2015

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Recommended Citation
in The Public Health Response to 2009 H1N1 (Michael Stoto and Melissa Higdon eds., Oxford Univ. Press 2015).

January 2015

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CHAPTER 12

Obstacles to pH1N1 Vaccine Availability

The Complex Contracting Relationship between Vaccine Manufacturers, the World Health Organization, and Donor and Beneficiary Governments

SAM F. HALABI

Introduction

When researchers in Mexico and the United States concluded that influenza-related hospitalizations in separate, noncontiguous areas of Mexico, southern California, and New York City uniquely affected children and young adults, they were alerted to the possibility that a new pandemic viral subtype of influenza had emerged (Cordova-Villalobos et al., 2009; see also Chapter 2). After the U.S. Centers for Disease Control and Prevention (CDC) received samples from two early H1N1 patients in mid April, 2009, researchers exposed banked blood samples taken before and after vaccinations from 2005 to the new virus (Centers for Disease Control and Prevention, 2009). Samples from children produced no antibodies whereas samples from adults vaccinated against seasonal flu showed a slight increase in antibodies against the pH1N1 virus. Because it did not appear that the seasonal vaccine would adequately protect adults against infection, the CDC recommended development of a vaccine specific to the new strain (Hancock et al., 2009). This recommendation was echoed in the World Health Organization's (WHO's) June 11, 2009, declaration of a Phase 6 pandemic. Under WHO classificatory scheme operating in 2009 (it has been revised in light of the H1N1 experience), in Phases 1 through 3 of a pandemic, influenza circulates predominantly in animals and there are few human infections. In Phase 4, there is sustained human-to-human transmission, and in Phases 5 and 6, sustained human transmission spreads to at least two WHO regions (Doshi, 2011).

The CDC's recommendation and WHO's declaration triggered a race by a small number of vaccine manufacturers to develop and then put into production a pandemic-specific vaccine because a market had instantaneously developed and some manufacturers already had in place agreements with governments that required them to shift to pandemic vaccine production (Centers for Disease Control and Prevention, 2012; World Health Organization, 2011). Aside from the governments that had already put procurement policies and contracts in place, the vast majority of the world's governments and the populations they represented lacked access to vaccines and looked to WHO to work with firms and potential donor governments to facilitate access. The gene sequence of wild-type pandemic pH1N1 was made publicly available April 27, 2009. By May 8, 2009, samples of wild-type virus had been sent from reference laboratories to vaccine manufacturers, all of which were in Europe and the United States, because they had the necessary high-level biological containment facilities. This chapter analyzes the obstacles standing between WHO, vaccine manufacturers, and the populations who needed the vaccines they produced.

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Vaccines are the first line of defense against influenza to prevent infection and to control spread of the disease because they are more effective and burden society less than nonpharmaceutical measures like masks, closing of public gathering places, and isolation of patients (Aledort et al., 2007; Carter and Plosker, 2008). The process by which a vaccine is first developed in a laboratory to its administration to a population engages the full range of governmental health agencies, community organizations, pharmaceutical firms, and international organizations that comprise the system the U.S. National Health Security Strategy sets at the core of improving public health emergency response.

Although recent pandemic influenza threats have originated in middle- or low-income countries, the capacity for pandemic influenza vaccine production is overwhelmingly concentrated in Australia, Europe, and North America (Crosse, 2008). These regions' pharmaceutical firms are in a persistent cycle of seasonal influenza vaccine production, which is based on surveillance reports detailing which influenza viruses are in circulation, how they are spreading, and how well the previous season's vaccine viruses protect against new strains. Although WHO recommends specific vaccine viruses after information is gathered from more than 100 national influenza centers in more than 100 countries, individual countries make their own decisions about licensing of vaccines subject to their own regulatory mechanisms.

When a new influenza strain emerges, the first step in vaccine response is to assess whether the seasonal influenza vaccine will produce adequate immunity to protect against the new strain. After researchers concluded the seasonal vaccine did not protect against pH1N1, pharmaceutical firms, five of which control approximately 80% of the influenza vaccine market, found themselves negotiating with WHO about conditions for donation, shipment, and distribution of vaccine. Governments with preexisting contracts sought

to preserve as much of their firms' capacity—that is, firms located within the territorial borders of the procuring governments—as necessary to inoculate their populations first before giving or selling to others. As a result, manufacturers negotiated with a much larger than usual number of procurement officials, regulators, health-care providers, and vaccine distributors (Hanquet et al., 2011).

From the manufacturers' perspective, these negotiations occurred in the shadow of potentially large liabilities related to their existing contractual arrangements with governments; detailed processes for vaccine approval, distribution, and marketing; and more general exposure should quickly developed vaccines generate unexpected adverse reactions or safety problems. Indeed, WHO prequalified some vaccines in as little as one day, even when ongoing studies showed significant adverse events (World Health Organization, 2010). Manufacturers were required to seek approval as if it were an entirely new vaccine. Under typical regimes, manufacturers must modify the new virus to grow efficiently (generally in eggs) so it may be used for vaccine production. This modification also ensures the vaccine virus may be handled safely. To develop antigens and injectable antiserum to measure vaccine potency, manufacturers must coordinate with reference laboratories and regulatory agencies. Vaccines must then be tested in human trials to assess safety and effectiveness. Regulatory approval for marketing and use is dependent on laboratory-generated evidence and clinical trial outcomes. Even safe and effective vaccines generate adverse events among those inoculated, ranging from (common) soreness at the injection site to fever, discomfort, and muscle pain to (rare) anaphylaxis and oculorespiratory syndrome (World Health Organization, 2012). One of the vaccines produced specifically for pH1N1 by GlaxoSmithKline has been associated with an increased risk of narcolepsy (Centers for Disease Control and Prevention, 2013). In many jurisdictions, manufacturers bear legal responsibility for these adverse events.

Manufacturers therefore face a range of legal barriers to production, donation, and discounted sale of pandemic vaccines like the process by which vaccines may be approved and registered with national regulatory authorities, protection from and indemnification for liability, and preexisting advance market commitment agreements that affect the ability to enter into additional contracts after a pandemic has been declared. In short, the global public health response is dependent on private-sector actors who must balance private-sector and public-sector demands on their resources.

Methods

Contracts between private parties are rarely available for public scrutiny unless litigation exposes them. Similarly, agreements between private-sector actors and public authorities are kept confidential in most circumstances unless they are specifically covered by open records laws, the bidding process for them

requires a high degree of transparency, or private-sector actors themselves make some or all of the agreements available. Confidentiality of agreements is particularly important when the agreement potentially affects national defense or security—circumstances that generally characterize governmental strategies for dealing with pandemics.

However, many aspects of the relationships between vaccine manufacturers, WHO, and donor and beneficiary governments have been revealed through testimonies before legislative bodies, postpandemic analyses undertaken by WHO, including a comprehensive assessment of its response, and conversations and interviews with persons representing governments, firms, and WHO. These primary sources were supplemented by analyses of the 2009 pH1N1 vaccine development and distribution problem published in the academic literature to develop as comprehensive picture as possible of vaccine contracting obstacles.

This document review was also supplemented by informal interviews with decision makers, many of whom did not have time for extensive, formal interviews. The data collected from the academic literature, WHO reports, and interviews were organized according to major legal obstacles, which were then vetted with public health researchers, practitioners, governmental officials, and one representative from a vaccine manufacturer to maximize the chance that all key issues were captured and no critical concerns were excluded. Although these methods cannot tell us the frequency with which specific issues arose, they are sufficient to ensure the major contracting obstacles facing manufacturers, governments, and WHO have been identified and explored.

Other issues also affected vaccine distribution, including supply line breaks, and inconsistencies and inadequate infrastructure to distribute vaccines once the legal uncertainties just described were resolved (see, for example, Chapter 10), but are beyond the scope of this chapter. Those problems included the availability and resilience of cold chain packaging, shelf-life, and planning within both public-sector actors such as the United Nations' (UN) Office for Project Services, UNICEF, and development agencies, along with private-sector actors like global logistics firms.

AQ : Please confirm whether the cross-reference to Chapter 10 in the sentence "Other issues also ..." is appropriate.

Results

The Legal Framework for pH1N1 Pandemic Influenza Vaccine Distribution

Development, approval, and distribution of the 2009 pH1N1 vaccine was shaped by preexisting frameworks that had been established to address the outbreak of H5N1 avian flu in Southeast Asia (McConnell, 2010). That subtype spread quickly around the globe but did not (and has not to date) evolved to become easily transmissible to humans. The concern that H5N1 may become easily transmissible to and then between humans resulted in both divergent

(if accelerated) regulatory approval processes, and a set of agreements entered into between two manufacturers—GlaxoSmithKline (GSK) and Sanofi Pasteur (Sanofi)—and the WHO donations of antivirals and prepandemic H5N1 vaccine doses. After the pN1H1 influenza strain was identified, WHO immediately began negotiations with "all known" influenza vaccine manufacturers (World Health Organization, 2011). Those discussions were shaped by planning for H5N1 (Hanquet et al., 2011).

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When the WHO declared a Phase 6 pandemic, GSK and Sanofi pledged 50 million and 60 million doses of H5N1 vaccine, respectively, although no legal agreements for donations were in place. GSK and Sanofi agreed to convert those commitments to pandemic influenza A pH1N1 vaccine and to increase the number of doses to 150 million. GSK and WHO signed an agreement for the donations on November 10, 2009, which resulted in just over 24 million doses actually donated. Sanofi announced a "flexible" donation of up to 100 million doses on June 17, 2009, but the donation agreement was not signed until December 2009. Novartis specifically eschewed donations, favoring pricing mechanisms to establish a "sustainable way" to deliver vaccine to developing countries.

Despite the small number of players, negotiations regarding all aspects of procurement were difficult and protracted, revealing a near-total lack of planning to move vaccine from the private-sector developers and manufacturers to the populations that needed them. Negotiations involved at least four manufacturers and 12 governments on the donor side, and nearly 100 governments on the beneficiary side (World Health Organization, 2011). WHO's negotiation with GSK served as a template for agreements with CSL Australia, MedImmune, and Sanofi, which concluded in December 2009. Novartis signed an agreement in January 2010, although a 2011 WHO assessment of its response to the pandemic strongly suggests the Novartis agreement differed from the other four. Legal agreements with governments followed those with firms: the United States (December 16, 2009), Australia (December 22, 2009), France (January 15, 2010), Belgium (January 29, 2010), Switzerland (March 16, 2010), Norway (March 19, 2010), Italy (April 16, 2010), the United Kingdom (May 28, 2010), and Singapore (June 21, 2010). Some states perceived that WHO "shopped" different agreements with different legal terms to different governments—a practice that generated suspicion among the donor governments and caused further delay in finalizing terms.

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The delay in placing agreements between firms, governments, and WHO was attributable to at least two causes. First, both firms and governments had entered into advance purchase agreements that constrained the ability of firms to donate or otherwise provide vaccines to WHO or governments directly. Second, vaccine manufacturers insisted on strong protections from liability should the pandemic influenza vaccine result in adverse health events in populations, and coverage for interests affected by specific title transfer arrangements.

Advance Purchase Agreements and Territorial Restraints

Long before WHO declared a pandemic, many countries, including Belgium, Canada, Finland, France, Germany, Italy, Switzerland, the Netherlands, the United States, and the United Kingdom, had already placed large orders of pH1N1 vaccine or had advanced agreements in place (Doshi and Jefferson, 2010). With advance purchase agreements (also known as *sleeping contracts*), a vaccine manufacturer agrees to supply its pandemic influenza vaccine as soon as possible after a pandemic has been declared and agrees to reserve a specified number of doses for the country or to more openly meet that country's orders first. When it commenced negotiations with manufacturers, WHO did not know about key aspects of the agreements. When asked whether they would be willing to reserve (not donate) 10% of real-time production for purchase by UN agencies, many vaccine manufacturers cited advance purchase agreements with high-income countries as a barrier. Contracting states noted the relatively inflexible terms of those agreements. A review of European Union member states' vaccine planning strategies after the pandemic highlighted the obstacles advanced purchase agreements pose:

> From the contracting country's perspective, it is clear that maximizing not only guaranteed access to vaccine, but also increased flexibility that can help to minimize costs and better calibrate orders to changing prognoses regarding the ongoing development of the pandemic. Convincing vaccine [manufacturers] to provide such flexibility is likely to pose a challenge and might well require finding ways of enhancing the negotiating power of contracting Member States. A forum for discussions among Member States of how to develop advance purchase contracts could be useful. (European Commission (2010)

Even aside from advance purchase agreements, the decision to dedicate physical infrastructure and human resources to pandemic influenza vaccine production is, from the manufacturers' view, a business decision. In a 2010 WHO report examining operational successes and failures of WHO Deployment Initiative (the umbrella term WHO used to describe its effort to procure vaccines from firms and governments, and to distribute them to needy countries), pharmaceutical firms noted that "support for WHO Deployment Initiative may have disrupted business in other areas and reduced their competitive strength" (World Health Organization, 2010, p. 9). Vaccine manufacturers, therefore, desire stockpiling agreements as a solution to business uncertainty, whereas procuring governments demand flexibility to fit the severity of the pandemic. The 2009 pH1N1 influenza pandemic has exacerbated this tension between firms and the governments wealthy enough to procure advanced vaccine production, and therefore what is left for populations in lesser developed or middle-income states. After the pH1N1 threat diminished, many more governments entered into advance purchase agreements with a wider divergence in legal terms for a larger number of doses of pandemic or prepandemic vaccine.

In addition to and accompanying advance purchase agreements, domestic law may nevertheless constrain the production and shipment environment of vaccine manufacturers. For example, GSK's facility in Sainte Foy, Quebec, must fill Canada's orders first before supplying to others, and Canada awarded its pandemic influenza vaccine contract to a Canadian company precisely because it feared foreign governments would restrict exports of vaccine doses (Fidler, 2010; Standing Senate Committee on Social Affairs, Parliament of Canada, 2010). The Australian government made it clear to the Australian manufacturer CSL that it must fulfill the government's domestic needs before exporting pH1N1 vaccine (Fidler, 2010). Despite clear acknowledgment that the 2009 outbreak originated in Mexico and leveled its most significant toll there, Mexico had "a terrifically difficult time getting access to the pandemic vaccine" as a result of the difficulties in assessing needs and distributing vaccines to target populations across the globe (Halabi, 2014, p. 148).

Regulatory Approval and Legal Liabilities

Each country's national regulatory authority responding to the pandemic imposed its own regulatory process for approving pH1N1 vaccines, authorizing their importation, and overseeing their distribution (World Health Organization, 2010). These processes ranged from one-time waivers of normal rules to detailed requirements for pediatric subgroup data, regulatory assessments capacity, quality control preparedness and capacity, and postmarketing safety surveillance and field assessment of efficacy and immunogenicity. Some regulatory agencies approved pandemic vaccines as a type of seasonal influenza vaccine, whereas others adapted an approval process in place for candidate H5N1 (avian flu) vaccines. The biochemistry of pH1N1 vaccines varied widely, with adjuvanted vaccines (an adjuvant is an inorganic or organic chemical, macromolecule, or entire cell of certain killed bacteria that enhance the immune response to an antigen) and vaccines produced using cell- rather than egg-based technology facing more significant regulatory review. In more than half the beneficiary countries, prequalification of a vaccine by WHO was not sufficient to obtain regulatory approval, and relatively few countries' national laws stated that products donated by the UN did not require national registration (World Health Organization, 2010).

These requirements, in turn, adversely affected efficacious donation and distribution. Even when a manufacturer agreed in principle to donate to WHO or other UN agencies (e.g., UNICEF), it might not agree to do so if the vaccine would be distributed in a country where that vaccine is not licensed (Crosse, 2008). Since at least 2006, industry representatives have stated that manufacturers would need advance assurance that governments would provide liability protection in order to donate vaccines. Indeed, some manufacturers will not even authorize use of the vaccine for clinical trials if not insured against legal liabilities. Because the initial urgency of the pandemic response required an unprecedented number of doses of a new vaccine to be deployed globally in

a period of only a few months, vaccine manufacturers required that all purchasers or recipients (many of which were European and North American governments) indemnify them for adverse events resulting from the use of the pandemic H1N1 vaccine, with exceptions allowed for failure to follow current good manufacturing processes or other discrete specifications.

Manufacturers required access to information on country regulatory processes that was often difficult to obtain. Reallocating products after this work had begun led to additional work for manufacturers and delayed delivery to countries (World Health Organization, 2010). In one instance, a change in the delivery schedule necessitated switching to the product of a different manufacturer, which triggered a de novo review of all aspects of vaccine approval (World Health Organization, 2010). The delays caused by this legal wrangling were substantial. For countries in WHO's African region, vaccines were deployed, on average, 261 days after a country expressed interest in donated vaccine (World Health Organization, 2010). Legal issues surrounding both title and transfer between manufacturers, governments, and beneficiary countries added to the delay (World Health Organization, 2010). "For those countries that were first hit by the emerging pandemic, like those in the Southern Hemisphere, but also for some countries in the Northern Hemisphere, the vaccines clearly came too late and well after the pandemic struck" (Osterhaus et al., 2011, p. 2769).

The complexity of this contracting universe explains, in part, discrepancies in pledged versus contractually committed vaccines. Availability of supply and differing appreciation of available safety and efficacy data influenced where and under what circumstances certain vaccines could be deployed to certain countries (Luetiegn, 2011). By the end of WHO Deployment Initiative in September 2010, 200 million doses of pandemic influenza A (pH1N1) 2009 vaccine had been pledged for donation, but only 122.5 million doses had been committed contractually. In total, 78 million doses of pandemic influenza A (pH1N1) 2009 were deployed to 77 countries.

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Implications for Policy and Practice

Although vaccines are the first line of defense to prevent infection and to control spread of pandemic influenza, the capability to develop and manufacture vaccine is almost entirely under the control of a small number of large pharmaceutical firms whose ability and willingness to respond to a pandemic are fundamentally intertwined with their regulatory and contractual relationships. If a seasonal vaccine is inadequate against a new pandemic influenza strain, which occurred with pH1N1, manufacturers must modify the new virus, coordinate with reference laboratories and regulatory agencies, conduct human trials, and decide whether, and to what extent, to switch seasonal vaccine production to pandemic vaccine production. In 2009, some agreements in place between firms and governments effectively forced this choice (Hanquet

et al., 2011). Vaccines must then be tested in human trials to assess safety and effectiveness. Regulatory approval for marketing and use is dependent on laboratory-generated evidence and clinical trial outcomes. Even safe and effective vaccines generate adverse events among those inoculated, and in many jurisdictions manufacturers bear legal responsibility for these adverse events (Swendiman and Jones, 2009).

Each of these aspects of the vaccine development process generated contracting obstacles when WHO and individual governments approached firms with requests for vaccine donation or purchase. Manufacturers faced differing regulatory and approval processes, uncertain protection from legal liabilities, constraints imposed by advance purchase agreements in place with mostly European and North American countries, and equally uncertain and undeveloped systems for distribution even if they could manufacture a limitless number of doses. In short, the global public health response to pandemic influenza in 2009 was dependent on private-sector actors who, under the circumstances then prevailing, demanded both legal assurances and relief from legal requirements in order to participate fully in that response. There were few effective mechanisms for dealing with that reality. An effective global strategy for the next influenza pandemic will require the identification of these contracting and regulatory obstacles, anticipation of new ones, and the creation of ex ante agreements and negotiation for that may facilitate vaccine development and distribution.

Although efforts are underway to increase vaccine manufacturing capacity in developing states, the capability remains overwhelmingly centered in large pharmaceutical firms located in Australia, Japan, Europe, and North America. There is a substantial consensus that capacity for vaccine production is tiny compared with the number of doses required in the event of the next pandemic. WHO, as well as North American and European governments, are funding programs to increase the supply of seasonal and pandemic influenza vaccines by expanding global coverage of seasonal flu vaccine, promoting new development sites (including in developing states), and enhancing research and development for novel influenza vaccines (Condon and Tapen, 2010).

WHO is optimistic the agreements put in place between donor governments and firms between November 2009 and March 2010 will provide a time-saving legal framework for production and distribution of vaccine or other medicines during the next pandemic (World Health Organization, 2010). However, there are reasons to doubt this will be the case based on systemwide response changes. For example, one of the controversial aspects of vaccine development and distribution between 2009 and 2010 was WHO's criteria for identifying a pandemic. Those criteria were based in some measure on geographic spread rather than severity. WHO has agreed to revise these criteria so that the next time it declares a pandemic, the declaration will reflect a more severe public health event on a widespread scale—a scenario likely to render existing legal agreements less applicable than WHO now hopes (Doshi, 2011).

As far as the 2009 pH1N1 experience goes, building capacity without a consistently updated framework for efficiently moving pandemic vaccine from the private sector to the public sphere may simply aggravate the legal and regulatory bottlenecks experienced between 2009 and 2010. The expansion of capacity in middle-income or developing countries enhances the contracting complexity that will likely be faced during the next pandemic. No agreements were reached with firms that are not members of the International Federation of Pharmaceutical Manufacturers Associations, which does not include the small but growing number of manufacturers in developing countries. For the most part, vaccine manufacturers and major purchasers still decide whether to suspend seasonal influenza vaccine production so that all production capacity can be used for pandemic vaccine. Manufacturers also decide whether production of pandemic vaccine can be safely scaled down or suspended in favor of seasonal vaccine. Advance agreements should exist between industry, WHO, and countries regarding these decisions or should at least create ongoing forums that keep relevant stakeholders current on a regular basis on how vaccine manufacturers' commitments affect overall capacity for production in the case of a pandemic.

Approval processes for national regulatory authorities created a major obstacle not just for initial agreements to donate, but also for logistical practicalities that favored deployment of pandemic vaccines as quickly as possible to countries that needed them as soon as possible. As with the vaccine framework developed for H1N1, regulatory harmonization has been shaped by pre-2009 preparations for emergence of a pandemic H5N1 influenza virus strain. WHO, in collaboration with health authorities from Canada, Japan, Spain, and the United States, convened three technical workshops between 2006 and 2007 to examine regulatory harmonization, but the results are shaped by detailed examination of countries with clear regulatory mandates and at least one major vaccine manufacturer. The 2009 H1N1 pandemic has not resulted in a measurable increase in agreements between national regulatory authorities or with WHO on data sharing, mutual recognition, of some or all aspects of vaccine approval.

Moreover, the difficulty lesser developed and middle-income countries experienced in obtaining pandemic H1N1 vaccine exacerbated already existing tensions over the process of developing medicines and vaccines (which frequently involves the use of flu samples obtained in developing countries) and making them available at affordable prices. In 2007, Indonesia withheld samples of influenza A (H5N1) from WHO, arguing that developing countries typically shared such samples for free only to have North American and European firms patent derivative medicines and vaccines for sale in richer states, out of reach (in financial and other terms) from developing countries. In response, WHO and the World Health Assembly adopted the Pandemic Influenza Preparedness Framework, under which member states and vaccine manufacturers have agreed on a standard material transfer agreement that regulates the terms under which countries agree to donate influenza samples,

the entities authorized to receive and research them, and the corresponding sharing of resulting vaccines and other intellectual properties (Halabi, 2014). WHO is currently negotiating with six vaccine manufacturers based on the standard material transfer agreement, with one agreement concluded with GSK. These agreements provide several options to manufacturers regarding the contributions they must make in exchange for virus access. Some of these options involve pandemic vaccine donation, while others involve antiviral donations, and still others authorize licensing of intellectual property to developing country manufacturers. These agreements, especially the options manufacturers choose, must coexist with the advance purchase agreements and, presumably, liability issues outlined above. Together with the proliferation of advance purchase agreements and the unknown extent of vaccine stockpiling agreements, the commitments made by manufacturers under WHO's Pandemic Influenza Preparedness Framework may render the legal framework used in 2009 obsolete.

Vaccines are the front line in the global response to the next pandemic influenza outbreak, and thus their manufacturers—together with public health agencies—form a critical public–private partnership. The seasonal–pandemic influenza vaccine production balance; the process by which vaccines are developed, researched, and approved for use by regulatory agencies; the potential liability manufacturers face; and the contractual limitations imposed by advance purchase agreements all portend potential delays for the necessary global health response. WHO has already noted that advance agreements between itself, countries, and industries should be negotiated without regard to virus subtype for a specified period of time (e.g., three to five years) and should be regularly reviewed and renewed. Countries that receive donated vaccine, as any purchaser of the vaccine, should adhere to the same practices of releasing and indemnifying manufacturers from certain legal liabilities. Whether donated or purchased, vaccine manufacturers have emphasized that liability protection is a crucial part of their participation in the broader response to pandemic influenza (International Federation of Pharmaceutical Manufacturers and Associations, 2006). As WHO's Final Report on the functioning of the International Health Regulations in relation to the 2009 A(PH1N1) pandemic noted:

> Despite the ultimate deployment of 78 million doses of pandemic influenza vaccine to 77 countries, numerous systemic difficulties impeded the timely distribution of donated vaccines. Among the key difficulties was a variation in willingness to donate, concerns about liability, complex negotiations over legal agreements, lack of procedures to bypass national regulatory requirements and limited national and local capacities to transport, store and administer vaccines. Some beneficiary countries felt WHO did not adequately explain that liability provisions included in the beneficiary agreement were the same as the liability provisions accepted by purchasing countries. All these difficulties proved daunting in the midst of a pandemic; some could have been reduced by more

concerted preparation and advance arrangements among all interested parties. (Available online at http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf?ua=1, p. 133)

Acknowledgments and Disclosures

This research was conducted after conversations with John Monahan, whose observations at the U.S. Department of State during the 2009 pandemic prompted the author's inquiry into the complex contracting environment in which pharmaceutical firms, governments, and international organizations operate. The author is grateful for comments from John Monahan, Bruce Gellin, Oscar Cabrera, Susan Kim, and Fernanda Alonso; and for research support from the O'Neill Institute for National and Global Health Law at Georgetown University. The data and conclusions have been published previously in one briefing report:

- Halabi, S. F. (2014). The uncertain future of vaccine development and deployment for influenza pandemic. O'Neill Institute for National and Global Health law briefing paper no. 8. Accessed March 19, 2014, at http://www.law.georgetown.edu/oneillinstitute/resources/documents/Briefing8Halabi.pdf.

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