A Care Ethics Analysis of Prescription Medication System Design

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

CVS Pharmacy is a large pharmaceutical chain company that recently acquired Target's Pharmacy stores in 2015 (*CVS Health and Target announce completed acquisition of Target's pharmacy and clinic businesses*, 2015). When CVS finalized this acquisition, the company stopped production of the Clear Rx Medication System, the patented pill bottle shape and corresponding label design that many existing Target customers relied upon to understand the key details of their prescriptions, and instituted a different medication system known as ScriptPath Prescription Scheduling (*Scriptpath*, 2017). Currently, extensive discussions are taking place regarding what makes a good pill bottle label and how to reduce the 33% of medication errors attributed to packaging and labeling confusion (Jeetu & Girish, 2010). However, there is limited discussion on whether or not it is ethical for large pharmaceutical companies to sell prescription medications with insufficient labels. In particular, there is limited discussion on whether or not CVS's decision to discontinue the use of the Clear Rx Medication System (Clear Rx) and transition to ScriptPath Prescription Scheduling (ScriptPath) was an ethical one. Neglecting to look at the ethical implication of this decision will lead to a missed opportunity to better understand the responsibility businesses in the pharmaceutical industry have to patients regarding the design of technology that is central to their relationship. Applying the care ethics framework, I argue that CVS's decision to discontinue Clear Rx and transition to ScriptPath was unethical because CVS through this decision violated responsibility standards and arguably failed to demonstrate competence of care its patients need. I will use care ethics because this framework draws on the responsibility that two parties have to maintain a relationship, to evaluate the morality of CVS's choice to discontinue Clear Rx and institute ScriptPath.

Background

Target introduced Clear Rx in 2005 after working with Deborah Alder, a designer that received her Master of Fine Arts in Design from the School of Visual Arts in 2002 (*Deborah adler design | about*, n.d.). Adler started redesigning prescription medication containers after her grandmother took her grandfather's medicine by mistake (*Deborah adler design | about*, n.d.). The design she created received a multitude of awards, and the research that went into creating the revolutionary design proved to correct many errors patients had when reading medication labels. CVS completed the acquisition of Target pharmacy in December of 2015 and gained the intellectual property for the Clear Rx bottle design (*CVS Health and Target announce completed acquisition of Target's pharmacy and clinic businesses,* 2015). A CVS spokesperson said CVS decided not to use this medication system moving forward because it is more efficient to fill prescriptions with the same bottle at all of its 9,600 pharmacies (*Unhappy Target customers send strong message on pill bottles*, 2016). This frustrated many of Target's old pharmacy customers, and there are reports of some patients digging through their trash to find the prescription bottles that helped them manage the different medications in their household (*Unhappy Target customers send strong message on pill bottles*, 2016). In October 2017, CVS rolled out ScriptPath, a prescription label system designed in part by Deborah Adler, the same person that designed Clear Rx (*Scriptpath*, 2017). The ScriptPath design for CVS's existing cylindrical pill bottle focuses on helping patients manage when they take their medicine.

Literature Review

There is a lot of research available on the central piece of technology that pharmacies and patients rely on to do business, the prescription pill bottle and its label. The research mostly

focuses on human factors analysis of how people engage with the pill bottle, as well as how to improve health literacy outcomes and general "poor patient comprehension and subsequent unintentional misuse of prescription drugs" (Webb et al., 2008). This research is invaluable and important to making needed changes to prescription bottles. However, this piece did not evaluate the morality of the decisions large chain pharmaceutical companies make to not improve the pill bottle shape or label design in a way that prioritizes their patients.

In the paper, *Patient-centered approach for improving prescription drug warning labels*, Webb at al. found that patients with limited literacy skills "indicated that the majority of icons were confusing, used difficult language, and text and icons were discordant" when reading warnings on different pill bottles. After taking feedback and completing usability testing on differently designed warning messages, they found that "shorter, clearer messages would be more likely to be read" and patients "preferred having icons that specifically depicted the message behavior" when it came to educating themselves on potential issues when taking medication (Webb et al., 2008). While this research highlights the ways to improve health literacy and access, it does not discuss the moral responsibility of pharmaceutical companies to change pill bottle labels from a state that is confusing for many patients, to a state that is clear for patients at all levels of health literacy ability.

In, *Applying human factors to develop an improved package design for (Rx) medication drug labels in a pharmacy setting,* Gerhart et al. discuss the clear hierarchy of information that should be presented on a pill bottle. The manufacturer's name and logo should not compete with the name of the medication, the strength, or any associated warnings, which are the critical pieces of information a patient needs (Gerhart et al, 2015). The authors show that prioritizing this hierarchy of information on a pill bottle label complies with the multitude of standards

established by the FDA. Within a legal perspective, it is possible to take user feedback and create a pill bottle that works not only for the patients but for the government as well. This piece failed to look at the ethical implications of choosing to follow FDA standards but not go one step further and listen to users to design a label that better communicates the critical pieces of information for each drug.

These are just two examples of a much larger body of human factors analysis of prescription bottle labels design choices and the implication that has on patients. The body of research focuses on how to create a better design and improve the outcomes for patients when they are taking medicine, but they do not look at the decision companies make when they choose an inferior, more cost-efficient design, over another. This paper will break down different design choices implemented on the two prescription bottle labels. and examine through the care ethics framework, how the presence of those design choices exhibits or shows oversight of care.

Conceptual Framework

The decision CVS made to discontinue the use of the Clear Rx Medication System and institute ScriptPath Medication system can be analyzed using the care ethics framework. Developed by Carol Gilligan and expanded upon by many others, care ethics is centered around the idea that morals are not learned but developed through the relationships and specific contexts people encounter. Care ethics believes that the connectedness between people is key and places special emphasis on the responsibility and moral obligations people have concerning one another (van de Poel and Royakkers, 2016). In particular, van de Poel and Royakkers argue that “In relationships the recognition of vulnerability and dependence play an important role, especially if the relationships are asymmetrical, such as the relationship between parent and child, between

employer and employee, or between doctor and patient" (van de Poel and Royakkers, 2016). Two roles can be assigned in care ethics, the one-caring or the cared-for, as defined by Nel Noddings. The one-caring involves empathy, which does not require "projection but reception" when understanding the person or object that the one-caring is fixed on. The cared-for responds to the presence of the one-caring and "feels the difference between being received and being held off or ignored" (Noddings, 2013). In asymmetrical roles, it is important for the people involved in a relationship to recognize the role they hold to better understand the level of care that is expected of them. In a pharmacy setting, the pharmacist and the pharmaceutical company are the ones-caring and the patients that seek help from the pharmacy are the cared-for.

When working within this framework it is important to define the word care before it is evaluated in different situations. Care can be used in different contexts as both an action or an attitude. As defined by Joan Tronto, "to act properly in accordance with an ethic of care requires that the four moral elements of care, attentiveness, responsibility, competence, and responsiveness, be integrated into an appropriate whole" (Tronto, 1994). This suggests that if one of these moral elements were missing then adequate care would not be demonstrated. Within pharmacy, responsibility can be defined as the ability to anticipate and answer patient's questions. Competence is defined as the ability to understand a patient's educational needs. For the remainder of the paper, I will analyze the decision CVS made to discontinue the use of Clear Rx and start ScriptPath against two of the four qualities of care, responsibility and competence.

Analysis

Using the care ethics framework, CVS's decision to discontinue Clear Rx and transition to ScriptPath was unethical because CVS through this decision violated responsibility standards

and arguably failed to demonstrate competence of care which are two of the four essential qualities of care. The following paragraphs take these two attributes of care and highlight where Clear RX showcases care in design that is absent or not done as well in ScriptPath.

Responsibility

CVS failed to provide adequate care to the patients the company serves when CVS did not meet responsibility standards established in prescription medication label design. Within the pharmacy industry, many have concluded that "a person with responsibility has to respond to questions. The possible question that will induce a response will be posed in the future" (Dessing & Flameling, 2003). This indicates that pharmacists must be ready to anticipate and answer questions from the patients that they serve. Responsibility is distributed among not just the pharmacists that directly interact with patients, but also with health care professionals like the management level figures within health care companies (Dessing & Flameling, 2003). For all of these stakeholders to uphold the proper standard of responsibility, "documentation and communication are essential to be responsible and to respond, now and at any other moment" (Dessing & Flameling, 2003). The labels on prescription medication are the main source of documentation that patients look at when taking medication because the critical information that the patient needs, like the drug name, strength, instructions on how to take the medication, etc. are all on the label. The National Academies of Sciences, Engineering, and Medicine discovered that "the container label is the patient's most tangible source of information about prescribed drugs" and "is a crucial line of defense against medication errors and adverse drug effects" (Literacy et al., 2015). Warnings related to the drug are important to document for patients to ensure they take the drug properly. To evaluate the responsible documentation that is needed to determine whether Clear Rx or ScriptPath upheld the level of responsibility that CVS is held to

in the pharmaceutical industry, I will evaluate the documentation of warnings on each pill bottle label.

Figure 1: Clear Rx Medication System Label. Source: https://adlerdesign.com/.

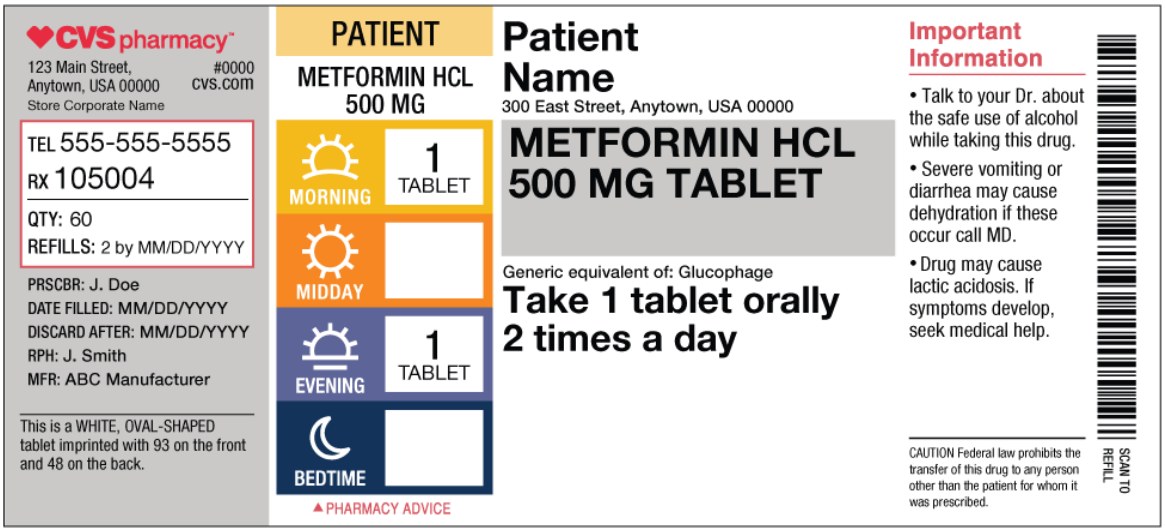

Figure 2: ScriptPath Prescription Scheduling Label. Source:

https://payorsolutions.cvshealth.com/insights/scriptpath-prescription-labels-help-make-adherence-easier.

In Figure 1, the Clear Rx label has one-half of the total label space dedicated to warnings, which is located on one side of the pill bottle. In Figure 2, the ScriptPath label has reserved one-fifth of the label for communicating warnings and is placed in between the drug name and instructions on one side and the refill barcode on the other side. By placing warnings on one side of the pill bottle, the Clear Rx design is reducing the number of distracting elements that could take away from the important content listed within the warnings. The warnings on ScriptPath have adequate space to list the messages, but they are placed close to many other segments of the label, making it harder to focus on just the text.

A recent study showed "shorter, clearer messages would be more likely to be read" when dealing with warnings on a pill bottle (Webb et al., 2008). The drug type in the examples are different, which means that there are different warnings attached to each pill bottle label, so a direct comparison of the examples is challenging. However, taking an average of the number of words used in the warnings will begin to indicate whether there is a difference in the number of words used in each message. Based on the examples in Figures 1 and 2, when reading down the label, Clear Rx has ten, five, fifteen, and eight words in each warning respectively. Reading down the ScriptPath label, the warnings have fourteen, twelve, and eleven words respectively. Clear Rx has an average of 9.5 words per warning, while ScriptPath has an average of 12.33 words per warning. This is a difference of about 3 words per message, which is a significant amount when dealing with the warning statements. By using more concise wording in the text, Clear Rx has structured the text of warnings better than ScriptPath.

Finally, pictograms are simple pictures that express ideas in a way that helps those who struggle with health literacy. Many studies have explored the Dual Coding Theory, a principle which states that people retain information better when verbal or written text is communicated in

conjunction with images (Wolpin et al., 2016). However, not just any pictograms work. Patients are more receptive to the ones that directly depict the message compared to the use of generic pictograms (Webb et al., 2008). As seen in Figures 1 and 2, Clear Rx has pictograms next to the warning text and ScriptPath does not. The designer of Clear Rx went a step further in the pictogram design and made images that are directly related to the warnings communicated. As seen in Figure 3, the use of common images helps communicate the key distinguishing takeaways from each warning message, like the pictogram of a water spigot that is used to communicate the need to take the drug with water. This direct depiction helps users remember the details of the warning message and aid understanding at all levels of health literacy.

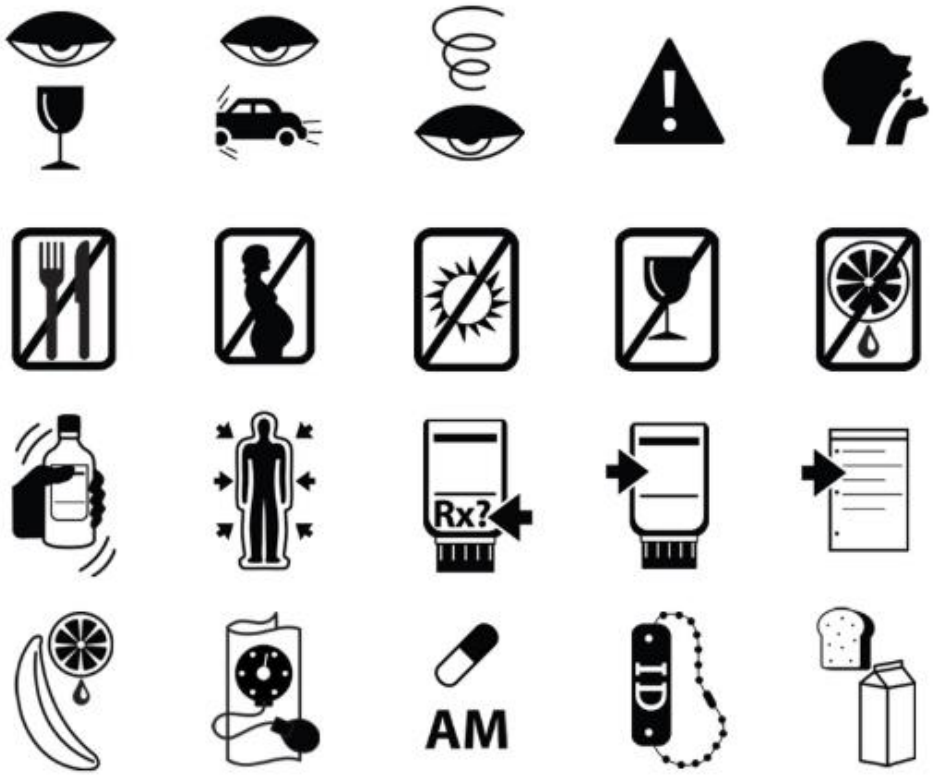

Figure 3: Pictograms developed by Deborah Adler for the Clear Rx Medication System. Source: https://adlerdesign.com/.

Through the analysis of the position and spacing of the warnings, the length of warning text and the use of pictograms, Clear Rx does a better job of utilizing different design principles to document warnings associated with the prescription drug compared to ScriptPath. Because Clear Rx can better document and draw attention to the warnings, CVS violated the standard of responsibility in documentation when transitioning to lesser prescription medication design and therefore did not demonstrate adequate care for its patients.

Competence

CVS failed to demonstrate suitable care for its patients when the company did not show adequate competence in understanding the patient educational needs through prescription medication label design. The American College of Clinical Pharmacy wrote a white paper arguing pharmacists need to be competent in communication and education, which is further defined as the ability to:

1. Identify appropriate patient educational needs.
2. Recognize patient education barriers.
3. Use appropriate educational methods to educate patients regarding drug therapy.
4. Use language appropriate for the patient.
5. Assess patient's level of knowledge and skill acquisition (Burke et al., 2008).

These aspects of competence contribute to educating patients effectively about their drugs in a way they understand. Gerhart et al., showed the critical information a patient needs is "brand name, established name or proper name, product strength\route(s) of administration, and warnings (if any) or cautionary statements" (Gerhart et al., 2015). Therefore, pharmaceutical companies must display critical information in a manner patients understand to share the responsibility of educating patients. To assess the extent to which CVS was competent, I will evaluate the organization of critical information on each pill bottle label.

Figure 1: Clear Rx Medication System Label. Source: https://adlerdesign.com/.

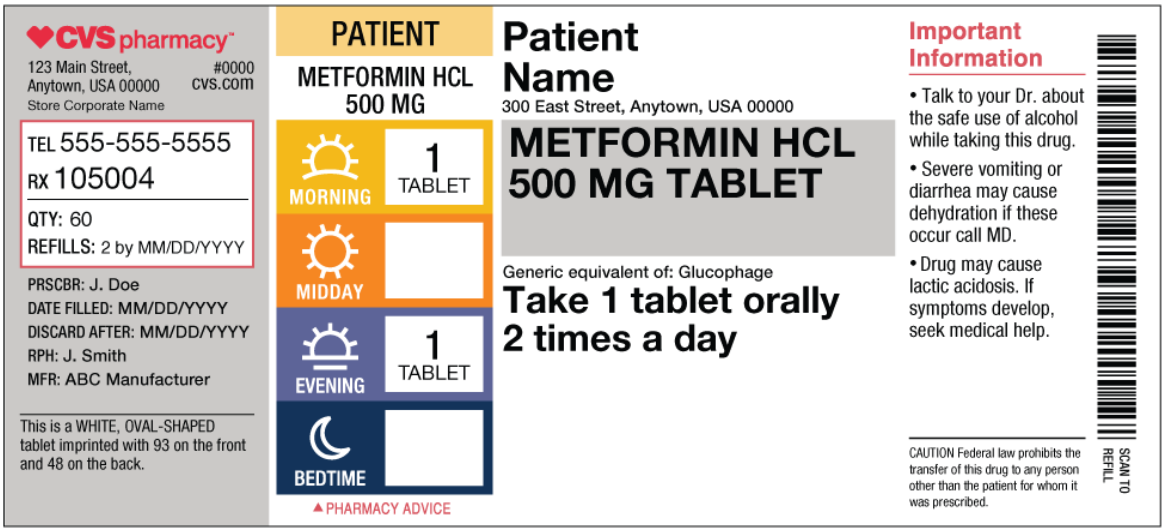

Figure 2: ScriptPath Prescription Scheduling Label. Source:

https://payorsolutions.cvshealth.com/insights/scriptpath-prescription-labels-help-make-adherence-easier.

To reiterate, the most important information to a patient is the drug name, the strength of the drug, and associated warnings. In Figure 1, one entire side of the label is dedicated to warnings, and the drug name and strength is located in the blue sections on the other side of the

label. Between 50-60% of the Clear Rx label is dedicated to critical information. In Figure 2, the warning section on the ScriptPath bottle is about 20% of the label, while the drug name and strength are in the adjacent gray box and take up about 8% of the label. ScriptPath has between 20-30% of the label dedicated to critical information. By giving a significant amount more of the label to critical information, the Clear Rx design recognizes the need to dedicate space to communicate essential information and make it easier for patients to focus visual attention on it.

Gerhart et al. said the pharmacy name and logo should not be above or get in the way of the most critical information (Gerhart et al., 2015). In both label designs, based on the perspective that the user is looking at the label, the patient may not be in the position to see the pharmacy name. When it is in view, Figure 1 shows that Clear Rx places the Target name and logo on the bottom of the label, as the eleventh item, reading from top to bottom. The drug name and strength are both listed as the second piece of information behind the patient's name. Figure 2 shows that ScriptPath places the CVS Logo at the top as the first piece of information on the label. The drug name is third and the strength is fourth, both behind the patient name and address. This design is in English so patients will be reading a majority of this label from left to right, top to bottom. By placing its logo at the top of the label and indirectly above the drug name, CVS is making it more likely that patients read its name and logo before everything else, prioritizing this piece of information. Purely by looking at the placement of this information, this violates the rule that the pharmacy name and logo should not compete with the most important information on the label.

Finally, both designs take advantage of colors and other Gestalt principles, visual perception processing rules that are universal and "do not have to be taught", to organize information (Yalcinkaya & Singh, 2019). One of these rules is the common region, the tendency

for elements that lie within the same bounded area, usually through the use of color, to be grouped (Wagemans et al., 2012). In the Clear Rx label, there are four colors used. Blue is associated with the drug name, strength, and RX number, red with the caution warnings, and black and white for the remainder of the text. The red for the logo is something the designer could not control and can be ignored in the analysis because both companies have a red name and logo. The introduction of color is very intentional here, the color blue is associated with only drug identifying information, and red is associated with only warnings. The ScriptPath label has eight different colors, yellow, orange, light blue and dark blue are used to indicate time of day. Yellow is also used for the patient name, gray is used for the drug name, strength, pharmacy, and refill information, red is used for warnings and advice text, and black and white for the remainder of the text. Color is used to create different regions on this label, but the type of information enclosed is not always related. Associating pharmacy, refill, contact information, drug name and strength together by placing this information in gray enclosures, CVS is placing all of these pieces at the same level of importance in the information hierarchy. Because the ScriptPath design did not use the Gestalt principles of closed region in a way that highlighted critical information but associated its brand name and logo at the same level of importance of critical information, CVS failed to educate and clearly distinguish critical information from the other pieces of information.

I argue that CVS did not make the drug name and strength the most salient pieces of information based upon the location and use of color. However, the drug name and strength were bolded, and the text size was increased, both of which are considered effective ways to make something more salient (Fabrikant et al., 2009). While these design principles were done well, they are not enough to keep the user's visual attention from the top left corner of the label.

Buscher et al. showed “the first fixation is typically placed on the most salient spot” but “memory and expectations also play important roles in subsequent fixations” (Buscher et al., 2009). The top left region is where most people out of habit look when viewing a web page. Since Kruikemeier et al. discovered that readers gain information in the same way through the web and printed material, it is reasonable to assume that when viewing the ScriptPath label, patients will fixate briefly on the drug name but by habit look in the top left corner and view the pharmacy brand and logo for a longer time (Kruikemeier et al., 2018). This means the design has divided the patient’s visual attention between critical and non-critical information. In the Clear Rx design, the drug name and strength is in the top-left region, which means the patient never has to split the visual attention from this critical information, thereby organizing information for a better overall design.

Through the analysis of the percent of the label dedicated to critical information, the order of information, and use of colors for associating information, Clear Rx medication system does a better job of utilizing different design principles to organize information in a way that communicates and educates the user about what information is most important and associated with each other. Because Clear Rx was designed in such a way that prioritized critical information, CVS violated the standard of competence in identifying patient needs and breaking down barriers to educating patients demonstrate CVS did not provide adequate care for its patients.

Conclusion

I have argued that after applying the care ethics framework, CVS’s decision to discontinue the Clear Rx and transition to ScriptPath was unethical because CVS through this

decision violated responsibility standards and arguably failed to demonstrate competence of care its patients need. It is not just enough to agree to provide care because “intending to provide care, even accepting responsibility for it, but then failing to provide good care, means that in the end the need for care is not met” (Tronto, 1994). It is not enough for pharmaceutical companies to agree to provide patients with the drug that the patients need for their well-being. Pharmaceutical companies need to consider the technology that carries the prescription medication, and the design of the prescription label because the label is one more way the company can provide care to the patient. While no one design is superior to all others when it comes to prescription medication systems, it is important to evaluate the use of various design principles and how they serve the greater goals of caring for the users of that technology to design responsibly in the future.

Word Count: 3,683

References

Burke, J. M., Miller, W. A., Spencer, A. P., Crank, C. W., Adkins, L., Bertch, K. E., Ragucci, D. P., Smith, W. E., & Valley, A. W. (2008). Clinical pharmacist competencies. *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*, *28*(6), 806–815. https://doi.org/10.1592/phco.28.6.806

Buscher, G., Cutrell, E., & Morris, M. R. (2009). *What do you see when you're surfing? Using eye tracking to predict salient regions of web pages*. https://www.microsoft.com/en-us/research/publication/what-do-you-see-when-youre-surfing-using-eye-tracking-to-predict-salient-regions-of-web-pages/

CVS Health and Target announce completed acquisition of Target's pharmacy and clinic businesses . (2015, December 16). CVS Health. https://cvshealth.com/newsroom/press-releases/cvs-health-and-target-announce-completed-acquisition-targets-pharmacy-and

Deborah adler design | about. (n.d.). Retrieved February 28, 2020, from https://adlerdesign.com/about/

Dessing, R. P., & Flameling, J. (2003). Ethics in pharmacy: A new definition of responsibility. *Pharmacy World and Science*, *25*(1), 3–10. https://doi.org/10.1023/A:1022493008431

Fabrikant, S. I., Hespanha, S. R., & Hegarty, M. (2009). Cognitively inspired and perceptually salient graphic displays for efficient spatial inference making. *Annals of the Association of American Geographers*, *100*(1), 13–29. https://doi.org/10.1080/00045600903362378

Gerhart, J. M., Spriggs, H., Hampton, T. W., Hoy, R. M. B., Strochlic, A. Y., Proulx, S., & Goetchius, D. B. (2015). Applying human factors to develop an improved package design for (Rx) medication drug labels in a pharmacy setting. *Journal of Safety Research*, *55*, 177–184. https://doi.org/10.1016/j.jsr.2015.08.005

Jeetu, G., & Girish, T. (2010). Prescription drug labeling medication errors: a big deal for pharmacists. *Journal of young pharmacists : JYP*, *2*(1), 107–111. https://doi.org/10.4103/0975-1483.62218

Kruikemeier, S., Lecheler, S., & Boyer, M. M. (2018). Learning from news on different media platforms: An eye-tracking experiment. *Political Communication*, *35*(1), 75–96. https://doi.org/10.1080/10584609.2017.1388310

Literacy, R. on H., Practice, B. on P. H. and P. H., Medicine, I. of, & The National Academies of Sciences, E. (2015). *Health literacy and medications*. National Academies Press (US). https://www.ncbi.nlm.nih.gov/books/NBK311242/

Noddings, N. (2013). *Caring: A relational approach to ethics and moral education* (Second Edition, Updated). Univ of California Press.

Poel, I.V., & Royakkers, L.M. (2016). Ethics, Technology, and Engineering: An Introduction.

Scriptpath: Prescription scheduling made easier . (2017, October 4). CVS Health. https://cvshealth.com/about/our-offerings/cvs-pharmacy/scriptpath-prescription-scheduling-made-easier

Tronto, J. C. (1994). *Moral boundaries: A political argument for an ethic of care*. Routledge.

Unhappy Target customers send strong message on pill bottles. (2016, September 27). AP NEWS. https://apnews.com/e4df7308887842359143aa111effec29

Wagemans, J., Elder, J. H., Kubovy, M., Palmer, S. E., Peterson, M. A., Singh, M., & von der Heydt, R. (2012). A century of gestalt psychology in visual perception i. Perceptual grouping and figure-ground organization. *Psychological Bulletin*, *138*(6), 1172–1217. https://doi.org/10.1037/a0029333

Webb, J., Davis, T. C., Bernadella, P., Clayman, M. L., Parker, R. M., Adler, D., & Wolf, M. S. (2008). Patient-centered approach for improving prescription drug warning labels. *Patient Education and Counseling*, *72*(3), 443–449. https://doi.org/10.1016/j.pec.2008.05.019

Wolpin, S. E., Nguyen., J. K., Parks., J. J., Lam, A. Y., Morisky., D. E., Fernando, L., Chu, A., & Berry., D. L. (2016). Redesigning pictographs for patients with low health literacy and establishing preliminary steps for delivery via smart phones. Pharmacy Practice, 14(2). https://doi.org/10.18549/PharmPract.2016.02.686

Yalcinkaya, M., & Singh, V. (2019). Exploring the use of Gestalt's principles in improving the visualization, user experience and comprehension of COBie data extension. *Engineering, Construction and Architectural Management*, *26*(6), 1024–1046. https://doi.org/10.1108/ECAM-10-2017-0226