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Best Practices For Successful Collaboration

lthough collaborations between companies are often necessary to bring new drugs or devices to market, many such collaborations end in unexpected acrimony and litigation. Companies can protect themselves in case a strategic alliance turns sour, however, by drafting agreements to minimize potential disputes with partners and by keeping the possibility of future disputes in mind throughout the collaboration. Any company engaging in a collaboration should consult with counsel for specific legal advice about how the following best practices can contribute to a successful collaboration relationship — or to success in litigation, if the relationship fails.

Make key contract provisions clear and objective. At the drafting stage, a company can reduce the litigation risk of provisions, allowing a collaboration partner to terminate the agreement or to prevent changes of control by defining the conditions for exercise of those rights as strictly and objectively as possible. For example, if a partner can terminate because of "safety concerns" regarding an investigational drug, clear language should define the types of safety concerns that can trigger that termination right (such as a death in a clinical trial, an FDA clinical hold based on safety issues, or a certain number or type of serious adverse events). Likewise, if a change-of-control provision restricts mergers with certain types of companies, defining those companies by name or by some objectively-determined criteria (e.g. Fortune 500 companies or NYSE-listed companies) can minimize later disputes about whether a particular merger can proceed. Using concrete, objective standards for these and any other contract provisions that impact critical business needs can make it easier for

a court or arbitrator to reach a quick, costeffective decision in related disputes, and may help eliminate disputes before they proceed to litigation at all.

Craft dispute-resolution provisions to reduce potential litigation expenses. Collaboration agreements typically require binding arbitration of disputes, which can benefit all parties by reducing costs and resolving disputes more quickly than litigation in court. To maximize these benefits, a company can craft an arbitration clause that defines the timing and scope of the arbitration process. For example, an agreement can expedite arbitration by setting fixed deadlines for completion of the arbitration or for the "discovery" process used for fact investigation. An agreement can also restrict the scope of discovery by limiting the number of depositions (or prohibiting them entirely) or limiting written discovery to an exchange of documents. Parties may also benefit from a mandatory mediation prior to arbitration, in which an unbiased third party can evaluate each side's position and preview the likely outcome of arbitration.

Document progress and interactions during the collaboration. Once collaboration begins, a company can protect its interests in future litigation by remembering that the partnership may end and keeping written records of the parties' work and important interactions. For example, if a joint steering committee or similar group oversees the collaboration, it should document its actions completely and accurately in meeting minutes or other records. Likewise, anyone who shares important information or makes decisions with a collaboration partner in person or by telephone can send a follow-up letter, email, or memo to the file to memorialize that fact. Documents predating any dispute carry great weight in litigation, and good record-taking may prevent he-said-she-said arguments on important issues years later.





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Raise problems and issues in real time. If a collaboration does not proceed as expected, raising concerns promptly with collaboration partners can help a company's position in eventual litigation. Addressing problems directly as soon as they arise may let a company resolve them without litigation, getting the collaboration back on track. If not, documenting the issue and the company's position promptly in writing may prevent an arbitrator from later deciding that the company agreed to the objectionable conduct through its "course of dealing" under the agreement.

Most partnerships begin in a spirit of optimism and cooperation, but almost half of biotech alliances terminate prior to a successful product launch. Clear, concrete agreement terms and cautious performance during the partnership can help minimize disputes and protect a company in litigation if — or when — a collaboration goes wrong.

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