Pharmacist provider status bill

- -Bill SB 493
- -Signed into law in 2013
- -Expanded the scope of practice of the pharmacy profession
- -Aid in the communication between pharmacists and other healthcare providers
    - -AKA healthcare integration
- -(State specific bill in California)

Effects of the legislation

- -Allows all pharmacists to furnish self-administered hormonal contraceptives
- -Furnish prescription nicotine replacement products for tobacco cessation
- -Creates an advanced practice pharmacist (APP) recognition
- -To become a registered app you must meet two of the three criteria
- -Earn certification in a relevant area of practice complete a post grad residency program
- -Have a provided clinical service to patients for 1 year under a collaborative practice agreement or protocol with a physician, APP pharmacist, CDTM pharmacist, or health system

What can APP (Advanced Practice Pharmacist) do?

- -Perform patient assessments
- -Order and interpret drug therapy
- -Refer patient to other health care providers
- -Initiate adjust and discontinue drug therapy
- -Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers

Franken and Collins FDA Amendment: Improving Generic Drug Competition

- -Senate approved May 11, 2017 as part of the Food and Drug Reauthorization Act
- -Supposed to help with price spikes in drugs; older drugs with only one manufacturer and no generic competitor are vulnerable to dramatic and sudden prices increases
- -FDA required to prioritize the review of certain generic applications within 8 months
    - -Drugs that have no more than three approved competitors
    - -Drugs that are on the drug shortage list

List of Actively marketed drugs

- -Aims to improve market competition by prevent shortages that result from market exists
- -All drug companies required to report to the FDA if they plan to :
    - -Remove a product from market,
    - -Withdraw an approved application
    - -Transfer an approved application within 180 days of such event
    - -FDA must have a list of gen drugs with no more than 3 approved competitive drug products on market and determine which drugs are medically necessary

Expediting generic drug development

-Provides additional support and enhance communication with certain applicants to improve the quality of applications from the beginning

-Establishes a process for communications in advance of the actual ANDA submission

-At the request FDA sponsor, can expedite the review of an application

-Can meet with FDA prior to submission of application

-Timely advice and communication to ensure collection of data necessary for approval

-Drug sponsor must report to FDA one year following approval on whether or not the drug is marketed

Improves Transparency in FDA reporting

-Regarding backlog and pending generic apps, priority review apps, facility inspections

-FDA required to report annually the:

-number of applications subject to priority review (generics, sole-source, and shortage drugs)

-Time it takes to schedule and complete facility inspections

-On a quarterly basis

-Number of ANDA applications filed prior to Oct. 1, 2014, that are still pending

-Number of applications for priority review and the amount withdrawn

-Average approval times

Epipen Controversy

-Price increased over 500% since 2007

-Moral/ethical issue

-CVS released generic competitor at ⅛ of the price in January 2017