Pain and Plenty
Income polarization and health in the 80's

Special Section: Health in California

INSIDE
Gyn Game:
The full, disturbing history of the contraceptive sponge  P. 13
To the Editor:

I've been a rural GP for five years and out of touch. Do you still exist? Does the Bulletin still exist? Do you need money? Can I subscribe?

Don Kollisch, MD
Monroe, NH

Yes, yes, yes, yes.

Editor

To the Editor:

Your issue on health care in the Reagan era was excellent, but you left out two important areas: the environment and nuclear war. Looking back in 20 or a hundred years, should civilization survive that long, I think it is very likely that the most shocking and devastating policies of the Reagan Administration will appear to be those which allow the continued pollution of our environment and the failure to take strong measures to clean up the mess that has already been made. This is all the more shocking in that, unlike most of the health care cutbacks you describe, this failure threatens all classes of society, and as such is criticized by the overwhelming majority of the population.

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The concerns over the public health consequences of adding low levels of antibiotics to animal feed have resurfaced after several years. Although opponents have waged vigorous past attacks on what Orville Schell has named the “pharmaceutical farm,” they were unable to overcome the arguments of those who raise (and slaughter) animals for profit. The meat and poultry producers argued that banning antibiotics in feed would only make consumers pay more at the market for such products. The pharmaceutical industry has also fought any attempts to limit or ban entirely use of antibiotics in feed. Both groups have claimed that there was little evidence to support the anti-additive position that such practices would lead to the proliferation of antibiotic-resistant infectious diseases in humans. They also showed evidence that antibiotic prophylaxis eliminated epidemics of disease that often raged through herds and flocks and hampered cost-effective productivity.

In 1977 the Food and Drug Administration, under the progressive leadership of Donald Kennedy, proposed banning the use of penicillin and tetracycline in animal feeds. Congress, under pressure from the farm and drug industry lobbies, stalled by asking the National Academy of Sciences (NAS) study the problem. Its 1980 report concluded that the relationship between antibiotic use in animal feed and resistant disease in humans had neither been proved nor disproved. This equivocal study was used by the opponents of a ban to further delay efforts by the FDA to restrict drug use in farm production.

The debate has resurfaced because of some new and important scientific evidence that bolsters the arguments of those supporting a ban. Most important is an epidemiological study focusing on an outbreak of Salmonella poisoning in the Midwest, described in the September 6 New England Journal of Medicine.

A state epidemiologist in Minnesota to whom the outbreak had been reported informed Scott A. Holberg, an epidemiologist with the Center for Disease Control in Atlanta, of some unusual factors. First, the particular strain of Salmonella was one rare to the northern part of the U.S. and second, most of those poisoned had taken antibiotics several days prior to the incident.

Working together, the two scientists attempted to determine if the most obvious possibility—contaminated antibiotics—had been the cause. Their investigation showed that in all likelihood it was not the antibiotics that had been the source of the infection. After a further search, these public health versions of Holmes and Watson found that the probable source of the bacteria was a herd of beef cattle that had been slaughtered in Minnesota and processed in several states, ending up as ground beef in the Minnesota supermarkets where eight out of the 11 victims shopped.

The weight of the evidence accumulated by these industrious epidemiologists offers persuasive evidence that the beef cattle had become “biological factories” of a drug resistant strain of Salmonella because they were fed low doses of antibiotics. Even more frightening, the drug-resistant Salmonella inflicts case fatalities at a rate of 21 times that of the usual Salmonella poison.

The lack of evidence of a causal relationship which the 1980 NAS study decreed appears to be in hand. The FDA is presently considering the Minnesota findings as well as other recent studies in order to determine whether it will recommend a ban. However, any FDA efforts to establish such a restriction will have to overcome the likely opposition of the chair of the House Appropriations Committee, Jamie Whitten (D-MI), a champion of the farm interests. Rep. Whitten also oversees the FDA and Department of Agriculture budgets. His resistance, along with the anti-regulatory stance of the current Administration, may be strong enough to ensure that even with clear scientific evidence of danger, the public health will continue to be placed in jeopardy in favor of profits.

Arthur A. Levin

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It will come as no surprise to our readers that Health/PAC does not believe that the profit motive should be the governing principle in the provision of health care. However I don’t think too many of you are aware of how frighteningly committed to a non-cost-based approach to life our board is.

The story of how this issue came to be 40 pages instead of our usual 32 provides a good example of this attitude. At our board meeting I presented a listing of all the articles we had for this issue and explained that they wouldn’t all fit. We don’t believe in chopping articles to pieces, so the obvious solution was to hold several for the following issue.

“We can’t hold that,” said an advocate of one piece. Someone else spoke up for another, several people for a third, and so on, until it was clear that we would have to go to 40 pages.

Now, readers of the New York Times and other publications may have noticed a remarkable correlation between how much news is fit to print and the amount of advertising bought for that day, but if the Health/PAC Bulletin prints more pages, it just costs us more money. This is not an item we have in large supply.

“Where will we get the money?” I asked at the meeting—rhetorically, since no one at Health/PAC has had a definitive answer to that question for years.

“We’ll get it,” was the obvious, traditional, and forthcoming answer. I hope it’s true. And in this issue we’re offering you a special personal incentive to make it true—a free renewal or gift subscription. This may not seem like a way for us to make money, but it is. See page four and find out why.

Jon Steinberg
Vital Signs

Poor Health

Just in case you had any doubts about the relationship between poverty and illness, a recent (September 22, 1984) study in Lancet should help convince you.

The researchers looked at patterns and frequency of certain illnesses in children in Glasgow, Scotland. Children coming from so-called "deprived districts" were nine times as likely to be admitted to the hospitals as their peers from other districts. The variables of "deprivation" most closely correlated with hospital admissions were household overcrowding and parental unemployment. The correlation with these variables was greater than any with vaccination against certain childhood diseases.

The authors caution that correlation does not mean causation, but conclude that the costs of eliminating such deprivation might be far outweighed by the benefits that would follow.

State of Grace

President Reagan is campaigning for a second term on a pledge to further remove government from the backs of the American people. Not satisfied with his own efforts at regulatory reform, in 1982 he asked chemical magnate Peter Grace and a cadre of business advisors how to make government leaner, if not meaner. One of Grace's best publicized, if not most accurate, findings was that most food stamp recipients are Puerto Rican.

Not deterred by this and other faux pas, Grace and company produced last year the voluminous Report of the President's Private Sector Survey on Cost Control, now available in paperback at your local bookstore.

As the latest battle plan in a long line of "good government" crusades by business, the Commission's report is pretty tepid stuff. Congress' General Accounting Office has already recommended most of the management improvements Grace calls for.

However, 60 percent of the $424 billion in potential savings enumerated by the Commission would require Congress to change policies and programs, according to a report issued jointly by the General Accounting Office and the Congressional Budget Office.

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Health / PAC's Share the Wealth Plan

*Share the Wealth* was Huey Long's slogan, and he was no fool. He was the one who half a century ago said, *If fascism comes to the United States, it will come wrapped in an American flag.*

We think he was on to something, so here's our proposition: If you walk into the institution of your choice and get the librarian to subscribe to the *Health / PAC Bulletin* at the institutional rate of $35, we'll give you a free one year renewal or new subscription as soon as we get the check. Just fill out the form below so we can be sure to credit you for your assistance.

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Pain and Plenty
Income Polarization and Health in the '80s
by Tony Bale

America is becoming a country of greater inequality. Millionaires, venture capitalists, and new enterprises proliferate, while rising hunger and homelessness become symbols of the widening spread of life chances, of a higher level of cruelty inflicted on the growing number at the bottom. These transformations in the American economy and our class structure are affecting the health system more profoundly than any changes in governmental health programs, spawning vast new transformations in the American economy and our class structure.

A new industrial framework is taking shape, bringing with it new patterns of accumulation and distribution of wealth, along with intensified class-based suffering. The shift from industrial to service employment is creating giant industries which replicate the structure of the largest service industry, health care: highly polarized incomes, with a few high earners and a great many employees who take home lower wages than comparable workers in the declining manufacturing industries.

Large scale industrial dislocation and the worst depression since the 1930’s are leaving large segments of the labor force uncertain about finding or keeping an adequately paying job. For members of the working class the lottery is the slim ticket to the fast growing Reagan era millionaire club.

For those with access to capital who want better odds, starting a new business in a field such as health care provides them. Even if the firm goes bankrupt, a venture capitalist might still give the failed entrepreneur money to start again. If our workplaces are more dangerous, if nuclear war seems nearer, if we have to keep our money moving faster just to stay even, if we’re more vulnerable to the financial consequences of a serious illness, it’s all part of the same polarizing process, raising risks for the many and opportunities for the few.

Impoverishment and Inequality
As the share of wealth held by the affluent increases and those at the lower end of the income scale become relatively poorer, middle income groups are experiencing their own polarization: many people in this category are slipping down the economic ladder while a smaller segment is enjoying a sizable upswing; the “middle middle” is shrinking.

Increasingly in the Reagan years, improvements in income have come through access to interest and financial gains. The decline in real wages has gone hand in hand with booming stock and bond markets. In the brief period from 1980 to 1982, the percentage of personal income derived from dividends, interest, and rents jumped from 16.4 percent to 18.7 percent, while the proportion coming from wages was slipping from 62.7 percent to 60.8 percent.

These growing differentials in the early Reagan years, a quite rapid shift for such large population groups, are outlined in the accompanying table—although not completely, since it does not reflect total assets or paper gains in financial markets, and thus tends to underestimate the share held by the wealthy.

Marilyn Moon and Isabel Sawhill of the Urban Institute estimate that between 1980 and 1984 the share of real disposable income of the top one fifth rose 1.9 percent while the share of each of the two lowest income fifths dropped 0.7 percent. Put in money terms, they estimate that between 1980 and 1984, using 1982 dollars, “the average income of the poorest one fifth of all families declined from $6,913 to $6,391, or by nearly eight percent, whereas the average income of the most affluent one fifth increased from $37,618 to $40,888, or by nearly nine percent.”

After a steep fall in the official poverty rate between 1961 and 1978—from 21.9 percent of the population to 11.4 percent—the number began to climb again in 1979, reaching 15 percent in 1982 and 15.2 percent in 1983. And the poor got poorer: the proportion at or below 75 percent of the official poverty line rose from 61 percent in 1978 to 68 percent in 1982. This official poverty line was $9,860 for a family of four in 1982. The same year a Gallup poll found Americans judged that a family of four needed $15,400 just to make ends meet.

Peter Gottschalk of the Institute for Research on Poverty at the University of Wisconsin has shown that most of the rise in poverty between 1979 and 1982 was related to a widening inequality in the distribution of income; most people became a little worse off, but the low income population became substantially poorer. Gottschalk calculates that “If all households had experienced equal decreases in market incomes and equal increases in transfer payments, poverty would have risen only 0.4 points instead of 3.3 points between 1979 and 1982.”

Within the poverty group there has been a dramatic shift in composition. Poverty among the elderly declined from 29.5 percent in 1967 to 14.5 percent in 1982, reflecting positive effects of government transfer programs. The largest increases in poverty from 1979 to 1982 on a proportional basis, have been among persons living in husband-wife families. In 1979, they comprised 34 percent of the poor; three years later they were almost 40 percent. This phenomenon affected minority

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families, and even those headed by white males: their percentage below the poverty line jumped from 5.9 to 8.7 percent.

This growing poverty among husband-wife families reflects worsening opportunities in the labor market, reduced access to government transfer programs, and the burden of taxes on low incomes. In 1982, 22 percent of the labor force experienced some unemployment; its average duration was 15.4 weeks. Even when the unemployment rate fell in 1983, the average duration rose, indicating the growing number of workers jobless for longer periods. Many of these people are now considered to be "no longer looking for work," and have therefore disappeared from the unemployment statistics. If they were included, according to the Joint Economic Committee of Congress, the unemployment rate this July would have been 9.7 percent rather than the official 7.5 percent. Increasingly, people at near-poor and poor income levels are forced into intermittent low-pay and part-time jobs. Sixteen million persons reported that they had been limited involuntarily to part-time work during 1982; this group had a poverty rate of 18 percent.

Reagan tax and budget cuts have accelerated the trend towards greater inequality. The Congressional Budget Office projects that in 1984 they will bring an average net loss of $390 for households with incomes under $10,000; a net gain of $2,900 for households with incomes of $40,000-$80,000; and a net (not the safety kind) gain of $8,270 for households over $80,000. Frank Levy and Richard Michel of the Urban Institute estimate that the average disposable income of the bottom fifth of American families has plunged 9.4 percent in the past five years and that of black women under age 65 ten percent, compared to a drop of one half of one percent for the top fifth.

Low-Income Wage-Earning Women

Moon and Sawhill estimate that a typical non-elderly female-headed family experienced a loss of 4.8 percent in income in the past four years; 90 percent of this slippage was due to Reagan Administration policies. During this period the incomes of non-elderly blacks declined both absolutely and relative to white incomes.

Characteristic of the many Reagan initiatives increasing hardships for low-income wage earners were the changes in Aid to Families with Dependent Children (AFDC) contained in the Omnibus Budget and Reconciliation Act (OBRA) of 1981.

Under the earlier (1969) program, the first $30 of earned income and one third of the remainder of gross income were disregarded in estimating welfare eligibility, thus allowing many mothers to work and stay on the AFDC rolls. OBRA limited this disregard to four months, and restricted eligibility to those earning under 150 percent of a state's need standard. It jettisoned the previous goal of encouraging people on welfare to work in favor of cutting costs and fighting "welfare dependency."

As a result of these changes, wage earners were cut off AFDC at rates varying from 39 to 60 percent, according to a General Accounting Office (GAO) study of five major cities. This loss was compounded by separate cuts in the food stamp program.

The income drop among those pushed off AFDC averaged between $115 and $229 a month, depending upon the city. In Dallas, 51.6 percent of those cut off AFDC had incomes below 75 percent of the poverty line; in Memphis 65 percent.

Once barred from AFDC, these people also lost their automatic Medicaid eligibility. This left 30 percent of them without health coverage in Boston, 60 percent in Dallas and Memphis. Some of the remainder were able to remain on Medicaid by virtue of their low incomes and Medicaid programs for the medically needy.

The GAO study found that between 14 and 24 percent of the
mothers terminated from AFDC reported that they had not sought treatment for themselves or their children for a medical problem they needed help with in the period following termination of AFDC and Medicaid. Eight to thirteen percent reported that they had been refused medical or dental treatment because they could not pay for it or did not have the right insurance.

The Access Crisis

Katherine Swartz of the Urban Institute studied health insurance coverage in Massachusetts for 1981 among the near poor, which she defined as those with incomes from 100 percent to 400 percent of the standard for Medicaid eligibility. (In February 1982 the AFDC Medicaid eligibility level for a two person family in Massachusetts was $3,768 and for a four person family $5,340.) Her study highlights the gaps in health insurance coverage, particularly for the growing numbers in the population she was examining.

Income, Swartz found, was the most important factor affecting coverage. Of those with incomes 100-200 percent of the Medicaid standard, 20.2 percent were uninsured; among those with incomes 200-300 percent of the standard, 11.1 percent were uninsured. Altogether, 13 percent of the near poor had no health insurance. One out of ten of the near poor working full time were uninsured, since low-wage jobs often did not provide coverage or sufficient income to purchase it privately. One out of five of the unemployed were uninsured.

According to Swartz, the 230,200 uninsured near poor in Massachusetts in 1981 came disproportionately from “the bottom one third of the near poor income range, non-whites, males, unemployed, in school, early retirees, craftsmen or service workers, people who had never worked, and people who live alone or with unrelated individuals.”

The National Access Survey by Louis Harris for the Robert Wood Johnson Foundation discovered that in 1982 8.2 percent of adults had no health insurance, including 7.1 percent of those in poverty. Six percent of families reported there had been times in the previous year when someone in the family needed medical care and didn’t obtain it; by 1983 this had jumped to 14 percent. The survey also found that 1.1 percent of the non-poor and 2.8 percent of the poor had been refused medical care for financial reasons. Almost ten percent of the poor and five percent of the non-poor reported that in the year before the survey they had more difficulty obtaining health care than they had experienced previously.

Although Medicaid eligibility was tightened during the Reagan depression, the number of poor people was growing, so the number of recipients remained roughly stable. Still, less than 40 percent of the population below the poverty line is on Medicaid.

Hospitals have responded to the rising low-income population and Medicaid cuts by reducing care for those unable to pay. “Despite an increase in poverty of 134 percent between 1980 and 1982, the real quantity of the nation’s hospital care to the poor increased only 1.5 percent” note Judith Feder and Jack Hadley of the Urban Institute. “In the 100 largest cities, where the population in poverty increased 18.1 percent, the volume of care to the poor was actually lower in 1982 than it was in 1980.” Between 1980 and 1982 the low income population in the cities with the largest increases grew 46.7 percent while expenditures on their hospital care grew only 5.6 percent.

Hospitals took steps to shrink access to their services afforded low income people and reduced the availability of unprofitable ones, such as drug programs and social services heavily utilized by the poor. Public hospitals have increased the share of their care provided free, but as the public sector shrinks fewer people can get these services. The hospital sector as a whole is getting smaller, but services for low-income people are disappearing at a disproportionately rapid rate.

As labor market dislocations force more people into low-wage, part-time, and non-unionized jobs, the number uncovered or with inadequate policies will increase. New corporate wellness programs and restricted health insurance coverage go hand in hand: employees must be prepared to work harder at staying healthy and bear more of the financial burden if they or members of their families do require treatment. Employers are forcing their non-union employees to pay more of their health care expenses out of their own pockets, and cost-sharing demands figure prominently in their negotiating posture with unions.

The health care delivery system is already being restructured towards greater rationing of care, achieved through prolonging pain for large numbers of people under the guise of eliminating unnecessary outlays through heightened cost consciousness. Increasing numbers of Americans are experiencing this pain coupled with anxiety as they are compelled to weigh the economic costs of care paid for out-of-pocket against present suffering and future risks from delays. The uncompensated care problem and closings of community hospitals are

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| Percentage Distribution of Money Income for All Families in Selected Years |
|-----------------------------|------|------|------|------|------|------|------|
| Top 5 Percent              | 15.9 | 15.5 | 15.6 | 15.5 | 15.7 | 15.4 | 16.0 |
| Highest Fifth              | 41.3 | 40.9 | 40.9 | 41.1 | 41.6 | 41.9 | 42.7 |
| Fourth Fifth               | 24.0 | 23.9 | 23.8 | 24.1 | 24.1 | 24.4 | 24.3 |
| Third Fifth                | 17.8 | 17.8 | 17.6 | 17.6 | 17.5 | 17.4 | 17.1 |
| Second Fifth               | 12.2 | 12.2 | 12.2 | 11.8 | 11.6 | 11.3 | 11.2 |
| Lowest Fifth               | 4.8  | 5.2  | 5.4  | 5.4  | 5.3  | 5.0  | 4.7  |

the other side of the declining ability of families to handle medical expenses at a time when labor market forces and public policy are pushing more and more of the poor and near poor into medical indigency.

The Reagan Administration wishes to wipe out at least part of the tax exemption for employee health insurance, which would heavily penalize those who have won good benefit programs, but with those with lower incomes are already paying much of the cost of medical care out-of-pocket. In 1980, multiple person families headed by someone under 65 earning less than $10,000 paid out $450 for medical care on average; a third of them paid all their insurance premiums, averaging $605. Their willingness to do so indicates the importance health services have among low-income people, since this money must come at the expense of food or other necessities. Still higher deductibles and co-payments would simply mean more rationing through endurance of pain.

The access crisis emerges from the conjuncture of several closely interrelated events: large numbers of people suffering reduced income; declining insurance coverage; rising health care costs; hospital and other provider closures in lower income areas; Reagan cuts in insurance and service programs; and the increasingly coldhearted and businesslike posture of the health care system. People in need find that if they lack the money, the right insurance, or the right DRG the health care system they thought existed no longer allows them entry with dignity, if it allows them entry at all. With increasing frequency, families must accept the evaporation of their savings or deep debt or else forgo treatment.

Even without further restrictions, an access crisis is building that may lead to a political demand for new initiatives guaranteeing access and equity in health services.

Health Insurance for the Unemployed

The 1982-83 crisis over health insurance for the unemployed, the most explosive access problem of the Reagan years, was a key test of political strength. In early 1983 Alice Rivlin, Director of the Congressional Budget Office, estimated that of the over 12 million unemployed men and women in December of 1982, 5.3 million had lost their health insurance, along with 5.4 million dependents. She predicted that many more would lose their coverage soon as their extended benefit programs expired.

This dismal picture was contradicted by a 1983 National Center for Health Services Research study, which projected data from a 1977 survey onto the 1982 depression and concluded that only 720,000 workers probably lost health coverage in 1982 and unemployment had little effect on utilization of services. This view in turn has been challenged by Sylvester Berki of the University of Michigan, whose preliminary analysis of his intensive study of unemployed Detroit-area workers showed that over two thirds lacked health insurance. Of these, 83 percent lost it when they lost their jobs, and the other 17 percent had no health insurance to begin with.

In the 1982 Robert Wood Johnson study mentioned previously, 28.6 percent of the unemployed adults surveyed had no health insurance. Among the unemployed, 16.8 percent found it more difficult to obtain health care than in the previous year; this was over three times the percentage for the employed. The unemployed also reported at a rate three times that of those with jobs that a serious illness had caused a major financial problem for their family.

Individual reports from areas of high unemployment spoke louder than statistics. Isaac Emerson, an unemployed truck driver from York, PA, told Congress how he, his wife, and four children live on his unemployment and what she makes as an Avon representative. Unable to afford to continue his health insurance at a premium of $352.35 a month, they constantly have to hold off getting medical attention.

On another occasion our oldest son cut his head and it was bleeding quite badly. But instead of taking him to the doctor, we had to take care of it ourselves, because we couldn't afford the doctor's bill. And just recently the schools told us that a son and daughter of ours had heart murmurs, and recommended that we take them to see a doctor. But we've had to hold off on that too, because we are afraid of what the doctor will find, and we can't afford to pay any extra bills right now.

Judy Duperry, a mother of two boys living in Bristol, CT, was laid off from her assembly job at General Motors in 1982. She was able to find only part time work in 1982, and her health insurance coverage ran out after a year of unemployment. Her six year old son has borderline leukemia, she told a Congressional committee in 1983, but on her tight budget she had been unable to keep up on the treatments: “I can't afford to pay the doctor visits and medication now that I don't have any health insurance. I just try to push the whole thing out of my mind and hope my son stays well.” When this son ran a high fever she "took him to the emergency room at Bristol Hospital, but they turned us away because I didn't have any insurance coverage and told me to go see my regular doctor." Duperry expressed the sentiments of many unemployed parents: “It doesn't seem fair to me that my children should have to go without care because there are no jobs available for me now.”

A bill to provide $4 billion to states for a program of health insurance for the unemployed passed the House in August 1983 but languished in the Senate due to strong Reagan Administration opposition. The main argument of Administration spokesperson David Stockman was the fiscal danger of adding a new, large entitlement program at a time of large budget deficits. Most ominously, in Stockman’s view, creation of an entitlement for those losing employer-financed health insurance through involuntary unemployment would create equity problems that might lead to pressure for entitlements from other groups: “Unemployed families without prior coverage; low income families with no recent work history who are ineligible for Medicaid; and self-employed workers who receive no special tax breaks for insurance.” (Emphasis in original.)

At the height of the 1982 depression, voluntary efforts among physicians, often working with organizations of the unemployed, were beginning to provide help in finding services and some free care. The American Medical Association supported a modest legislative initiative to pay some medical bills. The American Society of Internal Medicine urged its members to inform their unemployed patients that they could seek treatment for a reduced fee or free of charge. At a time when voluntary hospitals were printing maps showing unemployed workers how to get to the local public hospital, it is no wonder that the National Association of Public Hospitals strongly supported the labor-led drive for coverage for the unemployed.

Despite the broad base of support for aid, Congress failed to produce a new program. In the end, it gave Reagan his ver-
sion of a perfect health record: no new entitlements. The pro-
process of labor force dislocation, impoverishment, and
re-employment in lower paying jobs with less adequate health
coverage was allowed to take its course. With the recovery,
Congressional interest has waned for the moment, possibly to
be rekindled in the next recession.

Middle-Income Health Budgets
For the middle-income group, health care expenditures are
still largely manageable, although substantial. In both 1981 and
1982 the share of disposable personal income spent on medical
care rose 0.5 percent, bringing the total up to ten percent.
These were the largest yearly increases up to that time.
An ominous trend for family budgets is the rising out-of-
pocket cost of hospital care. In 1975 insurance paid 81.3 per-
cent of private consumer expenditures for hospital care; by
1980 the proportion had dropped to 75.5 percent, and by 1982
to 73.3 percent. This occurred while hospital room charges
were surging an average of 12.6 percent a year; they jumped
15.7 percent in 1982-82. These figures mean that hospital care
is taking a larger bite in insurance and out-of-pocket expenses
from many low- and middle-income family budgets.
As income rises, somewhat more is spent on medical care,
but the proportion of income spent declines sharply. In 1980,
average out-of-pocket medical expenses for multiple-person
families with an income under $10,000 were $432; for families
earning $20,000-$34,999 the average was $471, not much dif-
ferent in absolute terms, but significantly lower as a propor-
tion of income. Similarly, Gail Wilensky and her colleagues
at the National Center for Health Services Research have
calculated that family outlays for medical care and health in-
surance provided by employers left those with incomes under
$10,000 with an average of $998 in net expenses, while families
with $20,000-$30,000 incomes averaged $1,361 and families
with incomes of $50,000 and over averaged $1,452.

The Affluent
For many of the affluent in the Reagan Era, the health fac-
tor has swelled in importance for lifestyle and consumption
decisions. Diet, the presentation of the body, preference in
romantic partners, and outlook on life have all become
permeated with a stronger health component. This has
spawned new industries such as Nautilus gyms and dramati-
cally altered older ones such as health foods. The rapid growth
of the health service industry has been accompanied by
perhaps an even greater growth in the importance of the search
for health, the search for the external appearances of health,
and the insertion of all this searching into consumption pat-
terns outside the traditional health sphere.
The searchers see themselves as a battleground between the
forces of stress and impurity and those of healthful activity
and purity. For the affluent, the concern becomes less how to ob-
tain and pay for needed services than how to purchase and will
health. Many strive not just to be healthy, but to positively ex-
ude health to those around them.
Flush with funds newly liberated by the Reagan tax cuts, the
affluent have also seized upon the health care industry as a
source of lucrative investment opportunities. Between 1977 and
1981 shareholder equity in the four major hospital management companies shot up at a compounded annual rate of 41.2 percent. These and many other (non-public) hospitals have been improving their financial situation and their attractiveness to investors. In 1975, net revenues of community hospitals were a thin 0.7 percent greater than expenses; by 1981 this margin had expanded to 3.6 percent; in 1982 it rose to 4.2 percent.

In 1980 $3.56 billion in tax-exempt hospital bonds were issued, comprising 7.6 percent of the tax-exempt market. In 1983 the $9.55 billion issued made up 11.7 percent of all tax-exempts, and an estimated five to eight percent of the total bond market. Some hospitals now have as much as $100 in debt service figured into their cost per patient day.

For entrepreneurs, the health care industry presents vast opportunities for small companies marketing new technologies and services, such as auditing hospital bills.

"We're the result of increased emphasis on cost containment in private industry, which is beginning to do what anyone does when paying for a service—checking the bill before writing the check," June Novak, national director of American Claims Evaluation, Inc., told Hospitals magazine. In the past few years dozens of such firms have sprung up.

The proliferation of DRG’s, bill auditors, and other cost-control mechanisms has given impetus to another industry: hospital information systems. Currently they average about 1.8 percent of a hospital’s budget, but financial analysts predict this will rise to 2.5 percent by the end of the 1980’s. Financial, patient care, and departmental information systems each have their own markets, currently fought over by more than 140 companies ranging from old giants like IBM and Burroughs to a multitude of small new firms.

As new markets proliferate in an increasingly profit-oriented health system, small, fast-growing companies are picking off discrete chunks of the mammoth industry. The May 1984 issue of Inc., an entrepreneurial magazine, presents its annual list of the 100 publicly held companies that were small five years ago and have experienced the fastest growth in sales since. This golden list, which had a mean compounded average growth rate of 115 percent a year, included 26 companies in the health field, more than the number specializing in computers and related products. Among them were high tech firms specializing in recombinant DNA and computer-assisted medical diagnostics; deliverers of services such as home health care and HMO’s; and companies with more mundane income producers such as information processing for hospitals, weight loss centers, and marketing health care products.

Many new hot companies, such as for-profit HMO’s, appeal to investors guessing they will thrive in a more competitive, cost-cutting health system geared to leaner reimbursements and shifts away from hospital-based care. Along with the familiar large profits made from capturing a piece of the once seemingly limitless flow of public and private health dollars are new ones found in successful efforts to be in the right place as the flow begins to subside and shift directions.

Venture capitalists have been quick to participate in this boom. They buy substantial pieces of new or small companies, betting on both the growth of a product or service and the management’s ability to cash in on it. In 1982 the health care
industry and related fields drew in 3½ times as much venture capital as they had just four years earlier, $114 million going to 87 companies; by 1983 the investment was up to $150 million.

Investor enthusiasm for medical technology has now spread to health service delivery companies. One example among many is Urgent Care Centers of America, a California firm specializing in free-standing emergency centers. In its first year, ending August 31, 1983, Urgent Care lost $1.3 million. Nevertheless, by then the company had attracted venture capital and issued stock valued at $7.3 million when it came on the market in February—six months later it was worth twice that.

This is a common pattern in the current era of explosive growth. Dozens of health care companies have gone public to attract capital for expansion, and often these stock issues make huge paper profits for the chief stockholders. In 1982 32 medical product and service companies made initial stock offerings. In 1983 some 150 did, 17.5 percent of all companies going on the market for the first time.

Among the instant multi-millionaires that year was William Pierpoint, whose holdings in his Summit Health Ltd., a California hospital and nursing home company, were valued at $31.5 million when the stock went on the market. He and other new entrepreneurs, their companies, and their financial sponsors are becoming a major force in the health care system.

Physicians have also prospered recently. According to Medical Economics, 1982 was the first year in six that their median net income from private practice rose faster than inflation; its rise of 4.3 percent over the increase in the cost of living (to $93,270) was the sharpest in 15 years. In the same year the median income of all families fell by 1.4 percent.

The New Polarization

The health care system has become less a benevolent institution and more a dispenser and re-enforcer of socially created misfortune. Regulation of access through the implementation of pain has gone hand in hand with investments funnelled into growth markets rather than toward the most urgent needs.

Health care services did, for a time, become more accessible to low-income groups. To a degree, these services moderated the impact of the widespread threats to health experienced by many people at the lower end of the class structure. Reduced access to the health care system for the growing low-income population means a reduction in their standard of living—a time when their health care needs have been intensified by the reduction in preventive programs, their often highly toxic environment, and the high levels of illness associated with unemployment.

This reduction of access and the quality of life for low-income people is a product of the same competitive, cost-controlling entrepreneurial health care system providing the affluent with new means of capturing income to live their version of the good and healthy life. The pain is not the result of a correctable oversight; the way in which money flowing through the health care system is generated and transformed into commodities, services, and financial surpluses widens the gap in our polarizing class structure.

For the 44 percent of blacks, 33.2 percent of the poor, 44.2 percent of people with less than a high school education, and 29.9 percent of all adults who told the Robert Wood Johnson survey that they thought the health care system needs to be rebuilt, one answer is a new kind of health care system.

Resources

Mike Davis's "The Political Economy of Late-Imperial America," New Left Review (January-February, 1984) synthesizes and interprets much of the best recent information on changes in the American economy, class structure, and policy.

A good source on changes in industrial structure is the 1984 report Storm Clouds Over the Horizon: Labor Market Crisis and Industrial Policy by Barry Bluestone et. al., available from The Economic Education Project, 153 Aspinwall Avenue, Suite 2, Brookline, Mass. 02146.

Peter Gottschalk's work appears in an Institute for Research on Poverty Discussion Paper "Recent Increases in Poverty: Testimony Before the House Ways and Means Committee," one of hundreds of publications from this valuable source on poverty, social policy, and the American class structure. Send for their publications list at Social Science Building, 1180 Observatory Drive, Madison, Wisconsin 53706.


The Urban Institute has published numerous reports on health and social policies. Their list is available at 2000 M Street, N.W., Washington, C.D. 20037.


An Evaluation of the 1981 AFDC Changes: Initial Analyses along with numerous other reports on Federal health and social welfare programs can be obtained from the U.S. General Accounting Office's Document Handling and Information Services Facility, P.O. Box 6015, Gaithersburg, Md. 20760.

The "Special Report" Updated Report on Access to Health Care for the American People comes in the slick format with attractive graphics you'd expect from the Robert Wood Johnson Communications Office, P.O. Box 2316, Princeton, N.J. 08540.

Alice Rivlin's estimate, the Emerson and Duperry statements, and much else can be found in 1983 hearings before the Subcommittee on Health and the Environment of the House Committee on Education and Commerce, Health Benefits: Loss Due to Unemployment. David Stockman's testimony appears in 1983 hearings before the Subcommittee on Health of the Senate Committee on Finance, Health Insurance for the Unemployed. Both hearings are published by the Government Printing Office, Washington, D.C. 20402.

The NHGIS Annotated Bibliography gives references, summaries, and where to write for the numerous studies generated from the 1977 National Health Care Expenditures Study, including the Winter, 1984 article by Wintersky (Milbank Memorial Fund Quarterly) referred to in the text. Write to the National Center for Health Services Research, Publications and Information Branch, Room 7-44, 3700 East-West Highway, Hyattsville, MD 20782. More up to date calculations of out-of-pocket expenses and insurance coverage can be found in "Health Care Coverage and Insurance Premiums of Families: United States, 1983," one of the many publications of the National Center for Health Statistics, 3700 East-West Highway, Hyattsville, MD 20782.

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Gyn Game
The FDA and The Contraceptive Sponge
by Diane St. Clair

Some things you know you can sell. One is a sure cure for cancer. Another is a contraceptive that isn’t a drag, a mess, or dangerous... There’s a new product that claims to meet all three criteria—The Today contraceptive sponge.1

Today went on the market in 11 Western states heralded by a huge advertising campaign. Reports from California indicate that drug stores are selling out as soon as shipments are received.2

A new over the counter contraceptive that looks like a donut and is selling like hotcakes may soon become the favored form of vaginal birth control for millions of women.3

The U.S. Food and Drug Administration’s approval of the Today sponge in April 1983 brought the new contraceptive widespread media acclaim and a ready market of female consumers eager to find, at last, a condom for women. However only three months later the fanfare abruptly died down; the House Subcommittee on Intergovernmental relations and human resources held hearings to discuss possible shortcomings in the sponge manufacturer’s research and in FDA review procedures. Yet another birth control controversy had been ignited.

Contraceptive Technology
Before examining the controversy surrounding sponge safety and FDA review procedures, it is important to examine why the contraceptive sponge presented such an attractive option to women and to those who market contraception. Although women have been using vaginal methods of contraception for centuries, from homemade pastes and pieces of...
sea sponge to medically fitted diaphragms, use of barrier methods of contraception rapidly decreased in the 1960's. This decline coincided with the introduction of oral contraceptives (the pill) and intrauterine devices (IUD's). Compared to these methods, barrier devices were perceived to be obtrusive and unreliable. By 1965 the proportion of white married couples relying on the diaphragm for contraception had dropped to ten percent, and by 1976 to three percent.

The tide turned during the late 1970's, when reports on the potential adverse effects of the pill and the IUD caused many women to switch to barrier methods. Their concerns were placed into a broader socio-political context by a well informed and active women's health movement. Its adherents advocated a less interventionist approach to women's health care, focusing on issues such as safer methods of birth control, less intervention in pregnancy and childbirth, de-mystification of medicine and technology, and encouraging self-help and education to challenge the control of health by the medical profession. When combined with the negative publicity given the pill and the IUD, the impact of this new movement was dramatic. Among the more than one million women receiving first time contraception services each year at clinics of the Planned Parenthood Federation of America in 1980, 12.9 percent chose the diaphragm, up from 5.7 percent in 1975. Most of these users were women aged 25 to 29.

Despite their concerns about IUD's and oral contraceptives, many women continue to use them because they find that the diaphragm disrupts spontaneity and is aesthetically displeasing: spermicide must be applied at every coitus. Many women's clinics and a few physicians have been importing another barrier device from its British manufacturer to offer women an alternative. This device, the cervical cap, is made of a rubber similar to that used in the diaphragm and covers the cervix through suction; it can stay in place up to three days and does not require repeated applications or spermicide.

Although the cap has been used safely and effectively in Europe for over 150 years, in 1979 the FDA classified it as a Class III ("significant risk") medical device, thereby placing it in the same category as IUD's and heart pacemakers. (Diaphragms and condoms are considered Class II devices.) Unlike many products, the cap does not have powerful allies to advocate its case before the FDA. The large pharmaceutical houses which market contraceptives have expressed no interest in U.S. production—perhaps because the cap requires little spermicide, the major source of profit in diaphragm use.

This lack of interest and the FDA classification have left the field open for another barrier device which is safe, effective, and easy to use. The VLI Corporation, manufacture of the sponge, claimed its product was all of these, and more—since "one size fits all" it did not require a visit to the doctor. This attribute is no doubt attractive to women who may not have the money to see a physician or who may be reluctant to undergo a gynecological examination. As we shall see, all of these claimed virtues are open to question.

Is It Safe and Effective?

The Today sponge is a two-inch, round, white polyurethane cushion impregnated with one gram of the spermicide nonoxynol-9 (N-9). The manufacturer claims that it works by blocking the cervix, absorbing semen, and killing sperm. The primary concern about sponge safety centers on the presence of two known carcinogens—dioxane (not to be confused with dioxin) found in N-9, and 2,4-Toluene diamine (2,4-TDA) found in polyurethane.

Nonoxynol-9. According to the Associated Pharmacologists and Toxicologists, a Washington, DC based group which has called for the withdrawal of the sponge pending a review, dioxane is a contaminant of N-9 which forms during the synthesis of the spermicide.

FDA chemists first noted dioxane's carcinogenicity when it was administered orally to animals in 1979. Many studies have recently sparked a debate on its potential carcinogenicity and teratogenicity. A 1981 paper by Hershel Jick, et al., expressed concern that the use of spermicides in humans around the time of conception may be associated with congenital disorders. However an FDA Advisory Committee recently decided against placing a label on the spermicides which would warn pregnant women not to use them, declaring that the Jick study was faulty and only over the counter drugs intended for systemic absorption require such a label.

Despite this decision, Dr. Solomon Sobel, Director of the FDA's Metabolic and Endocrine Drug Products Division, hinted that the question of absorption of N-9 was not closed. In June 1983 Dr. Sobel signed off on an internal FDA memo which warned that N-9 may well be associated with increased fetal malformations and recommended a special warning for pregnant women on OTC vaginal products using spermicides.

In addition, an 1982 study done at the Harvard School of Public Health found that in vitro tests of N-9 induced dose-dependent malignant transformations in two mouse cell systems. The report concludes by saying,
studies of this nature have been published. The Jick study... in conjunction with our data, as well as the frequency with which these products are used, justify further investigation of the mutagenicity and teratogenicity of N-9.\textsuperscript{14}

Under Congressional questioning in July 1983, FDA scientists who approved the sponge testified that they were not aware of this study, which had been published a year earlier in Carcinogenesis, but expressed concern about it. FDA officials explained that specific reviews were not directed towards N-9 during sponge approval because it was considered safe, based on its 20 year use as an OTC contraceptive. They claimed that they were not even aware that dioxane was in N-9 until June 1983, when an outside group petitioned the FDA on sponge safety.\textsuperscript{15}

Congressman Ted Weiss (D-NY) noted that the FDA Advisory Panel on OTC Contraceptives and Other Drug Products relied on animal studies published in a 1969 article by Smyth and Calandra to establish the non-carcinogenicity of N-9 (VLI also relies on this study)\textsuperscript{16} and then pointed out that one of the co-authors, Joseph Calandra, was on trial in 1983 on charges of submitting fraudulent animal toxicology data to the FDA. When asked if they had requested independent validation of studies on N-9 performed by him, FDA officials admitted they had not.\textsuperscript{17}

Critics point out that the absorption and accumulation of N-9 in the body have been demonstrated in experiments using radioactive tracers.\textsuperscript{18} These studies show that N-9 is readily absorbed from the vagina into the bloodstream. Six days after a single intravaginal dose, the radioactive tracer was found in the urine and milk of lactating test animals. Other animal experiments have found that inflammation in the vaginal tissues is proportional to the dose of N-9 applied to the vagina.\textsuperscript{19}

Despite these studies and the sponge's large dose of N-9—one gram is more than is used in any other barrier contraceptive and was associated with hepatic neoplasias and mammary tumors in rats,\textsuperscript{26} they fixed safe dose levels for intravaginal use of 2,4-TDA solely on the basis of dietary considerations, not asking the VLI Corporation for any intravaginal testing. As Dr. Nathan Mantel, a mathematical statistician for 27 years at the National Cancer Institute, told the Weiss Committee, these are potent cancer-causing agents and it would be foolhardy to let those agents come into direct contact with sensitive tissues like those of the uterus or vagina, which are among the most important sites of cancer in women—a dose level which could safely be added to the diet might be far too high to bring directly to bear on these tissues.\textsuperscript{28}

Finally, as with N-9 the FDA has no data for 2,4-TDA on the amount which escapes from the sponge during use. Without this data, it is difficult to assess the carcinogenic risk to surrounding vaginal tissues.\textsuperscript{29}

**Toxic Shock Syndrome.** As of February 1980, the Centers for Disease Control had confirmed four cases of toxic shock syndrome (TSS) from sponge use,\textsuperscript{30} as of June the number was reported to be ten.\textsuperscript{31} Accurate and current totals are difficult to obtain because physicians are not required to report TSS.

The sponge manufacturer did not test for TSS in its clinical trials and, indeed, the FDA claims that this would have been impossible, since a proper study would require some 168,000 women. Most researchers share the CDC view that all that can be done is wait and see if sponge users get toxic shock, a potentially fatal disease.

Two microbiologists at New York University Medical Center disagree. Philip Tierno and Bruce Hanna have been studying TSS for four years; their conclusions have been published in journals such as Lancet and the American Journal of Obstetrics and Gynecology. A year ago they wrote the FDA to urge it to withdraw approval of the sponge on the grounds that it carries a high risk of TSS. They maintain that it is possible to determine whether there is an unnecessary risk by exposing sponges injected with staph aureus to the two nutrients most likely to be present in the sponge user's vagina—semen and menstrual blood.\textsuperscript{32} (Although package inserts warn against using the sponge during menstruation, Tierno points out that a woman may be wearing one when her menstrual cycle beings.)

**Effectiveness.** Although the VLI Corporation claims the sponge is as effective as a diaphragm, results of clinical trials do not confirm this. When women were randomly assigned either the sponge or a diaphragm in British and Canadian studies, one year pregnancy rates were significantly higher for sponge users: 27.3 per 100 women versus 10.2.\textsuperscript{33} In a similar recently completed U.S trial, the rate was 16.8 per 100 with the sponge and 12.5 for diaphragm users.\textsuperscript{34}
A Nurse Practitioner’s Experience

Is the sponge the contraceptive panacea women have been waiting for? On the surface it offers perfection in terms of availability, spontaneity, and expense. Yet, as a nurse practitioner, I admit to initial skepticism about the sponge’s simplicity. This arose from a variety of factors, among them the almost mysterious rapidity and inexactness of the FDA approval process; the debates over the potential carcinogenicity of Nonoxynol-9 and 2,4-TDA; and the puzzling assumption that one size sponge is appropriate for all women.

After a few months of working with women on family planning I have developed some additional concerns, although because this time has been brief, and the incidence of sponge use low in my practice, I can only offer anecdotal accounts.

I have seen several cases of severe vaginal irritation and/or infection immediately following sponge use. These cases have been difficult to treat, and have caused women much discomfort. On two occasions I have had to remove fragments from the cervix of women who thought that they had adequately removed the sponge. This could well increase the risk of irritation and/or infection, or even toxic shock syndrome—the manufacturer itself advises against the use of the sponge while menstruating, and my experience shows that women could begin menstruating with fragments of sponge remaining inside them.

Furthermore, although the manufacturer claims that no professional consultation is needed for use, I have found that teaching proper technique and practice for the sponge is no less important than it is for the vaginal diaphragm. A woman using a diaphragm goes through an extensive teaching/learning process with emphasis on learning pelvic anatomy and landmarks. She is then asked to demonstrate insertion and removal of the diaphragm, and a follow-up visit is arranged for a week later to ensure that she is using it correctly.

Although the sponge is sold over the counter on the presumption that all women feel comfortable with their understanding of their pelvic anatomy, and that all women are the same size, this is not true in my experience. I have had a patient who simply could not use the sponge because it would not cover her cervix.

A nurse practitioner

These trials also found that accidental pregnancy rates tended to be higher in sponge users who were parous, married, or 25 years of age or older. This may indicate that one size sponge does not fit all; parous women may need a larger diameter to assure a snug fit in the upper vagina.

When evaluating the sponge’s effectiveness, it is important to note that in clinical trials women have been given instruction in how to wear it and seen in follow-up visits to ensure that they were using it properly. In ordinary usage, women buy it over the counter and rely on the package insert. One may imagine that their pregnancy rates will be quite a bit higher than what was found in the trials.

Dr. Gerald Zatuchni, professor of obstetrics and gynecology at Northwestern University and director of the Program of Applied Research on Fertility Regulation, agrees with this prediction. After two years developing a contraceptive sponge, he abandoned the effort because the ten percent failure rate was considered too high.3 He believes the failure rates will be higher among women who have no individual instruction in how to use the sponge, and quips that if he doesn’t suggest its use “unless someone wants to get pregnant.” He has also commented that the idea that the same size sponge will fit every woman’s vagina “makes about as much sense as the idea that every woman could wear a size six shoe.”

Where the FDA Went Wrong

Questions about the sponge’s safety and efficacy inevitably raise questions about the FDA review and evaluation process. Although most consumers would consider the sponge a device, it is in fact classified as a drug; in the words of the FDA, it is “simply a delivery system for N-9.”5 It was considered a device when review began in 1977. At that point the sponge was made of a collatex material. In testimony before Congress, VLI president Bruce Vorhauer said that at the time his company had been working with Searle Pharmaceutical Company to develop the sponge, and when “I told them (Searle) that we were classified as a medical device...Searle couldn’t believe it. They had to write a letter to FDA and ask why...The FDA spent about six months evaluating that and they decided that really it wasn’t a device. It was a drug because we were using N-9.”58

Searle clearly believed it was easier to be an already existing drug than a new device. This proved to be correct: N-9 was accepted as “a time honored” spermicidal agent, requiring no scrutiny of the polyurethane material. It would have been more judicious to classify the sponge as both a drug and a device, and review it accordingly.

Dr. Mantel, the National Cancer Institute statistician mentioned earlier, charged in his congressional testimony that the FDA’s assessment of safe dose levels for 2,4-TDA was substantially overstated.39 He was not challenging the safety of the sponge, only taking issue with the way in which the FDA assessed safe dose levels and calculated its quantitative risk assessment.

Former FDA Commissioner Arthur Hull Hayes defended the FDA’s risk assessment process, but immediately afterward it emerged in the hearing that, in fact, no quantitative risk assessment of 2,4-TDA had been done by the FDA prior to its approval of the sponge; the assessment presented in the hearing was done only when the congressional committee requested one three months later—and even then it was based
on safe doses of the material as ingested rather than used vaginally.  

In his reply to FDA testimony, Dr. Mantel aptly wrote the committee, 

My own private opinion is that the FDA had, or thought they had, good reasons for approving the Today contraceptive sponge. The risk assessment had nothing to do with that decision. But, after the fact, when challenged, the FDA fabricated a risk assessment justification and it turned out to be faulty. The FDA should have replied to the challenge by giving their true reasons for approving the Today contraceptive sponge.  

There was dissent within the FDA as well. One chemist on the review committee failed to “sign off on the VLI sponge because he believed the manufacturer had not resolved inconsistencies in its reports. It was he who brought the presence of 2,4-TDA to the attention of FDA officials, and his greatest concern was the manufacturer’s varying figures of how much of it the sponge contained. 

This problem had a history. In mid-1980, when Schering-Plough was considering acquisition of VLI and the marketing rights to the sponge, its researchers detected the 2,4-TDA. In an internal memorandum, a Schering scientist warned, 

The presence of TDA in the finished sponge represents a medical and product liability hazard. The art teaches us that TDA was banned from hair dye . . . because it is mutagenic, teratogenic, and carcinogenic.  

Although the product was subsequently changed, the FDA chemist was concerned that 1) VLI had not developed a sensitive enough test to detect levels of 2,4-TDA, and 2) that 2,4-TDA might form over time as the sponge’s polyurethane degraded. He wanted to see stability test results for various lots of the sponge over time so that an expiration date could be affixed to the packaging. Such tests had not been done when the sponge was approved. 

The Clinical Trials 

The FDA required that 200 women be tested with the market version of the sponge for one year to assess its safety. VLI frequently says that more than 2,000 women were tested with the sponge for over six years. Actually, the current version was tested with 1,596 women; only 644 of them completed a full year’s study, and just 15 participated in VLI’s one extended wear test—using a sponge continuously for seven days. 

Only 267 of the women tested were from the U.S. Most of the rest were from developing nations—Guatemala, Bangladesh, Egypt, etc. These women are demographically dissimilar to women in the U.S. For example, 75 percent of them were married; in the U.S. trials only 25 percent were.  

Given the potential impact of sexual customs as well as economic and marital status on the safety and efficacy of contraceptive products, these overseas tests seem problematic, and a statistician from the FDA itself, Hoy M. Leung, has characterized such pooling of data from different countries as “not applicable to the U.S. population.”  

Post-Market Surveillance 

As is the case with most drugs and technologies, there is no post-marketing surveillance system in place to evaluate the sponge’s impact when thousands of women are purchasing it on the open market. Such surveillance should have been considered critical in the case of the sponge. It is an OTC drug and can be used without a physician consultation; several dangers have been suggested, including TSS; the controversy over whether or not N-9 causes birth defects continues. 

Suggestions for post-marketing surveillance systems which have been offered for contraceptive products in the past could be instituted to monitor the sponge. One method, pioneered by the Boston Drug Epidemiology Unit of Boston Medical Center, includes interviews using detailed standardized questionnaires with people who enter hospitals in various parts of the U.S. Associations between drugs and disease could emerge as data are collected. It is extremely likely that many women using the sponge would come to emergency rooms with sponge-related complications since a large percentage of these women probably would not have physicians. 

Surveillance systems are also theoretically possible in outpatient settings such as large group practices, where physicians could link diagnosis to drug exposure. This has not been successful here in the past, although such formal systems have worked well in the United Kingdom and Sweden. The FDA could certainly urge physicians to report TSS, extreme vaginal irritation, and/or cervical changes believed to be associated with the sponge to either the FDA itself or the CDC. 

If vaginal contraception leads to an abnormally high incidence of congenital malformations in women who become pregnant while using them, registers which collect information on malformation and tumors can be consulted, and the women could be interviewed about drug use. At present, the only post-surveillance system for the sponge is run by the VLI Corporation, whose toll free number operates only during business hours.
Conclusions

Should the sponge have been approved by the FDA? Given the evidence, it appears that its risks outweigh its benefits. At a dollar apiece, the sponge appeared to be a fairly inexpensive, simple, and safe answer to women's contraceptive needs. Now we have more questions than answers.

We may also hypothesize about subtle and/or indirect pressures on the FDA which helped win the sponge approval. Bruce Vorhauer, president of VLI, has admitted that if the U.S. Government's Agency for International Development had not picked up the $2 million tab for clinical testing, the sponge never would have made it to the market. The Los Angeles Times has reported that AID decided to finance the trials after VLI agreed to sell it the sponge at cost, presumably for use in the developing world, once it became a commercial success in the U.S. At the same time, as noted above, safe alternatives with no powerful backers such as the cervical cap are still awaiting FDA approval.

The debate over the safety and efficacy of the sponge will no doubt continue, with VLI insisting that it has done all the necessary tests and critics demanding more conclusive answers. "Women who are good feminists understandably have a mistrust of industry and the FDA," says VLI researcher Barbara North, "It seems a no-win situation."

One way VLI could ease this mistrust would be to voluntarily withdraw the sponge from the market until the questions put to it at the congressional hearings on sponge safety and loopholes in the FDA approval process are resolved. If it does not, thousands of women will continue to be guinea pigs in the sponge's largest clinical trial to date—public sale.

5.Ibid.
12.Ibid.
15.Ibid., Hearing before . . . p. 241.
17.Ibid., Hearing before . . . p. 263.
20.Ibid., Hearing before . . . p. 287.
21.Ibid., Hearing before . . . p. 301.
24.Ibid., Associated Pharmacologists and Toxicologists.
25.Ibid.
26.Ibid., Hearing before . . . p. 139.
27.Ibid., Hearing before . . . p. 301.
28.Ibid., Hearing before . . . p. 139.
29.Ibid., Hearing before . . . p. 301.
31.Private communication with Armand Lione, Director, Associated Pharmacologists and Toxicologists.
32.Ibid., Hearing before . . . p. 139.
33.Ibid., Hearing before . . . p. 139.
34.Ibid., Hearing before . . . p. 139.
35.Ibid., Hearing before . . . p. 139.
36.Ibid.
37.Ibid., Hearing before . . . p. 291.
38.Ibid., Hearing before . . . p. 291.
39.Ibid., Hearing before . . . p. 291.
40.Ibid., Hearing before . . . p. 291.
41.Ibid., Hearing before . . . p. 291.
42.Ibid., Hearing before . . . p. 291.
43.Ibid., Hearing before . . . p. 291.
44.Ibid., Hearing before . . . p. 291.
45.Ibid., Hearing before . . . p. 291.
47.Ibid., Hearing before . . . p. 291.
48.Ibid., Hearing before . . . p. 291.
50.Ibid., http://www.totally.com/health-care/the-new-birth-control-sponge-can-we-trust-it
At the start of the Reagan Administration, many health and safety advocates joked that the Declaration of Independence would have flunked a cost-benefit test. Now they are probably convinced that if Reagan had been president in 1863, he would have replaced slavery with indentured servitude after analyzing all the risks.¹

In contrast, environmentalists with the goal of reducing health hazards as much as possible are wary of efforts to rationalize regulation. Nicholas Ashford, director of MIT’s Center for Policy Alternatives, said last year that although demand for better science is replacing the cry for more cost accounting, hidden in both are “really political views that represent a preference not to regulate rather than to regulate.”²

This suspicion is widespread enough that in 1982 Lester Lave, a pioneer of cost-benefit analysis,³ felt compelled to declare that “No one should be under the illusion that quantitative risk assessment has a pro-industry or anti-environmental bias.”⁴

This concern with public disaffection has also penetrated the Reagan Administration, rocked by the negative publicity generated in the 1983 Environmental Protection Agency scandals. In his first major speech as EPA chief in July 1983, William Ruckelshaus demanded a clean break between science and politics. Adopting a recommendation of the National Research Council (NRC),⁵ he insisted that “risk assessment” and “risk management” would no longer get mixed up at EPA.⁶ (See Figure 1.)

One environmentalist who agrees with this approach is Dr. Ellen K. Silbergeld, chief toxics scientist for the Environmental Defense Fund, a national membership organization staffed by scientists, economists, and attorneys who specialize in energy, toxic chemicals, water resources, and wildlife. A former researcher at the Johns Hopkins School of Public Health and the National Institute of Health, Silbergeld has published more than 100 papers and is a member of the EPA Science Advisory Board. In a recent interview with Health/PAC, she defined risk assessment as a technique for assessing human experience and extrapolating from experiments with animals to human health effects, in order to describe the risks of different levels of chemical exposure (see box). She emphasized that effects in animals from such exposures can and must be used to predict human responses because epidemiology is too slow, imprecise, and expensive to be the sole basis of regulation.⁷

In her mind controversies arise when people link this tool of biological science with cost-benefit analysis or other social science methods for deciding at what level of risk to set a standard, and with what hazard controls. Called “risk management” by NRC, this latter exercise requires juggling of politics, economics, and technology.

While it may be unwise to identify risk assessment with risk management, both involve large methodological uncertainties. Silbergeld distinguished between two types of uncertainty in risk assessment: the question that “can inevitably be determined by some kind of scientific experiment, but at present we don’t have the information” and the question that is a matter of “philosophical belief” because it cannot be decided by any experiment.

For example, we know that in large amounts some chemicals cause cancer in animals, but we do not know how many cancers will result from exposures as small as those humans usually experience in the environment. The debate about saccharin and bladder cancer, for example, included a dispute over how to extrapolate from high to low doses.
"Is the dose-response curve linear, particularly is it linear at low doses?" is the question as Silbergeld posed it. "For some chemicals," she noted, "there is evidence to suggest that it may be, or that it is best fit by a linear line, and there is evidence for certain other carcinogens, such as vinyl chloride, that it is clearly not, that it may be better fit by other shaped curves. That's an area of great controversy, but one which may be partly resolved by experimental evidence." (See Figure 2.)

As an example of a philosophical question, unresolvable by experiment, Silbergeld chose "Do you operate at the upper limit of statistical confidence or at the mean?" when calculating effects in humans from those in animals, given that chance plays a part in all scientific results. Such a choice may depend in part on whether a scientist is more concerned about wrongly accusing a chemical manufacturer of harm (and uses the mean) or whether his or her greater fear is giving the chemical an unwarranted bill of health (and uses the upper limit).

While Dr. Silbergeld believes the distinction is clear between scientific and philosophical uncertainty, such procedural choices as above must be made—choices which are more or less conservative, that is more or less protective of public health. The National Research Council concluded that such choices are often not made explicitly in risk assessment and "the result is a mixture of fact, experience (often called intuition) and personal values that cannot be disentangled easily."8

In her recent doctoral thesis, Frances Lynn of the University of North Carolina described this mixture in more detail. Based on interviews with 136 occupational physicians and industrial hygienists from industry, academia and government, she found "Those scientists who self-identify as Republicans, Reagan voters and conservatives are more likely to believe in the existence of thresholds, question the use of animal data, support the use of cost-benefit analysis, and feel that Americans are overly sensitive to risk."9

Not surprisingly industry scientists tended to be more conservative politically and less protective medically than their counterparts in government. The attitudes of academic scientists fell in between.10 Although Dr. Lynn did not indicate whether the scientists she interviewed performed risk assessment routinely, her findings suggest how difficult it may be to disentangle the mixture of fact, experience, and value that NRC describes.

Even if a scientist's values did affect the way he or she deals...
with scientific (as opposed to philosophical) uncertainty, Silbergeld would probably still scrutinize those uncertainties that have the "biggest influence on the eventual answers." As already mentioned one of these is the shape of the dose-response curve. Even more important to Silbergeld is exposure assessment. (See Figure 1.) When determining how exposed to a contaminant the population is and from what sources, whether food, air, water, or soil, "the agency (EPA) too often makes the worst assumptions and takes the least scientific approach," she says. (See box.)

The National Research Council has high hopes that, by being more systematic than in past efforts, risk assessment will lead health and safety agencies to great certainty. NRC believes that with this technique the agencies will be able to determine priorities for research and regulation.

Ellen Silbergeld is much less optimistic. According to her there are not more than "ten or 12" substances that EPA knows enough about to do full risk assessments on; hardly enough chemicals to prioritize for regulation. Referring to the National Academy of Science's recent report, Toxicity Testing, the real problem, she says, is what to do with the thousands of chemicals on which we do not have enough data to "support even the flimsiest risk assessments."

She also expressed concern about the EPA staff's lack of public health training. When reminded that EPA was created in part because the U.S. Public Health Service (PHS) failed to cope with environmental problems, she said the two organizations "ought to get back together in a structural and regulatory sense. I don't think EPA is doing a very good job in its health and exposure assessments. But for the first time

FIGURE 1
Results of alternative extrapolation models for the same experimental data. NOTE: Dose-response functions were developed (Crump, in press) for data from a benzopyrene carcinogenesis experiment with mice conducted by Lee and O'Neill (1971).

FIGURE 2
Results of Alternative Extrapolation Models for the Same Experimental Data.

EXTRA RISK P(d) - P(0)

Supralinear

Linear

Sublinear II

Sublinear I

Threshold

one in a hundred

one in ten thousand

one in a million

one in a hundred million

one in ten billion

DOSE (Micrograms per Week)
Our Science and Theirs

The National Research Council went beyond Silbergeld in her demand for accountability by government health and safety agencies. Rather than requiring just a case-by-case examination of risk assessments, NRC recommended "uniform inference guidelines" for all steps in the process except exposure assessment, which is source-specific and still too uncertain.

An inference guideline is nothing more than a documented preference, e.g. for a linear dose-response curve over one with a threshold, a conversion of animal to human body size using weight rather than surface area, or a calculation of effects that includes benign as well as malignant tumors. The goal is to achieve consensus about as many choices as possible in order to avoid reinventing risk assessment every time a standard is established or revised.

Unfortunately the sticking point has always been the guidelines' flexibility. "Flexibility" means how easily a scientist can reject a consensus interpretation in favor of another based on convincing (new) scientific evidence. It also means how a guideline deals with uncertainty or incomplete data.

For example, in an article about cancer policy, Silbergeld rejected efforts by Anne Burford Gorsuch's EPA to favor a two-class model of carcinogenesis, with some carcinogens treated more leniently than others if they did not damage DNA directly, which is how many scientists believe cancer is caused. She found this approach incomplete because it discounted evidence that chemicals like dioxin could be powerful carcinogens in animals without affecting directly the cells' DNA, which controls hereditary traits.11

Given Gorsuch's record at EPA, one would suspect that this scientific inflexibility was politically motivated. It is not surprising that when Rep. James Scheuer (D-NY) asked Gorsuch why she was trying to replace the agency's Science Advisory Board, she reportedly responded "Oh, no, they are good scientists, except we want our scientists rather than their scientists."12

My child has Down's Syndrome. Is that caused by TCE? You say 'No' and give her a whole rundown on what causes Down's when she was really asking what is the evidence for birth defects [from trichloroethylene]."

The belief that better risk assessment is not purely a scientific problem is widely shared among environmentalists. The type of risk assessment board recommended by NRC, warns Frances Lynn, is "removed from public input and procedural guarantees," and what we need is "a more self-conscious scientific community" as well as a more informed citizenry.13


5. "Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies." National Research Council, Risk Assessment in the Federal Government: Managing the Process (Washington, DC: National Academy Press, 1983) p. 151.


7. Elizabeth Whelan, of the industry-sponsored American Council on Science and Health, called this "regulation at the drop of a rat." In Jonathan Lash, Katherine Gillman and David Sherman, A Season of Spoils: The Story of the Reagan Administration's Attack on the Environment (New York: Pantheon Books, 1984) p. 149. Lester Lave, formerly of the Brookings Institution, favored a hierarchy of tests with screening devices like medical case reports, structural comparisons to known carcinogens and mutagenicity assays of bacteria used before toxicology and epidemiology, which are more precise but more costly and time-consuming. See Lave, Quantitative Risk Assessment, pp. 28-33. Scientists may agree that the quality of all data must be examined, but they differ on the value of different types of evidence.


10. Ibid.


Building a Trojan Horse
Science Under the Reagan Administration
by Eric Holtzman

In most respects, the overall effects of Reagan's policies on funding for the basic sciences have been undramatic. Legislation and the administrative atmosphere have been oriented to encourage further private investment in research. Nevertheless, the major federal agencies funding non-military research, such as the National Science Foundation and the National Institutes of Health, have continued to receive significant increases in their allocations.

Unlike its attitude toward many other government programs, the Administration articulates a policy of strengthened support for basic research. Its policy makers argue that this is an appropriate role for the government in science, and they have restructured the non-defense science budget accordingly. On the other hand, they believe that research in development and application, and related work, e.g. on energy sources, should be done chiefly by private enterprise.

True, NIH and NSF funds are not adequate to support all the submitted research proposals that are worthy of support; funding increases have not kept up with inflation in every year or in every field. And true, some specific large projects favored by earlier administrations have been shelved and others advanced. But insofar as basic research in the life sciences and many other areas is concerned, events have transpired within an envelope resembling the one that probably would have evolved under a second Carter Administration.

Still to be determined, however, is how the regulatory and advisory roles of agencies like the NIH and NSF will fare. The NIH, for example, is supposed to participate in the regulation of commercial applications of "genetic engineering," but it is only very recently that it has been faced with the kinds of concrete decisions out of which longterm policies will evolve.

There has been a fairly large-scale turnover of high level personnel in the federal agencies that fund basic research, and discussion of possible further reorganizations continues. Both the turnover and the discussions have generated concern about the politicization of the science bureaucracy. There even are those — still only a few — who fear that the stage may somehow be set for a present day analogue of the loyalty programs and witchhunting of the '50's. However, some of the most unpleasant proposals for revamping federal science support practices — such as schemes that would increase the direct intrusion of elected officials or their designees into the design of NIH programs — emanate from longstanding Congressional momentum and from sources not obviously allied to the Reagan Administration. Thus far most of the Administration's new appointees have functioned within the range of basic research policies that has evolved over the past decade or two.

Among the life sciences, agriculture is receiving intensified attention from the federal government. In some quarters, the perception is popular that agricultural research is being stultified by bureaucratization and the influence of an old-boy network of researchers protected from peer review. In response, the structure of support is being examined, with the intention of invigorating a system of competitive grants in agricultural biotechnology. The principal funding source for the other life sciences, the NIH, tends to come off worse in the Administration's recent budget proposals than do the agencies with higher commitments to the physical sciences and engineering. But this may be misleading. Congress generally takes good care of the NIH, and one needn't be particularly cynical to suspect that the Administration is relying upon this tradition to make nice sounds about cutting budgets knowing the final allocation will not severely stunt the NIH's growth.

During the early phases of the Reagan presidency, educational programs at all levels, from the NSF-sponsored efforts to improve secondary school science to the training programs of the NIH, was under severe pressure or scrutiny. To an extent this carried over tendencies of the Carter era, although the attack on the social and behavioral sciences was a substantially new initiative. For most of the natural sciences, this atmosphere has been lifting lately, with the rediscovery of our failings in science education. The notion that we must mobilize to recruit and train our next generation of scientists is "in," although at present segments of Congress are more willing than the Administration is to come forth with large amounts of new money.

None of this is to say that things are wonderful, that science funding is truly adequate or equitably distributed or planned with appropriate attention to long-term perspectives, that the commercialization of biotechnology is proceeding along healthy directions, or that the priorities of federally funded research have shifted more toward meeting the needs of the most needy. It means simply that too much boat-rocking has been avoided.

This is largely because the sciences have functioned relatively well as sources of American profit, strength, and success within our existing framework, and because they are viewed as major potential elements for maintaining our world position. Japanese and Western European efforts in research and development consume percentages of the GNP equal to or greater than our own, and obviously are viewed with alarm. Scientific research is widely popular and, with exceptions, the scientific community is apolitical, roughly satisfied with things...
more or less as they are and, therefore, non-threatening to the social and political strategies and agendas of the Administration.

What is especially worrisome, at present, about the Administration's science policies is the increased role and visibility of the military. Far and away the largest percentage of what the federal government considers its research and development investment goes to the Department of Defense and its dependents, and these funds have increased dramatically. But frightening and deplorable as this is, it is not new; Reagan has simply added to an already elaborate edifice constructed by his predecessors.

“A more unique stamp of this Administration is its vigorous fostering of the open reinvasion of academic science by the military, which had been forced into a significant partial retreat, at least in visibility, during the Vietnam era. The life sciences are less a target than physics or engineering, but they are certainly not excluded. For example, a variety of basic molecular biological and neurobiological topics are included in the lists published by the Department of Defense and by the Army, Air Force, and Navy as appropriate for support in their expanded and attractive granting and contract programs for research. Some of these programs, such as those providing funds for new instrumentation, are directed towards what have recently been among the most pressing needs of scientists in universities and academic research institutes.

In some cases, the Defense Department grants and contracts accessible to life scientists have clear and direct military goals. There are, for example, disturbing signs of Administration interest in expanding the U.S. chemical and biological warfare efforts. These include the dogged insistence by the government, in the face of mounting contrary evidence, that "yellow rain" reflects field use of biological warfare agents by our "enemies," and the very ambiguous proposals regarding chemical warfare recently floated by Reagan.

On the other hand, often the programs sponsored by the military are designed, or at least publicized and administered, so that, as in the past, much research without any obvious direct military bearing can and is being funded. The rationale offered is that the military fully appreciates the time-honored arguments about the unexpected applications a given area of basic research may generate. At least as important as this, however, are more symbolic matters of legitimation and control. Department of Defense grants and contracts are reappearing in academic campuses and departments in benign guises—the military appears as a patron of the intellectual arts. As part of a decentralization program (coupled, perhaps, with an intelligent public relations policy aimed at de-emphasizing the Pentagon, forts and arsenals), for instance, the administration of the Army's basic research program has been moved to the Research Triangle "campus" in North Carolina, which is widely viewed as an excitingly innovative site for interaction between academe and industry. The recipients of Defense Department money have dusted off the old rationalizations: "better we should use the money for good things than that the funds go to real military projects." In other words, the borders between military and non-military are being increasingly blurred, and military intrusion into everyday scientific life is again becoming an unremarkable phenomenon. In many fields, including the life sciences, personnel can move comfortably back and forth between civilian agencies like the NSF and institutions with military connections.

Moreover, "national security" is reinflating as a criterion for evaluating and controlling activities that hitherto were regarded as outside the province of the loyalty-security apparatus. This has already become overt in a few fields. The recent successful insistence by the government that it have rights to prepublication screening of materials related to cryptography, with attendant rights of censorship, is probably the best known example. There has also been a spate of efforts to restrict the access of foreign visitors to certain types of scientific information and conferences.

If the experience of the '50s and '60s is any guide, such overt direct intervention may be less important in the long run than a poisoning of the atmosphere and perhaps occasional self-censorship, problems that presently are no more than dim fears on most campuses but could easily recrudesce. It is also easy to think of plausible circumstances under which Reaganism's appeal to the narrowest varieties of personal self-interest and its militarized approach to the national interest could be manipulated to spill over into a crusade to protect America's technological and research "supremacy" and to convert knowledge into profit more efficiently by limiting or controlling access and communication in broader and broader scientific realms.

Many researchers understand that relative openness of communication, national and international, is both a necessity for the long-term health of research, and partly a historical derivative of the success engendered by international cooperation in many basic research fields. Those scientists who think about such matters generally believe strongly that the relative autonomy of civilian research is important to defend and expand.

At present, however, most of the scientific community is agitated little, if at all, by the threats inherent in the developments outlined above, or by the problems slowly emerging from the currently accelerating privatization of biotechnology (see E. Holzman, Health/PAC Bulletin, July-August 1983). When funding is reasonably abundant, doubts tend to submerge. Nonetheless, there is some undertone of worry that the surprisingly gentle treatment the sciences have received at the hands of a most urgent Administration may have hidden costs which could be very high.

1. See, e.g. the summary by the President's Science Advisor, George Keyworth: Science 224:9-13, 1984.

2. For details of the proposed budget see, e.g. Bioscience 34 (4):214-218, 1984; Science 233:564-565.
When California's legislators were looking for ways to reduce the state's expected $2 billion deficit in 1982, the state Medicaid program was an attractive and obvious target. Medi-Cal was taking about one dollar in every eight spent from the General Fund and its costs were rising rapidly: led by outlays to hospitals, they had climbed 14 percent annually between fiscal years 1975-76 and 1981-82 while the overall state consumer price index was moving up at a rate of 9.7 percent.

In an effort to brake this rise, leaders in the legislature—with strong support from the governor and business, labor, and insurance industry groups—enacted a series of bills, overriding strong opposition from the hospital industry and the medical profession.

Advocates for the state's three million Medi-Cal recipients were able to influence this legislation only marginally, although it imposed far-reaching changes in the program. First, it eliminated nearly all the state's "medically indigent adults" (known commonly as MIA's) from Medi-Cal. Responsibility for their care was transferred to the counties along with about 70 percent of the funds the state would have spent on the group had they remained in Medi-Cal. This shifted a major burden. As heavy users of expensive hospital care—indeed, this is what had pushed many of them into the MIA category—they accounted for 16.4 percent of Medi-Cal's expenditures even though they made up only 9.2 percent of those eligible for the program. Furthermore, unlike other Medi-Cal programs the one for MIA's did not have federal matching funds. Under the new system, the state gave the counties $261 million for the second half of the 1982-83 fiscal year, when the change took effect, and still expected to save $110 million in that six months alone.

Aside from these savings, several other considerations influenced the legislators. They hoped that the infusion of state funds would shore up the overburdened, underfunded county health systems, and the program they were reorganizing served a fragmented and politically weak sector of the population.

Other aspects of Medi-Cal were also pared, through reductions in reimbursement rates to providers, lower income eligibility levels, increases in the share of costs paid by medically needy persons, very restrictive definitions of medical necessity for almost all services, and required prior authorization for all inpatient hospital care other than life-threatening emergencies. These cutbacks were expected to save the state General Fund about $140 million in the 1982-83 fiscal year.

Another of the most significant changes in Medi-Cal mandated the appointment of a special negotiator to conclude contracts with hospitals providing for reimbursement for inpatients under some system other than the old cost-based, fee-for-service policy. The negotiator was given unusually broad authority to set objectives and procedures, and the stakes for Medi-Cal patients were not small: once the contracts were signed, they could not go to other hospitals unless they required emergency care or care in children's or other specialized hospitals. This new policy was expected to save about $200 million (half state, half federal) in the 1982-83 fiscal year even though contracts were not expected to be operational until midway through it.

The insurance industry, fearful that Medi-Cal contract hospitals would attempt to make up for any reduced Medi-Cal revenues by shifting costs onto their backs, asked legislators to allow them to negotiate contract prices as well. The legislature hedged their pleas, and authorized private insurers and others to form preferred provider organizations (PPO's), negotiate favorable rates with doctors and hospitals, and pass any savings on to subscribers in the form of lower premiums.

Two years after these bills were enacted, evidence of their impact is beginning to accumulate. This article is based on findings of an informal consortium of researchers at University of California campuses in Los Angeles, Berkeley, and San Francisco who have shared research methods and information.

"Missing in Action?"

The MIA transfer was implemented differently in different counties. The legislation permitted those with a population under 300,000 to contract back to the state. Of the 43 counties eligible, 34 did; the state provided a scaled down form of Medi-Cal to their eligible indigent persons.

Among the larger counties, the mechanisms for providing MIA care have varied. Los Angeles County, like most, provides care only in county hospitals and clinics—except for emergency care, for which it will reimburse private hospitals. San Diego and Orange, two large suburban counties which have no county hospitals or county medical clinics, contract all MIA care (and other indigent health care) to private hospitals and clinics. Alameda County, a large urban county on San Francisco Bay, uses its county hospitals and clinics and also contracts with a group of community clinics. Most counties combined their MIA programs with their other indigent medical care responsibilities into a single program.

Although many MIA's had been receiving care from the counties under the Medi-Cal program, more than half had to...
make a transition from some form of private care (private doctors, private hospitals, and/or community clinics) to county facilities. In Los Angeles, for example, 45 percent of all hospitalized MIA's had used county hospitals for inpatient care under the Medi-Cal program, but only 29 percent of the MIA outpatient visits had been to county facilities.

Counties also differed widely in the costs they charged MIA's and other indigents as well as their eligibility standards for ability-to-pay (or sliding fee scale) plans. At one end of the spectrum is populous Santa Clara County south of San Francisco Bay, home to both Silicon Valley and farmlands; it maintains an open door policy, treating everyone in need and worrying about the bills later. At the other end is conservative Orange County, which made eligibility for its program dependent on getting sick, going to a hospital, getting financially screened by the hospital, and being further screened by the county. The result has been low utilization. In the middle is Los Angeles, as we will see in more detail.

MIA's in Los Angeles

Los Angeles County includes more than a third of the state's population and a third of its Medi-Cal beneficiaries. Although no county can really be considered typical, the Los Angeles policies and arrangements have been generally similar to those of the majority of medium and large counties. In some ways, what happened to MIA's in Los Angeles illustrates their fate generally in California—and what is likely to happen to many of the poor nationally as federal and state cutbacks eliminate more people from Medicaid.

Use of County Services

Los Angeles was one of three counties that took advantage of the "early assumption" option under which the county implemented the transfer on November 1, 1982, two months ahead of the rest of the state, in order to recoup 100 percent of the expected MIA costs for that period (instead of the 70 percent which counties would receive for the remaining six months of the fiscal year).

In the first few months both inpatient and outpatient services provided by the county climbed gradually, reaching more than 150,000 admissions and more than one million outpatient visits during the 1982-83 fiscal year. However, in judging how well the county met its new responsibilities for all MIA's as well as its continuing responsibilities for uninsured indigent patients, it is important to separate out the services provided to these patients from those provided to persons covered by Medi-Cal, Medicare, or other insurance.

By early 1983 admissions to L.A. County hospitals reached the county's projected levels of more than 13,000 per month. However, this number included many patients who had not lost their Medi-Cal coverage but who apparently had more difficulty getting care in the private sector. Thus in fiscal 1982-83, which included eight months of county responsibility for MIA's, 20 percent more Medi-Cal patients were admitted than previous experience would have predicted, and nine percent fewer MIA's and other indigent patients.

Outpatient visits followed a similar pattern, but were far fewer than expected. The more than one million outpatient visits to county health facilities—ten percent more than in the previous fiscal year—was only three fourths as many as the addition of MIA's who previously received their care from private sources would have indicated.

Because the county does not report the patient's source of payment for most clinic visits, we were unable to determine how much the rise that did occur represented new Medi-Cal patients as opposed to MIA's and other uninsured indigent patients the county was now mandated to serve. Figures from the county's three comprehensive health centers, which did include...
source of payment, from November 1982 through June 1983 suggest that growing use by indigent persons was accompanied by a rise in visits by Medi-Cal recipients, many of whom presumably experienced greater difficulty obtaining care in the private sector.

According to the county’s own projections and our analysis of the limited data available, it appears that the county has not been serving all the MIA’s and other indigents who previously had either been served by the county or had been cared for in the private sector but were now dependent on the county for medical care. These conclusions are borne out by other studies. (See, for example, the box on page 28 by Dr. Nicole Lurie.) This is understandable given county policies that influence access to health care: geographic availability, staffing of services, and financial policies and practices.

Geographic Availability

Los Angeles is a very large county, encompassing more than 4,000 square miles. Although population density is high, many residents are far from all six county hospitals. Nevertheless, medical conditions that require hospitalization apparently motivate people to overcome geographic and other barriers.

Ambulatory care is a different matter. General medical care is available at the six county hospitals, three comprehensive health centers, and only 12 of the county’s other clinics. Although Los Angeles has an extensive clinic system compared to many other counties, some urban areas—such as the Venice-Santa Monica area and parts of the San Gabriel Valley—are a two hour bus ride (each way) from the nearest county general medical care.

Staffing

Of the $143.4 million Los Angeles County received from the state to operate the MIA program during fiscal year 1982-83, only ten percent was budgeted to expand county health services to accommodate the expected increase in patient volume; although county officials estimated that 1,380 new patient care positions were needed, only 220 people were added.

As a result of understaffing, in some clinics waiting periods for appointments increased from one to two weeks to six to seven weeks; in others they increased by only one or two weeks. When someone arrives for an appointment or walks in for an urgent medical problem, waiting times can be as long as two to five hours, although some patients report waiting even longer than that.

Financial Policies and Practices

Until January 1983, the county maintained a formal policy of not telling patients about its ability-to-pay (ATP) plan, a sliding fee scale that adjusts charges to patients’ incomes. Patients were evaluated for ATP eligibility only if they specifically asked for it. Those who did not were charged $20 or $30 as an upfront clinic fee (not including prescription drugs) or billed for full charges (which are much higher than the upfront fee).

Following protests and threats of legal action from community organizations and legal services advocates, the county agreed to tell all patients who raised the issue of financial need about the ATP plan and its eligibility procedures. However, in February 1983, six weeks after the new policy was to take effect, a telephone survey of county facilities conducted by one of our researchers posing as an indigent patient in need of medical care found no personnel in any facility who mentioned the ATP plan. In March, receptionists at all the county hospitals, two of the three comprehensive health centers, but only two of eight clinics surveyed mentioned the ATP plan. Even in August our researcher had a difficult time obtaining such information from a few clinics. Clearly, even when the policy became somewhat more generous there were serious problems with its implementation, and financial barriers continued to vex many indigent patients.

Furthermore, the initial ATP policy excluded undocumented immigrants from all but emergency care; this restriction has been voluntarily withheld by the county after strong protests and threats of litigation by community advocates.

At its best, ATP screening is a lengthy process, requiring documentation of eligibility and often a separate visit to one of the hospitals or one of the 12 of 15 health centers and clinics that provide both general medical care and financial screening. Thus, although the ATP policy and procedures permit indigent persons in great need of medical care to get that care, they do discourage use of county health services.

Conclusions About the MIA Transfer

These findings are not unique to Los Angeles County. Although a few counties established more generous programs—Alameda County has a liberal ATP eligibility policy and provides geographically accessible care through both county facilities and community clinics—several are more restrictive. Orange County, for example, limited eligibility for its MIA program to particular episodes of illness or injury and sources of care to contract hospitals and hospital-based clinics. As a result, from January through June 1983, it handled only 14 percent of the outpatient visits and 55 percent of the inpatient days provided in a six month period the previous year under the Medi-Cal MIA program.

Overall, the MIA transfer has increased the barriers to care for this low-income population. These people and other indigents have been further segregated into the bottom of a two- or three-tier system of care. The accompanying transfer of funds from the state has undoubtedly helped the counties maintain their underfunded and faltering health systems, but it has not been sufficient to lift the medically indigent to the same level of care available to the insured population.

Medi-Cal Cuts

In addition to eliminating a quarter of a million medically indigent adults from Medi-Cal, the legislature reduced eligibility in the remaining categories of recipients, changed and reduced benefits, and reduced provider reimbursement.

Eligibility

The legislation required that “medically needy” persons would have to spend more of their own money before Medi-Cal took over payment of their medical bills.

Raising this “share of cost” proved to be a major problem for the elderly, the disabled, and the working poor. Throughout the state, the patients themselves, community clinic personnel, and private practice physicians reported that among these groups “People are sicker, blood pressures are higher, and diabetes is more out of control,” in the words of one physician with a substantial number of Medi-Cal patients. Physicians
Health Effects of Termination from Medi-Cal
by Nicole Lurie, M.D.

To assess the impact of California's transfer of responsibility for the care of medically indigent adults (MIAs) to county health systems, we identified and prospectively followed a group of 215 English and Spanish speaking MIAs who had made at least one visit to the UCLA general internal medicine group practice. After excluding those who refused, were too psychiatrically ill to complete a questionnaire, or could not be found, the sample size was 186 patients. All participants completed a questionnaire about their general health perceptions, access to care, and satisfaction with care prior to and six months following termination from Medi-Cal. To obtain more direct measures of health, we measured blood pressure in hypertensives and Hemoglobin A1c in diabetics. (Hemoglobin A1c is an indicator of diabetic control over the preceding few weeks.) A comparison group of 109 patients whose Medi-Cal was not discontinued (because they were blind, disabled or in families with dependent children) was also studied.

In the initial survey, there were no significant differences between MIA and comparison patients in gender, ethnic group, income, access to care, or satisfaction with care. On average, patients in the comparison group were slightly older. Over 95 percent of the MIAs could identify a usual course of care, and 91 percent were "extremely" or "very" satisfied with care they had received; 83 percent agreed with the statement, "I can get medical care whenever I need it." Members of the comparison group responded similarly, but they reported worse health, with a mean score of 39.3 on a 100-point scale versus 47.1 for the MIAs.

Prior to termination from Medi-Cal three quarters of the 61 hypertensive medically indigent adults had a normal diastolic blood pressure of 90 mm Hg, and three percent had diastolic blood pressure of 100 mm. In the comparison group, 61 percent of 50 hypertensives had diastolic blood pressure of 90 mm and 11 percent had readings in excess of 100 mm.

We were able to obtain information on 97 percent of the medically indigent adults and 90 percent of the comparison group patients six months following the MIAs' termination from Medi-Cal. There were five deaths in the MIA group and none in the comparison group. Causes of death were: gunshot wound, preleukemia, stroke (pontine hemorrhage), presumed myocardial infarction, and perforated ulcer.

The stroke occurred in a hypertensive patient who had uncontrolled hypertension at the time of our initial survey, at which time she was given extensive information about how to obtain care in the county health system. She had received some care from a private physician but was unable to afford her anti-hypertensive medicines.

The presumed myocardial infarction occurred in a man with known heart disease who had run out of cardiac medicines. He died after prolonged chest pain at home. The family of the patient with the perforated ulcer reported that he had been vomiting blood at home for ten days, but delayed seeking care because he felt he would be unable to pay an emergency room fee.

By the time of the follow-up survey all measures of access to and satisfaction with care had deteriorated among the MIAs. Only half had a regular source of care, compared with 95 percent six months earlier. Sixty percent were satisfied with their care, and only 38 percent felt that they could get care when needed. Their general health perceptions had decreased by eight points. There were no significant changes in these measures in the comparison group. Among the hypertensive MIAs there was a mean increase in diastolic blood pressure of 10mm Hg while blood pressure control in the comparison group patients had improved by an average of 5mm. Only 34 percent of the medically indigent adults had diastolic blood pressure below or equal to 90, compared with 75 percent previously, and the proportion with diastolic readings above 100 rose from three to 31 percent. Data from the Framingham study indicate that if this blood pressure rise in MIAs is sustained, their relative risk of dying would increase by 40 percent.

Diabetic control worsened by 15 percent in MIAs and by four percent in comparison patients, but the between group mean difference was not statistically significant at the .05 level.

Hypertensive and diabetic patients who regained some form of a third party coverage were more likely to have a regular provider, and those who had a regular provider were more likely to have a diastolic blood pressure less than or equal to 100mm.

The study demonstrated that termination of Medi-Cal benefits for these poor, chronically ill patients resulted in adverse outcomes. Further investigation is needed to determine whether the findings of this study can be generalized to other similar populations. Meanwhile, any future reductions in health benefits, particularly for poor or chronically ill patients, should be carefully considered in advance of their implementation. If implemented, they should be monitored clinically to be certain that adverse outcomes do not occur.

reported cases of patients waiting until abdominal pains, chest pains, skin conditions, and respiratory infections were more severe before seeking care. They also reported that fewer patients were getting follow-up care.

The courts were sympathetic to their plight, and when suits were brought forced the state to restore the previous income eligibility standards.

Benefits
The main cuts in benefits were procedural. The legislation specified that only "medically necessary" services could be provided under Medi-Cal, and it redefined these to include only those “necessary to protect life or prevent significant disability.” The list of medical procedures requiring prior authorization was greatly expanded.

Providers uniformly reported greatly disliking the bureaucratic inconvenience created by these changes. Some physicians complained that restrictions imposed by the medical necessity definition and the delays in obtaining treatment authorizations limited their diagnostic and treatment options. Others expressed the opinion that the more important and effective tools of medical practice were not unduly restricted.

Although physicians' views varied, it is evident that many patients suffered emotional pain and occasionally more severe medical problems. Treatment authorization requests are frequently denied or approved belatedly for tubal ligations, hysterectomies, abortions after 20 weeks, vaginal repairs, benign growths, cataract surgery, allergies, and a number of medications. One physician reported that it took four weeks for a treatment authorization request to be approved before he could biopsy a woman's breast lump, a delay he characterized as "medically treacherous." The woman "was in medical agony waiting," he said.

Reimbursement
Physician reimbursements were cut ten percent initially. This was reduced to seven percent in January 1983. Reimbursement was also pared for most other services. Even before these reductions, Medi-Cal reimbursement rates had fallen further and further behind "usual and customary" charges in the years
since the program was established in 1965. Low reimbursement rates have been the main reason given by physicians for not participating in Medi-Cal and Medicaid programs in other states. Even before the current round of cutbacks throughout the country, just six percent of all physicians cared for one third of all Medicaid patients and one fifth of all physicians saw no Medicaid patients at all.

The new cuts in reimbursement rates led more physicians to turn away new Medi-Cal patients. This has been most common among doctors who saw relatively few. Physicians with large Medi-Cal practices, on the other hand, have been in a double bind. They depend on Medi-Cal patients for their revenues, particularly if they practice in low-income areas, but Medi-Cal pays approximately the marginal costs of medical practice, not the higher average costs. As one physician with a high-volume Medi-Cal practice explained, "Our costs are about $136 an hour for seeing patients. But we only get about $32 per hour for seeing Medi-Cal patients."

Several such physicians said their overhead costs continued to increase while the MIA transfer, reductions in Medi-Cal eligibility, and the cuts in reimbursement rates sharply slashed their revenues. Some physicians in low-income minority areas reported considering abandoning these already medically underserved neighborhoods.

Aside from dampening primary care physician enthusiasm for Medi-Cal cases, low reimbursement rates have reduced referrals to specialists. Community clinic and private practice physicians who treat Medi-Cal patients reported that it was difficult—and in some cases impossible—to find psychiatrists, obstetricians, and orthopedists who would see their Medi-Cal patients.

Medi-Cal Hospital Contracting
The most significant, and undoubtedly the least detrimental, change mandated by the 1982 Medi-Cal legislation was selective contracting with hospitals for inpatient care. The objective was to encourage hospitals to compete for shares of their local Medi-Cal business.

This system abandoned the freedom-of-choice provisions that were the hallmark of the original Medicaid legislation in California as in the U.S. Congress, and threatened to segregate Medi-Cal recipients in a set of possibly inferior, second-class hospitals. However, the worst fears were not realized. Under pressure from advocates for the poor, the legislature specified nine criteria that the special negotiator was to follow in awarding contracts, including assuring patients’ access to care, the availability of specialized services, and quality of care, as well as other criteria intended to make the program economical and efficient.

The special negotiator, who was quickly dubbed the "Czar" because of his broad powers, made at least the contracting process work. Hospitals offered significant financial concessions when they bid across-the-board per diem rates to care for Medi-Cal patients, and the state saved at least $200 million a year. Access by Medi-Cal patients to general inpatient care and to specialized services such as obstetrics and neonatal intensive care seems to have been reasonably well protected, and contract hospitals do not appear to differ from noncontract hospitals in quality or efficiency.

Although the contracting process was successful, it is too early to judge whether the implementation will work as well. Actual access may be restricted more than suggested by an analysis of which hospitals received contracts. Contract hospitals with a heavy Medi-Cal load may find their revenues running substantially below their costs and have greater difficulties obtaining capital, so that they may end up providing second-class care to Medi-Cal patients or closing their doors altogether.

Conclusion
The MIA transfer and the other Medi-Cal cuts have clearly added to the burden of illness borne by the poor—in many cases, with serious adverse consequences.

The experience with the Medi-Cal cuts and reforms provides some lessons for similar efforts in other states. First, as an economically marginal and politically unorganized group, the poor will continue to be targets of cutbacks in health and other social programs. Medi-Cal, like all state Medical programs, covers only the most destitute persons. Until such programs are more universal in their coverage, benefiting more powerful groups and social classes as well as the poor, they will remain especially vulnerable.

Second, the loss of Medi-Cal coverage for medically indigent adults reduced potential access to, and actual use of, health services and greatly aggravated existing chronic medical conditions. In general, losing Medicaid benefits can be expected to reduce access to health services and cause measurable and often severe deterioration in the health status of many of those affected.

Third, non-Medicaid services designated for the poor should be carefully monitored to assess whether public policies unduly restrict access and to assure that policies to promote access are actually implemented.

Fourth, the experience in Los Angeles County, undoubtedly not unique within California or the country, suggests that organizations of poor people and their advocates should vigilantly monitor public programs intended for their benefit. The history of the Hill-Burton program suggests that the same conclusion applies to the provision of care by private institutions.

Finally, health care reforms that restructure the financing or organization of health care may save large sums of money without placing an undue burden of cost containment on the poor. Of all the Medi-Cal changes adopted in 1982, selective hospital contracting seems to demand the most from providers and the least from patients. Hospitals must lower costs by reducing procedures performed on patients and by becoming more efficient. Although there are clear risks for patients, there is reason to believe that the more optimistic scenario—that unnecessary diagnostic and therapeutic procedures will be eliminated and that personnel reductions will not lead to understaffing—may prevail.

Overall, the California cutbacks and reforms suggest that conservative budget cutting will continue to be largely at the expense of those least able to bear it. They also hold out at least the possibility of saving large sums of public and private health care dollars through more thoughtful and progressive reforms which require changes in the way doctors and hospitals function. Implementing these progressive reforms, and successfully opposing detrimental budget cuts, will usually require broad coalitions of groups which join forces on behalf of their common interests.
Among those attending a 1978 conference on “Women in the Workforce” sponsored by the California Federation of Labor were three northern California trade unionists who came seeking solutions to problems associated with Video Display Terminals (VDTs) at their workplaces. Barbara Gray of the Typographical Workers Union Local 21, Helen Palter of the Newspaper Guild Local 52, and Barbara Pottgen of the Office and Professional Employees Local 3 were concerned about eyestrain; neck, shoulder, and back aches; tension; and radiation exposure.

“While we didn’t find the answers to all our problems, we did find each other,” recalled Barbara Pottgen, “and we made a commitment to start working together to find common solutions to our common problems. . . . All of us were running into roadblocks in our grievance procedures and contract negotiations on VDT health and safety because it was such a new issue. Our employers were unimpressed with studies on VDT health hazards done in European countries, so we realized that we had to bring things closer to home.”

Out of this realization came the VDT coalition and hard data. With backing from 25 local and international unions, the three women petitioned the National Institute for Occupational Safety and Health to investigate VDT use at their workplaces. The ensuing study of radiation testing, industrial hygiene chemical monitoring, health problems, and ergonomic measurements was conducted at two newspaper agencies and an insurance company. Its widely quoted recommendations for adjustable machines and furniture, proper lighting, regular breaks from VDT work, and eye exams have lent legitimacy to union and worker demands for improved working conditions and have become the basis of legislation in several states.

Few pieces of machinery have been introduced so quickly and broadly as VDT terminals; an estimated seven to ten million are now in use in U.S. workplaces, often without regard to ergonomics, the human component of human-machine interaction. Glare created by improper lighting and poor work-station design; desks, chairs, and machines that don’t adjust; flickering or blurred images caused by infrequent maintenance; deskilled, fragmented, and low-paying jobs with production quotas all create visual, musculoskeletal, and stress-related problems.

Many union and non-union VDT workers anxious about these dangers as well as VDT radiation are concluding that they have to organize and educate themselves to protect their health—and that of any future children they might have. When three southern California women were leading a workshop at another California Labor Federation-sponsored conference on “Women in the Workplace” this year, they still did not have answers to the questions about radiation which had troubled their northern California counterparts six years earlier, nor could they claim that any of their offices had perfect ergonomic designs. They could, however, discuss achievements in educating VDT operators, their unions, and the public; in research at their workplaces; and in organizing efforts throughout the state. (Other organizations such as 9 to 5 have also done important work; this article focuses on California groups initiated specifically to address the issue of VDT working conditions.)

As in northern California, a request for workplace research was an early step in the development of a southern California grassroots coalition. In 1982 VDT workers who were members of the American Federation of State, County, and Municipal Employees approached the Los Angeles Committee on Occupational Safety and Health for help. Like other COSH groups around the country, LACOSH is a worker education and advocacy organization made up of unions and health and legal professionals; its Technical Committee provides assistance in occupational health and industrial hygiene.

Members of Local 3090 and the Technical Committee surveyed almost a third of the 3,500 clerical workers employed by the City of Los Angeles represented by the local. They found the same health problems noted in other studies and provided specific information about Los Angeles city offices which served as a basis for negotiating contract language.

This survey was more than a data collection process. Worker participation made it an organizing tool as well. LACOSH members attended a Health and Safety Committee meeting of the local to present information about VDT-related health problems and potential workplace causes, then worked closely with Committee members to develop the questionnaire and implement the survey methodology. Training for the survey gave the clerical workers on the Committee the knowledge, skills and interest to participate in developing contract language; the Committee is now working with the city administration to make specific changes.

The survey—and its usefulness in stimulating workplace changes—heightened interest in the VDT issue among other Los Angeles unions. It also illustrated the importance of

Linda Delp is co-chair of the LACOSH Technical Committee and a member of the VDT Task Force. This article was written with the help of Laura Stock (VDT Coalition), Pam Haynes (Air Transport Employees), and Wayne McCort (AFSCME 3235).
worker participation in the organizing process, a principle that became embedded in the Los Angeles VDT Task Force. The Task Force had its origins in a LACOSH-sponsored 1983 conference, “VDT’s—More than a Headache,” which brought together 140 participants from 25 different union locals as well as 9 to 5 representatives and workers from nonunionized offices. LACOSH followed up by convening a meeting of individuals interested in sharing experiences with workplace surveys, grievances, and collective bargaining. This developed into the Task Force, which began working with the Northern California VDT Coalition.

Thus both the Coalition and the Task Force were initiated by workers, received some organizational and leadership support from existing organizations, and then evolved into autonomous groups dedicated to training VDT operators in technical aspects of proper workplace design and incorporating them into the leadership.

Initially, for example, presentations of the NYCOSH slide show “Today’s Technology, Tomorrow’s Headache,” were made by LACOSH members; eventually VDT operators in the Task Force received training and practice and began to give presentations to their coworkers, at their union meetings, and at the request of other union locals. The Coalition’s quarterly communication and outreach newsletter Video Views is published by VDT operators and union representatives and contains both their articles and those of local health care professionals. VDT operators represent both groups at press conferences and on TV and radio.

Organizing for Legislation

Despite some union local gains in negotiating VDT contract language, collective bargaining is a slow, difficult process and even when successful benefits a very limited number of VDT operators; only 21.1 percent of all employees in the nonmanufacturing sector of the California economy are unionized.

VDT activists decided to supplement their workplace organizing with a drive for state action. Petitioning for a CAL/OSHA standard seemed futile—under conservative Republican Governor Deukmejian, the agency has been cutting back on enforcement and limiting the adoption of new standards. The members of the coalition and the Task Force thought a legislative effort made more sense. They realized getting a bill through would also be difficult, but reasoned that organizing for it would enhance public awareness of the issue.

Coalition members then developed a bill and asked the California Federation of Labor to sponsor it, with the understanding that both Coalition and Task Force members wanted to be consulted when changes were proposed. This strategy was selected as the most effective way to combine the grassroots organizing abilities of the Coalition and Task Force with the Labor Federation’s lobbying experience and communication network. (California AFL-CIO affiliates account for 80.9 percent of California union members.)

Assemblyman Tom Hayden carried the bill; representatives from his office, the Labor Federation, and the Coalition and Task Force joined forces to lobby for it and publicize the issue.

Political Realities

In a few short months, the bill had a varied life. It successfully passed the Labor Committee: it was then drastically altered in the Ways and Means Committee so that it reached the floor of the Assembly with only two provisions—the right of a VDT worker to transfer during pregnancy and the formation of a Task Force given only three months to convene, study the issue, and make recommendations. This gutted bill was then killed.

More letters, phone calls, visits to legislators, and better communication between Hayden, the Labor Federation, and the grassroots coalitions would have strengthened the drive for passage, but ultimately the bill failed due to tremendous opposition from Silicon Valley manufacturers and other employers throughout the state.

“What it really came down to is they don’t want anything on the books; nothing that will coopt their authority or power as an employer,” commented Pam Haynes, a member of the VDT Task Force. “It doesn’t really matter whether they have good or bad records with respect to workplace conditions.”

Success of Failure?

Two important principles are evident in the organizing strategy that evolved from the California grassroots VDT movements.

1. A multifaceted approach works—education, research, and contract negotiations in the workplace; public consciousness-raising through conferences and the media; and political action in the state legislature. VDT operators who had earlier heard a presentation in their workplace lobbied their legislators for the bill with letters and phone calls. A representative of the California Federation of Labor said, “This is the largest influx of activity around a single bill ever.”

Although the legislative effort was unsuccessful in itself this time, it was a valuable component of the overall campaign. It developed activists and heightened public awareness of the issue, which will aid workplace organizing and future political action.

2. All workplace activities, publicity, and political action should include VDT operators, empowering them with technical knowledge and political know-how. This will help them win immediate improvements in their offices and continue the longer-term effort to organize workers for better contracts, health and safety committees, and strong legislation.

NOTES

Chemical Reaction
Fighting A Toxic Waste Giveaway
by Gail Bateson

Thousands of communities located near hazardous waste sites across the nation are waiting for clean-up funds from the federal Superfund program, and anger and frustration are rising. Nowhere is this more evident than in California.

"It is those of us who have to live with that situation day after day, year after year, who really understand what the toxic waste issue is all about," said Penny Newman, leader of the community organization living below the Stringfellow Acid Pits in Riverside County. "We understand it from the viewpoint of people who cannot send their children into their own backyards to play because the air makes them ill. We understand it as friends who comfort young women who have just suffered their sixth miscarriage. We understand it as parents who lie awake at night listening to their children struggle to breathe or have to hold their child after one of his seizures."

Almost four years have passed since Congress passed the Superfund law providing $1.6 billion to begin immediate clean-up of those toxic dumpsites most likely to threaten public health or the environment. To date, over 35,000 abandoned hazardous waste sites have been identified, yet Superfund has cleaned up only six relatively small sites; the price tag for the most dangerous sites alone may run as high as $44 billion, according to a recent EPA estimate.

The toxic waste crisis has become a hot political issue this election year. In California, the safe control of toxic chemicals has joined crime and education among the top three public concerns. Federally, EPA Administrator William Ruckelshaus has refused to support pending Superfund legislation to provide more funds and mandatory deadlines for clean-up, and state officials are scrambling to come up with their own solutions. Conservative Republican Governor George Deukmejian proposed a $300 million bond measure last spring.

New York's Governor Mario Cuomo has suggested a $700 million hazardous waste bond measure for the 1987 ballot, and the citizens of Rhode Island will vote on a $5 million bond measure this November. Maine voters approved a $3 million bond issue in a special election in June.

Issuing these 20-30 year bonds backed by a state's general fund is analogous to taking out a mortgage on a house, explained California's toxic waste chief Joel Moskowitz, "The governor's proposal will let us live in a clean environment while we pay for it."

That's the catch: in a significant departure from previous legislation to control corporate pollution in the workplace and the general environment, the public is being asked to subsidize a major portion of the clean-up. The net effect is a public bailout of private businesses. "We have two choices," was the rationale of the relatively liberal Governor Cuomo, "we can abandon our obligation to keep the environment as livable as possible, or we can make the sacrifices necessary to meet that obligation. I believe this plan fairly distributes the sacrifices needed."

In California, the state Department of Health Services clouded the issue of who would pay for the bond measure with unsubstantiated estimates of both the amounts likely to be recovered from companies identified as responsible for some of the clean-up expense and reimbursements from the federal Superfund and the state's own $10 million a year superfund. (Over 85 percent of the federal Superfund and 100 percent of California's superfund is paid by oil and chemical industry feedstock and waste-end taxes.)

Environmental and citizens groups soon discovered that the home mortgage analogy fell apart when the actual dollars were put in the equation: the total cost of retiring the bonds would run between $800 million and $1 billion, of which the state and federal superfunds would at best provide about 30 percent. Furthermore, to date the state has not recovered a single dime from the responsible companies, and Governor Deukmejian slashed almost all 1984-85 Attorney General's office funding for litigation against hazardous waste violators.

The problem in California and at the federal level is not simply lack of money. California's Department of Health Services has been unable to spend its annual budget of $10 million during each of the past three years, and an independent government commission which reviewed the state's superfund program found "extensive organizational, management and resource deficiencies which we believe require major reforms if California is going to halt this crisis." The commission also opposed the use of general obligation bonds to raise clean-up funds, noting that "Placing the burden of paying for cleanups on the general taxpayer not only forces the victims to pay for the solution, but does little to create more incentives for industry to improve the way it manages hazardous wastes. If the costs of dumping hazardous wastes include the costs of cleaning up toxic waste sites, then economic pressures will encourage companies to find alternatives to dumping hazardous wastes in the ground."

Taking a similar position, a coalition of environmental, citizen, and community dumpsite organizations mounted an
intensive media and lobbying campaign which won a payback mechanism for the bond measure ensuring that general fund expenditures would eventually be reimbursed with money recovered from companies responsible for dumping, and any gaps would be filled through expansion and extension of the state superfund tax.

At this point the real battle began. Recognizing that Governor Deukmejian was determined to have some form of toxic bond measure on the November ballot, the petrochemical industry, led by Chevron and backed by Dow and the industry-dominated Council for Economic and Environmental Balance, unleashed an aggressive lobbying campaign.

Chevron agreed to a scaled-down $100 million bond measure and a 50 percent rise in state superfund taxes for a substantial price: its amendments to the bond measure would have given the petrochemical industry essentially all of the exemptions and exclusions from legal and financial responsibility for abandoned site clean-ups that they had been unable to win in previous state and federal legislative battles. These included:

- establishing state clean-up guidelines weaker than federal standards
- exemption from all future liability once the most “cost effective” clean-up plan was completed
- an arbitration process and liability standards making it more difficult to recover money from responsible parties
- no review of clean-up plans by citizens in affected communities, and no recourse for those citizens to petition for a more thorough site clean-up should initial efforts fail
- locking up crucial evidence in clean-up settlements needed by citizens who wish to bring suit for toxic-related health problems and property damage (including evidence such as site characterization and monitoring studies)

After discovering that they were excluded from last minute negotiations between the industry, the Governor’s office, the Attorney General’s office, and some state legislators, the environmental and citizens groups held a major press conference. The two major organizations tracking the bond measure—Campaign for Economic Democracy and the Environmental Defense Fund—joined community organizations representing the two most hazardous dumpsites in the state, Concerned Neighbors in Action at the Stringfellow Acid Pits and the Sacramento Toxics Alliance near the Aerojet site, in challenging that the bond measure could in fact result in more delays, superficial cleanup efforts, and serious limitations on the rights of citizens to voice their concerns.

Ensuing editorials and news stories throughout the state exposed industry’s proposed “wish list,” which heightened pressure on government officials to reject wholesale adoption of the Chevron proposal. This was buttressed by internal opposition from the Attorney General’s office, which agreed with the coalition’s objections and threatened to sign the ballot arguments against the bond measure unless substantial changes were made.

As a result, the measure that goes before California’s voters this November essentially ensures that the petrochemical industry will repay the $100 bond issue and remain liable for the long term clean-up and maintenance costs. Provisions were added to give affected citizens increased rights to review and comment on settlements negotiated with companies and the contents of clean-up plans. Industry did win inclusion of a complicated arbitration process which allocates financial liability among responsible parties by means of inadequate legal definitions; this will put the state at a distinct disadvantage when negotiating settlements with actual polluters. However these provision are separate from the actual bond measure, and can be amended in subsequent legislation.

Passage of the bond measure won’t guarantee that more sites will be cleaned up immediately, but it will remove one of the obstacles government agencies use to delay implementation of hazardous waste legislation. The key factor in clean-ups will remain the ability of citizen and environmental groups to keep the pressure on both the government and industry.
Mass. Line

Readers of our article on the new Massachusetts hospital reimbursement program in the last issue can learn a lot more about the Bay State's health care system and what a dedicated group of local activists can accomplish by subscribing to Staying Alive!, the publication of Commonhealth, Boston's health activist group. Individual subscriptions are only $5; Sustainers and institutions have the opportunity to contribute $25. Send your check or money order made out to Staying Alive! c/o H.O. Building-Mezzanine, Boston City Hospital, 818 Harrison Ave., Boston, MA 02118.

Gay Health

The National Lesbian/Gay Health Education Foundation is carrying out a national lesbian health needs survey pilot study with a grant from the Ms. Foundation. They are seeking as varied a group of women as possible to fill out their questionnaire. It must be completed and returned by November 30. For further information, contact the NGHEF at 550 Cresthill Ave., Atlanta, GA 30306. Tel. (404) 892-2459.

Herstory

Lynda Madaras, author of Womancare: A Gynecological Guide to Your Body and other books, would like help for her book for Little, Brown on self-help and other alternative health care systems for women. She is looking for women with medical problems who were unable or unwilling to be treated by an orthodox medical doctor and turned to other forms of care. The problems needn't be strictly gynecological or obstetrical. If such women or their clinician would be willing to share details of these experiences with strict confidentiality, they can write her at 1341 Ocean Blvd., Suite 222, Santa Monica, CA 90401.

Enabling

Publications for Parents and Families and Publications for Persons Who Have Disabilities and their Friends are two new catalogues listing free and low-cost materials. The former is a listing of publications dealing with speech disorders, hearing difficulties, learning disabilities, and other disabling conditions. The latter is a compendium of publications for teenagers and adults who have had a stroke, laryngectomy, or other disorders.

Single copies of either or both are available free if you send a stamped, self-addressed envelope to the National Easter Seal Society, 2023 W. Ogden Ave., Chicago, IL 60612.

Making Health an Issue

Americans have become a fevered multitude of runners, joggers, and aerobic dancers, but are we really any healthier? Our hospital bills say no. More and more we face health risks of our own making. “To Our Health,” a special issue of Environmental Action magazine, looks at health in America. The 32-page November/December issue is filled with useful information, including an article on “Best places to live in America,” and advice from such people as Dr. Benjamin Spock, Pete Seeger, and Martha Graham on living the good life. Other articles cover a study that finally links toxic wastes with cancer, how the government is neglecting cancer prevention, and how office health hazards can be eliminated.


by Hal Strelnick

To judge these two books by their covers, each adorned with a dollar sign instead of snakes encircling the staff of the medical caduceus, we might expect parallel examinations and dissections of the burgeoning business of health care, which now represents more than 10.5 percent of our GNP. But all similarities end with the covers—and so does most criticism of the industry. The author of The Medical Industrial Complex, Dr. Stanley Wohl, is said by the publisher's promotion packet to be involved with emergency medicine at the Stanford University Medical Center and to be the first president of InfoMed Systems, a health care economics and management research company. In fact, the book grew out of Wohl's research for a major brokerage house on the stocks of medical corporations. "Not one to bite the hand that feeds," Wohl confesses in the first chapter, "I acknowledge that I made my way through medical school and purchased my first home with money I made on the stock market."

The critique that he subsequently mounts against the health care corporations generally has the teeth and bite of loose dentures. He so admires the entrepreneurs of these corporations and is so captivated by the ideology of private enterprise that he can no more examine the consequences of their actions than Oedipus could bear to confront the consequences of his own in Sophocles' tragedy. The Oedipus complex is the foundation of psychoanalysis; this book is based on a patchwork of pseudo-analysis, stock analysis (of both the Wall Street and cliché varieties) and, all too often, no analysis (the British and Canadian health systems are dismissed in a single paragraph).

The term "medical-industrial complex" has its roots in President Dwight Eisenhower's 1960 farewell address warning of the dangers of the "military-industrial complex"—defense contractors and munitions manufacturers allied with the three competing branches of the military and their supporters in Congress and the Pentagon.

In 1969 the Health/PAC Bulletin adopted the term "medical-industrial complex" to describe the interlocking interests of the for-profit insurance, drug, and supply corporations, the not-for-profit academic medical empires, and the public dollars that support their services and research. In 1970 Fortune used the term to explain the dramatic growth in medical costs. But Stanley Wohl has taken his cue from New England Journal of Medicine editor Arnold Relman's 1980 article on the "new medical industrial complex" that noted the blurring of the traditional separation between the organizations providing for-profit products and those offering not-for-profit services, especially through the growth of for-profit hospital and nursing home chains.

Dr. Wohl, like Dr. Relman before him, levels his most severe criticism at the encroachment by corporations on the prerogatives and control of the health system by physicians who, they argue, know what is best for patients and patient care. Like Relman, he defends the academic physician (and medical center) against the philistine, unprofessional interests of corporate profits:

Most physicians still remember their medical school professors whose brilliant clinical acumen and impeccable ethics set the standard for the conduct of medical practice...The...teaching hospitals steadily show the least profit, yet they clearly make the greatest contribution to the health care system...The quality of hospital-based physicians determines the quality of the hospital...

He even congratulates Hospital Corporation of America for having four doctors and a dentist on its 18-member board of directors.

Wohl believes "the corporations conquered because over the last twenty years everyone else fouled up. Government, the medical profession, insurance companies, and the so-called health experts and consultants had produced a money-sapping monster." Later he absolves physicians of their responsibility for excessive health costs, first by claiming they had no "input" and then by blaming the victims: "so long as Americans continue to eat too much, drink too much, and exercise too little, the bills...will continue to grow."

Such analysis begs the significant questions: Why have these corporations entered health care now? What has changed in the economy and/or the health system? Facts and details that might help provide answers are in the book, but such questions are never posed, let alone answered.

Wohl does go beyond Relman and does make a contribution to the study of the new medical industrial complex ("new" in the sense of the "new" Nixon of the 1970's). His medical industrial complex is, in fact, the corporate health care industry: 1) the corporate owners and managers of general and psychiatric hospitals, nursing homes, dialysis, rehabilitation, surgical, and sports medicine centers, and emergicenters; 2) the corporate owners of large medical partnerships; 3) corporate manufacturers and distributors of pharmaceuticals and medical supplies; 4) conglomerates with subsidiaries in health care; 5) large technology corporations that serve many sectors of the economy but account for major expenditures in health care (e.g., IBM, Hewlett-Packard, General Electric, etc.); and 6) new specialty corporations within health care, such as the genetic engineering firms.

The corporate survey which makes up the second half of the book is often arbitrary (Wohl even admits to including Sears, Roebuck for no special reason) and neglects altogether the author's own category of conglomerates with important subsidiaries in health, such as Dow, DuPont, Monsanto, Revlon, Cheesborough-Ponds, and McDonnell-Douglas. For the serious investor, he includes a chart that notes which stock exchange each corporation is traded on.

Beyond the stock market quotations...
and quarterly earnings, what is included in this survey can often be quite revealing and demonstrates significant research. For example, Wolh retracts the history of Beverly Enterprises, the nation’s largest nursing home chain, explains how Hospital Corporation of America secured a controlling stock interest in Beverly and how it set out on its joint venture with Upjohn’s home health care subsidiary. Two thirds of the cost of these classic examples of vertical integration, Wolh notes, is being paid by public funds. It will, however, take a dedicated reader to find these gems. The text is plagued with annoying errors and littered with clichés and mixed metaphors, as if the typesetter worked from a dictaphone recording without any intervening editing.

Those looking for a more insightful, less rhetorical analysis of the corporate growth and competition taking place in the context of the Reagan Administration’s attempt to deregulate and defund health care won’t find it in the Institute of Medicine volume. This is actually a collection of papers prepared for a June 1981 Institute workshop that led to a two year study on physician involvement in for-profit enterprises in health care, due for completion at the end of 1984. These papers were supported, in part, by the Hospital Corporation of America.

While Wolh’s book is journalistic and written in conversational style, these essays share an academic tone of caution, tentativeness, and circumspection. Wolh strikes the pose of the indignant academic physician; the Institute of Medicine has assembled a chorus of lawyers, economists, financial analysts, philosophers, and health care researchers (no doctors) to examine the hospital–doctor-patient relationship, overloaded with potential conflicts of interest, from every point of view.

The two most interesting chapters for me were Jessica Townsend’s five case studies on what happens in a community when a corporation takes over a local hospital and Harold Luft’s effort to demonstrate how different economists and physicians think on the question of economic incentives in clinical decision-making.

Townsend argues that the acquisition process—what was consulted and who had input—has been more important than the terms of the agreement when a corporate chain buys or manages a community hospital. She found that the communities she looked at trusted their corporation but not hospital corporations in general, just as patients trust their doctors but not doctors.

After noting that economists view decision-making in medicine with a telescope and physicians look at it with a microscope, Luft focuses on the “wide gray area” where clinical decisions are not black and white and the physician’s often-hidden economic interests reign. His essay addresses the gulf between the microscopic and telescopic views but neglects those political and economic blinders that prevent the 20/20 vision of the rectroscope (“hindsight” in doctor’s jargon) from being applied to the American health system.

While these two books are complementary in style and content, together they remain an incomplete picture of what is complex about the medical industrial complex—the interlocking interests of for-profit, not-for-profit, professional, and public institutions—and what has promoted the spectacular growth of the for-profit sector, often at the public’s expense. Neither examines the exorbitant return on equity guaranteed by Medicaid and Medicare to proprietary hospitals and nursing homes; the accelerated depreciation and tax loopholes of the two major Reagan era budget cuts, TEFRA and OBRA; the huge indirect subsidies for research and development provided by the National Institutes of Health to medical centers and pharmaceutical and biotechnology firms; or the growing tendency of publicly-trained and -funded scientists to translate their knowledge and expertise into equity positions in new biotechnology firms.

While all acknowledge the for-profit sector’s ready access to capital, no one discusses how the rules of the game have been written—and thus how the marketplace has been shaped—or how the policy makers in Washington plan to address the basic conflict between profit and equitable, quality health care. Clearly, in Reagonomics there is no such conflict between them, so no corrective policy is necessary. Before making policy, we still need to get the medical industrial complex in better focus.

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To the Editor:

Edgar Leonel Dominguez Izas, M.D., was on his way home from the clinic in Quetzaltenango, Guatemala last March when he was abducted by what eyewitnesses said was the army and taken away in a car. As of the end of October there was no word on his fate. Another doctor left the clinic the same month after he was threatened by “death squads.” Their crime seems to have been serving the poor.

Thousands of people have been abducted and/or murdered by the military in Guatemala, and as you have noted hundreds of thousands have been brutalized and frightened into exile. Since our government is the prime ally of Guatemala’s rulers, a letter to the head of state/Minister of Defence about this specific case will show not only that Americans are concerned about Dr. Dominguez (who may, like many Guatemalans, be suffering savage torture), but are prepared to exert pressure here to lessen U.S. support for one of several Central American dictatorships.

His address is General Oscar Humberto Mejia Victores, Jefe de Estado y Ministro de Defensa Nacional, Palacio Nacional, Guatemala, Guatemala.

Arturo Kaufman
New York

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James Crandall
Des Moines, IA

Hal Strelnick, M.D. teaches in the Department of Social Medicine at Montefiore Medical Center in the Bronx and is a member of the Health/PAC Board.

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Bennett, Cleaves, M. (MD), with Charles Cameron, *Control Your High Blood Pressure Without Drugs* (Garden City, NY: Doubleday & Co. Inc., 1984) $15.95


Miller, Irwin, *The Health Care Survival Curve* (Homewood, IL: Dow Jones-Irwin, 1984) $22.50


Sheldon, Alan with Susan Windham, *Competitive Strategy for Health Care Organizations* (Homewood, IL: Dow Jones-Irwin, 1984) $30.00


Affairs of the Heart —
An Update

Critics of U.S. health care often point to stagnant or increasing mortality rates as evidence that our system may do wonders for the financial health of providers but does not address many health needs of the public.

One response to this attack has been to cite the reduction in death from heart disease. Long the number one cause of mortality in the U.S., in the first half or so of this century the rate and aggregate numbers of deaths it caused rose steadily. However beginning in the 1970's the totals have gone the other way — spectacularly.

In 1982 deaths from stroke were down almost 50 percent from 1962 and deaths from coronary heart disease (CHD) had plunged 30 percent or more. Estimates of lives saved in the last decade alone approach 300,000 to 500,000. This trend is clearly cloudly. Any reduction in case fatality has the U.S. been doing right?

In any case, the corroboration of McCarron's findings by Laragh and the Puerto Rican study indicates at the very least that a lot more attention must be paid to the relationship between diet and disease — attention that is long overdue.

Our next column will continue this update and include a discussion of the 1984 guidelines issued by the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure.

Arthur A. Levin is Director of the Center for Medical Consumers, publisher of Healthfacts.
In other words, just as “management reform” in the private sector often occurs at the expense of workers, so cost control in government can easily become an attack on the social wage.

Here are some of the targets of Grace and his colleagues: 1) taxing federal subsidies such as food stamps and Medicaid (if efforts to limit eligibility fail) 2) cutting health care expenditures ten percent by 1989 through a mixture of caps and competition 3) reducing the overlap between recipients of food stamp and child nutrition programs 4) giving the private sector a crack at running the health services of the Department of Defense and the Veterans Administration 5) tightening the appeals process for people denied disability insurance and supplemental security income.

Most of these ideas are not new; social Darwinism has pervaded the entire Reagan Administration. Repetition doesn’t make them any better.