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Off-Label Uses

In the wake of another court loss for the federal government on off-label uses of Food and Drug Administration-regulated products, Wiley Rein founding partner Bert Rein calls for the agency to focus its energies on giving practitioners better information on off-label uses, rather than clamping down on companies' discussions with providers.

When Will They Ever Learn: Time for a New FDA Perspective on Off-Label Use

BY BERT REIN

The Food and Drug Administration's failure to convict Vascular Solutions Inc. and its CEO for off-label promotion of VSI's Vari-Lase Short Kit [1], following on similar setbacks in the *Caronia, Amarin* and *Pacira* cases [2], should prompt FDA to reconsider its effectively unenforceable view that providing truthful information about off-label uses of approved prescription drugs and medical devices is an evil to be tolerated only because FDA cannot regulate medical practitioners or control information generated by anyone except regulated manufacturers.

Instead of seeking to plug an off-label use dike that now has more holes than FDA has fingers, FDA needs to adopt policies that capitalize on the clinical results of widespread and beneficial off-label use and seek to enhance, rather than foreclose, the flow of reliable information to treating practitioners.

Under First Amendment pressure, FDA has grudgingly relaxed its absolute restrictions on off-label speech by manufacturers and has promised a revised, but yet to be disclosed, liberalized policy. But nibbling at the edges of the issue, which is the likely outcome, will produce only further controversy and uncertainty. FDA would be far better advised to expend its scarce resources determining how to: capture the valuable information arising from clinical experimentation; independently analyze that data; and make that data and analysis accessible to practitioners.

Specifically, FDA needs to develop an electronic data platform that would permit practitioners, researchers

[1] See (14 PLIR 319, 3/4/16).
[2] See (13 PLIR 1159, 8/14/15) and (13 PLIR 1759, 12/18/15).

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and manufacturers to conveniently submit off-label use information in an organized format; to arrange for the monitoring and analysis of that data flow by independent experts; and to give practitioners the benefit of that analysis of the reliability and significance of off-label clinical experience. If Wikipedia can exploit the benefits of modern technology to crowd source information and analyze big data flows, the FDA should not ignore the opportunity technology presents to enhance the public health.

FDA views its approval process as foreclosing the sale of drugs and devices that are unsafe or ineffective and its approved labels as providing the best possible information about drug and device use. But generating post-approval changes to labelled use is a slow and expensive process which often can deter manufacturers from seeking expanded labelling and frequently makes the requirement of providing the best information the enemy of the good. Even if FDA could succeed in clamping down on off-label information flows and off-label use and increase its power and primacy, and experience shows it cannot, the quality of medical care would decline.

The failed prosecution in *VSI* should be a clear signal to FDA that pursuing a speech-suppressing objective is both unachievable and detrimental to the public health and counsel FDA to refocus its energies on how to give practitioners fairly evaluated access to the full range of information needed to make the best clinical judgments.

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