

TABLE 5.1 *All Delay-Related Petitions, by Year*

Year	Number of Delay-Related Petitions	Percentage of Yearly Total Petitions
2000	2	2/47 = 4.3%
2001	4	4/63 = 6.3%
2002	5	5/106 = 4.7%
2003	12	12/120 = 10.0%
2004	26	26/178 = 14.6%
2005	15	15/148 = 10.1%
2006	24	24/184 = 13.0%
2007	25	25/160 = 15.6%
2008	23	23/166 = 13.9%
2009	32	32/171 = 18.7%
2010	31	31/149 = 20.8%
2011	22	22/157 = 14.0%
2012	28	28/141 = 19.9%
<b>Total</b>	<b>249</b>	<b>249/1,790 = 13.9%</b>

concerning pharmaceuticals – have the potential to delay generic competition in those years.

This table also shows that petitions rose in popularity as a way to delay generics or raise issues about generics starting in 2003 and 2004. Not only did the number of citizen petitions rise noticeably after 2002, but the number of delay-related petitions also has sharply increased as a proportion of all petitions.

## 2 *When Are Citizen Petitions Filed in Relation to Final Approval?*

We now turn to the timing of when competitors file citizen petitions and the implications of that timing. The results we describe below show that many drug companies are filing citizen petitions as a last-ditch effort just months before generic approval. Moreover, many of these citizen petitions may be the *very last barrier* standing in the way of final generic approval.

These implications emerged when we graphed the amount of time between when a citizen petition was filed and when the generic application was approved. Our original hypothesis was that if citizen petitions are being used systematically to delay the approval of generics, citizen petitions might be deployed most effectively for that purpose near the end of a generic approval cycle. If filed earlier, a citizen