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**HEALTH CARE POLICY TRENDS IN THE NEXT MILLENNIUM:
THE ISSUES SHAPING OUR FUTURE**

Background Information
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**HEALTH CARE POLICY TRENDS IN THE NEXT MILLENNIUM:
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ISSUE: How should New Jersey's public policy establishment acknowledge and decide upon appropriate legislative and regulatory action(s) in response to the momentous implications of biomedical advances – such as the mapping of the human genome and genetic testing – with which we enter the next millennium? During the 1990s, the need to control costs changed the health care system in ways that could hardly have been imagined just a decade or two earlier. What can policymakers expect in the 21st century?

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New Jersey Policy Forums on Health & Medical Care

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INTRODUCTION

Historically, New Jersey has been a leader in health care and medical practice. During the next millennium, players in the state's health care industry will be challenged by continuing changes in the delivery, financing and provision of health care in both the public and private sectors. Policy makers will also confront bioethical issues raised by new medical technologies and advances in medical research anticipated to be so profound that the traditional nature of treatment protocols will experience a 180-degree change: ". . . if the efforts [of the various human genome mapping projects] are successful, health care will shift from a paradigm of detect and treat . . . to predict and prevent, with therapies of exquisite specificity aimed at the causes of disease" (Fisher, 1999).

This paper aims to identify some of the trends that will shape the future of health policy through interviews with: – Deborah J. Chollet, Ph.D., vice president of the Alpha Center; Judy Donlen, executive director of the Southern New Jersey Perinatal Cooperative; Paul B. Ginsburg, president of the Center for Studying Health System Change; Robert Pickens, M.D., chairman of the Biomedical Ethics Committee of the Medical Center at Princeton; Marian Gray Secundy, Ph.D., Director of the National Center for Bioethics in Research and Health Care at Tuskegee University; and Shirley M. Tilghman, Ph.D., director of Princeton University's new Institute for Integrative Genomics -- and to offer a brief history of developments in medical practice in New Jersey.

NEW JERSEY'S MEDICAL HERITAGE

According to medical historian Karen Reeds, some of New Jersey's earliest

health care providers were Lenape Indian herbalists. European settlers brought medicinal plants and remedies with them, but some also turned to the Lenapes for help.¹

In the decade before the Revolution, there were fewer than 100 doctors in New Jersey. In 1766 a number of those physicians got together at Duff's Tavern in New Brunswick to found the Medical Society of New Jersey, the first homegrown doctors' organization in the colonies. By 1772 the state had begun to license physicians.

New Jersey's first general hospital opened in Hoboken in 1863. As hospitals were established, most simply took over old houses. By the end of the 19th century, some hospitals had founded nursing schools to ensure that they would have trained nurses. Meanwhile, in south Jersey, people dissatisfied with mainstream medical care came from miles around to consult James Still. Known as "the black doctor of the Pinelands," he treated patients with herbal remedies he made himself from local plants.

In many ways, the state's geography was its destiny and had health consequences. Reeds explained that in the 19th century, factory owners were attracted to New Jersey because it had access to New York City and Philadelphia, and land was relatively cheap here. In addition, many immigrants had settled in the state, providing a source of skilled labor. Thus, New Jersey was one of the earliest states to become both industrialized and densely populated. That made it "the canary in the mine," said Reeds, as it experienced epidemics of infectious diseases and occupational disorders.

Cholera, typhoid, malaria, and other diseases posed threats, particularly to those

crammed into the tenements of Newark, Camden and Trenton. Local physicians and public health officials responded to epidemics with quarantines and vaccinations; they tried to see that citizens had clean water to drink. The state became a leader in the drive for better sanitation.

New Jersey physicians drew attention to occupational disorders as early as 1858, when more than 100 East Orange hat makers fell ill from mercury poisoning – the mercury was in the felt they worked with. In another significant incident, radiation poisoning killed a number of young New Jersey women in the 1920s. All had jobs painting luminescent numbers on watch dials with radium paint; they typically licked their brushes to get a fine point. “Even their breath was radioactive,” said Reeds. At the time, radium-infused water was a popular remedy. Essex County medical examiner Harrison Martland, M.D., was the first person to warn the public that radiation was dangerous.²

Beginning in the second half of the 19th century, drug companies built factories in New Jersey. Today much of the world’s pharmaceutical industry is concentrated here. Almost one third of all new drugs approved by the FDA are developed by companies based in New Jersey. Over the years, many medications, including early antibiotics, were developed here. In 1944, for example, researchers at the Waksman Institute of Microbiology at Rutgers discovered streptomycin. It made such a difference in the treatment of tuberculosis that by the early 1950s, TB sanitariums began to close.

Despite these medical milestones, New Jersey labored under a disadvantage for many years: it had no medical school of its own. Those who wanted to become doctors

had to go out of state for schooling, as did patients who needed highly specialized care and those who wanted to take part in a clinical trial for a new drug (clinical research is generally done by medical schools). It wasn’t until 1954 that the Seton Hall College of Medicine and Dentistry was founded in Jersey City. UMDNJ, the University of Medicine and Dentistry of New Jersey, was created in 1981. “Its growth has been spectacular,” said Reeds. Today, it is the country’s largest freestanding medical school– it’s not part of a university, it is a university. Thanks to a kind of synergy between UMDNJ and the state’s pharmaceutical companies, many clinical trials of new drugs now enroll New Jerseyans.

THE 21st CENTURY: WHAT WILL DRIVE CHANGE?

In the next century the same basic conflict will play out in every aspect of the American health system. The tug-of-war between the need to keep costs down and the need to help the uninsured will shape the system. More than 43 million Americans have no health insurance, though almost all other industrialized nations provide free basic health care for their citizens (Kilborn, 1999). According to Deborah J. Chollet, Ph.D., vice president of the Alpha Center (a non-partisan health policy center), the majority of the uninsured in the United States are low-wage workers. Statistically, families earning less than \$20,000 a year make up 17 percent of the population – and 54 percent of the uninsured. Chollet observed, “Whether we empower those people in the marketplace and how we do it have the potential to reconfigure health care.”

Bioethicist Marian Gray Secundy, Ph.D., Director of the National Center for

Bioethics in Research and Health Care at Tuskegee University, summed up the practical problem involved: how can we make health care available to all without rationing it? She pointed out that Americans have always assumed that people can have whatever medical care they can afford. If we acknowledge that in Medicare, for example, our resources are limited, we will have to make uncomfortable choices.

THE FUTURE OF PHARMACEUTICALS

“There’s been an explosion in drug spending,” economist Paul B. Ginsburg, Ph.D., explained. “Spending on pharmaceuticals rose by 14 percent per capita in 1998.” Ginsburg is the president of the Center for Studying Health System Change, a research organization.³ He cited three reasons for the rising costs: a rich pipeline of new drugs, made possible in part by a speed-up in the FDA’s approval process; the direct marketing of medications to consumers; and the fact that, in pricing their products today, drug companies know that they’ll often be paid for by the consumer’s health plan. Overall, medications often save money that would otherwise be spent on hospitalizations and to pay providers, but there are no data on how much they save.

New Jersey’s pharmaceutical industry will belatedly feel the pinch of managed care in the next century, said Ginsburg. He predicted that health plans will develop new mechanisms for containing costs, just as they found ways to hold down hospital expenses, for example, by controlling admissions and length of stay. If the cost of medications is brought under

control, that’s likely to affect research and development. Chollet explained that because drug prices in the U.S. are relatively unrestricted – and higher than in many other countries – Americans currently pay more than a quarter of the net cost of worldwide research and development (R&D) for pharmaceuticals. “I’m not arguing that unrestricted financing for drugs is good; it’s not,” she said. “But financing drives development.”

THE FUTURE OF PHYSICIANS

There are apt to be major changes in the way physicians are trained and practice medicine in the next century. To begin with, there is an apparent surplus of doctors. Today, for every two physicians who leave the profession, three enter it.⁴ Many people also believe there are too many specialists and too few primary care providers; at the moment, the ratio is 7:3 (Unger, 1999).⁵ Some blame the oversupply of doctors partly on graduates of foreign medical schools, who come here to do their residency and stay to practice medicine. One out of every four medical residents in the U.S. is an international medical graduate (IMG) (Unger, 1999). Secundy noted that all too often there’s a communication gap when IMGs provide care for people from lower socioeconomic groups in a city hospital. Not only is English the IMG’s second language, but in many cases their medical education hasn’t taught them how to communicate with people from a different cultural background.

“When we say that we can’t afford to spend so much per capita on health care because we need to give more people access to care, that creates a different dynamic ... Pharmaceuticals will be the first battlefield. The problem of how to finance prescription drugs in programs like Medicare is hugely important.”

- Deborah Chollet Ph. D.

COGME, the Council on Graduate Medical Education (a national organization), has proposed that in the future just 10 percent of residents should be IMGs and half of all residencies should be earmarked for future primary care providers (Unger, 1999). Limiting the number of

“Limiting the number of international medical graduates (IMGs) would affect New Jersey dramatically; ... 57 percent of the residents in New Jersey hospitals are IMGs, the highest percentage in the country.”

-Robert Pickens, M.D.

IMGs would affect New Jersey dramatically, said urologist Robert Pickens, M.D. Pickens chaired the recent New Jersey Commission on the Physician Workforce, established by the Medical Society of New Jersey. He explained that 57 percent of the residents in New Jersey hospitals are IMGs, the highest percentage in the country.⁶ The Commission’s report stated that “New Jersey has long relied on IMGs to provide quality medical care.... Any plan to decrease residency positions should not unfairly discriminate against IMGs” (New Jersey Commission on the Physician Workforce, 1999).

As for the assertion that there are too many specialists, Pickens observed that many specialists spend half their time doing primary care for their patients. For certain illnesses, he said, a specialist may provide the best primary care – people with heart problems may do better if their cardiologist handles their general care, for example.

Today, doctors are organizing to defend their autonomy and their income, and that, too, may affect the health care system. The American Medical Association (AMA) announced in June that it will form a union for physicians who are employees (those who work for hospitals, for example). It will also try to persuade Congress to change the anti-trust laws and allow self-employed doctors to unionize (Greenhouse, 1999).

Ginsburg believes Congress will refuse, for fear a physicians’ union would drive up health care costs. Nevertheless, Ginsburg thinks that physician-led organizations will play a greater role in the next century and will give doctors more clout in negotiating with health

plans. There will be more group practices and independent practice associations,⁷ according to Ginsburg, and more doctors will join forces with hospitals.

THE FUTURE OF HOSPITALS

Hospitals today are overbedded and some are struggling to survive. Patients spend less and less time in hospital, partly because of pressure to contain costs and partly because less invasive procedures make long stays unnecessary. Many hospitals now look to outpatient services to restore their lost income. They have added extended care and psychiatric facilities, home care and rehabilitation programs and other ancillary services, according to Pickens, who also chairs the Biomedical Ethics Committee of the Medical Center at Princeton. As Medicare cuts back on its fees for these outpatient services, Chollet suggested that the near future will see “lots of hospital mergers and closings.” “Hospitals will also face new competition from physicians in the next century,” said Ginsburg. For example, doctors are setting up their own facilities for imaging or ambulatory surgery.

Nevertheless, hospitals are not an endangered species. They have more leverage than most providers in negotiating with managed care plans, according to Ginsburg. He believes that their future lies

in supplying high-tech, outpatient services such as one-day surgery, imaging techniques such as MRIs, and sophisticated lab tests. Chollet suggested that if the government someday provides funding for long-term care, many hospitals may fill their empty beds with nursing home patients and people with disorders such as Alzheimer's, who need intermediate care.

THE HEALTH PLAN OF THE FUTURE

Under pressure from a consumer backlash, managed care loosened up in the late 1990s. PPOs (preferred provider organizations) and point-of-service HMOs grew in popularity; both allow members to go to doctors outside the plan's network, provided the members pay a bigger share of the cost. In addition, some plans began to offer members a broader choice of physicians. Some permitted members to go to certain specialists, such as gynecologists, dermatologists and allergists, without getting permission first from their primary care provider; others offered direct access to all specialists within the network. Some health plans say these changes are already pushing up costs (Center for Studying Health System Change, 1998).

Ginsburg predicted that the trend to more loosely managed care will continue and will lead to "somewhat higher cost increases...a sacrifice we're going to have to make so that people can feel more comfortable with managed care." He also suggested that with time, plans will identify the concessions to consumers that cost a lot or interfere with effective management of care and will drop them.

THE FUTURE OF MEDICARE

Next year, most of the six million Medicare beneficiaries who signed up for an

HMO will pay higher premiums and/or have fewer benefits. One out of ten will have been dropped by their HMO because it has pulled out of the Medicare market in their area (Pear, 1999).⁸ According to Ginsburg, this has happened partly because the Balanced Budget Act of 1997 cut payments to the HMOs but also as a consequence of the insurance underwriting cycle. In the early to mid 1990s, insurers competed aggressively to enter new markets, sometimes setting premiums below costs (Center for Studying Health System Change, 1998). "We're in the stage of the cycle where insurers are retrenching and leaving markets they're not doing well in," Ginsburg said.

Despite the recent setbacks to Medicare+Choice (the program that permits seniors to enroll in managed-care health plans), Ginsburg believes that in the next century managed-care plans will enroll more and more seniors. This change will happen no matter what approach is taken to reforming Medicare, though the approach will affect the speed of the transition, according to Ginsburg.

HOW WILL MEDICAL ADVANCES CHANGE THE SYSTEM?

Gene therapy, organ transplants derived from animals or from human tissue grown in the laboratory: these and other new medical technologies are just over the horizon. Some will raise bioethical issues.

Genetic testing and gene therapy: We're at the beginning of a medical revolution. The Human Genome Project has announced that it will have decoded the majority of human genes by next spring. According to geneticist Shirley M. Tilghman, Ph.D., director of Princeton University's new Institute for Integrative

Genomics,⁹ this compares in scientific importance to the research in physics that led to smashing the atom.

Already, people can be tested to find out whether they are likely to develop particular disorders. Genetic testing raises at least three serious ethical issues, according to Tilghman. First, she said, “we can test for a lot of things we can’t yet do anything about. It’s going to be very important to think through the implications of that.” Then there’s the problem of confidentiality. Tilghman observed that “there will come a time when everyone’s whole genome will be known.” However, she also noted that scores of bills have already been introduced in Congress and state legislatures, designed to prevent employers and/or insurers from discriminating on the basis of genetic testing. According to Chollet, genetic discrimination is already outlawed in some states, including New Jersey. Under its law, genetic information is treated as personal property; health plans aren’t allowed to ask for it and are forbidden to discriminate if tests are done and they’re not told the results (N.J.S.A. 17B:30-12 et seq.). Secundy noted that today some insurers refuse coverage or raise rates simply because someone has had genetic screening, no matter what the results. Tilghman suggested that we need to protect the confidentiality of all medical records, not just genetic tests.

As for Tilghman’s third ethical issue, genetic testing will make it possible for couples to have “designer babies.” By using in vitro fertilization, they can choose from a batch of fertilized eggs that have been genetically screened. Doctors will be able to point out which is potentially the best athlete or potentially the smartest. Farther into the future, scientists may be able to use gene therapy on embryos to enhance intelligence,

for example. Tilghman says that only the elite will be able to afford designer babies, and that this modern method of eugenics will lead to a further stratification of our society. Others argue that in a nation that values individual rights more than the common good, there’s no way to stop well-to-do couples from having designer babies. However, the issue could become entangled in abortion politics in the future. Tilghman noted that, in selecting some eggs, couples discard others; some people believe a fertilized egg is already a human soul.

To hasten the pace of development of genetic tests that can predict disease, ten major pharmaceutical companies have formed a consortium. They will work together to construct a map of the human genome that’s much more detailed than the one being developed by the Human Genome Project – and they’ll make their results available to all researchers. Ultimately, their work may make it possible for physicians to test patients genetically to find out which drug will do them the most good with the fewest side effects (Wade, April 1999).

As for gene therapy, so far it hasn’t worked. Tilghman explained that there are fundamental problems because the immune system evolved to resist exactly what gene therapy tries to do. For example, scientists have generally used viruses to deliver genes to the cells; the immune system fights them. In addition, said Tilghman, some genetic disorders occur because a gene is missing, along with the vital protein it generates. If scientists succeed in inserting the missing gene into a patient’s cells, and these added genes begin to make the missing protein, the patient’s immune system may form antibodies to that protein, treating it as a foreign organism. “We’re a long way from bedside gene therapy,” Tilghman said. However, she has no doubt that it’s only a

question of time.

Once gene therapy becomes available, will it escalate health care costs?

Tilghman said, "There's nothing inherently expensive about gene therapy as we currently conceive it." It may be costly at first, she said, until doctors learn to do it well, but there will also be savings. She pointed out that some genetic disorders are extremely expensive to treat. Curing them will save money. "I suspect those cost savings are going to massively outweigh the expense of gene therapy in its early phase," Tilghman said.

Xenotransplants: People who need a transplant may some day receive one from an animal that has been genetically engineered so that human immune systems will accept its organs. In a xenotransplant, an organ such as the pancreas is taken from an animal and implanted into a human being. The technique may lower medical costs, said Chollet, even as it saves lives. Currently, about 62,000 Americans are on waiting lists, hoping for a transplant; 4,000 will die before an organ donor is found (Stolberg, 1999). However, Secundy suggested that xenotransplants raise profound questions. How does this new technology affect our relationship with animals, she asked, and what we feel about the human experience? Who will get animal organs and who will be offered the scarce human sort? Articles in law reviews are already questioning how many human genes an animal must harbor before it has constitutional rights (Andrews, 1999).

Umbilical cord blood: The New Jersey legislature recently took steps to encourage a medical procedure that should

save lives and perhaps money in the future. New Jersey will provide a \$5 million loan so that the Coriell Institute for Medical

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-Shirley M. Tighman, Ph. D.

Research can freeze and store samples of umbilical cord blood in a public blood bank.¹⁰ Judy Donlen, executive director of the Southern New Jersey Perinatal Cooperative, explained that once the bank is in operation, pregnant

women will be asked to donate blood from their baby's umbilical cord, which would otherwise be discarded. Cord blood is rich in stem cells (Ludwin, 1997). These are special cells, found in many different organs and tissues, that make other cells; they're the body's repair system. The stem cells found in cord blood (and bone marrow) manufacture white and red blood cells and platelets.

Since 1990, more than 600 cord blood transplants have been done to treat disorders such as leukemia, lymphomas and life-threatening anemias. For cancer patients, cord blood can sometimes substitute for a bone marrow transplant. Stem cells from cord blood aren't as likely to be rejected by the recipient's immune system, so the genetic match between donor and recipient doesn't have to be as exact. A cord-blood transplant is also less costly (Ludwin, 1997).

Though some have suggested that umbilical cord blood be automatically collected and banked, Donlen explained that the cost is prohibitive. New Jersey's public bank, according to Donlen, is a compromise: its goal will be to collect enough specimens so that anyone can find a match if they need to. The stem cells in New Jersey's bank will also be used for research; it's possible that in

the future cord blood will become a vehicle for gene therapy (Stevens, 1997).

Embryonic Stem Cells (ES):

Whereas stem cells from cord blood can only manufacture blood cells, stem cells taken from an embryo can potentially generate any type of cell. Research on ES is controversial because these stem cells are derived from embryos discarded by fertility clinics or from aborted fetuses.¹¹ Yet scientists believe they may be able to use embryonic stem cells in a laboratory to grow new heart or liver tissue, for example – tissue that could repair a damaged organ (Wade, June 1999). Tilghman noted that scientists working on gene therapy are also interested in stem cell research.

CONCLUDING REMARKS AND POLICY IMPLICATIONS

Policymakers in the 21st century will face all of the challenges noted in this brief along with many others. Some of the issues that will come up may require them to look again at fundamental questions, such as our commitment to individual rights and choices and the extent to which we're willing to limit those choices in order to achieve the greatest good for the greatest number.

For all of the foreseeable future, health care policymakers will have to struggle to balance opposing needs:

- The need to provide access to health care for more people will conflict with the need to contain costs. A battle is shaping up already over pharmaceuticals, as some demand drug benefits for people in Medicare, Medicaid and private health plans, while others insist that we must stop spiraling drug costs.
- Policymakers concerned with health care providers will have to decide between regulation and letting the free market – supply and demand – handle problems like an overabundance of doctors and specialists. The push to reduce the physician surplus will also conflict with the push to open up opportunities to people of color. Right now African Americans, who represent 12.6 percent of the population, comprise 3 percent of physicians, and Hispanics, who are 10 percent of the population, comprise just 4.6 percent of doctors (Institute for the Future, 1998).
- In the next century, managed care will be caught between its promise to cut costs and the need to reassure plan members that they do have some control over their medical destiny. Legislators, when bombarded with consumer complaints, will have to balance cost containment against their mandate to protect their constituents. In addition, the pressure for evidence-based medicine will create tensions. To improve patient care, protocols will lay out treatment plans for doctors, based on the best medical practice (Institute for the Future, 1998). Yet this anticipated benefit of managed care must be balanced against the need to allow physicians to draw on their own experience and to innovate at times.
- In the future, hospitals will struggle to cut fat out of the system – overbedding, for example – even as they strive to ensure that, despite cost-cutting, they can still care for the indigent and train the physicians of the future. Meanwhile, for Medicare, the obvious challenge will be to cope with the care of aging baby boomers. However, in addition, as Medicare tries to enroll more and more

seniors in managed care, it will have to adjust its payments to reflect the risk health plans will take on when they enroll the sick and frail; otherwise, according to Ginsburg, insurers will be strongly motivated to seek out only the well.

- As medical advances occur, some will be controversial, generating conflict. Already, right-to-life organizations have geared up to try to prevent embryonic stem cell research. Some people would like to see human cloning banned, and lawmakers may also be asked to decide whether infertility clinics should be allowed to create designer babies. Animal rights activists will undoubtedly object to xenotransplants.

Beyond all these struggles, New Jersey policymakers who are leaders in the health care community will soon be called upon to take steps in another area.

- They will be asked to look at the goals of their public health agenda Healthy New Jersey 2000 – to determine the progress made in the 11 goal areas.
- They will then be asked to recommit the state – the health-care provider community and the citizenry – to finishing unfinished business and achieving new goals by 2010, through articulate leadership, vision, legislation and regulation.

Each of these issues comes with a distinct set of challenges and opportunities for local, state and national policymakers.

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ENDNOTES

¹ Dr. Reeds is the curator of an exhibit called “A State of Health: New Jersey’s Medical Heritage,” which is now touring the state. The historical information on New Jersey in this section came from an interview with Dr. Reeds and from the catalog for her exhibit (Reeds and Cowen, 1999).

² The story of the New Jersey radium poisonings has an epilogue. The tailings from the U.S. Radium Corporation, where the women worked, were removed and dumped in Montclair, said Reeds. The authorities are still trying to figure out how to get rid of this material.

³ The Center for Studying Health System Change is funded exclusively by the Robert Wood Johnson Foundation and is affiliated with Mathematica Policy Research Inc.

⁴ The physician surplus can be traced back to policies set in the 1960s, when the federal government, anticipating a doctor shortage, began to provide subsidies for educating doctors. Currently, federal agencies such as Medicare provide support for training to the tune of about \$70,000 per year for every hospital resident (Unger).

⁵ General internists, family physicians, and general pediatricians are considered to be primary care providers; some would add obstetrician-gynecologists to the list (Unger).

⁶ Of all New Jersey physicians, 45 percent graduated from a foreign medical school.

⁷ An independent practice association (IPA) contracts with health plans on behalf of doctors’ practices, which usually have some ownership in the association. Though the IPA negotiates for its members as if it were a group practice, the physicians it represents (groups and individuals) haven’t pooled their revenues; they continue to practice independently.

⁸ Seniors dropped by an HMO can return to traditional, fee-for-service Medicare or enroll in another managed-care plan if one is available in their area.

⁹ The Institute of Integrative Genomics will mount an interdisciplinary effort to study, not just single genes, but whole networks of genes as they work together. Many disorders are caused by mutations in more than one gene.

¹⁰ New Jersey already has several private banks for cord blood. They market their services directly to expectant parents, typically offering to bank their baby’s cord blood for a fee of \$1000 to \$1500 plus storage charges of \$90-\$100 per year. The blood is stored in case it’s needed someday by the baby or a relative who’s a close genetic match (Donlen).

¹¹ Congress has banned spending federal money for any research in which an embryo is destroyed (Wade, June 1999).