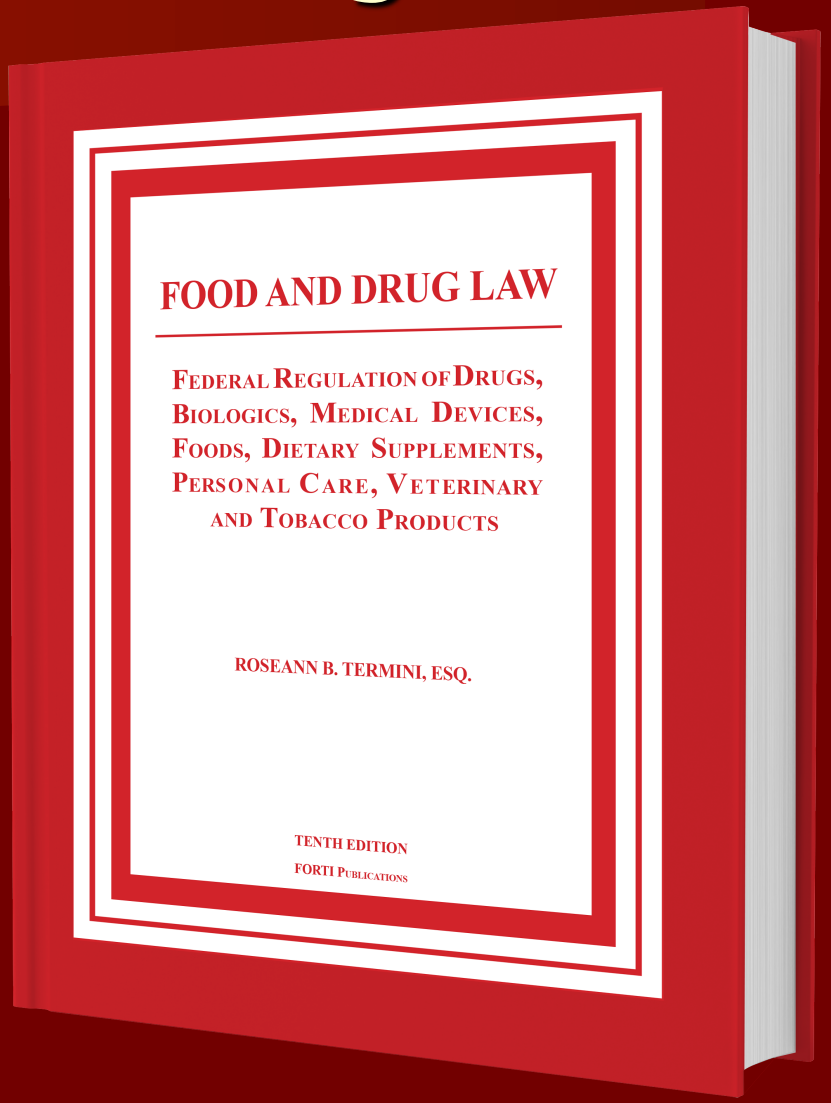
Right-to-Know Right-to-Try and Right-to-Request

Roseann B. Termini, Esq.

Food and Drug Law



Food and Drug Law

Roseann B. Termini, ***Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products Regulations***

www.fortipublications.com

Contact Information

- rbtermini@widener.edu
- www.fortipublications.com
- Publications SSRN Author page
- http://ssrn.com/author=944614
- All Topics Food and Drug Law Blog
- http://fortipublications.com/blog/
- https://twitter.com/RoseannTermini
- www.linkedin.com/in/roseanntermini/

Right to Try

- Right-to-Try or Right-to-Know
- Right-to-Request

Federal Movement in Right-to-Try

- Right-to-Try Federal Legislation
- Passed 2018
- Pub. L. No. 115-176
- 132 Stat. 1372

Federal Right to Try

- More ??????? than answers

Question

- Does the federal law provide additional benefits to patients than what is already provided by the FDA expanded use?

State Right -to -Try

- 41 States to date……

Question?

- Are the state Right-to-Try laws usurping FDA authority?

Examples of State Right-to-Try

- Alabama
- Alaska
- Arizona
- Arkansas
- California
- Colorado

FIRST STATE

- Colorado
- Right-to-Try Law includes Investigational Medical Devices

Federal Law

- Does not include investigational devices
- Prior legislative action

Autonomy

- Right-to-Know

Autonomy
Right to request

- Right-to-Try State vs. Federal Legislation vs. Federal Compassionate Use
- States Right-to-Try impetus for Federal "streamlined" process and Federal Rt.-to-Try Law (2018).
- *Individual Patient Expanded Access Applications* - Form FDA 3926 (June 2016)

Question

- Do these laws provide those who are desperately ill with "unrealistic false hope"?

Question

- Is there the promise of therapies that might not even be received?
- How does the physician handle the issue?
- What role do drug/medical device companies have?

Latest Federal Movement in Right to Try

- Right-to-Try or Right-to-Know
- Right-to-Request

Federal Law Lessons Learned

- Rush to Enactment
- Comparison to National Bioengineered Food Disclosure Law (GMO)
- Trigger Clause
- Vermont spurred federal GMO law

Investigational Human Drugs

- Critical Point- Mission of FDA
- Public protection
- FDA aims to foster public protection
- Efficient and expedient review

Review Time

- Could be insufficient for desperately ill.

Clinical Trials

- Might not qualify
- Protocols for eligibility

IND Process

- Investigational New Drug
- Several steps
- 30 day waiting period prior to clinical trials

Emergency Use IND

- Insufficient time for an IND submission
- Ineligible for existing study protocol

Solution

- Expanded access or commonly known as Compassionate use
- 21 C. F. R sec. 312.300
- Outside of the clinical trial
- Approval rate 99%

Involvement

- Several entities- for example:
- Manufacturer
- Health care practitioner
- Insurance company

Medical Devices

- Investigational devices similar to drugs
- Allows for shipment of unapproved devices for investigational reasons

Medical Device INDs

- Patient eligibility criteria

Expanded Access Medical Devices

- Emergency Use- life threatening condition

Humanitarian or Compassionate Use of Devices

- Life-threatening
- No alternative treatment
- Time of essence

FDA Action Pre Federal Right-to-Try

- FDA Expanded Access or Compassionate Use- outside of a clinical trial

Problem

- How to obtain?
- Efficiency

Solution

- FDA Streamlined process
- Impetus-perhaps due to state-right-to-try
- FDA released in 2016 Form 3926
- Guidance document 2017

Federal Right-to-Try

- Step towards patient autonomy
- Drug Manufacturer key player
- Insurers key players
- Health care providers key players

Sense of Senate

- Only expands the scope of individual liberty
- Alternative pathway alongside existing expanded access policies of FDA

Access

Access is contingent on the:

- Physician
- Manufacturer
- Insurance Companies

Proactive Solutions

- Collaborative Approach
- Amend to include Medical Devices
- What about Medical Foods and Dietary Supplements?
- Informed Consent

Goal Right-to-Request

- Whether State, Federal or FDA

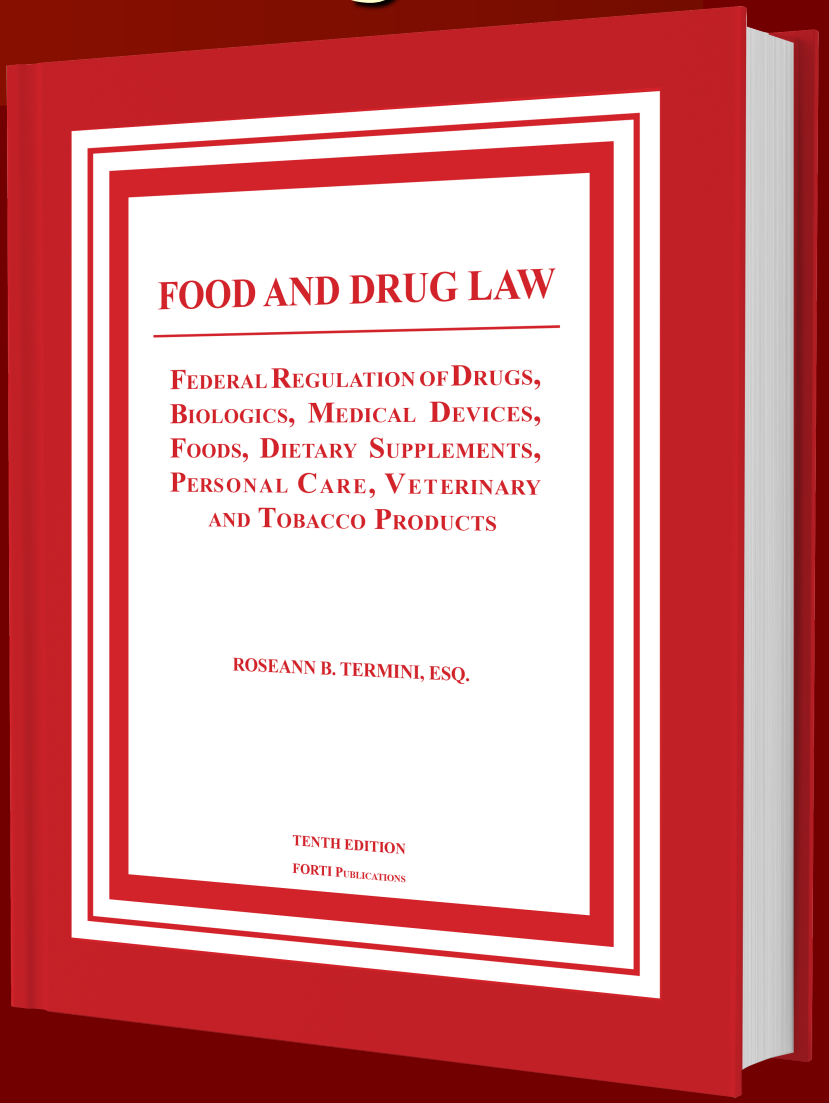
Best Practices

- User Friendly Approach
- Counsel
- Options
- Foster Patient Self-Determination

The Latest 'Federal Movement' in the Food and Drug Law Arena: The Federal Right-to-Try or Rather Right-to-Know and Thus Request Investigational Therapies for Individuals with a Life-Threatening Disease or Condition

- Indiana Health Law Review, Vol. 16, Issue 1, November 2018
- https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3239582

Food and Drug Law



Food and Drug Law

Roseann B. Termini, ***Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products Regulations***

www.fortipublications.com

Contact Information

- rbtermini@widener.edu
- www.fortipublications.com
- Publications SSRN Author page
- http://ssrn.com/author=944614
- All Topics Food and Drug Law Blog
- http://fortipublications.com/blog/
- https://twitter.com/RoseannTermini
- www.linkedin.com/in/roseanntermini/