the petition before generic manufacturers were able to "flood the market with non-crush-resistant generic Opana ER."[86]

The FDA failed to find Opana ER CRF significantly safer than Opana ER and even expressed concerns that it might lead to more abuse through injection. In denying the petition, the agency found that Opana ER was not removed from the market for reasons of safety or effectiveness.[87] This ruling ended a not uncommon example of companies espousing safety concerns through product hops and citizen petitions, for reasons more concerned with preserving a market than securing the public health.

Suboxone, the case that featured creative product hopping and allegations of REMS abuse, again provides yet another troubling tale related to opioids. As described in Section A of this chapter regarding REMS-based delay, the generics were forced to obtain a REMS waiver because they were unable to get the brand-name company, Reckitt, to cooperate. Immediately prior to the generic REMS waiver request, which would have allowed the generic to move forward if and when approved, Reckitt announced that it was pulling Suboxone tablets completely off the market (but did not immediately do so).[88] The company cited safety concerns related to pediatric exposure, and it followed up on the *same day* with a citizen petition asking the FDA to refrain from approving any generic application for Suboxone.[89] In its citizen petition, the brand-name company again cited pediatric exposure to demand that medications such as generic Suboxone include "targeted educational interventions on the risk of pediatric exposure" and individual-dose packaging.[90]

The FDA has a process that allows an application to move forward for a generic version of a drug no longer on the market, if the FDA determines that the drug was not removed for safety reasons.[91] The safety move coupled with the citizen petition

[86] Complaint for Mandatory, Declaratory, and Injunctive Relief, *Endo Pharm. Inc. v. U.S. Food & Drug Admin.*, No. 1:12-cv-01936 (D.D.C. Nov. 30, 2012), www.documentcloud.org/documents/2083598-opana-er-endo-complaint.html; *see also* Dreisbach, *How A Painkiller Designed to Deter Abuse Helped Spark an HIV Outbreak*, *supra* note 84.

[87] Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Robert Barto, Vice President, Reg. Aff., Endo Pharma., Inc., Re: No. FDA-2012-P-0895 (May 10, 2013) www.regulations.gov/document?D=FDA-2012-P-0895-0014 (denying Endo's citizen petition and finding that Opana ER was not withdrawn for reasons of safety or effectiveness); *see also FDA Statement: Original Opana ER Relisting Determination*, U.S. Food & Drug Admin. (May 10, 2013), www.fda.gov/Drugs/DrugSafety/ucm351357.htm.

[88] *In re Suboxone* (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 675–76 (E.D. Pa. Dec. 3, 2014).

[89] *Ibid.*; *see* Citizen Petition from Reckitt Benckiser Pharm., Inc. to Div. of Dockets Mgmt., U.S. Food and Drug Admin., No. FDA-2012-P-1028 (Sept. 5, 2012) [hereinafter Citizen Petition from Reckitt Benckiser], www.naabt.org/documents/Reckitt_Benckiser_Pharmaceuticals_Inc_2012_FDA_Citizen_Petition.pdf.

[90] *Ibid.*

[91] 21 C.F.R. § 314.161 (2015). A generic can file a citizen petition asking for an official determination of whether the reference drug was "withdrawn for safety or effectiveness reasons." If it is determined