U.S. FOOD & DRUG ADMINISTRATION

Regulatory Concerns and Challenges During and After the Covid-19 Pandemic: FDA/CDER/Division of Cardiology and Nephrology Perspective

Norman Stockbridge
norman.Stockbridge@fda.hhs.gov

Workload

- For the last few years, CDER has seen about 400 new INDs per month (includes some exemptions)
- Between March 2020 and now, it has been about 1000 new INDs per month
- May be tapering off a bit as there are fewer individual emergency IND requests

Workload-2

- Much of the extra work has been managed in antiviral and pulmonary/critical care divisions, with DCN a distant third.
- Efficient triage process instituted; often requiring fairly well-developed study plan before discussions
- Multiple guidances developed
- At least weekly meetings to harmonize on approaches
- Very strong encouragement to obtain controlled data

Workload-3

- Office of New Drugs underwent final/third stage of reorganization in March
  - Division of Cardiovascular and Renal Products → Division of Cardiology and Nephrology
  - Office of Cardiology, Hematology, Endocrinology, and Nephrology
  - RPMs (mostly) in Office-level Division
  - Pharm/Tox in Office-level Division
- Four senior cardiology reviewers retired or moved since Dec 31; no new hires
- One MO detailed to COVID triage

Workload-4

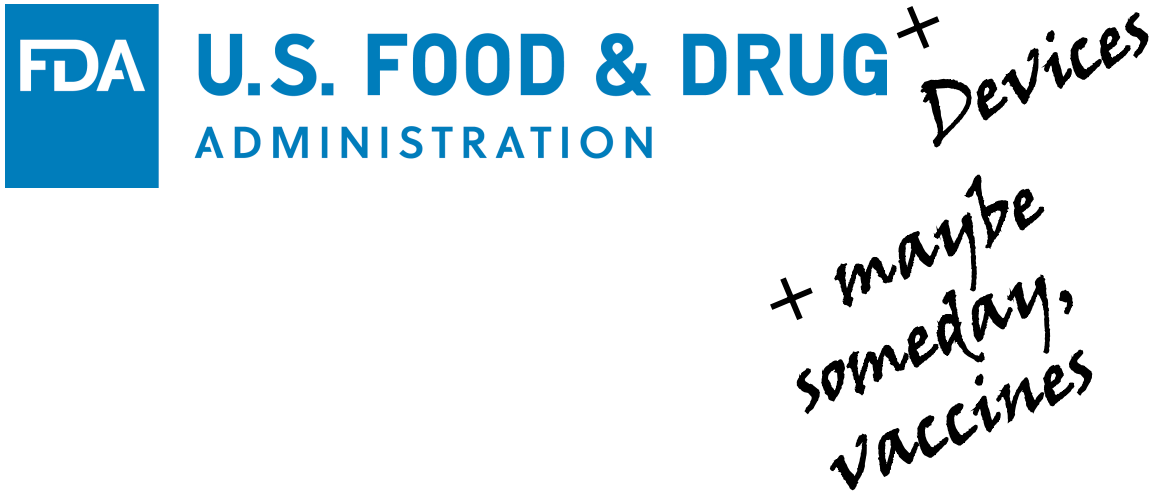
- Two cardiologists manage most work related to treatment of COVID
- Deputy Director has managed two EUAs—with CDRH—to ensure availability of dialysate solutions
- Numerous near-generic drugs for acute care settings requiring special attention to balance suboptimal manufacturing with life-threatening drug shortages.

Workload-5

- Uptick in meetings
  - Product-specific
    - Drugs to treat COVID
    - Programs impacted by COVID
    - General product development
  - Non-product-specific
    - How to cope with impact of COVID
    - What can we learn here to improve trials today and post-pandemic

Operating principles

- There has long been fat to trim and slow-uptake of more efficient processes. COVID may help the community overcome its inertia.
- The Agency is exploring all manner of analyses to cope with missing data in non-COVID studies. Some of these will not be compelling.
- Part of preparing for the post-COVID era is ensuring that regulatory standards are maintained.


FDA
U.S. FOOD & DRUG
ADMINISTRATION
+ Devices
+ maybe someday, vaccines