



EMERGENCY LEGAL PREPAREDNESS AND RESPONSE

Memorandum

MAY 18, 2012

Public Readiness and Emergency Preparedness (PREP) Act – Scope of Liability Protections

Questions Presented:

- (1) Are non-governmental entities or persons covered under liability protections of the federal PREP Act?
- (2) Are non-federally owned stockpiles of covered countermeasures covered via the PREP Act?

Responses:

(1) **Yes.** During a federally-declared emergency, the PREP Act authorizes the Secretary of the federal Department of Health and Human Services (DHHS) to extend liability protections to entities and individuals for injuries resulting from the distribution of “covered countermeasures” (e.g., flu vaccines, antiviral medications). Liability protections extend to any “covered persons” under the PREP Act, which includes any:

- 1) *manufacturer* of countermeasures;
- 2) *distributor* of countermeasures (“distributor” means a person or entity engaged in the distribution of drugs, biologics, or devices, including repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies);¹
- 3) *program planners* of countermeasures (i.e., individuals and entities involved in planning and administering programs for distribution of a countermeasure);
- 4) *qualified persons* who prescribe, administer, or dispense countermeasures (i.e., healthcare and other providers or others named by the Secretary who prescribe, administer, or dispense countermeasures); and

5) *officials, agents, and employees of any of these entities or persons.*²

A *person* includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.³ In sum, any entity or individual acting as a manufacturer, distributor, or program planner of countermeasures, and other qualified persons or affiliates of covered persons may be insulated from liability under the PREP Act, barring any willful misconduct.

(2) **Yes.** The PREP Act allows DHHS' Secretary to extend liability protection to any "covered countermeasure." Under the PREP Act, a "covered countermeasure" includes:

- 1) A qualified pandemic or epidemic product;
- 2) A security countermeasure; or
- 3) A drug, biological product, or device that is authorized for emergency use in accordance with section 564 of the Federal Food, Drug and Cosmetic act.⁴

Definitions for these categories do not specifically restrict application of liability protections to federally owned countermeasures.⁵ Instead, the definitions focus on the relationship between the product and the emergency condition. For example, a product can be a "qualified pandemic or epidemic product" if it is intended to address a pandemic, epidemic, or related circumstances and is approved under the Federal Food, Drug, and Cosmetic Act.⁶ Additionally, section 564 of this Act states that its provisions do not impair federal authority over federally-owned quantities of product (including the Strategic National Stockpile), which suggests application of PREP Act liability protections to resources in addition to federally-owned products.⁷

In describing limitations on PREP Act immunity, the Office of the Assistant Secretary for Preparedness and Response (ASPR) lists the following as beyond the scope of PREP Act liability protection: (1) willful misconduct; (2) activities outside the scope of the declaration (including effective dates and geographic area); (3) claims without a causal relationship to a covered countermeasure; (4) claims filed under foreign laws in foreign courts; and (5) non-tort claims (e.g., civil rights or labor law violations). *No limitation related to federal control of covered countermeasures is noted.*⁸

Additionally, previous PREP Act declarations support the interpretation that liability protections apply also to non-federally-owned products. For example, the most recent declaration (in response to H1N1 in 2010) specified that immunity for government program planners would apply with respect to covered countermeasures obtained not only from federal stockpiles, *but also those obtained through donation, commercial sale, and deployment of countermeasures from state, local, or private stockpiles.* It also indicated that immunity for other covered persons would apply "pursuant to any means of distribution"(see full quotation in reference below).⁹ For these reasons, it appears that PREP Act liability protections can apply to federally- and non-federally-controlled covered countermeasures.



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SUPPORTERS

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This document was developed by James G. Hodge, Jr., J.D., LL.M., Director, Network for Public Health Law – Western Region and Daniel G. Orenstein, J.D., Deputy Director, Network for Public Health Law – Western Region at the Sandra Day O'Connor College of Law, Arizona State University, with assistance from Sarah O'Keefe, J.D. candidate and legal researcher, and Andrew Sniegowski, R.N., J.D. candidate and legal researcher. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.

¹ 42 U.S.C. §247d-6d. Public Readiness and Emergency Preparedness Act. Available at: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf>.

² McCormick, E., McNeill Ransom, M., Kershner, S. Frequently Asked Questions about Federal Public Health Emergency Law, *Public Health Law Program Centers for Disease Control and Prevention*. Available at: <http://www.naccho.org/topics/infrastructure/PHLaw/upload/Microsoft-Word-FINAL-Public-Health-Emergency-Law-FAQ.pdf>; The Public Readiness and Preparedness Act (PREP): What you need to know. Michigan Department of Community Health. Available at: http://www.michigan.gov/documents/mdch/PREP_Act_Fact_Sheet_Michigan_Sept09_293378_7.pdf; 42 U.S.C. §247d-6d. Public Readiness and Emergency Preparedness Act. Available at: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf>.

³ The Public Readiness and Preparedness Act (PREP): What you need to know. Michigan Department of Community Health. Available at: http://www.michigan.gov/documents/mdch/PREP_Act_Fact_Sheet_Michigan_Sept09_293378_7.pdf; 42 U.S.C. §247d-6d. Public Readiness and Emergency Preparedness Act. Available at: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf>.

⁴ 42 U.S.C. §§ 247d-6d(i)(1)(A)-(C) (2006). Available at: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf>.

⁵ See 42 U.S.C. §§ 247d-6d(i)(7) (defining "Qualified pandemic or epidemic product") and 247d-6b(c)(1)(B) (defining "Security countermeasure"). Available at: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf>.

⁶ 42 U.S.C. § 247d-6d(i)(7). Available at: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf>.

("(7) Qualified pandemic or epidemic product

The term "qualified pandemic or epidemic product" means a drug . . . biological product . . . , or device . . . that is -

- (A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured -
 - (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
 - (II) to limit the harm such pandemic or epidemic might otherwise cause; or
- (ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); and
- (B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title").

⁷ 21 U.S.C. § 360bbb-3(j)(3). Available at: <<http://uscodebeta.house.gov/view.xhtml?req=granuleid:USC-title21-section360bbb-3&num=0>>.

⁸ U.S. Dep't of Health and Human Servs., Office of the Ass't Secretary for Preparedness and Response, *Public Readiness and Emergency Preparedness Act Questions and Answers* (Aug. 12, 2010), <www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx> .

⁹ Pandemic Influenza Vaccines – Amendment, 75 Fed. Reg. 10,270-10,271 (March 5, 2010). Available at: <<http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/html/2010-4644.htm>> The declaration states:

The immunity specified in section 319F-3(a) of the Act shall only be in effect with respect to: (1) Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding for vaccines against pandemic influenza A viruses with pandemic potential used and administered in accordance with this declaration, *and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the pandemic countermeasures following a declaration of an emergency*, as defined in section X below. In accordance with section 319F-3(b)(2)(E) of the Act, for governmental program planners, the immunity specified in section 319F-3(a) of the Act shall be in effect to the extent they obtain Covered Countermeasures through *voluntary means of distribution, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles*. For all other covered persons, including other program planners, the immunity specified in section 319F-3(a) of the Act shall, in accordance with section 319F-3(b)(2)(E) of the Act, be in effect *pursuant to any means of distribution*.

(emphasis added).