

National Pharma Audioconference

Revised PhRMA Code: Key Provisions

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Revised Code Includes:

- New provisions that reflect current requirements and practice
 - Content of promotional material
 - Separation of grant-making from sales/marketing
 - Prescriber data practices

- Better explanation and justification for certain industry practices
 - Why do companies hire physician consultants?
 - Why do companies meet with physicians and provide meals?



New Provisions That Will Change Current Practices

- Prohibition on practice-related items (e.g., pens, notepads)
- Prohibition on restaurant visits by sales reps
- Prohibition on entertainment for consultants
- Disclosure of consulting relationship by formulary members
- Compliance provision
 - Annual certification by CEO and Compliance Officer
 - Third party verification



Bottom Line

- New PhRMA Code is more comprehensive, nuanced and complicated than prior version
- New compliance provision entails a greater need for company oversight and monitoring
- Revised company policies need to be crystal clear
- Training will be key



Contact Information

Scott M. Lassman is a Partner and Co-Chair of the FDA Practice Group in the law firm of Wilmer, Cutler, Pickering, Hale & Dorr (WilmerHale), where he specializes in FDA legal, regulatory and policy issues. Prior to joining WilmerHale, Mr. Lassman served as Senior Assistant General Counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA), where he was responsible for FDA regulatory and policy matters. Mr. Lassman played a leading role in negotiating the \$400 million Prescription Drug User Fee Act (PDUFA) agreement with FDA, which recently was signed into law as FDAAA. Mr. Lassman's strong policy background at PhRMA is complemented by more than ten years of experience in private practice solving complex FDA legal and regulatory issues for pharmaceutical, biotechnology and medical device clients.

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