Notes from CCH Interview with FDAs Gail Bormel Interview

Gail Bormel, director of the Office of Compounding Quality and Compliance at FDA, spoke with APC's CEO Scott Brunner at CCH, providing APC members with some valuable insight into the thinking of the agency. Following are very high-level notes from that conversation; many of Bormel's statements have been paraphrased for brevity here and *are not* direct quotes.

- Regarding FDA's risk-centered messaging regarding compounding: As a regulatory agency, the FDA receives complaints and is responsible for warning the public of safety issues as opposed to promoting the benefits of pharmacy compounding.

- Enforcement priorities for the next year include notice-and-comment rule-making on the MOU, guidance on the wholesaling provision for 503Bs, and further developing bulks list for both 503A and 503B.

- The agency places emphasis on *serious* adverse events specifically related to drugs that are shipped interstate so that the FDA can help contain issues. The agency is not interested in adverse events that do not cause or threaten serious harm to a patient.

- Regarding 483s: In 2022, 25% of FDA inspections did not result in a 483 for 503A pharmacies (this data can be found on the FDA track website). Responses from pharmacies to 483s can be made public if the pharmacy specifically requests this. A goal is to improve on the timeliness of issuing, posting, and completing regulatory action or closing 483s. Also, FDA is interested in APC's suggestion that the agency produce a regular summary of frequent findings in 483s so the profession can better train on those issues.

- Regarding the temporary guidance allowing 503A pharmacies to help alleviate shortages during the COVID-19 pandemic, the FDA is not aware of any adverse events resulting from the work of 503As to source COVID drugs to hospitals under the guidance.

- Regarding compounded hormone therapy: if/when the agency takes action, it will be through the formal PCAC process.