HOUSE BILL 542 WILL NOT PREVENT NORTH CAROLINA FROM BRINGING MEDICAID FRAUD CASES AGAINST DRUG MANUFACTURERS OR SELLERS

HB 542 would bar product liability suits against manufacturers regarding drugs approved by the FDA and "designed, manufactured, packaged, labeled, sold, or represented" in compliance with FDA standards. The reason is simple: the FDA-approval process is long and arduous. Once the FDA approves a drug for a particular use, manufacturers must be able to rely on that decision.

The bill's narrow product liability exemption, however, would not prevent North Carolina from participating in state and national Medicaid fraud actions brought under state or federal False Claims Acts. In the last five years, North Carolina has been a plaintiff in over a dozen pharmaceutical cases under the state and federal FCA based, among other things, on alleged:

- Off-label Promotion by drug manufacturers
- Unlawful kickbacks to prescribing physicians
- Overbilling
- Best Price Manipulation

Most of these actions remain open – and will be settled, dismissed, or otherwise resolved without reference to HB 542's product liability exemption. Notably, most actions pertain to alleged schemes to market drugs for uses not approved by the FDA and therefore beyond the scope of the proposed exemption. Such actions have been called "unquestionably the most lucrative 'health care' FCA cases." John T. Boese, 1 *Civil False Claims and Qui Tam Actions* 1-43 (4th ed., 2011). And they are not the only avenues available to the Attorney General and whistleblower plaintiffs – with or without the proposed product liability exemption. Common allegations in other jurisdictions have included:

- Upcoding/Manipulation of Medicaid Reimbursement Codes
- False Certification (of compliance with relevant laws and regulations)
- Sale of Adulterated Drugs

HB 542's would not bar the State's participation these or other national Medicaid fraud cases. Thus, the bill will not impede the State's ability to recover from drug manufacturers and sellers any proceeds of Medicaid fraud under the state or federal False Claims Acts, just as this exemption has not impeded the State of Michigan's ability to recover such proceeds. Any suggestion to the contrary is mistaken and wrong.

Attached is a brief list of specific False Claims Act cases North Carolina has participated in that would not be barred or affected in any way by HB 542.

Multi-State FCA Actions in Which North Carolina Has participated – Not Affected by HB 542

United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., No. 1: 09-cv-01086 (E.D. Va.)
- Off label promotion

United States ex rel. Simpson v. Bayer Pharm. Corp., No. 2:05-cv-03895 (D. N.J.)
- Off-label promotion/Kickback

United States ex rel. Wolfson v. CVS Caremark Corp.. No. 2:10-cv-00376 (C.D. Ca.)
- Overbilling

United States ex rel. Keeler v. Eisai, Inc., No 1:09-cv-22302 (S.D. Fla.)
- Off-label promotion/Kickback

United States ex rel. Banigan v. Organon USA, Inc., No. 1:07-cv-12153 (D. Mass.)
- Off-label promotion/Kickback

United States ex rel. Spetter v. Abbott Labs. Inc., No. 1:10-cv-00006 (W.D. Va.)
- Off-label promotion/Kickback

United States ex rel. Beilfuss v. Allergan, Inc., No. 1:08-cv-01883 (N.D. Ga.)
- Off-label promotion/Kickback

United States ex rel. McCoyd v. Abbott Labs., No. 1:07-cv-00081 (W.D. Va.)
- Off-label promotion/Kickback

United States. ex rel. LaCorte v. Wyeth, No. 06-cv-11724 (D. Mass.)
- Off-label promotion/Kickback/Best Price

United States ex rel. Kieff v. Wyeth, No. 03-cv-12366 (D. Mass.)
- Off-label promotion/Kickback/Best Price

United States ex rel. Copeland v. Novartis Pharm. Corp., No. 06-cv-01630 (E.D. Pa.)
- Off-label promotion/Kickback