DEPARTMENT OF HEALTH & HUMAN SERVICES

Melissa T. Skolfield

Assistant Secretary for Public Affairs
Phone: (202) 690-7850 Fax: (202) 690-5673

To: Jose Cerda

DDC

Fax: 456-7028 Phone: 456-5568

Date: 1/30 Total number of pages sent: _____

Comments:

As discussed - thanks - we'd like to go soon

200 Independence Avenue, S.W., Bldg. HHH, Room 647-D, Washington, D.C. 20201

MS

HHS NEWS DRAFT (Revised) #8

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P98- ,
FOR IMMEDIATE RELEASE
January , 1998

FOOD AND DRUG ADMINISTRATION
Print Media: 301-827-6242
Broadcast Media: 301-827-3434
Consumer Inquiries: 800-532-4440

FDA PROPOSES NEW POLICY FOR HOME DRUG ABUSE TEST KITS

The Food and Drug Administration today proposed an approach that will make it easier for manufacturers to market home drug abuse specimen collection kits, while still ensuring that test results are accurate and reliable. The proposal would implement a policy that FDA announced in February 1997.

The agency will now allow all test kits to be marketed without prior approval as long as they meet certain criteria. In the past, the agency has required that it approve such products prior to marketing unless they were used in workplace, insurance or other controlled settings. Because of the new, more flexible policy, the agency will apply it across the board, including tests used in workplace, insurance, and other controlled settings.

"The proposal balances the need to assure the accuracy of tests for drugs of abuse and the goal of simplifying the regulatory requirements so that these tests are made available to parents and others as soon as feasible," said William B. Schultz, FDA Deputy Commissioner for Policy.

Drug abuse specimen collection kits are sold directly to parents, employers, and insurance companies. The testing procedures require that a specimen from the body, such as urine, be collected

- More -

and mailed to a designated laboratory for testing for drugs of abuse such as marijuana, PCP, or cocaine. The results are then communicated back to the parent (or other person who sent in the test specimen) by phone by the product's manufacturer.

FDA is proposing that these specimen collection kits be allowed to be marketed without prior agency approval as long as they meet the following criteria:

1. The test used by the laboratory to identify the existence of illegal drugs must be approved or otherwise recognized by FDA as accurate and reliable for laboratory use. FDA has already cleared more than 200 laboratory urine tests to detect drugs of abuse. This will ensure the accuracy of the test.

2. The laboratory performing the test must be certified to do the necessary screening and confirmatory test. Some 70 laboratories certified by the Substance Abuse and Mental Health Services Administration would meet this requirement, as well as numerous laboratories certified by other agencies and organizations. This will ensure the qualifications of the laboratory to perform the test.

3. The collection kits must be accurately labeled so consumers can easily use them, and samples must be clearly identified to avoid mix-ups. Accurate labeling will enable the lay person to understand what drugs the test can and cannot identify, the time frame within which drugs can be detected, how to properly collect the test specimen and mail it to the laboratory, how to interpret test results, and how to obtain professional counseling, if needed.

- More -

The proposal would apply to tests used in the home, workplace, insurance and sports settings. It would not apply to tests used in connection with law enforcement purposes.

The proposal provides 90 days for public comment. During the comment period, FDA will hold a public hearing on the proposal. To give the marketplace time to adjust to any changes, the new regulatory scheme would become effective one year after the final regulation is published.

###

Note: HHS press releases are available on the World Wide Web at http://www.dhhs.gov.

Monday, January 5, 1998 THE PHILADELPHIA INQUIRER

drug test kit

The issue is tangled in questions of accuracy and bias against minorities.

Drug-abuse tests using hair samples meet with criticism

By Frank Greve
INQUIRER WASHINGTON BUREAU

WASHINGTON — An increasingly popular test for drug abuse, based on the examination of hair strands for traces of narcotics, identifies far more users than standard urine tests, federal authorities agree.

But many worry that hair-based tests sometimes finger innocent subjects, such as children of drug abusers or police assigned to narcotics details, who may be exposed to drugs without taking them.

There also is concern that hair tests turn up disproportionate numbers of non-Caucasians. That's because some researchers have found that traces of drugs last longer in thick, dark hair than thin, light-colored hair.

"The scope of drug testing is expanding dramatically, and with expanding hair testing, the likelihood of bias will increase, too. It's a major problem," warned J. Michael Walsh, executive director of the President's Drug Advisory Council under Presidents Ronald Reagan and George Bush and now a consultant to the urinalysis industry.

The potential effects are wide-ranging. About 20 million Americans undergo drug tests each year, according to the Institute for a Drug-Free Workplace, a Washington-based alliance of drug-test proponents. The majority are job applicants without rights of appeal.

The U.S. military is testing one million recruits and personnel a year. Pilots, bus drivers and truckers all are tested under Department of Transportation regulations, as are nuclear-reactor operators and others in safety-sensitive positions regulated by the Department of Energy.

Drug testing also has grown commonplace in child-custody cases, probation and parole monitoring and decisions about welfare and public-housing eligibility.

About 80 percent of firms that test for drugs now rely solely on urine, and only 2 percent use hair. One reason is the law: Urine tests have universal acceptance in courts, while skepticism about the science behind hair tests persists.

Another reason is politics: Employers, state regulators and courts want a green light from federal public-health experts before they go ahead with hair testing. And the regulators remain skeptical.

To date, "hair analysis for the presence of drugs is unproven, unsupported by scientific literature or controlled trials," Food and Drug Administration spokeswoman Sharon Snider said.

"Hair testing may turn out to have a complementary role in workplace testing," said Robert Stevenson, deputy director of the Workplace Programs Division of the federal Center for Substance Abuse Prevention, "but we have yet to resolve remaining questions about its fairness and the ability to interpret results consistently."

Still, hair tests are becoming more popular, partly because they turn up more drug users than urinalysis and counter some urine-testing shortcomings.

Also important, however, are sustained lobbying and marketing efforts by Psychemedics Corp. of Cambridge, Mass., which dominates the hair-testing market. A decade ago, Psychemedics' biggest customers were Nevada casinos. Today, they include Anheuser-Busch, the Federal Reserve System and General Motors.

Florida entrepreneur H. Wayne Huizenga, founder of Blockbuster Entertainment and owner of the Florida Marlins baseball team, gets much of the credit. He led a group of investors that bought Psychemedics out of debt in 1989. With Blockbuster as a mainstay customer, the firm grew to have more than 750 clients, according to its 1996 Securities and Exchange Commission filings.

In that year, Florida legislators, pushed by Huizenga's lobbyist, approved hair testing. The state law grandfathered Psychemedics' patented hair-testing process and set high hurdles for future competitors. By the end of 1997, according to company general counsel William Thistle, Psychemedics had 1,000 clients.

In Washington, Psychemedics has won strong support among congressional Republicans for federal endorsement of hair testing. (The company spent $200,000 on congressional lobbying last year, lobbying records show.) But federal health scientists remain skeptical.

Thistle and other Psychemedics executives say their patented methods are unbiased and produce no "false positives" from innocent drug exposure. If hair testing was to supplant urine testing for drugs, Thistle ventured in an interview, from three to 10 times more illicit drug users would be caught.

"Drug users wouldn't be employed," Thistle said flatly, "or they'd be in rehabilitation programs."

There's no question the hair test is a tougher cop. Using scheduled urine tests, the New York City Police Department caught one drug abuser in seven years, according to a published report. In the first 18 months of random hair tests by Psychemedics, more than 30 NYPD employees tested positive.

In another comparison, involving 774 job applicants to Steelcase Corp., a Michigan furniture-maker, urinalysis tests were 2.7 percent positive. Psychemedics hair tests on the same applicants were 18 percent positive.

But hair testing has its flaws. For one, it can't catch recent drug use the way urine tests can, because traces of ingested drugs take about five to seven days to show up in hair.

On the other hand, hair tests can detect drug use within a 90-day period. The procedure entails meticulous lab analyses of inch-and-a-half snippets taken from the crown of the head, close to the scalp.

"We can't see what's immediate," Psychemedics general counsel Thistle said, "and they can't see what's *not* immediate."

Hair and urine tests are complementary in another way, researchers say: Urine tests catch marijuana easily and cocaine and heroin with great difficulty. Hair tests do just the opposite.

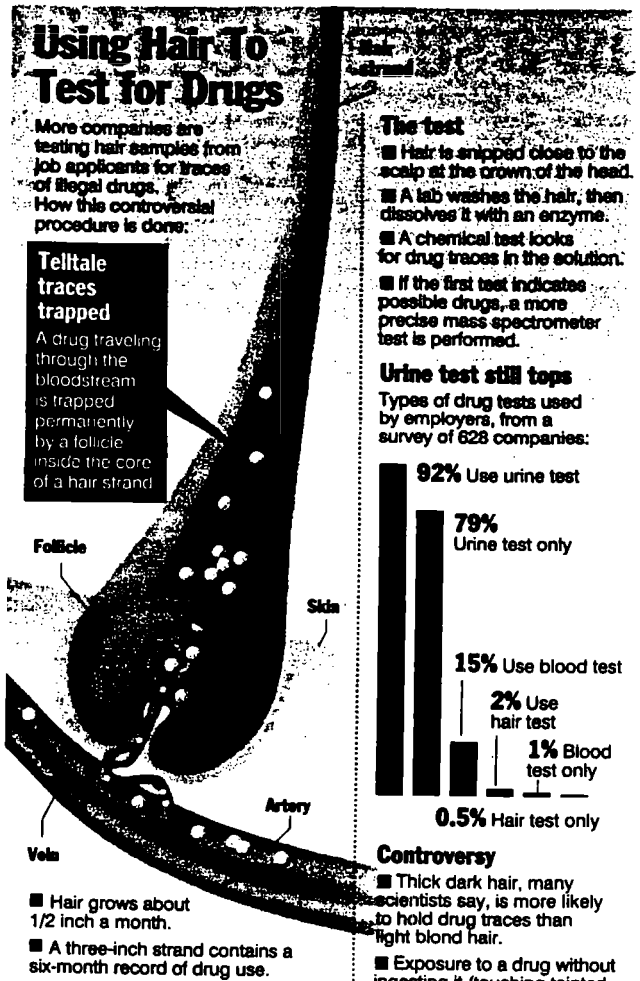
Using both tests seems logical, but, first, hair testing will have to overcome the doubts of such scientists as David Kidwell of the Naval Research Laboratory in Washington. He has found that young children of cocaine-consuming mothers often test positive for cocaine in hair tests.

Psychemedics insists that the children ingested the drug somehow, but Kidwell theorizes that the minute traces of cocaine necessary for a positive test adhered to the children's fingers or to their mothers' and were carried inside hair follicles in solution with sweat.

In another recent government-sponsored study, researchers at the University of Utah's Center for Human Toxicology injected piebald rats, which have patches of light and dark hair, with codeine, a mild opiate. Codeine concentrations in the rats' dark hair were 44 times higher than in their light hair.

In humans as well, "black hair seems to accumulate far more cocaine than light-brown or blond hair," said Edward J. Cone, chief of the chemistry and drug-metabolism section of the National Institute on Drug Abuse.

There is a "good possibility," Cone added, that "ethnic groups with dark hair are going to test positive for the drug more often."



Knight-Ridder Tribune / TIM GOHEEN

USA Today; 1-13-98

Beef with Oprah tests food speech laws

By Anita Manning
USA TODAY

A legal battle set to begin next week that pits talk show host Oprah Winfrey against a group of Texas cattle ranchers could test the validity of new laws in 13 states that ban malicious criticism of food.

The ranchers are suing Winfrey over a 1996 show during which an anti-meat activist suggested beef industry practices could promote mad cow disease.

Their suit will be the first test of "food disparagement" laws, which aim to protect farmers and ranchers from frightening and false claims about their products.

Supporters of the laws say it's only fair to require responsibility when it comes to saying things that could alarm the public unnecessarily and hurt the food industry.

Critics say the laws, enacted as consumers' concern over food safety is at an all-time high, are an effort to squelch debate on public health issues.

"What's more important than what we eat and what we drink?" asks Sandra Baron, executive director of the Libel Defense Resource Center. "Why would the public want those products, more than anything else in America, to be protected from criticism?"

She hasn't seen the Texas

By Chris Kasson, AP

Winfrey: Has been sued over show's mad cow discussion

statute, she says, but such laws generally are aimed at making it easier to bring lawsuits against those who make "statements that disparage fruits, vegetables, meat, poultry and fish, and make it harder to critique or criticize the means by which they're grown, transported, processed, distributed or sold."

But where, she asks, will it end? "I think there's an enormous risk that these laws will be applied to other categories of life," Baron says.

COVER STORY

John Stauber of the Center for Media & Democracy, co-author of *Mad Cow U.S.A.* (Common Courage Press, $24.95), agrees. "If the food industry can change libel laws, why not the chemical industry? Why not the auto industry?"

There probably are carmakers, he suggests, who would welcome "a car disparagement law."

That's not likely to happen, counters Washington, D.C., lawyer Dennis Johnson, who wrote the model on which the state statutes were based. The laws are meant to give farmers or ranchers legal recourse if someone knowingly makes a false claim about a food that causes consumers to refuse to buy it — and the grower to lose money, he says.

A food grower "has a one- or two-week window to do business. If the tomatoes or asparagus are ready to be picked, they gotta be picked," Johnson says. That doesn't apply to nonperishables. "Cars are going to be around awhile. The rule is designed for the farmer because he has one specific problem: that it is time sensitive."

The *Oprah* show that triggered the cattle ranchers' case aired on April 16, 1996. That was just a month after the British government had announced that 10 of its young citizens were dead or dying of a brain disease that might have been caused by eating beef from cows sick with mad cow disease, a similar dementia.

A guest on the show, Howard Lyman of the Humane Association of the U.S., compared bovine spongiform encephalopathy (BSE, the technical name for mad cow disease), with AIDS. He raised the possibility that a form of mad cow disease might exist in the USA, though the U.S. Department of Agriculture has never found a case.

Lyman pointed out that dead cows were ground up and used as a protein additive in cattle feed, a practice that is thought to have led to the emergence of BSE in Britain. The practice has since been banned.

On hearing this, Winfrey expressed alarm and, turning to her TV studio audience, said, "It has just stopped me cold from eating another burger."

The audience applauded but Wall Street did not. The price of cattle futures dropped almost immediately and stayed down for two months.

The effect on the market is a testament to the power and influence of Winfrey. But the beef industry has its own mus-

▶ Please see COVER STORY, next page

VIEWPOINTS

"These laws are a disaster for anyone who wants to exercise free speech rights regarding food safety issues. . . . It's completely un-American."

— John Stauber, Center for Media & Democracy

The bills do not say, "Thou shalt not speak ill of meat and milk. But if you make a statement relative to the safety of a product . . . be prepared to prove it."

— Steve Kopperud, American Feed Industry Association

Continued from 1D

COVER STORY

cle, and it didn't wait long to use it.

Texas rancher Paul F. Engler of Amarillo claimed he lost $6.7 million as a result of the *Oprah* show, and he, along with more than a dozen other beef ranchers, filed suit against Winfrey, Lyman, Harpo Productions and King World Productions, citing the Texas food disparagement law.

Since 1994, food disparagement laws also have been passed in Alabama, Arizona, Colorado, Florida, Georgia, Idaho, Louisiana, Mississippi, North Dakota, Ohio, Oklahoma and South Dakota. The laws grew out of a 1989 *60 Minutes* television report on the pesticide Alar. The report raised questions about the safety of apples, especially for children, Stauber says. "The apple industry sued because it said untruths were said about apples, and the industry suffered."

But the industry lost its suit, he says, because it couldn't convince the court the *60 Minutes* story was not true. "So the food industry decided to change U.S. libel law."

The Winfrey civil trial, which is expected to begin Tuesday in U.S. District Court, Amarillo, before Judge Mary Lou Robinson, is the first case brought under any of these state statutes and could signal whether they will stand up in court.

A second lawsuit has been filed, also in Amarillo, by a group of emu ranchers who charge that their business was slandered by an American Honda ad that ran from September 1996 through August 1997. The ad, meant to be funny, featured an emu rancher offering advice to a young man with the words: "Emu, Joe, it's the pork of the future." The emu ranchers say the ad "injured their good name."

"These laws," Stauber says, "are a disaster for anyone who wants to exercise free speech rights regarding food safety issues. . . . It's completely un-American."

And they may be unconstitutional, Baron says. "Most of the (food disparagement) bills have been written in such a way that they undermine basic elements of the old common law and libel law.

"I don't think they'll withstand constitutional scrutiny."

All parties involved have been placed under a strict court order not to speak publicly about any aspect of the trial. The National Cattlemen's Beef Association issued a statement saying it has no policy on the laws, but its members "are in support of efforts by agriculture and livestock producers to address economic havoc caused by sensational and untruthful reporting by the media."

Steve Kopperud, senior vice president of the American Feed Industry Association, says the laws give beleaguered farmers and ranchers a legal tool to use when "unfounded or capricious allegations" are made by "animal activists . . . trying to promote a political agenda."

The bills do not say, "Thou shalt not speak ill of meat and milk," Kopperud says, "but if you make a statement relative to the safety of a product and you knew or should have known the public statement is false, be prepared to prove it.

"There was never an intent to muzzle free speech, nor impinge on the First Amendment."

Some consumer advocates don't see it that way. "These laws are designed to create a chilling atmosphere so that no one should make any statement contrary to the orthodoxy of the food and cattle industry," says consumer activist Jeremy Rifkin of the Council for Economic Priorities and its Pure Food Campaign.

"The food industry is doing itself a disservice by lobbying for these laws," he says. "It shows they're not confident in these foods."

He acknowledges that sometimes food growers are injured by warnings raised by consumer advocates, and "sometimes we're wrong. But we all do have the right to have a robust debate around issues that concern the American consumer."

Caroline Smith DeWaal of the Center for Science in the Public Interest fears the laws could stifle public discussion about theoretical causes of foodborne disease.

"A lot of scientific study is about asking questions, postulating, developing theories about what is happening. If you have the facts, that's fine, but if you're working on something new, like mad cow disease or a new pathogen where we don't know the facts, it's important to be able to discuss ideas about how these might be getting into the food supply without fearing a lawsuit."

Lawyer Johnson says no one need fear legal action for debating or putting forth valid scientific theories.

"If someone sues under this bill, you're going to have to prove that this person knew the statement was false when he made it and that there are demonstrable damages," he says. "The burden is on the company or farmer or plaintiff who is suing to first show that the statement is false and that the person knew it was false."

The law is "not designed to chill free speech, it's not designed to stifle debate or to protect factory farming. It's designed to protect the small rancher so when we have a debate, the debate should be scientific or clearly identified as opinion."

But some experts say the laws already have muzzled public expression. Emory University law professor David J. Bederman says attorneys for media outlets call him every week concerned about stories to be aired or printed that could possibly run afoul of food disparagement laws.

"Stories get spiked every week," Bederman says. "The evil of these laws is that they do precisely what they were intended to do, which is to chill speech."

Three years ago Bederman attempted unsuccessfully to challenge Georgia's food disparagement law. The judge threw it out, saying a court case was unnecessary because no one had been sued under the statute.

The laws differ slightly from state to state, Bederman says, but all apply to public comments concerning perishable agricultural products and "they also agree that what they are trying to make actionable are false statements going to whether a food product is fit for human consumption. Clearly the plaintiffs in the Oprah case are saying that what Lyman said is that eating beef will give you mad cow disease."

He predicts that the ranchers' attorneys will claim Lyman implied that "a large percentage of the cattle population (in the USA) is already infected with BSE. What Lyman's lawyers will say is no, but that there is a risk. There's going to be a lot of science in this trial, in large part with both plaintiffs and defendants squaring off with what Lyman said."

The laws could have "very profound" constitutional implications, he says. "If it weren't so serious, it would be laughable."

Total Pages: 14

LRM ID: RJP8

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Wednesday, February 5, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO:	Legislative Liaison Officer - See Distribution below
FROM:	Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT:	Robert J. Pellicci
	PHONE: (202)395-4871 **FAX:** (202)395-6148
SUBJECT:	HHS Oversight Testimony on Policy Regarding Home Drug Test Kits
DEADLINE:	3:00 p.m. Wednesday, February 5, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Hearing is before the House Commerce Subcommittee on Oversight and Investigations on Thursday, February 6th. FDA Deputy Commissioner for Policy Bill Schultz is the Administration witness. **THIS IS A REVISED VERSION OF THE PREVIOUSLY CIRCULATED TESTIMONY. FDA Staff is scheduled to brief Commerce Committee staff at 4:00 p.m. TODAY.**
DISTRIBUTION LIST

AGENCIES:
26-COMMERCE - Michael A. Levitt - (202) 482-3151
61-JUSTICE - Andrew Fois - (202) 514-2141
76-National Economic Council - Sonyia Matthews - (202) 45/6-2174
89-Office of National Drug Control Policy - John Carnevale - (202) 39/5-6736

EOP:
Sally Katzen
Nancy A. Min
JENNINGS_C
Greg Simon
DRYE_E
Barry T. Clendenin
Richard J. Turman
Jim R. Esquea
JOHNATHAN Winer
Robert W. Schroeder
James C. Murr
Janet R. Forsgren
OMB LA
Dennis Burke

LRM ID: RJP8 SUBJECT: HHS Oversight Testimony on Policy Regarding Home Drug Test Kits

---

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the reponse of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this reponse sheet**

DRAFT
Feb. 4, 1997 -- 8:00 p.m.

TESTIMONY -- HOME DRUG TEST SYSTEMS

I. INTRODUCTION

Mr. Chairman, members of the Subcommittee. My name is William B. Schultz. I am the Deputy Commissioner for Policy at the Food and Drug Administration. Appearing with me today are Mary Pendergast, the Deputy Commissioner and Senior Advisor to the Commissioner, Dr. Bruce Burlington, the Director of the Center for Devices and Radiological Health, Joseph Levitt, the Deputy Director of the Center for Devices and Radiological Health, and Margaret Jane Porter, our Chief Counsel. We are here today to discuss FDA's regulation of products that can be used in the home and in other nonprofessional settings (over-the-counter (OTC)) to test for drugs of abuse.

Let me start by saying that the Agency has listened to the concerns you expressed regarding the regulation of drugs of abuse test systems. We have developed a common sense proposal that encompasses a level of regulation that takes into account the public health concerns associated with these test systems, but imposes the minimal level of regulation necessary to address those concerns. As outlined below, the approach we are proposing will be minimally disruptive for two reasons. First, it will eliminate the premarket approval or clearance requirements for drugs of abuse test systems that satisfy minimal criteria. Second, it provides for a long transition period to allow companies time to conform to the policy.

II. BACKGROUND.

Drugs of abuse test systems typically consist of a collection cup or other container for collecting a specimen, directions for use, packaging for storage or mailing, access to a laboratory testing service using an appropriate test, and access to test results and counseling. The consumer collects a specimen (such as urine) from the body and mails it to a laboratory, which performs the actual testing for the drugs or metabolites. The specimen usually is identified by a code number, which maintains confidentiality and protects against mix-ups. The test results are communicated back to the consumer. The consumer may or may not be asked to pay extra for confirmatory testing on those samples that screen positive.

On September 26, 1996, this Subcommittee held a hearing on home drugs of abuse test systems. Members of this Subcommittee raised several concerns about the Agency's regulation of home drugs of abuse test systems. First, you pointed to several internal Agency memoranda that suggested that some Agency employees held the view that concerns relating to the parent-child relationship or family discord may be relevant in making approval decisions on such test systems. FDA's evaluation of these home test systems must focus on scientific questions about whether the test is properly labeled and gives accurate results as well as any concerns about personal and public health. Concerns about the effect of a product on the parent-child relationship or family discord have no place in the Agency's determination as to whether that product meets the requirements of the Federal Food, Drug, and Cosmetic Act.

Second, members of the Subcommittee maintained that the Agency's categorization of these test systems as class III medical devices was unnecessarily stringent and that there are benefits to making these products available to parents. You also pointed out the inconsistency between the Agency's regulation of drugs of abuse test systems for use in the home setting and its policy of not actively regulating drugs of abuse test systems used in the workplace, insurance, sports, and law enforcement settings. After considering these issues, the Agency agrees that both of these arguments have merit.

Following the September 1996 hearing, we at FDA reevaluated our policies to determine the appropriate level of regulation for home drugs of abuse test systems. In fact, on October 3, 1996, we established an interim policy in which we agreed not to take regulatory action against persons distributing home drugs of abuse test systems so long as (1) the laboratory conducting the testing used an FDA-cleared test, (2) the testing laboratory met the Substance Abuse and Mental Health Services Administration (SAMHSA) or equivalent standards for performing such testing, and (3) the product had accurate labeling. A copy of the Agency's interim policy was provided to the Subcommittee and is appended to this testimony.

III. FDA AND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SUPPORT THE USE OF ACCURATE AND RELIABLE DRUGS OF ABUSE TESTING.

Before discussing the Agency's reevaluation of its policy on home drugs of abuse test systems, let me say that FDA does support the marketing of these test systems, provided they are accurate

and reliable. In fact, on January 21, 1997, we approved Dr. Brown's Home Drug Testing System, which meets all of the criteria under the Agency's original policy. Dr. Brown's test system, which was cleared through the PMA process, uses a drug screening urine test that has been cleared previously by FDA and incorporates confirmatory testing. Directions for use and for obtaining and interpreting results are included in the labeling to make it easier for parents to understand the test results. In addition, health representatives are available to convey the test results and provide information about the meaning of the test results and further medical referral if parents request additional help.

The Department of Health and Human Services supports accurate and reliable drugs of abuse testing. The Substance Abuse and Mental Health Services Administration (SAMHSA) certifies drug testing laboratories engaged in urine testing for federal agencies, identifies the tests that can be used, and trains physicians on the interpretation of drug testing results. Recognizing that the usefulness of testing for drugs of abuse resides in its accuracy and reliability, the National Institute on Drug Abuse (NIDA) sponsors a national program of research on basic methodology and clinical applicability of drug testing methods. In FY 1996, NIDA supported research at its own Intramural Research Laboratories, as well as six extramural research projects, to advance and refine its knowledge of the scientific basis and application of drugs of abuse testing. These projects encompass studies of the science of hair, saliva, and sweat testing and directly address scientific questions related to sensitivity, specificity, reproducibility, and reliability of the test methods, their relative strengths and weaknesses, and their applications -- the type of data that can form a basis for informed regulatory and approval decisions.

IV. THE AGENCY'S REEVALUATION OF ITS POLICY.

In reevaluating our policy on home drugs of abuse test systems, the Agency reached a number of conclusions. Our first principle is that these test systems must be accurate and reliable. Because there are more than 200 FDA-cleared urine tests for detecting drugs of abuse and hundreds of Federally certified laboratories capable of conducting this testing, accurate and reliable testing is available now.

Second, because there is value in having drugs of abuse test systems available for use in the home setting, we believe that it should be easier to get them onto the market for such use. We think we can accomplish this and still ensure that consumers get the right answer from these test systems.

Third, with respect to the inconsistency in our regulation of drugs of abuse test systems for use in the home setting and such systems used in the workplace, insurance, and sports settings, we have concluded that the same concerns about getting an accurate and reliable answer apply equally in all of those settings. Thus, we have concluded that FDA should apply the same rules to drugs of abuse test systems used in all nonprofessional settings. On this point, however, let me assure the Subcommittee that, in developing a regulatory approach, we have been sensitive to any potential disruption to the existing marketplace. We are seeking to ensure the reliability and accuracy of OTC drugs of abuse test systems, while minimizing the disruption to the marketplace, by

proposing reasonable criteria and a transition period for conformance with the criteria.

Fourth, we concluded that FDA should continue to exercise its enforcement discretion not to regulate testing for drugs of abuse in the law enforcement setting because there are other protections to assure sample integrity and test accuracy that are not available in the home, workplace, insurance, and sports settings. The additional protections include the use of rules of evidence in judicial proceedings and the representation of the accused (i.e., the person being tested) through the judicial process.

Finally, in reevaluating our policy on OTC drugs of abuse test systems, we determined that it is important to give the marketplace time to adjust to any changes in our regulatory approach. Therefore, the Agency is proposing to provide an adequate transition period for implementing its proposed policy. We recognize the importance of empowering parents to address the abuse of drugs by their children with reliable, accurate, and reasonably affordable detection capability. We must move aggressively, however, to assure parents of the reliability of such products for home use.

V. FDA'S PROPOSED POLICY.

FDA believes that three basic criteria are needed to assure that drugs of abuse test systems are safe and reliable for use in a nonprofessional setting. If these criteria are met, FDA proposes to

allow companies to market OTC drugs of abuse test systems without first obtaining premarket approval or clearance. The three criteria are as follows:

First, the laboratory test(s) must have been recognized by FDA as accurate and reliable for laboratory use. This will ensure that drugs of abuse test systems that are sold to consumers will be accurate and reliable. It would allow FDA to utilize the expertise of another Federal agency (e.g., SAMHSA) when that agency reaches a formal determination regarding the suitability of a particular test system.

Since FDA already has cleared more than 200 laboratory urine tests to detect drugs of abuse, companies would have a relatively easy route to marketing OTC drugs of abuse urine test systems. To the extent that FDA has cleared other types of laboratory tests to detect drugs of abuse, for example using sweat or saliva, companies seeking to market systems using those test also would have a relatively easy route to marketing. Once this new policy is implemented, however, companies seeking to market a system that uses a hair test or any other test that has not been recognized by FDA would need to establish the validity of the test with FDA prior to marketing. FDA's proposed policy implementation would allow ample time for companies to do this.

The second criterion for ensuring that drugs of abuse test systems are safe and reliable for use in a nonprofessional setting is that the laboratory performing the underlying test(s) must be able to reliably perform the necessary initial and confirmatory tests. This will ensure that testing is

performed by individuals with appropriate levels of training, knowledge and proficiency; that confirmatory testing is systematically performed on presumptively positive samples prior to issuance of the test results; and that assistance with interpretation of the test results and follow-up counseling is available to the consumer by a trained health professional, if requested.

We do not believe this criterion will create a barrier to marketing. There are 75 laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) that would meet the requirements set forth in the second criterion. In addition, there are thousands of laboratories certified in the area of toxicology testing under the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Many of these CLIA certified laboratories (e.g., the high complexity laboratories) also would have the appropriate types of controls.

The third criterion to ensure that drugs of abuse test systems are safe and reliable for use in a nonprofessional setting is that samples are adequately identified to avoid mix-ups and that the system is accurately labeled so that consumers can readily use it. This will ensure that the test system is accompanied by adequate directions that enable the lay person to: (a) understand the purpose of the test – i.e., what drugs can and cannot be identified in the specimen; (b) understand the detection period; and (c) properly collect the test specimen and mail it to the laboratory. The labeling also would provide information regarding interpretation of test results (e.g., false positives and false negatives) and how the consumer can contact a qualified health professional for assistance in that interpretation. FDA plans to develop guidance on issues such as how to

label the test system so that the consumer can understand the test results and to ensure that the specimen and the container remain properly identified and intact during mailing to the laboratory. The guidance also will address methods for providing consumers with adequate professional assistance in interpreting /understanding test results and providing counseling referrals, if needed. This third criterion will be easy to meet.

If the above three basic criteria are met, FDA proposes to allow companies to market OTC drugs of abuse test systems without first obtaining premarket approval or clearance, as was previously required. In other words, companies would not need to file a premarket approval application (PMA) or premarket notification (510(k)) before marketing these test systems. Drugs of abuse test systems for use in a nonprofessional setting, therefore, would be subject to very limited regulation.

Under FDA's proposal, FDA would consistently regulate: (a) home drugs of abuse test systems; and (b) drugs of abuse test systems that are used in the insurance, workplace, and sports settings. If the tests currently being marketed are reliable, the impact on testing provided in these latter venues is expected to be small for two reasons: First, FDA is proposing that the products be exempt from the premarket approval or clearance requirements of sections 515 and 510(k) (provided the conditions/criteria for assuring their accuracy and reliability are met); and second, if a manufacturer/distributor wants to market a test system for use in the insurance, workplace, or sports setting that does not rely on use of a laboratory test that has been recognized by FDA, the transition period prior to the effective date of the final rule will provide sufficient time to obtain

FDA recognition for any test that is accurate and reliable

VI. IMPLEMENTATION OF FDA'S PROPOSAL.

FDA intends to implement its proposed policy through notice-and-comment rulemaking. As part of the rulemaking process, following publication of the proposed rule, FDA will hold a public hearing to solicit additional public comment on its proposal. FDA will propose that the effective date for the final rule provide a reasonable transition period so that companies that need to submit their test to FDA for recognition will have sufficient time to collect the requisite data. The Agency expects to complete the notice and comment process and to have this new policy fully in place in approximately two years.

In the meantime, the Agency will not regulate drugs of abuse test systems used in the workplace, insurance, or sports settings. Because the Agency has not been actively regulating test systems used in these settings, we believe it is appropriate to provide notice and comment before changing its practice. The Agency also will not regulate the drugs of abuse hair test system that was the subject of the court settlement or OTC products that are substantially similar to that system. The Agency's October 3, 1996 interim policy will apply to all other test systems for use in the home setting. It will permit the marketing of home test systems that use FDA-cleared urine tests for drugs of abuse and home test systems that use any other FDA-cleared tests for drugs of abuse. Because there are more than 200 FDA-cleared tests for urine -- i.e., the

technology is there -- parents will have the benefit of a cleared/accurate test during the rulemaking.

According to Sunny Cloud's September 26, 1996 Congressional testimony, the urine testing portion of the Parent's Alert product is conducted by a SAMHSA certified laboratory. SAMHSA certified laboratories use only FDA-cleared urine tests. Therefore, the urine test system component of Ms. Cloud's product should meet the requirements set forth in our interim policy.[1]

VII. CONCLUSION.

As a consumer protection agency, FDA's most important role in overseeing the regulation of diagnostic tests is to assure that they provide the right answers. This consideration is critical for drugs of abuse test systems sold to consumers. FDA believes that its proposed regulatory approach would accomplish this goal because it focuses on the accuracy and reliability of the underlying test(s). At the same time, FDA's proposal would significantly ease the requirements

---

[1] We understand that a point of care saliva test also is included in the Parent's Alert product. The Agency's policy on OTC test systems for drugs of abuse does not apply to point of care tests. Point of care tests have always required FDA approval prior to marketing. FDA does not plan to change that policy. However, in an October 3, 1996 letter to Ms. Cloud, the Agency committed to not taking regulatory action against the Parent's Alert product until a policy on home test systems was in place. The Agency will honor that commitment and not take action against the point of care test in the Parent's Alert product until its proposed policy is in place.

that must be met in order to sell these products. Moreover, because it would provide an adequate transition period, there should be no interruption of the availability of test systems for use in nonprofessional settings.

Gay 'marriage' issue roils Hawaii primary

Mink survives; state senator loses

HONOLULU (AP) — Rep. Patsy Mink, who recently ran an open-letter-to-voters ad in Honolulu's two daily newspapers stating her opposition to same-sex "marriage," beat back a challenge from a fellow Democrat in Saturday's voting.

Mrs. Mink had held a comfortable lead in the polls, but state Sen. Robert Bunda's challenge was considered her biggest primary threat since she won election six years ago.

With the same-sex "marriage" case in state court emerging as a campaign issue, Mrs. Mink said she had voted against the Defense of Marriage Act because she believes it is unconstitutional.

The act — which codifies marriage under federal law as a union between a man and a woman and empowers states not to have to recognize other states' sanctioning of homosexual "marriages" — nonetheless won congressional approval and was signed into law early yesterday by President Clinton.

Mr. Bunda had charged that Mrs. Mink was trying to play both sides of the issue when she took out the ad this past week. Mrs. Mink claimed her position was being distorted.

In early returns, Mrs. Mink was leading Mr. Bunda, her main competitor, by a 2-1 margin. She will face Republican Tom Pico Jr., a Honolulu lawyer, in November.

In a legislative race also closely watched because of the homosexual "marriage" issue, Honolulu contractor Norman Sakamoto easily defeated state Sen. Rey Graulty, a fellow Democrat who had blocked a state Senate vote on a proposed state constitutional amendment to ban couples of the same sex from marrying. He has no GOP opposition.

The Hawaii Supreme Court has ruled that the state's ban on same-sex "marriage" is unconstitutional unless the state can show a compelling reason for continuing the ban. The trial, in which the state is trying to demonstrate a compelling reason, ended Friday in state court, and a ruling is expected in November.

In other voting Saturday, Honolulu Mayor Jeremy Harris was leading in his bid for re-election and Rep. Neil Abercrombie, a liberal Democrat, won his party's nomination for a fourth term.

Mr. Abercrombie's victory sets up a November rematch with unopposed Republican Orson Swindle, a national spokesman for Ross Perot's 1992 presidential campaign.

The Washington Times
MONDAY, SEPTEMBER 23, 1996 ★

House committee will investigate delay in approving drug-test kits

ASSOCIATED PRESS

As Republicans continue to blame President Clinton for rising teen-age drug use, a House panel will soon investigate whether federal regulators are blocking home drug tests parents could use on their children.

"Having a drug-testing kit at home could be the best tool ever for a kid to 'just say no,' but the bureaucrats at the FDA don't want Americans to have it," said Rep. Thomas J. Bliley Jr., Virginia Republican and chairman of the House Commerce Committee.

Lawrence Bachorik, an FDA spokesman, said the issue was not whether drug tests should be available to parents but if they are reliable and accurate.

"The FDA is doing what it always does," Mr. Bachorik said. "It is making sure these devices will work and will be accurate."

Mr. Bliley said the hearing this Thursday will shed light on the FDA's "quiet battle" to keep specimen-collection kits out of parents' hands. The hearing will be conducted by the Commerce Committee's subcommitte on oversight and investigations.

According to Mr. Bliley's committee, the FDA has tried on three separate occasions during the past three years to place the kits under the same level of scrutiny and regulation as heart pacemakers. The FDA classification for heart pacemakers is known as Class III.

Rep. Thomas J. Bliley Jr.

According to a memo of a December 1995 meeting between the FDA and makers of the kits, the agency "has decided that over-the-counter drug tests for teen-agers . . . require pre-market approval."

"This is a deliberate policy decision that has been made at a high level within the agency and is based on perceived risks associated with the possibility of misuse of the results of such tests (both correct and incorrect results)," the memo said.

"[The] FDA is concerned about issues such as anonymity, confidentiality, coercion and family discord," the memo said.

The Associated Press obtained a copy of the memo.

Sunny Cloud, a 47-year-old housewife in Marietta, Ga., has been fighting the FDA for nearly two years over a drug-test kit she has sold to more than 1,000 other parents.

She developed the kit and started Parents Alert Inc. after she came home unexpectedly one day in 1993 and caught her 15-year-old son smoking marijuana in the living room. Her son, who is now 19 and in college, told her he had been smoking the drug since the eighth grade.

Mrs. Cloud, who is expected to testify at the hearing, says the FDA contends the $40 kit, which contains a urine collection cup, jar and mailer, is a Class III medical device. She says the FDA wants her to submit the kit for pre-market approval so the agency can monitor it. So far, she has refused.

"They gave us a warning letter. We questioned it. They have no shut us down," Mrs. Cloud said

Illinois city's battle over desegregation blamed for tax rise

Rockford homeowners feel the bite

ROCKFORD, Ill. (AP) — For the past two decades or so, this city has waged an expensive war with itself.

In a battle that began in 1970, the city has spent more than $70 million so far on carrying out desegregation as well as fighting it. Local officials blame the costs for a sharp rise in property taxes that has made it more difficult to attract people to the city, about 80 miles west of Chicago.

"We loved Rockford," said Terri Watson, whose husband was transferred to the area recently. "The homes . . . seemed to have a lot of class, with nice, established neighborhoods, wooded areas, things we like. But the school issue and the tax issue made us choose a town outside of Rockford."

During the dispute, shifting tides of public opinion steered the city on a zigzag course: One school board would agree to comply with a desegregation plan, only to be replaced at the next election by new members who decided to resist.

Even now, after 26 years of fighting, the school board is still unsatisfied with the most recent court-ordered desegregation plan, which some members say will cost too much to implement.

In 1994, a federal court found blacks and Hispanics, who combined make up 30 percent of the students in the district, attended inferior schools, were unfairly placed on slower tracks and were taught by educators who were disproportionately white.

Board member Patti Delugas bristles at court-ordered steps such as hiring an administrative secretary at a starting salary higher than that paid to teachers. "There is no negotiation," she said. "The orders come down."

And the taxes go up.

From 1991 to 1996, the property taxes on a typical $100,000 home rose 31.5 percent, from $2,527 to $3,324.

The increase is surprising because the Rockford economy is relatively healthy, with an aerospace company and a machinery manufacturer as the top private employers. The tax base of the city, which has 143,000 residents, increased from $954 million in 1989 to $1.3 billion in 1993.

"Ninety-seven percent of the reason the taxes are high — and they are — is desegregation," said Diane Voneida, city director of community development.

Last year, 15,000 of about 60,000 property owners in the school district filed their taxes under protest.

"Property taxes are definitely an issue," real estate agent Jan Mansfield said. "We see an attempt made by newcomers to hit the outskirts to avoid the actual Rockford market if they can."

Residential sales have dipped 5 percent from a year ago, and gains in residential housing values have slowed to 2 percent so far this year from about 5 percent a year ago, she said.

"Some will move," said Roy Dawson, president of the local NAACP and a strong supporter of the desegregation effort. "But you have to right that wrong."

School desegregation has a long, difficult history in Rockford. In 1981, a federal lawsuit filed in 1970 was dismissed without agreement on a desegregation plan. The current litigation was filed in 1989. Five years later, a federal court found intentional discrimination in 10 areas.

Next fall, the district plans to implement a program that would give parents a "controlled choice" in selecting schools. But even this month, the seven-member school board challenged the desegregation spending plan, and officials said the school system might shut down for lack of money.

Mayor Charles Box said he has urged the elected school board to "get behind the court order and comply with it."

City officials express confidence in the long-term future, pointing to the National Association of Home Builders' Housing Opportunity Index, which last month ranked Rockford the most affordable city in the nation.

But for newcomers like Mrs. Watson, short-range worries outweigh the long-range optimism.

The Watsons paid slightly more to build a house in Roscoe, just outside Rockford. But they're paying less than the approximately $6,000 annual tax bill levied in Rockford on houses in the $200,000 range. Concerns about resale value and uncertainty about their 8-year-old's schooling convinced them they made the right choice.

"What we didn't like, is there's no end in sight on this desegregation issue," she said. "It's been going on for years. . . . We're not going to chance that with our child."

The Washington Times
MONDAY, SEPTEMBER 23, 1996 ★

The Washington Post

DATE: 1-22-97

PAGE: A1

Kit for Home Drug-Testing Is Approved

Shalala Calls Product An Option for Parents

By John Schwartz
Washington Post Staff Writer

Parents who suspect their children are using drugs soon will be able to use a government-approved home drug-testing kit.

The Food and Drug Administration yesterday gave the first approval to a drug test available without a prescription. The new kit, "Dr. Brown's Home Drug Testing System," tests urine for the presence of marijuana, PCP, amphetamines, cocaine, heroin, codeine and morphine.

The new product "gives parents another option to consider to help ensure that their children remain drug-free," said Donna E. Shalala, secretary of the Health and Human Services Department, in a statement yesterday. Shalala noted that parents should talk with their children about drug abuse directly.

"The Clinton administration has zero tolerance for illicit drugs," Shalala said. The approval comes four months after the FDA and the Clinton administration came under fire in Congress over the agency's attempts to restrict the distribution of a similar product.

The "Dr. Brown" of the test kit name is J. Theodore Brown, a clinical psychologist with a background in treating substance abuse. Brown, who formed Silver Spring-based Personal Health and Hygiene Inc. to market the product, said yesterday that he hoped to have the kits on the market within six weeks and expected to charge around $30. Users should expect results from one to three days after the lab receives the sample, Brown said.

"It's not like we invented the airplane or something, but I think it's a meaningful product," Brown said. "I think it's good for America."

Privacy advocates, however, have long said the easy availability of a drug test kit could violate the rights of those tested, whether in schools or the home.

Steven B. Duke of Yale Law School said he was "a little concerned about whether it's going to be employed in schools and other places." But he added that "one can hardly object categorically to its availability within the family. . . . Parents have always been able to snoop on their children, and this gives them another means of doing so." Still, Duke said, the availability of such a test "doesn't mean necessarily that it should be employed."

Brown said his company has addressed those concerns. "We do everything we possibly can in the instructions and all of the materials we will be providing to discourage any coerciveness or punitive behavior."

The new system is not a home diagnostic kit like those commonly available for pregnancy testing. Instead, it is a home collection kit, with a cup for collecting the sample and two plastic tubes with screw-on lids for shipping the sample to a laboratory for analysis. The tubes are protected in a plastic pouch and bubble wrap.

Once the testing laboratory receives the samples, it will screen them for drugs and then perform confirmation testing to minimize errors. The lab will then transmit results to Personal Hygiene, which is setting up a telephone results center for users to call.

The testing center will be staffed by phone representatives who not only will give the results of the test but also will provide information about interpreting the results and the potential for mistakes. The center also will offer referrals for drug abuse counseling if requested. Each sample has an identifying number so that users can phone the company, give the number and receive the results anonymously if desired.

Brown and the FDA did not release the name of the laboratory being used by the company, but the agency noted that the lab is certified by the Substance Abuse and Mental Health Services Administration, the College of American Pathologists and the Health Care Financing Administration.

Four months ago, the issue of home drug testing erupted in Congress. The FDA moved to block distribution of a test kit produced by a Georgia-based company, Parents Alert. Entrepreneur Sunny Cloud distributed the test without going through the FDA approval process that Brown completed.

The agency warned Cloud to stop distributing the test until it could prove the test was accurate and the accompanying procedures well thought out; lawmakers and commentators decried the FDA move as evidence of the overprotective "nanny state." The FDA allowed the kits to be sold until it could develop a policy for considering applications for the kits.

Brown had applied for approval of his device in February 1996, well before the Parents Alert flap. "The process that we had to go through with the Food and Drug Administration definitely improved the product," Brown said, though he added that it was "quite rigorous, to say the least."

Rep. Richard Burr (R-N.C.), who criticized the FDA for its position on Parents Alert last year, said he was "delighted" with the news of the approval. But he asked "when will the FDA set a permanent policy for the approval of home testing kits?"

FDA spokesman James O'Hara said yesterday that the agency was "in the final stages of reviewing our policy." Rep. Thomas J. Bliley Jr. (R-Va.) called for hearings in February on the FDA's handling of home test kit approvals.

A professional drug tester said yesterday that the FDA had been right to demand scientific rigor from marketers of any home test kits. Joseph J. Fortuna of Lorton-based Chemical Detection Services said that parents can benefit from professional help when it comes to drug testing. Simple drug tests are generally reliable, Fortuna said, but should not be mistaken for true confirmation of drug use.

"If they look at it as the final test without any other confirmational test, there could be problems" of misinterpretation by parents, Fortuna said. Absolute confirmation of drug abuse only comes with in-depth analysis and interpretation by professionals, he said.

Cloud called news of her competitor's approval "wonderful." The regulators, she said, "obviously realize that this is the thing to do—we parents need all the help we can get."

"I am so proud that Parents Alert was able to act as a catalyst to get this going," Cloud said.

The Washington Times
DATE: 1-22-97
PAGE: B-7

FDA OKs kits for drug testing at home

By Samuel Goldreich
THE WASHINGTON TIMES

The Food and Drug Administration has approved the first nonprescription home drug-testing kit, which a Silver Spring firm plans to market to parents in drugstores.

Personal Health & Hygiene Inc., a private company, won the nod four months after Republicans in Congress blasted the FDA for acting like a national "nanny" by threatening prosecution of a Georgia housewife who sold a similar urine-testing kit without seeking agency clearance.

"They submitted an application with the supporting data in February 1996, and we approved it," said Jim O'Hara, an FDA spokesman.

The test, Dr. Brown's Home Drug Testing System, passed the FDA's medical devices screening process. The kit will detect the presence of marijuana, PCP, amphetamines, cocaine, heroin, codeine and morphine.

"The approval of this test gives parents another option to consider to help ensure that their children remain drug-free," said Donna E. Shalala, the secretary of health and human services.

Two others began selling similar products based on kits made available to employers and police agencies, prompting warnings from the FDA in 1995 that mass marketing required separate approval.

The FDA dropped its threatened action against Psychemedics Corp. when the Cambridge, Mass., company petitioned a federal court for relief. Housewife Sunny Cloud prevailed in October when the agency adopted an interim policy allowing such kits a week after her case became a national election issue during congressional hearings.

The policy says home drug tests may be marketed without FDA approval if they meet three conditions: The laboratory conducting the testing uses FDA-cleared tests; the laboratory is certified by the Substance Abuse and Mental Health Services Administration; and the product has accurate labeling.

The Dr. Brown kit meets those standards. It has a tube for urine collection, storage and mail packaging, a laboratory testing service and results, and referral services. To obtain results, users call a toll-free number and identify themselves by kit identification numbers.

Date: 01/21/97 Time: 17:28
HFDA approves home drug abuse test

WASHINGTON (AP) An over-the-counter test that lets parents check their children for drug use won Food and Drug Administration approval Tuesday, the first in the controversial field to do so.

Dr. Brown's Home Drug Testing System can detect cocaine, heroin, marijuana, PCP, amphetamines and other drugs in a mail-in urine sample.

The approval comes four months after the Clinton administration battled congressional charges that, in the face of escalating teen-age drug use, the FDA was blocking parents' efforts to test their children.

``The approval of this test gives parents another option to consider to help ensure that their children remain drug-free,'' said Health and Human Services Secretary Donna Shalala.

But use of the test is not restricted to parents, leaving it open for anyone to use. Test creator J. Theodore Brown Jr., a Silver Spring, Md., psychologist, expects it to be widely used by relatives of people fresh out of drug treatment, who are ripe for relapse without the deterrent of daily testing.

``It's therapeutic, nonpunitive and comparatively inexpensive,'' Brown said. ``This system would be something to empower the individual citizen.''

Last September, critics attacked the FDA for cracking down on an Atlanta woman who sold 1,000 home drug test kits without the agency's knowledge. The FDA said it had no way to know if her test was accurate, but congressional critics argued the agency merely was keeping from parents the same tests employers can use and charged that it has no clear policy to say when home tests for any disease are ready for laymen.

The FDA relented, letting home drug tests be sold temporarily while it re-evaluates how strictly such kits should be regulated.

Before the fray erupted, Brown in January 1996 asked the FDA to approve his home drug test. On Tuesday the FDA wrote Brown that his kit was the first to win government approval, giving him a marketing advantage over unapproved competitors sold during the agency's temporary amnesty.

``Although parents can breathe a sigh of relief today, the FDA has neglected to lay out a strategy for approving any other home testing kits,'' said critic Rep. Richard Burr, R-N.C., who called on the FDA Tuesday to settle the issue for the growing home-testing industry.

Brown said his kits will reach drugstores within six weeks and will cost less than $30.

Consumers will mail a urine sample in a protective, tamper-proof package to a government-certified laboratory. The lab uses FDA-approved drug tests, doing confirmatory retesting to minimize false results. One to three days later, consumers using a code number to preserve anonymity call an 800 number for the results.

Every drug test can miss abuse, when, for example, the urine is sampled too late. It also can falsely signal abuse if, say, the person ate certain foods that mimic the metabolites drug tests measure.

Brown's Personal Health and Hygiene Inc. will explain those limitations before giving callers their test results, and will offer referrals for drug abuse counseling or medical care.
APNP-01-21-97 1733EST

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

Carol H. Rasco
Assistant to the President
for Domestic Policy

Los Angeles Times

DATE: 10-8-96
PAGE: A-4

Clinton, FDA Criticized for Limiting Sale of Drug Tests

■ Health: Kits designed for home use are marketed by a Georgia woman, who refuses to submit data for approval. She and GOP cite parents' rights.

By MELISSA HEALY
TIMES STAFF WRITER

WASHINGTON—The Clinton administration, already stung by Republican charges of complacency in the face of rising drug use, has come under a fresh round of fire for restricting sale of home drug tests designed for parents to administer to their children.

Although GOP presidential candidate Bob Dole has been responsible for most of the drug policy criticism so far, the latest salvos are coming from Republican lawmakers who accuse the Food and Drug Administration of denying parents a potent weapon for fighting drug abuse in the home.

Led by House Commerce Committee Chairman Thomas J. Bliley Jr. (R-Va.), Republicans cite the FDA's actions as a prime example of what they characterize as a heavy-handed approach to regulation in an area where they believe parents' rights should be paramount.

At issue is whether "Parents' Alert," a home drug test marketed by a one-woman firm in Georgia, should be commercially available without going through a lengthy FDA approval process.

Priced at $40, the test kit consists of a widely used, FDA-approved, urine-collection cup, an envelope for mailing it to a government-approved laboratory and a pamphlet explaining the meaning of the lab results, along with phone numbers of drug-abuse hotlines in the event of a positive result.

Since the mid-1980s, the FDA has treated home drug test kits as "Class 3 Medical Devices." The designation puts Parents' Alert in the category of medical devices presenting the most serious risks if misused by the intended consumers, in this case, parents.

Other Class 3 devices include X-ray machines (which are intended for use by trained medical clinicians), cardiac pacemakers, extended-wear contact lenses and anti-snoring devices placed in the mouth during sleep.

So far, the FDA has not approved an application for an over-the-counter test for illegal drugs, although in one case it approved the marketing of a home drug test by a physician's prescription.

In deliberations on past submissions and in a recent Capitol Hill hearing, FDA regulators have questioned whether parents, acting without a physician's assistance, can understand the results of a test and respond appropriately. Of particular concern is the possibility of a false-positive result, they said.

In notes taken during a 1995 meeting with FDA attorneys, one firm seeking the agency's approval for a home test cited the agency's concern that such tests could cause "family discord" and subject children to "coercion" from their parents.

Sunny Cloud, a Marietta, Ga., parent who began marketing Parents' Alert after she caught her son smoking marijuana three years ago, never has applied for FDA approval of the test. Defying the agency's warnings that she could be held liable for steep civil penalties if she continues to market the tests for home use, Cloud said that she has sold slightly more than 1,000 of the kits. Bliley's office, citing provisions in criminal law, said that Cloud could be subject to a year in prison for every kit she has sold.

Cloud, however, is adamant. Arguing that a virtually identical drug-test package has been used by major employers for years, she has refused to subject her product to the FDA approval process and is still selling the kits by mail order from her home.

Government regulators and their allies see the case as a commercial dispute started by a businesswoman who does not want to submit her product to government scrutiny intended to ensure its safety, reliability and benefit to consumers.

Cloud says that the dispute involves government regulation that is arrogant, bureaucratic and hostile to small businesses. But she contends that it involves a grander principle as well: the right of parents to rear their children free of government interference. Cloud is furious that the FDA would deny parents a tool for managing their children's affairs that corporations routinely use in managing their work forces.

"FDA was concerned about these tools because they said it would cause divisiveness and friction within the family," Cloud said in an interview. "Well, I didn't realize that FDA had powers that could extend into the living room. I thought parents could make those choices. My personal opinion is that [FDA's stated concern on the] efficacy of the test is really a red herring. This is about parents' rights."

The wrangle over Parents' Alert already has caused the FDA to modify its initial position and initiate a "review" of its policy that most home drug tests should be regulated as Class 3 devices. But in a recent hearing before Bliley's committee, agency regulators defended their earlier statements that parents might not have the ability to respond appropriately to test results.

For President Clinton, the issue presents a potentially tricky political dilemma. It pits the president's popular advocacy of "family-friendly" initiatives against the arguments of a regulatory agency charged with protecting consumers from the marketing of drugs and devices whose safety or effectiveness have not been proved.

In recent months, Clinton has championed a number of initiatives—from the V-chip to school uniforms—designed to help parents cope with society's negative influences on their children. Many would consider support for a home drug test consistent with the president's past actions. The FDA's decision to maintain regulatory obstacles to sale of the test kits—all with the administration's implicit assent—strikes some as a bad political move in the crucial final weeks of his reelection campaign.

Already, cracks in the administration's unity have appeared: In an interview last week, Gen. Barry McCaffrey, director of the White House Office of National Drug Control Policy, said that he believes families "ought to make up their own minds" about whether the test is right for them.

"We have home pregnancy tests, home AIDS tests," McCaffrey told the Christian Science Monitor. "Maybe we need a home drug test."

McCaffrey's comments prompted Bliley to fire yet another shot across the Clinton administration's bow.

"Parents might disagree whether to test their own children, but that's a decision that ought to be made by them—not by Washington bureaucrats," Bliley said. "Maybe Gen. McCaffrey can get on the phone with the Food and Drug Administration and give them the same message."

Cont'd

Los Angeles Times

DATE: 10/8/96
PAGE: A1

Rep. Waters Releases Data She Says Links CIA to Drug Trade

By RALPH FRAMMOLINO
and VICTOR MERINA
TIMES STAFF WRITERS

Hoping to bolster allegations of CIA complicity in South-Central Los Angeles' crack epidemic, U.S. Rep. Maxine Waters (D-Los Angeles) released documents Monday that she says provide further evidence of links between the spy agency and city's drug trade during the mid-1980s.

Waters said the documents—including a Los Angeles County sheriff's report—show that one suspected player in the South-Central cocaine network told authorities during a 1986 drug raid that he "worked with the CIA." The documents also state that evidence seized from his Mission Viejo home included military films and training manuals—material Waters said proves the ring had ties to the Contra army in Nicaragua.

Waters said, moreover, that the documents discovered during the raid have disappeared from the Sheriff's Department or are being hidden by the department, a contention disputed by Sheriff Sherman Block on Monday.

For the most part, the information released by Waters surfaced in 1990 during the trial of seven Los Angeles County sheriff's narcotics officers accused of skimming money and drugs during undercover operations. At that time, The Times and other news media recounted the statements of the man who claimed to work for the CIA and an allegation that documents were taken from the Sheriff's Department by federal authorities. Those statements were contained in a motion by one of the deputies' attorneys.

But with the controversy surrounding a series of articles by the San Jose Mercury News suggesting that the CIA was behind Los Angeles' crack explosion, even previously disclosed information has been given new life.

The Mercury News attributed the crack's spread in Los Angeles to a fund-raising effort by the Nicaraguan Contras, who allegedly used drug riches to arm their CIA-backed rebel armies. At the center of the effort, according to the newspaper, was a Nicaraguan expatriate named Oscar Danilo Blandon and a South-Central dealer named "Freeway" Ricky Ross, who is awaiting sentencing on drug charges in San Diego federal court.

Although the CIA has denied involvement with the cocaine sales—and the series has been criticized for failing to offer evidence of a CIA link to the traffickers' efforts—the stories have generated immense interest and outrage, fueled by Waters.

During her news conference, Waters responded to skepticism of the series by releasing documents aimed at supporting the notion of CIA involvement.

"I think this is further evidence of the fact that this ring existed, and they have said in more than one way and more than one time that they were connected to the CIA," Waters told the crowded gathering of reporters.

Standing at Central Avenue and Adams Boulevard, Waters pointed to a check-cashing outlet that she said was once a bar where Blandon sold 10 kilograms of cocaine a week during the 1980s, part of a far-flung operation that targeted the black community by employing 200 people and 14 locations to distribute the drugs.

"It is important to understand that law enforcement officials knew that Blandon and his operation sold cocaine mainly to blacks in the South-Central Los Angeles area," she said.

Waters also distributed copies of a search warrant affidavit and sheriff's reports about an Oct. 27, 1986, police raid on the Blandon operation, which led to no charges being filed.

Waters said she obtained the reports by showing up unannounced last week at the Sheriff's Department and demanding copies.

One report shows that a location police raided was the home of former Laguna Beach Police Officer Ronald Lister, then a private security consultant. Waters said that in a jailhouse interview, Ross identified Lister as a member of the Danilo ring who not only sold drugs but also provided Uzis, AK-47s, telephone scramblers and money counters for street gangs peddling crack.

According to a report by one deputy involved in the raid, Lister warned that "he had dealings in South America and worked with the CIA and added that his friends in Washington weren't going to like what was going on."

Waters also questioned Monday why materials taken from Lister's home—including the military training films and manuals—were not returned to him.

"These were the training films of the [Nicaraguan Democratic Force], this is the army of the Contras," she said, adding that the "evidence is somehow being held on to by the L.A. County sheriff's."

Reacting to Waters' suggestion of a cover-up in the Sheriff's Department, Block told reporters during a news conference that evidence taken from Lister's home, such as television monitors and ammunition, was used by the department. Other materials, including the training films and miscellaneous papers, were destroyed pursuant to department policy and state law because no charges were filed.

"There has been no effort to conceal anything," Block said.

Asked whether the CIA took any of the evidence seized in the raid, Block responded: "I'm saying it categorically, absolutely" that no one in the CIA removed the materials.

Block also said that when names of those with suspected links to the CIA surfaced during the investigation, a list was sent to the intelligence agency. According to Block, only one name was recognized and "all they said was they knew he was a cocaine dealer." The sheriff said he was not aware of the man's identity.

Waters, who made a surprise appearance at Block's news conference, insisted that charges should have been filed against Blandon, Lister and others targeted in the raids and that the documents should have been preserved. Block countered that prosecutors concluded there were not enough drugs to file trafficking charges.

According to FDA spokesman Jim O'Hara, such a call would be unnecessary.

"The administration wants parents to have the tools they need to fight drug abuse," O'Hara said. "The only question is how to make certain in this case that drug tests provide reliable and accurate information and that people know how to use it."

Los Angeles Times

DATE: 10-8-96
PAGE: A-3

U.S. Dealings With Mexican Government Sidestep Usual Rules

■ Diplomacy: Intimacy of the two countries' ties allows officials to avoid red tape. It also permits them to stray from policy stands.

By STANLEY MEISLER
TIMES STAFF WRITER

WASHINGTON—When Secretary of State Warren Christopher flew to Mexico City for an annual conference with Mexican leaders earlier this year, he took no fewer than eight other members of President Clinton's Cabinet with him—more than travel together anywhere else in the world.

The huge U.S. delegation was testimony to the importance the Clinton administration attaches to a good working relationship with its neighbor—and trading partner—to the south.

Christopher and his colleagues believed the U.S.-Mexican relationship had grown strong enough to weather troubling incidents, including the beating of suspected illegal immigrants by Riverside County sheriff's deputies and some tough remarks by a U.S. official about money laundering in Mexico.

But when they landed, they quickly found that their Mexican counterparts regarded the incidents as painful reminders of U.S. highhandedness. Mexican Foreign Minister Jose Angel Gurria Trevino lectured Christopher publicly about "trends that could jeopardize our relations and lead us down the road to confrontation and complaint."

When Jesus Silva Herzog, Mexico's ambassador in Washington, heard about Christopher's premature optimism, he groaned. "Oh, my God," the urbane ambassador exclaimed. "No one has listened."

No foreign country commands the attention of as many different parts of the U.S. government as Mexico—and yet, no other country seems to engender so much misunderstanding. Part of the problem, paradoxically, may be the intimacy and complexity of the relationship. Other countries have complicated political, economic and military ties with the United States; Mexico has all these plus shared environmental problems, a flood of illegal drugs and the constant irritant of illegal immigration.

As a result, the U.S. government deals with Mexico differently from the way it does most other countries. The usual diplomatic rules do not apply.

When Atty. Gen. Janet Reno wants to communicate with her counterparts in most foreign countries, she generally must set up her contact through the State Department, which manages U.S. foreign affairs. But when Reno wants to speak with Mexican Atty. Gen. Antonio Lozano Gracia, according to her aides, she just picks up the telephone and calls him.

Lozano and Reno speak with each other two or three times a month, partly in Spanish, mostly in English. Several significant U.S.-Mexican issues—such as drug enforcement and immigration—come up every day at the Justice Department. "A lot of our [domestic] problems don't stop at the border," says former Undersecretary of State Robert B. Zoellick, "and you just can't leave it to the guys in striped pants to deliver messages to each other."

Still, this intimacy, repeated in many other parts of the U.S. and Mexican governments, also makes it easier for officials on both sides to stray from official policy.

In April, for example, Thomas A. Constantine, head of the U.S. Drug Enforcement Administration, complained publicly that drug mafias were moving millions of dollars in cash from drug sales across the border into Mexico and depositing the funds in Mexican banks. "We've seen a trend of bringing the money across the southwest border in bulk cash, several millions of dollars at a time," he said, implying that Mexican authorities were not doing their part to stem the flow.

The Mexican Foreign Ministry went ballistic. "Constantine suggested that the Mexican banking system has been converted into a massive mechanism of money laundering when there is no concrete accusation or proof that confirms this," a ministry statement said.

The U.S. State Department wasn't happy either. Diplomats noted that the Mexican Congress was about to pass a bill instituting tough new measures against money laundering, and they worried that the DEA chief's blast might derail it. (The bill passed.)

"Managing U.S.-Mexican relations is like managing a three-ring circus," said the genial, Yale-educated Silva Herzog. "You have to juggle lots of balls in the air."

On the U.S. side, there are lots of jugglers. Asked where Mexico policy is managed in Washington, a State Department official replied almost wistfully, "We like to think that this is the place."

A deputy assistant secretary of state for Latin American affairs, aided by nine foreign service officers who study Mexico full time, chairs a group with representatives from a dozen or so agencies who meet once a month at the State Department to talk about Mexico policy. If the issues seem more important than usual, the group may be chaired by the assistant secretary of state.

These meetings, which serve as a clearinghouse for information about the government's varied Mexico activities, give the State Department a chance to monitor what is going on. "We don't want to take on Treasury's financial assistance program," the State Department official said. "But we want to help them. One of our jobs is to keep tabs. I think we do a reasonable job."

Cont'd

The New York Times

SATURDAY, OCTOBER 19, 1996

Drug Testing in the Home Is a Family Matter

To the Editor:

Contrary to your editorial "Drug Tests in the Home" (some editions, Oct. 10), Democrats and Republicans alike on the House Commerce Committee share the view that the Food and Drug Administration is acting capriciously in its reluctance to allow home drug-testing kits to be sold to parents. In fact, some of the most vocal opponents of the agency's position on home drug testing are Democrats like Representatives Ron Klink of Pennsylvania and Anna G. Eshoo of California.

I believe that American families are responsible enough to test their children for drugs. For thousands of parents, these tests would be a godsend — a way to monitor a child's behavior, help restore a trusting relationship with a child in recovery, or at least give teen-agers a good excuse to "just say no."

Moreover, the agency's contention that allowing parents to test teen-agers for drugs would cause coercion of teen-agers and create family discord is troubling to both Democrats and Republicans.

Drug use by teen-agers has never been a partisan issue and neither should be parents' accessibility to home drug-testing kits. Americans may disagree over whether they would ever test their own children for drugs, but that is a decision best left to families, not the Government.

(Rep.) THOMAS J. BLILEY JR.
Chairman, Commerce Committee
Washington, Oct. 16, 1996

Columbus's Roots

To the Editor:

An Oct. 14 news article quotes Elias Illescas, an organizer of the Hispanic Columbus Day Parade, as calling the discovery of America "a thoroughly Spanish event" and saying "Italy had nothing to do with it."

The Iberian-American historian German Arciniegas clearly states, "The discovery of America was in part an Italian enterprise" ("Amerigo and the New World"). The author notes that Christopher Columbus was born in Genoa, Italy, and that the inspirations of his life were the ancient Roman scholar Seneca, an Italian born in Roman Spain, who foretold a new world, and Marco Polo, the Venetian traveler to China.

To de-Italianize the discovery of America not only insults the Italian people but it is a gross distortion of history.

JOHN L. MANCINI
Floral Park, L.I., Oct. 15, 1996
The writer is secretary of programs at the Italic Studies Institute.

Yiddish and Toast

To the Editor:

Re the physics of tumbling toast (letter, Oct. 9): The landing of the falling slice — butter side up or down — has long figured in Yiddish folklore, marking the subtle distinction between two classic types: the schlemiel and the schlemazel.

Anyone unable to keep from dropping his toast at all is a schlemiel, someone who can't do anything right. But if the particular schlemiel's toast lands butter side down, then he is also luckless: bereft of mazel. He is, alas, a schlemazel.

MILL ROSEMAN
Eastport, L.I., Oct. 11, 1996

A Cable Monopoly

To the Editor:

Providing an outlet in New York City for a diversity of television news channels and live cable coverage of the City Council, as proposed by Gene Russianoff (Op-Ed, Oct. 16), would strengthen the life and and the economy of the city.

New Yorkers would not allow a main thoroughfare like Madison Avenue to be controlled by a single retailer. Yet, the allocation of cable channels raises concerns when we allow one company, Time Warner, to control the system and many of the sources of cable programming.

This city is the nation's center for production of news and nonfiction entertainment. We should consider how its cable television systems can serve the interests of the city as a whole.

MITCHELL L. MOSS
New York, Oct. 16, 1996
The writer is director, Taub Urban Research Center, New York Univ.

Expand Javits Center

To the Editor:

The Jacob K. Javits Convention Center has indeed been turned around under the administration of Gov. George E. Pataki ("Progress of the Javits Center," editorial, Oct. 12). Crime has been virtually eliminated, and the work force is being motivated by the most powerful incentive to provide customer satisfaction — keeping their jobs.

There is a problem, however: a severe and growing lack of available dates. The center is in the middle of the pack in terms of square footage and is falling behind every day as our major convention city competitors — Las Vegas, Chicago and Los Angeles — all continue to expand. Shows that wish to come here are being turned away.

By the end of the decade, New York will become the equivalent of a third world city, convention wise.

A trade show producer myself, I have three fashion industry trade shows at the center this month that will contribute 10,000 hotel night stays to the city's economy, as well as innumerable taxi rides, restaurant meals and theater tickets. My shows are typical.

Much coverage of the center focuses on whether it makes a profit. The $600 million or so that the state spent building the center would be a poor investment indeed if its goal was simply to make $1 million or $2 million.

We need to plan an expansion of the center, so that two of the city's brightest industries, tourism and conventions, can continue to power our economy into the next millennium.

DAVID LARKIN
New York, Oct. 15, 1996

Defense Department Condemns Torture Manual

To the Editor:

In an Oct. 4 letter, Robert Richter says he is filming a documentary and had spoken to three people from Latin American countries "who all link torture training to the United States Army's School of the Americas." Yet, during an interview with me in July, he presented none of this evidence.

In his letter, Mr. Richter attests correctly that I told him in July that I did not condone the use of any improper instruction material.

His question at the time stemmed from a single passage in a late June report referring to the past use of such material at the School of the Americas. I have since learned of a 1991-92 Defense Department investigation that determined that three manuals, out of some 300 manuals issued annually, at the school from 1989 to 1991 contained isolated objectionable material.

The Defense Department and the Army condemned the language and ordered the manuals destroyed, sending a clear message about human rights policy and standards, and to prevent any recurrence. The Defense Department and Army leadership today strongly endorse that past judgment and corrective action. At this time, the safeguards on the curriculum are being reviewed yet again.

In the July interview, I emphatically urged Mr. Richter to present to me or any other official any evidence he had, credible or otherwise, concerning any allegation of improper teaching. I made a specific commitment to him that any evidence would be fully investigated, and I repeated that commitment in a recent letter to him.

He has offered no evidence to me to date, nor to my knowledge has he presented evidence to any other official. Instead, he has chosen to make allegations in the press, citing unnamed sources. We continue to urge Mr. Richter to provide substance for his allegations, instead of maligning the many outstanding graduates of this school, whose curriculum, all in Spanish, is regarded as the best of any military institution in the world in its coverage of human rights.

JOE R. REEDER
Under Secretary of the Army
Washington, Oct. 15, 1996

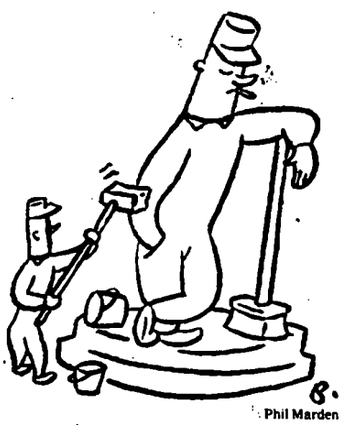
Love Your City, Love Its Weird Statues

To the Editor:

Joyce Purnick's argument that neglect is "a most fitting demise" for the Queens statue "Civic Virtue" (Metro Matters column, Oct. 14) is misguided. If New York City neglected all statues whose imagery and connotations various interest groups considered offensive, the city would be filled with decaying monuments.

Such distasteful works might include the Theodore Roosevelt statue in front of the American Museum of Natural History, with its stereotypical rendering of an African and a Native American flanking the heroic equestrian President; the "primitive" Indian hunter in Central Park, and, at the southeast corner of the park, the Gen. William Tecumseh Sherman statue, which is an insult to Southerners for its celebration of the rape of Atlanta.

The distasteful bare-breasted figures at the base of the Heinrich Heine Fountain near Yankee Stadium pose less of a threat — the disintegration of this fountain is already well under way. And then, of course, there is that nude prepubescent youth, Victory, on the front of the Maine Memorial in Columbus Circle. The list could continue.



Phil Marden

In these times of shrinking cultural budgets, the city must uphold its commitment to maintaining its historical monuments. Fortunately, the Parks Department and other guardians of the city's material cultural heritage have generally not resorted to what Ms. Purnick celebrates as "public censure through neglect."

MICHELE H. BOGART
Stony Brook, L.I., Oct. 15, 1996

The writer is professor and director of graduate studies, department of art, State University of New York.

Facts and Myths In New York Housing

To the Editor:

The professions of architecture and planning must share the blame for the tragic condition of housing for the poorest residents of our city as illustrated in your series "Housing's Hidden Crisis" (Oct. 6-11).

The gigantic designs of high-rise housing done from 1946 to 1966 failed to meet the needs of the occupants, and as that occupancy became more needy, these projects failed. In 1966 we in the design professions realized our error and returned to more human-scale urban housing. But we were too late. Public perception had been fixed. The news media and the politicians seized on the fears of people to create myths that would destroy support for affordable housing and drive our profession from this area of work.

Here are three of these myths:

- Public housing does not work. In fact, public housing, when properly managed, works well. In New York City and Jersey City there is a 10-year waiting list to get into the projects.
- Federal assistance to high-income and low-income housing is about equal. In fact, it was equal when Ronald Reagan became President, but aid to high-income housing is now 10 times greater.
- Architects and planners are not interested in designing affordable housing. In fact, we are interested and continue to work on such projects.

We must dispel these myths. Only a change of attitude will permit us to develop an equitable housing program.

HERBERT OPPENHEIMER
New York, Oct. 15, 1996

The writer is an architect.

Child Care Should Be Educational, Not Informal

To the Editor:

As an Oct. 14 news article reports, more New York children will need publicly financed day care as their mothers move from welfare to work. You suggest that I disagree with Gov. George E. Pataki's estimates on Federal funds for day care. That is not the case. Instead of providing custodial "informal" care, New York should invest funds in educational day care.

The policy initiative I introduced six weeks ago calls on the state to expand pre-kindergarten day care for 4-year-olds. Research proves that children who attend pre-kindergarten are 50 percent less likely to need special education and 26 percent less likely to fail in the early grades. Educational day care is the state's opportunity to prepare at-risk children to succeed in school.

BETSY MCCAUGHEY ROSS
Lieut. Gov. of New York
New York, Oct. 14, 1996

Difficult Subsidies

To the Editor:

New York City's policy covering children's day care is clearly shortsighted. A point not addressed in your Oct. 14 news article is the reluctance of the private licensed child-care center to enroll children eligible for the city subsidies because of the difficulty in obtaining payment.

As the director of a licensed child care center in the South Bronx that relies on these subsidies, I find that the city's government offices discourage parents from using licensed care and, instead, encourage them to use "informal" care, which saves New York City money.

My center, designed to serve children of parents in welfare-to-work academic and vocational training, has two virtually empty classrooms licensed for 3- to 5-year-olds as evidence.

ALISON PEPPER
Bronx, Oct. 15, 1996

10/4/96

TO: Bruce Reed ✓
Rahm Emanuel ✓
Dennis Burke

Post-It™ brand fax transmittal memo 7671	# of pages ▸ 4
To Bruce/Rahm	From Elizabeth Dye
Co.	Co.
Dept.	Phone # 456-5573
Fax # 716-357-5577	Fax #

FROM: Elizabeth Dye

SUBJECT: FDA policy on Home Drug Test kits

Attached is an update [redacted] from FDA re. over-the-counter home drug test kits. Note that FDA stated in a letter to Cong. Bliley that it will exercise enforcement discretion and not take any action against Sunny Cloud, or others marketing home test kits that meet basic criteria, until the Agency has completed its policy review. FDA has not yet changed its policy.
Also attached is final letter from Carol to Kessler.

FYI CNN is expected to run short segment on this issue Saturday; Dateline may run piece on Sunday.

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.

- 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.

- 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.

- 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 avaialability 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.

Talking Points:

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.

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

- 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.

- 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.

FAX TRANSMITTAL SHEET

To: Ed Rahm / Dennis

From: Beth

Fax #: 6-6423 6-7028

# of Pages (including cover page) 11

Comments: FYI Some of the correspondence on the drug test kit. FDA apparently has concerns about "product misuse" and has said the product requires "pre-market" approval.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 1996

Mr. Raymond C. Kubacki
President and CEO
Psychemedics Corporation
1280 Massachusetts Avenue
Cambridge, Massachusetts 02138

Re: PDT-90 Personal Drug Testing Service

Dear Mr. Kubacki:

This letter will confirm FDA's current decision not to actively regulate Psychemedics Corporation's "PDT-90 Personal Drug Testing Service." Consequently, there is currently no need for Psychemedics to have made a 510(k) submission, and therefore FDA will close its file on your recent 510(k) submission. In addition, FDA hereby formally withdraws its correspondence of November 20, 1995, addressed to Richard S. Morey, in response to the recent 510(k) submission. FDA also hereby formally withdraws the Warning Letter of August 30, 1995. The withdrawal of the Warning Letter includes withdrawal of all language concerning alleged adulteration and misbranding for the reasons stated therein.

This will also confirm that FDA does not intend to pursue enforcement action on any of the grounds contemplated in the Warning Letter dated August 30, 1995. FDA's decisions and the additional representations stated below are based on information currently available to it and are premised on the "PDT-90 Personal Drug Testing Service" remaining unchanged from the version submitted with your recent 510(k) submission.

Furthermore, although no further enforcement action is anticipated, FDA promises that unless and until it has first given you 30-days advance notice, in writing, it will not institute enforcement action alleging that the "PDT-90 Personal Drug Testing Service" is or contains an unapproved Class III medical device or is being marketed in violation of section 510(k). Furthermore, if FDA decides to trigger a 30-day warning period, and if during that period you make another 510(k) submission asserting that the "PDT-90 Personal Drug Testing Service" or any component thereof is substantially equivalent to a lawfully marketed Class II or Class I predicate device, or alternatively, if during that

Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115
May 8, 1996

From Rep. Barton asking rather pointed questions - FDA never responded!

The Honorable David A. Kessler, M.D.
Commissioner
Food and Drug Administration
Room 1471
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

It has been brought to my attention that FDA or high-level FDA officials may have adopted a policy against home drug testing because it could result in "coercion and family discord." According to a memorandum received by the Subcommittee, FDA officials of the Center of Device and Radiological Health met on December 8, 1995 with representatives of Psychemedics regarding FDA's November 20, 1995 decision that Psychemedics' PDT-90 Personal Testing Service is Not Substantially Equivalent ("NSE") to any predicate device. It has been reported that during this meeting, an FDA official stated that although FDA has made a policy decision to exercise its enforcement discretion not to regulate drug tests marketed exclusively for forensic purposes (e.g., law enforcement, employment), the FDA has decided that over-the-counter ("OTC") drug tests indicated for teenagers do not fall within this category and thus require premarket approval (or rigorous 510 (k) review). According to the same official, this is a deliberate policy decision that has been made at a high level within the Agency and is based upon perceived risks associated with the possibility of misuse of the results of such tests (both correct and incorrect results). In particular, the official stated that FDA is concerned about issues such as anonymity, confidentiality, coercion, and family discord. This policy was developed as a result of the marketing of two similar OTC test kits: home HIV test kits and home urine drug test kits.

In view of the public interest in home drug testing and the integrity of the FDA approval process, please provide the following by May 22, 1996:

(1) Memoranda of the December 8, 1995 meeting between FDA officials and Psychemedics.

(2) What is FDA's social policy position (as opposed to safety and efficacy concerns) on home drug testing? Please provide all FDA policy statements on home drug and HIV testing as well as home pregnancy testing. Please list all individuals at FDA who have been involved in developing this position. Please cite the legal authority for FDA to consider social policy issues in the approval process.

(3) List of all individuals from federal agencies and departments (including the White House) who have been in contact with FDA officials about home drug-testing issues.

(4) Please provide five examples of product categories where FDA has taken a policy position based in any way on social policy considerations raised by information generated by the product.

If you have any questions about this request, please contact Alan Slobodin of the Committee staff at (202) 225-2927. I appreciate your cooperation in this matter.

Sincerely,

Joe Barton
Chairman
Subcommittee on Oversight
and Investigations

cc: The Honorable Thomas J. Bliley, Jr., Chairman

The Honorable John D. Dingell, Ranking Minority Member

The Honorable Peter Deutsch, Ranking Minority Member
Subcommittee on Oversight and Investigations

LAW OFFICES
McKENNA & CUNEO, L.L.P.
1900 K STREET, N.W.
WASHINGTON, D.C. 20006
(202) 496-7500
FAX (202) 496-7756

LOS ANGELES
444 SOUTH FLOWER STREET
LOS ANGELES, CALIFORNIA 90071
(213) 688-1000

SAN FRANCISCO
STEUART STREET TOWER
ONE MARKET
SAN FRANCISCO, CALIFORNIA 94105
(415) 267-4000

SAN DIEGO
SUITE 3600, SYMPHONY TOWERS
750 B STREET
SAN DIEGO, CALIFORNIA 92101
(619) 595-5400

DENVER
SUITE 4800
370 SEVENTEENTH STREET
DENVER, COLORADO 80202
(303) 634-4000

DALLAS
3700 BANK ONE CENTER
1717 MAIN STREET
DALLAS, TEXAS 75201
(214) 748-5700

BRUSSELS
DO, RUE DES COLONIES
B-1000 BRUSSELS
BELGIUM
011 (32-2) 290-1811

SUZAN ONEL
DIRECT DIAL (202) 496-7117

August 22, 1996

By Facsimile/Confirmation by U.S. Mail

Ms. Donna E. Shalala
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Teen-age Drug Abuse

Dear Secretary Shalala:

Thank you for stating so succinctly in your comments to the recently released National Household Survey of Drug Abuse the position that we, as parents, have taken all along, "youth substance abuse is an American problem -- not a government problem . . . it's going to take the leadership of citizens and communities all across the country . . . and especially from parents, to save our children."

As concerned parents, the personnel in our firm agree with your statements. Our firm also represents a small company, Parent's Alert, Inc. ("Parent's Alert"), that is trying to do something about the problem of substance abuse among youngsters. Parent's Alert markets the "AT HOME DRUG TESTS" to assist concerned parents in learning whether their child is abusing alcohol or drug substances. While the effort is not taken for a device use subject to regulation by the Food and Drug Administration ("FDA"), the FDA has issued a Warning Letter to Parent's Alert alleging the product to be a device and Parent's Alert to be a manufacturer. This position is at odds with FDA's position with respect to similar products when used for screening or detection purposes in law enforcement, employment, and school settings. Frankly, we do not understand the agency's regulatory position in light of present and past administration's efforts to reduce substance abuse, especially among children, and FDA's recent initiative to regulate nicotine-containing cigarettes and smokeless tobacco products. Clearly smoking is harmful to children, but this harm surely pales when compared to the serious public health and societal problems caused by substance abuse.

LAW OFFICES
MCKENNA & CUNEO, L.L.P.

Yesterday, we sent the enclosed letter to FDA Commissioner Kessler seeking a response to a June 26, 1996 letter to the FDA. Because this matter ultimately has significant impact on the American public and has remained unresolved for over a year, we respectfully request your leadership in supporting Parent's Alert's efforts to reduce substance abuse among youngsters. Clearly, the availability of products such as the Parent's Alert drug testing kit could make a difference where it counts most, in the home.

Cordially,

Suzan Onel

Suzan Onel

SO/
Enclosure(s)
cc: S. Cloud
W. Bennett
B. Burlington
D. Kessler
L. Pilot

LAW OFFICES
McKENNA & CUNEO, L.L.P.
1900 K STREET, N.W.
WASHINGTON, D.C. 20006
(202) 496-7500
FAX (202) 496-7756

LOS ANGELES
444 SOUTH FLOWER STREET
LOS ANGELES, CALIFORNIA 90071
(213) 688-1000

SAN FRANCISCO
STEUART STREET TOWER
ONE MARKET
SAN FRANCISCO, CALIFORNIA 94105
(415) 267-4000

SAN DIEGO
SUITE 3200, SYMPHONY TOWERS
750 B STREET
SAN DIEGO, CALIFORNIA 92101
(619) 595-3400

DENVER
SUITE 4800
370 SEVENTEENTH STREET
DENVER, COLORADO 80202
(303) 634-4000

DALLAS
3700 BANK ONE CENTER
1717 MAIN STREET
DALLAS, TEXAS 75201
(214) 746-5700

BRUSSELS
88, AVE DES COLONIES
B-1000 BRUSSELS
BELGIUM
011 (32-2) 674-1411

LARRY R. PILOT
DIRECT DIAL (202) 496-7501

August 21, 1996

By Facsimile/Confirm By U.S. Mail

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

RE: Parent's Alert "AT HOME DRUG TESTS"

Dear Commissioner Kessler:

On June 26, 1996, I wrote the enclosed letter to Bruce Burlington, Director of the Center for Devices and Radiological Health. To date, I have received no response; and, the inability of the Food and Drug Administration (FDA) to provide responsible assistance on this matter exacerbates a major health and social problem in the United States.

Since yesterday the news has been replete with stories about a federal drug study that shows drug abuse by U.S. teen-agers skyrocketing 105 percent between 1992 and 1995. Recognizing the importance you place on pediatric disease prevention, it is disturbing that the FDA has done essentially nothing to implement initiatives to reduce drug abuse among youngsters. Clearly the FDA has a statutory mandate associated with the manufacturing, distribution and use of drugs. Yet, my experience on behalf of Parent's Alert, Inc. ("Parent's Alert") suggests that the FDA is functioning as an impediment to the responsible efforts of parents to deal with and raise their children to avoid the harms associated with substance abuse.

The August 18, 1996 issue of the Washington Post Parade magazine describes the results of a recent survey of American teen-agers. This survey indicates that 21% of respondents aged 13 to 17 consider drugs to be the worst influence on today's youth. This was identified as the single worst influence facing teens today. Smoking, in contrast, was not listed as a concern and, of those polled, only one teen in ten, or 9%, smokes cigarettes or drinks.

LAW OFFICES
McKENNA & CUNEO, L.L.P.

The plea that I make on behalf of Parent's Alert is that you recognize the importance of their efforts to reduce drug abuse among youngsters and support the effort that they have initiated. This is the very least the FDA can do. As I have indicated in prior correspondence, the effort by Parent's Alert is not undertaken for a device use subject to regulation by the FDA.

I implore you to respond affirmatively to my letter of June 26 and to apply FDA resources to a pediatric disease of epidemic proportions that directly results in death and long term, often irreversible, injury to American youngsters.

Cordially,

Larry R. Pilot

LRP/koc
Enclosure
cc: S. Cloud
W. Bennett
B. Burlington

DIRK E. HUTTENBACH, MD
FAPA, FAACAP

RIDGEVIEW INSTITUTE
PROFESSIONAL BUILDING SOUTH • SUITE 310
491 B. COBB DRIVE • SMYRNA, GA 30080
PHONE 770-434-6065

DIPLOMATE, AMERICAN BOARD OF PSYCHIATRY AND NEUROLOGY
GENERAL AND CHILD PSYCHIATRY
A.S.A.M. CERT. ADDICTION MEDICINE

CHILD, ADOLESCENT AND ADULT PSYCHIATRY
TELECOPIER 770-434-1223

September 4, 1996

Mrs. Dianne Cohen
Clinton-Gore Campaign
1100 Spring Street
Atlanta, Georgia 30309

Dear Dianne:

I presume you were in Chicago for the Democratic convention. I hope you enjoyed it.

I am writing in follow up to our telephone conversation of Tuesday, August 20, the day after I had met with Richard Green.

For the past two years I have been involved with Parent's Alert as a medical consultant. Parent's Alert is a company that makes urine drug screens available to parents in the same way that the Cobb County Medical Society (CCMS) Adolescent Urine Drug Screen Program has been doing since 1985. Parents served by Parent's Alert and the CCMS Program has been very pleased at having this service available.

The concern of Parent's Alert is that the Federal Drug Administration (FDA) sent a warning letter to us over a year ago, inaccurately calling our product a "medical device," which stymies possibilities of Parent's Alert serving parents and teenagers. This may deprive parents of a major prevention tool, available to employers, schools, courts, and the military. All these groups use urine drug screening as a behavioral tool to influence people away from illicit drug use. Parent's Alerts strongly feels that this should also be available to parents in influencing teenagers who show behaviors of concern.

The FDA has refused to respond to inquiries from Parent's Alert attorneys and concerned elected officials. Nevertheless, the FDA on March 26, 1996 withdrew a similar warning letter sent earlier to Psychemetics Corporation in regards to their "PDT-90 Personal Drug Testing Service," a test which allows parents to check for drug abuse via testing hair samples. This letter of withdrawal followed court action by Psychemetics Corporation. Copies of relevant correspondence are enclosed.

Mrs. Sunny Cloud, President Parent's Alert, and myself met with Richard Green on Monday, August 19. He could barely believe what we

Ms. Dianne Cohen
September 4, 1996
Page - 2 -

told him. Richard advised us to contact our elected representatives, more forcibly. Congressman Barr so far has been the most rapidly supportive. Richard also strongly advised us to contact you. Mrs. Cloud also is ready to raise the issue with the media.

Senator Robert Dole is now calling for a "Zero Tolerance Policy" on drug abuse while accusing President Clinton of being soft on drugs. Senator Dole wants the military to take a more active role to combat drug abuse. It makes little sense to us to mobilize the military while keeping parents from mobilizing to a greater extent. Parent's Alert exists to provide parents with more effective tools to address adolescent drug abuse at home, in the privacy of the home.

We would prefer that this issue not become a political football. Former Congressman Buddy Darden, Mr. Barr's predecessor, had been very supportive of adolescent drug screening. He was an original endorser of the CCMS Program. We would hope that Democrats as well as Republicans would want to do everything reasonably possible to prevent adolescent drug abuse.

We are eager to discuss this matter with the Clinton Administration. We hope that the FDA will reconsider its position of classifying our product as a "medical device" when all we are selling is a cardboard box with a plastic container with instructions. The contents of our box are already widely available elsewhere. Mrs. Sunny Cloud and I would be happy to meet with you to provide further details so you can more effectively present these concerns to the Clinton Administration.

We commend President Clinton for addressing the issue of nicotine addiction and cigarette smoking. Vice President Gore is willing to "fight till his last breath" to prevent adolescent smoking. We hope that Mr. Clinton and Mr. Gore feel likewise about other drugs of abuse.

We are very concerned about adolescent drug use and feel that prohibiting parents from protecting their own children makes little sense. We would like for the Clinton Administration to be aware that the FDA's stance has been counterproductive to the point of possibly leaving President Clinton appropriately open to criticism on the drug abuse prevention issue.

FDA inaction is inhibiting the ability of Parent's Alert to develop its business of providing an important service to parents.

I look forward to hearing from you and whether you might be of help in this matter.

Sincerely yours,

Dirk E. Huttenbach, M.D.
DEH:adw

enclosures

cc: Mrs. Sunny Cloud
Mr. Richard Green

SPECIAL

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001
9/24/96
LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: 5680
FILE NO: 1746
Total Page(s): 22

TO: Legislative Liaison Officer - See Distribution below:

FROM: Janet FORSGREN Janet Forsgren (for) Assistant Director for Legislative Reference

OMB CONTACT: Robert PELLICCI 395-4871 Legislative Assistant's Line: 395-7362
C=US, A=TELEMAIL, P=GOV+EOP, O=OMB, OU1=LRD, S=PELLICCI, G=ROBERT, I=J
pellicci_r@a1.eop.gov

SUBJECT: HHS Proposed Testimony on consumer access to home drug testing services and devices.

DEADLINE: Noon Wednesday, September 25,1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: Hearing is before the House Commerce Subcommittee on Oversight and Investigations on Thursday, September 26th. Dr. Bruce Burlington, Director of the Center for Devices and Radiological Health at FDA is the witness.

DISTRIBUTION LIST:

AGENCIES: 61-JUSTICE - Andrew Fois - 2025142141
76-National Economic Council - Sonyia Matthews - 2024562174
89-Office of National Drug Control Policy - John Carnevale - 2023956736
95-Office of Science and Technology Policy - Sam Seidel - 2024566020

EOP: Nancy-Ann Min
Sally Katzen
Mike Fitzpatrick
Chris Jennings
Elizabeth Drye
Diana Fortuna
Jeremy Ben-ami
Elena Kagan
Barry Clendenin
Richard Turman
Jim Esquea
Jonathan Winer
Ken Schwartz
Jim Murr
Janet Forsgren
OMB LA
Bob Damus

ET Dennis Burke

See last couple of pages
hearing 9:30 Wed.

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **5680**

FILE NO: **1746**

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet.
If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.
You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Robert PELLICCI 395-4871
Office of Management and Budget
Fax Number: 395-6148
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: HHS Proposed Testimony on consumer access to home drug testing services and devices.

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

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

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 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

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 professinal 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 collelotion 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 recepient 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 effctive 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 expediantly 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

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 phencycladine (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 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

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.

Drafted by: RCEccleston:9/19/96
Reviewed by: SGutman:9/19/96
DBBurlington:9/20/96
Revised by: RCEccleston:9/20/96
Comments by: DBBurlington:9/20/96
JKnight:9/20/96
CNoreio:9/20
SGutman:9/20/96
CUldriks:9/20/96
WPellerite:9/20/96
Revised by: RCEccleseten:9/20/96
Revised by: Dburlington/DThompson:smm:9/23/96
Comments by: Mpendergast/DBurlington/DSnyder:9/23/96
Revised by: DThompson/MPlaisier/KMulry:9/23/96

"It's an at-home polygraph. Now we can ask Junior if he's faking the at-home drug tests we're giving him."

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

bearing busybodies" at the Rockville-based agency.

But the FDA says the case is not so simple. In a letter last week to Bliley, 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."

Date: 03/04/98 Time: 15:28
U.S HHS: FDA proposes new policy for home drug abuse test kits

MAR 4, 1998, M2 Communications - The Food and Drug Administration today proposed an approach that will make it easier for manufacturers to market home drug abuse specimen collection kits, while still ensuring that test results are accurate and reliable. The proposal would implement existing FDA policy.

The Agency will now allow all test kits to be marketed without prior approval as long as they meet certain criteria. In the past, the Agency has required that it approve such products prior to marketing unless they were used in workplace, insurance or other controlled settings. Because of the new, more flexible policy, the Agency will apply it virtually across the board, including to tests used in workplace, insurance, and other controlled settings. It would not apply, however, to tests used in connection with law enforcement purposes.

"The proposal balances the need to assure the accuracy of tests for drugs of abuse and the goal of simplifying the regulatory requirements so that these tests are made available to parents and others as soon as feasible," said William B. Schultz, FDA Deputy Commissioner for Policy.

Drug abuse specimen collection kits are sold directly to parents, employers, and insurance companies. The testing procedures require that a specimen from the body, such as urine, be collected and mailed to a designated laboratory for testing for drugs of abuse such as marijuana, PCP, or cocaine. The results are then communicated back to the parent (or other person who sent in the test specimen) by phone by the product's manufacturer.

FDA is proposing that these specimen collection kits be allowed to be marketed without prior agency approval as long as they meet the following criteria:

1. The test used by the laboratory to identify the existence of illegal drugs must be approved or otherwise recognized by FDA as accurate and reliable for laboratory use. FDA has already cleared more than 200 laboratory urine tests to detect drugs of abuse. This will ensure the accuracy of the test.

2. The laboratory performing the test must be certified to do the necessary screening and confirmatory test. Some 70 laboratories certified by the Substance Abuse and Mental Health Services Administration would meet this requirement, as well as numerous laboratories certified by other agencies and organizations. This will ensure the qualifications of the laboratory to perform the test.

3. The collection kits must be accurately labeled so consumers can easily use them, and samples must be clearly identified to avoid mix-ups. Accurate labeling will enable the lay person to understand what drugs the test can and cannot identify, the time frame within which drugs can be detected, how to properly collect the test specimen and mail it to the laboratory, how to interpret test results, and how to obtain professional counseling, if needed.

The proposal provides 90 days for public comment. During the comment period, FDA will hold a public hearing on the proposal. To give the marketplace time to adjust to any changes, the new regulatory scheme

would become effective one year after the final regulation is published.

-0-

Home Drug Abuse Test Kits
up-date February 25, 1998

Scope: This proposed rule applies to OTC test sample collection systems for drugs of abuse testing. Such testing requires that a sample be collected and mailed to a certified lab for testing. The results are then communicated back to the sender. (This rule does not affect "point-of-cover" tests - i.e. where the testing is performed in the home setting and the results are read and interpreted by the consumer.)

General Points

* The bottom line of the proposal is that consumers should have access to test kits that provide accurate and reliable results as well as information on how to use the kits and how to interpret test results properly.

* These tests MUST meet the following criteria:

1. To ensure the accuracy of a test, the test itself must be approved or otherwise recognized by FDA as accurate and reliable for laboratory use. (FDA has already cleared more than 200 laboratory urine tests to detect drugs of abuse.)

2. To ensure the qualifications of the laboratory to perform the test, the laboratory performing the test must be certified to do the necessary screening and confirmatory test. (Some 70 laboratories certified by the Substance Abuse and Mental Health Services Administration would meet this requirement, as well as numerous laboratories certified by other organizations.)

3. To ensure that consumers have the information they need to use and interpret the tests, the collection kits must be accurately labeled and samples must be clearly identified to avoid mix-ups.

* The Clinton Administration has zero tolerance for illicit drugs. It is crucial for parents to talk openly with their children about the dangers of drug abuse. This test gives parents another option to consider to help ensure that their children remain drug-free.

Q. *Why is the FDA not including OTC drugs of abuse tests that use hair as the test specimen?*

* The proposed rule is generic and does not include or exclude any type of test specimen. All the rule does require is that whatever test specimen is used, the test be demonstrated to FDA that it is accurate and reliable.

* Regarding hair tests, FDA has not been presented with convincing scientific data demonstrating that such tests are accurate and reliable. Accordingly, FDA has legitimate concerns about the validity of these tests. To date, SAMHSA has not certified these tests for workplace testing. Therefore, the hair tests would not meet the criteria that the Agency has outlined to allow a test to be marketed.

* Under the proposal, there is ample time before the final rule is put into effect for companies to submit their test results to FDA for clearance. The hair testing companies can collect their test results and submit them to FDA to go through the premarket process.

Q. *Under a court settlement, Psychomedics can market its hair test. What effect does this have on that result?*

* The company is permitted to continue to market its test while this proposed rule is out for public comment and a final regulation is put into effect.

* In the interim, the company could collect its test results and submit them to FDA and go through the premarket process.

Q. *By making these tests available for home use, is FDA making it more difficult for school districts and other entities seeking to test young people for drug use?*

* No. In fact, FDA's proposed rule would increase the availability of such test collection kits for schools or parents or anyone else to use. That was one of the reasons for this proposal.

* All the FDA is doing is saying what types of tests can be used. The Agency's statutory obligation is to assure that a test kit provides accurate and reliable results and that it provides information on how to properly use the kits and interpret the results.

Q. *By making the tests available for home use, is the FDA encouraging parents to test their children for drug use?*

* FDA's proposal would simply provide parents with that option. If parents want to use one of these kits, that's their personal decision. The Agency's statutory obligation is to assure that consumers have access to a test kit that provides accurate and reliable results and provides information on how to properly use these kits and interpret their results.

Q. *The Agency announced this policy last February. Why did it take so long to release the proposal?*

* A year to develop a significant proposed regulation is not unusual. Moreover, FDA proceeded cautiously given the importance of the issue. Some rules, including this proposal, are also reviewed by HHS and the Office of Management and Budget, and that review takes time.

Q. *This new proposal puts in place a consistent policy on drug testing in the home, workplace*

and other settings. Why was there in the past a different policy for home versus workplace settings?

* In the past, FDA focussed its attention on tests sold over the counter that would be used in the home setting. However, given that the same concerns about getting an accurate and reliable answer apply in the home and workplace settings, under FDA's proposed rule, workplace testing will be regulated in the same manner as home testing. In both cases, it is important that the test kit provides accurate and reliable results.

Q. *Why doesn't the Agency's proposal include tests used in connection with law enforcement?*

* There are other protections to ensure sample integrity and test accuracy - the use of rules of evidence in judicial proceedings and the representation of the accused (i.e. the person being tested) through the judicial process.

Q. *How will FDA collect comments on its proposal?*

* The proposal provides 90 days for public comment. In addition, FDA has pledged to hold a public hearing during the comment period to solicit additional comments on its proposal.

Q. *When will this rule go into effect?*

* FDA believes it is important to give the marketplace time to adjust to any changes in regulatory approach.

* Therefore, FDA is proposing that the final rule become effective one year after its publication in the Federal Register, but not earlier than two years from the date of this proposed rule.

DRAFT

Draft w/ changes oked by Schultz 1/23 11pm .

DRAFT

P98- ,
FOR IMMEDIATE RELEASE
March , 1998

FOOD AND DRUG ADMINISTRATION
Print Media: 301-827-6242
Broadcast Media: 301-827-3434
Consumer Inquiries: 800-532-4440

FDA PROPOSES NEW POLICY FOR HOME DRUG ABUSE TEST KITS

The Food and Drug Administration today proposed an approach that will make it easier for manufacturers to market home drug abuse specimen collection kits, while still ensuring that test results are accurate and reliable. The proposal would implement existing FDA policy.

The Agency will now allow all test kits to be marketed without prior approval as long as they meet certain criteria. In the past, the Agency has required that it approve such products prior to marketing unless they were used in workplace, insurance or other controlled settings. Because of the new, more flexible policy, the Agency will apply it virtually across the board, including to tests used in workplace, insurance, and other controlled settings. It would not apply, however, to tests used in connection with law enforcement purposes.

"The proposal balances the need to assure the accuracy of tests for drugs of abuse and the goal of simplifying the regulatory requirements so that these tests are made available to parents and others as soon as feasible," said William B. Schultz, FDA Deputy Commissioner for Policy.

-More-

Drug abuse specimen collection kits are sold directly to parents, employers, and insurance companies. The testing procedures require that a specimen from the body, such as urine, be collected and mailed to a designated laboratory for testing for drugs of abuse such as marijuana, PCP, or cocaine. The results are then communicated back to the parent (or other person who sent in the test specimen) by phone by the product's manufacturer.

FDA is proposing that these specimen collection kits be allowed to be marketed without prior agency approval as long as they meet the following criteria:

1. The test used by the laboratory to identify the existence of illegal drugs must be approved or otherwise recognized by FDA as accurate and reliable for laboratory use. FDA has already cleared more than 200 laboratory urine tests to detect drugs of abuse. This will ensure the accuracy of the test.

2. The laboratory performing the test must be certified to do the necessary screening and confirmatory test. Some 70 laboratories certified by the Substance Abuse and Mental Health Services Administration would meet this requirement, as well as numerous laboratories certified by other agencies and organizations. This will ensure the qualifications of the laboratory to perform the test.

-More-

3. The collection kits must be accurately labeled so consumers can easily use them, and samples must be clearly identified to avoid mix-ups. Accurate labeling will enable the lay person to understand what drugs the test can and cannot identify, the time frame within which drugs can be detected, how to properly collect the test specimen and mail it to the laboratory, how to interpret test results, and how to obtain professional counseling, if needed.

FDA's proposal, which would require the same criteria for drug abuse specimen collection systems regardless of whether they are used in the insurance, sports, or workplace settings, provides a more consistent approach to regulating these products.

The proposal provides 90 days for public comment. During the comment period, FDA will hold a public hearing on the proposal. To give the marketplace time to adjust to any changes, the new regulatory scheme would become effective one year after the final regulation is published.

####