Laboratory Variability and Precise Clinical Decision Making

C-reactive protein levels are used as a criterion for initiating statin therapy and are also included in some risk scores for predicting cardiac events. It is sobering to learn from this report that there is so much intrapatient variability with the test: one-third of patients with a high value will have a normal value if the test is repeated soon afterward. Clinical decisions and risk prediction should be made based on at least 2 similar CRP levels.

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What Is More Valuable: Fenofibrate Patents or Fenofibrate Clinical Outcomes?

Dowing et al1 present the opinion that Abbott’s various brands of fenofibrate and fenofibric acid inappropriately manipulated the patent and drug approval process to protect brand profits. However, it is likely that Abbott would have provided substantial confidential rebates and discounts for its various branded fenofibrate products to maintain favorable formulary status and market share. Absent this and other confidential trial document information, it is impossible to know if and how much consumers were actually harmed by Abbott’s alleged behavior.

It is up to the courts (with the benefit of full evidentiary discovery) to decide whether brand product manufacturers have overstepped the limits in this and other similar cases. Brand manufacturers will use all sorts of defensive patents and legal strategies to restrict the launch and/or success of generic competitors as long as the expected benefits of such legal strategies exceed their expected costs. Each month of additional patent life can mean millions or tens of millions of additional dollars to the brand.

More regulation will only create more loopholes. The best solution is for informed consumers (eg, pharmacy and therapeutics [P&T] committees and payers) to be more aggressive in restricting brand product formulary status when there are no health benefits shown in the scientific literature for specific branded products or patent line extensions. Why did not more P&T committees use formulary restrictions and copayments to keep patients on earlier generic versions of fenofibrate products if the newer branded versions had no meaningful additional clinical benefits? Additional government regulation is not needed to protect P&T committees from themselves.