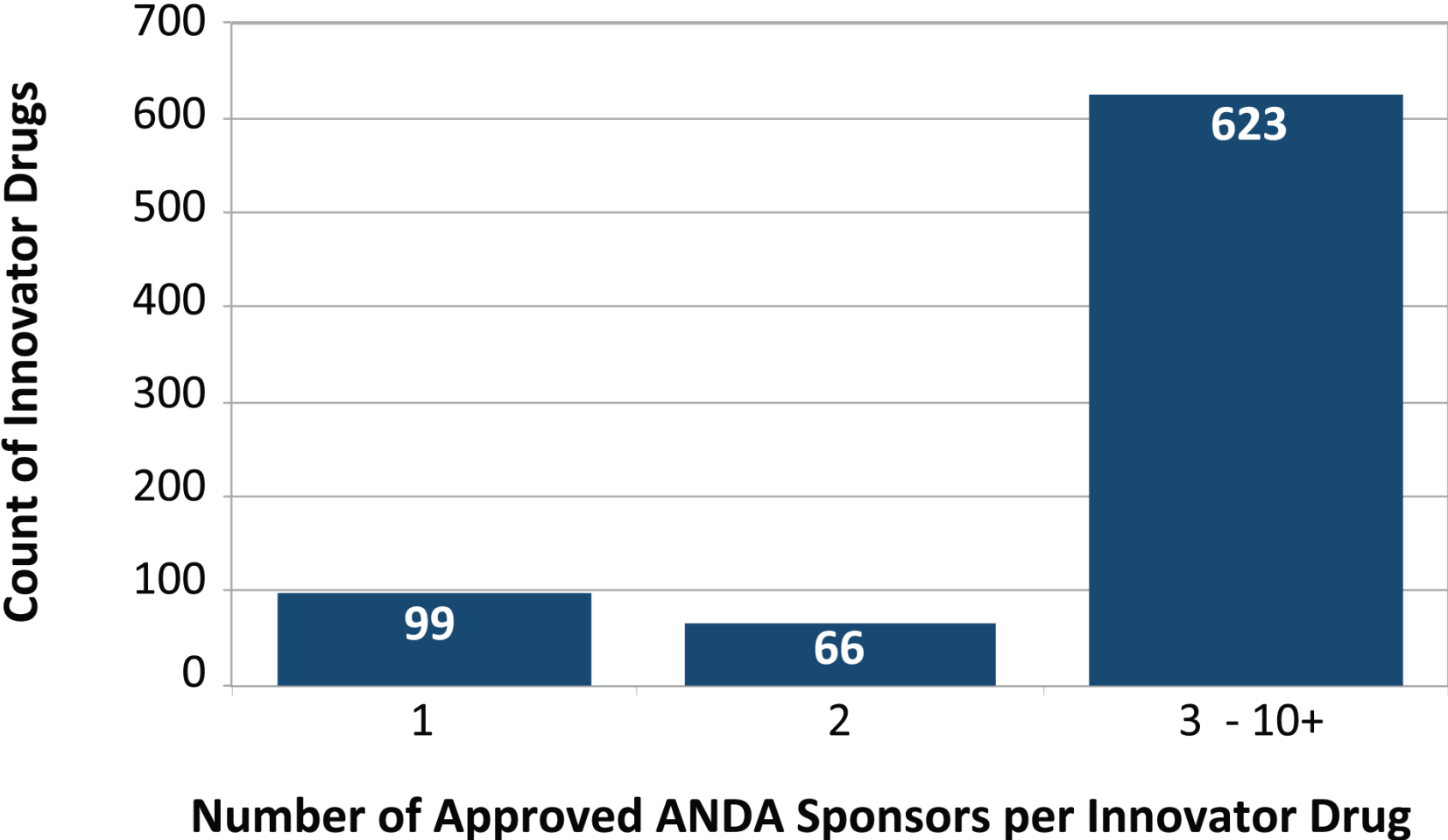
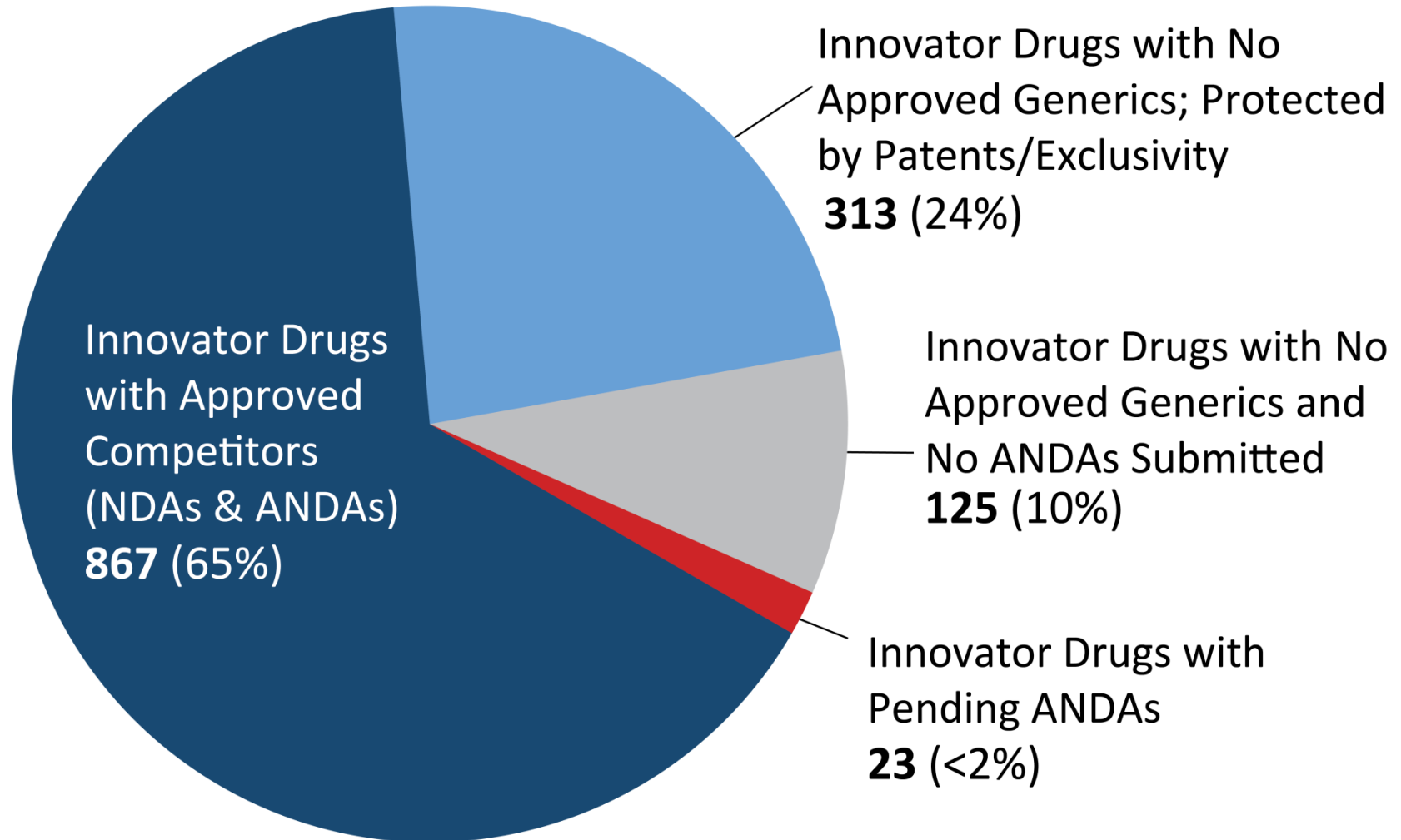


Approved Generic Sponsors per Innovator Drug



The Generic Drug Picture



The data used in this figure are from FDA's Orange Book (downloaded January 7, 2016). The unit of observation is the drug ingredient. Different useable forms (e.g., salts or esters) of the same core molecule are counted as separate drug ingredients; this does not differentiate between multiple dosage forms (e.g., capsules versus tablets) for the same drug ingredient. Each drug ingredient is identified as having either multiple approved sponsors (dark blue group) or a single approved sponsor.



ANDA 'Generics' Workload

Includes Pre-GDUFA ("backlog") and GDUFA ANDAs accepted for filing only; approximate workload

