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Revisiting the CVR: The Litigation Crucible

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In January 2016 we published an article touting the potential of contingent value rights ("CVRs") as tools for bridging valuation gaps in life sciences M&A transactions. In that article, however, we also tempered our enthusiasm by noting the not-insignificant risk posed by CVRs and earn-outs generally. In order to mitigate these risks, our article urged parties using CVRs to: *keep it collective, keep it nontransferable, keep it transparent, and keep it simple*. We will expand here upon the virtues of transparency and simplicity in light of recent CVR/earn-out litigation in New York and Delaware.[1]

Make Your Efforts Transparent

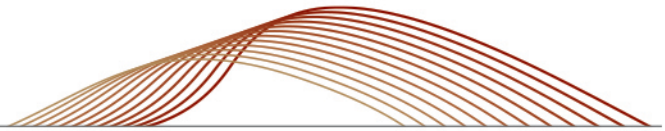
Transparency has played a significant role in the high-profile lawsuit between Sanofi and Genzyme's selling shareholders. Sanofi issued a CVR when it acquired Genzyme that would pay shareholders an additional $3.4 billion if the drug Lemtrada received FDA approval by March 31, 2014. In its CVR agreement, Sanofi agreed to exercise "diligent efforts" in reaching this milestone. However, when March 2014 passed without regulatory approval, the selling shareholders brought a claim in federal district court in New York, arguing that Sanofi violated the efforts covenant. In September 2016, the court denied Sanofi's motion to dismiss. While Sanofi's *actions* (or lack thereof) were key to the court's decision, the CVR's terms are the principal driver behind Sanofi's troubles.

Sanofi's CVR agreement defined "diligent efforts" as "using such efforts and employing such resources normally used by Persons in the pharmaceutical business . . . ." Exactly what efforts and resources would satisfy that standard is the subject of the ongoing litigation.

Although there is a long history in CVR and earn-out transactions of using "reasonable efforts" or similar standards, buyers may want to consider whether there are more concrete ways to codify efforts obligation. For example, a buyer could specify a floor, measured in dollars or percentages of time, revenue, labor, or capital resources, that the buyer must exceed in working toward a milestone. Another example could be the use of agreed upon budgets. A buyer with a reasonable amount of visibility into the first couple of years of a program could agree to a budget that would be expended on the program in the early years. Then, once that budget has been expended, and the buyer is therefore more financially invested, the seller's comfort regarding buyer's further efforts would come solely from the mutually aligned interests of the parties.

Make Your Milestones Boulders

A review of publicly available CVR agreements shows them to be replete with milestones turning on often undefined terms such as "efficacy," "front-line," "major market," and "successful conclusion." While such terms certainly have meaning under the Federal Food, Drug, and Cosmetic Act (the "Act"),



or to regulatory experts generally, they also come with a high degree of question begging when it comes time to pay out on the CVR. For example, since 1962, the Act has required that manufacturers of drug products establish a drug's effectiveness by "substantial evidence," which is further defined by the Act as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." This is fairly clear language as far as Congressional statutes go, and yet it has led to four plus decades of discussions (to put it politely) regarding the quantity and quality of the evidence needed to establish effectiveness. By using such terminology in a private agreement, without giving it further definition or context, the parties run the risk of importing the baggage of a 45 year regulatory debate into their contract. Indeed, disputes have arisen in the CVR context on the precise point that has been the fulcrum of the debate: whether efficacy is shown by the data measured at the end of a single clinical trial, at some point in the middle of a clinical trial, or whether it encompasses data from multiple clinical trials.

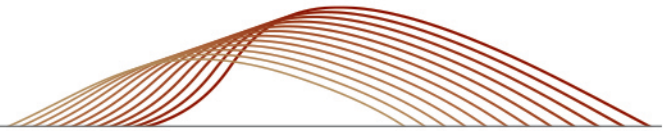
In one case pending before the Delaware Chancery the acquirer agreed to pay the target's selling shareholders additional compensation upon its principal product achieving certain developmental milestones. The shareholders have claimed that one such milestone—achieving "front-line" treatment status—was triggered in September 2014, when the European Union approved the product for treatment in a certain sub-population of patients. This sub-population expresses a rare genetic mutation that makes it unable to receive any other treatment. Given the apparently limited scope of the EU's approval, acquirer has refused to pay, arguing it was never the parties' intention to provide compensation for the product becoming an approved treatment in a sub-population for whom no other treatment will work. Rather, the acquirer argues the product was designed to treat the general population and that paying the shareholders additional compensation for its approval in this one small population would be like awarding them a default prize. On their part, the shareholders have argued that their agreement with the acquirer did not carve out regulatory approvals for treatment in sub-populations.

It seems to us the trouble in the disputes we have surveyed was not the words the parties used to define their milestones, but rather that the parties chose milestones that were hard to define or relied on so-called terms of art for their interpretation. A milestone is, by definition, a point on some map or metric. Unlike adding complexity to an abstract concept like "effort"—a concept not transparent from the start—making a milestone more complex invariably muddies exactly where that point is on the proverbial map. Buyers should instead seek to keep milestones as visible as possible.

An example of a simple milestone (contrasted with the ones described above, where defined terms remain open to interpretation, certain triggers contain sub-triggers, and one trigger remains contingent on the occurrence of another) would be where the CVRs provide the selling shareholders with the right to receive a cash payment of $[x] per share (typically a premium of the total consideration paid at closing) if, prior to [Date Certain], the FDA grants approval to market and sell in the United States a specific product in the acquired company's pipeline.

Conclusions

In structuring milestones, buyers can mitigate the threat of litigation by focusing their efforts on meeting certain objective, verifiable predicates—specific dates, specific third-party actions (*e.g.*, FDA



approval, or customer purchases)—and avoiding the intricacies of data collection and interpretation. Parties should always consider the "who" and the "whom": who exactly needs to approve the product, and for whom is the product approved. And finally, buyers (and sellers) may want to consider moving away from the traditional "efforts" covenant and instead use the budgeting or resource dedication concepts outlined above.

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If you have any questions concerning these developing issues, please do not hesitate to contact either of the following Paul Hastings New York lawyers:

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[1] All information relating to these cases was drawn from public sources.