

Table 10.3 Summary of Estimated Hours and Full-Time Equivalents (FTEs) by Cost Category and by Fiscal Year

Category	FY13	FY14	FY15 (First 2 Quarters Only)	Total
FTEs Estimated by Eastern Research Group, Inc. (ERG) for Biosimilar-Related Work				
IND, pre-IND, and BPD meetings	21.73	23.28	10.79	55.80
351(k) BLA review	0.00	0.95	11.79	12.75
Regular biosimilar-related meetings	3.56	2.90	2.15	8.62
Policy	8.96	8.42	6.31	23.69
Science and research	9.42	7.44	4.13	21.00
Outreach	0.00	0.00	1.29	1.29
CDER offices not covered by estimates above (provided by FDA)	10.95	11.02	21.40	43.37
FDA Office of the Commissioner ^a	12.98	13.43	11.41	37.82
Office of Regulatory Affairs (provided by FDA)	0.00	0.00	–	0.00
CBER (provided by FDA)	3.89	1.33	–	5.22
Total FTEs	70.99	68.90	70.93	210.83

Source: FDA, <http://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm459686.pdf>.

Note: FY13: fiscal year 2013; FY14: fiscal year 2014; FY15: fiscal year 2015.

^a FTEs for fiscal years 2013 and 2014 for the FDA Office of the Commissioner were estimated based on the share of total FDA salary that the Office of the Commissioner represents. These percentages were 21.34% for fiscal year 2013 and 21.18% for fiscal year 2014. ERG used the fiscal year 2014 percentage for fiscal year 2015 since an estimate of the percentage for fiscal year 2015 is not yet available. These percentages were then applied to the sum of all CDER, CBER, and Office of Regulatory Affairs FTEs in this table.

emerge as winners will have sophisticated scientific abilities, more like the developers of new drugs.

The FDA perspective on biosimilarity will emerge with greater clarity as more complex molecules are approved as biosimilars; in all likelihood, the FDA will hold advisory meetings wherein much will be disclosed, and that will provide a more focused understanding that the biosimilar sponsors will find very useful.

So, stay tuned. The FDA has opened the doors to the most revolutionary modality of treatment of critical illnesses becoming affordable; the cost savings from these products will make the small-molecule generic industry a dwarf. The value to humankind will be immeasurable, if only we are able to pay attention to what the former Commissioner of the FDA, Dr. Margaret Hamburg, to whom this book is dedicated, said:

Efforts to undermine trust in these [biosimilar] products are worrisome and represent a disservice to patients who could benefit from these lower-cost