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Ban on Medical Experiments Without Consent Is Relaxed

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By GINA KOLATA

For the first time in a half century, new Federal regulations allow investigators to enroll patients in some medical research studies without their consent.

The Food and Drug Administration regulations, which took effect on Friday, apply only in carefully circumscribed situations. The patients must have a life-threatening condition, like a severe head injury, and must be unable to say whether they want to be part of a study. They would be selected only if it was not feasible to obtain consent from a relative.

Furthermore, the community in which the research is done must be notified about the study, and the research design must have been reviewed and approved by the Food and Drug Administration.

Even the most ardent supporters of the new regulations say they understand the seriousness of what they have done. They have repealed a principle that dates back to the Nuremberg trials of Nazi doctors after World War II, when American judges were agonizing over rules that might prevent doctors from ever again using human subjects in horrendous experiments. The judges wrote a code of ethics, the Nuremberg Code, whose first principle was that no one should ever be forced to take part in a medical experiment. "The voluntary consent of the human subject is essential," they wrote.

"It's a tremendous philosophical change," said Dr. Norman Fost, director of the Center for Clinical Ethics at the University of Wisconsin, who lobbied for the change.

Bonnie Lee, a senior policy analyst at the drug agency who wrote the new regulations, said, "This is not something we did lightly or easily."

But supporters of the regulations say patients will benefit. The requirement for informed consent, they say, was hobbling research that could save lives.

Dr. Fost said the regulations would liberate researchers to study treatments that were desperately needed. Until now, he said, "research was not moving forward." The harm would be greater if patients were kept out of such studies, he argued, than if they were entered without their explicit consent.

Others, however, are gravely

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concerned. "It's a fateful step," Jay Katz, an ethicist and lawyer at Yale University, said in a telephone interview from Germany, where he was at a conference marking the 50th anniversary of the Nuremberg doctors' trials. "The first sentence of the first principle of the Nuremberg Code," he said, stated that nothing should be done to human beings without their consent. And now, he said, "here we are making exceptions."

The new rules arose out of the frustration of some ethicists and medical researchers. The problem, said Dr. Fost, was that the previous rules were making it virtually impossible to study treatments that must be provided to patients who are gravely ill or injured, with heart attacks, strokes or head injuries, for example, for whom time is of the essence, and whose relatives cannot be found in time to give permission for experimental treatments.

At the same time, scientists were testing seemingly nontoxic drugs in animals that promised to save the lives of many of these patients.

"All of this technology was bubbling up three or four years ago," Dr. Fost said. And, he added, most patients would have wanted to be part of studies of experimental treatments for their injuries or illness if they could have spoken for themselves.

Dr. Fost said that if the choice for a patient with a severe head injury was to receive standard treatment, which is of little help, or to be part of a study testing a drug that seems to have virtually no side effects and that has saved the brains of animals, "it seems to me that a reasonable person would very much want to be in the study," Dr. Fost said.

"Consent," Dr. Fost said, "is a means to an end." The goal, he added, "is to do what the patient would want."

And so Dr. Michelle H. Biros, an emergency medicine expert at the Hennepin County Medical Center in Minneapolis, Dr. Fost and others met privately in Washington two years ago and developed a consensus statement on waiving informed consent in emergencies. Their statement was published in The Journal of the American Medical Association in April 1995 and the campaign to get the Federal regulations changed was begun.

Now the group has succeeded. "We didn't accept all of their recommendations, but they certainly were very useful," Ms. Lee said.

Some medical researchers, like Dr. Raj Narayan, chairman of the department of neurosurgery at Temple University School of Medicine in Philadelphia, are delighted. Dr. Narayan, who studies patients with severe head injuries, agreed with Dr. Fost that patients would want to receive promising experimental drugs.

"We do not really have any good drug that has been proven to be beneficial for patients with head injuries," Dr. Narayan said. And the mortality rates are high — 30 percent to 40 percent in the best medical centers, and as high as 50 percent for some types of injury. "If it were my child or my family member or myself that was the patient with a severe head injury, I would definitely want to be included in a study," Dr. Narayan said.

Of course, most experimental drugs, no matter how promising in animal studies, never get to market. They fail to help patients when they are tested in clinical trials. But, Dr.

Some see lives being saved, while others see a threat to the helpless.

Narayan said, he thinks most people would be willing to take a chance, given the alternatives.

Others are not so sure. George Annas, an ethicist and health lawyer at Boston University, said, "Most people would not want a doctor to flip a coin when they come into an emergency room." Instead, he said, "they would want their doctor to do what is best for them." And, he added, "that is what you lose in this — you lose the right to have your doctor treat you however he thinks best."

Mr. Annas dismissed the argument that the research provided an opportunity for patients. "For most people, research is not an opportunity," he said. "The average person wants treatment, not an opportunity to be researched on." And, he added, "the idea that people might be denied new treatments is silly." An experimental drug is experimental because no one can say if it is useful or if its risks exceed its benefits. "If we knew it would work, it would be a treatment," Mr. Annas said.

His concern, he said, is that investigators are "just trying to make research more efficient at the expense of human rights." The potential downside, he said, "is that doctors won't try to get consent of the family anymore — now there's zero reason to look for them."

Mr. Katz is particularly concerned because the regulations allow doctors to enroll unconscious patients in studies in which some subjects are given dummy medication. "The new regulations send a dangerous message to the research community," he said. That message, he explained, is that it is more important for research to proceed than it is for patients to have an opportunity to agree to be research subjects.

Dr. Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania, takes a middle ground. Although he understands the arguments of people like Dr. Narayan, he said, concerned doctors are not the only ones who want the research to go forward. Drug companies and the makers of medical devices have a financial stake in seeing that the research is done.

And, Dr. Caplan added, perhaps most important, the Food and Drug Administration has taken away a shining symbol of researchers' concern for the protection of research subjects. So, he asked, is the benefit worth the risk of engendering distrust, of alienating people who might see doctors and drug companies as the worst sort of opportunists, experimenting on comatose people without their explicit consent? "Without much fanfare, we've veered away from a five-decade tradition," Dr. Caplan said.

Dr. Fost said he understood such concerns. It is frightening to many to think about casting off a symbol like informed consent. But, Dr. Fost said, "I'd say, 'Give me enough time to sit down and talk to people and things that seem outrageous on the surface may not be so after a while.' " It is not as though the investigators have not included safeguards, he said. In fact, he added, "there are so many safeguards that some people think we've safeguarded it to death."

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History Lesson: With Dow Up, Incumbent Wins

By FLOYD NORRIS

As goes Wall Street, so goes the election.

And if that pattern holds true today, Bill Clinton will be re-elected President.

But there are patterns that indicate the next four years may not be as friendly for shareholders. And if that is the case, the election in 2000 may not look so good for the Democrats.

Over the last century, the performance of the stock market during a Presidential term has proved to be a good, although not perfect, forecaster of Presidential election results. If the stock market put on a good show during the four years, the President's party generally stayed in the White House. And if it did poorly, the outs got in.

Using the Dow Jones industrial average from Election Day to Election Day to measure Presidential terms, President Clinton's tenure shows a gain of 85.8 percent, with the Dow having climbed from 3,252.48 to 6,041.68.

That is the third best performance during a Presidential term in the last century, going back to 1896, when the Dow was first calculated. The three terms that were better or comparable — Franklin D. Roosevelt's first term, Calvin Coolidge's full term and Dwight D. Eisenhower's first term — were all followed by landslide elections in which the incumbent party got at least 84 percent of the electoral votes.

But such great performances may help to breed expectations that cannot be fulfilled. The five top Presidential terms before this one — in terms of stock market performance — all ended with the incumbent party keeping the White House. But in four of the five cases, the story was different four years later, as the incumbents were swept out of office.

The only exception came in 1940, when Franklin Roosevelt won a third term. And he had the advantage of memories of the market crash under Herbert C. Hoover, which tarred the Republican Party for a generation.

Over all, in the 24 Presidential elections from 1900 to 1992, the incumbent party has been thrown out just nine times. And there has been a strong link between weak stock market performance and a subsequent defeat for the incumbents.

In nine of those 24 terms, the Dow declined over the four years, or showed a a paltry four-year gain of less than 9 percent. And in six of those, the incumbent party lost. The only exceptions were in 1940, when a 23.5 percent drop in the Dow over the previous four years did not keep Franklin Roosevelt from gaining a third term; in 1972, when Richard M. Nixon handily won re-election despite a small 4.1 percent rise, and 1904, when the Dow rose just 8.8 percent over the previous four years but Theodore Roosevelt was still able to win the election for a full term to follow the partial one after William McKinley's assassination.

Of the 15 four-year terms where the Dow showed gains of 9 percent or better, only three have ended with the incumbent party being tossed out. Although he was widely hated on Wall Street, and the market plunged when he scored an upset victory in 1948, the Dow rose 42.4 percent from the time Harry S. Truman was elected until Dwight Eisenhower won the race to replace him four years later.

The Dow had climbed 20.6 percent in President Eisenhower's second term, but John F. Kennedy still won a narrow victory in 1960. And in the biggest upset of all, at least by the Dow indicator, a 52.9 percent gain for the Dow during George Bush's Administration did not stop him from losing to Bill Clinton four years ago.

One thing the 1960 and 1992 defeats had in common was that while the most recent terms had seen good gains in stock prices, they were not nearly as good as the gains in the prior term for the same party. But there is no Wall Street explanation for why the Democrats could not hold on to the White House in 1952.

Using the results of past Presidential terms, as measured by the Dow, to forecast future ones is an imperfect science, to say the least. But there are patterns. Looking at the five best Presidential terms before the current one — Ronald Reagan's second term and Woodrow Wilson's first, in addition to the three cited above — the Dow has declined in three of the five following terms. Considering that there were only six declines in the period, that's a fairly strong correlation.

And then there is the second-term Democrat phenomenon. There have been only two Democrats elected to second full terms in the last century, Presidents Wilson and Franklin Roosevelt. And the second Wilson and Roosevelt terms provided two of the three worst terms of the century, with losses of more than 20 percent. Only the 74.9 percent plunge in the Hoover Administration was worse.

Seeking a pattern from two occurrences is not good science. But it remains true that Wall Street has never enjoyed the second term of a Democrat. And unless the pollsters and pundits are about to suffer their worst humiliation since 1948, a Democratic President will be re-elected to a second term today.

But perhaps this is a new era. From 1896 through 1980, only once — in Truman's term and the first Eisenhower term — did the Dow manage back-to-back rises of more than 30 percent a term. Since 1980, it has managed four such gains in a row.

Donkeys, Elephants, Bulls, Bears

Change in the Dow Jones industrial average in each Presidential term of office.

TERM	PRESIDENT	CHANGE
1896-00	McKinley	+ 48.7%
1900-04	McKinley/ T. Roosevelt	+ 8.8
1904-08	T. Roosevelt	+ 25.2
1908-12	Taft	+ 8.9
1912-16	Wilson	+ 62.1
1916-20	Wilson	- 20.3
1920-24	Harding/ Coolidge	+ 21.5
1924-28	Coolidge	+147.9
1928-32	Hoover	- 74.9
1932-36	F. Roosevelt	+173.6%
1936-40	F. Roosevelt	- 23.5
1940-44	F. Roosevelt	+ 9.4
1944-48	F. Roosevelt/ Truman	+ 28.3
1948-52	Truman	+ 42.4
1952-56	Eisenhower	+ 83.3
1956-60	Eisenhower	+ 20.6
1960-64	Kennedy/ L. Johnson	+ 46.5
1964-68	L. Johnson	+ 8.1%
1968-72	Nixon	+ 4.1
1972-76	Nixon-Ford	- 1.9
1976-80	Carter	- 3.0
1980-84	Reagan	+ 32.8
1984-88	Reagan	+ 71.0
1988-92	Bush	+ 52.9
1992-96	Clinton	+ 85.8*

Measured from Election Day to Election Day. *Through yesterday.

Sources: Dow Jones & Company; Datastream