BY STEPHEN J. HELLEBUSCH

Switching: Toward a Process

Introduction

It may be possible that, working together, industry professionals and the professionals at the Food and Drug Administration (FDA) can outline a process flexible enough to be useful in nearly all prescription-to-nonprescription switch situations.

Background

At a breakout session on techniques for predicting consumer behavior during the November 2000 joint Consumer Healthcare Products Association (CHPA)-FDA Conference, Steven L. Burton with what is now GlaxoSmithKline presented a flow chart, which described four steps in the prescription-to-nonprescription switch process:

1. Identify the target;
2. Develop and test communications;
3. Develop label comprehension; and
4. Conduct actual use study/real world simulation.

The Process

The idea of a flow chart to map the switch process is intriguing. After some thought, a more elaborate description of the process was developed. The main decision maker, driving this process, is envisioned as an internal switch team, typically made up of professionals from medical, drug regulatory and marketing, bringing in the subspecialties most appropriate to the proposed switch candidate. Often, the team will include outside consultants as well, typically from the clinical research discipline.

Ovals in the flow chart diagrams represent beginning and ending points. The rectangles represent work to be completed. The entire process begins with an understanding of the need that exists in the environment and the thought that the switch of a specific product may be able to address that need. It is also acknowledged that part of this need will be to demonstrate to FDA and an FDA Advisory Committee that the solution is necessary and viable. To speak to the process, each row in the flow chart will be examined separately.

Figure 1
Rx-to-OTC Switch Process—Part I

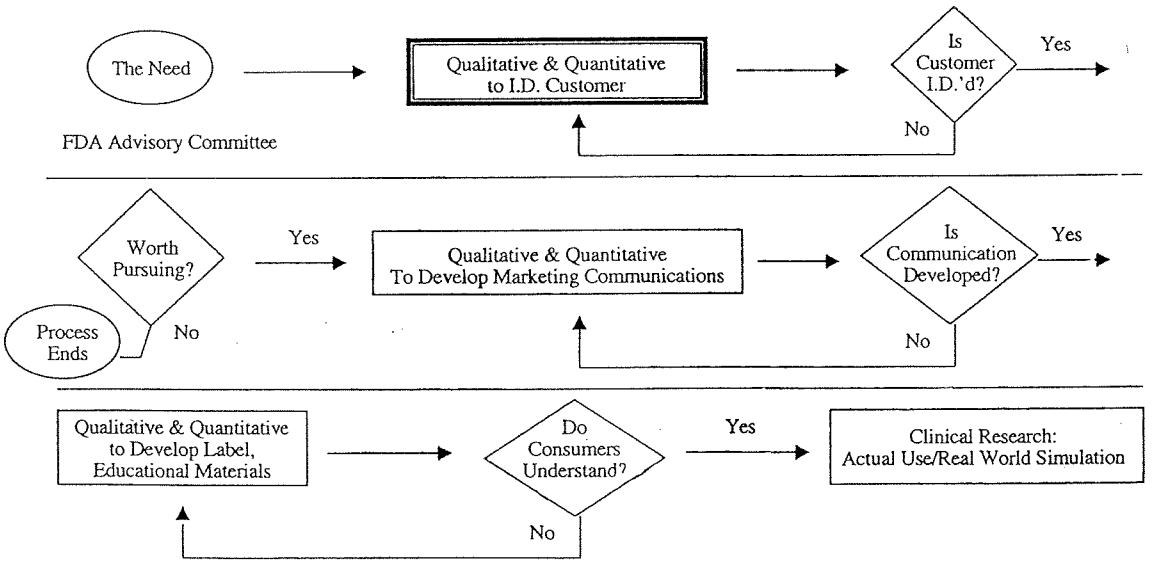


Figure 2
Rx-to-OTC Switch Process—Part II

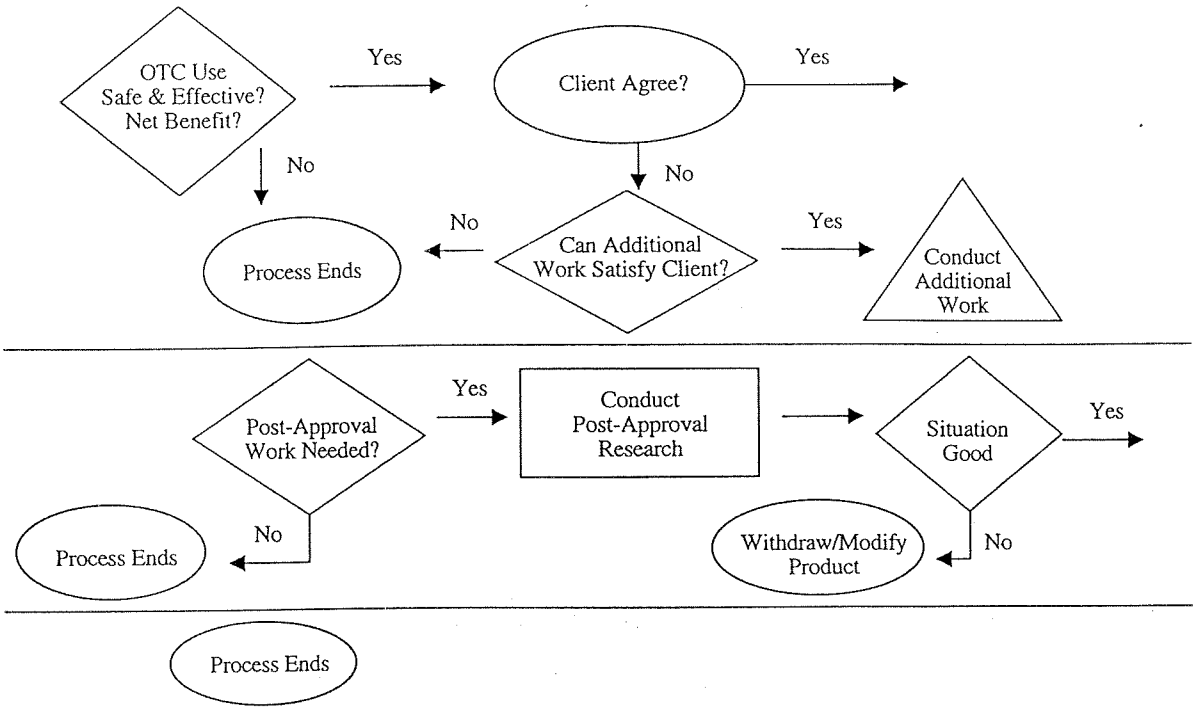
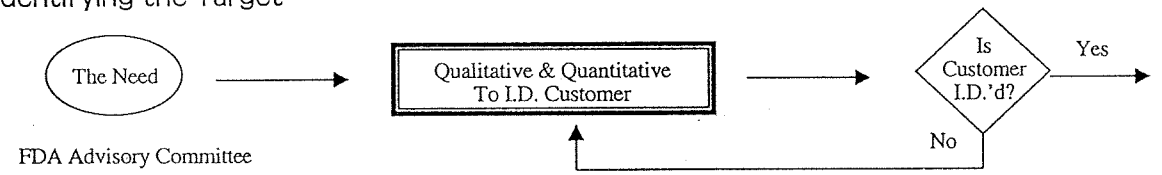


Figure 3
Identifying the Target



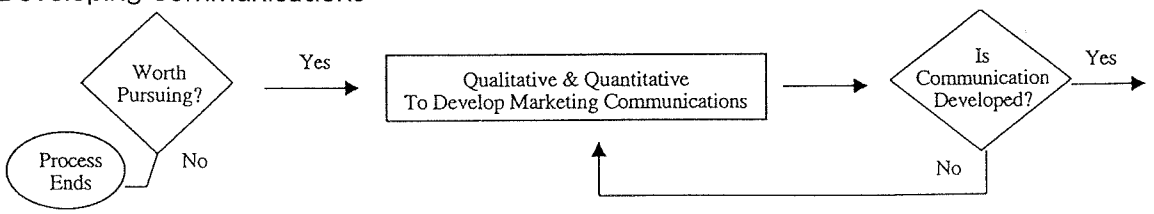
The first step in addressing this need is to identify the target audience. This need is typically met using qualitative and quantitative consumer behavioral research (also known as marketing research).

Diamonds in the diagrams represent decision points. If after conducting several projects, the switch team agrees that the target has been identified, the process continues. If the target is not yet adequately identified, additional research is conducted until it is.

Once the target is identified, the switch team must make a purely internal decision. Is the target worth pursuing? Pharmaceutical companies are businesses and this question must be asked from a strictly business perspective. For one of the earliest potential switches I was involved in, the answer at this stage was "no" and the process ended, as it should have.

If after identifying the target, the decision is that the switch is worthwhile, the research begins to develop

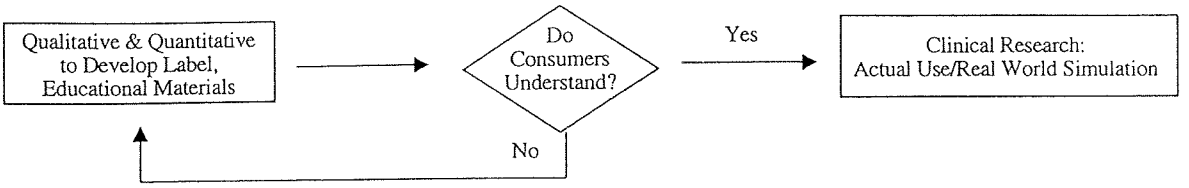
Figure 4
Developing Communications



marketing communications to the target. Typically, this research attempts to determine how to present the product to the target market accurately and in the most positive light to stimulate interest. At some point, the team decides that these communications are as sound as possible and the process continues.

If the available data lead to the judgment that the answer to both of these questions is "yes," the process moves to the next stage. If the answer to either of these questions is "no," the process stops. There is no possibility of continuing under the condition where safety and efficacy cannot be maintained, or there is no public

Figure 5
Develop Labeling, Educational Materials



The next steps are the ones typically presented to FDA and discussed in the Advisory Committee meetings. Having developed advertising and promotional communications, labeling and educational communications are developed using iterative consumer research. The work continues until the switch team judges that the answer is "yes," consumers understand, at which point the process moves to the acid test, an Actual Use Clinical Study.

The switch team uses all of the efforts completed by this time to make two very important decisions:

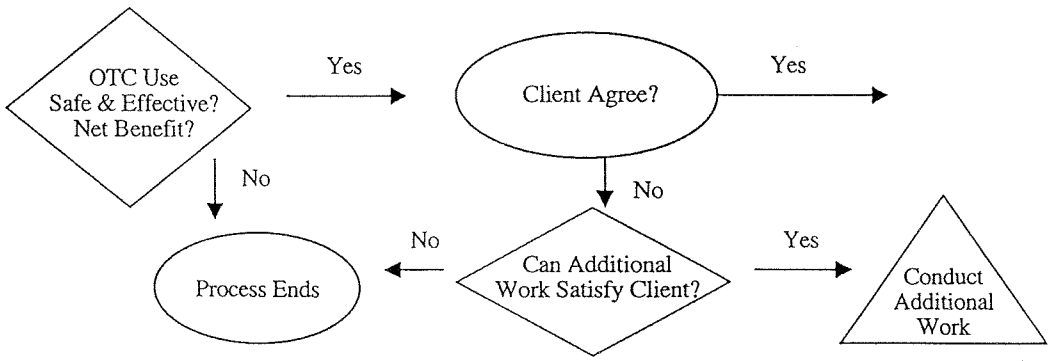
1. Can consumers use this product without a prescription, maintaining safety and efficacy?
2. Is it likely that there is a net public health benefit from switching this product?

health benefit, unless it is to conduct additional work to verify these conclusions. In that case, if additional research indicates that the answers to both questions are "yes," the process picks up again from this point.

The same steps can occur again within this part of the process. If the answer to both questions is "yes," the next step is to present the information to the client, FDA and its Advisory Committee. The client independently addresses the same two questions. If the client agrees with the switch team's assessment, the process continues. If it does not, another decision point arises. This is the point that Pravachol and Mevacor are at right now.

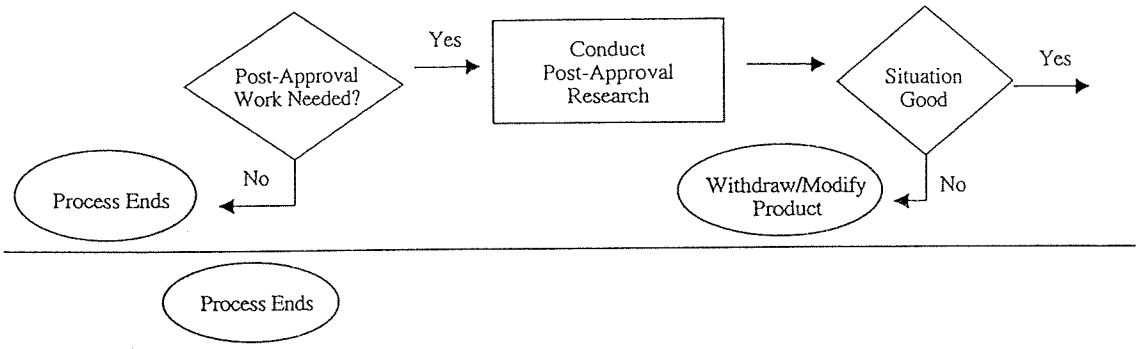
In this circumstance, the switch team must now decide whether it is possible that additional work can

Figure 6
Summarizing Rationale



satisfy the client. If the answer is "yes," additional work is conducted and a mini-process (not shown on the diagram) takes place. If that work is judged sufficient by the switch team, it is presented to the client; if it is not adequate, the process stops.

Figure 7
Post-Approval



If the Advisory Committee and FDA agree that the product can be used safely and effectively without a prescription and that having it available over-the-counter creates a net public health benefit, then a switch is usually imminent. The only other decision to be made, usually prior to approval, is shown in the last row of the flow chart—will any post-approval work be needed? Typically, post-approval work occurs when the judgment is that there will be a net public health benefit, but there is some degree of uncertainty, and additional data are needed. If no post-approval work is needed, the process ends with a successful switch.

If post-approval work is needed, it will be undertaken and evaluated at some point. Typically, consumer research is used to verify expectations. An example of a situation where post-approval research was required was the nicotine replacement products. After that work was conducted, the final decision was that the situation was good—a net public health benefit did result from these switches. There has not yet been a case where a product has gone through this process and then withdrawn, when post-approval research demonstrated that there were difficulties of some kind. Presumably, the product would need to be modified or withdrawn from the market should this occur.

Summary

There is a logical series of steps and decisions to be made in switching a product from prescription to nonprescription status. These steps can be diagrammed in flow chart fashion, and with communication among professionals who contribute to the flow chart the process can be improved.

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