

FDAAA – Report on DTC Advertising

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Overview of FDAAA Drug Advertising Provisions

- Title I – Prescription Drug User Fee Amendments of 2007
 - Sec. 104 – “Fees relating to advisory review of prescription-drug television advertising”
- Title IX – Enhanced Authorities Regarding Postmarket Safety of Drugs
 - **Sec. 901** – “Postmarket studies and clinical trials regarding human drugs; risk evaluation and mitigation strategies”
 - Sec. 906 – “Statement for inclusion in direct-to-consumer advertisements of drugs”



Section 901 of FDAAA Ad Provisions

- Sec. 901 of Title IX of FDAAA contains a number of provisions related to DTC advertising:
 - Prereview of DTC TV ads (adds § 503B to FDCA)
 - Clear, conspicuous, and neutral manner major statement requirement (amends § 502(n) of FDCA)
 - Civil monetary penalties for violative DTC ads (amends § 303 of FDCA)
 - **Report on DTC advertising**



Report on DTC Advertising

- “Not later than 24 months after enactment of this Act, the Secretary of Health and Human Services shall report to the Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. The Secretary shall utilize the Advisory Committee on Risk Communication established under this Act to advise the Secretary with respect to such report.”



Report on DTC Advertising

- “The Advisory Committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. The report required by this paragraph shall recommend effective ways to present and disseminate information to these populations.”



Report on DTC Advertising

- *“Such report shall also make recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical drug trials and shall recommend best practice approaches for increasing the inclusion of such subsets of the general population.”*



History

- Prior to FDAAA, Rx drug promotion provisions did not focus on specific audiences
 - FDAAA introduces provisions specific to DTCA, and within DTCA, considerations related to subsets of the general population



Other relevant provisions – 503B. Prereview of TV Ads

- Gives FDA the authority to require submission of any drug TV ad for review not later than 45 days before the ad is publicly disseminated
- In conducting its review of such an ad, FDA can make recommendations with respect to information included in the drug's PI:
 - on changes necessary to protect the consumer good & well-being; or
 - on changes consistent with the drug's PI; and
 - **if appropriate and if such information exists, on statements for inclusion in the ad to address the specific efficacy of the drug as it relates to specific populations, including the elderly, children, and racially and ethnically diverse communities**



Prereview of TV Ads, cont.

- In formulating recommendations during pre-review, FDA has to take into account the impact of the drug on elderly populations, children, and racially and ethnically diverse communities
- FDA has no authority to require changes in ads, except that:
 - We can require specific disclosures about serious risks if the ad would otherwise be false/misleading; and
 - We can require disclosure of the date of approval for 2 years post-approval if the ad would otherwise be false/misleading



Other relevant provisions - Prescription Drug Regulations

- **Foreign language pieces – 21 CFR 201.15; 201.16**
- **Promotion of use in a selected class of patients – 21 CFR 202.1(e)(7)(x)**



Questions?

