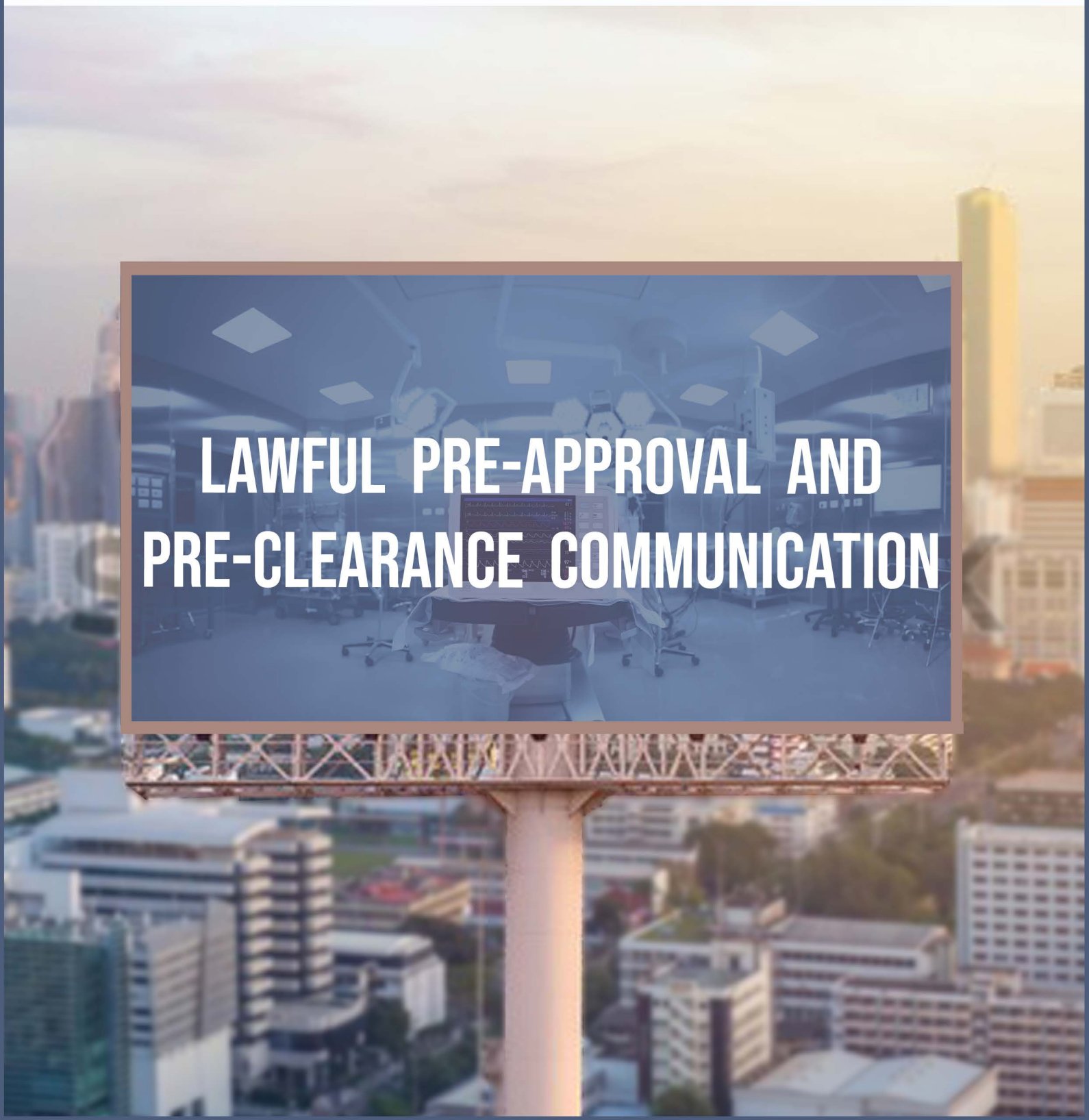
DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

Volume 09
Issue 02

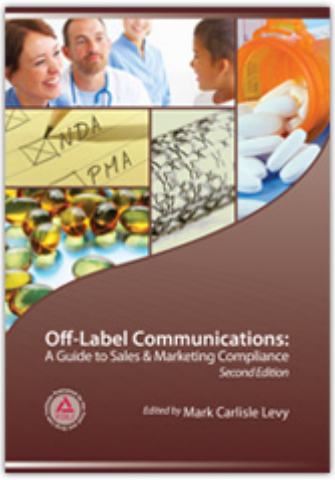


LAWFUL PRE-APPROVAL AND PRE-CLEARANCE COMMUNICATION

In this DuVal Client Alert, we list practical ways medical device companies can lawfully communicate about their products prior to FDA clearance or approval. We encourage you to consider these activities when developing your pre-launch strategy. We hope this DuVal Client Alert helps you avoid common pre-product launch legal pitfalls.

INTRODUCTION

There are many pre-clearance/approval activities a medical device company can lawfully engage in prior to attaining their 510(k) clearance/approval of a medical device. This DuVal Client Alert provides insight into these activities. The list of pre-clearance/approval communication activities below is a summary from a chapter titled, "*Off-label Discussion Before and During Clinical Trials—Avoiding Off-Label Pitfalls*," written by Mark DuVal, and Bradley Merrill Thompson of Epstein Becker & Green, P.C. This chapter is from the book, "*Off-Label Communications: A Guide to Sales & Marketing Compliance*," published by the Food and Drug Law Institute in 2009.[1] The Food & Drug Administration ("FDA") takes the position that it has jurisdiction and authority over any pre-clearance/approval communications about a product. There is, however, arguably more First Amendment protection for pre-clearance/approval communications and less authority for FDA because the product is not yet cleared and under FDA's jurisdiction and authority. Nevertheless FDA takes the position that it has full authority and jurisdiction whenever testing is done in interstate commerce or when an IDE (Investigational Device Exemption) is granted. Most companies do not want a statutory or constitutional challenge (although Allergan did sue the FDA in early October, claiming, among other things, that government restraints on off-label promotion violates First Amendment free speech rights), instead they want practical advice on what they can and cannot do. What follows is a brief list of activities in which companies can lawfully engage.



[1] Mark E. DuVal and Bradley M. Thompson, *Off-Label Communications: A Guide to Sales & Marketing Compliance* chapter 3 (2d ed., Food and Drug Law Institute, 2009).

THE LIST

Generally the FDA does not allow pre-clearance/approval *promotion*, but it does tolerate a fair amount of *communication* about a product pre-clearance/approval. The following are a list of activities with a brief synopsis of what generally can and cannot be done by a medical device company prior to clearance/approval. Your situation may differ from the generalizations made here. Please contact us if you have questions or if you would like specific legal advice or a qualified written opinion.

- Sales activity—A manufacturer cannot engage in traditional sales activity in selling a device pre-clearance/approval because in order to do so the manufacturer would need pre-clearance or approval. There are some things FDA does tolerate. For example, FDA tolerates early trade discussions with health care organizations about coming products that may affect the budget of a hospital or managed care organization. A company cannot make definitive safety and effectiveness claims about a product pre-clearance/approval, but it can discuss the clinical and other performance testing and the labeling which the company is seeking (with appropriate qualifications in the form of disclaimers). In addition, suppose a physician became aware of a company product in development through a channel or means independent of the company and asked a sales representative for information on an unsolicited basis. The company could provide a piece coming out of the R&D organization or clinical affairs (not sales and marketing) that discusses the status of the product and does not look like a glossy promotional piece. The key here is that 1) the request truly is unsolicited, 2) the response to the inquiry comes from the home office out of a centralized function like medical, clinical or regulatory (and does not report to the marketing or sales organization), and 3) the response provided does not look like a promotional piece.

- Marketing literature—Marketing literature cannot be created and provided to customers about a product prior to its approval unless it is being shown to a group of consulting physicians to provide comment to marketing as part of market research.

- Coming soon ads—"Coming Soon" ads are commonplace in the pharmaceutical world, but not medical devices, but they theoretically can be conducted in the device world. The FDA allows drugs to be marketed either discussing the drug without talking about the use to which it could be put, e.g., "Nexium—the Purple Pill coming soon" or discuss the fact that a new solution

for gastrointestinal reflux is coming, but not mention the name of the product. So you can do a brand marketing campaign to create awareness for the brand or you can talk about your company and the solution it will bring soon to a medical problem, without mentioning the product name, but you cannot do both promotional approaches at the same time pre-clearance/approval. Coming Soon ads are more difficult for medical device companies to conduct because they are expensive branding campaigns and often are not justified by the final market for a medical device.

- Trade shows & Medical Conventions—The general prohibition against selling applies to trade shows, but FDA does allow the following:

    - Display of an uncleared 510(k) whose application is pending at FDA. The theory is that devices subject to a substantial equivalence determination are generally not radically different from their predicates and have a lower risk profile and so FDA permits their display at a medical convention or trade show.
    - Display of a device unapproved in the United States but approved elsewhere in an international section of the booth (or at least clearly marked as such in the main booth).
    - Under a Notice of Availability (NOA) in which an advertisement of the device being studied in clinical trials is shown in the booth to recruit clinical investigators to those trials. The NOA must bear certain language found in the regulations and must not state or imply that the product has been proven to be safe or effective.
    - Discussion about an unapproved device or an unapproved use of an approved device could lawfully take place in a "medical affairs" section of the booth, in which answers to unsolicited questions may be asked by a physician and answered by a company representative from medical affairs or similar department. This is designed to allow medical and scientific discussions with those visiting the booth and to avoid sales-oriented discussions with sales personnel.

- Unsolicited request—The FDA has a long policy of permitting a company to answer unsolicited questions about approved or unapproved products truthfully and in a non-misleading way. If a question is asked, it may be answered even if the product is unapproved or the use is off-label. The answer must be truthful, not misleading and fairly balanced and must be responsive to the question

asked and not viewed as an opportunity to discuss more than what was requested.

- Company websites—The FDA recognizes that a company must educate potential investors and potential employees about the company, its products and perceived future. As such companies can modestly populate their website (in corporate updates, research sections or elsewhere) with information about their products as long as they don't make representations about safety and effectiveness that have not yet been established and put into labeling. The company can talk about the product, its performance data and clinical trial results including where it is in trials, the investigators, the hypothesis, the endpoints, inclusion and exclusion criteria, etc.

- Company public relations—As with company websites, the FDA recognizes that a company must educate potential investors and potential employees about the company, its products and perceived future. As such companies can issue press releases on a wide variety of milestones which keep the public informed about the company and so long as they don't make representations about safety and effectiveness that have not yet been established and put into labeling. In this fashion, the more milestones the company has/creates, the more opportunity there is to lawfully talk about their product.

- Sponsorship of broadcast programs—A manufacturer also can sponsor a series of internet, radio or television programs like "*WebMD*®" which may cover the manufacturer's product in clinical trials. Again the sponsor cannot create the program or, if offered to be part of it, control the content; but it may participate in it and provide relevant information for it. If the manufacturer controls the content, it owns the message.

- Sponsorship of CME programs—A company can through grants sponsor CME programs that may discuss new therapies in development, including the manufacturer's new product. A manufacturer cannot *control* the content of the program or its speakers, but is often allowed the opportunity to comment or even suggest both.

- Sponsorship of investigator-initiated trials—A company can through grants also sponsor investigator-initiated trials (IITs) covering on or off-label uses of its products. These kinds of trials often result in publications that, in turn, may be properly disseminated by the company. Grants cannot be given for IITs before

a product is approved because that would make a product available before FDA approval and undermine the approval process. Grants for IITs can be made available to study unapproved uses of a manufacturer's approved product.

- Market research—Market research is an opportunity to lawfully discuss your product with potential customers before it is approved. The FDA does not want market research to become a ploy for pre-clearance/approval marketing so it must be designed to provide legitimate feedback. When market research is conducted, information about your product must be imparted before feedback can be extracted. The information imparted about a product must be truthful, not misleading and fairly balanced and must not state that the product has been proven safe and effective before approval. The information imparted may also require disclaimers to accomplish the above.

- Publication planning—When research is being conducted it can and should result in a publication because this will serve as a basis for information which can be given out by a company at some point in time. If there are unsolicited requests for information about a product under development, a publication could be made available to the requestor pre-clearance/approval, but as with off-label dissemination, the response must be truthful, not misleading and fairly balanced and responsive to the question. In addition, the company cannot make representations about safety and effectiveness that have not yet been established and put into labeling.

- Consultancies—In addition to consultants used for market research, consultants can be hired to provide input on a wide variety of matters for the company. Again, in the process of extracting input from these experts, information will be imparted that will make them knowledgeable about the product. This makes more physicians aware of the product at the time of launch. Under the *Personal Services Safe Harbor* to the *Anti-kickback Statute*, the consulting relationship of course must 1) be bona fide and not a token arrangement, 2) it must be paid at fair market value, 3) it must not be based on the value or volume of the business or referrals, 4) the compensation must be set in advance, and 5) the arrangement must be in writing in a contract.

CONCLUSION

There are a myriad of activities that a medical device company can undertake to lawfully communicate pre-clearance/approval about a product. However, it is of paramount importance that these activities are done with the right intent in mind and with proper review and safeguards. These activities should not be conducted absent legal and regulatory review.

HOW DOES THIS RELATE TO MY COMPLIANCE PROGRAM?

Government oversight of the healthcare industry is becoming more and more intense. In October, Stryker executives were indicted for fraudulent promotion of surgical medical devices. Last June, Synthes executives were indicted for alleged off-label promotion of their devices. Two of the executives in that case plead guilty in August; they face six-figure fines and jail time. The pharmaceutical industry has also been hit. Last September Pfizer paid out $2.3 billion dollars in the largest healthcare fraud settlement ever. This was the largest fine ever handed out in the history of the United States. For exposing the wrongdoing, six whistleblowers will split more than $102 million in payments from the United States government under the False Claims Act. Increased prosecution makes effective compliance a necessity. All companies should have SOPs and a code of conduct in place to help companies be compliant with the False Claims Act, the Anti-Kickback Statute, FDA regulations, etc., and train employees on the law and company policy. Have you taken some time to reflect as a management team if what you have in place is sufficient to protect you from government prosecution? Is there any conduct your organization is engaged in that might draw prosecutorial attention; or the attention of a whistleblower or a competitor?

WE CAN HELP

Our firm has put together compliance programs and training covering company code of conduct, AdvaMed Code, Anti-kickback Statute, False Claims Act, advertising and promotion under the Food, Drug and Cosmetic Act, and HIPAA for nearly 100 companies. We can help your organization understand not only what it *cannot* do, but what it *can* do. In sum, our real-world experience can help you accomplish your goals in an appropriately aggressive yet compliant fashion.

DuVal & Associates
Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients appropriately aggressive, yet compliant, guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS

For more information, visit our website at www.duvalfdalaw.com or call Mark DuVal today for a consult at 612.338.7170 x102.