Journal of Clinical Research Best Practices

Vol. 17, No. 8, August 2021 "Happy Trials to You"

Weaponizing (and Disarming) Ambiguous Contract Language in Clinical Trial Agreements

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A clinical trial agreement (CTA) is a contract between a study sponsor (or CRO) and a research site. The document sets forth the responsibilities of the parties, how certain issues should be resolved and other matters. In the rare case when the parties cannot resolve a dispute between themselves, the CTA takes a central role in litigation.

The words "ambiguous" and "ambiguous language" are legal terms of art that refer to words or phrases that could have one or more meanings that are not resolved by reference to the document itself. During a clinical study, any ambiguous language in the CTA may create confusion about the parties' responsibilities. But if the CTA is ever litigated, ambiguous contract language opens the door into an entirely new realm: an unpredictable hall of mirrors where the original intent of the parties can dissolve under the ministrations of well-trained litigators. Even the smallest ambiguity can have severe, negative consequences and generate massive legal fees along the way.

If the clinical research industry had a single, standardized CTA template, armies of attorneys would quickly resolve any ambiguities. However, because most study sponsors have their own CTA templates and because many research sites, especially the larger ones, insist on their own contract language, it is easy for ambiguities to creep into CTAs and remain there for years.

CTA Ambiguity in Litigation

Ambiguous words in a CTA, or any contract, can be exploited in litigation to create a tactical advantage. The process is so common that the courts call it "torturing" the contract language.

During a research study, the parties have strong incentives to address ambiguities in a way that maintains their relationship. However, if the parties commence litigation, everything changes. If any text in a CTA can be interpreted in more than one way, each party will seize upon and fiercely defend the meaning that supports their position. Victory or defeat can hinge on the court's interpretation of a single word, or even a comma.

When litigators are backed into a corner, they may weaponize ambiguous contract language in a last-ditch effort to find an escape hatch. Both parties, and especially the one with the weaker position, will scour the CTA for any small ambiguity, emphasize its utmost importance and use it to throw sand in the gears of the other party's arguments. That's just litigators doing their job. Your job is to eliminate the opportunity.

A contract is like a lifeboat. Ships rarely sink, but you still want a lifeboat that does not leak. CTAs are rarely litigated, but you still want one without leaks created by ambiguity. In some cases, the parties intentionally agree to an ambiguous term (e.g., remaining silent on choice of legal jurisdiction). However, in most cases, it is good practice to clarify ambiguities, just in case the CTA ends up as Exhibit 1 in litigation, not to mention avoiding possible misunderstandings during the study.

Resolving Ambiguous Contract Language in Litigation

The principle of "freedom of contract" gives the parties the right to enter into any contract they wish, with the one exception that performance of the contract cannot entail violating any laws. Courts are bound to enforce contracts *exactly* as written. All contract law is based on this foundational rule. Courts may not change or tweak existing contract language after the fact no matter how unfair, misguided, erroneous or ill-advised the contract may appear to the court.

However, what happens if the instructions are unclear? If a critical word in a contract has two mutually exclusive meanings, which one should the court apply? A complex set of flexible rules have evolved to help the courts answer such questions.

Use of these rules can be demonstrated by an example:

> *Frigaliment Importing Co. v. B.N.S. International Sales Corp.,* 22 Ill.190 F. Supp. 116 (S.D.N.Y. 1960) involved a commercial transaction for the sale of poultry, in which the buyer and seller misunderstood each other's intentions. In this case, we learn that there are two types of chickens in the poultry industry, which are identified by specific technical terms. The first type is "fryers," which are young, tender and more expensive. The second type is "stewing chickens," which are old, tough and less expensive.
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> In *Frigaliment*, there appears to have been an honest misunderstanding: the buyer wanted to buy fryers, but the seller thought they wanted stewing chickens. The misunderstanding was not discovered during negotiations, perhaps because they were conducted in both German and English. The seller shipped stewing chickens, which the buyer did not want.
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> A lawsuit resulted. The court began by looking at the contract to determine which type of chickens the parties intended. Unfortunately, the only word used in the contract to describe the goods was the ambiguous term, "chickens."

The type of ambiguity seen in *Frigaliment* is so common that in many published decisions over many years, courts have developed an informal set of rules for addressing them, often called "the rules of construction" or "the canons of construction." These rules are not laws or even written down in any single authoritative document. It is best to think of them as guidelines or best practices, which can be applied in different ways in different legal jurisdictions and even courts.

The *Frigaliment* court started by using a very common rule of construction known as "trade usage." When in doubt, words in a commercial contract are assigned the meaning commonly used in that particular industry. However, this contract described the goods only as "chicken," which was not a technical term used in the industry.

The court needed another strategy and decided to look at the price of the goods, which was appropriate for stewing chickens and much too low for fryers. Thus, the court reasoned, it was unreasonable for the buyer to believe it was buying higher-cost fryers. The seller won the case, and the buyer was stuck with a truckload of tough old chicken. If the price had been exactly in the middle for the two types of chicken, the court may have had to look at another rule of construction.

Frigaliment demonstrates two key points:

- The presence of ambiguous contract language forces a departure from the rule that contracts are to be enforced as written and requires the court to engage its own (not your) judgment to resolve the dispute.

- The court has substantial latitude in applying the rules of construction. The process is not scientific and, while in principle it follows common sense, it is quite unpredictable.

A third key point not demonstrated in this simple example is that litigation favors attorneys capable of persuasive argument in extensive briefs that opposing counsel find difficult, time-consuming and expensive to counter.

Weaponizing Ambiguous Contract Language

Carl Sandburg said, "If the facts are against you, argue the law. If the law is against you, argue the facts. If the law and the facts are against you, pound the table and yell like hell!" We could add, "If the contract language is against you, torture the words to convince the court that they mean the exact opposite or nothing at all."

If a contract is extremely clear, any case arising out of that contract should be very quick and simple to adjudicate. For example, there is really only one question in a mortgage foreclosure case: Did you or did you not pay the mortgage? There is no language to torture. As a result, mortgage foreclosures are nearly indefensible.

However, the complexity of most contracts provides more latitude for argument. When faced with an unfavorable position, a skilled litigator will start by examining every word in the contract under a microscope to find something — anything — that is ambiguous. A little ambiguity can go a long way and even flip the outcome of a case. But even a mediocre argument and the resulting morass of briefs can slow an adversary's progress, increase costs, create uncertainty and force a settlement.

Lawyers are bound by their code of ethics not to assert arguments without merit solely for the purpose of delay; but in truth, the bar is low. In the author's opinion, the bar should be much higher and a good judge should not allow attorneys to waste time on arguments cooked up just to stave off inevitable defeat. Nevertheless, the more ambiguous the CTA language, the broader the latitude.

A Clinical Research Example of Ambiguity

The following example will demonstrate how common errors in CTAs could be exploited to name the investigator personally as a defendant and to put their personal assets at risk.

If a CTA is ever litigated, should the principal investigator ("Investigator") ever be named personally as a party to the case? Of course not. A typical CTA is a contract between two business entities: the study sponsor or CRO ("Sponsor") and the research site ("Site"). And yet, CTAs often contain ambiguities that would allow an aggressive litigator for the Sponsor to name the Investigator in the complaint. The problem relates to the how the Investigator's signature is managed in the document.

Sponsors often require an Investigator to sign the CTA under a signature block that contains the word "Agreed." With this signature, the Sponsor can be reasonably certain that the Investigator named in the CTA is the one who will perform the research and somewhat certain that the Investigator has read the agreement. This requirement seems reasonable but it may lead to very serious unintended consequences.

Anglo-American case law says that a signature anywhere on a contract indicates that a party has knowingly and willingly undertaken the obligations stated in the agreement unless text accompanying that signature clearly states otherwise. As a result, signing your name below the word "Agreed" on any contract makes you personally a party to the agreement and personally liable for all obligations contained in the contract.

Employees as individuals should not sign agreements in business-to-business transactions, so the best solution is for the Investigator to not sign at all. But, if the Sponsor insists, potential damage can be mitigated by using the phrase "Read and Acknowledged" instead of "Agreed" or, even better, "Investigator is not a party to this Agreement but has read and acknowledged it."

Would a court really hold the Investigator personally liable under a CTA between a Sponsor and a Site? Probably not, although an Investigator who owns the research site is more likely to be held personally liable than an Investigator employed by a large academic medical center. But the point is that the Investigator's signature created ambiguity that could have been easily avoided. For an aggressive or desperate litigant in need of a tactical edge, the ambiguity is easily weaponized. Extricating the Investigator from the case will require a drawn-out, brief-writing battle that drains resources and intimidates the Investigator.

Eliminating Ambiguous Language

Ambiguous language can occur anywhere in a CTA, so the best strategy for finding it is to stay alert.

Ambiguities often occur in the following places:

- Clauses with complex definitions or complex logic
- Language that relates to other clauses in the agreement
- Language that has been modified or added to a contract vs. original language.

When formulating or assessing CTA language, put yourself in the shoes of a litigator with a losing case for the other side, desperate to find any argument that might be weaponized.

Defined Terms

Contracts often define terms when the meaning of the term in common usage does not meet the needs of the contract. Defined terms are typically capitalized in a contract, signaling to the reader that the term has a specific definition.

Terms can be defined in a termination section or within a provision of the contract. In the latter case, the definition should be included with the first use of the term; otherwise, multiple definitions might create ambiguity.

Defined terms should be examined closely. For example, the word "confidential" has a common-use meaning; but, in a CTA, the term "Confidential Information" is normally defined in detail. In some cases, a contract can use both versions of the word (e.g., one capitalized and one not), leaving it to the reader to differentiate the two meanings.

"Adverse event" and "serious adverse event" provide another example since they could have different meanings based on the regulations, the protocol or the contract (e.g., if the study sponsor wants more events reported than required by law). Similarly, intellectual property terms like "invention" or "inventorship" can be based on statutory law or defined in the contract.

Enumeration

Courts use the term "enumeration" to describe the practice of listing items in a contract or statute. The technique is heavily used in CTAs, particularly in definitions. For example, a definition of "confidential information" might attempt to list every conceivable medium on which the information is stored. Enumeration is a good strategy for anticipating and avoiding misunderstandings. In the following passage from ACTA's Accelerated Clinical Trial

Agreement, it appears that the authors have carefully anticipated misunderstandings that are likely to occur when deciding what information, the Site is required to send to the Sponsor:

> "Data" shall mean all data and information generated by Institution in the performance of the Study and required to be delivered in accordance with the IRB-approved Protocol. Data does not include original Study subject or patient medical records, research notebooks, source documents or other routine internal documents kept in the Institution's ordinary course of business operations, which shall remain the sole and exclusive property of the Institution or medical provider.

This level of detail is not, however, without risk. One of the rules of construction states that an enumerated list should be construed to include only the items in that list. However, as with other rules of construction, common sense will usually prevail eventually.

Risk in Perspective

It can be intimidating to think that every word of a CTA you are drafting could someday be subjected to an aggressive effort to deliberately misinterpret those words. This scenario is a real possibility, but we do need to keep it in perspective. Very few contracts are ever litigated. Even fewer are litigated between study sponsors and research sites, where long-term relationships are valuable. On the other hand, ambiguities can also generate uncomfortable and time-consuming discussions outside of litigation.

Using the lifeboat metaphor from above, it is wise to find and fix leaks/ambiguities that could be problematic in the most likely topics of litigation (e.g., subject injury and indemnification). It is also wise to review clauses that govern actions that will be required during the study to ensure that those actions occur as expected by both parties.

Conclusion

When you are drafting or reviewing a CTA, invest a bit of time looking for ambiguities that could create problems down the road. A shipshape lifeboat/CTA can avoid a lot of bailing/argument later under the most inconvenient circumstances.

Author

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