Aside from restricted distribution programs run through specialty pharmacies, other REMS-based schemes have appeared. Frequently, a REMS program will ask a drug's manufacturers to develop a more detailed medication guide or a communication plan to inform doctors and patients about the elevated risks of a drug. For example, Gilenya (fingolimod), an immunosuppressant that treats relapses of multiple sclerosis, has a REMS that requires a communication plan with materials for doctors and patients, as well as an FDA-mandated pregnancy registry.[42]

When there are multiple manufacturers of a drug – for example, a brand and a generic – the FDA often requires all parties to develop and agree on the same REMS program, known simply as a Single Shared REMS program.[43] In particular, generic entry can be conditioned on FDA approval of a shared plan. The idea that a brand-name company will be willing to cooperate in the approval of a generic seems optimistic at best. Given that brand-name drug makers are able to delay entry by refusing to cooperate, it is not a surprise that some have taken advantage of it, creating another form of generic delay. The generic cannot get its drug approved until the brand-name company cooperates, and the brand-name company avoids cooperating to keep the generic off the market. It could be compared to a high school group project in which one member not only refuses to complete a fair share of the work, but also has an incentive to see the project fail in order to sabotage the grades of others in the group. And with the brand-name company already on the market, only the generics suffer from the delay.

The most notable case dealing with this strategy is *In re Suboxone*.[44] Suboxone is used for the treatment of addiction to opioids, such as heroin and oxycodone.[45] The drug has saved the lives of many addicts, but with severe consequences. Suboxone has itself become a street drug, and it carries the risk of severe side effects and withdrawal symptoms.[46] Suboxone includes both a semisynthetic opioid and a drug used to combat the effects of an opioid overdose (with unpleasant side effects), which is included for the sole purpose of deterring potential users from injecting the drug intravenously.[47]

Richard Rubin, *Pfizer Walks Away from Allergan Deal*, Wall St. J. (Apr. 6, 2016), www.wsj.com/articles/pfizer-walks-away-from-allergan-deal-1459939739.

42 *See Approved Risk Evaluation and Mitigation Strategies (REMS): Gilenya (fingolimod)*, U.S. Food & Drug Admin. (May 14, 2015), www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=22.

43 *In re Suboxone* (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 675 (E.D. Pa. Dec. 3, 2014) (granting dismissal of some counts and in part denying some counts).

44 *Ibid*.

45 Suboxone, www.suboxone.com.

46 *See* Deborah Sontag, *Addiction Treatment with a Dark Side*, N.Y. Times (Nov. 16, 2013), www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupe-can-be-savior-or-menace.html; *Risk Evaluation and Mitigation Strategy for Suboxone*, Indivior, www.suboxonefilmrems.com.

47 *See* Sontag, *Addiction Treatment*, *supra* note 46.