

## **Panel # 7: Class Actions as an Alternative to Regulation: The Unique Challenges Presented by Multiple Enforcers and Follow-On Lawsuits**

Most companies that manufacture, market and sell products are regulated by one or more governmental agencies. These comments will focus on the regulation of pharmaceutical and health care companies by the Food and Drug Administration (FDA) and the potential for erosion of that regulation by class action lawsuits and investigatory actions initiated by state and federal enforcement agencies. Issues surrounding Direct to Consumer (DTC) advertising will be used to illustrate the very real shift from true regulation to “regulation by litigation.”

### **Direct to Consumer Advertising: A Prime Example of the Problem**

Direct to consumer advertising is regulated by the FDA through regulations addressing the content, review and approval process for communications to consumers regarding pharmaceutical and health care products. At the core of those regulations is the concept that DTC advertising must be accurate, truthful and not misleading. The FDA staff charged with reviewing DTC advertising are well equipped to consider the complex scientific questions relating to a particular product’s safety and efficacy, and how such information should appropriately be communicated to consumers. The FDA has a wide array of enforcement powers over DTC advertising and has not been reluctant to require corrective advertising, or even withdrawal of an advertisement, where appropriate.

Pharmaceutical and health care companies have a strong incentive to respond to the FDA’s concerns about DTC advertising – to do otherwise would be in contravention of their patient focused missions. Intense competition among these companies acts as an additional regulatory force. Companies can work within the regulatory framework to monitor DTC advertising by, for example, alerting the FDA’s attention to specific aspects of their competitors’ advertising believed to be inaccurate. The FDA’s regulation of DTC advertising is also enhanced by the relationship between patients and the physicians and pharmacists who serve as important intermediaries with respect to health care information. Pharmaceutical companies should, and do, emphasize in their DTC advertising that patients must see their physicians to determine whether or not a particular product is right for them. Any questions or concerns about the content of DTC advertising can be addressed through the direct relationship between physician and patient.

Proponents of DTC advertising note that it provides consumers with basic information about diseases and potentially dangerous health conditions, calls their attention to potential treatment options, and encourages them to consult with their physicians. Opponents, however, argue that DTC advertising actually interferes with the physician patient relationship, encourages consumers to take unnecessary prescription drugs and leads to an increase in the cost of health care. Increasingly, these arguments are made in the context of class action lawsuits and/or become the central theme of government investigations.

## **Regulation through Litigation and Investigation**

During the past few years, *bona fide* regulatory attention to a particular DTC advertising issue has often spawned a series of lawsuits and/or investigations by those less well equipped to consider, and perhaps more importantly, make decisions about, complex scientific issues. For example, an FDA decision to require withdrawal of DTC advertising with respect to a particular product, is often followed by one or more state attorney general investigations and by class action lawsuits brought under broadly written state consumer protection laws by those purporting to represent the citizens of a state. Termed “regulation by litigation”, such actions often produce contradictory outcomes, do little to actually protect consumers, and may actually create an unsustainable patchwork of legal requirements that undermine the FDA regulatory scheme.

What is wrong with regulation through litigation or government investigation? First, it has not been the role of private plaintiffs’ attorneys nor the state attorneys general to develop science-based regulatory standards or to apply and enforce them. Both groups work in the adversarial arena where the ultimate outcome of an issue in controversy is often informed by only that information which is culled together to reach a specific goal. That process has little to do with regulation. Although experts may be employed to inform the process, particularly in lawsuits, the inherent need to support a specific outcome is not conducive to reaching a result without bias.

Second, the disparate outcomes of investigations and class action lawsuits creates confusion in the regulatory process. As one commentator has explained:

[I]t is federal law that governs what drug information gets disclosed, to whom, and at what point in time. And for good reason. This country decided long ago that it was better to have a single agency distributing uniform drug info than to have 50 state attorneys general (and their tort-law retinue) with varied political agendas sending out conflicting safety messages<sup>1</sup>.

If risk information is developed jurisdiction by jurisdiction with individual juries setting industry standards, or state by state through consent decrees, confusion will reign and consumers actually will be less well protected.

Finally, conflicting legal requirements will increase costs to the pharmaceutical and health care companies, and ultimately to consumers. Companies forced to comply with a myriad of rules developed through litigation and investigations must cover the cost of compliance. That means diverting funds from valuable research and development efforts and/or passing such costs along to consumers.

## **How Do We Address These Problems?**

Support the roles of existing regulators. Courts should discourage regulation through litigation by enforcing the federal preemption doctrine and accepting the

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<sup>1</sup> Editorial, *Paxil Man*, Wall St. J., June 21, 2004, at A16.

regulatory compliance defense thereby reinforcing the FDA's role as primary regulator. Before initiating, or accepting, an action intended to detect or pursue a suspected violation of the law, state attorneys general and courts should evaluate whether or not a regulatory agency has already appropriately considered an issue. Additionally, courts should recognize that the rule making process is superior to litigation in addressing issues of public concern. All sides have an opportunity to comment and the agency is not forced to choose between only two sides. The result is a level playing field where all companies must abide by regulations as opposed to complying with the inherently random outcomes of the litigation process.

Class actions in federal court. The repeated education of judges and juries, regarding scientific and technical issues, in state court class actions is inefficient and expensive. Such costs can be minimized if those actions are brought in the federal courts already grounded in the application of federal laws and regulations. Although the Class Action Fairness Act appears unlikely to make it to the Senate this year, the bill's goal of allowing more class actions to be brought in federal court would help alleviate the duplicative costs associated with state court class actions.

Encourage early disposition of class actions. Duplicative class action litigation will still take place, however, putative class actions that fail either on their merits or because they are inappropriate for class treatment should be disposed of quickly. Recent changes to Federal Rule 23 will be effective in minimizing the costs of such suits if those rules are correctly applied.

Limit attorneys' fees in follow-on class actions. Follow-on class actions create unnecessary procedural costs and reduce any class recovery of damages by the application of attorneys' fees. Compensation for class counsel is rolled into class action awards and is often obtained at the expense of the lawyers' own clients. Those fees may be justified where the plaintiffs' bar contributes to monitoring and enforcing compliance with the law. However, by definition, follow-on class actions do not qualify since the appropriate governmental agency already has acted to address an alleged violation of the law. Courts should consider that factor when evaluating attorneys' fees in follow-on actions.

## **Conclusion**

The problems created by attempts to "regulate" DTC advertising through litigation and investigation have been set forth to illustrate the point that the best way to protect consumer interests is through FDA regulation and enforcement. Follow-on actions have only served to detract from that process and, if allowed to proceed unfettered, will undermine the effectiveness of an existing and evolving regulatory scheme.