NLWJC - Kagan

DPC - Box 015 - Folder 010

Drugs - Home Drug Tests

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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

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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.

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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.

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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.

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Drugs - home drug testing

2.6.98

Rahm/Bruce/Elena:

Attached please find a draft HHS press release on FDA's proposed rule for "home drug test kits." HHS intends to codify its policy of the past year to allow manufacturers to market these kits without prior FDA approval so long as they meet 3 conditions:

1. That one of the more than 200 already FDA-approved testing procedures is used;
2. That one of the 70 FDA-certified labs determine the results; and
3. That the kits themselves be accurately labeled.

I think we should okay HHS' release and let them go through their 90-day comment period, conduct a public hearing and publish a final regulation before we're too out front on this. While Sunny Cloud -- the original person fighting FDA's policy -- is pleased with this decision -- it's unclear to me who may not like it. For instance, HHS expects the hair testing folks to be opposed (they're not currently approved by FDA and wouldn't benefit from this decision). However, if we want to try and get the President in on any stories about this proposed reg., we may want to consider having McCurry lead his brief with a statement the day HHS releases the reg. and attached press release.

Please advise. HHS promised not to do anything on this until consulting w/Rahm and us, but they want to get this out soon -- and with minimal fanfare.

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HHS NEWS DRAFT (Revised) #8

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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"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.

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- 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.

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

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To: Elena Kagan, Bruce N. Reed, BURKE_D @ A1@CD@LNGTWY, JENNINGS_C @ A1@CD@LNGTWY

cc:
Subject: Approved Home Drug Test Kit

FYI--FDA today approved "Mr. Brown's" home drug test kit. As you know, the Agency is revisiting its policy on such kits and, in the interim, is not enforcing against Sunny Cloud and others who have kits on the market. Mr. Brown's was approved under the regular FDA PMA reveiw process.

The company has been notified, and FDA/HHS will issue a press statement later today. Shalala is planning to make a statement (rare for specific device approvals), noting that the Administration has zero tolerance for kids' drug use, parents should have all tools available to them, and this will expand parents' choices. HHS is letting Rahm, WH Press, Hilley know.

The President has never commented directly on this issue, but Carol sent a letter to FDA expressing his views. (In VP debate, VP held FDA's interim no-enforcement policy up as an example of FDA's enlightenment). WH Press will be prepared for any calls.