

Commercialization Insight

Drugs and Biologics: In Between a Rock and Hard Place

Quick; is the answer \$1.3B or \$59M?

The frequently quoted number of \$1B plus for a branded new drug to be brought to market has been challenged by a new study in the *Journal of Health Economics* that claims the true cost is more like \$59M, moving much of the attributed cost to government and academic research resource investments, along with the unrecoverable costs associated with research and development into drugs that were not approved.

PCORI begins its work in earnest in 2011.

The Patient-Centered Outcomes Research Institute (PCORI) is the new institution created as part of last year's healthcare reform legislation, designed to fund studies that compare the effectiveness of drugs, devices, and methods of care to help policy makers, care providers, and patients make more informed decisions about treatment alternatives. In January the organization announced the membership of its Methodology Committee, comprised of academics, comparative effectiveness research groups, and physicians.

Anson Insight: *The changing dynamics of the pharmaceutical industry have done nothing to dissuade criticism from outside the industry that its costs are exaggerated and that its large profit margins is a major contributing factor to the unsustainable increase in healthcare expenditures in the US and other developed countries.*

However, those criticisms, which are nothing new, may seem mild compared to what may unfold from the still to be defined PCORI comparative effectiveness studies and outcomes based payment models that will replace the 40 year old transactional business model. Reducing the risk factors and time associated with drug development processes will become increasingly critical as Pharma is pressed from both sides, even as internal resources allocated to these efforts continue to diminish.

Compliance Insight

9,910 Form 483 Inspection Observations issued by FDA in 2010.

The activity level in field inspection and enforcement has increased significantly since Dr. Margaret Hamburg took office in 2009. These observations, if not dealt with in a timely and thorough manner, can lead to actual Warning Letters from FDA that site specific regulation violations and which demand more immediate action and raise the level of potential enforcement action by the agency.

Anson Insight: *In 2011 we advise our clients to prepare for increased scrutiny and activity level from FDA, with inspections and the possibility of 483 observations not likely to decrease from 2010 levels. Proactive measures that result from good quality systems, which help uncover issues before an inspection does, are always the best approach. However, if a company does receive a 483 observation, we also encourage you take it seriously, even if the problem is perceived internally to be somewhat minor. Failure to address observations lead to Warning Letters, which are taking an interesting twist of their own.....*

FTC and FDA Joint Warning Letters Tag Team

In what appears to be a relatively recent phenomenon, companies are now receiving warnings that bear the seal of both the Federal Trade Commission and Food & Drug Administration. These Warning Letters cite potential violations of both the FD&C Act and the FTC Act, ratcheting up compliance and legal costs associated with taking corrective actions to avoid even worse consequences.

Anson Insight: *Generally speaking, more cooperation between federal agencies is considered a good thing. Frequent public filings from industry state something to this effect to just about every proposed notice of rule-making published in the Federal Register, and certainly in public meetings on topics of a regulatory nature. As part of our work in mobile health care, Anson has filed similar documents praising and encouraging cooperation like that between the FCC and FDA, which signed an MOU last July between those two agencies, and for one between CMS and FDA regarding their pilot effort to combine safety and efficacy submissions and Medicare/Medicaid reimbursement reviews.*

However, like all things there are "unintended consequences". Perhaps we may end up regretting encouraging FTC and FDA to coordinate their oversight of healthcare product promotions; at the very least companies will need to be even more rigorous in reviewing their intended use materials and product claims.

Tracking Changes Insight

CDRH goes on the offensive to drive change in 2011

In the world of medical technology regulation, most often we are left anticipating long awaited change for long periods of time. In 2011, at least in regards to the FDA center responsible for medical device regulation this is not the case. Instead, we are all a bit taken aback by the pace of change coming out of CDRH just since the beginning of the new year. The Center announced three highly visible actions within a total of about a three week period.

1. The CDRH Plan of Action for 510(k) and Science
2. The CDRH Innovation Initiative
3. The Medical Device Data System (MDDS) Final Rule

All of these announcements are in response to the unyielding criticism of the FDA's current regulatory policies applied to medical devices. The industry and venture capital communities charge the agency with driving innovation off-shore and stifling growth, jobs, and innovation, while patient groups and some providers accuse the agency of being too lax in its review and monitoring of new and existing products and for being too close to industry.

Anson Insight: *The FDA is struggling right now, caught in the politics between a Republican House of Representatives and a Democratic Administration, between patient advocacy groups and industry, and facing a surge of new entrants to medical technology from outside traditional drug and device companies who already know the rules and what's expected, even if not always executing them to the agency's liking. Like anything or anyone pressed into a corner, this raises the risk of reactive response that is unfavorable and perhaps dangerous for those in proximity to the reaction. Anson advises our clients to pay close attention to current developments, particularly in CDRH, and adjust compliance efforts appropriately to mitigate risk as the world continues to change rapidly for both regulated and regulator.*