

September 25, 1996

Note to White House Press Office

From: Jim O'Hara, FDA Public Affairs

The House Commerce Committee's Subcommittee on Oversight and Investigations is holding hearing tomorrow (Thursday, 9/26) on FDA's regulation of in vitro diagnostics, that is, tests to determine whether a person has a disease or what levels of illegal drugs are in a person's body. The subcommittee will focus in particular on home test kits to determine if a person uses drugs. Republicans have charged in a press release issued Saturday that FDA is keeping home test kits off the market and that the agency is basing its decision on a fear that these kits will cause "family discord."

Talking Points

- o FDA does not have a policy against home test kits. The law requires that home test kits -- or any diagnostic -- be safe and effective and adequately labeled for its intended use. In the case of home test kits, the FDA wants a company to show that samples can be collected and maintained without contamination, that reliable and accurate results can be obtained in the analysis, and that there is a way to ensure that the results are interpreted correctly. FDA has approved a home test kit for HIV, the virus that causes AIDS, and home test kits for the early detection of pregnancy, to measure cholesterol and glucose levels, etc.
- o FDA is prepared to accept and review appropriate applications for home test kits for drugs of abuse, using the same criteria as for these other products.

Questions about specific products that the Republicans are using as examples should be referred to FDA's Office of Public Affairs: 301-443-1130.

Sen. Thompson Rejects Bid to Cut Inquiry Budget

By Helen Dewar
Washington Post Staff Writer

Senate Governmental Affairs Committee Chairman Fred D. Thompson (R-Tenn.) yesterday rejected Democratic calls for a compromise over funding for the panel's investigation of campaign financing abuses, saying his proposed budget of \$6.5 million is needed to assure a thorough inquiry into issues raised by Democrats as well as Republicans.

"I stand behind that budget. I will not relent," Thompson told the Senate Rules and Administration Committee, which has jurisdiction over committee spending, including special investigatory budgets.

In what appeared to be a hardening of the partisan impasse over funding for the investigation, Democrats continued to object to Thompson's proposal, saying \$1.8 million—the sum spent on last year's Whitewater inquiry—would be sufficient, at least as a first installment.

Nerves were further frayed when Thompson appeared to suggest Democrats were trying to "hamstring" the investigation. "The entire focus should not be—if we're really concerned about the integrity of our government—on figuring out every way of hamstringing our going forward," he said. Sen. John Glenn (Ohio), ranking committee Democrat, bristled and said he was not trying to "hamstring" anything, and Thompson said he was not talking about any Democrats on the committee.

Asked later if he was referring to Minority Leader Thomas A. Daschle (D-S.D.), who earlier said Democrats might filibuster if Republicans continue to insist on the \$6.5 million figure, Thompson declined to comment. Republicans are five seats short of the 60 needed to break a filibuster.

Faced with requests for extra funding for other investigations from as many as seven committees, the rules panel had hoped to concentrate yesterday on the committees' regular budgets. But Glenn said he could not agree to his committee's total funding request until the investigation funding was resolved, triggering a renewal of hostilities that lasted for two hours.

Glenn said \$6.5 million was "excessive" and "unjustified" and exceeds even the initial request for the Watergate investigation. He said the committee could allocate a smaller amount and approve more later if needed.

Thompson countered that Democrats want to cut funding for the inquiry after insisting its scope be broadened to assure it includes GOP fund-raising practices as well as questionable Democratic efforts on behalf of President Clinton's reelection. There's an old Tennessee saying, Thompson said: "If you're not willing to pay the freight, don't load the wagon."

Regulation Of Home Drug Tests Planned

FDA Would Certify Accuracy of Method

By Donna Abu-Nasr
Associated Press

In a bid to defuse a fight with Congress, the Food and Drug Administration proposed yesterday that home drug tests be regulated, albeit loosely, to ensure they give accurate results.

Congressional critics, many of whom challenge the FDA's right to involve itself in the kits, said the agency's decision to make numerous home urine test kits available is a step in the right direction. But they voiced misgivings that regulation may imperil marketing of other tests that examine hair for signs of drugs.

"It's a victory, of sorts," said Rep. Thomas J. Bliley Jr. (R-Va.), chairman of the House Commerce Committee. "The bad news is that [the FDA] felt compelled to stick their noses into this in the first place."

The FDA has made "a small concession to common sense," Rep. Joe Barton (R-Tex.) said as he opened a hearing of his commerce subcommittee on the subject. But, Barton said, "it now threatens to block over-the-counter access to hair testing systems."

At issue are kits that let consumers collect and mail samples of urine or hair to drug-testing laboratories. The kits are designed to allow parents to determine privately whether children are using illegal drugs.

Last fall, congressional critics attacked the FDA for cracking down on Sunny Cloud, an Atlanta housewife, for selling such kits without the agency's approval. Critics said the FDA, despite escalating teenage drug use, was keeping from parents kits that employers use to detect drugs.

The FDA argued that it did not know if Cloud's kit gave accurate readings, but it agreed to temporarily allow sale of such kits as it reevaluated the level of regulation they will require.

"The FDA does support the marketing of these test systems, provided they are accurate and reliable," deputy food and drug commissioner William Schulz said in outlining the proposal at the hearing.

After the agency completes work on the plan, it will be submitted for public comment before becoming an FDA regulation.

Under the proposal, most home kits could be sold without FDA permission as long as samples are mailed to laboratories where tests are done by a method the FDA has certified is accurate at detecting drugs, Schulz said.

Also, the kits must contain proper consumer instructions and, because no test is perfect, must disclose the chances of a false result.

The FDA has approved 200 urine tests, and most laboratories use one of them, so Cloud's home kit probably is permissible, Schulz said.

No laboratory drug test for hair has been approved, however. So unless the FDA approves such a test before the proposed regulation becomes final—probably in two years—kits that collect hair samples would have to go off the market pending formal FDA approval, Schulz said.

Slater Confirmed For Cabinet Post

Associated Press

Federal Highway Administrator Rodney E. Slater won Senate confirmation as secretary of transportation yesterday. The vote was 98 to 0.

Slater worked as executive assistant to Bill Clinton in 1983-87, when Clinton was governor of Arkansas. From 1987 to 1993, Slater was a member, and then chairman, of the Arkansas State Highway Commission. Clinton brought him to Washington as federal highway administrator in 1993.

A graduate of Eastern Michigan University and the University of Arkansas School of Law, Slater succeeds Federico Peña, Clinton's choice to be energy secretary.

The Washington Post

FRIDAY, FEBRUARY 7, 1997



A Slight Increase for Operations

Funding for Treasury operations would increase slightly under the Clinton budget. None of its programs would be eliminated or significantly cut. Clinton asks for \$11.7 billion in outlays for Treasury operations in 1998, up from \$10.7 billion in 1997. The budget proposes no cutbacks at the Internal Revenue Service, the agency that employs the vast majority of Treasury's work force. Clinton would increase spending for many of the department's law enforcement bureaus, including the Customs Service, the Bureau of Alcohol, Tobacco and Firearms and the Federal Law Enforcement Training Center.

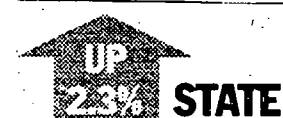
—Clay Chandler



Abandoning Ambitious Plans

This department's \$38.6 billion budget envisions a gradual scaling back in spending for highways, transit, airports and rail passenger service. Spending for air traffic control and the Coast Guard would rise gradually. The proposed budget total is almost the same as last year and generally abandons the ambitious plan to increase infrastructure spending, particularly for highways and transit. Safety spending would rise 7.5 percent to \$2.9 billion, including a hefty increase for the National Highway Traffic Safety Administration. And a new \$100 million program would help welfare recipients get to jobs and training.

—Don Phillips



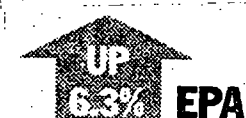
Reversing a Spending Slide

The decade-long slide in spending on international affairs and foreign aid would come to an end, reflecting the belief at the White House and the State Department that the United States cannot meet the commitments of global leadership if resources for diplomacy continue to dwindle.

The budget allocates \$19.45 billion to State Department operations, foreign aid, peacekeeping and international lending institutions. That is \$1.22 billion, or 6.7 percent, more than Congress appropriated this year. Spending for State's operations, i.e. running the department and embassies, would rise \$2.58 billion, up 2.3 percent. In addition to State, the Peace Corps, the U.S. Information Agency and the Arms Control and Disarmament Agency would receive modest budget increases. More than \$500 million would go to a new "Partnership for Freedom" to promote trade and fight crime in the former Soviet Union.

The proposed spending level does not include \$921 million that the administration plans to seek in a supplemental appropriation to pay this country's arrears to the United Nations.

—Thomas W. Lippman



Expedited Assault on Polluted Sites

Spending at the Environmental Protection Agency would increase by 6.3 percent, from \$6.3 billion in 1997 outlays to \$6.7 billion for fiscal 1998. The EPA budget would provide additional funds for a sped-up assault on contaminated sites that have languished for years.

The department's budget authority—the amount of money the government is authorized to commit over five years—would increase even more: by 12 percent with much of the increase going straight to the dump—specifically, to the more than 500 Superfund sites it hopes to clean up by the year 2000. EPA has earmarked \$1.5 billion out of its \$7.6 billion in authorized spending toward that. EPA Administrator Carol M. Browner says the cleanup will revitalize communities and fulfill a Clinton campaign promise to hit the 500 sites goal.

Browner's budget also includes a \$50 million increase to rehabilitate "brown fields," former industrial sites not polluted enough to make the Superfund list. Other highlights include \$36 million to implement the Food Safety and Safe Drinking Water acts approved by Congress last year, and an additional \$35 million to expand right-to-know laws that inform local communities about toxic pollution in their neighborhoods.

—Joby Warrick



Beefing Up Meat Inspection

The Clinton administration's \$58.7 billion budget for the Department of Agriculture, up from \$56.9 billion, requires the U.S. meat industry to pay 70 percent of the costs of a new inspection system for meat, poultry and eggs that took effect Jan. 27.

The government would collect \$390 million from the industry in fiscal 1998 to pay the salaries and benefits of inspectors. The change will add less than a penny a pound to meat and poultry prices, USDA estimates.

The administration asked for a \$1 billion increase for food stamps, contingent on Congress agreeing to modify the food stamp cuts in last year's welfare reform legislation.

The administration proposes increasing funding of the main food program for poor women, infants and children by \$137 million. Humanitarian Public Law 480 food donations abroad would stay unchanged, despite cuts in the broader program.

Increased funding is proposed for the conservation reserve program as well as for the wetlands reserve. Both have strong backing from environmentalists.

—Dan Morgan



A Gamble for Health Care

To increase funding for the nation's 171 veterans hospitals, the Clinton administration is taking a major gamble. It is asking Congress to allow the Department of Veterans Affairs to keep all the money it raises by billing insurance companies for veterans health care.

If the proposal—and a similar plan to require Medicare to reimburse the VA for veterans health care—is approved, the VA can avoid the impact of a budget that projects no increased appropriations for veterans health care through the year 2002. Without it, the department is almost certain to begin closing hospitals—or downgrading some to outpatient facilities. The VA health care budget runs about \$17 billion.

"VA health care is at the crossroads," said VA Secretary Jesse Brown, adding in a statement that he was "extremely enthusiastic" about his proposed budget. Officials said Brown, who last year had dismissed the administration's budget projections for his department as flawed, would be able to support the new budget.

The VA budget calls for total outlays of about \$40 billion, up only slightly from 1997. It would require the VA, which is losing about 10,000 workers this year, to lose another 5,000 next year.

—Bill McAllister

CHARGE

The Clinton Administration's FDA has pursued a social policy that prevents parents from testing their children for illegal drugs. Keeping home drug tests out of the hands of parents is just another liberal, big government idea that bureaucrats know better than parents how to raise children. This is why we are losing the war against drugs.

THE COUNTER

We want our parents to have all the tools they need to fight drugs -- and that means tests that can reliably and accurately tell them if their children have a drug problem. The FDA does not have a policy that prevents it from approving an over-the-counter (OTC) drug test kit that parents could use. The FDA is prepared to approve an OTC drug test kit if it is safe and effective and is adequately labeled for its intended use. This is the policy that has been in place since the mid-1980s. In 1985 there was a public advisory committee meeting that dealt with this issue and in 1988 the Agency published a guidance document for industry setting forth these criteria. At the same time, the Agency is reviewing its policy and will hold a public advisory committee meeting on this issue. In the mean time, FDA will exercise its enforcement discretion and will not take action against any home test collection system that meets certain criteria.

CHARGE

The Clinton Administration blocked Congress' efforts to reform the FDA this year. Because of that failure, FDA will continue to be a roadblock to the speedy approval of important new drugs and medical devices that could save patients' lives. Today, it takes 15 years for a new drug to be marketed in the United States because of the FDA bureaucracy.

THE COUNTER

First, let's deal in the facts: FDA is a world leader in the speedy approval of new drugs. Congress' own General Accounting Office found that the U.S. was faster than the United Kingdom, and an industry group found FDA was as fast as its United Kingdom counterpart and faster than those in France, Spain, Germany and Japan. All the important new drugs for AIDS were approved first in the United States and I announced an initiative in March to do the same thing for cancer drugs. In fact, the Clinton Administration through the Vice President's National Performance Review has been leading the reinvention of the FDA. More than 30 reinvention initiatives have been proposed and are being implemented. These initiatives reduce red tape without sacrificing important public health protections. We worked hard with members of Congress on FDA legislation, but time ran out.

THE WHITE HOUSE

WASHINGTON

October 3, 1996

David A. Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

I am writing regarding the Food and Drug Administration's (FDA's) policy on home drug test kits. I understand that FDA's approach to reviewing and approving home testing kits, including those for illegal drugs, was developed during the administrations of Presidents Reagan and Bush. The President is pleased that you intend to re-evaluate this policy as it applies to home tests for illegal substances.

As you know, The President is committed to ensuring parents have the tools they need to prevent their children from using illegal substances. He has supported drug testing of high school athletes and has fought Congress's efforts to cut funds for the Safe and Drug-Free Schools Act. This administration has encouraged states to adopt a "zero tolerance" standard for drivers under the age of 21 who drive while intoxicated. You and the President have worked together to end children's tobacco use.

The President believes parents should also have access to safe and effective home drug test kits. Of course, neither he nor I state a view as to whether the FDA should approve any particular home drug testing product as safe and effective. The President believes, however, that safe and reliable tests should be available to parents, and parents should be able to use such tests if they choose.

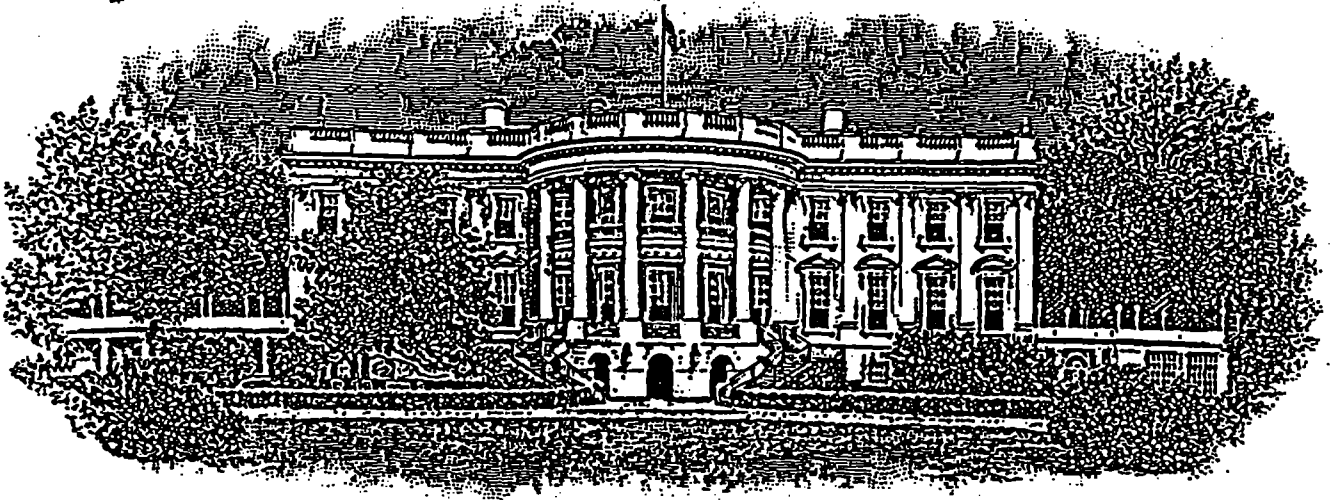
As parents seek to raise their children drug-free, it is important to make all potentially useful tools available to them. The President would want you to keep this in mind as FDA reviews its criteria for evaluating home drug test kits.

Sincerely,



Carol H. Rasco
Assistant to the President
for Domestic Policy

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Bul Corr

FAX NUMBER: 401-5783

TELEPHONE NUMBER: _____

FROM: Elizabeth Dwyer

TELEPHONE NUMBER: 6-5573

PAGES (INCLUDING COVER): _____

COMMENTS: FYI - Rasco for and

Qard A on drug test hits

October 4, 1996

Note to HHS, White House press offices

From: Jim O'Hara, FDA public affairs *JOH*

House Commerce Committee chairman Thomas Bliley (R-VA) wrote the President, Secretary Shalala and Dr. Kessler last Friday over the issue of home drug test kits. As agreed to by Committee staff and HHS legislative staff on Monday, the White House, the Secretary and the Commissioner responded to that letter yesterday.

- o The White House letter signed by OMB general counsel stated that FDA's draft testimony on home drug test kits received normal review under procedures dating back to the Administration of Franklin Roosevelt and that the review did not constitute any White House involvement in the formulation of policy.
- o The Department's letter stated that the draft testimony received normal review and again that the review did not constitute formulation of policy or approval of policy. It also noted that the Agency had committed during the September 26 hearing to re-evaluate its policy and thought that was appropriate.
- o The Agency's letter confirmed:
 - Agency officials' statements last week to members of the Commerce Committee that Ms. Sunny Cloud will not be subject to any regulatory action for the marketing of her kit in the past or while the policy is under review. Once a final policy is in place, Ms. Cloud would be expected to comply with it.
 - That while the Agency is reviewing its policy, the Agency intends to exercise its enforcement discretion and not take any regulatory action against any home test collection system that meets specified criteria. Any company doing so would likewise be expected to comply with a final policy. This exercise of enforcement discretion is not a reversal of policy; the policy is being re-evaluated.
 - The Agency will re-evaluate its policy with regard to these products expeditiously.
 - Agency decisions on how to regulate home test collection systems for drugs of abuse date back to the mid-1980s. Public discussions of how the Agency treats these products include a public advisory committee in 1985, a Federal Register notice of the availability of guidance to industry in 1988 and the Congressional testimony of then FDA Commissioner Frank Young in 1989. There is no Agency prohibition against the approval of these products.

THE WHITE HOUSE
WASHINGTON

DATE: 10/25/96

TO: *Elizabeth Dye*

FROM: *Elena Kagan*
White House Counsel
Room 125, OEOB, x6-7901

☒ FYI

☐ Appropriate Action

☐ Let's Discuss

☐ Per Our Conversation

☐ Per Your Request

☐ Please Return

☐ Other

ONE HUNDRED FOURTH CONGRESS

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**U.S. House of Representatives
Committee on Commerce**

Room 2125, Rayburn House Office Building

Washington, DC 20515-6115

October 16, 1996

The Honorable William Jefferson Clinton
President
The White House
Washington, D.C. 20500

Dear Mr. President:

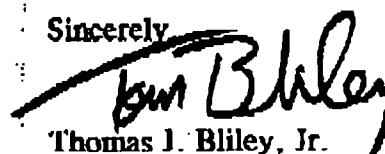
Almost a month ago, I sent you a letter (dated September 27, 1996) which requested the names of all White House officials who were consulted about the FDA's policy on home drug test kits for use by parents on their teenagers. To date, I still have not received the names of these officials.

The letters I received from Robert G. Damus and Janet Crist on October 2, 1996, were incomplete and failed to provide me with the information requested. The letters provided me with a list of White House offices responsible for reviewing the FDA's testimony given before the September 26, 1996 House Commerce Subcommittee hearing on home drug tests, but contained no response whatsoever to my request for the specific names of White House officials who were consulted about the FDA's policy. Nonetheless, I have been informed in writing by the FDA that personnel in the White House Office of National Drug Control Policy and the President's Drug Advisory Council were consulted on home drug testing issues.

I would like a complete response by October 21, 1996, including the names of all White House officials who were consulted about the FDA's decision to regulate the sales of specimen collection kits to parents. This is a very serious matter, Mr. President, which warrants your attention and a prompt response.

If your staff has any questions about this request, please contact Alan Slobodin of my staff at (202) 225-2927. Thank you for your attention to this matter.

Sincerely,



Thomas J. Bliley, Jr.

Chairman

cc: Honorable John D. Dingell, Ranking Minority Member
Honorable Joe Barton, Chairman, Subcommittee on Oversight and Investigations
Honorable Ron Klink, Ranking Minority Member
Subcommittee on Oversight and Investigations

**Office of Public Affairs
15-05 Parklawn
HFI-1
301-594-6004 or 301-443-3819 (fax)
301-443-1130 (phone)**

TO:**FROM:**Schultz, Friedman,**JIM O'HARA**Thompson, Rindergast,Alpert, Levitt, Rabb +
Elizabeth Doye**Number of pages (includes cover)**4**Message:**FYI

If this is not clear, please call and we will send
another fax. Thank you.

Remember for
Stan Friedman

Home drug tests

10/12/96
There's a right to reliability, too

As one clear measure of the desperation that drug abuse has brought to American households, consider that a half-dozen companies are now selling home drug-testing kits.

As an equally plain gauge of the silliness of this political season, consider that one outlaw manufacturer is being paraded as a crusader against a government alleged to be too soft on dope and too tough on entrepreneurs.

It is sad reality for many parents that despite deep concern and firm guidance, their children will use drugs. Understandably, these parents reach for a chemical test as another tool for protecting or restoring the health of their kids. Unsurprisingly, such testing is now widely available through physicians, clinics and counseling services.

But as testing tools go, the do-it-yourself type can be a very blunt instrument. It transforms the parent from counselor and confidant into cop and, possibly, spy. Even when the testing occurs in the open, with children providing samples of urine or hair, it is likely to introduce a coercive dimension to an already strained parent-child relationship. Some companies offer a more devious, less reliable alternative: a treated pad with which parents can wipe schoolbooks or stereos, purportedly capturing traces of drugs deposited by their kids — or anybody else who happened to touch the tested objects. Imagine the heart-to-heart after *those* results come back.

Sunny Cloud, the former Georgia schoolteacher whose home urine-test kit made headlines last week, says she

got the idea for her business after taking her own son for a drug test, and finding the experience expensive and disagreeable. She assembled a specimen cup, instruction booklet and prepaid laboratory mailer into a kit she priced at \$40 — and had sold about 1,000 of them when the U.S. Food and Drug Administration pointed out that federal law bars selling such an item until it's proved safe and effective.

Cloud and supporters call this a ludicrous interference in family decisionmaking, and argue that parents have a right to do home testing. On the latter point, not even the FDA would disagree. It has already approved a highly similar kit, as a prescription product.

But because Cloud has refused to submit her product for FDA review, there's no way for the agency to make sure that a specimen will reach the testing lab without contamination. Or that the lab has adequate safeguards against mixing up samples, which for confidentiality reasons are labeled with numbers, not names. Or that the lab results are reliable. If the FDA can't know these things, neither can consumers.

Despite its significant problems, a reliable home drug test should be available to parents. But the key word is *reliable*. In telling the FDA to take a hike, Sunny Cloud wasn't defending parents' rights. She was simply making a business decision, gambling that political pressure — and parental desperation — will help her triumph over a sensible regulation.

AP v5020 rw 3exec Home Testing, Bjt.770

10-15 8:39a

Home-Testing Becoming More Common, and Raising More Questions
With PM-Home Testing-Glance ,

AP Photos WX106, AX102

By LAURAN NEERGAARD

Associated Press Writer

WASHINGTON (AP) - Sunny Cloud ignited controversy when she charged the government was trying to stop her from helping frightened mothers test their children for drugs.

But the Atlanta housewife's battle highlights a broader issue: More and more Americans are diagnosing themselves with increasingly complex in-home medical tests, and the government has no policy to say when the advancing technology goes beyond what a layman can handle.

"It becomes a matter of social policy - what is an appropriate test for an individual to engage in themselves?" said Wayne Pines, a former Food and Drug Administration official who is a consultant to the medical device industry.

Cloud's home drug test "is a step along the way, and it's got a lot of people thinking," he said.

Home-testing is big business, with tests that let Americans check for high cholesterol, colon cancer, even the AIDS virus in the privacy of their bathrooms. These tests earned more than \$1 billion last year, a 13 percent jump from 1994.

The FDA regulates the effectiveness of home tests and makes sure laymen can use them and understand the results. Some decisions about some tests are straightforward, like pregnancy tests where chemically treated strips simply change color in urine samples.

Others pose more complicated challenges. The FDA wrangled for almost six years over whether Americans should be allowed to mail their blood samples to a laboratory and learn over the telephone if they had the AIDS virus. The FDA approved a home HIV test this year only after phone counseling was added.

But the FDA didn't use the experience to set a policy on how to balance rapidly evolving tests with the social concerns of how and when to sell them directly to laymen.

Will patients be hurt if tests are wrong? When do they see a doctor? Could they force a test on a family member? More basic, are there some tests - like those that detect genetic flaws that might cause incurable diseases - that laymen should never use?

Now Cloud's home drug test has the agency again facing these questions.

After Cloud caught her son smoking marijuana, she created kits to help other mothers detect teen drug use. The \$40 "Parents Alert" kits contain a cup to collect urine, a package to mail it to a federally certified laboratory and a toll-free telephone number where Cloud provides the lab's test results.

The FDA says Cloud violated federal law by selling more than 1,000 of the kits without its knowledge. But after congressional

Parents Alert stay on the market until the government re-evaluates how strictly to regulate it.

Scientists are expected to meet within two months to debate whether the FDA should simply check that Cloud uses reliable test methods and explains them to parents - or whether it should consider broader social questions, including whether false results create family strife.

Twice before, the FDA has opposed home drug tests for fear of "potential adverse consequences in parent-child or spousal relationships" if the test falsely detected drug use. Each time, top agency officials were divided over whether they should even consider such social concerns, and they never settled the issue.

The impasse shows the FDA can't "meet the needs of the ... market of the 21st century," said Rep. Richard Burr, R-N.C. He was outraged that the FDA suggested parents couldn't handle the tests as capably as doctors.

Cloud says her test doesn't need FDA scrutiny because it is identical to ones employers already give workers. Those tests are unregulated because they're used only for employment decisions, not medical diagnoses.

And Cloud insists she wouldn't sell an untrustworthy service. "I'm a mom. I don't want to confront my child" with an incorrect drug test, she said.

But Georgetown University testing expert Sorrel Schwartz says every laboratory makes mistakes, and their tests can falsely detect drugs if someone ingests something as innocent as a poppy-seed bagel.

"It's not oversight for paternalism, it's oversight to make sure people understand," Schwartz said.

Still, Cloud's case may be easy compared with other tests headed for the home. Now in development are kits to track cancer growth and make on-the-spot diagnoses of cocaine use.

"People are developing tests that are faster, easier and lend themselves to being used in less and less sophisticated environments," acknowledged Dr. Susan Alpert, FDA's chief of medical device evaluation. "We know it's coming."

[FDA]

**Office of Public Affairs
15-05 Parklawn
HFI-1**

**301-594-6004 or 301-443-3819 (fax)
301-443-1130 (phone)**

TO: Elizabeth
Dryd

FROM:

JIM O'HARA

202 456-7028

202-205-4102

Number of pages (includes cover) _____

Message: _____

If this is not clear, please call and we will send another fax. Thank you.

AP Story over weekend — may use
VP's remarks — policy will change —
Kathy McKernan knows — will let desk officer
know —

October 10, 1996

Note to HHS, White House press offices

From: Jim O'Hara, FDA public affairs (301) 443-1130 *JOH*

In VP debate last night, Vice President Gore raised the issue of FDA approval of home test kits for drugs of abuse. Following is some background information on this issue and talking points.

Since the mid-1980s the FDA has considered these kits medical devices that require pre-market approval. Questions have been raised whether this is the appropriate level of regulatory review. The FDA has recently announced that it will review this policy. The FDA does not have a policy against approving these devices. And while the policy is under review, the Agency has said it will use its enforcement discretion and intends not to take any action against any home drug test kit currently being sold that meets specific criteria. The Agency's concern is that these kits provide reliable and accurate information and are adequately labeled for their intended use.

Talking points and questions:

We want parents to have all the tools they need to protect their children and fight drug abuse.

Home test kits should be safe and effective and adequately labeled for their intended use, providing parents and children accurate and reliable information.

Q: The Vice President said the policy will be changed and you say it's under review. Is there a difference?

A: No. As we announced, the policy is being reviewed, and we expect there will be changes. We don't know what those changes will be and do not want to pre-judge what the right policy should be. In the meantime, though, FDA has said it does not intend to take any action.

Law Busters

PRESIDENT CLINTON and Bob Dole each have accepted millions of dollars in federal funds to run their campaigns. In return, they had to promise to observe the spending limits that are part of the federal campaign finance law. Having made the promises and received the funds, however, they then proceeded, each of them, systematically to breach the limits and evade such other aspects of the law as the ban on corporate and labor union contributions to campaigns. The principal dodge has been to use the national parties—the Democratic and Republican national committees—as straws through which to raise and spend money. Ostensibly, the national committee spending has been outside the campaigns, but in fact—again in each case—it has been an integral part of them.

No one in the jaded world of politics and political journalism does not understand these things to be true. But the common response—not just in this campaign but the last several, as the current pattern of evasion was developing—has been a shrug. Yeah, they do it, but if you stop them from doing it this way, they'll only find some other; there's no way to keep the money out without violating the First Amendment; the law is porous; it was never really meant to be enforced so much as to provide a kind of cover; this year is only different from the last, and the one before that, in degree—not kind—in the amount of money raised and perhaps the egregiousness of the offense. And on and on, until the edges of the problem have been ground down and the only sophisticated response to what might once have seemed an outrage is acceptance.

That's the culture. The permanent skunk at the

picnic, Goodie Two-Shoes Common Cause, tried to shake the culture up yesterday. The organization sent a letter to Attorney General Janet Reno saying the present system constituted a massive, willful violation of the law on the part of both parties. "The most massive violations . . . since the Watergate scandals," the group said, invoking the ultimate specter. The Federal Election Commission, one of the great success stories of our times in that it was carefully designed to be the ineffectual agency it is, has civil jurisdiction over violations of the campaign laws. But Common Cause says these are criminal violations as well; it cites the statutes themselves to that effect. The Justice Department has jurisdiction in criminal cases. The letter cites the department's own guidelines, to the effect that "intentional and factually aggravated violations . . . are crimes, subject to prosecution," provided that they are "willful," have to do with "core" provisions of the law, "involve a substantial sum of money," and like that.

Common Cause says these fit the guidelines and asks the attorney general, in the interest of avoiding conflict of interest, to appoint an independent counsel to investigate and prosecute if warranted. The law is not a game, and the people who break it ought to go to jail. Now there's a novel view of what this is about. The current system is a charade. The letter says to Authority: Enforce the law or drop it; you can't have it both ways. But, of course, they can have it both ways—and do. In the end, our own jaded guess is that the parties will keep up the spending, somehow, and keep the fig leaf in place as well. But a fig leaf is all it any longer is.

Home Drug Test Kits

CONCERNED AND diligent parents who fear their children are using drugs have now been offered assistance. Sunny Cloud, a Georgia businesswoman, found, when she caught her son smoking marijuana, that parents had no easy and relatively inexpensive way to test youngsters for drug use. She put together a kit and proceeded to market it under the trade name "Aware." The kit contains a plastic cup and a small jar for the collection and storage of a urine sample, a cardboard mailer addressed to a licensed lab and some printed instructional material. Testing is confidential with identifying numbers, not names. Results are obtained by telephone, at which time counseling is given, along with a drug hot-line number for further help.

Enter the U.S. Food and Drug Administration. Last year, the FDA warned Ms. Cloud that she was breaking the law by selling a "medical device" without government approval. At congressional hearings two weeks ago, Dr. D. Bruce Burlington, who is in charge of such matters at the FDA, testified that all diagnostic test kits—whether sold over-the-counter, through the mail or only to professionals at labs, medical offices and clinics—have to be tested for safety and efficacy. That surely makes sense, especially if the test—like those available for pregnancy, glucose monitoring and the like—is administered by a layman at home. But that is not the case with "Aware," which simply provides a set of containers, mailing instructions and printed material.

The test itself is performed by professionals at a federally licensed facility.

Both internal FDA documents and Dr. Burlington's testimony led some congressional critics to suspect that the agency's concerns are really with the competence of parents to interpret test results and to act in a manner that is not coercive or disruptive of family relationships. In other words, these scientists don't think parents in general can be trusted to act in the best interests of their children.

That view, it seems to us, is both paternalistic and misguided. It is in the same vein as the FDA's long resistance to allowing the marketing of home AIDS tests because patients were to be told results and offered counseling over the telephone and not in person. This concern for the emotional or psychological impact of test results on patients and their families may be admirable. But it is not a reason for denying FDA approval on grounds of safety and efficacy.

Parents who suspect their children are using drugs often want complete privacy in addressing the problem. They don't want to take the youngster to a drug clinic or even the family doctor. Kits that make confidential home testing possible ought to be available to parents. Absent a showing that this product is unsafe or produces inaccurate information at a rate exceeding other drug tests, it should be allowed on the market.

The Washington Post

THURSDAY, OCTOBER 10, 1996

A New Afghan Ordeal

RECALL THAT it was a struggle between modernizers and Islamic medievalists that pushed Afghanistan into the civil war that Moscow joined on one side and Washington on the other in an epic Cold War duel. The medievalists, though no longer supported by the United States, are now back with a vengeance in the form of the Taliban guerrillas. Many war-weary Afghans have welcomed their remarkable success, brought on perhaps more by nationalist passion than by arms, in pacifying most of Afghanistan. But with their takeover of Kabul, a city where foreigners still have some access, their other works can now be plainly seen. They are applying to the somewhat sophisticated cities the ideological style and iron discipline of village mullahs. The results have been hair-raising.

In Kabul and elsewhere, kites have been banned to children. Girls are being removed from the schools. Women are whipped on the street for appearing without their eyes covered and are being ousted from the workplace. Men are forced to pray five times a day. This radical fundamentalist design is being imposed without a flicker of consultation with the people affected. As a result, at great personal

risk thousands of educated middle-class professionals are fleeing, and others already abroad are not returning. Thus is a war-ravaged country being further deprived of many of its most essential contributing citizens.

Already the impact is being felt outside Afghanistan. Russia warily anticipates Taliban pressure on the still-unsubdued warlords of northern Afghanistan; they make up a buffer between Taliban and the fragile Muslim states of formerly Soviet Central Asia. Here the best course is for Russia, the United States and others, not least Taliban's patrons in Pakistan, to persuade all Afghan contenders to form a national unity government.

Foreigners have a further responsibility. They should put their full diplomatic weight behind the U.N. secretary general's warning that Taliban's extreme discrimination against women threatens vital relief and reconstruction aid to Afghanistan. It would be cruel if the Afghan people, just as they neared the possible end of an unbelievable 18-year ordeal, found themselves isolated internationally and wearing a totalitarian yoke at home.

Maryland Ballot Questions

MORE OFTEN than not, voters are surprised to find questions on the ballot involving issues that have somehow escaped their attention but suddenly seek their opinion. In Maryland, all ballots on Nov. 5 will include six proposed amendments to the state constitution, each having passed both houses of the General Assembly by a three-fifths vote of all elected members. All six merit approval; two of them affect only Harford County but must receive approvals from a majority of those voting in the state as well of those voting in Harford.

Question 1. Judicial Disabilities Commission. This commission investigates complaints against judges and can issue reprimands and recommend removal, censure or other actions. This amendment would expand the commission from seven to 11 members, with appointments subject to Senate confirmation.

Question 2. Executive Department Appointments. This would prevent a "lame duck" governor from making appointments to the executive branch (except for temporary emergency appointments under certain conditions).

Question 3. Dual Offices—Exceptions. This would allow nonelected members of a law enforce-

ment agency, a fire department or a rescue squad to hold another office of profit including membership in the General Assembly. This change was recommended by a task force that studied dual office-holding. Voters over the years have approved similar provisions for notaries public and members of the National Guard and military reserves.

Question 4. Charter Counties—Elections. This would empower a charter county to enact a local law providing for the filling of council vacancies by special elections, if the General Assembly passes enabling legislation to allow it. The assembly already has done this, with legislation allowing a charter county to enact a local law for the special elections.

Questions 5 and 6. Harford County. Question 5 would allow Harford to elect county council members by districts, by the entire county (as it does now) or by a combination. Question 5 would allow Harford to join other jurisdictions in Maryland that are authorized to use the "quick-take" method of condemning unimproved property for rights-of-way for road, storm drain, sewer or water construction or installations. It includes conditions and protections that other Maryland jurisdictions have.

The Washington Post

THURSDAY, OCTOBER 10, 1996

How to Make Pipelines Riskier

Given the rash of mishaps in recent years involving oil and natural gas pipelines, one might assume a deep Congressional interest in stronger pipeline regulation. There is no such interest. As they rushed to adjourn, both the Senate and House slipped through a bill tailored to industry wishes that weakens current rules governing pipeline safety. President Clinton would be wise to pocket-veto the legislation by refusing to sign it.

The bill would eliminate current requirements that oil and gas pipelines be inspected every two years and that maintenance workers earn Federal certification. It would require a cumbersome cost-assessment process that could invite paralyzing litigation. It would weaken special protections for sensitive areas like wetlands.

The present law was strengthened four years ago partly in response to the ruinous Exxon Bayway pipeline oil spill in New York Harbor. Since then, pipelines have ruptured or exploded in Edison, N.J., Texas, South Carolina and Virginia. Earlier this year the company that operates the Iroquois pipeline running from the Canadian border to Long Island paid \$22 million in fines for various violations of environmental laws.

The Republican majority has tried repeatedly to sneak through bills weakening safety and environmental regulations. It succeeded this time because the bill came to the floor when most of its opponents were preoccupied with other matters and could not mobilize quickly. Mr. Clinton is thus the last line of defense against a dangerous bill.

Drug Tests in the Home

The fracas over whether the Federal Government should allow the sale of mail-order kits that parents could use to test their children for illegal drugs has become obstreperously partisan. Congressional Republicans, eager to tar the Clinton Administration as soft on drugs and too hard on regulation, charge that the Food and Drug Administration has needlessly impeded marketing of the kits. The F.D.A. insists it must approve the kits and their instructional material to make sure the tests are administered and interpreted properly. There are also important issues involving confidentiality, privacy and informed consent when older children are involved. The whole matter needs a more thorough airing before an expert advisory committee to the F.D.A.

The issue has been raised in the case of Sunny Cloud, a Georgia woman who put together a home drug-test kit for parents after finding her 15-year-old son smoking marijuana at home. Her kit consists of a urine sample cup, two saliva alcohol-test strips, a laboratory requisition form, an information brochure and a marketing brochure. The samples are sent to an approved lab, which tests for drugs and returns the results.

Ms. Cloud never sought F.D.A. approval and

has resisted agency pressure to screen her product. Some of her supporters, particularly Representative Thomas Bliley of Virginia, argue that the F.D.A. is acting capriciously and irresponsibly because it has not sought to regulate drug tests used by law enforcement agencies or businesses. Mr. Bliley is incensed that agency officials justify the regulation of home drug-test kits for parents on the grounds of fear of family discord.

But the agency says it is asserting its authority over Ms. Cloud's kit so it can insure the integrity of materials during handling and make sure the literature is not misleading. For example, the agency wants parents to understand the probability of false positive and false negative test results, and that even true test results may justify counseling. A similar approach has been taken with over-the-counter drug tests for the AIDS virus.

At present, the F.D.A. gives home drug-test kits the same high level of scrutiny as pacemakers, which can slow up the approval process. The agency is reconsidering whether a more relaxed standard for the test kits, which include urine cups long on the market, would be satisfactory. That might be a fair compromise — provided the issues of privacy and confidentiality can be resolved.

Weather

Today: Windy, possible shower.
High 62. Low 46. Wind 10-20 mph.
Friday: Partly sunny, windy, cool.
High 58. Low 38. Wind 15-25 mph.
Yesterday: Temp. range: 52-69.
AQI: N/A. Details on Page E2.

The Washington Post

FINAL

Inside: The Weekly
Washington Home
Today's Contents on Page A2

119th Year No. 310

THURSDAY, OCTOBER 10, 1996

Printed May Vary in Areas Outside
Metropolitan Washington (See Box A2)

25c

Yankees' Fan
An Angel in
The OutfieldQuestionable Call
Helps Foil OriolesBy Jennifer Frey
Washington Post Staff Writer

NEW YORK, Oct. 9—The Baltimore Orioles lost the opening game of the American League Championship Series to the New York Yankees by a 5-4 score today at Yankee Stadium, after a controversial call by right field umpire Rich Garcia gave New York a game-tying homer and made a 12-year-old boy from New Jersey a fixture in baseball lore.

When Yankees rookie Derek Jeter hit a deep fly ball to right field in the bottom of the eighth inning, that boy—Jeff Maier, 12, of Old Tappan, N.J.—leaned over the wall, stuck out his glove, and deflected the ball just above the glove of Tony Tarasco, who was playing right field for the Orioles. As the ball fell over the wall into the stands, the Yankees—who were trailing, 4-3—rushed out of the dugout in celebration. Jeter broke into a home run trot. And Tarasco started screaming vehemently at Garcia, who had quickly called the play a home run.

As a result, Maier became the unlikely centerpiece to a drama that will be discussed, and rediscussed, for the rest of this best-of-seven series, and a long while after. What is certain is this: Almost everyone involved, including Garcia, agreed that Maier interfered with the ball. Garcia said after the game that he couldn't



Fan Jeff Maier sticks his glove out of Yankee Stadium stands to deflect ball from Orioles right fielder Tony Tarasco. Play was ruled a home run.

"I looked at the replay and I still don't think he could have caught the ball," said Garcia, who did not have the benefit of a replay when he made his original decision. "It probably was a situation where the ball would have hit the wall. ... I had a decision to make and I made it."

Orioles Manager Davey Johnson was ejected from the game for arguing with Garcia, and announced that the team was play-

ing protest with the American League office up to 24 hours after the game, but had not yet done so early last night. American League President Gene Budig would rule on the protest, but it is highly unlikely the outcome will be changed.

The Yankees—who went on to win the game on Bernie Williams's unquestioned homer in the 11th inning—happily took the run, but some players did ac-

Vice Presidential Nominees
Debate Effects of Tax CutBy Charles Babington
and Paul Duggan
Washington Post Staff Writers

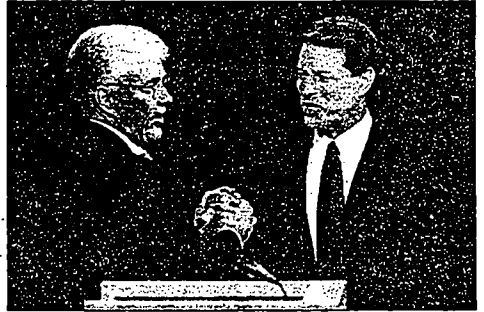
ST. PETERSBURG, Fla., Oct. 9—Vice President Gore and Republican nominee Jack Kemp focused their 90-minute debate tonight on the economy, with Kemp insisting that wide-ranging tax cuts are needed to spur growth and Gore arguing that the GOP plan is dangerous and irresponsible.

In polite but spirited exchanges, Kemp championed tax cuts as a remedy for a host of problems, including race relations, environmental threats and public incivility. Gore repeatedly said the Republican call for a 15 percent cut in marginal tax rates would "blow a hole in the deficit" and endanger Medicare, Medicaid, the environment and schools. Meanwhile he touted the new jobs and low inflation that President Clinton's administration has overseen.

In one of the few noneconomic discussions, Kemp attacked Clinton's refusal to ban a late-term abortion procedure that he called "ugly and gruesome. ... We should recognize that every human life is precious and there should be all of the protection we can give for an unborn human being."

Gore said the technique called "partial-birth" abortion by its opponents is used in rare cases. "What is really at stake here is whether a woman will have the right to choose," Gore said. He noted that the Republican platform calls for a constitutional ban on abortions under most circumstances. Kemp, however, said that "a constitutional amendment would not pass."

The debate—which many saw as See DEBATE, A24, Col. 4



Challenger Jack Kemp and Vice President Gore shake hands before their St. Petersburg, Fla., debate. Their running mates face off again on Wednesday.

Staying Low-Key, Gore Finds
Wedges Between Kemp, DoleBy Dan Balz
Washington Post Staff Writer

ST. PETERSBURG, Fla., Oct. 9—The comical joke that Vice President Gore is stiff and wooden, but tonight Gore turned those characteristics to his advantage. Through 90 minutes of debate, Jack Kemp—try as he might—couldn't knock the vice president off his message.

Kemp was typically optimistic; he was sometimes passionate and animated and occasionally un-Republican. In contrast, the vice president

and agenda and repeating at every possible turn his claim that the election of Kemp and Robert J. Dole represents a threat to "Medicare, Medicaid, education, and the environment" and the gains he said the administration has made the last four years.

If this was a preview of the presidential campaign in the year 2000, Gore and Kemp demonstrated—beyond loyalty to their running mates—that they can be appealing politicians with their own standing, their own ideas and their own convictions. And for tonight at least, the civility of their exchanges no doubt

JUSTICE BY THE NUMBERS

Last of Five Articles

Missteps Leave
Sentence Panel
Short of GoalsNeutrality Questioned,
Reports UnfinishedBy Mary Pat Flaherty,
and Joan Biskupic
Washington Post Staff Writers

Much of the power to remedy inequities in federal sentencing rests with the U.S. Sentencing Commission, a small agency that has as much impact as anyone in a courthouse on who goes to prison and for how long.

Yet 11 years after it was established the agency remains a disorganized, often ineffective advocate for change.

In a system built around the assumption of fairness under the law, the commission was designed to be the neutral rulemaker, guided by experts to correct quirks and inconsistencies in the 845-page U.S. Sentencing Guidelines manual and to anticipate new ones. Yet throughout its history, the commission has been hobbled by vacancies that delay work on major issues and criticized for risking its impartiality by politicking and favor-seeking with the Justice Department and other federal agencies.

Each of the commission's smallest revisions to the sentencing guidelines can dramatically affect the federal justice system, which handles about 40,000 defendants each year. A distinction it considered in 1993 on how to define and sentence a "minimal" player in a crime translated into a difference of 4,000 years of inmate time in the federal system, a substantial cost for taxpayers who pay about \$23,000 a year on average to house a federal inmate.

For all of that impact, the commission's operations in its spacious quarters at the Thurgood Marshall Federal Judiciary Building are surprisingly informal and, critics charge, inefficient. Few permanent records of meetings are kept, making See SENTENCING, A38, Col. 1

A Double-Barreled Drug Sting

Pr. George's Police Play Crack Buyers, Then Dealers

By Philip P. Pan
Washington Post Staff Writer

The hapless crack customers who came to 14th and Kanawha in Langley Park last weekend encountered dealers they had never seen before. In the busiest and most flagrant open-air drug market in the Washington suburbs, they could be forgiven for not noticing.

But they would not be forgiven for their transactions, because the "dealers" were undercover police officers participating in an operation that as of yesterday had netted 163 arrests—of alleged buyers and sellers—more than in any other narcotics initiative in Prince George's County since county-wide sweeps eight years ago.

Officers posed as buyers first, attacking

the supply side of the narcotics economy. Then, last week, county police said, they swept the dealers off the streets, replaced them with detectives in disguise and went after the customers.

The one-two punch was the department's latest attempt to shut down a Langley Park drug bazaar—spread out over several blocks in a neighborhood of brick garden apartments—that has resisted standard police crackdowns year after year.

County Police Chief John S. Farrell, who has scheduled a news conference for today, said the success of the new approach will be measured not by the numbers of arrests or convictions but by whether the market—and the crime associated with it—disappears.

See STING, A17, Col. 4



Police question a man who allegedly tried to buy crack cocaine from undercover officers.

As Vote Nears, Americans Tuning Out Campaign '96

By Howard Kurtz
Washington Post Staff Writer

By every available measure, both the press and the public are tuning out the contest between President Clinton and Bob Dole.

Only 24 percent of those questioned say they are following the election very closely, compared with 42 percent in 1992, according to a Pew Research Center survey. Four in 10 cannot name Dole's running mate. Ratings for the party conventions hit an all-time low and viewership for Sunday's presidential debate

was down nearly 20 percent from four years ago.

Network news coverage of the campaign dropped 40 percent last month from 1992, while the number of front-page stories in The Washington Post declined by half. News magazine covers have turned to adultery, diet pills and plastic surgery. "Oprah" took a pass on bookending Dole.

In short, more folks seem fascinated by John F. Kennedy Jr.'s wedding than the battle for his father's office.

"People are not connecting with this elec-

tion," says Time Managing Editor Walter Isaacson. "The story of this election is why people aren't connecting."

The big news organizations that field small armies to scour the country for quadrennial trends were prepared for every eventuality except the notion that people would turn them off. They have interviewed soccer moms, angry white men, urban blacks, suburban evangelicals, Reagan Democrats and Clinton Republicans, but have detected little passion for either candidate. With the president maintain-

See CAMPAIGN, A28, Col. 1

Revised Fiscal 1996 Deficit Expected
To Be Lowest Since '81, at \$109 BillionBy Clay Chandler
Washington Post Staff Writer

The federal government is expected to record a budget deficit of \$109 billion for fiscal year 1996, the smallest annual revenue shortfall since 1981, according to a preliminary estimate by the Congressional Budget Office.

The new CBO estimate, a sharp drop from the 1995 deficit of \$164 billion and the fourth consecutive decline in the figure, largely reflects higher-than-expected tax receipts generated by a surprisingly strong economy and a surge in revenue from tax payments on the sale of stocks, property and other assets, according to analysts familiar with the projections.

The CBO calculation prompted a scramble on

both ends of Pennsylvania Avenue to claim credit for shrinking deficits.

"Congress Brings Budget Deficit Down to \$109 Billion," declared Senate Budget Committee Chairman Pete V. Domenici (R-N.M.) and House Budget Committee Chairman John R. Kasich (R-Ohio) in a joint statement that first disclosed the new estimate yesterday. Domenici and Kasich noted that the new figure was well below the \$197 billion deficit proposed by President Clinton in his fiscal 1996 budget. In 1992, before the Republicans swept control of Congress, the CBO had projected a federal deficit of more than \$200 billion for the year that ended Sept. 30.

Clinton aides, not surprisingly, hailed the good news as a product of presidential leadership.

See DEFICIT, A4, Col. 1

John Warner's
TV Ad Uses
Altered PhotoSenator Casts Rival
As 'Political Insider'By Spencer S. Hsu
and Ellen Nakashima
Washington Post Staff Writers

An increasingly nasty Virginia Senate race took a bizarre turn yesterday, as Sen. John W. Warner's campaign acknowledged that its new ad contains a picture altered to make it appear that Democratic challenger Mark R. Warner is shaking hands with former governor L. Douglas Wilder in front of President Clinton.

The picture—in a commercial that casts Mark Warner as a liberal "political insider"—is similar to one that appeared in The Washington Post and several other newspapers on Oct. 22, 1994, showing Clinton embracing Wilder and Sen. Charles S. Robb (D-Va.) as they join hands at a rally in Alexandria. In the commercial, Robb's head has been replaced with Mark Warner's.

While hardly misrepresenting Mark Warner's politics—the former state Democratic Party chairman has supported Wilder and Clinton and was on the podium at the rally—the idea that the senator's campaign would release a commercial containing a deceptive photograph sent ripples through both political parties.

When questions about the picture began to surface yesterday, John Warner's campaign initially denied responsibility for the content of the ad, which was paid for by the Republican National Committee and released Monday night.

But late last night, the senator issued a statement blaming the altered photo on his media consultant, Greg Stevens & Co., which also is working for Republican Robert J. Dole's presidential campaign. The senator ordered the manipulated image deleted from the commercial, but stood by the ad's overall accuracy.

See CAMPAIGN, A18, Col. 1

INSIDE

Chemistry,
Physics Nobels

Two Americans and a Briton won the Nobel Prize in chemistry for discovery of a form of carbon and three Americans won in physics for revealing new properties for a form of helium.

NATION, Page A3

Officers on the Hill

The Pentagon will review Capitol Hill "fellowship" programs, including an informal arrangement between Speaker Gingrich and the Joint Chiefs.

FEDERAL PAGE, Page A19



Dennis, Chris,
Elizabeth

Home Drug Test Triggers Scuffle With FDA

Agency's Effort to Regulate Kit Draws Attacks From Lawmakers and Commentators

By John Schwartz
Washington Post Staff Writer

Sunny Cloud never expected to be at the center of a political firestorm. But when the Georgia woman's attempts to market a simple home drug test brought a warning from the Food and Drug Administration, she found that she had supporters in high places.

Cloud said that after she caught her own son smoking marijuana, she wanted to make the same kinds of drug screening tools used by businesses and athletic teams available to parents at home. Her \$40 "Parents Alert" kit included a plastic sample cup, a shipping box addressed to a federally licensed testing laboratory and other materials.

In 1995, the FDA warned her that she was selling what the agency considered to be a "Class III" medical device and that her company would have to go through the agency's approval process before marketing the kit directly to parents.

Cloud, who still has not applied for approval from the agency, said the FDA's actions mystify her—and recalled telling officials, "All the materials in this box have been commercially available for years. I just put it in a white box. You're trying to monitor a white box."

Now lawmakers and commentators are accusing the FDA of hindering the ability of parents to test their children for drugs—and claim it is because the agency is afraid the tests will cause "family discord."

Republican lawmakers were quick to capitalize on the dispute, which dovetails with attempts to characterize the Clinton administration as soft on drugs and to highlight results of a recent survey that show rising drug abuse among young people. At Sept. 26 congressional hearings on the kit, Commerce Committee Chairman Thomas J. Bliley Jr. (R-Va.) said he was outraged by the FDA's actions. Committee Republican staff members faxed talking points to radio talk show hosts urging them to take on the issue; the memo read, in part, that the kit provided "the best excuse for kids to 'Just Say No.' But the Clinton FDA doesn't want them to have it."

The seeming absurdity of the FDA's position also drew attacks from Democratic Reps. Anna G. Eshoo of California and Ron Klink of Pennsylvania.

Commentator George Will ridiculed the "tentacle of the nanny state" and the "overreaching over-

Under the laws governing the agency, Kessler wrote, all new medical devices must go through Class III review if they are not "substantially equivalent" to another device already approved for the same function to be sold directly to consumers. Its policies also require the agency to consider the broad public health issues raised by a new device, such as ensuring that the patient will be able to accurately interpret the results and act on them.

The interpretation of rules on determining the status of diagnostic kits that Kessler followed go back to the mid-1980s, predating the Clinton administration and even the appointment of Kessler by then-President Bush.

One former FDA official who now works with industry said he thinks the FDA should not be involved with internal family decisions—but added, "If, in fact, the legal definition calls for making this a Class III device, then it's not the FDA's fault. Congress needs to change the law."

And although it plays a prominent role in the Republican critique of the agency, the FDA did not bring up issues of "family discord" in Cloud's case. That phrase is drawn from a memo prepared by an attorney for a manufacturer of a different home drug test during negotiations with the FDA. That company took the FDA to court; the company and the agency reached a settlement and the product, which samples hair clippings, is now commercially available. Makers of a third product, a urine test called Aware, chose to go through the approval process and currently sell the test by prescription. Agency officials and the company have discussed going through a second advisory committee to air broader public health issues in order to allow direct-to-consumer sales, FDA officials said.

Rep. Richard Burr (R-N.C.) said drug tests deserve a light standard of review because they are different from AIDS tests: "The person who is tested in the case of a drug kit knows that they've taken drugs. On the AIDS kit, they take it, quite frankly, because they don't know if they have AIDS or not."

Cloud's attorney, Larry Pilot, said the distinction is crucial. The company's product is not intended to diagnose a medical condition, and so "is not subject to the definition of the

The Washington Post

SUNDAY, OCTOBER 6, 1996

hearing busybodies" at the Rockville-based agency.

But the FDA says the case is not so simple. In a letter last week to Buley, FDA Commissioner David A. Kessler said, "I share your concerns about helping parents fight illegal drug use and protect their children," and pledged to allow the kits to remain on the market until it completes a review of the issues and develops a broad policy for dealing with consumer drug tests.

term 'device,' and therefore not subject to FDA regulation."

Pilot said the "political spin" on his client's case was "predictable . . . in particular after the release of the survey of teenage drug abuse."

Pilot, a former FDA official who is now counsel to a trade group for medical device manufacturers, said the Cloud case shows the agency has its priorities confused: "For the Food and Drug Administration to spend all this money to regulate tobacco as drugs and then to ignore drugs as drugs is inexcusable."

October 4, 1996

Note to HHS, White House press offices

From: Jim O'Hara, FDA public affairs *JOH*

House Commerce Committee chairman Thomas Bliley (R-VA) wrote the President, Secretary Shalala and Dr. Kessler last Friday over the issue of home drug test kits. As agreed to by Committee staff and HHS legislative staff on Monday, the White House, the Secretary and the Commissioner responded to that letter yesterday.

- o The White House letter signed by OMB general counsel stated that FDA's draft testimony on home drug test kits received normal review under procedures dating back to the Administration of Franklin Roosevelt and that the review did not constitute any White House involvement in the formulation of policy.
- o The Department's letter stated that the draft testimony received normal review and again that the review did not constitute formulation of policy or approval of policy. It also noted that the Agency had committed during the September 26 hearing to re-evaluate its policy and thought that was appropriate.
- o The Agency's letter confirmed:
 - Agency officials' statements last week to members of the Commerce Committee that Ms. Sunny Cloud will not be subject to any regulatory action for the marketing of her kit in the past or while the policy is under review. Once a final policy is in place, Ms. Cloud would be expected to comply with it.
 - That while the Agency is reviewing its policy, the Agency intends to exercise its enforcement discretion and not take any regulatory action against any home test collection system that meets specified criteria. Any company doing so would likewise be expected to comply with a final policy. This exercise of enforcement discretion is not a reversal of policy; the policy is being re-evaluated.
 - The Agency will re-evaluate its policy with regard to these products expeditiously.
 - Agency decisions on how to regulate home test collection systems for drugs of abuse date back to the mid-1980s. Public discussions of how the Agency treats these products include a public advisory committee in 1985, a Federal Register notice of the availability of guidance to industry in 1988 and the Congressional testimony of then FDA Commissioner Frank Young in 1989. There is no Agency prohibition against the approval of these products.



A QUICK READ ON THE NEWS

NO. 1 IN THE USA . . . FIRST IN DAILY READERS

► Ask the candidates your question on education, 11A

Arrival: Republican candidate Bob Dole and President Clinton arrive for their debate at the Bushnell Memorial Hall in Hartford, Conn., Sunday. Aides say the president played cards on the flight to Connecticut. Dole said he quit preparing Saturday night to get "a good night's sleep."

By Tony Mauro
USA TODAY

By Walter Shapiro
USA TODAY

By Susan Page
and Jill Lawrence
USA TODAY

HARTFORD, Conn. — President Clinton and Republican rival Bob Dole clashed Sunday in a nationally televised debate dominated by charges over taxes and trustworthiness, and competing visions of the future.

On the offensive in their first face-to-face confrontation of the campaign, Dole outlined an unsparring portrait of Clinton as a president who exaggerates the truth and buckles to the interests of trial lawyers who contribute to his campaign.

For his part, Clinton argued Dole had opposed popular federal programs from Medicare to the farm income control bill.

to the Brady gun-control bill. The country has prospered during his term, Clinton said. "It's clear that we're better off

"Saddam Hussein is probably better off than he was four years ago," Dole replied. "But

Many analysts saw the 90-minute face-off as Dole's best chance to break through for an

But his road is steep: A USA TODAY/CNN/Gallup Poll puts Dole 18 points down, 54%-36%.

Missing from the scene: Ross Perot, the Reform Party candidate, who is in his last

"They've done everything they can to freeze us out," he

said earlier Sunday on CBS *Face the Nation*:

But sitting in a prime seat in Bushnell Memorial Hall was Billy Dale, invited by the Dole campaign as a reminder of the

administration's ethical travails. His 1993 ouster as head of the White House travel office prompted a bitter controversy.

► Clinton opened by praising Dole for his "record of public service" and saying he would

try "to make this campaign and this debate one of ideas not insults."

► Dole thanked him but then unleashed a string of jabs ranging from charges he exploited Medicare to "scare" se-

nors to failing to call President Bush by his title during their debate four years ago.

think my ideas are better for the future."

led by someone who voted against student loans, Head Start and the Department of

The two men debate again Oct. 16 in San Diego. Today Dole begins a two-day bus trip

in New Jersey, while Clinton accepts CEO endorsements in Connecticut and campaigns in New Hampshire and Maine.

Tideast talks

**the West Bank city to
be turned over to Pal**

estinian self-rule under the peace deal signed in 1993. Israel wants some

adjustments; the Palestinians refuse.

phor: reports he told President Clinton that Israel would leave the West Bank within 45 days. But

Officials at Sunday's talks also spoke about a news black-

out and moving meetings elsewhere, like Cyprus.

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The FDA's Nannies

It seems the Food and Drug Administration, which has taken it upon itself to regulate "family discord," is having trouble getting its own house in order. Recently on this page, Sally Satel reported on the agency's crusade against home drug testing. The same day, at Congressional hearings on the matter, the FDA's Steven Gutman acknowledged that the agency fears the "discord" and "coercion" that could result if parents test their kids for drugs. "I can deal with the results with my own child," Dr. Gutman testified, "but after all, I'm a doctor. I've got the benefit of two volumes of federal regulations on drug testing."

Dr. Gutman's testimony did not go over well. "In my 15 years in Congress, I don't believe I've ever heard the audience break into spontaneous boos and laughter at government witnesses," remarked House Commerce Committee Chairman Thomas Bliley (R., Va.). "They had to be warned five times to stop."

Commissioner David Kessler was apparently embarrassed enough that he asked for a Capitol Hill meeting with Mr. Bliley—but not enough to back down. According to Mr. Bliley,

Dr. Kessler merely promised to form an "advisory panel" to "study the issue." Meanwhile, his agency's approach turned from draconian to incoherent. The FDA's Bruce Burlington testified that the agency would "work with" Sunny L. Cloud, the Georgia entrepreneur who is marketing a home drug-testing kit the agency has tentatively deemed a "Class III medical device."

But when Ms. Cloud's lawyer returned to his office after the hearing, he found another warning letter from the agency that frets about "coercion," admonishing that Ms. Cloud risks prosecution if she continues marketing the kit. Then Dr. Burlington wrote to Rep. Joe Barton (R., Texas), promising to "defer any regulatory action" against Ms. Cloud, who, for her part, has no intention of backing down. "I think this should be a choice parents make," she says. "I didn't know that the powers of the FDA or any government agency extended into my living room."

The White House's drug czar, Gen. Barry McCaffrey, agrees. "I think families ought to make up their own minds about it," he told the Christian Science Monitor. Stay tuned.

Ladies Vanishing

Afghan clerics aren't the only Asian authorities desperate to keep their women under wraps. The only difference is that in Burma and Indonesia, authorities have got Aung San Suu Kyi and Megawati Sukarnoputri in political purdah. As objectionable as the banishment from public life of Afghan women is, the official squeeze on popular leaders Ms. Suu Kyi and Ms. Megawati is more threatening.

The forces holding them down—a military junta in Burma and what is in effect a one-party state apparatus in Indonesia—are strong enough to thwart the democratic aspirations not just of female politicians but of any and all deemed to pose a threat to the status quo. In the case of Afghanistan's women, sympathy with their plight is near-universal. It would appear that Ms. Suu Kyi and her fellow citizens are suffering so much today because so many of Burma's neighbors have signaled an utter lack of concern about their fate.

Ms. Megawati's situation is not as bad, at least not yet. The government of Indonesia, while it presides over an un-free political system, is most cer-

tainly not in the same league as Burma's State Law and Order Restoration Council, Slorc. Ms. Megawati still has some room, however tiny, for maneuver. She has engaged in a tug of war with a government that clearly would like to keep her out of the political picture, but without appearing any more heavy-handed than necessary.

Until now, Burma's neighbors have shown little concern about the behavior of the Burmese regime. At times, it has even appeared that some Asean members found championing Slorc a satisfying way to show contempt for the United States and other countries that called for some form of international action to help protect human rights in Burma. Not surprisingly, Asean's most democratically advanced members, the Philippines and Thailand, are the only ones with the open moral qualms.

Exile Burmese democrats have noted that "a state-monopolized, military command economy cannot contribute to the thriving Asian regional market economy." Words, and a cause, worthy of support.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 3 1996

The Honorable Thomas J. Bliley, Jr.
Chairman
Committee on Commerce
U.S. House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

This letter responds to your September 27, 1996 letter requesting information and documents regarding home drug test kits. In addition, I would like to follow up on several of the questions raised during the meeting we had that same day with other members of the Committee.

I share your concerns about helping parents fight illegal drug use and protect their children. We want to make certain that parents have the tools they need to do that. At our meeting, I committed to you that the Food and Drug Administration (FDA or the Agency) would reevaluate its policies related to over-the-counter home drug test kits for drugs of abuse. We will do so expeditiously. In the meantime, we are taking steps to insure that while this reevaluation is ongoing, parents will continue to have wide access to tests for drugs of abuse, now including home drug test kits, and all companies marketing or preparing to market such products will know how to proceed. As described in the attached guidance, until our policy review is completed FDA intends to exercise its enforcement discretion in a way that will insure the availability to parents of home drug test kits that are accurately labeled and incorporate reliable testing methods performed by certified laboratories.

We also are confirming that FDA does not intend to take any enforcement action against Ms. Cloud and Parent's Alert for the marketing and distribution of the Parent's Alert product that has occurred already, as well as for any marketing and distribution that may occur during the period of time the Agency is reevaluating its policy. At the conclusion of the Agency's reevaluation of this policy, FDA will announce the regulatory requirements that will be applicable from then on to over-the-counter drug test collection systems for drugs of abuse.

Page 2 -- The Honorable Thomas J. Bliley, Jr.

Finally, your letter suggests that the manner in which the Agency regulates home drug test kits for drugs of abuse is the result of newly developed policy. That is not the case. Since at least the mid-1980's, the Agency has regulated over-the-counter drug test kits for drugs of abuse as devices that require premarket approval, consistent with the requirements of the Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976. Under this statute, any device marketed after 1976 is automatically a Class III device which requires premarket approval, unless it is substantially equivalent to another device marketed for the same intended use prior to 1976 or to a device for the same intended use that was reclassified into Class I or Class II after 1976. The Agency knows of no home test kit for drugs of abuse that was marketed for over the counter use prior to 1976, and there has been no reclassification of such devices. We are enclosing copies of two documents that reflect these facts. While these are not "policy" documents, they do demonstrate that the regulatory approach taken regarding the Parent's Alert product reflects longstanding policy governing over-the-counter home drug test kits for drugs of abuse. We have enclosed them at Tab A.

In accordance with a September 30 meeting between Mr. Alan Slobodin and Mr. Reid Stuntz of the Committee staff and Mr. Marc Smolonsky, Office of Legislation, Department of Health and Human Services (HHS), each Agency to whom your letter of September 26 was addressed will respond separately. The answers to your questions are as follows:

- **The identities of all officials within the President's Drug Advisory Council, the President's Office of National Drug Control Policy, Secretary Shalala's National Institute of Drug Abuse and the Substance Abuse and Mental Health Services Agency, and the Food and Drug Administration who were responsible for or had consultation with the FDA concerning the home drug testing issue.**

See Tab B for a list and documents. As per the discussion between Committee staff and HHS staff referenced above, this list is limited to contacts Food and Drug Administration (FDA) employees had with the identified agencies from November 4, 1991 to present, that related to any home drug testing issue. Documentation of each contact, if available, is included.

Page 3 -- The Honorable Thomas J. Bliley, Jr.

- **The identities of all White House, Health and Human Services and Food and Drug Administration personnel who reviewed the prepared testimony of Dr. Bruce Burlington presented on behalf of the FDA for the September 26, 1996 hearing.**

Center for Devices and Radiological Health:

Dr. Bruce Burlington, Director
Joseph Levitt, Deputy Director for Regulations and Policy
Robert Eccleston, Special Assistant to the Director
Lillian Gill, Director, Office of Compliance
Dr. Steve Gutman, Director, Division of Clinical Laboratory Devices
Jackie Knight, Special Assistant to the Director
Cathy Norcio, Executive Secretariat
Casper Uldriks, Special Assistant to the Director of Compliance
Wally Pellerite, Assistant to the Director of Compliance

Office of the Commissioner:

Mary Pendergast, Deputy Commissioner/Senior Advisor to the Commissioner
Jim O'Hara, Associate Commissioner for Public Affairs
Diane Thompson, Associate Commissioner for Legislative Affairs
Melinda Plaisier, Acting Deputy Associate Commissioner for Legislative Affairs
Kevin Mulry, Legislative Analyst, Office of Legislative Affairs
John Mitchell, Director, Office of Special Investigations
Linda Kahan, Associate Chief Counsel for Enforcement, Office of the Chief Counsel
Doug Snyder, Associate Chief Counsel for Enforcement, Office of the Chief Counsel

- **All unexpurgated books, records, correspondence, notes, phone logs, memoranda, documents (including all drafts and without regard to whether they are on paper or recorded electronically), and electronic mail (irrespective of how stored, including but not limited to those stored on individual PCS or on file servers that are part of local area or wide area networks) related to the issue of home drug testing and to the preparation of**

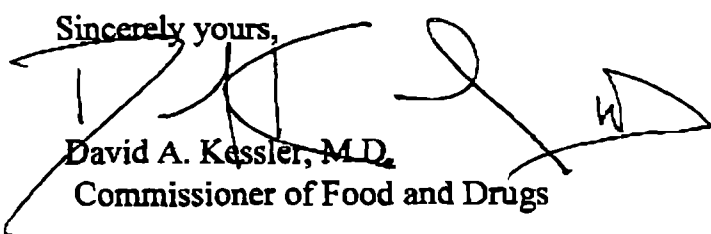
Page 4 -- The Honorable Thomas J. Bliley, Jr.

testimony by Dr. Burlington, Dr. Gutman and Lillian Gill at yesterday's hearing.

See Tab C. As per the discussion between Committee staff and HHS staff referenced above, the third question will be limited to a copy of the briefing book created and used in preparation of the September 26 hearing.

Some of the enclosed documents may contain trade secret, commercial confidential or other information that is not releasable to the public under the Freedom of Information regulations promulgated by this Agency. We, therefore, request that the Committee not publish or otherwise make public any of the information contained in these documents. We would, of course, be glad to discuss with the Committee staff the confidentiality of any specific document.

Sincerely yours,



David A. Kessler, M.D.

Commissioner of Food and Drugs

Enclosures

cc: Honorable John D. Dingell, Ranking Minority Member
Honorable Joe Barton, Chairman, Subcommittee on Oversight and Investigations
Honorable Ron Klink, Ranking Minority Member, Subcommittee on Oversight and Investigations

THE WHITE HOUSE

WASHINGTON

October 3, 1996

David A. Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

I am writing regarding the Food and Drug Administration's (FDA's) policy on home drug test kits. I understand that FDA's approach to reviewing and approving home testing kits, including those for illegal drugs, was developed during the administrations of Presidents Reagan and Bush. The President is pleased that you intend to re-evaluate this policy as it applies to home tests for illegal substances.

As you know, The President is committed to ensuring parents have the tools they need to prevent their children from using illegal substances. He has supported drug testing of high school athletes and has fought Congress's efforts to cut funds for the Safe and Drug-Free Schools Act. This administration has encouraged states to adopt a "zero tolerance" standard for drivers under the age of 21 who drive while intoxicated. You and the President have worked together to end children's tobacco use.

The President believes parents should also have access to safe and effective home drug test kits. Of course, neither he nor I state a view as to whether the FDA should approve any particular home drug testing product as safe and effective. The President believes, however, that safe and reliable tests should be available to parents, and parents should be able to use such tests if they choose.

As parents seek to raise their children drug-free, it is important to make all potentially useful tools available to them. The President would want you to keep this in mind as FDA reviews its criteria for evaluating home drug test kits.

Sincerely,



Carol H. Rasco
Assistant to the President
for Domestic Policy

THE WHITE HOUSE

WASHINGTON

October 3, 1996

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Commissioner
Food and Drug Administration
5600 Fishers Lane
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Sincerely,



Carol H. Rasco
Assistant to the President
for Domestic Policy



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857**PARENTS' ACCESS TO TESTS FOR DRUGS OF ABUSE****PURPOSE**

This guidance describes how FDA will exercise its enforcement discretion for home test collection systems for drugs of abuse. It is intended to provide for the availability of home test collection systems sold directly to parents for use in the home setting, while FDA develops a final policy regarding the appropriate level of regulation of these products. FDA intends to exercise its enforcement discretion and not take any regulatory action against persons distributing such products during this interim period, so long as the criteria listed below are met. Once a final policy is in place, manufacturers and distributors will be expected to be in compliance, or come into compliance, with that final policy.

SCOPE

This guidance covers home test collection systems for drugs of abuse that are intended to be sold directly to parents for use in the home setting. The testing procedures for these products require that a specimen from the body (e.g., urine) be collected at home and mailed to a designated laboratory for testing. Test results are then communicated back to the parent.

CRITERIA

FDA intends to exercise its enforcement discretion during this interim period with respect to home test collection systems and their components that meet all of the following criteria:

1. The tests(s) to be used by the laboratory have been cleared for marketing by FDA for identifying drugs of abuse in a laboratory setting;
2. The laboratory performing the test(s) has been certified by SAMHSA as having the necessary capability to reliably perform such test(s) or meets equivalent standards; and
3. The product ensures that samples are adequately identified to avoid mix-ups, and is accurately labeled so that parents can readily use it.

10/03/96

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FROM:

LARRY BACHORIK



U.S. Department of Health and Human Services
Food and Drug Administration

LAWRENCE BACHORIK, Ph.D.
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Message: WST Piece, as discussed

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A12

THE WALL STREET JOURNAL THURSDAY, SEPTEMBER 26, 1996

Is Your Kid on Drugs? The FDA Makes It Hard to Know

By SALLY SATTEL

Under the leadership of President Clinton and Commissioner David Kessler, the Food and Drug Administration is waging a tough and very public war on teenage smoking. Meanwhile, the same FDA has quietly made every effort to suppress a simple product that could help parents who fear their kids are using illegal drugs. Relying on the most tendentious bureaucratic reasoning, the agency has fought to keep off the market mail-order kits parents use at home to test their children for drugs. The FDA doesn't claim that the kits are un-
e or ineffective—the same tests are routinely used by hospitals, employers and parole officers—but that families can't be trusted to handle the results.

Two years ago Sunny L. Cloud, a Marietta, Ga., single mother of two, started marketing a service called Parent's Alert At Home Drug Testing. Ms. Cloud sold kits consisting of FDA-approved drug-testing materials—a cup to catch urine and two strips for blotting saliva—and a preaddressed mailer. Parents who purchase the kit send a urine or saliva sample to a lab using a code number. If the results are positive, the lab retests the sample, and a pediatric physician is available for consultation at Parent's Alert's 800 number.

In April 1995, a year after Ms. Cloud went into business, an FDA inspector de-

clared her company a "manufacturer" of a medical "device." In June an official warning letter arrived, informing Ms. Cloud that her product required premarket FDA approval—never mind that she was merely using FDA-approved supplies—or else her firm would be subject to seizure, injunction or civil penalties. "All I do is put two strips and a plastic cup in a box, but to them this is a Class III device. They are subjecting me to the same kinds of controls that makers of CAT scans and pacemakers must meet," Ms. Cloud says.

For 15 months Ms. Cloud, her lawyers and her congressmen have sought an explanation from the FDA, but the agency has ignored their queries. Today the FDA will finally be forced to account, as the House Commerce Committee holds hearings on regulation of home drug-testing kits.

Also testifying will be a representative of the Psychomedics Corporation, which sells a similar service that tests hair samples rather than urine or saliva. Like Ms. Cloud, Psychomedics received an FDA warning letter, claiming the envelope used for mailing the hair to the lab was a medical device requiring FDA approval. Psychomedics took the FDA to court, and the agency backed down. But Parent's Alert, which can't afford to wage a court battle, continues to operate under a regulatory cloud.

Why is the agency so zealous in its efforts to wipe out home drug testing? Because, quite simply, Dr. Kessler's FDA doesn't trust parents. It fears that the home tests will have "adverse consequences for the parent/child relationship," according to an internal FDA memo.

I asked Susan Alpert, director of the FDA's Office of Device Evaluation, to explain the FDA's objections to services like



David Kessler

Parent's Alert. "What if the child didn't deposit his urine specimen correctly or lick the saliva strip properly?" she said. "What if the urine container spilled in transit to the lab?" Fair questions—but Ms. Cloud told me that when she had offered to answer them, the FDA inspector

wasn't interested. Dr. Alpert also told me the agency is troubled by questions of confidentiality—never mind that the anonymous at-home tests, unlike those conducted by a doctor, don't end up on a child's permanent medical record.

Dr. Alpert freely admitted that the FDA's interest in regulating reach goes far beyond technical concerns: "Testing has important social implications. How the information is delivered and the counseling that goes with it are part of the test. We believe that information does have a risk."

To be sure, home drug testing raises questions about parental authority, child privacy and even psychological harm from insensitive handling of the results by parents. But such questions are none of the FDA's business. The agency's statutory mandate is to ensure the safety and efficacy of drugs and medical devices, not to intrude into family relations. "Parents may disagree on whether to use the test, keep it in the closet as a deterrent or maybe just trust their kids—but it's their decision," says House Commerce Committee Chairman Thomas J. Bliley Jr. (R., Va.).

Besides, it's an insult to concerned parents to assume they aren't sophisticated enough to understand the detailed instructions and caveats that come with Parent's Alert. Most of those who pay \$40 for a test kit are concerned mothers and fathers who want to relieve their aching worry that someone they love is in trouble—or get him help if he needs it. One Pennsylvania mother wrote Ms. Cloud to order a test because "I believe it will be easier for my 16-year-old daughter to say no if she can also say, 'My mom gives random drug tests.'"

With teenage drug use having doubled during the Clinton administration, it's ap-

palling that the same FDA that is adamant about keeping cigarettes away from minors is determined to withhold from parents a practical means of protecting their children from illegal drugs. "I'm tired of hearing people like Secretary [Donna] Shalala and General [Barry] McCaffrey say that parents must be empowered," says Ms. Cloud. "Why won't the government let us fight back?"

6

THE WHITE HOUSE
WASHINGTON

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☐ MARC SMOLONSKY

REMARKS

As requested

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☐ CARL TAYLOR

☐ _____

☐ _____

Drift

known or suspected drug problem is detection. FDA has granted market clearance for literally hundreds of screening products capable of detecting marijuana, cocaine, amphetamines, opiates (heroin, morphine and codeine) and phencyclidine (PCP). Of these, 60 are approved for use in point-of-care facilities. A more detailed inventory and description of these products is attached. The broad availability of these products and the concomitant array of testing services afford parents, law enforcement authorities, and employers, among others, a broad range of options as they attempt to ^{ensure} ~~assure~~ that home, school and workplace are drug free.

The Agency has some experience in assessing and applying the questions identified above to the data on a specific product intended for use in the home, the "Aware" home collection system. In reviewing this product we also considered the applicability of questions that had been raised in the review of home collection systems for HIV tests to a proposed system for drugs of abuse test. On the Aware product, we concluded that home specimen collection made sense in the context of professional use labeling: that is, when there was a drug abuse counselor, psychologist or physician 1) involved in the decision to use home

what is it
Josh

September 25, 1996

Note to White House Press Office

The House Commerce Committee's Subcommittee on Oversight and Investigations is holding hearing tomorrow (Thursday, 9/26) on FDA's regulation of in vitro diagnostics, that is, tests to determine whether a person has a disease or what levels of illegal drugs are in a person's body. The subcommittee will focus in particular on home test kits to determine if a person uses drugs. Republicans have charged in a press release issued Saturday that FDA is keeping home test kits off the market and that the agency is basing its decision on a fear that these kits will cause "family discord."

Talking Points

- o FDA does not have a policy against home test kits. The law requires that home test kits -- or any diagnostic -- be safe and effective and adequately labeled for its intended use. In the case of home test kits, the FDA wants a company to show that samples can be collected and maintained without contamination, that reliable and accurate results can be obtained in the analysis, and that there is a way to ensure that the results are interpreted correctly. FDA has approved a home test kit for HIV, the virus that causes AIDS, and home test kits for the early detection of pregnancy, to measure cholesterol and glucose levels, etc.
- o FDA is prepared to accept and review appropriate applications for home test kits for drugs of abuse, using the same criteria as for these other products.

Questions about specific products that the Republicans are using as examples should be referred to FDA's Office of Public Affairs: 301-443-1130.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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DRAFT

would allow the company to get the device into broader, but still limited, circulation in order to gain clinical experience, test public acceptance and recover the costs of development and production.

Regrettably, the company did not avail itself of this option. We have had no further substantive response from with the firm in the intervening months and have not received any new data or applications.

DRUGS OF ABUSE TESTING PRODUCTS

Let me say as both a father of three teenage children, and as a practicing emergency room physician who has seen first hand the ravages of illegal drug use, I understand very well the need to combat this public menace. The physical and psychological trauma it inflicts on casual users, addicts and their families can be devastating. Consequently, FDA is very sensitive to the need for readily available tests that can deliver accurate, meaningful results.

A critical first step to diagnosing and treating a person with a

FINAL

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A critical first step to diagnosing and treating a person with a known or suspected drug problem is detection. FDA has granted market clearance for literally hundreds of screening products capable of detecting marijuana, cocaine, amphetamines, opiates (heroin, morphine and codeine) and phencyclidine (PCP). Of these, 60 are approved for use in point-of-care facilities. The broad availability of these products and the concomitant array of

testing services afford parents, law enforcement authorities, and employers, among others, a broad range of options as they attempt to assure that home, school and workplace are drug free.

The Agency has some experience in assessing and applying the questions identified above to the data on a specific product intended for use in the home, the "Aware" home urine collection system. This test system consists of a specimen collection container, mailing kit and drug analysis for detection of use of drugs of abuse. In reviewing this product we also considered the applicability of questions that had been raised in the review of home collection systems for HIV tests to a proposed system for drugs of abuse test. On the Aware product, we concluded that home specimen collection made sense in the context of professional use labeling: that is, when there was a drug abuse counselor, psychologist or physician 1) involved in the decision to use home collection with direct reporting of results to the home, and 2) advising on interpretation of the results. We did not find sufficient evidence, however, to support direct to consumer OTC marketing of the test system. It was the Agency's view that the test accuracy and interpretability of the results required, the involvement of appropriate professionals.

As is the case for any in vitro diagnostic, in considering whether a product is safe and effective for use as an OTC test for drugs of abuse, the Agency considers the risks associated with such use. The impact of errors related to tests for drugs of abuse -- what can happen if someone relies on an inaccurate result or does not accurately interpret a result -- extends beyond purely physical medical consequences. Errors can mean either that a parent falsely believes that a child is using drugs, or that a parent falsely believes that a child is not using drugs. Such errors could cause unnecessary and harmful distress to the parents and child. Regardless of whether one characterizes such impacts on people's lives and well-being as social and ethical issues or as mental health issues, they are clearly foreseeable adverse consequences. Drug abuse is far too serious a matter to allow either situation to be commonplace.

As I said above, the issue is not whether parents should have such products available: the issue is to ascertain that such products are safe and effective for their intended use. In the final analysis, our market approval decisions are based on the safety and effectiveness of the device and its impact on public health.

SUMMARY

Mr. Chairman, we share the same goals of getting valuable new medical products into the hands of American consumers and health professionals as rapidly as possible. When the information is available on how properly to interpret medical test results, there are adequate directions for lay use, and we are satisfied that the tests can produce consistently accurate results, we believe the products should be available OTC. Unfortunately, to date such systems for drugs of abuse have not been shown to meet these criteria.

Our statutory and public health responsibilities compel us to make market approval decisions on the basis of evidence produced with high quality science. To settle for less would undermine the public trust and cause harm to scores of people throughout our nation.

This completes my prepared statement, Mr. Chairman. My colleagues and I would be pleased to respond to your questions.

Lamy - O'Hara

- punishment for false (+)
- false (-)

October 2, 1996

Klain has
seen it —
ok

MEMORANDUM TO: John Hilley
Bruce Reed
Rahm Emanuel
~~George Stephanopoulos~~ gone
Todd Stern
John Angell

FROM: Carol Rasco
Jack Quinn

SUBJECT: Draft Letter from POTUS to Commissioner Kessler
Regarding FDA's Policy on Home Drug Testing Kits

Attached for your review is a draft letter from the President to Commissioner David Kessler. As you know, Congressman Bliley's Committee held a hearing in the House last Thursday examining the FDA's approach to approving home kits to test for illegal drug use. Bliley has also requested information from the White House regarding the review of FDA's testimony. Bliley and others have argued that FDA is inappropriately interfering with parents' access to tests. Commissioner Kessler committed to Bliley after the hearing to review FDA's policy on drug test kits.

The attached letter would put the President on record supporting parents' access to safe and reliable test kits. We would not necessarily release the letter publicly, but the President could refer to it if asked to state his position. There has been some press coverage of this issue, and the FDA expects Dateline to run a segment on it as soon as this Sunday. Further, the issue may be raised in the Presidential debates. We therefore advise that the President send the attached letter commending Dr. Kessler for his decision to review FDA's policy and conveying his views to the Commissioner. ~~with Kessler's office~~

~~has just received a copy of the letter~~

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DEPUTY SECY

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Key talking points
home test kits

This Administration is fully committed to helping parents teach their children that drugs are illegal and wrong. We've developed new drug prevention materials that have gone free of charge to millions of parents, and fought Congress' attempts to cut funding for drug-free schools.

On this particular issue, it's important to remember that home drug tests have been considered "Class III medical devices" needing FDA approval since at least 1987. Commissioner Kessler has made it clear that the agency is re-evaluating this issue expeditiously. We believe that's the right thing to do.

September 25, 1996

Note to White House Press Office

The House Commerce Committee's Subcommittee on Oversight and Investigations is holding hearing tomorrow (Thursday, 9/26) on FDA's regulation of in vitro diagnostics, that is, tests to determine whether a person has a disease or what levels of illegal drugs are in a person's body. The subcommittee will focus in particular on home test kits to determine if a person uses drugs. Republicans have charged in a press release issued Saturday that FDA is keeping home test kits off the market and that the agency is basing its decision on a fear that these kits will cause "family discord."

Talking Points

- o FDA does not have a policy against home test kits. The law requires that home test kits -- or any diagnostic -- be safe and effective and adequately labeled for its intended use. In the case of home test kits, the FDA wants a company to show that samples can be collected and maintained without contamination, that reliable and accurate results can be obtained in the analysis, and that there is a way to ensure that the results are interpreted correctly. FDA has approved a home test kit for HIV, the virus that causes AIDS, and home test kits for the early detection of pregnancy, to measure cholesterol and glucose levels, etc.
- o FDA is prepared to accept and review appropriate applications for home test kits for drugs of abuse, using the same criteria as for these other products.

Questions about specific products that the Republicans are using as examples should be referred to FDA's Office of Public Affairs: 301-443-1130.

09/27/96 FRI 18:06 FAX 202 401 5783

DEPUTY SECY

A: The FDA is dedicated to working in the best interests of families and parents. As Commissioner Kessler said today, the Agency is re-evaluating the issue expeditiously. We believe that's the right thing to do.

Q: So did the White House or HHS overturn the FDA?

A: No. The FDA made the decision to look into the matter again.

Congressman Dillley has called for Bruce Burlington to resign. Will he?

A: Dr. Burlington has no intention of resigning. There's way too much partisan finger-pointing going on.

Q: How can you say that parents are the key to the struggle against youth drug use and then refuse to put power in their hands like this?

A: We've taken strong steps to put power back in parents hands. On the drug issue alone, we've developed new drug prevention materials that have gone free of charge to millions of households. Just last week, Secretary Shalala announced the release of the latest of these new materials.

But that's not all. If you look at this administration's record, what you will see is a powerful and consistent effort to help parents guide their children to Safe Passage through the teenage years. The President's support of drug testing for high school athletes. His calls for youth curfews and school uniforms. On the issue of violence in the media, his leadership in making the V-Chip and voluntary ratings system for TV a reality. On youth tobacco use, our historic new prevention initiative. This is a strong record of achievement.

Background: The FDA has approved home drug testing if prescribed by a medical professional.

Q: What about the charge that these decisions were made at the highest levels of FDA? Is that unusual?

A: Because two different divisions within FDA were considering two different home test kits (one for drugs and one for AIDS) the FDA commissioner's office did coordinate the agency's general policy on home testing. This is perfectly appropriate.

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Background

Yesterday Bruce Burlington, M.D., the FDA's Director of the Center for Devices and Radiological Health, testified before the House Commerce Committee's Subcommittee on Oversight and Investigations on the subject of home drug tests. (Dr. Burlington's testimony went through OMS and White House clearance.)

The FDA's main point at the hearing was that home drug tests have been considered "Class 3 medical devices" since at least 1987. That designation requires FDA approval before such a device can be marketed to the public.

Since the hearing, Congressman Bliley has made a number of accusations. He says that there were inappropriate contacts between the agency and HHS and the White House. He has also said that he is "baffled and outraged" that with teen drug use rising, the FDA refuses to give parents access to the same drug testing kits used already in workplace testing.

Specific questions should be referred to Jim O'Hara of the FDA. Questions about Congressman Bliley's latest letter to the President, General McCaffrey, and Secretary Shalala can be referred to Melissa Skolfield at HHS.

Q: Congressman Bliley says that the FDA decision on home drug testing for illegal drugs was developed only after consultations with the Secretary Shalala's office and the Clinton White House. Is that true?

A: No. There was no involvement of either Secretary's Shalala's office or the Clinton White House in the FDA's product approval process.

Q: But what about the 7/19/96 letter from Deputy FDA Commissioner Sharon Smith Rolston? Doesn't that letter confirm that NIDA, SAMHSA, and the President's Drug Advisory Council were all involved?

A: No. As the full text of the letter makes clear, there have been general contacts with other agencies and FDA on the overall issue of home drug testing. Those contacts were appropriate.

Q: Isn't the FDA position ridiculous? Why should these drug tests be OK for businesses to administer but not for parents?

**PRESIDENT CLINTON AND AMERICA'S COMMUNITIES:
MEETING THE CHALLENGE OF KEEPING OUR KIDS SAFE AND DRUG FREE
July, 1996**

long record of hard work, executive action and real success. President Clinton believes that the best way to ensure a safe, strong and secure America is to help our children grow up in an environment that lets them have every chance to enjoy this age of possibility. The President has taken a number of specific steps to provide our children with a safe passage from childhood to adulthood, including:

Presidential Guides and Manuals:

- * **Curfews.** President Clinton believes that curfews, when they are backed by a community of support and are a part of a larger plan to help fight juvenile crime, can play an important role in keeping our children safe. While highlighting a successful New Orleans program, the President encouraged cities nationwide to look at how curfews can help keep their children and their communities safe.
- * **School uniforms.** President Clinton has encouraged schools to adopt school uniform policies, which promote discipline and respect. The Administration has developed a guide for schools to assist them in establishing these policies, which is being distributed to 16,000 school districts.
- * **Truancy.** Truancy prevention initiatives have been shown to keep more children in school and dramatically reduce daytime crime, so the President has issued a guidebook to school districts nationwide which outlines the central characteristics of a comprehensive truancy prevention policy and highlights model initiatives in cities and towns across the country.

Drugs:

- * **Working to end teen tobacco use.** President Clinton has proposed restricting youth access to tobacco products, and reducing the advertising and promotional activities that make these products appealing to young people.
- * **Drug testing.** In January of 1995, the Clinton Administration supported high school athlete drug testing in an amicus brief to the Supreme Court, sending the message to parents and students that drug use will not be tolerated in our schools. [Vernonia School District 47J vs. Acton]
- * **Zero-tolerance on underage drinking.** The Clinton Administration has encouraged states to adopt a "zero tolerance" standard for drivers under the age of 21 who drive while intoxicated.
- * **Safe and Drug-Free Schools.** President Clinton expanded the Drug Free Schools Act into the Safe and Drug Free Schools Act in 1994, making violence prevention a key part of that program. The President has fought throughout his term for full funding of the program, fighting back a \$266 million cut by the House in 1996. Over 97 percent of the school districts in the country use these funds to keep violence and drugs away from students and our schools.
- * **Combatting youth drug use.** The number one goal of President Clinton's 1996 National Drug Control strategy is to motivate America's youth to reject illegal drugs and substance abuse. The first ever White House Conference on Youth, Drug Use and Violence in March 1996 launched a national media literacy and drug deglamorization campaign aimed at youth.

Guns:

- * **Fewer guns in the hands of our children.** President Clinton signed into law a youth handgun ban in his 1994 Crime Bill. The ban makes it a federal offense, with some exceptions, for an adult to transfer a handgun to a juvenile, or for a juvenile under the age of 18 to knowingly possess a handgun or handgun ammunition.
- * **Tracking illegal sales of guns to kids.** President Clinton initiated a crackdown on gun traffickers -- who peddle their arms to kids -- through a Federal Tracking System and law enforcement task forces. This will cut the supply of those firearms by helping to identify and prosecute traffickers.
- * **Zero tolerance.** In October 1994, President Clinton signed into law the Gun-Free Schools Act, and issued a Presidential Directive later that month to enforce "zero tolerance" in our schools -- you bring a gun to school, you don't come back for a year.
- * **Anti-gang and Youth Violence Control Act of 1996.** President Clinton sent this act to Congress to strengthen laws that will help stop the rise of youth violence and drug use, including expanded use of drug and gun courts.

--- DRAFT ---

October 3, 1996

Dr. David A. Kessler
Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

Dear Dr. Kessler:

I am writing regarding the Food and Drug Administration's (FDA's) policy on home drug test kits. I understand that FDA's approach to reviewing and approving home testing kits, including those for illegal drugs, was developed during the administrations of Presidents Reagan and Bush. The President is pleased that you intend to re-evaluate this policy as it applies to home tests for illegal substances.

As you know, The President is committed to ensuring parents have the tools they need to prevent their children from using illegal substances. He has supported drug testing of high school athletes and has fought Congress's efforts to cut funds for the Safe and Drug-Free Schools Act. This administration has encouraged states to adopt a "zero tolerance" standard for drivers under the age of 21 who drive while intoxicated. You and the President have worked together to end children's tobacco use.

The President believes parents should also have access to safe and effective home drug test kits. I understand such kits have been considered "Class III medical devices" needing FDA approval since at least 1987. The FDA clearly has a role to play in ensuring home drug tests are safe and effective. For this reason I do not state a view as to whether the FDA should approve any particular home drug testing product. The President believes, however, that safe and reliable tests should be available to parents, and parents should be able to use such tests if they choose.

As parents seek to raise their children drug-free, it is important to make all potentially useful tools available to them. I urge you to keep this in mind as FDA reviews its criteria for evaluating home drug test kits.

Sincerely,

Carol H. Rasco
Assistant to the President
for Domestic Policy

O'Hara
9/2

- to point of care drug tests -
- labeling has info. on reliability
- Nexus has transcript of hearing (last Thurs)

response on workplace - not in home -

- agency over period of years - made enforcement discretion decision - focus on consumer marketplace
- test kits used in workplace falls in "forensic" category.

Reporters -
ask -
Rationale - intended use of OTC device in consumer setting is what makes it PMA (class III) device. -

- other safeguards in marketplace employees can file law suits, grievances through unions -
- Agency made decision - enough safeguards on how device is used - we wouldn't put our resources into reg - a

Long-standing

History - fact that home test kits came
into market late 70's / early 80's

1985 - public ^{advisory} committee met how
to regulate
reliability
labeling
collecting/maintaining sample

1988 - Published "Points to Consider"
document in FR - put on
notice how FDA would regulate.

(Public Health Service had policy against AIDS
since 1980)
Most of interest on AIDS

1989 - Commissioner Frank Young testified
on home test kits - focused
on AIDS.

Since that time internally, Agency has
~~retained~~ unresolved issues. - PHS policy
had to be changed before FDA could
approve home test kits.

~~Since 80's - PMA kits~~

Agency - advisory committee in 1991 thought it could
be approved for OTC - Agency had Q's
- Company brought approval to market kit.

Re. Kessler
Smt:

ETA has committed to ^{Bibley} ~~to Kessler~~

looking at the entire issue - Should
this be class III - if so, do we
have the right criteria, are we
asking the right questions

- Transcript from 85 -

- Points to consider -

Young's testimony - v. general - not focused
on specific test kits

Bibley's ^{people} tried to get in White House Bulletin

Sueve Chapman - Chicago Tribune - editorial work

Dateline - plug on show - talked about
as early as this Sunday -
this weekend -
- Shooting yesterday

- Christian Science Monitor -

People keep talking about "it"

① general policy that these devices are medical devices — well established

have 2nd issue of how it gets regulated.

Devices used in work place — lot other

R's — Admit they want test to be accurate; reliable — but don't want Class III medical devices.

— enforcement discretion

— policy has developed
— based on individual applications

~~Office of Cabinet Affairs Sheet~~

Workplace testing —

rules are different
how?

how many tests...

Findings of advisory Cmt. Public?

"Aurora" test —

allowed it where

(1) drug abuse counselor, psychologist, ^{or} physician

- involved in decision to use home collection

- advising on interpretation of results

— allowed in work place under different conditions?

— rate of false positives and false negatives?

(FDA concluded test accuracy and interpretability of the results required the involvement of appropriate personnel)

— does M.D. prescribe?

— what else stated at hearing?

- Kessler's Statement — issued in what context —
just use talking points?

DRAFT -- DRAFT -- DRAFT -- SEPTEMBER 23, 1996

STATEMENT

BY

D. BRUCE BURLINGTON, M.D.

DIRECTOR

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON COMMERCE

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 1996

RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Subcommittee.

I am Bruce Burlington, Director of the Center for Devices and Radiologic Health (CDRH), Food and Drug Administration (FDA or the Agency), and am here today to discuss how FDA reviews medical diagnostic tests and evaluates whether they should be marketed for their intended use. My testimony will cover the means by which FDA assures these products can perform safely, effectively and in accordance with claims made by those who develop and manufacture them. As you requested, I will specifically address the review of test systems for drugs of abuse and provide an update on the Diasensor 1000 glucometer device made by Biocontrol Technology, Inc.

Appearing with me today are two senior members of my staff. Ms. Lillian Gill and Dr. Steve Gutman. Ms. Gill is the Director of the Office of Compliance, CDRH, which oversees all regulatory compliance and enforcement activities. Ms. Gill's background is in clinical laboratory and regulatory laboratory science.

Dr. Gutman, a clinical pathologist, is the Director of the Division of Clinical Laboratory Devices, CDRH, which is

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responsible for evaluating diagnostic medical devices. Prior to joining FDA, Dr. Gutman was director of the clinical laboratory at the Veterans Administration Hospital in Buffalo, New York.

FDA REGULATION OF DIAGNOSTIC TEST SYSTEMS

CDRH evaluates approximately 1000 new and upgraded diagnostic medical devices produced each year. These include products used in laboratories, in medical offices and clinics, and in home settings to test for various types of cancer, diabetes, genetic defects, cholesterol and blood sugar levels, pregnancy, and many other conditions.

Diagnostic test kits or systems, such as those used to measure the level of glucose in a person's blood or to detect the presence of alcohol or drugs of abuse, belong to a category of devices referred to as in vitro diagnostics. An in vitro diagnostic is a laboratory test which analyzes specimens taken from the body, such as blood, saliva or hair, and measures one specific chemical to see if it is present or measures how much is present. FDA regulates in vitro diagnostic test kits or systems as medical devices under the Federal Food, Drug and Cosmetic Act.

Our statutory authority broadly encompasses the test systems, including the diagnostic test itself, as well as ancillary equipment and collection devices, regardless of the various sites at which these products are used to collect and/or process specimens. This includes tests used in point-of-care facilities, such as doctors' offices and emergency rooms; hospital-based laboratories; freestanding laboratories; and in the home. It also includes tests provided through intermediary service providers.

As a practical matter, we focus our regulatory resources on the products themselves and on those products that are manufactured as self-contained kits or test systems for commercial distribution. In certain venues where specimen collection or point-of-care testing occurs, such as the workplace or hospitals, and free-standing laboratories, we defer to other authorities, such as the National Institute of Drug Abuse (NIDA). NIDA certifies drug testing laboratories and has provided specialized training for roughly 15,000 physicians on how properly to interpret drug testing results. We also rely upon agencies within the Department of Health and Human Services that are responsible for oversight of laboratories whose testing services

are subject to the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

For all medical devices, our role is to assess whether a product proposed for marketing is safe and effective for its intended use. The determination of whether a product is safe and effective is based on a variety of considerations which provide the Agency the basis for assessing the risks and benefits of the device. The intended use of the device is always a key element in such an assessment, because the risks associated with a device may vary depending on how and by whom it is going to be used. As I discuss in more detail below, this is particularly the case with in vitro diagnostic tests.

What is the guiding principle that underlies our evaluation of diagnostic testing devices? Very simply, it is to ensure that diagnostic test systems produce test results that are reliable, clinically meaningful, and provide sufficient information to assure the results can be interpreted accurately by the intended users. Each test system has a number of components, including the specimen test itself, criteria for use of test, specimen collection and handling, and reporting and interpretation of

results. The analysis of these various components and their relationship to each other all contribute to the assessment of whether the system is safe and effective for its intended use.

The first step in assessing whether a test system will be safe and effective for its intended use is having data that describes the accuracy of the specimen test itself. No in vitro diagnostic test yields perfect results. Sometimes the test is going to miss the presence of what it is supposed to be detecting. When this happens it is called a false negative. Sometimes it registers the presence of the substance even though it is not present. This result is called a false positive. Knowing the probability of false negatives and false positives, not just in abstract terms but why they occur and whether and how the rate varies among different populations, is absolutely essential in order to properly interpret the results and treat patients.

For example, let us look at the prostatic specific antigen test, which is designed to screen for prostate cancer. If this test detects the presence of cancer 95 percent of the time.

(sensitivity) when the disease is actually present, and detects the absence of the disease with the same high degree of accuracy

(specificity), what then does a positive result really mean? On its face, this sounds relatively straightforward to interpret. But in reality, the result does not necessarily mean that any one individual with a positive result has a high probability of having cancer. If you were to test a healthy group of relatively young men, in which the expected cancer prevalence is 5 in 10,000, you would end up with 490 false positives for every one true positive result. Some men who received false positive results probably had prostatic infections; others would be unexplained but most would be disease free. This example illustrates two points: that tests are fully interpretable only in the context of the prevalence of the disease or condition for which you are testing and confounding conditions; and that interpreting them correctly presents complex issues.

Companies make diagnostic tests for use in a variety of settings: sophisticated research and clinical laboratories; labs located in community hospitals and nursing homes; at the point of care by health professionals; and at home by consumers. These tests can be available on a prescription basis from health professionals or sold directly to consumers. Testing processes can entail patients undergoing tests on-site at a laboratory or having a

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specimen collected elsewhere, including at home, and shipped to a lab for testing. Test results can be stated as raw data or as conclusions drawn from the data, and they can be provided with or without professional interpretation or counseling. When we move out of the sophisticated laboratory to point-of-care facilities and home settings, where testing is either performed on-site or test specimens are collected, there are a host of issues that are inextricably linked to the fundamental question of whether a product works or not.

After we establish the accuracy of a particular test, we must evaluate data that indicates whether a test will perform acceptably in the particular setting and under the conditions contemplated by the intended use. Will the test be performed by individuals with appropriate levels of training, knowledge and proficiency? Will the system provide sufficient information on how to use the results to support its intended use, or its use in a particular setting? When collection is performed in one place and testing in another, is there a chain of custody to preserve the identity of test sample? Does the test sample deteriorate over time? Is the collection method easily understood? Can the user proficiently conduct the collection? If a test yields a

positive value, is confirmatory testing required? Is there a mechanism to provide access to confirmatory tests? Will the recipient of the test results know how to interpret them? If not, what assistance is available for such interpretation?

The full gamut of these questions does not apply to every test system or kit. The questions to which we seek answers depend heavily on how the product is to be used, for what purpose, and by whom. There are specific issues, for example, that pertain to all types of over-the-counter (OTC) diagnostic products. OTC products need adequate directions for use without the help or guidance of a health professional: directions that allow the lay public to understand the conditions under which use of the product is appropriate; directions on how to use the product properly; and directions that, for a diagnostic tool, enable the user to understand and act upon the information correctly. When we look at whether these principles have been met we need to consider the general state of knowledge in the community about the condition for which the test is being used, the likelihood of adverse events if someone uses the product without reading the directions or understanding the complexity involved in interpreting the results in various population groups.

Whether it is a new, breakthrough device like the Diasensor non-invasive glucose monitor or a test system to ascertain the presence of illegal drugs in humans, these are critical issues that must be resolved to ensure these test systems are safe and effective for their intended use. The reason for this is simple. People will act upon the results of these tests. Such actions can have significant, if not catastrophic consequences. Moreover, false positive and false negative results can have dire consequences that include delays in patients receiving needed medical treatment and patients receiving wrong, ineffective or unneeded treatments.

THE DIASENSOR GLUCOSE MONITOR

A product that illustrates the importance of assuring that a device works is the Diasensor glucose monitor. I know, Mr. Chairman, that you and other members of the Subcommittee will remember from your hearing last year that this is a novel, but still unproven, device which its inventors claim can be used to measure blood glucose levels in diabetics through intact skin of the forearm. FDA shares your interest and the interest of the

14 million Americans who suffer with diabetes in seeing a non-invasive glucose monitoring system available as soon as possible as an alternative to conventional finger stick testing.

If this product works as intended, it will be an incredible advance in the clinical management of diabetics. It could, for the first time, offer real vision-saving and even life-saving benefits through tight glucose control to millions of Americans who find the finger stick method of monitoring glucose unacceptable. Tight glucose control usually means one has to measure blood sugar 4 to 6 times a day and take 3 to 5 adjusted doses of insulin. The goal is to have average glucose levels close to that of nondiabetics.

Let me explain briefly a bit about the Diasensor system. The Diasensor machine is about the size of a typewriter. Hopefully, it can evolve in the future into a truly portable product. When patients use the current model, it must be individually calibrated and does not always give a reading. While this system would reduce the number of conventional finger sticks required on a daily basis, it would by no means eliminate them. Patients would need dozens of finger sticks during initial calibration of

the machine and more as part of monthly recalibrations. There also would be the need for confirmatory testing if the machine's readings were unexpectedly high or low or it could not give a reading on any given try.

The ability to achieve tight glucose control is dependent upon careful calibration of multiple daily insulin doses to the exact blood sugar levels. If glucose levels are not accurately measured, the results can be catastrophic. Incorrect insulin doses can cause insulin shock, with the potential for coma and seizures, or if one underdoses you can miss the whole intent and benefit of tight control -- close to normal blood sugar levels over the long term. So it should be obvious that the stakes of our making the right decision are very high indeed.

As with any medical device, we have to be sure that products work as they should and produce clinically dependable and useful results before they move into the clinical area and patients come to rely on them. When the manufacturer of the Diasensor first came to us in 1994, very limited clinical testing had been performed. In fact, only 6 patients -- all adults -- had been studied. The testing did not include episodes of very high or

very low blood sugar readings, readings which signal a dangerous situation for the patient. Factors such as age, and variability in skin color, thickness and condition, were not adequately explored, nor was the potential for a difference between patients being treated with insulin versus oral medication fully assessed. Finally, the testing was conducted using a prototype machine that collected but did not analyze patient data or produce actual readings. This analysis was done only at the company.

In mid-1995, after several meetings with the firm, we were told that the original study had been expanded to three clinical sites and a total of 85 patients. We carefully examined the data, but in the final analysis, the results were not encouraging. The company cited machine break-downs, calibration difficulties and a number of other problems that surfaced when the product was tested on a wider scale.

In the end, the company was able to provide data on only 8 of the 85 patients who had results the firm considered successful. And in these cases, the machine produced accurate readings less than half of the time. In those cases when readings were obtained, multiple differences were observed in

glucose levels when compared to results from back-up conventional testing.

Despite these very limited results, we agreed to present the study findings to an Agency advisory panel, as the company itself had been seeking. The company opted first for a meeting with staff from our Center which occurred in mid-November. A second meeting occurred this past January with me and senior agency officials. At that meeting, we informed the company that an open discussion of the testing results with our advisory panel was the best means for expediently reaching a decision on market approvability and the possible need for further data.

During review of the product by our advisory panel on February 26 of this year, there was strong agreement among representatives from the diabetic community and panel members on the need for a non-invasive method for monitoring glucose levels. With respect to the Diasensor product, however, the panel was concerned about the limited number of study cases. Although the company felt the results were acceptable, the panel concluded that the device's performance was totally unacceptable in at least one case and, even in the best cases, was too unreliable and

unpredictable. Panel members also felt that the Diasensor product should be tested in patients with low blood sugar levels to determine if the machine could provide accurate detection.

The panel review also produced an agreed upon course of action that entailed a broader study with a statistically valid sample. The need for such a study was perhaps best expressed by one of the advisory panel members. Dr. James Cooper, a physician and researcher with the Agency for Health Care Policy and Research and National Naval Medical Center, who has a daughter with diabetes, said:

"I do remain concerned about safety [of the device] and I don't think that the data that has been presented has established safety in the low blood sugar ranges, and I look forward to improvements and further data before the machine is marketed."

Following the advisory panel meeting, members of my staff reiterated their commitment to working cooperatively with the firm to design a mutually acceptable study protocol in an effort to facilitate the clinical investigation. This intermediate step

would allow the company to get the device into broader, but still limited, circulation in order to gain clinical experience, test public acceptance and recover the costs of development and production.

Regrettably, the company did not avail itself of this option. We have had no further substantive response from with the firm in the intervening months and have not received any new data or applications.

DRUGS OF ABUSE TESTING PRODUCTS

Let me say as both a father of three teenage children, and as a practicing emergency room physician who has seen first hand the ravages of illegal drug use, I understand very well the need to combat this public menace. The physical and psychological trauma it inflicts on casual users, addicts and their families can be devastating. Consequently, FDA is very sensitive to the need for readily available tests that can deliver accurate, meaningful results.

A critical first step to diagnosing and treating a person with a

collection with direct reporting of results to the home, and 2) advising on interpretation of the results. We did not find sufficient evidence, however, to support direct to consumer OTC marketing of the test system. It was the Agency's view that the test accuracy and interpretability of the results required, at least initially, the involvement of appropriate professionals.

As is the case for any in vitro diagnostic, in considering whether a product is safe and effective for use as an OTC test for drugs of abuse, the Agency considers the risks associated with such use. The impact of errors related to tests for drugs of abuse -- what can happen if someone relies on an inaccurate result or does not accurately interpret a result -- extends beyond purely physical medical consequences. Errors can mean either that a parent falsely believes that a child is using drugs, or that a parent falsely believes that a child is not using drugs. Such errors could cause unnecessary and harmful distress to the parents and child. Regardless of whether one characterizes such impacts on people's lives and well-being as social and ethical issues or as mental health issues, they are clearly foreseeable adverse consequences. Drug abuse is far too serious a matter to allow either situation to be commonplace.

In the final analysis, our market approval decisions are based on the safety and effectiveness of the device and its impact on public health.

SUMMARY

Mr. Chairman, we share the same goals of getting valuable new medical products into the hands of American consumers and health professionals as rapidly as possible. When the information is available on how properly to interpret medical test results, there are adequate directions for lay use, and we are satisfied that the tests can produce consistently accurate results, we believe the products should be made available for use directly by experience. Unfortunately, to date such systems for drugs of abuse have not been shown to meet acceptable levels of performance.

Our statutory and public health responsibilities compel us to make market approval decisions on the basis of evidence produced with high quality science. To settle for less would undermine the public trust and cause harm to scores of people throughout our nation.

This completes my prepared statement, Mr. Chairman. My colleagues and I would be pleased to respond to your questions.

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