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COVID-19 HEALTHCARE PROVIDER UPDATES

EXPERIMENTAL COVID TREATMENTS: OPERATIONAL, REGULATORY, AND PREP ACT TORT LIABILITY PROTECTIONS CONSIDERATIONS

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Agenda

- Undertaking research on novel treatments in the hospital setting
- Collaborations between health systems and manufacturers to get access to experimental treatments on a compassionate use basis
- The PREP Act

PREP ACT

PREP Act

- The Public Readiness and Emergency Preparedness Act was signed into law (Public Law 109-148) in December, 2005.
- Allows the HHS Secretary to issue a declaration to provide Federal and State liability immunity to "Covered Persons" against any claim of "loss" relating to the manufacture, distribution, administration, or use of "Covered Countermeasures," except for claims involving "willful misconduct."
- Has been used, for example, for outbreaks including:
  - Ebola
  - Zika
  - H1N1

PREP Act *(cont.)*

- Ostensible primary purpose was to insulate manufacturers producing vaccines for public health crises from liability
- However, HHS officials now are using the statutory authority more broadly
- The HHS Declaration pertaining to COVID-19 was published on March 17, retrospective to February 4, 2020, and continues through October 1, 2024
- Tracking the statute, the Declaration addresses the following key considerations:
  - Recommended Activities
  - Covered Persons
  - Covered Countermeasures

PREP Act *(cont.)*

- Recommended Activities
  - the manufacture, testing, design, development, distribution, administration, and use of the Covered Countermeasures
- Administration includes physical provision of the countermeasures, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

PREP Act *(cont.)*

- Covered Persons
  - Manufacturers
    - a contractor or subcontractor of a manufacturer, or its officials, agents, and employees; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer
  - Distributors
  - Program planners - State or local government . . . or other person who supervised or administered a program with respect to the administration . . . of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer . . . a covered countermeasure
  - Qualified persons – A licensed healthcare professional

PREP Act *(cont.)*

- Covered Countermeasures
  - Any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product,
  - a product to address a condition caused by a pandemic therapy, e.g., therapy to address adverse events, or
  - a product used to enhance the effectiveness of a countermeasure, e.g., vaccine adjuvant.
- Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

PREP Act *(cont.)*

- Qualified pandemic or epidemic products
  - Drugs, biologicals, and devices where treatment of the disease is its labeled indication
  - Drugs or biologicals used for treatment of the disease under an IND or IDE
  - Authorized by FDA under its emergency use authorization (EUA) authority
- In order to qualify for immunity, the Covered Person, Covered Activities and Covered Countermeasures, must be related to:
  - Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or
  - Activities authorized in accordance with the public health and medical response of the "Authority Having Jurisdiction" to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a "Declaration of an Emergency".

PREP Act *(cont.)*

- Impact of compliance with the PREP Act
  - Immunity from Federal or State law, including tort immunity, relating to death, injury, trauma, or damage to property
  - Note that immunity matures at the point of tort claim adjudication—either through administrative action or in federal court.
  - Liabilities not associated with the COVID treatment are not covered, even if they arise during COVID treatment

PREP Act *(cont.)*

- Willful Misconduct
  - Acts as an exception to the immunity
  - Includes acts taken for a wrongful purpose, without justification, or in blatant disregard that the risks outweigh the potential benefits

PREP Act *(cont.)*

- Practical considerations for conducting COVID-related clinical research Activities to maximize potential for PREP Act Immunity
  - Conduct research through one of the approved processes, such as seeking an EUA or filing an emergency IND, or an expanded access protocol, through submission of pre-IND with FDA or through BARDA meeting process
  - Ensure investigational product or investigational use is a covered countermeasure—either document through drug supplier or document internally
  - Ensure through the sponsor or internally that the appropriate government program or agreement is in place to cover the research
  - If working with a pharma sponsor, ensure agreement for research is properly drafted and roles and responsibilities of each party identified; ensure discussion of liability and indemnification
  - Ensure clinical trial documents inform participants of possible coverage under the PREP Act for injuries
  - Document that both the hospital and the clinician are intentionally seeking to comply with the PREP Act; note that there may be abbreviated regulatory functions, e.g., adverse event reporting or site monitors
  - Consider need for universal access for clinical trial data or other data sharing arrangements

Biography

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Andrew Ruskin counsels hospitals, pharmaceutical and medical device companies, and Medicare Advantage plans, among others, on a range of Medicare and Medicaid regulatory, litigation, and transactional matters. Andy advises on strategic issues surrounding coverage, reimbursement, and compliance, as well as drug pricing and price reporting. He defends clients in investigations by the US Attorney's Office and the Department of Health and Human Services Office of Inspector General, and he appears before several regulatory tribunals, such as the Provider Reimbursement Review Board and the HCPCS Committee.

Biography

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Kathleen Sanzo centers her practice on regulatory and compliance issues connected to products regulated by the US Food and Drug Administration (FDA). She leads and counsels clients on matters relating to prescription, OTC drug, and biotechnology products clinical testing; food, dietary supplement, and cosmetic product manufacture, approval, marketing, and distribution; device promotion and labeling issues; food, drug, and device compliance matters; and all consumer product issues regulated by the US Consumer Product Safety Commission (CPSC) and state enforcement agencies.

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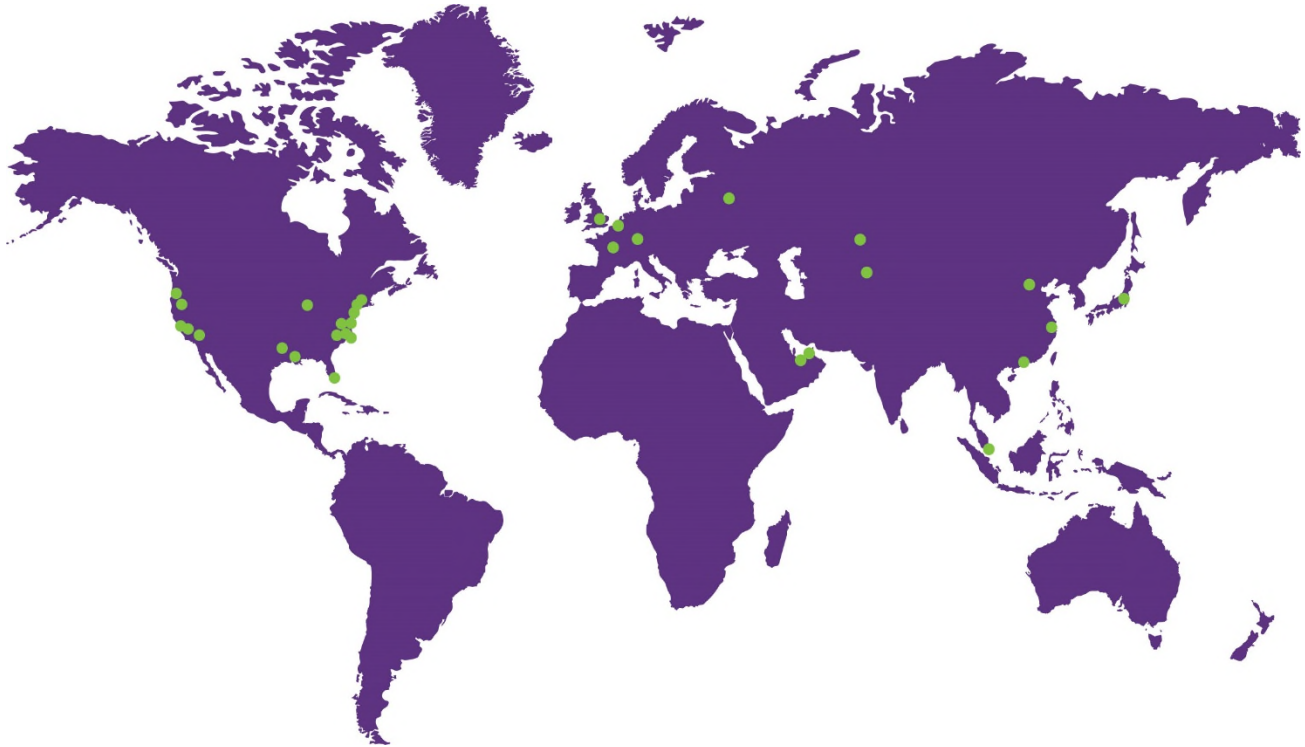

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