In many cases, however, the "concerned citizen" behind a petition is actually an enormous pharmaceutical company seeking to stop or delay approval of a generic drug through a variety of different arguments: direct attacks against the generic application and its bioequivalence or clinical data, appeals to safety, calls to preserve or add new exclusivities for the brand-name drug, and more. A number of these petitions seem frivolous or questionable in their aims, and these filings are troubling.[74] As described previously, a citizen petition is a small investment that can easily pay off. The value of the delay can be lucrative, even when the petition is quickly rejected – even a few months of additional delay can be worth hundreds of millions of dollars.

In Chapter 5, we will examine 12 years of citizen petitions; we offer here an interesting example we uncover during that research. Petition FDA-2007-P-0123, filed by the generic company Mutual Pharmaceuticals, sought to delay other generic applications for drug products containing felodipine by asking applicants to "incorporate either a prohibition/caution against co-administration of the drug with certain orange juice-containing products."[75] Felodipine, branded as Plendil, is a common treatment for high blood pressure. Apparently concerned about a study showing differential effects of Seville orange juice versus "regular" orange juice on the metabolism of the drug, the petition from Mutual requests the "innovator company of Plendil to identify for FDA *which specific orange juice* was used in the bioavailability … studies submitted in the [application]" [emphasis added].[76]

Seville oranges are smaller, more bitter oranges often used for marmalade and liqueurs, by the way. We did not know, either.

Anyway, in this petition, Mutual is essentially arguing that different types of orange juice used in brand and generic applications could be a major impediment to the approval of a drug application. Let us be clear – Mutual wanted another generic application delayed over what kind of orange juice was used in a study, even though Mutual already held generic approval based on the same studies.

The FDA forcefully denied nearly the entire petition, clearly stating, "We do not believe that the results of the Malhotra study present a serious safety concern."[77] In fact, the FDA seems to have a clear disdain for the claims made in the petition:

[74] *See* Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 261 (2012).

[75] Citizen Petition from United Research Laboratories, Inc., Mutual Pharmaceutical Company, Inc., to Div. of Dockets Mgmt., U.S. Food and Drug Admin, No. FDA-2007-P-0123, at 1 (Nov. 29, 2007), www.regulations.gov/#!documentDetail;D=FDA-2007-P-0123-0002.

[76] *Ibid*. at 2.

[77] Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Robert Dettery, Vice President, Reg. Aff., Mutual Pharmaceutical Company, Inc., Re: No. FDA-2007-P-0123, at 4 (Apr. 17, 2008) [hereinafter "FDA Response to Mutual"], www.regulations.gov/#!documentDetail;D=FDA-2007-P-0123-0009 (granting in part and denying in part Mutual's petitions). The FDA did grant Mutual's request that a portion of the brand-name Plendil labeling stating