Meeting: **FDA Public Forum On Consumer Medicine Information**

Topic: **Enhanced Safety Through Prescription Labeling**

Presenter: **Stacy Kaufman, President**

ScriptChek Visual Verification Systems, Inc.

Date: July 31, 2003

Time: 1:30 pm

Location: L' enfant Conference Center, Washington, D.C.

Good afternoon. My name is Stacy Kaufman. I am a business and marketing professional…living in South Florida…who has become passionately interested and dedicated to medication safety as a result of my own confusion and mix-ups with medications. As a result of my own realizations, through personal experience, a dedicated team of individuals and I have been working hard to research and understand the sources and media through which consumers are provided with or gain access to vital safety information about the medications they are taking. I know from my own experience, that I did not absorb information that I needed to know about my medications and, living in Florida in a community with a large senior population, I recognize that many seniors taking multiple medications are equally if not more uninformed about the many medications THEY take.

After researching available literature, published studies, and speaking to countless U.S. residents as well as retail pharmacists, our team zeroed in on the prescription label itself as being a perfect venue to address our primary objective – putting the power of medication information directly and visibly in the hands of CONSUMERS. To achieve this goal however we realized that more printable space was needed on pharmacy labels versus the current standard format. The label format design that you see overhead consists of one contiguous label with an extended information tab, which provides within the context of current pharmacy systems, an easy to implement, consumer friendly, highly visible media through which vital information can be made available to consumers right on their prescription bottles.

In addition to introducing our work for the first time to the FDA and the public through this welcome forum, our purpose and goal today is to also applaud the FDA and the pharmacy industry's desire to empower consumers with better tools to educate themselves and to monitor and take charge of their own medication safety.

In the short time we have here today, I would like to first…by way of background…highlight some of the most interesting and relevant findings from our research and end by introducing to the panel the solution our team has been working on and honing for about two years now in collaboration with several prominent members of the pharmacy, pharmaceutical, and medication safety advocacy constituents across the country.

With the number of prescriptions dispensed annually in the U.S. surpassing 3.0 billion last year and prescription growth forecasted to continue it's rapid pace in coming years, the number of opportunities for medication errors and mix-ups as well as the social and economic impact of those occurrences quickly becomes staggering. Most if not all of you here today are likely to be familiar with the Institute of Medicine's 1999 report titled "To Err is Human" which provided many valuable statistics highlighting the importance of medication safety. The findings of that report and others like it are no doubt in large part the reason why we are all here today. Perhaps the most important take-away from the Institute's report is that the shear volume of prescriptions and their pace of growth are, quite simply,

overwhelming the systems and processes in place for patient counseling and education as well as for prevention of medication mix-ups…all while pharmacies try to maintain some degree of profitability.

NACDS (the National Association of Chain Drugs Stores) reports there to be thousands of vacant pharmacist positions in the pharmacy industry today. Reliance on lesser skilled and educated worker is becoming more and more commonplace just to keep up the pace required to dispense an ever-growing number of prescriptions month after month year after year. While numerous technology solutions exist to streamline or automate the prescription dispensing process, those solutions are often costly and / or complex to implement.

In the face of these challenging forces, how can consumers (our parents, our children, our friends) best be protected from avoidable medication mix-ups? Relying on the 80/20 rule, one answer we believe, derives from the following statistics, which are summarized on the overhead screen. U.S. Pharmacopoeia reports that 17% of medication errors are dispensing related. In 2001… NACDS published findings from a nationwide survey they conducted among community and hospital pharmacists

asking them about their experience relative to medication errors. Three of the top six reported causes of medication error were related to the wrong medication being dispensed…whether wrong dose, wrong drug, or wrong route of administration. The others among the top six errors were related to patient safety information including failure to catch interactions, failure to catch contraindications, and failure to warn patients of potential hazards.

Also interesting are the same NACDS survey findings regarding the MOST COMMON FACTORS contributing to medication errors, as reported, again, by community and hospital pharmacists. I will highlight just the top five reported factors: work overload, inadequate staffing, look alike / sound alike drugs, failure to catch a technician's error, and similarity in packaging. Results and findings like these might lead one to the logical and obvious conclusion that at least one solution to elimination of many common medication errors lies within the pharmacy dispensing processes and procedures themselves…perhaps due to inadequate computer systems, prescription checking procedures, levels of staffing, pharmacy automation, among others. While improvements in most of these areas can perhaps

reduce the error rate, the associated costs, disruption, and time related to such changes, again, can be prohibitive for many pharmacies across the country.

Having the advantage perhaps of studying these issues from the perspective of a consumer, not a pharmacy or pharmacist, it seems impractical to rely solely on pharmacy operations to eliminate a large percentage of medication mix-ups. Pharmacies are already overwhelmed and financially strapped, yet the prescription volume continues to grow and grow. So AS CONSUMERS, our focus and approach to the issue of medication safety has been largely directed at empowering ourselves…CONSUMERS… by providing highly visible access to critical medication safety information directly on prescription labels…the prescription labels attached directly to prescription bottles dispensed from pharmacies. The prescription bottle label is an enduring source of information that a patient sees every time they open their prescription bottle AND most importantly, stays with the medication for the FULL LIFE of the prescription.

The label design we came up with, we call the SCRIPTCHEK label. In many ways the ScriptChek label meets the same objectives the FDA advocated for, with the new easy-to-read labels for OTC products. The FDA goals in that case were achieved by requiring a standard format consisting of important and very specific drug safety, use and warning information, thus providing consumers with a clear understanding of the specific OTC product. The ScriptChek label offers the pharmacy world a label that creatively triples the amount of printable space within the context of existing pharmacy systems and printer configurations, thus allowing the immediate opportunity to provide a large enough area for specific valuable drug information. In fact, ease of implementation by pharmacies only requires minor print routine modifications.

Shown on the overhead screen is a digital photo image depicting our vision for the ScriptChek label. The sample includes label content developed with input from some of the nation's largest pharmacy chains as well as Convergent Label Technologies, the nation's largest producer of prescription label stock for pharmacies. I would like to highlight a few of the label features in the short

time I have remaining, and would be happy to supply anyone who might be interested, with a sample label or e-mail copy of the digital photo.

A few quick highlights on the vision behind the ScriptChek label. The label has sufficient space to include a photographic image and text description of the medication prescribed by a patient's doctor to allow both pharmacists and consumers to verify the drug and dose dispensed for accuracy. We have also included an area where a patient, caregiver, or family member can write on the label what the medication is for so individuals don't get their medications mixed up. The extra space also allows pharmacies to print label content with much larger type size, making legibility of prescription labels much easier… including warning and other safety information…. a particular benefit for the nation's growing population of senior citizens. The label also provides sufficient space to allow for supplemental safety information such as drug-drug or drug-food interactions or contraindications to watch out for. There is also space for bar coding, compliance feedback, multiple languages, and directions on where to find disease specific information and resources. Perhaps most important in the context of this forum here

today, we have included in our label vision a powerful consumer call to action in the form of the universally recognized STOP SIGN.

If you saw a stop sign on the prescription label attached to your medicine bottle, would that not get your attention? Would you not stop and see what its for? That STOP SIGN and the adjacent text message is there to remind consumers to take a few minutes and read the medication leaflet that accompanied their prescription from the pharmacy! How many people tare open the bag with their prescription inside and throw the bag and the medication leaflet in the trash without reading it. Even if they do take the time to read through the leaflet when they first get their medicine, how often do they save it to refer to at a later date if needed? How often do they read that leaflet when they get their refills? How many people take that leaflet with them to reference when they go on a trip?

Our goal in designing the ScriptChek label was a design that is notable, easy to read, accommodates considerably more information than current pharmacy labels are able to, and stays with each medication for the life of the prescription. In addition, the label fits seamlessly within the current

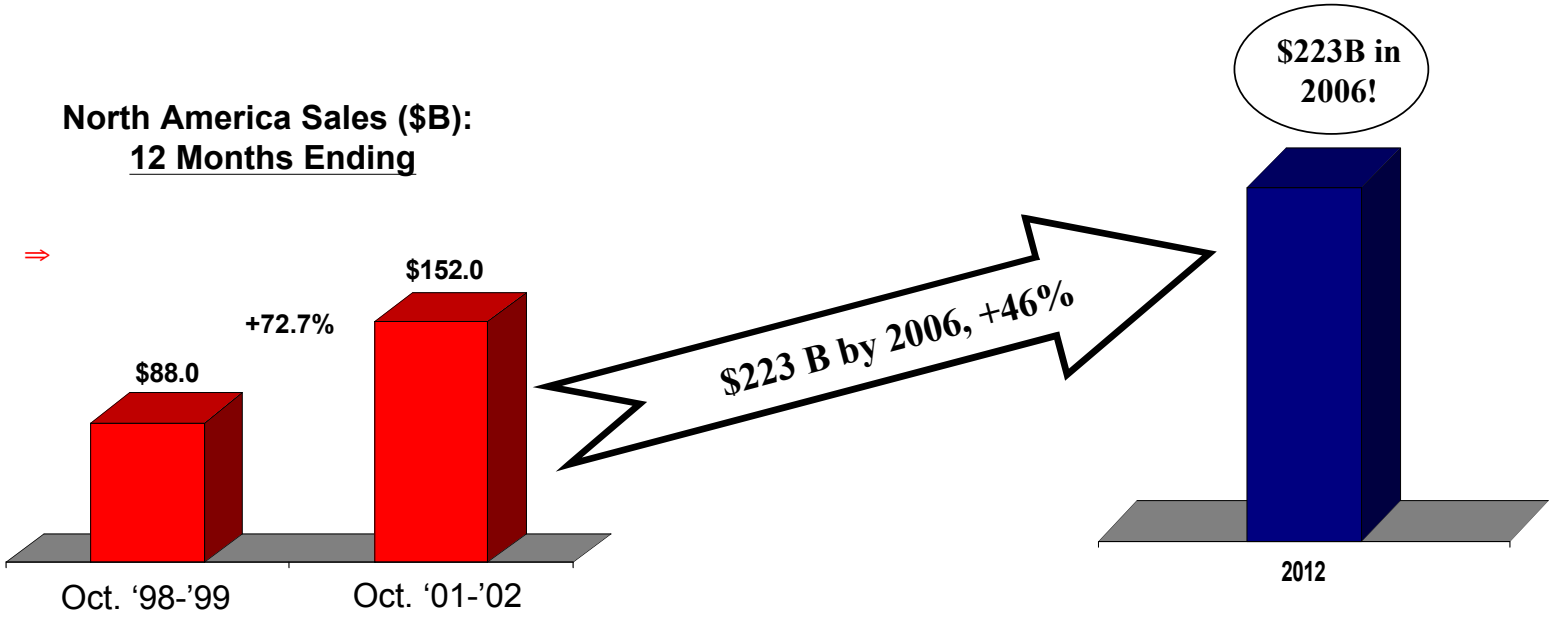
pharmacy operating systems and processes. We are proud to be able to introduce the fruits of our months of labor in this public and very relevant forum here today. And we would like to thank the representatives of the pharmacy and pharmaceutical industries that have guided us along the way. I look forward to addressing any questions during the Q&A session later this afternoon and invite anyone who wants to discuss or inquire further about the ScriptChek label to contact me directly at my office in Florida at 954-423-4161. **Thank you.**

Enhanced Safety Through Prescription Labeling

Putting Medication Information Visibly in Consumers' Hands

ScriptChek Visual Verification Systems, Inc

Prescription Volume Continues Rapid Rise



Source: IMS Health

Prescription Growth Overwhelming Systems

⇒ Increasing Consumer Demand

- Aging baby boomers
- Lifestyle Drugs Grow in Popularity
- TV and Internet Enhance Awareness
- HMOs & Discount Cards Increase Access / Lower Cost For Seniors

⇒ Manufacturers Feeding Demand

- More advertising
- Steadily increasing number of drug approvals by the FDA per year
- New technologies yielding medical break-throughs
- New drug screening techniques accelerate development processes

⇒ Pharmacists and Pharmacies Strain To Keep Up

- Growing prescription volume per store
- Over 6,000 pharmacist job vacancies nationwide
- New pharmacy development not able to keep pace

Medication Errors Are A Growing Problem

⇒ **Approximately 17% of medication errors are dispensing related**
(U.S. Pharmacopoeia data published in CIBC World Markets Report September 2001)

⇒ **Most common types of medication errors**
(as reported by community and hospital pharmacists*)

– Wrong dosage	48%
– Wrong drug given	32%
– Wrong route of administration	10%
– Failure to catch interactions	22%
– Failure to catch contraindications	17%
– Failure to warn patients of potential hazards	15%
– Other	46%

*** Indicates the percentage of respondents stating that these types of errors happen often or sometimes vs. those indicating that these errors rarely or never occur.**

Source: Drug Topics May 21, 2001

Medication Errors Are A Growing Problem

⇒ **Most common contributing factors**
(Reported by community and hospital pharmacists*)

– Work Overload	3.9
– Inadequate staffing	3.5
– Look-alike/sound-alike drugs	3.2
– Failure to catch a technician's errors	3.1
– Similarity in packaging	3.1
– Illegible prescriptions	3.0
– Insufficient prescription information	2.5
– Confusion/unclear labels	2.4
– Lack of system-wide control policies or procedure	2.2

***Reported on a scale of 1-5, with 5 indicating the problem contributed "a great deal" to medication errors in their pharmacy.**

Source: Drug Topics May 21, 2001

Safety For The Life of A Prescription

More Information

Simple and Convenient