

**Statement to the Senate Special Committee on Aging from Richard J. Scholz, RPh., Esq.**

**Chairman Nelson, Ranking Minority Member Collins, Members of the Committee, and distinguished panelists:**

I am Richard J. Scholz, RPh., Esq., Managing Member of Jacobs Scholz & Associates, LLC, Amelia Island, Florida. It is a pleasure to be here today to discuss the opportunities and challenges of protecting seniors from medication mistakes and adverse drug events via a focus on communicating medication labeling more effectively to patients. The lens through which I view this complex issue is very personal: thirty-six years of experience as a community pharmacist, chain pharmacy executive, founder of a national pharmacy benefit management corporation, pharmaceutical industry advisory board member, litigation of wrongful death from adverse drug events, and chief legal officer of a multidisciplinary group medical practice. I currently serve on the Board of Directors of the Pharmaceutical Printed Literature Association (PPLA) as a delegate of G&K Vijuk International, Elmhurst, Illinois. Aside from my professional experiences, much of the context of my comments today arise from observing the medication management challenges of my eighty-three year old mother, along with many similarly situated Floridians and American senior citizens.

Protecting American citizens from adverse drug events via improved printed communication about prescription medicines to consumers is not a new policy discussion. The first FDA reviewed, pharmaceutical manufacturer printed and distributed, pharmacy dispensed consumer-oriented written information was required on isoproterenol inhalation products in

1968.<sup>1</sup> In 1979, when I was a community pharmacist practicing in a predominately senior citizen neighborhood of Cleveland, Ohio, the FDA proposed a rule that would have required manufacturers to produce and distribute (after FDA review) written information known as patient package inserts (PPI) for pharmacists to provide to patients.<sup>2</sup> In 1982, the FDA withdrew the proposed PPI regulation with the promise of a private-sector solution to improve communication about prescription medicines to consumers.<sup>3</sup> In 1996, Public Law 104-180 required adoption of an action plan to assess the effectiveness of current private-sector approaches used to provide oral and written prescription information to consumers. FDA committed to monitor the progress of this private-sector effort. Unfortunately, periodic FDA surveys showed that, although distribution of written prescription drug information increased, the usefulness of the information was highly variable. As a result, in 1995, FDA proposed a regulation entitled *Prescription Drug Product Labeling: Medication Guide Requirements*, designed to set specific distribution and quality goals and time frames for distributing written information. The regulation had the following goals:

- By the year 2000, 75 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions.
- By 2006, 95 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions.<sup>4</sup>

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<sup>1</sup> Action Plan For The Provision of Useful Prescription Medicine Information, HHS, December 1996, p. 9.

<sup>2</sup> Action Plan For The Provision of Useful Prescription Medicine Information, HHS, December 1996, p.9.

<sup>3</sup> Action Plan For The Provision of Useful Prescription Medicine Information, HHS, December 1996, p.9.

<sup>4</sup> Guidance Useful Written Consumer Medication Information (CMI), HHS, July 2006 Procedural, p.2.

Several independent studies evaluated the progress toward achieving the goals for distribution and quality of useful written information to consumers, and in each case the data demonstrated pharmacy printed CMI has fallen woefully short of meeting goals for useful written patient information. In a study published in 2003, University of Wisconsin School of Pharmacy researchers found that consumers received written information with greater than seventy-five percent of prescriptions, but the length and quality of the information varied greatly. “A majority of the leaflets did not include adequate information about contraindications, precautions and how to avoid them.”<sup>5</sup> Five years later, University of Florida, College of Pharmacy researchers found that the dispensation of written patient information had increased to over ninety percent of prescriptions at retail pharmacies, with some improvement in overall quality as compared to the 2003 study. The University of Florida study determined only sixty percent of the written patient medication leaflets dispensed to patients in the study adhered to the threshold for acceptable quality, and identified shortcomings in the provision of critical information about the management of medication, significant redundancy of information , poor formatting, and inadequate legibility and reading level. <sup>6</sup> Each study addressed the critical components of CMI, as defined by FDA, but did not address the quality, presentation, and format of CMI that will result in adequate patient comprehension and ultimately, appropriate actions to improve patient safety.

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<sup>5</sup> Svarstad, BL, Bultman, DC, Mount, JK, Tabak, ER. Evaluation of Written Prescription Information in Community Pharmacies: A Study in Eight States J Am Pharm Assoc. 2003;43:383-93.

<sup>6</sup> Kimberlin, CL, Winterstein, AG, Expert and Consumer Evaluation of Consumer Medication Information-2008; Final Report to the U.S. Department of Health and Human Services and the Food and Drug Administration, November 4, 2008

Consumer health and the cost of U.S. health care are hugely affected by adverse drug events and misuse of prescription medication:

- In 1995, FDA estimated that hospitalizations associated with outpatient adverse (drug) reactions cost \$4.4 billion per year;<sup>7</sup>
- In its 2006 report on medication errors, the Institute of Medicine estimates that 1.5 million errors occur annually in the United States. A large proportion of these occur in the outpatient setting, generating costs of more than \$3.5 billion. Poor labeling was identified as a critical source of those errors;<sup>8</sup>
- Poor adherence to medication regimens accounts for substantial worsening of disease, death, and increased health care costs in the United States;<sup>9 10 11 12 13</sup>
- Of all medication-related hospital admissions in the U.S., 33-69% are due to poor medication adherence, with a resultant cost of approximately \$100 billion a year;<sup>14 15</sup>

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<sup>7</sup> 71 FR 3922 at 3974; January 24, 2006

<sup>8</sup> *Health Affairs* 26, no.3 (2007):731-740; 10.1377/hlthaff.26.3.731

<sup>9</sup> McDonnell PJ, Jacobs MR, Hospital admissions resulting from preventable adverse drug reactions. *Ann Pharmacother* 2002; 36:1331-6.

<sup>10</sup> Schiff GD, Fung S, Speroff T, McNutt RA, Decompensated heart failure: symptoms, patterns of onset, and contributing factors. *Am J Med* 2003;114:625-30.

<sup>11</sup> Senst BI, Acheson LE, Genest RP, et al. Practical approach to determining costs and frequency of adverse drug events in a health care network. *Am J Health Syst Pharm* 2001; 58:1126-32.

<sup>12</sup> Misdrabi D, Llorca PM, Lancon C, Bayle FJ, Compliance in schizophrenia: predictive factors, therapeutic considerations and research implications. *Encephale* 2002;28:226-72.

<sup>13</sup> Rodgers PT, Ruffin DM. Medication nonadherence: Part II-a pilot study in patients with congestive heart failure. *Manag Care Interface* 1998;11(9):67-9, 75.

<sup>14</sup> Levy G, Zamacona MK, Jusko WJ, Developing compliance instructions for drug labeling. *Clin Pharmacol Ther* 2000;68:586-91.

<sup>15</sup> Berg JS, Dischler J, Wagner DJ, Raia JJ, Palmer-Shevlin N. Medication compliance: a healthcare problem. *Ann Pharmacother* 1993;27 Suppl 9:S1-S24.

- Adherence with medication therapy is generally low- approximately 50% to 65% on average, for common chronic conditions such as hypertension and diabetes;<sup>16 17</sup>
- 4.5 million ambulatory visits related to adverse drug events occur each year.<sup>18</sup>

It is what patients know and understand that makes a difference in patient behavior and their health status.<sup>19</sup> Written prescription information is an essential part of patient counseling because it can reinforce instructions or warnings, improve patient understanding and recall of instructions, increase patient satisfaction, and provide supplemental information during brief pharmacy visits.<sup>5</sup> U.S. prescription drug consumers, especially senior citizens, are challenged by the fragmented delivery system of communication regarding their prescription drugs and are uniquely susceptible to conflicting information and misinformation. They receive prescription drug information from their physician(s), pharmacist(s), pharmaceutical manufactures via direct to consumer advertising, insurance companies via drug formulary communication, and family and friends, but are ill equipped to comprehend and process this divergent information. In an article published in Health Affairs, the authors document the prescription drug information communication challenges faced by consumers:

“Surveys indicate that most patients prefer to receive information regarding their prescriptions from their physicians, as learned intermediaries.

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<sup>16</sup> Nichol MB, Venturini F, Sung JCY. A critical evaluation of the methodology of the literature on medication compliance. *Ann Pharmacother*, 1999;33:531-540

<sup>17</sup> Schlenk Ea, Burke LE, Rand C., Behavioral strategies to improve medication-taking compliance. In: Burke LE, Ockene IS, eds. *Compliance in Healthcare and Research*, Armonk, NY; Futura Publishing Co: 2001:57-70.

<sup>18</sup> Sarkar, U, Lopez, A, Maselli, J, Gonzales, R, Adverse Drug Events in U.S. Adult Ambulatory Medical Care: *Health Serv Res*. 2011 October; 46(5): 1517-1533.o]doi:10.1111/j.1475-6773.2011.01269.x

<sup>19</sup> Office of Disease Prevention and Health Promotions in the U.S. Department of Health and Human Services. *Health People 2000 National Goals*.

However, there is considerable evidence that such discussions occur infrequently and are often quite limited. A recent study evaluated audiotaped office visits and found major shortfalls in the quality of information communicated to patients about their prescribed medicines; physicians explained adverse effects and duration of therapy in only about a third of the discussions and provided patients with instruction for use in only 55 percent of the discussions. Communications with pharmacists is also inadequate. As a result, many patients rely on written information, either on labels or in package inserts.

About half of all Americans have difficulty reading and using health information; poor literacy is a critical barrier to adequate care. These problems are especially important concerning medication information. In a recent multisite study of primary care patients, nearly half were unable to understand one or more of the label instructions of five common prescription drugs. Another study evaluated low-literacy patients' ability to interpret warning stickers (usually colorful stickers often indiscriminately placed on the backs of prescription bottles) and found profound deficits in their understanding. Elderly patients have particular difficulty reading, and understanding drug labeling. In a survey of older hospitalized patients prior to discharge, only 40 percent reported no problems in reading their drug labels, and even fewer reported that they had a clear understanding of the instructions. Another survey of geriatric patients found that they frequently did not understand how to time their dosing in relation to meals.”<sup>8</sup>

As a nation, we have failed to empower our citizens with critical information to participate in the management of their prescription drug regimens, resulting in therapeutic failures and excessive costs. For more than a decade, patient advocates and others have expressed concerns about the quality and consistency of patient drug information.<sup>20</sup> It is a challenge that was recognized in 1979, delegated to a fragmented private-sector to search for a solution, yet remains unsolved thirty-three years later.

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<sup>20</sup> GAO-13-592 Electronic Drug labeling July 8, 2013 p.7.

Senior citizens and all Americans would greatly benefit from Congress amending the Food Drug and Cosmetic Act to enable the FDA to regulate the authorship, content, format, color scheme, printing, and dissemination requirements for patient medication information to ensure consistency of communication of drug identification, indications for use, clinical benefits, directions for use, proper dosage instructions, warnings, contraindications, side effects, and measures patients may take to minimize side effects and enhance the success of their therapy. The legislation must include a mandate for: 1) FDA approved content, 2) a universal PMI format that has been scientifically studied using real patient cognitive studies to clearly demonstrate its quality and effectiveness, 3) be manufacturer printed and distributed, and 4) mandatory pharmacy dispensing, with each prescription dispensed in an outpatient setting.

It is what patients know and understand that makes a difference in patient behavior, and thus, their health status. Please empower our citizens with the tools and knowledge to participate in the complex U.S. healthcare delivery system and optimize the return on investment of our health care resources. The safety and well-being of America's patients, especially our elderly Americans, is too important to do otherwise.

On behalf of the thousands of patients I have been fortunate to serve as a pharmacist, the patients I have represented as a health care attorney, and the millions of Americans whose empowerment depends on knowledge only available through concise, consistent, written, FDA approved and manufacturer delivered communication, I thank you for this opportunity.

I welcome any questions or further inquiry.

**RICHARD J. SCHOLZ, RPh., Esq.**

**Managing Member, Jacobs Scholz & Associates, LLC.**

Mr. Scholz graduated from The Ohio State University College of Pharmacy in 1977, became a Licensed Pharmacist in the state of Ohio, and embarked on a career in community pharmacy. During his years of practice in the community pharmacy setting, he was responsible for implementing a regional drug chain pharmacy computerized record system, founded and managed an institutional pharmacy services division to serve the long term care industry, and created an FDA approved repackaging operation. In 1987, Mr. Scholz founded Complete Pharmacy Network, a pharmacy benefit management company that pioneered the implementation of real time computerized pharmacy management and cost controls to clients throughout the United States. During his tenure as CEO of Complete Pharmacy Network, he led a management team that successfully built a nationwide pharmacy provider network, created technology based drug therapy management strategies, and developed client marketing and retention programs. In the summer of 2005, Mr. Scholz graduated cum laude from Florida Coastal School of Law in Jacksonville, Florida and became a member of the Florida Bar in 2006. Mr. Scholz joined the law firm of Jacobs and Associates, PA in 2005 to build a legal practice focused on business law, health care, and government relations. In 2008, Scholz became a founding member in the firm of Jacobs Scholz & Associates, LLC. Scholz was appointed as a delegate to the Pharmaceutical Printed Literature Association (PPLA) by Vijuk Equipment Inc. (now, G&K Vijuk International) in 2010 to further the communication of the importance of printed literature to educate health care professionals and consumers and optimize pharmacy outcomes.