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*Comments of Anthony Barraeta, Counsel, Kaiser Permanente  
FDA Regulation of OTC Drug Products Public Hearing  
Docket No. 00N-1256*

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Today's hearing highlights important issues – the appropriate timing of a switch of a drug from prescription to over-the-counter status, and the basis upon which a decision to make a switch should be made.

***Kaiser Permanente and Its Interest***

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An integrated health delivery system, Kaiser Permanente organizes and provides or coordinates its members' care, including preventive care such as well-baby and prenatal care, immunizations, screening diagnostics; hospital and medical services, and internal pharmacy services. Kaiser Permanente serves 8.6 million members in 11 states, including California, Colorado, Georgia, Hawaii, Kansas, Maryland, Missouri, Ohio, Oregon, Virginia and Washington, and the District of Columbia. As a pharmacy provider, Kaiser Permanente fills over 40 million prescriptions for its members annually. Kaiser Permanente spends over \$1.6 billion on prescription drugs annually. Over 90 percent of Kaiser members have a prepaid drug benefit.

Kaiser Permanente's multi-faceted experience – representing medical practice, pharmacy practice, institutional health care services and serving as the financing entity for health care coverage – places it in a unique position to examine marketplace dynamics in the pharmaceutical industry. In addition, as the organization responsible for collecting member dues and delivering care, Kaiser Permanente must concern itself with the need to assure that member's resources are used in as effective a manner as possible. Combining our concern with high quality care with the need to assure affordable cost leads to an acute interest in market anomalies that exist.

The significant delay in prescription-to-OTC switches in some cases, and the curious timing in others, causes us to question whether these decisions are being made with an eye to good health and economic value for patients and consumers. We believe that it is critical that FDA considers these concerns in its role overseeing these processes.

When it comes to considering prescription-to-OTC switches, Kaiser Permanente believes that the fundamental concerns of the FDA should be prioritized in the interest of patients and consumers. The first concern should be the question of clinical safety. Second, FDA should consider maximizing the quality of care by assuring that an appropriate level of quality of care can be met. Third, the economic interests of consumers, both individually and collectively, should take a primacy over the economic interests of the sponsor. As a result, the process by which Rx-to-OTC switches are considered should not be driven by sponsor requests. While the sponsor likely has much of the data that could inform a

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switch, FDA need not, and should not, wait until the sponsor requests a switch in status before it contemplates determining whether one is in consumers' best interest.

### *Clinical Safety and Access*

For diseases and medical conditions that now have drugs on the OTC market, the key question should be the relative safety of a new candidate for treatment of the same condition compared to existing drugs already on the OTC market. While a variety of drugs could be examined, the less-sedating antihistamines are the obvious examples here. Already, more sedating alternatives have been switched to OTC status. Manufacturers of less-sedating antihistamines have promoted a favorable safety profile based on the question of sedation. That many other countries, presumably at the sponsors' request, have made the newer drugs available without a prescription should provide some information about whether such drugs as these can be switched to OTC status.

In anticipation of this hearing, our drug information staff in Downey and Oakland, California reviewed records of adverse drug reactions maintained within our Program in California. We learned that during a study period from January 1, 1998 to April 30, 2000, adverse drug reactions may have occurred in 12 patients out of 5866 patients taking less-sedating antihistamines and no other drugs, representing 10,036 patients months of therapy. This works out to one report per 836 months of therapy. Less systematically, we surveyed our physician chiefs of allergy in Northern California for their experiences with patients taking less-sedating antihistamines. They have uniformly reported few, if any, significant adverse drug reactions, and expressed a high level of comfort in the possibility that these drugs might be made available as OTC therapies in the near future.

### *Monitoring*

Considering access and consumer economic benefit, relieving patients of the need to see a physician to obtain a prescription to have access to a drug clearly makes more sense in some cases than others. An important consideration should be whether the drug is for treatment of a condition that requires ongoing monitoring, or drugs that require some ongoing monitoring of toxicity. In a case like the cholesterol lowering drugs, some of which call for liver function testing at the outset of treatment, there is a real question about whether patients can safely self-treat with those drugs. Because cholesterol lowering effect is dose related, at higher doses the potential for toxicity is increased. Opinions of physicians practicing in the Permanente Medical Groups vary on whether or not these drugs should be made OTC.

In other cases, requiring a prescription does provide a level of monitoring that a patient will be seen periodically by a qualified practitioner. We strongly recommend that FDA consult with a wide range of practicing physician experts before taking steps to switch to OTC status a drug that is used to treat a condition that physicians believe ought to be

continuously monitored. There may well be additional methods (besides taking advantage of the prescription requirement) to encourage patients to be seen regularly, but these should be understood in advance.

We would be happy to serve as a resource to FDA for on-the-ground physician expert opinions as FDA considers whether to switch drugs to OTC status.

### ***Economic Considerations***

We can only assume that the product sponsors have elected not to seek to switch the less-sedating antihistamines to OTC status because they have determined that it is not in their economic interest to do so. Prescription status dictates that the physician prescriber ultimately selects the drug. In addition, a majority of Americans today have a prescription drug benefit. The confluence of these factors means that sponsors find it more profitable to compete on detailing and name recognition than on price. With the explosion of direct-to-consumer advertising in these products, we have a sponsor's dream – induced demand as a result of third party payment, and competition on brand-recognition advertising, not quality or price. It is more than just a curiosity that the timing of many sponsor efforts to switch a drug from prescription to OTC status coincides with the pending expiration of market exclusivity, and the manufacturer perceives greater potential profitability in a brand-focused OTC market than a generic prescription market. This should not be the primary motivation of Rx-to-OTC switches.

### ***Effect on Third Party Coverage***

More frequent prescription-to-OTC switches raise a secondary, but important, consumer question. Most drug coverage plans do not cover over-the-counter drugs other than insulin. Kaiser Permanente has a somewhat more liberal approach, covering OTCs when they are listed on the formulary and are prescribed by a plan physician. This is similar to the practice in some other countries, such as New Zealand, which does subsidize less-sedating antihistamines that are already available OTC under its reference pricing scheme. Competition drives prices lower and access could be enhanced if plans could elect to cover OTCs when they determined it to be sensible.

Consumers' economic interests flow from the dual roles that consumers play in the U.S. health care system. They both use drugs and ultimately subsidize drug coverage through insurance premiums, state or federal taxes or reduced wages in exchange for employer – sponsored health insurance. Third party payers directly subsidize drug coverage and manage drug benefits for consumers. These groups should be able to work out whether prepaying for drugs through a social insurance system is more cost-effective than paying at the point of sale, particularly when price competition is likely to be much more powerful (and prices therefore lower) in an OTC environment. As it stands today, however, these determinations rest nearly exclusively in the hands of the product sponsor

because they are the ones who determine whether or not a drug should be marketed as an OTC.

In some cases, aggregate consumer benefit may best be achieved by having less coverage than currently exists in some categories. This is likely to be true when a drug is targeted by sponsors to treat very large populations of potential patients and heavily marketed like any other consumer product. In other cases, particularly for serious conditions that afflict narrower populations, continued coverage makes more sense from an insurance standpoint. In addition, plans are likely to seek to continue coverage of "prescribed OTCs" when one therapy is OTC and other, more expensive but medically unnecessary therapies are available only by prescription.

### *Conclusion*

We recommend that no single test of appropriateness for OTC switching be maintained, as each condition and each therapy are likely to raise specific concerns. The existing standards the FDA applies with regard to safety seem fairly well focused on addressing the clinical issues that do exist. The fundamental question is how proactive should FDA be in assessing whether or not a therapy should be switched to OTC status. Our view is that this should be a continuous process, whether or not a sponsor's petition is before the FDA, assessing whether consumer and patient needs can best be met by expanding access to OTC drugs.

Once a disease or medical condition has been determined to be amenable to self-diagnosis and treatment by patients, and a drug has been approved for OTC marketing, the question whether another drug with similar characteristics should be switched to OTC status should rest primarily on the relative risk and safety profile compared to the existing OTC drug. This is particularly relevant in the case of the less-sedating antihistamines.

Thank you for your consideration of Kaiser Permanente's views.