Managing Liability Related to Public Health Emergency Medical Countermeasures
The U.S. Approach

European Commission workshop on the joint procurement of medical countermeasures/ High-level hearing on the implementation of the Council Recommendation on seasonal influenza vaccination

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Background

• Drug and vaccine development is an expensive, high risk undertaking

• The priorities of the private capital markets, instead of the priorities of government, tend to drive the development of pharmaceuticals.

• Historically, it is not unusual for a manufacturer of emergency medical countermeasures to find that, under ordinary tort law and liability models, developing, manufacturing, and deploying a product is far more economically risky than the potential economic gain from the sale of the product.

• Therefore, in cases where the governmental national security and public health interest in availability of emergency medical countermeasures is sufficiently high, liability protections and compensation models have been considered to reduce risk for manufacturers and to compensate those that might be injured as result of the administration or use of medical countermeasures.
Two General Approaches to Managing Liability

In the context of administration of medical countermeasures during a public health emergency, liability protections for potentially liable entities (e.g. vaccine manufacturers, donor countries, etc.) may be implemented as “indemnification” and/or “immunity”.

**Immunity**
Potentially liable entities are granted immunity by a particular jurisdiction (e.g. by the United States) and cannot be sued in that jurisdiction as specified under the terms of immunity (e.g., the law and implementing regulations/declarations).

- Given the lack of legal recourse available to injured individuals, a no-fault injury compensation program can be made available to compensate claimants in the event they suffer injuries or adverse events resulting from the administration or use of the medical countermeasure.

**Indemnification**
Claimants can initiate legal claims for loss or damage in a jurisdiction against liable entities (e.g. manufacturers, etc.). If a court determines that the liable entities owe the claimants, those liable entities pay the claimants for loss or damage.

- Liable entities may rely on a third party to indemnify them for the cost incurred paying the claimants.
  - The third party providing indemnification (insurance company, donor or recipient countries’ governments, international organization, etc.) may be responsible for directly paying or reimbursing claims brought against the liable entity.
Immunity Approach: The U.S. PREP Act

• The Public Readiness and Emergency Preparedness Act (PREP Act) provides liability immunity in US courts related to the manufacture, testing, development, distribution, administration and use of medical countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics.

• The legislation also authorized the establishment of a program to compensate eligible individuals who suffer injuries from administration or use of products covered by the PREP Act’s immunity provisions.
Immunity Approach: The U.S. PREP Act (cont’d)

- Immunity means that courts must dismiss claims brought against any entity or individual covered by the PREP Act.

- Claims that U.S. courts must dismiss include claims for any loss that is related to any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in a Declaration.

- This includes, but is not limited to, claims for:
  - death; physical, mental, or emotional injury, illness, disability, or condition or fear of any such injury, illness, disability, or condition;
  - any need for medical monitoring; or
  - property damage or loss, including business interruption loss.

- The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct.
Who May be Afforded Immunity Under a PREP Act Declaration?

• Manufacturers and distributors of countermeasures;

• Program planners, i.e., individuals and entities involved in planning, administering, or supervising programs for distribution of a countermeasure, e.g., State or local governments, Indian tribes, or private sector employers or community groups that establish requirements or provide guidance, technical or scientific advice or assistance, or provide a facility;

• Qualified persons, i.e., persons who prescribe, administer, or dispense countermeasures such as healthcare and other providers or other categories of persons named in a Declaration, e.g., volunteers;

• Officials, agents, and employees of any of these entities or persons; and

• The United States.
What Countermeasures May be Covered by Immunity from Liability?

A “covered countermeasure” may be:

- A qualified pandemic or epidemic product;
- A security countermeasure;
- An unapproved drug, biological product, or device used under an Emergency Use Authorization (EUA) issued by FDA;
- An approved drug, biological product, or device used pursuant to Federal law in conditions that are in consistent with its approval; or
- An unapproved drug, biological product, or device, or an approved drug, biological product, or device intended for an unapproved use, that is intended for emergency use and shipped and held by a government agency or someone working on that agency’s behalf for use only when that use is authorized.

In general, these are products that are approved, cleared, or licensed by FDA; authorized for investigational use, i.e. an Investigational New Drug (“IND”) or Investigational Device Exemption (“IDE”), by FDA, authorized under an EUA by FDA, or otherwise permitted to be held or used for emergency use in accordance with Federal law.
No-Fault Compensation for Eligible Individuals

• In addition to liability protections, the PREP Act established the Countermeasures Injury Compensation Program (CICP) to provide compensation to eligible individuals for serious physical injuries or death directly caused by the administration or use of countermeasures identified in declarations issued by the Secretary of Health and Human Services.

• If an individual qualifies for CICP benefits, that person may be compensated for:
  ─ Medical expenses (unreimbursed/out-of-pocket medical expenses that are reasonable and necessary to diagnose or treat your covered injury and to diagnose, treat, or prevent its health complications)
  ─ Lost employment income; Survivor death benefits

• The CICP is the payer of last resort and can only reimburse or pay for those damages that are not covered by other third-party payers, such as health insurance, Veterans Affairs benefits, or Workers’ Compensation.

• Funds must be appropriated by Congress into the CICP to pay these claims.

Past PREP Act Declarations

• Since enactment in 2005, PREP Act Declarations have been issued for pandemic influenza vaccines, antivirals (Relenza®, Tamiflu®, Peramivir®), respiratory protection devices, respiratory support devices, and diagnostics; and all countermeasures against anthrax, smallpox, acute radiation syndrome, and botulinum toxin.

• PREP Act Declarations have served as an incentive to researchers and manufacturers to develop countermeasures that may be procured by the Biomedical Advanced Research and Development Authority (BARDA) for the Strategic National Stockpile (SNS).

• Declarations for pandemic influenza countermeasures were relied on by manufacturers, States, localities, health care providers, and others to respond to the 2009 H1N1 influenza pandemic. In two lawsuits filed after the H1N1 influenza pandemic PREP Act protection was upheld by the court.

• The CICP has paid claims arising from the H1N1 pandemic influenza response, largely for claims related to vaccination. The CICP has paid 21 claims for injuries from the 2009 H1N1 vaccine and one claim for injuries from the smallpox vaccine.
• The HHS Secretary has made a declaration under the PREP Act to facilitate the development and availability of experimental Ebola vaccines and therapeutics.

• The declarations are intended to assist in the global effort to help combat the current epidemic in West Africa and help prevent future outbreaks there.

"My strong hope in issuing this PREP Act declaration in the United States is that other nations will also enact appropriate liability protection and compensation legislation," “As a global community, we must ensure that legitimate concerns about liability do not hold back the possibility of developing an Ebola vaccine, an essential strategy in our global response to the Ebola epidemic in West Africa.”

- Secretary Burwell