New Data Undermine Anti-Cholesterol Guidelines; Changes Coming, P. 2

PROBE

David Zimmerman's newsletter on science, media, policy and health.

Vol. 1, No. 4 January 1, 1992, New York, NY $5

Open Letter to the President

Hon. George F. Bush
The White House

Dear Mr. President:

When Magic Johnson revealed he is infected with the AIDS virus, you asked Americans to suggest specific ways to control this deadly scourge.

I write here to propose one such method. With your interest and support, it can be developed and put into place quickly — within months — to begin blocking AIDS virus (HIV) transmission, and AIDS. It will begin to limit the AIDS epidemic the first day it is put to use.

The method is simple: Re-engineer hypodermic syringes so they can be used only one time.

Federal statistics, as you know, show that almost one-third of AIDS transmissions now occur through drug users' needles. A significant added toll results from infected addicts' sexual encounters.

Clearly, if a syringe only can be used once, because it blocks, jams, or is rendered inoperative in some other way as the first injection is completed, then AIDS (and hepatitis) will no longer be carried in the syringe to a second user. *The syringe cannot be reused.*

The technology to produce these self-destructing (SD) syringes already exists. Hundreds of American and foreign inventors, doctors, and small and large business people are working to develop these instruments. Plans have been drawn, prototypes built, and tests are in progress. Over 100 U.S. patents have been issued or are pending. A scientific conference has been held at a major university on this new option for controlling AIDS' spread.

The technical people thus are ready to move forward. *But:*

Because of the cost, social complexity, and political risk of introducing an AIDS prevention method that will help drug users survive, along with the many "innocents" they infect, the technical workers say the SD option cannot advance until the federal government signals its interest. They ask if you are willing to support this effort, based initially on its promise, and subsequently on an ongoing demonstration of its public health merit.

Some difficulties certainly can be anticipated at the outset in manufacturing and deploying this simple AIDS-prevention tool. A major policy question is: How will these instruments be distributed?

They might be handed out. Better, they might be sold, without prescription (as hypodermic syringes already are in most states).

If the SDs initially prove satisfactory in the hands of legitimate users — doctors, nurses, and diabetic patients who inject themselves with insulin — then steps might be taken, on your initiative, to restrict the current, dangerously *re*-usable syringes, and make SDs easily attainable in their place. Major U.S. instrument makers have been working on SD design and development for several years. Given your mandate, I am confident they can complete their R&D work quickly, and bring SDs to market.

A technical literature is accruing on SDs; I am sending a file to your Office of Science and Technology Policy.

You demonstrated in Desert Shield and Desert Storm, Mr. President, that our nation can rapidly and skillfully deploy human and material resources to meet a serious external challenge. You have said, often, that the key to America's greatness is our inventiveness — and our will to succeed.

AIDS is our Saddam from within.

I believe that with your leadership significant inroads can be made against it. It is a test of democracy, in a technologically advanced nation, to deploy resources to meet people's most critical needs.

Stopping AIDS, Magic Johnson reminds us, is at the top of that list today. I am

Respectfully Yours,

Research Studies Cast Doubt

The scientific underpinning of the National Cholesterol Education Program (NCEP) is being ripped and shredded in the scientific literature.

Just a year ago (Dec. 19, '90), the American Medical Association published a special issue of its *Journal* on cholesterol and heart disease, and held a press briefing on this theme in New York. The message: Rigorous and sustained dietary reform, and exercise — supplemented for many people with drug therapy — are needed.

Many well-intentioned physicians and scientists continue to hold this view. So do a growing claque of nutritional zealots — including vegetarians and animal-rights advocates who simply want everyone to stop eating meat. Companies that hope to profit from the present diet mania also are staunch exponents.

The RJR Nabisco Company, for example, through its Nabisco Foods Group, has created an NCEP sound-alike that it calls the *Fleischmann's Cholesterol Management Program* (FCMP). (RJR's health commitment can be judged by its "Old Joe" the camel promotion, which analysts, writing in *JAMA* (Dec. 11), say is successfully luring kids to smoke Camels — a charge the company denies.)

RJR Nabisco makes Fleischmann's margarine — a diet aid for lowering cholesterol. Its FMCP designates 200 mg/dl cholesterol in blood as the starting point for a "high blood cholesterol level." FCMP's danger line thus is 40 points *lower* than NCEP's; according to NCEP, it would put 50% of all Americans over 20 in Fleischmann's self-serving "high" risk category.

Americans have enjoyed a salutary *drop* in heart attack and stroke deaths since 1950. Heart-saving dietary reformers claim part of the credit, even though cholesterol control efforts did not start in earnest until the 1970's.

These claims now are being discounted

Deaths Soar In Helsinki Heart treatment Cohort

The Helsinki Heart Study has been a landmark in the effort to convince high-risk patients (and their doctors) to "intervene" — to change lifestyles — and so save lives.

Healthy but high-risk Finnish business men were recruited in 1974. Half had "intensive" dietary counseling were urged not to smoke and, if necessary, were treated with drugs to lower blood pressure and cholesterol. The other men were followed as controls through the course of the study.

After five years, the Helsinki researchers found the treatment group had a 46% reduction in cardiovascular disease risk. *But*: Inexplicably, the death rate in these treated men already was higher than in the controls. This *increase in deaths in the intervention group* has continued to rise through the years.

The Helsinki team described their 15-year followup (10 years from the end of the clinical trial) in the *Journal of the American Medical Association* (*JAMA*) last year (Sept. 4, pp. 1225-29): They recorded 34 cardiac deaths in the treatment group, *vs* only 14 in the controls (612 treated; 610 controls). The risk of death thus was 2½ times higher in the men in the intervention group!

Also unexplained — and extraordinary — there were 13 violent deaths in the intervention group (11 by accidents; 2 by suicide), but only 1 violent death in the controls.

This bad news from Helsinki is not an isolated finding. Other studies have found increased non-cardiac deaths in intervention groups. A recent combined analysis (meta-analysis), cited by the Helsinki doctors, found "a significant increase in deaths not related to illness (deaths from accidents, suicide or violence) in [six] groups receiving treatment to lower cholesterol concentrations, relative to controls."

Neither the Helsinki research group, nor a *JAMA* editorialist commenting on their findings offer any credible guess why cholesterol control efforts appear to be having the opposite — deadly — effect from the one intended. But it seems that they are.

Projected Life Salvage Small In Dutch Study

Epidemiologists divided 80 Dutch men with high to very-high cholesterol levels (251 to 387) into two groups. They put half on a diet like NCEP's. They did not treat the others.

Five weeks later, the treated men's (average) cholesterols, beneficially, were 18 points lower than the controls', and their HDL's were significantly higher. But after 26 weeks, the treated men's advantage in total cholesterol had dropped to 12 points. The HDL advantage was no longer significant.

Extrapolating these short-term findings to the long term, and applying formulas derived in earlier studies, the researchers say in the *American Journal of Epidemiology* (July 1, pp. 39-48) that if the benefit they obtained were sustained through time, the coronary death rate would drop from 12.5 per 1,000 high-risk men to 11 per 1,000 in a six year period. This is a saving of roughly 1 life per 4,000 high-risk men per year. It is a negligible advantage in our view, and one that almost certainly would be cancelled if dieters have a higher risk of noncoronary deaths, as other studies described on this page show.

PROBE

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PROBE is written and published independently, initially on a monthly schedule. Subscription: $53 per year. Editorial office: 121 E. 26th St., New York City, NY 10010. Phone: 212-545-0088. For subscriptions, Box 1321, Cathedral Station, New York, NY 10025.

On Heart-Saving Guidelines

from, of all places, the Framingham Heart Study — which is a fount for proscriptive cholesterol guidelines. In a report to the American Heart Association, in Anaheim, late last year, endocrinologist Peter W.F. Wilson, M.D., said coronary heart disease deaths in Framingham, Mass., have fallen 60% in one generation. *But*:

Stopping smoking, control of hypertension, *and* cholesterol control all together account for only a quarter (27%) of this life-saving says Dr. Wilson. Most is due to better *medical* and *surgical* care for heart attack victims.

"Cardiologists are accounting for a significant portion of the mortality decline," Dr. Wilson told the AP.

The deluge of scientific reports that cast doubt on NCEP's strictures comes from many widely-divergent sources. A few are summarized on these pages.

To gauge their effect, we phoned internist Basil M. Rifkind, M.D., an NIH official who is a close scientific advisor to NCEP.

"I think I am keeping up" with the critical reports, he said.

"There are different ways you can cut this cake about cholesterol and other risk factors. There's probably no single way of devising a prevention program, so it's reasonable to hear from other groups that want a modification here and there."

The NCEP approach, over all, continues to be valid, he said, although issues like cost, and the higher death rates reported in the treated patients require further study. Some of the critics' assumptions are "quite reasonable," he said. "But some are questionable."

Asked if the criticism has stimulated any re-thinking at NCEP, Dr. Rifkind answered:

"The process has already started."

He said that a new adult treatment advisory panel has convened "to consider many of the issues that have been raised," and "update" the guidelines.

Quality of Life is Hurt by NCEP Intervention

The ill effects of anti-cholesterol diets and drugs rarely are addressed by NCEP supporters. So four Canadian physicians tried to do so.

They developed a decision-analysis computer simulation to weigh the "potential deleterious effects of [cholesterol] screening and treatment on the quality of life." Their findings were published in the *Annals of Internal Medicine* (Aug. 15).

The "disutility" of diagnosis and drugs, internists Murray Krahn, M.D., and his University of Toronto colleagues write, are the negative effects of "medicalizing" a condition — high cholesterol — that afflicts half of all men ages 40 to 59. These downers include the stigma of being labelled — and of labelling oneself — a patient, and the time, cost and anxiety of regular cholesterol-checking medical visits. Also: the cost of drugs and their side effects. Diet's "disutility" entails the "decreased quality of life engendered by [the] rigid dietary proscriptions" NCEP proposes.

To be weighed against these treatment disutilities is the rarer, but more severe disutility of heart disease. In an initial model, the researchers scored the disutility of diet as 2%; the disutility of drugs as an additional 2%; and the disutility of coronary heart disease as 20%.

They then tried to determine the cost-benefit ratio of an "aggressive" NCEP-like intervention, which initiates diagnosis at age 20, proposes dietary therapy at a total cholesterol of 240 (or of 200 if there is an additional risk factor), and drug therapy at 275. They compared the NCEP paradigm to a more "conservative" one used by Canadian doctors, in which screening starts only later, at age 35; diet therapy is initiated for only cholesterol over 265; and drug therapy only if diet fails.

Using these assumptions, Dr. Krahn and his colleagues found the outcome was essentially a "toss-up." The "conservative" Canadian mode would provide slightly *more* "quality adjusted life years" than the "aggressive" NCEP-like protocol.

"It's a question of potential harm *versus* potential gains," Dr. Krahn later told Reuters. "We concluded that if treatment in and of itself is a bad thing, then perhaps we shouldn't be treating as many people."

The Canadians' challenging study is too complex to adequately summarize here. For reprints write: Murray Krahn, M.D., 399 Bathurst, Toronto, Ontario M5T 2S8.

Our Diligence Challenged

Our opening critique of NCEP's effort to radically change what Americans eat (PROBE, Oct. I, '91) drew criticism from two well informed readers: one is a journalist who is deeply concerned about heart disease, the other a physician who studies dietary change as a way to prevent illnesses.

The doctor said the NCEP Stage One Diet — which virtually eliminates eggs — is recommended for people in risk groups, but *not* for all Americans. We checked back with NCEP, and this diet — less than 30% of calories as fat; less than 10% as saturated fat; and less than 300 mg/day cholesterol — *is* what is recommended for *all* Americans.

A second objection, from our journalist friend, was that we picked poor scientific studies to make our points. We don't think that's so. But to be sure, we've made an effort, in this follow-up piece, to cite very highly respected publications, some of which have a strong *pro*-NCEP editorial bias.

A third criticism was our directed at our contention that the feasibility of preventing heart deaths by radically changing Americans' diet has never been established in a major scientific study. The time and the major cost would be prohibitive, we were told at NIH. We note, however, a report in *Science* that European researchers plan a long-term study of 250,000 subjects on lifestyle and cancer. *Science* does not give the projected cost — which must be huge. This strengthens our view that money must be made available for the major studies needed to justify telling people they can live longer only by restricting their pleasures in life.

New England (Journal) Fudge?

Diet Benefit Claims May Not Match Data

Lipid researchers at Stanford put moderately overweight men and women (ages 25-49) on NCEP's "heart healthy diet." Half also were given an exercise regimen. A control group went untreated.

This research was supported by the National Heart, Lung and Blood Institute, NCEP's parent agency.

The lipidologists conclude, in their prominent abstract:

"Regular exercise in overweight men and women *enhances* the improvement in plasma lipoprotein levels that results from the adoption of a low-saturated fat, low-cholesterol diet." (*New England Journal of Medicine*, Aug. 15, pp. 461-66; emphasis added) The researchers analyzed three plasma lipids: triglyceride, LDL ("bad") cholesterol and HDL ("good") cholesterol.

Significance Sought

For exercise to "enhance" the diet's "improvement" in lipid risk, diet alone should be better than no treatment, and diet plus exercise should be better than diet alone. To be meaningful, senior author Peter D. Wood, D.Sc., who is a lipid biochemist, said by phone, these differences should be statistically significant.

Examination of the authors' tabular data shows, however, that such step-wise, statistically-significant progressive benefit does not occur in *any* of the 6 measures depicted in their charts.

In men, diet alone was not significantly better than the controls, although diet plus exercise were significantly better than diet alone for triglyceride and for HDL. But for LDL cholesterol, men on diet plus exercise did *worse* than those on diet alone.

HDL Falls in Women

Among women, triglyceride rose, rather than fell, with diet alone. Adding exercise yielded significant advantage over the controls, but not against diet alone. Diet alone *did* significantly lower women's LDL cholesterol, compared to controls. But adding exercise provided insignificant added benefit. Worse, HDL cholesterol fell in the controls, but fell further in dieters. Exercise did not "enhance" the diet's effect, but did raise HDL enough to counteract the ill effects of the diet alone. In short, the data do not seem to support the authors' conclusions.

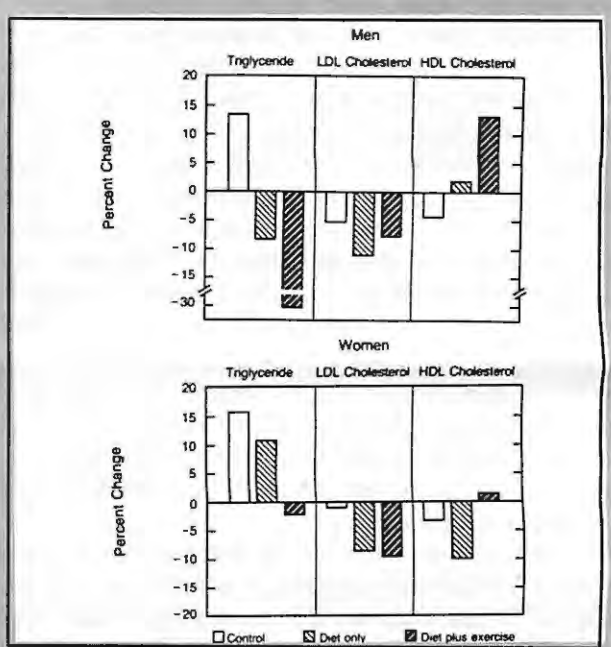
They blame NCEP's "heart healthy diet," and not the exercise for the study's weak results. They note that men who lost weight in the present study had only a 2% increase in HDL cholesterol. But in an earlier study, in which subjects lost weight by eating *less* of "a typical American diet," the HDL cholesterol levels rose a salutary 11%.

Going over these data by phone, Dr. Wood essentially agreed with our interpretation of his group's specific findings, saying for example that "in women the prudent diet not only eliminates the [salutary] rise in HDL, it produces a fall." But, he said, "over all, there's an improvement in going onto the prudent diet because you have a reduction in LDL."

He said he stood by the published "conclusions" that regular exercise "enhances" diet's effects. He said he had worked with *Journal* editors to summarize the findings succinctly and accurately in the paper's abstract.

"The trouble is that it's a brief abstract," he said, "and you do what you can with it."

Conclusions. Regular exercise in overweight men and women enhances the improvement in plasma lipoprotein levels that results from the adoption of a low-saturated-fat, low-cholesterol diet. (N Engl J Med 1991; 325:461-6.)



If exercise "enhanced" diet's effect on serum lipids, triglyceride and LDL cholesterol should fall, and HDL cholesterol should rise significantly with each level of treatment. This did not occur in these 6 sets of measures, according to the authors' data: Source: *The New England Journal of Medicine*, with permission.

What If Foie Gras, Butter Do Not Harm the Heart?

Cynics may discount the data, described on page one of the *New York Times* at the head of the holiday season (Nov. 17): Gascons, who produce — and eat — more *pâté de foie gras* than anyone else, have an extraordinarily high intake of saturated fats, but also have the lowest heart attack death rate in France (and one that is *far* lower than the U.S.) But what will these cynics say about the study from Cardiff, in Wales, earlier last year, which suggests that milk, cream and butter also may protect against heart disease, or — at least — may not promote it!

The Cardiff epidemiologists published preliminary data from

continued on page 8

Dead Lamprey's 'Fictive Swimming' May Help Paraplegic People to Walk

College Park, MD

After neurobiologist Avis Cohen, Ph.D., completely transects — *severs* — the spinal cord of a lamprey, at mid-body, this eel-like aquatic animal retains the capacity to swim with its characteristic rhythmical body motion.

Researcher Cohen can go a bold step further with these parasitic creatures, which, when wild, subsist by sucking onto and consuming trout and other fishes:

She dissects out the spinal cord, detaches it from the brain, and suspends it in a nutrient bath that contains a neurotransmitter, glutamate. Sensors that she attaches along the isolated cord pick up the same, rhythmic firing of motor *neurons*, or nerve cells, that generate the lamprey's natural undulative locomotion. Cohen calls this neural activity "fictive swimming."

She and a handful of other like-minded scientists see it as valuable for people. They say it is a revolutionary neurophysiologic model that probably can be developed to provide real and nonfictive locomotion — walking — for spinally crippled men and women who now are condemned to wheel chairs.

Spinal Cord Controls Legs

The researchers' thesis is this:

Walking and other forms of locomotion have been previously thought to be generated "from above" — from the brain. The jarring observation that chickens sometimes run around, briefly, after their heads are cut off has been ignored, or has been incorrectly attributed to simple "reflexes."

The standard, brain-based view has meant that, short of spinal cord regrowth, reattachment, and functional rehabilitation — all still dicey propositions — restoration of walking might not be possible. Computer-programmed electric stimulation of the nerves used in walking also has been a bust thus far.

Surprisingly, however, the lamprey experiments, and others like it, show that locomotion is *not* mediated by the brain. It rather seems to be mediated below the head, in networks of nerves in and around the spinal cord, which some have called *central pattern generators (CPGs)*.

"The motor pattern for swimming in lampreys, as in all vertebrates, is generated by . . . CPGs intrinsic to the spinal cord," Cohen wrote a few years ago (*Trends in NeuroSciences*, May 1988). "CPGs interact with, but do not require, input from the brain or sensory receptors."

She added, in a recent briefing for writers here at the University of Maryland, where she works:

"The brain says *Walk!* and don't bother me with the details. The spinal cord is able to do all that organization."

Spinally-organized walking has been demonstrated in mammals, particularly cats, by researchers in Montreal and Los Angeles. A cat's brain is removed — so it is dead — and its body is suspended in a sling, over a treadmill. As the treadmill belt turns, the animal's paws lift and fall in ordinary, neurologically complex walking movements. If an impediment is placed on the belt, the foot that encounters it jerks upward, as a living animal's or person's will if it stubs its toe on a stone. These aversive movements clearly are not mediated by the brain, for these animal "preparations" are brainless. Rather, spinal walking seems to be modulated by sensory nerve input from the limbs to the CPGs.

In animal experiments that more closely parallel the plight of paraplegic and quadriplegic patients, neurophysiologist Reggie Edgerton, Ph.D., of UCLA, works with cats whose spinal cords are transected, and trains them to walk on a treadmill.

Training Needed

"They can step," he said from Los Angeles, in a recent telephone interview. "And, if you change the [belt's] rate of speed, they will change their rate of stepping. . . . They even sometime will change into a gallop at high speeds."

But: If these "spinalized" cats are taught to stand, rather than walk — as humans paralyzed by spnal injury now are taught to sit, immobile, in a chair — their spinal cords' ability to produce stepping motions soon vanishes, Edgerton says. This suggests, he added, that to develop this behavioral model for human use, the *training* — which he described as repetitive patterned movements of the limbs for walking, or conceivably for cycling — should begin soon after injury, so that the innate, spinally-organized movements are preserved and reinforced.

At UCLA, Dr. Edgerton, with neurologist Bruce Dobkin, M.D., already has begun translating these animal discoveries into clinical experiments on patients with spinal cord injuries and strokes. They reported their findings for the first time to the Neurotrauma Society, in New Orleans, late last year.

Patients Studied

Patients are suspended in slings over a treadmill, and are helped to make walking movements during training sessions. As yet, none has regained the ability to walk, Edgerton said. But when he and Dr. Dobkin placed sensors over these subjects' leg and foot muscles, and helped them tread the belt, they recorded "fairly dramatic" neuronal activity — a sort of *fictive walking*, as it were, in human subjects.

These subjects all were a year post-injury. Dr. Edgerton said the researchers' assumption, as yet untested, is that earlier intervention will be more successful.

Much R&D work needs to be done. But Edgerton said he is "quite confident" that this wholly-new approach to spinal injury eventually will prove useful. Basic biologist Cohen shares his optimism, but complains that clinicians' inertia and the lack of R&D funding have hindered progress.

"It's very sad! We've lost thirty years," she said.

"There are lots of young men in chairs who want to be guinea pigs — their lives are ruined."

Brain Rehab Reform Coming — Slowly

(Last month, PROBE investigated the rehab care provided to traumatic brain injury (TBI) patients after discharge from acute-care trauma centers that are increasingly successful in saving their lives. A look at steps being taken to improve TBI rehab follows here.)

Progress is being made in developing and validating brain injury rehab techniques, and in creating service networks to provide this complex care, experts say. They predict the quality of care, and cost/benefit ratio will improve as the result.

Researchers say they are encouraged by preliminary evidence that stimulation of people who are comatose by music, familiar or unfamiliar voices, or tactile or other stimuli, appears to help them wake up. These methods sometimes are referred to as *coma stimulation*, or *comstim*.

Efficacy Is Unproved

Neurosurgeon Arthur Winter, M.D., of the New Jersey Neurological Institute, in Livingston, reports he has worked on cases in which stimulation — moving the unconscious patient's limbs, for example, or playing music — has been shown to affect the brain. In one PET (positron emission tomography) study, radioactively tagged glucose was shown to concentrate in the appropriate areas of the brain in response to these stimuli; glucose is the fuel for brain work.

"Listening. Hearing. All of these stimuli — you *can* stimulate the brain!" Dr. Winter said, in a telephone interview. What is more, he added, "if these patients are *not* constantly stimulated, they actually regress."

The effectiveness of comstim — which is widely used, and routinely charged to patients' accounts — in measurably rehabilitating patients' mental function is, however, not known.

"To my knowledge, there is no specific protocol that has been developed that documents the efficacy of coma stimulation," neuropsychologist Wayne Gordon, Ph.D., of Mt. Sinai Medical Center, in New York City, said by phone. "Most reports of coma stimulation's utility have been anecdotal."

Dr. Gordon is a leading planner in the TBI rehab field. He directs two major R&D programs — one federal, one regional.

In the federal effort, Mt. Sinai is one of five model programs, funded by the National Institutes of Health, that are moving — slowly, Gordon acknowledges — to develop baseline data and standards of care covering patients' progression from trauma center through residential rehab to outpatient treatment.

"What we're learning now is how to do it!" Gordon says.

About 150 patients have been treated, and entered into a data base from the five centers, Gordon said. He foresees publication of these findings next year (1993).

In a newer, regional program in the Northeast, Dr. Gordon and his associates are trying to define and develop new programs; train professional workers and improve TBI patient care. Public policy issues also are being addressed, he said.

"Traumatic brain injury rehabilitation is both program-intensive and labor-intensive," he told colleagues at a recent symposium in New York.

The reason, he explained by phone, is that these patients have widely varying needs, which may require individualized rehab methods. Complicating matters, he said, it is "very difficult" to predict a patient's needs and outcome at the start.

Standards Raised

Care providers' abusive fiscal practices are being addressed, Gordon declared. New York State, he noted "is paying tremendous amounts of dollars to send people out of state" for residential rehab because there are too few in-state facilities.

"I'm sure they're trying to find ways to cut that cost as much as they can," he added.

Professional standards are being established. Psychologist Leonard Diller, Ph.D., of New York University Medical Center said, in a telephone interview, "there is progress — which is inching along in several directions."

A national body, the Commission for Accreditation of Rehabilitation Facilities, has developed standards for TBI rehabs, Diller explained, and is continuing to refine them using "very sophisticated" advisory committees. In addition, professional societies of rehab specialists "are starting to set up standards for practitioners."

TBI Rehabs Grew Like Topsy; Systematic Improvement Now Is Sought

Several explanations are offered for the sudden upsurge of TBI rehab facilities, and the abuses that are alleged to have followed. One is that, starting in about 1980, advances in acute TBI care — in ambulances, emergency rooms and neurosurgical ICU's — allowed many patients to survive who earlier would have died. But restrictive regulations, and shortages of beds curtailed these patients' stays in acute care hospitals.

"Unfortunately, it started kind of backwards," recalls brain-injury nurse Donna Whitam, R.N., of New York University Medical Center in Manhattan. "We had a lot of providers without any system."

Even now, she added, "there is just no regulation."

Financially-stressed local and state governments lacked money to build TBI rehab facilities. Proprietary care providers, some already in the nursing home business, quickly responded to this need — sometimes by opening facilities in or near their nursing homes. Or, they opened wholly new TBI centers. Generous payments from Medicaid and private insurers have been available to encourage them.

Reform now is in the wings, driven in part by a tightening of funding. One new direction already is evident:

Many rehab services will be provided in the community, on an outpatient basis. Says Sherry Watson, of the National Head Injury Foundation's Survivors Council:

"You gotta get back to where you came from, to family and friends. When you're taken away from that, you don't have anything. . . .

"Think what 10, 20 or 40 thousand dolars a month would do if you were in the community!"

Clash of Values Is Reported Very Expertly

Washington

The best newspaper story we read last year on a medical subject was by *Washington Post* reporter Benjamin Weiser. He depicted with crystal clarity the opposing values of religious fundamentalism and secular humanism as they clashed over the fate of a pain-racked, dying AIDS baby.

"The Case of Baby Rena" (July 14, 15) explores the basic and irreconcilable conflict between Rena's parents and her doctors. Weiser writes:

"Murray Pollack, a physician at Children's Hospital, felt the time had come to change the rules. His 18-month old patient . . . was dying. . . . For six weeks, . . . she had been breathing only with the help of a respirator.

"She was in so much pain that Pollack kept her constantly sedated. When nurses performed even the simplest procedures, such as weighing her, her blood pressure shot up and tears streamed down her face. But a tube in her throat made it impossible for her to utter a sound."

The doctor wanted to turn the respirator off and let Rena die. But her foster parents said no. The hospital backed them. Dr. Pollack's position — which Weiser says is gaining support from his medical colleagues and from some medical ethicists — is that doctors ought to be *unilaterally empowered* to make the decision to stop life-support for patients like Rena. The rationale, Weiser writes, was spelled out by the chief of the hospital's ethics committee, who believes parents should not have the "paramount right" to choose in all health care matters.

Books & Ideas

Useless Care Not Required

Pediatricians, he said, have been entrusted by society to promote good health. They are not obligated to render useless "care" just because parents request it.

The foster parents, Weiser makes clear, deeply loved Rena. They relied on Jesus to save her. But they also claimed for themselves the right to interpret God's will.

At a showdown meeting of the hospital ethics committee, the father said:

"It's most important to find out what God desires or what God wills for Rena . . . because the one who gives life should ultimately be the one who allows life to be taken. God has not given man the authority to serve as God."

He added:

"If we give up now, we won't fully . . . know that God's word is true."

This prompted the hospital's Catholic chaplain, Sister Mary Small, to think — but not to say, because she did not want to challenge the parents' convictions — that God did not need respirators to work miracles.

A consulting physician from Johns Hopkins, in Baltimore, concurred: "This . . . unfortunate . . . child . . . will die soon barring a miracle, but such miracles do not require intensive care medicine intervention."

But the parents prevailed. The respirator stayed on.

When, soon, Rena clearly was about to expire, Dr. Pollack could not get the parents to relent, or even acknowledge her status. Reporter Weiser suggests they were blinded by their faith, and their rejection of medical understanding.

Death Approaches

"She called me. I heard her say . . . 'Ma-ma.' Her mouth moved," the mother said. A few hours later, a doctor who is an evangelical Christian phoned to say Rena had died. He told Weiser that the mother sounded stunned:

"You're kidding," she said.

Dr. Pollack, in a post mortem comment, said of the parents:

"They do not respond to the pain issue. They said it is God's will." He added:

"I was very, very angry that here, in the last moments of this child's death, they couldn't even find a touch of humanism to hold her, and to comfort her, in a manner such that her last heartbeat would be in her mother's . . . arms."

# # #

PROBE readers can obtain a free copy of "The Case of Baby Rena" by writing to reporter Benjamin Weiser, News Dept, *Washington Post*, 1150 15th St., N.W., Washington, DC 20071.

Is BSE Worth Doing?

Years ago we were struck by the zeal with which the American Cancer Society (ACS) promoted breast self-examination (BSE), for the early detection — and treatment — of breast cancer. "BSE is all we've got for women to do!" an ACS spokeswoman said, adamantly, after we pointed out there was no evidence showing it to be beneficial. But ACS then was busily teaching BSE to school girls, although breast cancer almost never occurs before age 20, and is rare before 40.

Researchers, meanwhile began to study BSE. In one recent report, in the *Journal of the National Cancer Institute*, University of Washington cancer epidemiologists found that "BSE, as practiced by most Seattle women, is of little or no benefit," albeit, a "small percentage (8%)" who performed it exceptionally well did enjoy a 35% decrease in advanced cancers.

An editorialist in the NCI *Journal* says two other recent studies "showed a lack of effect of BSE." Taken together, he adds, the three studies "provide no support for... BSE."

We phoned the ACS to learn their current policy on BSE, in light of the recent studies: They are wavering, but still recommend BSE — along with periodic mammograms and breast exams by a doctor.

Foie Gras . . .

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a five-year study of men in nearby Welsh villages. The more milk these men drank, the less likely they were to suffer ischemic heart disease (IHD): Men who drank no milk had a 10% prevalence of heart attack and related diseases. But men who drank a pint or more daily had only one-eighth that risk; 1.2% had IHD.

The results were similar, but less dramatic between butter and margarine: Men who ate only polyunsaturated margarine had a 9.6% prevalence of IHD; men who used only butter had half that.

British journalists, quoting the researchers, wrote stories under headlines like "Milk 'Helps Avert Heart Disease.'"

The Welsh study was sponsored by the Medical Research Council (MRC), the British NIH. An MRC official complained that the data had not been peer-reviewed.

Obligingly, three public health specialists in London published the data in a letter to the *British Medical Journal* (March 30, pp. 785-86), in order to critique the study. They said the data were "unadjusted" for other risk factors, then presented their own similar data from 24 British towns. They revealed they had found some of the same trends as their Cardiff colleagues, albeit the differences between groups were less dramatic. These experts then adjusted their own data — *not* the Cardiff data — for other risk factors, and concluded:

"When . . . background characteristics are taken into account, we can find no significant difference between milk intake or fat spread use and the incidence of heart attack in these middle-aged British men."

So, then, butter and milk may *not* be protective, if you believe the Londoners' data, not the Welshmens'. But: If, as the Londoners say, there is "no significant association" between milk/fat use and IHD, then, what's the beef about dairy products?

(Yes, we *do* know the answer: "There *always* are other studies that show . . ." But these endlessly contradictory studies certainly are a poor basis for turning dietary proscription into social policy.)

PROBE

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