Safety Measures for Prescription Labeling: 21st Century Best Practices

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Program Overview:

To provide participants with an understanding of safety measures for prescription labeling.

OBJECTIVES:

After completing this program, participants will be able to:

- Discuss patient literacy as a barrier to understanding prescription label instructions
- List items required on a prescription label by the FDA or state boards of pharmacy
- Identify aspects of existing medication labels that prevent clear understanding of directions or reasons for use
- Describe at least four changes to medication labels that can improve clarity and reduce errors; include a discussion of relatively recent initiatives

Case Presentation: Label Confusion

Review the label below. Identify six challenges to correct use of this label by a patient and identify six improvements that could increase clarity and safety. Make sure that at least two of these improvements can be implemented without changes in software programming or additional cost to the pharmacy.

YOUR PHARMACY	Store#0001	2/23/2012
123 Pharmacy St, USA	Rx#54321	(333)123-1234
Your Patient Name	(333)234-3456	7/7/1946
Naproxen (Naprosyn)	550 mg tablet	Qty: 28
Take one pill two times daily.		2/22/2013
Prescriber Name	(333)345-5678	Refills: 0

Overview[1-10]

An estimated 1.5 million drug errors are made in the United States each year[1] and according to US Pharmacopeia (USP), nearly one third of these are a result of prescription label confusion.[2,3] Medication errors are most prevalent in outpatient settings in which patients provide self-care with at least one of the 13,000 prescription drugs approved by the US Food and Drug Administration (FDA).[4,5]

Adequate comprehension of label directions is essential for ultimate safety and quality care. However, consumers are bombarded with drug information from multiple sources, including the internet, patient labels and leaflets, TV ads, warning labels, and family or friends.[1,5-7] Complicating this information overload is the number of medications prescribed to an individual: nearly one third of all people who use prescription medications take at least five different drugs.[8] The rate and number of prescription drug errors will only continue to increase as the number of prescribed medications increases, unless patient understanding of labels and instructions improves.[9] Health literacy efforts started in 2002 and 2006 by the American College of Physicians (ACP) Foundation and the Institute of Medicine (IOM) respectively, in which they aim to reduce errors and improve safety; concurrent efforts are underway to improve the format of prescription label containers and increase readability.[7]

Every prescription provided to a patient requires a label, and many prescriptions also have accompanying consumer medical information (CMI) leaflets for additional safety details. Often, this label and package leaflet are the best and only source of information for the patient—the only tangible descriptor of what medication they are taking, how to take it, and what to consider for safest use.[10] Pharmacy labels are crucial and undervalued as tools for patient safety; thus, they deserve and require improved, optimal designs.

Design confusion[1,4,5,10]

Current pharmacy labels have many layers of confusion for patients: they are cluttered, variably formatted among and even within pharmacies, have non-standardized and vague language from providers, and are often on too high of a grade level readability to be understandable for many adults in the United States. The accompanying warnings can be too ambiguous or too numerous even for people at higher reading levels, so the information is frequently ignored.[5]

Labels now are poorly designed, with a focus on the business of pharmacy, not on the patient. Drug information is rarely grouped together; instead, accessory facts and provider details are interspersed, highlighted, and featured as distractions from the most important details to the patient.[4,10] The result is a label that cannot provide concise safety instructions or risks information in a consistent manner. Although patients need cohesive and relevant drug information, they more often receive too much, too complex, and too variable information to be useful.[1]

Risk groups[3,5,8-11]

Although label safety is a relevant concern for the patient community at large, numerous risk populations exist. In fact, the IOM estimates that 90 million adults in the United States—half of the adults in the country—have difficulties with the health information provided.[3,9] Health literacy, or the ability to understand and use directions for improving health or self-treating a disease, is poor enough to cause patients to misread dosages or warning safety instructions approximately half of the time.[8] In addition to expected populations with low health literacy—namely poor, recent immigrants and non-native speakers of English as a second language (ESL)—the elderly and patients with multiple medications and disease states have the greatest problems with comprehension.[3,11] For example, patients who have five or more medicines misuse medications more often than those who have three to four medications; likewise, patients who have three to four medications misuse them more often than patients who have only one or two medications. This proportional effect possibly results from the high number of instructions, overlapping instructions, or the challenges of great number of chronic health problems.[9] Poorer patients face additional challenges because of their low literacy levels as well as their reduced access to quality information.[5]

Poor provider efforts[1,2,4-9]

Health care providers shoulder the burden of care to all patients, not only the ones who have adequate access to their drug information.[2,5,7] Labels are provided with medications under the assumption of prior instruction by physicians first and counseling by pharmacists next; labels are simply the written reminder of the patient-provider interactions.[1] However, this communication is strikingly uneven. Although patients desire communication with their health professionals, only approximately 30% report actually receiving it,[3] and providers even less

frequently check for thorough patient comprehension.[9] These knowledge and care gaps are large and only increase the medication use errors. Health care providers frequently miss opportunities to counsel and empower patients, so quality written information on labels is even more vital for safe medicine use. Improving label readability is the place for an action plan to improve care, increase safety and communication, and protect patients.[4]

Regulatory involvement[1,4,5,8,12]

Label improvement, like other health care initiatives, is not simple or straightforward. It involves changes at the patient, prescriber, pharmacist, business, and technology levels. Open communication between patients and their providers can proactively increase patient education. Implementing electronic prescribing practices benefits providers and patients alike by reducing errors, increasing clarity, and promoting two-way communication among physicians and pharmacists.[4,8] However, few efforts have been successfully made to standardize medication labels through regulatory bodies at state and federal levels. Central oversight has the potential to organize medical information for the patient and highlight the most important safety details.[1,4,5] However, the FDA remains primarily a recommending and monitoring body for label formats, and no good evidence-based studies yet support regulation as the effective means for label improvement and consistency.[5,12] Federal initiatives have increased the quality of some medication information.[4] Professionals acknowledge a need for label improvement on prescription drugs as well, but they emphasize the importance of balancing improvements with the limiting effects of regulated behavior change.

Specific Label Challenges[1-6,10-15]

Two basic challenges in label safety are simply defining what constitutes a label and what its purpose is. The important data that comprise an average 2-square-inch prescription label are surprisingly inconsistent in content and design despite the singular purpose of providing a reference of safety and instruction for correct self-use of a federally controlled substance.[5,6,10,13]

Labels have vague and often overlapping requirements for basic patient content, and accessory information to support business practices frequently complicates the label presentation and end use. The FDA, The National Association of Boards of Pharmacy (NABP), and individual state boards all outline differing minimum required items on each label; regulatory enforcement of these mandates is sporadic if available at all.[5] Placement of the recommended or required items included on a label is historically unmonitored as well.

For example, the FDA outlines the following content for minimal label inclusion: drug name and strength, filled quantity, pharmacy name, provider name, prescription expiration, patient name, and drug directions. The pharmacy store number, location, and phone number; provider phone number; total pill quantity; and manufacturer name are optional content.[3,5] The format for these contents is developed by private software vendors, unlike the requirements for drug manufacturers in producing prescribing information for health care professionals, which is

regulated carefully by the FDA for content and format.[1] State boards identify additional distinct standards for label content, including the drug brand and generic names, the quantity filled and number of refills, the drug dose, and the expiration as well as the store name and phone number, prescriber, patient name, filled date, and warnings.[13,14] Because individual states boards control labeling, at least 31 types of labels are found among the 50 states.[5] These formats frequently feature superfluous business items on the label, such as pharmacy logos, and are not streamlined for ease of patient use or for distinction of important health information.[5,13,15]

Physical clutter[3,4,10,12]

The physical placement of items on a label and the sheer number of details on this small space are enough to impair understanding for most patients. Prescription labels today are organized for ease of pharmacy use rather than patient use; instead of emphasizing drug names and directions with highlighted or bolded text, most labels feature colored boxes or special fonts for the prescription logo, store number, or fill date for pharmacist verification during a fill. These secondary details are not grouped together but are interspersed among the drug information.[3,10] In fact, the prescription name and store number are nearly always (84% of the time) placed first on a label and were identified as the most prominent items on nearly all prescription labels in an evaluation of six pharmacy chain label practices in 2007.[3] In addition, the large amount of print on a label typically encourages vertical placement of auxiliary warning materials, which can overlap portions of the label itself on small containers. This cluttered, multidirectional approach particularly overwhelms patients and fails to emphasize the importance of safety warnings and medicine directions. The need to move the container to read the instructions and safety data likewise disregards the significance of the label as a straightforward educational tool.[3,4]

Prescription variability[1-6,10,16]

Variation among labels has a drastic effect on patient safety. The different ways of presenting drug brand, generic names, and dosage strengths for the same drug range from abbreviation choices to alternate spellings of drug names; these changes also increase confusion for patients, who expect these details to remain consistent with each refill. The assorted label details and formats fail to fulfill these expectations of label regularity.[3-5]

Variations within the pharmacy regarding auxiliary label placement and changes among pharmacies regarding the color and selection of these warning stickers, especially when used for the same medications, poorly communicate safety issues to patients. Despite the positive association of establishing habits with overall self-care, auxiliary label selection and placement remain highly variable within pharmacies; any printed label can be added to a container, and the choice and placement are matters of professional discretion and choice. Although these warnings are very important for patient safety, their value is untapped in part from lack of attention to their details.[5,10]

Label variability among chains is high and is based more on business software than on patient comprehension.[6] Poor standardization starts with drug information entry, which varies by prescriber practices and technician drug selection[1,10]; it is reinforced by state board requirements that do not format the drug information; and it is supplemented by a lack of communication between the provider and pharmacist to provide consistent instructions to the patient at all levels of health professional interaction.[2,16]

Patient health literacy[1,3,5,7,9,17-22]

Perhaps the most challenging area of label comprehension—but one with the greatest potential for improvement—is poor patient literacy. Health care professionals are not only prescribers and dispensers, they are also educators who can address knowledge gaps on the individual level through professional counseling interactions with patients.

The IOM asserts that poor health literacy contributes to medication misuse in up to half of the US population.[3] An estimated 90 million people (between one third and one half of the US population) have limited health literacy—a constrained ability to obtain, understand, and use medical information for decision making purposes.[5] The elderly are at greatest risk, with 60% displaying limited health literacy,[5] and people with low education levels and multiple chronic diseases also are at a higher risk.[3] People with poor health literacy often have problems that compound their already impaired self-care ability: low-literate patients most often ignore labels, especially warning labels, and they have reduced access to information from print and electronic sources to supplement of health care professional advice.[1,5,9]

Health literacy on average is lower than general literacy in the United States,[5] so comprehension of health instructions may be underestimated by traditional readability tests. Multiple 21st century tools help identify and define insufficient levels of health literacy. Language comprehension is assessed by survey in people age 16 years or older on the National Assessment of Adult Literacy (NAAL); the Rapid Estimate of Adult Literacy in Medicine (REALM) is the most common method of rating medical literacy, using grade level distinctions that correlate to well-known general literacy standards and tools.[9,17-20]

In 2003, an evaluation of health literacy was included in the NAAL for the first time. This survey identified the ability of participants to use different types of written information, such as prose, business documents, or reports. Health literacy skills were ranked as below basic, basic, intermediate, or proficient. Participants included a cross-section of the population also seen in pharmacies across the United States—the elderly, the uninsured, people with disabilities, and people without high school level education, in addition to educated professionals and young adults. Thirty-six percent of NAAL survey participants had basic or below-basic health literacy skills and could not reliably understand instructions for routine medication use. Approximately half of participants exhibited intermediate literacy skills and a better ability to follow most

written directions, but only the 12% who were ranked as proficient were able to perform calculations about their dosages or similar complex demonstrations of literacy.[5,19,20]

Literacy evaluations with REALM testing are often conducted by health literacy experts, who score participants into one of three reading levels: 6th grade and lower (i.e., low), 7th to 8th grade (i.e., marginal), or 9th grade and above (i.e., adequate). Prospective health literacy studies between 2006 and 2009 that used REALM testing identified severe limitations to medication understanding. Understanding of instructions is directly proportional to literacy level, such that the ability to follow directions increases measurably with each increase in reading grade level.[9] People who have low or marginal literacy misinterpret medicine directions the most. However, even patients with adequate ability struggle; in a 2006 study, approximately one third of participants who tested at or above 9th grade comprehension misunderstood a prescription direction.[9,17,18]

Health care professionals are frequently unaware of the challenges faced by these patients, and even people with adequate literacy can be confused without the aid of a health care provider. In a study of teach-back demonstrations to evaluate patient understanding of vague, implied, or specific label directions, the interpretation by patients revealed minimal accuracy. Nearly one fourth of patients interpreted tablespoon quantities as teaspoons; one third of all patients could not total the daily milligram dose of a prescription. One half of all patients—and one third of adequate literacy patients—could not explain their instructions back to the provider; 20% of patients with adequate literacy were unable to identify the number of doses they needed to take of a medication each day.[9,10,17]

Errors are most common, regardless of literacy, when patients must evaluate numerical information. The most poorly understood prescription concepts include dosing, especially the number of times to take a medicine each day, or the number of total pills taken each day. Errors increase with greater numbers of doses and more numerous medications.[9,17] Almost equally misunderstood are the times of day to take a medicine, also known as the dosing schedule. Even simple schedules are complicated for highly literate users when the schedules overlap or when the directions are ambiguous.[9,17,21] Implicit instructions fail to direct patients to a specific time period or fail to describe details, such as whether to wake at night for a dose or to use medicine only during daytime hours, for example.[21]

The ambiguity of implied directions is prevalent in part as a result of outdated prescription writing styles and complacent pharmacy interpretation; both practices reduce communication and consistency between professionals and impair readability for the end user.[18,22] Traditional Latin writing and abbreviations, which encourage vague instruction, still abound in handwritten prescriptions. In addition, the label wording as translated in the pharmacy is often converted to a reading level above that of most patients: one third of prescription labels are at a high school grade level or higher.[7]

Typography complications[3,4]

Label legibility itself is impacted by the use of abbreviated or chemical names, highlighting and color choice, and font selection and sizing. Labels that use abbreviations, a variety of colors, and multi-directional text foster poor interpretation.[3,4] Font styles and sizes complicate visual ease of reading even more. Font sizes, in fact, are the most variable factor of prescription labels between pharmacies. The most common size used for drug names and instructions is 9 point, which is considered substantially too small to be easily read, especially by the elderly. This font size is often smaller than the size used for non-required details, such as the pharmacy logo. Important warnings are frequently even smaller, at only 6 point, and are on low-contrast colored backgrounds.[3]

Best Practices for Label Improvement

Overall, the challenges to appropriate self-care through label interpretation can appear insurmountable.

Label improvement options are as broad as the problems faced by current standards. Simple changes in container sizes, auxiliary labeling, text legibility, typographic considerations, and readability of directions, especially when implemented together, can cause significant changes in professional behavior and patient safety.

Addressing clutter[3-7,10,15,23]

Reducing clutter by streamlining the required, accessory, and business information helps emphasize the most important patient details in a reader-friendly manner.[15] To increase readability, labels should use logic, white space, and easy wording at a minimum, suggests the Institute for Safe Medication Practices (ISMP) and USP.[3,6,15]

Important primary information needs to be clear and simple: the patient name, drug brand and generic names, drug strength, and directions are most essential. The expiration for each medicine is described most clearly as a "use by" date.[15] Drug descriptions and indications, of related importance, should be included near the drug information when space allows.

Secondary details, at times required by state law, often relate to the business of dispensing and include the doctor name, the pharmacy name and phone number, the prescription number, the refill amounts, and the quantity dispensed. These data are best separated from drug information by white space or physical location: for traditional round containers, a large vial that provides nearly flat readability and room for warnings labels divides business and drug details and minimizes the need to move a label to read all of it.[3,5,7,10,15]

Extra details to consider removing and replacing with white space include drug manufacturer names and superfluous patient details (e.g., address). A drug description and an indication are

value-added safety tools; however, their addition potentially crowds out essential instructions and warnings, so they are not always warranted.[7,15,23] Dates other than the fill and use by dates likewise should be removed to reduce patient confusion.

Physical presentation[3,6,7,10]

High contrasts between directions and business information, through use of font sizes, highlighting, and white space separators, are encouraged by the USP as effective for improving clarity. White space overall, and larger spaces between direction lines in particular, improves readability especially for the elderly, according to the ISMP.[7]

Logically grouped information helps pharmacists and patients alike, and no single method is absolutely best. One successful format identified by the ISMP suggests grouping provider and pharmacy information at the bottom of a label, with dosing at a distance away from it for maximal safety. Similarly, USP evaluations identified recommendations to feature items of greatest patient need first: moving the drug name, dose, and instructions to the top of the label (instead of the typical pharmacy information there), with extra details set lower and smaller than this medical information, is best.[7,10]

Auxiliary warnings add a second but necessary level of potential clutter to a label. Using a larger container allows pharmacists to place labels horizontally, but this only addresses one aspect of warning label confusion.[3,7] Physical placement matters, and consistent location placement—by establishing standard habits in the pharmacy—likewise establishes a routine expectation by the patient, which can reduce the likelihood of ignoring the information.[7] Pharmacist efforts to select only the most relevant auxiliary warning labels require clinical judgment, because no program or computer system can completely evaluate the best warnings for a given patient.[3] Warning labels will continue to use multiple colors and small print until software changes occur,[3,6] but using well-placed warnings consistently—with the same warning for the drug on every refill—encourages patient understanding and increases perceived pharmacy reliability.[7] In addition, minimizing warning label numbers to only the most important, evidence-based medicine selections provides a greater emphasis to the patient, and the essential information is less distracting and less likely to be ignored.[3,10]

Best typographic options[3,5,7,10,15,24,25]

Typographic details factor in the label effectiveness at least as much as physical placement of labels and instructions. Consensus by the NABP, the USP, and the ISMP, supplemented by the ACP Foundation and private researchers, agree that simple, high contrast (i.e., white background), spacious fonts are essential; likewise, non-italicized sans serif choices (e.g., fonts such as Arial, which do not use curled script endings) provide the most visual ease.[3,5,7,10,15] Though highlight or bold features can improve reading when used judiciously on patient-centered text, neither are necessary for readability.[7,15] Font size and placement are crucial for legibility, however. Both the USP and the NABP recommend 12-point font as the minimum for

directions to all patients, especially to elderly patients[3,5,10]; an ISMP task force reported that 12-point minimum font reduces errors more effectively than standard, 9-point font on labels.[7]

Lettering styles matter for safety as well. All capitalized writing, rather than emphasizing importance, reduces readability, because it is less familiar to eyesight.[5,10] Instead, sentence case is preferred, especially for directions.[5,7,10,15] Other traditional letter styles to feature include dropped hanging letters (eg, "g" tail below the line) in the directions and tallman writing for drug names.[7,24] The practice of using tallman lettering within a pharmacy has reduced medication errors related to incorrect drug selection at entry, in particular for confusing, sound-alike and look-alike name pairs. For example, hydroxyzine and hydralazine are distinguished in systems with tallman lettering as hydrOXYzine and hydrALAzine, respectively, to emphasize the risk of mistaken selection. These style efforts can extend to the practice of writing a prescription and to use of this format on patient labels to consistently counteract errors at each step.[7,24,25]

Label safety improvements in practice[26-29]

In the face of reports from such large institutions as USP and ISMP, pharmacy chains and business software vendors are beginning to implement recommended improvements. With the efforts of a graphic design student, the Target ClearRx label was the first to improve the label style, and thus readability, in May 2005. This new format—a drastic change from previous standards—incorporates numerous safety changes and embodies many best practices of design, with safe medication use by elderly as a primary goal. The ClearRx label uses horizontal writing, highlights the drug name rather than pharmacy name, surrounds instructions with white space, provides business information separately in a smaller font, and includes an attachable information leaflet with a drug description and relevant warnings.[26,27] To implement this massive label improvement required new, customized, flat-sided medication containers that accommodated the front and back label halves. This label shape features an extra safety measure of the drug name across the top of each bottle as well.[28]

Few changes across the market have been made since ClearRx was introduced. In 2007, Caremark and CVS implemented a similar but smaller effort at label reform, called EasyRead. While keeping the traditional container and label shapes, EasyRead labels made strategic readability changes to improve understanding particularly for elderly patients. Increased font sizes, contrasting black font on light blue backgrounds, pill descriptions, and collection of refill information onto one section of the label have been received positively in patient surveys about the change.[29]

Small steps toward effective change[2,5-7,10,17,24,30,31]

The label improvements made by Target and CVS, and additional changes recommended by the ISMP, are effective but are also costly and time consuming to initiate. Even without large-scale changes, clinicians can begin improving safety within available label structures. Enhancing

literacy efforts is the means of this outreach: critical language changes, removal of ambiguity, and improved patient counseling provide clear information. Although potentially large changes can be made through broad professional education efforts, smaller improvements in communication practices are free and timely to implement in nearly any setting.[10]

Medicine directions present the largest potential for immediately increasing precision and reducing label variation. Changes to patient instructions do not require readability tests or software changes—only common-sense decisions throughout the pharmacy department to optimize label use.[5,10]

Physicians, as the primary prescribers, have the first burden of change and warrant the support of allied health professionals who communicate with them. Avoidance of outdated Latin wording or Latin-derived abbreviations at the time of writing confers many benefits toward safety.[2,7,10] Latin is more likely to be misinterpreted by technicians at entry; in addition, translated Latin often results in too high a readability level, 10th grade on average, for patients.[2,10,24] Most important, Latin and its translated abbreviations embody ambiguity, particularly regarding the times of doses[31] —a critical problem area for many patients. By writing prescription directions with the USP standard of literacy instructions instead,[2,5,7,10,30] physicians provide explicit statements of what they want patients to do. For example, the implicit twice daily Latin translation of BID can become every 12 hours, the more direct wording. Feedback studies of explicit instructions identify adherence increases by as much as 90% when Latin is avoided and uniform scheduling is promoted.[5,31] Pharmacists should encourage and assist physicians in this directive role with open communication and positive feedback.

As the last health professional to communicate with the patient about medicine before self-care begins, pharmacists make the ultimate decisions to guide medicine use. First, pharmacists should translate prescriber directions into common and easy words and avoid abbreviations.[7,10] Here, the universal medication schedule is quite helpful at promoting easy wording to ensure consistent translation of "BID" to "2 times daily" for example.[5] A clear label with simple instructions can help patients visualize the medication use and can support successful counseling and patients teach-back.[6,17]

The best pharmacy practices for providing understandable instructions revolve around functional numeracy and dosage timing. At entry, pharmacy staff should use numbers instead of text, as supported by USP and ISMP research.[7,10] Whole numbers show patients the amount to take and avoid difficult terms such as "twice".[7] With numerical entry, though, decimals should be avoided for clarity.[7] Directions with actual times and the number of times to use a drug each day, as well as any meal directions, are most explanatory.[10] Specific directions tell patients whether a TID dosing schedule should be spread over 12 or 24 hours, for example, when stated clearly as "Take 1 tablet by mouth at breakfast, at lunch, and at dinner every

day."[10] However, directions should avoid giving patients an exact hour of day for a dose, because that high level of specificity appears to reduce adherence by increasing anxiety about taking the drug at the accurate time; take at bedtime, therefore, is preferred to take at 8 PM.[10] Starting with label changes on the container is the first step to improvement of medication use and reduction of errors by outpatients as they continue self-care.[5,10]

Regulatory Potentials Addressed[1,3-7,12,15,32]

The longstanding problem of label variability lacks federal regulatory oversight, and label problems results at least in part from the vague FDA standards and light state governance. Counseling by a learned intermediary occurs infrequently, and many professional organizations consider standard warnings and directions necessary for consumer safety.[1,5,7] Equitable care is more likely if a consistent format is provided across pharmacies, and federal regulation is likely the best option for implementing consistency, especially for warnings labels for drugs.[1] The push for standardization and federal regulation has grown in the past decade as the ISMP, NABP, IOM, and more organizations have worked to spread awareness of safety concerns about existing labels. In addition to the IOM task force on label standardization in 2008, the influential USP proposed enforcement concepts of newly developed label standards in 2012 that build upon safety concepts featured by the ACP Foundation.[6] Benefits of required standardization include widespread simultaneous change as well as business accountability for label consistency in formats, sizes, colors, and more. However, FDA attempts to increase accessible information are often rebuked by manufacturers, professionals, and even patients.[5]

ISMP, USP, and FDA consistently emphasize the benefits of a common drug nomenclature and clear patient drug information.[4] No evidence-based medicine yet supports regulation as the best way to achieve these goals, though, and voluntary efforts have not yet been successful on a large scale. The AMA, ASHP, and consumer groups support changes to prescriber habits to improve literacy and reduce errors; standardized pill cards, picture calendars, and literacy assessments are now being developed to empower patients and their safety. If literacy efforts are low-cost and improve the message, they should be enacted. However, this consensus for change is limited by the time needed to implement plans and educate providers.[5,6,12]

Concerns about regulatory impact come from all directions: businesses, pharmacists, physicians, pharmacies, manufacturers, and more. An IOM round table clearly articulated concerns, which focus on reduction of proprietary individuality and changes that place a burden of care and liability on the pharmaceutical industry instead of on the provider.[1,32] Although health professionals acknowledge current label deficits, they also voice concerns about the time required for system upgrades, the efforts added to their workloads, and the costs of implementing changes to prescribing and dispensing practices.[12]

Perhaps the largest argument against regulatory control is the poor history of the FDA efforts on CMI leaflets. These leaflets are required by CMS for nearly 2,000 high-risk drugs as

identified by the FDA. Most pharmacies provide a CMI or similar leaflet with every prescription, and the development of leaflet content is controlled by private industry. Patient information has not been improved through competitive business practices. Rather, the information is considered diluted and verbose, so the leaflets are primarily ignored by consumers.[1,32]

FDA successes with Nutrition Facts and OTC Drug Facts support regulatory possibilities, though. These two well-received national initiatives involve label changes that comply with myriad state regulations. Both formats distill large amounts of complex knowledge into small bites of essential consumer information. Like prescriptions, the labels and warnings on these food and OTC drug products are the most vital information for patient safety and healthcare.[1,12]

Conclusion

Label improvements must be implemented on multiple levels for optimal safety features. Although a best-case scenario might eventually involve long-term regulatory efforts, this standardization will require educational efforts, new software and equipment, and more. These changes cannot be the only attempt; they should be supplemented by professional education and counseling efforts. Education about patient literacy in particular supports the goal of reducing errors, lowering barriers to safety now, and supporting future regulatory development. Examples of successful initiatives by prescribers and pharmacists can fuel broad, evidence-based education and literacy reform efforts. Small changes of concise and clear written instructions and teaching careful pharmacy staff interpretation of explicit directions are easy and free to undertake, despite the time constraints of health professions. These efforts can begin to change the standard of practice over time with potentially large impacts. Whether legally mandated or implemented privately, simple consistency and literacy endeavors comprise a pharmacist's professional duty to the patient.

Case Resolution: Label Improvements

Patient name and DOB	Naproxen (generic for Naprosyn)
Prescription number	550 mg tablet #28
Rx name, number, phone	1 Refill(s)
Doctor name and phone	Take 1 tablet every day at
Date filled: 03/03/12	breakfast and at dinner.
Use by: 03/03/13	Warning label white space

Problems Identified	*Problems Resolved*
Vertical warnings	Dedicated horizontal warning label space
Mix-match placement of drug and provider info	Physician/pharmacist information apart from drug
Small font unreadable and business focused	Increased drug detail fonts to at least 12 point
Cluttered label without spacing	Increased white space around lines of text
Expiration date not well identified for literacy	“Use by” text included for expiration date
More patient data on label than necessary for ID	Remove patient address from container label*
Ambiguous text directions do not describe timing	Explicit, timed text with numbers to replace words

*If allowed by state regulations for container labeling.

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