I'm Not Dead (Yet): FDA Continues to Enforce Unlawful Product Promotion

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Many of us remember the classic bit in the epic 1975 Monty Python and the Holy Grail movie, where the Dead Collector asks the pestilence-infested community to bring out its dead, and one hapless individual calls out, "I'm not dead." So, could be the Food and Drug Administration's recent cry after it issued this month a Warning Letter to a Canadian medical device company selling its product in the United States.[1]

We all know about the trials and tribulations of FDA's attempts to enforce against off-label promotion. We have issued a number of Bulletins and presented a number of webinars on the subject.[2] However, as we have cautioned clients, FDA is not going to stop taking action concerning promotional conduct when it considers it appropriate.

Background

- A company marketed a cleared device. However, the device included new features that the original product did not. As such, FDA concluded the changes could significantly affect safety or effectiveness, thereby requiring a new 510(k) application.
- FDA said the product was adulterated and misbranded.
- FDA learned of the sale through an inspection.
- The agency sent an Untitled Letter first.

AGG Observations

- As a reminder, FDA may take action against a company outside the United States (here, Canada) for selling a product into this country.
- FDA provided a first bite at the apple to the company, by issuing an Untitled Letter first, approximately six months before the Warning Letter.
- Responding to an Untitled Letter allows you to ask questions to learn what is influencing FDA's position and to advance arguments that will address the agency's concerns. The successful advocate will seek a solution that allows both parties to move forward without a complete sense of defeat or futility. Failing to respond, increases the probability of a subsequent Warning Letter.
- While we cannot tell from the Warning Letter itself, it appears that the company might have made what it perceived to be a number of small changes to the device over time, which ultimately FDA determined were major changes, requiring a new 510(k).
- The agency became aware of the sale during an inspection; it is not clear whether this was prompted by a competitor complaint or a safety issue. However, it is a reminder that FDA need not review a product website or attend a medical meeting to proceed against violative promotional conduct.
- FDA is not going away. FDA's not dead yet.

1 https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm547175.htm
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