

OFF-LABEL USE OF MEDICAL PRODUCTS: WARRANTY AND INDEMNIFICATION CONSIDERATIONS IN PURCHASE AGREEMENTS

When you purchase an item, you assume that it can be used in any reasonable manner and the warranties will apply. The same is true of buyers of medical products. Take the humble tongue depressor. Regulated by the Food and Drug Administration ("FDA") pursuant to 21 C.F.R. § 800.6230, the tongue depressor is "...a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues...." However, it is commonly used to stabilize painful and swollen digits, to spread creams and ointments and, when not taking care of patients, to make science fair projects. In all of these uses, you expect to depend on the manufacturer to make the tongue depressor using good quality materials with minimal splinters - in other words, to make the product so that it would meet the warranties of workmanship and performance. Whether or not the use is the on-label or approved use, barring a design issue, the quality of workmanship and materials remains the same.

In attempts to limit their exposure, suppliers of medical products often attempt to carve out off-label use in warranties and indemnification provisions of product purchase agreements with customers. While the reasoning is not always clear, some suppliers may be concerned that if they do not carve out off-label uses, they will be perceived as engaging in off-label marketing to health care providers by the FDA, which is prohibited. This article provides a brief overview of what purchasing entities should consider with regards to off-label use when negotiating purchase agreements for medical products.

The mere fact that a product warranty covers quality of workmanship and materials without regard to use does not indicate whether the supplier promoted a particular use of the item. Off-label use by a provider is not illegal. The FDA understands that providers have the right to make treatment decisions, including decisions about off-label uses, based on scientific knowledge and clinical experience. Off-label use does not imply that the provider is performing services below the standard of care required in the fields of medicine or applicable health care profession. In fact, approved uses of medical products often start with an off-label use simply because of the cost and time required to obtain approval of additional uses from the FDA.

Inclusion of warranties in supply chain agreements is critical for providers as a way to offer protection to the purchasing entity in the event a product does not perform properly. Providers using these products will use them off-label regardless of whether such uses are carved out of the applicable purchase agreement, and they are likely not even aware of the terms pertaining to the products they use or potential exposure to the purchasing entity if the product is defective or violates warranties of performance or workmanship.

Only where a unique characteristic of the off-label use creates a condition not present in on-label uses, and that condition is the cause of the failure, should off-label use not be covered by the warranties. In such cases, other legal theories may attach to such claims when the off-label use created the condition of harm. Therefore, purchasers of medical products should be extremely cautious of agreeing to broad off-label carve-outs in warranty sections of purchase agreements.

For example, if a product fails because the material was of poor quality or because the workmanship was second-rate, the supplier should be responsible. A supplier may try to add language that voids the warranty of performance if the products are used outside of the products' labeling or specifications, or may even use the term off-label, which limits a supplier's warranty responsibility to maintain, service or replace that product to uses that are strictly on the product's label and will disregard the quality of the materials and workmanship if the use is not used in this manner. This breaks the causal relationship between the product defect and the failure of the product if it is used off-label and relieves the supplier of all obligations to warrant the product once it is used off-label. This type of carve-out may also affect a potential product's liability claim by a patient or other third party even if the off-label use had no effect on the product's performance.

DISCLAIMER OF WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

A disclaimer of a warranty of fitness for a particular purpose may be more understandable when it comes to off-label use since giving a warranty for a particular off-label purpose could be viewed by the FDA as off-label marketing. A potential risk of agreeing to such a disclaimer in a purchase agreement is that the warranty of fitness for a particular purpose would also apply to the on-label uses of the

product. Without this warranty, the purchasing entity must rely on the representation that the supplier is complying with all applicable laws and any FDA requirements, but the remedies provided under Article 2 of the Uniform Commercial Code for breach of the warranty of fitness for a particular purpose would no longer be available.

INDEMNIFICATION FOR INTELLECTUAL PROPERTY INFRINGEMENT

In purchase agreements for medical products, the purchasing entity typically seeks from a warranty that the supplier owns all rights necessary to sell the product without infringing any rights of any third party. While suppliers typically seek to limit the intellectual property warranty to on-label uses only, considerations differ for utility patents and method patents. Utility patents should not be affected by the use. If, however, a method patent is involved, the supplier may have a valid concern, and further discussions may be necessary. Ultimately, if a supplier is permitted to exclude off-label use from its obligation to indemnify for intellectual property infringement, the purchasing entity could be required to cover its own costs of any litigation related to an infringement claim that the provider's off-label use violated a third party's rights. While the labeling of a product does not necessarily correlate directly with intellectual property rights, because of the growing number of method patents in the health care industry, deviations from on-label uses can increase infringement risks. Thus, agreeing to carve out off-label use from a supplier's obligation to indemnify for intellectual property infringement can leave a purchasing entity exposed to significant liability.

INDEMNIFICATION FOR PRODUCT LIABILITY

A purchasing entity should also see indemnification for product liability in its purchase agreements with suppliers. In the event a supplier tries to carve out off-label use from its indemnification obligation, the purchase would not be covered in the event the product was defective but used in a manner that was considered off-label. The damages could be significant if the defective product harmed or caused the death of a patient or individual, especially in the case of spine and orthopedic products, which is an industry that pushes hard for carving out off-label use in product liability. There may be times where the nature of the off-label use increases the risk of a product failure; however, this is often not the case. If the off-label use contributed to the injury, a claim might exist that the use violated the standard of care, raising a negligence claim rather than a product liability case. More often than not, suppliers attempt to seek complete relief from being subject to litigation for product liability claims related to off-label use rather than bearing their associated costs for a defective product. Thus, permitting an off-label use carve-out eliminates the supplier's obligation to indemnify such defective products and leaves the purchasing entity to bear any litigation costs it may incur for defending or dismissing any claims for a defective product used off-label.

PRACTICAL TAKEAWAYS

When purchasing entities are negotiating purchase agreements with suppliers and the supplier seeks to carve out off-label use, it is important to assess and weigh the risks associated with a particular product and consider the following:

- Only agreeing to carve out off-label use when it comes to certain products, based on unique design or use characteristics; however, that should occur only after careful factual analysis.
- Discussing the use of the product with the providers who will use it regarding the applicability and current off-label uses of that product.
- Assessing whether there may be a future off-label use of the product that may be widely adopted.
- Confirming that a carve-out for off-label use will not hinder a provider's ability to freely use its professional judgment regarding the best treatment for its patients.

If you have any questions about off-label use, please contact:

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Please note that this discussion is focused on off-label related to the use of medical devices (products) and not pharmaceuticals, which are similarly subject to off-label use concerns.