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Domestic Policy Council

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Overhaul of Organ-Donation System Supported by White House Gets a Boost

By LAURIE MCGINLEY
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—A federal advisory committee called for wider geographic sharing of livers and other organs, bolstering Clinton administration efforts to overhaul the current system to steer more organs to sicker patients.

The prestigious Institute of Medicine, in a report requested by Congress, said that broader sharing would result in more organs being transplanted into patients who are the most gravely ill, and thus save lives. These are patients who are listed as status 1 or 2a, meaning they have less than a week to live because of acute or chronic liver failure. At the same time, fewer organs would be steered toward patients who aren't as sick and whose survival is less dependent upon receiving an organ.

The report by the institute, which is an arm of the National Academy of Sciences, is the latest development in the emotionally charged issue of how to divvy up the inadequate supply of organs for transplants. Last year, about 21,000 people received an organ transplant, but 4,000 patients died awaiting one. About 62,000 people currently are on waiting lists.

"The current system of organ procurement and allocation works reasonably well, but significant improvements in both its fairness and its effectiveness could be made," said Edward Penhoet of the University of California at Berkeley, who headed the institute's advisory panel.

In April 1998, the Department of Health and Human Services, decrying a wide variation in waiting times across the country, issued a regulation requiring much broader sharing of organs. The aim of the regulations, which were supposed to take effect last October, was to ensure that the patients with the most urgent medical needs got the organs first. A battle ensued, with small transplant centers and the United Network for Organ Sharing, the federal contractor for the organ-transplant system, opposing the regulations. Last fall, Congress decided to delay the rules for a year.

The advisory panel, while not endorsing the HHS rules, recommended that, for livers, "organ allocation areas" be created that would serve at least nine million people; within those areas, patients with the more urgent medical needs would get the livers first. UNOS is already moving toward wider organ sharing for the sickest patients, but the panel recommendation goes further.

HHS Secretary Donna Shalala applauded the recommendation, saying that broader organ sharing "is at the heart of the regulations we have issued."

Still, UNOS found some things to cheer in the report—notably, the committee's conclusion that the wide variation in waiting times wasn't a reliable indication of whether the system was working. In fact, the panel found, the sickest patients wait the same amount of time for organs, no matter where they live. "UNOS is really heartened to read this report," said Margo Akerman, a vice president of UNOS.

But the report found that the system is less fair for less critically ill patients and that there was "no credible evidence" that smaller transplant centers would be hurt by broader sharing. The report also recommended much more stringent federal oversight of the system, something UNOS has resisted.

THE WALL STREET JOURNAL
WEDNESDAY, JULY 21, 1999

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Bill

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Drug Makers Fault the Details Of Clinton Medicare Proposal

By ROBERT PEAR

WASHINGTON, July 15 — Top executives of the pharmaceutical industry said today that they shared President Clinton's goal of increasing Medicare beneficiaries' access to prescription drugs, but for the first time they criticized specific features of his proposal. In particular, they said they feared that it could lead to price controls.

The executives drafted plans for lobbying and advertising at a meeting of the board of the Pharmaceutical Research and Manufacturers of America, a trade group for the industry.

After the meeting, Gordon M. Binder, chairman of the association and chief executive of Amgen Inc., said: "All seniors should have access to our medicines, and we hope something can be done by Congress and the President this year. But it should be done in the right way, not the wrong way, or else it could discourage the development of new medicines."

The association represents more than 100 companies, and 28 participated in today's meeting. People who attended said the board had discussed plans for a $30 million advertising campaign and had reviewed two sample television commercials. Possible themes for the campaign include "no price controls" and "we don't want the Government in our medicine cabinet."

Drug companies said they wanted to be seen as constructive and did not want to be vilified by the President and Hillary Rodham Clinton, both of whom in 1993 accused the industry of price-gouging. But the executives acknowledged that the industry did not have an alternative to Mr. Clinton's proposal.

Alan F. Holmer, president of the association, said drug makers had many "questions and concerns" about the President's plan, under which the Government would pay half the drug costs incurred by a Medicare beneficiary, with the maximum annual Federal payment rising gradually, to $2,500 in 2008.

"We are greatly concerned that the proposal, as currently structured, would inevitably lead to limits on access to medicines," Mr. Holmer said. "Under this proposal, the Federal Health Care Financing Administration would become the largest drug purchaser in the world. The history of Medicare and H.C.F.A. is that policy makers start with unrealistically low cost estimates. Then, having promised seniors a new benefit, the Government limits access to treatments — in this case, medicines — and imposes price controls in order to pay for it."

Chris Jennings, a White House aide, said there was no basis for the industry's concern. "The President's proposal has no price controls," Mr. Jennings said. "And there's no intention to inject price controls."

A drug company lobbyist who attended today's meeting conceded that "on its face, it's hard to find the price controls" in the President's plan. Rather than overtly regulating drug prices, he noted, the Government would hire private companies to manage drug benefits for the elderly and disabled.

But if the costs exceed estimates — as has often happened in the Medicare program — the Government "will take it out of our hide," the lobbyist said, by cutting payments for drugs.

Mr. Holmer asserted that the President's proposal "would subsidize the rich at taxpayers' expense," since taxes paid by workers with low and moderate incomes would help pay for prescription drug benefits for wealthy retirees.

Drug company executives said they also worried that the new benefit proposed by Mr. Clinton would supplant drug coverage now provided to retirees through the voluntary efforts of employers.

"To discourage employers from abandoning those efforts," Mr. Holmer said, "the President would reimburse employers for most of their current costs — a massive Federal outlay, but no better coverage for seniors."

At its meeting, the pharmaceutical association reaffirmed that its goal was to "improve coverage of prescription drugs through the private sector," including Medicare health maintenance organizations, "rather than the traditional Medicare fee-for-service program."

The industry is searching for the best mechanism to achieve that goal, and is struggling with the question of whether the Government should guarantee drug coverage for all Medicare beneficiaries or just for the neediest ones.

Clinton Tells Colorado Youths He'll Stand Fast on Gun Control

By KATHARINE Q. SEELYE

WASHINGTON, July 15 — President Clinton said today that he would veto the juvenile-justice bill if it emerged from Congress with provisions that weakened existing gun controls.

"I will not in any way, shape or form countenance a weakening of the law," Mr. Clinton declared at the White House, standing in front of 50 students from Colorado — 6 of them from Columbine High School in Littleton — who are in Washington to lobby Congress for gun controls included in the Senate version of the bill.

The President noted that the Senate legislation also included a weakening provision, eliminating background checks on people who retrieve their guns from pawnshops. Even as he issued his veto threat, though, he said that he was not fully aware of what else was in the bill and that "the Attorney General has to give me a briefing on it before I can make a final decision."

The juvenile-justice bill as adopted by the Senate would impose a number of new gun controls, including an expansion of background checks on purchasers and a ban on the import of high-capacity ammunition clips. The House version provides no controls, and the students are lobbying for the Senate provisions to be included in whatever bill emerges from a conference committee.

The President spoke today after meeting privately with the students at the White House. The students, organized by a gun-control group that sprung up in Colorado after the killings at Columbine High in April, have proved to be an unusual lobbying force. Most lobbyists come to Washington begging for a moment with lawmakers, which both sides generally like to keep private. These young lobbyists, in contrast, have been sought out by politicians.

This afternoon Vice President Al Gore, who has made school shootings a focal point of his Presidential campaign, went to the Capitol, where he and Representative Richard A. Gephardt of Missouri, the House Democratic leader, posed with them. The youths also met with Colorado's six member House delegation, its two Senators and more than two dozen other lawmakers they had identified as swing votes on gun control.

Jody Gold, an Internet consultant who is one of the group's chaperones, said the students had discussed with President Clinton how to keep Congress focused on gun control now that Columbine had faded from the news. The President's advice to the students, Mr. Gold said, was to expand their numbers in Colorado, create similar groups in other states and return next year.

But despite Democrats' continuing pessimism that meaningful gun control will be enacted this year, Mr. Clinton said it was not too late for Congress to heed the students' message.

"Don't forget Littleton," he urged Congress. "Don't allow the victims of Columbine to have died in vain. Don't forget the 13 children who die every day from gun violence. Many, many, many of them can be saved. We must not lose the urgency of our mission."

The New York Times

FRIDAY, JULY 16, 1999

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Report Outlines Problems With Donated Drugs Sent Overseas

By REED ABELSON

Public health officials have long suspected that many drugs donated to aid groups to be sent overseas do not meet local medical needs or are likely to expire before they can be used. A new study by the Harvard School of Public Health concludes that concerns over the quality of donated drugs are well founded.

The study, to be released today, is the first to look closely at drug donations from the United States — a byzantine process that is rarely made public by drug manufacturers or relief agencies. The study focused on two major American relief agencies, which cooperated on the condition that they not be identified, and used field studies in three countries, Armenia, Haiti and Tanzania.

Most drugs donated and sent over the two to three years of the study — between 1994 and 1997 — were considered useful and helped those in need. And the study cited many examples of how the donations improved the quality of life in various countries.

But a significant amount of donations — anywhere from 10 percent to 42 percent, looking at the figures from the two agencies in each of the three countries — were not listed by the recipient country or the World Health Organization as high-priority drugs.

The study also found that, looking at worldwide data from the aid agencies, about 30 percent of the drugs had a year or less until expiration, and 6 percent had less than 100 days.

In the study, local health organizations in Haiti, for example, reported that they received many drugs that did not meet their needs and many that had expired.

World Health Organization guidelines say drugs should be given at least a year before the expiration date because of the time it takes to distribute them, and most drugs have a much longer shelf life. Expired drugs can lose their effectiveness, and many relief workers feel that donated drugs should meet the same standards as those used at home.

"There are problems and issues at all levels," said Michael R. Reich, a professor of international health policy at Harvard who conducted the study.

He pointed out that relief organizations, drug companies, charities, local governments and the hospitals and clinics all share responsibility for making sure that donations are handled in a way that will determine whether the drugs meet local medical needs, and all bear some responsibility for the large amount of waste.

Relief workers concerned about the problem say that as long as pharmaceutical companies can expect valuable tax breaks and a way to rid themselves of excess inventory when they donate goods, the stream of unwanted donations is likely to continue. Charities, too, benefit by handling these gifts, since they can be used to magnify the size of their programs.

The study did not address American tax law but focused instead on actions the relief agencies and companies could take.

If anything, Mr. Reich said, the study may paint too bright a picture for having relied on the cooperation of charities whose data and practices may have been better than average. "There is a real need for all these organizations to think hard about their practices," he said.

The study was sponsored by the Partnership for Quality Medical Donations, a group formed by drug companies and relief agencies to try to improve their donations. Mr. Reich emphasized that the study was conducted independently and not reviewed by the sponsors before being sent to press for publication today in the Bulletin of the World Health Organization.

Mr. Reich's work "suggests there is a good deal that is useful about these donations, but that there is a lot of work to be done," said Jim Russo, the executive director of the partnership. "Now we know where we stand."

Beyond its analysis, the study also provided fresh anecdotal evidence about shipments of unwanted drugs — drugs that did not meet the specific needs of the country or were likely to expire before they could be used.

In Haiti, for example, individuals who hand-carried medicine into the country in response to local requests were seen as a better source of needed drugs than the American relief agencies, which deal in bulk. Those agencies were viewed as having "a container ready to go" and eager to send the drugs whether or not they addressed the specific needs of the local hospital or clinic, according to the study.

Two of the nine health organizations surveyed reported that half of the drugs reaching them had already expired.

And in Armenia, despite the Government's strong role in screening donations, many health organizations were given large supplies of combination remedies that contained both a painkiller and a decongestant. Combination drugs are less useful because patients might not need both. "Unpacked boxes of the product were observed, stacked on floors and on top of shelves up to the ceilings," the study noted.

The study was not conducted during periods of particular crisis in each of the three countries, when the quality of donations might worsen, Mr. Reich said. The reports of relief workers in Albania and Macedonia earlier this year suggested that much of the aid streaming into the region during the Kosovo crisis was inappropriate.

Although Albania itself could supply only about a fifth of the drugs and medical supplies needed by its hospitals, according to the World Health Organization, many of the drugs that arrived had expired or were unfamiliar to local health professionals.

The cost to local hospitals or clinics of inappropriate or unusable drugs is significant. Not only is safe disposal expensive because of various local regulations, but in some countries recipients must also pay to transport the drugs or pay fees to the government based on the value of the donations. If the donations are no good, that is money that could have been spent on more useful drugs.

In surveying various companies and relief agencies, the Harvard group found a wide range of drug-donation policies. Mr. Reich called for more uniform standards among both donor companies and the aid agencies and more discussion of whether donations are appropriate.

"Everyone agrees that there is a need for better definitions of best practices," he said. The World Health Organization's guidelines on what drugs should be donated have helped to raise overall awareness, he said.

The partnership, which is currently composed of seven drug companies and six charities, plans to meet this fall with the World Health Organization to try to improve the process of drug donations, Mr. Russo said.

Mexico Drug Czar Shot At

MEXICO CITY, Aug. 15 (AP) — Mexico's top anti-drug prosecutor escaped uninjured today when two men fired at his car. Two people were wounded.

The prosecutor, Mariano Herrán Salvatti, and his wife were riding in a four-wheel-drive vehicle on a main street in Mexico City early this afternoon when they were fired on by two gunmen riding on the backs of motorcycles, he told reporters. Mr. Herrán Salvatti's bodyguards exchanged fire with the gunmen.

One bodyguard and one of the gunmen were wounded.

Mr. Herrán Salvatti was appointed drug czar in March 1997 after his predecessor, Gen. Jesús Gutiérrez Rebollo, was arrested on charges that he took payoffs from a major drug trafficker. He had previously been Mexico City's chief prosecutor.

The New York Times
MONDAY, AUGUST 16, 1999

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we tell him?
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The Washington Times
MONDAY, AUGUST 16, 1999

PETE DU PONT

A better medicine for seniors

Let me start out by saying Congress predicted nine of the last three national "crises." Many of you will remember the swine flu scare back in the 1970s. Congress got it in its head that swine flu was going to be a huge health problem, and so it pulled out all stops, spent millions of dollars and had everyone vaccinated.

Fortunately, the dreaded flu crisis never arose. Nor did we learn the lesson that Congress is easily excitable and willing to throw money and a new program at almost anything if it sees a political advantage.

And that's precisely what it sees when looking at a proposal to provide seniors with a new prescription-drug benefit. But surely there is a better way to address the problem than the president's plan, which would expand Medicare at a time when Medicare's unfunded liability ($8.9 trillion over the next 75 years) is twice the size of Social Security's.

If Congress has to pass legislation, here are four suggestions that would make things better without making Medicare worse.

• Free Medigap. In order to limit their financial exposure, most seniors acquire, either through a former employer or private purchase, supplemental insurance, which pays many or all of the expenses that Medicare does not. Like Medicare, the federal government tightly controls the Medigap policies.

Were insurers given more freedom, they could create plans that responded to the needs of the market. Specifically, if insurers were free to forgo coverage of many routine expenses, they could offer more generous drug coverage — with no increase in premiums.

• Free Medicare. Some 16 percent of seniors have shifted out of traditional Medicare and into a private-sector HMO, and 95 percent of them provide their enrollees with a prescription-drug benefit.

However, the Clinton administration and a Medicare bureaucracy hostile to any challenge to its power and authority have combined to halt and even reverse the trend. After the administration cut reimbursement rates to Medicare HMOs this year, many HMOs dropped out of the program, leaving some 450,000 seniors, many who had drug coverage, scrambling to find another HMO or return to Medicare. Another 99 HMOs intend to leave next year, affecting 325,000 more seniors.

What could the private sector do for the elderly if they were free of Medicare restraints? A Milliman & Robertson analysis finds that with the average amount Medicare currently spends on each senior, a private plan could in principle establish a $1,585 across-the-board deductible and cover hospital, physician and drug costs above that deductible. Although a deductible of that size seems like a lot of money, many seniors are already spending $1,500 to $2,000 a year for Medigap coverage. What if they took that money they currently spend on Medigap premiums and put it in the bank?

• Free Roth IRAs. Many workers already set aside $2,000 a year after taxes in Roth IRA retirement accounts that grow tax-free. After age 59½, the funds can be withdrawn without penalty for any purpose, including medical expenses. Since the elderly by definition satisfy the age test, Roth IRAs could potentially serve as "back-ended" Medical Savings Accounts for the elderly.

However, there are two small problems. First, the law prohibits taxpayers from depositing more in a Roth IRA than they receive in earned income in each year. Since only about 18 percent of those age 65 and over work (and therefore have earned income), this restriction excludes the vast majority of seniors.

Second, unless deposits are held for at least five years, the interest earned is not tax-free. Clearly, this restriction discourages the type of annual deposits and withdrawals that are needed for health care.

The solution is to allow seniors to deposit the maximum in their accounts (regardless of the amount of earned income) and let them use the funds at any time without tax consequences — provided that the Roth IRA backs up a Medicare or (even better) a Medicare+Choice private health plan.

• Free the states. Finally, Congress should free up the states by letting them use these funds for the purpose of providing prescription drug coverage for the elderly poor, perhaps by using a risk pool. More than half the states have high-risk pools that permit uninsured people who have been denied health insurance to obtain coverage for a reasonable premium. They could do the same for those who have been denied prescription-drug coverage.

These proposals would create no new taxes (even if they were called premiums) and would cost the government nothing. At a time when Medicare is in financial trouble, it makes much more sense to look at smaller, less-expensive and targeted solutions for those seniors who need help.

Pete du Pont, former governor of Delaware, is policy chairman for the National Center for Policy Analysis.

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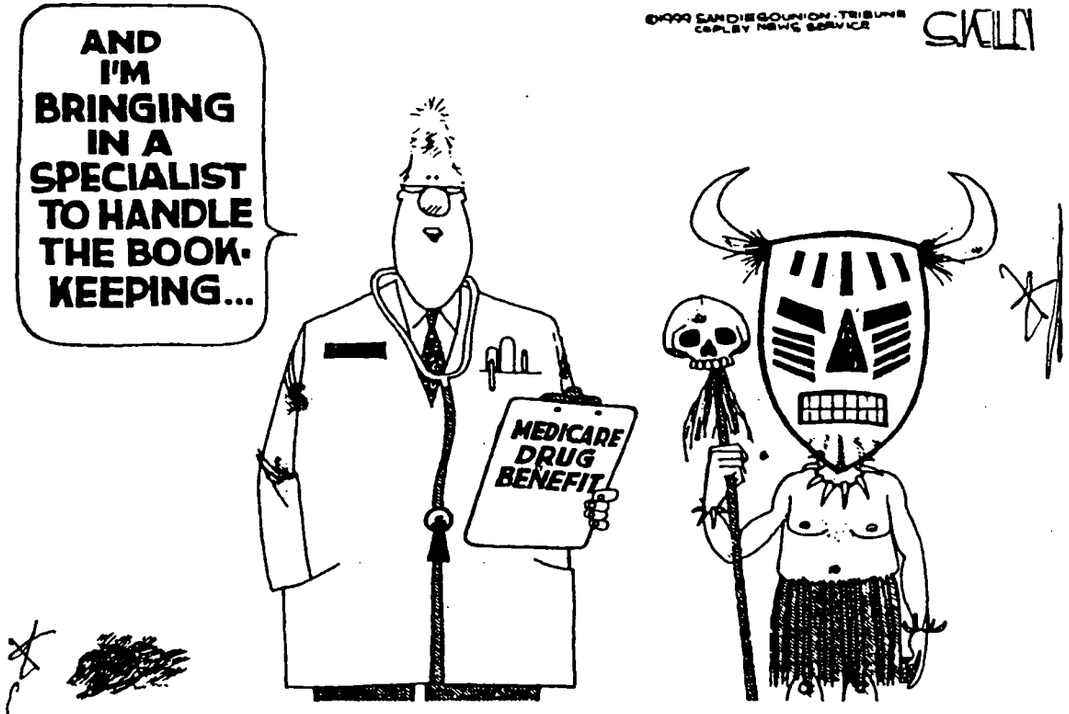

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The New York Times
MONDAY, AUGUST 16, 1999

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7-20-99

Report Says Profit-Making Health Plans Damage Care

By SHERYL GAY STOLBERG

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The research, by a team from Harvard University and Public Citizen, an advocacy group in Washington, is the first comprehensive comparison of investor-owned and nonprofit plans. The authors found that on every one of 14 quality-of-care indicators, the for-profits scored worse. But because the researchers favored national health insurance, some questioned their findings.

"The market is destroying our health care system," Dr. David U. Himmelstein, associate professor of medicine at Harvard University Medical School and the study's lead author, said in a telephone interview. "We have had a decade or more of policies aimed at making health care a business, and they have failed."

Investor-owned health plans, which are typically made up of loose networks of doctors, have come to dominate the American medical landscape in recent years. These plans, offered by companies like Aetna, U.S. Healthcare and Cigna Healthcare, last year covered 62 percent of all patients in H.M.O.'s, as compared to 26 percent in 1985. Yet most research on quality of care in H.M.O.'s has focused on traditional nonprofits, among them Kaiser Permanente, in California, and H.I.P., based in New York.

The new study, which appears this week in the Journal of the American Medical Association, analyzed quality-of-care data from 248 investor-owned and 81 not-for-profit plans in 45 states and the District of Columbia. These plans provided coverage to 56 percent of all Americans enrolled in H.M.O.'s in 1996, the year from which the patient information was drawn.

Among the findings: In profit-making H.M.O.'s just 63.9 percent of 2-year-olds were fully immunized, as compared to 72.3 percent in nonprofits. Lifesaving beta-blocker drugs were given to 59.2 percent of heart attack patients in for-profit plans, but 70.6 percent of patients in nonprofits got the drugs. Diabetes patients were less likely to receive annual eye exams to prevent blindness in profit-making plans; the figure was 35.1 percent, as against 47.9 percent in nonprofits.

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The study is being published just as the Senate is embroiled in a divisive debate over how to protect patients' rights and regulate H.M.O.'s. While the authors say the timing is coincidental, the work is already influencing the discussion. In a statement released today, Senator Edward M. Kennedy, the Massachussetts Democrat who is pushing for H.M.O. regulation, said the research "contains strong new support for H.M.O. reform."

But representatives of the insurance industry, which opposes regulation, argue just the opposite. They say the study demonstrates that, even at their worst, health maintenance organizations provide better care to patients than fee-for-service arrangements that were common 10 years ago.

"The best conclusion that can be drawn from this study is that managed care is improving the quality of health care for those Americans that are covered by health plans," said Susan Pisano, a spokeswoman for the American Association of Health Plans, which represents both for-profit and nonprofit plans.

Ms. Pisano also accused the authors of confusing "analysis and ideology."

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"There is no question that he has an agenda, but I think he is reading his data correctly," said Professor Ginzberg, adding that it was hardly surprising that nonprofit plans deliver better care. "Let's face it, people went into the for-profit managed care business to make bucks," he said. The study was made public here today at the offices of Public Citizen, whose director, Dr. Sidney M. Wolfe, was a co-author.

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The New York Times

WEDNESDAY, JULY 14, 1999

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The New York Times
WEDNESDAY, JULY 14, 1999

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The New York Times
WEDNESDAY, JULY 14, 1999

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July 14, 1999

The President
The White House
Washington, DC 20500

Dear Mr. President:

As a home care provider serving Iowa and Illinois Medicare Beneficiaries, I am writing to spark your interest in an idea that would save Medicare dollars and improve the quality of life for Medicare recipients.

Allowing home antibiotic infusion therapy to be a covered home health benefit, Medicare beneficiaries could have their homes as a choice in where they receive this service. Many Medicare beneficiaries request to receive antibiotic infusion therapy at home but must stay in the hospital or nursing home to get antibiotic infusion therapy covered by Medicare. This means many days of institutionalization just to receive the drug therapy. The other alternative is outpatient coverage, which causes many exhausting trips to the hospital or physician's office in a single day for a homebound patient.

Cost savings can be established with active patient teaching and computerized infusion pumps in the home setting. Most private insurance plans and HMO plans recognize the significant cost savings that can be realized by covering IV medications in the home. When Medicare Primary patients are covered under an HMO plan or have a secondary insurance plan, they are encouraged to utilize early hospital discharge.

I am requesting an opportunity to speak with you about the idea of a home antibiotic infusion therapy pilot project for Medicare beneficiaries.

Thank you for your time. Someday home antibiotic infusion therapy may be a choice you would want for yourself or your family. Please contact me at your convenience.

Sincerely,

Renee Rand

Renee Rand
Operations Manager
Option Care of the Quad Cities

cc: Senator Tom Harkin

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Drug Makers Fault the Details Of Clinton Medicare Proposal

By ROBERT PEAR

WASHINGTON, July 15 — Top executives of the pharmaceutical industry said today that they shared President Clinton's goal of increasing Medicare beneficiaries' access to prescription drugs, but for the first time they criticized specific features of his proposal. In particular, they said they feared that it could lead to price controls.

The executives drafted plans for lobbying and advertising at a meeting of the board of the Pharmaceutical Research and Manufacturers of America, a trade group for the industry.

After the meeting, Gordon M. Binder, chairman of the association and chief executive of Amgen Inc., said: "All seniors should have access to our medicines, and we hope something can be done by Congress and the President this year. But it should be done in the right way, not the wrong way, or else it could discourage the development of new medicines."

The association represents more than 100 companies, and 28 participated in today's meeting. People who attended said the board had discussed plans for a $30 million advertising campaign and had reviewed two sample television commercials. Possible themes for the campaign include "no price controls" and "we don't want the Government in our medicine cabinet."

Drug companies said they wanted to be seen as constructive and did not want to be vilified by the President and Hillary Rodham Clinton, both of whom in 1993 accused the industry of price-gouging. But the executives acknowledged that the industry did not have an alternative to Mr. Clinton's proposal.

Alan F. Holmer, president of the association, said drug makers had many "questions and concerns" about the President's plan, under which the Government would pay half the drug costs incurred by a Medicare beneficiary, with the maximum annual Federal payment rising gradually, to $2,500 in 2008.

"We are greatly concerned that the proposal, as currently structured, would inevitably lead to limits on access to medicines," Mr. Holmer said. "Under this proposal, the Federal Health Care Financing Administration would become the largest drug purchaser in the world. The history of Medicare and H.C.F.A. is that policy makers start with unrealistically low cost estimates. Then, having promised seniors a new benefit, the Government limits access to treatments — in this case, medicines — and imposes price controls in order to pay for it."

Chris Jennings, a White House aide, said there was no basis for the industry's concern. "The President's proposal has no price controls," Mr. Jennings said. "And there's no intention to inject price controls."

A drug company lobbyist who attended today's meeting conceded that "on its face, it's hard to find the price controls" in the President's plan. Rather than overtly regulating drug prices, he noted, the Government would hire private companies to manage drug benefits for the elderly and disabled.

But if the costs exceed estimates — as has often happened in the Medicare program — the Government "will take it out of our hide," the lobbyist said, by cutting payments for drugs.

Mr. Holmer asserted that the President's proposal "would subsidize the rich at taxpayers' expense," since taxes paid by workers with low and moderate incomes would help pay for prescription drug benefits for wealthy retirees.

Drug company executives said they also worried that the new benefit proposed by Mr. Clinton would supplant drug coverage now provided to retirees through the voluntary efforts of employers.

"To discourage employers from abandoning those efforts," Mr. Holmer said, "the President would reimburse employers for most of their current costs — a massive Federal outlay, but no better coverage for seniors."

At its meeting, the pharmaceutical association reaffirmed that its goal was to "improve coverage of prescription drugs through the private sector," including Medicare health maintenance organizations, "rather than the traditional Medicare fee-for-service program."

The industry is searching for the best mechanism to achieve that goal, and is struggling with the question of whether the Government should guarantee drug coverage for all Medicare beneficiaries or just for the neediest ones.

Clinton Tells Colorado Youths He'll Stand Fast on Gun Control

By KATHARINE Q. SEELYE

WASHINGTON, July 15 — President Clinton said today that he would veto the juvenile-justice bill if it emerged from Congress with provisions that weakened existing gun controls.

"I will not in any way, shape or form countenance a weakening of the law," Mr. Clinton declared at the White House, standing in front of 80 students from Colorado — 6 of them from Columbine High School in Littleton — who are in Washington to lobby Congress for gun controls included in the Senate version of the bill.

The President noted that the Senate legislation also included a weakening provision, eliminating background checks on people who retrieve their guns from pawnshops. Even as he issued his veto threat, though, he said that he was not fully aware of what else was in the bill and that "the Attorney General has to give me a briefing on it before I can make a final decision."

The juvenile-justice bill as adopted by the Senate would impose a number of new gun controls, including an expansion of background checks on purchasers and a ban on the import of high-capacity ammunition clips. The House version provides no controls, and the students are lobbying for the Senate provisions to be included in whatever bill emerges from a conference committee.

The President spoke today after meeting privately with the students in the White House. The students, organized by a gun-control group that sprang up in Colorado after the killings at Columbine High in April, have proved to be an unusual lobbying force. Most lobbyists come to Washington begging for a moment with lawmakers, which both sides generally like to keep private. These young lobbyists, in contrast, have been sought out by politicians.

This afternoon Vice President Al Gore, who has made school shootings a focal point of his Presidential campaign, went to the Capitol, where he and Representative Richard A. Gephardt of Missouri, the House Democratic leader, posed with them. The youths also met with Colorado's six member House delegation, its two Senators and more than two dozen other lawmakers they had identified as swing votes on gun control.

Jody Gold, an Internet consultant who is one of the group's chaperones, said the students had discussed with President Clinton how to keep Congress focused on gun control now that Columbine had faded from the news. The President's advice to the students, Mr. Gold said, was to expand their numbers in Colorado, create similar groups in other states and return next year.

But despite Democrats' continuing pessimism that meaningful gun control will be enacted this year, Mr. Clinton said it was not too late for Congress to heed the students' message.

"Don't forget Littleton," he urged Congress. "Don't allow the victims of Columbine to have died in vain. Don't forget the 13 children who die every day from gun violence. Many, many, many of them can be saved. We must not lose the urgency of our mission."

The New York Times

FRIDAY, JULY 16, 1999

Kate Britton

To: The President —

Monday, 11 pm

Letter: 4 pp

attachments: 8 pp

Warning

Intermittent material from a pro-Life friend worth reading

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Kate Britton

The Washington Post, Front Page, Sunday, May 23, 1999
"Federal Embryo Research Is Backed"

"A presidentially appointed ethics panel has decided to recommend that the federal government begin funding some research on human embryos, saying the moral cost of destroying embryos in research is outweighed by the social good that could come from the work. [The commission states that,] 'We have moral obligations to the future health...of people, and we need to balance these with...the symbolic moral obligation we have to the embryo...It is...permissible to destroy embryos where it is necessary to save people.'"

Monday evening, May 24, 1999

Dear Bill,

I feel compelled to respond to the decision by your panel to recommend to you the killing of human embryos, which it seeks to justify by stating that the intention of the killing is the enhancement of the lives of other humans. My response will be to quote for you from the teachings of two of this century's most eminent spokesmen in the arena of bioethics, Dr. Jerome Lejeune and Pope John Paul II.

Jerome Lejeune, M.D.
From France, known as the "Father of Genetics" for his discovery of the first-known genetically based human disorder, Down Syndrome.

The excerpt which follows has been taken from testimony given before the Honorable William Dale Young, August 10, 1989, Circuit Court for Blount County, State of Tennessee. Proceedings concerned a domestic relations case in which a divorcing couple were in dispute over the matter of possession of frozen embryos conceived by them in an in vitro fertilization procedure undertaken earlier. The father desired the embryos to be destroyed; the mother desired either to retain

mother. Dr. Lejeune traveled from Paris to serve as an expert witness in the field of genetics. The Court found in favor of the mother, determining that the best interest of the children [sic]was that they be made available for implantation, their only hope of survival. Dr. Lejeune's testimony has been judged subsequently to be a masterpiece of science and ethics, conveying truth which can be of benefit far beyond the boundaries of the State of Tennessee.

Q. Doctor [Lejeune], can you tell us what we can tell about these human beings from [the stage of] three cells forward?

A. The amount of information which is inside the zygote [Note: When a zygote divides it becomes an embryo.]**...is [so] big that nobody can measure it. I have to explain that very simply. You have the two meters of DNA, one coming from the father, one coming from the mother...[T]o spell out this amount of information which is absolutely necessary (otherwise no life would be possible)...[n]o computer in the world would have a storage enough just to fill the amount of data...Nobody knows how to do it. You have to realize that this...information which makes a man enormous compared to the...computer [is] because it's a man which has made the computer; it's not the computer which has made the man.**

Q. Do you regard an early human being as having the same moral rights as a later human being such as myself?

A. You have to excuse me. I'm very, very direct. As far as your nature is concerned, I cannot see any difference between the early human being you were and the late human being you are, because in both case[s], you were and are a member of our species. What defines a human being is: He belongs to our species. So an early one or a late one has not changed from its species to another species. It belongs to our kin. That is a definition. And I would say very precisely that I have the same respect, no matter the amount of kilograms and no matter the differentiation of tissue.

Q. [Dr. Lejeune], I take it you would believe, from your testimony today, that it is morally very wrong to intentionally kill a zygote?

A. I think it's no good; it's killing a member of our species.

Q. And it would be the same as if we were to kill twenty years later the person the zygote would become?

A. It's difficult to tell because you ask me a justice question. I'm a biologist.

Q. But those are your beliefs?

A. My belief is that it's no good to kill a member of our kin, very simple belief. [End of Dr. Lejeune]

Pope John Paul II
The Splendor of Truth
Encyclical Letter, 1993

Section 51. **Only in reference to the human person in his unified totality, that is, as a soul which expresses itself in a body and a body informed by an immortal spirit, can the specifically human meaning of the body be grasped...By rejecting all manipulations which alter human meaning, the Church serves man and shows him the path on which he can find God.**

Section 80. **Reason attests that there are objects of the human act which are by their nature "incapable of being ordered" to God, because they radically contradict the good of the person made in His image. These are the acts which, in the Church's moral tradition, have been termed "intrinsically evil": they are evil *always and per se,* on account of their very object, and quite apart from the ulterior intentions of the one acting and the circumstances. Whatever is hostile to life itself...[and] whatever violates the integrity of the human person, such as mutilation...[is] a negation of the honor due to the Creator.** [Note: Mutilation of the human embryo by dissection, which causes death, is required in order to harvest stem cells.] **So long as they infect human civilization the[se practices] contaminate those who inflict them more than those who suffer the injustice [of the practices]...[I]t is never lawful, even for the gravest reasons, to do evil that good may come of it (cf. Romans 3:8)--to intend directly something which of its very nature contradicts the moral order, and which therefore must be judged unworthy of man, even though the intention if to protect or promote the welfare of society in general.**

(4)

Section 81. **Intentions can never transform an act intrinsically evil by virtue of its object into an act "subjectively" good or defensible as a choice.**

Section 82. **An intention is good when it has as its aim the true good of the person in view of his ultimate end.** [Note: Man's ultimate end is full participation in the life of God.] [End of Pope John Paul II]

Bill, I appeal to you to deny as unethical any granting of federal funds for research which requires the killing of human embryos, who in fairness must be considered "non-consenting human subjects." Many prominent scientists attest to the fact that there are alternatives to the harvesting of stem cells from embryos as well as that the need for fetal cells as a source of stem cells for medical research has already been eclipsed by the more readily available (to say nothing of the capacity for consent!) adult stem cells. [See attachments.]

Scripture informs us that man's dignity comes from his capacity to honor His Creator by his choices. Implicit in our freedom, great as it is, is the truth that not all choices do honor Him. Some options have only the trappings of good, but in fact are evil and require rejection. *"You may eat freely of every tree in the garden; but of [this] tree you shall not eat."* Genesis 2:16

Bill, I ask you to use your executive authority to inform the National Institutes of Health that your own sensitivities (informed, cautious and resonating with the majority of Americans) must determine the outcome of the matter of the killing of human embryos. God will not fail to supply you with the necessary *fortitude* for this decision, if you ask Him. (See *today's* meditation on that!) Tell them, on this one, you've got to live with yourself.

"Whoever receives one child in My name, receives Me." Matthew 18:5

+ In the love of Christ,

Kate

Apologies for length yet I could have said so much more. I have tried to select the best for you to consider and pray about.

Kate Britton

Scientific Experts Agree: Embryonic Stem Cells Are Unnecessary for Medical Progress

New research suggesting that nerve stem cells "can de-differentiate and reinvent themselves" as blood-producing stem cells "means that the need for fetal cells as a source of stem cells for medical research may soon be eclipsed by the more readily available and less controversial adult stem cells."

- D. Josefson, "Adult stem cells may be redefinable," *British Medical Journal*, 30 Jan. 1999, p. 282

* * *

Commenting on the same findings: "The research shows 'there are alternative strategies' to harvesting stem cells from embryos, said Dr. Ronald McKay, a National Institutes of Health researcher and a pioneer in stem cell studies."

- P. Recer, "Patient's Cells May Grow New Organs," Associated Press, Jan. 21, 1999

* * *

Recent research shows that mesenchymal stem cells in adult bone marrow "can in principle be used to repair bone, cartilage, tendon and many other injured or aged tissues... The cells would be derived in many cases from the patient's own bone marrow and thus present no problem of immune rejection."

- N. Wade, "Discovery Bolsters a Hope for Regeneration," *New York Times*, April 2, 1999, p. A17

* * *

Due to advances in the use of the anti-aging enzyme telomerase, "the ability to rejuvenate specific cells in the body opens up a dazzling array of possibilities. Doctors could grow skin grafts for burn victims using their own skin, insulin-producing cells for diabetics, or muscle tissue for sufferers of muscular dystrophy."

- R. Larson, "Scientists find new life for old cells," *Washington Times*, Dec. 29, 1998, p. A1

* * *

Adult "precursor" or stem cells "may prove much more useful to medical science" than embryonic cells. "Scientists used to think that such potential for cellular regeneration was present only in embryos – that, for example, humans had made their lifetime supply of brain cells by age 17. But that canon is steadily eroding... 'I think we will find these stem cells in any organ that we look,' says Harvard Medical School researcher Evan Y. Snyder."

- L. Johannes, "Adult Stem Cells Have Advantage Battling Disease," *Wall Street Journal*, April 13, 1999, p. B1

* * *

"This suggests that there is a stem cell in the adult bone marrow that is capable of becoming anything if you give it the right signal."

- Bryon Petersen of University of Pittsburgh Medical Center, quoted in P. Recer, "Cell Used to Make New Liver Tissue," Associated Press, May 13, 1999

* * *

Commenting on new ways to "regenerate" and transplant patients' own brain cells to treat Parkinson's and other diseases: "What we have is a protocol in which we don't have to harvest 12 or 15 fetuses, we don't have to give immunosuppressant therapy, and we don't have to worry about viral disease transmission."

- Michel Levesque, director of neurofunctional surgery at Cedars-Sinai Medical Center in Los Angeles, quoted in M. Moran, "For cell transplants, is one brain better than two?", *American Medical News*, May 3, 1999, p. 29

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"For generations, scientific dogma held that the adult brain cannot repair itself, because it lacks stem cells. Wrong. Recently, scientists found that adult brains do indeed harbor stem cells... Since stem cells divide endlessly, a single sample started from a human fetus could provide all that's needed. But the recipient's immune system might attack these as foreign. Perhaps the patient's own body is a better source of stem cells... [Moreover,] brain stem cells may not be a necessary ingredient for custom-making new brain tissue. Scientists believe it may be possible to reprogram more readily available kinds of stem cells, such as the ones that produce skin, so that they will churn out brain cells, instead."

- D. Haney, AP Medical Editor, "Scientists Try to Grow Brain Parts," Associated Press, May 1, 1999

Engineering Researchers Help Biomedical Firm Win Grant for Novel Treatment of Tendon Injuries

April 2, 1997
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Cincinnati -- People who suffer serious tendon injuries like President Clinton's might recover more quickly and more completely using a new treatment being tested by researchers in the University of Cincinnati College of Engineering. The treatment was developed by Osiris Therapeutics, Inc. of Baltimore.

The treatment is based on human mesenchymal stem cells, embryonic-like cells responsible for the formation of cartilage, bone, muscle, tendons, ligaments and other connective tissue. Osiris is developing therapies using a patient's own stem cells to regenerate tissue damaged by injuries or disease. Normally, the healing process is very slow and inefficient because there are so few stem cells available.

Preliminary research results using animal models indicate that stem cell implants dramatically reduce the time required for healing following tendon surgery. Randell Young, the manager of preclinical studies for Osiris, said experiments showed "a significant increase in tendon repair strength as early as four weeks after surgery" with continued improvement up to 12 weeks after surgery.

David Butler, a professor of engineering mechanics at the University of Cincinnati, found that stem cells could regenerate about two-thirds of normal tendon strength within four weeks. The re-grown tendon could also absorb nearly the same amount of energy as a normal tendon. More important, the quality of tissue was good. "It was a rapid improvement in both quality and quantity of tissue," said Butler.

The preliminary results were reported at the annual meeting of the Orthopaedic Research Society in San Francisco. The next phase of the research will focus on the patellar tendon and the Achilles tendon, because those two tendons are subjected to the greatest amount of force. And as President Clinton will find, the normal recovery time is typically quite long.

"It's going to be debilitating for him," said Butler. "it will be six weeks to three months of rehab. Jogging? He's done with that for quite some time, at least six months."

There are over half a million injuries in the United States each year to patellar, quadriceps, Achilles and rotator cuff tendons. Those numbers are likely to increase in coming years as the number of older Americans increases. "Age is a factor," said Professor *Ed Grood*, who collaborates with Butler in the *Noyes-Giannestras Biomechanics Laboratory* at UC. "As you get older, your ligaments and tendons get weaker. They're more susceptible to injury."

The National Institutes of Health just awarded Osiris a two-year $750,000 Small Business Innovation Research (SBIR) grant to continue development of the treatment in collaboration with the University of Cincinnati researchers.

Osiris President and CEO James Burns said he's encouraged by the progress made so far on the research and said the large SBIR grant indicates the National Institutes of Health believes stem cell implants are a promising approach. "The ability to restore patient function to normal within one to two months would provide a substantial breakthrough in the treatment of soft tissue injuries," said Burns.

A key to using mesenchymal stem cells is the way they are implanted into the body. Researchers have found that the cells respond not only to chemical signals inside the body, but also to physical stresses. Therefore, Osiris has developed customized implants which maximize the quality and quantity of new tissue produced. Osiris researchers are also exploring the use of mesenchymal stem cells to regenerate bone, cartilage and muscle.

Human studies are awaiting FDA approval.

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Stem Cells Move Closer To Treating Patients

The stem cell story continues with today's news that some forms of these pluripotent cells are much closer to treating human disease than previously suspected. In a report in the April 2 issue of *Science*, researchers announce they're much farther along in the ability to prod certain stem cells into becoming normal, mature human tissues than most people realize.

(Editor's Note: For an earlier UniSci story on research in this area, see Cultured Stem Cells Open New Era In Biology And Medicine.)

The stem cells used in the current study, unlike the embryonic stem cells (ESs) unveiled last November at Johns Hopkins -- which theoretically can produce any cell type in the body -- are more specialized. They typically develop into a smaller number of specific tissues.

In this case, the researchers have nudged the stem cells in question -- called mesenchymal stem cells (MSCs) -- into forming cartilage, bone and fat cells apparently identical to the usual human versions.

The MSCs are harvested from adult tissues, skirting the ethical issues that the more basic stem cells carry and avoiding the prohibition on the use of federal money for research using human embryonic stem cells.

MSCs are currently being tried experimentally for breast cancer patients whose bone marrow has been damaged by chemotherapy; the scientists have also used human MSCs to repair tendon and bone injury in animals. Possibilities abound, they say, for such applications as restoring heart muscle after heart attacks or repairing cartilage in joints before arthritis really sets in.

The research reported in the *Science* paper took place at Osiris Therapeutics, a Baltimore biotech company. Daniel Marshak, Ph.D., the lead researcher, has appointments in two departments at the Johns Hopkins University School of Medicine.

[Contact: Marjorie Centofanti]

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Cell Used to Make New Liver Tissue

By Paul Recer
AP Science Writer
Thursday, May 13, 1999; 3:06 p.m. EDT

WASHINGTON (AP) -- Special bone marrow cells have been shown to convert into basic liver tissue, raising the possibility of one day using a patient's own marrow to repair failing livers, researchers say.

In laboratory rat studies at the University of Pittsburgh Medical Center, researchers found in bone marrow a master, or stem, cell that under special conditions will convert itself into functioning liver tissue cells.

Bryon Petersen, lead author of the study to be published Friday in the journal Science, said the work is the first step toward learning how to rescue failing livers using the body's own stem cells.

Petersen said that in new experiments he already has shown that injecting the special marrow cells into rats causes the animals to form new liver tissue.

Although the work only has been demonstrated in laboratory animals, Petersen said other studies strongly suggest humans also have bone marrow cells that will convert into liver cells.

``What we have learned from the rat, we should be able to extrapolate to the humans," said Petersen. But he cautioned that perfecting the technique for humans may take a decade.

Dr. John M. Vierling, liver specialist at Cedars-Sinai Medical Center in Los Angeles and chairman of the board of the American Liver Foundation, said the research raises ``very exciting" possibilities for reviving dying livers.

Vierling said that other researchers have been trying with little success to find in the liver stem cells that could make new tissue. If the cells can be isolated from the bone marrow and cultured, he said, it raises the possibility of finding a virtually unlimited supply of key liver cells.

``The ability to take something from scratch, so to speak, and grow it up in the quantity that you need would be extraordinary," Vierling said.

Dr. Mark F. Pittenger, a researcher at Osiris Therapeutics in Baltimore who recently found in bone marrow the stem cells for bone, cartilage and fat, called Petersen's ``a significant step forward."

``It bodes well for our learning how to regenerate organs," said Pittenger. ``Liver disease is a very serious problem."

The American Liver Foundation says about 26,000 Americans die annually from liver disease. About 5 million in the U.S. are infected with hepatitis B or C, virus diseases that are a major cause of liver failure.

Petersen said that his research investigated how some people with liver failures are able to grow new liver tissue. Some patients with failing livers recover after the organ spontaneously grows new cells, he said.

The liver often can generate new hepatocytes, or a type of healthy liver cells, after an injury or disease. But Petersen said that some patients who do not make new hepatocytes still end up growing new liver tissue and recovering.

Just how this happens, said Petersen, long has been a mystery. Researchers suspected some special cells in the bone marrow somehow were prompted to start making new cells for the distressed organ.

Peterson said research using the lab rats proves the bone marrow is the source of these new liver cells.

In the study, Petersen and his colleagues destroyed the bone marrow of female rats and replaced it with marrow from male rats. This meant that the female rats had bone marrow that carried the male Y chromosome, which could be used to identify cells.

The scientists treated the female rats with a chemical that prevented their livers from regenerating and then damaged the livers, mimicking an injury.

Two weeks later, the livers were removed and the researchers found they contained new liver cells that carried the Y chromosome marker. This meant that cells from the bone marrow had gone to the failing livers and started the regeneration process.

``This suggests that there is a stem cell in the adult bone marrow that is capable of becoming anything if you give it the right signal," said Petersen. ``I have been able to show that there is a cell in the bone marrow for the liver."

He said there is preliminary work in his lab that shows the bone

marrow also has a stem cell that converts into pancreatic cells.

Petersen said that once researchers learn to isolate stem cells from the bone marrow, switch them into liver cells, and then grow them into large quantities, it may be possible to rescue failing livers with simple injections.

Vierling cautioned, however, that the technique would not totally replace the need for liver transplants.

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