A new upcoming U.S. Supreme Court decision and a new report by Congress will be setting the stage for congressional attention to federal drug-labeling rules. Having given the Food and Drug Administration (FDA) new authority in 2006 to force drug-labeling changes quickly as part of the FDA Amendments Act (FDAAA), it is becoming clear that the House and Senate will have to review the matter again, this time with a sharper, Democratic-edged shovel. Ideas that were excluded from the FDAAA because of opposition by Republicans and the Bush administration are likely to be revisited and approved. These actions include allowing consumers to sue pharmaceutical companies in state courts over drug labels.

A major concern in the Supreme Court case is whether Wyeth Pharmaceuticals should have changed the label on its anti-nausea drug Phenergan (promethazine) without the FDA's approval. The FDA currently has a “changes being effected” (CBE) labeling regulation—21 C.F.R. §314.70(c)—that specifies when drug manufacturers can make quick changes to labels, such as strengthening safety language, without the agency’s prior approval. That CBE rule was the subject of a scathing report from Representative Henry Waxman (D-Calif.) in late October and was a side issue in a Supreme Court decision and a new report by Congress, which also touches on the pre-emption matter.

The report issued by Representative Waxman’s House Oversight and Investigations Committee in late October argued that the FDA had recently restricted CBE authority twice—one time as part of the 2006 Physician Labeling Rule and a second time in a CBE rule issued in August 2008. The Waxman report was controversial because it said that top FDA officials in career safety and drug evaluation and research (CDER), who sent comments to Jane Axelrad, JD, Associate Director for Policy in CDER. On May 22, 2003, as the pre-emption policy was being developed, Dr. Jenkins wrote:

The premise of the basis for much of the argument for why we are proposing to invoke preemption seems to be based on a false assumption that the FDA approved labeling is fully accurate and up-to-date in a real time basis. We know that such an assumption is false.

Both the Supreme Court case and the Waxman report underscore the necessity for pharmacists to scrutinize label instructions, even with drugs like promethazine, which has been around since the 1950s. Pharmacists should be aware of any controversies relating to the adverse effects of particular drugs or to information that might not be reflected in the labeling, such as the IV-push method used with promethazine.