



To: All Field Staff
AMDR Member-Companies
From: Daniel J. Vukelich, Esq.
President, AMDR
Date: May 23, 2011
Re: Ethicon “Licensing” Contract Language

It has again come to AMDR’s attention that subsidiaries of Johnson & Johnson (J&J), including Ethicon™ and DePuy Spine™, may be including in their hospital sales contracts new “licensing” provisions that potentially limit your hospital customers’ rights concerning the “single use” medical devices they purchase from J&J.

Typically, under a section labeled, 2.25 “Single-Use Products,” these proposed contracts state,

- (a) The [hospital] Customer shall ensure that any patented Single-Use Product that it purchases is used once, and only once, in delivering patient care and the Company (J&J) conveys no right in any such Single-Use Product other than the right to use such Single-Use Product once, and only once. For purposes of this agreement, a “Single-Use Product” means any Product that is labeled “For Single Use,” “Single-Use Only,” or “Do Not Reuse,” or is otherwise labeled to indicate that the Product is to be used once, and only once, in delivering patient care.*
- (b) This agreement does not grant the Customer, or any other person or entity, any license to reprocess, remanufacture, or reconstruct any patented Single-Use Product. The sale or use of any reprocessed, remanufactured or reconstructed patented Single-Use Product will be subject to available remedies for patent infringement.*

In AMDR’s view, this new contract language proposed by J&J companies is yet another attempt to limit a hospital’s freedom to purchase lawful and FDA-regulated reprocessed medical devices. J&J is attempting to enforce the “single use” designation by forcing the hospital to agree to a “single use” license. We encourage you to urge your customers not to sign these contracts, or to simply strike out paragraphs (a) and (b) above before signing any contract with J&J or its subsidiaries. Hospitals may purchase and use any FDA-cleared or approved product they choose, including reprocessed “single use” devices. AMDR views this as inappropriate competitor interference and, depending on the other contract terms, possibly anti-competitive contracting behavior.

(for advice for hospitals, please turn over)

AMDR's advice for hospital customers:

1. Do not sign contracts that include this or similar language, or simply cross out provisions (a) and (b) above before signing.
2. If pressured, do not sign. If uncomfortable, do not sign. Take these contracts to your hospital's Risk Management department for assistance, and alert your reprocessing vendor.
3. Inform J&J sales representatives that your hospital is committed to purchasing both J&J devices and reprocessed devices, and that interference in the hospital's reprocessing program by J&J sales representatives, including limiting contract language like that above, will not be tolerated, and may result in a loss of hospital privileges.
4. Enforce the policy.