



Serving the Innovator and Entrepreneur in the Medical Device Industry

March 21, 2000

8 1 4 9 '00 MAR 22 P 4 :32

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

Subject: Docket No. 99N-4784 -- Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment upon the Food and Drug Administration's (FDA's) proposal to amend its premarket notification regulations to require applicants to submit a redacted version of each premarket notification submission (510(k)) for which the FDA has issued an order declaring a device to be substantially equivalent to a legally marketed predicate device.

MDMA recognizes that this proposed rule would allow the FDA to focus further its limited resources on the premarket review of medical devices. However, we do not believe that the FDA has the statutory authority to require 510(k) applicants to include a statement that would commit the applicant to provide a redacted version of the 510(k) within 30 days of the FDA's finding the device substantially equivalent.

According to section 513(i)(3) of the Federal Food, Drug and Cosmetic Act ("the Act") (21 U.S.C. 360c(i)(3)), as amended, "the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person." We recognize that the information which a 510(k) applicant must provide to requestors when it elects not to provide a summary of the 510(k) to the FDA is the same information that the FDA would require of the submitter under this proposed regulation, *i.e.*, a redacted 510(k). Nevertheless, the law does not require submissions of the redacted 510(k) to the FDA. Furthermore, the FDA's proposed rule would override the applicant's right under law to decide whether to submit a summary of the 510(k) to the FDA or to make information on the 510(k) available upon request.

The FDA's overstepping of the law in this proposed rule is compounded by the provision under which the FDA would consider failure to submit a redacted 510(k) to be a "prohibited act" under sections 301(p) and (q) of the Act (21 U.S.C. 331(p) and (q)). Since the proposed requirement to submit a redacted 510(k) is not authorized by the Act, MDMA fails to see how the FDA can propose that failure to adhere to the proposed requirement would subject the applicant to FDA enforcement action and possible civil penalties.

MDMA acknowledges the potential benefits of the proposed requirements to both applicants and the FDA. However, we do not believe the law gives the FDA the authority to mandate these requirements. MDMA recommends, therefore, that the FDA establish a process for the voluntary submission of redacted 510(k)s and work with industry organizations such as MDMA to educate potential applicants about the value of the process.

Very sincerely yours,

Stephen J. Northrup
Executive Director

99N-4784

C9

THE WHITE HOUSE ***BULLETIN***

BULLETIN NEWS NETWORK, 8260 GREENSBORO DRIVE, SUITE 320, MCLEAN, VA 22102 FAX 703-749-0060 TEL 703-749-0040

8 8 3 5 '00 JAN 18 A10 :33

MEMORANDUM FOR JANE E HENNEY
DEPARTMENT OF HEALTH AND HUMAN
ROCKVILLE MD

SUBJECT: TODAY'S BRIEFING

DATE: THURSDAY, JANUARY 13, 2000

OFF THE WIRES:

- **Details Emerge In Israeli-Syrian Peace Talks.** According to a document presented to Israeli and Syrian negotiators by President Clinton at the recent peace talks in West Virginia, Israeli negotiators demanded that Jewish settlers be allowed to stay in the Golan Heights after an Israeli troop withdrawal. However, Israel did not commit to a pullback from the entire plateau. The document also confirms that Syria has agreed to dual management of Golan's water sources and also accepted the creation of an early warning station in Golan to be operated by American and French forces. The document was meant to summarize positions in the peace talks, and was published today by the Haaretz Daily, an Israeli newspaper. The document also showed that both sides have agreed to full diplomatic relations, open border crossings, free trade and cooperation in the field of tourism. However, Israel did demand a timetable for each step. Israeli Prime Minister Ehud Barak's office today described the document as "a preliminary American document, which, as is stated in writing, has no binding force."

Meanwhile, according to White House deputy press secretary Jake Siewert, President Clinton and Syrian President Hafez Assad talked by telephone today on the status of Syrian-Israeli peace talks scheduled to resume next week in the US. Siewert said that Clinton and Assad talked about "the status, and how we can make progress when the next round commences."

- **Bhutto Lobbies US Delegation To Push For Pakistan's Return To Democracy.** Former Pakistani Prime Minister Benazir Bhutto wrote a letter today to the four US Senator delegation scheduled to arrive in Pakistan today, urging them to actively push for the return of democracy there. In her letter to Senate Minority Leader Tom Daschle, Bhutto asked for the US to commit to returning democracy to Pakistan and create a timetable, as well as calling on Pakistan to release political prisoners and make new conditions for fresh US financial aid to Pakistan. Bhutto said, "Such a message would clearly convey that in the 21st century, democracy, human rights and the rule of law are the values which are respected and upon which lie the dignity of nations in the global community." It was not clear whether or not the delegation would meet new military leader Gen. Pervez Musharraf, but US Embassy spokesman Mark Wentworth said they would press in meetings with Pakistani leadership a timetable for a return to democracy.
- **Wholesale Prices Surged in 1999.** The Labor Department reported today that wholesale prices increased by 3 percent in 1999, the biggest increase in nine years. However, outside of the energy and food categories, wholesale prices rose only 0.9 percent. The Producer Price Index rose 0.3 percent for the month of December, which was in line with most analysts' expectations.
- **Retail Sales Up 1.2% In December.** The Commerce Department reported today that retail sales for December were \$259.6 billion, an increase of 1.2 percent from the previous month and up 9.7 percent from December 1998. Total sales for the 12 months of 1999 were \$3.0 trillion, up 8.9 percent from the 1998 total.

IN THE WHITE HOUSE AND AROUND TOWN:

- **EPA Slams Koch Industries With \$30 Million Fine.** EPA Administrator Carol Browner called an early afternoon press conference to announce that the agency is levying a \$30 million civil penalty against Koch Industries, a major pipeline company. The penalty is for oil spills affecting navigable waterways in six states -- Texas, Oklahoma, Kansas, Louisiana, Missouri, and Alabama.
- **Clinton Proposes Doubling Investment Incentives In Poor Areas.** At the predominately Hispanic Boricua College in Brooklyn, New York today, President Clinton launched a small-business development center and proposed a plan to more than double a tax credit for businesses which invest in economically depressed areas. The plan is part of Clinton's "New Markets" initiative, which he first unveiled last year and toured poor communities in support for. Clinton said, "Over the past year, I've been to places that presidents don't normally go. I've been to Watts. I've been to inner city Newark; inner city Atlanta; the poorest housing projects in Chicago and East St. Louis; the barrios of south Phoenix and Hartford; rural and farming communities in my native state of Arkansas and Mississippi and Kentucky. I've been to the Pine Ridge Indian reservation in South Dakota where the unemployment rate is 73 percent. In every one of these places and here as well, I see potential, not hopelessness." Clinton added, "If we cannot fulfill our responsibility now to give every American a chance to live up to his or her God-given potential, when in the wide world will we ever get around to it? If we can't do it now, when will we ever do it?"

Clinton continued, "Every American should be supporting this, not only because it's morally right to give people who are poor and who don't have access to capital the chance to live their dream, but because it is in our self-interest as a nation if we want to keep this astonishing economic revival going. And more and more people are coming to understand that." Clinton added, "For every dollar in equity capital you invest in America's new markets, we will give another dollar in government-backed loans, affectively doubling the investment. Altogether, we think this program...will stimulate \$1.3 billion over five years in new investment to start up and expand businesses in areas that have been left behind in urban and rural America."

Treasury Secretary Lawrence Summers said today on CNN, "This is the time for these kinds of initiatives because for the first time in many, many years we have an economy where jobs are looking for people. That means we need to make sure that that supply [of capital] is there...in every part of the country." White House Economic Adviser Gene Sperling said, "This tax credit would now leverage \$15 billion of equity investment in lower income parts of America, both urban and rural."

- **House Budget Committee Begins To Outline Fraud, Waste And Abuse In The Budget.** With President Clinton and Vice President Gore rolling out a new spending initiative nearly every day, the task of writing a budget for the next fiscal year becomes increasingly complicated. Congressional Republicans are convinced that President Clinton, in the last year of his presidency, is putting together a highly political budget that will ignore the spending caps contained in the 1997 Balanced Budget Agreement. Congressional Republicans are considering their options to hold down spending, and one step in that process is to draw attention to the waste and fraud already occurring in the Federal budget.

With the President calling for a \$2 billion per year infusion into the Earned Income Tax Credit program, one of the findings in the House Budget Committee's forthcoming report on Waste, Fraud, Abuse and Mismanagement is an IRS finding that 68 percent of the EITC payouts in 1998 were invalid. The \$448 million in invalid EITC payments in 1998 were but a fraction of an estimated \$19.1 billion in improper payments estimated by the budget committee, drawing from GAO and inspector general reports. Since several agencies were unable to quantify their improper payments, the Budget Committee believes the amount of improper payments in 1998 substantially exceeds the \$19.1 billion figure.

In addition, the Budget Committee has determined that at least ten of the 14 programs designated in 1990 by the GAO to be at high risk for fraud and waste remain at high risk. Fifteen additional programs have been added to that list since 1993.

- o **Government May Buy Back \$25 Billion In National Debt.** According to an administration official, the Treasury Department has finished work on regulations, which would allow the buying back of a portion of the country's national debt. The official said that about \$25 billion could be bought back this year. Treasury Secretary Lawrence Summers is scheduled to publicly release the proposed rules later today. The debt buybacks would be the first since 1972.

- o **Arney To Propose New Direction For Health Care Reform.** House Majority Leader Dick Arney is scheduled to address the Health Coverage 2000 forum later this afternoon, where he will propose moving the debate on health care reform in a new direction that he characterizes as "Patient Power."

In his speech, Arney is expected to challenge President Clinton and Vice President Gore to provide tax breaks for the uninsured, saying, "Don't limit yourself to a tax break for employers only. Make sure uninsured individuals get something too. ... And Mr. President, don't limit yourself to a mere 25-percent subsidy, as your Vice President has proposed. Instead, give a 100-percent subsidy, up to a cap. After all, what good is it to offer a subsidy on one-fourth of a person's costs, if that person can't afford the three-fourths that isn't subsidized?"

Challenging the insurance industry, Arney is expected to call on them to "abandon gatekeepers and preauthorization review"; "step out of the way"; "leave doctors free to tend to their patients"; and "do it soon."

Saying Congress would send President Clinton a "patient-protection" bill "by Easter," Arney said it would include:

- Expanded and improved Medical Savings Accounts.
- Flexible spending account rollovers.
- Group-pooling options like health-marts and association plans.
- A new tax deduction for people who pay at least 50 percent of their own health insurance premiums.

Summing up the tenets of "Patient Power," Arney will say it includes four rights for all Americans: the right to choose doctors and hospitals; the right to choose insurance; the right to choose health benefits; and the right to direct the course of health care treatments.

Meanwhile, industry sources are enthusiastic at seeing the different players who are attending the forum, many of which have been at odds for years on the health care debate, working toward common goals. Key among them is a tax-credit based reform package sponsored by the Health Insurance Association of America, which appears to have won the backing of Families USA. Industry sources are also pleased to see a renewed emphasis on helping the uninsured, even as Congress devotes most of its attention, as one source put it, with "perfecting" coverage for people who already have it.

- o **Reno Again Says Cuban Boy Must Be Returned To Father.** Attorney General Janet Reno today reiterated her opinion that six-year old Elian Gonzalez should be returned to Cuban as quickly as possible in line with the recent Immigration and Naturalization Services' decision. Reno again stated that the Florida state court had no jurisdiction in an immigration matter and thus was null and void. Reno said, "We are just trying to make sure that people understand that what is at issue is a father who wants his son home, and grandparents who want their grandson home. And these are bonds that should be honored." Reno added, "I think it is so important that people of good will come together, work through the processes of the law as soon as possible, and get the boy home to his father." Reno continued, "I think his father should be able to speak for him, and I think he should be with his father. His father might be half way around the world. His father might be in Miami. His father might be in Cuba. But the father has expressed a wish that the child be with him and for the process to return him. And I think that's what the decision should be."

When asked what kind of enforceable action to Federal Government could take to return Gonzalez, Reno replied, "What we're trying to do is to make sure that the process is clear, that the law is followed, and we will work with everyone to see that that happens." She added, "What should be done here with a little 6-year-old boy is that people let the law take its course and then appropriately

work together to see that what the law determines is right is done." When asked about the possibility of sending Federal Marshals to get the boy, Reno said, "As we have talked about the political process, I would also urge the wonderful media to stop doing what-ifs and stop setting up dramatic confrontations, and let's not say that there is confrontation that will resolve it. Let's say that the court process should take its course and let's see what happens. ... Don't go in and pick up little boys like that." When asked if the Justice Department "plans to go into Federal court this week to deal with this issue," Reno replied, "We're looking at all our options."

- o **NFIB Calls For Repeal Of Installment Tax Provision.** The National Federation of Independent Business (NFIB) announced this morning its intention to push for the repeal of an installment tax provision enacted into law at the end of last year's congressional session, which it called "extremely detrimental."

The provision in question was included in the Conference Report of HR 1180, the Ticket to Work Incentives Improvement Act of 1999. Under it, the NFIB said in a statement that "many small-business owners who sell their businesses will now have to immediately pay in one lump sum all capital gain taxes resulting from the sale, even if the sale's payments are spread out in installments over a period of several years." NFIB further claimed that an "unintended consequence" of the provision "has been to adversely affect the sale of closely held businesses," which in most cases "use the installment method."

- o **Clinton To Propose Tax Credit For Electronic Filing Of Taxes.** According to Treasury Secretary Lawrence Summers, President Clinton will ask Congress this year to create a tax credit of up to \$10 for people who file Federal income taxes electronically. The new credit will be included in Clinton's fiscal 2001 budget request to Congress next month. It will be a \$10 refundable tax credit for taxpayers filing online and a \$5 credit for people who file over the telephone using the IRS' Telefile. Summers said the credit "will provide an incentive for filing on line and reward individual taxpayers while simultaneously helping the IRS become more efficient."
- o **Study Shows Income Gap Grew In Most States During The 1990s.** The Economic Policy Institute and the Center for Budget and Policy Priorities, today held a press conference to release an analysis of income disparities in the states. According to the study, despite strong economic growth and tight labor markets, income disparities in most states are significantly greater in the late 1990s than in the 1980s. In two-thirds of the states, the study says, the gap in incomes between the top 20 percent of families and the bottom 20 percent of families grew between the late 1980s and the late 1990s. In three-fourths of the states, income gaps between the top fifth and middle fifth of families grew over the last decade. Other report findings include:
 - For the US as a whole in the late 1990s, the income of families in the top 20 percent of income distribution was \$137,5000, or more than ten times as large as the poorest 20 percent of families.
 - From the late 1970s to the late 1990s, in every state but three, the incomes of families in the top 20 percent have grown, with the average growth exceeding \$34,000 (in 1997 dollars) after adjustment for inflation. In 31 states, the incomes of the upper fifth of families jumped by more than 30 percent over the last two decades.
 - Incomes in the poorest fifth of families declined in 18 states between the late 1970s and the late 1990s.
- o **NARAL Report Says Texas Tops List Of Anti-Abortion States.** The National Abortion Rights Action League today released an annual report, "Who Decides, A State-by-State Review of Abortion and Reproductive Rights," which documents state actions to limit the availability of abortion. According to a release describing the report, Texas and Michigan enacted more anti-choice measures "than any state in any single year since NARAL began tracking these measures in 1991." Said NARAL president Kate Michelman: "Bush uses the slogan 'compassionate conservative' to describe himself, but it hardly describes the record he has compiled as Governor when it comes to reproductive choice. Most of the new restrictions he signed into law in 1999 target young women in crisis, restricting their access to reproductive health services, including family planning, abortion, and reproductive health counseling

services. As NARAL's report illustrates, America is at a crossroads. As we enter the new millennium, we must decide as individuals and as a nation which road to choose. Down one road lies an anti-choice President, an anti-choice Court, and the end of legal abortion. Down the other lies an America in which women are entrusted with the freedom and knowledge to make informed choices about their reproductive options."

- o **League Of Conservation Voters Says Bush Has Worst Environmental Record.** The League of Conservation Voters (LCV) this morning released its 2000 Presidential Profiles on the environment, finding Gov. George W. Bush's record on environmental issues to be the weakest among the major party candidates. Said League president Deb Callahan: "George W. Bush's tenure as governor of Texas is marked by weak state environmental regulations, neglect of Texas state parks, worsening air quality and a general governing philosophy that, if applied nationally, would jeopardize three decades of national environmental progress." Callahan praised Sen. John McCain for embracing conservation in recent comments, but also noted his 20 percent career legislative rating with the League. The group said both Vice President Al Gore and former Sen. Bill Bradley have strong environmental records.
- o **Project Vote Smart Releases Report, Complains Of Low Candidate Participation.** Project Vote Smart released its presidential voter guide today, while decrying the response rate of the latest crop of candidates as the worst ever. Peggy Lampl, a board member of the group, said at a press conference, "The 2000 election crop of front-runners is the worst in Project Vote Smart's history, at least in terms of answering the candidate questionnaire. Only four out of the nine press-designated frontrunners chose to answer the survey and give the public an idea of their intentions, if they are going to be elected president." Among the candidates declining to respond to the group's questionnaire were Vice President Al Gore, former Sen. Bill Bradley, and Gov. George W. Bush. Alan Keyes submitted his answers after the deadline, according to the group.
- o **Bush Praises His Father.** As former President George Bush was campaigning on his son's behalf in Iowa, Gov. George W. Bush was asked by a group of workers at a campaign stop how he would compare himself with his father. First Bush joked, "Well, I got half my mother in me." He then added, "I think he was a great president because first and foremost, he was a great dad. We'll let historians judge, if I become the president. ... It's a fair question, but I would give you such an unfair answer because I am so subjective. He's an extraordinary man and I know people may disagree with my politics and stuff, but you can never disagree on the fact that he set the right priorities: his faith, his family and his country."

POLL WATCH:

Bradley, McCain Lead In New NH Poll; But Voters Think Gore, Bush Will Win Nominations. A Quinnipiac College poll of 1,297 registered New Hampshire voters conducted Jan. 7-11 (+/-2.7%) showed: **Democratic Primary (416 Democratic Primary Voters; +/- 4.8%)**

- 47% said they would vote for Bill Bradley; 37% would vote for Al Gore.
- 64% think Gore will win the Democratic nomination; 18% said Bradley would win it.

GOP Primary (567 Republican Primary Voters; +/-4.1%)

- 37% said they would vote for Sen. John McCain; 28% would vote for George W. Bush.
- 65% think Bush will win the Republican nomination; 11% said McCain would win it.

Gore, Bush Maintain Wide Leads In Iowa. A Research 2000 Iowa poll of 610 likely caucus goers, conducted for KCCI television of Des Moines and KIMT television of Mason City over January 8-11 (+/- 4%), shows:

GOP Caucus. (309 likely GOP caucus goers, +/- 6%)

- 46% (44% of men, 47% of women) would vote for George W. Bush; 20% (21% of men, 19% of women) would vote for Steve Forbes; 8% (12% of men, 5% of women) would vote for John McCain;

7% (8% of men, 6% of women) would vote for Gary Bauer; 7% (8% of men, 6% of women) would vote for Alan Keyes; 1% would vote for Orrin Hatch; 11% (6% of men, 16% of women) were undecided.

Democratic Caucus. (301 likely Democratic caucus goers, +/- 6%)

- 52% (49% of men, 55% of women) would vote for Al Gore; 34% (38% of men, 30% of women) would vote for Bill Bradley; 14% (13% of men, 15% of women) were undecided.

General Election Matchups.

- 51% (55% of men, 47% of women) would vote for George W. Bush; 43% (39% of men, 47% of women) would vote for Al Gore; 6% were undecided.
- 50% (53% of men, 47% of women) would vote for Bush; 41% (39% of men, 43% of women) would vote for Bill Bradley; 9% (8% of men, 10% of women) were undecided.

Bush Leads In Second Iowa Poll. An Iowa Project 2000 poll, conducted by PSI on January 10 (+/- 5.61%) for Capital Communications shows”

- 46.3% would vote for George W. Bush; 17.3% would vote for Steve Forbes; 9.7% would vote for John McCain; 7% would vote for Gary Bauer; 6% would vote for Alan Keyes; 1.7% would vote for Orrin Hatch; 12% were undecided.

Health Association Iowa Poll Shows Little Support For HMO Reform, Big Leads For Bush, Gore. An Ayres, McHenry & Associates survey for the American Association of Health Plans of 300 likely Iowa Republican presidential caucus voters (+/-5.77%) and 318 likely Democratic caucus voters (+/-5.61%) conducted January 9-10 shows:

Republican Caucus.

- 46% would vote for George W. Bush; 24% would vote for Steve Forbes; 7% would vote for John McCain; 6% would vote for Alan Keyes; 5% would vote for Gary Bauer; 2% would vote for Orrin Hatch; 10% were undecided.

Democratic Caucus.

- 48% would vote for Al Gore; 33% would vote for Bill Bradley; 19% were undecided.

Issues.

- “In response to an open-ended question asking the most important issue in determining their votes in the presidential caucuses, no Republican caucus-goers and only 1 percent of Democratic caucus-goers name HMO reform. Among the Republicans, taxes ranks first with 22 percent, followed by morality/traditional values with 17 percent, and candidate character and abortion with 5 percent each. No other issue receives at least five percent of mentions.”
- “Among the Democrats, elementary/secondary education ranks first with 14 percent, followed by health care with 13 percent, Social Security with 6 percent, and taxes with 5 percent. No other issue receives at least five percent of mentions. The 13 percent for health care includes 5 percent who say health care in general, 5 percent who say funding Medicare, and 1 percent each who say health care costs, including prescription drugs in Medicare, and reforming HMOs.”
- “When asked to choose among several specific issues that will have the greatest effect on their presidential caucus votes, only 2 percent of Republican caucus-goers and 3 percent of Democratic caucus-goers choose HMO reform. Thirty-two percent of the Republicans choose taxes, 18 percent choose education, 15 percent choose national defense, 12 percent choose health care, and 11 percent choose the economy with no other issue reaching double-digits.”
- “The 12 percent of Republican caucus-goers who choose health care includes 2 percent each who say health care costs, funding Medicare, including prescription drugs in Medicare, covering the uninsured, HMO reform, and some other aspect of health care.”
- “Thirty-one percent of the Democrats choose some aspect of health care as the most important effect on their vote, followed by 29 percent who choose education, 16 percent for the economy, and 7 percent for the environment. No other issue surpasses 5 percent.”
- “The 31 percent for health care includes 8 percent who choose covering the uninsured, 7 percent who choose funding Medicare, 6 percent who choose including prescription drugs in Medicare, 3 percent

who choose health care costs, 3 percent who choose HMO reform, and 4 percent who choose some other aspect of health care.”

LAST LAUGHS:

Late Night Political Humor.

Jay Leno: “Whoa, did you see the Republican candidates? Oh, man, it looked like a bad robot show at Chuckee Cheese.”

Jay Leno: “The other night they did a report on the Republican candidates. And they asked them each what their first jobs were. It was interesting. I guess, George W. Bush, his first job, runner at a law firm. That's what he did. John McCain, his first job, newspaper delivery boy. He delivered papers. And if Steve Forbes gets elected, his first job will be President of the US.”

Jay Leno: “In an effort to appeal to voters, Donald Trump has lost 35 pounds -- his girlfriend.”

Jay Leno: “President Clinton, pretty excited about moving to the suburbs of New York. He told reporters today he had never done it with a soccer mom before.”

Conan O'Brien: “Apparently, this is not good news for her, but in the paper, Hillary Clinton is slipping in the polls. Have you heard about that? She's not doing so well in the polls. Apparently, one of the reasons is that she's not connecting with female voters. That's what they're saying. True story. Yeah. Right. Hillary said, 'You know, it's hard to connect with women when you've called them at 3:00 AM and told them to stay the hell away from your husband.’”

Conan O'Brien: “Presidential candidates George W. Bush and John McCain did something pretty interesting. They shook hands, and they agreed not to take part in any negative advertising. Isn't that cool? I thought that was neat. Yeah. I think, though, they've gotten a little carried away, because George W.'s newest ad says John McCain is a patriotic American and a great kisser.”

Conan O'Brien: “Five of the nine candidates for president had their first jobs in media related fields. That was interesting. They all worked in media, I guess. It's true. Steve Forbes worked in a magazine's mailroom. Bill Bradley was a paperboy. And Al Gore worked as a radio antenna.”

David Letterman: “First Lady Hillary Clinton is on the program tonight, ladies and gentlemen. I'm a little nervous. This, of course, means just about this time tomorrow: I'll be getting my ass audited.”

David Letterman: “I've been thinking about this long and hard. I came up with one question, and this is what it will be: 'Is the government controlling the weather?’”

Craig Kilborn: “Bidding is now under way at Sotheby's for one of the 25 original copies of the Declaration of Independence. Some experts are questioning the authenticity of this particular document, which begins, 'We, the peeps, in order to keep it real.’”

Copyright 1999 by the Bulletin News Network, Inc. Reproduction without permission prohibited. The White House Bulletin -- written by an editorial staff of former White House and congressional officials relying on inside sources and wire service reports -- is published 50 weeks a year on business days by the Bulletin News Network, McLean, VA. For subscription information, please contact our Circulation Department at (703) 749-0040. You can find us on the Internet at www.bulletinnews.com.



Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

1900 K STREET, N.W. / SUITE 100 / WASHINGTON, D.C. 20006