Drug Information and Patient Safety: Raising the Bar for Pharmacy

While close to nine out of 10 pharmacies are giving consumers written information about their medications, what's being handed out falls short of the FDA's standards for useful information. One problem is the legibility of the information being generated by pharmacy systems. The National Council on Patient Information and Education (NCPIE) is leading the private-sector initiative to bring the industry into compliance. In this interview, Ray Bullman, executive vice president of NCPIE, talks to *ComputerTalk* Publisher Bill Lockwood about the issues that must be addressed to avoid regulatory action.

NCPIE's Ray Bullman: "Improving the look of printed information with larger type, more white space, use of bullet points, etc., can go a long way toward making such information truly useful."

CT: A good starting point may be to provide the chronology of events, starting with the 1995 FDA proposed rule to promote the proper use of prescription drugs, that got us to where we are today.

Bullman: On August 24, 1995 — prior to the passage of Public Law 104-180 on August 6, 1996 — FDA published a proposed rule that would require manufacturers to prepare and distribute, or provide the means of distributing, a medication guide, or "Med Guide," to accompany outpatient prescription drugs. At the same time, FDA proposed two alternative approaches for implementation of the medication guide program.

Under the first approach, implementation of the program would be deferred if the private sector voluntarily met predetermined standards for quality and distribution of useful patient information within specified time frames. And under the second approach, FDA would finalize the Med Guide program only for products posing a serious and significant public health concern.

FDA also set forth its goal for the medication guide program: namely, that by the year 2000, at least 75% of people receiving new prescriptions should be given useful written medicine information. In addition, the FDA proposed that, by 2006, the distribution goal should be increased to 95% of people who receive new prescriptions.

On August 6, 1996, Congress enacted PL 104-180. Section 601 of that law adopted the distribution and information quality goals of FDA's proposed rule: the distribution of useful written information to 75% of individuals receiving new prescriptions by 2000 and to 95% by the year 2006. The law also required that HHS, within 30 days of its enactment, request that a broad cross-section of national stakeholder organizations collaborate to develop an action plan to: 1) assess the effectiveness of private-sector approaches used to provide prescription information to consumers; 2) develop guidelines for providing effective prescription information consistent with the findings of such assessment; 3) provide for the transmission of useful information to the public; 4) develop a mecha-

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nism to assess periodically the quality of prescription information and the frequency with which such information is provided to consumers; and 5) provide for compliance with relevant state regulations.

NCPIE, along with nearly three dozen other organizations, participated in the development of the "Action Plan for the Provision of Useful Prescription Medicine Information." The action plan was submitted to the secretary of HHS, who accepted the private-sector plan in January 1997. FDA was precluded from implementing its original proposed rule, or any other regulation or guideline developing a medication guide program, if private-sector organizations met the requirements of the long-range action plan within the time frame provided in PL 104-180. The law also required HHS to review the status of private-sector initiatives designed to achieve the goals of the action plan by January 1, 2001. If the goals were not achieved by that date, the secretary was required to seek public comment on other initiatives that might be carried out to meet such goals.

On December 1, 1998, FDA published a final medication guide rule. The rule provides authority for FDA to require "Med Guides" for five to 10 drug products per year. Med Guides are reserved for drug products with serious and significant side effects, as determined by FDA. Currently, there are 19 medication guides, 13 for drugs and six for biologics.

Pursuant to PL 104-180, in 2001, FDA assessed private-sector progress in meeting the interim year-2000 goals of the action plan. FDA's talk paper, "Success of Private-Sector Patient Information with Prescription Medicines Assessed," is available at www.fda.gov/bbs/topics/answers/2002/ans01153.html.

On July 31 of this year, FDA held a public meeting on written prescription information for patients. It was at that meeting that FDA sought input in the following areas:

What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs, and to meet the year-2006 goal?

What barriers exist for the private sector to meet the year-2006 goal, and what plans exist to overcome these barriers?

What should the role of FDA be in assuring full implementation of the action plan to meet the year-2006 goal?

What other initiatives should FDA consider for providing patients with useful written information about prescription drugs, as endorsed by PL 104-180? Such initiatives could include the possibility of FDA requiring manufacturers to provide authorized dispensers with the means to distribute useful written information approved by FDA.

On July 31, NCPIE outlined a collaborative plan to meet the year-2006 action plan goals. The details are available at http://www.talkaboutrx.org/cmi.html.

CT: Can you give us a few details of the Keystone Action Plan?

Bullman: Bill, the Keystone Action Plan for the provision of useful prescription medicine information proposes guidelines addressing the content and format of useful written prescription medicine information. Per the action plan, useful information should be sufficiently comprehensive and communicated in such a way that consumers can make informed choices about how to receive the most benefit from medicines and protect themselves from harm. Both substance and presentation of the information are important. The criteria for useful prescription medicine information are that it must be scientifically accurate, unbiased in content and tone, sufficiently specific and comprehensive, understandable and presented in a legible format, and timely and current, as well as enable the patient to use the medicine properly and appropriately in order to receive the maximum benefit and avoid harm.

As for the format and language guidelines, the action plan states that the design should ensure that the information is readable and legible. Important information should be prominent and conspicuous. It should be written at the sixth-to-eight-grade reading levels and be produced at higher levels. Complex terms should be avoided. Pictograms to accompany the text are encouraged and minimum font size should be 10-point type. Use of upper and lower case lettering is preferable to use of all capital letters. Key points should be highlighted or boxed in, ornate typefaces and italics should be avoided, and the information should be available in English and Spanish.

The components of useful information should appear in the following order: name, both brand and generic; warnings; indications for use; contraindications; precautions; possible adverse reactions; risks in terms of tolerance to and dependence on; proper use, including what to do in case of missed doses; special instructions; storage instructions; general information; and a disclaimer summary to advise contacting the person's healthcare provider for more information.

As for the suggested headings for useful written information, these include personalized information that is boxed in; established name and brand name; 'This medicine is used for…'; 'Do not take this medicine if…'; 'How to take this medi-

cine…'; 'Side effects include…'; and general information.

CT: Then there was the University of Wisconsin survey. Tell us about the results of this survey.

Bullman: Bill, in June 2000, FDA renewed its contract with the National Association of Boards of Pharmacy and the University of Wisconsin School of Pharmacy to conduct its assessment of private-sector activities. FDA released the findings of its assessment on June 18, 2002. This can be found at http://www.fda.gov/cder/reports/prescriptioninfo/default.htm. This is the final report submitted by Dr. Bonnie Svarstad at the University of Wisconsin School of Pharmacy in Madison. The report found that the distribution goal was met — 89% of patients received written drug information, surpassing the 75% target for 2000 — but that the quality goals were not met. None of the patient information printouts satisfied all of the action plan criteria for usefulness. According to FDA, the average usefulness of the information contained in printouts assessed was 50%. In particular, the leaflets were deemed deficient in the communication of risk and safety information. In addition, consumer reviewers found the information difficult to read.

The assessment was conducted using hidden shoppers who visited 384 pharmacies randomly selected and in virtually every state. Each shopper purchased four prescription drugs — atenolol, atorvastatin, glyburide, and nitroglycerin — and collected all the printed drug information given with the drug products. More than 1,300 printouts were collected and evaluated by an expert panel and a consumer panel. End points were penetration or distribution and usefulness of each material per the eight specific Keystone criteria. Bill, there were two key findings of the assessment. First, since the distribution score was 89%, it is clear that most community pharmacies now provide a computer-generated patient information leaflet with every new prescription. However, leaflet length varies considerably. Approximately 38% of the leaflets were relatively short or abbreviated — less than 5.6 inches in length — and 62% were standard length — 5.6 inches long or longer.

Second, the findings show that the leaflet quality varies widely. Relatively high marks were given by the expert panelists for accuracy, unbiased information, and up-to-date information. In contrast, expert ratings generally fell below the acceptable threshold on five of eight of the remaining criteria. Ratings were especially low on criteria dealing with the risks of drug treatment and on general information. Consumer reviewers also noted variability on leaflet quality and were especially critical of print size, print quality, line spacing, and overall ease of reading.

CT: What's interesting is that not every pharmacy hands out drug information with new prescriptions. But aside from this, based on what you just described, there's still work to be done to bring drug leaflets into compliance with Keystone and PL 104-180. Let's just focus on the design and formatting aspect for the purposes of this discussion. What needs to be done here?

Bullman: Based on the sample printouts that the FDA displayed at its recent public meeting on July 31, there is considerable work to be done toward meeting the design criteria contained in the Keystone Action Plan. Essentially none of the evaluated leaflets met key design criteria in the action plan. These include 10-point type and avoidance of certain fonts; line length less than or equal to 40 letters; bolding, boxing, or summary to highlight important points; provision of adequate space between lines, margins, and paragraphs; use of good ink-and-paper contrast; upper and lower case letters; true headings; and bullet points.

Simply put, organizations involved in the development and distribution of printed drug information, particularly the drug information developers, the pharmacy system integrators, and both chain and independent pharmacies, need to start right now collaborating on the design, testing, and refinement of leaflets that are more consumer friendly. Improving the look of printed information with larger type, more white space, use of bullet points, etc., can go a long way toward making such information truly useful.

If this process does not start now, we are unlikely to meet the 2006 target. In that case, the federal government will have little recourse but to seek a regulatory solution — requiring pharmaceutical-manufacturer-prepared and FDA-approved medication guides for all drug products.

CT: Seems like, from what you are telling us, that the Keystone criteria will increase the length of leaflets and pose a problem with single-pass labels, where space is fairly restricted for this information. Is pharmacy looking at more expense to be in compliance?

Bullman: Producing more useful printed drug information that meets the design and content criteria of the action plan is likely to be more expensive for pharmacy than maintaining the status quo. At the same time, it is clear that the status quo is not acceptable to consumers, to

Congress, and to the FDA. Consumers today expect to receive, and to be able to use, high-quality information about their prescription medicines.

It is inconceivable that consumer information about prescription medicines cannot be conveyed in a more accessible and useful format. Consumers get both food product and over-the-counter medicine information in easy-to-use label formats. It is counterintuitive to deliver prescription medicine information that is not easy to use.

From what pharmacy groups have told NCPIE and FDA, there are significant limitations with the single-pass system vis-à-vis generation of printouts. Quite simply, a multipage medicine printout cannot be generated with a single-pass system. Should we give up? Creative, committed stakeholders can come up with solutions to the technical problems and can deliver more comprehensive, useful information. A question to pharmacies is, in this era of pharmaceutical care: Do your patients and customers deserve any less?

Based on recent printouts that my family members have received with several prescription products, there would seem to be enough space available on the current printout to make considerable layout and design improvements. As much as a third of the available space is not even used, and much of the useable space is consumed with store advertising. This space should be prioritized for consumer medicine information.

CT: Where system integrators are using the same source for the leaflets in their systems, there is variation in type size used, elimination of categories within the leaflets that are printed for the same drug, and even lack of standardized inclusion of disclaimer information and the source of the information. It looks like what's happening is that leaflets are being sized to fit a given space — whether it is a single sheet of paper or the space allocated on a single-pass label — based on the longest leaflet. We're talking about a major overhaul in the way things are done now, aren't we?

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Bullman: Bill, it's difficult to gauge just how much overhaul is really needed right now. As a starting point, I would suggest that senior management of the system integrator companies take five key steps. These would be:

1) Commit to meeting the action plan goals for the provision of useful prescription medicine information. This means, as a first step, ensuring that everyone in the company knows about the Keystone Action Plan, its target goals for 2006, the leaflet design characteristics specified in the action plan, and the potential regulatory implications of failing to meet the action plan goals.

2) Conduct an internal action plan quality assessment to determine if the patient information being generated by your systems is compliant with the Keystone criteria for useful information. How does it stack up vis-à-vis the recommended action plan content criteria? How does it stack up vis-à-vis the layout and design criteria in the action plan?

3) Educate your customers about the action plan. Tell them your company is committed to meeting the action plan goals and to working with them to produce Keystone-compliant medicine information. That means committing to some experimentation, problem solving, and trial-and-error testing and revision, including assessing consumers' reactions to revised and reformatted medicine information.

4) Start now. The FDA's final assessment of consumer medicine information will be conducted in 2007. That gives the private sector 36 months to design, test, validate, and incorporate action-plan-compliant consumer medicine information into the retail pharmacy marketplace.

5) Share your insights and successes. Join NCPIE's consumer medicine information (CMI) initiative. This puts you in contact with a broad base of organizations committed to meeting the Keystone Action Plan goals. Members of the CMI initiative include national pharmacy and pharmacist organizations, drug information database companies, consumer organizations, and pharmaceutical manufacturers. Senior FDA personnel are available to consult and advise as the CMI initiative moves forward.

To participate in the NCPIE CMI initiative, they can contact me or Lee Rucker, who is senior vice president of policy and public affairs.

CT: In a perfect world where every pharmacy is using laser printers to print drug leaflets, and applying the Keystone criteria, legibility and readability should no longer be an issue. But we don't have this perfect world quite yet. Dot-matrix

printers are still being used. How is this being addressed?

Bullman: Relying on dot-matrix printers does not prohibit us from increasing the font size to at least 10 points, using bulleted and bolded formats, and prioritizing allocation of available leaflet space to conveying consumer medicine information.

CT: Consumer health web sites that let people print out drug information look like they are closer to the Keystone design criteria than what is coming out of pharmacy computers. The fact that these sites are getting the information as XML files is probably one reason. What's your assessment of the web site output you've looked at? Is it a role model for where we want to go in community pharmacy?

Bullman: The Internet is an ideal medium for conveying action-plan-compliant CMI. It's essentially a color-rich canvas on which text and graphics can be readily incorporated to produce easy-to-read information. That said, the same shortcomings related to content deficiencies pointed out by FDA in its year-2000 assessment of printed prescription medicine information could apply to web-based medicine information. Several nonprofit organizations and private companies that produce consumer medicine information on the Internet are also involved in NCPIE's CMI initiative. This mix of information producers focusing on overcoming the same challenges to meet the action plan goals will be very helpful.

Dr. Svarstad has pointed out that XML-formatted information was perceived much more favorably by consumer panelists than similar product information collected at retail pharmacies. This is very telling and a helpful insight into how consumers perceive 'useful.' Clearly, micro type, which is scrunched to the top half of a page, with little open spacing and no graphical treatment, isn't perceived as useful. In many respects, the adage about first impressions applies to printed medicine information. If it's not inviting to the eye, it's not likely to be read.

CT: At the public hearing the FDA held at the end of July, there were a number of private-sector steps being taken to address risk and safety issues. What was your takeaway from that meeting?

Bullman: FDA's public meeting was an important milestone. It reiterated how seriously the agency takes ensuring that consumers receive useful information about their medicines. While recognizing the progress that private-sector, voluntary efforts have made in the delivery of useful medicine information, the FDA pointed out that its assessment indicates there is, as of its year-2000 assessment, a significant shortfall in communicating essential safety and risk information to consumers in a format that can be easily read with understanding. The meeting also provided a platform for critics of private-sector solutions to again demand that the FDA require pharmaceutical manufacturers to produce — and distribute — medication guides for all drug products on the market.

Based on some of the comments at the July public meeting and afterward, I wouldn't be surprised if the FDA broadens the denominator for its 2006 assessment by including mail-order prescription medicine information. I am not as sure as to whether it would or could include freestanding medicine information on the Internet as part of its 2006 final action plan assessment.

CT: This seems like a good opportunity to tell us where NCPIE fits into all of this, and the plan developed to help avoid regulatory action on the part of the FDA.

Bullman: NCPIE, as a multistakeholder coalition, and in fact with encouragement from FDA, has stepped forward to serve as a convener and catalyst to stimulate progress among the private sector to meet the action plan goals for 2006. NCPIE, at the invitation of then Secretary of Health Donna Shalala, served on the Keystone Action Plan Committee in 1996. Our members made up approximately half of the 34 action plan committee members, and our board of directors is committed to succeeding in this important area of medicine communication.

In early 2003, NCPIE organized its CMI initiative. Our first step was to bring together stakeholder groups to explore development of a multistakeholder program to ensure that the action plan goals for 2006 are met. At that meeting, which you attended, Bill, representing ASAP, along with representatives from over a dozen other organizations, we organized three committees: criteria, implementation, and education. Over the next several months, the committees met regularly to frame out their respective missions and plans. At FDA's July 31 public meeting, NCPIE framed its planned course of action to achieve the Keystone goals. Summaries of our presentations are available to your readers on our web site www.talkaboutrx .org.

CT: And, come 2006, then what?

Bullman: Actually, Bill, 2006 will be a busy implementation period. The FDA will conduct its final assessment in calendar-year 2007. In 2006, with full commitment and

participation by ASAP's members — the system integrators — plus retail pharmacy and the drug information producers, everyone will be refining and differentiating action-plan-compliant consumer information. NCPIE will be busy educating the public to convey and reinforce the importance of reading and heeding accompanying prescription medicine information — and, when in doubt, asking questions of their pharmacist and other healthcare providers. NCPIE, since our beginning in 1982, has embraced the role that high-quality written information can play as a support or adjunct to medication counseling by the healthcare professional. This hasn't changed. What will have changed is that the printed medicine information will have become more useful. CT

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