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Saliva or Specimen? Your Preference Please

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Summary: Recent technological advances are making oral fluid and urine testing more useful as underwriting techniques for life insurers. In this session, the relative merits of these tests are examined.

Mr. Edward A. Turner: The quality of our panel must have drawn all of you here. We're going to have three speakers; our first speaker is Kevin Crowley with Epitope.

Mr. Kevin M. Crowley: I'm a vice president with Epitope, responsible for market development. I want to start by telling you something about Epitope. Epitope is a public company headquartered in Beaverton, Oregon. Within Epitope there are two divisions, one in the agricultural area called Agritope. Their role is to commercialize genetically altered fruits and vegetables toward the goal of longer shelf lives. This really has nothing to do with the insurance industry. The second division's name is Epitope Medical Products. The role of this division is the development and commercialization of diagnostic products. In respect to the

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insurance industry, Epitope has developed a product called Episcreen, which I'll discuss today.

The Episcreen oral fluid collection product has been approved by the U.S. Food and Drug Administration (FDA) for diagnostic and risk-assessment testing. This product, along with the western blot confirmatory product, has been approved by the FDA.

The Episcreen device allows for the noninvasive collection of an oral fluid specimen. Being noninvasive, the device is painless and therefore creates no discomfort for the applicant. The device is highly stable with a long shelf life and is very portable, lending itself to collection of the specimen in any setting—in a person's home, in an agent's office or an applicant's office. The device or kit consists of the treated pad on a stick and a transport bottle containing a proprietary preservative. For insurance testing purposes, the device specimen can be used for the testing of HIV, cotinine and cocaine. Again, the FDA has approved this device for HIV testing for both the screening and the confirmatory procedures.

The actual collection procedure is very simple and straightforward. It does not require a phlebotomist—an individual trained in the collection of blood. In fact, the specimen can be collected by the applicant, and the facilitator of the collection can be an agent, broker, or a paramedic. The actual collection of the specimen will take place as the applicant places the pad, which is on a stick, in the lower mouth between the cheek and gum, and rubs the pad back and forth several times for it to become moist. Then they would allow it to sit in their mouth for two minutes. At the end of the two minutes, the applicant removes the pad on a stick and places it in the transport tube and hands it to the facilitator—again, the facilitator being the agent, the paramedic, or broker. That facilitator would then send the tube off to the laboratory for testing.

The status of HIV in this country is endemic. In the U.S. in the late 1980s the insurance industry started testing for HIV. Today acquired immune deficiency syndrome (AIDS) is the leading cause of death in the U.S. for those between the ages of 25 and 44. For the insurance industry, the risk is great. Beyond the fact that AIDS is a major cause of death in the U.S., there are other driving forces that are bringing insurance companies to the conclusion that additional HIV testing is necessary. The key force is antiselection, which means your competition is testing for AIDS and you are not. Viatical companies, who market their services very strongly, are prepared to purchase a policy from an individual with AIDS, and give that person 50–80% of the face value of that policy within days of the person applying to the viatical settlement company. That becomes cash in that individual's hands that they would like to have.

Also, the home HIV collection market is heating up as was highlighted in a recent lead article in the *U.S. Today* business section. The current players in that market are Johnson & Johnson and Home Access, and new soon-to-be players include Chemtrak and SmithKline Beecham (SB), who will be marketing Epitope's product under the brand label Orasure.

Johnson & Johnson estimates home HIV collection sales to be 30 million tests per year. Companies like Johnson & Johnson and SB don't make many mistakes in their market research. I can tell you that SB has spent over $10 million in the market research of that particular market—the home market for HIV. I know that Johnson & Johnson has spent a similar amount because we had discussions with Johnson & Johnson in addition to SmithKline Beecham.

As reported in *The New England Journal of Medicine,* it was estimated that only 18% of the general public has ever been tested for HIV and that only 34% of those at risk have been tested. There are many, many people who would like to know their HIV status, but are intimidated by a face-to-face encounter in order to find out what their status is. I believe the key to the home collection is that it is anonymous. An individual can walk into a pharmacy in an adjacent town, and they can buy the product. They don't know the person who is selling the product to them; the person selling the product doesn't know them. They can buy the product, go to the seclusion of their house, very quickly provide a sample and send it off to the laboratory for testing. All of this is taking place anonymously. They get the result back.

If the result is positive, it's a pretty safe bet that within a week or so of finding out and being coached by somebody, if not arriving at the conclusion on their own, the person is going to dash off and buy life insurance. That's pretty much a given. Again, a key factor in what will be the successful marketing of an HIV home collection product is that it is anonymous. Unfortunately, this works to the disadvantage of the insurance companies—it helps drive antiselection.

Currently in the U.S. life insurance market today there are approximately 14 million insurance policies issued each year. From this, less than 40% of all the applicants have been tested for HIV, and only those who desire a policy of $100,000 a year or greater have been tested. And $100,000 is currently the magical threshold for testing in your industry. This to me seems very, very strange in that I've only been involved with the life insurance industry for a few short years, but prior to that I spent over 20 years in the diagnostic market, and a major company that I worked for was a developer and marketer of an HIV testing product. I've heard several comments that where the HIV condition resides is not where the insurance industry has been doing the testing. I would suggest to you that generally the people who

are buying the $100,000 and above policy—and I'm generalizing here—are going to be of an older age and their socioeconomic status is going to be quite different than where the disease really does reside. Again, respectfully, I would suggest to you that you have been testing the wrong group of applicants. Nevertheless, fewer than 40% of the applicants have been tested for HIV.

In recent months, this magical $100,000 threshold has been lowered by numerous companies in order to protect their long-term economic interests. If I can go off on a tangent here for a moment, I liken all this to what I call a U.S. mentality. "Let me get through my term in office," which is like the governor of a state who doesn't want to build the highways today during his term. Let the next guy build them, even though they know from the demographics that they need them now. We're not very much like the Japanese. The Japanese think ahead five or ten years. We tend to think quarter to quarter in the U.S., but at some point in time someone is going to have to pay the toll for testing that didn't take place.

It's very difficult to challenge the decisions made by those companies who have lowered their testing threshold when one understands that the very same market, the home HIV marketers have targeted currently, represents 50% of all insurance policies issued each year and 63% of all policy value. I'm here to tell you again that these are the markets that Johnson & Johnson is going after and so is SmithKline Beecham. Don't let me leave out Home Access and Chemtrak when they get there. They're all targeting the same markets.

The actual majority of those companies who have lowered their testing threshold have done so with the use of oral fluid testing. For those companies oral fluid was an economically sound solution because it could be accomplished at a lower cost than blood by utilizing the agent, broker, or the paramedic. When using the paramedic, they were using this person at a reduced collection cost for the oral fluid versus what they'd be paying to have blood collected. The problem is, as I see it, you need to test all the applicants for HIV, but currently it's too expensive to do it by blood. The solution would seem to be to take an alternative route, be it oral fluid or urine, but doing it by agent collection, or if you feel more comfortable, through the paramedic services, but at a reduced cost.

A large, Canadian-based insurance company recently shared their results using Episcreen at the American Academy of Insurance Medicine (AAIM) meeting. This company, prior to utilizing Episcreen for their screening purposes, did not test below $250,000. Please remember a couple of things transpired here. First, in Canada, they generally test only at very high levels. Second, there was no FDA involved in Canada, so they began utilizing this product about four years ago. As a result of the Episcreen testing, this company picked up a substantial number of HIV

and cocaine positives. Of particular interest, I think, is that 13.8% of the applicants had what is becoming known as “smoker's amnesia.” That means these people were smokers, but on their application they claim they're not. That finding is going to translate into additional income for this company.

This same Canadian company calculated that after the total cost of Episcreen testing—that's the cost of the device, the testing, laboratory, etc. and lost premiums, what they didn't collect because they declined these people—that they had a net positive cash flow of $1.7 million, plus an additional increase of $1.6 million in cotinine premiums. Let me explain that. When we had an individual that applied and they said they were not a smoker and they were found to be a smoker upon testing, the insurance company then went back and in a gentle way, confronted the proposed insured. The proposed insured finally came through with—“yes, I probably had one or two cigarettes a day”—and that went on to ultimately they're saying—“I'm a smoker”—and they did pay the higher premium. That was money in the insurance company's pocket, of course.

What is not reflected in the presentation of the AAIM is the fact that approximately $40 per applicant was saved when the collection of the specimen took place under agent supervision. In other words, there was, in the case of this company, the elimination of the paramedic. If one is going to do the HIV testing with Episcreen because you find value in it, then I guess the question is, what route do you take. Do you utilize a paramedic? Do you go with agent collection? Either route is fine, but there is an additional savings being realized if one does choose to go the agent route.

The summary of the medical director who made this presentation at the AAIM meeting (and by the way I'm leaving out company names because I'm going to give some examples from other companies and some of these companies have not made their data public yet), is that Episcreen is faster and less expensive than blood sampling. It can be carried out by the agent or broker, and it results in an excellent improvement in cash flow. Really, that's what the game is all about.

Let me go on and share with you some quick data that I gathered from a couple of other companies that have started to test below that $100,000-policy-level threshold. I'm going to call these companies A, B, C, D and E. Company A began testing three months ago. The testing range for this company was $25,000, which became, by the way, their revised minimum issue amount. They have previously issued smaller policies, but they chose to drop those lower policies, which is interesting. It's an option.

In this particular case with Company A, they're doing the oral fluid testing up to $250,000. I must tell you that this is more of an "outlier" because most companies that are going with the oral fluid testing, at least up to this point in time, are not going that high in their testing. I would say some of them are going up to $250,000, but it's not a nationwide trend. They're doing it in high-risk states, etc. The age is 16–50. This is by agent collection. For this company, the medical director couldn't believe the results they got. They've gotten two more HIV positives in May. The results that they had found in the below-$100,000 category are at least double what the actuaries had predicted.

Next, Company B is located in Texas, so they started a pilot program in Texas. The net of all of it was that the oral fluid product had much higher acceptability from the applicant than did blood testing. That's point number one. Point number two is that out of the first 109 applications, they picked up two HIVs and one cocaine. Each of these was a $75,000 policy. They've already paid for their testing for the year. These people are getting ready to roll out nationally now.

Company C actually started in one state over a year ago. This is a high-risk state. This is done by agent collection. The testing range is $5,000–100,000. I should comment, they are contemplating now raising the $100,000-maximum level because they're so happy with the program. I'm not up here selling them; I'm relaying the facts. I think what's particularly interesting here, in the first two months, is that they had a 50% amnesia factor for smoking. After six months it was down to 9%. Again, the actuarial predictions as to the number of positives they would pick up on this were blown out of the water.

Company D began testing two years ago in selected states. They are now in the very final stages of a nationwide rollout. I wish I could be more exact for you on the testing range and ages, but, again, they've approached this on a state-by-state basis and it does vary considerably. One other thing I would have liked to have been able to present to you is on the cotinine cases with these data. Unfortunately I just don't have it because the company hasn't gotten around to calculating that value yet. By the way, the last company I just shared with you is doing agent collection.

The final company, Company E, is doing paramedic collection. Actually, they're also getting ready to do agent collection with selected brokers that they feel they can trust. They've had success with the program. When I say success with the program, I mean the people at the home office are very pleased with it. Not only that, but the marketing types, the agents, etc. have embraced it. It's fair to mention here that with this particular company, not all policies or products are tested with

oral fluid, although they do have a few of their preferred products that are being tested with oral fluid.

A general comment that I would like to make is that the oral fluid product is not a product for all lines. In my estimation, it will work for certain policy ranges, for certain age groups. It doesn't work for all policy levels. It's not what is best for the insurance company for all policy levels.

In closing, insurance companies need to test everyone for HIV because HIV home collection is available and is anonymous. In addition, this disease, given its form of transmission, lends itself more to the smaller policy face amounts and younger age people. Second, oral fluid with or without agent collection is simply less expensive than blood.

Mr. Turner: Our next speaker is Dick Van Maanen of Calypte. He will give the perspective of a urine testing provider.

Mr. Dick Van Maanen: A lot of what Kevin has already discussed with respect to oral fluid testing I will be saying also about urine-only testing. What I'd like to talk about is: first, how HIV testing has been undertaken in past insurance purchase situations; second, what is the current state of the HIV epidemic in America; and third, what do we know about over-the-counter anonymous testing and what kind of implications does that have for the insurance providers. I'd like to talk briefly about noninvasive HIV testing in a generic sense—whether it's urine or oral fluid—and then talk specifically about some aspects of urine testing.

There are about 14 million policies issued annually in the U.S. but only five to six million of them actually get tested for HIV. That leaves eight or nine million that are untested, and you have to ask why. The obvious answer is that, traditionally, HIV testing did cost a lot of money. That's something that insurance companies want to avoid if they can. When they go to their tables, they come up with this threshold value for HIV testing of about $100,000. We can then easily understand why so many people go untested, given the fact that almost half of the policies are valued at less than $50,000 and about a third of them are valued between $50,000–100,000.

HIV in America, as already mentioned, is the number one cause of death for Americans age 25–44. It’s the number one cause for men; the number three cause for women, but collectively it’s still number one. We, of course, are aware that there is a disproportionate representation of African-Americans and Hispanics who acquire this infection, and women constitute the most rapidly growing segment of

the population for HIV infection. In 1996, they comprised about one out of every five new AIDS cases reported.

It has been stated that the rate of HIV infection is stabilizing or declining. That's certainly true for AIDS deaths. Most of this is attributed to the availability of a new combination therapies but, in spite of that, we're still seeing about 60,000 new cases of AIDS per year. As a cautionary note on these new therapies, I would say that while they're certainly very promising, we don't have a great deal of history on them. We don't know how effective they're going to be long term. There are already reports that these combination therapies can reduce the amount of virus circulating in the blood, the virus does continue to proliferate in the lymph, which is not a good sign. Despite some of the positive progress that we've made in fighting this disease, it's clear to me that this is a problem that we're going to be working with for a long, long time to come.

Fifty percent of those people who are infected do not realize their condition and are not diagnosed until they have symptoms of AIDS or within perhaps a year of getting those symptoms. For reasons that Kevin already addressed, the environment in which people get tested for HIV has not really been conducive to encouraging people to get tested. People stay away from testing centers because they don't want their name on a state registry. They fear stigmatization, discrimination, loss of insurance, etc. What that means is there are a lot of people out there who are at risk or are positive and are not being diagnosed. Last year, two systems were licensed by the FDA for anonymous HIV testing and the appeal of the system is anonymity.

In February at a national public health meeting held in Houston, the Centers for Disease Control released some demographics as to who was using these systems. Based on the first 100,000 tests sold, they showed a prevalence in that population of about 1%. The people purchasing the test were one-third female and two-thirds male; 82% Caucasian, 6% African-American, and the rest were unknown. Sixty percent of the people who bought the test had never been tested before and I think that speaks to the fact that the anonymity of the system really draws people in for testing. Perhaps another very interesting aspect of this is that the top two leading purchasing groups, the reasons that people cited for buying the test in the first place, were that they were either a man who had a female partner or a woman who had a male partner and they felt that there was some risk involved.

I don't know the exact profile of the insurance-purchasing public at large, but my guess is that a group that is one-third female, two-thirds male, 80% Caucasian heterosexuals is probably not far off from the insurance-buying population. What does all of this mean? HIV is the leading cause of death in the age group that buys

half of all the policies, contributes over 40% of the premiums, and comprises 63% of the coverage obligations. At a prevalence rate of 0.7% what it means is that this age group constitutes a multi-billion-dollar disparity between premium revenue and coverage obligations. The 1995 questionnaire estimate of AIDS claims in the U.S. was $1.6 billion, which by any measure is more than pocket change. It is reasonable to believe that people who are accessing anonymous testing services are also trying to buy insurance. Last then, as a natural consequence of this, it's reasonable to believe that companies that fail to test for HIV will attract a disproportionate percentage of HIV-positive applicants. This is obviously the antiselection concern.

Now let's discuss noninvasive testing. Kevin and I would agree that the good approach is to look at ways to test more people more cost effectively. In general terms, whether we're talking about oral fluid or urine, the benefits are quite similar. It's a painless procedure that is well-accepted and appreciated by applicants. As Kevin already mentioned, one of the best ways to reduce your cost is to reduce the cost of sample collection. Since these samples are physically collected by the applicant, you can eliminate or significantly reduce the paramedic expense. This can provide cost-effective, HIV antiselection protection and various studies have looked at what the break-even threshold becomes when you do this. Some reports will show policies as low as $3,000—I've seen $6,000, $7,000, and $10,000. If you plug in your own values related to age, how significant the risk is in your state, etc., I'm sure that your threshold numbers will not differ significantly.

Of course, as Kevin also mentioned, you can recover lost revenue by identifying applicants who have smokers amnesia by testing people who would not have been tested for nicotine in the past. You cannot identify them and, of course, adjust your "nonsmoker" premium rates accordingly. In addition, depending on how extensively you do testing, you can identify applicants who should be rated or declined for other reasons.

There are a few concerns with noninvasive testing. One issue is agent collection. What is the willingness of the agent to collect a sample and the reliability of that collection? The willingness, I think, comes from a notion from some American agents that it's not professional to be involved in this process. I think a little education will lead them to the conclusion that the only professional way to do their job is to be part of the solution to this problem. HIV is a fact of modern life, it's a threat to their business, and it's something that they have a role with their company in managing.

The reliability of agent collection is not so much a matter of whether agents can collect the sample and ship it in properly, but whether some agents may be tempted

to send a sample in that is not necessarily that of the applicant. It has been proposed that those companies that have captive sales forces can better manage this. My personal feeling is that the appropriate sanctions would be more than adequate to ensure that agents, in fact, do what they're supposed to do with these samples. The other concern is non-blood testing; you must determine if you want to raise the threshold at which you do a full, blood workup. Now you're looking at replacement of a fairly broad, risk-assessment tool, which includes blood, and you receive less information. I can say that there is no non-blood system today that can rival a blood plus urine sampling system for completeness of risk analysis. But, depending on age, depending on policy size, depending on risk factors in your state, we can get a very adequate and thorough risk assessment.

Now we'll talk briefly about the urine test. Calypte, by the way, is a small California-based company. We have two offices—one in Berkeley and one in Alameda, where I work. The test, which has been licensed by the FDA is the Screening EIA test. It's used in a laboratory. It's not a home test. Handling the sample is safe because while the urine of HIV-infected people does contain HIV antibodies, it does not contain infectious virus. Sample collection is easy because it is untreated urine. You simply collect it into a nonsterile urine tube and transport it to the lab. It's very stable in transit.

Sample collection, of course, is simple, familiar and, hopefully, painless. In addition, urine sampling for medical purposes or insurance purposes is nothing new. It has been done for a very long period of time. In fact, people would bring their urine samples to urine collectors in the 16th century. What they would do was bring their urine sample in and it sits in a vial. There was a chart that showed various colors of the urine and various ways in which the urine might separate out into different layers. Depending upon what happened, these individuals would create a diagnosis. We're a little bit better than that today, but at least we know that urine collection is not something new.

Our EIA Test is rated as 99% sensitive and 99+% specific. We did look at life insurance applicants in our clinical trials for this product. We looked at over 7,000 insurance applicants for which we had both urine and serum. As the urine method did in fact detect all seven of the true positives in that group, the sensitivity of the urine method was 100% in our testing trails.

The follow-up to a repeatedly reactive screening test is a confirmatory test, which is normally a western blot test. A urine western blot is currently under review. All of the data that have been requested by the FDA has been supplied. We can only hope now that the FDA will do as they've assured us by giving us a prompt and hopefully favorable response. The only data that I can share publicly at this time

comes from the first phase of trials, which showed sensitivity of 99.8–100% specificity. We are also very pleased to note that the indeterminate rate was less than 1%, which I think establishes a new benchmark in western blots.

Of course, if you're going to collect urine samples for HIV, you might as well do something else with that sample. As I mentioned before, urine has been a very commonly tested sample type. What can you do with it? You can test for essentially all drugs of abuse. Most drugs of abuse tests are available for urine samples. This is actually important because you see tremendous regional differences across the country in terms of which drugs are in vogue, and other items that can be detected in urine, including anti-HIV drugs, cotinine, glucose, antialbumin, and blood in the urine. It's a rather flexible sample that allows you to go well beyond HIV testing. The collection of urine as the only sample facilitates the screening of the most important risk factors of applicants whose age and policy value comprise the bulk of the policies that are written. Urine testing, on its own, allows you to identify HIV, drugs of abuse, smoking, diabetes and hypertension.

In conclusion, HIV continues to be a significant health risk in the age group that purchases half of the life insurance policies in the U.S. Failure to test more universally leaves you potentially vulnerable to antiselection threats. Noninvasive testing, whether by urine or oral fluid, is one way to solve this problem. If you're going to do this testing, you will enjoy a secondary benefit by testing for other factors, which will allow you to charge higher rates or to decline people for other reasons.

Mr. Philip E. McHale: My function here is to give a reinsurer's opinion and concerns of oral-fluid-only and urine-only testing. The best way to start my speech is to quickly outline the reinsurance marketplace, look at the direct writer's marketplace, and then discuss our concerns about these noninvasive tests.

From the reinsurer's standpoint, the rates we charge are consistently being driven downward. This is due to competition among direct writers and among reinsurers. Recently there has been a rather large increase in quota-share-reinsurance arrangements. The reinsurer sees more of the small cases under these quota-share arrangements. Our exposure to risk is different than it is on excess arrangements. We are counting on the recent, marked mortality improvement being driven by preferred classifications. This is the same item that the direct writer is counting on for their improved mortality. The direct writer marketplace has fierce competition relative to premium rates or cost of insurance and market share.

Preferred programs are providing meaningful, measurable, short-to-midrange mortality improvement. I don't think we've had any programs around long enough

to know if these results last. I understand from talking to some of our pricing folks that they're doing some pretty lengthy projections into the future on mortality improvement using preferred underwriting programs. A fact that we should all be aware of is that savings in the costs of underwriting requirements generally only benefit the direct writer. Most of the time the reinsurer does not participate in those reduced cost savings. As these gentlemen have discussed, the urine and saliva tests are performed at lesser costs than blood plus urine tests, but generally speaking, that's to the direct writer's benefit, not ours. This becomes a real concern to reinsurers when they're in a quota-share arrangement.

Let's look at concerns from a reinsurer's perspective. First, we'll deal with lost protective value. My main concern is not saliva versus urine; it is the use of urine or saliva HIV testing for amounts of insurance that are currently tested via blood plus a urinalysis and the resulting lost protective value. Relative to HIV testing alone, saliva, urine, and blood are all equally acceptable. However, the additional blood test values, which may no longer be obtained, represent a significant decrease in the protective value of routine evidence obtained today. This does not take into account the fact that the paramedic exam will not be obtained either if agent collection is used.

My own personal view is that blood testing is probably the single most important factor in the mortality improvement we are all projecting into the future to justify lower prices. If blood-testing thresholds must be increased, the overall HIV testing threshold must be lowered. In other words, we have to get some of this back somewhere, and I don't think it's an even trade. When we talk to clients and they are interested in increasing their blood-testing threshold, we say for every $2 up, you come down $1. Saliva or urine are a reasonable method for testing amounts below blood-testing limits, which have never been tested before.

Another concern that I have is that the decisions to change and increase blood-testing thresholds are being made by one discipline only, and in this case it's the underwriters. Here's a chance to cut some cost. If your company is anything like Transamerica, "cut costs and increase productivity" is heard every day. Here's an opportunity to cut costs, but I think you have to stop and look and be sure that you really want to save the money in this area. Actuaries and reinsurers may not, and I think they are often not asked for their input. Basic mortality assumptions may need to be increased by 3–4% points. I'm saying if 50% of a certain table is your basic overall mortality assumption, you probably need to boost that assumption up 3% or 4% if you're going to start to raise blood-testing thresholds. Additionally, the preferred mortality discount may need to be decreased 10–30% for those individuals not being blood tested. For instance, if you have 50% of the table as your overall mortality assumption and you reduce that by ten points down to 40%

for preferred risks, depending on your preferred guidelines and if you have some blood-testing value included, you might need to shorten that discount up to perhaps 41%, 42%, or 43% if you're not going to get the blood.

There are other ways of addressing this issue. You can change preferred criteria instead, but that may change your overall competitive position. Then we get into the super-preferred categories, and they are coming out in droves at this point. The very restricted preferred categories are often very difficult to change without decreasing the overall value of the preferred mortality.

The reinsurer's reaction will vary based on the direct writer's retention, type of reinsurance arrangement, excess versus quota share, and the percentage of reinsurance being affected in their analysis. The reinsurer's evaluation may be very different from the direct writer's on both excess and quota-share arrangements, where the reinsurer's share exceeds the direct writer's.

Home collection is something we all need to be very, very concerned about. Home collection creates the potential for significantly increasing the antiselection against our industry. I suggest that all business be tested for HIV.

Lab One just recently came out with another issue of their *Insight* magazine. This is an excellent issue about this whole, testing topic. It covers HIV, cocaine, cotinine, etc. On the first page under Table 1, it shows that the positive HIV antibody rates for oral fluid testing were more than four times higher than that of serum testing, and this is comparing oral fluids against serum from 1996. There are 120,000 oral fluids, so it's not a small number. Even on similar amounts of insurance, positive rates on oral fluid specimens were higher. This could be due to several factors, including the fact that some insurance companies have begun oral fluid programs in higher risk states and the sentinel effect. Both of these gentlemen alluded to the sentinel effect. If people know that they're going to get caught, they aren't going to get tested.

Again, I'm saying that all business should be tested for HIV. I think we should hold current blood-testing limits where they are. I do not propose that blood-testing limits be raised, and we should use saliva or urine for all amounts below current blood-testing limits. The costs are really too high to justify getting into blood testing for small face amounts.

Now we get to agent collection, the unscrupulous agent, and the chain of custody. The unscrupulous agent controls this collection. Some companies try to monitor this, and I guess other companies are using agents and just hope for the best. Some companies have used a random phone method, and will call folks and ask if they

have had the test administered. There is no longer the control of the independent third party collecting the specimens you had when individuals went to the paramedics. This particular reinsurer is not anxious to recommend agent collection when saliva or urine is replacing blood unless methods exist for detailed monitoring, and this might include a captive field force and telephone monitoring. One particular company has a lot of information based on zip codes. They don't use that to turn people down, but they do use it to monitor results, and have had some degree of success. Saliva and urine testing in this situation are only being used for amounts below current blood testing.

I have a couple of comments on urine only and saliva-only testing. For urine-only testing, a positive urine HIV result requires a confirmatory blood test. Does this jeopardize confidentiality? If this is the only reason you would go back for a blood test after you have received your other basic underwriting requirements, are you tipping your hand as to why you're going back and therefore jeopardizing confidentiality?

The next issue is diabetes. The urine test for diabetes is not as definitive a test as provided by a blood test. Also, for kidney disease, the urine-only test is not as definitive a test as provided via the blood test.

For the oral fluid and urine-only tests, HIV sensitivity and specificity are very close to blood testing results. Tobacco and cocaine and urine versus saliva are comparable. No real advantage of one test over the other. Drugs of abuse are only checked at a company's request, and you always run into a problem because the urine has long since been disposed of, and you've got to send the individual back to have him tested.

For diabetes, the presence of glucose in urine is not the gold standard or the best test. Elevated levels are not found nearly as often with urine as compared to blood testing. Also, glucose in the urine may be due to a low renal threshold, which is generally a benign condition. If you use saliva or urine, some undiagnosed, unadmitted diabetics will be missed. Others may be unjustifiably and substantially rated or declined. The end result could be an occasional, additional claim or good business being returned as not taken because you're rated too severely. For kidney disease, urine testing does provide meaningful protective value. Blood values help the underwriter refine urinalysis results and result in more accurate risk assessments, but urine measures are reasonably good values. When I started in this business, that's all we had. We got an application, an examination, and a urinalysis. It wasn't until the beginning of the 1970s when we finally started getting into some blood testing.

Let's look at some other considerations. Are agents willing to go back to collecting urine samples? They may not be willing to collect saliva samples either. There used to be a lot of griping from agents about collecting urine. They've been out of that business for about 10–12 years. Again, agent collection may jeopardize the chain of custody. If HIV is the only abnormal result, you routinely request a blood test to evaluate further, and confidentiality may be jeopardized.

In summary, which test is best? I think from a protective value standpoint, urine is better. From the standpoint of "no repeat" testing and ease of collection, my vote would go to saliva.

There's an item that you will hear about relative to saliva testing and the issue of kit wastage. I think most of the major laboratories do provide a service now to try to help monitor that so that you don't have a kit sitting in the agent's trunk frying in the heat or lost in their files.

Here's a comparison you may want to take to heart. Urine kits are about $2 each. Oral fluid kits are about $5.25 each. I've heard about kit wastage numbers on oral fluid. If you can get it down under 3:1, you're doing good, and that's kind of scary as far as I'm concerned.

The areas where the use of saliva or urine appear to be best suited are for amounts below current blood-testing limits so that all business is tested for HIV. Remember home collection. Consider them for emerging markets, such as banks and other financial institutions. They may also work for simplified issue programs and single-premium products. Agent or financial-institution-employee collection is better than no testing for HIV. Perhaps you'd like to use saliva or urine testing as a reward for your very best agents.

Based on my experience, banks want smoker-distinct products—in other words, they want a smoker and nonsmoker rate. They also want fee income, and they're not very keen about selling the very best product from a premium-rate standpoint to their customers. Another concern that I have is that simplified issue products in banks, especially at amounts of $100,000 and under, will appeal to the lower socioeconomic levels of their customer base. These folks will use cocaine more than the upscale market that we're accustomed to in the insurance business. There will be more smokers in that group, and there probably will be more HIV positives in that group, but to convince a bank to use oral fluids is a whole other issue.

Financial institutions do not understand the HIV risk. We need to educate them in that area, and once you begin to go through the educational process you will find some lights go on. We've dealt with several banks. We dealt with one who has a

reinsurance company. When we talked about using saliva, they raised some resistance. However, after they thought about it and talked to their captive reinsurance company, they changed their minds. For some of the other financial institutions, they don't have the first idea about HIV risk and what it could do to profitability. Many of these institutions, especially the banks, don't share the mortality risk. They're getting a fee income only, so their interest in the issue is different from that of the insurance company.

We have received objections from the banks. We've talked about platform employees collecting the saliva sample, and they say there's no privacy for collection. I suggest that they build a cubicle, raise the walls a little higher, and maybe that would work.

Let's consider a perceived potential risk. If the test is positive and/or the proposed insured has a problem while the test is being administered, there could be some negative ramifications for the bank. I guess with all the legal action we see going on, that's probably not impossible.

For the international markets, the technology for saliva and urine testing for HIV is not known or is not well understood. The hepatitis risk is much larger outside of the U.S., and this particular reinsurer wants a liver function test for international markets. Consequently, I don't suggest introducing saliva or urine-only testing outside the U.S., although I realize that somebody will take it there.

There is a myth about the impetus behind the movement towards saliva and urine-only testing that I would like to address. I belong to an organization called the Impaired Risk Underwriters Association. There's about 45 of us involved in the underwriting business and we had our meeting about a month ago. I checked with them and most of the underwriters that are not reinsurers are in the brokerage marketplace. We've been hearing that the change from blood to saliva or urine is agent driven, especially the saliva. However, I can't get one of these guys to tell me that comment is correct. So I'm saying right now that the change from blood to saliva or urine is not agent driven. If agents want saliva instead of blood, will they accept a decrease in their compensation to cover the extra mortality risk? I don't think so.

That concludes my remarks on this. I am convinced that if the actuarial, underwriting, sales and marketing folks at each and every company represented here do not work very closely together and in full cooperation during the next five years, you'll be working elsewhere because that's how strong the competition is.

Mr. Crowley: In regard to kit wastage, that is something to be concerned with, but as you said, all of the laboratories have come up with an inventory management control system to assist the insurance company with managing the kits. The Canadian study that I reviewed in my presentation has been using our product for four years. Their usage factor is 1:4 kits for every one applicant, so that's versus the 3:1 ratio referred to in the study you mentioned.

Mr. McHale: The other point, Phil, is that with respect to changing one body fluid to another, actually Met Life in Canada just switched from one body fluid to oral fluid at the agent's request. It was agent driven. They felt they were at a competitive disadvantage being on the other body fluid because most Canadian companies now have gone, or a large percentage of them are now going, to oral fluid. They just felt they were at a competitive disadvantage, so that was driven from the grass roots, which is very different from what I've seen in this industry in the U.S. This industry is very much controlled, I believe, from the home office. I thought that was interesting.

Mr. Henry C. George*: I thought Phil McHale's presentation was one of the best I've seen. The one comment you made that I do disagree with is the acceptance of agent collection of oral fluid in the mainstream market. In response to a question at the HOLUA Meeting earlier this week, about half the companies are either actively using or were comfortable with agent collection. At Lab One, I've been told by my colleagues that 90% of the companies that have done oral fluid testing in the first half of this year have done so by agent collection. I have probably spoken to 5,000 agents in the last few years, and I have seen very, very little resistance to agent collection. For the most part there is a buy-in. My experience with all companies in all markets tells us that we'd better pull together on this issue, or we'll both be out watching other people do financial services in the 21st century. I believe that.

Mr. McHale: The only thing that I would add or say a little bit differently is that I think in probably the next five to ten years the large majority of companies will be brokerage companies. Those with captive field forces are going to go away and they're going to go away pretty soon. That's my own personal opinion.

Mr. George: But I don't think those brokers will object to collecting it and I also think that we have the technology to make sure that it probably is done correctly.

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*Mr. George, not a member of the sponsoring organizations, is Senior Vice President of Lab OneIncorporated in Greendale, WI.

Mr. Crowley: I will tell you that DNA testing is possible by agent collection. There's no question.

Mr. Van Maanen: One of the points that you made was the concern for confidentiality if you have to go back and collect a blood test on a urine reactive HIV. I guess I would say that with any luck at all and FDA willingness, that will only be an issue for a very short period of time, although I'm obviously constrained from saying exactly when I think that's going to happen. In addition to the fact that tests like urine glucose are not the ideal, you can legitimately go back and collect the blood on an abnormal urine glucose for that very reason. Could you not advise our agents that there are all kinds of reasons why certain screens performed on urine could trigger additional testing?

Mr. McHale: I believe yes, you could go back for kidney function, etc. However, I think you're going to make yourself a general nuisance in the field force with that approach.

Mr. Crowley: I think again this is a difficult question of looking at these alternative fluids in previously untested populations versus as a replacement for blood testing. One of the methods that has been proposed for less costly but independent sample collection is sending applicants to actual brick-and-mortar sites, where people can show up more or less at their convenience within some specified period of time, and provide samples. That can be done and is being done at reduced expense already. That is another option that's available for third-party collection.

From The Floor: Phil, I misunderstood your mortality reduction percentages.

Mr. McHale: I was saying if your overall mortality assumption is about 50% of the table and your preferred mortality projection is about 40% of the same table, that you might increase that to 42% or 43% if you're going to lose your blood-testing values. That's assuming that you previously used blood-testing values in your preferred classification mortality assumption.

Mr. Van Maanen: Actually, I'm curious to know if you've done the tables and have identified significantly different protective value differences between urine or oral fluid only testing versus the traditional blood plus urine. At what point is it appropriate for the reinsurer to assist the direct company in the payment of that additional testing? At what point is it cost effective for the reinsurer to assist the direct company to maintain that more expansive level of testing?

Mr. McHale: I have not done that analysis.