.
Red dot.
original
back to me
(W)
5.30.00

THE WHITE HOUSE

WASHINGTON

May 22, 2000

Mrs. Rosalynn Carter
The Carter Center
One Copenhill
Atlanta, Georgia 30307

Dear Rosalynn:

Thank you for your letter seeking an executive order to boost immunization rates among children and adolescents. I have shared your letter as well as Dr. Cook's with my health care advisor, Chris Jennings, and asked him to respond to you directly.

As you may know, my fiscal 2001 budget proposes almost $1 billion for childhood immunizations, including the Vaccines for Children program and CDC's discretionary immunization program. My Administration is working hard to ensure that all our nation's children are protected against preventable diseases, and I was glad to get your ideas on how we can further advance this crucial goal.

I'm glad to know that you enjoyed your time at the White House -- I loved seeing all the kids! Hillary and I hope to see you again soon, and we send our best.

Sincerely,

Bill

EB - 1/21/00
Correspondence
PLM

ROSALYNN CARTER

6 April 2000

Dear Bill,

In January 2000, the American Academy of Pediatrics (AAP) wrote to you with a suggestion to help address the low immunization rates of children in certain segments of our society (copy enclosed). The Academy asked you to issue an Executive Order to all government agencies and programs serving children and adolescents instructing them to assess immunization status as part of their enrollment process. For a number of years, the Women, Infants, and Children Program (WIC) has done this with real success in their population group. The result is that WIC children maintain a higher immunization rate than the national average.

The Centers for Disease Control and Prevention (CDC) has identified 11 areas of special need in this country, mostly inner cities. In spite of targeted efforts and extra expenditures by the CDC, the immunization rates in these areas have increased only marginally. Your Executive Order combined with a concerted, dedicated response by all appropriate federal agencies could do more to improve these statistics and ultimately the health of America's children than anything attempted thus far.

Those of us working on immunization issues remember and appreciate that you began your administration with an initiative devoted to the National Immunization Program. Your issuance of an Executive Order now will reinforce those projects already under way and encourage renewed commitment. Moreover, you will grant a degree of permanence to the immunization program that presently is missing. From a personal perspective, you will give a tremendous boost to the work Betty Bumpers and I are doing to see that all children enjoy full protection from preventable childhood diseases.

Leadership in addressing the challenges confronting America's youth will be a legacy of your presidency. The AAP's proposal will build upon that heritage and set a new standard for the administrations that follow. I urge you to accept the Academy's suggestion and in so doing, make another important contribution to the well-being of all Americans.

With appreciation for your consideration and my warm best wishes,

Sincerely,

Rosalynn Carter

We enjoyed our visit to the White House & Camp David immensely! Thanks so much

The Honorable William Clinton
The President of the United States
Washington, D.C. 20500

American Academy of Pediatrics

Reply To:
Department of Federal Affairs
American Academy of Pediatrics
The Homer Building
601 Thirteenth Street, NW
Suite 400 North
Washington, DC 20005
202/347-8600
800/336-5475
Fax: 202/393-6137
e-mail: kids1st@aap.org
http://www.aap.org

January 24, 2000

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear President Clinton:

Let me again praise your leadership over the past seven years as "the children's President." As you continue in your final year to issue significant directives to strengthen your program initiatives, we need your bully pulpit to return to the childhood immunization program. We are requesting that an Executive Order be issued to all Departments and Agencies serving children and adolescents to assess immunization status as part of their enrollment process.

Through the leadership of Senator Dale Bumpers, the benefits of such cooperative arrangements have been demonstrated between the immunization and WIC programs. More needs to be done with other programs to assure that our nation's children and adolescents are protected from preventable diseases.

While our immunization rates are at an all time high, the CDC has identified eleven pockets of need where immunization rates are extremely low. Most of these are inner city areas where as many as 60% of children served by government programs reside. Hence, we are missing important opportunities to make sure that no child's immunization record is incomplete.

We intend for such an Order to be similar to and complement your recent Order regarding SCHIP outreach and enrollment.

Mr. President, the legacy you leave America's children and their families will serve them well into the new century. The American Academy of Pediatrics is pleased to continue to play a significant role with you in this process.

Sincerely yours,

Donald E. Cook, MD
President

DEC:jn

By Robert Hanashiro, USA TODAY

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RU-486 may face FDA limits

Abortion-pill backers fear a lack of access

By Rita Rubin
USA TODAY

▶ Politics of modified foods, 6D

The Food and Drug Administration is considering major restrictions on the "abortion pill" RU-486, including establishing a registry of doctors permitted to use it, leaders of abortion-rights groups said Tuesday.

"The FDA appeared to be interested in being able to track the use of the drug from the factory to the office and to the patient," says Paul Blumenthal, medical director of Planned Parenthood's Maryland affiliate, who attended a conference Friday at which word of the potential restrictions surfaced.

In February, the FDA said it would approve the sale of RU-486, also called mifepristone, once some final, undisclosed issues were worked out. The drug could be administered discreetly as part of a primary-care or gynecology practice. Abortion-rights proponents hope that doctors who fear inciting abortion foes by providing surgical abortions will use RU-486.

"The FDA is considering placing so many restrictions on doctors who want to use the drug that few will be interested in using it," says Vicki Saporta, director of the National Abortion Federation, which is developing educational materials on RU-486 for doctors. "The great promise that it has to improve access to women who are seeking early abortion services will be lost."

Blumenthal says the FDA is considering limiting the use of RU-486 to doctors who also know how to perform surgical abortions and whose practices are within an hour's trip of an emergency room.

Laura Echevarria, director of media relations for the National Right to Life Committee, says such restrictions are necessary because RU-486 carries a risk of excessive bleeding.

But the FDA has not limited the prescribing of drugs that are riskier, says Gloria Feldt, Planned Parenthood's president. More than half a million European women have used RU-486, she says.

Neither the FDA nor the Population Council, which holds the U.S. marketing rights, nor the Danco Group, the Population Council's licensee, would comment on ongoing discussions about the drug's distribution.

"FDA is not in a position to comment on a product application," spokeswoman Susan Cruzan says. "For any new product, FDA's job is to examine not only whether that product is effective, but also whether it can be used safely."

But Cruzan notes that the notion of a "credentialing system" for prescribing mifepristone was raised four years ago by the FDA advisory committee that recommended approving the drug.

Danco spokeswoman Heather O'Neill says that the FDA's proposed distribution plan "is more restrictive than we envisioned and entails more controls than we proposed."

5-26-00

Doctor Yes

How Is Merrill Lynch Limiting Health Costs? By Expanding Benefits

Its Generous Plan Includes More Scrutiny of Care Provided to Employees

Exercise Pool Gets an OK

Al

By Carol Gentry
Special to The Wall Street Journal

There are health plans, and there are health plans. And then, there is Merrill Lynch & Co.'s health plan.

By just about any standard, the financial-services giant is generous in what it covers. For example, it sets no limits on how long its employees can get care in a mental hospital—an approach virtually unheard of elsewhere.

The company regularly retools its coverage to accommodate special needs. For a secretary rendered mute by Lou Gehrig's disease, it approved a synthetic speech machine that costs $6,000.

Early Detection

Even when Merrill Lynch turns down a request, it can do so in an unusually forgiving way. A disabled former employee suffering from multiple sclerosis asked Merrill to cover construction of a large swimming pool, so he could get exercise therapy. Can't do that, Merrill said, though we will cover a pool 4 feet by 6 feet.

But here's the really odd part: The company says its approach appears to be saving money. Adjusted for inflation, its health costs have declined even while benefits have expanded. And Merrill spends less per employee than many similarly sized companies. In fact, a half-dozen other corporations have copied its health plan, and the government will run a pilot project of it for thousands of federal workers this summer.

The story of how the nation's largest investment firm built its own benefits program rather than use an off-the-shelf plan challenges many of the assumptions that led employers into managed care. Instead of controlling costs by restricting employees' access to specialists or brand-name drugs, Merrill says it saved money by focusing on the quality of care and early detection.

The Company's Role

The company's experience also illustrates a fact that gets lost in the managed-care debate: If you work at a big company, it's probably your boss, not your HMO, who calls the shots. While small employers usually have to buy a standard health plan with preset limitations, large companies can act as their own insurer. They can make decisions about coverage and hire an insurer to act as the middleman and pay the claims.

Many corporations are content to delegate authority over the scope of coverage to insurance administrators, says Kenneth J. Reifert, director of global benefits for Merrill Lynch. "They want to distance themselves from a tough decision."

Merrill Lynch's different route dates back to 1987, when William Schreyer, chief executive at the time, underwent open-heart surgery. Shortly thereafter, he brought in a young cardiologist, Lonny Reisman, to screen Merrill executives for heart problems.

Soon after Dr. Reisman arrived, he met with Herbert Allison Jr., who was then Merrill's head of human resources and later became its president. Mr. Allison asked Dr. Reisman his opinion of the company's cost-containment strategy. "I think it stinks," Dr. Reisman says he told him. "You're completely missing the point. It isn't about resource consumption, it's about clinical excellence." He suggested that if Merrill focused on improving quality of care, the company could solve its cost problems.

Mr. Allison introduced him to the then-director of health benefits, Mr. Reifert, and the two visited insurance contractors nationwide, conducting random audits of staffers' medical care. Records showed employees with untreated sky-high blood pressure or out-of-control glucose levels. Some Merrill employees had spent days in the hospital being treated for the wrong disease. Ominous results on screening tests weren't always followed up.

'A Blank Check'

Meanwhile, insurers' prices were soaring. "We were giving them a blank check," Mr. Reifert says.

He and Dr. Reisman tried to recruit HMOs as partners for a quality-improvement project. But they couldn't get the HMOs' attention.

So Merrill formed a coalition with other major employers to lobby health plans to put more emphasis on monitoring quality. The bird dogs for the group were Dr. Reisman, who by now was a full-time consultant to Merrill employed by the William M. Mercer consulting company, and his colleague at Mercer, Charles Blanksteen.

The two started a company to serve as an incubator for the quality-improvement project. With encouragement and money from Merrill and venture capitalists, the firm evolved to become the closely held Active Health Management Inc.

They began by examining the treatment given to Merrill employees and dependents who had generated more than $50,000 in claims in a year. They checked on whether those patients had been properly diagnosed, were being given the best

Please Turn to Page A16, Column 1

Chris — this is what it's test?

John

1/2

possible treatment (whatever the cost) and were being monitored properly.

When the answer was no, the patient's doctor would get a call from a Merrill medical consultant with a few tactful suggestions. Then, Dr. Reisman would check on the patient from time to time.

But Active Health and Merrill Lynch managers concluded they needed to intervene much sooner—not after a heart attack, but when a patient with angina went untreated; not after a stroke, but when a patient failed to fill a prescription for blood-pressure medicine. What they needed was computer software to alert them to danger signals, so they could alert the patient's physician. Active Health developed a program that could take in data from throughout the system—doctors, laboratories, hospitals and pharmacies—and flag mistakes, misdiagnoses and disasters waiting to happen.

Next, Merrill needed a national insurer to handle payment of bills and follow up on hazards the computer flagged. The big insurers declined, but there was another possibility: String together Blue Cross and Blue Shield networks across the country, under the leadership of Empire Blue Cross and Blue Shield of New York. Michael Stocker, Empire's CEO, was enthusiastic.

Merrill Lynch officials decided that while Empire would handle bill payment, they would determine what the coverage should be. The company said it would abide by the principle of following the advice of the best medical experts.

That strategy sometimes puts the company in a lonely position. Most insurers, for example, don't cover behavioral therapy for children with autism, saying it's the province of education, not health care. Merrill Lynch covers the treatment in some early cases where experts say such therapy can bring lasting improvement.

Merrill Lynch doesn't coerce patients into taking a generic drug if the doctor wants them to have a brand name. "We want patients to get what the doctor is prescribing," says Shari Goldfarb, a vice president for global benefits.

When Viagra came out, the company that manages Merrill's prescription-drug program called Mr. Reifert's staff to say that a lot of companies weren't covering the anti-impotence drug. After checking with Active Health, Merrill gave the go-ahead. "Impotence is a medical condition," says Louis DiMaria, vice president and manager of international benefits planning. "So we're covering it. Simple."

Merrill Lynch's plan sets no arbitrary limits on the number of home-health visits or the number of days for inpatient hospital care for mental health, substance abuse or rehabilitation. Coverage remains at 100% as long as doctors consider the treatment medically necessary and the patient is improving.

Most insurers set caps on those services because they have been overused by hospitals and because the treatment for such problems wasn't clear-cut. But Mr. Reifert says it's now clear that psychiatric problems can stem from biochemical irregularities. So why would the company cover them differently than physical ailments?

It doesn't make sense to kick patients out of the hospital when they're making progress, adds John Brence, a vice president for global benefits. The same logic governs home visits, he says. If there are set limits, "sooner or later, somebody's going to need care beyond that," he says. "And if they don't get that care, they're going to get sicker and end up going back to the hospital."

Merrill Lynch insists it knows where to draw the line. When some New York employees asked for acupuncture coverage, the staff and its Active Health physicians said OK—but only if it's done by an acupuncturist with traditional medical training.

When a request came in for a new type of mammogram that was still being tested, Active Health suggested Merrill say no. There were still too many problems to trust its reliability, they said.

Employees who aren't satisfied with answers from benefits managers can appeal to a panel from Merrill's human-resources staff. But employees say Merrill goes to extraordinary lengths on their behalf.

Once, Merrill sent a Learjet, staffed with a surgeon, from Germany to Kenya to pick up a manager's desperately ill wife stricken while on vacation with a blood clot on the brain. Mr. Reifert blanched at the price—almost $100,000—but paid it at the recommendation of Merrill Lynch's medical director, Donald Gemson, who decided that Kenya and neighboring countries lacked the imaging equipment and experienced surgeons required to treat the problem. The patient recovered.

Employees have heartily endorsed Merrill's health plan and its quality-monitoring system, tested in 1998 and fully implemented in January 1999. In the mid-1990s, many of them had gone to managed-care plans to get away from deductibles, paperwork and coverage of only 80% of the bill. But when they heard that the new Merrill plan had none of those features, and still covered three out of four doctors and nine out of 10 hospitals, they jumped back in. Now 80% of the company's employees are on the new plan.

Insurance industry groups say that HMOs and other insurers have already used technology to develop quality-monitoring systems, and private employers don't need their own system. "This isn't anything new," said Charles N. Kahn III, president of Health Insurance Association of America.

But Active Health says the Merrill system is far ahead of the usual insurance company efforts because it focuses only on quality, not on cost, and because it has such a huge database. Thus, Active Health was warning doctors about drug interactions and other risks with the heartburn drug Propulsid more than a year before the manufacturer acknowledged them and pulled it off the market in March.

In some ways, Merrill's generous coverage is an extension of similar policies that go back decades. The company opened its first on-site health clinic more than 50 years ago, and it now has clinics at 10 Merrill locations, designed to save workers time and increase the chance that problems will be detected early.

Karen Scales, who works in Merrill's New York headquarters, saves about four hours a month by getting her allergy shots downstairs. But she values the clinic for more than convenience: Her first skin cancer was spotted there, and she was referred to Memorial Sloan-Kettering Cancer Center, which has now removed three. Ms. Scales says she "never, ever would have gone" for screening if it hadn't been so convenient.

While the clinics rang up 80,000 visits last year, they account for less than 2% of Merrill's $130 million a year in medical spending. The lion's share goes into the health-insurance system.

So what evidence is there that Merrill's approach saves money? The company's medical cost per employee last year, including workers' own contributions, was roughly $3,600—about 25% less than the average found in a benchmarking study of 54 large employers by the Towers Perrin consulting company last summer.

Merrill Lynch has fewer retirees to cover than many large corporations, such as auto makers, Mr. Reifert says, so it's possible there are other factors at work. But he also notes figures that show Merrill Lynch's health insurance costs per capita dropped slightly between 1995 and 1999, when adjusted for medical inflation during that period.

The company also has found that the rate of large claims (more than $50,000) has been steadily declining. There were 2.2 claims per 1,000 people covered in 1999, vs. 3.3 per 1,000 in 1995. Meanwhile, the average for a high-cost claim remained stable at around $100,000.

Mr. Brence calculates that the reduction in high-cost cases saved Merrill $6.5 million in direct medical costs over the five-year period—not to mention the reduction in suffering and time lost for employees.

After seeing Merrill's experience, other companies have signed up for the Active Health/Empire system, including Marriott International Inc., Sears, Roebuck & Co. and Circuit City Stores Inc.

The plan puts "dollars in the right place," says Gary Krueger, manager of group benefits for Circuit City, "as opposed to buying something that's just managing access to care."

The quality-monitoring system also caught the federal government's interest. This summer, the government will begin a pilot project, to last at least a year, using the system for 40,000 federal employees in New York and an undetermined number of other workers elsewhere in the country.

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Jennings

VP attended [illegible] work at this — which federal employees & how many are in the pics?

Bruce

5-26-00

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Clawing

Can we do anything about this?

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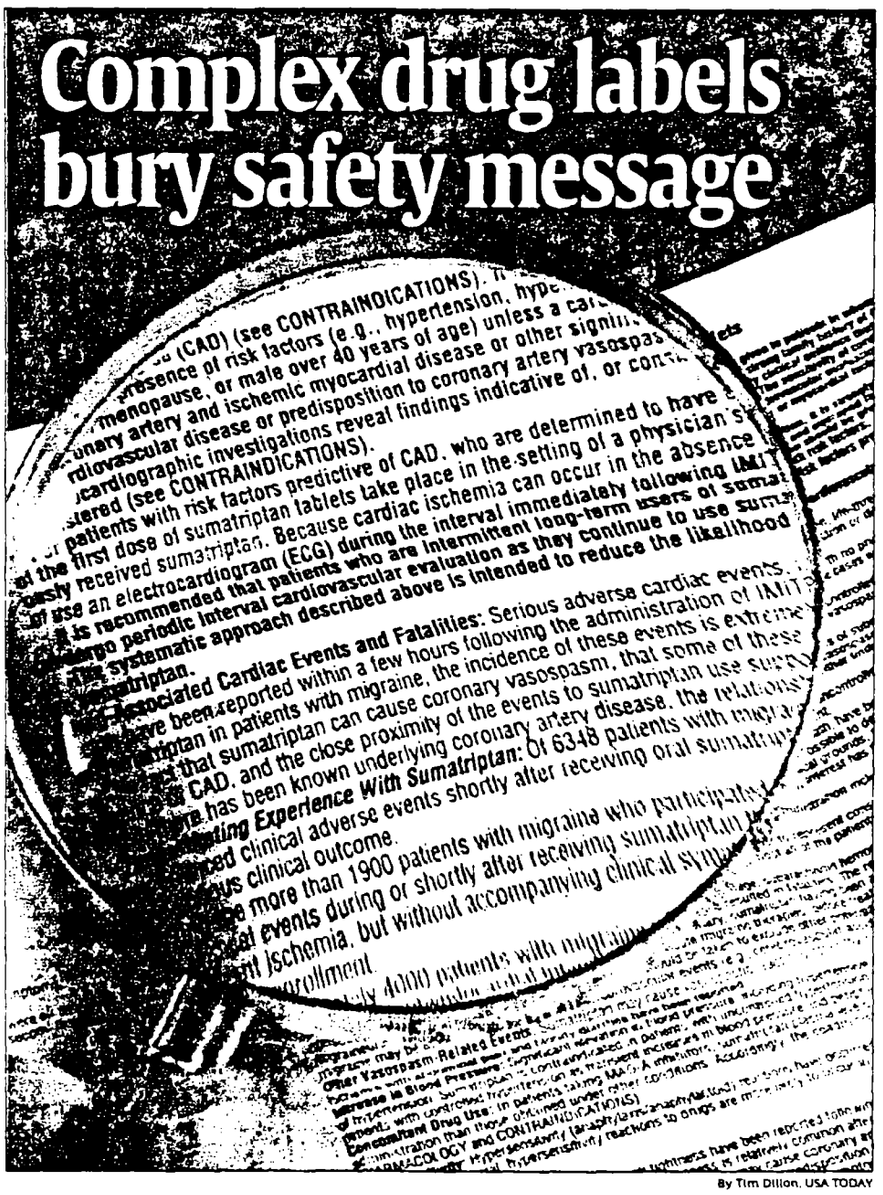

By Tim Dillon, USA TODAY

Tough to keep up: Patients often never see package inserts; when they do, the type is hard to read.

Warnings elude patients, doctors alike

By Rita Rubin
USA TODAY

A1

If all the information that's supposed to be on prescription labels actually were printed there, pill bottles would have to be 2 feet high. At least.

Cover story

Most people don't have medicine cabinets the size of refrigerators. So drug labels have evolved into package inserts, those tightly folded sheets of paper covered with fine print detailing risks and benefits. In many cases, patients never even see the package insert, and when they do, the tiny typeface and medical jargon often leave them more confused than ever.

Prescribing and taking medicine has never been more complicated, and critics say patients are becoming sick or dying as a result.

Recent drug withdrawals suggest that doctors, never mind their patients, aren't keeping up. Either they're overlooking warnings scattered throughout inserts or they're not even reading the leaflets.

"Less than 1% of physicians have seen a label in the last year," cardiologist Robert Califf, director of Duke University's Clinical Research Center, estimated at a recent Food and Drug Administration advisory committee meeting.

In less than two years, three widely prescribed drugs have been pulled from the market in part, at least, because doctors ignored the package inserts. A fourth will disappear from drugstore shelves this summer for the same reason.

FDA critics say the agency, which regulates package inserts, expects too much of the leaflets. In-

Please see COVER STORY next page ▸

1/2

stead of withholding approval of potentially dangerous drugs, critics say, the agency sends them to market with inserts jam-packed with warnings.

"Should we have relatively dangerous drugs and simply warn people that they might kill or seriously injure them?" asks Thomas Moore, a health policy fellow at George Washington University in Washington, D.C. "My perception is that the top management of the FDA seems to have a more permissive view than we have historically had."

He and like-minded FDA-watchers are quick to tick off Propulsid, Rezulin, Posicor and Duract, four drugs whose inserts underwent multiple revisions as new safety concerns came to light. In each case, the manufacturer also mailed "Dear Doctor" letters to alert physicians of label changes.

Apparently, though, some doctors never saw the warnings, and patients died. The last three drugs are now off the market, and Propulsid, which is used to treat severe heartburn, will follow them by mid-August.

"FDA has an almost ritualistic belief in labeling changes, as if they have some magical property to change behavior," says Jerry Avorn, chief of the division that tracks adverse medication events at the Brigham and Women's Hospital in Boston. "There is very little data to support that belief."

The FDA's own research backs Avorn.

In a "talk paper" in January, the FDA noted that 85% of the 270 Propulsid-related adverse side effects reported to the agency — including 70 deaths — occurred in patients with risk factors already listed on the drug's label, such as congestive heart failure or use of antibiotics or antidepressants.

And after Rezulin's label was changed in late 1997 to recommend monthly liver function tests, the FDA found that far fewer than 10% of patients had the tests.

Apparently, even the agency's expert advisers don't always follow the package insert instructions.

At the recent advisory committee meeting, an FDA staff member had to remind urologists on the panel about how to treat patients with Muse, an injectable impotence treatment. Instead of sending men home with a prescription, doctors are supposed to administer the first dose in their office so they can watch for possible side effects.

Flawed system

In many cases, package inserts "are far from perfect," acknowledges Rachel Behrman of the FDA's medical policy office. "We are working hard to improve that."

Recognizing that patients as well as doctors need to read package inserts, the FDA hopes to make them "more user-friendly, more informative, more consistent," she says.

"If you flip through the *PDR* (the *Physicians Desk Reference*, the medication bible that reprints package inserts for nearly all prescription drugs) today, some of our labels are very good, and some are not."

The older the drug, the more likely its package insert is to fall in the latter category, she says; until recent years, comprehensiveness superceded clarity.

Still, "the best available science is often not communicated adequately to practicing doctors to shape their prescribing decisions," says Avorn, who lectures Harvard Medical School students on the subject.

Rezulin, a diabetes drug, looked so dangerous that Avorn and his colleagues advised diabetes doctors at their hospital to stop prescribing it a year before Parke-Davis, at the FDA's urging, pulled it from the market.

"I'm astonished that the additional year of product life even existed," Avorn says.

Why does the FDA approve such medications and allow them to stay on the market? "There are very strong economic and political pressures when a company has spent hundreds of millions of dollars to develop a drug," Avorn says.

Wyeth-Ayerst Laboratories yanked Duract, a painkiller in the same class of drugs as ibuprofen, naproxen and others, from the market in June 1998 after reports of four deaths and eight transplants resulting from severe liver failure. According to the company, all but one of the cases occurred among patients who took the drug for more than 10 days, against the label's advice.

Just two weeks before Duract came off the market, Roche Laboratories pulled Posicor, which is used to treat high blood pressure and chest pain.

Taking Posicor with any of a number of commonly used drugs, including some heart disease treatments, could lead to potentially fatal heartbeat irregularities, the same problem that led to Propulsid's impending withdrawal.

As with Propulsid, changes to Posicor's label were designed to minimize the drug interaction risk.

"In principle, drug interactions can be addressed by appropriate labeling; however, with respect to Posicor, Roche Laboratories believes that the complexity of such prescribing information would make it too difficult to implement," the company wrote in a "Dear Doctor" letter announcing Posicor's withdrawal.

At least one drug, sorivudine for shingles, never made it to the U.S. market because of concerns about the effectiveness of label warnings. The pill was withdrawn in Japan after 15 users died in just its first month on the market. They had developed aplastic anemia, a blood disorder, after taking sorivudine with a common anti-cancer drug.

Three years later, Bristol Myers Squibb representatives argued before an FDA advisory committee that a "black box warning" — like the ones on cigarette packages — would adequately minimize sorivudine's risks.

"No one was convinced that it would work," says Raymond Woosley, chairman of pharmacology at Georgetown University in Washington, D.C., and a member of that committee, which recommended not approving sorivudine.

Because a drug already on the market, acyclovir, provided a similar benefit with far less risk, the agency followed the advisory committee's recommendation, the FDA's Behrman says. "We believed zero deaths was the only acceptable number."

Risk vs. benefits

Rezulin, on the other hand, was the first drug of its class. FDA officials have said the agency sought to remove that drug from the market only after similar, safer medications became available.

"I've heard that line, but I don't buy it," Avorn says. "It's as if we don't have other medications to treat diabetes."

The risk/benefit issue arose at the FDA advisory committee meeting, where panelists recommended approval of Uprima, which would be the second impotence pill on the market.

Pre-market studies showed that the drug can trigger fainting, especially when taken with alcohol, so committee members suggested a black box warning against drinking on Uprima's label.

But panel member Thomas Graboys, who had to leave the meeting early, says he would have voted against Uprima, partly because of concerns about the label's ability to protect patients.

When the condition a drug treats isn't life-threatening, only the lowest level of risk is acceptable, says Graboys, director of the Lown Cardiovascular Center at Brigham and Women's Hospital.

Much inappropriate prescribing could be eliminated if doctors actually read package inserts or looked up the drugs in their *PDRs* before prescribing them, Woosley says.

Instead, they rely on memory, a Herculean task when one considers that one doctor might prescribe scores of drugs. But that's what they're taught to do in medical school, Woosley says. Doctors wrote nearly 3 billion prescriptions last year; the number is expected to reach 4 billion annually by 2004.

"We've got to start by changing the way we teach people," he says. Among his students, "the kid who gets the 'A' is the one who says 'I don't know, but I'll look that up and get back to you.' "

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Drug pricing probed

Inquiry finds overpayments could cost $1 billion a year

By Julie Appleby
USA TODAY

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The Justice Department and state attorneys general are investigating drug industry pricing practices that could cost taxpayers more than $1 billion a year, USA TODAY has learned.

The investigation "has revealed a pattern of misrepresentation by some drug manufacturers" resulting in Medicare and Medicaid "substantially" overpaying for certain drugs, a letter from the New York Attorney General's office says. The letter was sent in February to about 40 state Medicaid pharmacy directors.

▶ Medicare reimburses $47 for a drug that costs a doctor $10

At issue is a practice that allows doctors, clinics and other medical providers to bill federal and state health programs for more than they actually pay for some drugs — and pocket the difference.

Currently, for example, doctors can charge federal Medicare programs $17 for a dose for leucovorin, a cancer treatment that costs them $2.75. Another cancer drug, doxorubicin, costs doctors about $10, but they can charge $47.

Drug companies, investigators allege, set wholesale prices high because they know providers will in fact buy the drugs cheaper but still bill for the higher amount. This attracts providers to their products.

In an effort to alter that practice, the Justice Department is hoping to set up a new pricing system for some drugs. It has asked First Databank of San Bruno, Calif., a private firm that provides drug price information to the states, to change the way it reports prices for about 50 drugs.

Instead of relying upon manufacturers to set the wholesale prices, First Databank will list prices that state Medicaid fraud investigators have determined are closer to what medical providers actually pay. As a result, reimbursements would be more realistic, investigators believe.

First Databank confirmed that it will switch to prices provided by investigators.

The move, one of the first times states have acted in concert on drug costs, is certain to rattle the drug industry and medical providers.

"You will in all likelihood receive initial complaints or objections about lowered Medicaid payments," warns the New York Attorney General's Office letter.

Doctors say the additional reimbursements are needed to offset the miserly payments made by the Medicaid and Medicare programs in other areas.

But proponents say the move could save state Medicaid programs tens of millions of dollars a year. It will not, however, affect Medicare because Medicare does not use First Databank figures.

The drugs in question are not the type patients walk into a pharmacy to get. Instead, they are powerful products generally given by injection or intravenously.

The Department of Health & Human Services' Office of the Inspector General has issued several reports about the "spread" between wholesale prices of some drugs and actual drug charges, saying Medicare and Medicaid are overbilled about $1 billion annually.

In 1997, more than a dozen drug companies were subpoenaed as part of the investigation.

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AIDS Drug Discounts Offered to 3rd World

By David Brown A1
Washington Post Staff Writer

Five pharmaceutical companies have agreed to drastically lower the prices they will charge for AIDS drugs used in developing countries.

Although the agreement announced yesterday by the United Nations AIDS agency (UNAIDS) so far amounts to little more than a statement of principles, the goal appears to be to price AIDS drugs such that manufacturers get little or no profit from their sales in poor countries.

To take advantage of the rock-bottom prices, however, a country's medical system would have to be able to test for the AIDS virus, counsel people found to be carrying it, deliver the drugs in a timely fashion, and monitor the health of patients taking them. In many places, the cost of that medical "infrastructure" may be prohibitive, even if the drugs aren't.

Nevertheless, the announcement may turn out to be an epochal moment in the 20-year-old AIDS pandemic.

"It is a breakthrough in the sense that for the first time, a group of pharmaceutical companies are open to significantly decreasing the price of their products in poor markets," said Peter Piot, the head of UNAIDS, which is sponsored by U.N. agencies, the World Health Organization and the World Bank.

"Industry has taken a very big step in making pricing and profits no longer a major point of contention in the AIDS control discussion," said Nils Daulaire, president of the Global Health Council, a lobbying organization for international public health issues. "Now we can turn to issues of developing care programs, and better prevention programs."

The price of AIDS drugs has been a source of rancor ever since AZT, the first one, was introduced in 1987. With the rise of life-extending, health-restoring "combination therapy" in recent years, the cost of treatment has become a cruel symbol of the epidemic's inequities.

Of the 34 million people around the world infected with human immunodeficiency virus (HIV), 95 percent live in developing nations. Close to 70 percent live in sub-Saharan Africa, where few people are able to afford the $10,000-a-year, three-drug combinations used in the United States and other industrialized nations.

Triple-combination therapy reduced AIDS mortality in the United States 42 percent in 1997, the first full year the drugs were introduced. In some clinics with highly experienced practitioners and patients able and willing to take the pill-heavy combinations, deaths dropped by two-thirds.

The drug companies agreeing in principle to lowering prices are Glaxo Wellcome (headquartered in England), F. Hoffmann-La Roche (Switzerland), Boehringer Ingelheim (Germany), and Bristol-Myers Squibb and Merck (both United States).

Representatives of the last two were present at the United Nations in early December when Secretary General Kofi Annan convened a meeting to establish an "international partnership" to address AIDS in Africa. Subsequently, the other three companies expressed interest in greatly improving access of their products to developing countries. Piot and Daniel Tarantola, the senior policy adviser to Gro-Harlem Brundtland, head of the World Health Organization (WHO), intensively negotiated with the companies over the last three weeks.

Both men warned against any feeling that yesterday's announcement, first reported in the Wall Street Journal, was the beginning of the end of AIDS in Africa.

"This is more than we've had before," Tarantola said. "But we have to be aware that there are risks attached to this opportunity, such as the risk of raising expectations unduly and the risk of draining resources from other high-priority health problems."

Piot said the commitment to very low drug prices "is only one step in a complex process. Frankly, it would be outright irresponsible to dump these drugs where they wouldn't be used properly. It would promote [drug] resistance, and wouldn't help the patients anyway."

One of the few hints at how low the prices might go was offered by Glaxo Wellcome, which said it would sell Combivir, which contains the antiviral drugs AZT and 3TC in one pill, for about $2 a daily dose. The current "average global price" for Combivir is $16.50, said Ben Plumley, who manages the company's drug access programs for developing countries.

He wouldn't reveal how much it costs to manufacture the pills, or how much above cost the $2 price is. However, he said the company's objective in setting that price "is really to try to help make a contribution to this public health crisis, rather than open up new markets."

Piot said no rules on pricing had been set. Setting strict guidelines that all five companies—and possibly more in the future—would follow probably would violate antitrust laws, he added. Nevertheless, the prices are expected to be very low.

"Our position is that the benchmark is manufacturing cost and what it takes to get the drugs there [to developing countries]. The actual negotiations are starting now. My expectation is that it will be really production costs, plus a few pennies for everything that is needed so that they won't lose money on it."

UNAIDS in 1998 began a program testing the feasibility of delivering state-of-the-art AIDS treatment in four developing countries—Uganda, Ivory Coast, Chile and Vietnam. The numbers of people affected, however, are trivial. In Uganda, for example, 800 HIV-positive patients are in the program, out of more than 930,000 people infected. In Ivory Coast, 600 people are in the program.

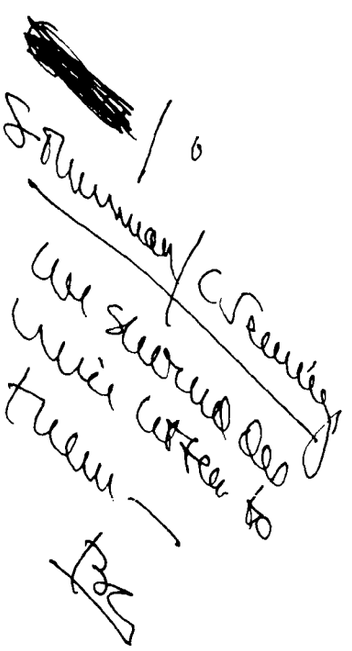
Dismissed by some as ridiculous tokenism, this initiative now will offer crucial lessons in what it takes to deliver triple therapy in resource-poor countries, said its head, Badara Samb.

"We come with the possibility of extending the lessons we have learned," he said.

One of the lessons is that the cost of the professional training, patient testing and equipment has been about $2,500 per patient per year in Uganda and Ivory Coast. (This is about half the cost of the drugs, which with the discounts has been about $5,000 per year for triple therapy.) Especially expensive has been the cost of the "reagents"—chemicals and other items—necessary to run the equipment that measures bloodstream viral load.

Samb said he hopes that with drug companies committed to drastically reducing prices, the firms that sell laboratory stocks will soon follow.

"If we come to a situation where the drugs are much cheaper than the expense of following the patients, then it will be difficult for the companies to maintain those prices," he said.



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Into Africa

Makers of AIDS Drugs Agree to Slash Prices For Developing World

Five Firms' Pact With U.N. Will Still Leave Medicine Unaffordable for Millions

Black Markets and Generics

By MICHAEL WALDHOLZ
Staff Reporter of THE WALL STREET JOURNAL

In a landmark response to the AIDS crisis in Africa, five of the world's largest pharmaceutical companies are offering to slash the prices of HIV drugs for people living in poor nations.

The companies' unprecedented joint agreement, which is expected to be announced by the United Nations today, should make it possible for considerably more people in the devastated continent to gain access to the life-saving but extremely costly drugs that have revolutionized treatment in the U.S. and Europe.

Following delicate discussions with United Nations officials on ways to mount a broad attack on AIDS in developing lands, several companies are pledging to sell their drugs there for as little as pennies above manufacturing costs. Some are considering prices as much as 85% or 90% below the prices Americans pay, or about one-fifth of the already-discounted prices now charged in some African nations.

Assault on Drug Costs
The drug industry faces more political and legal attacks over drug prices and profits. Article on page B1.

"It's the first time the companies are collectively willing to discuss a truly significant decline in prices," says Peter Piot, director of the United Nations AIDS Program, who has been negotiating the agreement since early April. "It is something many of us have long hoped for."

Groundbreaking as the agreement is, it falls far short of a solution to the AIDS catastrophe in Africa, and it contains problems of its own. The pact may make it possible for tens of thousands of Africans, and someday maybe hundreds of thousands, to afford the drugs, yet the continent has an estimated 23 million people infected with HIV, the virus that causes AIDS. For most, even the new prices will remain too high.

Moreover, Africa has nowhere near enough of the trained medical people needed for the complex drug regimen, a failing the agreement says must be remedied. The AIDS therapy is a taxing program that must be followed to the letter; lapses risk not only a worsening of the disease in individual cases, but also the development of AIDS strains resistant to the drugs, with potentially deadly consequences for the whole world.

'Long Overdue'

"The companies' initiative is an excellent idea, long overdue," says Jose Zuniga, executive director of the International Association of Physicians In AIDS Care. But he adds: "If the offer isn't well thought-out and combined with funding to educate people about how to use the drugs or build health services to provide and monitor their use, the drugs' availability in Africa could be disastrous. These are potentially dangerous medicines."

For the companies, the initiative holds big risks. Cutting prices so deeply will expose closely guarded secrets about manufacturing costs and profit margins. This is likely to feed a clamor in the U.S. for curbs on drug prices. At the same time, companies fear that if they don't sharply cut prices for poor nations, those nations will turn en masse to generic AIDS drugs that are being produced in several countries in violation of corporate patents. Finally, the initiative holds the risk of spurring a black market in AIDS drugs.

The participants in the breakthrough drug-cost agreement are Bristol-Myers Squibb Co., Glaxo Wellcome PLC, Merck & Co., Boehringer Ingelheim GmbH and Roche Holding AG. Mindful of antitrust law, they haven't discussed specific prices among themselves but only in individual negotiations with U.N. officials.

Broad Effort Sought

Exact prices aren't likely to be settled upon for several more weeks. But Glaxo, for instance, has made clear it is willing to offer its Combivir for $2 a day. This is a mixture of AZT and 3TC, two drugs that form the backbone of AIDS therapy. Two dollars is about one-third of Combivir's current daily cost in Uganda and one-fifth of its price in the U.S. People close to the negotiators say the company might be willing to go even lower in price. Long-term AIDS therapy often requires the addition of at least one other drug, such as a protease inhibitor, which could drive the price up to between $5 and $7 a day.

A "joint statement of intent" being released by the U.N. today makes clear that pricing is only one piece of the puzzle. It calls as well for new efforts in prevention, health-care infrastructure, international funding and political commitment by afflicted nations. A major obstacle to combating AIDS in sub-Saharan Africa is that many nations have been slow to acknowledge the extent of the epidemic, which has left millions of children orphaned, slashed life expectancies, swamped health-care services and crippled already-enfeebled economies.

As things stand, only the fortunate few in many developing countries have had access to modern AIDS therapy. Richard Constant Okou, 36 years old and infected since 1988, has been able to keep working at a bank in Uganda, and thereby keep paying for his children's education, because he takes daily doses of three anti-HIV medicines. "I can't afford the drugs," he says, noting his monthly salary of about $500.

Mr. Okou, who wears loose-fitting sandals because one of the drugs produces a painful nerve condition in his feet, says he regularly receives a "care package" of the drugs from a doctor in Europe he once met. Several weeks ago, he had just enough drugs on hand to last a few more days. "I just got an e-mail saying a friend will be bringing me more drugs soon," he says. "It's not very reliable."


Richard Constant Okou

Mindful of the tremendous need, the U.N.'s Dr. Piot and others have implored the drug industry for more than three years to cut prices. Responses before today have been spotty and individual. Pfizer Inc. recently agreed to give away Diflucan, its costly drug for AIDS-related fungal infections, in South Africa. Bristol-Myers Squibb last year said it would donate $100 million over five years to bolster health-care services in Africa. Other drug makers have made somewhat similar commitments, but the companies haven't previously worked together on the acute affordability problem.

What sparked today's five-company response was an impassioned plea by U.N. Secretary General Kofi Annan at a special session on AIDS in December. At the meeting, Glaxo Chairman Sir Richard Sykes said his company was committed to a policy of offering "preferential" prices to poorer nations. Afterward, Bristol-Myers Vice Chairman Kenneth Weg suggested that he and Sir Richard encourage a trade group to convene a series of private talks with executives from their companies plus Merck, Roche and Boehringer Ingelheim. Following a meeting in London in early March, the five agreed on a new system of preferential pricing, and on April 3, Mr. Weg presented the idea to Dr. Piot.

Even with the new prices, the combination of three or more drugs needed to quell the virus will cost perhaps $150 or $200 a month. That's far below the $800 or so a month the combo now costs in Africa (or $1,000 a month in the U.S.). But per-capita income in Africa is less than $50 a month, and few African countries or employers pay for any health care. Even much-cheaper drugs for ills such as malaria, tuberculosis and sexually transmitted diseases other than AIDS aren't widely available outside Africa's urban areas.

The Patent Issue

Many in Africa will surely see the drug companies' proposal as laudable but late and insufficient. Skeptics, especially some African governments long antagonistic to multinational corporations, are sure to view it as a cynical public-relations effort to mute the thunder of criticism in the U.S. and in poor nations over high drug prices. The action comes two months before the World AIDS Conference in Durban, South Africa, where activists have been planning noisy demonstrations to demand drug-company concessions.

One of their demands is that companies allow wider use of generic copies of their AIDS drugs. Over the past year, several African governments have threatened to buy these inexpensive generic versions, which are being produced in Brazil, Thailand and India without regard to company patents. In one dramatic example, a day's supply of AZT that sells for $10 in the U.S. is sold by generics makers in Brazil for $1.08.

One indication of the rising generic threat: The Clinton administration yesterday reiterated a trade policy that would allow African nations facing health emergencies to authorize companies to make generic AIDS drugs, regardless of U.S. patents.

Enforcing patents, even in desperately poor nations, is an important component in the five companies' agreement. Several say they agreed to take part only after the director-general of the World Health Organization, Gro Harlem Brundtland, gave a January speech in which she, too, appealed to the drug companies. In an effort to "inspire" an industry response, she says, she pointedly stated that to "stimulate innovation," WHO believes drug makers' "intellectual property rights" should be protected.

"We saw her statement as a call to action," says Per Wold-Olsen, president of Merck's Europe, Middle East and Asia operations. The joint agreement contains the same sort of promise to protect intellectual property. Mr. Wold-Olsen has declined so far to tell the U.N. or WHO exactly how much Merck will cut prices. "We have signaled that we will be flexible," he says. "We will be very flexible."

Profit Margins

The companies are reluctant to say they will price drugs at cost because doing so would reveal a coveted industry secret: that profit for these and other drugs, once research costs have been covered, can equal 90% of the prices charged. The drug makers already fear that pressure for price controls would rise with certain legislative

proposals to have Medicare pay for outpatient prescription drugs. Offering much lower prices in other countries could also increase U.S. price-control pressures, they worry.

Within Africa, deep price cuts could set off a wave of other changes in health care. "With the prices so high, there was little incentive for the governments to build the health infrastructure to provide care," says James Wolfensohn, president of the World Bank, which is part of the new agreement. "The companies' offer may now stimulate that effort and inspire wealthy nations to help fund it." The World Bank has tentatively agreed to provide added grants and loans to help educate health providers and buy the medicines.

Mr. Wolfensohn says one of the biggest obstacles in Africa is that less than 5% of its HIV-infected people know their status. "How can you treat people who aren't aware they are infected?" he says. Lowering prices "is a good step forward, but it doesn't solve the problem, not by any means."

Other concerns about an influx of somewhat-more-affordable AIDS drugs in developing countries are that this could tempt corruption among government employees or produce civil protest among those unable to get the medicines. And if the low-priced drugs fell into the wrong hands, the result could be black-market AIDS medicines showing up in developed nations where prices are much higher.

Pilot Program

The companies' price pledge is likely to startle many Africans battling AIDS. Just two weeks ago, Peter Mugenyi, who runs an AIDS clinic in Kampala, Uganda, went to Geneva to press Dr. Piot to organize an international effort to lower prices and improve services. "Can you even begin to imagine," Dr. Mugenyi says, "how a doctor feels when he knows there is treatment for a merciless disease but no way to get it to your patients simply because of its cost?"

Dr. Mugenyi has been involved in a pilot program set up by UNAIDS—which is linked to both the U.N. and WHO—to promote drug affordability. It is an effort by a small team of UNAIDS staffers who have struggled since 1997 to wrest significant price cuts from drug makers and prove that lower prices could blunt the African AIDS epidemic. Many believe this effort, led by a physician named Joseph Saba, helped lay the groundwork for the price promises now being made.

The idea actually came from a former Glaxo executive, Peter Young, who in 1996 was looking for a way to get Glaxo's AZT and 3TC into developing nations. He approached the U.N. in 1996 with a proposal: If it would make sure the drugs were used properly, Glaxo would offer them at reduced prices. Mr. Young sold the idea to his bosses at Glaxo by arguing that unless it cut prices, Africans would eventually buy large quantities of AIDS drugs from illegal generic producers, and then those patent violators, fattened by profits, might extend their sales to developed nations. That would threaten products generating about $1 billion a year in revenue for Glaxo.

A U.N. group under Dr. Saba created test programs in Uganda and the Ivory Coast. Setting up a nonprofit company and wangling some funding from drug makers, Dr. Saba began bargaining for discounts on HIV drugs in return for making sure they didn't fall into black-market hands. The nonprofit company agreed to sell the drugs only to patients treated by doctors or clinics that could prove they knew how to use them.

Glitches Arise

Right off, the plan ran into problems. Doctors were flooded with requests for the drugs after UNAIDS announced the project at a news conference in Kampala in 1997. Doing so "was a very big mistake," says Dr. Mugenyi. "People came here saying they wanted the new medicines they'd read about in the papers and heard about on the radio. But we didn't have the medicines yet, and of course people didn't even understand how expensive they'd still be or that the drugs were going to have to be taken daily for the rest of their life."

It wasn't until mid-1998 that the nonprofit company got its first shipment of discounted AIDS drugs from Bristol-Myers, Glaxo, Roche and several other companies. And then, the price discounts were wiped out when Uganda devalued its currency by almost half. As a result, a three-drug combination needed to keep AIDS at bay still costs $800 to $1,000 a month in Uganda. In a country where 1.5 million people are infected, fewer than a thousand are buying the drugs from the nonprofit.

However, research by Axios, a Dublin-based drug-marketing consultant that helped Dr. Saba, suggests that thousands more could afford the combination therapy if its price fell to $100 or so a month. It's a critical point, because Dr. Saba's pilot program has come under intense criticism from international public-health providers, who argue that focusing so much effort on the enormously costly medicines is an impractical, wealthy-nation response to a poor-nation problem.

Far more Africans would benefit, this argument goes, if the continent's limited resources were used to buy low-priced drugs for sexually transmitted diseases or malaria, to improve water sanitation and nutrition and to educate people in how to *avoid* HIV infection. This, the critics say, could be accomplished with an influx of money supporting local healers, religious groups or the thousands of grass-roots nongovernment organizations that provide much of the social and health-care service on the continent.

"I understand that argument," says Dr. Saba, a Lebanese-born, French-trained physician who once worked for WHO in Rwanda. "But why should those who could use the drugs suffer because the drugs aren't the solution for most everyone else?"

Subsidies Sought

The companies and the U.N. hope that with drugs' prices brought somewhat closer to affordability, subsidies to help pay for them may be forthcoming from employers, African governments and donor organizations such as the World Bank or U.S. and European governments. The argument that Axios, the marketing consultant, makes to drug companies is that by lowering prices dramatically, they can spur a market for their products where one doesn't now exist.

"We've been advising the drug companies they need to do two things," says the head of Axios, Brian Elliott. "Drop the price and provide some funding to underwrite the cost of expanding health services, such as HIV testing or counseling programs, that will assure the drugs are used correctly."

Before the creation of the UNAIDS program, the few hundred people receiving HIV therapy in Uganda were those well-off enough to buy the drug abroad or people such as Mr. Okou using a wide number of creative techniques. What the UNAIDS program provides, at least in Kampala, is "reliability in access and price," says Sowedi Muyingo, who was hired by UNAIDS to be the general manager of the nonprofit company, Medical Access Ltd. "Even though the prices here are still too high for most people, the doctors who treat HIV patients know when they prescribe the drugs that we have a steady and secure supply at prices they can count on."

Indeed, the U.N. is using the Uganda project as an example of what can be done in Africa when the government, foreign-aid organizations and drug makers cooperate on a grass-roots level. And the drug companies make clear they won't offer the deeply discounted prices without assurances of a secure distribution system. To speed things along, the pharmaceutical coalition has hired McKinsey & Co. to design these types of programs for other African countries.

Skimping on the Drugs

Mr. Muyingo—a 30-year-old with an M.B.A., an entreprenurial instinct and a salesman's cunning—has turned UNAIDS' Uganda nonprofit company into an efficient, two-person operation that negotiates prices with the drug makers, imports the drugs and keeps track of every physician who prescribes and every patient who uses the medicines. He does all this out of a tiny one-room office on the second floor of a medical-supplies warehouse. One floor below, the country's entire cache of AIDS drugs sits in bins in a specially locked floor-to-ceiling steel-caged closet, its contents literally worth their weight in gold at the prices predating the coalition's new offer.

One person who already is benefiting from the UNAIDS drug-access program is a shy 20-year-old called Prudence. She believes she became HIV-positive through rape two years ago by a fellow student, her only sexual encounter. In November, she learned she was infected after she began feeling weak and developed a severe rash. Prudence visited Gideon Rukundo, a 27-year-old physician at the publicly funded Mulago Hospital who only recently learned how to administer HIV drugs.

Dr. Rukundo says he would like to study in the U.S. someday to become better adept at helping his patients. Right now he treats about 21 patients with the drugs, buying directly from Medical Access, but only with cash given to him each month by his patients. Prudence began taking a three-drug combination in December, but her mother, who pays for the therapy out of her salary and savings, has said she is having trouble keeping up the payments.

"I don't want to be a burden to my mother, but I don't want to get sick," Prudence says.

Already, she has cut back to two medicines from three, reducing her mother's monthly bill by half to about $300. To stretch out the drugs, Prudence says she often takes the drugs every other day instead of daily, behavior that concerns Dr. Rukundo because it could cause the virus inside her to mutate into a dangerous, drug-resistant form. "If my patients can afford the three drugs, that's what I give them, but I have to believe two drugs are better than none," he says.

So far, the drugs Prudence takes are keeping her infection in remission, but Dr. Rukundo frets that she can't pay for a $150 test to detect if the virus is re-emerging. "Without the test, it's impossible for me to tell if the drugs are still working," Dr. Rukundo says.

Clinton Tries To Expedite AIDS Drugs Into Africa

By NEIL A. LEWIS

WASHINGTON, May 10 — President Clinton, in the face of strong opposition from the United States pharmaceutical industry, issued an executive order today to make AIDS drugs available far more cheaply throughout sub-Saharan Africa.

The order declares that the United States government will not seek to interfere with countries in that region that may violate American patent law in order to provide AIDS drugs at lower prices. The language of the executive order is nearly identical to an amendment that was deleted at the behest of the drug industry from an African trade bill that Congress is considering this week.

The order issued by President Clinton essentially extended to most of Africa a special arrangement provided last year to South Africa.

"This order is intended to help stop the spread of this devastating disease by making H.I.V./AIDS-related drugs and medical technologies more accessible and affordable in sub-Saharan African countries," Charlene Barshefsky, the United States trade representative, said today. She said she believed it struck a balance between fighting the disease and maintaining the integrity of patents.

In practice, officials said, that means that Washington will not object if African countries move to greatly reduce the price of AIDS drugs, either by licensing local companies to produce generic versions or importing the drugs from third countries where they are available at lower cost.

Both practices may be challenged under United States patent laws. But Senator Dianne Feinstein, the California Democrat who had co-sponsored the amendment that was deleted from the Africa trade bill, said the two practices were "fully consistent with World Trade Organization rules, which allow countries flexibility in addressing public health concerns." Senator Feinstein said that the deletion of the amendment she sponsored with Senator Russell D. Feingold, a Wisconsin Democrat, threatened to impede the fight against AIDS in Africa.

She said that some 34 million people in sub-Saharan Africa have been infected with the disease since its onset and nearly 12 million have died. "The fatalities in sub-Saharan Africa represent 83 percent of the world's total H.I.V./AIDS-related deaths," she said.

Alan F. Holmer, the president of the Pharmaceutical Research and Manufacturers of America, the principal trade group for the drug industry, said the executive order set a troubling precedent.

Mr. Holmer said that he agreed there was a great need to fight the disease vigorously and he welcomed the sections of the executive order that call for increased education and improvement of public health services. "However, the approach taken by the President's executive order sets an undesirable and inappropriate precedent by adopting a discriminatory approach to intellectual property laws and focusing exclusively on pharmaceuticals," he said.

Industry officials said that they believed it was wrong to carve out an exception for one disease and one region. "If Africa today, why not Asia tomorrow or even the United States," said one official.

Jeff Jacobs, the director of government affairs of AIDS Action, a major lobbying group, today praised Mr. Clinton for his executive order. "The best medicines to fight AIDS are outrageously expensive," he said. "Almost nobody in the developing countries can afford these therapies, yet that is where the epidemic is raging. Americans can be proud of their president today."

The compromise version of the trade bill was approved by the House last week and is expected to win final passage in the Senate, possibly Thursday. It gives African and Caribbean countries broad new trading privileges by expanding duty-free access to American markets.

The Senate majority leader, Trent Lott, a Mississippi Republican, suggested to reporters on Tuesday that he disapproved of any plan to substitute the dropped Feinstein-Feingold amendment with an executive order.

"There seems to be a pattern now of him doing executive orders that exceed what he should be doing," Mr. Lott said. "That should be done legislatively. He doesn't make the laws. And so I would hope that he would be careful about doing that."

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