

*Drugs - FDA
Home
Testing
kits*

September 25, 1996

Note to White House Press Office

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

Talking Points

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

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

Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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DEPUTY SECT

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Key talking points
home test kits

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

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

CHARGE

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

THE COUNTER

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

CHARGE

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

THE COUNTER

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

TO: Bruce Reed / Rahm Emanuel

FROM: Elizabeth Dreye / Elena Kagan

DATE: 10-03-96

OF PAGES: 3
(including cover)

FAX NUMBER: 716-356-9397

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MESSAGE:

If you have any questions, please contact Elizabeth Dreye @ 302-456-5573
or Elena Kagan @ 456-7594

October 3, 1996

MEMORANDUM TO: John Hilley
Bruce Reed
Rahm Emanuel
Todd Stern
John Angell

FROM: Carol Rasco
Jack Quinn

SUBJECT: Draft Letter Stating the President's Views
regarding FDA's Policy on Home Drug Testing Kits

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

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

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Drugs - FDA

October 3, 1996

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

Dear Dr. Kessler:

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

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

The President believes parents should also have access to safe and effective home drug test kits. I understand such kits have been considered "Class III medical devices" needing FDA approval since at least 1987. The FDA clearly has a role to play in ensuring home drug tests are safe and effective. For this reason neither the President nor I state a view as to whether the FDA should approve any particular home drug testing product. The President believes, however, that safe and reliable tests should be available to parents, and parents should be able to use such tests if they choose.

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

Sincerely,

Carol M. Rasco
Assistant to the President
for Domestic Policy