A mammoth bill that Congress was expected to pass this month gives the FDA more authority to combat drug shortages, although skeptics may argue that the new muscle probably won’t win any flexing contests. Shortages of drugs, especially chemotherapy agents, have been a growing problem for over a decade.

The new authority is contained in separate bills that were passed by the House of Representatives and the Senate in May. These bills extend the Prescription Drug User Fee Act (PDUFA), whose authority runs out on September 30, 2012. Wrapped around that PDUFA extension are new user-fee programs for generic drugs and biosimilars and many other expansions of FDA authority in a number of areas. One of those expansions allows the FDA to require information from drug manufacturers when they realize that they are about to run out of specific categories of drugs, either permanently or temporarily.

The FDA has already made many of the changes anticipated by the PDUFA reauthorization bill. In December 2011, the FDA published an interim final rule that, among other things, expanded reporting beyond permanent manufacturing stoppages to temporary ones. The agency followed up in February 2012 with a draft guidance defining some of the terms it used in that interim final rule.

For example, the FDA’s reporting requirement applies only to “sole” manufacturers, but some companies have been confused about what constitutes a “sole” manufacturer. The interim final rule clarified that “sole” does not mean the sole holder of an approved New Drug Application (NDA) or an Abbreviated NDA (ANDA). Therefore, a drug company cannot rely on the Orange Book as the source for determining whether it is a sole manufacturer; instead, the manufacturer must rely on commercial data.

Neither the House nor the Senate bill goes very far beyond what the FDA is already doing, nor does either chamber go much beyond a requirement to report shortages. Both bills appear to apply to all manufacturers, not just sole manufacturers. The Senate bill, for example, says that a temporary manufacturing stoppage must lead to a “meaningful disruption” before the company is required to make a report. This term is defined as “reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and impacts the ability of the manufacturer to fill orders or meet expected demand for its product.” This definition leaves considerable discretion for manufacturers.

Currently, the FDA reporting requirement applies to manufacturers of life-sustaining, life-sustaining, and debilitating disease-preventing drugs. The House bill maintains these three categories, but the Senate bill adds two more categories: sterile injectable products and drugs used during emergency medical care or surgery. A 2011 FDA report said that of the 127 drugs in short supply that the agency looked at in 2010–2011, sterile injectables accounted for the majority (80%).

The major therapeutic drug classes in short supply included oncology agents (28%), antibiotics (13%), and electrolyte/nutrition medications (11%).

A permanent manufacturing discontinuation of a product must be reported at least 6 months before the date of the discontinuance. If 6 months’ notice is not possible, the manufacturer must notify the FDA as soon as practicable. When a shortage is reported, both House and Senate bills give the FDA new authority to approve alternative drugs more quickly or to expedite the inspection or re-inspection of a company’s premises. These steps might help mitigate or prevent a drug shortage.

Regardless of how the slightly differing House and Senate provisions are combined in a final bill, the legislation will not include provisions to prevent drug shortages. Neither bill forces a company to make a more thorough approach to risk management in order to prevent shortages, even though internal corporate manufacturing problems—as opposed to foreseeable manufacturing discontinuations—are as much a cause of the problem as anything else.

Nor will the final bill do anything to force manufacturers to conduct better contingency planning. According to the FDA, in an analysis of 127 drug shortages between January 1, 2010, and August 26, 2011, approximately 60% of the shortages were caused by circumstances that perhaps could have been avoided or limited if the manufacturer had undertaken enhanced redundancy or contingency planning.

The legislation does not incorporate changes that have been supported by many hospital executives. For example, during hearings in a House subcommittee last September, Mike Alkire, Chief Operating Office of the Premier Healthcare Alliance, advocated giving the Drug Enforcement Administration (DEA) more flexibility to modify or transfer quotas among manufacturers when a company stops producing a drug that contains a controlled substance. That provision is not included in either bill. It is unclear whether a final bill would require the reporting of anticipated shortages of biologics. Importantly, neither the House nor the Senate bill gives the FDA the authority to enforce its reporting rules—authority it now lacks.

Extending the reporting requirement to sterile injectables, as the Senate bill does, would mitigate some shortages. It will be interesting to see whether that provision makes it into the final bill. Still, a lot of provisions that were never considered would have given the FDA much more muscle.