Meeting Summary

- Use of Color on Pharmaceutical Labeling and Packaging Part 15 Hearing
- Date: March 7, 2005
- Location: Lister Hill Auditorium on NIH Campus, Bethesda, Maryland

Background

On March 7, 2005, the Center for Drug Evaluation and Research (CDER) held a Part 15 Hearing to obtain public comment about the practice of using color on pharmaceutical labeling and packaging in an effort to identify, classify or differentiate drug products. The practice of applying color is controversial among patient safety groups; the practice having both supporters and detractors. A number of drug and device manufacturers already use color schemes to draw attention to their products. Ophthalmic, anesthetic, dental and insulin drug products as well as medical devices use color to classify, identify or differentiate drugs among classes or to facilitate the correct use of a medical device. Individual practitioner groups often endorse the use of colors to help differentiate among drugs. However, to date, there is little scientific evidence that applying color is effective in reducing medication errors and there is no validated scientific method to corroborate the usefulness of applying colors on pharmaceutical products packaging and labeling for that purpose. As there appeared to be little evidence that adding color is a useful tool in identifying drug products and opinions on the usefulness of applying color in this way varied, FDA/CDER convened a Part 15 hearing and asked a series of specific questions that are articulated below. The following is a summary of the Part 15 Hearing on Use of Color on Pharmaceutical Labeling and Packaging.

Part 15 Hearing Summary

Dr. Paul Seligman, Director of CDER's Office of Pharmacoepidemiology and Statistical Science, chaired the Part 15 Hearing on Use of Color on Pharmaceutical Labeling and Packaging and gave an overview. He said the meeting was convened in order to:

- Obtain feedback on advantages and disadvantages of using color to identify, classify or differentiate drugs from interested external partners,
- Hear whether there was specific data that demonstrate whether the practice works in reducing medication errors or actually contributes to medication errors, and to
- Learn whether the use of color within certain drug classes improves patient safety or hinders patient safety.

The following participated as the FDA expert panel:

- Dr. Robert Meyer, Director of ODE II, CDER
- Dr. Wiley Chambers, Deputy Director, Division of Anti-Inflammatory. Analgesic and Ophthalmologic Drug Products, CDER
- Mr. Peter Carstensen, Senior Systems Engineer, Division of Device User Programs and Systems Analysis, Center for Devices and Radiological Health
- Commander Carol Holquist, Director, Division of Medication Errors and Technical Support, CDER
- Dr. Paul Seligman, Director, Office of Pharmacoepidemiology and Statistical Science, CDER

Commander Carol Holquist described the different color techniques including:

- Color matching – application of color to match one item to another—used in medical device area
- Color differentiation – use of color to enhance features on a label, labeling and packaging to distinguish or differentiate one item or product strength from another
- Color coding – systematic application of color to aid in identifying, differentiating or classifying a drug generally within the same pharmacological class
- Color branding – use of color to differentiate drugs within the same pharmacologic class that is managed by a single sponsor.

She also said that some medical groups (such as American Academy of Ophthalmology and the American Dental Association) endorse color coding because it enables quick identification of a specific pharmacological class by the color alone. She said that some patient safety groups disagreed and said the practice contributes to medication errors. She articulated the following FDA questions, which were posed for pubic comment.

1. How and under what circumstances has the use of color on pharmaceutical packaging and/or labeling demonstrated an improvement in patient care? If there is no discernible improvement, please describe what you consider to be deficiencies in the program.

2. Are there specific classes of drugs where use of color has demonstrated value? Are there classes where use of color is a hindrance to public safety?

3. Are there drug products currently marketed that do not use color but should use color to aid in identification of the drug? If so, how should color be used?

4. How should the effectiveness of application of color on drug products be scientifically validated?

Charles E. Myers, Group Vice President, Professional Development and Member Services, American Society of Health-Systems Pharmacists (ASHP) spoke first. He said that ASHP endorses reading the product label and opposes dependence by hospital and pharmacy staff to identify drug products based on application of color. He also said that errors are occurring because hospitals are complex environments where thousands of drugs, categorized according to pharmacologic class are used every day during healthcare delivery. He said that there are numerous providers in hospitals including specialty and non specialty doctors, pharmacists, nurses, respiratory therapists, dialysis staff, ER staff, physician assistants and others – and that all would need to be educated about any particular color scheme. He also cited practical problems of using colors including the numbers of colors and all the different places where colors would need to be consistently applied (e.g., paper labels, cardboard cartons, glass ampoules and plastic syringes). Even though some subspecialty doctors support the practice of color coding, selecting drugs

based on application of color on the label or package is problematic in the broader sense. In the face of all this complexity, there is little scientific evidence that use of colors on drug packaging improves patient safety. He also said that color differentiation could be an effective tool when it is used to make information on drug labels stand out. Finally, he said that FDA should ask for human factors testing that uses the criteria of reducing medication errors as a determining factor in achieving success.

Dr. Mary Baker and Dr. Thomas Willer spoke next from Hospira, Inc. who provided an overview of their injectable drug and medical device company. They also said that they oppose the use of color coding because of the limited numbers of colors, because lighting and proximity have an effect on the readability of labels and because the use of color can discourage label reading. They support the use of color on the labeling in order to highlight and enhance label information including product name, drug concentration and key warnings. They discussed the use of a label enhancement committee within their own company that is charged with doing a periodic review of labeling systems or classes of drugs. This committee also reviews clinician complaints about look-alike drugs, review color labeling in their line and if possible in competitors line and consider storage related issues. They said that use of color can enhance, but should not replace the primary identifier, that is the label. They said there was no data about specific classes of drugs where color has impacted on patient safety, either positively or negatively. Finally, they suggest scientific validation regarding the efficacy of using color on labels that would involve market testing with different populations and said that whatever changes with regard to using colors to classify, differentiate or identify drug would require a substantial educational campaign directed towards physicians, nurses and pharmacists.

Eric Sheinan of the United States Pharmacopeia (USP) said that currently USP had no specific policy regarding use of color on drug labeling and packaging. He said that drug specific color coding that spans the continuum of all drugs and dosage forms could possibly increase medication errors. The USP Council of Experts did not support color coding because:

- It encourages the reliance on color in selecting a product rather than reading the product label
- There are limited numbers of colors in the spectrum
- Certain colors in poor lighting could look like other colors

He did an overview of MER and MEDMARX data collection systems. Both have received reports where color mix-ups in labeling and packaging have caused medication errors. According to MER, 360 medication errors related to color coding issues were reported between 1994 – 2004. Of those, slightly over 50% were potential errors while the majority of actual errors caused no harm to the patient. However, 4.7% did cause harm, including 4 fatalities. Out of the 360 medication errors, 50 indicated where the error occurred; most occurred in the dispensing phase. Products involved in harmful errors include high alert drugs heparin, magnesium sulfate, and potassium chloride concentrate for injection.

Examples of major errors

- Patient dies when nitrous oxide gas was administered instead of oxygen partly due to inability to distinguish between the adaptor colors

- Patient dies of heart failure when a nurse flushes his IV line with potassium chloride instead of heparin; both drugs were in the patient's medication drawer and were in similar sized vials with similarly colored labels

- After a patient received sufentanyl instead of fentanyl, he experienced respiratory arrest – difficulty in distinguishing red fentanyl labeling vs. green sufentanyl labeling because of color blindness. Patient recovered.

Finally, he said that standardizing the appearance of labeling and packaging in order to reduce medication errors is untested. USP suggested that a cautionary approach should be undertaken and, if used, only on a case-by-case basis.

Dr. Michael Cohen, who is the President of the Institute for Safe Medication Practices spoke. He began his presentation by defining the differences between color differentiation, color coding, color branding and color matching. Dr. Cohen stated he was not aware of any research-based evidence regarding the use of color and reduction of medication errors. However, he is aware of two centers that are looking at color (UK and Texas). Some of the early results do show that color coding actually does not help to prevent medication errors. Although color coding may help to differentiate drug classes it may increase intra-class medication errors. He then gave examples of the use of color code by drug class and various drugs within a class such at the one used in operating rooms. Dr. Cohen supports the use of these user-applied color-coded labels. Color coding can be useful in the operating room with a small number of individuals and a small number of drugs in an enclosed environment, however, he is concerned about the broader application on a class of drugs that may be used in multiple settings (e.g., intensive care units and emergency rooms). Dr. Cohen believes that there is a lack of education available for health practitioners about the meanings of the colors on the drug packages and labels. He said an educational campaign is necessary to alert practitioners to not only the meaning of these colors, but also the potential for error by health care practitioner reliance on using color to identify and dispense drugs.

He said we understand the importance of reading the label three times but that occasionally we are distracted because the label is crowded with other information. He makes the following recommendations:

- Never rely on a single variable such as color to eliminate error.
- Always take into account the amount and size of text on the label, the corporate dress and the shape and size of the logo as well as the backgrounds that are used.
- Similar dosage strengths are misleading and are leading to medication errors.

- Some corporate stylized labels are distracting and draw attention away from reading the label.

If manufacturers are going to apply color to drug labels, it is necessary to have prototype testing by practitioners. He makes the following recommendations:

- Do prototype testing with practitioners within their own environments by using a failure mode and effects analysis process including the following variables:
    - Consider the work environment and work process and the inconsistent nature of different types of practitioner environments or use and work processes.
    - Consider storage requirements, confusion among other drugs within the same color class, etc.

- Failure mode and effects analysis by companies should be required by FDA and the following criteria should be considered:
    - the ordering and inventory process, how the drug is stored and delivered and that
    - testing the true size of items that actually go into the user environment is necessary.

Summary of ISMP recommendations:

- Attention should be drawn to the drug name and strength and total amount in the container.
- Practitioner testing could help detect medication errors before they become a widespread problem.
- Color can be used successfully to differentiate products, to draw attention to important information or to enhance recognition of unique letter characters.
- Practitioner input and expert analysis along the lines of failure mode and effects analysis e.g., gathering data from the practitioners and then having an expert panel examine the data and perform their own failure mode and effects analysis methods should be conducted.
- Large-scale scientific studies are not needed nor would they be very fruitful.
- Practitioner input or expert analysis alone is insufficient.
- Label consults with ODS is important. Support for error reporting and more rapid response by FDA for serious problems is needed.
- Reserve color coding for only high alert drugs such as insulin, neuromuscular blockers, and concentrated electrolytes but only after testing and feedback about prototypes.
- Color should be associated with label information such that it does not draw attention away from identifying the name and strength of the drug.
- Better health care practitioner education about the use of color on drug products packaging and labeling is necessary – it needs to be uniform throughout the industry.

- The use of color may be effective, but only when it's one of several different variables.
- Evidence based medicine is not always necessary in order to determine what strategies are needed to improve safety.
- The Division of Medication Errors and Technical Support should be the final decision maker in FDA when post-market medication errors occur because of problematic drug labeling and packaging.

Dr. Mary Ann McElligott from Novo-Nordisk was the next public speaker. She provided a description of color branding, which was the color technique that Novo Nordisk used to differentiate among insulin and insulin analogue products. She said that color branding was meant to use color to distinguish one item from another, was not intended for the color to be a substitution for reading the label, that the color was chosen by the manufacturer for the brand and that there was no systematized standardized application of a color code that included pre-assigned colors for use by all of industry as is the case for color coding. She said that she believes that that color branding helps in differentiating products within their own insulin and insulin product line. She also said the company was experiencing medication errors at pharmacy dispensing level, and that there is nothing in the literature about the risks associated with adding color, except in the case of color coding certain products, where application of color across a class of drugs can lead to difficulty in distinguishing among similar colors. She said that color branding may help reduce product selection errors within a manufacturers' product line and although not proven, may reduce medication errors. She also said that there was nothing in CFR saying that color is not allowed to be applied to the insulin labels.

Dr. Joseph Cranston from the American Medical Association spoke and described three color coding systems for drugs including:

- the USP black cap packaging requirements for potassium chloride for injection concentrate
- AAO uniform color coding system for caps and labels of commercially available topical ocular medications – this is supported in one agency guidance
- ASTM Standards for color coding of user applied for user-applied syringe labels in anesthesiology – the system assigns a specific color to each class of anesthesia drugs and is supported by anesthesia community.

Although these systems receive wide support within the physician groups, scientific evidence that shows color coding reduces medication errors is extremely limited and for the most part, is anecdotal.

He described the following potential problems:

- Limit of discernible numbers of colors available for commercial use
- Subtle distinctions in color are poorly discernible unless products are truly adjacent to one another

- Color coding of drug classes can increase the chance of intra-class medication errors
- Colors may fade when exposed to light
- It is not always possible to reproduce Pantone colors from batch to batch
- Approximately 8% of men and less than 1% of women have difficulty with color vision
- Color coding can be error prone, if it is not applied consistently across the industry or within a single manufacturer product line
- Physician and other health professionals may be unable to remember large or multiple color coding systems
- Color coding may offer a false sense of security and result in failure to read the label.

He recommended that FDA, USP and the pharmaceutical industry consider carefully the ramifications of color coding products in order to reduce medication errors. He also said that there is a need to conduct further research on the effectiveness or lack thereof of color coding of drug products to reduce medication errors.

Dr. Frank Kyle spoke from the American Dental Association (ADA) and said that ADA developed a uniform color coding system for local anesthetic cartridges in order to supplement the necessary step of reading the cartridge label, which can be very small. He also said that ADA is not aware of any reports of error as the result of implementing the color coding system. The ADA color coding system has been presented to the International Organization for Standardization to include as an international standard for dental and local anesthetics.

Dr. Alan Jensen from the American Academy of Ophthalmology (AAO) presented. He said that ophthalmologists have been using a color coding system successfully for twenty years and although there is no science to prove it, believes it provides an additional level of safety for both patients and doctors. In this color coding system, the colored tops correspond with certain classes of drugs (e.g. all antibiotics) and the purpose is not to identify the precise drug but the class of drugs. He acknowledged that the process could lead to intra-class errors. He said that the generic drug manufacturers use white tops on their products making it hard for the doctor and patient. He said color coding is not the total answer and that physicians still must read the label and there should be uniformity in labeling. However AAO endorses the color coding system for topical ocular medications because:

- Many patients are elderly and partially sighted and the color coding system makes it easier for sight impaired to identify their medications by colored tops.

- The system results in a time saver for the physician who can read the label on the drugs once a day - at the beginning the day

- This system was developed in cooperation with the FDA and the manufacturers

AAO recommends that the uniform system of color coding for caps, labels and ideally the bottle tops for all topical ocular medications.

Dr. James Broselow was our final speaker at the Part 15 Hearing. He began his presentation explaining the relationship between children's length and their weight and how the Broslow tape and color coding system was developed. He said that length is a good predictor of weight, that studies were conducted to support this correlation and that the group that developed the PALS course did a national study that showed length was the best predictor of weight. Also, a number of studies were conducted in hospitals that demonstrated length as the best predictor of endotracheal tube sizes enabling other medical devices for children to be placed into length zones. Dr. Broslow then began to introduce the same color coding principals with over the counter medications and referred to it as color Coding Kids. This concept is based on 3 issues:

- Length is the best predictor of weight.
- Length defines ideal body weight in the sense that many acute drugs just go into the water part of the body
- Length is the best correlation with equipment that you are using at the same time of the medication administrations.

According to Dr. Broselow, this system works because you don't always need to have a patient's weight in order to use this system. You can measure the child with the tape and get the color that corresponds to their length. With respect to over-the-counter medications, Dr. Broselow stated that it is impossible to overdose any normal child by length because length predicts their ideal body weight. Another advantage is that this system can be used internationally and language barriers would virtually disappear. Duke University did one study that was published on this concept. The published article in "Archives of Pediatrics" said that the public had very poor performance of dosing over-the-counter medications to children and there was nearly 100 percent correct dosing using the Broselow color coding method. Dr Broselow suggests that you could use this system with any kind of an OTC medication and he believes this color scheme can be tied into infusion devices, defibrillators and equipment, anything that has sizing associated with it because color is a truly universal language.

Dr. Paul Seligman closed the meeting and thanked the meeting presenters for participating. He said that FDA will review the oral presentations and written comments received in the docket on this issue before deciding next steps.

Written comments were received from the following organizations:

- The American Psychological Association
- American Regent
- Clarke Container
- Medical Packaging, Inc.
- Glaxo Smith Kline
- Karel Van Der Waarde

- West Pharmaceuticals
- ColorCon
- Apotex, Inc.
- Baxter Healthcare Corporation
- The American Society of Anesthesiologists

The comments are summarized below:

The American Psychological Association said that there has been some research on the utilization of color as a factor in safety communications (warnings) and there are guidelines such as the ANSI Standard for product warnings (ANSI Z535). There is also a history of color coding medications by dosage level. Color can be important to help recognize a container's contents and might be useful to enhance the conspicuity of significant information on the label or to emphasize the importance of the label. However, there are problems with this approach because:

- Individuals who are color blind may be unable to detect the differences between colors
- It isn't clear how these guidelines could be set up across manufacturers and the benefit would be lost if manufacturers use a different color scheme
- There is a need to consider contrast and saturation of the colors used as well as the pattern of the coloration and how color is being used as a redundant or adjunct cue and
- There is no empirical evidence showing that color has provided the potential benefits shown.

Effectiveness of application of colors on drug products should be scientifically validated prior to authorizing its use for that purpose. This would require experimental studies comparing the performance of users interacting with drug labeling with or without color cues and tested by health professionals likely to come into contact with the drug products. Products would need to be labeled with a range of colors and patterns that will be on the marketed product. These controlled laboratory studies would represent the first step and it is important to understand whether color is effective in the real world including studies that look at variations in user knowledge. Constraints on time available to cross check the medication needs to be factored in. Without controlled laboratory studies in conjunction with clinical trials and the collection of errors made over time, it will not be possible to firmly establish the benefits and dangers associated with use of color for pharmaceutical product packaging and labeling.

American Regent said they were opposed to industry-wide mandatory color coding, but supported the use of color differentiation with a company's product line and believed the decision to color code should be left to the discretion of the manufacturer and not FDA.

Clarke Container said that medicine containers should continue to be amber and that drug containers should not be blue, green or red to attract a child's attention. Although, all colors offer the same light protection, they said this practice raises a safety hazard

because brightly colored vials may look like a colored candy container to a small child or elderly person.

Baxter Healthcare Corporation believes that labeling and packaging should be reviewed and evaluated in its entirety during the drug and medical device approval process. It should be an interactive process between the sponsor and each FDA review division and decided on a case by case basis. Baxter does not support the use of color coding to aid in the classification and identification of all drug products. Color is only one factor and other tools are available, such as type size, font, location of information and labeling content. They support color coding in very limited and specific settings where the use of color coding is likely to result in a decrease of medical errors.

Medical Packaging, Inc. is a company that manufactures unit dose packaging systems for hospitals and FDA regulated repackagers and provides 12 different colors of cellophane packaging allowing facilities to color code on drug labels. They spoke on behalf of customers, who said that they believe that color coding helps with reducing medication errors and that FDA should continue testing the viability of color coding.

West Pharmaceutical Services said that use of color for differentiation and possible anti-counterfeiting measures for drugs is a useful tool. West supports the use of color on pharmaceutical packaging because it adds a second level of protection in identifying, classifying and differentiating drug products.

Apotex Inc., opposes color coding of drug labeling because:

- It may promote or result in the health professional not reading the drug label
- Bar coding should be emphasized to help identify the product
- It may increase potential dangers for color blind users
- And the spectrum of color used and control measures would be excessive

They agree with color differentiation because:

- It can help distinguish between various strengths and or pack sizes of a particular product
- It can help distinguish between drugs that have look or sound alike names, or are similar in other characteristics
- The colors used do not have specific meaning and are not standardized in the industry which will force the health professional to read the label.

Dr. Karel van der Waarde said that a single visual variable, such as color, cannot be evaluated without taking other visual variables into account (packaging dimensions, location and corporate identity). He made the following recommendations:

- Color can only be observed on a surface and always in combination with other visual stimuli. Scientific investigations between a single variable such as color and human activities have not demonstrated reliable, valid or applicable results.

- It is essential to observe and analyze the activities of people when they handle medicines. Both "best practice" as well as "worst case" need to be recorded with supporting evidence of potential causes. This provides a range of answers to the question: how does visual information help or hinder an activity? Criteria and test results are essential because they provide comparative materials to determine whether a modified label is an improvement.
- In order to determine what works or not in terms of modifying the label, involving users is essential. User testing should be an integral part of information development and its importance can not be underestimated. Without involving actual users, it is impossible to determine if criteria have been met or if progress has been made.

He recommends the following scientific approach:

- Describe the current state through observation and benchmarking, collecting data, developing criteria and analyzing influences
- Involve all stakeholders from the beginning of the process
- Develop prototypes, consisting of several cycles of writing, designing and testing
- Implement the solutions in practice
- Monitor the practice to see what changes occur

GlaxoSmithKline (GSK) submitted written comments to the docket. They said that black and white copy is still most commonly used and it is appropriate for the majority of labeling and packaging for prescription drug products. There are considerations particular in relationship to patient directed labeling and packaging that merit the use of color in labeling. GSK said that the following two examples demonstrate where use of color in labeling can minimize medication errors:

- Relenza is an antiviral drug product for the treatment of influenza in selected patients. Use of color in these instructions added visual clarity to the labeling, and in their view, increased the likelihood that consumers would understand the instructions.

- Proper use of Imitrex, particularly in the context of the symptoms associated with migraine, requires careful attention to instructions in labeling on use of the auto-injector. GSK prepared patient-directed instructions for use, including color components, which are approved as labeling and packaged with the prescription.

- Color could be used effectively in Medication Guides by highlighting the new or revised information for the patient.

GSK cited the following examples (among others) of where use of color in drug packaging has minimized medication errors:

- Accutane and Thalomid are supplied to pharmacists as solid oral dosage forms inside a carton. These cartons have a prominent color symbol intended to alert

pharmacists and patients, at the point of dispensing, to the critical need to avoid use of the drug in pregnant women.

The Colorcon comment said that that the use of color on the drug packaging and labeling as well as on the drug product itself, in the case of solid oral dosage forms, could help identify the drug. They cited examples of legislation from California, Oregon and Wyoming that was drafted to reduce the medication errors by employing color, as one of three key drug identification elements of the pharmaceutical product, i.e., color on-tablet and on-package/label. Some comments submitted to the legislation said that including the physical description of the pill color, shape and imprint code on the prescription vial label has been helpful in preventing medication errors. It said that there was demonstrated value of use of color on all classes of drugs and that color, along with shape and imprint code, of the solid dose form, on label and on-package can reinforce the drug identity to the patient, the pharmacist and care-giver. Color recognition is essential to patient compliance in order to identify the pill. The use of color, and other key identification aids should be used by all drug manufacturers to thwart counterfeiters and at the same time make it easy for the patient and pharmacist to identify the drug. They said the use of color is a key essential element in the design of the dosage form and that the label should specify the color, shape and identification code of the drug. The author of California Senate Bill Number SB 292 passed in the Senate on September 9, 2003 said that numerous studies have found high rates of medical errors in hospital settings. They said that the Campaign for Patient Safety conducted an analysis of drug dispensing errors that were reported to the California Board of Pharmacy between June 1997 and March 2000. The analysis shows that by far, the largest numbers of dispensing errors were occurring because pharmacists were dispensing different medications than prescribed.

In response to the question about whether application of color on drug packages and labeling was effective in reducing medication errors, Colorcon said that the five years of experience by the Oregon State Board of Pharmacy in the prevention of medication errors, resulting from the inclusion of a physical description of drugs on the containers labels, should be used as a practical in-use measurement, in addition to a scientifically validated study. Similar considerations of "in-use measure" should be given to the States of Wyoming and California beginning in 2006.

The American Society of Anesthesiologists (ASA) submitted a written comment. They mentioned that ASA adopted a formal "Statement on the Labeling of Pharmaceuticals for Use in Anesthesiology" in October, 2004. Of note, nine classes of drugs commonly used in the administration of anesthesia should have a standard background color established by user-applied syringe by ASTM international standards. Drug classes that should be included under this standard were induction agents, muscle relaxants, vasopressors, muscle relaxants, relaxant antagonists, major tranquilizers, hypotensive agents, local anesthetics and anticholinergic agents. They said that color coding can help clarify drug classification, but that prominently featuring the drug name, concentration and volume is most important to ensure that the proper drug is used. Many anesthesiologists support the use of color coding, however results of empirical studies are inconclusive. One study published in 2004 (Fasting S, Gisvold SE. Adverse drug errors in anesthesia and the

impact of coloured syringe labels *Can J Anesth.*) suggest a reduction in drug errors, but also say that color alone may be an insufficient visual cue to eliminate errors. In addition, relative syringe size may also have played a part. ASA said that drug used in those situations where the anesthesiologist is administering multiple drugs rapidly and performing additional duties would most likely benefit from color coding although studies to date have not demonstrated this benefit. Multi-drug rapid-response situations include the induction of anesthesia and emergencies where the anesthesiologist is using epinephrine, ephedrine, phenylephrine and resuscitation drugs. ASA suggests using the survey of hospitals conducted by ISMP as a good starting point in identifying which drugs don't use color but should use color on drug packaging and labeling. Some of these drugs include IV adrenergic agonists, IV narcotics and opiates and IV general anesthetics. Finally, ASA believes the best way to evaluate the effectiveness of color-coding is a multi-centered prospective analysis of the effect of color-coding ampoules and syringes consistently with each other or possibly of coloring the liquid medicine itself. Simulator trials could be used effectively as well as to analyze, in detail, the effect of color-coding on reducing medication errors and improving patient care.