



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW -USA

**HIV SELF-TESTING
REGULATION AND POLICY**



FOREWORD

While the focus of much of the global community may be moving on from HIV and AIDS to other issues, it cannot yet be said to be “the end of AIDS” in Africa. HIV & AIDS will continue to impact communities and public health systems in eastern and southern Africa for decades to come and both morbidity and mortality in the region will be significantly increased as HIV & AIDS influences health issues such as TB, maternal mortality, and sexual and reproductive health more broadly.

One of the key critical success factors in fulfilling the UNAIDS and global goal of zero new infections, zero deaths and zero discrimination is people knowing their own HIV sero-status and having the ability to act on the knowledge. Yet in eastern and southern Africa, despite decades of investment in HIV testing and counselling, many people still do not know their status.

Across the region there remain wide variations in data regarding the proportion of the general population who have accessed HTC. Figures for 2011¹ show Botswana at over 60% (2011), Malawi at 34%, and Zambia 15%. **Presently less than half of all Africans know their HIV status, and only 25% received an HIV test in 2012¹.** Uptake and access to HIV testing is lower among members of key population communities who, while facing a higher HIV burden, also face issues of stigma, discrimination and other barriers to access.

It is in this context that SAT believes in thinking out-of-the-box. After decades of investment more of the same is unlikely to be a game changer with regard to increasing the number of people empowered by knowledge of their own status to take action.

HIV self-testing may be just such an ‘out-of-the-box’ solution. Defined as, ‘when a test is collected, performed and interpreted in private by the individual who wants to know their HIV status’, self-testing, in combination with other new thinking on HTC opens new possibilities for reach and engagement.

To explore this possibility, SAT commissioned a multi-country legal review of national policies and legislation that frame and provide the context for thinking about HIV self-testing.

With the generous coordination from the Thomson Reuters Foundation, SAT worked with a strong team of international and Southern African legal firms to conduct a review of the laws relevant to HIV self-testing (HIVST) in their respective jurisdictions, namely Botswana, Malawi, Mozambique, South Africa, Tanzania, Zambia and Zimbabwe as well as France, the UK (England) and the USA. All work conducted by the firms (see below) was done on a pro bono basis as a contribution to global development.

The review sought to answer key contextual questions that would frame any pilot or projects that countries might choose to take up to increase numbers of the population who know their HIV status. Included were questions such as, “Is HIV self-testing legal and, if so, under what conditions?”, “What legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this

¹ UNAIDS 2013; WHO 2013

distribution?” and “What are the human rights issues surrounding HIVST?” The review looked across SAT’s countries of operating but also went broader to explore the situation in the USA, France and the UK – all of which have now legalised self-testing after thorough national debates and scientific input.

In the last stages of the review SAT and the University of Witwatersrand Reproductive Health Institute hosted a Consultative Workshop in March 2014 with participants from governments, National AIDS Councils, key population groups, community organisations, WHO, medical experts and researchers. The think tank worked with the emerging review as well as with evidence from two very successful research/pilot sites in the SADC region and explored what the possibilities and practicalities of implementing self-testing might be. The think tank report may also be accessed on the SAT website above.

The issue of self-testing is not uncontroversial, and it has been known to raise strong feelings both for and against. The think tank was useful and hearing from the research sites de-bunked many of the myths about self-testing such as “it is incompatible with referring people into the health system”, or “people will not understand how to use it or how to interpret the results”. Innovators in a number of places, not least in the SADC region, have worked hard and designed and tested solutions and in some cases products to overcome these challenges.

HIV self-testing is not a magic bullet. In combination with other innovative thinking, however, it may hold the key to increasing reach of testing, opening new options for hard to reach communities, making life easier for serodiscordant couples and supporting both prevention and treatment.

We are pleased to present to you the HIVST Legal Report for United States of America. This report is intended to inform SAT and all its strategic partners about the legal framework and human rights implications relevant to HIVST in United States of America.

The summary consolidated findings for all the above mentioned countries as well as individual country reports are available at SAT on request as well as on the website, www.satregional.org .

It is our fervent hope that the findings will have a catalytic effect on dialogues on this subject and forge a way for HIV self-testing in United States of America and across the region.

Welcome to the conversation. We look forward to your feedback.

Jonathan Gunthorp



Executive Director - SAT

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Special thanks go to Arnold & Porter LLP (United States of America) who provided pro bono legal services to undertake the review on HIV Self-Testing in United States of America and Arnold & Porter (USA), in particular to Catherine Young for coordinating the legal review in all the participating countries.

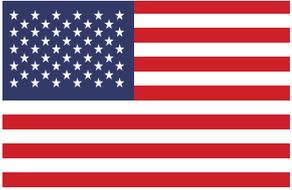
SAT also wishes to thank civil society organisations and partners who attended the HIV Self-testing Consultative Workshop in March 2014 to discuss the draft legal reports, including the merits, challenges and opportunities of integrating HIV self-testing into existing community level HIV and SRHR programmes.

SAT is grateful to Wits Reproductive Health Institute for all their technical support and input during the March 2014 HIV Self-Testing Consultative Workshop.

Last but not least, we would like to thank Thomson Reuters Foundation's global pro bono service, TrustLaw, who helped coordinate the project and brokered, free of charge, the relationships between SAT and the legal firms.

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1. INTRODUCTION

- 1.1 The purpose of this memorandum is to provide Southern African AIDS Trust (“SAT”) with information and guidance as it explores options for promoting and implementing HIV self-testing in sub-Saharan Africa, Botswana, Malawi, Mozambique, Tanzania, Zambia and Zimbabwe. Although rapid HIV self-testing has not been widely implemented in many countries, the United States approved the first such test for home use in 2012. To inform SAT’s work in Africa, this memorandum therefore outlines the U.S. system for regulating HIV self-testing and the process by which self-testing was approved. Policy arguments for and against self-testing are also presented.
- 1.2 Given the differences among the U.S. regulatory system for medical devices and that of other countries, certain information presented in this memorandum may not be readily transferrable to other jurisdictions with different legal and regulatory compositions. Further, because of the unique context surrounding HIV laws in the United States -- including variable state and local laws regarding criminalization, confidentiality, and treatment -- the arguments in support of HIV self-testing may not be directly applicable to other countries. We have prepared this memorandum with these limitations in mind, however we nevertheless believe that the discussion of HIV self-testing within the United States provides helpful context for many of the legal and human rights issues implicated by SAT’s efforts. A table summarising the applicable laws on each of the questions and issues SAT has highlighted is provided in section 7 (Further Information).
- 1.3 This memorandum first provides background on how HIV tests are approved for commercial distribution in the United States, and then discusses the policy arguments for and against self-testing raised in the debate over approval in the United States. Furthermore, the memorandum discusses the first self-testing option available in the United States, which required mailing a specimen to a qualified laboratory to receive results, as well as the first rapid at-home test approved for use. Finally, this memorandum concludes with thoughts on how lessons from the U.S. experience with HIV self-testing can be applied in other countries.

2. BACKGROUND ON U.S. REGULATION OF HIV SELF-TESTING

- 2.1 In the United States, tests that are used to determine whether an individual is infected with HIV are regulated by the Food and Drug Administration (the “FDA” or “agency”) under authority provided to the agency by legislation¹ enacted by the United States Congress. The FDA regulates the commercial distribution of numerous types of products including drugs, medical devices, biological products, dietary supplements, food, cosmetics, and tobacco products. Most HIV tests are considered “medical devices” because they are in vitro diagnostic instruments intended for the use in the diagnosis of disease,² see Federal Food, Drug, and Cosmetic Act § 201(h), and are regulated by the FDA’s Center for Biologics Evaluation and Research (“CBER”) under the FDA’s medical device authorities.³
- 2.2 HIV tests for professional and in-home use generally require premarket approval (“PMA”) prior to marketing, which is the process of scientific and regulatory review through which the FDA evaluates the safety and effectiveness of a medical device. This process requires the submission of a premarket approval application

¹ The relevant legislation is the Federal Food, Drug, and Cosmetic Act, which is routinely amended by legislation affecting the FDA’s authority to regulate drugs and devices. Broadly speaking, Congress provides wide latitude to the FDA to regulate these products, and the FDA regulates these tests as medical devices through its Center for Biologics Evaluation and Research.

² FDA has not issued a regulation defining and classifying HIV tests (including HIV STs). Consequently, HIV tests are by default regulated as Class III medical devices. HIV tests, including HIV STs, are generally categorized as “in vitro diagnostic devices,” which are defined in FDA regulations as “those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae . . . intended for use in the collection, preparation, and examination of specimens taken from the human body”). 21 C.F.R. § 809.3

³ In vitro tests for HIV that are recommended for blood donor screening and related blood bank practices are licensed as biologics, whereas in vitro tests for HIV that are not performed in relation to blood bank practices (e.g., quantitative HIV assays and diagnostic tests that evaluate specimens other than blood) are regulated by CBER as medical devices. See FDA, Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2 (December 1999).

to the FDA, and approval of a PMA application is based on a determination by the FDA that the application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. Bringing a medical device to market through the PMA pathway can be a very lengthy process, and applicants typically conduct extensive clinical studies to support the approval of their products.

- 2.3 In the U.S., there are four general categories of tests that can be used to test for HIV infection: (i) laboratory assays conducted by trained professionals, (ii) rapid HIV tests conducted in healthcare settings, (iii) mail-in tests, and (iv) in-home tests. HIV ST can be defined as testing in which the individual collects his or her own sample.⁴ In most cases, the diagnosis of HIV infection is conducted primarily through the use of laboratory-based assays or a rapid HIV test performed by a healthcare professional (“HCP”) in a healthcare setting.⁵ For individuals who wish to test anonymously, two categories of home-based testing options are also available. Mail-in tests allow a user to collect a dried blood specimen using an over-the-counter home specimen collection system. This specimen is then mailed to a laboratory for testing by a trained professional, and results are subsequently provided to the user via telephone. See *infra*, Section IV, Home Access HIV-1 Testing. In addition to mail-in testing, the FDA recently approved the OraQuick In-Home HIV Test (“In-Home Test”) -- the first entirely home-based test that individuals can use to receive a nearly immediate determination of HIV infection. See *infra*, Section V, OraQuick In-Home HIV Test. In its approval letter, FDA described OraQuick as “a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in human oral fluid specimens” intended for over-the-counter “consumer use as an aid in the diagnosis of infection with HIV-1 and HIV-2.” Unlike the mail-in tests, testing with OraQuick requires a user to be responsible for all aspects of the testing process, including administration of the test and interpretation of the results. Counselors are available to speak with individuals testing with the OraQuick product, however individuals still receive their results independently. It requires an affirmative step on the part of a self-testing individual to be put in touch with such a counselor.
- 2.4 Finally, as noted above, there are a number of laws related to home testing that are not addressed in this memorandum due to the uniqueness of the U.S. system. Privacy protections are an important consideration in any discussion of at home testing. Improper disclosure of HIV status can have many serious consequences because of the misperceptions, stigma, and discrimination surrounding HIV, including violence, social ostracism, and denial of employment. The United States has robust privacy laws and confidentiality guarantees for health information, including federal standards to protect the privacy and security of medical records, and also anti-discrimination laws that govern the use of such information when disclosed. Notably, however, power in the United States is shared between the federal and state governments, and local jurisdictions within the states also may have regulations governing issues related to HIV. Some laws related to the rights and obligations of disclosure of HIV-status are state-based and therefore may vary widely. Accordingly, it is difficult to draw conclusions or formulate specific recommendations based on the U.S. experience that will be relevant to the legal environment in Southern Africa. Similarly, it is difficult to draw generalities about criminal issues related to HIV from the perspective of the United States (e.g., those criminalizing the transmission or exposure to HIV) because these largely are state laws and vary from state to state. Indeed, not even all of the states have laws that specifically criminalize knowingly exposing another person to HIV. Due to these idiosyncrasies, we have limited our analysis and research in this memorandum to the broad legal and policy issues surrounding the implementation of HIV self-testing within the United States. For a high level summary of the applicable laws on each of the questions and issues SAT has highlighted please refer to the table provided in section 7.

3. PUBLIC POLICY ARGUMENTS FOR AND AGAINST SELF-TESTING IN THE UNITED STATES

- 3.1 Approval of the OraQuick In-Home Test in the U.S. was the culmination of a debate regarding home HIV collection and testing kits that spanned more than two decades, with fervent arguments made on both sides. Traditional testing methods unquestionably fail to reach a substantial number of infected persons. In certain cases, the shortcomings of traditional, provider-based testing prevent early detection, which generally permits greater treatment success.⁶
- 3.2 Self-testing advocates argue that given the importance of early treatment and knowledge in mitigating the spread of HIV, any tool that can facilitate awareness of HIV status should be implemented. Moreover, people with HIV may fear social isolation and employment discrimination should their status be discovered, and at-home testing provides a discreet and convenient method of determining an individual’s HIV status. As a result, self-testing can minimize some of the barriers of stigma and inconvenience associated with testing in professional settings and may improve testing uptake.⁷ Increased rates of testing, moreover, may reduce HIV/AIDS-related stigma by normalizing HIV testing and perhaps even positive diagnoses.⁸

⁴ See Sue Napierala Mavedzenge, Rachel Baggaley, and Elizabeth L. Corbett, *A Review of Self-Testing for HIV: Research and Policy Priorities in a New Era of HIV Prevention*, 57:1 CLIN. INFECT. DIS. 126 (July, 2013).

⁵ If a patient tests positive through one of these assays, a second test is conducted to confirm the results.

⁶ Sheldon Campbell and Roger Klein, *Home Testing to Detect Human Immunodeficiency Virus: Boon or Bane*, 44:10 J. CLIN. MICROBIO. 3473, 3473 (2006).

⁷ E.g., A. David Paltiel and Rochelle P. Walensky, *Home HIV Testing: Good News but Not a Game Changer*, *Annals of Internal Med.* 744, 745 (2012).

⁸ Janne Krause et al., *Acceptability of HIV Self-Testing: A Systematic Literature Review*, 13 BMC Pub. Health 735, 1 (2013).

- 3.3 Further, rapid, at-home tests like OraQuick may facilitate linkage to care better than traditional testing methods. Specifically, because some traditional testing can take up to two weeks, certain individuals fail to return to receive their results and thus are lost to follow-up care or counseling.⁹ And because at-home testing permits individuals to deal with the testing and results on their own time, proponents assert that it may actually decrease psychological distress compared to testing in the professional setting.¹⁰
- 3.4 In contrast, opponents have argued that the purported benefits of self-testing in terms of detecting cases and reducing transmission are overstated and unrealistic. In part, these arguments are premised on the idea that self-testing options would “attract a predominantly affluent clientele composed of persons at low risk for infection (the ‘worried well’ and new sexual partners), persons with very recent (and therefore undetectable high-risk exposures,¹¹ and persons with known HIV infection seeking to monitor their therapy or to pursue a misperception that treatment has reversed their seropositivity.”¹² Commentators also have criticized the practical benefits of at-home tests given that positive results require confirmation in the clinical setting.¹³
- 3.5 Other concerns commonly raised are related to accuracy, error, and misuse.¹⁴ The issue of false negatives is particularly significant with OraQuick, which generally cannot detect infection within the first ninety days of exposure. On this point, moreover, it bears mention that people generally are most infectious in the early weeks after infection. Further, there was concern that testers would misinterpret their results as final diagnoses and fail to seek follow-up testing or care.¹⁵ There were also concerns that positive results might increase suicides or could be misused to persecute HIV-positive individuals.¹⁶ Additionally, critics questioned the ability of lay people to conduct self-testing accurately.
- 3.6 Critics further have emphasized that testing cannot itself reduce the incidence of HIV or improve access to treatment. Testing in the professional setting generally provides a more direct link to counseling support and care, whereas disclosure of at-home test results and utilization of counseling services and care depend on the individual’s willingness to take action. Further, willingness aside, some individuals may have difficulty understanding and accessing information and services, particularly persons with limited means and education.¹⁷

4. FIRST FDA-APPROVED SELF-TESTING OPTION: HOME ACCESS HIV-1 TESTING

4.1 Background

- 4.1.1 The Home Access Express HIV-1 Test System (“Home Access Test”), which is sold in the United States under the trade names Home Access® and Home Access® Express and manufactured by Home Access Health Corporation, was the first FDA-approved home testing option in the United States, approved on July 22, 1996. The product is approved for the purpose of anonymous HIV-1 testing for self-use by adults (defined as eighteen years or older). Although the test requires a blood sample, it is designed for use by individuals who have no training or experience in drawing blood specimens. The FDA approved the Home Access Test to provide education about HIV infection and risk reduction and to offer counseling, medical/psychosocial referrals, and assistance in partner notification. As indicated in the product’s name, the Home Access Test only indicates the presence of the HIV-1 strain of the virus; in contrast, the OraQuick In-Home Test, discussed below, can identify the existence of HIV-1 and HIV-2.

⁹ Alexi A. Wright and Ingrid T. Katz, Home Testing for HIV, 354:5 N. Eng. J. Med. 437, 439 (2006).

¹⁰ Carrie Arnold, At-Home HIV Test Poses Dilemmas and Opportunities, 380 World Report 1045, 1046 (2012).

¹¹ The test detects a person’s immune system’s response to the virus. People typically develop a detectable response within six weeks of infection; most people will have developed a detectable within three months.

¹² E.g., Paltiel, supra note 7, at 744.

¹³ E.g., id.

¹⁴ Campbell, supra note 6, at 3475.

¹⁵ Wright, supra note 9, at 439.

¹⁶ Roger Parloff, “The Quiet Scandal of the HIV Home Test Kit: Did the FDA’s Former Ban on Home Testing Kits Result in Thousands of Avoidable Infections,” CNNMoney (July 9, 2012).

¹⁷ Krause, supra note 8, at 7.

4.2 Use of the home access HIV tests

- 4.2.1 In order to use Home Access, individuals collect a blood specimen, which is then shipped to a qualified testing laboratory. The first step in the process is for the individual to call a toll-free number to register the unique 11-digit number provided in the kit. Following that point, the individual takes a blood sample and ships it to a Home Access testing center. The product comes with a “Directional Insert” that explains the process for collecting a blood sample. In general, the procedure requires an individual to draw a small amount of blood from a finger, and the Home Access Test and Home Access Express kits come with all the equipment necessary to draw the sample. Clinical tests have demonstrated that 98% of Home Access product users collect blood samples as effectively as phlebotomists, thus effectively eliminating concerns about specimen collection.¹⁸ Results of the Home Access Express test are ready in three business days, and the results of the regular Home Access test are ready in seven business days.
- 4.2.2 Test results from the Home Access products are extremely reliable. Because blood is used (rather than saliva, as with the OraQuick test), the sensitivity of the Home Access tests is effectively 100% (i.e., in clinical studies, the Home Access testing methods identified HIV-positive persons as positive in all cases).¹⁹ Consequently, the FDA has approved the product for marketing as having “99.9%” accuracy. In addition, the product packaging indicates that it is as “Reliable as Tests Used By Doctors and Hospitals.” In comparison to the OraQuick In-Home Test, discussed further below, the 99.9% accuracy rate runs across individuals who are determined to be both HIV positive and negative. On the other hand, while the OraQuick In-Home Test determines HIV negativity to a degree of 99.9%, HIV positivity is determined only to a 91.7% degree of accuracy.

4.3 Patient notification

- 4.3.1 It is notable from a policy perspective that the makers of the Home Access Test “reserve the right to defer giving test results to clients who are likely to harm themselves or others after they obtain their results.”²⁰ Although the packaging does not indicate how Home Access personnel may reach this conclusion, this warning nevertheless reflects one of the central concerns with HIV home testing in general, i.e., that certain individuals may not be equipped to deal with an HIV positive diagnosis.
- 4.3.2 To ensure results are conveyed in an appropriate fashion, with sensitivity to patient reaction, the Home Access Test results are classified into three categories: (1) negative; (2) indeterminate; and (3) positive. Many individuals who are determined to be HIV negative will receive their results from an automated system established by Home Access Health Corporation; these individuals will, upon request, have the option of speaking with a counselor. All individuals with indeterminate or positive results will receive results directly from live counselors. Individuals testing positive may speak with counselors 6 times over a 12-month period after their results become available.
- 4.3.3 In order to address concerns with patient reaction, counselors who deliver positive results are charged with assessing the coping skills, availability of personal support networks, and ability to inform sexual/needle-sharing partners. Information can be provided by the counselors to assist the individual with informing others about the positive test results, and, if requested, counselors will refer individuals to their local public health services. Clients with positive results are also referred to physicians or clinics within their geographic location, as well as a referral to the National AIDS Hotline and other psychosocial services if they want.

4.4 Policy and practical considerations

- 4.4.1 A major benefit to a mail-in self-testing option that relies on a blood sample, such as the Home Access Test, is that an individual’s specimen can be tested in a qualified laboratory, and the efficacy of the testing comes with a higher degree of reliability and accuracy. In addition, individuals who test positive receive their results from a counselor who is trained to convey that news with sensitivity and can immediately provide information for the individual to access other healthcare and psychosocial services.

¹⁸ Home Access HIV-1 Test System Summary of Safety and Effectiveness, available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm091849.pdf>. Blood samples are tested according to Organon Teknika Corporation Vironostika HIV-1 enzyme immunoassay (“EIA”) licensed protocol or the Genetic Systems LAV EIA HIV-1 EIA, at the direction of the Home Access Health Corporation. The Waldheim Pharmazeutika Flurognost Immunoflourescent HIV-1 Antibody (“IFA”) test is performed on all repeatedly EIA reactive blood spot samples.

¹⁹ Id. at 13.

²⁰ Home Access FDA Labeling available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM091852.pdf>.

- 4.4.2 On the other hand, testing with a mail-in option like the Home Access Test requires a significant infrastructure to operate. Not only does this system rely upon the use of qualified testing laboratories and an effective mailing system, but an important element of the Home Access Test is the ability of the manufacturer to connect individuals with positive (or indeterminate) results with counselors. A mail-in option also involves a necessary delay in the receipt of results, which may cause anxiety or frustration for the impacted individual. In contrast, a rapid, complete self-testing option permits individuals with the ability to test at home, in complete confidence, and receive immediate results. As a practical policy consideration, counseling should always be made available to individuals who are testing on their own, but with the OraQuick product, individuals merely have the option to call in to receive counseling, which lessens the operational burdens involved.

5. APPROVAL OF ORAQUICK IN-HOME HIV SELF-TEST

5.1 Background

- 5.1.1 As discussed above, the FDA approved the OraQuick In-Home Test in 2012. The agency has been criticized for not approving rapid at-home testing sooner -- the FDA first received a marketing request for a rapid at-home test in 1988.²¹ The agency deliberated on that request for approximately two years before deciding to restrict HIV testing to healthcare professionals.²² Over time, the agency's position shifted. As discussed above, the agency approved home-collection kits for HIV testing in 1996.²³ In 2005 and 2006, the agency held public hearings on the approval of the OraQuick In-Home Test, considering testimony from a diverse group of interested parties, including "physicians, evangelists, gay activists, venture capitalists, and public health officials."²⁴ The agency considered the legal performance requirements for home tests against the backdrop of the OraQuick In-Home Test's potential public health impact.

5.2 Use of OraQuick

- 5.2.1 OraQuick is manufactured by OraSure Technologies, Inc. The OraQuick In-Home HIV Test is based on the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test ("OraQuick Advance Test"), which is a lab-based professional HIV test that was first approved for marketing in 2003. The OraQuick In-Home HIV Test has the same design and is manufactured through the same process as the OraQuick ADVANCE Test. The only differences between the two products are in the packaging and labeling.
- 5.2.2 The OraQuick In-Home HIV Test is a single-use, qualitative immunoassay that is approved for the detection of antibodies to HIV-1 and HIV-2 in human oral fluid samples only. The test is available for purchase without a prescription online as well as at several commercial retail stores that are available throughout the U.S. The test is only approved for use in individuals 17 and older, with the barcode used to advise store clerks on the age restriction at the point of purchase.²⁵ When using the OraQuick In-Home Test, the user is responsible for all aspects of testing including collection of the specimen, administration of the test, and interpretation of the results. The In-Home Test is not intended for conclusive determination of HIV status. Rather, as set forth in product labeling, the In-Home Test is intended for consumer use "as an aid in the diagnosis of infection with HIV-1 and HIV-2" (emphasis added). Accordingly, the product labeling includes several statements advising users that confirmatory testing is needed (e.g., "A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting," and "A positive result means that you may have HIV. A doctor, clinic or healthcare professional must confirm your OraQuick® InHome HIV Test result.>").
- 5.2.3 To obtain a result using the OraQuick In-Home HIV Test, the user swabs his/her upper and lower gums to collect an oral fluid specimen onto a test stick. The user then places the test stick inside a test tube containing a developer solution, after which the user must wait 20 to 40 minutes before reading the results. If the specimen contains antibodies that react with HIV antigens, a reddish purple line appears in the device's "test zone" qualitatively indicating the presence of antibodies

²¹ In 1988, the FDA declined to accept an application for a rapid home blood test for HIV. Parloff, *supra* note 16.

²² Wright, *supra* note 9, at 438. The FDA was sued over the decision.

²³ *Id.*

²⁴ *Id.* at 437.

²⁵ Berman, Shira. "At-Home Rapid HIV Testing: An Interview with FDA," *Medscape* (August 1, 2012) (Interview with Elliot Cowan, Chief of the Product Review Branch in the Division of Emerging and Transfusion Transmitted Disease at CBER).

to HIV-1 and/or 2 in the specimen. In addition to the line in the test zone, if the test is functioning properly, a reddish-purple “control” line will also appear in the test’s “control zone.” If no antibodies to HIV-1 or HIV-2 are present in the specimen, only the control line is visible and the test should be interpreted as negative. By contrast, if antibodies to HIV-1 or HIV-2 are present in the specimen, two distinct lines appear in the test device window. Regulatory review

A. CLINICAL STUDIES AND RISK-BENEFIT ANALYSIS

- 5.2.4 FDA’s approval of the OraQuick In-Home HIV Test was predicated in part on the results of three categories of clinical studies: Phase I Studies to establish the performance of the test in the hands of trained users and the inherent sensitivity and specificity of the test, Phase II Studies to establish the performance of the test in the hands of untrained users under observation, and a Phase III Study to establish the performance of the test system as a whole in the hands of untrained users in the actual intended use setting (at home). As part of the Phase II Studies, OraSure conducted a Quantitative Label Comprehension Study to assess the ability of users to correctly comprehend key messages from the packaging and labeling, including understanding of key warnings, proper test procedures, and test result interpretation. All but one of the observed comprehension scores in the study were >80% with the majority being >90%.²⁶ In addition to the Quantitative Label Comprehension Study, the Phase II Studies also included a Device Interpretation Study, which tested the ability of users to interpret pre-determined test results that were fabricated to represent a negative, positive, weak positive, or invalid test result. Although users did not perform as well as expected in the Device Interpretation Test, FDA nevertheless advised OraSure that it could proceed with the Phase III Study.
- 5.2.5 The Phase III Study, which was designed to have users self-test as if they purchased the product, was, among other things, intended to establish the sensitivity and specificity of the test when used in the home. The specificity of the test as assessed in this study was calculated to be 99.98%, with 1 of the 4,903 HIV-negative subjects reporting a false-positive (as compared to confirmatory testing). The sensitivity was calculated to be 91.67%, with 8 of 96 HIV-positive subjects recording a false negative. This sensitivity value was lower than a pre-specified minimum sensitivity of 95% recommended by FDA’s Blood Products Advisory Committee and lower than the sensitivity seen with the OraQuick ADVANCE Test (which has the same design and technological characteristics as the In-Home Test).
- 5.2.6 Given the test’s lower than recommended sensitivity, FDA decided to “conduct a formal risk-benefit assessment to look at the public health implications of a test performing at this particular level of sensitivity.”²⁷ FDA developed a risk–benefit model based on the projected number and sub-populations of individuals that would use the OraQuick In-Home HIV Test who would not otherwise be tested for HIV. FDA’s risk–benefit model also considered that the lower sensitivity of the self-test could result in increased rates of HIV transmission due to the increased number of false negatives as compared to professional-use tests. Through this risk analysis, FDA determined that there was a potential for the OraQuick In-Home HIV Test to inform an additional 44,000 individuals about their HIV status, and that this in turn was projected to avert about 4,000 new HIV transmissions in the first year of marketing the test. FDA explained in its Summary of Safety and Effectiveness that “these model outcomes indicate both an individual benefit (new diagnosis) and a net public health benefit (HIV transmissions averted).”
- 5.2.7 However, as noted in the Summary of Safety and Effectiveness, the risk–benefit model also showed an individual health risk in the form of false negatives among people who would not otherwise be tested, with the model projecting approximately 4,500 false negative results in the first year of use alone. Regardless, FDA concluded that although the sensitivity of the test fell below the pre-specified minimum level of 95%, the projected individual and public health benefits “indicate a favorable benefit/risk profile.” The FDA explained that “the information provided in the PMA and the benefit-risk model developed by FDA indicate that the projected benefits of the OraQuick® In-Home HIV Test outweigh the risks of false positive and false negative test results,” concluding that “the available data provide reasonable assurance that the OraQuick® In-Home HIV Test is safe and effective for its intended use and support approval of the OraQuick® In Home HIV Test.” With its approval, the FDA stressed that OraQuick is not one-hundred percent effective and is not intended to replace professional, facility-based HIV testing. Rather, OraQuick is another means to facilitate

²⁶ The one exception was for the key message “what to do next if you are negative” for which the comprehension score was lower (77.5%).

²⁷ Berman, Shira. “At-Home Rapid HIV Testing: An Interview with FDA,” Medscape (August 1, 2012) (Interview with Elliot Cowan, Chief of the Product Review Branch in the Division of Emerging and Transfusion Transmitted Disease at CBER).

finding out HIV status, particularly by persons who might not otherwise be tested.²⁸

B. PRODUCT LABELING AND SUPPORTING INFRASTRUCTURE

5.2.8 During review of the OraQuick In-Home HIV Test, FDA recognized the importance of the product's labeling in mitigating the risks associated with use of the test. In particular, FDA's Blood Products Advisory Committee emphasized the importance of stressing how results should be understood by including the following instructions to users:

- A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting;
- A negative result with this test does not mean that you are definitely not infected with HIV, particularly when exposure may have been within the previous three months; and
- Retesting is recommended if you test negative and continue to engage in behavior that puts you at risk for HIV infection.

5.2.9 In addition to incorporating the above messages, the product labeling also includes numerous other warnings and precautions, including that:

- Using this test earlier than 3 months after a risk event may not produce an accurate result.
- Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
- Persons with increased risk for HIV infection should not interpret a negative test to indicate that engaging in high-risk behavior is safe.
- This test is not to be used by individuals under the age of 17.

5.2.10 Unlike with professional HIV tests, in-person pre- or post-testing counseling is not required with the OraQuick In-Home HIV Test. Rather, product labeling is used in lieu of live counseling, as included with each test kit are a pre-test informational booklet entitled "HIV, Testing & Me" and a post-test booklet entitled "What your results mean to You!" For those users who want live counseling, however, the option is available through a "support center." OraSure has put into place an OraQuick Consumer Support Center call-in center that is available 24 hours a day/7 days a week/365 days a year. The Center, which has bilingual capability in Spanish and English, is designed to provide consumers with basic HIV/AIDS information, assistance in how to correctly perform and interpret the test, and referrals for confirmatory-follow-up testing and HIV care. Although Consumer Support Center Calls are confidential, the Summary of Safety and Effectiveness states that the Consumer Support Center can collect the caller's ZIP code, gender, test results, and age group, as well as inferred emotional status and whether the caller is a repeat caller. Additional system-generated information that can be collected includes the date of the call, agent, language, time of the call, resolution, questions asked, topic, area code, and action taken. As a condition of approval, the FDA is requiring OraSure to conduct surveillance of the Consumer Support Center usage to collect, and report annually to FDA, information on the number of individuals reporting positive results, negative results, and unknown results, "as well as demographic information that does not breach caller confidentiality."²⁹

6. CONCLUSIONS

6.1 Although there are significant policy arguments on both sides of the debate, HIV self-testing with a product like OraQuick can provide a meaningful supplement to HIV testing generally. From a policy standpoint, strategic implementation of self-testing necessarily will require understanding the perspectives of healthcare providers, patients, and various community groups in each community being considered. The United States has seen arguments made both in favor and against self-testing for a significant period of time, and the FDA's approval of such a product ultimately reflects a carefully considered approach. As discussed above, numerous safeguards have been built into self-testing with OraQuick, including the availability of a counseling telephone line.

6.2 Practically, although testing in a healthcare facility or with a mail-in option like the Home Access product may include a greater degree of reliability, there is also a significant level of dependability with a product like OraQuick. Indeed, a complete self-testing option presents a significantly easier implementation framework, especially given the considerable infrastructure necessary to roll out a product like Home Access. Moreover, self-testing is discreet and may significantly reduce the likelihood of discrimination or stigma -- while at the

²⁸ See, e.g., Report on the First International Symposium on Self-Testing For HIV: The Legal, Ethical, Gender, Human Rights and Public Health Implications of HIV Self-Testing Scale-Up, WHO (Apr. 2013).

²⁹ FDA, Approval Letter: OraQuick In-Home Test (July 3, 2012), available at <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm310592.htm>

same time informing individuals of their status. Self-testing with a product like OraQuick should generally not be seen as a replacement for the availability of comprehensive provider-based HIV testing, but the potential positive impact identified by regulators in the United States -- both through informing individuals of their HIV status and also by preventing new infections -- cannot be understated.

7. FURTHER INFORMATION

7.1 The table below is designed to provide context for various questions surrounding the regulation and implementation of HIV self-testing. In particular, this chart indicates certain U.S. laws that are implicated in relation to the questions raised and provides some background context. Please note, many of these issues are addressed not at a federal level in the U.S. legal system, but instead are governed and regulated by the individual U.S. states. For these issues, the table provides only generalities.

Question	US Laws Implicated
Are HIV self-testing kits currently legal?	HIVST kits are regulated as medical devices under the Federal Food, Drug, and Cosmetic Act.
What legislation governs the distribution of HIVST kits?	Federal laws, including the Food, Drug, and Cosmetic Act, govern medical device distribution. Additionally, approximately 25 states have regulatory oversight programs for device distribution; regulations vary.
What rules/conditions exist concerning the distribution of HIVST kits or similar devices?	Federal and State laws apply (see above). The distribution of medical devices, including HIVST kits, is subject to pre-market approval from the Food and Drug Administration.
The human rights issues surrounding HIV	Nothing specific beyond what is reflected in State and Federal laws.
Does every person have a right to be tested?	There has been no express recognition of a Federal right to HIV-testing. Many local health departments, public health clinics, and physicians offer HIV testing. Some testing is free. Some states require the provision of HIV testing to patients within a particular age range (e.g., New York requires that hospitals and primary care providers offer HIV tests to all patients between the ages of 13 and 64) or a particular subset (e.g., California requires providers to offer to test pregnant women).
Can a person be compelled to make any disclosures concerning a positive diagnosis?	Federal and State laws govern the protection of individuals' rights not to disclose HIV status, and also mandate disclosure in certain circumstances (e.g., notification to sexual partners of possible exposure to HIV).
Can a person be forced to take a test?	Federal and State laws govern mandatory testing. Mandatory HIV testing includes blood and organ donors and military personnel and, in certain circumstances, persons accused of sexual crimes, newborns, and prison inmates. In certain cases, HIV testing may be offered as opt-out instead of opt-in. Opt-out testing means the test is done unless the patient explicitly refuses.
Can a parent be compelled to have their children tested for HIV?	Yes, minors can sometimes be tested against their parents' wishes. Many states authorize minors to make decisions about their own medical care, especially in the context of HIV testing.
What is the law regarding discrimination based on a person's diagnosis with HIV?	Federal and State laws govern discrimination issues. Notable Federal laws include the Federal Americans with Disabilities Act ("ADA"), which prohibits discrimination on the basis of disability. The U.S.'s highest court has held that HIV-infection is a disability under the ADA.
If A Kit Is Faulty/Gives An Inaccurate Diagnosis, what Is The Liability Of the Supplier, to:	State laws, including consumer protection and products liability laws, are implicated and payment is not an essential prerequisite to all liability. Additionally, in certain liability regimes third parties may have a right of action against suppliers.
The Patient:	
Third Parties:	
Is the answer different if a kit is supplied free of charge?	

<p>Must a person consent to HIV testing?</p> <p>Does consent have to be in writing?</p>	<p>State laws generally govern informed consent issues. The U.S. Centers for Disease Control and Prevention does not recommend separate written consent for HIV testing beyond general informed consent for medical care notifying the patient that an HIV test will be performed unless the patient declines. Currently, most states have laws consistent with CDC recommendations. See http://www.cdc.gov/hiv/policies/law/states/index.html; http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf</p>
<p>What is the legal age to give consent?</p> <p>What powers do parents/guardians hold in relation to consent process?</p>	<p>Generally, State laws govern age of consent and range between 14 and 18 years of age. Note, however, that capacity to consent is not based on age alone, but an individual's ability to understand and appreciate the consequences of his/her decisions (often as adjudicated by a court of law or other state officials).</p> <p>All of the states have specific laws regarding minors consenting to HIV testing. Certain states, however, permit physicians to notify parents of their child's HIV test results.</p>
<p>What are the rules/norms concerning the provision of counselling to those with a positive diagnosis?</p>	<p>States have various laws regarding counselling. See http://www.cdc.gov/hiv/policies/law/states/index.html; http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf</p> <p>Counselling may be pre-test as well as post-test.</p>
<p>Are test results confidential?</p>	<p>The Health Insurance Portability and Accountability Act ("HIPAA") is designed, in pertinent part, to protect the privacy of patients' medical records and health information. HIV tests may be taken confidentially or anonymously. Confidential testing means that the individual's name is attached to the test results, anonymous testing means that the individual gets a unique identifier that allows him/her to access his/her test results.</p> <p>Testing sites report positive HIV-test results to state health departments for surveillance purposes. State health departments, in turn, report to the U.S. Centers for Disease Control and Prevention, the federal agency responsible for tracking national public health trends. See http://www.cdc.gov/hiv/policies/law/states/index.html; http://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/2011%20UCSF%20Quick%20Reference%20Guide%20on%20HIV%20Testing%20Laws.pdf</p> <p>Some states require name-based reporting of HIV-test results to public health agencies.</p> <p>Additionally, there are special rules for the disclosure of HIV-status of persons serving time in jails or prisons under the Federal occupational health and safety standards.</p>

<p>Does a person have to disclose their HIV status to their:</p> <ul style="list-style-type: none"> • Partner • Employer • Insurance provider 	<p>Many states mandate notification of sexual partners and needle-sharing partners of possible exposure to HIV, commonly called “partner notification” laws.</p> <p>Generally, an individual is under no legal obligation to disclose his/her HIV-status to his/her employer unless it affects his/her ability to perform the job. Under the ADA, prospective employers cannot make inquiries about a prospective employee’s health or the existence of a disability, including HIV-status, prior to making a conditional job offer. Importantly, the ADA does not protect the confidentiality of voluntarily disclosed information, including information about HIV-status.</p> <p>Whether an insurance plan can ask if an individual has been tested for HIV depends on the type of insurance. For example, an individual policy insurer may ask information about an individual's HIV/AIDS status. If an insurer has the right to ask, individuals must provide truthful answers.</p>
<p>Is it a criminal offence to transmit/attempt to transmit HIV?</p>	<p>More than half the States criminalize transmission of HIV. See http://projects.propublica.org/tables/penalties</p> <p>Some States provide for sentencing enhancement for sexual offenses involving risk of exposure to HIV.</p>

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