An information design approach to labeling.

A response to the FDA request for comments about the 'Use of Color on Pharmaceutical Product Labels, Labeling and Packaging' (Docket No. 2005N-0036).

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Summary

The following text questions the assumptions, discusses the issues, and provides recommendations related to the use of color in pharmaceutical labels and packaging.

The assumptions underlying the *FDA-request for comments* are problematic for several reasons. These reasons are related to the evaluation of effectiveness of visual communication, the perceived need for scientific evidence and scientific methods, and a limited perspective on the current practical use of color. These reasons make a reconsideration of the foundations for the discussions about the use of color for pharmaceutical information necessary.

I think that the ultimate aim of pharmaceutical labeling is to optimally support the activities that people need to undertake to handle and use medicines safely and effectively. The four issues that are mentioned in '*II. Scope of the hearing*' provide a suitable frame to discuss this.

The first issue is related to the need to start from the activities of people who have to handle pharmaceuticals. Only people who actually look at pharmaceutical information can provide valid judgements about the effectiveness of information. The second issue indicates that it is essential to consider the context in which pharmaceutical information is used in order to be able to gauge effects. Issue three highlights the importance of accurately considering the current use of color in practice. And the final issue implies that, in order to make valid statements about effects, it might be useful to apply an approach that integrates the benchmarking, development, implementation, and monitoring of pharmaceutical information.

A re-formulation of the assumptions and the discussion of the issues provides a basis for the following recommendations:

1 - Consider all visual variables together.
2 - Start from the activities and expectations of people.
3 - Involve people in the design process.
4 - Consider an Information Design approach to validate the qualities of pharmaceutical information.

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Assumption 1: The effects of colors can be determined.

The *FDA-Request for comments* states:

> "The purpose of the hearing is to obtain public input on the benefits and potential drawbacks of applying color to drug packaging and labeling to help identify, classify, or differentiate those products."

This paragraph makes the assumption that it is possible to single out 'color' as a variable that can be judged on its own. It also implies that color only influences the 'identification, classification and differentiation of pharmaceutical information', and that these activities are identical in all circumstances. These three assumptions are incorrect for the following reasons:

A single visual variable, such as color, cannot be evaluated without taking other visual variables into account. Examples of other visual variables are texts, packaging dimensions, location, and corporate identity of the manufacturer. In practice and during scientific experiments, an evaluator cannot separate color from these other variables. This impossibility was first mentioned by Buckingham (1931). Lund (1999) provides a recent overview of the arguments.

Identification, classification and differentiation are only three of the activities that need to be undertaken by people when they look at pharmaceutical information. Different users, such as pharmacists, patients, nurses, and doctors, have to achieve different aims with the aid of visual information. Examples of other activities are searching, scanning, comparing, checking, locating, and remembering (Sless, 2004).

Activities are not generalizable. Medicines are handled in different circumstances, such as emergency situations, in hospitals, in operating suites, and at home. In each of these situations, the environment (lighting, urgency) and adjacent artefacts differ. These different circumstances must be taken into account before the benefits or drawbacks of the use of colour can be discussed. For example, identification of a pharmaceutical package by a pharmacist in a dispensing pharmacy is different from the identification of the same package by a patient at home. It is likely that the pharmacist has stored medicines in alphabetical order, and this is unlikely to be the case in a domestic situation.

In order to improve the support of the activities of people when they handle medicines and are looking at pharmaceutical information, it is necessary to consider all visual variables simultaneously, for specific activities, and in a specific context. Establishing the effect of a single visual variable - such as color - on behaviour has proven to be extremely difficult in the past and it might not deliver the expected results.

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References:

Buckingham, B. R. (1931) *New data on the typography of textbooks*. Yearbook of the National Society for the Study of education. 30. pp 93-125.

Lund, Ole (1999). *Knowledge construction in typography: the case of legibility research and the legibility of sans serif typefaces*. University of Reading. Phd Thesis.

Sless, David (2004) *Labelling code of practice. Designing usable non-prescription medicine labels for consumers*. Communication Research Institute of Australia

Assumption 2: The need for scientific evidence and methods.

The *FDA-request for comments* mentions:

> "To date, there is little scientific evidence that applying color is effective in reducing medication errors."

This statement is true within the boundaries of scientific evidence in the medico-pharmaceutical domain. However, it does not mean that this evidence cannot be found in other domains. Publications about color in cartography (MacEachren), air traffic control radar screens (Reynolds), warning design (Edworthy and Adams), and hospital signage (Miller and Lewis) provide ample evidence of the value of color differentiation in relation to specific activities of people. Colin Ware's publication offers an overview of the perceptual background. Characteristic for all these approaches is that color is not perceived as a single variable, but is always studied within a context and for a specific purpose.

The *FDA-request for comments* also states:

> "Furthermore, there is no validated scientific method to corroborate the benefits of using colors on pharmaceuticals in this fashion."

The relations between scientific methods and visual design practice have been discussed by Zwaga, Boersema and Hoonhout (1999). They state that the apparant lack of scientifically validated data about visual variables does not mean that practical knowledge about the development of visual information that optimally supports the activities of people is not available. Experienced visual communication specialists and usability experts can provide this knowledge.

In practice, several parts of the visual design process apply scientific methods, but only where these are appropriate and suitable. For example, the description of the current state of affairs in a contextual enquiry relies heavily on antropology, and usability studies are based in ergonomics and applied psychology.

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References:

Edworthy, J. and Adams, A. (1996) *Warning Design. A research prospective.* London: Taylor and Francis.

MacEachren, Alan M. (1995) *How maps work. Representation, visualization and design.* Guilford Press.

Miller, Colette and Lewis, David. (2000) *Wayfinding: guidance for healthcare facilities.* London: Stationary Office.

Reynolds, Linda. (1996) 'The functional use of colour on visual display units: air traffic control displays.' *Information Design Journal.* 8(2) pp 109-124.

Ware, Colin. (2000) *Information visualization. Perception for design* Academic press. Especially pp 127-148 'Applications of color in visualization'.

Zwaga, H., Boersema, T., Hoonhout, J. (1999) 'By way of introduction: guidelines and design specifications in information design.' pp xvii - xxxiv in: Zwaga, H., Boersema, T., Hoonhout, J. (eds) *Visual information for everyday use. Design and research perspectives.* London: Taylor and Francis.

Assumption 3: Use of color techniques.

The request for comments mentions four uses of color:

> "The following color techniques are used on pharmaceutical products and medical devices:
> - Color Coding [...]
> - Color Differentiation [...]
> - Color Branding [...]
> - Color Matching [...]"

Three of these categories are mentioned in Report 5 of the AMA. These categories are based on a literature search in the medical and pharmaceutical domain. This approach is certainly useful, but it might have been appropriate to look at practice as well.

A quick glance at a collection of pharmaceutical labels indicates that color is also used for other purposes. The following list is not in any particular order and it is unlikely that it is complete. Colors are used:

a) to comply with the Corporate identity of the manufacturer/license holder.
b) to warn. Warnings can either appear on labels added by a pharmacist, or on the outer packaging.
c) to emphasize, or to make specific information more salient.
d) to relate information that belongs together.
e) for no immediately obvious purpose. This assumes that the default color of texts is black on a white background.

An analysis of current practice might reveal even more purposes. Such an analysis needs to take the life-cycle of pharmaceutical information into account. During the production, dispensing, administration and storage, information is added through extra labels, handwritten notes, and additional packaging. These additions need to be studied in order to obtain a complete insight into the role of color.

Both literature searches and analysis of practice are necessary to build a taxonomy of the use of color used in pharmaceutical information. The focal point of such an investigation should be to collect and describe both 'best practice' and 'worst cases' for each of the purposes in particular situations.

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References:

Report 5 of the Council on Scientific Affairs (A-04). The Role of Color Coding in Medication Error Reduction (http://www.ama-assn.org/ama/pub/category/13662.html)

Issue 1: How to use color?

The *FDA-request for comments* asks public comments about four issues. The first issue is:

> *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.*

This question reduces the scope of the general aim of pharmaceutical information by focusing on 'color' and 'patient care' only. These are not the only two elements that are worth considering.

Color cannot be separated as a single variable, and it is therefore not possible to relate color unequivocally to patient care. People look at color on packaging, leaflets, brochures, and websites in context: together with all the other visual variables.

Patient care is only one purpose of pharmaceutical information. Pharmaceutical packaging and labeling is handled by a number of people, such as pharmacists, doctors, patients, nurses, and health carers. It would not be beneficial to focus on the needs of patients only, without taking the needs of the other user-groups into account. In order to improve pharmaceutical packaging, it is essential to take the perspectives of the different participants into account.

Improvements need to be related to human activities. The three activities mentioned (identification, differentiation and classification) do not provide a complete picture. These activities differ per group, and can probably be detailed even further. All activities need to be optimally supported by the label and packaging.

In order to make progress, it might be necessary to rephrase this question. It is necessary to shift the focus from 'the use of color on pharmaceutical packaging and/or labeling' to 'the activities that people have to conduct with the support of pharmaceutical information'. The emphasis shoud move away from the labeling itself towards the activities that people need to conduct with the support of the information. The question becomes:

> *How can pharmaceutical packaging and/or labeling optimally support the activities of people who handle medicines?*

To answer this question, it is first necessary to investigate the activities of people. This investigation will reveal which information is lacking, what the sequence of information should be, and which information is the most important for certain activities. This approach has proven to be effective in areas as diverse as 'design of user manuals' (Schriver) and 'signage systems' (Arthur).

References:

Arthur, Paul and Passini, Romedi. (2004) *Wayfinding: People, Signs, and Architecture*. Toronto: Focus.

Schriver, Karen. (1997) *Dynamics in document design*. New York: John Wiley & Sons.

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Issue 2: Demonstrated value?

The second issue relates color and drug classes:

> *"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?"*

This question implies a medical-pharmaceutical perspective. This perspective ignores the context in which drugs are used.

It is not the 'class of drugs' that causes medication errors, increase costs, or reduce effectiveness. It is the handling of a drug in a particular context that can be classified as problematic. The focus of the development of information about drugs should be on the activity of people who handle and use the drug - supported by the available information. Focusing solely on the drugs themselves, or focusing on the accompanying information, will not be beneficial.

A second argument that makes the focus on a particular drug class inappropriate, is that a complete collection of all medicines in a particular class (all strengths, all manufacturers, all amounts per pack) rarely occurs in practice. If color would be used to systematically differentiate between all drugs in a class, it would not be optimally effective. The noticeable differences between individual drugs that are available in a particular location would be less salient, because the system needs to accomodate for all drugs in a class.

Furthermore, some classes of drugs are used in different contexts. It is likely that a hospital pharmacy stocks a large number of different injectable painkillers. A general practitioner who is visiting a patient at home is likely to carry only one or two of these drugs. The selection of a single medicines differs because the 'target medicine' is surrounded by different medicines. Color might not be the most appropriate visual variable to suit both situations.

The above statements do not imply that color should not be used to distinguish between drugs in a particular class. Color should be used, but always in combination with other visual variables (Filik).

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References:

Filik, Ruth., Purdy, Kevin., Gale, Alastair. (2004) *'Medication errors and the judicious use of colour on the labelling of medicines.'* In P. McCabe (Ed.), Contemporary Ergonomics 2004 (pp.351-355). London: CRC Press.

Issue 3: Current use?

The third issue questions the current use of color:

> *"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?"*

Identification is likely to be a process consisting of several steps. These steps vary according to the situation and the person who needs to identify. Two examples show the difference.

Example 1: Situation: A pharmacist has received a prescription and needs to identify the outerpackaging to dispense the product. Depending on the starting point, it consists of activities like understanding ('Which product is required?'), remembering ('Have I seen this product before?'), searching for appropriate starting point ('It should be about here'), detailed searching ('..., air..., Airo..., Akin..., Akinspray, Aknemycin.'), selecting ('cream or solution?'), taking pack from shelf, checking ingredient (is 'erythromycine' correct?'), checking strength ('20 mg?'), and comparing the information on the pack with the information on the prescripion form ('is this correct?').

Example 2: Situation: A patient experiencing the first asthma attack in fall stands in front of his medicine drawer. Again, it depends on the start of the identification process, but it is likely that the following activities occur. Formulating the question ('it was a grey inhaler with a blue cap'), searching for boxes that might contain inhalers ('I see two inhalers'), picking both boxes from the drawer, selecting ('was it this one ... albutarol? or this one with beclom ...?'), deciding ('which one should I take?')

In both examples, color - in combination with other visual variables - can be an appropriate way to support several of the activities . The visual memory ('It is a small white box with a turquoise banner') supports these activities.

Before progressing, it is necessary to make a thorough inventory of the ways in which colors are used in current practice, with special reference to the importance of visual memory.

Issue 4: Scientific validation?

The fourth issue addresses the need for a scientific validation:

> *"How should the effectiveness of application of color on drug products be scientifically validated?"*

The approach used by information designers can be used as a guide. This approach consists of five steps (Sless, 1995 a&b). These steps are:

1. Describing the current state of affairs through observation and benchmarking. Collecting data, developing criteria and analysing influences.
2. Involving all stakeholders. Projects require the input from all relevant perspectives, and it is vital for the success of a project to involve all factions from the start.
3. Development of prototypes, consisting of several cycles of writing, designing and testing.
4. Implementing the solutions in practice.
5. Monitoring practice, to see which changes occur.

This approach has proven to be successful in the development of effective labeling and effective labelling legislation in Australia (Therapeutic Goods Order) and its related *Labelling Code of Practice: Designing usable non-prescription medicine labels for consumers.*

The information design approach is effective because it starts from the activities and expectations of people who are dealing with pharmaceutical information. The main aim is to develop pharmaceutical information that supports these activities effectively. Benchmarking, user testing, and monitoring therefore play a central role in this approach. These three activities have clear scientific roots. The scientific component of the other steps, such as involving all stakeholders, writing texts, designing documents and implementation into practice, is less relevant. In these steps, experience and practical knowledge can be more appropriate.

References.

Sless, David. (1995a) *Information Design for the Information Age*. CRIA (http://www.communication.org.au/)
Sless, David. (1995b) *Designing better medicine labels*. CRIA. (http://www.communication.org.au/)
Therapeutic Goods Order No 69A. (http://www.tga.gov.au/docs/html/tgo/tgo69a.htm)

Recommendations

The recommendations below are based upon both the discussion of the assumptions and the responses to the four issues that are stated in the *FDA-request for comments*.

Recommendation 1:

"Consider all visual variables together."

The FDA requested comments about the use of color in pharmaceutical labeling. The arguments in this response show that focusing on color might not be the most fruitful approach.

Color can only be observed on a surface, and always in combination with other visual stimuli. Focusing solely on color ignores the influence of the context in which the colors are observed, and ignores the activities and abilities of the observer.

For this reason, scientific investigations which aimed to show relations between a single visual variable - such as color - and human activities have not provided reliable, valid nor applicable results.

Color is an inseparable element of any pharmaceutical label. People who look at pharmaceutical labeling cannot perceive visual variables individually, but perceive all variables simultaneously. Developers of visual information - graphic designers, document designers, information designers - consider all visual variables simultaneously when they create the visual design of pharmaceutical labeling. And scientists who investigated the responses of people to visual information in context were able to draw valid, reliable and applicable conclusions.

Recommendation 2:

"Start from the activities and expectations of people."

It is essential to describe and analyse the activities of people when they handle and use medicines. Observing and recording the current state of affairs needs to be done to find out what is going well, and which activities need additional or a different type of support. Both 'best practice' as well as 'worst cases' need to be recorded with supporting evidence of potentical causes. This provides a range of answers to the question: 'how does visual information help or hinder an activity'.

Such an inquiry will also reveal the expectations of people. Every person who handles pharmaceutical information at the moment is familiar with the current visual presentation, including color-palettes and color-systems. Ignoring this familiarity in further developments will lead to errors, increase anxiety, and requires extra time.

The results of the observations will indicate which situations need to be dealt with most urgently. The results will also provide many detailed comments about particular labels that are useful as input for the next generation of labeling.

Special attention should be given to the establishment of criteria that indicate the success or failure of each activity. Benchmark tests can provide actual data about particular problematic or successful activities. The criteria and testresults are essential because they provide comparative materials to decide if a modified label can be seen as an improvement.

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Recommendation 3:

"Involve people in the design process"

If the benefits and potential drawbacks of modifications of pharmaceutical labeling on activities of people need to be discussed, than involving people who use this information in context is essential. Establishing the quality of pharmaceutical information can only be done by people who use specific information to achieve a specific aim in a particular situation. It cannot be judged in design studios or in research facilities. Neither designers nor researchers can accurately predict if information is suitable in a particular practical situation. No amount of discussion can replace the results of tests with actual users.

User testing must therefore be an integral part of information development, and its importance cannot be stressed enough. Without the involvement of actual users, it is not possible to establish if criteria have been met, or even if any progress has been made.

Recommendation 4:

"Consider an Information Design approach to validate the qualities of pharmaceutical information."

The earlier recommendations need to be embedded into a general approach. This approach is very briefly outlined on page 8 and stimulates a 'performance based' development of pharmaceutical labeling. It might be worth considering this approach if a long-term view on the qualities of pharmaceutical information is required.

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Dr Karel van der Waarde studied graphic design in the Netherlands (Eindhoven) and in the UK (Leicester, Reading). He received his doctorate in 1994 for: *'An investigations into the suitability of the graphic presentation of patient package inserts'*. In 1995, he started a design - research consultancy in Belgium specializing in the testing of information design. The company develops patient information leaflets, instructions, forms, protocols, and the information architecture for websites. Karel van der Waarde frequently publishes and lectures about visual information. He is moderator of the InfoDesign and InfoDesign-cafe discussion lists and co-owner of the InformationDesign.org website.

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