MEMORANDUM

To: FDA-2019-P-5151
From: Sara Beardsley, Senior Advisor to the Chief Counsel, Food and Drug Administration
Re: 11/8/19 Call with Amy Saharia, Sarah Harris, Tom Sheehan, and Philip Lidal
Date: January 24, 2020

On November 8, 2019, I participated in a phone conversation concerning a citizen petition filed by GlaxoSmithKline (GSK) found at the above listed docket. Amy Saharia and Sarah Harris, counsel at Williams & Connolly, led the call. Two other GSK representatives were also reported on the phone; my notes reflect the names Tom Sheehan and Philip Lidal. At the outset of the conversation, I explained that the GSK representatives and their counsel should not cover new information, and that any new information should be sent to the citizen petition docket. I approached the call as a listening session.

During the call, Amy Saharia stated that she planned to provide background in two areas: (1) why GSK filed the petition, and (2) the preemption issues raised by the related district court litigation concerning Zofran (*In re Zofran (Ondansetron) Prods. Liab. Litig*., 1:15md2657 (D. Mass.)).

Ms. Saharia stated that the Zofran district court litigation is unlike many product liability cases because there was no recall of Zofran, and no warnings related to the risks in question have been added to the drug's labeling. She noted that the Zofran product liability cases were filed starting in 2015 on the heels of a separate citizen petition, which she characterized as a strategic bet by Plaintiffs' lawyers. She noted that that citizen petition was denied by FDA.

Ms. Saharia stated that GSK views this case as the first significant decision on preemption since *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). She stated that the Zofran district court case had been argued that week, and that the timing of the ruling was in doubt based on GSK's pending citizen petition. She stated that the judge had invited further briefing, and that briefs were due the following week. She said that the question was whether FDA was "fully informed" under *Albrecht*, and that Plaintiffs' main focus was the first category of evidence identified in the citizen petition (three animal reproductive toxicity studies).

Ms. Saharia expressed the view that the case could have an outsized influence on how other courts decide preemption in light of *Albrecht*. In her view, the outcome of the case could have an impact on FDA for two reasons. First, she said Plaintiffs' view of materiality could mean that FDA would be flooded with information by new drug application (NDA) holders. Second, she

stated that Plaintiffs' theory requires judges to second-guess FDA's prior position, which GSK views as an attack on FDA's authority. Finally, she noted that including a warning under state law that is not required by FDA could mislead the public.

Ms. Saharia noted that the citizen petition was novel, and that GSK put a lot of thought into it before submitting it. She stated that such an approach is not something GSK envisions doing often. She stated her view that this situation was unique because FDA had actually rejected the warnings in the past. She stated that GSK would not have filed the petition if they thought they did something wrong, and that GSK wants FDA's views on this question. Because Novartis is now the NDA holder, GSK believed this was the only way they could present the question to FDA. Ms. Saharia noted that GSK had been advocating that the judge involve FDA, and that Plaintiffs had not wanted FDA involved.

Finally, Ms. Saharia noted that GSK was aware that Novartis may soon be engaging in discussions about labeling changes based on epidemiological studies, and that could be an opportunity for FDA to discuss what's in the Zofran labeling.

She noted that the bellwether trial was set for January 2020, although that may change based on the citizen petition.

The call concluded with Ms. Saharia offering to provide additional information as needed. I did not follow up with Ms. Saharia after the call.