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, following on similar setbacks in the Caronia, Amarin and Pacira cases, 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
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 indepen-
dent 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 informa-
tion 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 ex-
pensive 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 ex-
perience 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 judg-
ments.