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# **HOME TESTING DEVICES: FDA CLEARANCE AND MONITORING ACTIVITIES**

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**OFFICE OF INSPECTOR GENERAL**  
**OFFICE OF ANALYSIS AND INSPECTIONS**

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**OCTOBER 1989**

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FDA CLEARANCE AND MONITORING  
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**Richard P. Kusserow  
INSPECTOR GENERAL**

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## EXECUTIVE SUMMARY

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### **PURPOSE**

The purpose of this study was to assess the adequacy of the Food and Drug Administration's (FDA) clearance process in ensuring the safety and effectiveness of home testing kits and the degree to which their efficacy is monitored once available for sale. This inspection was requested by the Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives.

### **BACKGROUND**

Home use medical devices, like professional use medical devices, must be cleared by the FDA prior to marketing. Both home use and professional use medical devices are reviewed by FDA according to the Medical Device Amendments of 1976.

The Medical Device Amendments to the Food, Drug and Cosmetic Act enacted in May 1976 required the FDA to classify all devices in commercial distribution prior to May 28, 1976 as Class I, II or III devices depending on the level of control needed to ensure their safety and effectiveness. Class I devices are those devices for which general controls (such as prohibitions against adulteration and misbranding and adherence to good manufacturing practices) are sufficient to ensure their safety and effectiveness. Class II devices are those devices for which performance standards, in addition to general controls, are necessary to ensure their safety and effectiveness. Class III devices are those for which inadequate information exists to determine if general controls and performance standards are sufficient to ensure their safety and effectiveness and therefore require premarket approval (PMA).

The Act further specified that manufacturers wishing to introduce a device into the market subsequent to May 28, 1976 are required to make a premarket notification (510(k)) to the FDA prior to such marketing. The premarket notification must establish that the new device is substantially equivalent to a device on the market prior to May 28, 1976, or a device marketed after that date and placed into Class I or II (a predicate device). If the device is found substantially equivalent to a predicate device, it is placed in the class in which its predicate device has been placed. If FDA finds the device not substantially equivalent, or substantially equivalent to a Class III device, a PMA is required.

If a manufacturer wishes to market a home use testing device, the firm must submit the necessary documentation to FDA under the 510(k) or PMA process just as it would if the product were intended for professional use. For manufacturers wishing to market home use in-vitro diagnostic devices (such as pregnancy tests), the FDA has provided draft guidance on how they may address concerns relating to proper and appropriate use of the test by consumers.

Once devices are cleared for the market, FDA monitors their performance primarily through the Device Experience Network (DEN) and inspections of manufacturing facilities, operations and records. The FDA may also act on information it receives on device safety and performance from other sources, such as the Consumer Product Safety Commission.

## **FINDINGS**

- Although home use testing devices are readily available to consumers, and a significant number of consumers use such tests, limited information is available on why, and how effectively, consumers use some of these tests.
- The association representatives we interviewed believe that FDA has generally acted cautiously and appropriately in applying the Medical Device Amendments of 1976 to home use tests. Their concerns revolved around (1) how to ensure the reliability and proper interpretation of test results obtained in the home and (2) how FDA will react to the proposed marketing of certain home tests (such as tests for strep and the HIV virus) which would have serious repercussions for individual and public health if false results are obtained or proper follow-up does not take place.
- As with professional use Class II devices, no performance standards have been developed for home testing kits which are categorized as Class II devices.
- The FDA has given significant attention, and attached considerable importance, to manufacturer labeling of home use medical tests.

## **RECOMMENDATIONS**

- The FDA should devise ways to increase its knowledge concerning actual consumer experiences with home use testing devices.
- The FDA should place continuing emphasis on consumer field evaluations to ensure the accuracy and reliability of home testing devices.
- The FDA should continue its efforts to work with manufacturers to improve product design, labeling and instructions in order to increase the public's ability to appropriately use the home testing kits it clears.

## **AGENCY COMMENTS**

The Office of Inspector General solicited comments to the draft of this report from the Assistant Secretary of Health. The Public Health Service (PHS) responded with a number of technical comments which we have incorporated in the final report. The technical comments were helpful in clarifying FDA's role and activities in regard to home testing devices.

The PHS agreed with three recommendations contained in the draft report, although it questioned the availability of the necessary resources at FDA to implement the recommendations. Agency comments regarding these recommendations are reproduced in the report.

The PHS disagreed with a fourth recommendation contained in the draft of the report which suggested that the FDA propose a legislative change to require that all devices be substantially equivalent to a currently marketed device, rather than a pre-1976 device, in order to ensure that devices entering the market incorporate technological advances made since 1976. This recommendation was first made to the Congress by the General Accounting Office in 1988. The PHS argued that such a change would fundamentally alter the classification and regulation of medical devices. Further, the PHS argued that no evidence of a "technological lag" suggesting the need for such a change had been documented. Regardless of the possible merits of such a change, we agree with PHS that insufficient justification for such a recommendation has been presented in this report. Consequently we have deleted the recommendation from our final report.

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## INTRODUCTION

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### BACKGROUND

Results received from medical tests are a critical part of the diagnosis and treatment of disease and illness. Consequently, it is important for proper diagnosis and treatment that such tests are as accurate as possible. In 1988, the Office of Inspector General (OIG) issued reports which described practices in traditional laboratories and physician office laboratories (POLs) that compromised the integrity of medical testing. Due to the concerns regarding the accuracy and reliability of medical testing expressed by the OIG and others, the Congress passed the Clinical Laboratory Improvement Act Amendments of 1988 (CLIA). The Act modified quality assurance controls and established a new system of Federal regulation of medical testing.

However, not all medical testing takes place inside the hospitals, independent laboratories, and physicians' offices to which these new requirements apply. Many Americans engage in some sort of medical testing in the privacy of their own homes. It is estimated that 20 percent of U.S. households use at least one home testing product, accounting for industry sales of \$600 to \$800 million annually. Analysts have predicted that all American households will engage regularly in home testing of some sort by the year 2000.<sup>1</sup>

Medical testing devices or technology intended for home use vary in complexity, design and application. Generally they are categorized into three types. Monitoring devices aid individuals in ongoing assessment of a chronic condition. These devices include blood pressure monitors used by hypertensives to monitor their own blood pressure and glucose monitors used by diabetics to monitor glucose levels in their blood or urine. Screening devices screen for the presence or absence of an unexpected condition or disease; these include tests to detect colon cancer in asymptomatic individuals. Diagnostic tests aid individuals in identifying the presence or absence of a *suspected* condition or disease. Examples of diagnostic tests are pregnancy tests and tests to detect urinary tract infections. Generally health care experts express more concern regarding diagnostic tests than screening or monitoring tests, since the former are more likely to be used by individuals with symptoms of a certain condition or disease who are using the test prior to (or instead of) consulting a physician for diagnosis.

While home use tests may not differ substantially from professional use tests in purpose or technology, several important distinctions do exist. A physician performing a medical test will use the results of the test along with his or her physical examination of the patient, knowledge of the patient's medical history, and results of other medical tests to make a diagnosis or draw a conclusion. The medical test will be performed by a health care professional with experience and training collecting samples, introducing reagents into the specimen and administering the test. However, as the Food and Drug Administration (FDA) has pointed out,

consumers using the same medical test (1) may be unable to evaluate test results in light of other considerations such as physical condition or family history; (2) might perform the test incorrectly or draw inappropriate conclusions from results; (3) may not take the necessary follow-up action; and (4) may not collect and handle body specimens correctly.<sup>2</sup>

### ***Pre-Marketing Clearance***

Home use medical devices, like professional use medical devices, must be cleared by the FDA prior to marketing. Both home use and professional use medical devices are reviewed by FDA according to the Medical Device Amendments of 1976.

The Medical Device Amendments to the Food, Drug and Cosmetic Act enacted in May 1976 required the FDA to classify all devices in commercial distribution prior to May 28, 1976 as Class I, II or III devices depending on the level of control needed to ensure their safety and effectiveness. Class I devices are those devices for which general controls (such as prohibitions against adulteration and misbranding and adherence to good manufacturing practices) are sufficient to ensure their safety and effectiveness. Class II devices are those devices for which performance standards, in addition to general controls, are necessary to ensure their safety and effectiveness. Class III devices are those for which inadequate information exists to determine if general controls and performance standards are sufficient to ensure their safety and effectiveness and therefore require premarket approval (PMA).

The Act further specified that manufacturers wishing to introduce a device into the market subsequent to May 28, 1976 are required to make a premarket notification (510(k)) to the FDA prior to such marketing. The premarket notification must establish that the new device is substantially equivalent to a device on the market prior to May 28, 1976, or a device marketed after that date and placed into Class I or II (a predicate device). If the device is found substantially equivalent to a predicate device, it is placed in the class in which its predicate device has been placed. If FDA finds the device not substantially equivalent, or substantially equivalent to a Class III device, PMA is required.

If a manufacturer wishes to market a home use testing device, the firm must submit the necessary documentation to FDA under the 510(k) or PMA process just as it would if the product were intended for professional use. For manufacturers wishing to market home use in-vitro diagnostic devices (such as pregnancy tests), the FDA has provided draft guidance on how they may address concerns relating to proper and appropriate use of the test by consumers. The FDA suggests that manufacturers conduct consumer field evaluations to test the accuracy of their tests in the hands of intended users; incorporate an internal quality control test; and design appropriate and understandable labeling. Manufacturers must also adhere to good manufacturing practices and prohibitions against misbranding and adulteration that apply to the marketing of any medical device.<sup>3</sup>



## ***Post-Marketing Surveillance***

Once devices are cleared for the market, FDA monitors their performance primarily through the Device Experience Network (DEN) and inspections of manufacturing facilities, operations and records. The FDA may also act on information it receives on device safety and performance from other sources, such as the Consumer Product Safety Commission.

The DEN is a central repository for the collection and assessment of problem reports concerning medical devices received primarily from the Medical Device Reporting system (MDR) and the Medical Device and Laboratory Product Problem Reporting Program (PRP). The MDR system, established in 1984, is a mandatory system of reporting by manufacturers of device problems linked to death, serious injury, or device malfunction that might contribute to death or serious injury. The PRP, established in 1976, is a voluntary system of reporting by health care professionals of any device problems they believe deserve attention by FDA.

## **PURPOSE**

The purpose of this study was to assess the adequacy of FDA's clearance process in ensuring the safety and effectiveness of home testing kits and the degree to which their efficacy is monitored once available for sale. This inspection was requested by the Chairman, Subcommittee on Regulation and Business Opportunities, Committee on Small Business, U.S. House of Representatives.

## **METHODOLOGY**

In order to gather information to address the questions above, the OIG:

- interviewed a number of persons representing the FDA, particularly in the Center for Devices and Radiological Health (CDRH), on the 510(k) process and FDA's Device Experience Network;
- interviewed representatives of professional associations, including the American Pharmaceutical Association, College of American Pathologists, the American Medical Association, the Health Industry Manufacturers Association, and the American Public Health Association concerning consumer use of home testing devices and the FDA's clearance of such tests;
- visited 34 pharmacies in eight cities (Boston, New York, Philadelphia, Atlanta, Chicago, Dallas, Kansas City, and San Francisco) to assess the relative availability of home use testing devices and kits;

- reviewed a random sample of 510(k) submissions made for home test devices;
- reviewed complaints received through the Medical Device Reporting system and the Problem Product Reporting system concerning in-vitro diagnostic products (professional and home use);
- analyzed a sampling of test instructions for home use medical tests for content and readability; and
- reviewed applicable regulations and FDA guidance for manufacturers of home use testing kits.

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## FINDINGS

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*Although home use testing devices are readily available to consumers, and a significant number of consumers use such tests, limited information is available on why, and how effectively, consumers use some of these tests.*

As discussed previously, many Americans test themselves in their own homes, and their number is expected to grow. A public poll conducted by the Roper Organization in 1986 found that 12 percent of the 1,997 adults contacted had used a blood pressure test device at home; 7 percent had used a blood sugar measurement device at home; and 5 percent had used a colon cancer test kit at home. Nine percent of the women contacted in the polling had used a pregnancy test at home.<sup>4</sup>

Home testing kits of various types are readily available to consumers. Of the 34 pharmacies we visited in the course of work on this study, all carried at least one type of in-vitro home testing kit. All but one pharmacy sold pregnancy tests; 28 of the the 34 (82 percent) sold ovulation monitoring tests. Likewise, 82 percent of the pharmacies we visited also sold some kind of glucose or sugar testing kits (blood or urine). Half of the pharmacies we visited sold colorectal screening kits. Many of the pharmacists we visited also sold devices such as glucose monitoring devices and blood pressure monitors.

While glucose monitoring in the home is a widely accepted form of self-assessment and monitoring for diabetics and extensive documentation exists to support its use, little information exists as to value and use of other types of products—particularly diagnostic tests—purchased by the consumer without consultation or supervision by a health care professional. For example, are women who use at-home pregnancy tests delaying important visits to their physicians or seeking care earlier as a result of their use of a home test? Do such women purchase home kits because they are more convenient or less costly than going to a physician, because they desire privacy, or because they are curious? Would women who buy pregnancy tests see a physician instead, or forego the visit altogether, if the home test were not available?

Documentation that does exist regarding consumer experiences with various forms of home testing is limited. For example, the Roper Organization poll found that between 83 and 90 percent of adults who had used home testing devices found them useful. However, the Roper pollsters did not ask if the tests contributed to early identification of a condition or disease, and variances in individual definitions of the word “useful” make it difficult to assign meaning to this statistic. A survey of physicians found that over half (and over 90 percent of the obstetrician/gynecologists surveyed) had received office visits from individuals due to home tests;<sup>5</sup> but the number of individuals who are falsely reassured by an incorrect result and fail to consult a physician for treatment, or postpone that treatment while the problem persists, is unknown.

Controlled studies of lay persons' experiences with pregnancy tests have provided some troubling results. For example, one study of 109 women performing home pregnancy tests found kit accuracy ranging from 46 percent to 89 percent, in contrast to manufacturers' claims of accuracy averaging 97 percent.<sup>6</sup> Another study found that 9.5 percent of results obtained by laypersons with one home test kit, and 12.5 percent of results obtained by the same group with another test kit, differed from the results obtained on the same samples of urine by chemical technologists using professional use tests.<sup>7</sup>

The FDA itself receives very little information on the experience of consumers with certain types of home use devices. Based on data provided by the FDA, only 18 reports received through the Medical Device Reporting (MDR) program since 1984 and the Problem Reporting Program (PRP) since 1976, concern at-home pregnancy tests.<sup>8</sup> Significantly more complaints, numbering in the thousands, have been logged concerning glucose monitors and strips for urine or blood testing. According to FDA officials, most complaints and information received through the MDR and PRP systems come from health care professionals and manufacturers, not consumers. Unless a consumer is knowledgeable or consults a health care professional (as in the case of diabetics using glucose monitors), a negative experience with a home use testing device is likely to go unreported to the FDA.

***Home use tests account for a small percentage of devices cleared under the Medical Device Amendments.***

Home test devices constitute a small portion of FDA's total activity in premarket notification and classification. Out of 17,416 "substantially equivalent" decisions made by FDA between 1985 and 1988, 51 (or less than half a percent) were home testing kits or devices. Between May 28, 1976 and January 1, 1989, FDA cleared 128 submissions for home use test kits, averaging 10 each year.

Of these 128 510(k) submissions cleared, at least 38 (30 percent) were at-home pregnancy tests. The majority of the remainder were tests to detect levels of glucose, ketone, and other elements of interest in the urine and blood. Others cleared through the 510(k) process during this period were tests to detect hidden blood in the stool and ovulation predictors.

Two tests to detect gonorrhea in males were cleared by FDA during this period, one in 1982 and another in 1984. As a communicable disease, gonorrhea can be spread to other individuals from a carrier if he is not properly counseled and treated to avoid contaminating others. According to FDA and other sources, these kits are not currently marketed.<sup>9</sup> In more recent FDA decisions regarding two other home tests for communicable diseases—one to detect streptococcal antigen, and another to detect the presence of the HIV virus—the agency has determined that tests are not substantially equivalent to any predicate device. Both tests are now being considered within the PMA process.

It may be that the HIV and strep tests signal a change in the kinds of home testing devices FDA will have to review in the future: diagnostic tests for communicable diseases of all kinds (including sexually transmitted diseases such as syphilis and herpes) as well as noncommunicable diseases. Of course, FDA's decisions regarding these two products will likely have a substantial impact on future development of similar products.

*The association representatives we interviewed believe that FDA has generally acted cautiously and appropriately in applying the Medical Device Amendments of 1976 to home use tests.*

The association representatives expressed general approval of FDA's course to date in clearing medical devices for home use. These experts commended FDA for its public hearings on home tests in 1985 and on the home test kits for the HIV virus in 1989, at which the agency solicited public comments and opinions regarding the usefulness, benefits and limits of home use devices and the development of its policies for clearing such devices. The major concerns expressed by those interviewed were (1) how to ensure the reliability and proper interpretation of test results obtained in the home and (2) how FDA will react to the proposed marketing of certain home tests (such as tests for strep and the HIV virus) which could have serious repercussions for individual and public health if false results are obtained or proper follow-up does not take place.

Partly in response to these kinds of concerns, FDA released its draft guidance to manufacturers of home in-vitro diagnostic products (IVDs)<sup>10</sup> in November 1988, soliciting public comment. Among other things, FDA indicates that it will require consumer field evaluations and will consider questions of risk and benefit associated with marketing an IVD to laypersons when assessing 510(k) submissions for home test devices.

While most of the individuals we interviewed found this approach reasonable, at least one manufacturing firm commenting on the guidance has questioned whether the risk/benefit analysis constitutes a "mini-PMA" within the 510(k) process. In response, FDA officials we interviewed suggested that an assessment of risk and benefit constitutes a proper part of their comparative analysis of a device's safety and effectiveness. For this reason, the draft guidance states that "consideration of risk and benefit is inherent in the evaluation of safety and effectiveness" and encourages manufacturers of home testing products to submit information on risks and benefits as part of their 510(k) submissions.

While FDA has been criticized by some for requiring too much data to support the 510(k) submissions for home use products, others have questioned whether they have asked for enough—or whether such devices should be cleared by FDA at all. The American Public Health Association, for example, has written to FDA that it has strong reservations concerning home testing, and suggests that "[h]ome testing by consumers should be limited to on-going monitoring activities under the supervision of a physician." The American Pharmaceutical Association suggests that certain types of home testing devices be distributed only through licensed health care professionals, such as pharmacists or physicians.

***Medical tests are generally developed first for professional use, and later modified in design or labeling to be used in home environments. If such modifications and the changes in conditions of use do not raise new unanswered questions of safety and effectiveness, FDA may determine that the home use is substantially equivalent to the professional use device.***

As with any medical device submitted through the 510(k) process, the question of whether a new home test is substantially equivalent to a predicate device is the primary point of inquiry. In determining whether a device is substantially equivalent, FDA has considerable latitude under the Medical Device Amendments. Substantial equivalence was defined in the Report by the Committee on Interstate and Foreign Commerce on the Medical Device Amendments of 1976 as:

*...not...so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products...*

Congress challenged FDA to steer a constructive middle course in making determinations of substantial equivalence. The Committee report went on to say that "...the term [substantial equivalence] should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness."

In spite of the issues described previously in this report that arise when a device is manufactured for home use, rather than professional use, FDA may ultimately determine that a home-use device is substantially equivalent to a professional-use device. The FDA does not, for example, consider that the intended use of a professional use device and that of a home use device is necessarily, or by definition, different. [Under FDA's procedures, if the intended uses of a new and currently marketed device are different, the new device is automatically deemed not substantially equivalent.] Rather, FDA assesses how the differences between a home use device and a predicate device for professional use (in technological characteristics or the change in *conditions* of use) affect safety and effectiveness.

The FDA states in its draft guidance to manufacturers: "When the use of an in-home IVD can be demonstrated to be substantially equivalent, in terms of safety and effectiveness, to a clinical laboratory device when used by a health professional, and the device meets all labeling and other...requirements, it will generally satisfy requirements for market clearance." The FDA proposes in this document to address the issue of safety and effectiveness of home IVDs in part by suggesting that manufacturers conduct consumer field evaluations demonstrating the ability of intended users *unassisted* to perform the test accurately *following the manufacturer's instructions provided in the labeling*. The document does not specify to what extent accuracy (however measured) obtained by consumers conducting the home test in the field evaluation can deviate from the accuracy obtained by health care professionals using the clinical laboratory device and still be considered acceptable for the purposes of

demonstrating substantial equivalence, nor are detailed standards provided for the conduct of consumer field studies.

***As with all medical devices, performance standards have not yet been developed for Class II home tests.***

Virtually all home use devices cleared by the FDA since 1976 have been placed in Class I or Class II. However, no performance standards have been developed for any Class II devices (professional use as well as home use). The FDA estimated to the General Accounting Office (GAO) that development of performance standards for Class II devices would take 50,000 staff years;<sup>11</sup> instead, it relies on its own draft guidance and voluntary standards to judge the performance of medical devices.

As a result, no home testing devices are subject to specific performance standards. The GAO pointed out previously in its 1988 report on medical devices that if such standards were developed, the performance of new devices could be measured against the standards rather than a predicate device.

The FDA, in comments to the draft report, pointed out that while performance standards have not been developed for Class II devices, “FDA has a greater inspectional frequency for Class II devices” and “Class II (and Class III) devices often have a higher priority than Class I devices for other regulatory and educational actions....” The agency cited its device priority system under which certain devices are selected and targeted for attention. The FDA also discussed in its comments “alternative measures [to the setting of performance standards] to resolve problems with Class II devices” including the use of voluntary standards mentioned above, educational programs, safety alerts, and labeling regulations and guidance.

***The FDA has given significant attention, and attached considerable importance, to manufacturer labeling of home use medical tests.***

For any medical device, manufacturers must give “adequate directions for use.” The 1988 FDA draft guidance to manufacturers discusses how manufacturers may meet the test of “adequate directions for use” when developing labeling for home use diagnostic devices.

Our review of 510(k) submissions found that FDA reviewers often required labeling changes from manufacturers to improve user understanding of instructions and the limits of the test. This diligence on the part of FDA reviewers has resulted in a degree of conformity and ease of understanding in product labeling. Our review of labeling and instructions for six at-home pregnancy tests, for example, revealed that instructions frequently (1) include step-wise directions with pictorials; (2) are written at a relatively low (8th grade) reading level; (3) discuss limits of the test; (4) discuss how false results might be obtained; and (5) suggest consultation with a physician if the test is positive, and retesting if the test is negative and symptoms persist.

Certain differences do remain. Only 2 of the 6 test instructions revealed test accuracy obtained by consumers in field evaluations as compared to accuracy obtained by technicians using the test in laboratories, with the higher accuracy ratings obtained in the laboratory either most prominently or exclusively displayed in all six tests. Only one pregnancy test discussed the need for women testing positive to refrain from certain behaviors, including smoking and drinking, pending consultation with her physician.

The FDA is now in the process of completing a study on human factors in blood glucose monitoring, which concentrates in part on "the quality and quantity of instructional material available to meter users for learning proper meter operation and maintenance."<sup>12</sup> The study also assesses the design of various blood glucose meters and the extent to which their design helps or hinders operation by lay users. The FDA expects to issue a final report on the study in October 1989, and to share the results (including suggestions for improving instructions and instrument design) with blood glucose manufacturers and professional associations at various forums beginning in the fall of 1989.



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## RECOMMENDATIONS

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***The FDA should devise ways to increase its knowledge concerning actual consumer experiences with home use testing devices.***

The OIG plans to conduct, in consultation with FDA, a follow-up study in this area which will include a random telephone survey of consumers to address questions such as the extent of use of home use in-vitro products; the range of decisions made by consumers as a result of testing; and the value consumers see in such tests in monitoring or assessing their own health status. The FDA officials we spoke to agreed that such a survey would be useful in developing policies for the clearance and post-marketing surveillance of home testing kits.

The FDA should consider additional ways of obtaining information on user experience, including limited, one-time cooperative ventures with manufacturers to include a postcard insert in packaging addressed to FDA (pre-identified with lot number, product name, and other identifying information) concerning consumers' satisfaction and experiences with certain kinds of products.

The FDA might also consider requiring manufacturers to include in product labeling for certain home use products a telephone number and/or address consumers can use to report product-specific complaints to the United States Pharmacopeia (which now receives such complaints directed to the MDR and PRP systems) or FDA district offices. We recognize, however, that such a step risks some number of inappropriate or nonspecific contacts that would not contribute to FDA's understanding or knowledge of problems related to specific in-home devices. However, information collected through the MDR and PRP systems for professional use devices is a source of information for FDA in taking corrective actions to improve the safety and effectiveness of these products. It is reasonable to assume that information collected for home use tests would prove of similar value.

### ***PHS Comment***

We generally concur. We agree that more could be done in this area and, in fact, are assisting the OIG in conducting their follow-up study of consumer use and experiences with home use testing devices. FDA's Center for Devices and Radiological Health (CDRH) has already received a draft statement of work from the OIG for a contract to conduct a telephone survey of consumers. While we believe it would more appropriate for the FDA, rather than OIG, to design and implement such a contract (due to FDA's programmatic responsibilities and experience in this area), we are glad to cooperate with OIG in conducting this project.

However, absent the OIG effort, FDA does not have the programmatic resources to collect, interpret, and evaluate direct consumer feedback regarding their experiences with home testing devices. Therefore, we do not agree with other efforts described in this

recommendation. We are also opposed to having manufacturers insert postcards in their products that users could use to send experience information directly to us. If just 20 percent of the U.S. households currently use home test kits, this suggestion could have the potential to generate an unmanageable number of reports. We currently do not have the resources to receive and evaluate that large an amount of data. Manufacturers should be responsible for monitoring their own products. They are in a better position to evaluate the significance of user reports and react faster when an actual problem is identified.

For similar reasons, we oppose product labeling which would include a telephone and/or address consumers could use to report product complaints to FDA, District Offices, or the United States Pharmacopeia. This would require a revision in the labeling regulations and generate a potentially large number of consumer complaints. We do not have the resources to handle this volume.

However, we would like to point that each FDA District Office has a Consumer Affairs Officer (CAO) to work directly with consumers. The CAOs have ready access to CDRH and we have always been available to help with inquiries as necessary. In addition, FDA field offices have a standard system for accepting and following up on all consumer complaints. CDRH receives copies of these complaints although device complaints are not numerous.

### ***OIG Response***

We appreciate PHS concerns in regard to FDA resources that might be required to pursue some of the alternatives we suggest. However, we continue to believe that creative strategies can be employed which would not involve a substantial or inappropriate use of FDA resources. For example, use of the postcard insert might be implemented on a sample basis, or limited to certain kinds of products. Efforts might be directed at one-time, rather than ongoing, evaluations which would limit the number of resources required over the long term. It is possible that some efforts might be contracted out, or funded under some existing method such as the PHS Medical Effectiveness Research initiative.

It is quite probable that, given its expertise in this area, the agency could develop other, less resource intensive strategies to obtain information on consumer experiences which have not occurred to us. Our intent is not to prescribe which strategies ought to be employed; rather, it is to recommend that workable strategies be developed. If PHS believes that additional resources are required to carry out the strategies it develops, the agency could reassign or request additional resources.

***The FDA should place continuing emphasis on consumer field evaluations to ensure the accuracy and reliability of home testing devices.***

As previously discussed, various quality assurance mechanisms are present for medical testing in hospitals, independent laboratories, and physician office laboratories. For example, tests are performed by qualified personnel familiar with quality control procedures (such as maintaining positive and negative controls). These controls are not present in the home environment, where the test might be carried out under adverse conditions by inexperienced users.

In this environment, performance standards would be one tool in helping to ensure a minimum degree of test safety and effectiveness. Under current law, however, the development of performance standards is a time and labor-consuming effort. Further, it is probable that more complex and life-affecting medical devices would take priority in FDA's efforts to develop performance standards for Class II medical devices. Therefore, it is unlikely that performance standards will be developed for home tests in the near future, unless legislative change occurs to streamline the procedure, limit the number of devices in Class II, or place additional resources at FDA to devote to the task.

Regardless of whether performance standards are developed for home use tests, consumer field evaluations are the key to ensuring that a given test performs accurately and reliably in the hands of consumers. Standards, when and if developed, should be tied to the performance of the test in these field evaluations. In the absence of standards, consumer field evaluations can assure that the test performs at least as well for lay persons as for health professionals.

For this reason, FDA should focus particular attention, as it has begun to do, on this aspect of the clearance process for home use testing devices. The FDA should ensure that such field evaluations are conducted in a consistent and statistically valid manner. Additional guidance from FDA to manufacturers on how to conduct these trials may be necessary.

Further, FDA should require manufacturers to disclose the results of consumer field evaluations, in understandable language, when discussing the accuracy of their products. Such information is important if consumers are to be fully informed of the limits of the test and the likelihood or possibility of obtaining a false result.

#### ***PHS Comment***

We agree. As noted in FDA's draft guidance for home in-vitro diagnostic products, consumer field evaluations will continue to play an important part in FDA's assessment of 510(k) submissions of home testing devices.

As to standards for the conduct of such consumer field evaluations, the National Committee for Clinical Laboratory Standards (NCCLS), a national standard-setting organization, has been

presented with proposals from the Consumer Federation of America to develop industry guidelines for carrying out these evaluations.

Various programs in FDA's Center for Devices and Radiological Health's Office of Training and Assistance are exploring methods to evaluate the accuracy of home testing devices used by non-professionals. A recently completed FDA contract study on Human Factor Analysis of Blood Glucose Monitoring supports usability testing as a valid tool for use by manufacturers, and also outlines a method for assessing the usability [of] instructions for use. In addition, the Office of Training and Assistance has just completed a revised labeling document to aid manufacturers. Finally, a NCCLS subcommittee is developing an industry guidance document entitled, "Labeling of Home-Use In-Vitro Diagnostic Products" which complements and builds on the FDA draft guidance to manufacturers of home in-vitro diagnostic products referenced in the OIG report.

***The FDA should continue its efforts to work with manufacturers to improve product design, labeling and instructions in order to increase the public's ability to appropriately use the home testing kits it clears.***

Continued emphasis on labeling considerations by FDA reviewers of 510(k) submissions is an important element in ensuring that home testing devices can be used successfully by untrained consumers. Without understandable guidance, consumers may misuse the test to the detriment of their own and (in the case of tests for communicable diseases) possibly others' health.

The work of the FDA on blood glucose monitors will provide FDA with important information on the labeling and design of these home use devices. If it is successful, the cooperative approach between FDA and blood glucose manufacturers in improving product design, labeling and instructions of these products would be an appropriate model for FDA to apply to other home testing devices.

#### ***PHS Comment***

We agree. As stated in the OIG report, FDA has worked with manufacturers, primarily through the 510(k) process, to improve product design, labeling and instructions. In addition, FDA has worked with various organizations such as the Health Industry Manufacturers Association (a trade association for a majority of device manufacturers), Regulatory Affairs Professional Society (a professional society for regulatory specialists in industry), and the above mentioned National Committee for Clinical Laboratory Standards (a national standards-setting organization) to facilitate the necessary dialogue for product improvement.

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## ENDNOTES

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1. See Thomas A. Gossel, *American Journal of Hospital Pharmacy*, Volume 45 (May 1988), p. 1119.
2. Food and Drug Administration, Center for Devices and Radiological Health, "Assessing the Safety and Effectiveness of Home Use In-Vitro Devices: Draft Points to Consider," October 1988.
3. Marketing factors, including competitive pressures and concerns regarding product liability, also encourage manufacturer responsibility in developing and marketing medical products for home use.
4. Roper Organization, survey conducted December 6, 1986 to December 13, 1986, Roper Report 87-1 (March 1987).
5. M. Ratafia, "Diagnostics in Physicians' Offices," *American Clinical Product Review*, November 1985, p. 12-22.
6. Mary L. Doshi, MA, "Accuracy of Consumer Performed In-Home Tests for Early Pregnancy Detection," *American Journal of Public Health*, Volume 76, Number 5 (May 1986).
7. Joycelyn M. Hicks, Ph.D. and Mariet Iosefsohn, M.S., "Reliability of Home Pregnancy Test Kits in the Hands of Laypersons," *New England Journal of Medicine* (February 2, 1989), pp. 320-321.
8. Ten of these reports were made by pharmacists, four by consumers, one by the manufacturer, and two by unknown sources. One report was made by a physician who unsuccessfully used a home pregnancy test to determine the presence of testicular cancer, a nonindicated use of the test.
9. States objected because individuals could obtain positive test results through home testing and avoid reporting requirements imposed on individuals tested in professional health care environments. Manufacturers of the kits could not be contacted for an interview.
10. In vitro diagnostic products are "those reagents, instruments and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." 21 CFR 809.3(a).

11. The General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved, GAO/PEMD-88-14, p. 52.

12. Pacific Science & Engineering Group, Inc., "Human Factors Analysis of Blood Glucose Monitoring," Food and Drug Administration, Contract 223-87-6023.