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

Roseann B. Termini, Esq.
Food and Drug Law

FOOD AND DRUG LAW

FEDERAL REGULATION OF DRUGS, BIOLOGICS, MEDICAL DEVICES, FOODS, DIETARY SUPPLEMENTS, PERSONAL CARE, VETERINARY AND TOBACCO PRODUCTS

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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

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Federal Law

- Does not include investigational devices
- Prior legislative action
Right-to-Know
Autonomy

Right to request

- Right-to-Try State vs. Federal Legislation vs. Federal Compassionate Use
- 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

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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

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Solution

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

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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

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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

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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

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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

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