HB 1132 UNF (Opposed)

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Testimony in Opposition to HB 1132

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My name is Judy Butler and I am testifying against House Bill 1132. I'm a Senior Research Fellow at PharmedOut, a project at Georgetown University that examines how pharmaceutical marketing practices influence evidence-based prescribing. I am a Maryland resident and have no conflicts of interest.

Every drug label describes the specific uses that have passed FDA's stringent scientific review of risks and benefits. That protects the patient. Unapproved or "off-label" uses rarely have the same level of evidence. About three-quarters (73%) of off-label prescriptions are written for conditions with little or no scientific support for efficacy.[1] Physicians can already prescribe off-label, and they already do so way too often.

Right now, manufacturers may only promote approved uses. That's the way it should be. If there's no proof of benefit, there should be no promotion. If there is proof of benefit, the manufacturer can and should seek a label change.

Off-label promotion is illegal for good reason. It's a lot easier for drug makers to spread rumors of benefit than to perform clinical trials, and many drug companies have been fined for doing

[1] Radley DC, Finkelstein SN, Stafford RS. Off-label Prescribing Among Office-Based Physicians. *Arch Intern Med.* 2006;166(9):1021–1026. doi:10.1001/archinte.166.9.1021

just that.[2] If passed, HB1132 would give a free pass to companies to promote unproven drugs and devices that may be ineffective or dangerous. While some off-label use of drugs is necessary, off-label promotion never is.[3]

Simply qualifying off-label promotion as "truthful," as HB1132 does, will not protect patients. For off-label uses, industry chooses which studies to fund, which studies to publish, and how to present those studies. Let's say there is one published study of a drug that looks promising for an off-label purpose. Maybe there are nine studies that show the drug didn't work. Maybe the company funded 10 studies and only published the one it liked. Companies routinely publish "evidence" with selective data reporting and misleading conclusions.[4,5] For an approved use, FDA looks at both published and unpublished studies, and can make objective assessments. That's why the FDA-approved label is so important.

Any off-label promotion will necessarily be one sided: the side of industry. Allowing off-label promotion removes the best protection patients have against unproven treatments. Allowing corporate communications about unapproved uses can only harm public health. Thank you.

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[2] Arnold DG, Stewart OJ, Beck T. Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities. *JAMA.* 2020;324(19):1995–1997. doi:10.1001/jama.2020.18740

[3] Gazarian M, Kelly M, McPhee JR et al. Off-label use of medicines: consensus recommendations for evaluating appropriateness. *Med J Aus.* 2006;185(10):544-548. doi:10.5694/j.1326-5377.2006.tb00689

[4] Chopra SS. Industry Funding of Clinical Trials: Benefit or Bias? *JAMA.* 2003;290(1):113–114. doi:10.1001/jama.290.1.113

[5] Fugh-Berman AJ. The Haunting of Medical Journals: How Ghostwriting Sold "HRT". *PLoS Med* 2010:7(9): e1000335. doi:10.1371/journal.pmed.1000335