Moreover, prior to 2007, the FDA files did not explicitly denote when a citizen petition targeted a generic application.

Despite these challenges, we set out to assemble a data set of citizen petitions that had the potential to delay generic applications, along with links to the relevant generic application and timing data. All of this information had to be assembled by hand, piecing together information from citizen petition letters and various generic application files.

Through this approach, we assembled several data sets that allowed us to analyze the timing of when citizen petitions are filed during the generic drug approval process. It also allowed us to see the frequency with which petitions that have the potential to delay are filed.[4] As we describe the method we used to painstakingly piece the information together, we will do our best to include interesting tidbits and insights along the way. (We have to entertain you somehow.)

2 *Compiling All Citizen Petitions from 2000 to 2012*

To begin our analysis, we compiled all documents related to citizen petitions that were filed with the FDA between the beginning of 2000 and the end of 2012, using publicly available FDA databases. We limited our data set to citizen petitions filed prior to 2013 because test analyses indicated that citizen petitions filed after that time frequently related to drugs that had not yet been approved. Without final approval files, one cannot find much of the information necessary for the analysis. One also cannot reach timing conclusions about events within the approval process, given that the process is still underway.

For the period from 2000 to 2012, we obtained 19,520 documents. Multiple documents, however, can correspond to a single citizen petition. For example, supplemental data, support letters, and the FDA's actual response are different types of

[4] For an in-depth discussion of the methodology, see Robin Feldman, Evan Frondorf, Andrew K. Cordova, & Connie Wang, *Empirical Evidence of Drug Pricing Games – A Citizen's Pathway Gone Astray* Stan. Tech. L. Rev. (forthcoming 2017), http://ssrn.com/abstract=2833151. In simplified form, the process can be described as follows: (1) We compiled all citizen petitions and related documents filed between 2000 and 2012; (2) We identified citizen petitions related to pharmaceuticals, with a particular focus on generic drugs; (3) We read each remaining citizen petition and determined which of these petitions were related to generic drugs or had the power to delay generic approval, regardless of the merits or circumstances of the petition; (4) We constructed a data set of all generic applications approved between 2006 and 2015, recording the approval date for each application; (5) We compiled filing dates for the generic applications, pulling them when available from PDFs of letters within the FDA's databases. When filing information was not publicly available, we were able to estimate a filing date down to the quarter-year for most drugs; (6) We matched each citizen petition with the generic application most relevant to the requests made in the petition; (7) Using these citizen petition–generic application pairs, we constructed metrics with the goal of isolating the timing of petitions during the generic drug approval process.