FDANEWS Webinar

FDA and Politics: A Look at FDA Achievements and What Lies Ahead

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Marc J. Scheineson, Esq.
Partner
Alston & Bird LLP
202-239-3465
marc.scheineson@alston.com

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Policy Drivers of FDA Agenda

- Agenda of Trump Administration
- Agenda of HHS Secretary Alex Azar
- Agenda of Congress
- Agenda of FDA Commissioner

The Trump Agenda

Trump Agenda (cont.)

- Promote domestic manufacture through lower corporate taxes; trade incentives
- Increase FDA industry user fees
- Repeal medical device tax
- Reduce regulation by federal agency hiring freeze; repeal and prevent new regulations
- Leverage industry reduction of drug prices
- Ban or restrict ENDS flavors to reduce youth usage

Azar HHS Agenda

- Keep Donald J. Trump happy; retain HHS job
- FDA, not HHS, is where "rubber meets road"
- Insure FDA informs and coordinates policy decisions with HHS
- Input into selection of nominated FDA Commissioner
- Reduce Rx drug prices; allow for finding that limited drug imports won't jeopardize public health
- Reduce youth use of ENDS; maintain declining use of tobacco products

Agenda of Congress

- Manifest through Legislation
  - PDUFA VI (Reauthorization every 5 yrs.)
  - 21st Century Cures Act
  - Annual Appropriations- contain hard and soft earmarks
- Confirmation Process for FDA Commissioners
  - Gottlieb Confirmation Hearings-Senate HELP Committee (4/15/17)
  - Resigned effective March 31, 2019-"To spend more time with his family"
  - Acting Commissioner Sharpless appointed 4/5/19
  - Federal Vacancies Reform Act requires nomination within 210 days (no later than 11/1/19)
  - Competition between Dr. Ned Sharpless and Dr. Stephen Hahn (MD Anderson)

Agenda of Congress (cont.)

- Informal methods used by Legislative Branch to influence Executive Branch policy
  - Letters to FDA on behalf of constituents (~2,500/yr.)
  - Committee hearings
  - Requested committee and staff briefings
  - Telephone calls to FDA policymakers

FDA Reauthorization Act of 2017 (FDARA)

- 42.5% FDA budget based on User Fees
  - ~$2 billion+/yr.
  - $8.50 per American per year
- Reauthorization required every 5-yrs.
- Must pass legislation carries "germane" FDA reform initiatives
- PDUFA, MDUFA, etc. include "commitment letters" or performance standards; annual FDA reporting required to Congress

Submission Type	FY 13	FY 14	FY 15	FY 16	FY 17*	FY 18	FY 13 to FY 17 5-Year Average	FY 18 Compared to 5-Year Average
Original Priority NMEs and BLAs	19	28	25	23	31	51	25	+104%
Original Standard NMEs and BLAs	35	21	32	24	22	23	27	-15%
Original Priority non-NME NDAs	8	10	9	12	24	20	13	+54%
Original Standard non-NME NDAs	76	72	84	72	81	64	77	-17%
Class 1 Resubmitted NDAs and BLAs	11	7	7	5	8	9	8	+13%
Class 2 Resubmitted NDAs and BLAs	38	35	37	31	49	50	38	+32%
Priority NDA and BLA Efficacy Supplements	29	40	52	54	78	109	51	+114%
Standard NDA and BLA Efficacy Supplements	123	165	136	145	173	147	148	-1%
Class 1 Resubmitted NDA and BLA Efficacy Supplements	2	7	0	3	3	3	3	0%
Class 2 Resubmitted NDA and BLA Efficacy Supplements	10	10	11	11	11	10	11	-9%
NDA and BLA Manufacturing Supplements requiring prior approval	873	776	765	842	968	1,020	845	+21%
NDA and BLA Manufacturing Supplements not requiring prior approval	1,542	1,392	1,614	1,475	1,540	1,506	1,513	0%

* FY 2017 numbers were changed to reflect updates to data presented in the FY 2017 PDUFA performance report.

Detailed 2018-2019 PDUFA Deliverables

- Streamlining electronic submission processes
- Adaptive design for clinical trials
- Continue Sentinel development
- Enhance use of biomarkers
- Use of Real World Evidence
- Expedite formal meetings with sponsors
- Adopt Good Review Management Principles
- Improve FDA hiring and retention of trained scientists
- Enhance regulatory science and improve drug and device development
- Enhance transparency and accountability
- Use innovative designs in clinical trials
- Interactive development for rare disease INDs
- Modernized time-reporting implementation plan

Detailed Deliverables-21st Century Cures

- Issuance of patient focused drug development guidance
- Qualification of drug development tools
- Grants for studying continuous manufacturing
- Novel clinical trial designs
- Identification and use of Real World Evidence
- Informed consent waivers or alterations for clinical investigations
- Accelerated review for regenerative advanced therapies
- Expedited review of combination products
- Limited population pathway for antibacterial and antifungal drugs
- Breakthrough devices program
- Expansion of use of humanitarian device exemption
- Training to CDRH reviewers on use of recognized standards
- Expansion of exemptions for Class I and II devices
- CLIA waiver improvements
- Least burdensome device review
- Clarifying medical software regulation
- Expanding hiring authority for scientific, technical and professional personnel
- Establishment of food and drug intercenter institutes (e.g., Oncology Center of Excellence)
- Guidelines for best practices for drug and device surveillance

Gottlieb Agenda

- Strong leader; media savvy like Dr. David Kessler
- Years of prior FDA management experience let him “hit ground running”
- Multiple press releases daily; 5-7 of new projects weekly
- Served as Commissioner from 5/9/17-4/30/19 (less than 2-yrs.)
- Priorities included: curtail opioid abuse; reduce drug prices by expediting generic and biosimilar approvals; greater FDA transparency; expedite product review

Gottlieb Agenda (cont.)

- Forcefully address opioid abuse epidemic
  - Extended ER/LA REMS; include evidence of prescriber pain management training
  - Updated boxed warnings
  - Withdrew Opana ER from market
  - Incentives to develop new non-opioid pain meds.
  - Restricted number of pills dispensed
  - Developed evidence of ineffective chronic use
  - Stronger Import Alerts
  - Curtailing illicit Internet marketing
  - Interdiction in International Mail Facilities
  - Expansion of Office of Criminal Investigations; lab capacity for testing in Forensic Chemistry Center
  - New enforcement authority (SUPPORT Act)

Gottlieb Agenda (cont.)

- Reconstruct Tobacco Regulation
  - ANPRM to reduce product nicotine levels
  - Delay due date for preapproval application SE Reports, PMTAs
  - ANPRM for flavored tobacco product performance standards
  - Alarmed by reported increased youth usage of ENDS
    - Elicited voluntary concessions from JUUL and 5 ENDS makers
      - Curtail sale of flavor PODS at retail
      - On-line age verification
      - Support for 21-yr. minimum tobacco purchase age
      - Eventual agreement to end “SWITCH” media campaign
  - Draft Guidance prevent sale of flavored tobacco product to youth
  -

Gottlieb Agenda (cont.)

- Streamline product application review
  - IND templates for 30-day reviews
  - Increase approvals of combination drug + devices
- Safety signal tracker
- Update guidance measuring clinical effectiveness using RWE
- Growing Sentinel's ability to detect new safety problems
- Enhance FAERS-enhancing analytics; more info. Available to public
- Reexamine breast implants and use of acellular dermis matrix for breast reconstruction

Sharpless Agenda

- Keep head down and avoid controversy that might jeopardize nomination and Senate confirmation
- Continue progress to meet statutory deadlines and user fee “commitment letters”
- Day-to-day running of Agency
- Continue to implement major initiatives of Azar/Gottlieb
  - Tobacco flavor ban; reduced youth usage of ENDS
  - Reducing opioid abuse epidemic
  - Measures to reduce Rx drug prices

21st Century Cures Act

- Breakthrough devices (Sec. 3051)- Priority review and management attention if designated as "more effective treatment or diagnosis for life threatening or irreversibly debilitating disease or condition"
- Humanitarian device exemption (Sec. 3052)- Doubles the ceiling of affected persons annually from 4,000 to 8,000
- Recognition of standards (Sec. 3053)- Allows ruling from FDA w/in 60-days on recognition of standard
- Exemption process (Sec. 2054)- Requires review of classifications in 2017 and every 5-yrs. To consider if Class I or II devices should be exempt with listing of newly-exempted devices in lieu of amending classification regs.
- IRBs (Sec. 3056)- Allows single IRB to oversee multicenter device trial
- CLIA waivers (Sec. 3057)- Allow easier access to exemptions of IVDs from CLIA inspections

21st Century Cures Act (cont.)

- Least burdensome device review. (Sec. 3058)- Requires CDRH reviewer training on implementing elements of least burdensome requirements; Ombudsman audit; requests for additional information from PMA sponsors must be "minimum required information" to support safety and effectiveness determination"
- Device reuse (Sec. 3059)- FDA must list reusable device types where 510(k)s must include validated instructions for cleaning, disinfection and sterilization
- Clarifying regulated software (Sec. 3060)- Defines categories of software removed from device definition (e.g., wellness, admin. support to hospitals, EHRs, displaying data to doctors unless for diagnosis; etc.)
- Combination products and regenerative medicine- details guidance required to prevent multi-center review of equipment used in cell therapy, etc.

What's Next

What's Next (cont.)

- Stephen Hahn likely nominee for FDA Commissioner
- Sharpless can hold acting role indefinitely while Hahn awaits confirmation
- May return to role as NIH-NCI Director following confirmation
- Role of Republican v. Democratic campaign contributions
- Criticism of delay in curtailing vaping injuries/deaths; declining generic approvals; delay in CBD regulation
- Protracted vetting process

What's Next

- Biography of Stephen Hahn
  - Radiation oncologist
  - Chief Medical Executive-MD Anderson Cancer Center
  - Former Vice Chair- Research Department of Radiology, Univ. of Penn.
  - Former Chief-NCI Prostate Cancer Clinic
  - Former Senior Investigator
  - PHS Commander
  - Little published literature or policy positions
  - Likely to rely on HHS leadership and FDA Trump appointees
  - Unlikely to become activist Commissioner like Gottlieb/Kessler
  - Potential 1-year term

Questions