The nine-month period during which generics and the brand-name company could not come to an agreement on a REMS may have been worth upward of $1 billion in Suboxone sales. This is an enormous sum to result from a disagreement presumably not over the medication itself, but over how its use would be monitored and how the risks would be explained to the public.[62]

In the resulting lawsuit, the judge in 2014 dismissed the generic company's standalone claim that Reckitt's actions regarding the REMS amounted to an antitrust violation.[63] The saga of *Suboxone* continues in Part B of this chapter, however, with further complaints of anticompetitive behavior.[64] In short, it is clear that although the FDA would like to encourage everyone "to play nicely together on the playground," mere talk is unlikely to achieve this goal.[65] When billions are on the line, the games are bound to get rough. As the FDA admitted in another REMS case, the agency simply lacks an effective mechanism to force the two parties to reach agreement.[66]

Over the last few years, legislators have begun to offer potential solutions to REMS-related delay issues. One bill, introduced in the House of Representatives in late 2015, attempted to tackle the two main forms of REMS abuse – denial of samples for generic testing and unwillingness to cooperate on single-shared REMS.[67] The bill would require brand-name drug companies to provide samples (after FDA approval) to prospective generics at a nondiscriminatory, commercially reasonable,

2015) (D.D.C. denied motion for temporary restraining order May 21, 2015. Prometheus dropped suit June 11, 2015 where a brand-name company filed suit against the FDA for granting a second REMS waiver in 2014.). The FDA responded by noting, in part, that the brand-name company "dragg[ed] its feet for more than three years rather than collaborate with [the generic]." *See* Federal Defendants' Opposition to Plaintiff's Motion for a Temporary Restraining Order And/Or Preliminary Injunction at 6, *Prometheus Lab. Inc. v. Burwell*, No. 15-cv-00742 (D.D.C. May 28, 2015), www.fdalawblog.net/LOTRONEX%20-%20Roxane%20TRO-PI%20Opp.pdf. Less than a month later, Prometheus completely dropped its suit. *See* Karst, *supra*.

62 Assuming $1.55 billion in sales of Suboxone in 2012. This assumes that the REMS delay was the only issue standing in the way of generic approval, which is not a fully unreasonable assumption. As will be discussed in the next section, immediately before the generics applied for a REMS waiver, Reckitt announced a withdrawal of Suboxone tablets from the market and filed a citizen petition asking for the generic application not to be approved. Immediately after the citizen petition was dismissed in early 2013, the generic applications were approved. Thus, it is possible that generic entry could have been approved immediately after the REMS waiver was approved had Reckitt not taken further action.

63 *In re Suboxone*, 64 F. Supp. 3d at 688.

64 *See* the next section for more details.

65 *See* Ctr. for Drug Evaluation & Res., *supra* note 59, at 272 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research) (discussing difficulties of getting parties to work together to set up a joint REMS).

66 Federal Defendants' Opposition to Plaintiff's Motion for a Temporary Restraining Order and/or Preliminary Injunction, *Prometheus Lab. Inc. v. Burwell*, No. 15-cv-00742, at 15 (D.D.C. May 28, 2015), www.fdalawblog.net/LOTRONEX%20-%20Roxane%20TRO-PI%20Opp.pdf.

67 *See* Fair Access for Safe and Timely Generics Act of 2015, H.R. 2841, 114th Cong. (2015).