The Current Status of the Private Sector's Efforts to Provide Useful Written Prescription Drug Information to Consumers
(Docket No. 03N-0168)

Comment Submitted By:
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Thank you for the opportunity to present my comments today on this important consumer protection issue. I am responding to the FDA's request for comment in my capacity as Director of the Center for Medical Consumers, a non-profit consumer advocacy organization located in New York City.

In the spirit of full disclosure I would like to state for the record that the Center is a 501c3 not for profit organization and does not receive any grants from the health care industry, including any manufacturer of drugs, devices, biologics or medical equipment. You should also know that I served as a member of the congressionally established *Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information* that issued its report to HHS in December 1996. And, I am currently the consumer member of the FDA's *Drug Safety and Risk Management Advisory Committee* (DSaRM).

Since it's founding in 1976, the Center has advocated on behalf of the rights of consumers and patients to know everything there is to know about a prescription drug or medical device. I believe that open access to this information is critical to patient safety, and a necessary condition of informed decision-making and informed consent. And I would suggest that the demonstrated decades of failure of the various private sector interests to provide high quality written prescription drug information to consumers should be a matter of urgent concern from what is after all, a public health agency.

People define the goals of providing consumers and patients with written information about their prescription drugs from different perspectives. Some see it as a means to improve patient "compliance" with drug regimens, others as a way to encourage people to take the drugs prescribed to them and still other as a means of educating people about proper use. I have a different set of priorities in mind. The first is that of protecting consumers from the risks inherent in prescription drugs; second, providing the means by which a patient can give informed consent to taking a drug in the first place and third is optimizing the benefits of the medication.

The FDA asked that public comment address four questions that were posed in the Federal Register notice of this meeting. The first two are really more appropriate for an industry response - so I will comment only on the last two.

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What should the role of the FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?

To my mind the answer is simple: The FDA should mandate the distribution of "useful" written consumer drug information with all prescriptions and only count as "useful" the written information that conforms to the Action Plan guidelines for content and format. These guidelines represent a set of criteria for judging the "quality" of the information and after development by the Steering Committee were formally accepted by the Secretary of Health & Human Services.

Useful Written Drug Information for Consumers: An Urgent Public Health Priority

In its 2001 report, Crossing the Quality Chasm, the Institute of Medicine's (IOM) Committee on the Quality of Health Care in America wrote:

"Health care today harms too frequently and routinely fails to deliver its potential benefits".

That preventable patient harm from prescription drugs is an urgent public health problem is to my mind beyond question. Consider the following: *PharmaTrends,* an industry data analyst firm estimates that 3,340,000,000 outpatient prescriptions were written in 2002. That's an average of 10 prescriptions a year for every woman, man and child in America. That's also 3, 340,000,000 opportunities for a patient to be injured by a preventable medication error; to be unaware that a drug's risks may exceed its benefits or not to understand that perhaps they shouldn't have been prescribed or dispensed a particular drug in the first place.

The evidence of serious harm to patients as a result of medication errors, adverse drug reactions and drug interactions is substantial and growing. Because of this overwhelming evidence it is, I believe, unconscionable for industry and health professional self-interest to be permitted to take precedence over the well-being and safety of patients. But that is exactly what has happened over the past twenty-five years. In my view, the time for government's continued reliance on a demonstrably failed voluntary, private sector effort is over.

Why is written drug information for consumer so important? Well, for one thing experts have suggested that a meaningful reduction in patient harm could be achieved if consumers and patients were better informed about the drugs they take. In its 1999 report on medical errors, the IOM's Committee of the Quality of Health Care recommended that:

"A major unused resource in most hospitals, clinics and practices is the patient. Not only do patients have a right to know the medications they are receiving, the reasons for them, their expected effects and possible complications, they should also know what the pills or injections look like and how often they are to receive them."

Historically, face-to-face prescription drug counseling by doctors and pharmacists has been viewed as the principal means to inform patients. In fact, physicians like to refer to their roles as "the learned intermediary." Unfortunately, there is considerable evidence suggesting that prescribers and dispensers spend little or no time counseling patients about the prescriptions they take. Also, in our current financially stressed health care system, doctors, nurses and pharmacists complain that they have less and less time to spend with individual patients. And there are some logistical complications; for example a growing number of patients receive their prescriptions at home by mail.

There is also good reason to believe that the drug information imparted by prescribers may not necessarily be scientifically accurate, up to date or free of professional or specialty bias. I would also suggest that there is little disagreement that the amount of information flowing from published studies, the National Institutes of Health, specialty society guidelines, protocols, care maps and the like is simply overwhelming. Many experts believe it is humanely impossible for a single clinician to keep up. In others words, your intermediary may not be so "learned."

It seems unlikely, based on what we know (or don't know) about changing professional behavior that rapid progress can be made to change professional behavior so that evidence-based prescribing and dispensing is the norm. Also, it would take a revolution in the way health care is currently organized and financed to encourage sufficient time and incentives for doctors, nurses and pharmacists to spend the time necessary to counsel patients and to do so without any bias based on their professional or entrepreneur interests. And lastly, we cannot ignore the pernicious influence of industry's intense product promotions to doctors and pharmacists in shaping their knowledge base about the safety and effectiveness of prescription drugs. Because of these realities, an FDA mandate that prescriptions be accompanied by high quality written consumer drug information is, I respectfully suggest, a critical, absolutely appropriate "safety net" to protect patients from harm.

Thirty-Five Years in the Making and Still Counting:

Today, we have been asked by the agency to once again provide comment and guidance about the provision of written prescription drug information to consumers. We are re-visiting this issue in July 2003 - some 35 years after the FDA first required that labeling written in non-technical language be given to consumers whenever certain prescription drugs or devices were dispensed. I think that to fully understand why we are having this meeting three decades after a written consumer information initiative was first undertaken by the FDA, it is important to have a sense of the history of efforts to provide better consumer information about the risks and benefits of prescription drugs

Tom McGiness has provided us with a short history of the battles over written drug information for consumers.

Since 1968, despite seemingly broad agreement that providing better information to consumers about their prescription drugs is a laudable, potentially health-enhancing

goal, we have witnessed a contentious struggle over how best to accomplish that task, what such information should include and whose responsibility is it to produce, distribute and evaluate the information.

A proposal to mandate broad distribution of PPIs was finalized by the Carter administration in 1979. It was subsequently withdrawn by the FDA after newly elected President Reagan rejected the initiative, which conservatives likely saw as a example of government excess, in favor of a "hands off" private sector approach – a bias that has dominated this public policy discussion ever since.

Eight years ago, in what I would characterize as a frank acknowledgment of the failure of the private sector to achieve the desired goals of the 1980 PPI program after some fifteen decades of effort, the FDA published a new proposed rule in The Federal Register titled "*Prescription Drug Product Labeling; Medication Guide Requirements*" [Docket No. 93N-0371].

In the narrative accompanying the proposed rule the FDA noted that:

"During the hearing that led to the withdrawal of the 1980 PPI regulations, promises were made by representatives of the pharmaceutical industry, medical and pharmacy community that if FDA withdrew the PPI regulations, the private sector would develop a variety of systems that would meet the goals of the proposed PPI program. These promises have not yet been fulfilled."

While the 1995 proposed rule, quickly dubbed "Med Guides," still looked to the private sector to deliver on its promises, the agency at least recognized the need to establish criteria for what comprised "useful" written information. This important step meant that: (1) there could be uniformity and consistency in the information provided; (2) there would be assurance that the information provided consumers is scientifically accurate and otherwise "useful" as defined by the FDA and; (3) perhaps most important, criteria provided the tools to objectively evaluate the quality of the drug information being published and distributed by the private sector.

In support of the 1995 proposed Med Guide rule, the FDA argued that:

"...improved dissemination of accurate, thorough and understandable information about prescription drug products is necessary to fulfill patients' need and right to be informed."

When the FDA convened a two-day meeting to discuss the proposed rule, it was trashed by every professional and industry group, including doctors, information publishers, pharmacy trade associations, pharmacists and others.

The objections of trade and professionals associations ultimately held sway in Congress. The FDA was "banned" implement its Med Guide proposal or any other mandate under Public Law 104-180 enacted in 1996. The law directed the Secretary of

Health and Human Services to convene *the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information.* The Steering Committee, with a diverse membership of 34 pharmacy, pharmacist, information publisher, professional and consumer organizations hammered out an Action Plan" for the Secretary in the required 120 days. The Action Plan, somewhat surprisingly, contained content and format criteria that were almost identical to Med Guides and that were accepted by the Secretary.

Private Sector Effort Evaluated in 2001 and Found Wanting:

The FDA, in compliance with the Action Plan and Public Law 104-180 contracted with the National Association of Boards of Pharmacy (NABP) for a national study to assess the usefulness of written information bring distributed to patients. A subcontractor, the University of Wisconsin, Madison School of Pharmacy, conducted a more in-depth evaluation that which relied on professional shoppers to collect the materials and both consumer and expert evaluators to judge the materials based on the criteria recommended in the Action Plan.

I would suggest that despite the somewhat positive tone adopted in FDA's press releases when the study was released, the results of that evaluation in December 2001, provides strong evidence that more than two decades of private sector efforts have fallen considerably short of the Action Plan's goals.

Even though I have some reservations about the way in which the Action Plan criteria were judged by the expert panel (Sid Wolfe talked about some of the problems with the evaluation earlier), the results still to point to serious shortfalls in regard to patient safety. For example, looking at Table 3. in the 2001 evaluation reports, we learn that for all four drugs studied, the mean level of adherence to Action Plan criteria hovered at about 50%. Now I went to school decades ago I would think that getting 50% on an evaluation is still a failing grade. So, what do we know? We know that half of the people getting written information at their community pharmacy are getting information deficient in critical criteria – and I would suggest are placed in harm's way as a result. And, by the way, this is after 25 years of private sector effort!

The FDA's *Drug Safety and Risk Management Advisory Committee* (DsaRM) met one year ago to consider whether, based on the University of Wisconsin evaluation of written information provided in community pharmacies, the private sector had achieved the Year 2001 goal established by the Action Plan. My position at that meeting was, that based on the results of the evaluation, the voluntary, private sector effort had clearly failed to meet the Action Plan's 2001 interim goal. I argued that the FDA, under the authority granted by Public Law 104-180, should take appropriate steps to ensure that the Action Plan's 2006 goal for provision of "useful" written information to consumers would be met. Well as I have already suggested, there is only one responsible action for

the FDA – and that is to enforce the Action Plan criteria and to mandate that written information, meeting the criteria, be dispensed with every prescription.

The last question posed by the FDA:

What other initiatives should FDA consider for providing patients with useful written information about prescription drugs?

Isn't it time to move to unit of use packaging? I can only guess why has this been so strongly resisted in the U.S. healthcare system I would argue that unit of use packaging presents real opportunities for improving patient safety. Moving to unit of use packaging would allow FDA to mandate that drug manufacturers be the responsible party for the provision of "useful" written consumer information by incorporating it with the packaging provided to dispensers. The quality criteria would be evaluated prior to approval so that we get information to consumers that is as close to 100% compliance with the criteria as humanely possible. Unit of use packaging incorporating written consumer information eliminates distribution failures; it standardizes the content and format of information and the information stays with the packaging, and thus the patient, for the full course of the treatment.