

24th Annual Pharmaceutical & Medical Device Ethics & Compliance Congress – Mini Summit 53:
What Do Health Equity Initiatives Mean for Compliance Professionals?

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*Are you a caregiver to the following?
(select all that apply)*

- Elder
- Child
- Partner/Friend/Loved One

What is Health Equity?

Evaluating Initiatives

- **Compliance with applicable laws, regulations, and company policy**
 - Review relevant guidance as well as company policies & procedures (e.g., on clinical trials, grants, sponsorships, corporate donations, patient support programs, interactions with patients and patient organizations, interactions with HCPs, speaker programs, ad boards, and needs assessment and FMV procedures)
 - Evaluate and mitigate potential risks of providing ancillary services, financial assistance
- **Ensure the goal of the initiative is genuinely based on health equity/social determinants of health (HE/SDOH) principles**
 - Initiative should be based on reliable and respected HE/SDOH research and scholarship
 - Distinguish branded from unbranded – initiative should not be used as a sales tool to target HCPs based on volume/value of expected or past referrals. Unbranded initiatives focus on increasing education and awareness of health disparities and improving patient access without reference to product or treatment.
 - When initiatives go beyond general, high-level education and awareness it is particularly important to check for relevant guardrails and consult Legal/Compliance for further review as needed
- **Document the intent** of the initiative at the outset to describe how it supports HE/SDOH goal (e.g., initiative aims to educate on the impact of implicit bias on treating decisions)
- **Careful communications**
 - Use of accurate and relevant data, appropriately cited
 - Consider the clinical trial patient population
 - Be cautious about drawing conclusions about social/health impacts of untreated disease in certain populations
 - Do not overstate or misrepresent the company's commitment or what it can reasonably achieve
- **Review and reassess** throughout the program/initiative to ensure it aligns with overall HE/SDOH efforts