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THE VOID IN USEFUL CONSUMER RX INFORMATION: PAST, PRESENT AND FUTURE *Congressional Deadline For Action May be Impossible to Meet With Pharmacy-Based Systems*

Introduction

This paper, sponsored by the Pharmaceutical Printed Literature Association (PPLA), explores the state of useful printed prescription (Rx) information for patients, and weighs approaches toward realizing the goals Congress set out for 2006 relative to useful prescription drug information for patients under Public Law 104-180. The law requires that, by 2006, 95 percent of new prescriptions filled will be accompanied by written information that is complete, consistent, accurate, comprehensible and legible. The law also required interim progress toward this goal to be assessed in 2001. That year, a study sponsored by the U.S. Food and Drug Administration (FDA) concluded that none of the information distributed with sampled prescriptions met all legal parameters for patient usefulness.

The PPLA supports manufacturer-produced and FDA-approved patient information for all prescription medications as the best means of achieving Congress's 2006 goals. This paper will show that the solution can be implemented readily, cost effectively, and in the best interest of consumers.

The PPLA is the world's sole trade group exclusively representing printers of pharmaceutical inserts, labels and cartons. Chartered in 2001, the not-for-profit trade association serves as the voice of manufacturers, and provides a forum for members to advance patient safety and risk communication. The PPLA supports health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. In addition, the PPLA is an educational resource for strategic partners and the public.

While PPLA members share a business interest in the advancement of manufacturer-produced, FDA-approved drug information, this interest is set aside for purposes of this paper. The PPLA instead is employing this platform to add our voice to that of public interest groups that are calling for consumer-friendly printed Rx information to help patients derive the greatest benefit, while avoiding dangerous and costly risks, from their drug regimens.

Executive Summary

Inadequate access to useful patient prescription drug information contributes directly to unnecessary and costly emergency room visits and hospital admissions. In 1995, FDA estimated that the cost of these hospitalizations was \$20 billion annually. In 2000, the Institute of Medicine reported that 7,000 hospital deaths resulted from medication errors caused in part by improper administration of drugs. The same report found that 10 percent of adverse drug events were linked to errors in the use of drugs as a result of communication failures.

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Consumers spend billions of dollars on prescription drugs annually, yet very few are appropriately advised via written drug information how to achieve maximum benefit, while avoiding potentially fatal adverse events, from their drug regimens. Even fewer consumers realize that there is no federal review of the overwhelming majority of printed material they receive when filling prescriptions.

For three decades FDA has struggled, and failed, to institute requirements and conventions to afford consumers useful prescription drug information with every new prescription filled. Now the opportunity is at hand to require FDA approval of prescription information such that patients will find it to be accurate, legible, consistent, comprehensive and comprehensible. Scientific and anecdotal evidence affirms the effectiveness of useful printed drug literature in assuring appropriate patient compliance and risk avoidance with drug regimens.

Although PL 104-180 directs FDA to assure that year 2006 goals are met, the agency has handed off execution to this end to private, unregulated parties that consistently have demonstrated their inability to meet FDA standards for useful printed drug information. FDA has taken public comment on the problem, and commissioned research on it. The results continue to call into question how, and if, year 2006 objectives can be met given the track record of private vendors in reliably delivering high quality prescription drug information to patients.

The PPLA joins with public interest, health care and trade organizations in calling upon FDA to immediately require agency approved patient prescription drug information in the form of patient package inserts (PPIs) or medication guides. FDA's own research has shown that these leaflets meet high standards of quality and usefulness. In fact, the agency briefly required manufacturers to provide them with all prescription drugs until political and economic forces favoring for-profit private suppliers prevailed.

This paper presents evidence that approved patient literature for all prescription drugs is not only feasible but the most-likely-to-succeed means of achieving Congress's 2006 directives. It further serves as a call to action in the interest of public safety through gold-standard risk communication.

At present, FDA regulates only a small portion of prescription information that consumers receive. The agency requires medication guides (MedGuides) to accompany a limited number of drug products that pose a serious or significant health concern. Medications in this class include the acne drug Accutane, which has been decisively linked to suicide and birth defects. MedGuides are the only form of mandatory FDA-approved patient information that pharmacists must distribute with each prescription filled for this limited number of drugs.

There are a few other types of patient-safety information that the agency approves and requires manufacturers to produce. However, there is no requirement obliging pharmacists to distribute them when filling prescriptions. These information types are the following:

- **Package Insert (PI)** — FDA requires manufacturers to produce PIs as part of mandatory labeling for all prescription medications. Although PIs contain some information useful to patients, they are written for health care providers in great detail using highly technical language.

- **Patient Package Insert (PPI)** — FDA further requires manufacturers to provide more patient-friendly PPIs for perhaps 150 drugs not life-threatening enough to warrant a MedGuide, but for which side effects and inappropriate compliance significantly impact treatment outcomes. For example, PPIs are required for birth control pills. They must be distributed at pharmacies with every prescription for which they apply only if they are part of the manufacturer's original packaging.
- **Direct-to-Consumer (DTC) Drug Advertising** — Patients also have access to FDA-approved drug information that is required to accompany DTC advertising, such as those printed in magazines and newspapers. This information for the most part closely models a drug's PI and therefore is better suited to health care providers. The balance of risk information to promotional messaging further calls usefulness into question.

FDA's current policy placing patient prescription information almost entirely in the hands of private, unregulated third parties is virtually unknown to consumers. The prescription information an unsuspecting public usually receives, assuming any is provided, typically consists of single-page sheets that are printed out as prescriptions are filled and then stapled to, or stuffed in, the pharmacy bag. Compiled by drug data vendors and software companies that contract with pharmacies, these leaflets receive no federal review. As a result, a consumer filling the same prescription at five different pharmacies could receive five different drug sheets, or none at all. Worse still, private system leaflets have been found to lack key compliance enabling and patient-safety information such as indications and adverse events.

Overview

The United States is unique when it comes to educating consumers about the prescription (Rx) drugs they consume. Throughout Europe, Asia and other parts of the world, printed literature intended for patients is prepared by the Rx drug manufacturer, reviewed by government officials, and attached to drug packages. But in the United States, for nearly all drug products, the only required information prepared by the manufacturer is intended for physicians and pharmacy personnel, not the patient. With no national legal standard requiring that reliable consumer information accompany Rx drug products, consumer interest groups have argued for decades that the U.S. prescription drug distribution system is woefully inadequate and results in serious personal injury and death every year.

To address this long-standing concern, Congress passed legislation in 1996 (Public Law 104-180) requiring FDA to achieve the 95 percent standards by 2006. If these cannot be met under the existing, pharmacy-based paradigm, Congress calls for FDA to intervene potentially with requirements, like those in place throughout the developed world, compelling pharmaceutical manufacturers to prepare consumer leaflets, and pharmacists to distribute them. Now, as the 2006 deadline approaches, it appears unlikely the existing system will meet congressional goals.

What is at stake? Certain industry and public interest groups assert that the existing U.S. system cannot be "fixed" due to factors that include:

- Reliance on unregulated vendors that supply pharmacies with hardware, software and content for generating Rx leaflets.
- Pharmacy printing systems that are capable of printing only a limited amount of information.

- The ability of pharmacies to alter information from Rx drug manufacturers.

FDA's 2001 research revealed additional causes for concern. The study entailed a survey of 384 pharmacies nationwide. Conducted at the agency's behest by the University of Wisconsin School of Pharmacy and the National Association of Boards of Pharmacy (NABP), the study sought to gauge whether two PL 104-180 milestones established for 2001 had been met:

1. 75 percent of patients received written information when filling new prescriptions.
2. The information received was "useful" as rated under measures endorsed by the U.S. Department of Health and Human Services (HHS), under which FDA operates. The standards were accuracy, consistency, non-promotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

While the 2001 results found that nearly 90 percent of survey participants received some form of written information when filling prescriptions, it revealed that 11 percent of pharmacies handed out no literature whatsoever¹. More significantly, it showed that ***none of the information dispensed met the stipulated usefulness criteria; instead, on average, it met only about 50 percent of the prescribed usefulness measures.*** These results boded ill for industry's ability to meet the far more challenging 95-percent requirement for 2006.

With these findings, and under law, HHS was to have promptly taken public comment on remedial strategies. Yet HHS and FDA failed to do so until the advocacy group Public Citizen filed suit in 2003 demanding compliance. In settling the suit, and at long last, the agency took public testimony in July that year.

During the agency hearing, numerous public interest organizations presented data and anecdotal evidence showing that private industry is at once endangering consumers and failing to meet legal requirements. Several groups argued that the means exist to achieve the usefulness goal by 2006, if not earlier, simply and cost effectively, by expanding or revising information already prepared by drug manufacturers, and approved by FDA.

Private industry representatives testifying in 2003 predictably argued in favor of the status quo, claiming repeatedly that the current unregulated system is working, even though it has failed for decades to consistently deliver useful drug information as defined by law. One representative comment was made by John Coster, vice president of policy and programs for the National Association of Chain Drug Stores: "I would not characterize the initiatives of the private sector as failed...I think we're on the right track."²

Why is Useful Patient Information Important?

According to the Institute of Medicine, more than 300 studies show that health-related materials far exceed the average reading ability of adult Americans³. Health literature is filled with compelling evidence that illustrates the wellness benefits associated with printed information for Rx medications that patients can understand, refer back to, and easily carry with them. These data correlate to two desired outcomes:

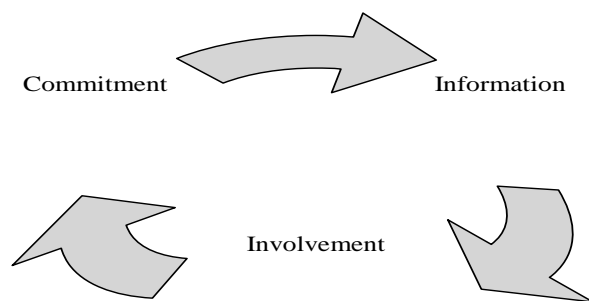
maximum benefit from prescription medications, and avoidance of potentially life threatening, painful and costly adverse events.

Realizing Maximum Benefit

Prescription drugs are prominent in the news today, with headlines about costs, Medicare drug benefits, drug re-importation and counterfeiting featured daily in the print and broadcast media. Useful patient information can help individuals and the health care system maximize the enormous benefits of prescription drugs.

Hundreds of billions of dollars are spent each year on prescription drugs. The actual numbers are difficult to pin down, and sources ranging from the Centers for Medicare and Medicaid Services to *The Wall Street Journal* put the dollar count for total U.S. spending on Rx drugs in 2003 at a staggering \$181 billion and \$216 billion, respectively⁴. These huge sums are paralleled by those spent within the pharmaceutical industry on research and development, as well as on advertising and marketing. The payoff is innumerable “miracle” drugs that consumers invest in heavily for relief of suffering and improved quality of life. Rx drugs lower blood pressure and cholesterol levels; they make life more livable for those suffering from such debilitating conditions as arthritis and depression. They save lives in emergency rooms.

In his best-selling book, *The Seven Habits of Highly Effective People*, Stephen Covey provides a model that applies to useful patient information.⁵



While this model may not be associated frequently with drug labeling and packaging, it seems apt in conveying the importance of information relative to positive human behavior. Covey’s paradigm also has been widely accepted in the corporate world for its universal applicability in engendering human engagement. Its utility in modeling effective paths toward patient compliance seems equally unassailable. High quality drug information enables the patient to become more involved in his or her drug regimen, and thereby more committed to the prescribed course of therapy, which in turn results in improved compliance.

- According to a 2003 report published by the World Health Organization, only about 50 percent of patients in developed countries suffering from chronic illness follow prescribed drug regimens. In the United States, a mere 49 percent of individuals treated for hypertension adhere to prescribed therapies. Among the causes for noncompliance cited in the report was “misun-

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derstanding of treatment instructions.”⁶

- In a widely publicized report by the Institutes of Medicine (IOM), entitled *To Err Is Human: Building a Safer Health System* (2000), one cited study found that 10 percent of adverse drug events were linked to errors in the use of the drug as a result of communication failure.
- The same report observed that management of complex therapies, particularly among the elderly, is highly challenging and requires special methods to address the patient’s ability to understand and remember dosage timing and amount, and modifications in behavior the regimen requires.
- A 2004 IOM report, entitled *Health Literacy: A Prescription to End Confusion*, noted that the ability of “patients and consumers to manage their own health and medical care can be improved through better provider-patient communication and greater inclusion of the patient in treatment decisions.”⁷
- Poor compliance with medication and care regimens can be dangerous, yet serious mistakes may occur because the patient cannot read the instructions. HIV-positive adults with low functional health literacy missed more treatment doses than those with high health literacy because they were confused by the instructions in a study of 182 patients.⁸

Avoiding Adverse Events

Inadequate access to useful patient information is a major cause of inappropriate use of prescription medications that contributes directly to unnecessary emergency room visits and hospital admissions. In 1995, FDA estimated that the cost of these hospitalizations was \$20 billion annually.⁹ Other organizations estimated the costs to be as high as \$77 billion¹⁰, which was the same amount the U.S. spent on prescription medications in 1995.¹¹ According to FDA’s calculations, during that year alone Americans spent one extra dollar for every dollar spent on prescription drugs as a result of avoidable adverse events.¹²

In a 2001 analysis of 265 reports of medication errors, FDA discovered that 20 percent of the reported errors were attributable to drug labels and labeling, including 1.9 percent directly related to the drug insert and printed or electronic reference information.¹³ Additional data further indicate the effectiveness of useful patient prescription information in helping consumers avoid adverse events:

- Up to 5 percent of costly hospital admissions are attributed to drug-related illness that could have been mitigated by useful printed patient information.¹⁴
- Adverse drug reactions linked to lack of useful drug information occur in 20 percent of ambulatory patients.¹⁵
- Written information about medicines can help patients recognize problem side effects and then give that information to their doctor or pharmacist.¹⁶

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Useful printed Rx information for patients, as defined by HHS, holds another key role in the public interest. Approved patient information that is mandatory, as are MedGuides, is the only objective source of drug-safety information available to consumers who are deluged with DTC drug advertising through every American media channel.

What is Useful Patient Information?

Patient advocates generally agree with HHS's definition of usefulness; printed leaflets must be scientifically accurate, consistent, non-promotional in tone and content, specific, comprehensive, understandable and legible. The PPLA joins with these groups, adding that usefulness can only be achieved if Rx information is consistent with, or derived from, professional labeling; approved by FDA; manufacturer produced; and required to be distributed with every prescription filled. Even the most informative and readable leaflet, such as the PPI, cannot be considered useful if consumers do not receive it, as they may not unless pharmacies are compelled to distribute them. Clearly, as Dr. Svarstad's study revealed, patient Rx leaflets today fall lamentably short of these quality standards.

Under the current pharmacy-based system controlling the type and quality of prescription information patients receive, the same consumer can fill a prescription for the same medication at several different pharmacies and receive a different drug sheet, or no drug sheet, each time. The leaflets may be illegible because of printer quality at a given pharmacy; they may even contain different information because pharmacies sometimes omit important text to accommodate a single-page format.

According to *The Washington Post*, pharmacies of a major grocery store chain serving the Washington, D.C., area routinely altered Rx drug sheets, unbeknownst to consumers. As reported in the *Post*, the chain was prohibited by contract from altering the drug information provided to them by vendor Facts and Comparisons. However, a review conducted in 2002 showed that "the patient information printed by [the pharmacies] was not the full file created by Facts and Comparisons. Three sections omitted from the pharmacy-produced leaflets were titled: 'Before using this medication,' 'Overdose,' and 'Additional information.'" According to the *Post*, these missing sections were restored only after the chain was contacted by a reporter. The company's spokesperson confirmed that stores had opted only "to provide the basic information."¹⁷

Even when patient information from third-party data vendors is not omitted from leaflets, many still fail to help consumers. The Institute of Medicine offered this text from an actual patient information sheet:

"Therefore, patients should be monitored for extraocular CMV infections and retinitis in the opposite eye, if only one infected eye is being treated."¹⁸

The IOM followed up with the research-based finding that 40 million Americans cannot read text like this at all, and 90 million have difficulty understanding complex text. Among many anecdotes the report provided was a case involving a mother attempting to properly administer oral prescription medicine to her toddler for an ear infection. According to the report, "After carefully studying the label on the bottle and deciding that it doesn't tell how to take the medicine, she fills a teaspoon and pours the antibiotic into her daughter's painful ear," furthering the child's discomfort while negating the medicine's efficacy.¹⁹

As was explained in the Executive Summary, the only mandatory, FDA-approved, consumer-friendly information currently available to the public exists in the form of MedGuides that are required for a small number of drugs or drug classes FDA considers particularly dangerous when used improperly. Patients filling prescriptions also may receive, on rare occasion and mostly at the manufacturers' discretion, FDA-approved PPIs with some drug products and a large variety of drug samples. By specific request of the pharmacist, consumers usually can obtain the drug's package insert, which is not written in consumer-friendly language.

Under the current pharmacy-based system, the average consumer will, at best, receive an unregulated and very brief leaflet. The vendors producing these sheets need not, and so usually do not, conform to a single standard guiding content and format. Nor are these vendors obliged to account for where the information has originated. During FDA's July 2003 hearing, the National Association of Chain Drug Stores' Dr. Coster told the agency that their members often do not know where their vendors get the leaflet information.

How is FDA Progressing In Meeting Congressional Requirements?

Attempts to establish mandatory, gold standard prescription information for patients have been controversial and bitterly contested by private industry even when precipitated by tragedy. FDA's first PPI requirement was enacted in 1968 for asthma inhalers following deaths due to inappropriate use. Subsequent decades marked seesawing regulatory sorties in which FDA proposals were presented and final rules issued, only to be reversed as presidential and congressional leadership shifted, and industry successfully lobbied in protest of further regulation.

Opponents of regulation consistently prevailed with arguments that new rules would require extra investments that would make prescriptions more costly, and that more information is not needed or wanted by consumers. The first point was well countered by Dr. Janet Woodcock, former director of FDA's Center for Drug Evaluation and Research, during a 2000 public workshop in which she observed, "A century or more of a professional model that didn't trust patients with information has created much inertia to be overcome."²⁰

A brief recap of PPI and MedGuide history picks up in 1970, two years after the first PPI requirement, when FDA approved patient inserts to be included with packaging for hormone drugs, or birth control pills. Ten years later, FDA issued a final rule requiring PPIs for a large number of Rx drugs, only to reverse itself following intense protest from the private sector and the installation of a new presidential administration.

In 1995, FDA issued its "MedGuide proposal" requiring medication guides for drugs most likely to cause harm if not taken properly, and requiring PPIs for all drugs not accompanied by MedGuides. As FDA was taking comment on the proposal, Congress passed PL 104-180 prohibiting the agency from imposing additional patient information rules, and allowing private industry instead to voluntarily work to meet the objectives of FDA's 1995 proposal.

This act of Congress set the milestones discussed earlier for private industry to reach in implementing the desired targets for widely available and useful Rx information. The milestones were to be

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monitored by FDA, and the agency was to evaluate the usefulness of patient information. While the law barred FDA from implementing uniform content or formatting if private industry was meeting the stipulated availability and usefulness goals, this provision was to be revoked if, by 2001, 75 percent of individuals receiving new prescriptions failed to also receive useful written information. If these criteria were not met, the law called for public input to meet the goals.

Time continued to elapse and, in 2001, FDA commissioned the NABP study on useful Rx information for patients, in compliance with PL 104-180. NABP brought in the University of Wisconsin School of Pharmacy to conduct the study, led by Dr. Bonnie Svarstad, to see what pharmacies were giving to patients filling new prescriptions. Dr. Svarstad's team hired a professional shopping firm to fill prescriptions for four widely prescribed drugs in different classes at 384 randomly selected pharmacies nationwide. The study concluded that while 89 percent of shoppers posing as patients received some drug information — well in excess of the 75-percent goal — the average usefulness of the information was only about 50 percent, alarmingly short of the legal requirement. With this finding, FDA was to take public comment on corrective strategies. The agency failed to do so, however, until 2003 when it scheduled a hearing in response to the lawsuit filed by Public Citizen.

At the hearing, consumer groups called for FDA to take regulatory action to correct usefulness deficiencies, collectively observing that private industry is failing to meet legal usefulness objectives. Industry, on the other hand, said the voluntary system is on track to meet congressional targets as evidenced by the finding that 89 percent of patients received leaflets. Some representatives of private industry disagreed with the University of Wisconsin findings that most leaflets were not useful.

As of summer 2004, FDA had issued no further guidance or rules in response to the 2003 public hearing. Instead, the agency appears to be applying its resources to exhaust all private industry options in advance of 2006. Usefulness will prospectively be studied again in 2007. If, at that time, government-sponsored research establishes that private industry continues to fail consumers with regard to useful information for prescriptions, and barring legislation that amends PL 104-180, FDA may be compelled to issue further regulations.

What Are the Key Factors, Positions and Issues Moving Forward?

Public safety advocates have repeatedly questioned FDA's rationale for maintaining a system and policy that have been shown for decades to be flawed and not in the best interests of the public. This section reviews the various participants in the issue, and the positions they have taken relative to regulatory policy. In explaining the current thinking at FDA, Arthur Levin, consumer representative for FDA's Drug Safety and Risk Management Advisory Committee, commented in 2004 that former FDA Commissioner Mark McClellan:

“...could have chosen to make a ‘bold’ decision and mandate that drug makers provide written prescription drug information for consumers meeting FDA criteria for scientific accuracy and usefulness. I suspect that his failure to act decisively to provide consumers with, in his own words, ‘information they can trust to make smart decisions’ is another example of Dr. McClellan’s

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pragmatism. Rather than boldly engaging in battle with the anti-regulatory forces of industry, the Bush administration and a conservative Congress, Dr. McClellan has chosen to ignore his own words and risk the public's health."²¹

Intense industry opposition to further regulation could be a determining factor behind FDA's inaction. Agency officials also have stated in numerous public meetings that FDA does not have the resources to review additional PPIs or MedGuides that might arise should their use become mandatory.

Pharmaceutical manufacturers also are seeking to phase out printed literature intended for health care professionals as demonstrated in 1999 when manufacturers announced plans for a "paperless labeling initiative." Sponsored by the pharmaceutical industry's trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), the program seeks to replace printed PIs with electronic alternatives. A primary benefit of the system cited by PhRMA is that it would enable faster information updates.

The first trial of PhRMA's paperless labeling initiative was a proof-of-concept alpha test at 10 pharmacies in 2002; a larger trial was slated for 2004. In June 2004, PhRMA announced a beta test to begin the following month at 265 of America's estimated 55,000 pharmacies.²² Evaluation of the system was slated for late 2004. Provided that results are positive, PhRMA projected nationwide deployment to tens of thousands of additional pharmacies sometime in 2005. While the program's scope and roll out schedule are aggressive when weighed against a drawn out, multi-year launch, the initiative has support within FDA.

The PhRMA program is focused on health care providers, but it has implications to the information patients may receive when filling prescriptions. The system employs third-party vendor prescribing information, both physician and patient focused, which has been shown to be inferior for consumers. PhRMA's partners in the initiative, notably the primary content provider Thomson Healthcare, see the program as a means of meeting congressional goals for year 2006. According to Mukesh Mehta, vice president of regulatory affairs and labeling at Thomson:

"This initiative will insure that every dispensing site in the United States and its territories will have access to the most current FDA approved prescribing information. The ultimate impact is that the patient will benefit by receiving better information from the health care providers. This effort will also promote better health care and patient safety by reducing medication errors due to the use of outdated [prescribing] information."²³

Dr. Mehta does not address how usefulness, specifically, will be established on the consumer's behalf through such a system, were it to be successfully deployed as envisioned by PhRMA. Based on comments filed with FDA, and public testimony by the trade group and its constituents, the paperless labeling initiative represents little more than a higher-tech version of the existing private system whose well documented shortcomings far exceed the technical.

Moreover, successful implementation of a paperless system rests on the ability of some sponsors to provide computer equipment to all drug-dispensing points, free of charge. With this equipment installed,

labeling information and updates could be sent to users in unalterable files. PhRMA has indicated that there may be financial incentives to create such a system because it would serve as a “direct portal” to physicians and pharmacists.

While such a system could help improve the timeliness of Rx information for professionals, a number of issues, beyond the sheer scope of this considerable implementation, must be carefully weighed before PhRMA’s system can be used as a replacement to printed prescription labeling. Among these considerations are the following points:

- FDA has no authority to regulate the use of electronic databases in pharmaceutical dispensing sites; therefore the public has no guarantee that these systems will operate properly.
- Although PhRMA’s plan calls for the no-cost provision of needed computer equipment at pharmacies and other dispensing points, no entity has been publicly identified to take responsibility for these resources. Lacking such a sponsor, pharmacies could be compelled to bear the costs of additional systems. Many pharmacies, particularly small, independent and rural ones, lack such resources.
- Field doctors, pharmacists working from mobile dispensing sites, and those in rural areas of the country cannot be served effectively by electronic means.
- Pharmacy and hospital health care personnel must always have access to critical prescription drug information; in emergency settings and situations, health care practitioners in immediate need of prescribing information would be challenged by the system.
- Electronic formats are subject to power outages, equipment failure and corruption.

Another participant in FDA’s effort to meet year 2006 goals is the National Council on Patient Information and Education (NCPIE). This not-for-profit organization was formed in 1982 with support from FDA’s Committee on Patient Education. NCPIE serves as a major coordinating body for private-sector initiatives working to improve communication about prescription medicines to consumers. FDA supported NCPIE’s formation the same year the agency withdrew its 1979 proposed rule requiring PPIs for about 375 prescription medicines.

In 2002, after the University of Wisconsin study results revealed that sorry state of in-pharmacy Rx sheets, FDA enlisted NCPIE to serve as a catalyst to help private industry do a better job in providing quality prescription leaflets. In response, NCPIE launched its Consumer Medicine Information (CMI) Initiative in 2003. To date, NCPIE has formed three committees to drive the CMI Initiative: Criteria, Education and Implementation. Objectives and challenges also have been identified. Any further progress as of mid 2004, however, has not been discernable through FDA’s public channels.

Despite a head start of nearly 19 years, NCPIE had not succeeded in coalescing private industry toward meeting regulatory goals. A great many of NCPIE’s members have close ties to the private system, and health literacy is conspicuously under-represented within the organization. With these

factors in play, the question arises whether NCPIE has the ability to realistically implement congressional goals for 2006.

PhRMA and NCPIE were among the organizations testifying during FDA's July 2003 hearing to evaluate the status of useful printed Rx information for patients. Also testifying were patient-safety groups Public Citizen, the Center for Medical Consumers, and the PPLA, among others. In testimony and comments filed with FDA afterward, the latter three organizations called for mandatory, FDA-approved, manufacturer-produced printed prescription information for patients. Other groups, including the National Organization for Rare Disorders and the Pharmacists Planning Service, indicated support for this position, either in its entirety or its spirit.

Particularly notable among the comments FDA heard at the 2003 meeting was the following from Amy Allina, Program and Policy Director for the National Women's Health Network:

“Those of you who know my organization know that we've been involved in trying to get useful information to patients about medication since we were founded 27 years ago...[A]fter listening to everything over the course of the day, I can't help but say that there's been an enormous amount of time [spent] by a huge number of people invested in this over 25 years...But we're still in a situation where the information that's getting to consumers is either inaccurate or not useful, not comprehensible and that's in cases where it is getting to consumers...[I]t seems clear to me that... it's long past time for this — the process of getting written information to patients to be made mandatory and to be overseen by the FDA.”²⁴

Drug manufacturers Merck and Pfizer also urged FDA to encourage use of manufacturers' Rx information. In comments filed with FDA, both companies requested greater emphasis on FDA-regulated materials in the voluntary system. Merck took a particularly strong stand on the matter in written comments, stating, “To date, voluntary private sector efforts have failed to meet the goals [of the 1996 law]...Because they are FDA-approved, these PPIs are the best sources of current information about prescription drugs.”

Other challenges have been raised in support of the existing pharmacy-based system. They are presented below, with counterpoints:

- **It has been argued that additional regulations will interfere with the patient-care provider interface and counseling.**

This challenge might be compelling were it not for the fact that, with or without additional regulations, research has shown that very little counseling actually takes place at drug dispensing sites. According to Dr. Bonnie Svarstad in testimony before FDA in February 2000, the University of Wisconsin study revealed that, in Dr. Svarstad's words:

“...[O]nly 35 percent of the written information sheets were given to the client or the patient, patient observer, with some kind of mention or with some kind of oral review, or with some kind of encouragement to read it. In other words, in the majority of the

cases, according to the state inspectors, these written information sheets are being stuffed in the bag. They are not being discussed, reviewed, or mentioned in a positive way by the pharmacist. And I would warn us all to remember that what evidence we do have on the effects of written information would suggest that their efficacy depends on oral review...If you are not encouraged to read it, many people will not read it. But if you are encouraged to read it, people will read it.”²⁵

The Institute of Medicine also observed shortcomings in provider-patient communication. The IOM’s 2004 health literacy report cited as related factors the “relative infrequency and brevity of visits, language barriers, differences between providers’ and patients’ agendas and communication styles and other cultural barriers, lack of trust between the patient and provider,” and so on.²⁶

- **Others say that pharmacies cannot store all the leaflets that would be required for mandatory FDA-approved patient information.**

The means currently exist — and are being employed at present by a number of manufacturers for many products — to attach approved, manufacturer-produced, patient information directly to pharmaceutical packaging, thereby alleviating storage and fulfillment challenges at dispensing locations. This cost-effective and existing technology affords benefits that extend beyond storage solutions. If manufacturers were required to attach removable leaflets as part of their approved labeling, consumers would benefit from having constant access to useful Rx information, and dispensing sites would not need to alter workflow practices to provide the public with important drug information.

- **Some claim that the financial burden of mandatory patient information will not justify the benefits.**

The technology and resources are in place today to implement a mandatory program at virtually no additional cost to industry or consumers. Manufacturer-produced, FDA-approved Rx information has already been developed for all drugs for which manufacturers employ direct-to-consumer advertising in publications. Many of these do not comply with regulators’ usefulness guidelines, but could easily and affordably be made compliant with funds budgeted for print advertising. In this way, one consumer-friendly document can serve several risk and liability management purposes to manufacturers’ economic benefit. Additionally, the required PI is a source of a great deal of information that can be made consumer-friendly with simplified language.

For pharmacies, the financial impact of mandatory patient information would seem equally negligible, if not favorable. Such a program would free pharmacies from the need to contract with data vendors, and improve efficiency and customer service because printed-out leaflets would no longer be required.

Conclusions and Recommendations

As the taxpayer-funded guardian of medical consumer safety, FDA has a fiduciary and legal responsibility to correct the failing pharmacy-based system for printed patient literature. FDA should address this issue

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immediately and aggressively in light of the well established fact that this information lacks utility to consumers, and that one in ten pharmacies do not distribute any information at all. Barring quick and decisive rulemaking on FDA's part, pharmacies will continue to withhold drug information that patients need and want. This need is amplified by the unfortunate reality that too many consumers receive the bulk of their Rx information in DTC advertising — hardly an objective medium.

The impact of further inaction is likely to be carried into other consumer information channels, as well. As Dr. Leander Fontaine notes in the journal *Drug Safety*, barring changes to the current system, "...other sources of product information will grow even more important and reduce the effectiveness of labeling for risk management. These sources include pocket guides for [health care practitioners], medication books for patients, information offered on the internet and for electronic office, pharmacy and hospital information systems, which may not be fully consistent with labeling, and not current."¹

It is time for FDA to act decisively in the best interest of American consumers. The current approach has proved a failure, and has provided a direct link to increases in patient risk and health care costs. Even the agency's own Drug Safety and Risk Management Advisory Committee urged FDA to exercise its authority to take over this critically important task from private industry. Key risk information available with every prescription will not be consistently, comprehensibly and legibly provided unless the agency compels manufacturers to take the lead.

To this end, FDA would be well advised to convene a work group comprised of regulatory officials, learned intermediaries and literacy experts to address the task of developing MedGuides or PPIs for all drugs currently lacking them. If the Agency opts to continue its present course, however, stakeholders are left with no recourse other than to appeal directly to lawmakers in the Senate and House of Representatives to petition in favor of more consumer-supportive statutes and regulatory leadership.

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For more information about this white paper and the current status of useful printed prescription information for patients, please contact the Pharmaceutical Printed Literature Association at 703-538-5799, or via e-mail at info@pplaonline.org. Visit the PPLA on the Web at www.pplaonline.org.

Additional Resources

Center for Medical Consumers:

http://www.medicalconsumers.org/pages/advocacy.html#written_prescriptiondrug_info

Useful Printed Patient Information — Testimony of Arthur Levin, Consumer Representative, FDA Drug Safety and Risk Management Advisory Committee; Director, Center for Medical Consumers:

http://www.medicalconsumers.org/pages/advocacy.html#written_prescriptiondrug_info

Public Citizen, Health Research Group:

<http://www.citizen.org/hrg/>

Useful Printed Patient Information — Testimony of Sidney Wolfe and Larry Sasich, Public Citizen Health Research Group:

<http://www.citizen.org/publications/release.cfm?ID=7269&secID=1685&catID=126>

National Council on Patient Information and Education:

<http://www.talkaboutrx.org>

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¹ Transcript of a Public Meeting: “Current Status of Useful Written Prescription Drug Information for Patients, Volume 1,” FDA, February 29, 2000, p. 38, <http://www.fda.gov/cder/Offices/ODS/tranvol1.htm>.

² Transcript of a Public Meeting: “Current Status of Useful Written Prescription Drug Information for Consumers,” FDA, July 31, 2003, pp. 115-116, <http://www.fda.gov/ohrms/dockets/dockets/03n0168/03n-0168-tr00001-vol4.pdf>.

³ Report: “Health Literacy: A Prescription to End Confusion,” Institute of Medicine, April 2004, p. 124, <http://www.iom.edu/report.asp?id=19723>.

⁴ “National Health Expenditure Amounts by Type of Expenditure and Source of Funds: Calendar Years 1965-2011,” Centers for Medicare & Medicaid Services; “Pfizer Case Signals Tougher Action On Off-Label Drug Use,” The Wall Street Journal, May 14, 2004.

⁵ “The 7 Habits of Highly Effective People,” Stephen R. Covey, Simon & Schuster, 1990.

⁶ Report: “Adherence To Long-Term Therapies: Evidence For Action,” World Health Organization, 2003, pdf, p. 14 in Section II, http://www.who.int/chronic_conditions/en/section2.pdf.

⁷ Report: “Health Literacy: A Prescription to End Confusion,” Institute of Medicine, 2004, p. 25, <http://www.iom.edu/report.asp?id=19723>.

⁸ American Journal of Preventive Medicine, 2000.

⁹ Transcript of a Public Meeting: “Current Status of Useful Written Prescription Drug Information for Patients, Volume 1,” FDA, February 29, 2000, p. 5, <http://www.fda.gov/cder/Offices/ODS/tranvol1.htm>.

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¹⁰ Ibid.

¹¹ Ibid.

¹² Ibid.

¹³ “Med Error reports to FDA show a mixed bag,” FDA Safety Page, Drug Topics, M.R. Thomas, C. Holquist, J. Phillips, October 1, 2001; also “The Role of Labeling in Pharmacovigilance and Risk Management,” A. Leander Fontaine, 2004.

¹⁴ 21 CFR Parts 201, 208, 314 and 601, 1995; “Adverse Reactions to Drugs,” A.J.J. Wood and J.A. Oates, 1991.

¹⁵ Ibid.

¹⁶ “Your Role In Reducing Medication Errors,” National Council on Patient Information and Education, 2001.

¹⁷ “Not-So-Fine Print: Patient Drug Leaflets Omit Key Warnings, Other Information,” Francesca Lunzer Kritz, *The Washington Post*, August 13, 2002.

¹⁸ Report: “Health Literacy: A Prescription to End Confusion,” Institute of Medicine, 2004, p. 2, <http://www.iom.edu/report.asp?id=19723>.

¹⁹ Report: “Health Literacy: A Prescription to End Confusion,” Institute of Medicine, 2004, p. 3, <http://www.iom.edu/report.asp?id=19723>.

²⁰ Transcript of a Public Meeting: “Current Status of Useful Written Prescription Drug Information for Patients, Volume 1,” FDA, February 29, 2000, <http://www.fda.gov/cder/Offices/ODS/tranvol1.htm>.

²¹ “Praise for FDA Commissioner Boldness May Not be Deserved,” Arthur A. Levin, *PPLA News*, March 2004, <http://www.pplaonline.org/PPLANewsVol3Issue10304.pdf>.

²² National Association of Chain Drug Stores Web Site, June 2004: “Nationwide, there are more than 35,000 pharmacies operated by traditional chain pharmacy companies, supermarkets, and mass merchants. In addition, there are another nearly 20,000 independent pharmacies.” <Http://www.nacds.org/wmspage.cfm?parm1=72>.

²³ Transcript of a Public Meeting: “Current Status of Useful Written Prescription Drug Information for Consumers,” FDA, July 31, 2003, pp. 100-101, <http://www.fda.gov/ohrms/dockets/dockets/03n0168/03n-0168-tr00001-vol4.pdf>.

²⁴ Transcript of a Public Meeting: “Current Status of Useful Written Prescription Drug Information for Consumers,” FDA, July 31, 2003, p. 223, <http://www.fda.gov/ohrms/dockets/dockets/03n0168/03n-0168-tr00001-vol4.pdf>.

²⁵ Transcript of a Public Meeting: “Current Status of Useful Written Prescription Drug Information for Patients, Volume 1,” FDA, February 29, 2000, p. 29, <http://www.fda.gov/cder/Offices/ODS/tranvol1.htm>.

²⁶ Report: “Health Literacy: A Prescription to End Confusion,” Institute of Medicine, 2004, p. 176, <http://www.iom.edu/report.asp?id=19723>.

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