

Bedlam on the Streets Increasingly, the mentally ill have nowhere to go. That's their problem — and ours.

By Michael Winerip

Maybe they should have just stenciled it in large letters on Andrew Goldstein's forehead: "TICKING TIME BOMB. SUFFERS SCHIZOPHRENIA. IF OFF MEDICATION, RUN FOR COVER!" The news accounts of his arrest for pushing Kendra Webdale under a subway train in New York that first Sunday afternoon in January must have sent a cold shiver through the hundreds of psychiatrists, therapists and social workers who had treated this seriously mentally ill man.

They knew he was dangerous. In the two years before Kendra Webdale was instantly killed on the tracks, Andrew Goldstein attacked at least 13 other people. The hospital staff members who kept treating and discharging Goldstein knew that he repeatedly attacked strangers in public places. They knew because he had attacked them — two psychiatrists, a nurse, a social worker and a therapy aide in two years' time. Over and over, his hospital charts carried warnings.

5/6/98: High risk for violence. 7/31/98: Last 6-12 months patient has been acting aggressively and impulsively by striking out unprovoked.

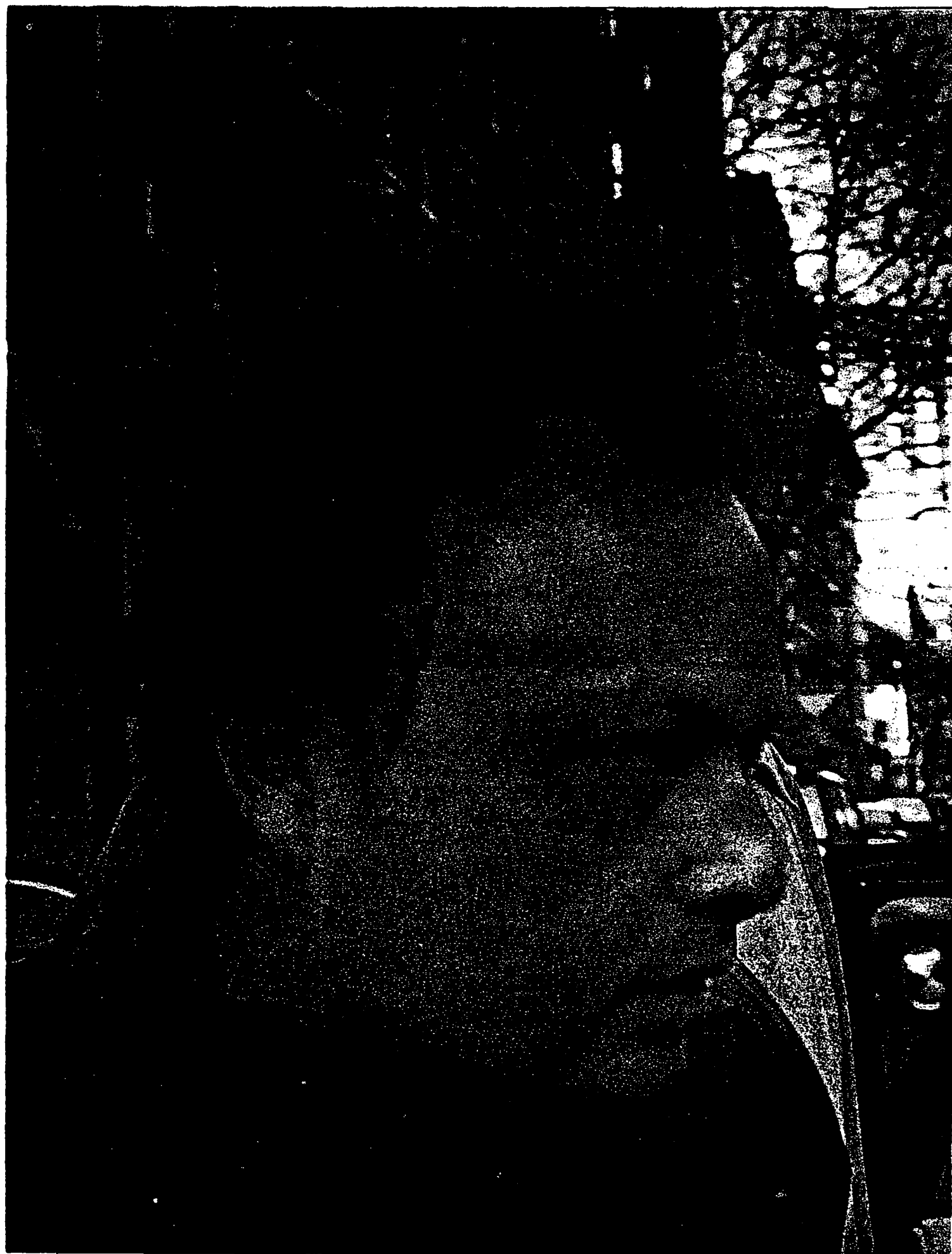
They knew. Long before this subway push and another one last month, the state of the nation's shattered mental-health system all but assured such calamities. Yet for each hospitalization — there were 13 in 1997 and 1998 alone — Goldstein was given medication, then discharged, often after just a few days, to live on his own in a basement apartment. And now the consequences were front-page news: "Horror on the Tracks," read the tabloid headlines, "The Face of a Madman."

They knew. He was hospitalized after assaulting a psychiatrist at a Queens clinic. *11/14/97: Suddenly, without any warning, patient springs up and attacks one of doctors, pushing her into a door and then onto the floor.* He was hospitalized after threatening a woman at a Waldbaum's supermarket; after attacking two strangers at a Burger King; after fighting with an apartment mate. *3/2/98: Broke down roommate's door because he could not control the impulse.* And particularly chilling, six months before Kendra Webdale's death, he was hospitalized for striking another woman he did not know on a New York subway. *6/20/98: Brought to E.R. by E.M.S. after patient lost motor control and punched a girl on the subway.*

Sometimes he was delivered to the hospitals by well-meaning police officers trying to get him treatment. More often, Goldstein walked into the psychiatric E.R. on his own, seeking help. This 29-year-old Jewish male (as the records describe him), who before schizophrenia set in had been so bright that he graduated from Bronx High School of Science, one of the city's elite public high schools, now was repeatedly explaining to E.R. doctors that he was confused or couldn't remember how to get home or that his brain had stopped working.

Six weeks before Webdale, on Nov. 20, 1998, he arrived at Jamaica Hospital in Queens, again asking to be hospitalized. *Walked in the E.R. complaining of hearing voices, people following him and being*

It didn't have to happen:
Andrew Goldstein leaving the
police station in January.



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inhabited by people. . . . "They removed my brain, I don't know why. I am hearing these voices telling me something will happen. . . . I cannot cope."

How psychotic was Goldstein when he was off his medicine? At various times, he has told psychiatrists that he was turning purple, that he had shrunk six to eight inches, that he had lost his neck, had developed an oversize penis because of contaminated food and that a homosexual man named Larry was stealing his excrement from the toilet "through interpolation" then eating it with a knife and fork. The voices seemed so real, so relentless, that on Nov. 24 a psychiatrist wrote, "He requested eyeglasses so that he will find the people talking to him."

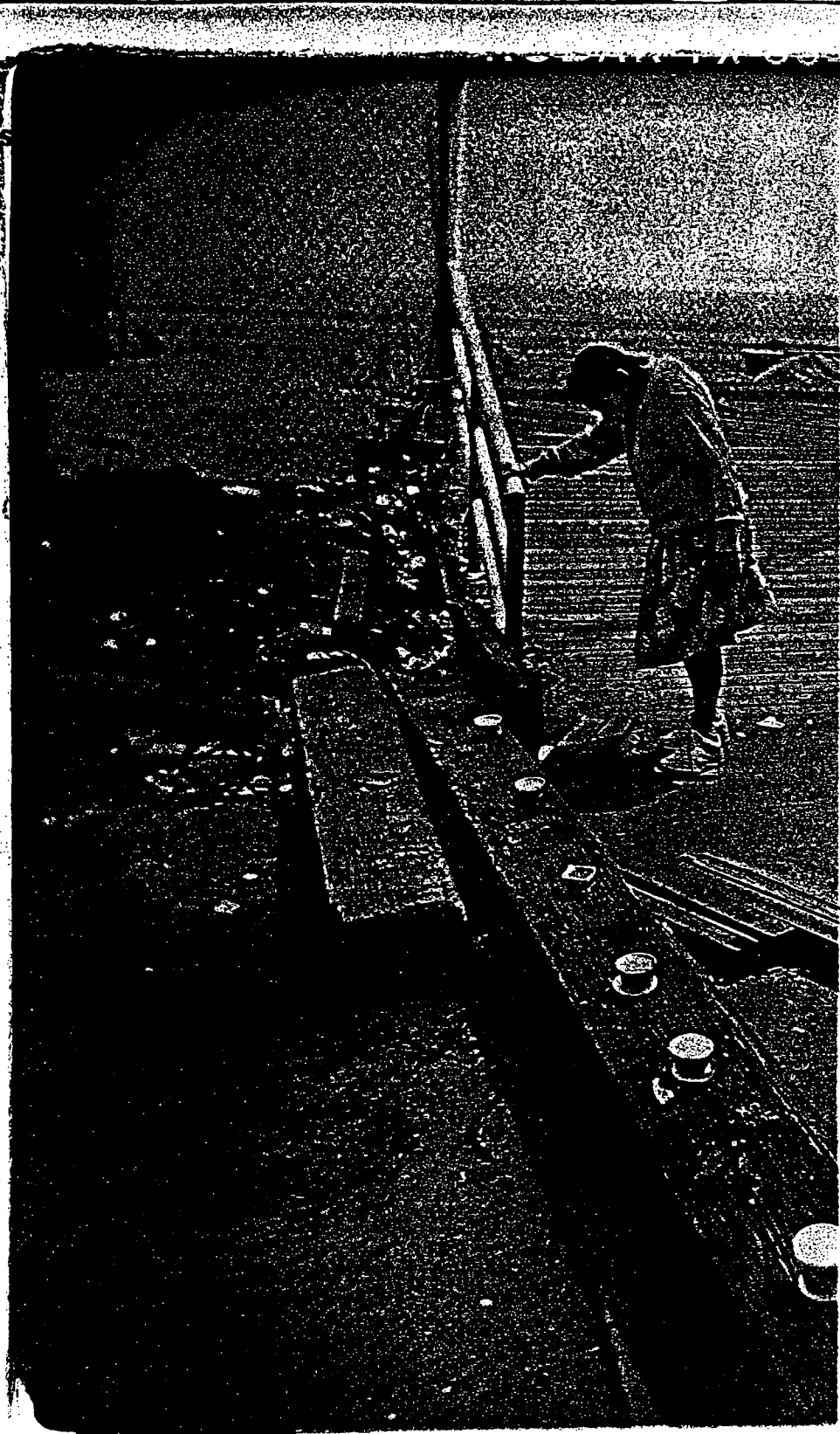
He Wanted Help

When a mental patient kills, there is often an outcry for tougher commitment laws, but this was not the problem in Goldstein's case. He signed himself in voluntarily for all 13 of his hospitalizations. His problem was what happened after discharge. The social workers assigned to plan his release knew he shouldn't have been living on his own, and so did Goldstein, but everywhere they looked they were turned down. They found waiting lists for long-term care at state hospitals, waiting lists for supervised housing at state-financed group homes, waiting lists for a state-financed intensive-case manager, who would have visited Goldstein daily at his apartment to make sure he was coping and taking his meds.

More than once he requested long-term hospitalization at Creedmoor, the state hospital nearby. In 1997, he walked into the Creedmoor lobby, asking to be admitted. "I want to be hospitalized," he said. "I need a placement." But in a cost-cutting drive, New York has been pushing hard to reduce its patient census and to shut state hospitals. Goldstein was instead referred to an emergency room, where he stayed overnight and was released.

Again, in July 1998, Goldstein cooperated with psychiatrists, this time during a monthlong stay at Brookdale Hospital, in hopes of getting long-term care at Creedmoor. Brookdale psychiatrists had a well-documented case. In a month's time, Goldstein committed three violent acts: punching the young woman on the subway; attacking a Brookdale therapist, a psychiatrist, a social worker and a ward aide; striking a Brookdale nurse in the face. This time, Creedmoor officials agreed in principle to take him, but explained that there was a waiting list, that they were under orders to give priority to mental patients from prison and that they did not

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Rockaway, Queens, is a shabby seaside resort of boarding houses and for-profit adult homes that have long been a dumping ground for state's mental hospitals. The district manager for the community board has been fighting the problem for years.

know when they would have an opening. Days later, Goldstein was discharged from Brookdale.

Another reasonable alternative would have been a supervised group home or single-room-occupancy hotel staffed by counselors around the clock. Goldstein repeatedly asked for such a placement, but openings are rare, since Gov. George Pataki financed no new supervised

community residences for the mentally ill during his first four-year term and just 200 S.R.C beds statewide. "Working on getting him a residence in Manhattan within the next three to six months," says a Dec. 16, 1998, note, 18 days before he pushed Webdale.

At the very least, Goldstein should have had an intensive-case manager, a state-financed



Goldstein's last hospitalization before Webdale was at North General, from Nov. 24 to Dec. 15. Because of cost-saving measures mandated under managed care, hospitals that operate short-term, or "acute care," psychiatric units are under great financial pressure to discharge patients within three weeks. So two weeks into his stay, on Dec. 9, even as Goldstein was still being described by North General's psychiatrist as "disorganized, thought-disordered ... talking to himself ... very delusional," the discharge team had already set his release for the next week.

Sure enough, on Dec. 15, North General discharged Goldstein with a week's supply of medicine and a form advising him to report to Bleuler Psychotherapy Center for counseling. This was like a bad joke — that a man so sick, with his history, would be sent into the community with so little support. At clinics like Bleuler, state financing is minimal. Social workers have large caseloads with no time to visit clients. Since September, Bleuler had supposedly

ing, the feeling disappeared and came back. ... I pushed the woman who had blond

A Confidential Case

Because of patient confidentiality laws, Andrew Goldstein's psychiatric file will become public, even when he goes to trial on the manslaughter charge. But it was given to the people who see his treatment record as a harrowing testament to the failure of the mental-health system.

There is a long list of institutions and individuals who should be held accountable for what happened to Goldstein and Webdale. At the top of that list belong Governor Pataki and the State of New York, for it is the state that, for the last 150 years, have had primary responsibility for citizens who are seriously mentally ill, and it is the states, beginning with institutionalization in the 1950's, that have consistently shirked that responsibility.

I felt a sensation, like something was entering me. ... I got the urge to push, shove or sidekick. As the train was coming, the feeling disappeared and came back. ... I pushed the woman who had blond hair.'

been treating Goldstein, but he had missed most of his appointments and had repeatedly gone off his meds.

It happened again: he missed two clinic appointments in late December. He stopped taking his medication. If he had had an intensive-case manager or a group-home counselor, or both, it would have been their job to find him and see what was wrong. At Bleuler, it wasn't anyone's job. Instead, on Dec. 26, a Bleuler worker mailed a form letter requesting that Goldstein phone the clinic by Jan. 6, 1999, or else his case would be closed.

On Jan. 3, 1999, at 5:06 P.M., the N train pulled into the station at 23d Street and Broadway. Kendra Webdale was a vivacious 32-year-old who had come to the city three years before from upstate and was working as a receptionist with dreams of landing a big job in the music industry. To Andrew Goldstein, she was another stranger. He never saw her face. As he later wrote in his confession: "I felt a sensation, like something was entering me. ... I got the urge to push, shove or sidekick. As the train was com-

With the introduction of antipsychotic medication, state hospitals nationwide began turning patients into the community. There was a good deal that was hopeful about this; by many state hospitals had become snake pits, the states never created the outpatient services that were supposed to replace those hospitals, landing many of the seriously mentally ill on the streets. In 1953, there were 93,000 patients in New York's state mental hospitals; today the number is 6,000 and dropping. And while last patients are often very troubled (one-quarter have criminal backgrounds), the state's special discharge teams continue to turn them out the door — even when there is no place for them to go. The New York State Office of Mental Health provides only 21,000 supervised community beds. And during Pataki's first term, the state financed just 200 new beds with 24-hour supervision.

The problems in New York are the problems in virtually every state. Fewer than half of Americans with schizophrenia receive adequate care, according to a 1998 national study.

caseworker whose job would have been to visit him daily at his apartment. On Dec. 11, 1998 — 23 days before Webdale — a North General Hospital social worker wrote that an intensive-case manager was needed, because "patient is unable to manage his money, does not take care of himself and becomes noncompliant with meds." But that waiting list was months long, too.

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Bazelton Center for Mental Health Law estimates that spending by the 50 states on treatment for the seriously mentally ill is a third less today than it was in the 1950's (once numbers are adjusted for inflation and population growth).

While this is a danger primarily to the mentally ill and their families, who bear the brunt of the states' neglect, it is also a danger to the public. From the many studies on mental illness and violence, we know that treated mentally ill people living in the community are no more a risk than the general population. But if a person is off medication and psychotic, he becomes a greater risk for violence; if you add substance abuse to that psychosis, the risk grows significantly, and one of the strongest predictors of whether a mentally ill person will be violent is whether he has been violent before.

It is the most sensational cases of the untreated-turned-violent that make headlines: Russell Weston Jr., ruled incompetent to stand trial for killing two U.S. Capitol police officers; Sergei Babarin, who murdered a man and a woman at a Mormon library in Utah; John Salvi 3d, who shot to death two abortion-clinic workers in Brookline, Mass.; Mark Bechard, judged criminally insane for killing two nuns in Maine, and last month, another New York subway case, Julio Perez, charged with attempted murder for pushing a father of three in front of a rush-hour train, severing the man's legs.

Even in such criminal cases, the failings of the mental-health system are rarely exposed because most psychiatric records never become public. A few examples among many I looked into: in February, newspapers reported that Calvin Bostick, a homeless man, was arrested for setting fire to the Church of St. Anthony of Padua in Queens. But only from confidential state documents would you learn that between 1967 and 1998, Bostick had been treated and released 25 times from five state psychiatric institutions. And when he was out in the community, he built a criminal record of 18 convictions — for arson, assault, robbery and drugs.

When Kaid Farhn was arrested in December for nearly choking to death a 3-year-old girl standing with her mother in a Brooklyn subway station, it did not make news. He was recently found unfit to stand trial and confined for treatment — the second time in two years. In 1997, Farhn was arrested for assaulting three people, judged unfit and sent to the state psychiatric hospital on Staten Island, where, according to state documents, he was released after three weeks.

There are now far more mentally ill in the nation's jails and prisons (200,000) than in state hospitals (61,700). With 3,000 mentally ill in-

mates on Rikers Island, the New York City jail is now, in effect, the state's largest psychiatric facility. In a year's time, according to a study by the Urban Justice Center, 15,000 prisoners in Rikers are treated for serious mental illness.

Some, like Goldstein, are awaiting trial on violent crimes. But far more have been too sick to cope alone in the community and were arrested for shoplifting, disturbing the peace, public lewdness, intoxication, drug use, fare-beating. Many would never have landed behind bars if there were adequate community care.

And that is the larger, quieter scandal behind the states' failure. While some of the untreated are dangerous, far more suffer unnecessarily from their own illnesses. After years of declining numbers, the population of homeless adults is rising again in New York City shelters; it is estimated that of the 7,200 homeless, 2,200 to 3,000 are mentally ill. These days, commuters are noticing more disoriented people begging on the city's subways; police precinct commanders report a growth in "E.D.P." (emotionally disturbed persons) cases. "The number of disturbed people out there is definitely creeping

A community-program success story: A schizophrenic and former crack user who has done prison time, Thayer Gamble has cleaned up his act with the help of Pathways to Housing. His caseworker makes sure he keeps it clean.

back up," says Mary Brosnahan, director of the Coalition for the Homeless in New York Ci

A Return to the 1840's

O n a winter's night, I visited the city's Atlantic Avenue shelter in Brooklyn — a run-down, dark, drafty military armory that houses 300 men. It is a mean, hard place; the previous shelter manager was assaulted

there and never returned to work. Everywhere disoriented men were talking to themselves, staring into space, rocking back and forth, their faces hidden like shades in hooded sweatshirts. A man with mangy hair, a foul smell and red plaid pants walked up to a top-ranking city official and explained that he was Albert Einstein. "I'm paranoid," Einstein said. "I think I did something I didn't do."

To Muzzy Rosenblatt, then the city's Acting Commissioner of Homeless Services, it is the mental-health system that seems crazy. "I shouldn't have mentally ill people in our shelters," he says. "They should be in mental health programs."

he hundreds of psychiatrists, therapists and social workers who had treated Goldstein knew he was dangerous. the two years before Kendra's death he attacked at least 13 other people.

The state's Commissioner of Mental Health under Governor Pataki is James Stone, and advocates for the mentally ill have been so frustrated by his department's failure to finance more community-housing programs these last four years that they bitterly refer to this period as "the Stone Age." Indeed, in some ways we're back to where we were in the 1840's, when the legendary reformer Dorothea Dix set out to shame Massachusetts legislators into doing something for the mentally ill, who were locked away in the basements of local almshouses and jails. In 1843, Dix completed a 32-page exposé, "Memorial to the Massachusetts Legislature": "I proceed, Gentlemen, briefly to call your attention to the present state of Insane persons confined within this Commonwealth in cages, closets, stalls, pens! Chained, naked, beaten with rods and lashed into obedience!"

Dix described the care of each mentally ill person she had seen: "Saugus poorhouse: Apartment entirely unfurnished; no chair, table, nor bed ... cold very cold. ... On the floor sat a woman, her limbs immovably contracted, so that the knees were brought upward to the chin; the face was concealed, the head rested on the folded arms." Her accounts reminded me of the basement apartment in Brooklyn where Andrew Goldstein lived last year, as described in Jamaica Hospital records: "One-room unit, nonfunctioning bathroom, unsafe electrical wires hanging from ceiling, no electricity, foul smell of dead and decaying mice, lock to room broken. In general, conditions unsuitable for living."

Though a moralist, Dix understood that it was all about money, as David Gollaher points out in his biography of her, "Voice for the Mad." The 1840 Massachusetts census counted 978 "lunatics"; the two state asylums had only 353 beds. The state, Dix implored, must appropriate 60,000 to create beds for the 625 neglected; cities and towns were too small and too poor to finance their own asylums, she argued. Shamed into it, Massachusetts found the money. And that was what cemented the states' responsibility for the seriously mentally ill.

One hundred and fifty years later, neither the Giuliani administration nor the nonprofit agencies that rely on state funds to provide housing for the mentally ill have been able to shame Pataki into doing the same for them. The Republican

realized we weren't going to get a lot from this Governor. He just wasn't into it. So we were happy to get anything."

In 1990, when the first New York/New York agreement was signed, advocates celebrated. This time they held a protest rally, on April 29, picketing Governor Pataki's New York City office. "Pataki where are you?" chanted the 500. "Remember the homeless!"

A Broken Contract

Neither Governor Pataki nor Commissioner Stone would be interviewed for this article, and the spokesman for the state Office of Mental Health, Roger Klingman, requested written questions and supplied written responses. He would not comment on the Goldstein case,

because "state mental-hygiene law does not permit us to discuss information from a patient's clinical record." He described the state system as "large and varied," and wrote that New York's community housing program is "one of the largest if not the largest such system in the country."

Unfortunately, there are no comparative qualitative studies of state systems, and efforts to create national standards are in the early stages, says Clarke Ross, a public-policy expert at the National Alliance for the Mentally Ill. However, Ross says, any such measure would include the numbers of mentally ill in jails and prisons, as well as homeless, and in those areas, New York also has the dubious distinction of being a leader.

One measure of how low the national standard is when it comes to caring for the seriously mentally ill is to compare their deinstitutionalization with the movement of mentally retarded adults into the community during the same period, which is one of the more impressive social revolutions of our time.

In the early 1970's, after Geraldo Rivera sneaked a camera into the Willowbrook state institution for the mentally retarded on Staten Island, exposing snake-pit conditions, family members sued. Gov. Hugh Carey could have got the state off cheap by agreeing to improve Willowbrook, but instead signed a consent decree that forged a remarkable social contract for the mentally retarded: for each person discharged, the state would finance a group home or an apartment bed. That compassionate agreement helped to set a national standard.

By 1998, the state had financed 32,000 community beds for the mentally retarded — even though those beds are two to three times as costly as the 21,000 available to the mentally ill. (Mentally retarded residents need far more staff



Left: Advocates for the mentally ill picketed Governor Pataki's New York City office in April. Right: Julio Perez, accused of pushing a man in front of a rush-hour subway train.

Mayor is no Dorothea Dix, but Rudolph Giuliani does understand the problems of having lots of disoriented people on the streets and subways in a city where so many live so close together. Two years ago, he asked the Governor to renew a 1990 housing agreement for the mentally ill between the city and state, known as New York/New York. That agreement, made between Gov. Mario Cuomo and Mayor David Dinkins, provided 3,600 new units of housing for the mentally ill in the city, with the state financing two-thirds and the city the remainder. It had a big impact. At the time, there were 9,300 adults in city homeless shelters. By the mid-1990's, when the New York/New York beds were opened, the shelter census dropped to 6,000.

But those beds are full now, the homeless population has risen and so the Mayor asked this Governor to help create New York/New York II. Giuliani was willing to put in \$85 million for new construction — to match the city's 1990 share — and hoped that Pataki would create a new program on the scope of the first.

Not this Governor. For two years those New York/New York II talks were stalled, with Pataki unwilling to commit more than \$45 million for construction — a third of what city officials say was needed. This despite personal appeals to the Governor from an array of prominent New Yorkers, including John Cardinal O'Connor. Finally in mid-April, the Mayor gave up on the Governor's doing more and put the best face on a watered-down agreement. In the end, for the state's share, Pataki agreed to build just 500 new supervised S.R.O. beds over five years — on top of the mere 200 already in the state budget; in contrast, during Cuomo's last five years, the state financed or pledged 3,200 such beds. As one Giuliani aide told me: "A long time ago we

There are now far more mentally ill in the nation's jails and prisons (200,000) than in state hospitals (61,700). With 3,000 mentally ill inmates, Rikers Island in New York has, in effect, become the state's largest psychiatric facility.

support.) Although Pataki hadn't come close to matching his predecessors — the list of mentally retarded adults in New York waiting for housing grew to 6,000 by last year — he has always at least paid lip service to the social contract forged by Carey, building the mentally retarded between 480 and 1,100 new community beds each year.

Then last June, just as Pataki's re-election campaign was getting under way, newspapers in suburban Westchester County reported that there were 26 mentally retarded adults found living in homeless shelters there — prompting outrage. Pataki's response was swift. Ten weeks before the election, he suddenly announced a program to finance 5,000 new community beds for the mentally retarded called New York Cares. It means that community beds built or pledged for the mentally retarded now outnumber those for the mentally ill by some 15,000. Indeed, the Governor's 1999 budget calls for a \$40 million increase in spending for the mentally retarded; for the mentally ill, a \$27 million cut.

Why haven't we forged the same social contract for the mentally ill? After all, there are as many as 3,000 mentally ill in New York City's shelters. One reason has to do with timing. In the mid-1970's, when Governor Carey signed the Willowbrook consent decree, there was already a well-organized lobby for the mentally retarded. But the mentally ill had no lobby yet; the National Alliance for the Mentally Ill, which today boasts more than 200,000 members, was not founded until 1979. It wasn't until the mid-1980's, after deinstitutionalization had created a large, menacing homeless population, that New York began financing a substantial number of community beds for the mentally ill. But by then, the Reagan revolution had set in, activist judges were no longer in favor and government spending for the poor was in decline. Just as new community-housing programs were showing real success, money was drying up and advocates couldn't find a judge or governor to forge that social contract for the mentally ill.

In the early 1990's, I spent two years all but living at a well-run, state-financed group home for a book on the mentally ill. What I saw made me a believer in quality community programs and in the nonprofit agencies that use state money to run them. There were problems at the home, but they did not spill into the streets, because counselors were there to defuse the crises.

Today there is an impressive array of state-financed community models, from the heavily regimented to the lightly supervised, that have been developed by nonprofits: group homes for mentally ill substance abusers that use an abstinence model and have 24-hour supervision; S.R.O.'s, where people have their own rooms, share kitchens and get support from casework-

ers and psychiatrists with offices on the premises; rent-subsidy programs to pay for an apartment in an affordable building in the community, with a case manager who might visit as often as every day or as rarely as once a month.

The programs are so varied because the needs of the mentally ill vary, too. Among the least restrictive is Pathways to Housing, a program based in Harlem and Queens, which gives homeless mentally ill people who have long resisted treatment apartments even if they still have a drinking or drug problem and do not want to take medication. They are assigned a case manager who sees them regularly, making sure their problems with meds or substance abuse are reasonably under control. Though many Pathways residents had been homeless for more than a decade, 88 percent were still housed in this program after five years.

Thayer Gamble, 43, is one. Talk about a time bomb: he is schizophrenic, was suicidal, used crack and has been imprisoned several times. Four years ago a hospital social worker referred him to Pathways, which gave him an apartment and a caseworker, Ben Tallerson. Tallerson visited Gamble's Harlem apartment regularly. Because Tallerson knew Gamble, he realized one reason Gamble had trouble taking his medication properly. "He can't read," Tallerson says. "He didn't know what it meant to take meds A.M. and P.M." Tallerson drew it out for him, the sun for A.M., the moon for P.M. And two years ago, when Gamble started on crack again, Tallerson noticed. "When Thayer's going good," he says, "he has clean habits, he keeps himself clean, his apartment is clean. Now I start seeing his physical appearance is sloppy, he's smelly, he's hanging on the streets." Tallerson urged him into a detox program. As Gamble says, "I have his beeper number — if I'm having a problem at 3:30 in the morning, I can call Ben."

THERE ARE THOUSANDS OF MENTALLY ILL NEW Yorkers whose lives are better because of state-financed programs like Pathways — it's just that success is less visible than failure. Cecil Dozier, 44, panhandled at the corner of Bleeker and Thompson in Greenwich Village last fall. He is now in a program for mentally ill substance abusers run by Volunteers of America. Bladimir Lopez, who slept by the Dumpster at a McDonald's

on 125th Street, is in a supervised S.R.O. for a mentally ill run by the Center for Urban Community Services. So is Robert Whynot, who used to beg on the subways until he made \$35, then bought himself a bag of heroin, half a gram coke and a metro card ("so I wouldn't get arrested for fare-beating"). Now for the first time, 40, he is getting treated for manic depression.

Even the New York City shelter system has made considerable progress, converting 1,000 shelter beds to mental-health-service beds run by nonprofits. These community programs cost between \$10,000 and \$43,000 per person, per year. All, however, are cheaper than a year at a state hospital (\$135,000) or Rikers Island (\$69,000).

The Push to Discharge

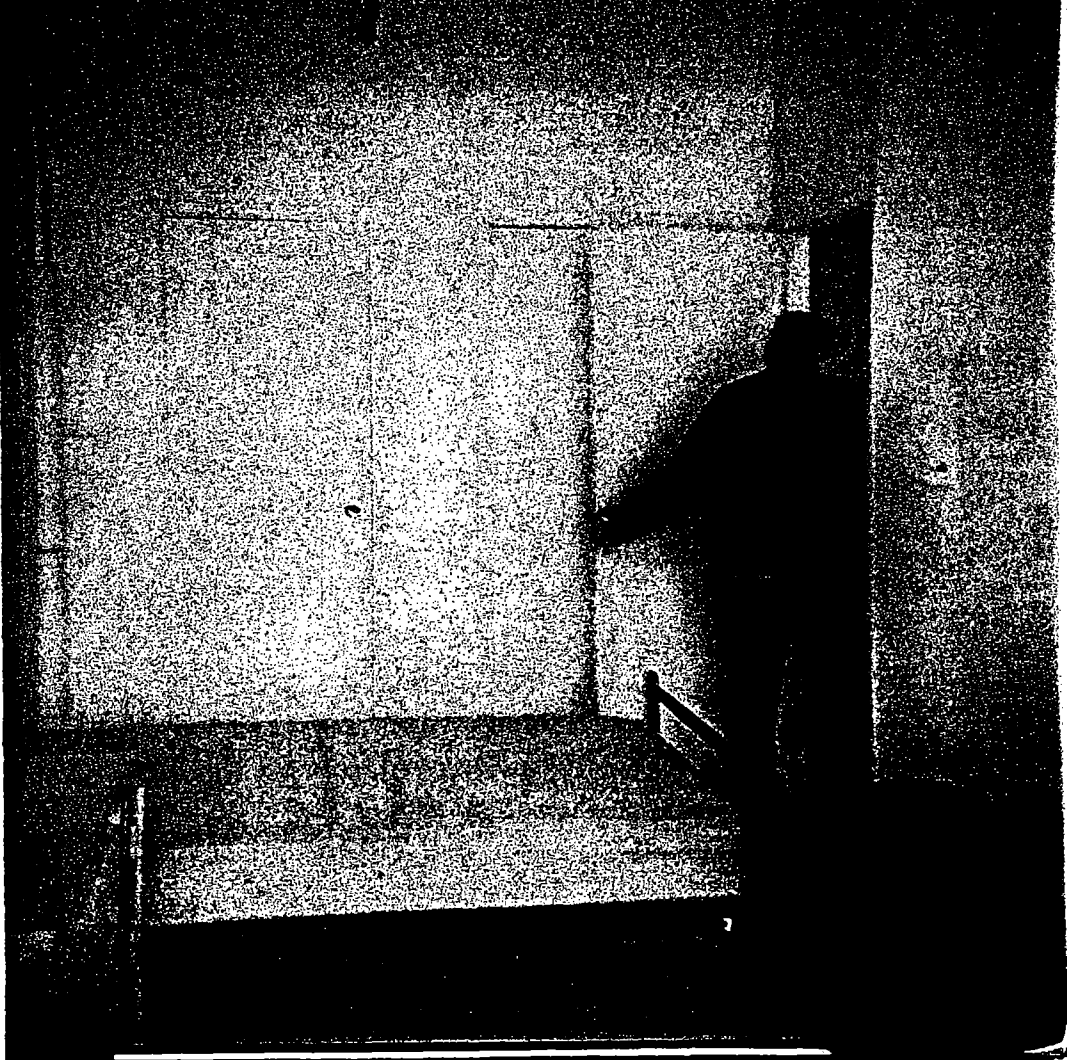
In 15 years of reporting on mental health, I have never seen the system in such disarray. Unprecedented cost-cutting measures are undermining safety valves that had long been in place. I count six dangers — for the mentally ill and the public — that have come into play in the last few years.

Danger 1: The last 6,000 long-term hospital patients that the state is working so hard to discharge are twice as likely to have a criminal background as patients from a decade ago.

Danger 2: While many of these patients continue to live in 24-hour supervised community residences, those beds are full. Even if the first New York/New York II beds open as scheduled, more than a year from now, there won't be anywhere near enough to absorb these new discharges, alone the growing number of homeless.

Danger 3: Psychiatric wards of general hospitals used to have the flexibility to keep a patient like Goldstein for months or transfer him to a state hospital for long-term care. But state hospitals are now taking few admissions, and managed care is pressing the general hospitals to discharge within three weeks. The five acute care hospitals that treated Goldstein can receive up to \$700 a day during those first weeks. But after that the medicated schizophrenic is usually considered "stable" by insurance companies, and compensation can drop to \$175 a day or be denied altogether. And even at \$175 a day, hospitals lose money. As a result, there is a revolving door for patients, who quickly lapse without community support.

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Though its failures are more visible, the state can make a difference: Robert Whynot, another success story, used to beg until he had enough money to buy drugs; now, at 40, he is living in a supervised S.R.O. and finally getting treatment for manic depression.

Danger 4: There are a record number of mentally ill in prisons and jails now being released — without any discharge planning.

Danger 5: The crackdown on Federal disability and welfare benefits will leave more mentally ill people with no Government support.

Danger 6: Government watchdog agencies like the Commission on Quality Care for the Mentally Disabled in New York have had their budgets cut and their jurisdictions narrowed in recent years. Over the last decade, the commission's staff has been reduced 25 percent. It is far less likely today to undertake major inquiries. During Cuomo's administration, the Legislature authorized the commission to do a sweeping investigation of the adult-home industry; that authorization has not been renewed.

THE REASON THE MENTAL-HEALTH SYSTEM behaves so irrationally is usually money. There is a rush to close state hospitals because that saves

money, but there is no incentive to build the badly needed community housing to replace them because that costs money.

The Pataki administration has given each state hospital an annual census-reduction goal. Mimi Koenigsberg was a social worker at Manhattan Psychiatric Center for 24 years, and in that time she never saw a push for discharges like the one begun in early 1998 by the hospital's director, Eileen Consilvio. "We started having these weekly discharge meetings," Koenigsberg recalls. "She'd say: 'Why isn't so-and-so going, he's been ready for weeks; this one's been ready for months. . . . Just get them off the census.'"

Klingman, the state mental-health-office spokesman, says that these meetings are conducted "to assure that discharge planning is proceeding appropriately." But the process plainly worried doctors at the Manhattan state hospital, where more than half the patients have a criminal record. According to minutes of a March 17, 1998, meeting of the psychiatry staff, "In the

need to reduce census it appeared to some present that they were being ordered by nonmedical staff to discharge patients prematurely."

A measure of how difficult these last patients are and how indifferent the state can be came in the form of a December ruling, by the New York State Labor Department, that Hudson River Psychiatric Center in Poughkeepsie is a hazardous workplace. It was the first such ruling in state history. While Klingman dismisses the case as a union ploy, the Governor's own labor department noted that state "employees have suffered broken bones, bites . . . and have been choked until they were unconscious" by patients. The report said that most injuries to workers came when wardens were below minimum staffing levels.

In one case, a single patient assaulted aides and nurses 37 times over two months. The local union president Judy Watts-Devine, repeatedly asked James Regan, the hospital director, to transfer the patient to a high-security facility for violent cases, but was ignored. And then Mary Veltre, a nurse, became the 38th case: she was kicked in the pelvis and taken to a local emergency room. At that point, Watts-Devine told the director, "I'm going to call every TV station and every newspaper unless you get this man out of here." And he did.

Still, in the next few years, the state hopes to reduce its long-term census from 6,000 to as low as 3,700. With so much pressure from Albany to release, discharge teams routinely mislead the nonprofit housing providers about the severity of patients' problems, in hopes of arranging a placement quicker, in a less supervised setting, no matter how inappropriate. The Colonial is a run-down hotel on 112th Street in Manhattan. Colonial tenants complain of filthy, smelly conditions, fights in the narrow hallways and people living crowded into small rooms. Rockland Psychiatric Center acknowledges discharging 75 to 100 patients to the Colonial in recent years. Elizabeth Kane, a tenants' lawyer for the Goddard Riverside Community Center, called Rockland at one point to complain. "I didn't know if they realized what a dangerous, stupid place it was to send a fragile person," she recalls. "They said, 'We know, but we don't have any choices.'"

Even the building manager, John Klein, who denies tenants' complaints, says: "I don't think you'd want to live in a . . . Continued on page 56

MENTALLY ILL

Continued from page 49

building like this. The problem is, there's no place for these people."

On Dec. 30, 1998, Rockland discharged a 43-year-old man to the Colonial. His sole support was a case-management team. Diane Sonde, who oversaw it, argued that the man needed a 24-hour supervised residence. Rockland disagreed.

The state never told Sonde's team key details of the man's history: that he was so sick that he had been in state hospitals 32 of the last 34 years; that he had a history of sexual assault; that he had been transferred to a high-security state facility four times because he was too dangerous for a regular state hospital.

After a few days at the Colonial, the man cornered a woman on Sonde's team, sexually exposed himself and threatened her. He was immediately returned to

Rockland. Only then did Sonde begin to piece together his real story. Nor was it the first time that the state had tried dumping this troubled man: in August 1998, Rockland discharged him to a city homeless shelter, only to have him walk back into a city hospital two days later, asking for help.

It is not that community programs won't take tough cases but that they want adequate resources from the state. A few years ago, Kingsboro Psychiatric Center in Brooklyn sent a man to a discharge interview at the Institute of Community Living, a large nonprofit housing agency. The state's two-page summary mentioned that the man had previously tried suicide. What the state summary did not mention was that the suicide attempt came after the man murdered his father. The community program learned this while interviewing him and confronted state officials, and he was re-

turned to Kingsboro. Klingman claims that Kingsboro officials didn't know the man had committed a murder because it was part of his juvenile record and was sealed. In a year, Kingsboro tried again, but this time the nonprofit agreed to take him only if he was in a 24-hour supervised residence with an intensive-case manager. And the state agreed.

All the big nonprofit community providers say the same thing: they can't trust state hospitals to tell the truth. "They mislead us," says Steve Warren, director of Services for the Underserved, a nonprofit with 800 state-financed beds. "They'll fudge on people with arson and sexual crimes. They're trying to package them in the best way they can, to get them out."

An Unnecessary Death

The sad saga of a schizophrenic 51-year-old named Peter Fazio, a long-term pa-

tient at Manhattan Psychiatric Center, illustrates the consequences of the state's relentless push to discharge. Before his schizophrenia hit, in the 1960's, Fazio was an A student at Bergen Catholic in suburban New Jersey and won a full scholarship to Manhattan College. After the illness, he was wild. He was estranged from his family, at one point holding his mother hostage for five days before police arrested him. He lived in Bowery flophouses until he murdered another resident, suffocating the victim by shoving a sock into his mouth. At the time, the police were struck by how much other flophouse residents despised Fazio.

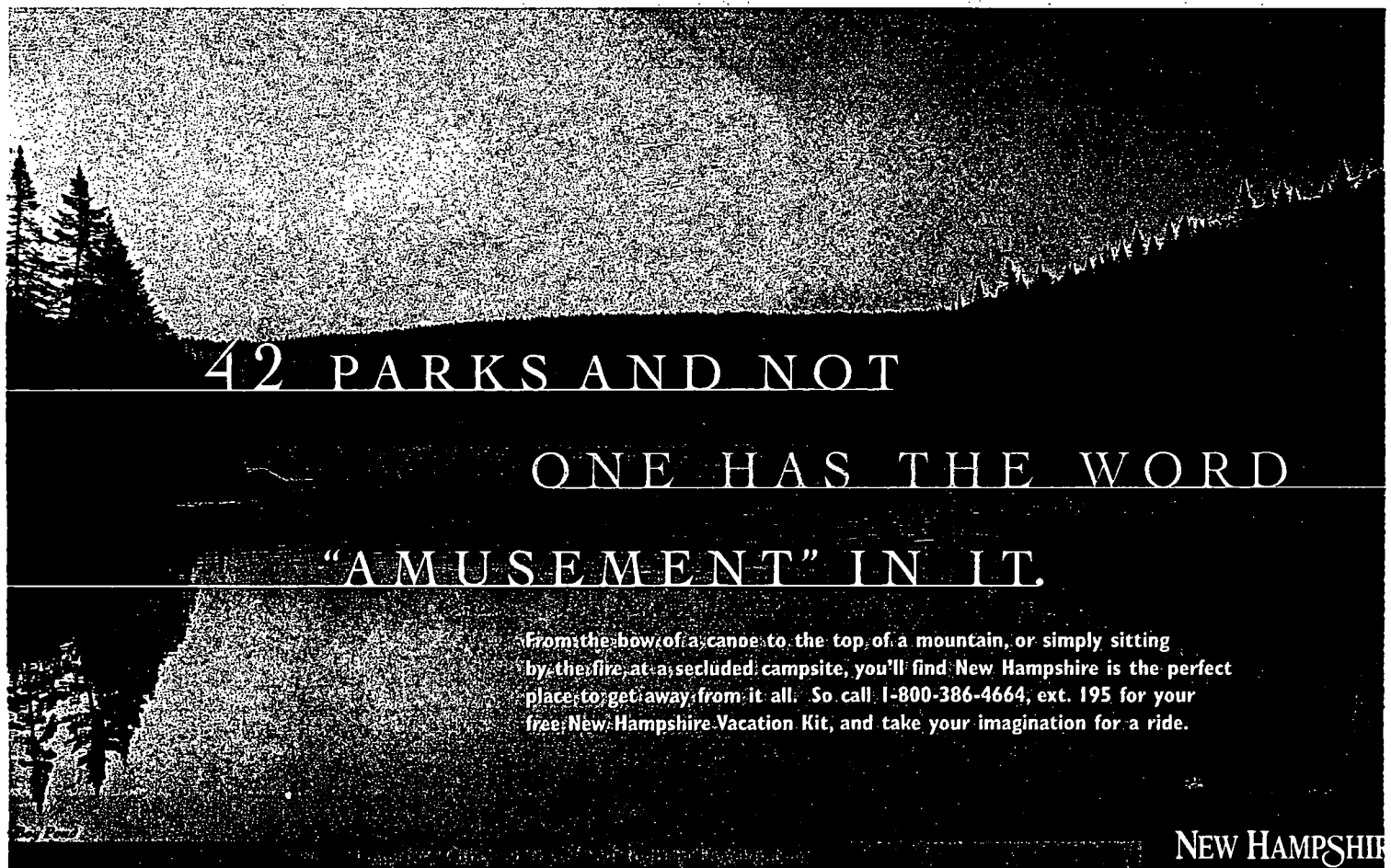
In jail, he stopped eating and was kept alive by a feeding tube. At Attica prison, he tried hanging himself in 1986. For the next two years, he later told a therapist, he planned how he would kill himself after his prison discharge. In May

1988, two days after that release, he slit his chest open with a scalpel, then stuck a boning knife into his heart. Miraculously, he lived, and was sent to Manhattan Psychiatric, where he spent the next 10 years. While still a troubled patient — record describe him as "sadistic" and "hostile" to fellow patients, as repeatedly pacing the halls, paranoid and arrogant — for the first time, he found a niche. He relished waking early to read the newspaper, sold bread from a little cart, got along with staff members and enjoyed grounds privileges.

When discharge was discussed, he commented "There's nothing more to enjoy outside." When pressed, he repeatedly threatened suicide. A social worker's note describes talk in January 1997 about discharge: "I asked about suicide. He said, 'Yeah, I'd basically go that route.'"

Hospital officials were

Continued on page 6.



42 PARKS AND NOT

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NEW HAMPSHIRE

MENTALLY ILL

Continued from page 56

well aware that Fazio had repeatedly threatened suicide if released. "When discharge planning is discussed," says a May 1997 note, "Fazio retreats." The note continues: "I will hurt myself. Alert: He is a serious risk."

In the months leading to his final night at the hospital, July 26, 1998, Fazio "complained he and other patients are being pushed by the administration to be discharged whether they are ready or not," according to records. During therapy he asked, "Is the reason they're pushing discharge now that they want to save money?"

For a few months, the record indicates, he was more positive about leaving, but by spring 1998, as the staff pressed, he is described as "depressed" and "not very happy or ready to talk about discharge." He worried that people in the community would know he was a murderer. In May, he told a case manager that twice before at the hospital he had tried suicide but had mentioned it to no one. Still the staff pressed, and on June 3 a discharge team, sent to the hospital by the state to lower the census, indicated that Fazio was ready to go.

On July 6, he was taken to visit a community residence, though he refused a placement there. On July 12, an aide noted his "regression" and "isolation," and a July 22 note mentioned his ambivalence and fear. On July 25, his next to last night at Manhattan Psychiatric, he stayed in his room at dinnertime, according to a hospital worker I interviewed: "He says, 'I'm being discharged, I really don't want to leave.' He was very depressed."

The next evening, Fazio again did not go to dinner, but this time was found in the bathroom, "in a pool of blood," a final hospital note says. "Body was cold to the touch." Using a razor,

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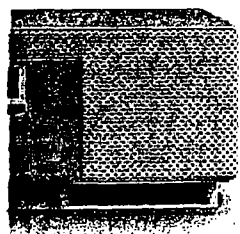
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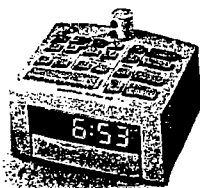
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he had cut a wedge out of
his neck, piercing his jugular.

The story has an adden-
dum. The state's quality-
care commission did a brief
report on Fazio's suicide,
finding "no deficiencies" by
the hospital. The report
said, "We found no evi-
dence that Mr. Fazio had
threatened suicide since
mid-1996" (though in Fa-
zio's hospital notes I count
seven suicide threats in
1997 alone). The report
found "nothing signifi-
cantly unusual in the life of
Mr. Fazio in the weeks or
days prior to his death" and
concluded that Fazio's
death was "unpredictable,
thus not preventable."

The report offered no
theory as to why Fazio did
kill himself. However, it did
mention that two hospital
workers who had talked to
the media were disciplined
for violating the confidenti-
ality of the dead man.

Off the Streets

Rockaway, Queens,
is a shabby seaside
resort of old
boarding houses
and for-profit adult homes
that have long been a dump-
ing ground for the state's
mental hospitals. Jonathan
Gaska, district manager for
Rockaway's community
board, has been fighting the
problem for years. "There's
no supervision — you have
sick people urinating on the
lawns," he says. "We have a
guy who walks around with
a mop on his head. You feel
sorry for people like that.
They act odd, they dress
odd and they hang around
outside all the time — it
keeps people away." To dis-
courage the mentally ill
from sitting on the benches
in front of the Park Inn
adult home, the benches
were removed. Now the
mentally ill stand in front of
the Park Inn.

A few years ago, Steve
Warren, the director of Ser-
vices for the Underserved,
offered to take over a partic-
ularly bad adult home and
run it properly. He took civ-

ic leaders to see housing
programs that he ran all over
the city. "They were good,"
Gaska says. "Warren was so
open. Everyone's like,
'What's the deal?' We're al-
ways being lied to." When
Warren started to redesign
the Rockaway adult home,
he spoke to the home's res-
idents about why they were
always on the street. "You
know why?" Warren recalls.
"There were 125 people
crowded in that adult home,
two or three to a room. To
get privacy, the street was
the only place to go."

With a \$1.2 million state
grant, he redesigned the
place, reducing the size to a
71-bed S.R.O. where every-
one has a small apartment.
There are also several
lounges and recreation areas.
The state provided financing
for an extensive staff, includ-
ing eight case managers, two
substance-abuse counselors,
a psychiatrist and a nurse.
The facility costs the gov-
ernment \$25,000 per person,

per year, three times the sub-
sidy for one of those awful
adult homes.

"The place is as good as
advertised," Gaska says.
"The state has to be able to
make other places do what
they're doing."

ONCE, FOR A YEAR, IN 1994,
Andrew Goldstein was in a
group home on the grounds
of Creedmoor state hospi-
tal and did well, regularly
taking his medication.
8/17/94: *Follows schedule
well, is uniformly polite,
friendly and cooperative.* But
that group home is highly
supervised, costing \$41,600
per person, per year, and
there is great pressure for
state workers to move res-
idents on to less-supervised,
less-expensive programs,
even if it's too soon.

A state discharge team set
up screening appointments
for Goldstein at a few apart-
ment programs that offered
moderate supervision. But

Continued on page 70

ANSWERS TO PUZZLES

OF MAY 16, 1999

AGITATES	CLAMOR	COIF	NIBS
VINEGARY	NEGIRA	HARI	ASAP
EVAPERON	TSAKD	INES	PASA
RENE	SODAS	ENDOR	DECODER
SNEERS	DINER	ASTIR	SALOME
COM	STREWN	ISE	SPIRES
ELIZABETH	TI	COCO	CHANEL
ANT	PEDI	EAR	REEVE
RESEND	IRON	SIDE	SLO
ESSES	TOURS	COLGATES	ALOMAR
ENT	ONAN	SISSY	SALAMIS
ADES	DCII	EPI	DOM
NOMAN	GALLANT	EDISON	JOAN
FARC	GREENS	ABORTED	UNSER
NME	SAT	CORE	MAWS
ICINESS	SPATE	ELON	NET
PLANES	ARMOIRES	DATED	GASPE
BRS	BOUNCERS	HEATER	ARDOR
RAF	TARA	CAY	MARIE
CURIE	DIAN	FOSSEY	ASPENS
ELK	ELEVEN	SEW	STARES
DORMS	DICKS	DISCOS	PARADE
PAESE	EASEL	HALT	IRKS
LORETTA	LYNN	VICTORIA	ATEE
EVER	AGLINT	ENDEAVOR	NERD
DEBS	LEONAS	RESTLESS	

MORRISON	C	J	O	M
I	U	M	E	A
LENGLE	I	U	L	K
T	E	A	W	I
LDER	LOWELL	PARKER	E	J
D	A	Y	E	H
K	WHITE	N	C	Y
S	SAVENS	H	D	H
S	O	V	D	H
HURSTON	BEAUVOIR	A	V	E
L	STEWART	D	E	
PLATH	E	T	O	TARBELL
E	U	SEXTON	L	T
TYLER	I	A	PIERCY	
E	S	ANGELOU	H	
ALCOTT	E	S	R	
S	R	E	SITWELL	I
D	RAWLINGS	E	U	S
A	T	I	N	BROWNE
LEVERTOV	N	I	I	
E	N	T	SAGAN	FERBER

Quotation: Thoughts have no sex.
— Clare Boothe Luce

MENTALLY ILL

Continued from page 66

he was judged too low-functioning and didn't pass those interviews. A system driven by an individual's well-being would let him stay at the Creedmoor home and try again later; a system driven by money cannot wait. So when he wasn't well enough for a program with moderate support, the team pushed him to move to a place with almost no support, an adult home.

GOLDSTEIN REJECTED THE first adult home he was shown as too large, a 200-bed facility in Rockaway, but social workers kept pressing. 10/31/94: *He has been told he cannot go to Delaware to visit his father until his housing placement is made.* So he chose the very next thing he was offered, Leben Home in Queens, with 361 beds, the second-largest adult home

in the state. For Goldstein, that was the beginning of the downward spiral to the basement apartment and Webdale. He tried several times after that to get back into a supervised residence, including the one at Creedmoor, where he had lived in 1994, but with no luck.

On Sept. 12, 1997, after Goldstein walked into Bellevue Hospital's E.R. seeking help, a hospital social worker noted: "Patient states he would like to return to S.C.C.R." — the group home — "at Creedmoor. Spoke with Carol Erman, the secretary, who states patient was a resident, however, he can only be referred from Creedmoor inpatient. She referred patient to David Frazier for community residence. Mr. Frazier reviewed chart but was unable to accept referral as there were no beds available."

The next day, Bellevue discharged Goldstein to his

basement apartment. The social worker noted that she had given him a piece of paper with the phone number of a mobile crisis unit to call if he became disoriented again; the social worker also noted that he had no phone.

FOR YEARS, INSTEAD OF resources, there have been shortcut solutions that push the problem around. The latest, inspired by the Goldstein case, is an effort to pass an outpatient commitment law for New York. It would allow people resistant to treatment to be committed to a supervised community program, and if they are not compliant with medication, they would be hospitalized. Supporters see it as a way to control the resistant mentally ill and leverage the system for more resources; if more people are committed to community programs, the state will have to build more. Opponents fear it will deprive

the mentally ill of the right to control their treatment.

I doubt it would make much difference either way. The reality is that commitment is no longer much of a civil liberties threat — state hospitals don't want patients, and the short-term hospitals can't get rid of them fast enough. If New York had outpatient commitment, it probably would not be enforced because the resources aren't there; or if it were enforced, given current resources, one group of people that needs care would be pushed aside for another group that also needs it. There are 37 states with outpatient commitment laws, and most have systems as dysfunctional as New York's.

What I found most haunting about Goldstein's 3,500-page file was his repeated pleas for services that had no vacancies. There was no room at the inn.

Last month at a court

hearing, Goldstein's lawyers, Harvey Fishbein and Jack Hoffinger, argued that he was not fit to stand trial. Judge Carol Berkman disagreed, finding him competent. But she also hinted that she understood the larger scope of the crime. "I have no doubt," she said "that someday, probably after we are all gone, people will look back at our treatment of mental illness under the law and be shocked and appalled."

When Dorothea Dix had finished shaming Massachusetts into spending more money, she set off to shame New York. In her 1844 report to Albany's legislators, she urged them to live up to the state motto "Excelsior! Excelsior!"

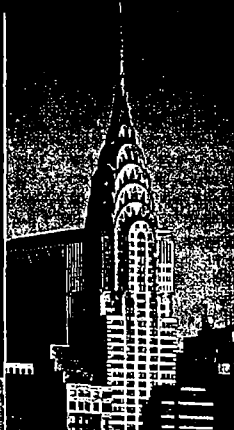
Excelsior is probably shooting a little high when it comes to social services in America these days, but the time is long overdue to establish a social contract for the mentally ill. ■

LUXURY HOMES AND ESTATES

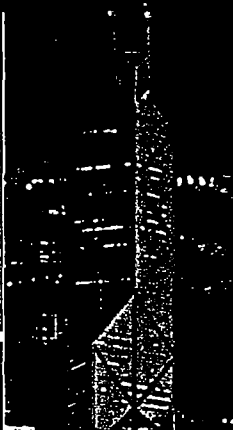
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DATE:

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FROM:

Rm Manderscheid

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(301) 443-3343

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NUMBER OF PAGES (including cover page):

4

NOTE:

As discussed.

Rm Manderscheid

Persons with Mental Illness

Mental and emotional illnesses are very pervasive. They directly affect at least 25% of adults (about 50 million persons) (Regier et al, 1993) and at least 20% of children (about 14 million persons) (Friedman et al, 1996) in the United States in any given year. Among these adults, at least 10 million suffer from serious mental illness, and for children ages 9-17, 3.5 to 4.5 million suffer from serious emotional disturbance depending on the level of disability considered. But these figures do not tell about the full impact of mental illness. Virtually every family in the US has at least one member who suffers from one or more mental health problems. The effects on families can be devastating, as is shown in the attached review of Danielle Steel's new book, "His Bright Light: The Story of Nick Traina" (Dealcor Press, 1999). As told by Ms. Steel, the problem is difficult to identify, difficult to treat, costly, and potentially fatal.

In adults, mental illness is about 8 times as likely for people in poverty compared with affluent people. (Hollingshead and Redlich, 1958; Redlich, 1986) Females are more likely to have mental illness than males (Stroup and Manderscheid, 1988), and particular mental illnesses are more common in different age groups, for example, many elderly people suffer from depression (Guest, 1999). Since more people from minority groups are in poverty, more people from minority groups are likely to experience mental illness than others (Regier et al, 1993).

The economic costs of mental illness are staggering. When considered for all mental disorders, the total economic costs sum to almost \$150 billion dollars per year (Rice and Miller, 1993). Because many families do not have adequate health insurance coverage for mental illness, the economic costs to families can be devastating.

Mental illness also leads to pervasive disability. Among persons with serious mental illness, at least half are not in the labor force at all, and among those who are, almost one-fifth are unemployed. Almost one-quarter of persons with serious mental illness live in poverty. (Gonzalez-Willis et al, 1998)

Care of Persons with Serious Mental Illness

Among the 10 million adults with serious mental illness, only slightly more than one-third receive stable treatment. This means that at least 6.6 million of these adults with serious mental illness do not have stable treatment. (Stable treatment is defined as receiving treatment in a year and not dropping out.) Of those who did not have stable treatment, only about 1 in 8 dropped out of treatment; the remaining 7 out of 8 failed to obtain any treatment at all in a one year period. Among children with serious emotional disturbance, figures are comparable. No more than 1.5 million children receive care in any organized mental health setting.

With the advent of Medicaid managed care and the implementation of national welfare reform, several things are being observed. Fewer resources are available for Medicaid managed care. (Among States that entered managed behavioral healthcare early, as little as 65%-75% of original Medicaid resources are still available at the end of the first year.) This means that those on the Medicaid rolls have greater difficulty accessing what care is available. National welfare reform

has reduced the number of families that are eligible for Medicaid. (In some instances these reductions may constitute as much as 30% of the Medicaid rolls.) The net effect of both of these changes is to increase pressure on the State mental health agencies and their Block Grant funds to deliver care to adults with serious mentally illness and children with serious emotional disturbance who need mental health care.

In the private sector, the annual value of behavioral healthcare benefits (incorporating day, visit and dollar limits) has fallen from about \$154 in 1988 to \$70 in 1998, a decrease of more than 50 percent. This decline in the value of behavioral healthcare benefits is reflected in the number of mental health encounters per thousand people covered, which declined from 378 to 285 between 1993 and 1997, a decrease of almost 25 percent. By contrast, general health encounters per thousand people enrolled, increased from 1928 to 2091 during this period.

Dr. Manderscheid
Ms. Henderson
301-443-3343 - voice
301-443-7926 - fax

Book Forum

CONFRONTING MENTAL ILLNESS

His Bright Light: The Story of Nick Traina, by Danielle Steel. New York, Delacorte Press, 1998, 296 pp., \$25.00.

Nurturance, compassion, and love reflect a mother's intense feelings for her first-born son. Danielle Steel conveys each of these and much more in *His Bright Light: The Story of Nick Traina*. Ms. Steel portrays them with a very skilled writer's eye for nuance, development, and tragedy. Her heart-wrenching effort to tell us how mental health professionals could have served Nick Traina better is extremely courageous and completely open. We need to listen ever so carefully to Nick's story.

Nick was an exceptionally bright child with much love for his family. He could be stern, funny, and insightful, sometimes all at once. As he matured, his world expanded and his interests developed. He became a talented writer, composer, and singer. His peer group assumed great importance. Girls entered his life. Nick started to experience problems in school. His emotions were much more erratic. He became very self-analytical. He entered the world of mental illness, one of 3.5 to 4.5 million teenagers who are seriously emotionally disturbed.

As Nick's behavior became more extreme—bouts of depression punctuated by periods of high emotion—his mother and his family became gravely concerned for his well-being. Family confidants were consulted; his mother took Nick to specialists. He went to a residential program. Much money was spent. Nothing seemed to work.

The family was desperate for a treatment or drug that would help Nick: "It was a time of terrifying frustration. I am a capable competent person, with ample funds at my disposal. If I couldn't make things happen for Nick, I shudder to think at what happens to people who are too shy or too frightened to speak up, people who don't know their way around" (p. 126).

Different diagnoses were offered; a depression drug was prescribed. Nick's symptoms were mitigated only slightly. A new crisis occurred; Nick was placed into hospital inpatient care, first with other teenagers, then with other adults. He went to live with another family for two years. Specialists were consulted.

Nick's medication was switched to lithium after he was given a new diagnosis of manic depression with attention deficit disorder. His life seemed to be miraculously changed. Nick took lithium regularly for 2 years. He became an accomplished singer. There were occasional inpatient stays.

Nick's independence led him to refuse to take his medication. Using a combination of drugs, including heroin, he attempted suicide once, twice, then three times. Legal intervention was used to make sure he received care. Nick's rock band went on tour. His fourth suicide attempt was successful, his final tragedy.

We can, should, must do better. We must improve training of all mental health professionals; we must improve our capacity to recognize, diagnose, and treat much earlier. We

must listen ever so much more closely to family members and consumers when they seek our help. Managed care can distract us, but Nick Traina is the real reason for psychiatry and the other mental health professions.

This exceptional book is required reading. Danielle Steel has an awful lot to teach us. We have to learn well and act expeditiously to prevent future tragedies.

RONALD W. MANDERSCHIED, PH.D.
Rockville, Md.

Out of the Shadows: Confronting America's Mental Illness Crisis, 2nd ed., by E. Fuller Torrey, M.D. New York, John Wiley & Sons, 1996, 244 pp., \$27.95; \$16.95 (paper, published 1998).

Whenever the plight of families of individuals with serious mental illness who refuse treatment has reached our national consciousness, it has been in the context of blatant tragedy. Reluctantly, we see our patients and their families in the headlines. We also see our own predicament in that of the Kaczynski, Laudor, and Hinckley families, who tried desperately to get their loved ones to accept treatment. Far more common than the tragedies that make headlines are the ones that test the bonds of families and the moral resolve of physicians and therapists who are entrusted with the care of the seriously mentally ill.

In *Out of the Shadows*, E. Fuller Torrey compiles cases such as that of a man brought to the hospital with acute symptoms of manic depression who rejected the advice of the doctor on call and the pleas of his family to stay and be treated. He walked out of the emergency room and several hours later hanged himself. Dr. Torrey also tells the tale of a woman with chronic schizophrenia who walked into a shopping mall and opened fire with a gun, killing three, and the story of a homeless woman in New York who roamed the streets conversing with the President until the day she was found raped and stabbed to death.

What these tales have in common with the cases that make the headlines is the seriously mentally ill person's refusal to be treated. Citing such cases and the societal barriers that keep such people out of treatment, Dr. Torrey offers us a provocative indictment of how we in the United States treat people suffering from serious mental illness. He writes with passion and combativeness, and the crisis he describes should stir even the uninitiated to anger. This book should be required reading for every psychiatrist, psychologist, social worker, nurse, and therapist treating patients with serious mental illness. It will also appeal to a much wider audience with an interest in civil liberties, medical ethics, and social policy.

The crisis is spelled out in tragic detail at the outset. We learn that in a given 1-year period, approximately 5.6 million people 9 years old or older have a severe mental illness, such as schizophrenia or bipolar disorder, and that approximately 2.2 million of these people are untreated. Of these, 150,000 are homeless and 159,000 are incarcerated, mostly for

THE VACCINE REACTION

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Special Report

Published by the National Vaccine Information Center
Barbara Lee Fisher, Editor

September 1998

HEPATITIS B VACCINE: THE UNTOLD STORY

Parents Question Forced Vaccination As Reports of Hepatitis B Vaccine Reactions Multiply

In increasing numbers, parents across the country are contacting the National Vaccine Information Center (NVIC) to report opposition to regulations being enacted by state health department officials that legally require children to be injected with three doses of hepatitis B vaccine before being allowed to attend daycare, kindergarten, elementary school, high school or college. Simultaneously, as more schools and employers bow to pressure from government health officials and require individuals to show proof they have been injected with hepatitis B vaccine before being allowed to get an education or a job, reports of serious health problems following hepatitis B vaccination among children and adults are multiplying.

The National Vaccine Information Center (NVIC) maintains that federal and state public health officials are promoting forced vaccination with hepatitis B vaccine without truthfully informing the public about the risks of hepatitis B disease in America or the known and unknown risks of hepatitis B vaccine. Without being provided with accurate and complete information about disease and vaccine risks, citizens cannot exercise informed consent, which becomes a human right when an individual considers undergoing a medical procedure that could cause injury or death.

Following is a general overview of what is and is not known about hepatitis B disease, the hepatitis B vaccine and the politics of hepatitis B vaccination.

HEPATITIS B NOT HIGHLY CONTAGIOUS - Unlike other infectious diseases for which vaccines have been developed and mandated in the U.S., hepatitis B is not common in childhood and is not highly contagious. Hepatitis B is primarily an adult disease transmitted through infected body fluids, most frequently infected blood, and is prevalent in high risk populations such as needle using drug addicts; sexually promiscuous heterosexual and homosexual adults; residents and staff of custodial institutions such as prisons; health care workers exposed to blood; persons who require repeated blood transfusions and babies born to infected mothers.

According to *CDC Prevention Guidelines: A Guide to Action* (1997), a book written by federal public health officials at the U.S. government Centers for Disease Control (CDC), "the sources of [hepatitis B] infection for most cases include intravenous drug use (28%), heterosexual contact with infected persons or multiple partners (22%) and homosexual activity (9%)." According to *Harrison's Principles of Internal Medicine* (1994), mother to child transmission of hepatitis B "is uncommon in North America and western Europe."

Although CDC officials have made statements that hepatitis B is easy to catch through sharing toothbrushes or razors, Eric Mast, M.D., Chief of the Surveillance Section, Hepatitis Branch of the CDC, stated in a 1997 public hearing that: "although [the hepatitis B virus] is present in moderate concentrations in saliva, it's not transmitted commonly by casual contact."

HEPATITIS B NOT A KILLER FOR MOST - Symptoms of hepatitis B disease include nausea, vomiting, fatigue, low grade fever, pain and swelling in joints, headache and cough that may occur one to two weeks before the onset of jaundice (yellowing of the skin) and enlargement and tenderness of the liver, which can last for three to four weeks. Fatigue can last up to a year. According to *Harrison's*, in cases of acute hepatitis B "most patients do not require hospital care" and "95 percent of patients have a favorable course and recover completely" with the case-fatality ratio being "very low (approximately 0.1 percent)."

Those who recover completely from hepatitis B infection acquire life-long immunity. Of those who do not recover completely, fewer than 5 percent become chronic carriers of the virus with just one quarter of these in danger of developing life threatening liver disease later in life, according to *Robbins Pathologic Basis of Disease* (1994), a medical college textbook.

The Guide to Clinical Preventive Services (1996), written under the supervision of the U.S. Department of Health and Human Services (DHHS), states that the risk of developing a chronic hepatitis B infection is higher in infected infants than in infected older children and adults: "Infections during infancy, while estimated to represent only 1-3% of cases, account for 20-30% of chronic infections." Because infants born to infected mothers are at highest risk for developing chronic hepatitis B infections, routine screening of pregnant women for hepatitis B infection is one of the most important public health measures that can be taken to prevent chronic hepatitis B carriers. *The Merck Manual* (1992), a major medical reference used by physicians, notes that "postexposure vaccination is recommended for newborn infants of hepatitis B positive mothers."

HEPATITIS B LOW IN U.S. - The U.S. and western Europe have always had among the lowest rates of hepatitis B disease in the world (0.1% to 0.5% of the general population) compared to countries in the Far East and Africa, where the disease affects 5-20% or more of the population. According to *Guide to Clinical Preventive Services*, in the U.S. "the greatest reported incidence [of hepatitis B] occurs in adults aged 20-39" and "the number of cases peaked in 1985 and has shown a continuous gradual decline since that time."

Even though hepatitis B disease is uncommon in the general population in the U.S., it continues to be high among those engaged in high-risk behaviors, especially IV drug use. *Guide to Clinical Preventive Services* states that "In recent years, a growing number of injection drug users have become infected; currently, between 60% and 80% of persons who use illicit drugs parenterally (through the skin such as with a needle stick) have serologic evidence of [hepatitis B] infection."

In 1991, there were 18,003 cases of hepatitis B reported in the U.S. out of a total U.S. population of 248 million. According to the October 31, 1997 *Morbidity and Mortality Weekly Report* published by the CDC, in 1996 there were 10,637 cases of hepatitis B reported in the U.S. with 279 cases reported in children under the age of 14 and the CDC stated that "Hepatitis B continues to decline in most states, primarily because of a decrease in the number of cases among injecting drug users and, to a lesser extent, among both homosexuals and heterosexuals of both sexes."

CDC RECOMMENDS ALL INFANTS GET HEP B VACCINE - Even though hepatitis B is an adult disease, is not highly contagious, is not deadly for most who contract it, and is not in epidemic form in the U.S. (except among high risk groups such as IV drug addicts), in 1991 the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) recommended that all infants be injected with the first dose of hepatitis B vaccine at birth before being discharged from the hospital newborn nursery. A similar recommendation was also made by the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP). This, despite the fact very little is known about the health and integrity of an individual baby's immune and neurological systems at birth.

In 1991, media reports generated by the CDC used hepatitis B disease statistics that were not anchored in documented fact but are still used today to promote mass hepatitis B vaccination. Most of the inflated disease statistics originate with statements generated by the Centers for Disease Control. In the 1991 ACIP Recommendations calling for mass vaccination with hepatitis B vaccine published in the *Morbidity and Mortality Weekly Report*, the CDC states that there are an "estimated 1 million-1.25 million persons with chronic hepatitis B infection in the United States" and that "each year approximately 4,000-5,000 of these persons die from chronic liver disease" and that "an estimated 200,000-300,000 new [hepatitis B] infections occurred annually during the period 1980-1991." The CDC gives no scientific reference for this data other than the CDC.

Just one year before the government's call for mass vaccination, hepatitis B vaccine maker SmithKline Beecham in their 1990 hepatitis B vaccine product insert stated, "The CDC estimates that there are approximately 0.5 to 1.0 million chronic carriers of hepatitis B virus in the U.S. and that this pool of carriers grows by 2% to 3% (12,000 to 20,000 individuals) annually."

FEDERAL RECOMMENDATIONS BECOME STATE LAWS - Because vaccination requirements are controlled by states and not the federal government, in order for federal health officials to achieve their goal of a 100 percent vaccination rate with new vaccines marketed by drug companies, they must persuade states to turn federal vaccine policies into state law. And, because during the past 50 years, most state legislatures have completely turned over the power to mandate vaccines to state health department officials, very infrequently do state legislators take a vote to approve the mandating of a new vaccine such as hepatitis B. So, while American children born in 1948 were only required by state health officials to show proof of smallpox vaccination to enter school, American children born in 1998 are required by most states to be injected with 33 or 34 doses of 9 or 10 different viral and bacterial vaccines to enter school, including three doses of hepatitis B vaccine.

FEDERAL HEALTH OFFICIALS GIVE STATE HEALTH OFFICIALS MONEY TO FORCE HEP B VACCINATION - Following the 1991 CDC recommendation for universal use of hepatitis B vaccine by all children, state health department officials began issuing mandates requiring children

to show proof they have been injected with three doses of hepatitis B vaccine in order to attend daycare or school. By the end of 1997, 35 states had regulations on the books requiring children to get 3 doses of hepatitis B vaccine and, yet, only 15 states had passed laws requiring prenatal screening of pregnant mothers for hepatitis B infection.

To encourage states to mandate use of hepatitis B vaccine by all children, federal health officials at the Centers for Disease Control give grants and other financial incentives to state health departments to reward them for promoting mass vaccination. Since 1965, the CDC has given state health departments hundreds of millions of dollars through categorical grant programs to promote mass use of federally recommended vaccines. At the same time, if state health officials do not show federal health officials proof they have attained a certain vaccination rate in their state, federal grants to state health departments can be withheld.

In 1993, the Comprehensive Childhood Immunization Act of 1993 was passed giving the Department of Health and Human Services (DHHS) the authority to award more than \$400 million to states to set up state vaccine registries to tag and track children and enforce mandatory vaccination with federally recommended vaccines, including hepatitis B vaccine. The Performance Grant Program rewards a state with either \$50, \$75 or \$100 per child who is fully vaccinated with all federally recommended vaccines, including hepatitis B vaccine and, in 1995, DHHS Secretary Donna Shalala gave the states the power to approve a newborn's social security number in order to set up vaccine tracking registries in more than half the states. The CDC plan is to hook up the state vaccine tracking registries in order to create a de facto centralized electronic database containing every child's medical records.

PHARMACEUTICAL INDUSTRY ALSO FUNDS FORCED HEP B VACCINATION -

In addition to federal grants, many states get money from the Robert Wood Johnson Foundation (Johnson & Johnson), which operates All Kids Count, to set up vaccine tracking systems to enforce state vaccination mandates. (In 1989, Merck & Co., the U.S. manufacturer of the measles, mumps, rubella (MMR), chicken pox and hepatitis B vaccines, joined with Johnson & Johnson to form Worldwide Consumer Pharmaceuticals Co. with the goal of becoming "one of the premier worldwide consumer products companies." Merck's 1997 vaccine sales reached 1 billion dollars.)

All Kids Count is a project of the Task Force for Child Survival and Development headquartered at The Carter Center (former President Jimmy Carter) in Atlanta, which is directed by former CDC director Dr. William Foege. The Task Force is supported by the World Health Organization, World Bank, Rockefeller Foundation, United Nation's Population Fund and vaccine manufacturers, entities which also sponsor the Children's Vaccine Initiative (CVI). The CVI, headquartered in Geneva, was launched in 1990 at the World Summit for Children and promotes "the development and utilization" of vaccines by all of the world's children.

Forced vaccination with hepatitis B vaccine is also promoted in states by non-profit organizations such as Every Child by Two, founded in 1991 by former First Lady Rosalyn Carter and Betty Bumpers, wife of Arkansas Senator Dale Bumpers. Every Child by Two is funded in part by grants from Merck, Lederle and Connaught, the three largest U.S. vaccine manufacturers.

The non-profit CDC Foundation, which began operation in 1995, has raised more than \$15 million in the past four years to augment the CDC's campaign to enforce mass vaccination. The CDC Foundation, the Task

Force for Child Survival & Development and vaccine manufacturers funded the recent National Immunization Conference held in Atlanta.

The five-year-old non-profit Immunization Action Coalition operates the Hepatitis B Coalition, which nationally promotes hepatitis B vaccination for all children. Funding comes from private donations, including a grant from SmithKline Beecham, manufacturer of the hepatitis B vaccine, and a new \$750,000 grant from the Centers for Disease Control. A newsletter produced by this group contains the assurance that "Everything herein is reviewed by the Centers for Disease Control and Prevention for technical accuracy (unless it is an opinion piece written by a non-CDC author)."

PHARMACISTS NOW VACCINATE - SmithKline Beecham, through the American Pharmaceutical Association, has also funded a nationwide campaign called "Pharmacy-Based Immunization Advocacy" which allows pharmacists to vaccinate children and adults. As of 1998, the Hepatitis B Coalition reports that 23 states have passed laws giving pharmacists the right to sell and administer hepatitis B and other vaccines.

FAMILIES PENALIZED FOR REFUSING HEP B VACCINE - As state health departments accumulate power and money to force vaccination with all federally recommended vaccines, including hepatitis B vaccine, child and adult citizens are punished by both federal and state health officials with economic sanctions for refusing to comply. Refusal to be injected with hepatitis B vaccine can result in citizens being denied an education, including enrollment in daycare, elementary school, high school, college and graduate school; denial of health insurance; denial of employment; denial of federal entitlement benefits for poor children including food under the Women, Infants and Children (WIC) program and medical care under Medicaid. In some states, like Texas, a needy family loses \$25 per month per child in state health benefits if all children have not received all federally recommended vaccines, including hepatitis B vaccine.

HEP B VACCINE LICENSED BY FDA WITHOUT ADEQUATE PROOF OF LONG TERM SAFETY - In 1986, the FDA gave Merck & Co. a license to market the first recombinant DNA hepatitis B vaccine, which replaced the old hepatitis B vaccines made from blood taken from human chronic hepatitis B virus carriers. In awarding Merck & Co. and, later, SmithKline Beecham Pharmaceuticals, licenses to market their genetically engineered hepatitis B vaccines in the U.S., the FDA allowed both drug companies to use "safety" studies which only included a few thousand children monitored for only four or five days after vaccination to check for reactions. As "proof" their hepatitis B vaccine is safe to be used in children, Merck & Co. stated in their 1993 product insert that "In a group of studies, 1636 doses of RECOMBIVAX HB were administered to 653 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose."

Merck & Co. found that injection site and systemic complaints, such as fatigue and weakness, fever, headache and arthralgia (joint pain), were reported following up to 17 percent of all hepatitis B injections. Because the FDA did not require drug companies to provide scientific evidence that hepatitis B vaccine does not compromise the immune and neurological systems of children and adults over weeks, months or years post-vaccination, Merck & Co. warns in the 1996 product insert that "As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials" and SmithKline Beecham (1993) has a similar warning that "it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions."

Another warning in the Merck 1996 product insert is "it is also not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity" and "it is not known whether the vaccine is excreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when the vaccine is administered to a nursing woman."

And, although doctors routinely inject hepatitis B vaccine into children along with many other vaccines such as DPT, HIB, MMR and chicken pox vaccine, Merck & Co. state in the 1996 product insert: "Specific data are not yet available for the simultaneous administration of RECOMBIVAX HB with other vaccines."

HEP B VACCINE EFFICACY ALSO QUESTIONED - All vaccines stimulate only an artificial, temporary immunity, and the length of immunity conferred by the hepatitis B vaccine and the future need for more "booster" doses later in life is still not clear. Merck & Co state in their 1996 hepatitis B vaccine product insert that "the duration of the protective effect of RECOMBIVAX HB in healthy vaccinees is unknown at present and the need for booster doses is not yet defined."

In the *CDC Prevention Guidelines: A Guide to Action* (1997), the CDC states "The duration of protection [of hepatitis B vaccine] and need for booster doses are not yet fully defined. Between 30% and 50% of persons who develop adequate antibody after three doses of vaccine will lose detectable antibody within 7 years but protection against viremic infection and clinical disease appears to persist." If immunity only lasts 7 years, babies vaccinated with hepatitis B vaccine may be candidates for more shots at age seven.

IOM REPORT REVEALS LACK OF ADEQUATE SCIENTIFIC STUDIES - In *Adverse Events Associated with Childhood Vaccines* published in 1994 by the Institute of Medicine, National Academy of Sciences, observations about the limitations of hepatitis B vaccine studies included the statements that "it is important to note that individual trials usually involved a few hundred subjects for study...when larger vaccination programs were monitored, observations of adverse events were necessarily less detailed and less accurately reported" and "the studies were not designed to assess serious, rare adverse events; the total number of recipients is too small and the follow-up generally too short to detect rare or delayed serious adverse reactions."

The IOM report also noted that no controlled observational studies or controlled clinical trials have ever been held to evaluate repeated reports that hepatitis B vaccine can cause Guillain-Barre syndrome; arthritis; transverse myelitis, optic neuritis, multiple sclerosis and other central demyelinating diseases of the nervous system (degeneration of the myelin sheath of the brain that helps transmit nerve impulses); or sudden infant death syndrome (SIDS).

A major conclusion of the Institute of Medicine report was that almost no basic science research has been undertaken to define at the cellular and molecular level the biological mechanism of vaccine-induced injury and death. The report concluded that "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee...the committee encountered many gaps and limitations in knowledge bearing directly or indirectly on the safety of vaccines. These include inadequate understanding of the biologic mechanisms underlying adverse events following natural infection or immunization, insufficient or inconsistent information from case reports and case series...and inadequate size or length of follow-up of many population-based epidemiologic studies...."

MEDICAL LITERATURE CITES IMMUNE SYSTEM/BRAIN DAMAGE - During the

past decade, there have been many reports in the medical literature (primarily in international medical journals rather than U.S. medical journals) that hepatitis B vaccination is causing chronic immune and neurological disease in children and adults, including *lupus*: Tudela & Bonal (1992); Mamoux & Dumont (1994); Guiserix (1996); *arthritis, including polyarthritis and rheumatoid arthritis*: Christan & Helin (1987); Hachulla et al (1990); Rogerson & Nye (1990); Biasi et al (1993); (1994); Vautier & Carty (1994); Hassan & Oldham (1994); *Rheumatic Review* (1994); Gross et al (1995); Pope et al (1995); Cathebras et al (1996); Soubrier et al (1997); *Guillain Barre Syndrome GBS*: Shaw et al (1988); Tuohy (1989); *demyelinating disorders such as optic neuritis, Bell's Palsy, demyelinating neuropathy, transverse myelitis and multiple sclerosis*: Shaw et al (1988); WHO (1990); Reutens et al (1990); Herroelen et al (1991); Nadler (1993); Brezin et al (1993); Mahassin et al (1993); Kaplanski et al (1995); Baglivo et al (1996); Marsaudon & Barrault (1996); Berkman et al (1996); Waisbren (1997); *diabetes mellitus*: Poutasi (1996); Classen (1996); *chronic fatigue*: Salit (1993); Delage et al (1993); *vascular disorders*: Fried et al (1987); Goolsby (1989); Cockwell et al (1990); Poullin & Gabriel (1994); Mathieu et al (1996); Graniel et al (1997); and others.

In 1996, Burton A. Waisbren, M.D., a cell biologist and infectious disease specialist, who is a founding member of the Infectious Disease Society of America and past President of the Infectious Disease Society of Milwaukee, pointed out in the *Wisconsin Medical Journal* that "there is an increasing number of reports in the refereed medical literature about demyelinating diseases occurring after an individual has received the hepatitis B vaccination...since the hepatitis B virus itself has been reported to cause autoimmune problems, should we not be wary of giving antigens that seem to have triggered these problems?" Waisbren, in a presentation before a 1996 Institute of Medicine Vaccine Safety Forum, warned that genetically engineered hepatitis B vaccines contain polypeptide sequences that are present in human neurologic tissues such as myelin and that, by a mechanism called molecular mimicry, these polypeptides can act as autoantigens which can induce autoimmune demyelinating diseases of the brain such as multiple sclerosis.

In that same year, Montinari et al published a study in Italy evaluating 30 children and adults, the majority aged 3 to 9 months, who suffered central nervous system disorders, such as seizures and autism, following hepatitis B vaccination. The purpose of the study was to investigate whether there is an immunogenetic basis (autoimmune type) responsible for the demyelination process in the brain that can occur following recombinant hepatitis B vaccination. The authors concluded "autoimmune diseases are more frequent in nations where vaccines are widely used, the so called "clear" communities" and they identified several potential genetic markers that "may visualize risk patients for autoimmune diseases following hepatitis B vaccination.

Montinari's work to identify genetic factors for predisposition to hepatitis B vaccine reactions is important in light of the study in 1989 by Alper et al to identify genetic factors for those who do not respond to hepatitis B vaccination. In that study, the authors concluded that there was genetic predisposition to failure to respond to the vaccine. They stated: "These results support our hypothesis that the production of anti-HBsAg [vaccine-induced antibodies] is a dominant trait and that the inability to produce high titers of anti-HBsAg after adequate immunization is a recessive trait..." The authors concluded that the genetic markers they identified are most prevalent in caucasians of European descent "and is associated with a wide variety of diseases with autoimmune features in this population, including Type 1 diabetes mellitus..."

In 1996, Barthelow Classen, M.D., CEO of Classen Immunotherapies Inc., published an epidemiologic study in the *New Zealand Medical Journal* and reported that there was a 60 percent increase in Type 1 diabetes (juvenile diabetes) following a massive campaign in New Zealand from 1988 to 1991 to vaccinate babies six weeks of age or older with hepatitis B vaccine. His analysis of a group of 100,000 New Zealand children prospectively followed since 1982 showed that the incidence of diabetes before the hepatitis B vaccination program began in 1988 was 11.2 cases per 100,000 children per year while the incidence of diabetes following the hepatitis B vaccination campaign was 18.2 cases per 100,000 children per year.

VACCINE INJURIES REPORTED AT NVIC CONFERENCE ON VACCINATION -

At the First International Public Conference on Vaccination sponsored by the NVIC on September 13-15, 1997 in Alexandria, Virginia, physicians and scientists from around the world gathered to speak about vaccine-induced chronic illness. Canadian physician Byron Hyde, M.D., Chairman of the Nightingale Research Foundation, and an internationally recognized authority on myalgic encephalomyelitis (also known as chronic fatigue syndrome), spoke about the data he has accumulated on more than 200 cases of serious immune and neurological dysfunction following hepatitis B vaccination. Dr. Hyde said:

"There was a nurse in Wisconsin who had had two immunizations against hepatitis B. After the second, she started to complain. They insisted that she have three more [shots], full dosage. They gave her the first, she complained of headaches, pain, and they told her this was anxiety neurosis. They gave her the fourth and fifth and she lost I.Q., measurable loss of intelligence, measurable loss in stamina, all of the things you see in the worst cases of ME or chronic fatigue syndrome.....A lot of these cases that we've looked at suggest demyelinating disease, disseminated myelitis, localized injuries, three unexplained deaths...the problem with all of this is that nobody has ever seriously studied it...."

Dr. Hyde was particularly critical of the poor science and medicine that hurts patients. He concluded "Almost all of these people who had adverse reactions after the first immunization, after the second immunization were individuals who had immunological side effects and who told their physicians and the physicians did nothing about it but continued to proceed with immunization... I think part of the problem is the pharmaceutical companies and the governments themselves have attempted to say 'Here, take this sugar pill, it is danger-free, it is a wonderful thing, it has no risk, no problems' and doctors have become lazy and actually believed this dangerous philosophy put out by the pharmaceutical companies and the governments."

HEP B VACCINE INFANT DEATHS REPORTED IN VAERS - Even though fewer than 10 percent of all doctors report health problems following vaccination, there are more than 16,000 reports of hospitalizations, injuries and deaths following hepatitis B vaccination that have been reported to the U.S. government Vaccine Adverse Event Reporting System (VAERS) since July 1990. There are reports of deaths in infants under one month of age following hepatitis B vaccination in VAERS, with most of the deaths being classified as sudden infant death syndrome (SIDS), even though SIDS is not historically recognized in the medical literature as occurring in babies under two months of age.

One of those death reports was made for a 15-day old baby boy who died within 48 hours of his first dose of hepatitis B vaccine. His father testified at a 1995 Institute of Medicine Vaccine Safety Forum workshop. He described what happened:

"For the first 13 days of his life, Nicholas was no different than any other baby. He ate well. When he slept, he slept well. He acted just like my first son acted when he came home from the hospital." Nicholas was given a hepatitis B shot at his regular check up at the pediatrician's office on the 13th day of his life. His father said:

"That night when I got home from work, I noticed that Nicholas was crying a lot more than usual. In fact, he was screaming some of the time. He was acting differently, but because we had just taken him to the doctor for a checkup and they told us he was a big healthy boy, we thought everything was OK. When he was just acting fussy, like babies sometimes do, we didn't know anything about vaccines or that they can cause problems for some babies."

"Nicholas cried on and off for most of the night. When I got up and went to work the next day, he was still crying on and off. He continued during most of the day and into the evening. The next morning, his mother found him dead in his crib. From the way he looked, he had been dead for several hours."

An autopsy was done the next day. A couple of weeks later, our pediatrician told us over the phone that the autopsy showed Nicholas had died of sudden infant death syndrome. He told us Nicholas was one of the healthiest babies he had ever seen.... What I didn't know then but I know now is that the pediatrician had made a report within 17 days of Nicholas' death to the government's Vaccine Adverse Event Reporting System, VAERS. In VAERS, Nicholas' death is listed as SIDS. Even though I didn't know anything about vaccines or SIDS, something told me that there was a reason why Nicholas died, and I had to find out why."

After seeing an article in the *Washington Post* about the Institute of Medicine report on adverse events associated with childhood vaccines, Nicholas's father called the National Vaccine Information Center and began talking to experts and researching infant death and vaccines. Eventually a clinical professor of pathology, who had reviewed Nicholas' medical records, autopsy and slides, stated in writing that Nicholas did not die of SIDS but died a cardiac death, caused by passive congestive changes with pulmonary edema and hemorrhage caused by the active immunization with hepatitis B vaccine. The pathologist stated "I do not believe this was a sudden infant death syndrome death. Sudden infant death syndrome is the most abused diagnosis in pediatric pathology. In this particular case, the infant was two weeks old. Sudden infant death at two weeks old is so rare as to be virtually unheard of."

The pathologist went on to say that Nicholas was at high risk for congestive heart failure because his mother had gestational diabetes, but that he would definitely have survived were it not for the stress induced by the hepatitis B vaccination.

Nicholas's father, in his testimony before the Institute of Medicine, asked "How many other newborn babies are dying from the effects of hepatitis B vaccine, but are being wrongly diagnosed as SIDS and no one ever knows the difference? I looked at the computer printouts of VAERS reports at the National Vaccine Information Center, and I saw there were other reports of babies just a few days or weeks old, who have died shortly after hepatitis B vaccination. Many are listed as SIDS deaths, but are they?"

ADULTS REPORT HEP B VACCINE INJURY AND DEATH TO NVIC - As hepatitis B requirements force more adults to get vaccinated as a condition for getting a higher education or working in the health care field, NVIC is receiving more and more reaction reports like this one from a disabled nurse, who recently wrote in:

"24 hours after my first [hepatitis B] shot, I had muscle pain in legs and arms - was told this was 'normal.' Same thing after 2nd shot. Six weeks after 2nd shot I had my first episode of Raynauds [temporary loss of blood flow to fingers resulting in tingling, throbbing, swelling, intense pain] and also began having rashes on arms and neck. At this point it was minor and not constant. I asked if it had anything to do with the vaccine and was told no.

"Six months after the 1st shot, I received the booster. From then (1995) to today, I have constant daily fevers up to 100.5, tormenting rashes and prickling on arms, hands, neck and legs, muscle degeneration, joint pain with restricted movement, difficulty swallowing and Raynauds has become severe.

"I was perfectly healthy until the hepatitis B vaccinations and still all the doctors tell me it has nothing to do with my illness. I had reactions to two of the drugs they tried to treat me with. I am on total disability because of these symptoms. I am an RN but was taught that the vaccines were perfectly safe."

PARENTS OPPOSE HEPATITIS B VACCINE MANDATE IN ILLINOIS - In the spring of 1997, a suburban Chicago mother of two daughters, ages 9 and 11, became concerned when she received a notice from the school system stating that her older daughter had to be vaccinated with hepatitis B vaccine by September 1997 or she would be barred from attending school. Although both of Kathy Rothschild's daughters were fully vaccinated with all other childhood vaccines, she didn't know anyone with hepatitis B and couldn't understand why her daughter had to get the vaccine. Her research led her to a public library and then to NVIC.

With the help of Kathy Rothschild's State Senator, Kathy Parker, an agreement by the Illinois Department of Health to not voice opposition, and with support from NVIC members around the state, a bill passed the Illinois Senate 52-2 on March 20, 1997, allowing parents the right to philosophical exemption to vaccination. The bill also created a Task Force and required the Board of Health to hold public hearings to review how Illinois public health employees add new vaccines to state vaccination laws and how they implement those laws.

After the bill overwhelmingly passed the Senate, the Illinois Department of Health went back on its pledge not to oppose the bill and vigorously fought against the bill in the House, successfully killing it in committee before it had a chance to come to a floor vote. However, the health department did agree to roll back the hepatitis B mandate for one year (until September 1998) and to hold three public hearings, which resulted in testimony from physician expert witnesses and parents and reinforced the dangers of hepatitis B vaccine and the need for informed consent rights to be established within state vaccine requirements.

DOCTOR, MOTHERS SAY VACCINE SAFETY DATA POOR - In a December 1997 public hearing in Chicago before the Illinois Board of Health, Mayer Eisenstein, M.D., M.P.H., who is board certified in public health and preventive medicine, quality assurance utilization review, by the National Board of Medical Examiners and has recently completed a law degree, testified against the proposed hepatitis B mandate. He said: "The idea of giving this vaccine to a one-day old baby, a newborn, is preposterous. There is no scientific evidence for this. In fact, I called up the [hepatitis B vaccine] manufacturer and I had [a representative] come to St. Mary of Nazareth Hospital, where I am Chairman of the Department of Medicine, and I asked him: 'Show me your evidence on one-day old infants as to side effects [from the hepatitis B vaccine]' - we have none. Our studies were done on 5 and 10 year olds....As a father, grandfather.

a physician, as a lawyer, I want the option of not giving it to my children unless I believe the scientific evidence is there."

Later during the public hearing, a mother whose child reacted to the hepatitis B vaccine testified that "We were told unless we had the shot our children were not getting into school. In the past, I got the shots for my children. So I went and got the [hepatitis B] shot. First shot, my daughter got slightly sick. We didn't associate it with the shot. We associated it with possible flu. Her legs hurt. Her back hurt...."

"The second shot, within two days of this shot, my daughter's symptoms went from mild to severe abdominal pain around the clock. She couldn't eat. She couldn't sleep. Her legs hurt. She broke out in a rash. She had eczema over most of her body. Going to the doctor, we were told it was in her head, that she needed a psychiatrist. Then we decided we would find out for ourselves.

"It was the people who gave me [information on the vaccine], the list that I should have gotten first that said what the reactions were, including severe abdominal pain, eczema, rash, hair loss. My doctor didn't tell me that. I was given a piece of paper that said reactions would be a minimum, maybe a small fever. She had a fever the whole time.

"I never knew any of this existed, and this is \$18,000 later, a child who [had to be] out of school for the first three months and was tutored at home. I don't want to see other kids go through this. I think there should be more testing done. I think the parents should know that this shot isn't for something that's easily picked up. This is for sexual transmission or drug use. My child is ten years old. She plays with Barbie dolls and paints her fingernails. She doesn't know about this stuff. I don't want to give her a shot to protect her from something and someplace she's not at yet."

CITIZENS MAKE PLEA FOR INFORMED CONSENT - Before testifying at a Board of Health public hearing held in Springfield on March 26, 1998, NVIC held a press conference in the State Capitol building. Then, along with scores of Illinois parents who traveled to Springfield to make public comment, NVIC President Barbara Loe Fisher Reverend Robert VandenBosch, President of the American Research Foundation, and Bonnie Dunbar, Ph.D., professor of cell biology at Baylor College of Medicine in Houston, presented formal testimony.

Fisher told the Board of Health "There is a six year old girl named Katherine lying in a bed in Skokie, Illinois unable to lift her head off her pillow or walk to the bathroom. Just 13 weeks ago, Katherine was an ice skater with boundless energy and a dream of going to the Olympics. Her mother didn't want her to get the hepatitis B shot but her pediatrician told her it was a political issue like AIDS and the American Academy of Pediatrics (AAP) was going to mandate the vaccine soon. Katherine got that hepatitis B shot and now she may never skate again. Where were her informed consent rights? And where will the doctors from the state health department and the CDC and the AAP be when her mother carries her up the stairs to the bathroom? And will the state of Illinois pay her medical bills when her insurance runs out after DHHS and the Justice Department oppose giving her federal compensation?"

During limited public comment time, all of the parents asked the Board of Health to allow citizens to follow the judgement of their conscience when making vaccination decisions for their children, including the right

to exercise informed consent to vaccination without suffering harassment and punishment at the hands of state health and school officials. Some, like a young man who was kicked out of an Illinois college in the middle of the semester because of his sincere religious beliefs, asked for the right to follow his religious convictions without being punished by doctors employed by the state. He said:

"They have refused to give me credit for this semester and have told me not to attend class and have cancelled my appointment with my advisors. I applied for a religious exemption. Both my parents wrote letters identifying my objection. We were refused on the grounds that, in order for a religious exemption to occur, I must identify 'a recognized church or religious organization.' I don't believe that anyone has a right to judge my religion. How does recognition of my belief by another human being make it more or less? I am confused by the word 'organized.' How does the number of people or the structure under which they operate validate my beliefs? This is a violation of my Constitutional right to religious freedom."

Rev. Robert VandenBosch, an ethicist, warned that "The First Amendment [of the U.S. Constitution] clearly defines the free exercise of religious beliefs and the moral rights of individuals to obey the judgement of their conscience in matters of life and death. The Ninth Amendment of the Constitution guarantees that governmental authority cannot override individual rights of conscience. It states: 'The enumeration of the Constitution of certain rights shall not be construed to deny or disparage others retained by the people.' One of the rights retained by the people is the right of conscience."

PROFESSOR OF CELL BIOLOGY INVESTIGATES HEP B VACCINE DAMAGE -

Professor Bonnie Dunbar, Ph.D., who has a distinguished 25 year career in academic and laboratory science and has been honored by the U.S. National Institutes of Health (NIH) for her pioneering work in contraceptive vaccine development, presented at the March 26 Illinois Board of Health hearing and described disabling reactions to hepatitis B vaccine suffered by her brother and a research assistant.

"Three years ago my brother, who is a geologist Ph.D. agronomist with four college degrees, came to work with me at Baylor College of Medicine to work on a collaborative project in molecular genetic engineering of wheat proteins. He was required to take the hepatitis B vaccine. Within 24 hours to four days after the first injection, he had fever and severe fatigue for one week. Two to four weeks after that injection, he ended up with a whole series of symptoms that now 15 doctors have said are clearly symptoms of an adverse reaction to this vaccination. Even workman's compensation for the state of Texas is compensating him for over \$300,000 worth of medical expenses."

"At about the same time, a 21-year old girl, a medical student, came to work in my lab for the summer. She, too, had to get the hepatitis B vaccine. After the first injection, she had fever and fatigue. Three weeks following her second injection, she lost vision in her one eye but, after 6 months, regained most of her sight. She was reluctant to get the third dose of vaccine, and talked with her doctor and he told her this [hepatitis B] vaccine is the safest, there's no problem. After the third injection, she ended up in the hospital for two months extremely ill and she has lost all of her eyesight in one eye."

Dr. Dunbar went on to explain to the Board of Health members that during the past three years of collecting data on the hepatitis B vaccine, she has been contacted by hundreds of doctors and patients around the world who have reported severe autoimmune and neurological complications to hepatitis B vaccination in previously

healthy children and adults, including serious rashes, fever, joint pain, chronic fatigue, multiple sclerosis and lupus-like symptoms, rheumatoid arthritis and neurological dysfunction. As a basic science researcher with expertise in cell and molecular biology, she is investigating the possibility that molecular mimicry or other autoimmune mechanisms may be the reason why the genetically engineered hepatitis B vaccine "tricks" the immune systems of genetically susceptible individuals into attacking their own bodies, causing debilitating autoimmune disorders.

After analyzing the data she has accumulated, Dr. Dunbar, in collaboration with colleagues at other academic and medical institutions, applied for a NIH research grant to investigate the role that genetic factors may play in hepatitis B vaccine reactions and in vaccine failures. Their goal is to identify genetic markers so high risk children and adults could be screened out of the mass vaccination program and spared injury and death. The grant was turned down twice by the government in July 1997 and July 1998 but Dr. Dunbar and her colleagues are in the process of refiling the grant, along with additional data.

HEP B VACCINE VICTIMS IN FRANCE SUE - An article in the July 31, 1998 issue of *Science*, an American scientific journal, reports that French attorneys representing 15,000 French citizens filed a lawsuit against the French government "accusing it of understating the vaccine's risks and exaggerating the benefits for the average person." One French physician has reportedly collected data on more than 600 people suffering from serious immune and neurological dysfunction following hepatitis B vaccination, many with symptoms resembling multiple sclerosis. *Science* quotes a World Health Organization official as saying "These fears [of the hepatitis B vaccine] are quite unfounded" and reveals that CDC employee Robert Chen, who is responsible for monitoring vaccine safety for the U.S. government, has a simple explanation for the growing number of reports of hepatitis B vaccine associated injury and death in the U.S., Canada and Europe. His scientific analysis leads him to believe that "It's human nature to attribute cause to almost anything that precedes a tragedy."

HEP B VACCINATION CAN MEAN A POSITIVE HEP B BLOOD TEST - A little known fact about hepatitis B vaccine is that those who are vaccinated can test positive for hepatitis B on some routine blood tests. NVIC has received calls from adults who report that, after getting hepatitis B vaccine, they are testing positive for hepatitis B when they undergo routine blood tests in doctor's offices. The Red Cross maintains that more sensitive lab tests used by blood banks can differentiate between hepatitis B antibodies produced by disease and those produced by the vaccine.

HIV vaccines now being tested in humans also produce positive tests for HIV. As noted in a September 1997 *Washington Post* article about HIV vaccine trials: "Foremost among the worries of many would-be volunteers is the problem of forever testing positive for AIDS antibodies...although sophisticated laboratory tests can usually tell the difference between AIDS antibodies caused by a vaccine and those that indicate a real HIV infection, few laboratories are equipped to make that distinction. Moreover, as vaccines get better by more closely mimicking the real infection, it will become more difficult to distinguish between the two."

IS FORCED HEPATITIS B VACCINATION PAVING WAY FOR FORCED VACCINATION WITH AIDS VACCINE? - Hepatitis B is the first disease transmitted not by casual contact like smallpox or polio, but by high risk behavior such as IV drug use and sexual promiscuity, that has been mandated for use by all children. With the identical transmission routes as HIV, there are

strong indications that forced vaccination of infants and children with hepatitis B is a trial run for forced vaccination with an AIDS vaccine when it is put on the market in the next few years. AIDS vaccines are currently in human trials as a race to bring them to market intensified after a call last year by President Clinton to make the creation and use of an AIDS vaccine "a national mission."

CDC PLANS FOR MASS VACCINATION OF ALL CHILDREN WITH AIDS VACCINE

- In a February 12, 1997 meeting of the CDC's Advisory Committee on Immunization Practices (ACIP), Neal Halsey, M.D., chairman of the American Academy of Pediatrics (AAP) Committee on Infectious Diseases, AAP liaison member of the ACIP and Director of the Institute of Vaccine Safety at John's Hopkins University, reminded HIV vaccine researchers and developers at the meeting that the CDC plans to target 11 to 12 year old children for "universal application" of an HIV vaccine. Halsey told them:

"One of the things that's happened in the past with vaccines is that sometimes the manufacturers have developed them and tested them primarily in an age group or a population which may not be the final target population that this committee has considered. Over the last few years we have developed a statement on adolescent immunization and it probably would be worth your reading that, and others, because we really see age 11 to 12 as the target age for introduction of vaccines for prevention of sexually transmitted diseases. And I know that, at this time, you are really studying adults and you're also some distance away from the actual - having a [HIV] vaccine in hand that might be licensed and approved - but at least it would be nice if there were studies that were planned in parallel when you move another step in the direction of actually having a candidate vaccine, realizing where WE think we would want to use universal application of such a vaccine. And so I think maybe [you should get] a copy of the adolescent immunization statement."

With the Children's Vaccine Initiative (CVI) and pharmaceutical industry setting up the mechanism for global mass vaccination of children and adults, including the creation of national and international vaccine tracking systems, countries with low HIV rates like the U.S. and Europe will be forced to use an HIV vaccine in order to pay for the vaccination of populations in Asia and Africa where HIV infection rates are skyrocketing. In 1996, HIV vaccine developer Stanley Plotkin, M.D., of Pasteur Merieux Pharmaceuticals (who developed the rubella vaccine and has been a vaccine policymaker member of the AAP Committee on Infectious Disease and AAP liaison member of the ACIP) explained why mandatory vaccination in rich countries like the U.S. help deliver vaccines to Third World markets:

"The keystone of the [global mass vaccination] system is that the research costs [of drug companies] are recouped in North America and Europe and the vaccines are sold in the developing world at much, much lower margins...the relatively high rate of childhood vaccination seen lately in most parts of the world is the result of that system," explained Plotkin.

CDC TELLS CONGRESS ABOUT FUTURE VACCINES - In testimony before the U.S. Senate Committee on Labor and Human Resources in 1997, CDC official Walter Orenstein, M.D., made a bid to persuade Congress to reauthorize 288 million dollars for the CDC's Immunization Grant Program in the \$427 million 1998 DHHS budget request for immunization activities. In a review of the history of vaccination, Dr. Orenstein recounted that, although almost a century passed between the development of the smallpox vaccine in 1796 and that of the rabies vaccine in the 1880's, by the middle of the 20th century there were nearly two dozen vaccines on the market.

Painting a picture of the future, Orenstein said: "On the horizon are vaccine technologies that would have been considered science fiction just a decade ago, but are now reported at scientific meetings. Snippets of synthetic DNA have worked as experimental vaccines in animals. Edible plants have been bioengineered to become vaccine factories....vaccines have been enclosed in microscopic capsules, permitting them to be released slowly over time..."

Orenstein reminded legislators that "Every day about 11,000 babies are born in this country. Each of these children starts with immunization coverage of zero. There is why our responsibility to our Nation's children never ends: it must be sustained every day of every year....completing state-based immunization registries is the cornerstone of assuring disease prevention."

VACCINE REGISTRIES TO TAG, TRACK, FORCE VACCINATION -

Even though CDC officials admit that there is already a 96 percent vaccination rate in the U.S. with federally recommended vaccines, they are setting up state vaccine tracking registries and plan to link them together to create a de facto national electronic tracking system to ensure mass compliance with federal vaccine policies. Citizens will be tagged with a number at birth and tracked even when moving from state to state.

In 1995, DHHS Secretary Donna Shalala appropriated the social security numbers assigned to newborns to allow states to enter all babies in state vaccine tracking systems. In 1996, the Health Insurance Portability and Accountability Act (HIPAA), also known as the Kennedy-Kassebaum legislation, outlined plans for a "unique health care identifier" number, which is an alternative to the social security number, to be assigned to citizens at birth and electronically monitor their medical records, including vaccination records.

In a 1998 CDC publication entitled *Initiative on Immunization Registries*, the CDC states that "we see [vaccine] registries as a possible first step in the development of an electronic pediatric record" and "computerized registries will eventually be capable of capturing immunization for individuals of all ages" and "until a unique personal identifier can be established on a national basis, multiple means of identification must be used [in state vaccine registries]." Core data that is now collected in many state vaccine tracking systems include a citizen's name, address, phone number, social security number, birth date, sex, race, primary language, patient birth order, patient birth registration number, patient Medicaid number, mother's name (including maiden name) and social security number and father's name and social security number.

Most often state officials automatically enroll newborns into the vaccine registry without informing parents or giving them the right to "opt-out" of the registry. In the state of Texas, PROVE, a parent group led by Dawn Richardson, worked to get legislation passed in 1997 requiring the state health departments to obtain a parent's prior written consent to enroll a child in a vaccine registry.

The CDC goes on to state that one of their main goals is "establishing a target date to achieve the goal of establishing immunization registries in every community in the Nation" and "promoting the inter-operability of registries with other developing medical information systems" and "promoting the automated exchange of immunization records between registries."

WHAT YOU CAN DO - If you want to make informed, voluntary decisions about hepatitis B vaccination, there are several actions you can take to educate your community and protect your informed consent and privacy rights.

Circulate this newsletter in your community among your family, friends, and neighbors. Get reprints by sending in the enclosed reprint order card. Reprints are available for \$1.25 each. Bulk pricing is available. Give copies to your doctors, lawyers, teachers, school principals, nurses and others. Send a copy to your favorite newspaper, radio and TV station. Send a copy to your state and federal legislators with a personal letter.

Report vaccine reactions by calling NVIC at 1-800-909SHOT or accessing NVIC's website at www.909SHOT.com.

If you are pregnant, get tested for hepatitis B disease. If you are infected, your baby is a candidate for vaccination.

Stand up for your informed consent rights. If you do not test positive for hepatitis B; do not fall into one of the high risk categories described in this newsletter; and decide you do not want your newborn vaccinated before leaving the hospital newborn nursery, you can amend the "consent for medical treatment" forms you sign upon entering the hospital before giving birth by writing on the form that you do not give consent for hepatitis B vaccination of your baby in the hospital. Check to see if your state has a vaccine tracking system and, if you do not want your baby enrolled in a tracking system, find out how you can exercise your informed consent rights.

Get more information, including checking your state vaccination laws for requirements and exemptions. Hepatitis B vaccine is required in 35 states. There are medical exemptions in all states, religious exemption in all but two states (West Virginia and Mississippi) and philosophical exemption in 16 states.

Don't let anyone intimidate or coerce you into taking action before you have had the opportunity to become fully informed about all your options and are comfortable with your vaccination decision.

THE VACCINE REACTION

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INTERNATIONAL ROUNDUP

Japan's Trade Surplus Falls Again. Japan's current account surplus fell for the second consecutive month in March, providing further evidence that it has passed its peak. According to Japan's Ministry of Finance, the current account fell to just under \$9 billion, a 3.5 percent drop from February and 25.5 percent below its level last March. The smaller-than-expected surplus was largely the result of a substantial increase in the current transfers deficit, which jumped to \$4.3 billion in March, a 258 percent increase over the previous year.

Poorer Nations Starting More Anti-Dumping Cases. A record 26 countries opened anti-dumping investigations in 1998, up from 22 the year before and just 7 a decade ago, according to a new study based on World Trade Organization data. The United States, the EU, Australia, and Canada—traditionally the most active users of anti-dumping measures—accounted for just a third of the 225 cases opened last year. These four accounted for over 80 percent of cases in the late 1980s. (The EU has a single trade policy and is therefore treated as a single entity.) Developing countries have become relatively more active: South Africa opened the most cases, 41, and India opened 30, compared with 34 cases initiated by the United States and 22 by the EU. The EU was the target of the most anti-dumping cases, 42, followed by China with 23. Anti-dumping activity was most intense in the steel sector, which accounted for almost 40 percent of all cases opened last year.

World Bank Speaks Out Against Tobacco. Developing countries can prevent millions of premature deaths and much disability if they adopt measures to reduce the demand for tobacco, according to a new study from the World Bank. The study found that increasing the price of cigarettes is the most effective way to reduce demand. It estimates that increasing the price by 10 percent would reduce demand by about 8 percent in low- to middle-income countries and 4 percent in high-income countries. The Bank estimates that such an increase in price worldwide would cause 40 million current smokers to quit. The study found that advertising bans, dissemination of research on the health consequences of smoking, and nicotine replacement therapy are effective in reducing demand. Supply restrictions, by contrast, were judged to be ineffective ways to reduce smoking. The bank noted, for example, that attempts to restrict cigarette sales to minors have been largely unsuccessful, even in developed countries with substantial enforcement capacity.

Brazil Stays on Target. Brazil's government announced this week that it had hit two targets established by the IMF as part of the \$41.5 billion aid package announced in November. Brazil's primary budget surplus exceeded 9 billion reais (\$5.6 billion) in the first quarter of 1999, easily surpassing the goal of 6 billion reais set in the IMF agreement. Brazil also met all the foreign-debt targets specified in the agreement, with short-term foreign debt of \$3.6 billion at the end of March, compared with the IMF ceiling of \$5.3 billion.

Contamination of Poliovirus Vaccines With Simian Virus 40 (1955-1963) and Subsequent Cancer Rates

Howard D. Strickler, MD, MPH; Philip S. Rosenberg, PhD; Susan S. Devesa, PhD; Joan Hertel; Joseph F. Fraumeni, Jr, MD; James J. Goedert, MD

Context.—Poliovirus vaccine contaminated with live simian virus 40 (SV40), a macaque polyomavirus that is tumorigenic in rodents, was used extensively in the United States between 1955 and 1963. Simian virus 40 DNA has recently been detected in several rare human tumors, including ependymomas, osteosarcomas, and mesotheliomas.

Objective.—To determine the risk of ependymoma, osteosarcoma, and mesothelioma among Americans who as children received SV40-contaminated poliovirus vaccine.

Design.—Retrospective cohort study using data from the Surveillance, Epidemiology, and End Results program (1973-1993) and the Connecticut Tumor Registry (1950-1969), as well as national mortality statistics (1947-1973).

Setting.—United States.

Participants.—Birth cohorts that were likely to have received SV40-contaminated poliovirus vaccine as infants, born 1956 through 1962 (60 811 730 person-years of observation); as children, born 1947 through 1952 (46 430 953 person-years); or that were unexposed, born 1964 through 1969 (44 959 979 person-years).

Main Outcome Measures.—Relative risk (RR) of each cancer among exposed compared with unexposed birth cohorts.

Results.—Age-specific cancer rates were generally low and were not significantly elevated in birth cohorts exposed to SV40-contaminated vaccine. Specifically, compared with the unexposed, the relative risk of ependymoma was not increased in the cohorts exposed as infants (RR, 1.06; 95% confidence interval [CI], 0.69-1.63), or as children (RR, 0.98; 95% CI, 0.57-1.69) nor did the exposed have an increased risk of all brain cancers. Osteosarcoma incidence also showed no relation to exposure as infants (RR, 0.87; 95% CI, 0.71-1.06) or children (RR, 0.85; 95% CI, 0.59-1.22). Last, mesotheliomas were not significantly associated with exposure, although the cohorts studied have not yet reached the age at which these tumors tend to occur.

Conclusions.—After more than 30 years of follow-up, exposure to SV40-contaminated poliovirus vaccine was not associated with significantly increased rates of ependymomas and other brain cancers, osteosarcomas, or mesotheliomas in the United States.

DNA SEQUENCES homologous to simian virus 40 (SV40), a macaque polyomavirus that can induce cancer in rodents,^{1,2} were recently detected in several rare human tumors, including ependymomas,^{3,4} osteosarcomas,⁵ and mesotheliomas.⁷ Tens of millions of Americans were exposed to this virus between 1955 and 1963 as a consequence of adventitious contamination of the early poliovirus vaccines, produced in Asian macaque kidney cell cultures. By 1961, between 80% to 90% of all US children younger than 20 years had been injected at least once with formalin-inactivated poliovirus vaccine (IPV) containing SV40.⁸ Because SV40 is relatively resistant to formalin killing, the IPV contained variable amounts, commonly low titers, of live SV40. The oral poliovirus vaccine began mass distribution in the United States in 1963 and was SV40-negative.⁸

Earlier studies of cancer risk following exposure to SV40-contaminated vaccines were generally limited by small sample size or short follow-up.⁹⁻¹⁶ One exception, a large study in the German Democratic Republic with 22 years of follow-up, found no significant differences in cancer rates between the 885 783 individuals who received SV40-contaminated poliovirus vaccine as infants, compared with similarly aged individuals born a few years later, who received only SV40-negative vaccine.¹⁶

No epidemiologic studies, however, have evaluated the specific types of cancers found recently to contain SV40 DNA. In addition, many of the earlier investigations, including the German study, examined mainly oral poliovirus vaccine. The impact of the major single-source exposure to SV40 in the United States, in-

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jected IPV,⁸ has not been adequately assessed. Both animal and human studies have shown that the route of SV40 exposure is biologically important.^{9,10} Notably, tumors in animals were all induced by injection and neonates were particularly susceptible.^{12,17} Therefore, more than 30 years after millions of American infants and children were immunized with SV40-contaminated poliovirus vaccine, it is now possible to investigate the long-term carcinogenic effects of parenteral exposure to SV40 in early life.

METHODS

The risk of immunization with SV40-contaminated IPV was determined according to birth cohort based on published information,⁸ and was used to define 3 comparison groups: (1) individuals at high risk of exposure in infancy, born 1956 through 1962; (2) those at high risk of exposure as children, born 1947 through 1952; and (3) unexposed individuals born a few years later, 1964 through 1969. Cancer incidence and mortality rates in these 3 cohorts were then compared on an age-specific basis (as described below).

Cancer incidence rates in the United States were obtained from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute, which since 1973 has collected detailed information regarding new cancer cases diagnosed among residents of 9 representative areas with approximately 10% of the total US population.¹⁸ Additional incidence data were obtained from the Connecticut Tumor Registry, the only cancer registry in the United States that was well established prior to 1955. Cancer mortality data for the entire country were obtained from the National Center for Health Statistics, and the population and demographic data from the US Bureau of the Census.

The cancers studied included ependymomas, osteosarcomas, and mesotheliomas, which have been reported to contain SV40 DNA. In addition, all primary brain cancers were studied as a group, since it has been suggested that a variety of brain tumors might contain SV40 DNA.⁵ For each birth cohort, we calculated age-specific cancer incidence rates by single year of age per 100 000 person-years at risk. We used Poisson regression to assess whether the age-specific incidence rates varied according to birth cohort, and fitted a sequence of models to assess whether the relationship between the log of the incidence rate and age was best described as uniform, linear, quadratic, or as a cubic spline with 2 or 3 segments. We used the likelihood ratio test to determine the best-fit model for age and the significance of birth cohort. In summary, we optimally controlled for the effects of

age to best assess whether exposure history (determined by year of birth) was related to the incidence of cancer. For individual age-specific incidence or mortality figures of special interest, 95% confidence intervals (CIs) were determined assuming a Poisson distribution.¹⁹ Last, time trends in age-specific cancer incidence in Connecticut from 1950 through 1969 were examined for any changes in rates that could be attributed to SV40-contaminated vaccine exposure.

RESULTS

The observed and fitted (smoothed) age-specific cancer incidence rates in the SEER catchment area for 1973 through 1993 are presented by birth cohort in Figure 1. In general, the exposed groups did not experience elevated rates of cancer, and the likelihood ratio tests found no significant increases in cancer risk among the cohorts exposed as infants (60 811 730 person-years of observation for each cancer studied) or children (46 430 953 person-years), compared with the unexposed birth cohort (44 959 979 person-years).

Ependymoma incidence rates, based on 200 total cases in the data set, were similar in each of the 3 comparison groups (Figure 1, A), with observed fluctuations reflecting the small numbers of this rare tumor at any given age. For example, at age 13 years there were 5 cases (95% CI, 2.15-15.43) compared with 2 cases (95% CI, 0.55-16.53) in the cohorts that were exposed as infants and unexposed, respectively. Ependymoma incidence was best fitted using a quadratic model for age, and showed no overall difference among the cohorts (χ^2 , 0.19 on 2 df; $P=.91$). Specifically, incidence in the cohorts exposed as infants (RR, 1.06; 95% CI, 0.69-1.63) or children (RR, 0.98; 95% CI, 0.57-1.69) was not elevated as compared with the unexposed cohort (goodness of fit, 70.2 on 77 df).

Since the SEER program began in 1973, these data could not be used to study ependymoma incidence in the age group at highest risk, children under the age of 4 years.²⁰ To address this limitation, we studied time trends in incidence among children 0 to 4 years of age in Connecticut, from 1950 to 1969 (Figure 2). Ependymoma incidence in this age group (based on 22 cases and 5 036 496 person-years of observation) was actually higher during the period 1950 through 1954, just prior to the mass immunization program, than in 1960 through 1964, when the greatest effect of SV40 exposure on ependymoma incidence would be expected; ie, as a result of exposures during both 1954 through 1959 and 1960 through 1963. Similar data for individuals 5 to 9 and 10 to 14 years of

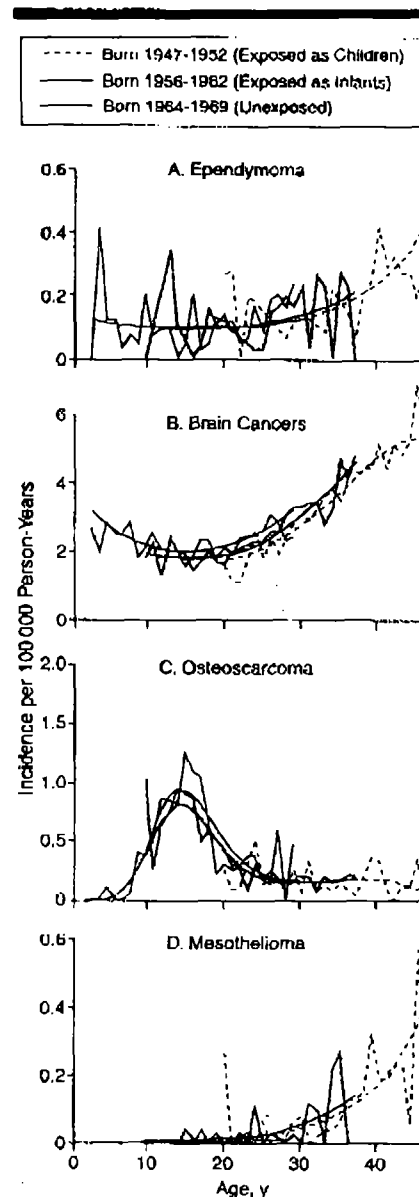


Figure 1.—Incidence of selected cancers in the United States by birth cohort and simian virus 40-contaminated vaccine exposure. Superimposed on the incidence rates in the figure are the best-fitting Poisson models that were used to describe the data statistically.

age in Connecticut also showed no relation between ependymoma incidence and the period of vaccine contamination.

Brain cancer incidence (Figure 1, B), was best fitted using a 2-segment spline function for age (goodness of fit, 62.71 on 75 df). These tumors were relatively common (4162 total cases) and the variation according to birth cohort was statistically significant (χ^2 , 10.89 on 2 df; $P=.004$). However, compared with the unexposed cohort, incidence was incrementally lower in the cohorts exposed to SV40-contaminated vaccine as infants (RR,

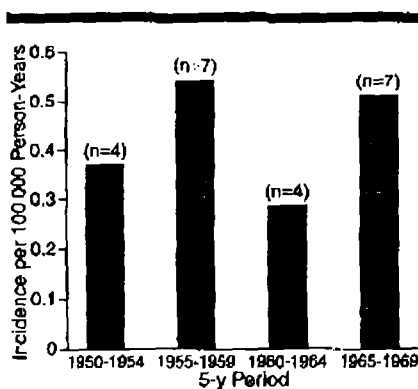


Figure 2.—Incidence of ependymoma among children 0 to 4 years of age in Connecticut, "before" (1950-1954), "during" (1955-1964), and "after" (1965-1969) the mass immunization of children with simian virus 40-contaminated poliovirus vaccines. The number of cases during each period is indicated in parentheses at the top of each bar.

0.90; 95% CI 0.82-0.99) or children (RR, 0.82; 95% CI, 0.73-0.92), respectively.

Because these data did not address brain cancers in the youngest individuals, we examined US cancer mortality rates among individuals younger than 5 years. The cohort exposed as children was not immunized with IPV until after their fifth birthday. However, brain cancer mortality was higher in this group (2.04 per 100 000 person-years) than in the cohort exposed as infants (1.27 per 100 000 person-years). Brain cancer mortality, therefore, was greater among young children not yet vaccinated than in young children injected with contaminated IPV during infancy. Notably, in the cohort born after 1963 and never exposed to SV40-contaminated vaccine, the rate was 1.04, showing that brain cancer deaths among infants continued to decrease over time. Each rate was significantly different from the others based on a total of 4643 brain cancer deaths and 333 163 427 person-years of observation.

Osteosarcomas were studied in the age groups at highest risk of developing the disease, the teenage and young adult years (Figure 1, C). The age-specific incidence data, based on 522 total cases in the data set, were well fit using a cubic spline with 2 segments (goodness of fit, 94.87 on 75 df). However, Poisson regression showed no significant differences in risk (χ^2 , 2.12 on 2 df; $P=.346$) between the unexposed cohort and the cohorts exposed as infants (RR, 0.87; 95% CI, 0.71-1.06) or children (RR, 0.85; 95% CI, 0.59-1.22). Note the initial peak at 10 years of age in the cohort exposed as infants represented just 2 cases (95% CI, 0.55-16.53). Similarly, trends in osteosarcoma incidence rates over time in Connecticut showed no increases that

could be attributed to SV40-contaminated vaccines (data not shown).

Mesotheliomas (Figure 1, D) showed no significant cohort effect (χ^2 , 2.90 on 2 df; $P=.23$) in the linear age model that provided the best fit (goodness of fit, 60.13 on 78 df). The risk in the cohorts exposed as infants (RR, 3.00; 95% CI, 0.67-13.11) or children (RR, 2.45; 95% CI, 0.50-12.03) was elevated as compared with the unexposed. However, the birth cohorts studied have not yet reached the age at which most mesotheliomas occur, resulting in few cases (a total of 71) and imprecise estimates of risk.

COMMENT

Contamination of the early poliovirus vaccines with SV40 has reemerged as a public health concern following recent reports that SV40 DNA may be present in osteosarcomas, mesotheliomas, ependymomas, and perhaps other types of brain cancer.³⁻⁷ The extensive parenteral exposure of infants is a particular cause for concern as animal studies have shown that injected neonates are particularly susceptible to SV40-induced tumors.^{1,2,8,9,17} However, more than 30 years after this extensive single-source exposure in the United States, the birth cohorts exposed as infants or children showed no significant increase in those cancers reported to have high prevalence of SV40 DNA.

This result is reassuring, as it is likely that we would have observed an effect on cancer rates if one existed. As discussed, almost all US children under the age of 20 years in 1961 had been injected 1 or more times with SV40-contaminated IPV.⁸ Furthermore, because of the large number of individuals studied and the long period of follow-up, each cohort contributed a large number of person-years to the data. To help judge the uncertainty in our analyses of incidence rates, we calculated the 95% CIs around the estimates of cancer risk in the exposed birth cohorts. For ependymomas and osteosarcomas, even the upper limit of risk was quite small, and for brain cancers there was a significant inverse relation. Few cases of mesothelioma occurred in any groups.

A causal relation between SV40 exposure and ependymomas in children would involve a short incubation time, if the recent detection of SV40 DNA in ependymomas in infants is to be believed. Therefore, the absence of an SV40-contaminated vaccine effect on ependymoma cancer rates in the Connecticut children 0 to 4 years of age is consistent with the cohort analyses. Together the null results argue against a relation between vaccine-related SV40 exposure and the development of ependymomas.

In addition, overall brain cancer incidence rates were actually lower in the exposed birth cohorts. This pattern seems unlikely to represent a protective effect of SV40-contaminated vaccines, but it probably reflects the increase in brain cancer incidence over calendar time that has been well described in the literature.²⁰ To specifically evaluate brain cancers in young children and infants we assessed cancer mortality rates, but no relation was seen between SV40-contaminated vaccine exposure and the development of brain cancers in children under 5 years of age.

The age-specific incidence of osteosarcoma was not significantly different in exposed or unexposed cohorts, including the teenage years when osteosarcomas are most common.²¹ In addition, trends in osteosarcoma incidence in Connecticut showed no changes that could be attributed to the period of vaccine contamination. The interpretation of this finding is limited, since the postulated incubation time of SV40-induced osteosarcoma is not as defined as it is for ependymoma. However, the overall patterns observed for osteosarcoma incidence argue against an association with vaccine-related SV40 exposure.

Mesothelioma incidence rates showed a nonsignificant increase among the exposed groups. Few individuals developed mesothelioma in any of the comparison groups, however, and the modest case numbers made estimates of RR imprecise. Mesotheliomas could not be directly studied in the older age groups, which are ordinarily at highest risk, since individuals in the exposed cohorts were at most 46 years of age in 1993. This is important, as mesothelioma incidence has increased dramatically over time, but only among older individuals who were unlikely to have received the contaminated vaccines. Therefore, other factors, notably asbestos exposure, likely explain the increases in mesothelioma incidence rates that have been observed. Final conclusions about the relation of mesotheliomas to SV40-contaminated vaccines will not be possible until the individuals exposed as infants and children reach a more advanced age.

Several limitations to this investigation need to be considered. It is important that this report not be viewed as strong evidence against the role of SV40 as a human pathogen. For example, SV40 may have been in the human population for some time, unrelated to vaccine exposure, as suggested by the finding of SV40 antibodies in serum samples around the world that were collected before introduction of poliovirus vaccines.⁸ It is also possible that SV40 only has tumorigenic potential in humans exposed un-

der different conditions and higher levels of virus than were associated with poliovirus vaccine. Vaccine-related exposure to SV40 in many countries has involved either oral administration or mostly low viral titers in injected inoculations.⁸ In general, the unavailability of specific information regarding the actual SV40 titer of each inoculation has limited the power of population-based studies of this kind. Finally, comparisons among birth cohorts measure the net im-

pact of all protective and adverse factors that influence the risk of cancer in the cohorts, and not just the factor under investigation (ie, SV40 exposure).

In summary, our study failed to detect any significant increases in the risk of cancers reported to contain SV40 DNA among the birth cohorts exposed to SV40-contaminated vaccine. In effect, ependymomas and osteosarcomas have remained rare cancers,^{20,21} while the rising rates for mesotheliomas have in-

volved older age groups unlikely to have received SV40 contaminated vaccine. Thus, approximately 30 years after millions of Americans were parenterally exposed as infants or children, the absence of a discernible effect in our study adds to the evidence that no relation exists between exposure to SV40-contaminated vaccine and the development of cancer. As the exposed cohorts mature, however, it will be important to continue monitoring of cancer risks.

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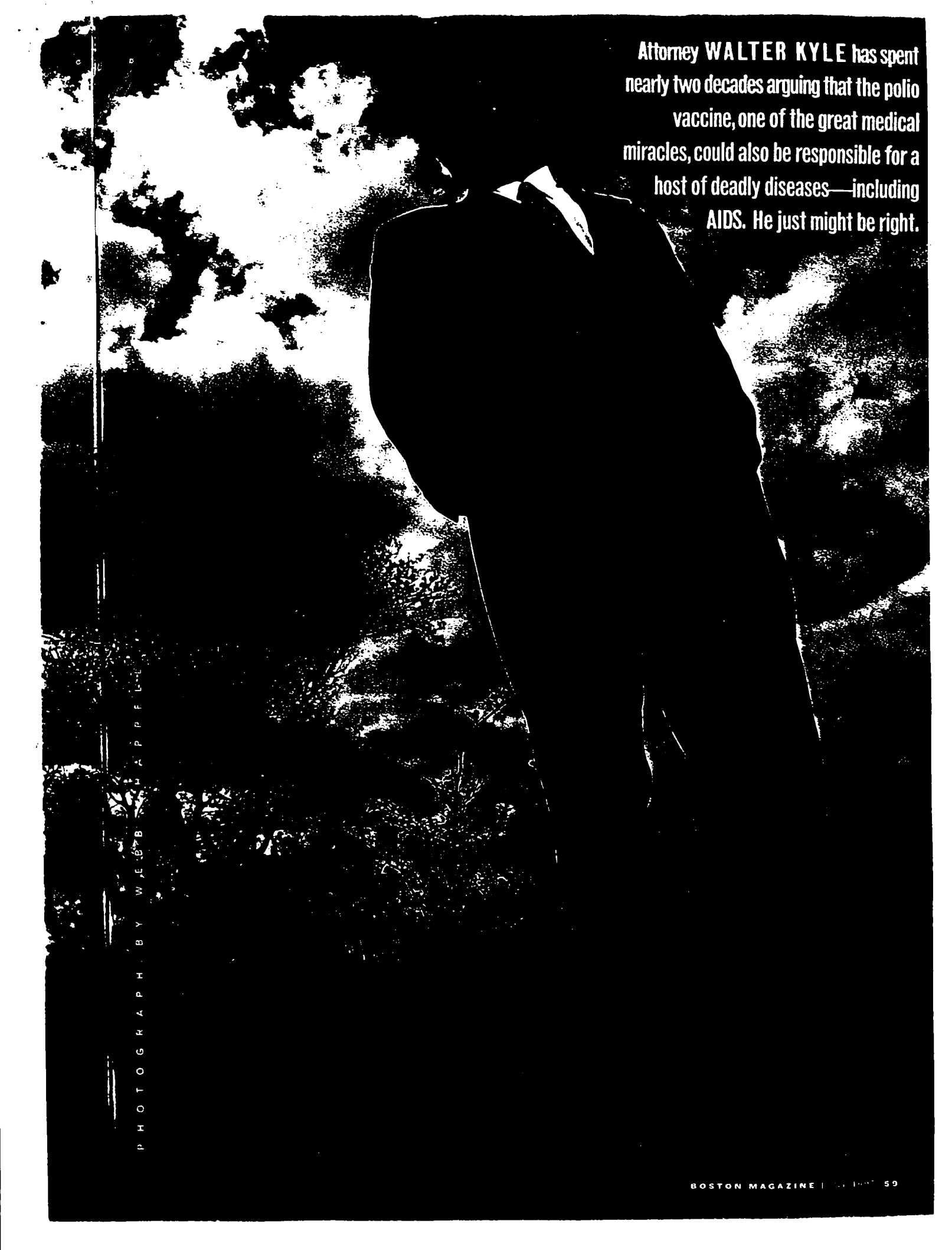
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Walter Kyle (see
article attached) brought it
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Walter Kyle
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Kyle strongly believes
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Peggy



Attorney WALTER KYLE has spent nearly two decades arguing that the polio vaccine, one of the great medical miracles, could also be responsible for a host of deadly diseases—including AIDS. He just might be right.

PHOTOGRAPH BY WEBB HAPPEL

THE LONELY CRUSADE OF WALTER KYLE

By Debbie Bookchin and Jim Schumacher

DIRECTLY ABOVE THE GIFTED HAND, an upscale antiques and crafts store in the center of Hingham, a black and gold sign neatly mounted on the white clapboard of an immaculately kept Colonial house announces the offices of Walter S. Kyle, Attorney at Law. At first blush, Walter Kyle seems to blend perfectly into the backdrop of Hingham's amalgam of suburban chic and historic elegance. He is a handsome and affable 47-year-old Arkansas transplant whose soft-spoken and gentlemanly bearing suggest ease and comfort. His tidy office is tastefully turned out: a small cherry desk adorned with an antique brass faux-gas lamp, leather chairs, striking vermillion drapes, newly hung Williamsburg Collection wallpaper, and Persian-style rugs covering polished pine floors.



THE CURE: Almost everyone born before 1955 remembers the swath of terror that polio cut through the American psyche.

On a glass-encased shelf sits a gold-framed, inscribed photograph of Kyle and his son Robert standing with President Clinton in the Oval Office; nearby sits another of Kyle standing directly behind Clinton as he gives a speech in New Hampshire during the 1992 primary. Clinton, who told *Boston Magazine* he has known Walter Kyle "most of his life" and is "grateful for his friendship," tapped Kyle to serve as his New Hampshire field director during the 1992 presidential race. Dressed in a conservative blue suit that fits snugly over his athletic frame, Kyle could easily be mistaken for a smooth and prosperous lawyer, at home in the corridors of power.

Yet Kyle has devoted most of his career to a single-minded and iconoclastic pursuit that has earned him no love in Washington or in the boardrooms of America's pharmaceutical giants: attacking the polio vaccine. The vaccine is one of modern medicine's most revered miracles; but Kyle has borne witness to its darker side. Not only can the vaccine itself cause paralysis and death by infecting recipients with polio, but Kyle says there is plenty of reason to believe that it may be the repository for a variety of monkey viruses that can cause disease in human beings. That is because all polio vaccine produced for consumption in this country is grown on the kidney tissues of monkeys, which are notorious reservoirs for all kinds of viruses. He believes that federal health regulators have at times allowed contaminated batches of vaccine to be distributed to infants and children in this country. He has even hypothesized that one possible source of the AIDS virus was through contaminated polio vaccine.

The Food and Drug Administration (FDA) counters that the vaccine is free of all known monkey viruses. Kyle believes he has evidence to prove otherwise. In three undisclosed locations in the Boston area, Kyle, in the course of 20 years of litigation, has collected more than 100,000 pages of internal drug company memoranda and government documents. He says the internal memos paint a damning picture of a vaccine production process rife with contamination problems and a government that doesn't seem to care. "Why would anyone think it's okay to give American kids a vaccine that might be contaminated with monkey viruses?" says Kyle. "But that's exactly what's been going on with the polio vaccine. For 40 years they've been engaged in a massive experiment with our children. Every parent should be angry."

TODAY IT IS EASY TO FORGET how deeply the fear of polio gripped the nation during the first half of this century. But almost everyone born before 1955 remembers the swath of terror the disease cut through the American psyche. Parents would reach into a crib to pick up their infants and, to their horror, find that overnight their legs had turned limp and lifeless. Polio could take the most robust and athletic children and reduce them to weakened cripples, condemned to a lifetime on crutches or worse, entombment in an iron lung. Polio didn't single out the poor and sickly; it struck healthy, middle-class kids and adults too. It was unpredictable. No one seemed to know how the disease was spread, so no one knew how to avoid it. In the epidemic of 1916, the first of almost four straight decades of annual epidemics in this country, 27,000 people were paralyzed and 6,000 died. As recently as 1952, 58,000 people contracted the disease. Every summer, as polio epidemics worsened throughout the 1940s and early 1950s, parents prayed their children would be spared. Polio had become a national scourge. Deliverance from it could not come soon enough.

When after extensive research in the early fifties a young, unknown Debbie Bookchin and Jim Schumacher are freelance writers who live in Vermont.

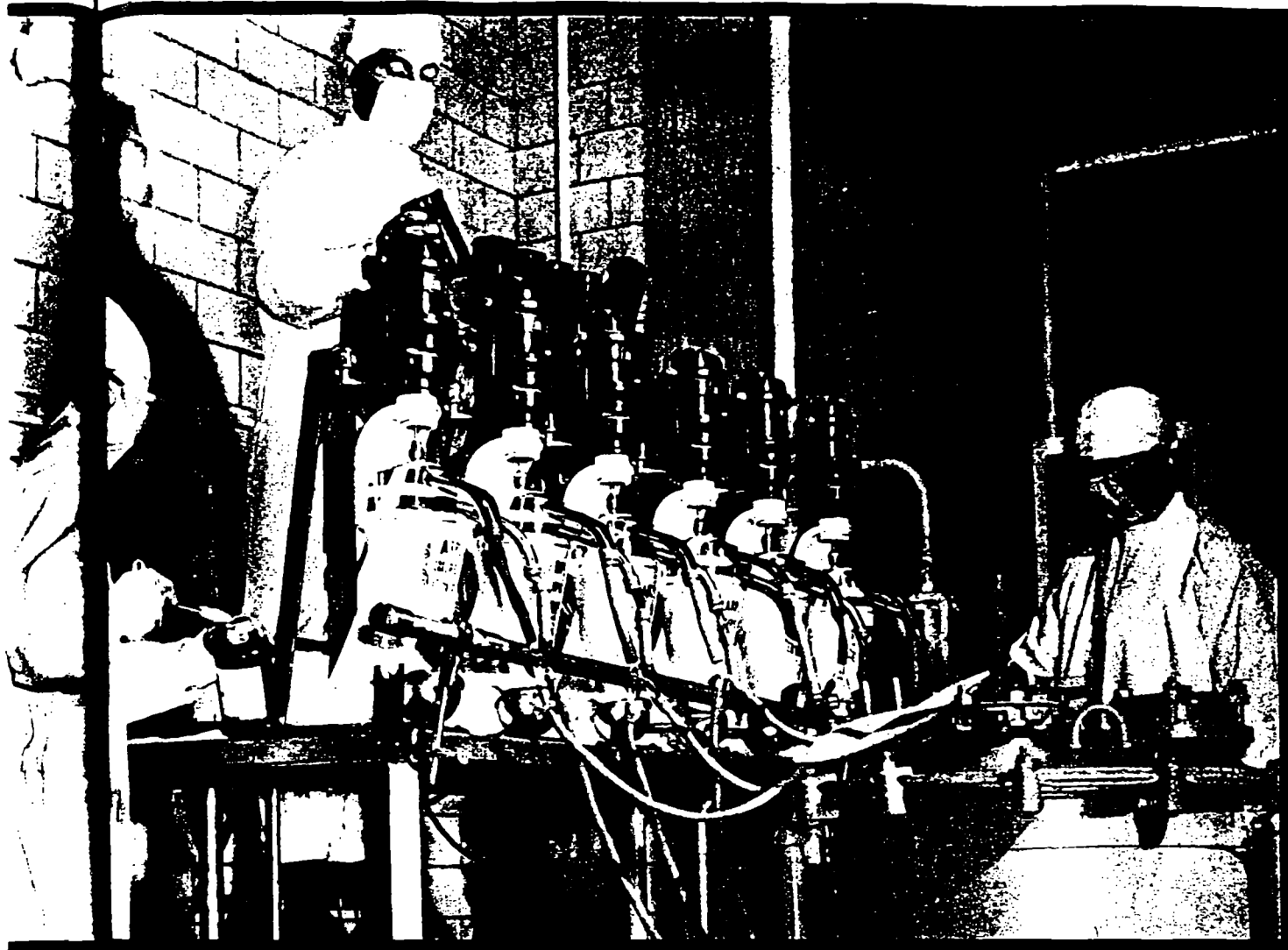
"ASK ANY MOTHER if she would approve of her child being given a vaccine that was potentially contaminated with monkey viruses," Barbara Loe Fisher says of the polio vaccine. "I think she would tell you, 'No, thank you.'"

microbiologist from the University of Pittsburgh named Jonas Salk developed a vaccine, he became an instant American hero. On April 12, 1955, the 10th anniversary of the death of Franklin D. Roosevelt, perhaps the most famous American polio victim, church bells rang throughout the land to celebrate the success of the trials of Salk's vaccine and its availability for massive immunization. Between the inactivated Salk vaccine and later Albert Sabin's "live" oral vaccine, polio was completely eradicated in this country by the late seventies. The success of the polio vaccine has stood as a singular achievement that is universally regarded as an unparalleled triumph of American know-how over what was as close to a plague as this country had ever known.

In 1977, when Walter Kyle was preparing to take the Arkansas bar exam, the last thing on his mind was the polio vaccine. The second in a family of overachievers (his two sisters both practice law, one in Texas, the other in Arkansas; a brother is a neurosurgeon) and a proficient pilot, Kyle had planned to pursue aviation law. He recalls that he used to fly seaplanes for Chalk's International to Bimini (before Gary Hart made it famous with Donna Rice aboard the yacht *Monkey Business*) after graduating from the University of Miami in Coral Gables. At Miami, Kyle received degrees in mechanical and electrical engineering, and then spent two years testing autopilot systems by pushing planes to their maximum speeds and taking them into a dive to see if they would crack up before he could recover.

After he'd had his fill of engineering feats, Kyle returned home to attend law school at the University of Arkansas in Fayetteville, where his old friend Bill Clinton and Bill's new wife, Hillary, were two of his professors. (Kyle recalls that the future First Lady was "more intimidating" in the classroom than her husband.) Two weeks after graduating, Kyle took the bar exam, skipping the lengthy bar preparation course most students consider prerequisite. He already had a job lined up with a law firm in Ft. Lauderdale.

Then the wife of one of his plane mechanics suddenly became paralyzed—a victim of what doctors call "contact" polio. Like almost 3 million Americans each year, she had brought her infant son to his pediatrician for a routine polio immunization. And like those other Americans she had no idea that her son's ingestion of the live oral vaccine held any danger for her or her child. But three weeks after he received the vaccine, she became permanently paralyzed from the waist down. The statistical risk of paralysis from the vaccine is considered negligible, but each year 8 to 10 people in the United States contract polio after receiving the oral vaccine or, as in the young mother's case,



PANDORA'S BOX: Above, workers in 1955, processing the polio vaccine. Kyle believes the continued use of monkey tissue in making the vaccine has exposed millions of Americans to many simian viruses.

after being exposed weeks later to the poliovirus in the stools of a recently vaccinated child. In 1963, the United States had switched from an inactivated injected vaccine and began to use the live virus vaccine. One reason the country began using the live vaccine was to increase the number of people being immunized in this fashion.

When Kyle learned that government policy included this kind of deliberate exposure of care givers to the deadly virus, he was outraged. "These people were innocents whose lives were ruined all because of a massive government program to inoculate people with a live virus without their consent," he says. "I thought it was a travesty." One day after passing the bar exam, he signed up his first case, agreeing to represent the woman and her family against one of the world's largest drug manufacturers, Lederle Laboratories, now known as Wyeth-Lederle Vaccines and Pediatrics, in Radnor, Pennsylvania, the nation's only manufacturer of live polio vaccine.

Kyle took his paralysis case to a well-known tort attorney, Henry Woods, now an Arkansas federal judge. On the day they were to start the trial, the two men won a sizable settlement from Lederle for their client. As far as Woods was concerned, the case was over. Not so Kyle. In 1979 he filed suit against the federal government on behalf of his paralyzed client, claiming not only that the government had failed to follow its own regulations to ensure that the vaccine was safe for people in close proximity to those inoculated, but that it was an invasion of a constitutional right to privacy for the U.S. gov-

ernment to expose people to the virus without their knowledge or consent. When the U.S. Court of Appeals for the Eighth Circuit, in St. Louis, agreed with Kyle that the government could be held liable

on certain claims just like any private citizen, Kyle significantly advanced the rights of anyone harmed by vaccines to sue the government for negligence. Since then he has been involved in nearly 100 claims on behalf of vaccine-damaged clients.

Far from prospering from these claims, Kyle has often not been paid for his vaccine work and has found that he has to devote increasing amounts of his time to more garden variety tort law to make ends meet. But even if they haven't made him rich, his vaccine litigations have secured him a minor place in legal history. In 1988, the United States Supreme Court cited his 1981 case in a landmark decision recognizing the rights of any vaccine-damaged individual to sue the federal government for failure to follow its own regulations. "He has touched a lot of people through his work," says Clinton. "He has always been hard working, determined, and compassionate."

IT WAS DURING HIS INITIAL case that Kyle received his first big batch of internal documents from Lederle. (Continued on page 93)

Walter Kyle

(Continued from page 61)

In his discovery requests, Kyle had asked for Lederle's neurovirulence-testing data—the tests that ensure the vaccine won't cripple anyone. In response, he received a flood of documents and noticed that many contained references to “adventitious agents.” Memo after memo documented Lederle's problem with the agents. Says Kyle, “It became obvious that what they were talking about was unwanted live monkey viruses that they couldn't get rid of.” The realization piqued his curiosity.

Kyle started setting aside every document that mentioned adventitious agents. When he later turned to analyze them, he realized that the memos were describing a witch's brew of contaminants, including simian measles, foamy viruses, simian virus 40 (SV40), adenoviruses, and simian cytomegalovirus, known to scientists by its acronym SCMV. The Lederle memos dated from the early sixties to 1987 show that these adventitious agents had been plaguing the process of manufacturing vaccine for decades, forcing Lederle to discard what would have become millions of doses of vaccine.

Kyle cites a 1983 memo describing an internal company study of 13 years of vaccine production. The memo documents that Lederle was forced to junk almost half—43 percent—of all vaccine-in-production largely because of viral contamination problems. The memos show Lederle also had other contamination issues. A 1977 memo reports that even though the vaccine manufacturing process was supposed to be sterile, bacterial contamination forced the rejection of a large amount of vaccine-in-production. An internal company investigation found that mold, yeast, and strep were living in the company's air duct system.

As Kyle continued to collect Lederle memos, he realized that they mentioned one specific “adventitious agent” again and again: simian cytomegalovirus. According to Kyle's documents, simian CMV and CMV-like agents have proved to be a chronic problem for Lederle, which frequently had difficulty keeping the virus out of monkey-kidney-tissue preparations—the so-called harvests of poliovirus-containing fluids from the kidney tissues. Kyle believes the virus or its DNA has almost certainly made it beyond the vaccine-in-production stage and into some doses of the final vaccine released to the public, a charge that Lederle denies.

SCMV is a member of the herpes virus family. Its human counterpart, human cytomegalovirus, can cause retinal and gastrointestinal disorders and malaise. It is considered quite dangerous to infants or people with compromised immune systems. HCMV easily infects if it is ingested orally. If SCMV were present in oral polio vaccine, something offi-

cials from the Food and Drug Administration adamantly deny, it would be, they acknowledge, a cause for serious concern.

Lederle, which sells 16 million to 20 million doses of the vaccine each year, most of it to the U.S. government, insists all monkey tissue it obtains is tested and screened for adventitious agents before it is used for vaccine production and that it “strictly adhere[s]” to FDA regulations. Doug Petkus, a Lederle spokesman, asserts that the screening process used by Lederle is designed to insure that the vaccine be free of all foreign viruses, including SCMV. Another Lederle spokesperson, Audrey Ashby, maintains that “monkeys contaminated with cytomegalovirus have never been used for oral polio vaccine production.”

But internal company memos from 1972 suggest that for many years SCMV-infected monkeys were used. In August 1972, Ronald

Kyle believes that the simian counterpart to HIV, or possibly even an HIV progenitor, may have been released in millions of doses of polio vaccine in the seventies.

Vallancourt, a veterinarian who was head of Lederle's polio production, described a study the company had undertaken with the FDA to examine how widely SCMV contaminated monkey tissue. In a memo titled “Cytomegalovirus Contingency Plan,” Vallancourt noted that the joint study had found all 11 monkeys examined harbored the virus. Worse, he noted, 7 of the 11 infected monkeys “would have passed our existing test standards,” an acknowledgment on Vallancourt's part that the monkeys would have been found suitable for vaccine production. Vallancourt concluded that the 1972 study suggested that SCMV “has been present in our environment for at least as long as the poliovirus vaccine has been produced. Therefore, all substrate [kidney tissue] used to this date have conceivably been ‘contaminated.’”

The possibility of vaccine contamination was apparently of no concern to federal health officials at the time. As far back as 1968, a Lederle official had boasted that Roderrick Murray, the head of the federal agency then charged with vaccine safety, had “agreed” with the company “that the adventitious agents . . . are of little consequence for an oral preparation in that such a large experience exists with the use of oral polio vaccine without any evidence of trouble related to these agents.” Kyle's memos indicate that government health officials never followed up on the joint SCMV study. In one 1972 memo,

Vallancourt even observed: “Cytomegalovirus . . . is not being tested for at this time. For a manufacturer, and especially a regulatory agency, to accept this situation can only be judged a dichotomy but it has its basis in the fact that this agent is extremely cell-associated and cannot end up in the final vaccine.” Kyle disputes Vallancourt's conclusion, focusing instead on Lederle's failure to test for SCMV. “If they weren't testing for this virus at least until after 1972, and they admit the monkeys were all contaminated, then Americans got contaminated vaccine,” he says.

In 1973, Vallancourt informed his superiors at Lederle that federal officials had never again raised the subject of the SCMV contamination since the completion of the joint study the previous year. In another 1973 memo, he predicted that “our CMV problem will be pushed further and further into the background.” Vallancourt was right, as underscored by the resignation of a government scientist named Kendall O. Smith, an electron microscopist, who in 1968 had first discovered widespread SCMV contamination of commercial African green monkey kidney tissues—the exact type used for polio vaccine manufacture. In a 1969 paper published in the *Journal of the National Cancer Institute*, Smith noted that SCMV often escaped detection by conventional methods and warned that existing testing protocols were inadequate. Smith quit the FDA in disgust over the agency's failure to react to the virus. In 1972, he told the journal *Science* that he found it “unforgivable” that federal regulations governing polio vaccine production had not been changed to ensure more thorough screening against the virus. Those regulations are essentially unchanged today.

BARBARA LOE FISHER is a five-foot-one-inch, 49-year-old Washington, D.C., mother-turned-activist who heads the National Vaccine Information Center (NVIC), headquartered in Vienna, Virginia. From the organization's airy, second-story office just outside the Beltway, she and co-founder Kathi Williams have long pushed for greater government disclosure of the little-studied deleterious effects of vaccines upon some recipients and for parents to be allowed to make informed decisions about what vaccines their children receive. The notion of live monkey viruses in the polio vaccine strikes Fisher as alarming and par for the course, at the same time. “Our organization is very concerned that there seems to be so little interest on the part of the government about the issue of exposing millions of children to viruses and other biological agents from other species,” she says. “Nobody knows what the long-term impact might be.”

Fisher notes that as recently as 1995, Swiss scientists found evidence that the live

Walter Kyle

measles-mumps-rubella vaccine, grown on cell cultures of chicken embryos, might be contaminated with avian leukosis virus, which can cause a leukemia-like illness in birds. As long as the polio vaccine and a handful of others are to be mandated for every child, the government has an obligation to prove they are free of contaminants, she says. "Ask any mother if she would approve of her child being given a vaccine that was potentially contaminated with monkey viruses," she says of the polio vaccine. "I think she would tell you, 'No thank you.'"

Cecil Fox was a senior scientist with the National Institutes of Health for 18 years until 1991. There he did cancer research and became a prominent AIDS researcher who discovered that the virus that causes AIDS could live outside the bloodstream and in the lymph nodes. Fox has been concerned about the polio vaccine for many years. He takes issue with Vallancourt's 1972 assertion that since SCMV is "cell-associated" it could not end up in the final vaccine, arguing that fluids containing CMV-infected cells are notoriously difficult to clean up. "Saying it's cell-associated is taking a great leap of faith," he says. "There's no good way of cleaning up a cultured medium or liquid in which a fair amount of CMV has been present. You may be able to filter out all the infected cells, but that doesn't mean that the liquid is no longer infectious."

Although he remains a supporter of the oral polio vaccine, he cautions that continued reliance on monkey kidney tissues for vaccine production carries risks. "There's no way to ensure purity. All you need is one virus in one cell," he says. The use of monkeys, he says, is "a Pandora's box: The risk is that there are still monkey viruses that have not yet been discovered that can be transmitted to humans."

Fox is particularly concerned about the inactivated vaccine, which he believes holds far greater risk than the oral vaccine for transmitting monkey viruses to humans, because it is injected directly into the body. Fox's concern is of renewed interest because the Centers for Disease Control and the Massachusetts Department of Public Health have recently recommended using inactivated vaccine for some of the four recommended childhood doses of polio vaccine in response to concerns about polio caused by the live vaccine. Fox stresses that for many years the original Salk vaccine—an injected vaccine—may have been contaminated with up to 60 different monkey viruses, which he has referred to as the "crabgrass" of the polio vaccine.

At least one of these viruses, simian virus 40 (SV40), was not always killed by the formaldehyde used to inactivate the Salk vaccine. Between 1954 and 1963, up to 98 million Ameri-



MEDICAL MIRACLE: Jonas Salk created the vaccine that freed the world from the horrors of polio.

cans were exposed to SV40 through the polio vaccine. By 1963, all vaccine manufacturers had switched to African green monkeys, a species that is not infected with SV40; and all stocks of contaminated polio vaccine were no longer on the market. Long presumed harmless, SV40 genetic material has recently been discovered in some human brain, bone, and lung cancers. Scientists speculate that it is an oncornavirus, a cancer-causing virus, but that it may take years to cause certain cancers. Fox, who now heads a Gaithersburg, Maryland, research firm, says SV40 highlights the dangers associated with monkeys. "When you inject ground-up monkey guts into children, all kinds of things can happen."

Kyle speculates that the government was reluctant to get tough on Lederle's SCMV problem because it feared running out of vaccine. In fact, Vallancourt noted in his "Cytomegalovirus Contingency Plan" that the company held all the cards should the government decide to crack down on CMV: "Unless and until Pfizer's Diplovax [a rival vaccine] is in abundant supply, the FDA cannot risk Lederle being off the market."

Kyle also believes that Lederle's SCMV problems likely did not end 25 years ago. The 1983 memo, which had documented that the company had tossed almost half of its vaccine-in-production because of contamination problems, cited SCMV as the top culprit. Kyle has also collected hundreds of pages of Lederle's

monthly reports on poliovirus harvests. The reports document that SCMV continued to torment the vaccine manufacturer well into the 1980s. From October 1980 to March 1981, SCMV was particularly vexing, forcing the company to reject 65 percent of its harvests. A January 1981 report complained: "Rejections of harvest produced in October, November ... and December ... have been very high—11 in a row ... and 13 of 14 overall. An unidentified viral agent, strongly resembling or presumed to be cytomegalovirus, is the cause."

In 1986, Lederle was forced to scrap 16 percent of all harvests because of SCMV. As recently as 1987, the last year for which Kyle has information, Lederle documented that it had discarded 30 percent of all its poliovirus harvests during the first half of the year, 8 percent because of SCMV contamination.

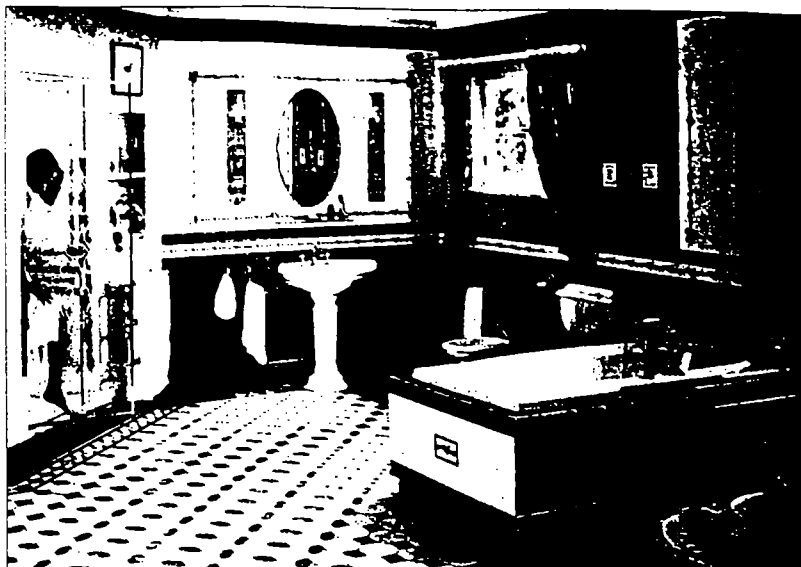
FDA OFFICIALS DISMISS the possibility that the polio vaccine released to the public could be contaminated by SCMV or any other known monkey virus. In a lengthy interview, William Egan, a chemist and deputy director of the FDA's Office of Vaccines Research and Review, and two of his subordinates asserted that the oral polio vaccine is, and has been, free of foreign viruses since SV40 contamination ended in 1963. But as a senior FDA official later clarified: "We can't screen for something we don't know about. We maintain it's free of viruses we

know how to protect from." Many of the scientists contacted for this article who work with monkeys, including Ronald Desrosiers, professor of microbiology and molecular genetics at Harvard Medical School and chairman of the microbiology division of New England Regional Primate Research Center, believe that only a small fraction of the viruses harbored by monkeys have been identified. Desrosiers once described use of monkey tissue in polio vaccine preparation as "a ticking time bomb waiting to explode."

According to Peter Reeve, a virologist and associate director of the FDA's division of viral products, the FDA ceased its own testing for viral contaminants more than 15 years ago. "There was no more point in putting time or effort into getting negative results," Reeve said. "It became clear that it was not necessary to repeat the [manufacturer's] tests because there was a lot of time and money involved." Lederle continues to check for viral contaminants according to the FDA requirements, which place the obligation of testing products on the manufacturer. The FDA itself conducts only routine virulence tests in its effort to minimize vaccine-associated polio.

Kyle says the disclosure that the FDA has suspended its own testing is an example of what he characterizes as the "incestuous relationship" between the agency and the drug companies it regulates. Fisher from the NVIC is also angered by the news, which she says proves her point that the polio vaccine receives little scrutiny because of its sacred-cow status. "They're supposed to be the watchdogs," she says. "But the reality is that they have such a cozy relationship with the drug companies that they are much too lax in regulating the vaccine. They have no business allowing manufacturers to use any sort of animal tissue if they can't guarantee its safety."

Could monkey viruses from the oral polio vaccine have infected people? W. John Martin, a professor of pathology at the University of Southern California, announced in 1995 that he had isolated a virus that was closely related to SCMV from the brains and peripheral blood of two people with neuropsychiatric diseases. Writing in a peer-reviewed journal, *Clinical and Diagnostic Virology*, he posited that the likely source was contaminated doses of the oral polio vaccine. Gary Hayward, a renowned herpes virus expert at Johns Hopkins University, has confirmed that the genetic sequences Martin has sent him are very close to those of an African green monkey cytomegalovirus. "The virus he's working with is not from baboons, or chimpanzees or rhesus. It's definitely from an African green monkey-like species," says Hayward. Martin's work has not been replicated and no one knows today whether Martin's hypothesis—that SCMV or an SCMV variant could be related to chronic fatigue syndrome and other immune-depressive diseases—has



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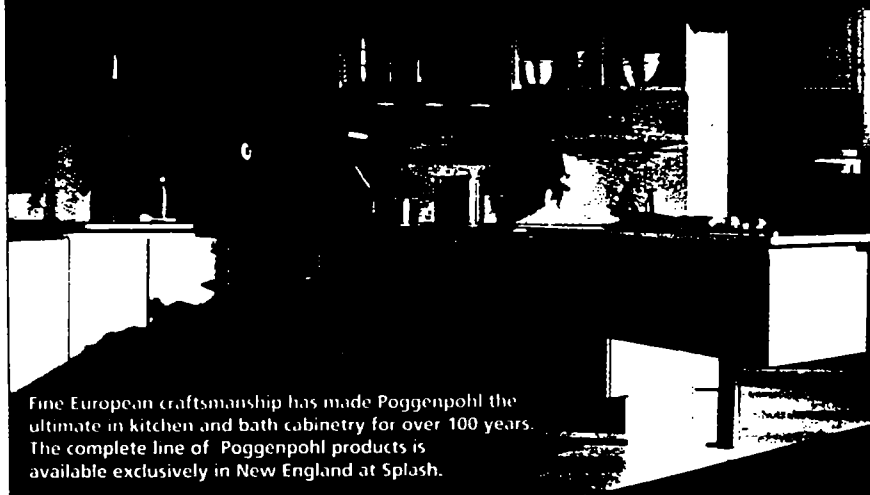
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Walter Kyle

any basis.

Martin says his belief that monkey viruses could be playing a role in human disease stems from his own experience testing vaccines at the FDA in the late seventies. He recalls being suspicious of viral DNA in a batch of vaccine and seeking permission from his superior to test it further. Permission was denied, and the agency released the batch containing millions of individual doses.

Martin's story is confirmed by a colleague from the time, G.S. Aulakh, a scientist who recalled that his superiors at the FDA rejected Martin's efforts to test the contaminant. "Nobody tested to see if it was harmful or not," Aulakh recalls. He adds that he has not seen or spoken to Martin since the two men worked together nearly 20 years ago, but his memory of his boss's brush-off is the same. "They told me the testing would scare the people, and it's not in the interest of the American people and this organization to do it," Aulakh says. A postscript: A few years later Martin's superior retired from the FDA and took a job as a senior vice-president with American Cyanamid, the parent company of Lederle.

HARLAND WINTER is a pediatric gastroenterologist who holds multiple staff positions at Children's Hospital, Massachusetts General, and Boston Medical Center. He is an associate professor at the medical schools of Harvard and Boston University. In his home, Winter has a reproduction of an ancient Egyptian papyrus drawing of a person with a polio-withered leg, a reminder that polio has afflicted mankind for millennia. Now polio is near extinction worldwide. But he echoes other clinicians when he says that fear of monkey viruses shouldn't scare people from the vaccine. "I think it would be terrible if people became so concerned about taking vaccines that polio would return," he says.

Susan Lett, medical director of the immunization program of the Massachusetts Department of Public Health, explains that even though the Western Hemisphere was declared polio free in 1991, the possibility of exposure to the virus always exists until the disease is wiped out. "The risk for that happening is declining based on rapid advances in other countries," Lett says, but she adds that people should continue to make sure their children are vaccinated. She says the CDC has never provided her with any data indicating the current vaccine contains dangerous contaminants. "We are all committed at every level to having the safest vaccines available," she says.

For his part, Kyle contends he is not anti-vaccine. What bothers him is the pattern he feels his memos reveal. "There's no reason American kids should be exposed to danger-

ous viruses because of government sloppiness and indifference," he says. Kyle believes that lax regulation of the vaccine has not only exposed Americans to SCMV and other monkey viruses but possibly to a far greater danger—AIDS. He believes that SIV (the simian counterpart to HIV, the human virus that causes AIDS) or possibly even an HIV-progenitor may have been released in millions of doses of polio vaccine in the seventies.

SIV infects up to 50 percent of African green monkeys in the wild. But since it is asymptomatic in the monkeys, Kyle believes infected African greens would not have been excluded from vaccine production prior to the discovery of the virus in 1985. Since then, all monkeys used to make vaccine have been tested for the virus.

Kyle focuses principally on one lot—2 million to 3 million individual doses—of vaccine

"It's in the best interests of the drug companies not to do anything," says a prominent scientist. "Until somebody like Walter Kyle raises enough hell, it's going to continue that way."

released in 1977. The FDA was so concerned about the lot that its release was delayed for an unprecedented 20 months. FDA scientists had discovered the batch, listed as "Lot 3-444," might contain retroviruses (SIV and HIV are retroviruses). Although no one at the time knew about the existence of AIDS, the possibility the vaccine could contain retroviruses prompted the agency to send micrographs—photographs taken through an electron microscope—of suspected viral material found in the batch to three electron microscopists at the National Institutes of Health for review.

Though the scientists were unsure about the identity of the material, the FDA decided the lot was free of contaminants and released it for public consumption. Kyle says that far from making a definitive determination concerning the vaccine's safety, one NIH scientist, in a memo to the FDA, worried about the possibility of retroviruses in the vaccine and warned of the potential for cross-species transfer of viruses. Kyle speculates that Lot 3-444 and perhaps others may have been contaminated with SIV or an HIV progenitor.

It was after he had received and reviewed the extensive documentation on Lot 3-444 that Kyle began research that led him to posit an alternative source for AIDS in North America. In the seventies, some clinicians were administering repeated doses of the oral vaccine to gay men in California and New

York as an unorthodox cure for herpes lesions. Kyle believes that the live virus, which normally would pass through the gut in children without adverse effect, found access to the bloodstream in gay men as a result of the open lesions and sexual activities. Kyle believes that when the HIV-like virus entered the blood stream, it began its deadly work.

Kyle's theory, far from being dismissed, was published in 1992 by *The Lancet*, one of the most prestigious medical journals in the world. Partially in response to Kyle's claims, this past year FDA scientists tested samples from 12 lots of old polio vaccine for the presence of HIV and SIV. The results, they say, were negative. Howard Umovitz, a Berkeley microbiologist who is founder and science director of the Chronic Illness Research Foundation, has reviewed the FDA study. He says even if HIV or SIV were not found, the finding of other markers associated with nonpolio viruses is significant. "What's shocking is that there is a polymerase DNA [an enzyme characteristic of a retrovirus]," Umovitz says. "Because these are vaccines that should only contain [the poliovirus which is] an RNA virus. What it tells us is that they have no idea what's spilling over into the vaccine."

John Coffin, a Tufts professor of molecular biology and microbiology who serves as a senior editor of the highly respected *Journal of Virology*, feels Kyle's AIDS theory "doesn't make a great deal of sense." Like many other scientists, Coffin believes the likely source for the AIDS virus in humans is chimpanzees, not African green monkeys. He observes that the polio vaccine has a 40-year safety record that is "well established" and believes that the vaccine is completely safe as far as retroviruses are concerned. Nonetheless, Coffin says, there is always a possibility of cross-species viral contamination when animal tissues are used. "By continuing to grow the vaccine on monkey tissues, there clearly is a discernible risk," he says. "It would make a lot of sense to move away from monkey tissue."

That view is shared by a number of scientists, including Jonathan Allan, a virologist and internationally known AIDS researcher at the Southwest Foundation for Biomedical Research in San Antonio, Texas. Allan is a supporter of the polio vaccine and says he has no reason to believe it is contaminated. But he agrees that continued use of monkey kidney cells for polio vaccine production is foolhardy.

"There's a lot of scientific evidence that points to the possibility that monkey viruses that typically cause little or no disease in their natural hosts can have disastrous consequences when they jump ship into humans," says Allan, who was a vocal dissident on an FDA panel that approved the baboon bone marrow transplant for AIDS patient Jeff Getty in 1995. In a 1996 *New York Times* op-ed essay, he castigated the FDA and CDC for "muddled" priorities, saying,

"Once a virus invades the human population it is nearly impossible to eradicate it." Allan, like many other scientists interviewed for this article, believes the United States should abandon the use of monkeys and join countries such as Great Britain and Canada that have used more expensive cloned human cells to produce oral and inactivated polio vaccine for many years.

RECENTLY, WALTER KYLE has begun to turn his attention to the many new unexplained diseases that have arisen in the second half of this century. What if some are connected with viral contaminants in vaccines? In Kyle's very first vaccine case, Lederle argued that his client had become paralyzed by a polio vaccine that would not have affected any normal person because she was immuno-compromised in some fashion. Kyle says it was the other way around, and he was angered that the drug company engaged in what he calls a classic "blame the victim strategy." His client was fine until she was exposed to the vaccine. "My thought was there was some agent—monkey viral contaminant—that transmitted transient immune deficiency," he says. "That's why she got paralyzed."

Now Kyle is having tissues and blood samples from clients who have unexplained immune system disorders tested, searching for clues that they may be harboring in their blood monkey virus sequences that came from the polio vaccine. Kyle admits it's a chilling idea that millions of Americans could be walking around with monkey viruses, but given what he knows, it hardly seems far-fetched. What is scarier to him is the continued use of monkeys to manufacture the polio vaccine and continued government indifference. "Why do we continue to take risks with our children when the rest of the world abandoned monkeys a long time ago?" he asks in frustration. "When are we going to wise up?"

Today, even as more and more scientists recognize that there are safer alternatives, Americans continue to have no choice when it comes to polio vaccine: both the oral and injected vaccines available in this country are exclusively grown on monkey kidney cells. Pasteur Mérieux Connaught manufactures an inactivated vaccine from monkeys for U.S. consumption but produces the vaccine on clean cloned human cell lines for Canadian use. Cecil Fox maintains that, despite all the problems associated with monkeys, there is no financial incentive for vaccine manufacturers to give them up.

"It's easy. We've done it for a long time, so we keep on doing it," he says. Fox doubts that U.S. policy will change in the near future, even though the technology exists to readily make a vaccine safe from all contaminants. "It's in the best interests of the stockholders of these companies not to do anything," he says. "Until somebody like Walter Kyle raises enough hell, it's going to continue that way." **B**

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MEETING REPORT



Workshop on Simian Virus 40 (SV40): a Possible Human Polyomavirus*

27-28th January 1997—Natcher Center, National Institutes of Health, Bethesda, MD, U.S.A.

Andrew M. Lewis Jr and William Egan

Office of Vaccine Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration, Bethesda, MD, U.S.A.

Background to the workshop

SV40 was an unknown contaminant of early polio and adenovirus vaccines. Following the discovery by Sweet and Hilleman¹ of SV40 in the monkey kidney cells used to produce the polio vaccine, methods were developed for SV40 removal and vaccines were soon thereafter SV40 free. For nearly 20 years after SV40 was removed from these vaccines, a number of studies and epidemiological surveys evaluated the human exposure to SV40 from the vaccine and the possible relationships between exposure to polio vaccines and the development of neoplastic diseases. These studies did not produce any convincing evidence, in humans, for an association between exposure to SV40 in these vaccines and the development of neoplastic diseases.^{2,3} Although there had been occasional reports of the isolation of SV40 from human tissues, these isolations were infrequent and inconsistent in terms of the tissue from which they were recovered. Due to these inconsistencies, the possibility that SV40 was aetiologically related to any of these diseases received little attention.

Between 1992 and the fall of 1996, however, a number of papers appeared describing the consistent detection (15-80% of samples), by PCR-based methods, of SV40 DNA in a wide variety of human

tumours,^{4,10} including choroid plexus tumours, ependymomas, mesotheliomas, and osteosarcomas (tumour types which incidentally, resembled the tumour types that developed in rodents either injected with SV40 or carrying SV40 transgenes,^{11,12}); SV40 DNA was also reported to be present in some normal tissues.⁸ Each of these studies^{4,10} called attention to the inadvertent human exposure to SV40 that resulted from the use of polio and adenovirus vaccines prepared in the late 1950s and early 1960s. The frequency and consistency of the PCR data in these reports re-ignited an interest in the consequences of human exposure to SV40.

In response to the scientific questions and the public health implications raised by the finding of SV40 sequences in various normal and tumour tissues, six federal agencies* sponsored a workshop to discuss these issues and consider the possibility that SV40 was an infectious agent in humans.

Workshop summary

The two-day workshop was divided among four **Speaker Sessions** (*Session 1*: Presence of SV40 virus and SV40 DNA in human tissues; *Session 2*: Other human polyoma viruses; *Session 3*: Human exposure to SV40; *Session 4*: Mechanisms of SV40 oncogenesis) and three **Panel-Audience Discussions** (*Discussion 1*: Issues related to the detection of SV40 DNA in human tissues; *Discussion 2*: SV40 as a putative human commensal; *Discussion 3*: SV40 as an oncogenic virus and possible human pathogen).

The first session of the workshop began with a review of SV40 biology and a discussion of the organization and functioning of the SV40 genome

*Sponsored by the Center for Biologics Evaluation and Research, Food and Drug Administration; the National Cancer Institute Division of Cancer Epidemiology and Genetics and the National Institute of Child Health and Human Development, National Institutes of Health; the National Center for Infectious Diseases and the National Vaccine Program, Centers for Disease Control and Prevention; and the National Vaccine Program Office.

and a review of the early (pre-1990s) history of SV40 as an infectious agent in simians and humans. These reviews were followed by six presentations detailing the finding of SV40 sequences in human tumours - choroid plexus tumours and ependymomas, brain and bone tumours, and mesotheliomas. The detection of SV40 sequences in normal tissue was also presented. In contrast, one research group presented their findings that, in a study of a large number of mesotheliomas, SV40 sequences were not detectable. In this Session, convincing evidence was presented that SV40 was present in mesotheliomas, while equally convincing evidence claimed that SV40 was not present in mesotheliomas. The origin of this discrepancy in results was not apparent; it was not argued that the discrepancy arose from the sampling of different populations.

The molecular biology and pathogenesis of the human polyoma viruses, BK and JC, were reviewed in the second session; BK and JC occur as latent infectious agents in most humans and are identical to SV40 over approximately 75% of their early genomes. The near universal presence of either BK or JC, or both, in humans and the near identity of the early portions of their genomes requires that, in order to determine whether SV40 DNA is present in a particular sample, PCR primers be selected from unique genomic regions. The primers used in the above-mentioned studies were directed against unique regions of the SV40 genome and were not the source of the conflicting data on the mesotheliomas. The cross-reactivity between antisera to BK or JC with SV40 was also noted to be a problem.

Session 3 began with a reprise, by Dr Maurice Hilleman, of the discovery of SV40 in monkey kidney tissue and its relationship to polio vaccines. Dr Hilleman noted that only a small fraction of the SV40 (approximately 1 in 10 000 viral particles) escaped inactivation during formalin treatment under the conditions used to inactivate the polio vaccine. The presence of SV40 in adenovirus vaccines and the formation of SV40-adenovirus hybrids was also discussed, as was a host range analysis of SV40 and SV40/BK-JC hybrids.

The extensive testing that is now performed to demonstrate the absence of SV40 in licensed polio vaccines was presented by two polio vaccine manufacturers (Lederle Wyeth and Connaught, Inc.). The results of testing of past (SV40-contaminated) and recent (SV40-free) lots of polio vaccines by PCR techniques was presented by investigators from the National Institute for Biological Standards and Control (NIBSC) in the U.K.; these NIBSC

researchers detected SV40 DNA in the early, known SV40-contaminated polio vaccine lots, but did not detect SV40 sequences in vaccine lots manufactured after SV40 removal. The evidence that current polio vaccine is free of SV40 is convincing.

The epidemiology of cancers reported to contain SV40 DNA sequences in the United States and in Sweden provided the material for the final presentations of Session 3. Epidemiological surveys using data from three tumour registries, two in the United States and one in Sweden, were presented. These surveys compared the incidence of choroid plexus tumours, ependymomas, mesotheliomas, and osteosarcomas in cohorts who would have been exposed to SV40 in polio vaccines with those, who due to their date of birth, would not have been exposed. These surveys did not detect any relationship between exposure to SV40 in the early polio vaccines and the development of these tumours. In addition, they found no association between exposure to early polio vaccines and the incidence of other tumours including tumours of the brain and ovary.

Session 4 dealt with the mechanisms by which SV40 may induce neoplastic transformation. Rodent (hamster and mouse) models of human disease were presented as were *in vitro* studies of transformation in rodent and human cells. Two studies were presented, suggesting that the SV40 T protein present in mesotheliomas binds to p53 and Rb cell cycle control proteins. Such SV40 T protein-p53 protein and SV40 T protein-Rb protein interactions are thought to contribute to cell cycle deregulation during transformation. However, the actual contribution to transformation that the binding of SV40 T protein with p53 and Rb protein has not been resolved.

There was general agreement that, before the potential role for SV40 in human neoplasia can be resolved, it will be necessary to reassess the presence of SV40 DNA in human tissues using standardized, quantitative PCR assays and to determine whether the SV40 DNA that is present is integrated into cellular DNA or is present as an episome. Furthermore, the percentage of cells in mesotheliomas, and other tumours, that contain SV40 DNA needs to be determined and p53 and Rb protein metabolism in mesothelioma cells that do and do not contain SV40 DNA needs to be compared. There was a consensus expressed at the workshop that the current lack of data precluded the assignment of a definitive role for SV40 in neoplastic disease in humans.

The data presented during the first three sessions, and discussed by two panels, called attention to technical issues that need to be resolved before the issue of whether SV40 is in the population and is associated with human disease can be settled definitively. The first of these issues is the possibility that the PCR assay, even using carefully controlled conditions, is not sufficiently reliable in its ability to amplify the low levels of SV40 DNA sequences that may be present in pathological specimens obtained from human tissues. Two laboratories were unable to detect SV40 DNA in any of the human tissues (including mesotheliomas) they tested; one laboratory suggested that primers considered to be specific for SV40 DNA could amplify host DNA sequences. It was generally agreed that the conditions for standardizing the PCR assay to detect SV40-specific DNA and the sensitivity of the assay conditions used needed to be worked out and evaluated against a defined set of reagents in laboratories who wished to pursue these types of studies.

A second issue that was raised during the first session was the cross-reactivity of antibodies to SV40, BK and JC viruses and the lack of a serological assay that can be used with confidence to identify SV40-specific antibodies in samples of human serum. Based on serological data and the occasional isolation of SV40 strains with unique DNA sequence anomalies that differentiate them from laboratory strains, SV40 in some form may be in the population. The question of whether SV40 was introduced into humans by the polio or adenovirus vaccines or whether an SV40-like agent has been infecting humans before the introduction of these vaccines needs to be addressed. Between 5 and 20% of serum samples, taken from humans before the introduction of the polio vaccine in 1954 or from humans in remote regions who were not exposed to polio vaccines or from individuals who were born after polio vaccines no longer contained SV40, contain antibodies that react with SV40.^{2,13,14} Many, but not all of these sera also react with BK or JC virus. As most humans are infected with BK and JC virus during childhood, antibodies to BK, JC or an SV40-like agent could be present in any combination in single serum specimens.

Taken together, the serological and virus isolation data suggest the possibility that an SV40-like agent was present in the human population before the introduction of the polio vaccine. To begin to resolve the possible public health issues raised by the exposure to SV40 in viral vaccines in the 1950s

and 1960s; it was agreed that it is important to develop reliable serological assays that can be used to determine whether SV40 or an SV40-like virus was infecting humans prior to the first use of the polio vaccine.

Based on the discussions during the workshop, the following initiatives should be considered. Working groups should be convened to evaluate and resolve the problems with the specificity and sensitivity of the PCR assay and to evaluate serological assays that might be used to detect antibodies that are specific for SV40. Another group should be empanelled to consider ways of looking for SV40 in the environment. There was also agreement that the issue of potential SV40 transmission from mother to child must be investigated. Work to expand the number of completely sequenced genomes from SV40 field isolates, especially isolates obtained from old lots of polio and adenovirus vaccines needs to be encouraged. Attempts to isolate more strains of SV40 from human tissues needs to be encouraged. In addition, the location and condition of materials needed for future studies, such as archived tumour specimens and serum samples should be established.

The workshop sponsors were encouraged by the consistency of the results of recent epidemiological surveys with the results of the earlier surveys suggesting no measurable increase in neoplastic diseases has occurred in humans exposed to SV40 contaminated polio vaccines. There is the sense that the workshop will serve as the stimulus to definitively answer the questions that have persisted following the human exposure to SV40 in viral vaccines developed in rhesus monkey cells in the 1950s. Mechanisms for implementing the initiatives needed to resolve the issues raised during the workshop are being developed and follow-up working groups will be established.

The proceedings of the workshop will be published, hopefully by December 1997, in "Developments in Biological Standardization". Transcripts as well as audio recordings of the workshop are available. Information regarding these materials can be obtained from The Food and Drug Administration Freedom of Information Staff HF1-35, Room 12A-16, 5600 Fishers Lane, Rockville MD 20857. Tel. 310-443-1813.

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Medicare Cutbacks Prove Painful to Some

Patients Are Caught Short As Therapy Benefits Wane

By DAVID S. HILZENBATH
Washington Post Staff Writer

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This year, an estimated 200,000 elderly or disabled patients will pay for a little-noticed cut in Medicare benefits that lawmakers tucked into the Balanced Budget Act of 1997.

At the time, politicians boasted of simultaneously saving Medicare from financial ruin and adding popular benefits such as mammograms and Pap smears. Yet generally not discussed was that they also placed a \$1,500 annual cap on physical and speech therapy combined, and a second \$1,500 limit on occupational therapy.

As many patients are discovering, the caps kicked in on Jan. 1, potentially impairing patients' rehabilitation from illness and injury. Patients recuperating from strokes, amputation and head trauma, as well as those grappling with degenerative diseases such as Parkinson's and multiple sclerosis, are exhausting their annual benefits and losing access to therapy.

Many patients can't afford the additional out-of-pocket expenses and are instead ending their therapy prematurely.

After Ruth M. Irwin, 67, of Pinellas Park, Fla., lost a leg to diabetes complications, physical therapy helped her walk again with the aid of an artificial limb and a pair of

four-pronged canes. But Irwin stopped her three-times-a-week visits to a rehabilitation center in February after she hit the \$1,500 annual limit. She had not achieved her goal of

walking with only one cane and freeing the other hand.

Without regular therapy, Irwin said she lost much of her strength and balance; soon, she again needed a walker. In early April she tripped over a curb and broke three ribs. Now she is homebound and in a wheelchair.

"If I had been taking therapy, that wouldn't have happened to me," said Irwin, a retired office manager living on Social Security. "I'm mad that the country's doing this to me at this late stage in my life."

The limits on rehabilitation services were projected to save the federal health insurance program for the elderly and disabled \$1.7 billion over five years, part of \$115 billion over five years that lawmakers and the president wrung from Medicare to keep it solvent. Inserted by Rep. Bill Thomas (R-Calif.), chairman of the health subcommittee of the House Ways and Means Committee, the limits were intended to curb a rapidly growing expense. The Clinton administration and Democrats on the House subcommittee went along with them.

"Many of the decisions that we made were probably a bit more arbitrary than we would have liked," Thomas said in an interview, adding that Congress was handicapped by a lack of data from Medicare on the potential effects.

"I think the data is beginning to indicate that a thorough reexamination is appropriate, and we're in the process of doing that," Thomas said.

Some lawmakers predicted trouble for some elderly patients, but the imperative to balance the budget towered above other concerns.

"We were all in this together that costs were ... totally running out of control and that there was significant abuse" of the therapy benefit, a Democratic House aide said. Yet, "everybody who looks at it knows it's bad health policy," the aide said.

An estimated 1 in 7 Medicare beneficiaries who seek rehabilitation therapy, or about 200,000 people, will reach one of the caps this year, said Stephanie Maxwell, a senior analyst at Congress's Medicare Payment Advisory Commission.

There are exceptions to the policy: It doesn't involve hospital patients, beneficiaries receiving home care, or nursing home patients in the first 100 days of a post-hospital stay covered by Medicare.

There also are ways of getting around the limits, at least in theory. Unless patients are in a nursing home, they can avoid the caps by seeking treatment at a hospital outpatient clinic. For at least the rest of the year, they also have the option of continuing therapy by moving from clinic to clinic, using \$1,500 of treatment at each one. The federal Health Care Financing Administration is allowing that strategy temporarily because its computers are not yet equipped to enforce the law.

For some patients, though, neither of those options is practical. At best, shifting from one therapist to another sacrifices continuity of care, patients and therapists said.

Dorothy Delacroix of Bethesda, who has suffered a series of strokes and a recent bout of pneumonia, wanted to resume treatment at a National Rehabilitation Hospital satellite clinic in Bethesda, where she had been treated earlier this year. Delacroix, 73, said she hopes to regain the ability to walk to her mailbox and stand in her kitchen long enough to make lunch. But she has exhausted her \$1,500 benefit at NRH, and recently shifted to Suburban Hospital for a six-week physical therapy regimen prescribed by her doctor.

The new therapist spent part of Delacroix's first appointment reviewing her medical history, something her former therapist already knew. Initially, the treatment "didn't work so hot because it was a new personality" and they had to learn how to work together, said Delacroix's husband, Gene.

Irwin, the Florida amputee, said it was too difficult for her to get to another physical therapy clinic or to manage the distance from the parking lot to the entrance of her local hospital.

Some therapists have begun rationing treatment to make the \$1,500 last longer, but that approach entails another set of costs and issues.

Multiple sclerosis patient Avis C. Campbell of Alexandria, 44, said she hadn't been to therapy in about two weeks and that she has had difficulty keeping up with her exercises. "I don't do it on my own like I should ... because you lose your balance and stuff," Campbell said. "At the therapist, they're there to catch you if you fall or to hold you up."

"Basically, we have been unable to give adequate therapy to neurologically impaired patients," said Linda Sigmund, a Fairfax neurologist. "They haven't been able to recover fully because of the caps."

Benjamin C. Hamilton, 79, of Derwood, Md., whose leg was amputated below the knee in September, believes he would have made faster progress if his therapist hadn't reduced the frequency of his visits from twice a week to once a week. Early in the new year, Hamilton recalled, his therapist told him, "We're going to have to cut back, because we're limited to so many dollars." As a result, "some things we didn't get to at all," Hamilton said.

Patients say paying out of pocket for therapy can be prohibitive—or simply not worth the price.

Retired ophthalmologist Bernard Gerwin, 97, recently used up his \$1,500 physical therapy allotment at the Marriott Brighton Gardens assisted living facility in Bethesda—and he was shocked to learn that it would cost him \$45 for every 15 minutes of therapy, or \$180 an hour, to continue.

Gerwin considered the charge "exorbitant" and stopped therapy. "I can do my own exercises," Gerwin said.

Some nursing homes are still providing therapy to patients who have exhausted their coverage, yet that

takes money away from other nursing home residents and services.

The facilities may not have much of a choice. If they want to do business with Medicare, "nursing homes are still required to provide their patients with all necessary

care, including rehabilitation," said Robert Berenson, director of the Health Care Financing Administration's Center for Health Plans and Providers.

Businesses as well as patients have felt the squeeze. For companies that provide rehabilitation therapy under contract to nursing homes, the Balanced Budget Act delivered a double whammy. Even before the limits kicked in this year, the Balanced Budget Act began imposing a new payment system on skilled nursing facilities that has sharply reduced demand for therapy services.

Integrated Health Services, based in Owings Mills, eliminated 1,000 jobs in December, and its stock has lost 88.6 percent of its value in less than a year. NovaCare Inc., based in King of Prussia, Pa., has cut therapists' salaries by 25 percent and laid off more than 5,000 employees.

At a meeting convened April 23 by the agency, which runs Medicare, therapists and nursing home

representatives denounced the caps as a meat-cleaver approach to budget cutting.

The Ways and Means Health subcommittee initially set the limits at \$900, but they were raised to \$1,500 in conference with the Senate.

Lawmakers settled on the dollar limits "not because it was sound health policy but because it was the number that was needed" to balance the budget, a Democratic congressional aide said.

Medicare spending on therapy had more than doubled from 1990 to 1993, and the General Accounting Office, a congressional watchdog agency, warned that providers were exploiting the program.

In retrospect, lawmakers might have achieved their budgetary goals without the therapy limits. Overall, Medicare spending has slowed much more than Congress anticipated when it adopted the Balanced Budget Act.

Even as the therapy provision was being written, members of

Congress saw it as flawed. The law gives the secretary of health and human services until Jan. 1, 2001, to propose a revised approach that takes into account the needs of individual patients. Since the law was signed, some lawmakers have proposed repealing the caps.

Meanwhile, critics say the savings on therapy could be somewhat illusory if the caps cause patients to linger in nursing homes or contribute to more injuries.

The triple rib fracture that incapacitated Irwin is a case in point. Since the mishap, Irwin has been receiving regular visits by a registered nurse and a home health aide, all at Medicare's expense.

She's also receiving physical therapy three times a week, because now that she's homebound, she's exempt from the \$1,500 cap.

"It's going to cost them a heck of a lot more if they got to keep me like this for years, until I die," Irwin said.

The Washington Post
MONDAY, MAY 10, 1999

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Usual Enemies Trade Roles in Medicare-Funds Battle

By LAURIE MCGINLEY

Staff Reporter of THE WALL STREET JOURNAL
WASHINGTON—Ready for a role reversal on Medicare?

Key congressional Republicans, often the most vocal proponents of restraining Medicare spending, are considering pumping billions of dollars into the program over the next several years. Clinton-administration officials, who like to cast themselves as Medicare's defenders, are resisting, saying it is far from clear that any extra money is needed.

The crosscurrents set the stage for what is likely to be the only significant Medicare battle of the year. Other high-voltage issues, such as long-term overhaul of the health program for 39 million elderly and disabled Americans, and its lack of a prescription-drug benefit, will be debated in coming months, but aren't likely to be acted on until after next year's elections.

In the spending debate, "What you've got, at first glance, is a flip-flop from what you'd normally expect," says Robert Laszewski, a health-care analyst. Actually, he says, the positions reflect the natural alliances of the GOP-controlled Congress and the Democratic administration.

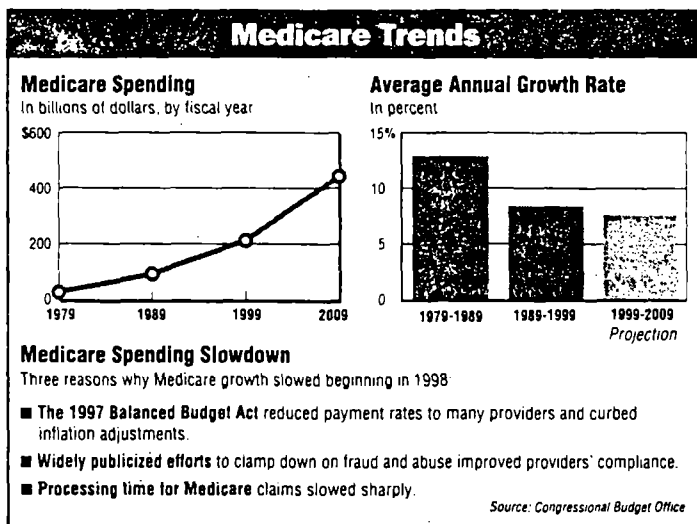
With their close ties to business, some Republicans are responding to vehement protests from health-care providers, especially for-profit nursing-home chains, hospitals and health-maintenance organizations. These providers argue that the 1997 Balanced Budget Act has cut Medicare far more deeply than expected, threatening patient care and the financial viability of many companies.

California GOP Rep. William Thomas, the influential chairman of the House Ways and Means health subcommittee, has told lobbyists he would like to increase Medicare spending by \$10 billion or so over the next several years. An aide to Ohio GOP Rep. John Kasich, chairman of the House Budget Committee, says his boss believes that home health-care spending may need to be bolstered. In another area, a senior GOP budget staffer suggests Congress would welcome a move by the administration to postpone a new payment system being used for nursing homes.

Administration officials, who have never been especially sympathetic to providers, are skeptical of such proposals—and of what they see as the industry's sky-is-falling arguments. They say they don't see any evidence that patients, as opposed to corporate bottom lines, are currently at risk.

"Although we have heard many serious concerns raised, we have yet to receive the type of data necessary to justify opening up the balanced-budget agreement," says Christopher Jennings, a White House health-policy adviser. Underscoring the biggest barrier to changing the law, Health and Human Services Secretary Donna Shalala, pointedly reminded Congress that any changes "would require offsetting cuts elsewhere or new revenues."

Their view has some support in Congress. Budget hawks on both sides of the aisle are resistant to turning on the Medicare spigot. And many conservative Republicans would like to use any extra



budget-surplus money for a tax cut.

Nevertheless, the administration might find itself undercut by congressional Democrats, several of whom would like to help struggling providers as the 2000 elections loom. Urban lawmakers are championing the cause of academic medical centers; rural ones want improved funding for home health care and rural hospitals and HMOs. In addition, there is bipartisan concern over a \$1,500-a-year cap on rehabilitation therapy that has prompted complaints from elderly patients to Congress.

There is little question that a striking change is occurring in Medicare. For the first six months of the current fiscal year, program spending fell \$2.6 billion from a year before, its first decline ever. Lobbyists cite the impact of the balanced-budget law, which was supposed to curb Medicare by \$106 billion over five years, but may be hitting far harder.

Administration officials and budget analysts dispute that, however. They say the Medicare decrease is due in large part to a temporary slowdown in payments to providers. In addition, they say, some providers, such as hospitals, are billing Medicare more conservatively as a result of the government's aggressive fraud-and-abuse initiatives.

Within Congress, some lawmakers are interested in increasing spending in some areas but not others. For example, Republican Sen. Charles Grassley of Iowa, chairman of the Special Committee on Aging, wants to spend more money on rehab therapy, but he has questions about financially strapped nursing-home chains.

"How is it that some providers are in such distress, while others seem not to be?" he asked in a recent floor statement. Did the big, troubled nursing-home chains grow too quickly, taking on more debt than they could manage? Unless these questions are answered, he warned, "we could wind up subsidizing the mistakes of well-compensated executives."

In a similar vein, Democratic Rep.

Fortney Stark of California has asked the General Accounting Office, the congressional watchdog agency, to investigate whether hospitals have been hurt by Medicare reductions, or by miserly payments by private managed-care companies.

Meanwhile, California's Rep. Thomas, a chief architect of the 1997 balanced-budget law, says he hasn't settled on the size of a possible Medicare-spending increase. He says his first priority is to get the Medicare agency, the Health Care Financing Administration, to change its implementation of the balanced-budget act to loosen the purse strings somewhat. He claims the agency has been far too restrictive—an assertion disputed by administration officials, who

say the agency had little discretion in carrying out the law.

Mr. Thomas is also determined to make sure that Democrats don't use against Republicans any Medicare problems resulting from the balanced-budget law. In a "Medicare Emergency Alert" sent to GOP colleagues in early spring, he said he planned "to develop talking points and position papers to help Republicans defend their record of saving Medicare, and to enable us to place the blame for any negative changes to quality care solidly on the administration."

Whatever happens this year will depend in large part on new figures, to be released by the Congressional Budget Office in late June or early July, showing the size of the federal budget surplus. Among the important questions: How will the Kosovo war affect the surplus? Will Medicare spending still be falling?

Lobbying groups, meanwhile, continue to pound on Congress for relief. The American Hospital Association, which represents 5,000 hospitals across the country, is sending faxes of stories about financially ailing hospitals to Congress and the media. "The Balanced Budget Act, Real Pain for Real People," reads the headline.

The American Health Care Association, which represents skilled nursing facilities, is mapping out an extensive lobbying effort, including a possible \$1.5 million advertising campaign, in an effort to persuade both Congress and the administration to make changes.

A preliminary blueprint calls for setting up a "war room" to coordinate the campaign, initiating a "grass-roots" letter-writing drive and hiring of coordinators in important congressional districts "with strong personal relationships with their members."

THE WALL STREET JOURNAL

TUESDAY, MAY 11, 1999

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